WOMEN'S HEALTH INITIATIVE

Women's Health Initiative
2008 Annual Progress Report

Data as of: August 15, 2008

Prepared by
WHI Clinical Coordinating Center
Fred Hutchinson Cancer Research Center

Ross Prentice, Principal Investigator

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1. Overview

1.0 Preliminary Remarks

This report documents the experience of the WHI Extension Study (ES) activities through August 15, 2008, summarizing consent activities, follow-up response rates, study outcomes and performance. In addition, this report includes summaries of efforts using core resources for biomarker and intermediate endpoint studies, ancillary studies with particular focus on those using the biospecimen repository, and a summary of publications.

The implementation of the WHI Extension Study required a recruitment process to obtain consent from WHI participants and some modification of the follow-up and outcomes adjudication process primarily aimed at streamlining. These activities are documented below. Data presentations on vital status and outcome rates for each study component are provided without further explanation as these follow the same conventions as have been previously described. A few introductory remarks are presented below as orientation to the presentations on core and ancillary study activities.

The NHLBI contracted with 39 of the original WHI Clinical Centers (now referred to as Field Centers) to conduct follow-up through 2010. The Principal Investigators and the sponsoring institutions are presented in Table 1.1. Several changes have occurred during this past year. Drs. Annlouise Assaf (Pawtucket-Memorial Hospital of RI), William Elliott (Chicago-Rush Presbyterian), Susan Hendricks (Detroit-Wayne State University), Richard Katz (George Washington University) and Evelyn Whitlock (Portland-Kaiser Foundation Research Institute) have left WHI to pursue other activities. WHI welcomes new Principal Investigators Drs. Charles Eaton, Lynda Powell, Michael Simon, Lisa Martin and Yvonne Michael and in these sites.

1.1 Consent to Extension Study Follow-up

Approval of WHI-ES follow-up was received from NHLBI on October 12, 2004. Clinical trial participants were consented primarily in conjunction with their close-out visits, scheduled to occur between October 1, 2004 and March 31, 2005. Observational Study participants were consented by various means as determined by individual centers (mail, phone/mail, group meetings). The opportunity to join the WHI-ES will not be closed to any WHI participant but active efforts to recruit participants have ended.

The UCSD center (La Jolla) was not funded to conduct follow-up during the ES. After discussions between the NHLBI, UCSD and the WHI Clinical Coordinating Center (CCC), it was agreed that the CCC would recruit and follow LaJolla participants during the ES. In total, 60% of the eligible LaJolla participants have consented to extended follow-up.

WHI-ES consent rates are provided by study component and arm in Table 1.2, by demographic characteristics in Table 1.3 and by center in Table 1.4. Overall, 82% of eligible CT participants and 73% of eligible OS participants have agreed to further follow-up.

1.2 Extension Study Follow-up

The ES study follow-up plan entails an annual mailed contact to obtain self-reported outcomes (Form 33–*Medical History Update*), hormone therapy use (Form 150–*Hormone Use Update*) among HT trial participants, and quality of life (Form 151–*Activities of Daily Living*). A one-time collection of historical diagnoses of Parkinson's disease and diabetes (Form 134–*Addendum to Medical History Update*) was also collected during the first ES follow-up year.

The annual contact is administered through up to three mailings from the CCC over a five month period followed by FC follow-up of non-responders after seven months. Currently follow-up for Year 3 has been initiated for over 85% of participants. Form 33–*Medical History Update* is viewed as the primary indicator of response. Response rates to the third year of follow-up remain high (84.3% respond to the first mailing, 93.1% respond overall), only 0.5% lower than the previous year of follow-up (Table 1.5). Response rates are somewhat lower in the clinical trial components than in the observational study, presumably because this follow-up plan is new to CT participants.

Field Centers are responsible for data collection from women who cannot be followed by mail and from non-responders to the three CCC mailings. Among those women for whom the CCC mailing interval has expired, an estimated 6.9% require Field Center follow-up and of these, 95.1% have provided a Form 33 in the third year (Table 1.6). The response rates for Form 151 are lower generally than for other instruments because Field Center follow-up for this form is optional. Responses to Form 134 are also low in Year 2 and beyond because this form was to be collected only in Year 1; later response rates represent only activities for participants who did not respond in Year 1. Differences between study components are small with the exception that follow-up of HT participants appears to be somewhat more difficult.

1.3 Outcomes

The list of potential outcomes being investigated for the WHI-ES has changed somewhat from WHI. The most important changes are:

- Angina and CHF are no longer adjudicated
- Outpatient stroke is adjudicated (not adjudicated during WHI)
- Hip fracture continues to be adjudicated but no other fractures (during WHI other fractures were adjudicated for Clinical Trial participants)
- Hospitalizations of a single night are no longer investigated, unless they occur in conjunction with a self-report of a designated WHI-ES outcome

Outcomes adjudication for the WHI-ES is centralized. Field Centers collect documents from self- or proxy-reported cases and forward them to the CCC. The CCC forwards purported cases of designated WHI outcomes to an adjudicator specific to the disease category. Outcomes identified from other hospitalizations are first reviewed by CCC outcomes staff and then either forwarded to an appropriate adjudicator, or closed administratively. Adjudicators are divided into committees responsible for cardiovascular events (which include VTE but not stroke), stroke, hip fractures, fatal events, and cancer. The cancer committee consists of trained cancer coders at the CCC. All other committees consist of physician adjudicators, many of whom were local physician adjudicators during WHI. There

is a large overlap between the fatal events committee and the cardiovascular committee. Every case is reviewed by a single adjudicator. QA procedures, which will involve double adjudication of at least 10% of the cases by another adjudicator from the same committee, are currently being implemented.

Venous thromboembolism (VTE) events continue to be investigated only for (former) HT participants. For each outcome type, only the first occurrence since the beginning of WHI is investigated. For example, a woman who has a confirmed MI during WHI will not be investigated for MI during the WHI-ES. A complete list of adjudicated outcomes for the WHI-ES may be found in the WHI-ES protocol.

In this report, events in the clinical trial components (Sections 2 through 4) are considered to have occurred during the intervention period and during the post-intervention period for each study component using the following definitions for the end of interventions:

Clinical trial	End of Intervention period
Estrogen+Progestin	July 7, 2002
Estrogen Alone	February 29, 2004
Dietary Modification	April 8, 2005
Calcium/Vitamin D	For each participant, the earlier of date of unblinding or April 8, 2005

A tabulation of all designated outcomes currently available based on the current procedures for adjudication are presented by age and race/ethnicity for OS participants in Section 5 and for CT participants combined in Section 6.

1.4 Central Adjudication

Agreement rates between self-report and confirmed outcomes occurring during the WHI extension are provided in Tables 7.1 and 7.2. Because there is not always a one-to-one correspondence between self-reported and adjudicated outcomes, the agreement is presented in two ways.

Table 7.1 presents the final status of all self-reports that are designated for adjudication. A self-report for a particular outcome is considered closed if all adjudications associated with the outcome are closed. In the rare situation where a self-report of a specific event is associated with several adjudication cases, perhaps because of several associated hospitalizations, the original event would not be considered closed in this table, even if the original event has been confirmed. This is a reason for discrepancies between numbers in these tables and other tables in this report.

If a self-report is closed, it is considered "confirmed" if any of the associated adjudication cases confirms the exact self-reported outcome. If this is not the case, the result is classified by whether a related outcome is found in the documentation. For this purpose, all cardiovascular outcomes are considered related, all cancers are considered related, and all fractures are considered related. If no related outcome is confirmed, we determine whether any outcome has been confirmed. For the denied cases, we separate those that are denied for administrative reasons (e.g., no release of information [ROI] obtained) from those where the

records indicate that no outcomes occurred. These agreement rates vary considerably across diseases.

Table 7.2 examines agreement in the reverse direction, tabulating the fraction of confirmed outcomes investigated as a result of a self-report for that exact outcome, a related outcome, an unrelated outcome, or a hospitalization.

1.5 Data Quality and Study Performance Reports

Reports summarizing Field Center activities (Tables 8.1 to 8.5) are produced monthly and posted on the staff website for investigators and Field Center staff use. The Performance Monitoring Committee also uses these reports to monitor study activities.

Participants return questionnaires to the CCC by mail for scanning. Forms that cannot be scanned are key-entered. CCC staff also review all the returned forms for comments the participant many have written on the form and indicate which forms need to be reviewed by Field Center staff (Table 8.6).

The current status of outcomes adjudication indicates that outcomes processing by FCs is excellent (Table 8.7), with timeliness of documenting and forwarding cases better than it ever was during WHI. All adjudications are up-to-date with the flow of cases (Table 8.8). For stroke, additional adjudicators were engaged in the process during the previous year and since then the backlog of over 950 cases has been reduced to a normal flow. Adjudication of other hospitalizations is a lower priority, however thanks to some streamlining activities even this backlog has been reduced considerably.

A current outcomes priority is to SEER-code the non-primary cancers that up to now mostly have been adjudicated only for fact of cancer. In late 2007, the EC approved a proposal to extend the SEER-ICD-02 cancer coding to include non-primary cancers rather than just primary cancers. CCC cancer coders began coding these 9,307 non-primary cancer cases, and have hired additional coders to assist in this workload.

1.6 Specimen Repository

The current inventory of the WHI specimen repository is described in *Tables 9.1 – CT Outcomes Cases with Blood, 9.2 – OS Outcomes Cases with Blood*, and *Table 9.3 – CT and OS Outcomes with DNA Available.* These tabulations show the estimated volume of each type of specimen (serum, EDTA plasma, citrate plasma, DNA) available according to the primary outcomes of interest in the clinical trial and observational study components separately. Table 9.4 tabulates the number of funded studies using these specimens by outcome type and specimen type. Specimen availability is not shown for women who have not experienced one of these outcomes because of the large supply of potential controls. Urine samples, collected at the three bone mineral densitometry clinics, are also not shown but these resources have not yet been used for any purpose. .

The WHI specimen resources have been divided into three accounts, (1) that which is available to WHI investigators now to support core or ancillary study activities, (2) that which is reserved for Broad Agency Announcement awardees (see below); and (3) that

which is reserved for use by WHI investigators at the end of the Extension Follow-up period. Tabulations for each of these accounts is available upon request.

1.7 Core, Collaborative, Broad Agency Announcement, and Ancillary Study Activities

WHI investigators are involved in numerous activities funded by the program designed to further explicate the results of the clinical trials, to expand the scope of our understanding of intervention effects, and to identify and evaluate biomarkers of disease through use of the WHI repository. These core studies are summarized briefly in Table 10.1. Consortium studies in which the WHI has been invited to participate are shown in Table 10.2.

In January 2006, the NHLBI released a Broad Agency Announcement (BAA) to the larger scientific community, requesting proposals designed to use WHI specimens. The 12 awardees were announced in January 2007 and all are now active. These studies are listed in Table 10.3. A second BAA competition for WHI specimens and funding occurred during 2008 and awards will be announced in December 2008.

WHI investigators and their colleagues continue to propose ancillary studies to use WHI resources. Together these efforts are aimed to maximize the use of these resources to provide insight into the causes and mechanisms of disease. A summary of all proposed ancillary studies and associated status is found in Table 10.4 with a detailed listing in Table 10.5.

Participant enrollments to ancillary studies requiring a separate consent are tabulated by Field Center and shown in Table 10.6. Nearly 34,000 participants were involved in ancillary studies during WHI and nearly 29,000 during the Extension Study. Table 10.7 provides the distribution of enrollments per participant. Approximately 17% of ES participants are enrolled in one or more ancillary study, and of these, the majority participate in only one.

A detailed progress report from the WHI Memory Study (WHIMS) Coordinating Center for the studies associated with cognition and dementia is provided in the Appendix.

1.8 Publications

WHI investigators remain engaged in the publication process. To date, 888 manuscript proposals have been received and 704 approved for development by the Publications and Presentations committee. Of these, 375 have been published or are in press, including 72 since the last report. A summary of manuscript stage from 'Manuscript proposal and writing group approved' through 'Published' is provided in Table 11.1 and a listing of these proposals is provided in Table 11.2.

Table 1.3
Consent Status by Age and Race/Ethnicity

Data as of: August 15, 2008

WHI Enrollment	Enrolled in WHI	Eligible for extension[1]	Consented N	Consented %
Clinical Trial	68132	63332	52176	82.4
Age				
50-54	9188	8754	7237	82.7
55-59	14661	13940	11724	84.1
60-69	31389	29290	24528	83.7
70-79	12894	11348	8687	76.6
Race/Ethnicity				
American Indian	292	260	185	71.2
Asian/Pacific Islander	1519	1414	1105	78.1
Black	6983	6423	4769	74.2
Hispanic	2875	2686	1791	66.7
White	55525	51682	43680	84.5
Unknown	938	867	646	74.5
Observational Study	93676	86744	63230	72.9
Age				
50-54	12381	11969	8995	75.2
55-59	17329	16565	12732	76.9
60-69	41200	38502	28582	74.2
70-79	22766	19708	12921	65.6
Race/Ethnicity				
American Indian	421	372	217	58.3
Asian/Pacific Islander	2671	2444	1291	52.8
Black	7635	6868	3585	52.2
Hispanic	3609	3333	1598	47.9
White	78016	72504	55766	76.9
Unknown	1324	1223	773	63.2

[1] Eligibility defined as alive at the beginning of consent and willing to be contacted.

Table 1.4
Extension Consent Summary by Field Center

Data as of August 15, 2008

	DM			HT			CaD			CT			OS		
	Eligible	Consent	%	Eligible	Consent	%	Eligible	Consent	%	Eligible	Consent	%	Eligible	Consent	%
Atlanta	1329	1068	80.4	534	441	82.6	834	722	86.6	1611	1298	80.6	2311	1831	79.2
Bettendorf	470	400	85.1	708	624	88.1	658	596	90.6	1051	922	87.7	1404	1110	79.1
Birmingham	1237	955	77.2	705	579	82.1	887	762	85.9	1695	1334	78.7	2303	1343	58.3
Bowman	1024	808	78.9	567	425	75.0	652	539	82.7	1408	1091	77.5	2083	1569	75.3
Brigham	1643	1429	87.0	770	664	86.2	1024	939	91.7	2206	1906	86.4	2841	2310	81.3
Buffalo	1057	1001	94.7	631	577	91.4	921	883	95.9	1490	1395	93.6	2042	1733	84.9
Chapel Hill	1061	943	88.9	586	488	83.3	719	650	90.4	1447	1264	87.4	1972	1584	80.3
Chi-Rush	872	627	71.9	495	353	71.3	785	604	76.9	1226	880	71.8	1881	1029	54.7
Chicago	1121	952	84.9	518	443	85.5	759	687	90.5	1493	1266	84.8	1754	1369	78.1
Cincinnati	967	881	91.1	495	444	89.7	859	803	93.5	1298	1176	90.6	2076	1616	77.8
Columbus	1072	898	83.8	558	454	81.4	845	732	86.6	1456	1199	82.3	2098	1705	81.3
Des Moines	478	400	83.7	865	624	72.1	807	638	79.1	1237	938	75.8	1513	1091	72.1
Detroit	914	707	77.4	470	360	76.6	806	650	80.6	1220	938	76.9	1911	1416	74.1
Gainesville	1289	1182	91.7	875	800	91.4	852	798	93.7	1935	1771	91.5	2565	2176	84.8
GWU-DC	1069	929	86.9	525	453	86.3	814	746	91.6	1443	1245	86.3	2132	1681	78.8
Honolulu	1006	804	79.9	372	283	76.1	628	523	83.3	1280	1003	78.4	1897	984	51.9
Houston	845	636	75.3	427	269	63.0	573	437	76.3	1160	829	71.5	1906	1403	73.6
Irvine	1104	943	85.4	550	452	82.2	881	779	88.4	1509	1274	84.4	2062	1665	80.7
L.A.	1156	912	78.9	554	410	74.0	971	803	82.7	1559	1213	77.8	2056	1615	78.6
La Jolla	1525	976	64.0	682	329	48.2	1080	721	66.8	1986	1194	60.1	3188	1884	59.1
Madison	1032	929	90.0	622	563	90.5	867	801	92.4	1484	1343	90.5	1855	1420	76.5
Medlantic	1027	880	85.7	544	448	82.4	782	694	88.7	1367	1157	84.6	2036	1456	71.5
Memphis	1164	866	74.4	663	483	72.9	839	661	78.8	1558	1148	73.7	2250	1249	55.5
Miami	1009	729	72.2	544	387	71.1	500	378	75.6	1377	987	71.7	1254	695	55.4
Milwaukee	1084	973	89.8	683	589	86.2	953	876	91.9	1531	1352	88.3	2113	1586	75.1
Minneapolis	1262	1097	86.9	793	654	82.5	1045	949	90.8	1877	1606	85.6	2576	1949	75.7
Nevada	980	849	86.6	572	480	83.9	923	816	88.4	1362	1163	85.4	1957	1551	79.3
Newark	1269	1011	79.7	490	393	80.2	836	713	85.3	1600	1277	79.8	2369	1686	71.2
New Brunswick	375	328	87.5	368	330	89.7	436	402	92.2	657	580	88.3	779	651	83.6
NY-City	1223	1003	82.0	698	560	80.2	827	718	86.8	1767	1435	81.2	2710	1526	56.3
Oakland	1022	903	88.4	583	512	87.8	628	577	91.9	1468	1296	88.3	1895	1480	78.1
Pawtucket	1892	1676	88.6	898	780	86.9	1328	1217	91.6	2488	2187	87.9	3395	2685	79.1
Pittsburgh	1096	1005	91.7	595	540	90.8	804	754	93.8	1528	1395	91.3	1733	1381	79.7
Portland	1111	950	85.5	592	524	88.5	827	750	90.7	1523	1323	86.9	2082	1565	75.2
San Antonio	873	621	71.1	658	448	68.1	793	584	73.6	1261	875	69.4	1709	962	56.3
Seattle	1097	904	82.4	686	542	79.0	804	682	84.8	1681	1358	80.8	1515	1070	70.6
Stanford	1226	1071	87.4	633	558	88.2	948	866	91.4	1639	1445	88.2	2465	2045	83.0

Table 1.4 (continued)

Table 1.4 (continued)
Extension Consent Summary by Field Center

Data as of August 15, 2008

	DM			HT			CaD			CT			OS		
	Eligible	Consent	%	Eligible	Consent	%	Eligible	Consent	%	Eligible	Consent	%	Eligible	Consent	%
Stonybrook	936	801	85.6	473	400	84.6	572	509	89.0	1266	1083	85.5	1915	1467	76.6
Torrance	745	554	74.4	288	206	71.5	507	405	79.9	916	673	73.5	1385	877	63.3
Tucson	1387	1077	77.6	714	508	71.1	1007	816	81.0	1929	1461	75.7	2544	1650	64.9
UC Davis	1358	1135	83.6	642	542	84.4	1033	904	87.5	1790	1488	83.1	2107	1393	66.1
Worcester	1153	1045	90.6	568	514	90.5	833	778	93.4	1553	1408	90.7	2105	1772	84.2
Total	45560	37858	83.1	25194	20433	81.1	34447	29862	86.7	63332	52176	82.4	86744	63230	72.9

Table 1.5
Response Rates to CCC Annual Mailings, Extension Year 1

Data as of August 15, 2008

	1st Mailing Period				2nd Mailing Period						3rd Mailing Period					
Study	Form	Sent Mail 1	Response		Past 2nd mailing period	Sent Mail 2		Response		Cumulative response	Past 3rd mailing period	Sent Mail 3		Response		Cumulative Response
Total	33	113981	96608	84.8%	113981	17826	15.6%	8717	48.9%	92.4%	113981	7883	6.9%	2903	36.8%	95.0%
	134	113991	95149	83.5%	113991	19196	16.8%	9588	50.0%	91.9%	113991	8315	7.3%	3042	36.6%	94.6%
	150	20240	15903	78.6%	20240	4496	22.2%	1904	42.4%	88.0%	20240	2247	11.1%	737	32.8%	91.6%
	151	81906	67510	82.4%	81906	14826	18.1%	7200	48.6%	91.2%	81906	6559	8.0%	2374	36.2%	94.1%
HT	33	20235	15887	78.5%	20235	4503	22.3%	1903	42.3%	87.9%	20235	2243	11.1%	734	32.7%	91.5%
	134	20237	15707	77.6%	20237	4680	23.1%	1999	42.7%	87.5%	20237	2311	11.4%	736	31.9%	91.1%
	150	20240	15903	78.6%	20240	4496	22.2%	1904	42.4%	88.0%	20240	2247	11.1%	737	32.8%	91.6%
	151	20241	15875	78.4%	20241	4520	22.3%	1917	42.4%	87.9%	20241	2258	11.2%	747	33.1%	91.6%
DM	33	37611	30715	81.7%	37611	7216	19.2%	3430	47.5%	90.8%	37611	3257	8.7%	1153	35.4%	93.9%
	134	37614	30339	80.7%	37614	7589	20.2%	3648	48.1%	90.4%	37614	3407	9.1%	1189	34.9%	93.5%
	150	6060	4655	76.8%	6060	1473	24.3%	615	41.8%	87.0%	6060	763	12.6%	235	30.8%	90.8%
	151	37618	30564	81.3%	37618	7390	19.6%	3573	48.4%	90.8%	37618	3293	8.8%	1178	35.8%	93.9%
CaD	33	29670	24166	81.5%	29670	5746	19.4%	2673	46.5%	90.5%	29670	2633	8.9%	943	35.8%	93.6%
	134	29673	23898	80.5%	29673	6008	20.3%	2819	46.9%	90.0%	29673	2735	9.2%	964	35.3%	93.3%
	150	12815	10148	79.2%	12815	2771	21.6%	1187	42.8%	88.5%	12815	1365	10.7%	469	34.4%	92.1%
	151	29678	24078	81.1%	29678	5846	19.7%	2756	47.1%	90.4%	29678	2657	9.0%	963	36.2%	93.7%
OS	33	62195	54662	87.9%	62195	7578	12.2%	3991	52.7%	94.3%	62195	3147	5.1%	1251	39.8%	96.3%
	134	62200	53708	86.4%	62200	8447	13.6%	4581	54.2%	93.7%	62200	3375	5.4%	1347	39.9%	95.9%
	151	30107	25724	85.4%	30107	4391	14.6%	2329	53.0%	93.2%	30107	1771	5.9%	683	38.6%	95.5%

Table 1.5 (continued for year 2)
Response Rates to CCC Annual Mailings, Extension Year 2

Data as of August 15, 2008

	1st Mailing Period				2nd Mailing Period						3rd Mailing Period					
Study	Form	Sent Mail 1	Response		Past 2nd mailing period	Sent Mail 2		Response		Cumulative Response	Past 3rd mailing period	Sent Mail 3		Response		Cumulative Response
Total	33	112945	95639	84.7%	112945	18499	16.4%	7847	42.4%	91.6%	112945	6282	5.6%	2185	34.8%	93.6%
	134[1]	1414	550	38.9%	1414	778	55.0%	126	16.2%	47.8%	1414	429	30.3%	63	14.7%	52.3%
	150	19782	15709	79.4%	19782	4167	21.1%	1552	37.3%	87.3%	19782	1561	7.9%	468	30.0%	89.6%
	151	112991	95499	84.5%	112991	18693	16.5%	7987	42.7%	91.6%	112991	6323	5.6%	2212	35.0%	93.6%
HT	33	19780	15694	79.3%	19780	4182	21.1%	1564	37.4%	87.3%	19780	1563	7.9%	472	30.2%	89.6%
	134[1]	332	63	19.0%	332	237	71.4%	32	13.5%	28.6%	332	148	44.6%	11	7.4%	31.9%
	150	19782	15709	79.4%	19782	4167	21.1%	1552	37.3%	87.3%	19782	1561	7.9%	468	30.0%	89.6%
	151	19785	15701	79.4%	19785	4195	21.2%	1569	37.4%	87.3%	19785	1567	7.9%	473	30.2%	89.7%
DM	33	36972	30737	83.1%	36972	6651	18.0%	2750	41.4%	90.6%	36972	2229	6.0%	767	34.4%	92.7%
	134[1]	376	87	23.1%	376	249	66.2%	23	9.2%	29.3%	376	144	38.3%	21	14.6%	34.8%
	150	5931	4657	78.5%	5931	1321	22.3%	478	36.2%	86.6%	5931	502	8.5%	154	30.7%	89.2%
	151	36981	30703	83.0%	36981	6703	18.1%	2793	41.7%	90.6%	36981	2238	6.1%	768	34.3%	92.7%
CaD	33	29172	24141	82.8%	29172	5309	18.2%	2139	40.3%	90.1%	29172	1823	6.3%	609	33.4%	92.2%
	134[1]	351	77	21.9%	351	236	67.2%	22	9.3%	28.2%	351	146	41.6%	15	10.3%	32.5%
	150	12538	10066	80.3%	12538	2529	20.2%	958	37.9%	87.9%	12538	940	7.5%	286	30.4%	90.2%
	151	29173	24109	82.6%	29173	5350	18.3%	2165	40.5%	90.1%	29173	1832	6.3%	613	33.5%	92.2%
OS	33	62122	53853	86.7%	62122	8997	14.5%	4018	44.7%	93.2%	62122	2995	4.8%	1102	36.8%	94.9%
	134[1]	805	416	51.7%	805	365	45.3%	79	21.6%	61.5%	805	179	22.2%	32	17.9%	65.5%
	151	62155	53746	86.5%	62155	9125	14.7%	4108	45.0%	93.1%	62155	3025	4.9%	1124	37.2%	94.9%

[1] Required only in Extension study Follow-up Year 1. Year 2 and 3 responses reflect data collected from Year 1 non-respondents.

Table 1.5 (continued for year 3)
Response Rates to CCC Annual Mailings, Extension Year 3

Data as of August 15, 2008

	1st Mailing Period				2nd Mailing Period					3rd Mailing Period					
Study	Form	Sent Mail 1	Response		Past 2nd mailing period	Sent Mail 2		Response		Cumulative Response	Past 3rd mailing period	Sent Mail 3		Response		Cumulative Response
Total	33	98106	82677	84.3%	83217	13032	15.7%	5614	43.1%	91.1%	83217	5967	7.2%	1673	28.0%	93.1%
	134[1]	206	31	15.1%	191	124	64.9%	8	6.5%	19.9%	191	103	53.9%	9	8.7%	24.6%
	150	14446	11459	79.3%	11172	2241	20.1%	835	37.3%	86.7%	1172	1186	10.6%	268	22.6%	89.1%
	151	98103	82623	84.2%	83214	13096	15.7%	5654	43.2%	91.1%	83214	6013	7.2%	1698	28.2%	93.1%
HT	33	14449	11440	79.2%	11175	2256	20.2%	850	37.7%	86.6%	11175	1178	10.5%	269	22.8%	89.0%
	134[1]	60	4	6.7%	54	43	79.6%	2	4.7%	11.1%	54	38	70.4%	4	10.5%	18.5%
	150	14446	11459	79.3%	11172	2241	20.1%	835	37.3%	86.7%	11172	1186	10.6%	268	22.6%	89.1%
	151	14447	11466	79.4%	11173	2245	20.1%	840	37.4%	86.7%	11173	1183	10.6%	269	22.7%	89.1%
DM	33	26980	22172	82.2%	20654	3686	17.9%	1529	41.5%	89.4%	20654	1801	8.7%	506	28.1%	91.8%
	134[1]	64	1	1.6%	58	46	79.3%	3	6.5%	6.9%	58	39	67.2%	4	10.3%	13.8%
	150	4307	3341	77.6%	3399	745	21.9%	254	34.1%	84.8%	3399	424	12.5%	104	24.5%	87.9%
	151	26979	22176	82.2%	20653	3682	17.8%	1524	41.4%	89.4%	20653	1813	8.8%	514	28.4%	91.9%
CaD	33	21279	17513	82.3%	16255	2868	17.6%	1206	42.1%	89.5%	16255	1377	8.5%	365	26.5%	91.7%
	134[1]	67	3	4.5%	60	46	76.7%	4	8.7%	11.7%	60	38	63.3%	1	2.6%	13.3%
	150	9188	7390	80.4%	7131	1372	19.2%	512	37.3%	87.4%	7131	708	9.9%	167	23.6%	89.7%
	151	21278	17524	82.4%	16254	2864	17.6%	1205	42.1%	89.5%	16254	1381	8.5%	366	26.5%	91.8%
OS	33	60986	52399	85.9%	54789	7843	14.3%	3495	44.6%	92.3%	54789	3412	6.2%	1004	29.4%	94.1%
	134[1]	106	26	24.5%	101	56	55.5%	4	7.1%	28.7%	101	45	44.6%	4	8.9%	32.7%
	151	60985	52326	85.8%	54788	7913	14.4%	3544	44.8%	92.2%	54788	3441	6.3%	1020	29.6%	94.1%

[1] Required only in Extension study Follow-up Year 1. Year 2 and 3 responses reflect data collected from Year 1 non-respondents.

Table 1.6
Response Rates to Field Center Follow-up and Cumulative Response--Extension Study Follow-up Year 1

Data as of August 15, 2008

Study	Form	Eligible for FC Follow-up	Respondents		Total Estimated Response Rate
Total	33	5434	4982	91.7%	98.3%
	134	6093	4970	81.6%	97.9%
	150	1614	1150	71.3%	96.8%
	151	4875	1667	34.2%	94.7%
HT	33	1542	1326	86.0%	97.6%
	134	1677	1302	77.6%	97.0%
	150	1614	1150	71.3%	96.8%
	151	1631	602	36.9%	94.0%
DM	33	2174	1876	86.3%	98.4%
	134	2365	1839	77.8%	98.0%
	150	541	390	72.1%	96.7%
	151	2282	736	32.3%	95.4%
CaD	33	1718	1477	86.0%	98.2%
	134	1876	1457	77.7%	97.8%
	150	947	672	71.0%	96.9%
	151	1810	621	34.3%	95.4%
OS	33	2241	2230	99.5%	98.4%
	134	2609	2271	87.0%	98.0%
	151	1505	525	34.9%	94.2%

Table 1.6 (continued for year 2)
Response Rates to Field Center Follow-up and Cumulative Response--Extension Study Follow-up Year 2

Data as of August 15, 2008

Study	Form	Eligible for FC Follow-up	Respondents		Total Estimated Response Rate
Total	33	7007	6719	95.9%	98.4%
	134[1]	1406	432	30.7%	43.9%
	150	2009	1678	83.5%	96.5%
	151	7448	4539	60.9%	96.5%
HT	33	1943	1838	94.6%	97.3%
	134[1]	393	138	35.1%	36.9%
	150	2009	1678	83.5%	96.5%
	151	2042	1296	63.5%	94.7%
DM	33	2649	2534	95.7%	98.3%
	134[1]	518	173	33.4%	36.6%
	150	633	543	85.8%	96.7%
	151	2804	1749	62.4%	96.2%
CaD	33	2165	2055	94.9%	98.1%
	134[1]	416	151	36.3%	38.7%
	150	1189	993	83.5%	96.7%
	151	2295	1463	63.8%	96.1%
OS	33	3031	2930	96.7%	98.8%
	134[1]	622	168	27.0%	50.7%
	151	3252	1923	59.1%	97.1%

[1] Required only in Extension Study Follow-up Year 1. Year 2 and 3 responses reflect data collected from Year 1 non-respondents.

Table 1.6 (continued for year 3)
Response Rates to Field Center Follow-up and Cumulative Response--Extension Study Follow-up Year 3

Data as of August 15, 2008

Study	Form	Eligible for FC Follow-up	Respondents		Total Estimated Response Rate
Total	33	1918	1824	95.1%	98.3%
	134[1]	372	40	10.8%	12.6%
	150	190	155	81.6%	95.8%
	151	2025	1236	61.0%	96.4%
HT	33	186	167	89.8%	96.4%
	134[1]	34	4	11.8%	12.9%
	150	190	155	81.6%	95.8%
	151	194	110	56.7%	93.1%
DM	33	287	268	93.4%	97.5%
	134[1]	46	6	13.0%	13.2%
	150	73	65	89.0%	96.2%
	151	302	183	60.6%	94.8%
CaD	33	228	207	90.8%	97.1%
	134[1]	36	6	16.7%	13.9%
	150	123	100	81.3%	95.8%
	151	240	146	60.8%	94.6%
OS	33	1517	1456	96.0%	98.4%
	134[1]	310	32	10.3%	12.6%
	151	1602	992	61.9%	96.7%

[1] Required only in Extension Study Follow-up Year 1. Year 2 and 3 responses reflect data collected from Year 1 non-respondents.

Table 2.1
Hormone Therapy Component Age – and Race/Ethnicity

Data as of August 15, 2008

HT Participants	Total Randomized	% of Overall Goal	Distribution	Design Assumption
Age				
Overall	**27,347**			
50-54	3,420	125%	13%	10%
55-59	5,413	99%	20%	20%
60-69	12,360	100%	45%	45%
70-79	6,154	90%	23%	25%
Without Uterus	**10,739**			
50-54	1,396	113%	13%	10%
55-59	1,917	78%	18%	20%
60-69	4,851	88%	45%	45%
70-79	2,575	84%	24%	25%
With Uterus	**16,608**			
50-54	2,024	135%	12%	10%
55-59	3,496	116%	21%	20%
60-69	7,509	111%	45%	45%
70-79	3,579	95%	22%	25%
Race/Ethnicity				
Overall	**27,347**			
American Indian	130		<1%	
Asian	527		2%	
Black	2,738		10%	
Hispanic	1,537		6%	
White	22,030		81%	
Unknown	385		1%	
Without Uterus	**10,739**			
American Indian	75		1%	
Asian	164		2%	
Black	1,616		15%	
Hispanic	651		6%	
White	8,084		75%	
Unknown	149		1%	
With Uterus	**16,608**			
American Indian	55		<1%	
Asian	363		2%	
Black	1,122		7%	
Hispanic	886		5%	
White	13,946		84%	
Unknown	236		1%	

Table 2.2
Lost-to-Follow-up and Vital Status: HT Participants by Hysterectomy Status

Data as of: August 15, 2008
Extension Participants Only

	Without Uterus (N=7,645)		With Uterus (N=12,788)		HT Participants (N=20,433)	
	N	%	N	%	N	%
Vital Status/Participation						
Deceased	299	3.9	455	3.6	754	3.7
Alive: Current Participation[1]	7049	92.2	11938	93.4	18987	92.9
Alive: Recent Participation[2]	155	2.0	182	1.4	337	1.6
Alive: Past/Unknown Participation[3]	3	<0.1	5	<0.1	8	<0.1
Stopped Follow-Up[4]	80	1.0	134	1.0	214	1.0
Lost to Follow-Up[5]	59	0.8	74	0.6	133	0.7

Data as of: September 12, 2005
Events through Study Closeout

	Without Uterus (N=10,739)		With Uterus (N=16,608)		HT Participants (N=27,347)	
	N	%	N	%	N	%
Vital Status/Participation						
Deceased	727	6.8	918	5.5	1645	6.0
Alive: Current Participation[6]	9302	86.6	14897	89.7	24199	88.5
Alive: Recent Participation[7]	89	0.8	78	0.5	167	0.6
Alive: Past/Unknown Participation[8]	4	<0.1	4	<0.1	8	<0.1
Stopped Follow-Up[4]	475	4.4	538	3.2	1013	3.7
Lost to Follow-Up[5]	142	1.3	173	1.0	315	1.2

[1] Participants who have filled in a Form 33 within the last 15 months.
[2] Participants who last filled in a Form 33 between 15 and 24 months ago.
[3] Participants without a Form 33 within the last 24 months, who have been located (as indicated on Form 23) within the last 6 months.
[4] Participants with codes 5 (no follow-up) or 8 (absolutely no follow-up) on Form 7 or 9.
[5] Participants not in any of the above categories.
[6] Participants who have filled in a Form 33 within the last 9 months.
[7] Participants who last filled in a Form 33 between 9 and 18 months ago.
[8] Participants without a Form 33 within the last 18 months, who have been located (as indicated on Form 23) within the last 6 months.

Table 2.3
Verified Outcomes (Annualized Percentages) by Age for Hormone Therapy

Data as of: August 15, 2008

Outcomes	Total		Age 50-54		55-59		60-69		70-79	
Number randomized	27347		3420		5413		12360		6154	
Mean follow-up (months)	121.7		128.4		125.6		121.6		114.8	
Cardiovascular										
CHD[1]	1351	(0.49%)	67	(0.18%)	145	(0.26%)	623	(0.50%)	516	(0.88%)
CHD death[2]	408	(0.15%)	15	(0.04%)	33	(0.06%)	165	(0.13%)	195	(0.33%)
Total MI[3]	1063	(0.38%)	54	(0.15%)	120	(0.21%)	497	(0.40%)	392	(0.67%)
Clinical MI	1030	(0.37%)	53	(0.14%)	118	(0.21%)	480	(0.38%)	379	(0.64%)
CABG/PTCA	1606	(0.58%)	78	(0.21%)	211	(0.37%)	810	(0.65%)	507	(0.86%)
Carotid artery disease	273	(0.10%)	5	(0.01%)	30	(0.05%)	148	(0.12%)	90	(0.15%)
Stroke	911	(0.33%)	36	(0.10%)	84	(0.15%)	406	(0.32%)	385	(0.65%)
Non-disabling stroke[4]	504	(0.18%)	28	(0.08%)	57	(0.10%)	220	(0.18%)	199	(0.34%)
Fatal/disabling stroke[4]	344	(0.12%)	5	(0.01%)	21	(0.04%)	153	(0.12%)	165	(0.28%)
Unknown status from stroke[4]	63	(0.02%)	3	(0.01%)	6	(0.01%)	33	(0.03%)	21	(0.04%)
PVD	274	(0.10%)	14	(0.04%)	29	(0.05%)	145	(0.12%)	86	(0.15%)
DVT	502	(0.18%)	30	(0.08%)	71	(0.13%)	228	(0.18%)	173	(0.29%)
Pulmonary embolism	367	(0.13%)	25	(0.07%)	49	(0.09%)	173	(0.14%)	120	(0.20%)
Coronary disease[5]	3162	(1.14%)	170	(0.46%)	381	(0.67%)	1488	(1.19%)	1123	(1.91%)
DVT/PE	702	(0.25%)	40	(0.11%)	94	(0.17%)	335	(0.27%)	233	(0.40%)
Total cardiovascular disease	4687	(1.69%)	247	(0.68%)	568	(1.00%)	2203	(1.76%)	1669	(2.83%)
Cancer										
Breast cancer	1181	(0.43%)	118	(0.32%)	219	(0.39%)	563	(0.45%)	281	(0.48%)
Invasive breast cancer	955	(0.34%)	91	(0.25%)	176	(0.31%)	445	(0.36%)	243	(0.41%)
Non-invasive breast cancer	237	(0.09%)	28	(0.08%)	44	(0.08%)	125	(0.10%)	40	(0.07%)
Ovarian cancer	102	(0.04%)	5	(0.01%)	21	(0.04%)	55	(0.04%)	21	(0.04%)
Endometrial cancer[6]	125	(0.04%)	11	(0.03%)	26	(0.05%)	61	(0.05%)	27	(0.05%)
Colorectal cancer	396	(0.14%)	23	(0.06%)	46	(0.08%)	194	(0.15%)	133	(0.23%)
Other cancer[7]	1622	(0.58%)	126	(0.34%)	238	(0.42%)	765	(0.61%)	493	(0.84%)
Total cancer	3279	(1.18%)	272	(0.74%)	537	(0.95%)	1560	(1.25%)	910	(1.55%)
Fractures										
Hip fracture	578	(0.21%)	8	(0.02%)	37	(0.07%)	204	(0.16%)	329	(0.56%)
Deaths										
Cardiovascular deaths	737	(0.27%)	26	(0.07%)	57	(0.10%)	284	(0.23%)	370	(0.63%)
Cancer deaths	965	(0.35%)	48	(0.13%)	112	(0.20%)	466	(0.37%)	339	(0.58%)
Other known cause	508	(0.18%)	22	(0.06%)	62	(0.11%)	201	(0.16%)	223	(0.38%)
Unknown cause	85	(0.03%)	6	(0.02%)	10	(0.02%)	35	(0.03%)	34	(0.06%)
Not yet adjudicated	209	(0.08%)	7	(0.02%)	17	(0.03%)	92	(0.07%)	93	(0.16%)
Total death	2504	(0.90%)	109	(0.30%)	258	(0.46%)	1078	(0.86%)	1059	(1.80%)

[1] "CHD" includes clinical MI, evolving Q-wave MI, and CHD death; Q-wave MI is not collected in the WHI Extension Study.
[2] "CHD death" includes definite and possible CHD death.
[3] "Total MI" includes clinical MI and evolving Q-wave MI; Q-wave MI is not collected in the WHI Extension Study.
[4] Non-disabling stroke includes Glasgow scales 1 and 2; fatal/disabling includes Glasgow scales 3-5 and death within 1 month of stroke; and unknown status includes Glasgow scale 6 and status not yet known.
[5] "Coronary disease" includes clinical MI, evolving Q-wave MI, possible evolving Q-wave MI, CHD death, angina, congestive heart failure, and CABG/PTCA; Q-wave MI, angina, and congestive heart failure are not collected in the WHI Extension Study.
[6] Only women without a baseline hysterectomy are used to compute the annual rates of endometrial cancer.
[7] Only one report of "other cancer" is counted per woman; however, the first of each type is adjudicated. Excludes non-melanoma skin cancer.

Table 2.4
Verified Outcomes (Annualized Percentages) by Race/Ethnicity for Hormone Therapy

Data as of: August 15, 2008

Outcomes	Race/Ethnicity: American Indian/ Alaskan Native		Asian/Pacific Islander		Black/African American		Hispanic/ Latino		White		Unknown	
Number randomized	130		527		2738		1537		22030		385	
Mean follow-up (months)	114.2		114.5		118.7		113.0		123.0		115.6	
Cardiovascular												
CHD[1]	5	(0.40%)	17	(0.34%)	132	(0.49%)	38	(0.26%)	1137	(0.50%)	22	(0.59%)
CHD death[2]	2	(0.16%)	6	(0.12%)	62	(0.23%)	9	(0.06%)	326	(0.14%)	3	(0.08%)
Total MI[3]	4	(0.32%)	15	(0.30%)	85	(0.31%)	31	(0.21%)	908	(0.40%)	20	(0.54%)
Clinical MI	4	(0.32%)	14	(0.28%)	84	(0.31%)	29	(0.20%)	880	(0.39%)	19	(0.51%)
CABG/PTCA	7	(0.57%)	19	(0.38%)	124	(0.46%)	59	(0.41%)	1373	(0.61%)	24	(0.65%)
Carotid artery disease	1	(0.08%)	1	(0.02%)	11	(0.04%)	3	(0.02%)	254	(0.11%)	3	(0.08%)
Stroke	6	(0.49%)	13	(0.26%)	117	(0.43%)	26	(0.18%)	735	(0.33%)	14	(0.38%)
Non-disabling stroke[4]	3	(0.24%)	8	(0.16%)	63	(0.23%)	15	(0.10%)	408	(0.18%)	7	(0.19%)
Fatal/disabling stroke[4]	3	(0.24%)	5	(0.10%)	44	(0.16%)	7	(0.05%)	281	(0.12%)	4	(0.11%)
Unknown status from stroke[4]	0	(0.00%)	0	(0.00%)	10	(0.04%)	4	(0.03%)	46	(0.02%)	3	(0.08%)
PVD	2	(0.16%)	3	(0.06%)	30	(0.11%)	2	(0.01%)	236	(0.10%)	1	(0.03%)
DVT	3	(0.24%)	2	(0.04%)	51	(0.19%)	7	(0.05%)	436	(0.19%)	3	(0.08%)
Pulmonary embolism	3	(0.24%)	1	(0.02%)	44	(0.16%)	4	(0.03%)	312	(0.14%)	3	(0.08%)
Coronary disease[5]	12	(0.97%)	40	(0.80%)	332	(1.23%)	114	(0.79%)	2619	(1.16%)	45	(1.21%)
DVT/PE	6	(0.49%)	2	(0.04%)	77	(0.28%)	9	(0.06%)	603	(0.27%)	5	(0.13%)
Total cardiovascular disease	22	(1.78%)	55	(1.09%)	500	(1.85%)	145	(1.00%)	3908	(1.73%)	57	(1.54%)
Cancer												
Breast cancer	3	(0.24%)	25	(0.50%)	100	(0.37%)	36	(0.25%)	1005	(0.44%)	12	(0.32%)
Invasive breast cancer	3	(0.24%)	19	(0.38%)	81	(0.30%)	27	(0.19%)	817	(0.36%)	8	(0.22%)
Non-invasive breast cancer	0	(0.00%)	7	(0.14%)	19	(0.07%)	9	(0.06%)	198	(0.09%)	4	(0.11%)
Ovarian cancer	0	(0.00%)	2	(0.04%)	7	(0.03%)	0	(0.00%)	91	(0.04%)	2	(0.05%)
Endometrial cancer[6]	1	(0.08%)	1	(0.02%)	7	(0.03%)	6	(0.04%)	108	(0.05%)	2	(0.05%)
Colorectal cancer	1	(0.08%)	9	(0.18%)	30	(0.11%)	14	(0.10%)	333	(0.15%)	9	(0.24%)
Other cancer[7]	7	(0.57%)	31	(0.62%)	119	(0.44%)	52	(0.36%)	1394	(0.62%)	19	(0.51%)
Total cancer	12	(0.97%)	68	(1.35%)	254	(0.94%)	102	(0.70%)	2802	(1.24%)	41	(1.11%)
Fractures												
Hip fracture	3	(0.24%)	6	(0.12%)	12	(0.04%)	10	(0.07%)	543	(0.24%)	4	(0.11%)
Deaths												
Cardiovascular deaths	4	(0.32%)	11	(0.22%)	105	(0.39%)	16	(0.11%)	594	(0.26%)	7	(0.19%)
Cancer deaths	5	(0.40%)	21	(0.42%)	80	(0.30%)	36	(0.25%)	811	(0.36%)	12	(0.32%)
Other known cause	4	(0.32%)	5	(0.10%)	44	(0.16%)	9	(0.06%)	436	(0.19%)	10	(0.27%)
Unknown cause	0	(0.00%)	2	(0.04%)	17	(0.06%)	3	(0.02%)	62	(0.03%)	1	(0.03%)
Not yet adjudicated	1	(0.08%)	2	(0.04%)	15	(0.06%)	6	(0.04%)	184	(0.08%)	1	(0.03%)
Total Death	14	(1.13%)	41	(0.82%)	261	(0.96%)	70	(0.48%)	2087	(0.92%)	31	(0.84%)

[1] "CHD" includes clinical MI, evolving Q-wave MI, and CHD death; Q-wave MI is not collected in the WHI Extension Study.
[2] "CHD death" includes definite and possible CHD death.
[3] "Total MI" includes clinical MI and evolving Q-wave MI; Q-wave MI is not collected in the WHI Extension Study.
[4] Non-disabling stroke includes Glasgow scales 1 and 2; fatal/disabling includes Glasgow scales 3-5 and death within 1 month of stroke; and unknown status includes Glasgow scale 6 and status not yet known.
[5] "Coronary disease" includes clinical MI, evolving Q-wave MI, possible evolving Q-wave MI, CHD death, angina, congestive heart failure, and CABG/PTCA; Q-wave MI, angina, and congestive heart failure are not collected in the WHI Extension Study.
[6] Only women without a baseline hysterectomy are used to compute the annual rates of endometrial cancer.
[7] Only one report of "other cancer" is counted per woman; however, the first of each type is adjudicated. Excludes non-melanoma skin cancer.

Table 2.5
Verified Outcomes (Annualized Percentages) for HT Participants Without and With Uterus

Data as of: August 15, 2008

Outcomes	Without Uterus		With Uterus	
Number randomized	10739		16608	
Mean follow-up (months)	119.9		122.9	
Cardiovascular				
CHD[1]	621	(0.58%)	730	(0.43%)
CHD death[2]	209	(0.19%)	199	(0.12%)
Total MI[3]	477	(0.44%)	586	(0.34%)
Clinical MI	462	(0.43%)	568	(0.33%)
CABG/PTCA	747	(0.70%)	859	(0.51%)
Carotid artery disease	139	(0.13%)	134	(0.08%)
Stroke	407	(0.38%)	504	(0.30%)
Non-disabling stroke[4]	212	(0.20%)	292	(0.17%)
Fatal/disabling stroke[4]	161	(0.15%)	183	(0.11%)
Unknown status from stroke[4]	34	(0.03%)	29	(0.02%)
PVD	128	(0.12%)	146	(0.09%)
DVT	200	(0.19%)	302	(0.18%)
Pulmonary embolism	139	(0.13%)	228	(0.13%)
Coronary disease[5]	1510	(1.41%)	1652	(0.97%)
DVT/PE	284	(0.26%)	418	(0.25%)
Total cardiovascular disease	2151	(2.00%)	2536	(1.49%)
Cancer				
Breast cancer	398	(0.37%)	783	(0.46%)
Invasive breast cancer	325	(0.30%)	630	(0.37%)
Non-invasive breast cancer	75	(0.07%)	162	(0.10%)
Ovarian cancer	25	(0.02%)	77	(0.05%)
Endometrial cancer[6]	0	N/A	125	(0.07%)
Colorectal cancer	161	(0.15%)	235	(0.14%)
Other cancer[7]	643	(0.60%)	979	(0.58%)
Total cancer	1186	(1.11%)	2093	(1.23%)
Fractures				
Hip fracture	212	(0.20%)	366	(0.22%)
Deaths				
Cardiovascular deaths	358	(0.33%)	379	(0.22%)
Cancer deaths	402	(0.37%)	563	(0.33%)
Other known cause	196	(0.18%)	312	(0.18%)
Unknown cause	34	(0.03%)	51	(0.03%)
Not yet adjudicated	85	(0.08%)	124	(0.07%)
Total death	1075	(1.00%)	1429	(0.84%)

[1] "CHD" includes clinical MI, evolving Q-wave MI, and CHD death; Q-wave MI is not collected in the WHI Extension Study.
[2] "CHD death" includes definite and possible CHD death.
[3] "Total MI" includes clinical MI and evolving Q-wave MI; Q-wave MI is not collected in the WHI Extension Study.
[4] Non-disabling stroke includes Glasgow scales 1 and 2; fatal/disabling includes Glasgow scales 3-5 and death within 1 month of stroke; and unknown status includes Glasgow scale 6 and status not yet known.
[5] "Coronary disease" includes clinical MI, evolving Q-wave MI, possible evolving Q-wave MI, CHD death, angina, congestive heart failure, and CABG/PTCA; Q-wave MI, angina, and congestive heart failure are not collected in the WHI Extension Study.
[6] Only women without a baseline hysterectomy are used to compute the annual rates of endometrial cancer.
[7] Only one report of "other cancer" is counted per woman; however, the first of each type is adjudicated. Excludes non-melanoma skin cancer.

Table 2.6
Counts (Annualized Percentages) of Participants with Self-Reported Outcomes by Age and Race/Ethnicity for HT Participants Who Did Not Report a Prevalent Condition at Baseline

Data as of: August 15, 2008

Outcome	Total		Age 50-54		55-59		60-69		70-79	
Number randomized	27347		3420		5413		12360		6154	
Mean follow-up (months)	121.7		128.4		125.6		121.6		114.8	
Hospitalizations										
Ever	16023	(5.78%)	1445	(3.95%)	2591	(4.57%)	7517	(6.00%)	4470	(7.59%)
Two or more	9865	(3.56%)	717	(1.96%)	1432	(2.53%)	4647	(3.71%)	3069	(5.21%)
Other										
Diabetes (treated)	3004	(1.14%)	434	(1.23%)	592	(1.10%)	1403	(1.18%)	575	(1.03%)
Gallbladder disease[1, 2]	2117	(1.03%)	282	(1.01%)	443	(1.04%)	988	(1.08%)	404	(0.95%)
Hysterectomy	892	(0.52%)	87	(0.40%)	183	(0.50%)	439	(0.57%)	183	(0.53%)
Glaucoma[2]	3203	(1.36%)	287	(0.90%)	548	(1.12%)	1519	(1.44%)	849	(1.74%)
Osteoporosis[2]	6115	(2.63%)	477	(1.50%)	962	(1.98%)	2955	(2.82%)	1721	(3.62%)
Osteoarthritis[3]	6079	(3.52%)	784	(2.81%)	1265	(3.19%)	2788	(3.71%)	1242	(4.15%)
Rheumatoid arthritis[2]	1698	(0.73%)	211	(0.68%)	341	(0.71%)	764	(0.73%)	382	(0.77%)
Intestinal polyps	5088	(1.97%)	576	(1.63%)	993	(1.84%)	2514	(2.16%)	1005	(1.93%)
Lupus	342	(0.12%)	40	(0.11%)	71	(0.13%)	155	(0.12%)	76	(0.13%)
Kidney stones[2, 3]	769	(0.37%)	94	(0.35%)	143	(0.34%)	346	(0.37%)	186	(0.41%)
Cataracts[2, 3]	8650	(4.69%)	505	(1.87%)	1345	(3.21%)	4578	(5.41%)	2222	(7.16%)
Pills for hypertension	8865	(4.48%)	1031	(3.48%)	1761	(4.01%)	4080	(4.68%)	1993	(5.35%)

Outcomes	Race/Ethnicity: Am Indian/ Alaskan Native		Asian/Pacific Islander		Black/African American		Hispanic/ Latino		White		Unknown	
Number randomized	130		527		2738		1537		22030		385	
Mean follow-up (months)	114.2		114.5		118.7		113.0		123.0		115.6	
Hospitalizations												
Ever	76	(6.15%)	229	(4.55%)	1597	(5.90%)	685	(4.73%)	13220	(5.85%)	216	(5.82%)
Two or more	56	(4.53%)	121	(2.41%)	989	(3.65%)	354	(2.44%)	8223	(3.64%)	122	(3.29%)
Other												
Diabetes (treated)	14	(1.29%)	61	(1.32%)	452	(1.90%)	259	(1.94%)	2176	(1.00%)	42	(1.22%)
Gallbladder disease[1, 2]	13	(1.53%)	32	(0.79%)	187	(0.86%)	129	(1.31%)	1730	(1.05%)	26	(0.96%)
Hysterectomy	3	(0.59%)	8	(0.23%)	60	(0.54%)	43	(0.51%)	768	(0.53%)	10	(0.44%)
Glaucoma[2]	16	(1.54%)	60	(1.40%)	410	(1.84%)	190	(1.50%)	2480	(1.29%)	47	(1.54%)
Osteoporosis[2]	32	(3.04%)	141	(3.29%)	349	(1.50%)	338	(2.76%)	5162	(2.74%)	93	(2.98%)
Osteoarthritis[3]	40	(4.76%)	123	(3.46%)	606	(3.67%)	424	(4.21%)	4791	(3.44%)	95	(3.94%)
Rheumatoid arthritis[2]	15	(1.53%)	30	(0.70%)	272	(1.23%)	220	(1.76%)	1126	(0.59%)	35	(1.13%)
Intestinal polyps	24	(2.10%)	76	(1.66%)	534	(2.12%)	239	(1.73%)	4157	(1.98%)	58	(1.70%)
Lupus	2	(0.16%)	4	(0.08%)	38	(0.14%)	24	(0.17%)	272	(0.12%)	2	(0.05%)
Kidney stones[2, 3]	9	(1.01%)	25	(0.65%)	82	(0.40%)	62	(0.56%)	583	(0.34%)	8	(0.28%)
Cataracts[2, 3]	44	(5.11%)	143	(4.22%)	790	(4.31%)	450	(4.21%)	7110	(4.78%)	113	(4.55%)
Pills for hypertension	52	(5.90%)	155	(4.41%)	772	(5.70%)	531	(4.88%)	7250	(4.35%)	105	(4.29%)

[1] "Gallbladder disease" includes self-reports of both hospitalized and non-hospitalized events.
[2] Data not collected for WHI Extension Study.
[3] These outcomes have not been self-reported on all versions of Form 33 during WHI follow-up. The annualized percentages are corrected for the different amounts of follow-up.

Table 2.7
Selected Medication Use after Stopping of the HT Intervention

Data as of: August 15, 2008

	Without Uterus				With Uterus			
	E-alone		Placebo		E+P		Placebo	
	N	%	N	%	N	%	N	%
Use after stopping but before closeout[1]								
Number due for medication collection					7463		7063	
% missing medication information					20.3%		21.0%	
Estrogen	N/A		N/A		385	6.5	301	5.4
Osteoporosis[2]	N/A		N/A		739	12.4	949	17.0
SERM	N/A		N/A		124	2.1	118	2.1
Use during extension[3]								
Number in extension	3778		3867		6545		6243	
Extension Year 1								
Any prescription hormone	219	6.6	122	3.7	240	4.2	177	3.2
E-alone use	154	4.7	92	2.7	151	2.6	122	2.2
E+P use	18	0.5	16	0.5	110	1.9	43	0.8
Non-prescription (natural) hormone	92	2.8	84	2.5	172	3.0	155	2.8
Osteoporosis[4]	572	17.6	688	21.0	1275	22.6	1457	26.9
SERM	72	2.2	95	2.9	222	3.9	167	3.0
Extension Year 2								
Any prescription hormone	182	5.5	114	3.4	214	3.7	134	2.4
E-alone use	132	4.0	101	3.0	150	2.5	122	2.2
E+P use	24	0.7	19	0.6	85	1.4	42	0.8
Non-prescription (natural) hormone	61	1.9	69	2.1	119	2.1	124	2.3
Osteoporosis[4]	568	17.3	674	20.1	1281	22.2	1437	26.2
SERM	78	2.3	100	3.0	194	3.3	174	3.1
Extension Year 3								
Any prescription hormone	142	4.9	98	3.4	189	3.7	133	2.8
E-alone use	107	3.7	93	3.2	121	2.4	104	2.1
E+P use	17	0.6	16	0.5	60	1.2	34	0.7
Non-prescription (natural) hormone	48	1.7	42	1.5	111	2.2	99	2.1
Osteoporosis[4]	470	16.5	540	18.9	1125	22.3	1270	26.5
SERM	64	2.2	79	2.7	183	3.6	141	2.9

[1] Collected at annual visits 1, 3, 6, and 9. Insufficient data available on the E-alone participants.
[2] Bisphosphonate or calcitonin.
[3] Use at any time during the extension year.
[4] Bisphosphonate, calcitonin, or PTH.

Table 3.1
Dietary Modification Component Age – and Race/Ethnicity – Specific Recruitment

Data as of August 15, 2008

	Total Randomized	% of Overall Goal	Distribution	Design Assumption
Age	**48,835**			
50-54	6,961	149%	14%	10%
55-59	11,037	118%	23%	20%
60-69	22,715	108%	47%	45%
70-79	8,122	70%	17%	25%
Race/Ethnicity	**48,835**			
American Indian	202		<1%	
Asian	1,105		2%	
Black	5,262		11%	
Hispanic	1,845		4%	
White	39,762		81%	
Unknown	659		1%	

Table 3.2
Lost-to-Follow-up and Vital Status: DM Participants

Data as of: August 15, 2008
Extension Participants Only

	DM Participants (N=37,858)	
	N	%
Vital Status/Participation		
Deceased	1061	2.8
Alive: Current Participation[1]	35904	94.8
Alive: Recent Participation[2]	506	1.3
Alive: Past/Unknown Participation[3]	7	<0.1
Stopped Follow-Up[4]	224	0.6
Lost to Follow-Up[5]	156	0.4

Data as of: September 12, 2005
Events through Study Closeout

	DM Participants (N =48,835)	
	N	%
Vital Status/Participation		
Deceased	2404	4.9
Alive: Current Participation[6]	44116	90.3
Alive: Recent Participation[7]	235	0.5
Alive: Past/Unknown Participation[8]	5	<0.1
Stopped Follow-Up[4]	1553	3.2
Lost to Follow-Up[5]	522	1.1

1 Participants who have filled in a Form 33 within the last 15 months.
2 Participants who last filled in a Form 33 between 15 and 24 months ago.
3 Participants without a Form 33 within the last 24 months, who have been located (as indicated on Form 23) within the last 6 months.
4 Participants with codes 5 (no follow-up) or 8 (absolutely no follow-up) on Form 7 and 9.
5 Participants not in any of the above categories.
6 Participants who have filled in a Form 33 within the last 9 months.
7 Participants who last filled in a Form 33 between 9 and 18 months ago.
8 Participants without a Form 33 within the last 18 months, who have been located (as indicated on Form 23) within the last 6 months.

Table 3.3
Nutrient Intake Monitoring

Data as of August 15, 2008

	Intervention			Control			Difference		
	N	Mean	SD	N	Mean	SD	Mean[1]	SE	p-value[2]
% Energy from Fat									
24 Hr Recall, post-baseline	226	23.0	9.2	262	32.1	7.6	9.2	0.8	<.01
24 Hr Recall, Year 3 Cohort	787	24.8	8.5	1183	33.0	7.6	8.3	0.4	<.01
24 Hr Recall, Year 6 Cohort	766	26.6	9.1	1167	33.9	7.8	7.3	0.4	<.01
24 Hr Recall, Year 9 Cohort	154	28.5	8.6	264	35.2	8.4	6.7	0.9	<.01
24 Hr Recall, Ext. Year 1 Cohort	281	30.4	9.4	392	34.4	9.2	4.0	0.7	<.01
Total Energy (kcal)									
24 Hr Recall, post-baseline	226	1519.8	418.2	262	1652.8	516.5	133.0	43.0	<.01
24 Hr Recall, Year 3 Cohort	787	1431.8	391.6	1183	1589.9	489.3	158.1	20.8	<.01
24 Hr Recall, Year 6 Cohort	766	1388.8	391.0	1167	1544.2	482.1	155.4	20.8	<.01
24 Hr Recall, Year 9 Cohort	154	1406.7	384.6	264	1516.8	452.9	110.2	43.5	0.02
24 Hr Recall, Ext. Year 1 Cohort	281	1419.1	457.4	392	1578.7	533.7	159.7	39.3	<.01
Total Fat (g)									
24 Hr Recall, post-baseline	226	39.6	21.9	262	60.5	26.9	20.9	2.2	<.01
24 Hr Recall, Year 3 Cohort	787	39.8	18.7	1183	59.9	25.6	20.0	1.1	<.01
24 Hr Recall, Year 6 Cohort	766	41.5	20.0	1167	59.7	26.1	18.1	1.1	<.01
24 Hr Recall, Year 9 Cohort	154	45.1	18.6	264	60.9	26.3	15.9	2.4	<.01
24 Hr Recall, Ext. Year 1 Cohort	281	48.9	24.7	392	62.2	30.9	13.3	2.2	<.01
Saturated Fat (g)									
24 Hr Recall, post-baseline	226	12.9	7.9	262	20.1	9.6	7.2	0.8	<.01
24 Hr Recall, Year 3 Cohort	787	12.4	6.8	1183	19.7	9.3	7.3	0.4	<.01
24 Hr Recall, Year 6 Cohort	766	13.1	7.1	1167	19.5	9.7	6.4	0.4	<.01
24 Hr Recall, Year 9 Cohort	154	14.5	6.8	264	20.6	10.2	6.1	0.9	<.01
24 Hr Recall, Ext. Year 1 Cohort	281	15.6	9.3	392	20.8	13.4	5.2	0.9	<.01
Polyunsaturated Fat (g)									
24 Hr Recall, post-baseline	226	8.3	5.0	262	12.6	7.3	4.3	0.6	<.01
24 Hr Recall, Year 3 Cohort	787	8.7	4.6	1183	12.2	6.9	3.6	0.3	<.01
24 Hr Recall, Year 6 Cohort	766	8.8	4.6	1167	12.3	6.2	3.5	0.3	<.01
24 Hr Recall, Year 9 Cohort	154	9.6	4.4	264	12.2	5.7	2.7	0.5	<.01
24 Hr Recall, Ext. Year 1 Cohort	281	10.8	7.0	392	13.2	8.3	2.4	0.6	<.01

[1] Absolute difference.
[2] P-values based on testing in the natural log scale except for % Energy from fat.

Table 3.4
Verified Outcomes (Annualized Percentages) by Age for Dietary Modification

Data as of: August 15, 2008

Outcome	Total		Age 50-54		55-59		60-69		70-79	
Number randomized	48835		6961		11037		22715		8122	
Mean follow-up (months)	125.6		133.3		129.7		124.2		117.2	
Cancer										
Breast cancer	2672	(0.52%)	331	(0.43%)	614	(0.51%)	1262	(0.54%)	465	(0.59%)
Invasive breast cancer	2173	(0.43%)	249	(0.32%)	503	(0.42%)	1038	(0.44%)	383	(0.48%)
Non-invasive breast cancer	530	(0.10%)	85	(0.11%)	118	(0.10%)	239	(0.10%)	88	(0.11%)
Ovarian cancer	234	(0.05%)	25	(0.03%)	45	(0.04%)	120	(0.05%)	44	(0.06%)
Endometrial cancer[1]	374	(0.07%)	48	(0.06%)	88	(0.07%)	181	(0.08%)	57	(0.07%)
Colorectal cancer	640	(0.13%)	40	(0.05%)	109	(0.09%)	321	(0.14%)	170	(0.21%)
Other cancer[2]	2620	(0.51%)	231	(0.30%)	458	(0.38%)	1327	(0.56%)	604	(0.76%)
Total cancer	6207	(1.21%)	641	(0.83%)	1253	(1.05%)	3036	(1.29%)	1277	(1.61%)
Cardiovascular										
CHD[3]	1813	(0.35%)	98	(0.13%)	224	(0.19%)	873	(0.37%)	618	(0.78%)
CHD death[4]	504	(0.10%)	23	(0.03%)	39	(0.03%)	240	(0.10%)	202	(0.25%)
Total MI[5]	1468	(0.29%)	79	(0.10%)	195	(0.16%)	701	(0.30%)	493	(0.62%)
Clinical MI	1415	(0.28%)	73	(0.09%)	188	(0.16%)	675	(0.29%)	479	(0.60%)
CABG/PTCA	2371	(0.46%)	118	(0.15%)	329	(0.28%)	1287	(0.55%)	637	(0.80%)
Carotid artery disease	367	(0.07%)	13	(0.02%)	44	(0.04%)	198	(0.08%)	112	(0.14%)
Stroke	1404	(0.27%)	62	(0.08%)	149	(0.12%)	668	(0.28%)	525	(0.66%)
PVD	326	(0.06%)	17	(0.02%)	44	(0.04%)	166	(0.07%)	99	(0.12%)
Coronary disease[6]	4600	(0.90%)	258	(0.33%)	620	(0.52%)	2336	(0.99%)	1386	(1.75%)
Total cardiovascular disease	6128	(1.20%)	328	(0.42%)	810	(0.68%)	3078	(1.31%)	1912	(2.41%)
Fractures										
Hip fracture	757	(0.15%)	17	(0.02%)	51	(0.04%)	324	(0.14%)	365	(0.46%)
Deaths										
Cardiovascular deaths	965	(0.19%)	39	(0.05%)	73	(0.06%)	420	(0.18%)	433	(0.55%)
Cancer deaths	1512	(0.30%)	93	(0.12%)	223	(0.19%)	757	(0.32%)	439	(0.55%)
Other known cause	712	(0.14%)	35	(0.05%)	76	(0.06%)	301	(0.13%)	300	(0.38%)
Unknown cause	100	(0.02%)	3	(<0.01%)	10	(0.01%)	50	(0.02%)	37	(0.05%)
Not yet adjudicated	329	(0.06%)	20	(0.03%)	25	(0.02%)	155	(0.07%)	129	(0.16%)
Total death	3618	(0.71%)	190	(0.25%)	407	(0.34%)	1683	(0.72%)	1338	(1.69%)

[1] Only women without a baseline hysterectomy are used to compute the annual rates of endometrial cancer.

[2] Only one report of "other cancer" is counted per woman; however, the first of each type is adjudicated. Excludes non-melanoma skin cancer.

[3] "CHD" includes clinical MI, evolving Q-wave MI, and CHD death; Q-wave MI is not collected in the WHI Extension Study.

[4] "CHD death" includes definite and possible CHD death.

[5] "Total MI" includes clinical MI and evolving Q-wave MI is not collected in the WHI Extension Study.

[6] "Coronary disease" includes clinical MI, evolving Q-wave MI, possible evolving Q-wave MI, CHD death, angina, congestive heart failure, and CABG/PTCA; Q-wave MI, angina, and congestive heart failure are not collected in the WHI Extension Study.

Table 3.5
Verified Outcomes (Annualized Percentages) by Race/Ethnicity for Dietary Modification

Data as of: August 15, 2008

Outcome	Race/Ethnicity											
	American Indian/Alaskan Native		Asian/Pacific Islander		Black/African American		Hispanic/ Latino		White		Unknown	
Number randomized	202		1105		5262		1845		39762		659	
Mean follow-up (months)	119.3		121.2		120.4		115.0		127.0		118.5	
Cancer												
Breast cancer	5	(0.25%)	61	(0.55%)	224	(0.42%)	65	(0.37%)	2287	(0.54%)	30	(0.46%)
Invasive breast cancer	4	(0.20%)	46	(0.41%)	173	(0.33%)	52	(0.29%)	1874	(0.45%)	24	(0.37%)
Non-invasive breast cancer	1	(0.05%)	15	(0.13%)	54	(0.10%)	14	(0.08%)	440	(0.10%)	6	(0.09%)
Ovarian cancer	1	(0.05%)	6	(0.05%)	14	(0.03%)	8	(0.05%)	202	(0.05%)	3	(0.05%)
Endometrial cancer[1]	0	(0.00%)	4	(0.04%)	21	(0.04%)	9	(0.05%)	334	(0.08%)	6	(0.09%)
Colorectal cancer	4	(0.20%)	10	(0.09%)	74	(0.14%)	18	(0.10%)	526	(0.12%)	8	(0.12%)
Other cancer[2]	7	(0.35%)	39	(0.35%)	203	(0.38%)	51	(0.29%)	2290	(0.54%)	30	(0.46%)
Total cancer	15	(0.75%)	113	(1.01%)	510	(0.97%)	142	(0.80%)	5357	(1.27%)	70	(1.08%)
Cardiovascular												
CHD[3]	4	(0.20%)	20	(0.18%)	191	(0.36%)	34	(0.19%)	1540	(0.37%)	24	(0.37%)
CHD death[4]	0	(0.00%)	4	(0.04%)	77	(0.15%)	10	(0.06%)	402	(0.10%)	11	(0.17%)
Total MI[5]	4	(0.20%)	19	(0.17%)	136	(0.26%)	28	(0.16%)	1262	(0.30%)	19	(0.29%)
Clinical MI	4	(0.20%)	19	(0.17%)	131	(0.25%)	27	(0.15%)	1216	(0.29%)	18	(0.28%)
CABG/PTCA	7	(0.35%)	21	(0.19%)	216	(0.41%)	55	(0.31%)	2047	(0.49%)	25	(0.38%)
Carotid artery disease	2	(0.10%)	1	(0.01%)	23	(0.04%)	3	(0.02%)	333	(0.08%)	5	(0.08%)
Stroke	5	(0.25%)	23	(0.21%)	188	(0.36%)	36	(0.20%)	1132	(0.27%)	20	(0.31%)
PVD	3	(0.15%)	3	(0.03%)	61	(0.12%)	3	(0.02%)	252	(0.06%)	4	(0.06%)
Coronary disease[6]	16	(0.80%)	51	(0.46%)	563	(1.07%)	117	(0.66%)	3795	(0.90%)	58	(0.89%)
Total cardiovascular disease	24	(1.20%)	77	(0.69%)	749	(1.42%)	155	(0.88%)	5043	(1.20%)	80	(1.23%)
Fractures												
Hip fracture	2	(0.10%)	8	(0.07%)	18	(0.03%)	15	(0.08%)	706	(0.17%)	8	(0.12%)
Deaths												
Cardiovascular deaths	2	(0.10%)	12	(0.11%)	146	(0.28%)	18	(0.10%)	774	(0.18%)	13	(0.20%)
Cancer deaths	7	(0.35%)	24	(0.21%)	128	(0.24%)	37	(0.21%)	1295	(0.31%)	21	(0.32%)
Other known cause	10	(0.50%)	9	(0.08%)	80	(0.15%)	14	(0.08%)	590	(0.14%)	9	(0.14%)
Unknown cause	1	(0.05%)	1	(0.01%)	15	(0.03%)	2	(0.01%)	77	(0.02%)	4	(0.06%)
Not yet adjudicated	2	(0.10%)	1	(0.01%)	36	(0.07%)	9	(0.05%)	275	(0.07%)	6	(0.09%)
Total death	22	(1.10%)	47	(0.42%)	405	(0.77%)	80	(0.45%)	3011	(0.72%)	53	(0.81%)

1 Only women without a baseline hysterectomy are used to compute the annual rates of endometrial cancer.
2 Only one report of "other cancer" is counted per woman; however, the first of each type is adjudicated. Excludes non-melanoma skin cancer.
3 "CHD" includes clinical MI, evolving Q-wave MI, and CHD death; Q-wave MI is not collected in the WHI Extension Study.
4 "CHD death" includes definite and possible CHD death.
5 "Total MI" includes clinical MI and evolving Q-wave MI; Q-wave MI is not collected in the WHI Extension Study.
6 "Coronary disease" includes clinical MI, evolving Q-wave MI, possible evolving Q-wave MI, CHD death, angina, congestive heart failure, and CABG/PTCA; Q-wave MI, angina, and congestive heart failure are not collected in the WHI Extension Study.

Table 3.6
Counts (Annualized Percentages) of Participants with Self-Reported Outcomes by Age and Race/Ethnicity for DM Participants Who Did Not Report a Prevalent Condition at Baseline

Data as of: August 15, 2008

Outcome	Total		Age 50-54		55-59		60-69		70-79	
Number randomized	48835		6961		11037		22715		8122	
Mean follow-up (months)	125.6		133.3		129.7		124.2		117.2	
Hospitalizations										
Ever	28245	(5.53%)	3008	(3.89%)	5477	(4.59%)	13812	(5.88%)	5948	(7.50%)
Two or more	16942	(3.32%)	1463	(1.89%)	2965	(2.49%)	8490	(3.61%)	4024	(5.07%)
Other										
DVT[1]	692	(0.14%)	43	(0.06%)	99	(0.09%)	337	(0.15%)	213	(0.28%)
Pulmonary embolism	505	(0.10%)	37	(0.05%)	82	(0.07%)	258	(0.11%)	128	(0.16%)
Diabetes (treated)	5034	(1.03%)	734	(0.97%)	1148	(1.00%)	2363	(1.05%)	789	(1.05%)
Gallbladder disease[2, 3]	3830	(1.02%)	573	(0.95%)	902	(1.01%)	1802	(1.07%)	553	(0.97%)
Hysterectomy	1884	(0.65%)	277	(0.63%)	450	(0.62%)	907	(0.69%)	250	(0.58%)
Glaucoma[3]	5318	(1.23%)	567	(0.85%)	1098	(1.08%)	2589	(1.32%)	1064	(1.63%)
Osteoporosis[3]	10221	(2.42%)	1129	(1.70%)	1969	(1.95%)	5021	(2.62%)	2102	(3.33%)
Osteoarthritis[4]	11725	(3.70%)	1802	(3.10%)	2807	(3.43%)	5382	(3.93%)	1734	(4.38%)
Rheumatoid arthritis[3]	2849	(0.66%)	399	(0.60%)	631	(0.62%)	1319	(0.67%)	500	(0.75%)
Intestinal polyps	9888	(2.08%)	1355	(1.81%)	2293	(2.02%)	4846	(2.24%)	1394	(1.98%)
Lupus	593	(0.12%)	93	(0.12%)	135	(0.11%)	286	(0.12%)	79	(0.10%)
Kidney stones[3, 4]	1319	(0.35%)	175	(0.32%)	281	(0.32%)	654	(0.37%)	209	(0.35%)
Cataracts[3, 4]	15485	(4.53%)	1157	(2.07%)	2859	(3.32%)	8462	(5.36%)	3007	(7.14%)
Pills for hypertension	15162	(4.24%)	2052	(3.30%)	3459	(3.84%)	7196	(4.55%)	2455	(5.19%)

Outcomes	Race/Ethnicity: Am Indian/ Alaskan Native		Asian/Pacific Islander		Black/African American		Hispanic/ Latino		White		Unknown	
Number randomized	202		1105		5262		1845		39762		659	
Mean follow-up (months)	119.3		121.2		120.4		115.0		127.0		118.5	
Hospitalizations												
Ever	107	(5.33%)	463	(4.15%)	2941	(5.57%)	845	(4.78%)	23539	(5.59%)	350	(5.38%)
Two or more	70	(3.49%)	219	(1.96%)	1801	(3.41%)	465	(2.63%)	14187	(3.37%)	200	(3.07%)
Other												
DVT[1]	2	(0.10%)	0	(0.00%)	71	(0.14%)	11	(0.06%)	597	(0.15%)	11	(0.17%)
Pulmonary embolism	2	(0.10%)	1	(0.01%)	54	(0.10%)	5	(0.03%)	437	(0.10%)	6	(0.09%)
Diabetes (treated)	25	(1.34%)	131	(1.24%)	857	(1.82%)	257	(1.55%)	3689	(0.90%)	75	(1.22%)
Gallbladder disease[2, 3]	14	(1.09%)	60	(0.68%)	304	(0.73%)	152	(1.28%)	3250	(1.06%)	50	(1.02%)
Hysterectomy	5	(0.53%)	32	(0.45%)	121	(0.51%)	58	(0.61%)	1656	(0.67%)	12	(0.33%)
Glaucoma[3]	30	(1.75%)	108	(1.15%)	763	(1.75%)	201	(1.32%)	4152	(1.17%)	64	(1.19%)
Osteoporosis[3]	43	(2.52%)	272	(2.95%)	679	(1.50%)	409	(2.79%)	8678	(2.50%)	140	(2.64%)
Osteoarthritis[4]	50	(4.32%)	272	(3.36%)	1193	(3.76%)	480	(3.99%)	9557	(3.68%)	173	(4.28%)
Rheumatoid arthritis[3]	23	(1.44%)	49	(0.52%)	506	(1.16%)	222	(1.48%)	1998	(0.56%)	51	(0.94%)
Intestinal polyps	51	(2.73%)	207	(2.02%)	1091	(2.21%)	325	(1.93%)	8079	(2.07%)	135	(2.25%)
Lupus	4	(0.20%)	10	(0.09%)	88	(0.17%)	21	(0.12%)	462	(0.11%)	8	(0.12%)
Kidney stones[3, 4]	9	(0.63%)	27	(0.33%)	137	(0.35%)	58	(0.43%)	1071	(0.35%)	17	(0.35%)
Cataracts[3, 4]	61	(4.62%)	306	(4.04%)	1510	(4.17%)	537	(4.21%)	12867	(4.60%)	204	(4.64%)
Pills for hypertension	54	(4.13%)	312	(4.15%)	1500	(5.65%)	610	(4.65%)	12500	(4.10%)	186	(4.23%)

[1] Inpatient DVT only.
[2] "Gallbladder disease" includes self-reports of both hospitalized and non-hospitalized events.
[3] Data not collected for WHI Extension Study.
[4] These outcomes have not been self-reported on all versions of Form 33 during WHI follow-up. The annualized percentages are corrected for the different amounts of follow-up.

Table 4.1
Calcium and Vitamin D Component Age – and Race/Ethnicity – Specific Recruitment

Data as of August 15, 2008

	Total Randomized	% of Overall Goal	Distribution	Design Assumption
Age	**36,282**			
50-54	5,153	118%	14%	10%
55-59	8,269	95%	23%	20%
60-69	16,519	84%	46%	45%
70-79	6,341	58%	17%	25%
Race/Ethnicity	**36,282**			
American Indian	149		<1%	
Asian	721		2%	
Black	3,315		9%	
Hispanic	1,502		4%	
White	30,155		83%	
Unknown	440		1%	

Table 4.2
Lost-to-Follow-up and Vital Status: CaD Participants

Data as of: August 15, 2008
Extension Participants Only

	CaD Participants (N=29,862) N	%
Vital Status/Participation		
Deceased	893	3.0
Alive: Current Participation[1]	28222	94.5
Alive: Recent Participation[2]	399	1.3
Alive: Past/Unknown Participation[3]	6	<0.1
Stopped Follow-Up[4]	197	0.7
Lost to Follow-Up[5]	145	0.5

Data as of: September 12, 2005
Events through Study Closeout

	CaD Participants (N = 36,282) N	%
Vital Status/Participation		
Deceased	1551	4.3
Alive: Current Participation[6]	32652	90.0
Alive: Recent Participation[7]	1099	3.0
Alive: Past/Unknown Participation[8]	27	0.1
Stopped Follow-Up[4]	684	1.9
Lost to Follow-Up[5]	269	0.7

[1] Participants who have filled in a Form 33 within the last 15 months.
[2] Participants who last filled in a Form 33 between 15 and 24 months ago.
[3] Participants without a Form 33 within the last 24 months, who have been located (as indicated on Form 23) within the last 6 months.
[4] Participants with codes 5 (no follow-up) or 8 (absolutely no follow-up) on Form 7 or 9.
[5] Participants not in any of the above categories.
[6] Participants who have filled in a Form 33 within the last 9 months.
[7] Participants who last filled in a Form 33 between 9 and 18 months ago.
[8] Participants without a Form 33 within the last 18 months, who have been located (as indicated on Form 23) within the last 6 months.

Table 4.3
Verified Outcomes (Annualized Percentages) by Age for Calcium and Vitamin D

Data as of August 15, 2008

Outcome	Total		Age 50-54		55-59		60-69		70-79	
Number of participants	36282		5153		8269		16519		6341	
Mean follow-up (months)	114.7		121.3		118.5		113.5		107.4	
Fractures										
Hip fracture	588	(0.17%)	12	(0.02%)	54	(0.07%)	225	(0.14%)	297	(0.52%)
Cancer										
Colorectal cancer	435	(0.13%)	29	(0.06%)	64	(0.08%)	219	(0.14%)	123	(0.22%)
Breast cancer	1755	(0.51%)	211	(0.41%)	415	(0.51%)	824	(0.53%)	305	(0.54%)
Invasive breast cancer	1415	(0.41%)	160	(0.31%)	338	(0.41%)	666	(0.43%)	251	(0.44%)
Non-invasive breast cancer	360	(0.10%)	52	(0.10%)	80	(0.10%)	168	(0.11%)	60	(0.11%)
Ovarian cancer	158	(0.05%)	18	(0.03%)	40	(0.05%)	72	(0.05%)	28	(0.05%)
Endometrial cancer[1]	232	(0.07%)	32	(0.06%)	54	(0.07%)	105	(0.07%)	41	(0.07%)
Other cancer[2]	1855	(0.53%)	163	(0.31%)	320	(0.39%)	925	(0.59%)	447	(0.79%)
Total cancer	4238	(1.22%)	437	(0.84%)	864	(1.06%)	2037	(1.30%)	900	(1.59%)
Cardiovascular										
CHD[3]	1338	(0.39%)	67	(0.13%)	165	(0.20%)	645	(0.41%)	461	(0.81%)
CHD death[4]	371	(0.11%)	15	(0.03%)	34	(0.04%)	156	(0.10%)	166	(0.29%)
Total MI[5]	1080	(0.31%)	55	(0.11%)	136	(0.17%)	538	(0.34%)	351	(0.62%)
Clinical MI	1031	(0.30%)	51	(0.10%)	131	(0.16%)	514	(0.33%)	335	(0.59%)
CABG/PTCA	1752	(0.51%)	88	(0.17%)	237	(0.29%)	941	(0.60%)	486	(0.86%)
Carotid artery disease	290	(0.08%)	11	(0.02%)	36	(0.04%)	160	(0.10%)	83	(0.15%)
Stroke	1009	(0.29%)	47	(0.09%)	110	(0.13%)	459	(0.29%)	393	(0.69%)
PVD	259	(0.07%)	10	(0.02%)	35	(0.04%)	131	(0.08%)	83	(0.15%)
Coronary disease[6]	3334	(0.96%)	183	(0.35%)	455	(0.56%)	1671	(1.07%)	1025	(1.81%)
Total cardiovascular disease	4473	(1.29%)	239	(0.46%)	601	(0.74%)	2214	(1.42%)	1419	(2.50%)
Deaths										
Cardiovascular deaths	704	(0.20%)	27	(0.05%)	59	(0.07%)	288	(0.18%)	330	(0.58%)
Cancer deaths	1052	(0.30%)	77	(0.15%)	152	(0.19%)	525	(0.34%)	298	(0.52%)
Other known cause	493	(0.14%)	22	(0.04%)	65	(0.08%)	205	(0.13%)	201	(0.35%)
Unknown cause	75	(0.02%)	4	(0.01%)	11	(0.01%)	37	(0.02%)	23	(0.04%)
Not yet adjudicated	244	(0.07%)	13	(0.02%)	21	(0.03%)	110	(0.07%)	100	(0.18%)
Total death	2568	(0.74%)	143	(0.27%)	308	(0.38%)	1165	(0.75%)	952	(1.68%)

[1] Only women without a baseline hysterectomy are used to compute the annual rates of endometrial cancer.
[2] Only one report of "other cancer" is counted per woman; however, the first of each type is adjudicated. Excludes non-melanoma skin cancer.
[3] "CHD" includes clinical MI, evolving Q-wave MI, and CHD death; Q-wave MI is not collected in the WHI Extension Study.
[4] "CHD death" includes definite and possible CHD death.
[5] "Total MI" includes clinical MI and evolving Q-wave MI; Q-wave MI is not collected in the WHI Extension Study.
[6] "Coronary disease" includes clinical MI, evolving Q-wave MI, possible evolving Q-wave MI, CHD death, angina, congestive heart failure, and CABG/PTCA; Q-wave MI, angina, and congestive heart failure are not collected in the WHI Extension Study.

Table 4.4
Verified Outcomes (Annualized Percentages) by Race/Ethnicity for Calcium and Vitamin D

Data as of August 15, 2008

Outcome	Race/Ethnicity											
	American Indian/Alaskan Native		Asian/Pacific Islander		Black/African American		Hispanic/ Latino		White		Unknown	
Number of participants	149		721		3315		1502		30155		440	
Mean follow-up (months)	110.6		109.3		110.6		107.1		115.8		107.7	
Fractures												
Hip fracture	3	(0.22%)	8	(0.12%)	8	(0.03%)	8	(0.06%)	560	(0.19%)	1	(0.03%)
Cancer												
Colorectal cancer	2	(0.15%)	6	(0.09%)	42	(0.14%)	10	(0.07%)	369	(0.13%)	6	(0.15%)
Breast cancer	4	(0.29%)	34	(0.52%)	133	(0.44%)	46	(0.34%)	1521	(0.52%)	17	(0.43%)
Invasive breast cancer	3	(0.22%)	24	(0.37%)	103	(0.34%)	36	(0.27%)	1234	(0.42%)	15	(0.38%)
Non-invasive breast cancer	1	(0.07%)	11	(0.17%)	32	(0.10%)	11	(0.08%)	303	(0.10%)	2	(0.05%)
Ovarian cancer	0	(0.00%)	6	(0.09%)	9	(0.03%)	6	(0.04%)	135	(0.05%)	2	(0.05%)
Endometrial cancer[1]	1	(0.08%)	3	(0.05%)	9	(0.03%)	6	(0.04%)	209	(0.07%)	4	(0.10%)
Other cancer[2]	5	(0.36%)	28	(0.43%)	121	(0.40%)	40	(0.30%)	1645	(0.57%)	16	(0.41%)
Total cancer	11	(0.80%)	74	(1.13%)	303	(0.99%)	101	(0.75%)	3705	(1.27%)	44	(1.11%)
Cardiovascular												
CHD[3]	5	(0.36%)	11	(0.17%)	117	(0.38%)	32	(0.24%)	1154	(0.40%)	19	(0.48%)
CHD death[4]	1	(0.07%)	2	(0.03%)	48	(0.16%)	9	(0.07%)	304	(0.10%)	7	(0.18%)
Total MI[5]	5	(0.36%)	10	(0.15%)	80	(0.26%)	27	(0.20%)	942	(0.32%)	16	(0.41%)
Clinical MI	5	(0.36%)	10	(0.15%)	77	(0.25%)	26	(0.19%)	898	(0.31%)	15	(0.38%)
CABG/PTCA	5	(0.36%)	17	(0.26%)	134	(0.44%)	54	(0.40%)	1519	(0.52%)	23	(0.58%)
Carotid artery disease	1	(0.07%)	1	(0.02%)	13	(0.04%)	3	(0.02%)	268	(0.09%)	4	(0.10%)
Stroke	6	(0.44%)	21	(0.32%)	104	(0.34%)	26	(0.19%)	836	(0.29%)	16	(0.41%)
PVD	2	(0.15%)	3	(0.05%)	35	(0.11%)	1	(0.01%)	216	(0.07%)	2	(0.05%)
Coronary disease[6]	10	(0.73%)	34	(0.52%)	335	(1.10%)	102	(0.76%)	2812	(0.97%)	41	(1.04%)
Total cardiovascular disease	16	(1.17%)	55	(0.84%)	448	(1.47%)	130	(0.97%)	3767	(1.29%)	57	(1.44%)
Deaths												
Cardiovascular deaths	1	(0.07%)	10	(0.15%)	89	(0.29%)	18	(0.13%)	576	(0.20%)	10	(0.25%)
Cancer deaths	2	(0.15%)	22	(0.34%)	75	(0.25%)	28	(0.21%)	912	(0.31%)	13	(0.33%)
Other known cause	7	(0.51%)	7	(0.11%)	41	(0.13%)	8	(0.06%)	422	(0.15%)	8	(0.20%)
Unknown cause	0	(0.00%)	1	(0.02%)	14	(0.05%)	2	(0.01%)	56	(0.02%)	2	(0.05%)
Not yet adjudicated	2	(0.15%)	2	(0.03%)	26	(0.09%)	8	(0.06%)	204	(0.07%)	2	(0.05%)
Total death	12	(0.87%)	42	(0.64%)	245	(0.80%)	64	(0.48%)	2170	(0.75%)	35	(0.89%)

[1] Only women without a baseline hysterectomy are used to compute the annual rates of endometrial cancer.
[2] Only one report of "other cancer" is counted per woman; however, the first of each type is adjudicated. Excludes non-melanoma skin cancer.
[3] "CHD" includes clinical MI, evolving Q-wave MI, and CHD death; Q-wave MI is not collected in the WHI Extension Study.
[4] "CHD death" includes definite and possible CHD death.
[5] "Total MI" includes clinical MI and evolving Q-wave MI; Q-wave MI is not collected in the WHI Extension Study.
[6] "Coronary disease" includes clinical MI, evolving Q-wave MI, possible evolving Q-wave MI, CHD death, angina, congestive heart failure, and CABG/PTCA; Q-wave MI, angina, and congestive heart failure are not collected in the WHI Extension Study.

Table 4.5
Counts (Annualized Percentages) of Participants with Self-Reported Outcomes by Age and Race/Ethnicity for CaD Participants Who Did Not Report a Prevalent Condition at Baseline

Data as of August 15, 2008

Outcome	Total		Age 50-54		55-59		60-69		70-79	
Number randomized	36282		5153		8269		16519		6341	
Mean follow-up (months)	114.7		121.3		118.5		113.5		107.4	
Hospitalizations										
Ever	20084	(5.79%)	2087	(4.01%)	3874	(4.74%)	9655	(6.18%)	4468	(7.87%)
Two or more	11573	(3.34%)	942	(1.81%)	2045	(2.50%)	5695	(3.64%)	2891	(5.09%)
Other										
DVT[1]	497	(0.15%)	32	(0.06%)	84	(0.11%)	223	(0.15%)	158	(0.29%)
Pulmonary embolism	353	(0.10%)	30	(0.06%)	63	(0.08%)	181	(0.12%)	79	(0.14%)
Diabetes (treated)	3740	(1.12%)	564	(1.11%)	831	(1.06%)	1748	(1.17%)	597	(1.11%)
Gallbladder disease[2,3]	2485	(0.97%)	367	(0.91%)	602	(0.98%)	1157	(1.02%)	359	(0.87%)
Hysterectomy	1227	(0.60%)	169	(0.56%)	307	(0.61%)	576	(0.63%)	175	(0.55%)
Glaucoma[3]	3730	(1.28%)	401	(0.89%)	770	(1.10%)	1773	(1.36%)	786	(1.68%)
Osteoporosis[3]	7136	(2.47%)	736	(1.64%)	1362	(1.97%)	3451	(2.67%)	1587	(3.47%)
Osteoarthritis[4]	8324	(3.83%)	1271	(3.25%)	1979	(3.51%)	3784	(4.08%)	1290	(4.45%)
Rheumatoid arthritis[3]	1879	(0.64%)	267	(0.60%)	435	(0.63%)	834	(0.64%)	343	(0.72%)
Intestinal polyps	6954	(2.15%)	972	(1.93%)	1587	(2.04%)	3331	(2.31%)	1064	(2.10%)
Lupus	418	(0.12%)	65	(0.13%)	101	(0.12%)	179	(0.11%)	73	(0.13%)
Kidney stones[3,4]	819	(0.31%)	111	(0.29%)	180	(0.29%)	383	(0.32%)	145	(0.33%)
Cataracts[3,4]	11122	(4.80%)	818	(2.17%)	2096	(3.55%)	5937	(5.66%)	2271	(7.53%)
Pills for hypertension	11509	(4.63%)	1549	(3.64%)	2645	(4.20%)	5326	(4.95%)	1989	(5.66%)

Outcomes	Race/Ethnicity: American Indian/ Alaskan Native		Asian/Pacific Islander		Black/African American		Hispanic/ Latino		White		Unknown	
Number randomized	149		721		3315		1502		30155		440	
Mean follow-up (months)	110.6		109.3		110.6		107.1		115.8		107.7	
Hospitalizations												
Ever	77	(5.61%)	301	(4.58%)	1794	(5.87%)	650	(4.85%)	17029	(5.85%)	233	(5.90%)
Two or more	54	(3.93%)	143	(2.18%)	1066	(3.49%)	329	(2.46%)	9852	(3.39%)	129	(3.27%)
Other												
DVT[1]	5	(0.37%)	1	(0.02%)	52	(0.17%)	9	(0.07%)	424	(0.15%)	6	(0.15%)
Pulmonary embolism	3	(0.22%)	0	(0.00%)	37	(0.12%)	4	(0.03%)	304	(0.11%)	5	(0.13%)
Diabetes (treated)	18	(1.41%)	86	(1.39%)	534	(1.95%)	235	(1.86%)	2814	(1.00%)	53	(1.43%)
Gallbladder disease[2,3]	10	(1.07%)	39	(0.75%)	169	(0.69%)	121	(1.31%)	2118	(0.99%)	28	(0.96%)
Hysterectomy	3	(0.53%)	19	(0.44%)	67	(0.51%)	42	(0.56%)	1086	(0.62%)	10	(0.45%)
Glaucoma[3]	20	(1.72%)	59	(1.07%)	472	(1.87%)	177	(1.52%)	2969	(1.21%)	33	(1.00%)
Osteoporosis[3]	30	(2.57%)	156	(2.82%)	409	(1.57%)	299	(2.66%)	6160	(2.55%)	82	(2.52%)
Osteoarthritis[4]	47	(5.38%)	165	(3.42%)	740	(3.99%)	391	(4.26%)	6865	(3.79%)	116	(4.44%)
Rheumatoid arthritis[3]	17	(1.57%)	29	(0.53%)	304	(1.22%)	152	(1.33%)	1349	(0.55%)	28	(0.86%)
Intestinal polyps	36	(2.84%)	111	(1.84%)	673	(2.36%)	232	(1.81%)	5822	(2.15%)	80	(2.20%)
Lupus	4	(0.30%)	3	(0.05%)	52	(0.17%)	16	(0.12%)	340	(0.12%)	3	(0.08%)
Kidney stones[3,4]	7	(0.67%)	18	(0.36%)	73	(0.32%)	46	(0.45%)	667	(0.30%)	8	(0.26%)
Cataracts[3,4]	51	(5.34%)	178	(4.02%)	909	(4.36%)	440	(4.54%)	9409	(4.87%)	135	(4.95%)
Pills for hypertension	41	(4.69%)	204	(4.49%)	999	(6.29%)	520	(5.04%)	9626	(4.49%)	119	(4.74%)

[1] Inpatient DVT only.
[2] "Gallbladder disease" includes self-reports of both hospitalized and non-hospitalized events.
[3] Data not collected for WHI Extension Study.
[4] These outcomes have not been self-reported on all versions of Form 33 during WHI follow-up. The annualized percentages are corrected for the different amounts of follow-up.

Table 5.1
Observational Study Age and Race/Ethnicity Specific Recruitment

Data as of August 15, 2008

	Total Enrolled	Distribution
Age	**93,676**	
50-54	12,381	13%
55-59	17,329	18%
60-69	41,200	44%
70-79	22,766	24%
Race/Ethnicity	**93,676**	
American Indian	421	<1%
Asian	2,671	3%
Black	7,635	8%
Hispanic	3,609	4%
White	78,016	83%
Unknown	1,324	1%

Table 5.2
Lost-to-Follow-up and Vital Status: OS Participants

Data as of: August 15, 2008
Extension Participants Only

	OS Participants (N=63,230)	
	N	%
Vital Status/Participation		
Deceased	1966	3.1
Alive: Current Participation[1]	59981	94.9
Alive: Recent Participation[2]	831	1.3
Alive: Past/Unknown Participation[3]	10	<0.1
Stopped Follow-Up[4]	288	0.5
Lost to Follow-Up[5]	154	0.2

Data as of: September 12, 2005
Events through Study Closeout

	OS Participants (N =93,676)	
	N	%
Vital Status/Participation		
Deceased	6260	6.7
Alive: Current Participation[1]	78092	83.4
Alive: Recent Participation[2]	4818	5.1
Alive: Past/Unknown Participation[3]	51	0.1
Stopped Follow-Up[4]	2347	2.5
Lost to Follow-Up[5]	2105	2.2

[1] Participants who have filled in a Form 33 within the last 15 months.
[2] Participants who last filled in a Form 33 between 15 and 24 months ago.
[3] Participants without a Form 33 within the last 24 months, who have been located (as indicated on Form 23) within the last 6 months.
[4] Participants with codes 5 (no follow-up) or 8 (absolutely no follow-up) on Form 7 or 9.
[5] Participants not in any of the above categories.

Table 5.3
Verified Outcomes (Annualized Percentages) by Age for OS Participants

Data as of August 15, 2008

Outcome	Total		Age 50-54		55-59		60-69		70-79	
Number enrolled	93676		12381		17329		41200		22766	
Mean follow-up (months)	117.2		124.1		122.9		117.2		109.1	
Cardiovascular										
CHD[1]	3249	(0.36%)	115	(0.09%)	262	(0.15%)	1345	(0.33%)	1527	(0.74%)
CHD death[2]	1075	(0.12%)	26	(0.02%)	52	(0.03%)	371	(0.09%)	626	(0.30%)
Clinical MI	2505	(0.27%)	95	(0.07%)	223	(0.13%)	1089	(0.27%)	1098	(0.53%)
Angina	2837	(0.31%)	124	(0.10%)	318	(0.18%)	1320	(0.33%)	1075	(0.52%)
CABG/PTCA	4060	(0.44%)	164	(0.13%)	438	(0.25%)	1992	(0.50%)	1466	(0.71%)
Carotid artery disease	730	(0.08%)	36	(0.03%)	70	(0.04%)	320	(0.08%)	304	(0.15%)
Congestive heart failure	2305	(0.25%)	81	(0.06%)	174	(0.10%)	886	(0.22%)	1164	(0.56%)
Stroke	2576	(0.28%)	70	(0.05%)	197	(0.11%)	1041	(0.26%)	1268	(0.61%)
PVD	686	(0.07%)	19	(0.01%)	63	(0.04%)	299	(0.07%)	305	(0.15%)
Coronary disease[3]	7986	(0.87%)	330	(0.26%)	787	(0.44%)	3518	(0.87%)	3351	(1.62%)
Total cardiovascular disease	11079	(1.21%)	434	(0.34%)	1058	(0.60%)	4797	(1.19%)	4790	(2.31%)
Cancer										
Breast cancer	5031	(0.55%)	570	(0.45%)	873	(0.49%)	2344	(0.58%)	1244	(0.60%)
Invasive breast cancer	4189	(0.46%)	457	(0.36%)	711	(0.40%)	1952	(0.49%)	1069	(0.52%)
Non-invasive breast cancer	880	(0.10%)	119	(0.09%)	167	(0.09%)	411	(0.10%)	183	(0.09%)
Ovarian cancer	442	(0.05%)	44	(0.03%)	79	(0.04%)	203	(0.05%)	116	(0.06%)
Endometrial cancer[4]	691	(0.07%)	64	(0.05%)	113	(0.06%)	319	(0.08%)	195	(0.09%)
Colorectal cancer	1109	(0.12%)	63	(0.05%)	113	(0.06%)	503	(0.13%)	430	(0.21%)
Other cancer[5]	5107	(0.56%)	358	(0.28%)	669	(0.38%)	2407	(0.60%)	1673	(0.81%)
Total cancer	11708	(1.28%)	1057	(0.83%)	1759	(0.99%)	5446	(1.35%)	3446	(1.66%)
Fractures										
Hip fracture	1642	(0.18%)	36	(0.03%)	105	(0.06%)	550	(0.14%)	951	(0.46%)
Deaths										
Cardiovascular deaths	2290	(0.25%)	53	(0.04%)	125	(0.07%)	779	(0.19%)	1333	(0.64%)
Cancer deaths	3310	(0.36%)	191	(0.15%)	372	(0.21%)	1467	(0.36%)	1280	(0.62%)
Other known cause	1844	(0.20%)	85	(0.07%)	140	(0.08%)	668	(0.17%)	951	(0.46%)
Unknown cause	324	(0.04%)	16	(0.01%)	31	(0.02%)	119	(0.03%)	158	(0.08%)
Not yet adjudicated	766	(0.08%)	31	(0.02%)	50	(0.03%)	304	(0.08%)	381	(0.18%)
Total death	8534	(0.93%)	376	(0.29%)	718	(0.40%)	3337	(0.83%)	4103	(1.98%)

[1] "CHD" includes clinical MI and CHD death.
[2] "CHD death" includes definite and possible CHD death.
[3] "Coronary disease" includes clinical MI, CHD death, angina, congestive heart failure, and CABG/PTCA; angina and congestive heart failure are not collected in the WHI Extension Study.
[4] Only women without a baseline hysterectomy are used to compute the annual rates of endometrial cancer.
[5] Only one report of "other cancer " is counted per woman; however, the first of each type is adjudicated. Excludes non-melanoma skin cancer.

Table 5.4
Verified Outcomes (Annualized Percentages) by Race/Ethnicity for OS Participants

Data as of August 15, 2008

Outcomes	Race/Ethnicity: American Indian/Alaskan Native		Asian/Pacific Islander		Black/African American		Hispanic/ Latino		White		Unknown	
Number enrolled	421		2671		7635		3609		78016		1324	
Mean follow-up (months)	105.5		107.2		104.6		100.4		119.7		111.2	
Cardiovascular												
CHD[1]	20	(0.54%)	53	(0.22%)	280	(0.42%)	57	(0.19%)	2790	(0.36%)	49	(0.40%)
CHD death[2]	10	(0.27%)	18	(0.08%)	128	(0.19%)	17	(0.06%)	884	(0.11%)	18	(0.15%)
Clinical MI	12	(0.32%)	40	(0.17%)	181	(0.27%)	47	(0.16%)	2189	(0.28%)	36	(0.29%)
Angina	18	(0.49%)	40	(0.17%)	250	(0.38%)	80	(0.26%)	2415	(0.31%)	34	(0.28%)
CABG/PTCA	23	(0.62%)	55	(0.23%)	248	(0.37%)	96	(0.32%)	3584	(0.46%)	54	(0.44%)
Carotid artery disease	4	(0.11%)	7	(0.03%)	30	(0.05%)	12	(0.04%)	665	(0.09%)	12	(0.10%)
Congestive heart failure	16	(0.43%)	22	(0.09%)	235	(0.35%)	42	(0.14%)	1956	(0.25%)	34	(0.28%)
Stroke	13	(0.35%)	62	(0.26%)	224	(0.34%)	57	(0.19%)	2180	(0.28%)	40	(0.33%)
PVD	3	(0.08%)	4	(0.02%)	72	(0.11%)	7	(0.02%)	587	(0.08%)	13	(0.11%)
Coronary disease[3]	50	(1.35%)	114	(0.48%)	690	(1.04%)	183	(0.61%)	6845	(0.88%)	104	(0.85%)
Total cardiovascular disease	61	(1.65%)	181	(0.76%)	954	(1.43%)	246	(0.81%)	9478	(1.22%)	159	(1.30%)
Cancer												
Breast cancer	14	(0.38%)	112	(0.47%)	317	(0.48%)	116	(0.38%)	4421	(0.57%)	51	(0.42%)
Invasive breast cancer	13	(0.35%)	95	(0.40%)	256	(0.38%)	97	(0.32%)	3685	(0.47%)	43	(0.35%)
Non-invasive breast cancer	1	(0.03%)	18	(0.08%)	65	(0.10%)	20	(0.07%)	767	(0.10%)	9	(0.07%)
Ovarian cancer	1	(0.03%)	5	(0.02%)	20	(0.03%)	15	(0.05%)	399	(0.05%)	2	(0.02%)
Endometrial cancer[4]	1	(0.03%)	10	(0.04%)	22	(0.03%)	11	(0.04%)	635	(0.08%)	12	(0.10%)
Colorectal cancer	4	(0.11%)	22	(0.09%)	108	(0.16%)	23	(0.08%)	940	(0.12%)	12	(0.10%)
Other cancer[5]	16	(0.43%)	96	(0.40%)	323	(0.49%)	90	(0.30%)	4514	(0.58%)	68	(0.55%)
Total cancer	36	(0.97%)	232	(0.97%)	747	(1.12%)	249	(0.82%)	10308	(1.32%)	136	(1.11%)
Fractures												
Hip fracture	5	(0.14%)	16	(0.07%)	37	(0.06%)	16	(0.05%)	1548	(0.20%)	20	(0.16%)
Deaths												
Cardiovascular deaths	16	(0.43%)	46	(0.19%)	242	(0.36%)	46	(0.15%)	1905	(0.24%)	35	(0.29%)
Cancer deaths	13	(0.35%)	64	(0.27%)	256	(0.38%)	74	(0.24%)	2866	(0.37%)	37	(0.30%)
Other known cause	24	(0.65%)	35	(0.15%)	154	(0.23%)	65	(0.22%)	1545	(0.20%)	21	(0.17%)
Unknown cause	1	(0.03%)	5	(0.02%)	57	(0.09%)	12	(0.04%)	245	(0.03%)	4	(0.03%)
Not yet adjudicated	6	(0.16%)	6	(0.03%)	69	(0.10%)	13	(0.04%)	658	(0.08%)	14	(0.11%)
Total death	60	(1.62%)	156	(0.65%)	778	(1.17%)	210	(0.70%)	7219	(0.93%)	111	(0.90%)

[1] "CHD" includes clinical MI and CHD death.
[2] "CHD death" includes definite and possible CHD death.
[3] "Coronary disease" includes clinical MI, CHD death, angina, congestive heart failure, and CABG/PTCA; angina and congestive heart failure are not collected in the WHI Extension Study.
[4] Only women without a baseline hysterectomy are used to compute the annual rates of endometrial cancer.
[5] Only one report of "other cancer" is counted per woman; however, the first of each type is adjudicated. Excludes non-melanoma skin.

Table 5.5
Counts (Annualized Percentages) of Participants with Self-Reported Outcomes by Age and Race/Ethnicity for OS Participants Who Did Not Report a Prevalent Condition at Baseline

Data as of August 15, 2008

Outcome	Total		Age 50-54		55-59		60-69		70-79	
Number randomized	93676		12381		17329		41200		22766	
Mean follow-up (months)	117.2		124.1		122.9		117.2		109.1	
Hospitalizations										
Ever	51114	(5.59%)	4793	(3.74%)	7727	(4.36%)	23233	(5.78%)	15361	(7.42%)
Two or more	29365	(3.21%)	2210	(1.73%)	3847	(2.17%)	13398	(3.33%)	9910	(4.79%)
Other										
DVT[1]	1007	(0.11%)	64	(0.05%)	130	(0.08%)	461	(0.12%)	352	(0.18%)
Pulmonary embolism	722	(0.08%)	59	(0.05%)	106	(0.06%)	331	(0.08%)	226	(0.11%)
Diabetes (treated)	7004	(0.79%)	909	(0.73%)	1303	(0.76%)	3225	(0.83%)	1567	(0.79%)
Gallbladder disease[2,3]	5690	(0.96%)	835	(0.97%)	1153	(0.99%)	2549	(0.99%)	1153	(0.85%)
Hysterectomy	4120	(0.45%)	577	(0.45%)	799	(0.45%)	1898	(0.47%)	846	(0.41%)
Glaucoma[3]	8516	(1.27%)	852	(0.89%)	1379	(1.05%)	3910	(1.33%)	2375	(1.57%)
Osteoporosis[3]	20767	(3.22%)	2110	(2.24%)	3384	(2.64%)	9540	(3.40%)	5733	(4.02%)
Osteoarthritis[4]	19593	(3.68%)	2688	(2.91%)	3823	(3.29%)	8726	(3.88%)	4356	(4.38%)
Rheumatoid arthritis[3]	4607	(0.69%)	638	(0.68%)	885	(0.69%)	1898	(0.65%)	1186	(0.77%)
Intestinal polyps	16658	(2.01%)	2095	(1.72%)	3359	(2.02%)	7757	(2.15%)	3447	(1.93%)
Lupus	1196	(0.13%)	162	(0.13%)	233	(0.13%)	535	(0.13%)	266	(0.13%)
Kidney stones[3,4]	2327	(0.39%)	292	(0.36%)	436	(0.39%)	996	(0.38%)	603	(0.43%)
Cataracts[3,4]	27206	(5.35%)	1735	(2.14%)	4109	(3.73%)	14089	(6.19%)	7273	(8.09%)
Pills for hypertension	26255	(3.99%)	3153	(2.96%)	4770	(3.43%)	11729	(4.17%)	6603	(5.05%)

Outcomes	Race/Ethnicity: American Indian/ Alaskan Native		Asian/Pacific Islander		Black/African American		Hispanic/ Latino		White		Unknown	
Number randomized	421		2671		7635		3609		78016		1324	
Mean follow-up (months)	105.5		107.2		104.6		100.4		119.7		111.2	
Hospitalizations												
Ever	236	(6.38%)	944	(3.95%)	3866	(5.81%)	1432	(4.74%)	43966	(5.65%)	670	(5.46%)
Two or more	143	(3.86%)	410	(1.72%)	2136	(3.21%)	689	(2.28%)	25606	(3.29%)	381	(3.10%)
Other												
DVT[1]	4	(0.11%)	5	(0.02%)	88	(0.14%)	14	(0.05%)	884	(0.12%)	12	(0.10%)
Pulmonary embolism	3	(0.08%)	4	(0.02%)	51	(0.08%)	9	(0.03%)	649	(0.08%)	6	(0.05%)
Diabetes (treated)	57	(1.78%)	219	(0.96%)	961	(1.63%)	407	(1.44%)	5246	(0.69%)	114	(0.97%)
Gallbladder disease[2,3]	31	(1.32%)	81	(0.46%)	377	(0.78%)	232	(1.20%)	4892	(0.98%)	77	(0.95%)
Hysterectomy	18	(0.49%)	80	(0.34%)	254	(0.38%)	185	(0.61%)	3518	(0.45%)	65	(0.53%)
Glaucoma[3]	45	(1.64%)	253	(1.35%)	997	(2.00%)	312	(1.33%)	6787	(1.19%)	122	(1.32%)
Osteoporosis[3]	92	(3.36%)	630	(3.52%)	1078	(2.09%)	739	(3.25%)	17902	(3.30%)	326	(3.68%)
Osteoarthritis[4]	72	(3.51%)	599	(3.56%)	1493	(3.87%)	830	(4.19%)	16312	(3.64%)	287	(3.84%)
Rheumatoid arthritis[3]	38	(1.39%)	98	(0.52%)	664	(1.34%)	385	(1.68%)	3333	(0.59%)	89	(0.98%)
Intestinal polyps	59	(1.75%)	394	(1.85%)	1270	(2.08%)	500	(1.77%)	14232	(2.02%)	203	(1.84%)
Lupus	8	(0.22%)	22	(0.09%)	119	(0.18%)	63	(0.21%)	968	(0.12%)	16	(0.13%)
Kidney stones[3,4]	18	(0.72%)	41	(0.24%)	266	(0.57%)	125	(0.59%)	1832	(0.37%)	45	(0.54%)
Cataracts[3,4]	105	(4.89%)	685	(4.92%)	1951	(4.84%)	905	(4.61%)	23165	(5.44%)	395	(5.68%)
Pills for hypertension	111	(4.67%)	657	(3.90%)	1855	(5.66%)	1009	(4.44%)	22232	(3.87%)	391	(4.51%)

[1] Inpatient DVT only.
[2] "Gallbladder disease" includes self-reports of both hospitalized and non-hospitalized events.
[3] Data not collected for WHI extension study.
[4] These outcomes have not been self-reported on all versions of Form 33. The annualized percentages are corrected for the different amounts of follow-up.

Table 5.6
First Reported Verified Outcomes Before and After AV-3[1] for OS Participants

Data as of August 15, 2008

Outcome	Number of Events	
	Before AV-3	After AV-3
Cardiovascular		
CHD[2]	761	2488
CHD death[3]	178	897
Clinical MI	640	1865
Angina	1270	1567
CABG/PTCA	1166	2894
Carotid artery disease	225	505
Congestive heart failure	719	1586
Stroke	596	1980
PVD	198	488
Coronary disease[4]	2586	5400
Total cardiovascular disease	3471	7608
Cancer		
Breast cancer	1605	3426
Invasive breast cancer	1340	2849
Non-invasive breast cancer	271	609
Ovarian cancer	136	306
Endometrial cancer	214	477
Colorectal cancer	332	777
Other cancer[5]	1435	3672
Total cancer	3645	8063
Fractures		
Hip fracture	294	1348
Deaths		
Cardiovascular deaths	372	1918
Cancer deaths	618	2692
Deaths: other known cause	225	1619
Deaths: unknown cause	59	265
Deaths: not yet adjudicated	0	766
Total death	1274	7260

[1] AV-3 date is the blood draw date for participants with an AV-3 blood draw and the OS enrollment date plus 3 years for participants without an AV-3 blood draw. All participants have been enrolled for at least 3 years.
[2] "CHD" includes clinical MI and CHD death.
[3] "CHD death" includes definite and possible CHD death.
[4] "Coronary disease" includes clinical MI, CHD death, angina, congestive heart failure, and CABG/PTCA; angina and congestive heart failure are not collected in the WHI Extension Study.
[5] Only one report of "other cancer" is counted per woman; however, the first of each type is adjudicated. Excludes non-melanoma skin cancer.

Table 5.7
Counts of Participants with Self-Reported Outcomes Before and After AV-3[1] for OS Participants Who Did Not Report a Prevalent Condition at Baseline

Data as of August 15, 2008

	Number of Events	
Outcome	**Before AV-3**	**After AV-3**
Ever hospitalized	19160	31954
DVT[2]	227	780
Pulmonary embolism	130	592
Diabetes (treated)	1694	5098
Gallbladder disease[3, 4]	2137	3553
Hysterectomy	1359	2761
Glaucoma[4]	2755	5761
Osteoporosis[4]	8703	12064
Osteoarthritis[5]	6339	13254
Rheumatoid arthritis[4]	1723	2884
Intestinal polyps	4397	12261
Lupus	348	848
Kidney stones[4, 5]	646	1681
Cataracts[4, 5]	9145	18061
Pills for hypertension	8141	18114

[1] AV-3 date is the blood draw date for participants with an AV-3 blood draw and the OS enrollment date plus 3 years for participants without an AV-3 blood draw. All participants have been enrolled for at least 3 years.
[2] Inpatient DVT only.
[3] "Gallbladder disease" includes self-reports of both hospitalized and non-hospitalized events.
[4] Not collected on Form 33 after March 31, 2005.
[5] These outcomes have not been self-reported on all versions of Form 33. The annualized percentages are corrected for the different amounts of follow-up.

Table 6.1
Verified Outcomes (Annualized Percentages) by Age for CT Participants

Data as of: August 15, 2008

Outcome	Total		Age 50-54		55-59		60-69		70-79	
Number randomized	68132		9188		14661		31389		12894	
Mean follow-up (months)	124.2		131.9		128.5		123.2		116.2	
Cardiovascular										
CHD[1]	2809	(0.40%)	148	(0.15%)	324	(0.21%)	1303	(0.40%)	1034	(0.83%)
CHD death[2]	814	(0.12%)	34	(0.03%)	62	(0.04%)	352	(0.11%)	366	(0.29%)
Total MI[3]	2242	(0.32%)	120	(0.12%)	275	(0.18%)	1044	(0.32%)	803	(0.64%)
Clinical MI	2165	(0.31%)	114	(0.11%)	267	(0.17%)	1006	(0.31%)	778	(0.62%)
Angina[4]	2414	(0.34%)	129	(0.13%)	331	(0.21%)	1215	(0.38%)	739	(0.59%)
CABG/PTCA	3531	(0.50%)	176	(0.17%)	469	(0.30%)	1847	(0.57%)	1039	(0.83%)
Carotid artery disease	576	(0.08%)	16	(0.02%)	70	(0.04%)	306	(0.09%)	184	(0.15%)
Congestive heart failure[4]	1750	(0.25%)	81	(0.08%)	172	(0.11%)	746	(0.23%)	751	(0.60%)
Stroke	2043	(0.29%)	80	(0.08%)	200	(0.13%)	943	(0.29%)	820	(0.66%)
PVD	527	(0.07%)	28	(0.03%)	67	(0.04%)	270	(0.08%)	162	(0.13%)
Coronary disease[5]	6887	(0.98%)	380	(0.38%)	885	(0.56%)	3346	(1.04%)	2276	(1.82%)
Total cardiovascular disease	9136	(1.30%)	472	(0.47%)	1144	(0.73%)	4418	(1.37%)	3102	(2.48%)
Cancer										
Breast cancer	3475	(0.49%)	402	(0.40%)	754	(0.48%)	1644	(0.51%)	675	(0.54%)
Invasive breast cancer	2822	(0.40%)	308	(0.31%)	618	(0.39%)	1332	(0.41%)	564	(0.45%)
Non-invasive breast cancer	693	(0.10%)	98	(0.10%)	144	(0.09%)	332	(0.10%)	119	(0.10%)
Ovary cancer	307	(0.04%)	26	(0.03%)	64	(0.04%)	158	(0.05%)	59	(0.05%)
Endometrial cancer[6]	457	(0.06%)	51	(0.05%)	104	(0.07%)	224	(0.07%)	78	(0.06%)
Colorectal cancer	904	(0.13%)	52	(0.05%)	138	(0.09%)	452	(0.14%)	262	(0.21%)
Other cancer[7]	3768	(0.53%)	302	(0.30%)	624	(0.40%)	1859	(0.58%)	983	(0.79%)
Total cancer	8480	(1.20%)	794	(0.79%)	1618	(1.03%)	4108	(1.27%)	1960	(1.57%)
Fractures										
Hip fracture	1195	(0.17%)	24	(0.02%)	81	(0.05%)	465	(0.14%)	625	(0.50%)
Deaths										
Cardiovascular deaths	1518	(0.22%)	56	(0.06%)	112	(0.07%)	614	(0.19%)	736	(0.59%)
Cancer deaths	2199	(0.31%)	126	(0.12%)	301	(0.19%)	1085	(0.34%)	687	(0.55%)
Other known cause	1090	(0.15%)	51	(0.05%)	116	(0.07%)	449	(0.14%)	474	(0.38%)
Unknown cause	169	(0.02%)	9	(0.01%)	17	(0.01%)	77	(0.02%)	66	(0.05%)
Not yet adjudicated	484	(0.07%)	24	(0.02%)	37	(0.02%)	222	(0.07%)	201	(0.16%)
Total death	5460	(0.77%)	266	(0.26%)	583	(0.37%)	2447	(0.76%)	2164	(1.73%)

[1] "CHD" includes clinical MI and CHD death.
[2] "CHD death" includes definite and possible CHD death.
[3] "Total MI" includes clinical MI and evolving Q-wave MI.
[4] Angina and CHF are not verified outcomes in the WHI Extension Study. Reported statistics represent experience during the original program.
[5] "Coronary disease" includes clinical MI, evolving Q-wave MI, possible evolving Q-wave MI, CHD death, angina, congestive heart failure, and CABG/PTCA.
[6] Only women without a baseline hysterectomy are used to compute the annual rates of endometrial cancer.
[7] Only one report of "other cancer" is counted per woman; however, the first of each type is adjudicated. Excludes non-melanoma skin cancer.

Table 6.2
Verified Outcomes (Annualized Percentages) by Race/Ethnicity for CT Participants

Data as of: August 15, 2008

Outcome	Race/Ethnicity											
	American Indian/Alaskan Native		Asian/Pacific Islander		Black/African American		Hispanic/ Latino		White		Unknown	
Number randomized	292		1519		6983		2875		55525		938	
Mean follow-up (months)	116.9		119.2		119.6		114.0		125.6		117.4	
Cardiovascular												
CHD[1]	8	(0.28%)	36	(0.24%)	274	(0.39%)	62	(0.23%)	2390	(0.41%)	39	(0.43%)
CHD death[2]	2	(0.07%)	9	(0.06%)	120	(0.17%)	16	(0.06%)	654	(0.11%)	13	(0.14%)
Total MI[3]	7	(0.25%)	33	(0.22%)	188	(0.27%)	51	(0.19%)	1931	(0.33%)	32	(0.35%)
Clinical MI	7	(0.25%)	32	(0.21%)	183	(0.26%)	49	(0.18%)	1864	(0.32%)	30	(0.33%)
Angina[4]	12	(0.42%)	30	(0.20%)	298	(0.43%)	80	(0.29%)	1964	(0.34%)	30	(0.33%)
CABG/PTCA	13	(0.46%)	36	(0.24%)	303	(0.44%)	95	(0.35%)	3041	(0.52%)	43	(0.47%)
Carotid artery disease	3	(0.11%)	2	(0.01%)	33	(0.05%)	5	(0.02%)	525	(0.09%)	8	(0.09%)
Congestive heart failure[5]	5	(0.18%)	17	(0.11%)	244	(0.35%)	49	(0.18%)	1411	(0.24%)	24	(0.26%)
Stroke	8	(0.28%)	34	(0.23%)	259	(0.37%)	56	(0.21%)	1657	(0.29%)	29	(0.32%)
PVD	5	(0.18%)	5	(0.03%)	79	(0.11%)	5	(0.02%)	428	(0.07%)	5	(0.05%)
Coronary disease[5]	25	(0.88%)	85	(0.56%)	773	(1.11%)	195	(0.71%)	5719	(0.98%)	90	(0.98%)
Total cardiovascular disease	36	(1.27%)	122	(0.81%)	1035	(1.49%)	251	(0.92%)	7574	(1.30%)	118	(1.29%)
Cancer												
Breast cancer	7	(0.25%)	79	(0.52%)	288	(0.41%)	85	(0.31%)	2980	(0.51%)	36	(0.39%)
Invasive breast cancer	6	(0.21%)	59	(0.39%)	228	(0.33%)	69	(0.25%)	2432	(0.42%)	28	(0.31%)
Non-invasive breast cancer	1	(0.04%)	21	(0.14%)	63	(0.09%)	17	(0.06%)	583	(0.10%)	8	(0.09%)
Ovary cancer	1	(0.04%)	8	(0.05%)	18	(0.03%)	8	(0.03%)	267	(0.05%)	5	(0.05%)
Endometrial cancer[6]	1	(0.04%)	5	(0.03%)	27	(0.04%)	13	(0.05%)	403	(0.07%)	8	(0.09%)
Colorectal cancer	5	(0.18%)	16	(0.11%)	93	(0.13%)	25	(0.09%)	750	(0.13%)	15	(0.16%)
Other cancer[7]	12	(0.42%)	63	(0.42%)	276	(0.40%)	92	(0.34%)	3285	(0.57%)	40	(0.44%)
Total cancer	24	(0.84%)	164	(1.09%)	673	(0.97%)	210	(0.77%)	7313	(1.26%)	96	(1.05%)
Fractures												
Hip fracture	5	(0.18%)	12	(0.08%)	28	(0.04%)	20	(0.07%)	1121	(0.19%)	9	(0.10%)
Deaths												
Cardiovascular deaths	6	(0.21%)	21	(0.14%)	214	(0.31%)	30	(0.11%)	1229	(0.21%)	18	(0.20%)
Cancer deaths	10	(0.35%)	40	(0.26%)	181	(0.26%)	63	(0.23%)	1878	(0.32%)	27	(0.29%)
Other known cause	11	(0.39%)	12	(0.08%)	105	(0.15%)	21	(0.08%)	925	(0.16%)	16	(0.17%)
Unknown cause	1	(0.04%)	3	(0.02%)	29	(0.04%)	5	(0.02%)	126	(0.02%)	5	(0.05%)
Not yet adjudicated	3	(0.11%)	3	(0.02%)	50	(0.07%)	13	(0.05%)	408	(0.07%)	7	(0.08%)
Total death	31	(1.09%)	79	(0.52%)	579	(0.83%)	132	(0.48%)	4566	(0.79%)	73	(0.80%)

[1] "CHD" includes clinical MI, evolving Q-wave MI, and CHD death.
[2] "CHD death" includes definite and possible CHD death.
[3] "Total MI" includes clinical MI and evolving Q-wave MI.
[4] Angina and CHF are not verified outcomes in the WHI Extension Study. Reported statistics represent experience during the original program.
[5] "Coronary disease" includes clinical MI, evolving Q-wave MI, possible evolving Q-wave MI, CHD death, angina, congestive heart failure, and CABG/PTCA.
[6] Only women without a baseline hysterectomy are used to compute the annual rates of endometrial cancer.
[7] Only one report of "other cancer" is counted per woman; however, the first of each type is adjudicated. Excludes non-melanoma skin cancer.

Table 6.3
Counts (Annualized Percentages) of Participants with Self-Reported Outcomes by Age and Race/Ethnicity for CT Participants Who Did Not Report a Prevalent Condition at Baseline

Data as of: August 15, 2008

Outcome	Total	Age 50-54	55-59	60-69	70-79
Number randomized	68132	9188	14661	31389	12894
Mean follow-up (months)	124.2	131.9	128.5	123.2	116.2
Hospitalizations					
Ever	39531 (5.61%)	3938 (3.90%)	7186 (4.58%)	19021 (5.90%)	9386 (7.52%)
Two or more	23862 (3.38%)	1928 (1.91%)	3906 (2.49%)	11649 (3.62%)	6379 (5.11%)
Other					
DVT[1]	1026 (0.15%)	64 (0.06%)	142 (0.09%)	480 (0.15%)	340 (0.28%)
Pulmonary embolism	705 (0.10%)	51 (0.05%)	105 (0.07%)	350 (0.11%)	199 (0.16%)
Diabetes (treated)	6972 (1.03%)	984 (1.00%)	1492 (0.99%)	3285 (1.07%)	1211 (1.02%)
Gallbladder disease[2,3]	5248 (1.01%)	746 (0.95%)	1195 (1.02%)	2463 (1.06%)	844 (0.94%)
Hysterectomy	2529 (0.61%)	324 (0.56%)	582 (0.60%)	1232 (0.66%)	391 (0.56%)
Glaucoma[3]	7570 (1.27%)	745 (0.85%)	1457 (1.08%)	3664 (1.36%)	1704 (1.66%)
Osteoporosis[3]	14702 (2.52%)	1453 (1.67%)	2636 (1.98%)	7143 (2.70%)	3470 (3.49%)
Osteoarthritis[4]	15914 (3.65%)	2301 (3.03%)	3637 (3.35%)	7294 (3.86%)	2682 (4.27%)
Rheumatoid arthritis[3]	4012 (0.67%)	538 (0.62%)	866 (0.65%)	1823 (0.68%)	785 (0.74%)
Intestinal polyps	13390 (2.05%)	1728 (1.77%)	2938 (1.97%)	6570 (2.21%)	2154 (1.95%)
Lupus	849 (0.12%)	126 (0.13%)	190 (0.12%)	394 (0.12%)	139 (0.11%)
Kidney stones[3,4]	1877 (0.36%)	241 (0.33%)	379 (0.33%)	898 (0.37%)	359 (0.38%)
Cataracts[3,4]	21575 (4.59%)	1468 (2.00%)	3732 (3.27%)	11651 (5.38%)	4724 (7.15%)
Pills for hypertension	21386 (4.29%)	2725 (3.33%)	4617 (3.85%)	10039 (4.57%)	4005 (5.24%)

Outcomes	Race/Ethnicity: Am Indian/ Alaskan Native	Asian/Pacific Islander	Black/African American	Hispanic/ Latino	White	Unknown
Number randomized	292	1519	6983	2875	55525	938
Mean follow-up (months)	116.9	119.2	119.6	114.0	125.6	117.4
Hospitalizations						
Ever	163 (5.73%)	647 (4.29%)	3963 (5.70%)	1297 (4.75%)	32958 (5.67%)	503 (5.48%)
Two or more	112 (3.94%)	316 (2.09%)	2415 (3.47%)	698 (2.56%)	20036 (3.45%)	285 (3.11%)
Other						
DVT[1]	5 (0.18%)	2 (0.01%)	108 (0.16%)	18 (0.07%)	881 (0.16%)	12 (0.13%)
Pulmonary embolism	4 (0.14%)	3 (0.02%)	70 (0.10%)	8 (0.03%)	612 (0.11%)	8 (0.09%)
Diabetes (treated)	33 (1.28%)	179 (1.26%)	1131 (1.83%)	433 (1.70%)	5095 (0.91%)	101 (1.17%)
Gallbladder disease[2,3]	22 (1.17%)	86 (0.72%)	420 (0.76%)	243 (1.30%)	4403 (1.04%)	74 (1.07%)
Hysterectomy	7 (0.56%)	40 (0.41%)	163 (0.54%)	87 (0.57%)	2212 (0.63%)	20 (0.37%)
Glaucoma[3]	40 (1.66%)	153 (1.20%)	1008 (1.75%)	338 (1.43%)	5932 (1.21%)	99 (1.30%)
Osteoporosis[3]	66 (2.73%)	389 (3.10%)	911 (1.53%)	639 (2.80%)	12488 (2.60%)	209 (2.76%)
Osteoarthritis[4]	77 (4.50%)	376 (3.44%)	1558 (3.72%)	764 (4.08%)	12895 (3.61%)	244 (4.19%)
Rheumatoid arthritis[3]	32 (1.40%)	74 (0.58%)	683 (1.19%)	358 (1.53%)	2788 (0.57%)	77 (1.00%)
Intestinal polyps	65 (2.48%)	267 (1.93%)	1415 (2.18%)	475 (1.82%)	10992 (2.04%)	176 (2.08%)
Lupus	6 (0.21%)	14 (0.09%)	116 (0.17%)	41 (0.15%)	663 (0.11%)	9 (0.10%)
Kidney stones[3,4]	15 (0.73%)	47 (0.41%)	190 (0.36%)	100 (0.48%)	1501 (0.35%)	24 (0.35%)
Cataracts[3,4]	92 (4.82%)	428 (4.19%)	2003 (4.22%)	828 (4.17%)	17931 (4.67%)	293 (4.71%)
Pills for hypertension	88 (4.70%)	440 (4.27%)	1978 (5.66%)	952 (4.66%)	17670 (4.16%)	258 (4.21%)

[1] Inpatient DVT only.
[2] "Gallbladder disease" includes self-reports of both hospitalized and non-hospitalized events.
[3] Data not collected for WHI extension study.
[4] These outcomes have not been self-reported on all versions of Form 33 during WHI follow-up. The annualized percentages are corrected for the different amounts of follow-up.

Table 6.4
First Reported Verified Outcomes Before and After AV-1[1] for CT Participants

Data as of August 15, 2008

Outcome	Number of Events	
	Before AV-1	After AV-1
Cardiovascular		
CHD[2]	215	2594
CHD death[3]	44	770
Clinical MI	181	1984
Angina	300	2114
CABG/PTCA	252	3279
Carotid artery disease	63	513
Congestive heart failure	114	1636
Stroke	143	1900
PVD	33	494
Coronary disease[4]	611	6276
Total cardiovascular disease	839	8297
Cancer		
Breast cancer	201	3274
Invasive breast cancer	158	2664
Non-invasive breast cancer	43	650
Ovarian cancer	20	287
Endometrial cancer	40	417
Colorectal cancer	79	825
Other cancer[5]	280	3488
Total cancer	613	7867
Fractures		
Hip fracture	50	1145
Deaths		
Cardiovascular deaths	73	1445
Cancer deaths	53	2146
Deaths: other known cause	17	1073
Deaths: unknown cause	5	164
Deaths: not yet adjudicated	0	484
Total death	148	5312

[1] AV-1 date is the blood draw for participants with an AV-1 blood draw and the CT randomization date plus 1 year for participants without an AV-1 blood draw. All participants have been enrolled for at least 1 year.
[2] "CHD" includes clinical MI and CHD death.
[3] "CHD death" includes definite and possible CHD death.
[4] "Coronary disease" includes clinical MI, CHD death, angina, congestive heart failure, and CABG/PTCA; angina and congestive heart failure are not collected in the WHI Extension Study.
[5] Only one report of "other cancer" is counted per woman; however, the first of each type is adjudicated. Excludes non-melanoma skin cancer.

Table 6.5
Counts of Participants with Self-Reported Outcomes Before and After AV-1[1] for CT Participants Who Did Not Report a Prevalent Condition at Baseline

Data as of August 15, 2008

Outcome	Number of Events	
	Before AV-1	After AV-1
Ever hospitalized	5492	34039
DVT[2]	90	936
Pulmonary embolism	48	657
Diabetes (treated)	561	6174
Gallbladder disease[3,4]	606	4642
Hysterectomy	158	1709
Glaucoma[4]	767	6803
Osteoporosis[4]	1502	13200
Osteoarthritis[5]	1248	14666
Rheumatoid arthritis[4]	587	3425
Intestinal polyps	956	12434
Lupus	75	774
Kidney stones[4,5]	128	1749
Cataracts [4,5]	1660	19915
Pills for hypertension	2190	19196

[1] AV-1 date is the blood draw date for participants with an AV-1 blood draw and the CT randomization date plus 1 year for participants without an AV-1 blood draw. All participants have been enrolled for at least 1 year.

[2] Inpatient DVT only.

[3] "Gallbladder disease" includes self-reports of both hospitalized and non-hospitalized events.

[4] Not collected on Form 33 after March 31,2005.

[5] These outcomes have not been self-reported on all versions of Form 33. The annualized percentages are corrected for the different amounts of follow-up.

Table 6.6
Verified Other Cancers (Annualized Percentages): CT and OS Participants

Data as of: August 15, 2008

	CT		OS	
Number of participants	68132		93676	
Mean follow-up time (months)	124.2		117.2	
Ppts with other cancer	3768	(0.53%)	5107	(0.56%)
Accessory sinus	1	(<0.01%)	1	(<0.01%)
Adrenal gland	1	(<0.01%)	7	(<0.01%)
Anus	17	(<0.01%)	32	(<0.01%)
Appendix	10	(<0.01%)	12	(<0.01%)
Biliary tract, parts of (other/unspecified)	53	(0.01%)	55	(0.01%)
Bladder	223	(0.03%)	275	(0.03%)
Bones/joints/articular cartilage (limbs)	4	(<0.01%)	8	(<0.01%)
Bones/joints/articular cartilage (other)	6	(<0.01%)	2	(<0.01%)
Brain	97	(0.01%)	102	(0.01%)
Cervix	51	(0.01%)	46	(0.01%)
Central Nervous System (excludes brain)	0	(0.00%)	3	(<0.01%)
Connective/subcutaneous/soft tissues	37	(0.01%)	45	(<0.01%)
Endocrine glands, related structures	6	(<0.01%)	7	(<0.01%)
Esophagus	42	(0.01%)	47	(0.01%)
Eye and adnexa	20	(<0.01%)	16	(<0.01%)
Genital organs	51	(0.01%)	51	(0.01%)
Kidney	176	(0.02%)	228	(0.02%)
Larynx	19	(<0.01%)	13	(<0.01%)
Leukemia	186	(0.03%)	247	(0.03%)
Liver	43	(0.01%)	51	(0.01%)
Lung	751	(0.11%)	990	(0.11%)
Lymph nodes	12	(<0.01%)	9	(<0.01%)
Lymphoma, Hodgkins	23	(<0.01%)	23	(<0.01%)
Lymphoma, Non-Hodgkins	351	(0.05%)	504	(0.06%)
Melanoma of the skin	491	(0.07%)	631	(0.07%)
Multiple myeloma	129	(0.02%)	125	(0.01%)
Oral (mouth)	24	(<0.01%)	18	(<0.01%)
Palate	8	(<0.01%)	12	(<0.01%)
Pancreas	192	(0.03%)	232	(0.03%)
Parotid gland (Stensen's duct)	11	(<0.01%)	24	(<0.01%)
Peripheral nerves and autonomic nervous system	1	(<0.01%)	5	(<0.01%)
Pyriform sinus	1	(<0.01%)	4	(<0.01%)
Respiratory system, intrathoracic, other	10	(<0.01%)	20	(<0.01%)
Salivary glands, major (other/unspecified)	4	(<0.01%)	11	(<0.01%)
Stomach	56	(0.01%)	79	(0.01%)
Thyroid	107	(0.02%)	157	(0.02%)
Tongue, part of (other/unspecified)	24	(<0.01%)	25	(<0.01%)
Urinary organs (other/unspecified)	18	(<0.01%)	35	(<0.01%)
Uterus, not otherwise specified	45	(0.01%)	86	(0.01%)
Other/unknown site of cancer	256	(0.04%)	354	(0.04%)
Other/unknown cancers reported on death form	314	(0.04%)	630	(0.07%)

Table 6.7
Locally Verified Other Fractures (Annualized Percentages): CT and OS Participants

Data as of August 15, 2008

	CT		OS	
Number of participants	68132		93676	
Mean follow-up time (months)	124.2		117.2	
Self-Reports				
Elbow	724	(0.10%)	946	(0.10%)
Foot	2537	(0.36%)	3181	(0.35%)
Hand	625	(0.09%)	682	(0.07%)
Hip	1294	(0.18%)	1796	(0.20%)
Knee	925	(0.13%)	1215	(0.13%)
Lower arm	3549	(0.50%)	4447	(0.49%)
Lower leg	2824	(0.40%)	3451	(0.38%)
Pelvis	663	(0.09%)	1076	(0.12%)
Tailbone	230	(0.03%)	326	(0.04%)
Upper arm	1704	(0.24%)	2106	(0.23%)
Upper leg	447	(0.06%)	665	(0.07%)
Spine	1917	(0.27%)	2803	(0.31%)
Other	2854	(0.40%)	3162	(0.35%)
Total fracture	15371	(2.18%)	19791	(2.16%)

Data as of: August 18, 2006
Events through Intervention Closeout

	CT		OS	
Number of participants	68132		6365	
Mean follow-up time (months)	96.1		97.6	
Locally verified				
Ppts with other fractures[1]	8335	(1.53%)	773	(1.49%)
Ankle	1352	(0.25%)	128	(0.25%)
Carpal bone(s) in wrist	192	(0.04%)	13	(0.03%)
Clavicle or collar bone	147	(0.03%)	14	(0.03%)
Elbow, not otherwise specified	31	(0.01%)	1	(<0.01%)
Humerus, shaft/unspecified	86	(0.02%)	7	(0.01%)
Humerus, upper end	842	(0.15%)	69	(0.13%)
Lower end of humerus	104	(0.02%)	10	(0.02%)
Metacarpal bone(s)	272	(0.05%)	27	(0.05%)
Patella	358	(0.07%)	29	(0.06%)
Pelvis	361	(0.07%)	51	(0.10%)
Radius or ulna	2227	(0.41%)	208	(0.40%)
Sacrum and coccyx	107	(0.02%)	12	(0.02%)
Scapula	37	(0.01%)	6	(0.01%)
IShaft of femur	113	(0.02%)	9	(0.02%)
Tarsal/metatarsal bones	1291	(0.24%)	128	(0.25%)
Tibia and fibula	640	(0.12%)	32	(0.06%)
Tibial plateau	176	(0.03%)	10	(0.02%)
Upper radius/ulna	381	(0.07%)	34	(0.07%)
Vertebral	828	(0.15%)	121	(0.23%)
Unknown other fracture	0	(0.00%)	0	(0.00%)

[1] "Other fractures" excludes non-vertebral fractures indicated as pathological.

Table 6.8
Cause of Death (Annualized Percentages): CT and OS Participants

Data as of: August 15, 2008

	CT		OS	
Number Randomized	68132		93676	
Mean Follow-up Time (months)	124.2		117.2	
Total death	5460	(0.77%)	8534	(0.93%)
Adjudicated death	4976	(0.71%)	7768	(0.85%)
Centrally adjudicated death	4937	(0.70%)	1759	(0.19%)
Locally adjudicated death (final)	1	(<0.01%)	5889	(0.64%)
Temporary adjudicated death	0	(0.00%)	0	(0.00%)
Identified by NDI search	38	(0.01%)	120	(0.01%)
Cardiovascular				
Atherosclerotic cardiac	814	(0.12%)	1075	(0.12%)
CHD deaths locally adjudicated before 10/99	0	(0.00%)	82	(0.01%)
Definite CHD deaths	388	(0.06%)	453	(0.05%)
Possible CHD deaths	426	(0.06%)	540	(0.06%)
Cerebrovascular	385	(0.05%)	586	(0.06%)
Pulmonary embolism	50	(0.01%)	56	(0.01%)
Other cardiovascular	245	(0.03%)	477	(0.05%)
Unknown cardiovascular	24	(<0.01%)	96	(0.01%)
Total cardiovascular deaths	1518	(0.22%)	2290	(0.25%)
Cancer				
Breast cancer	150	(0.02%)	478	(0.05%)
Ovarian cancer	146	(0.02%)	235	(0.03%)
Endometrial cancer	38	(0.01%)	60	(0.01%)
Colorectal cancer	198	(0.03%)	279	(0.03%)
Other cancer	1551	(0.22%)	2088	(0.23%)
Unknown cancer site	116	(0.02%)	170	(0.02%)
Total cancer deaths	2199	(0.31%)	3310	(0.36%)
Accident/injury				
Homicide	7	(<0.01%)	11	(<0.01%)
Accident	148	(0.02%)	171	(0.02%)
Suicide	15	(<0.01%)	29	(<0.01%)
Other injury	9	(<0.01%)	26	(<0.01%)
Total accidental deaths	179	(0.03%)	237	(0.03%)
Other				
Other known cause	911	(0.13%)	1607	(0.18%)
Unknown cause	653	(0.09%)	1090	(0.12%)
Total deaths – other causes	1564	(0.22%)	2697	(0.29%)

Table 7.1
Agreement of the Central Adjudications with Self-Reports

Data as of: August 15, 2008

	Participants with a self-report[1]	Closed		Confirmed		Denied – related outcome found[2]		Denied – unrelated outcome found		Denied – no outcome found		Administrative denials	
		N	%[3]	N	(%)[3]	N	(%)[3]	N	(%)[3]	N	(%)[3]	N	(%)[3]
Cardiovascular													
Clinical MI	984	938	95%	670	(71%)	63	(7%)	5	(1%)	199	(21%)	1	(0%)
CABG	515	498	97%	444	(89%)	17	(3%)	1	(0%)	36	(7%)	0	(0%)
PTCA	1583	1522	96%	1266	(83%)	81	(5%)	12	(1%)	163	(11%)	0	(0%)
Carotid artery disease	308	301	98%	235	(78%)	28	(9%)	0	(0%)	33	(11%)	5	(2%)
Stroke/TIA[4]	1505	1327	88%	794	(60%)	0	(0%)	0	(0%)	527	(40%)	6	(0%)
PVD	327	316	97%	191	(60%)	12	(4%)	13	(4%)	99	(31%)	1	(0%)
DVT[5]	119	114	96%	72	(63%)	8	(7%)	11	(10%)	22	(19%)	1	(1%)
Pulmonary embolism[5]	65	62	95%	54	(87%)	0	(0%)	3	(5%)	5	(8%)	0	(0%)
Cancers													
Breast cancer	1662	1599	96%	1558	(97%)	5	(0%)	0	(0%)	35	(2%)	1	(0%)
Ovarian cancer	188	178	95%	120	(67%)	50	(28%)	1	(1%)	7	(4%)	0	(0%)
Endometrial cancer	197	185	94%	170	(92%)	10	(5%)	1	(1%)	4	(2%)	0	(0%)
Cervical cancer	24	23	96%	2	(9%)	20	(87%)	0	(0%)	1	(4%)	0	(0%)
Colorectal cancer	450	433	96%	361	(83%)	36	(8%)	0	(0%)	34	(8%)	2	(0%)
Melanoma	332	237	71%	206	(87%)	12	(5%)	0	(0%)	14	(6%)	5	(2%)
Lung cancer	540	403	75%	340	(84%)	28	(7%)	0	(0%)	35	(9%)	0	(0%)
Liver cancer	83	63	76%	16	(25%)	24	(38%)	0	(0%)	22	(35%)	1	(2%)
Bone cancer	48	35	73%	0	(0%)	19	(54%)	1	(3%)	15	(43%)	0	(0%)
Lymphoma/Hodgkin's	219	194	89%	173	(89%)	13	(7%)	0	(0%)	7	(4%)	1	(1%)
Leukemia	155	110	71%	89	(81%)	10	(9%)	0	(0%)	11	(10%)	0	(0%)
Meningioma	11	9	82%	0	(0%)	2	(22%)	0	(0%)	7	(78%)	0	(0%)
Other cancer[6]	1055	817	77%	0	(0%)	698	(85%)	0	(0%)	107	(13%)	12	(1%)
Fractures													
Hip fracture	966	929	96%	774	(83%)	0	(0%)	0	(0%)	152	(16%)	3	(0%)
Upper leg fracture[7]	282	275	98%	0	(0%)	126	(46%)	0	(0%)	148	(54%)	1	(0%)

[1] Excludes duplicates and prior conditions.
[2] All cardiovascular outcomes are considered related, all cancers are considered related and all fractures are considered related.
[3] Percentages between parenthese are relative to "closed".
[4] Stroke and TIA have a combined self-report. Only stroke is monitored.
[5] HRT participants only.
[6] Any cancer other than those listed above, excluding non-melanoma skin cancer.
[7] Upper leg fractures are only investigated for possible occurrence of hip fracture.

Table 7.2
Source of Outcomes Identified by Central Adjudications

Data as of: August 15, 2008

	Centrally confirmed	Reason for central investigation					
		Self-report same outcome		Self-report related outcome[1]		Self-report unrelated outcome[2]	
	N	N	%	N	%	N	%
Cardiovascular							
Clinical MI	1065	671	63%	315	30%	79	7%
CABG	483	444	92%	30	6%	9	2%
PTCA	1362	1269	93%	82	6%	11	1%
Carotid artery disease	272	236	87%	3	1%	33	12%
Stroke	933	839	90%	0	0%	94	10%
PVD	278	192	69%	59	21%	27	10%
DVT	93	72	77%	5	5%	16	17%
Pulmonary embolism	72	54	75%	4	6%	14	19%
Cancers							
Breast cancer	1569	1560	99%	5	<1%	4	<1%
Ovarian cancer	137	120	88%	5	4%	12	9%
Endometrial cancer	220	170	77%	44	20%	6	3%
Cervical cancer	2	2	100%	0	0%	0	0%
Colorectal cancer	375	351	94%	8	2%	16	4%
Melanoma	211	206	98%	5	2%	0	0%
Lung cancer	372	340	91%	21	6%	11	3%
Liver cancer	20	16	80%	3	15%	1	5%
Lymphoma/Hodgkin's	218	176	81%	35	16%	7	3%
Leukemia	106	90	85%	10	9%	6	6%
Other cancer	754	0	0%	722	96%	32	4%
Fractures							
Hip fracture	913	774	85%	113	12%	26	3%

[1] All cardiovascular outcomes are considered related, all cancers are considered related and all fractures are considered related.
[2] Includes self-report of hospitalizations.

Table 8.1
Form 33/33D - Medical History Update/(Detail) Workload

Data as of 9/30/08

	Form 33 – Medical History Update 6-01-07 thru 5-31-08						Ppts on FC Mail003-Due for FC Collection Data as of 9/30/08		Form 33D – Medical History Update (Detail) Cummulative[1 & 2]							
			CCC Mailings Not Collected		Outstanding Info Errors (Cum)				Due	Missing		Incomplete		Ave Collected per Month last 12 mo	Form 33D Workload (miss + incomp)	
	# Due[1]	% Collected	#	%	#	%	#	% Collected	#	#	%	#	%	#	# cases	% months
Atlanta	3,036	96.4	359	11.8	10	0.3	6	0.2	419	19	4.5	1	0.3	34	20	0.6
Birmingham	2,608	94.8	421	16.1			21	0.8	432	1	0.2			36	1	0.0
Bowman	2,567	93.8	288	11.2	14	0.6	77	3.0	322	53	16.5	3	1.1	25	56	2.2
Brigham	4,130	97.8	263	6.4	1	0.0	3	0.1	594	4	0.7	1	0.2	50	5	0.1
Buffalo	2,988	97.1	208	7.0	2	0.1	29	1.0	440	2	0.5	1	0.2	37	3	0.1
Chapel Hill	2,764	96.0	275	9.9	4	0.2	45	1.6	371	46	12.4	7	2.2	28	53	1.9
Chicago-Rush	1,838	94.2	246	13.4	7	0.4	38	2.1	256	12	4.7			24	12	0.5
Chicago	2,541	97.0	189	7.4	4	0.2	32	1.3	350	10	2.9	2	0.6	33	12	0.4
Cincinnati	2,724	94.6	227	8.3	8	0.3	54	2.0	371	37	10.0	3	0.9	28	40	1.4
Columbus	2,789	98.1	173	6.2	5	0.2	5	0.2	463	6	1.3			39	6	0.2
Detroit	2,292	96.5	212	9.2	2	0.1	39	1.7	337	18	5.3	1	0.3	29	19	0.7
Gainesville	3,829	95.4	481	12.6	6	0.2	81	2.1	616	15	2.4	2	0.3	53	17	0.3
GWU-DC	2,849	95.2	221	7.8	22	0.8	57	2.0	305	15	4.9	7	2.4	27	22	0.8
Honolulu	1,950	97.6	177	9.1			2	0.1	166					14		
Houston	2,167	96.2	186	8.6	2	0.1	24	1.1	294	14	4.8	1	0.4	24	15	0.6
IC-Bettendorf	1,975	98.8	88	4.5	2	0.1	1	0.1	327	14	4.3	2	0.6	27	16	0.6
IC-Des Moines	1,964	98.8	67	3.4	2	0.1	5	0.3	293	5	1.7			26	5	0.2
Irvine	2,838	95.0	179	6.3	30	1.1	74	2.6	343	24	7.0			29	24	0.8
LA	2,711	95.8	147	5.4	2	0.1	47	1.7	343	30	8.7			28	30	1.1
LaJolla	3,005	92.7	220	7.3	20	0.7	129	4.3	426	34	8.0			37	34	0.9
Madison	2,665	97.4	114	4.3	10	0.4	30	1.1	347	23	6.6	2	0.6	30	25	0.8
Medlantic	2,544	94.7	500	19.7	5	0.2	85	3.3	326	8	2.5	2	0.6	28	10	0.4
Memphis	2,282	96.4	241	10.6	11	0.5	14	0.6	302	5	1.7	1	0.3	25	6	0.2
Miami	1,655	91.8	298	18.0	54	3.6	67	4.0	215	19	8.8	1	0.5	17	20	1.2
Milwaukee	2,849	96.7	120	4.2	22	0.8	42	1.5	378	14	3.7	5	1.4	37	19	0.5

Table 8.1 (continued)
Form 33/33D - Medical History Update/(Detail) Workload

Data as of 9/30/08

	Form 33 – Medical History Update 6-01-07 thru 5-31-08						Ppts on FC Mail003-Due for FC Collection Data as of 9/30/08		Form 33D – Medical History Update (Detail) Cummulative[1 & 2]							
			CCC Mailings Not Collected		Outstanding Info Errors (Cum)				Due	Missing		Incomplete		Ave Collected per Month last 12 mo	Form 33D Workload (miss + incomp)	
	# Due[1]	% Collected	#	%	#	%	#	% Collected	#	#	%	#	%	#	# cases	% months
Minneapolis	3,482	97.9	143	4.1	4	0.1	24	0.7	457	30	6.6			39	30	0.8
Nevada	2,594	95.1	262	10.1	1	0.0	50	1.9	388	1	0.3	3	0.8	33	4	0.1
Newark	2,896	92.7	280	9.7	1	0.0	110	3.8	383	33	8.6			30	33	1.1
New Brunswick	1,184	95.8	170	14.4	5	0.4	24	2.0	134	11	8.2	1	0.8	11	12	1.1
NYC	2,866	94.9	317	11.1			25	0.9	386	2	0.5	2	0.5	32	4	0.1
Oakland	2,695	98.2	173	6.4	8	0.3	11	0.4	302	11	3.6	1	0.3	25	12	0.5
Pawtucket	4,693	96.8	363	7.7			21	0.4	707	3	0.4	7	1.0	60	10	0.2
Pittsburgh	2,663	96.6	226	8.5	9	0.3	36	1.4	460	14	3.0			39	14	0.4
Portland	2,801	93.1	239	8.5	10	0.4	98	3.5	336	27	8.0			27	27	1.0
San Antonio	1,780	92.4	222	12.5	2	0.1	54	3.0	187	55	29.4			12	55	4.7
Seattle	2,353	95.8	152	6.5	1	0.0	51	2.2	302	7	2.3	4	1.4	26	11	0.4
Stanford	3,378	97.7	219	6.5	6	0.2	22	0.7	431	3	0.7	3	0.7	36	6	0.2
StonyBrook	2,482	95.7	272	11.0	5	0.2	13	0.5	410	4	1.0	2	0.5	34	6	0.2
Torrance	1,502	95.5	118	7.9	6	0.4	13	0.9	205	8	3.9	2	1.0	17	10	0.6
Tucson	3,004	93.5	316	10.5	12	0.4	71	2.4	453	17	3.8	1	0.2	37	18	0.5
UCDavis	2,753	96.1	189	6.9	14	0.5	47	1.7	386	17	4.4			33	17	0.5
Worcester	3,076	97.9	217	7.1	4	0.1	13	0.4	434	3	0.7	14	3.2	36	17	0.5
All FCs	111,762	95.9	9,778	8.7	333	0.3	1,690	1.5	15,397	674	4.4	82	0.6	1,292	756	0.6

1 - Excludes absolutely no contact and deceased participants
2 - Form 33Ds due, missing, and incomplete in the last 12 months

Table 8.2
Outcomes Processing Workload

Data as of 9/30/08

							Closed Cases	Outcomes Workload			Deaths (Ext)			
	Open Cases	No Docs Request	No Docs Receive	No Docs Process	≥ 1 Doc Process	Open > 12 Mos	Avg # per Mo for last 12 Mo	Est # Months to Process Open Cases	Est Workload for Open cases and Form 33D		Cum[1]	Open		# Open cases with Deaths
	#	#	#	#	#	#			# cases	# months	#	#	%	
Atlanta	70		64	6		8	37	1.9	90	2.5	103	7	6.8	10
Birmingham	34	4	29	1			34	1.0	35	1.0	88	4	4.5	8
Bowman	82	44	24	14		3	23	3.6	138	5.8	89	21	23.6	24
Brigham	40	9	31				43	0.9	45	1.0	92	7	7.6	12
Buffalo	99	27	54	18			46	2.2	102	2.2	141	25	17.7	51
ChapelHill	11	5	2	4			25	0.4	64	2.3	78	2	2.6	5
Chicago-Rush	60	20	36	4		3	23	2.6	72	3.1	57	11	19.3	15
Chicago	88	33	37	18			37	2.4	100	2.7	100	12	12.0	40
Cincinnati	28	3	25			2	28	1.0	68	2.4	71	15	21.1	5
Columbus	114	5	109			4	42	2.7	120	2.9	124	16	12.9	55
Detroit	40	15	16	9			23	1.7	59	2.4	60	17	28.3	16
Gainesville	153	86	63	4			57	2.7	170	3.0	124	20	16.1	37
GWU-DC	104	13	88	3		4	21	4.9	126	5.7	68	7	10.3	8
Honolulu	9		9				14	0.6	9	0.6	36			
Houston	62	17	27	18		1	24	2.5	77	3.2	65	11	16.9	23
IC-Bettendorf	48	21	23	4			28	1.7	64	2.3	57	8	14.0	14
IC-Des Moines	63	26	18	19			25	2.5	68	2.7	59	18	30.5	26
Irvine	90	40	35	15		3	25	3.6	114	4.5	83	24	28.9	25
LA	100		59	41		16	20	5.1	130	6.2	94	38	40.4	42
LaJolla	89	39	36	14		1	35	2.6	123	3.5	84	12	14.3	21
Madison	58	8	26	24		1	26	2.2	83	3.1	99	18	18.2	23
Medlantic	38	1	32	5			28	1.4	48	1.7	76	3	3.9	5
Memphis	28	1	25	2			26	1.1	34	1.3	102	7	6.9	7
Miami	70	10	40	20		4	14	4.9	90	6.0	43	15	34.9	21
Milwaukee	33	17	16				32	1.0	52	1.6	82	7	8.5	12

Table 8.2 (continued)
Outcomes Processing Workload

Data as of 9/30/08

	Open Cases	No Docs Request	No Docs Receive	No Docs Process	≥ 1 Doc Process	Open > 12 Mos	Closed Cases: Avg # per Mo for last 12 Mo	Outcomes Workload: Est # Months to Process Open Cases	Est Workload for Open cases and Form 33D		Deaths (Ext): Cum[1]	Open		# Open cases with Deaths
	#	#	#	#	#	#			# cases	# months	#	#	%	
Minneapolis	79	8	45	26			33	2.4	109	3.2	83	17	20.5	28
Nevada	51	4	36	11		1	42	1.2	55	1.3	127	7	5.5	16
Newark	98	33	65			2	32	3.1	131	4.2	70	30	42.9	49
New Brunswick	43	19	23	1		5	14	3.1	55	4.2	54	12	22.2	13
NYC	87	23	59	5			28	3.1	91	3.2	89	19	21.3	33
Oakland	69	3	55	11			26	2.7	81	3.1	92	8	8.7	13
Pawtucket	141		140	1		8	59	2.4	151	2.6	195	49	25.1	64
Pittsburgh	69	14	48	7			44	1.6	83	1.9	110	14	12.7	28
Portland	92	41	36	15		4	25	3.6	119	4.6	89	7	7.9	11
San Antonio	14	8	4	2			7	2.0	69	6.7	50	7	14.0	9
Seattle	60	17	21	22		1	28	2.1	71	2.5	67	15	22.4	31
Stanford	69	31	8	30			32	2.1	75	2.3	109	14	12.8	22
StonyBrook	64	7	56	1		2	40	1.6	70	1.8	81	9	11.1	16
Torrance	62	2	60			7	17	3.6	72	4.2	44	12	27.3	15
Tucson	147	59	57	31		23	40	3.7	165	4.2	120	28	23.3	56
UCDavis	110	103	3	4		4	37	3.0	127	3.5	121	15	12.4	38
Worcester	37	19	12	6			35	1.1	54	1.5	113	7	6.2	9
All FCs	2,903	835	1,652	416		107	1,273	2.3	3,659	2.9	3,689	595	16.1	956

1 - Deaths from Form 120-Initial Notification of Death, Ver. 8

Table 8.3
Closure Codes for Closed Outcomes Cases

Data as of 9/30/08

	Form 33 - Medical History Update	Forwarded to CCC C-9		Not Adjudicated C-10		Duplicate C-11		No Doc in 12 Months C-12		No ROI C-13		Admin C-14	
	#	#	%	#	%	#	%	#	%	#	%	No	%
Atlanta	1,257	1,091	86.8	69	5.5	52	4.1	39	3.1	6	0.5		
Birmingham	1,180	1,078	91.4	89	7.5	12	1.0					1	0.1
Bowman	869	759	87.3	59	6.8	35	4.0	1	0.1	15	1.7		
Brigham	1,505	1,246	82.8	140	9.3	113	7.5	1	0.1	4	0.3	1	0.1
Buffalo	1,402	1,210	86.3	106	7.6	70	5.0	2	0.1	13	0.9		
ChapelHill	976	954	97.7	11	1.1	8	0.8			3	0.3		
Chicago-Rush	750	504	67.2	158	21.1	54	7.2	21	2.8	11	1.5	2	0.3
Chicago	1,231	1,038	84.3	91	7.4	66	5.4	6	0.5	26	2.1	4	0.3
Cincinnati	1,211	1,072	88.5	62	5.1	76	6.3	1	0.1				
Columbus	1,338	1,195	89.3	122	9.1	20	1.5	1	0.1				
Detroit	804	667	83.0	86	10.7	32	4.0	4	0.5	14	1.7	1	0.1
Gainesville	1,927	1,659	86.1	211	10.9	55	2.9	2	0.1				
GWU-DC	819	669	81.7	92	11.2	48	5.9	7	0.9	3	0.4		
Honolulu	483	429	88.8	34	7.0	19	3.9	1	0.2				
Houston	804	655	81.5	86	10.7	27	3.4	17	2.1	19	2.4		
IC-Bettendorf	948	823	86.8	61	6.4	57	6.0	1	0.1	5	0.5	1	0.1
IC-Des Moines	798	669	83.8	77	9.6	41	5.1	4	0.5	3	0.4	4	0.5
Irvine	727	593	81.6	80	11.0	22	3.0	19	2.6	12	1.7	1	0.1
LA	757	583	77.0	118	15.6	24	3.2	23	3.0	9	1.2		
LaJolla	1,135	883	77.8	145	12.8	89	7.8	9	0.8	9	0.8		
Madison	1,038	898	86.5	72	6.9	54	5.2	8	0.8	6	0.6		
Medlantic	891	766	86.0	83	9.3	36	4.0	2	0.2	3	0.3	1	0.1
Memphis	893	794	88.9	84	9.4	8	0.9			5	0.6	2	0.2
Miami	520	427	82.1	60	11.5	32	6.2			1	0.2		
Milwaukee	1,008	937	93.0	58	5.8	13	1.3						

Table 8.3 (continued)
Closure Codes for Closed Outcomes Cases

Data as of 9/30/08

	Form 33 - Medical History Update	Forwarded to CCC C-9		Not Adjudicated C-10		Duplicate C-11		No Doc in 12 Months C-12		No ROI C-13		Admin C-14	
	#	#	%	#	%	#	%	#	%	#	%	No	%
Minneapolis	1,042	929	89.2	67	6.4	35	3.4			11	1.1		
Nevada	1,395	1,083	77.6	187	13.4	118	8.5	5	0.4	2	0.1		
Newark	1,107	862	77.9	187	16.9	32	2.9	4	0.4	22	2.0		
New Brunswick	514	452	87.9	17	3.3	10	1.9	29	5.6	5	1.0	1	0.2
NYC	1,008	912	90.5	56	5.6	24	2.4	3	0.3	13	1.3		
Oakland	871	766	87.9	64	7.3	33	3.8	2	0.2	6	0.7		
Pawtucket	2,051	1,820	88.7	161	7.8	50	2.4	2	0.1	18	0.9		
Pittsburgh	1,637	1,482	90.5	71	4.3	79	4.8	4	0.2	1	0.1		
Portland	963	781	81.1	81	8.4	73	7.6	15	1.6	6	0.6	6	0.6
San Antonio	296	252	85.1	24	8.1	6	2.0	4	1.4			10	3.4
Seattle	932	758	81.3	98	10.5	61	6.5	6	0.6	9	1.0		
Stanford	1,186	998	84.1	125	10.5	59	5.0			4	0.3		
StonyBrook	1,507	1,170	77.6	164	10.9	165	10.9	1	0.1	3	0.2	4	0.3
Torrance	538	442	82.2	79	14.7	15	2.8	1	0.2	1	0.2		
Tucson	1,322	1,077	81.5	93	7.0	94	7.1	23	1.7	34	2.6	1	0.1
UCDavis	1,162	983	84.6	114	9.8	52	4.5	1	0.1	12	1.0		
Worcester	1,342	1,170	87.2	148	11.0	24	1.8						
All FCs	44,144	37,536	85.0	3,990	9.0	1,993	4.5	269	0.6	314	0.7	40	0.1

Table 8.4
Participant Follow-up Status[1]

Data as of 9/30/08

	# Participants	Full		Partial/Custom		Proxy		Lost		No Follow-up		Absolutely No Contact		Deceased	
		#	%	#	%	#	%	#	%	#	%	#	%	#	%
Atlanta	3,129	2,657	84.9	341	10.9	23	0.7	1	0.0			3	0.1	104	3.3
Birmingham	2,677	2,488	92.9	74	2.8	1	0.0	1	0.0	9	0.3	13	0.5	91	3.4
Bowman	2,660	2,416	90.8	94	3.5			6	0.2	45	1.7	4	0.2	95	3.6
Brigham	4,216	3,928	93.2	162	3.8	22	0.5			4	0.1	5	0.1	95	2.3
Buffalo	3,128	2,797	89.4	106	3.4	41	1.3	4	0.1	13	0.4	18	0.6	149	4.8
ChapelHill	2,848	2,671	93.8	37	1.3	40	1.4			9	0.3	8	0.3	83	2.9
Chicago-Rush	1,909	1,671	87.5	143	7.5			17	0.9			21	1.1	57	3.0
Chicago	2,635	2,174	82.5	324	12.3	20	0.8	4	0.2	5	0.2	6	0.2	102	3.9
Cincinnati	2,792	2,591	92.8	95	3.4	19	0.7	14	0.5			1	0.0	72	2.6
Columbus	2,904	2,645	91.1	126	4.3	2	0.1					5	0.2	126	4.3
Detroit	2,354	2,039	86.6	227	9.6	3	0.1	9	0.4			15	0.6	61	2.6
Gainesville	3,947	3,322	84.2	463	11.7	15	0.4	6	0.2	4	0.1	11	0.3	126	3.2
GWU-DC	2,926	2,703	92.4	104	3.6	10	0.3	18	0.6	5	0.2	15	0.5	71	2.4
Honolulu	1,987	1,855	93.4	73	3.7	3	0.2			3	0.2	17	0.9	36	1.8
Houston	2,232	2,023	90.6	123	5.5	4	0.2	4	0.2			12	0.5	66	3.0
Iowa City-Bettendorf	2,032	1,821	89.6	134	6.6	8	0.4			1	0.0	8	0.4	60	3.0
Iowa City - Des Moines	2,029	1,793	88.4	148	7.3	10	0.5			2	0.1	16	0.8	60	3.0
Irvine	2,939	2,586	88.0	203	6.9	2	0.1	33	1.1	1	0.0	29	1.0	85	2.9
LA	2,828	2,530	89.5	148	5.2			16	0.6	5	0.2	34	1.2	95	3.4
LaJolla	3,078	2,727	88.6	217	7.1	5	0.2	38	1.2	4	0.1	3	0.1	84	2.7
Madison	2,763	2,499	90.4	120	4.3	29	1.0	2	0.1	7	0.3	5	0.2	101	3.7
Medlantic	2,613	2,123	81.2	358	13.7	16	0.6	28	1.1	7	0.3	5	0.2	76	2.9
Memphis	2,397	2,110	88.0	135	5.6	19	0.8			1	0.0	28	1.2	104	4.3
Miami	1,682	1,395	82.9	210	12.5	8	0.5	17	1.0	9	0.5			43	2.6
Milwaukee	2,938	2,720	92.6	106	3.6	7	0.2	4	0.1	2	0.1	16	0.5	83	2.8

Table 8.4 (continued)
Participant Follow-up Status[1]

Data as of 9/30/08

	# Participants	Full		Partial/Custom		Proxy		Lost		No Follow-up		Absolutely No Contact		Deceased	
		#	%	#	%	#	%	#	%	#	%	#	%	#	%
Minneapolis	3,555	3,271	92.0	165	4.6	17	0.5	1	0.0	11	0.3	3	0.1	87	2.4
Nevada	2,714	2,445	90.1	113	4.2	6	0.2	10	0.4	3	0.1			137	5.0
Newark	2,963	2,711	91.5	123	4.2	2	0.1	43	1.5			13	0.4	71	2.4
New Brunswick	1,231	930	75.5	225	18.3	11	0.9	4	0.3	4	0.3	2	0.2	55	4.5
NYC	2,961	2,750	92.9	85	2.9	1	0.0	20	0.7			14	0.5	91	3.1
Oakland	2,776	2,598	93.6	37	1.3	32	1.2	2	0.1	4	0.1	5	0.2	98	3.5
Pawtucket	4,872	4,561	93.6	25	0.5	50	1.0			25	0.5	7	0.1	204	4.2
Pittsburgh	2,776	2,478	89.3	151	5.4	12	0.4	5	0.2	9	0.3	9	0.3	112	4.0
Portland	2,888	2,666	92.3	87	3.0	2	0.1	26	0.9	3	0.1	14	0.5	90	3.1
San Antonio	1,837	1,745	95.0			3	0.2	18	1.0	6	0.3	11	0.6	54	2.9
Seattle	2,428	2,107	86.8	211	8.7	15	0.6	11	0.5	2	0.1	13	0.5	69	2.8
Stanford	3,490	3,146	90.1	198	5.7	15	0.4	2	0.1	1	0.0	12	0.3	116	3.3
StonyBrook	2,550	2,344	91.9	113	4.4	1	0.0					8	0.3	84	3.3
Torrance	1,550	1,308	84.4	160	10.3	1	0.1	15	1.0	17	1.1	5	0.3	44	2.8
Tucson	3,111	2,587	83.2	329	10.6	13	0.4	24	0.8	28	0.9	8	0.3	122	3.9
UCDavis	2,881	2,499	86.7	220	7.6	8	0.3	15	0.5	4	0.1	12	0.4	123	4.3
Worcester	3,180	2,997	94.2	18	0.6	44	1.4					2	0.1	119	3.7
All FCs	115,406	103,427	89.6	6,531	5.7	540	0.5	418	0.4	253	0.2	436	0.4	3,801	3.3

1 - Follow-up Status from Form 9-WHI ES Participation Status, Ver. 8; Lost calculated by WHIX (see April 4, 2007, upgrade notes); Deceased from Form 120-Initial Notification of Death (all versions)

Table 8.5
Form Collection: Forms 150 and 151

Data as of 9/30/08

Collections for 06-01-07 thru 05-31-08	Form 150- Hormone Use Update (HT)				Form 151 - Activities of Daily Living			
	Total		CCC Mailings Not Collected		Total		CCC Mailings Not Collected	
	# Due[1]	% Collected	#	%	# Due[1]	% Collected	#	%
Atlanta	430	96.7	75	17.4	3,030	95.2	145	4.8
Birmingham	553	94.0	104	18.8	2,576	94.5	142	5.5
Bowman	409	90.7	66	16.1	2,567	93.7	162	6.3
Brigham	647	97.1	68	10.5	4,126	94.0	248	6.0
Buffalo	541	96.5	46	8.5	2,988	96.7	98	3.3
Chapel Hill	467	93.8	67	14.3	2,763	90.7	258	9.3
Chicago-Rush	335	94.6	69	20.6	1,835	94.1	108	5.9
Chicago	416	94.2	50	12.0	2,538	96.6	86	3.4
Cincinnati	427	93.7	52	12.2	2,723	94.3	154	5.7
Columbus	435	97.5	38	8.7	2,789	98.1	53	1.9
Detroit	347	93.9	59	17.0	2,290	96.4	83	3.6
Gainesville	775	93.3	124	16.0	3,820	95.0	190	5.0
GWU-DC	443	92.3	51	11.5	2,848	92.2	221	7.8
Honolulu	272	94.9	39	14.3	1,939	91.4	166	8.6
Houston	260	91.5	42	16.2	2,163	96.0	86	4.0
IC-Bettendorf	597	98.3	32	5.4	1,975	95.8	82	4.2
IC-Des Moines	598	98.5	23	3.8	1,963	97.4	51	2.6
Irvine	429	90.4	56	13.1	2,837	95.0	141	5.0
LA	384	94.8	30	7.8	2,709	95.5	122	4.5
LaJolla	323	89.2	35	10.8	3,004	92.6	222	7.4
Madison	546	96.5	29	5.3	2,665	97.4	68	2.6
Medlantic	433	91.5	122	28.2	2,539	94.6	137	5.4
Memphis	442	96.8	59	13.3	2,273	96.3	83	3.7
Miami	380	85.3	119	31.3	1,643	91.4	141	8.6
Milwaukee	565	95.0	33	5.8	2,846	96.2	107	3.8

Table 8.5 (continued)
Form Collection: Forms 150 and 151

Data as of 9/30/08

Collections for 06-01-07 thru 05-31-08	Form 150- Hormone Use Update (HT)				Form 151 - Activities of Daily Living			
	Total		CCC Mailings Not Collected		Total		CCC Mailings Not Collected	
	# Due[1]	% Collected	#	%	# Due[1]	% Collected	#	%
Minneapolis	641	96.7	38	5.9	3,478	96.1	134	3.9
Nevada	460	93.7	59	12.8	2,593	95.0	130	5.0
Newark	379	90.8	46	12.1	2,892	90.8	266	9.2
New Brunswick	313	93.0	59	18.8	1,176	95.2	56	4.8
NYC	536	91.8	104	19.4	2,859	89.8	293	10.2
Oakland	494	97.2	41	8.3	2,684	97.8	60	2.2
Pawtucket	748	96.1	71	9.5	4,687	96.6	161	3.4
Pittsburgh	505	95.4	54	10.7	2,662	96.5	93	3.5
Portland	501	90.2	56	11.2	2,793	92.6	206	7.4
San Antonio	435	86.2	95	21.8	1,778	92.3	137	7.7
Seattle	526	94.3	47	8.9	2,353	95.7	101	4.3
Stanford	533	96.6	56	10.5	3,374	97.0	101	3.0
Stony Brook	383	95.6	53	13.8	2,462	95.1	121	4.9
Torrance	198	89.9	33	16.7	1,502	93.3	101	6.7
Tucson	480	91.7	77	16.0	2,994	93.1	206	6.9
UC Davis	511	95.1	49	9.6	2,753	95.5	123	4.5
Worcester	486	96.1	47	9.7	3,070	94.3	176	5.7
All FCs	19,583	94.2	2,473	12.6	111,559	94.8	5,819	5.2

1 - Excludes absolutely no contact and deceased participants

Table 8.6
CCC Data Entry Volume

8-16-07 to 9-30-08

Form	Forms					Sheets Scanned	Forms with Comments	
	Total	Key-Entered		Scanned				
	#	#	%	#	%	#	#	%
33 – Medical History Update	114,272	309	0.3	113,963	99.7	227,926	21,594	18.9
120 – Initial Notice of Death	326	326	100.0	0	0	0	0	0
134 – Addendum to Medical History Update	78	0	0.0	78	100	78	0	0
150 – Hormone Use Update	19,255	34	0.2	19,221	99.8	76,884	35	0.2
151 – Activities of Daily Living	114,345	286	0.3	114,059	99.7	114,059	699	0.6
Totals	248,276	955	0.4	247,321	99.6	418,947	22,328	9.0

Table 8.7
Status of Adjudication

Data as of 10/6/08

Committees	Total # Cases in WHIX	Cases at FCs Not Yet Forwarded to CCC				Cases at CCC								
						Referred From (included in total # of cases in WHIX				QA				
		< 14 Days	14-29 Days	≥ 30 Days	Total (not fwd to CCC)	Rec'd from FCs	Form 125 Review	Other Committee	Total Cases (exc QA)	Adj QA[1]	Pull Lists/ CDE [2]	Misc QA	Total QA	Total Cases
Extension														
Primary Cancers	3,080	49	20	2	71	2,843	115	51	3,009		763		763	3,772
Other Cancers	2,740	44	23	5	72	2,665		3	2,668					2,668
CVD (plus PE, DVT)	5,936	55	37	5	97	4,946	768	125	5,839	551	816		1367	7,206
Fatal Events	3,459	58	17	17	92	3,346	13	8	3,367	146	8		154	3,521
Stroke	2,934	25	18	3	46	2,444	372	72	2,888	138	16		154	3,042
Fracture	1,501	30	13	3	46	1,389	48	18	1,455	96			96	1,551
Misc (non committee specific)											178		178	178
Extension Total	19,650	261	128	35	424	17,633	1,316	277	19,226	931	1,781		2712	21,938
Form 125-Hospital	22,960	323	192	42	557	22,403			22,403					22,403
Pre-Extension Other Cancers														
Other Cancers [4]	8,568			6	6	7,207		1,355	8,562		745		745	9,307
Total	8,568			6	6	7,207		1,355	8,562		745		745	9,307

1 - Adj QA = All Cases assigned as an adjudicator QA case (open & closed).

2 - Pull List/CDE(Custom Data Extracts) see r:\reports\outcomes\status of adj qa added: tab 'pull lists data'.

3 - Misc QA

4 - Other Cancers - For breakdown see r:\reports\outcomes\status of adj qa added: tab 'other cancers to code'.

Table 8.8
CCC Adjudication Workload

Data as of 10/6/08

	# Cases at CCC			CCC Action Required					
	Total	**Closed**	**Remaining**	**To Forward to Adjudicator**	**Wait for Return from Adjudicator**	**Data Enter and Close**	**Total**	**Total QA[1] To Do**	**Pull List/CDE To Do**
Extension									
Primary Cancers	3,772	3,153	619	90	38	46	174		445
Other Cancers	2,668	2,006	662	599	16	47	662		
CVD (plus PE, DVT)	7,206	6,823	383	81	68	88	237	146	
Fatal Events	3,521	3,324	197	111	42	24	177	12	8
Stroke	3,042	2,748	294	116	110	66	292	2	
Fracture	1,551	1,475	76	28		32	60	16	
Misc (non committee specific)	178	17	161						161
Extension Total	21,938	19,546	2,392	1,025	274	303	1,602	176	614
Form 125-Hospital	22,403	19,099	3,304	2,885	393	26	3,304		
				Total Number of Cases to Data Enter & Close:		**566**			
				Breakdown of Above Cases:					
				Cases Ready for Data Entry:					
				Adudicator Forms:		101			
				Form 125 (Hosp):		237			
				Forms Requiring Adj Review:		43			
				Pending Full Committee Review:		20			
				Pending Queries:		165			
Pre-Extension Other Cancers									
Other Cancers	9,307	3,858	5,449	5,407	1	24	5,432		
Total	9,307	3,858	5,449	5,407	1	24	5,432		

Table 9.1
CT Outcomes Cases with Blood Sample by Estimated Volume (in ml)
after Accounting for Approved Core, BAA, and Ancillary Studies

					Volume of Designated Bood Components (ml)**																	
					0*		>0 - <.5		.5 - <1		1 - <1.5		1.5 - <2		2 - <2.5		2.5 - <3		3 - <3.5		3.5 - <4		4+	
Visit	Outcome As of 8-07	Total Ppts	No Draw	Blood Type	Ppt	%	Ppt	%	Ppt	%	Ppt	%	Ppt	%	Ppt	%	Ppt	%	Ppt	%	Ppt	%	Ppt	%
Base-line	Breast Cancer	3,220	10	Serum	16	0%	2	0%	4	0%	27	1%	13	0%	131	4%	82	3%	683	21%	110	3%	2,152	67%
				Citrate	22	1%	4	0%	1	0%	41	1%	13	0%	209	6%	8	0%	2,922	91%				
				EDTA	45	1%			1	0%	12	0%	12	0%	231	7%	2	0%	2,917	91%				
	Breast Cancer, Invasive	2,608	8	Serum	12	0%	2	0%	3	0%	24	1%	13	0%	121	5%	76	3%	615	24%	49	2%	1,693	65%
				Citrate	16	1%	2	0%	1	0%	37	1%	11	0%	172	7%	6	0%	2,363	91%				
				EDTA	37	1%			1	0%	9	0%	8	0%	191	7%	1	0%	2,361	91%				
	Breast Cancer, Non-Inv	647	2	Serum	4	1%			1	0%	3	0%			11	2%	6	1%	76	12%	61	9%	485	75%
				Citrate	6	1%	2	0%			5	1%	2	0%	40	6%	2	0%	590	91%				
				EDTA	9	1%					3	0%	4	1%	43	7%	1	0%	587	91%				
	CHD	2,571	11	Serum	17	1%	6	0%	7	0%	65	3%	43	2%	318	12%	43	2%	312	12%	195	8%	1,565	61%
				Citrate	28	1%	19	1%	16	1%	192	7%	63	2%	293	11%	4	0%	1,956	76%				
				EDTA	42	2%	8	0%	22	1%	61	2%	186	7%	284	11%	3	0%	1,965	76%				
	Clinical MI	1,983	10	Serum	15	1%	3	0%	5	0%	48	2%	37	2%	250	13%	33	2%	232	12%	153	8%	1,207	61%
				Citrate	21	1%	15	1%	14	1%	151	8%	51	3%	228	11%	4	0%	1,499	76%				
				EDTA	33	2%	8	0%	15	1%	50	3%	143	7%	219	11%	3	0%	1,512	76%				
	Colorectal Cancer	832	2	Serum	3	0%					9	1%	6	1%	19	2%	6	1%	108	13%	32	4%	649	78%
				Citrate	9	1%	4	0%	1	0%	19	2%	3	0%	63	8%	1	0%	732	88%				
				EDTA	18	2%			2	0%	7	1%	3	0%	73	9%			729	88%				
	DVT/PE	695	3	Serum	3	0%	3	0%	1	0%	15	2%	9	1%	81	12%	47	7%	249	36%	92	13%	195	28%
				Citrate	10	1%	23	3%	7	1%	166	24%	42	6%	53	8%	1	0%	393	57%				
				EDTA	10	1%	3	0%	3	0%	31	4%	10	1%	238	34%	6	1%	394	57%				
	Endometrial Cancer	430	2	Serum	4	1%			1	0%	2	0%	1	0%	10	2%	3	1%	33	8%	4	1%	372	87%
				Citrate	5	1%					11	3%	4	1%	20	5%			390	91%				
				EDTA	6	1%					3	1%	6	1%	29	7%			386	90%				
	Hip Fracture	1,008	3	Serum	6	1%	2	0%	2	0%	15	1%	12	1%	59	6%	31	3%	193	19%	91	9%	597	59%
				Citrate	7	1%	5	0%	1	0%	37	4%	15	1%	67	7%	3	0%	873	87%				
				EDTA	8	1%	1	0%	1	0%	8	1%	12	1%	89	9%	4	0%	885	88%				
	Ovarian Cancer	276	0	Serum					1	0%	6	2%	1	0%	4	1%	2	1%	33	12%	5	2%	224	81%
				Citrate	3	1%			1	0%	7	3%	2	1%	18	7%			245	89%				
				EDTA	1	0%					4	1%	4	1%	23	8%			244	88%				
	Stroke	1,742	8	Serum	12	1%	6	0%	10	1%	48	3%	37	2%	259	15%	46	3%	279	16%	27	2%	1,018	58%
				Citrate	24	1%	20	1%	11	1%	241	14%	59	3%	269	15%	44	3%	1,074	62%				
				EDTA	29	2%	1	0%	2	0%	39	2%	21	1%	353	20%	4	0%	1,293	74%				

*Participants with no draw included in 0 volume column
**Includes sample reserved for BAA (2 ml serum, 1 ml citrate, and 1 ml EDTA) and future WHI use (1 ml each serum, citrate, and EDTA)
Represents conservative estimate of 1 ml in each vial collected, with 4 serum, 3 citrate, and 3 EDTA vials collected at baseline for CT/OS, at AV1 for CT, and at AV3 for OS.

Table 9.1 (continued)
CT Outcomes Cases with Blood Sample by Estimated Volume (in ml)
after Accounting for Approved Core, BAA, and Ancillary Studies

					Volume of Designated Bood Components (ml)**																	
Visit	Outcome As of 8-07	Total Ppts	No Draw	Blood Type	0* Ppt	%	>0 - <.5 Ppt	%	.5 - <1 Ppt	%	1 - <1.5 Ppt	%	1.5 - <2 Ppt	%	2 - <2.5 Ppt	%	2.5 - <3 Ppt	%	3 - <3.5 Ppt	%	3.5 - <4 Ppt	%	4+ Ppt	%
AV1	Breast Cancer	3,019	173	Serum	176	6%	1	0%	2	0%	23	1%	7	0%	89	3%	71	2%	473	16%	376	12%	1,801	60%
				Citrate	182	6%	1	0%	2	0%	32	1%	2	0%	186	6%	4	0%	2,613	87%				
				EDTA	208	7%					11	0%	8	0%	206	7%			2,591	86%				
	Breast Cancer, Invasive	2,450	149	Serum	152	6%	1	0%	2	0%	19	1%	7	0%	82	3%	68	3%	429	18%	344	14%	1,346	55%
				Citrate	156	6%	1	0%	1	0%	29	1%	1	0%	146	6%	4	0%	2,114	86%				
				EDTA	178	7%					9	0%	7	0%	166	7%			2,094	85%				
	Breast Cancer, Non-Inv	604	24	Serum	24	4%					5	1%			7	1%	3	0%	48	8%	37	6%	480	79%
				Citrate	26	4%			1	0%	4	1%	1	0%	41	7%			532	88%				
				EDTA	31	5%					2	0%	1	0%	40	7%			531	88%				
	CHD	2,356	196	Serum	197	8%	1	0%	2	0%	21	1%	4	0%	58	2%	57	2%	312	13%	58	2%	1,646	70%
				Citrate	220	9%	12	1%	7	0%	113	5%	50	2%	237	10%	4	0%	1,716	73%				
				EDTA	229	10%	4	0%	13	1%	45	2%	96	4%	242	10%			1,731	73%				
	Clinical MI	1,802	135	Serum	135	7%	1	0%	2	0%	19	1%	4	0%	45	2%	43	2%	246	14%	39	2%	1,268	70%
				Citrate	158	9%	9	0%	5	0%	90	5%	40	2%	183	10%	4	0%	1,316	73%				
				EDTA	163	9%	4	0%	8	0%	38	2%	75	4%	188	10%			1,330	74%				
	Colorectal Cancer	753	48	Serum	48	6%	1	0%			8	1%	3	0%	8	1%	11	1%	64	8%	63	8%	547	73%
				Citrate	51	7%	3	0%	1	0%	13	2%	3	0%	53	7%	1	0%	628	83%				
				EDTA	57	8%			1	0%	5	1%	4	1%	56	7%	1	0%	629	84%				
	DVT/PE	605	42	Serum	42	7%					2	0%	1	0%	13	2%	18	3%	94	16%	43	7%	392	65%
				Citrate	52	9%	13	2%	6	1%	91	15%	26	4%	54	9%	2	0%	362	60%				
				EDTA	49	8%	2	0%	2	0%	22	4%	7	1%	158	26%			366	60%				
	Endometrial Cancer	390	20	Serum	20	5%					1	0%	1	0%	9	2%	2	1%	30	8%	9	2%	318	82%
				Citrate	24	6%					9	2%	1	0%	19	5%			338	87%				
				EDTA	24	6%					1	0%	3	1%	26	7%			338	87%				
	Hip Fracture	958	57	Serum	57	6%	1	0%	1	0%	8	1%	5	1%	23	2%	24	3%	95	10%	102	11%	642	67%
				Citrate	69	7%	2	0%	1	0%	30	3%	10	1%	61	6%	3	0%	784	82%				
				EDTA	73	8%			1	0%	13	1%	6	1%	77	8%			790	82%				
	Ovarian Cancer	256	16	Serum	16	6%					3	1%					5	2%	28	11%	3	1%	201	79%
				Citrate	17	7%	1	0%			3	1%	3	1%	22	9%			210	82%				
				EDTA	19	7%					1	0%	2	1%	26	10%			208	81%				
	Stroke	1,598	112	Serum	115	7%	3	0%			15	1%	8	1%	33	2%	64	4%	229	14%	87	5%	1,044	65%
				Citrate	126	8%	10	1%	7	0%	164	10%	44	3%	269	17%	37	2%	942	59%				
				EDTA	138	9%					33	2%	15	1%	255	16%			1,158	72%				

*Participants with no draw included in 0 volume column
**Includes sample reserved for BAA (2 ml serum, 1 ml citrate, and 1 ml EDTA) and future WHI use (1 ml each serum, citrate, and EDTA)
Represents conservative estimate of 1 ml in each vial collected, with 4 serum, 3 citrate, and 3 EDTA vials collected at baseline for CT/OS, at AV1 for CT, and at AV3 for OS.

Table 9.2
OS Outcomes Cases with Blood Sample by Estimated Volume (in ml)
after Accounting for Approved Core, BAA, and Ancillary Studies

					Volume of Designated Blood Components (ml)**																	
	Outcome	Total	No	Blood	0*		>0 - <.5		.5 - <1		1 - <1.5		1.5 - <2		2 - <2.5		2.5 - <3		3 - <3.5		3.5 - <4		4+	
Visit	As of 8-07	Ppts	Draw	Type	Ppt	%	Ppt	%	Ppt	%	Ppt	%	Ppt	%	Ppt	%	Ppt	%	Ppt	%	Ppt	%	Ppt	%
Base-line	Breast Cancer	4,735	9	Serum	17	0%	2	0%	5	0%	36	1%	26	1%	195	4%	273	6%	614	13%	1,053	22%	2,514	53%
				Citrate	52	1%	5	0%	6	0%	48	1%	54	1%	380	8%	851	18%	3,339	71%				
				EDTA	90	2%	2	0%	4	0%	100	2%	149	3%	603	13%	1,083	23%	2,704	57%				
	Breast Cancer, Invasive	3,933	8	Serum	15	0%	2	0%	5	0%	29	1%	22	1%	183	5%	259	7%	574	15%	873	22%	1,971	50%
				Citrate	45	1%	5	0%	5	0%	41	1%	49	1%	337	9%	753	19%	2,698	69%				
				EDTA	76	2%	2	0%	4	0%	88	2%	126	3%	531	14%	914	23%	2,192	56%				
	Breast Cancer, Non-Inv	834	1	Serum	2	0%					8	1%	5	1%	13	2%	16	2%	44	5%	185	22%	561	67%
				Citrate	7	1%			1	0%	7	1%	5	1%	46	6%	104	12%	664	80%				
				EDTA	14	2%					12	1%	24	3%	77	9%	177	21%	530	64%				
	CHD	2,968	3	Serum	9	0%	8	0%	17	1%	62	2%	38	1%	284	10%	78	3%	256	9%	416	14%	1,800	61%
				Citrate	53	2%	33	1%	36	1%	222	7%	150	5%	625	21%	449	15%	1,400	47%				
				EDTA	69	2%	14	0%	23	1%	218	7%	201	7%	797	27%	304	10%	1,342	45%				
	Clinical MI	2,276	2	Serum	6	0%	7	0%	13	1%	45	2%	34	1%	231	10%	65	3%	203	9%	373	16%	1,299	57%
				Citrate	42	2%	28	1%	35	2%	171	8%	130	6%	497	22%	332	15%	1,041	46%				
				EDTA	51	2%	13	1%	21	1%	178	8%	165	7%	636	28%	246	11%	966	42%				
	Colorectal Cancer	1,026	1	Serum	3	0%	1	0%	9	1%	9	1%	59	6%	95	9%	128	12%	235	23%	326	32%	161	16%
				Citrate	13	1%	3	0%	5	0%	20	2%	29	3%	197	19%	339	33%	420	41%				
				EDTA	28	3%	17	2%	32	3%	59	6%	446	43%	318	31%	10	1%	116	11%				
	DVT/PE	90	0	Serum											8	9%	1	1%	2	2%	7	8%	72	80%
				Citrate									3	3%	9	10%	2	2%	76	84%				
				EDTA	3	3%					5	6%	2	2%	10	11%	6	7%	64	71%				
	Endometrial Cancer	642	1	Serum	3	0%	1	0%	4	1%	6	1%	3	0%	41	6%	48	7%	144	22%	278	43%	114	18%
				Citrate	8	1%					12	2%	12	2%	70	11%	179	28%	361	56%				
				EDTA	18	3%			2	0%	19	3%	27	4%	66	10%	321	50%	189	29%				
	Hip Fracture	1,428	2	Serum	4	0%	2	0%	11	1%	45	3%	73	5%	166	12%	146	10%	124	9%	87	6%	770	54%
				Citrate	16	1%	2	0%	1	0%	15	1%	23	2%	131	9%	83	6%	1,157	81%				
				EDTA	33	2%	2	0%	2	0%	33	2%	52	4%	175	12%	109	8%	1,022	72%				
	Ovarian Cancer	407	0	Serum	1	0%			1	0%	3	1%	5	1%	10	2%	14	3%	135	33%	162	40%	76	19%
				Citrate	4	1%	1	0%	1	0%	2	0%	3	1%	23	6%	19	5%	354	87%				
				EDTA	6	1%			1	0%	6	1%	11	3%	38	9%	211	52%	134	33%				
	Stroke	2,131	1	Serum	2	0%	3	0%	9	0%	21	1%	34	2%	88	4%	69	3%	222	10%	655	31%	1,028	48%
				Citrate	25	1%	13	1%	19	1%	177	8%	311	15%	545	26%	67	3%	974	46%				
				EDTA	33	2%	14	1%	58	3%	428	20%	664	31%	689	32%	38	2%	207	10%				

*Participants with no draw included in 0 volume column
**Includes sample reserved for BAA (2 ml serum, 1 ml citrate, and 1 ml EDTA) and future WHI use (1 ml each serum, citrate, and EDTA)
Represents conservative estimate of 1 ml in each aliquot collected

Table 9.2 (continued)
OS Outcomes Cases with Blood Sample by Estimated Volume (in ml)
after Accounting for Approved Core, BAA, and Ancillary Studies

					Volume of Designated Blood Components (ml)**																	
	Outcome	Total	No	Blood	0*		>0 - <.5		.5 - <1		1 - <1.5		1.5 - <2		2 - <2.5		2.5 - <3		3 - <3.5		3.5 - <4		4+	
Visit	As of 8-07	Ppts	Draw	Type	Ppt	%	Ppt	%	Ppt	%	Ppt	%	Ppt	%	Ppt	%	Ppt	%	Ppt	%	Ppt	%	Ppt	%
AV3	Breast Cancer	3,129	425	Serum	428	14%					8	0%			16	1%	1	0%	48	2%	72	2%	2,556	82%
				Citrate	470	15%					15	0%			29	1%			2,635	84%				
				EDTA	511	16%	1	0%			19	1%	12	0%	258	8%	246	8%	2,122	68%				
	Breast Cancer, Invasive	2,596	362	Serum	365	14%					8	0%			16	1%	1	0%	40	2%	61	2%	2,105	81%
				Citrate	400	15%					12	0%			25	1%			2,177	84%				
				EDTA	431	17%	1	0%			17	1%	12	0%	240	9%	239	9%	1,687	65%				
	Breast Cancer, Non-Inv	559	67	Serum	67	12%					1	0%							8	1%	11	2%	472	84%
				Citrate	74	13%					4	1%			4	1%			479	86%				
				EDTA	84	15%					2	0%	1	0%	20	4%	7	1%	454	81%				
	Colorectal Cancer	694	125	Serum	127	18%			2	0%			3	0%	2	0%	3	0%	7	1%	430	62%	120	17%
				Citrate	130	19%					2	0%			10	1%			554	80%				
				EDTA	137	20%					6	1%	3	0%	52	7%	68	10%	431	62%				
	CHD	2,207	449	Serum	451	20%					4	0%	1	0%	11	0%	13	1%	68	3%	87	4%	1,573	71%
				Citrate	467	21%					6	0%			85	4%			1,654	75%				
				EDTA	496	22%	1	0%			54	2%	14	1%	498	23%	100	5%	1,057	48%				
	Clinical MI	1,635	273	Serum	274	17%					2	0%	1	0%	9	1%	11	1%	48	3%	68	4%	1,223	75%
				Citrate	286	17%					5	0%			68	4%			1,281	78%				
				EDTA	310	19%	1	0%			45	3%	9	1%	408	25%	80	5%	795	49%				
	DVT/PE	66	16	Serum	17	26%					2	3%							1	2%	1	2%	46	70%
				Citrate	19	29%													47	71%				
				EDTA	20	30%									3	5%			44	67%				
	Stroke	1,535	313	Serum	313	20%					5	0%			10	1%	2	0%	24	2%	25	2%	1,156	75%
				Citrate	329	21%					9	1%			26	2%			1,176	77%				
				EDTA	350	23%					13	1%	2	0%	85	6%	18	1%	1,077	70%				
	Endometrial Cancer	429	66	Serum	66	15%									4	1%			12	3%	11	3%	336	78%
				Citrate	69	16%					2	0%			5	1%			354	83%				
				EDTA	74	17%					2	0%	1	0%	13	3%	4	1%	339	79%				
	Ovarian Cancer	271	58	Serum	59	22%									1	0%			17	6%	53	20%	141	52%
				Citrate	61	23%					2	1%			2	1%			207	76%				
				EDTA	63	23%					1	0%			9	3%	2	1%	198	73%				
	Hip Fracture	1,134	188	Serum	192	17%					1	0%			8	1%			17	1%	21	2%	896	79%
				Citrate	200	18%					5	0%			8	1%			921	81%				
				EDTA	210	19%					5	0%	2	0%	46	4%	10	1%	863	76%				

*Participants with no draw included in 0 volume column
**Includes sample reserved for BAA (2 ml serum, 1 ml citrate, and 1 ml EDTA) and future WHI use (1 ml each serum, citrate, and EDT)
Represents conservative estimate of 1 ml in each aliquot collected

Table 9.3
CT and OS Outcomes Cases with DNA* Available
Data as of 10-9-08

Outcome As of 10-9-08	Ppts	No DNA Available[1]		< 25 ug Extracted, no Buffy Coat Available for Extraction[2]		< 25 ug Extracted, with Buffy Coat Available for Extraction[3]		> 25 ug Extracted[4]	
		#	%	#	%	#	%	#	%
CT									
Breast Cancer	3220	40	1.2%	18	0.6%	968	30.1%	2194	68.1%
Breast Cancer Invasive	2608	29	1.1%	16	0.6%	450	17.3%	2113	81.0%
Breast Cancer, Non Invasive	647	11	1.7%	2	0.3%	532	82.2%	102	15.8%
CHD	2571	37	1.4%	26	1.0%	1580	61.5%	928	36.1%
Clinical MI	1983	27	1.4%	19	1.0%	1210	61.0%	727	36.7%
Colorectal Cancer	832	14	1.7%	5	0.6%	629	75.6%	184	22.1%
DVT/PE	695	5	0.7%	14	2.0%	332	47.8%	344	49.5%
Endometrial Cancer	430	5	1.2%	2	0.5%	322	74.9%	101	23.5%
Hip Fracture	1008	24	2.4%	40	4.0%	28	2.8%	916	90.9%
Ovarian Cancer	276	4	1.4%	2	0.7%	216	78.3%	54	19.6%
Stroke	1742	29	1.7%	120	6.9%	156	9.0%	1437	82.5%
OS									
Breast Cancer	4735	52	1.1%	11	0.2%	1041	22.0%	3631	76.7%
Breast Cancer Invasive	3933	47	1.2%	11	0.3%	516	13.1%	3359	85.4%
Breast Cancer, Non Invasive	834	5	0.6%	1	0.1%	530	63.5%	298	35.7%
CHD	2968	44	1.5%	21	0.7%	386	13.0%	2517	84.8%
Clinical MI	2276	31	1.4%	14	0.6%	295	13.0%	1936	85.1%
Colorectal Cancer	1026	16	1.6%	5	0.5%	140	13.6%	865	84.3%
DVT/PE	90	1	1.1%	0	0.0%	50	55.6%	39	43.3%
Endometrial Cancer	642	6	0.9%	0	0.0%	247	38.5%	389	60.6%
Hip Fracture	1428	19	1.3%	10	0.7%	70	4.9%	1329	93.1%
Ovarian Cancer	407	7	1.7%	2	0.5%	281	69.0%	117	28.7%
Stroke	2131	40	1.9%	22	1.0%	92	4.3%	1977	92.8%

*DNA measured by OD ratio or Pico Green
[1] < 25 ug DNA in inventory, either in daughter or parent aliquots, and no buffy coat available
[2] < 25 ug DNA in inventory, either in daughter or parent aliquots, and no buffy coat available
[3] < 25 ug DNA in inventory, either in daughter or parent aliquots, and 1 or more buffy coats not yet extracted
[4] 25+ ug DNA in inventory, either in daughter or parent aliquots, regardless of number of buffy coats not yet extracted

Table 9.4
Number of Funded Core, Collaborative, BAA, and Ancillary Studies Using Blood Sample by Outcome[1] and Specimen Type

	Serum/Plasma Only	Both Serum/Plasma and DNA[2]	DNA[2] Only	GWAS	Total
Cancer					
Breast Cancer	9	1	2	3	15
Colon Cancer				1	1
Colorectal Cancer	4	4	3		11
Endometrial Cancer	2		1		3
Lung Cancer		1			1
Malignant Melanoma			1		1
Multiple Myeloma		1			1
Pancreatic Cancer		2		1	3
Ovarian Cancer	2				2
Other Cancer				2	2
Cardiovascular					
CHD	10	1	1	1	13
Hypertension		1			1
Stroke	7	2	1	1	11
VTE	2	1			3
Fracture					
Elbow, Lower Humerus	1				1
Hip Fracture	4	1	1	1	7
Spine Fracture	2				2
Overall Fracture	1				1
Other					
Eye Disease	1				1
Frailty-disability		1			1
Sarcopenia		1			1
Type 2 Diabetes		1			1
Controls	35	15	8	8	66

[1] Several studies include more than one outcome
[2] DNA for selected SNPs

Table 10.1
Approved and Proposed Core Studies[1]

Ref #	Title	Status	Study Pop	Blood	Analytes/Data	Used in Approved Publications
W1	CT core analytes	Complete	CT, 6% subsample *Baseline, Y1, Y3, and Y6	Y	Citrate 1.05 ml: FVII Ag; FVIIC; fibrinogen EDTA 1.05 ml: HDL-C; HDL-2; HDL-3; LDL-C; Lp(a); cholesterol; triglyceride Serum 1.05 ml: alpha-carotene; alpha-tocopherol; beta-carotene; beta-cryptoxanthine; gamma-tocopherol; glucose; insulin; lutein and zeaxanthin; lycopene; retinol	204, 210, 222, 240, 273, 345, 347, 350, 447, 448, 449, 520, 521, 524
W2	OS-measurement precision study (OS-MPS)	Complete	OS, n = 1061 *Baseline and 3 month repeat	Y	Citrate 1.05 ml: FVII Ag; FVIIC; fibrinogen EDTA 1.05 ml: HDL-C; HDL-2; HDL-3; LDL-C; Lp(a); cholesterol; triglyceride Serum 1.05 ml: alpha-carotene; alpha-tocopherol; beta-carotene; beta-cryptoxanthine; gamma-tocopherol; glucose; insulin; lutein and zeaxanthin; lycopene; retinol	524, 442
W4	National validation and quality control assurance of vitamin D absorption from CaD tablets for WHI	Complete	CaD, n=448	Y	Serum 1.05 ml: 25-OH Vitamin D_3	
W5	Correlates of endogenous sex hormone concentrations in WHI	Complete	DM, n=300 *Baseline and Y1	Y	Serum 3.05 ml: albumin; androstenedione; bioavailable estradiol; DHEA; DHEAS; dihydrotestosterone; estradiol; estrone; estrone sulfate; progesterone; prolactin; SHBG; testosterone	20, 280
W6	CVD biomarkers - Phase I	Funded	HT Cases: n=402 CHD, 272 stroke, 223 VTE Controls: n=877 *Baseline and Y1	Y	Citrate 1.05 ml: ATIII; CRP; D-dimers; FIX conc; FVIII activity; fibrinogen; PAI-1 Ag; PAP; protein C; protein S free; protein S total; prothrombin Ag; F1+2; TAFI; vWF DNA 3 ug: FXIII val34leu; FV Leiden; FV-HR2; MTHF reductase polymorphism; PAI-1; PT19911; PT20210; ESR1 Exon 1 +30; ESR1 IVS1 -1415; ESR1 IVS1 -1505; ESR1 IVS1 -354; ESR1 IVS1 -401; ESR beta - 1730 A/G; GP1ba M145T; integrin alpha 2 - 807 C/T; platelet glycoprotein IIIa - P1(A1), (A2)	204, 210, 222, 273, 345, 347, 350, 380, 429, 445, 526, 589, 854

Table 10.1 (continued)
Approved and Proposed Core Studies[1]

Ref #	Title	Status	Study Pop	Blood	Analytes/Data	Used in Approved Publications
W6 (Con't)	CVD Biomarkers - Phase I	Funded	HT Cases: n=402 CHD, 272 stroke, 223 VTE Controls: n=877 *Baseline and Y1	Y	EDTA 1.3 ml: HDL-C; HDL size; large HDL; medium HDL; small HDL; HDL particles (total); LDL-C; LDL size; large LDL; medium LDL; small LDL (total); LDL particles (total); very small LDL; VLDL size; large VLDL/chylomicrons; medium VLDL;small VLDL; VLDL particles (total); VLDL trig; trig; Lp(a); E-selectin; HDL-C; HDL-2; HDL-3; homocysteine; IL-6; LDL-C; cholesterol; triglyceride Serum 0.05 ml: MMP9	
W7	Genome-wide scan on breast cancer, CHD, and stroke	Funded	OS/HT Phase I-II (OS) Cases: n=1,800 breast cancer, 1,800 CHD, 1,721 stroke Controls: n=same Phase III (HT) Cases: n=345 breast cancer, 319 CHD, 494 stroke Controls: n=same	Y	DNA 2 ug: GWAS – Phase I on pools of 125 samples; Phase II using about 3% SNPs (~6000) from Stage I; Phase III – validation of about 100 from Stage II in HT DNA 2 ug: GWAS: Phase I: 360,000 SNPs on pools of 125 samples; Phase II: 3% of SNPs (~6000) identified in Stage I; Phase III: validation in HT samples	
W8	Nutritional biomarkers study (NBS)	Funded	DM, n=544, with 111 of these in repeat sample	Y	NBS 24 hr urine: vol; nitrogen g/day; nitrogen g/L; sodium; potassium NBS spot urine 4 ml: % fat; DE-SU3; DE-SU4; DE-SU5; DE-SU6; EE3/5; EE4/6; fat-free mass; fluid; H2CONST; internal check DSRatio; LOT; Nd; No; O18-SU3; O18-SU4; O18-SU5; O18-SU6; O18CONST; RCO2-3/5; RCO2-4/6; TEE-CONRQ RQ control group (38.1/44.7/17.2 % E from F/C/P); TEE-INTVRQ intervention (29.8/52.7/17.5 % E from F/C/P); TEE-USRQ RQ assumed general US (34/47/18 %E F/C/P); total body water; r-H2O Serum 0.2 ml: alpha-carotene, alpha-tocopherol, beta-carotene, folate, gamma-tocopherol, cholesterol	464, 624, 646, 708, 831
W9	Biological markers of the effect of HT on risk of fractures in the Women's Health Initiative Clinical Trial	Funded	HT Cases: n=750* Controls: n=750 *All hip + non-spine to reach 750	Y	Serum 0.65 ml: total, bioavailable, and free estradiol; SHBG	433

Table 10.1 (continued)
Approved and Proposed Core Studies[1]

Ref #	Title	Status	Study Pop	Blood	Analytes/Data	Used in Approved Publications
W10	Biological markers of the effect of HT on risk of breast cancer in the Women's Health Initiative Clinical Trial	Funded	HT Cases: n=758 Controls: n=758	Y	Serum 0.95 ml: Total, bioavailable, and free estradiol, estrone sulfate, estrone, SHBG at Baseline and Year 1; progesterone and total, bioavailable, and free testosterone at Baseline only	
W11	CVD biomarkers - Phase II: strokes after Feb 2001	Funded	HT Cases: n=316] Controls: n=316 *Baseline and Y1	Y	Citrate 0.9 ml: free TFPI; TFPI activity; total TFPI; APC-ETP DNA 1 ug: ESR1 Exon 1 +30; ESR1 IVS1 -1415; ESR1 IVS1 -1505; ESR1 IVS1 -354; ESR1 IVS1 -401; estrogen receptor beta - 1730 A/G; GP1ba M145T; integrin alpha 2 - 807 C/T; platelet glycoprotein IIIa - P1(A1), (A2) Serum 0.25 ml: glucose; insulin	435
W14	CVD biomarkers - Phase I: additional assays	Funded	HT Cases: n=390 CHD, 270 stroke,220 VTE Controls: n=390 CHD, 270 stroke, 220 VTE *Baseline and Y1	Y	Citrate 0.95 ml: free TFPI; TFPI activity; total TFPI; APC-ETP Serum 0.25 ml: glucose; insulin	
W15	CaD Vitamin D levels in CaD participants with colorectal cancer or fractures	Funded	CaD Cases: n=1,830 Controls: n=1,830	Y	Serum 0.2 ml: 25-OH-Vitamin D_3	450, 451, 581, 861
W18	HT hormone pretest	Funded	HT, n=200 *Baseline and Y1	Y	Serum 0.95 ml: total, free, and bioavailable estradiol, estrone, SHBG on both E-Alone and E+P samples; progesterone and total, bioavailable, and free testosterone on E+P only samples.	795
W19	WHI HT proteomic pilot Study	Funded	HT, n=200 *Baseline and Y1	Y	Serum 0.55 ml: proteomics	843
W20	WHI-EDRN pilot study for the identification of circulating biomarkers for colon cancer in pre-clinical specimens	Funded	OS Colon Cancer: 100 Controls: 120	Y	EDTA 0.55 ml: proteomics	
W22	Vitamin D in 6% blood subsample of CaD	On hold	CaD	Y	Serum 0.2 ml: 25-OH Vitamin D_3	

Table 10.1 (continued)
Approved and Proposed Core Studies[1]

Ref #	Title	Status	Study Pop	Blood	Analytes/Data	Used in Approved Publications
W23	Genotyping to explore CaD intervention effect on hip fracture	Dropped	CaD Cases: n=357 Controls: n=357	Y	DNA 1 ug: 3 SNPs of the Vit D receptor (VDR) gene: Bsm I, Apa I, Taq I; 4 SNPs in the non-coding region of CYP27B1; 4 SNPs of the calcium sensing receptor (CASR): CA repeat; A986; R990G; Q1011E	
W24	CaD Vitamin D and breast cancer	Funded	CaD Cases: n=1,376 Controls: n=1,376	Y	Serum 0.2 ml: 25-OH Vitamin D_3	470
W25	WHI coronary artery calcification study in E-Alone (WHI-CACS)	Funded	HT (E-Alone) n = 1,141 aged 50-59	N	Coronary artery calcification	503, 506, 570, 591, 806, 816
W26	Food grouping in WHI by FHCRC Nutrition Shared Resource group	Funded	DM	N	4DFR food group codes	
W27	AS218-Nutrition and physical activity assessment study (NPAAS) lab assays	Funded	OS; n=450	Y	NPAAS 24 hr urine: vol; nitrogen g/day, nitrogen g/L NPAAS spot urine 4 ml: % fat; DE-SU3; DE-SU4; DE-SU5; DE-SU6; EE3/5; EE4/6; fat-free mass; Fluid; H2CONST; internal check DSRatio; LOT; Nd; No; O18-SU3; O18-SU4; O18-SU5; O18-SU6; O18CONST; RCO2-3/5; RCO2-4/6; TEE-CONRQ RQ control group (38.1/44.7/17.2 % E from F/C/P); TEE-INTVRQ intervention (29.8/52.7/17.5 %E from F/C/P); TEE-USRQ RQ assumed general US (34/47/18 % E F/C/P); total body water; r-H2O Serum 0.2 ml: alpha-carotene, alpha-tocopherol, beta-carotene, folate, gamma-tocopherol, cholesterol	
W28	Medicare claims data pilot	Funded	OS/CT, participants aged 65+	N	Medicare claims data for 2 years on all WHI participants aged 65+.	
W30	Dietary assessment study	Complete	DM, n=166	N	4DFR nutrient analyses; repeat 24 hr recalls; repeat FFQs	35
W31	4DFR and ovarian cancer	Complete	DM, n=160	N	4DFR analyses for DM other cancer paper	469
W32	Form 125 –Hospital-ization coding	On Hold	CT/OS	N	Diagnosis codes for text written on WHI Form 125 – Hospitalization	
W33	4DFR and DM breast cancer	Complete	DM	N	4DFR analyses for DM breast cancer paper	448

Table 10.1 (continued)
Approved and Proposed Core Studies[1]

Ref #	Title	Status	Study Pop	Blood	Analytes/Data	Used in Approved Publications
W34	Extension of WHI stroke genome-wide association study (W7)	Funded	OS/CT Cases: 1,328 CT, 268 OS Controls: 1,596	Y	DNA 1 ug: 5,400 SNP GWAS; gene sequencing of selected genes	
W35	Full CMS data on all CT/OS participants	Funded	OS/CT	N	CMS Medicare health data	
W38	WHI-CACs and lipids and inflamation	Not Approved	HT Case: 422 CAC > 10 Control: 422 CAC=0	Y	EDTA 0.5 ml: NMR lipids, CRP, E-selectin, homocysteine, MMP-9, glucose, insulin, osteoprotogerin, CTx	
W39	27-hydroxycholesterol inhibits cardiovascular effects of estrogen	Funded	HT CHD: 359 Controls: 820 * same as W6 CHD	Y	Serum 0.55 ul: 27-OH-cholesterol	
W40	Validation of W18-HT proteins using ELISA	Funded	HT E-Alone 100 samples	Y	Serum .55 ml: AHSG; CLL16; CP; FIX; F10; IGF-1; IGFBP-1; IGFBP-2; IGFBP-3; IGFBP-4; IGFBP-6; KNG1; MMP-2; Protein Z; SHBG; VTN; Vit D Binding	
W41	Medications inventory on WHI Extension participants	Funded	OS/CT	N	Current medications and current supplements	
W42	SEER code WHI and ES non-primary cancers	Funded	OS/CT 6,670 non-primary cancers	N	SEER coding of non-primary cancers	
W43	Extend breast cancer SNP studies to include DNA sequencing of selected genes	Funded	HT E+P Phase 1: Breast Ca: 60 Controls Phase 2: Breast cancer: 150; Controls 150	Y	DNA 0 ug (use previously sent samples): gene sequencing	
W44	Biological validation of E+P effects on the serum proteome and comparison of E+P and E-Alone effects (see W18 and W40)	PO approved	HT 50 E+P at baseline and AV1 50 E-Alone at baseline and AV1 (used in W40)	Y	Serum 0.55 ml E+P and 0 ml E-Alone: AGTASE; Apo D; Apo F; B2M; CCL18; CSF1; LCN2; LGALS3BP; MCAM; RNASE4; THBS1; TNC; XLKD1 E+P only: CP, F10, IGF-1, IGFBP-1; IGFBP-2; IGFBP-4	

[1] Core studies are conducted using internal WHI Funds included in the Clinical Coordinating Center budget. Studies are developed and monitored by a study-wide Core Resources Working Group. NHLBI conducts additional peer review of proposed uses beyond those specified in the study protocol (certain subsamples) and pilot projects.

Table 10.2
Miscellaneous Collaborative Studies

#	Title	PIs	Approved	Funded	Status	Study Dates	Study Population*	Blood Study
M3	Cancer genetic markers of susceptibility (CGEMS) initiative	Anc: Chanock WHI: Prentice	Y	Y	Funded		OS/CT Breast:2956 Controls:2956 *Caucasians only	Y
M4	NCI Pancreatic cancer cohort consortium (PanScan)	Anc: Chanock WHI: LaCroix	Y	Y	Funded	9/1/06-9/1/08	OS/CT Pancreatic cancer:283 Controls:283	Y
M5	SHARe (SNP Health Association Resource) GWAS	Anc: NHLBI WHI:	Y	Y	Funded		OS/CT *13,000 Blacks, Hispanics	Y
M6	Epidemiologic investigation of putative genetic variants: The Women's Health Initiative	Anc: Kooperberg WHI: Kooperberg	Y	Y	Funded		OS/CT Diabetes, heart disease, cancer, and other common diseases:28,000 Controls:28,000	Y
M8	NCI GWAS in bladder cancer	Anc: Chanock WHI:	N	N	Proposed		OS/CT Bladder Cancer:256 Controls: 256	Y
M9	NCI GWAS in renal cell carcinoma (RCC): expansion of a primary scan	Anc: Chanock WHI:	N	N	Proposed	10/1/08-10/31/10	OS/CT Kidney Cancer:300 Controls:300 *Non-Hispanic Caucasians	Y
M10	NCI GWAS in upper gastrointestinal (UGI) cancers	Anc: Taylor WHI:	N	N	Proposed		OS/CT Esophagus Cancer:80 Stomach Cancer:119 Controls:199	Y
M11	NCI - The associations of pepsinogen I/II ratio, polymorphisms in alcohol metabolizing genes, and telomere length with gastric cancer risk	Anc: Dong WHI: Anderson	N	N	Proposed	10/1/08-10/31/10	OS/CT Stomach Cancer:119 Controls:238	Y

Table 10.3
Broad Agency Announcement Activities

BAA	Title	PI	Institution
1	Ancestry Association Analyses of WHI Traits	Dr. Michael Seldin	University of California, Davis
2	High-Dimensional Genotype in Relation to Breast Cancer and WHI Clinical Trial Interventions	Dr. Ross Prentice	Fred Hutchinson Cancer Research Center
3	Genome-wide Association Study to Identify Genetic Components of Hip Fracture	Dr. Rebecca Jackson	Ohio State University Research Foundation
4	Proteomics and the Health Effects of Postmenopausal Hormone Therapy	Dr. Ross Prentice	Fred Hutchinson Cancer Research Center
5	Identification and Validation of Circulating Biomarkers for the Early Detection of Breast Cancer in Pre-Clinical Specimens	Dr. Christopher Li	Fred Hutchinson Cancer Research Center
6	Interaction Effects of Genes in the Inflammatory Pathway and Dietary, Supplement, and Medication Exposures on General Cancer Risk	Dr. Jianfeng Xu	Wake Forest University
7	Endogenous Estradiol and the Effects of Estrogen Therapy on Major Outcomes of WHI	Dr. Steve Cummings	California Pacific Medical Center
8	Predictive Value of Nutrient Biomarkers for CHD Death	Dr. Alice Lichtenstein	Tufts University
9	Biochemical Antecedents of Fracture in Minority Women	Dr. Jane Cauley	University of Pittsburgh
10	Adipokines and Risk of Obesity-Related Diseases	Dr. Gloria Ho	Albert Einstein College of Medicine
11	Physical Activity, Obesity, Inflammation and CHD in a Multi-Ethnic Cohort of Women	Dr. I-Min Lee	Brigham and Women's Hospital
12	Hormone Therapy, Estrogen Metabolism and Risk of Breast Cancer or Hip Fracture in the WHI Hormone Trial	Dr. Lewis Kuller	University of Pittsburgh

Table 10.4
Summary of Ancillary Studies

Current Status	Number of Studies
Study proposed	4
Dropped	105
Not approved	28
Approved	6
Submitted for funding	5
Not funded	4
Funded	37
Data analysis in progress	15
Complete	57
Total	261

Table 10.5
All Ancillary Studies

AS #	Title	PIs	Approved	Funded	Status	Study Dates	Study Population*	Blood Study	Ms #(s)
262	Women's Health Initiative memory study of younger women (WHIMS-Y)	Anc: Shumaker WHI: Shumaker	N	N	Proposed		HT All ppts aged 50-54	N	
261	Genetic variants of serum lipid concentrations in different ethnic groups	Anc: Wang WHI: Smoller	N	N	Not Approved	01/01/09-12/31/12	OS/CT	Y	
260	Anti-anticyclic citrulinated peptide (anti-CCP) antibody as a test for rheumatoid arthritis (RA)	Anc: Kuller WHI: Kuller	N	N	Proposed	07/01/08-12/31/08	OS	Y	
259	Telomere length and breast cancer in women	Anc: Liu WHI: Nathan	N	N	Proposed	07/01/08-06/30/10	OS Breast Cancer:2100 Controls:2100	Y	
258	Genetic variants in Wnt pathway and benign breast disease and breast cancer risks	Anc: Agalliu WHI: Smoller	Y	N	PO Approved	07/01/09-06/30/13	OS/CT Breast Cancer:5414 Benign Breast Disease:1798 Controls:7212 *OS invasive (3933) and CT/OS non-invasive (1481) breast cancer; CT Breast Disease (1798)	Y	
257	Nutritional and genetic risk factors for age-related macular degeneration	Anc: Mares WHI: Sarto	Y	N	Submitted	12/31/08-08/31/09	OS Eye:361 Controls:1426	Y	
255	Androgens and CHD in women with type 2 diabetes	Anc: Rajpathak WHI: Smoller	N	N	Not Approved	01/01/08-08/31/10	OS	Y	
254	Telomere and its biochemical and genetic regulators as predictors for clinical diabetes in women	Anc: Liu WHI: Nathan	Y	N	ASC Approved	07/01/08-07/01/10	OS Type 2 Diabetes:1800 Controls:2650	Y	
253	Serum selenium and pancreatic cancer risk	Anc: Stolzenberg WHI: LaCroix	N	N	Not Approved		OS/CT	Y	
252	Environmental determinants of cognitive aging in WHIMS	Anc: Chen WHI: Heiss	Y	N	Submitted	07/01/08-06/30/13	HT	N	
251	Acute cardiovascular events and air pollution	Anc: Whitsel WHI: Heiss	Y	N	PO Approved	07/01/08-06/30/11	OS/CT	N	
250	Genetic contributions to cognitive decline in normal and pathological aging in older post-menopausal women and modification by hormone therapy	Anc: Driscoll WHI: Shumaker	Y	N	PO Approved	07/01/08-07/01/10	HT All 7279 WHIMS Ppts	Y	

Table 10.5 (continued)
All Ancillary Studies

AS #	Title	PIs	Approved	Funded	Status	Study Dates	Study Population*	Blood Study	Ms #(s)
249	Epidemiology of alcohol metabolism genes, alcohol and Women's Health Outcomes	Anc: Freiberg WHI: Kuller	Y	N	Not Funded	05/01/09-04/30/14	OS/CT Breast Cancer:4500 MI:1900 Stroke:1800 Controls:10942 *CVD: 1117 Alcohol related cancer: 3390	Y	
248	Hormone therapy, changes in subpopulations of triglyceride-rich lipoproteins and HDL, and development of CHD in women.	Anc: Lamon-Fava WHI: Wassertheil-Smoller	N	N	Not Approved	07/01/08-06/30/12	OS/CT CHD:444 Controls:444	Y	
247	Genetic factors associated with the risk of Parkinson Disease in the multiethnic cohort of the WHI	Anc: Saunders-Pullman WHI: Wassertheil-Smoller	N	N	Not Approved	01/01/08-12/31/10	OS/CT Death - other cause:1376 Controls:450	Y	
246	Prospective study of hormones, autoantibodies and biomarkers and risk of systemic lupus erythematosus in women	Anc: Costenbader WHI: Manson	N	N	Not Approved	07/01/08-06/01/13	OS/CT Death - other cause:547 Controls:1641	Y	
245	Ghrelin, adiposity-derived hormones, and colorectal cancer	Anc: Lin WHI: Manson	N	N	Not Approved	01/01/09-12/31/11	OS Colorectal Cancer:700 Controls:700	Y	
244	Women's Health Initiative memory study epidemiology of cognitive health (WHIMS-ECOH)	Anc: Shumaker WHI: Vitolins	Y	N	Submitted	10/01/07-09/30/12	HT	N	
243	Validation of direct measures of physical activity: an ancillary study to the Women's Health Initiative (WHI) Nutrition and Physical Activity Assessment Study (NPAAS; AS218)	Anc: Sternfeld WHI: Caan	Y	Y	Complete	04/15/07-12/31/08	OS 70 Ppts@Oakland	N	
242	DNA repair, telomere length and cutaneous malignant melanoma risk	Anc: Han WHI: Manson	Y	Y	Funded	05/01/08-04/30/10	OS Melanoma - Skin:277 Controls:277	Y	
241	Dietary relationships to inflammatory bowel disease (IBD) in older women	Anc: Tamboli WHI: Wallace	N	N	Not Approved	04/01/07-04/01/08	OS	N	
240	Microalbuminuria and cardiovascular risk in the WHI	Anc: Hsia WHI: Hsia	N	N	Tabled	02/01/07-01/31/08	OS/CT CHD:5500	Y	

Table 10.5 (continued)
All Ancillary Studies

AS #	Title	PIs	Approved	Funded	Status	Study Dates	Study Population*	Blood Study	Ms #(s)
239	Biomarkers related to energy balance and renal cell cancer	Anc: Cho WHI: Manson	N	N	Not Approved	03/01/08-02/28/12	OS/CT Renal Cancer:182 Controls:546	Y	
238	Genetic and biochemical predictors of Type 2 DM in women	Anc: Liu WHI: Nathan	Y	N	Not Funded	08/01/08-07/31/11	OS Type 2 Diabetes:1800 Controls:2500	Y	
237	The hypothalamic-pituitary-adrenal (HPA) axis and postmenopausal breast cancer risk	Anc: Dorgan WHI: Lasser	Y	N	Submitted	03/01/09-02/28/12	OS Breast Cancer:1000 Controls:1000 *Caucasion only	Y	
236	Choline/betaine habitual intake and chronic disease endpoints	Anc: Siega-Riz WHI: Heiss	Y	Y	Funded	10/01/07-09/01/08	OS/CT	N	
235	Pilot study to explore assoc between task performance on fMRI w/ cog functioning and vascular, genetic & inflam. risk factors in WHISCA ppt characterized by differing body weight & waist-hip ratios	Anc: Kerwin WHI: Kotchen	Y	Y	Funded	11/01/06-06/30/08	CT	N	
234	Adipokines, inflammation and energy balance in postmenopausal women	Anc: Neuhouser WHI: Prentice	N	N	Not Approved	11/01/07-10/31/10	DM	N	
233	WHIMS (AS39) extension	Anc: Shumaker WHI: Shumaker	N	Y	Analysis	12/13/03-06/30/08	HT 3074 Ppts@32 clinics	N	
232	Carotenoids and incidence and progression of age-related eye disease in women	Anc: Mares-Perlman WHI: Sarto	Y	N	Not Funded	02/01/09-12/31/09	OS Eye:650 Controls:1250	Y	
231	Relationship between circulating nutrient biomarkers and death from coronary heart disease or myocardial infarct	Anc: Lichtenstein WHI: Van Horn	N	N	Not Approved	09/01/07-08/31/09	OS CHD:1200 Controls:1200	Y	
230	Markers of inflammation and renal function and the risk of coronary heart disease and mortality in women with diabetes	Anc: Rajpathak WHI: Smoller	N	N	Not Approved	10/20/08-10/20/10	OS CHD:764 Controls:1736 *764 CHD cases and 500 death cases, 382 and 250 of which respectively are baseline diabetes	Y	

Table 10.5 (continued)
All Ancillary Studies

AS #	Title	PIs	Approved	Funded	Status	Study Dates	Study Population*	Blood Study	Ms #(s)
229	Genome wide, case-control analysis of SNP associations with cardiovascular disease in African American women	Anc: Carlson WHI: LaCroix	Y	N	Dropped	09/20/06-09/20/09	OS CHD:1825 Controls:1825	Y	
228	Obesity, diet, physical activity and medicare costs	Anc: Yan WHI: Van Horn	Y	N	PO Approved	01/01/07-12/31/11	OS/CT	N	
227	Risk factors and biomarkers for Parkinson's disease	Anc: Ascherio WHI: Manson	N	N	Proposed		OS/CT	Y	
226	Ambient air pollution and sleep disturbance in postmenopausal women	Anc: Chen WHI: Heiss	Y	N	Submitted	09/01/07-08/31/12	OS/CT	N	844
225	Potential gene-environment interaction on the association between chronic air pollution exposure and incident MI in the WHI OS	Anc: Sullivan WHI: Beresford	N	N	Not Approved		OS	N	
224	Genome-wide association study for nonsynonymous SNPs in colon cancer	Anc: Peters WHI: Prentice	Y	Y	Funded	07/02/07-08/31/12	OS Colon cancer:930 Controls:930 *Shares controls and genotyping data with BA03 where possible.	Y	
223	Women's Health Initiative cancer survivor cohort: biological, psychosocial, and behavioral predictors of survival: pilot study	Anc: Paskett WHI: Jackson	Y	Y	Funded	10/01/05-09/01/07	OS/CT	N	
222	Developmental research of air pollution as a cause of common cancers	Anc: DeRoos WHI: LaCroix	N	N	Not Approved		OS/CT	N	
221	Dietary modification, calcium/vitamin D supplementation, and change in breast density	Anc: Rohan WHI: Smoller	Y	N	Dropped	04/15/05-04/14/10	Ppts in DM & CaD	N	
220	Neighborhoods, women, and coronary heart disease: a prospective study	Anc: Bird WHI: Margolis	Y	Y	Funded	07/01/07-04/30/10	OS/CT	N	703, 704, 705, 726, 824, 854
219	Diet and eye health in the WHI: end of trial study: pilot study	Anc: Mares WHI: Sarto	N	Y	Funded	01/01/06-12/31/06	DM 400 Ppts@Madison	N	577
218	WHI nutrition and physical activity assessment study (NPAAS)	Anc: Prentice WHI: Neuhouser	Y	Y	Funded	07/12/06-06/30/09	OS	N	
217	Validation of the self-report of rheumatoid arthritis and systemic lupus erythematosus: The Women's Health Initiative	Anc: Wallitt WHI: Howard	Y	Y	Complete	07/01/04-06/01/06	CT	N	635

Table 10.5 (continued)
All Ancillary Studies

AS #	Title	PIs	Approved	Funded	Status	Study Dates	Study Population*	Blood Study	Ms #(s)
216	Decision-making about cancer screening among older women	Anc: Messina WHI: Lane	Y	Y	Funded	07/01/06-06/30/08	OS/CT 1300 Ppts@Stonybrk	N	
215	UGTs, NSAIDs, and breast cancer risk in the WHI Observational Study	Anc: Lampe WHI: Prentice	Y	N	Expired	12/01/05-11/30/09	OS Breast Cancer:3398 Controls:3398 450 Ppts@9 clinics	Y	
214	Prospective cohort collaborative in pancreatic cancer epidemiology and pathogenesis (AS146 extension)	Anc: Fuchs WHI: Manson	Y	Y	Funded	09/01/07-06/30/12	OS Pancreatic Cancer:200 Controls:400	Y	
213	Assays for early detection of cancer	Anc: Hendrix WHI: Hendrix	N	N	Not Approved		OS Ovarian Cancer:200 Controls:200	Y	
212	Biochemical antecedents of fracture in minority women (funded as BA09)	Anc: Cauley WHI: Kuller	Y	N	Dropped	07/01/07-06/30/11	OS Fracture (general):1320 Controls:1320	Y	
211	Homocysteine levels, B vitamins and bone health in women	Anc: LeBoff WHI: Manson	Y	N	Expired	12/01/07-11/30/10	OS Fracture (general):2500 Controls:2500 *2500 cases/2500 controls for EDTA plasma (B+Y3) and DNA; 400 cases/400 controls for serum and urine	Y	
210	The effect of a low fat diet on lipid profiles and adipokines in post-menopausal women: potential modulation by select genetic variants	Anc: Thomson WHI: Bassford	N	N	Not Approved		DM	Y	
209	Red blood cell omega-3 and trans fatty levels and the risk of coronary heart disease death	Anc: Robinson WHI: Wallace	Y	N	Expired	04/01/06-03/31/08	OS CHD:800 Controls:800	Y	
208	Pro and anti-Iflammatory cytokines and colorectal cancer	Anc: Ho WHI: Smoller	Y	Y	Funded	04/25/08-03/31/11	OS Colorectal Cancer:500 Controls:900 *same cases/controls as AS 129	Y	
207	IGF and multiple myeloma	Anc: Colditz WHI: Manson	Y	Y	Funded	08/01/07-05/31/10	OS/CT Multiple Myeloma:213 Controls:426	Y	

Table 10.5 (continued)
All Ancillary Studies

AS #	Title	PIs	Approved	Funded	Status	Study Dates	Study Population*	Blood Study	Ms #(s)
206	Selenium, genetic variation in selenoenzymes and colorectal cancer	Anc: Peters WHI: Prentice	Y	Y	Funded	07/01/06-06/30/09	OS Colorectal Cancer:805 Controls:805 *Same cases/controls as AS195; controls include 100 Y3 samples	Y	814, 815, 828
205	Genome-wide scan of cardiovascular disease and breast cancer and combined postmenopausal hormone therapy	Anc: Prentice WHI: Grimm	N	N	Tabled		OS/CT Breast Cancer:	Y	
204	Genetic susceptibility of chronic kidney disease	Anc: Vupputuri WHI: Heiss	N	N	Not Approved		OS Kidney Disease:2278 *CT:3836 (959 cases/ 2877controls) OS:5276 (1319 cases/3957 controls)	Y	
203	Infection of Helicobacter pylori, other Helicobacter species and the risk of pancreatic cancer among postmenopausal women	Anc: Ye WHI: Margolis	N	N	Not Approved		OS Pancreatic Cancer:310 Controls:620 *420 CT (140 cases/280 controls 510 OS (170 cases/ 340 controls)	Y	
202	Insulin/IGF and risk of benign breast disease (BBD): a cohort study	Anc: Rohan WHI: Smoller	N	N	Not Approved		CT Benign Breast Disease:1000 Controls:1700	Y	
201	Effect of hormone therapy on angiotensin II and microalbuminuria among postmenopausal women	Anc: Agarwal WHI: Bonds	N	N	Not Approved		HT Microalbuminuria:820 Controls:820 *120 samples for blood measurements	Y	
200	Women's Health Initiative cancer survivor cohort: biological, psychosocial, and behavioral predictors of survival	Anc: Paskett WHI: Jackson	N	N	Not Approved		OS *3129 OS cases and 498 CT cases – breast, colorectal, endometrial, and ovarian cancers	Y	
199	Genetic factors of muscle loss (added to AS191)	Anc: Chen WHI: Bassford	Y	Y	Funded		OS Sarcopenia:800 Controls:2000 *Combined with AS191	Y	
198	Women's thoughts and feelings about participating in a clinical trial	Anc: Furniss WHI: Lasser	N	N	PO Approved		HT	N	
197	Validity of self-reported diabetes mellitus in the Women's Health Initiative	Anc: Margolis WHI: Margolis	Y	Y	Funded	07/01/07-06/30/09	CT 487 Ppts@3 clinics	N	

Table 10.5 (continued)
All Ancillary Studies

AS #	Title	PIs	Approved	Funded	Status	Study Dates	Study Population*	Blood Study	Ms #(s)
196	Heart failure evaluation in post-menopausal women: the Women's Health Initiative study	Anc: Klein WHI: Van Horn	Y	Y	Funded	09/30/07-08/31/08	HT	N	364
195	Candidate pathways in colorectal carcinogenesis: one-carbon metabolism and inflammation	Anc: Ulrich WHI: Prentice	Y	Y	Funded	05/01/08-01/31/13	OS Colorectal Cancer:955 Controls:955 *Same cases/controls as AS 206	Y	
194	Genetic epidemiology of hip fracture in WHI & SOF	Anc: Zmuda WHI: Kuller	N	N	Dropped		OS Fracture - Hip:700 Controls:1400	Y	
193	Immune dysregulation in the pathogenesis of non Hodgkin's lymphoma	Anc: DeRoos WHI: LaCroix	N	N	Not Approved		OS Lymphoma, Non Hodgkins:500 Controls:1000 *300 OS cases, 600 OS controls; 200 CT cases, 400 CT controls	Y	
192	Estrogen and progesterone-related genes and colorectal cancer risk	Anc: Zhang WHI: Manson	Y	Y	Funded	09/01/06-08/31/10	OS Colorectal Cancer:644 Controls:1288 *Requests 10% blind duplicates (96 pairs)	Y	
191	Biomarkers and Genetic Factors Related to Sarcopenia in Older Women (includes AS199)	Anc: Chen WHI: Bassford	Y	Y	Funded	09/15/07-06/30/12	OS Sarcopenia:800 Controls:2000 *Identification of cases done in AS153	Y	
190	Insulin resistance and vitamin D	Anc: Hsia WHI: Hsia	N	N	Not Approved		CaD Insulin Resistance	Y	
189	Biochemical and anthropometric heterogeneity among morbid obese women in the Women's Health Initiative Observational Study	Anc: Mackey WHI: Kuller	Y	Y	Funded	05/01/06-04/30/09	OS CHD:144 Controls:1172	Y	698, 699
188	Inflammation and the risk of hormonally-linked cancer	Anc: Modugno WHI: Kuller	Y	N	Dropped	07/01/07-06/30/10	OS Breast Cancer:500 Endometrial Cancer:500 Ovarian Cancer:350 Controls:1250 *Maximize case/control overlap with AS129. Extra 750 breast cancer cases for DNA analyses	Y	

Table 10.5 (continued)
All Ancillary Studies

AS #	Title	PIs	Approved	Funded	Status	Study Dates	Study Population*	Blood Study	Ms #(s)
187	Serum fatty acids and salicylic acid in relation to incidence of ischemic stroke in postmenopausal women	Anc: He WHI: Van Horn	Y	Y	Funded	04/01/08-03/31/10	OS Stroke:972 Controls:972 *shares cases and controls with AS 126	Y	
186	Plasma fatty acids and risk of non-Hodgkin's lymphoma in the Women's Health Initiative Observational Study: a nested case-control study	Anc: Chiu WHI: Van Horn	N	N	Not Approved		OS Lymphoma, Non Hodgkins:290 Controls:870	Y	
185	An assessment of symptoms and symptom self-management for women abruptly stopping hormone replacement study pills (extension of AS160)	Anc: Ritenbaugh WHI: Ritenbaugh	Y	N	Dropped	03/19/04-09/30/04	HT E alone	N	
184	Measures for changes in skeletal muscle mass	Anc: Chen WHI: Bassford	Y	N	Dropped		OS/CT	N	
183	Effects of hormone therapy on subclinical neurological pathology: WHIMS-MRI	Anc: Shumaker WHI: Shumaker	Y	Y	Analysis	07/01/04-06/30/08	HT E+P 1,450 Ppts@14 WHIMS clinics	N	542, 625, 626, 680, 683, 696, 727, 794
182	Genetic and epigenetic markers of lung cancer risk in post-menopausal women	Anc: Schlecht WHI: Smoller	Y	N	Dropped	04/01/07-03/30/10	OS Cancer of Lung:720 Controls:1440	Y	
181	Estradiol, cytokines, and bone turnover: effects on hip fracture	Anc: Cauley WHI: Kuller	Y	Y	Analysis	07/01/05-06/30/09	OS Fracture - Hip:400 Controls:400 *same as AS90	Y	634, 681, 714, 861
180	Macrovascular complications of diabetes in postmenopausal women	Anc: Li WHI: Johnson	Y	N	Expired	12/01/05-11/30/09	OS Type 2 Diabetes:3164	Y	
179	Frailty in WHI: drugs, inflammatory and genetic markers	Anc: LaCroix WHI: LaCroix	Y	Y	Funded	09/15/05-07/31/08	OS Fraility-disability:900 Controls:900	Y	301, 302, 303, 662, 663
178	Mammographic density and invasive breast cancer	Anc: Pisano WHI: Heiss	Y	Y	Analysis	03/12/04-08/31/08	CT 793 Ppts@34 clinics Breast Cancer	N	
177	Relative risk differences between FFQs and food records	Anc: Subar WHI: Patterson	Y	Y	Complete	09/30/03-09/30/04	DM	N	

Table 10.5 (continued)
All Ancillary Studies

AS #	Title	PIs	Approved	Funded	Status	Study Dates	Study Population*	Blood Study	Ms #(s)
176	Long term breast and colorectal cancer survivors in the OS	Anc: Rahmani WHI: Smoller	N	N	Dropped		OS	N	
175	Physical function determinants in minority women	Anc: Nicholas WHI: Bassford	Y	Y	Funded	12/01/03-12/01/10	OS	N	
174	Proinflammatory markers and colorectal cancer	Anc: Ho WHI: Smoller	N	N	Not Approved		OS Colorectal Cancer:500 Controls:900	Y	
173	Relationship of biomarkers and genetic markers to risk of congestive heart failure	Anc: Chae WHI: Manson	N	N	Not Approved		OS CHF:656 Controls:1312	Y	
172	Estrogen receptor polymorphisms and cardiovascular effects of HRT	Anc: Herrington WHI: Burke	N	N	Dropped		CT	N	
171	Analysis of heart rate variability from ultra-short records: the WHI study	Anc: Michael WHI: Ritenbaugh	Y	Y	Complete	01/01/03-06/01/03	CT	N	
170	WHI nutrition and diabetes study (WHINDS)	Anc: Margolis WHI: Margolis	N	N	Dropped	01/01/04-12/31/06	DM	N	
169	Risk factors for hemorrhagic stroke among postmenopausal women	Anc: Kaplan WHI: Smoller	Y	N	Expired	04/01/06-07/30/10	OS Stroke:357 Controls:757	Y	
168	Plasma inflammatory markers and colorectal cancer	Anc: Ho WHI: Smoller	N	N	Dropped		OS	Y	
167	Sex hormones, risk factors, and risk of ER+ and ER- breast cancer	Anc: Cummings WHI: Cummings	Y	Y	Funded	01/01/05-12/31/06	OS Breast Cancer:311 Controls:592	Y	622
166	Estrogen replacement therapy and autoantibodies	Anc: Mackay WHI: Smoller	N	N	Dropped		OS	Y	
165	Subclinical thyroid dysfunction and risk of myocardial infarction and stroke	Anc: Hartmann WHI: Heiss	Y	Y	Analysis	09/01/04-07/31/08	OS CHD:800 Stroke:591 Controls:3136	Y	
164	The IGF system and coronary heart disease	Anc: Kaplan WHI: Smoller	Y	N	Expired	01/01/06-12/31/06	OS CHD:350 Controls:350	Y	
163	Hormone use following the WHI E+P trial termination: a pilot study	Anc: Hays WHI: Hays	N	Y	Complete	01/01/03-12/01/04	HT E+P	N	

Table 10.5 (continued)
All Ancillary Studies

AS #	Title	PIs	Approved	Funded	Status	Study Dates	Study Population*	Blood Study	Ms #(s)
162	Interactive telephone strategy to maintain diet change	Anc: Beresford WHI: Beresford	N	N	Tabled	07/01/03-06/30/08	CT	N	
161	Bone mass response to termination of Estrogen + Progestin	Anc: Cauley WHI: Kuller	Y	Y	Funded	07/10/02-10/01/02	HT E+P	N	
160	An assessment of symptoms and symptom self-management for women abruptly stopping hormone replacement study pills	Anc: Valanis WHI: Ritenbaugh	Y	Y	Complete	07/01/02-08/17/02	HT E+P	N	
159	The insulin-like growth factor (IGF) system and coronary heart disease	Anc: Kaplan WHI: Smoller	N	N	Dropped		OS	Y	
158	Potential mediators of the association of depression with CVD	Anc: Wylie-Rosett WHI: Smoller	N	N	Dropped		OS	Y	
157	Prediction of CHD among postmenopausal women using NMR spectroscopy lipoproteins	Anc: Kuller WHI: Kuller	N	N	Dropped		OS	Y	
156	The effect of domestic violence on health care costs and utilization	Anc: Mouton WHI: Schenken	Y	N	Not Funded	11/01/02-09/30/05	OS	N	
155	Carotenoids, transforming growth factors, and breast cancer risk	Anc: Rohan WHI: Smoller	Y	N	Dropped		OS Breast Cancer:3500 Controls:3500	Y	
154	Serum and DNA precursors of colon cancer	Anc: Garland WHI: Langer	N	N	Not Approved	09/01/02-08/30/03	OS Colon cancer:400 Controls:400	Y	
153	Longitudinal changes in hip geometry and skeletal muscle	Anc: Chen WHI: Bassford	Y	Y	Funded	08/15/03-06/30/08	OS 47 Ppts@Tucson Fracture - Hip	N	340, 456, 487, 489, 547, 566, 569, 633, 658, 687, 690, 691, 712, 888
152	Growth factor genes and female breast, colorectal, and endometrial cancers	Anc: Ho WHI: Smoller	Y	Y	Analysis	08/01/03-07/31/07	OS Breast Cancer:900 Colorectal Cancer:500 Endometrial Cancer:300 Controls:900 *Same as AS129	Y	559, 689, 776, 789, 790, 791
151	Behavioral management of urinary incontinence in African-american women	Anc: Ruff WHI: Howard	N	N	Dropped		OS	N	

Table 10.5 (continued)
All Ancillary Studies

AS #	Title	PIs	Approved	Funded	Status	Study Dates	Study Population*	Blood Study	Ms #(s)
150	Effect of airborne particulate matter and other air pollutants on the incidence of cardiovascular events in the Women's Health Initiative Observational Study	Anc: Kaufman WHI: Anderson	Y	Y	Analysis	05/01/02-05/31/06	OS/CT CHD:	N	363, 725
149	Gene-environment interactions and human breast cancer risk	Anc: Hu WHI: Paskett	Y	N	Dropped	06/01/04-05/31/06	OS Breast Cancer:800 Controls:800	Y	
148	Relationship between monoclonal hemopoiesis and other molecular abnormalities and the development of leukemia in older women	Anc: Preisler WHI: Black	Y	N	Expired		OS Leukemia:59 Controls:177	Y	
147	Gene-gene and gene-environment interactions and breast cancer risk	Anc: Eng WHI: Jackson	N	N	Dropped		OS	Y	
146	A prospective study of pancreatic cancer pathogenesis	Anc: Fuchs WHI: Manson	Y	Y	Complete	03/01/03-12/31/04	OS Pancreatic Cancer:104 Controls:312	Y	482, 483, 484, 576
145	Pancreatic cancer	Anc: Whitcomb WHI: Kuller	N	N	Dropped		OS	Y	
144	Interactions of polymorphisms in selected genes of thrombogenic & thrombolytic systems with hormone replacement therapy as risk factors for atherothrombotic events in postmenopausal women	Anc: Liu WHI: Liu	N	N	Dropped		OS	Y	163
143	Treatment of elevated cholesterol among US postmenopausal women	Anc: Kaplan WHI: Smoller	N	N	Dropped		OS	Y	
142	Thrombosis-related genes in population subgroups narrowly defined by race, ethnicity, and place of birth	Anc: Kaplan WHI: Smoller	N	N	Dropped		OS	Y	
141	Periodontal disease and subclinical cardiovascular disease in post-menopausal women	Anc: Dorn WHI: Trevisan	Y	Y	Complete	06/01/01-03/16/05	OS	N	
140	Air pollution and electrocardiographic abnormalities	Anc: Whitsel WHI: Heiss	Y	Y	Funded	09/01/03-05/31/09	CT	N	388, 389, 415, 430, 528, 529, 608, 609, 710, 850, 854

Table 10.5 (continued)
All Ancillary Studies

AS #	Title	PIs	Approved	Funded	Status	Study Dates	Study Population*	Blood Study	Ms #(s)
139	Follow-up of healthy breast cancer survivors in the WHI Observational Study	Anc: Paskett WHI: Burke	Y	Y	Complete	02/01/02-01/31/03	OS	N	
138	The study of tamoxifen, raloxifene, and cognition (Co-STAR)	Anc: Shumaker WHI: Shumaker	N	N	Dropped		HT	N	
137	Postmenopause CHD risk: platelet genes and hormone therapy	Anc: Bray WHI: Hays	Y	Y	Analysis	09/27/03-08/31/07	OS CHD:1060 Controls:2120	Y	593
136	The natural history of female pelvic organ prolapse	Anc: Handa WHI: Robbins	N	N	Dropped		HT	N	
135	Natural history of pelvic organ prolapse in WHI women	Anc: Nygaard WHI: Wallace	Y	Y	Complete	02/01/02-06/30/07	HT	N	317, 323, 331, 495, 592
134	Serum estrogen hormone metabolites, hormone replacement therapy and the risk of breast cancer	Anc: Modugno WHI: Kuller	Y	Y	Complete	07/01/02-05/31/04	OS Breast Cancer:200 Controls:200	Y	209
133	Biochemical and genetic predictors of incident hypertension in white and black women	Anc: Sesso WHI: Manson	Y	Y	Funded	08/01/04-07/31/08	OS Hypertension:800 Controls:800	Y	654, 655
132	A prospective study of genetic and biochemical predictors of Type 2 diabetes mellitus	Anc: Liu WHI: Manson	Y	Y	Analysis	08/01/02-07/31/08	OS Type 2 Diabetes:1800 Controls:2500	Y	339, 369, 376, 486, 550, 554, 555, 572, 573, 582, 594, 660, 664, 668, 688, 709, 719
131	Sex steroid hormones, inflammatory cytokines and the risk of rheumatoid arthritis: a nested case control study	Anc: Shadick WHI: Manson	N	N	Dropped		OS	Y	
130	Randomized controlled trial of fat reduction, calcium/Vitamin D supplementation, hormone replacement therapy, and risk of proliferative forms of benign breast disease	Anc: Rohan WHI: Smoller	Y	Y	Analysis	07/01/01-07/31/07	CT 3901 Ppts@49 clinics Benign Breast Disease	N	508, 509, 544, 584, 585, 586, 587

Table 10.5 (continued)
All Ancillary Studies

AS #	Title	PIs	Approved	Funded	Status	Study Dates	Study Population*	Blood Study	Ms #(s)
129	Association of diabetes and insulin-like growth factor-I (IGF-I) with risks of colorectal, breast, and endometrial cancer	Anc: Strickler WHI: Smoller	Y	Y	Complete	01/15/02-12/31/05	OS Breast Cancer:900 Colorectal Cancer:500 Endometrial Cancer:300 Controls:900 *same as AS152	Y	459, 460, 461
128	Mismatch repair gene associated malignancies in women	Anc: Weber WHI: Smoller	Y	N	Expired	04/01/04-03/31/08	OS Colorectal Cancer:1025 Endometrial Cancer:710 Ovarian Cancer:405 Controls:1000 *sharing ovarian cases with AS97	Y	
127	CHD risk perception study	Anc: Barnhart WHI: Smoller	Y	Y	Funded	05/15/02-04/30/07	OS	N	659
126	Stroke risk factors and molecular markers in postmenopausal women	Anc: Smoller WHI: Smoller	Y	Y	Analysis	08/01/03-07/31/06	OS Stroke:972 Controls:972	Y	601, 602, 603, 604, 672, 679, 829
125	Osteoporosis in caribbean hispanic women	Anc: Cohen WHI: Smoller	N	N	Dropped		OS/CT	N	
124	Sociocultural influences on motivation for and maintenance of health-related dietary change among women	Anc: Namie WHI: Langer	Y	Y	Complete	06/01/00-12/01/00	DM	N	
123	Genetic and ethnic determinants of nicotine addiction in postmenopausal women	Anc: David WHI: Assaf	N	N	Dropped		OS/CT	N	
122	Feasibility study of computerized tailored dietary feedback	Anc: Glanz WHI: Curb	Y	Y	Complete	03/10/00-09/01/00	DM	N	
121	Hyperinsulinemia and ovarian cancer	Anc: Modugno WHI: Kuller	Y	Y	Complete	09/01/02-08/31/04	OS Ovarian Cancer:225 Controls:225 *originally a subset of AS97	Y	
120	Epidemiology of cervical and lumbar stenosis	Anc: Vogt WHI: Kuller	N	N	Dropped		OS	N	
119	The longevity consortium	Anc: Langer WHI: Langer	N	N	Dropped		OS/CT	N	

Table 10.5 (continued)
All Ancillary Studies

AS #	Title	PIs	Approved	Funded	Status	Study Dates	Study Population*	Blood Study	Ms #(s)
118	Accuracy of food portion estimation among postmenopausal women	Anc: Coy WHI: Hubble	Y	Y	Complete	12/01/99-04/01/00	DM	N	312
117	Risk factors for dry eye syndrome in postmenopausal women	Anc: Nichols WHI: Jackson	Y	Y	Analysis	02/01/01-04/30/12	OS 217 Ppts@Columbus	N	
116	National validation and quality assurance of vitamin D absorption from CaD tablets	Anc: Garland WHI: Langer	N	N	Dropped		CaD	N	
115	Diabetes in postmenopausal women	Anc: Howard WHI: Howard	N	N	Dropped		OS/CT Type 2 Diabetes	N	
114	Effects of hormone replacement therapy on cardiac function and ischemia	Anc: Haan WHI: Robbins	N	N	Dropped		HT	N	
113	Some aspects of mediterranean diet in relation to risk of chronic diseases among postmenopausal women	Anc: Hakim WHI: Bassford	Y	Y	Complete	08/01/99-07/31/02	OS	N	
112	Motivators and barriers to exercise in older women	Anc: Haan WHI: Haan	N	N	Dropped		OS	N	
111	Glycemic Index/glycemic load and blood lipids in the WHI	Anc: Shikany WHI: Lewis	Y	Y	Complete	07/01/03-06/30/05	OS/CT	N	172, 385, 463, 574
110	Sex steroid hormones and risk of coronary heart disease: a nested case control study	Anc: Rexrode WHI: Manson	Y	Y	Complete	09/01/00-07/31/05	OS CHD:385 Controls:385 *79 matched cases-controls and 92 cases (but not controls) overlap with AS83.	Y	159, 160, 266, 305
109	Proteomics initiative	Anc: Hsia WHI: Hsia	N	N	Dropped	10/01/02-09/30/05	HT CHD:100 Controls:100	Y	
108	Gene-environment effects and colorectal cancer	Anc: Lin WHI: Chlebowski	Y	Y	Complete	04/01/03-07/31/07	OS Colorectal Cancer:50 Controls:150	Y	507, 610
107	Hashimoto's thyroiditis in postmenopausal women	Anc: Zakarija WHI: O'Sullivan	N	N	Not Approved	12/01/02-11/30/05	OS	Y	
106	Gene-diet interactions in human breast cancer risk	Anc: Hu WHI: Paskett	N	N	Dropped		OS/CT	N	

Table 10.5 (continued)
All Ancillary Studies

AS #	Title	PIs	Approved	Funded	Status	Study Dates	Study Population*	Blood Study	Ms #(s)
105	Carotenoids in age-related eye disease study	Anc: Mares-Perlman WHI: Sarto	Y	Y	Funded	06/01/00-04/30/04	OS 2007 Ppts@4 clinics Eye:1000 Controls:1000	Y	307, 308, 309, 310, 371, 444, 452, 498, 835
104	Tamoxifen prevention: Is it acceptable to women at risk?	Anc: Melnikow WHI: Robbins	Y	Y	Complete	07/01/99-06/30/02	OS	N	
103	Effects of hormone replacement therapy on cognitive aging: Women's Health Initiative study of cognitive aging (WHISCA)	Anc: Shumaker WHI: Shumaker	Y	Y	Funded	04/01/99-06/30/08	HT 2266 Ppts@15 clinics	N	216, 237, 325, 579, 598, 695
102	Quality of life improvements and willingness to pay: an investigation of selective estrogen receptor modulators	Anc: Fouad WHI: Oberman	Y	Y	Complete	09/01/98-10/01/98	OS	N	
101	Women's Health oral history project	Anc: Allen WHI: Allen	N	N	Dropped			N	
100	Genetic, biochemical and behavioral determinants of obesity	Anc: Hays WHI: Hays	Y	Y	Funded	01/01/99-04/30/04	OS 797 Ppts@3 clinics	N	
99	Genetics of non-insulin dependent diabetes (GENNID)	Anc: Chlebowski WHI: Chlebowski	Y	Y	Complete	12/01/98-03/31/00	OS/CT	N	
98	Bone mineral density as a predictor for periodontitis	Anc: Wactawski-Wende WHI: Trevisan	Y	Y	Funded	04/01/02-03/30/07	OS 969 Ppts@Buffalo	N	271, 326, 527, 632, 652, 813
97	Modeling serum markers for cost-effective ovarian cancer screening	Anc: Anderson WHI: Anderson	Y	Y	Funded	09/30/01-06/30/09	OS Ovarian Cancer:280 Controls:558	Y	381
96	Longitudinal insulin sensitivity and postmenopausal HRT	Anc: Cottrell WHI:	N	N	Dropped		OS/CT	N	
95	Work organization, psychological distress, and health among minority older women	Anc: Rodriguez WHI: Curb	Y	Y	Complete	12/01/97-12/01/97	OS	N	
94	The effect of lowfat Dietary Modification on markers of bone turnover and bone mineral density	Anc: Jackson WHI: Jackson	N	N	Dropped		OS/CT	N	
93	The epidemiology of venous disease	Anc: Criqui WHI: Langer	Y	Y	Complete	03/11/98-06/30/99	OS	N	

Table 10.5 (continued)
All Ancillary Studies

AS #	Title	PIs	Approved	Funded	Status	Study Dates	Study Population*	Blood Study	Ms #(s)
92	Fasting glucose in baseline plasma from all CT participants	Anc: Howard WHI: Howard	N	N	Tabled		CT	N	
91	Alterations in calcium and calcitropic hormone levels in 4 ethnic groups in response to CaD supplementation: possible effect modulation by VDR phenotype	Anc: Lester WHI:	N	N	Dropped		CT	N	
90	WHI sex hormone and genetic risk factors for hip fracture	Anc: Cummings WHI: Cummings	Y	Y	Funded	04/01/03-03/31/07	OS Fracture - Hip:400 Controls:400 *same as AS181	Y	479, 480, 481, 543, 563
89	Effect of HRT on plasma homocysteine concentration	Anc: Manson WHI: Manson	N	N	Dropped		HT	N	
88	Cholesterol distribution in lipoprotein particles in WHI DM Intervention participants consuming a low-fat dietary pattern compared to Comparison participants consuming their usual fat intake	Anc: Tinker WHI: Grimm	N	N	Dropped		DM	N	
87	The effect of dietary change on blood flavonoid and F2-isoprostane levels	Anc: Simon WHI: Hendrix	N	N	Dropped		DM	N	
86	A pilot study to determine the sensitivity of Form 39 to impaired executive control function (ECF) as measured by the CLOX: an executive clock-drawing task	Anc: Polk WHI: Schenken	Y	Y	Complete		HT	N	
85	Brain imaging with fluorometatyrosine in post-menopausal women on or off hormonal replacement therapy - implications for schizophrenia	Anc: Nordahl WHI:	N	N	Dropped			N	
84	Estrogen, vitamin E and cognitive change in women	Anc: Dunn WHI: Van Horn	Y	Y	Funded	09/01/01-08/31/08	OS/CT 546 Ppts@2 clinics	N	421, 539, 588, 600, 616, 621
83	Thrombotic, inflammatory and genetic markers for coronary heart disease in postmenopausal women: a WHI umbrella study	Anc: Ridker WHI: Manson	Y	Y	Complete	09/01/99-08/31/03	OS CHD:650 Controls:650	Y	127, 128, 129
82	Extension of bone mineral density assessment in WHI Native American women	Anc: Chen WHI: Ritenbaugh	Y	Y	Complete	07/01/97-06/30/01	OS	N	

Table 10.5 (continued)
All Ancillary Studies

AS #	Title	PIs	Approved	Funded	Status	Study Dates	Study Population*	Blood Study	Ms #(s)
81	Androgeneic hair growth in postmenopausal women	Anc: Freeman WHI: Smoller	N	N	Dropped		OS	N	
80	Combine effect of HRT and heritable prothrombotic mutations on the risk of deep venous thrombosis (DVT) and pulmonary embolus (PE)	Anc: Psaty WHI: Psaty	N	N	Dropped		HT	N	
79	How a low fat diet is related to adiposity and body fat distribution: cross-sectional and longitudinal evaluation	Anc: Wylie-Rosett WHI: Smoller	N	N	Dropped		OS/CT	N	
78	Community strategy to retain women enrolled in research	Anc: Fouad WHI: Oberman	Y	Y	Complete	07/01/97-09/30/97	CT	N	
77	HRT decision project	Anc: Kerner WHI: Langer	N	N	Dropped		OS/CT	N	
76	Tailored messages to enhance adherence of older women to dietary programs for breast cancer control	Anc: Chlebowski WHI: Chlebowski	Y	Y	Complete	09/01/97-08/13/98	DM	N	
75	Adherence to dietary modification in the WHI	Anc: Rosal WHI: Ockene	Y	Y	Analysis	09/01/97-08/30/02	DM	N	117, 126, 267
74	The effectiveness of individual versus group behavioral strategies to increase participants adherence	Anc: Wodarski WHI: Trevisan	Y	Y	Complete	07/01/97-09/30/97	DM	N	
73	Psychosocial and cultural determinants of NIDDM in Latinas	Anc: Ritenbaugh WHI: Langer	Y	Y	Complete	05/01/97-04/30/98	OS	N	
72	Ethnicity, body composition, bone density and breast cancer	Anc: Chen WHI: Ritenbaugh	Y	N	Dropped	09/01/97-08/30/02	OS	N	
71	Assessing stages of change in postmenopausal women enrolled in the Dietary Modification arm if the WHI	Anc: Brewer WHI: Applegate	N	N	Dropped		DM	N	
70	The prevalence and prognostic importance of myocardial ischemia during daily life, and its relationship to migraine status: WHI	Anc: Sheps WHI: Heiss	Y	Y	Complete	09/01/97-08/31/00	OS	N	171, 183, 281, 716
69	Birth place and CVD risk in women	Anc: Wylie-Rosett WHI: Smoller	N	N	Dropped		OS/CT	N	

Table 10.5 (continued)
All Ancillary Studies

AS #	Title	PIs	Approved	Funded	Status	Study Dates	Study Population*	Blood Study	Ms #(s)
68	Coronary artery calcification detected with Ultrafast CT as an indication of CAD in OS participants	Anc: Hsia WHI: Hsia	Y	Y	Complete	01/01/97-12/31/05	OS 735 Ppts@2 clinics	N	
67	Prevalence and natural history of autoimmune thyroid disease in postmenopausal women	Anc: Zakarija WHI: O'Sullivan	Y	Y	Funded	03/31/97-02/28/10	OS	N	
66	Quantitative, patient-specific serially comparable (QPS) mammography	Anc: Morrisett WHI: Foreyt	N	N	Dropped		OS/CT	N	
65	Benign breast disease	Anc: Rohan WHI: Rohan	Y	Y	Complete	07/01/98-08/30/00	DM 101 Ppts@12 clinics	N	
64	Examine mammography sensitivity in WHI women	Anc: Foreyt WHI: Foreyt	N	N	Dropped		CT	N	
63	Development and evaluation of eating style index	Anc: Haines WHI: Heiss	Y	Y	Complete	10/01/96-06/30/99	OS	N	
62	Prevention of age-related maculopathy in the WHI HRT CT: WHI-SE	Anc: Haan WHI: Robbins	Y	Y	Analysis	01/01/99-01/01/07	HT 4430 Ppts@21 clinics	N	250, 251, 253, 476, 819
61	Longitudinal assessment of memory functioning in the WHI clinical trial	Anc: Ober WHI: Robbins	Y	Y	Analysis	09/01/96-08/31/09	HT	N	
60	Fat intake in husbands of WHI dietary arm participants	Anc: Shikany WHI: Oberman	Y	Y	Complete	12/01/96-12/01/96	DM	N	
59	Prevalence and natural history of autoimmune thyroid disease (AITD) in postmenopausal women	Anc: Zakarija WHI: Greenland	N	N	Dropped		OS/CT	N	
58	Enrollment of hispanic women in prevention trials	Anc: Trapido WHI: Baum	N	N	Dropped		OS/CT	N	
57	Hispanic women's advocacy and retention strategies	Anc: Ritenbaugh WHI: Ritenbaugh	Y	Y	Complete	09/01/96-08/31/98	OS	N	
56	Behavioral and psychosocial predictors of dietary change in postmenopausal women	Anc: Pleuss WHI: Burke	Y	Y	Complete	09/01/96-08/31/98	DM	N	
55	Predictors of participation among latinos in clinical trials	Anc: Talavera WHI: Talavera	N	N	Dropped		OS/CT	N	
54	Women and minority recruitment / retention: a community-based Intervention	Anc: Fouad WHI: Oberman	N	N	Dropped		DM	N	
53	A prospective study of diet and hormones in the development of prostate cancer	Anc: Kabat WHI: Smoller	N	N	Dropped		OS/CT	N	

Table 10.5 (continued)
All Ancillary Studies

AS #	Title	PIs	Approved	Funded	Status	Study Dates	Study Population*	Blood Study	Ms #(s)
52	Genetic polymorphisms in the hormonal etiology of breast cancer	Anc: McTiernan WHI: McTiernan	N	N	Dropped		OS Breast Cancer:	N	
51	Cross-sectional and longitudinal evaluation of bone quality	Anc: LeBlanc WHI: Foreyt	N	N	Dropped		OS/CT	N	
50	Nutrition practice guidelines for maintaining low-fat dietary change in post menopausal women	Anc: Burrows WHI: Grimm	Y	Y	Complete	10/01/96-09/30/97	DM	N	
49	Applying creative self-monitoring in the WHI	Anc: Rahmani WHI: Rahmani	N	N	Dropped		DM	N	
48	Prostate cancer survey of spouses of WHI screened women	Anc: Smoller WHI: Smoller	Y	Y	Complete	02/01/96-06/30/96	OS/CT	N	
47	Effect of diet intervention on motivation to make other health-related changes	Anc: WHI: Langer	Y	Y	Complete	05/01/96-04/30/97	DM	N	
46	Prostate and colorectal cancer in WHI dietary arm husbands	Anc: Oberman WHI: Oberman	N	N	Dropped		DM	N	
45	Response set biases in dietary self-report in the WHI DM	Anc: Herbert WHI: Herbert	N	N	Dropped		DM	N	
44	Estrogen and vaginal pH	Anc: Schaeffer WHI: Greenland	N	N	Dropped		HT	N	
43	Decrease of bone mass in older women	Anc: Goodman WHI: Judd	N	N	Dropped		CT	N	
42	Impact of insurance status on health outcomes and health services utilization in the WHI	Anc: Hsia WHI: Miller	N	N	Dropped	11/01/96-10/31/99	OS	N	
41	Metabolism of lipoprotein and HRT	Anc: Morrisett WHI: Foreyt	N	N	Dropped		OS	N	
40	Ethnic and age differences in use of mammography	Anc: Smoller WHI: Smoller	Y	Y	Complete		OS	N	

Table 10.5 (continued)
All Ancillary Studies

AS #	Title	PIs	Approved	Funded	Status	Study Dates	Study Population*	Blood Study	Ms #(s)
39	The effects of HRT on the development and progression of dementia (WHIMS)	Anc: Shumaker WHI: Shumaker	Y	Y	Complete	06/01/96-05/31/05	HT 7528 Ppts@48 clinics	N	60, 138, 157, 173, 225, 226, 274, 276, 332, 336, 360, 370, 390, 399, 427, 546, 558, 595, 597, 639, 665, 670, 683, 727, 750, 883
38	Hemostatic/thrombotic and genetic markers for coronary disease in postmenopausal women	Anc: Ridker WHI: Manson	N	N	Dropped		OS	Y	
37	Lipid markers of atherosclerotic disease in post menopausal women	Anc: Manson WHI: Manson	N	N	Dropped		OS	Y	
36	HRT and changes in mammographic density	Anc: Hulka WHI: Heiss	Y	Y	Complete	01/31/98-12/31/02	HT 857 Ppts@19 clinics Breast Cancer	N	285, 358, 694
35	Risk factors for fatigue in women ages 50 to 75	Anc: Hartz WHI: Kotchen	N	N	Dropped		CT	N	
34	Ethnic differences in hip bone geometry by DXA and QCT	Anc: Nelson WHI: Hendrix	Y	Y	Complete	12/01/96-12/31/02	HT 311 Ppts@Detroit	N	
33	The association of HRT with abdominal and total body fat in postmenopausal women	Anc: Mayo WHI: Oberman	Y	Y	Complete	07/31/95-03/31/96	OS	N	
32	Recruitment techniques in getting minority women to participate in breast cancer clinical trials	Anc: Boe WHI: Langer	N	N	Dropped		OS/CT	N	
31	Eye care use	Anc: Kleinstein WHI: Oberman	Y	Y	Complete		OS	N	
30	The role of endocrine factors in the etiology of lung cancer in women	Anc: Kabat WHI: Smoller	N	N	Dropped		OS	N	
29	HRT and cardiovascular biomarkers related to oxidation status and platelet function	Anc: Gaziano WHI: Manson	N	N	Dropped		HT	N	

Table 10.5 (continued)
All Ancillary Studies

AS #	Title	PIs	Approved	Funded	Status	Study Dates	Study Population*	Blood Study	Ms #(s)
28	Perspectives on aging	Anc: Smoller WHI: Smoller	N	N	Dropped		OS/CT	N	
27	Vitamin D, calcium, and breast cancer	Anc: Hulka WHI: Sheps	N	N	Dropped		OS/CT	Y	
26	HRT and knee/hip osteoarthritis	Anc: Cerhan WHI: Wallace	N	N	Dropped		HT	N	
25	Ankle-arm blood pressure index measurement	Anc: Masaki WHI: Curb	Y	Y	Complete	02/01/96- 01/01/98	OS	N	
24	Cross-ethnic comparisons of skeletal health of postmenopausal women in San Diego county	Anc: Schneider WHI: Langer	Y	Y	Complete	01/03/95- 01/02/97	OS	N	
23	Non-steroidal anti-inflammatory drugs and cancers of the breast and colon	Anc: Harris WHI: Jackson	N	N	Dropped		OS/CT	N	
22	Vascular compliance as a predictor of cardiovascular disease in postmenopausal women	Anc: Robinson WHI: Grimm	N	N	Dropped		CT	N	
21	Effect of DM, HRT and CaD admin on progression of coronary atherosclerosis assessed by EBCT	Anc: Detrano WHI: Chlebowski	N	N	Dropped		CT	N	
20	Coronary screening of postmenopausal women using EBCT	Anc: Detrano WHI: Chlebowski	N	N	Dropped		OS	N	
19	Coagulation proteins, anticardiolipin antibodies and stroke in women	Anc: Orencia WHI: Greenland	N	N	Dropped		OS/CT	N	
18	WHT:FSMP DM follow-up	Anc: Grizzle WHI: Bowen	N	N	Dropped		DM	N	
17	Domestic violence in older women	Anc: Mouton WHI: Lasser	Y	Y	Complete	10/25/94- 10/24/96	OS	N	
16	Lower extremity atherosclerotic disease	Anc: McDermott WHI: Greenland	N	N	Dropped		OS	N	
15	The relationship between osteopenia and periodontitis	Anc: Wactawski-Wende WHI: Trevisan	Y	Y	Complete	09/16/96- 09/15/01	OS 1468 Ppts@Buffalo	N	553
14	High density lipoprotein metabolism	Anc: Going WHI: Moon	Y	Y	Complete	07/01/94- 06/30/96	OS	N	
13	Prevalence and correlates of lumbar spinal stenosis	Anc: Vogt WHI: Kuller	Y	Y	Complete		CT	N	

Table 10.5 (continued)
All Ancillary Studies

AS #	Title	PIs	Approved	Funded	Status	Study Dates	Study Population*	Blood Study	Ms #(s)
12	Empowerment/nutritional counseling	Anc: Mouton WHI: Lasser	N	N	Dropped		DM	N	
11	Validation and exploration of sleep and mood predictors	Anc: Kripke WHI: Langer	Y	Y	Complete	08/01/95-07/31/99	OS	N	43, 749
10	Urinary estrogen metabolites and breast cancer risk	Anc: Meilahn WHI: Kuller	N	N	Dropped		DM	N	
9	Oral bone loss	Anc: Jeffcoat WHI: Lewis	Y	Y	Complete	05/29/95-11/30/04	OS 450 Ppts@Birming	N	72
8	Partner's health study	Anc: Langer WHI: Langer	N	N	Dropped			N	
7	Effect of HRT on cardiovascular morbidity and mortality in postmenopausal women with a low ankle/arm BPI	Anc: Kuller WHI: Kuller	N	N	Dropped		HT	N	
6	Incidence and Impact of Arthritis in Older Women	Anc: Hughes WHI: Greenland	N	N	Dropped		OS/CT	N	
5	Explanations for the development of fat distaste	Anc: Green WHI: Bowen	Y	Y	Complete	04/01/95-09/30/96	DM	N	
4	Dietary modification and prostate cancer in WHI husbands	Anc: Shikany WHI: Oberman	N	N	Dropped		DM	N	
3	PLCO offer to WHI-partners (PLCO-Partners)	Anc: Weissfeld WHI: Kuller	N	N	Dropped		OS/CT	N	
2	Prostate, lung, colorectal, and ovarian cancer screening trial (PLCO-OS)	Anc: Weissfeld WHI: Kuller	N	N	Dropped		OS/CT	N	
1	Arterial disease artherosclerosis prevention Trial (ADAPT)	Anc: Crouse WHI: Burke	N	N	Dropped		DM	N	

*Number of clinics includes number of satellite sites.

Table 10.6
Recruitment to Ancillary Studies Requiring Separate Consents by Field Centers
Data as of August 15, 2008

	9	15	34	36	39	62	65	68	84	98	100	103	105
	Oral Bone Loss	The Relationship Between Osteopenia and Periodontitis	Ethnic Differences in Hip Bone Geometry by DXA and QCT	HRT and Changes in Mammographic Density	The Effects of HRT on the Development and Progression of Dementia (WHIMS)	Prevention of Age-Related Maculopathy in the WHI HRT CT: WHI-SE	Benign Breast Disease	Coronary Artery Calcification Detected with Ultrafast CT as an Indication of CAD in OS	Estrogen, Vitamin E and Cognitive Change in Women	Bone Mineral Density as a Predictor for Periodontitis	Genetic, Biochemical and Behav Determinants of Obesity	Effects of HRT on Cognitive Aging: WHI Studyof Cognitive Aging(WHISCA)	Carotenoids in Age-Related Eye Disease Study
Total	**450**	**1468**	**311**	**857**	**7528**	**4430**	**101**	**735**	**546**	**969**	**797**	**2266**	**2007**

Table 10.6 (continued)
Recruitment to Ancillary Studies Requiring Separate Consents by Field Centers
Data as of August 15, 2008

	117	130	153	178	197	216	218	219	233	W25	W30	Total
	Risk Factors for Dry Eye Syndrome in Postmenopausal Women	Randomized Controlled Trial of Fat Reduction, Calcium/ Vitamin D Supplementation, HRT, and Risk of Proliferative Forms of Benign Breast Disease	Longitudinal Changes in Hip Geometry and Skeletal Muscle	Mammographic Density and Invasive Breast Cancer	Validity of self-reported diabetes mellitus in the WHI	Decision-making About Cancer Screening Among Older Women	WHI Nutrition and Physical Activity Assessment Study (NPAAS)	Diet and Eye Health in the WHI: End of Trial Study	WHIMS Extension	WHI Coronary Artery Calcification Study in E-Alone	Dietary Assessment Study	
Total	**217**	**3901**	**47**	**793**	**487**	**1300**	**450**	**400**	**3074**	**1141**	**134**	**34409**

Table 10.7
Participant Enrollment in WHI Ancillary Studies
Requiring Separate Consents

Data as of August 15, 2008

CT+OS			
	Ppts	**%**	
CT+OS	161808		
Not Enrolled in Ancillary Studies	137731	85.12	
Enrolled in Ancillary Studies	24077	14.88	
Number of Studies	**Ppts**	**%**	**Enrollments**
1	17299	10.69	17299
2	4374	2.70	8748
3	1776	1.10	5328
4	558	0.34	2232
5	68	0.04	340
6	2	0.00	12
Total	**24077**	**14.88**	**33959**

Extension			
	Ppts	**%**	
Consented to Extension	115406		
Not Enrolled in Ancillary Studies	95516	82.77	
Enrolled in Ancillary Studies	19890	17.23	
Number of Studies	**Ppts**	**%**	**Enrollments**
1	13818	11.97	13818
2	3782	3.28	7564
3	1670	1.45	5010
4	551	0.48	2204
5	67	0.06	335
6	2	0.00	12
Total	**19890**	**17.23**	**28943**

Table 10.8
Funded Collaborative, BAA, and Ancillary Studies PI List

Investigator		PI for Study #	Sponsoring WHI PI for Study #	Supporting CCC PI for Study #
Last Name	**First Name**			
Anderson	Garnet	97	97, 150	97, 121, 129, 140, 150, BA6, BA11
Barnhart	Janice	127		
Bassford	Tamsen		113, 153, 175, 191, 199	
Bird	Cloe	220		
Bowen	Deborah			39
Bray	Paul	137		
Burke	Greg		56, 139	
Burrows	Beth	50		
Caan	Bette		243	
Cauley	Jane	161, 181, BA9		
Chanock	Stephen	M3, M4		
Chen	Zhao	82, 153, 191, 199, M2		
Chlebowski	Rowan	76, 99	76, 99, 108	
Cochrane	Barbara			242, 223, 196, 214, 192, 167, 133, 110, 134, 146
Colditz	Graham	207		
Coy	Christine	118		
Criqui	Michael	93		
Cummings	Steve	90, 167, BA7		
Curb	David		25, 95, 122	
Dorn	Joan	141		
Dunn	Julie	84		
Fouad	Mona	78, 102		
Fuchs	Charles	146, 214		
Glanz	Karen	122		
Going	Scott	14		
Green	Pamela	5		
Haan	Mary	62		
Haines	Pam	63		
Hakim	Iman	113		
Han	Jiali	242		
Hartmann	Katherine	165		
Hays	Jennifer	100, 163	100, 137, 163,	
He	Ka	187		
Heiss	Gerardo		36, 63, 70, 140, 165, 178, 236	
Hendrix	Susan		34	
Ho	Gloria	152, 208, BA10		
Howard	Barbara		217	
Hsia	Judith	68	68	
Hubble	Allan		118	
Hulka	Barbara	36		

Table 10.8 (continued)
Funded Collaborative, BAA, and Ancillary Studies PI List

Investigator		PI for Study #	Sponsoring WHI PI for Study #	Supporting CCC PI for Study #
Last Name	First Name			
Jackson	Rebecca	BA3	117, 223, BA3	
Jeffcoat	Marjorie	9		
Kaufman	Joel	150		
Kerwin	Diana	235		
Klein	Liviu	196		
Kleinstein	Robert	31		
Kooperberg	Charles	M6	M6	90, 126, BA10, BA12, M6
Kotchen	Jane		235	
Kripke	Daniel	11		
Kuller	Lew	BA12	13, 121, 134, 161, 181, 189	
LaCroix	Andrea	179	179, M4	83, 137, 153, 165, 179, 181, 191, 199, BA3, BA7, BA9, M4
Lane	Dorothy		216	
Langer	Robert		11, 24, 47, 73, 93, 124	
Lasser	Norm		17	
Lee	I-Minn	BA11		
Lewis	Beth		9, 111	
Li	Rongling	BA5		
Lichtenstein	Alice	BA8		
Lin	Henry	108		
Liu	Simin	132		
Lund	Bernedine			224, 206
Mackey	Rachel	189		
Manson	JoAnn		83, 110, 132, 133, 146, 192, 207, 214, 242, BA11	
Mares	Julie	219, M1		
Mares-Perlman		105		
Margolis	Karen	197	197, 220	
Masaki	Kamal	25		
Mayo	Charlotte	33		
McTiernan	Anne			36, 178
Melnikow	Joy	104		
Messina	Catherine	216		
Michael	Yvonne	171		
Modugno	Francesmary	121, 134		
Moon	Tom		14	
Mouton	Charles	17		
Namie	Joylin	124		
Nelson	Dorothy	34		
Neuhouser	Marian			130, 195, 207, 236, BA8
Nicholas	J.	175		
Nichols	Kelley	117		

Table 10.8 (continued)
Funded Collaborative, BAA, and Ancillary Studies PI List

Investigator		PI for Study #	Sponsoring WHI PI for Study #	Supporting CCC PI for Study #
Last Name	First Name			
Nygaard	Ingrid	135		
O'Sullivan	Mary Jo		67	
Ober	Beth	61		
Oberman	Albert		33, 31, 60, 78, 102	
Ockene	Judith		75	
Paskett	Electra	139, 223,		
Patterson	Ruth		177	65, 108 , 177
Peters	Ulrike	206, 224		
Pisano	Etta	178		
Pleuss	Joan	56		
Polk	M.J.	86		
Prentice	Ross	218, BA2, BA4	195, 206, 218, 224, BA2, BA4, M3	84, 195, 206, 218, 224, BA1, BA2, BA4, BA5, M3
Rexrode	Kathryn	110		
Ridker	Paul	83		
Ritenbaugh	Cheryl	57, 73	57, 82, 171, 160	
Robbins	John		61, 62, 104, BA1	
Rodriguez	Beatriz	95		
Rohan	Tom	65, 130		
Rosal	Milagros	75		
Sarto	Gloria		105, 219, M1	
Schenken	Robert		86	
Schneider	Diane	24		
Seldin	Michael	BA1		
Sesso	Howard	133		
Sheps	David	70		
Shikany	James	60, 111		
Shumaker	Sally	39, 103, 183, 233	39, 103, 183, 233	
Siega-Riz	Anna Maria	236		
Smoller	Sylvia	40, 48, 126,	40, 48, 126, 127, 129, 130, 152, 208, BA10	
Sternfeld	Barbara	243		
Strickler	Howard	129		
Subar	Amy	177		
Tinker	Lesley			105, 111, 132, 152, 187, 189, 208, 218, 219, M1
Trevisan	Maurizio		15, 74, 98, 141	
Ulrich	Cornelia	195		
Valanis	Barbara	160		
Van Horn	Linda		84, 187, 196	
Vogt	Molly	13		
Wactawski-Wende	Jean	15, 98		
Wallace	Robert		135	

Table 10.8 (continued)
Funded Collaborative, BAA, and Ancillary Studies PI List

Investigator		PI for Study #	Sponsoring WHI PI for Study #	Supporting CCC PI for Study #
Last Name	First Name			
Wallitt	Brian	217		
Whitsel	Eric	140		
Wodarski	Lois	74		
Xu	Jianfeng	BA6		
Zakarija	Margita	67		
Zhang	Shumin	192		

Table 11.1
WHI Manuscript Stages

Stage #	Definition	Number
12	Published	354
11	In press / accepted by journal	21
10	Submitted to journal	38
9	Final manuscript approved by P&P Committee	22
8	Final manuscript submitted to P&P Committee	10
7	Draft manuscript	22
6	Analysis completed	18
5	Analysis in progress	49
4	Analysis proposed	14
3	Manuscript proposal and writing group approved	105

Table 11.2
Publications – Stages 3 through 12

Ms ID	Title	Authors	Stage	Data Focus	Reference	Study
1	Informed consent in the Women's Health Initiative Clinical Trial and Observational Study	**McTiernan**, Rossouw, Manson, Franzi, Taylor, Carleton, Johnson, Nevitt	12	Gen	J Womens Health. 1995;4(5):519-29	
4	The Women's Health Initiative: Overview of the nutrition components	**Tinker**, Burrows, Henry, Patterson, VanHorn, Rupp	12	Gen	In: Krummel DA, Kris-Etherton PM, eds. Nutrition and women's health. Gaithersburg, MD: Aspen Publishers, 1996:510-42	
5	Women's Health Initiative: Why now? What is it? What's new?	**Matthews**, Shumaker, Bowen, Langer, Hunt, Kaplan, Klesges, Ritenbaugh	12	Gen	Am Psychol. 1997 Feb;52(2):101-16	
6	Low-fat diet practices of older women: Prevalence and implications for dietary assessment	**Patterson**, Kristal, Coates, Tylavsky, Ritenbaugh, VanHorn, Caggiula, Snetselaar	12	Gen	J Am Diet Assoc. 1996 Jul;96(7):670-9	
7	The evolution of the Women's Health Initiative: Perspectives from the NIH	**Rossouw**, Finnegan, Harlan, Pinn, Clifford, McGowan	12	Gen	J Am Med Womens Assoc. 1995 Mar-Apr;50(2):50-5	
8	Design of the Women's Health Initiative clinical trial and observational study	**The Women's Health Initiative Study Group**	12	Gen	Control Clin Trials. 1998 Feb;19(1):61-109	
9	Approaches to monitoring the results of long-term disease prevention trials: Examples from the Women's Health Initiative	**Freedman**, Anderson, Kipnis, Prentice, Wang, Rossouw, Wittes, DeMets	12	CT	Control Clin Trials. 1996;Dec 17(6):509-525	
11	The role of randomized controlled trials in assessing the benefits and risks of long-term hormone replacement therapy: Example of the Women's Health Initiative.	**Prentice**, Rossouw, Johnson, Freedman, McTiernan	12	CT	Menopause. 1996;3(2):71-76	
12	Is insurance a more important determinant of healthcare access than perceived health? Evidence from the Women's Health Initiative	**Hsia**, Kemper, Sofaer, Bowen, Kiefe, Zapka, Mason, Lillington, Limacher	12	Gen	J Womens Health Gend Based Med. 2000 Oct;9(8):881-9	
13	Depression and cardiovascular sequelae in postmenopausal women. The Women's Health Initiative (WHI)	**Wassertheil-Smoller**, Shumaker, Ockene, Talavera, Greenland, Cochrane, Robbins, Aragaki, Dunbar	12	Gen	Arch Intern Med. 2004 Feb 9;164(3):289-98	

See Table 11.1 for Stage # key.

Table 11.2 (continued)
Publications – Stages 3 through 12

Ms ID	Title	Authors	Status	Data Focus	Reference	Study
16	Differences between estimated caloric requirements and self-reported caloric intake in the Women's Health Initiative	**Hebert**, Patterson, Gorfine, Ebbeling, St. Jeor, Chlebowski	12	Gen	Ann Epidemiol. 2003 Oct;13(9):629-37	
17	Sexual orientation and health: Comparisons in the Women's Health Initiative sample	**Valanis**, Bowen, Bassford, Whitlock, Charney, Carter	12	CT	Arch Fam Med. 2000 Sep-Oct;9(9):843-53	
19	Ethnic, socioeconomic, and lifestyle correlates of obesity in U.S. women: The Women's Health Initiative	**Manson**, Lewis, Kotchen, Allen, Johnson, Stefanick, Foreyt, Klesges, Tinker, Noonan, Perri, Hall	12	Gen	Clin J Womens Health. 2001;Dec 1(5):225-34	
20	Relation of demographic factors, menstrual history, reproduction and medication use to sex hormones in postmenopausal women	**McTiernan**, Wu, Barnabei, Chen, Hendrix, Modugno, Rohan, Stanczyk, Wang	12	CT	Breast Cancer Res Treat. 2008 Mar;108(2):217-231. Epub 2007 May 22	W5
21	Hypertension and its treatment in postmenopausal women: Baseline data from the Women's Health Initiative	**Wassertheil-Smoller**, Anderson, Psaty, Black, Manson, Wong, Francis, Grimm, Kotchen, Langer, Lasser	12	OS	Hypertension. 2000 Nov;36(5):780-9	
22	Pelvic organ prolapse in the Women's Health Initiative: Gravity and gravidity	**Hendrix**, Clark, Nygaard, Aragaki, Barnabei, McTiernan	12	CT	Am J Obstet Gynecol. 2002 Jun;186(6):1160-6	
24	Estimation of the correlation between nutrient intake measures under restricted sampling	**Wang**, Anderson, Prentice	12	Gen	Biometrics. 1999 Sep;55(3):711-7	
25	Estrogen and progestin use and the QT interval in postmenopausal women	**Kadish**, Greenland, Limacher, Frishman, Daugherty, Schwartz	12	CT	Ann Noninvasive Electrocardiol. 2004 Oct;9(4):366-74	
26	Special populations recruitment for the Women's Health Initiative: Successes and limitations	**Fouad**, Corbie-Smith, Curb, Howard, Mouton, Simon, Talavera, Thompson, Wang, White, Young	12	Gen	Control Clin Trials. 2004 Aug;25(4):335-52	
27	The effects of insurance coverage and ethnicity on mammography utilization in a postmenopausal population	**Bush**, Langer	12	Gen	West J Med. 1998 Apr;168(4):236-40	
35	Measurement characteristics of the Women's Health Initiative food frequency questionnaire	**Patterson**, Kristal, Tinker, Carter, Bolton, Agurs-Collins	12	Gen	Ann Epidemiol. 1999 Apr;9(3):178-87	W30
40	The associations between health and domestic violence in older women: Results of a pilot study	**Mouton**, Rovi, Furniss, Lasser	12	OS	J Womens Health Gend Based Med. 1999 Nov;8(9):1173-9	

Table 11.2 (continued)
Publications – Stages 3 through 12

Ms ID	Title	Authors	Status	Data Focus	Reference	Study
41	Cross-sectional correlates of fasting hyperinsulinaemia in post-menopausal women of different ethnic origin	**Pradhan**, Manson, Hendrix, Johnson, Wagenknecht, Haan, Weidner, LaCroix, Cook	12	Gen	Diabet Med. 2006 Jan;23(1):77-85	
43	Sleep complaints of postmenopausal women	**Kripke**, Brunner, Freeman, Hendrix, Jackson, Masaki, Carter	12	CT	Clin J Womens Health. 2001;1(5):244-52	AS11
51	Relationship of social support and social burden to repeated breast cancer screening in the Women's Health Initiative	**Messina**, Lane, Glanz, West, Taylor, Frishman, Powell	12	Gen	Health Psychol. 2004 Nov;23(6):582-94	
55	Factor structure and measurement invariance of the Women's Health Initiative Insomnia Rating Scale	**Levine**, Kaplan, Kripke, Bowen, Naughton, Shumaker	12	Gen	Psychol Assess. 2003 Jun;15(2):123-36	
59	Risk factors for kidney stones in postmenopausal women in the southern United States	**Hall**, Pettinger, Oberman, Watts, Johnson, Paskett, Limacher, Hays	12	Gen	Am J Med Sci. 2001 Jul;322(1):12-8	
60	The Women's Health Initiative Memory Study (WHIMS): A trial of the effect of estrogen therapy in preventing and slowing the progression of dementia [WHIMS]	**Shumaker**, Reboussin, Espeland, Rapp, McBee, Dailey, Bowen, Terrell, Jones	12	WHIMS	Control Clin Trials. 1998 Dec;19(6):604-21	AS39
62	Self-reported urogential symptoms in postmenopausal women: Women's Health Initiative	**Pastore**, Carter, Hulka, Wells	12	Gen	Maturitas. 2004 Dec 10;49(4):292-303	
63	The importance of health insurance as a determinant of cancer screening: Evidence from the Women's Health Initiative	**Hsia**, Kemper, Kiefe, Zapka, Sofaer, Pettinger, Bowen, Limacher, Lillington, Mason	12	OS	Prev Med. 2000 Sep;31(3):261-70	
66	Walking compared with vigorous exercise for the prevention of cardiovascular events in women	**Manson**, Greenland, LaCroix, Stefanick, Mouton, Oberman, Perri, Sheps, Pettinger, Siscovick	12	OS	N Engl J Med. 2002 Sep 5;347(10):716-25	
67	Yogurt consumption is associated with healthy behavior in postmenopausal women	**Mossavar-Rahmani**, Garland, Caan, Hebert, Wodarski, Vitolins, Himes, Parker	12	OS	Clin J Womens Health. 2002;2(3):128-134	
69	Correlates of serum lypocene in older women	**Casso**, White, Patterson, Agurs-Collins, Kooperberg, Haines	12	CT	Nutr Cancer. 2000;36:163-69	
70	Correlates of serum alpha- and gamma-tocopherol in the Women's Health Initiative	**White**, Kristal, Shikany, Wilson, Chen, Mares-Perlman, Masaki, Caan	12	CT	Ann Epidemiol. 2001 Feb;11(2):136-44	

Table 11.2 (continued)
Publications – Stages 3 through 12

Ms ID	Title	Authors	Status	Data Focus	Reference	Study
71	The Women's Health Initiative: Goals, rationale, and current status	**Liu**	12	Gen	Menopausal Medicine. 1998;6(2):1-4	
72	Postmenopausal bone loss and its relationship to oral bone loss	**Jeffcoat**, Lewis, Reddy, Wang, Redford	12	Gen	Periodontol. 2000; June23(1):94-102	AS9
76	Differences in eating pattern labels between maintainers and nonmaintainers in the Women's Health Initiative	**Hopkins**, Burrows, Bowen, Tinker	12	CT	J Nutr Educ. 2001 Sep-Oct;33(5):278-83	
78	Lack of a relation between vitamin and mineral antioxidants and bone mineral density: Results from the Women's Health Initiative	**Wolf**, Cauley, Pettinger, Jackson, LaCroix, LeBoff, Lewis, Nevitt, Simon, Stone, Wactawski-Wende	12	Gen	Am J Clin Nutr. 2005 Sep;82(3):581-8	
80	Insulin resistance and weight gain in postmenopausal women of diverse ethnic groups	**Howard**, Adams-Campbell, Allen, Black, Pasaro, Rodabough, Rodriguez, Safford, Stevens, Wagenknecht	12	Gen	Int J Obes Relat Metab Disord. 2004 Aug;28(8):1039-47	
83	Recreational physical activity and the risk of breast cancer in postmenopausal women: The Women's Health Initiative Cohort Study	**McTiernan**, Kooperberg, White, Wilcox, Coates, Adams-Campbell, Woods, Ockene	12	Gen	JAMA. 2003 Sep 10;290(10):1331-6	
84	Research staff turnover and participant adherence in the Women's Health Initiative	**Jackson**, Berman, Huber, Snetselaar, Granek, Boe, Milas, Spivak, Chlebowski	12	CT	Control Clin Trials. 2003 Aug;24(4):422-35	
85	The Women's Health Initiative: Rationale, design and progress report	**Johnson**, Anderson, Barad, Stefanick	12	CT	J Br Menopause Soc. 1999;5:155-9	
86	The effects of physical and emotional status on adherence to a low-fat dietary pattern in the Women's Health Initiative	**Tinker**, Perri, Patterson, Bowen, McIntosh, Parker, Sevick, Wodarski	12	CT	J Am Diet Assoc. 2002 Jun;102(6):789-800, 888	
88	Estimating normal hemogram values for postmenopausal women	**Assaf**, Carleton, Miller, Coccio	12	Gen	Clin J Womens Health. 2000;1(1):23-28	
91	Compliance with National Cholesterol Education Program dietary and lifestyle guidelines among older women with self-reported hypercholesterolemia. The Women's Health Initiative	**Hsia**, Rodabough, Rosal, Cochrane, Howard, Snetselaar, Frishman, Stefanick	12	OS	Am J Med. 2002 Oct 1;113(5):384-92	

Table 11.2 (continued)
Publications – Stages 3 through 12

Ms ID	Title	Authors	Status	Data Focus	Reference	Study
92	Comparison of self-report, hospital discharge codes, and adjudication of cardiovascular events in the Women's Health Initiative	**Heckbert**, Kooperberg, Safford, Psaty, Hsia, McTiernan, Gaziano, Frishman, Curb	12	Gen	Am J Epidemiol. 2004 Dec 15;160(12):1152-8	
93	Fat intake in husbands of participants in the dietary modification component of the Women's Health Initiative	**Shikany**	12	Gen	Nutr Res. 2002;22:577-586	
95	The effects of widowhood on physical and mental health, health behaviors, and health outcomes: The Women's Health Initiative	**Wilcox**, Evenson, Aragaki, Wassertheil-Smoller, Mouton, Loevinger	12	OS	Health Psychol. 2003 Sep;22(5):513-22	
98	Antioxidant supplement use in Women's Health Initiative participants	**Shikany**, Patterson, Agurs-Collins, Anderson	12	Gen	Prev Med. 2003 Mar;36(3):379-87	
99	Risk factor clustering in the insulin resistance syndrome and its relationship to cardiovascular disease in postmenopausal white, black, hispanic, and Asian/Pacific Islander women	**Howard**, Criqui, Curb, Rodabough, Safford, Santoro, Wilson, Wylie-Rosette	12	OS	Metabolism. 2003 Mar;52(3):362-71	
100	Frequency and predictive value of a mammographic recommendation for short-interval follow-up	**Yasmeen**, Romano, Pettinger, Chlebowski, Robbins, Lane, Hendrix	12	Gen	J Natl Cancer Inst. 2003 Mar 19;95(6):429-36	
102	Association between cardiovascular outcomes and antihypertensive drug treatment in older women	**Wassertheil-Smoller**, Psaty, Greenland, Oberman, Kotchen, Mouton, Black, Aragaki, Trevisan	12	OS	JAMA. 2004 Dec 15;292(23):2849-59	
103	The Women's Health Initiative: Recruitment complete--looking back and looking forward	**Rossouw**, Hurd	12	CT	J Womens Health. 1999 Jan-Feb;8(1):3-5	
104	Promoting adherence and retention to clinical trials in special populations: A Women's Health Initiative workshop	**Wilcox**, Shumaker, Bowen, Naughton, Rosal, Ludlam, Dugan, Hunt, Stevens	12	Gen	Control Clin Trials. 2001 Jun;22(3):279-89	
105	Retention of under-served women in clinical trials: A focus group study	**Johnson**, Williams, Nagy, Fouad	12	CT	Ethn Dis. 2003 Spring;13(2):268-78	
107	Vigorous leisure activity through women's adult life: The Women's Health Initiative Observational Cohort Study	**Evenson**, Wilcox, Pettinger, Brunner King, McTiernan	12	OS	Am J Epidemiol. 2002 Nov 15;156(10):945-53	
108	Cross-sectional geometry, bone strength, and bone mass in the proximal femur in black and white postmenopausal women	**Nelson**, Barondess, Hendrix, Beck	12	CT	J Bone Miner Res. 2000 Oct;15(10):1992-7	

Table 11.2 (continued)
Publications – Stages 3 through 12

Ms ID	Title	Authors	Status	Data Focus	Reference	Study
111	Effects of fat content on fat hedonics: Cognition or taste?	**Bowen**, Green, Vizenor, Vu, Kreuter, Rolls	12	OS	Physiol Behav. 2003 Feb;78(2):247-53	
112	Results of an adjunct dietary intervention program in the Women's Health Initiative	**Bowen**, Ehret, Pedersen, Snetselaar, Johnson, Tinker, Hollinger, Lichty, Bland, Sivertsen, Ocken, Staats Beedoe	12	OS	J Am Diet Assoc. 2002 Nov;102(11):1631-7	
113	Prior oral contraception and postmenopausal fracture: A Women's Health Initiative observational cohort study	**Barad**, Kooperberg, Wactawski-Wende, Liu, Hendrix, Watts	12	Gen	Fertil Steril. 2005 Aug;84(2):374-83	
115	Prevalence and 3-year incidence of abuse among postmenopausal women	**Mouton**, Rodabough, Rovi, Hunt, Talamantes, Brzyski, Burge	12	OS	Am J Public Health. 2004 Apr;94(4):605-12	
120	Obesity, body size, and risk of postmenopausal breast cancer: the Women's Health Initiative (United States)	**Morimoto**, White, Chen, Chlebowski, Hays, Kuller, Lopez, Manson, Margolis, Muti, Stefanick, McTiernan	12	OS	Cancer Causes Control. 2002 Oct;13(8):741-51	
122	Statin use, clinical fracture, and bone density in postmenopausal women: Results from the Women's Health Initiative Observational Study	**LaCroix**, Cauley, Pettinger, Hsia, Bauer, McGowan, Chen, Lewis, McNeeley, Pasaro, Jackson	12	OS	Ann Intern Med. 2003 Jul 15;139(2):97-104	
126	Influences on older women's adherence to a low-fat diet in the Women's Health Initiative	**Kearney**, Rosal, Ockene, Churchill	12	CT	Psychosom Med. 2002 May-Jun;64(3):450-7	AS75
128	Inflammatory biomarkers, hormone replacement therapy, and incident coronary heart disease: Prospective analysis from the Women's Health Initiative observational study	**Pradhan**, Manson, Rossouw, Siscovick, Mouton, Rifai, Wallace, Jackson, Pettinger, Ridker	12	OS	JAMA. 2002 Aug 28;288(8):980-7	AS83
129	Tissue plasminogen activator antigen and D-dimer as markers for atherothrombotic risk among healthy postmenopausal women	**Pradhan**, LaCroix, Langer, Trevisan, Lewis, Hsia, Oberman, Kotchen, Ridker	12	OS	Circulation. 2004 Jul 20;110(3):292-300. Epub 2004 Jul 6	AS83
130	Baseline associations between postmenopausal hormone therapy and inflammatory, haemostatic, and lipid biomarkers of coronary heart disease. The Women's Health Initiative Observational Study	**Langer**, Pradhan, Lewis, Manson, Rossouw, Hendrix, LaCroix, Ridker	12	OS	Thromb Haemost. 2005 Jun;93(6):1108-16	
132	Association of nonmelanoma skin cancer with second malignancy	**Rosenberg**, Greenland, Khandekar, Loar, Ascensao, Lopez	12	Gen	Cancer. 2004 Jan 1;100(1):130-8	

Table 11.2 (continued)
Publications – Stages 3 through 12

Ms ID	Title	Authors	Status	Data Focus	Reference	Study
134	Additional self-monitoring tools in the dietary modification component of the Women's Health Initiative	**Mossavar-Rahmani**, Henry, Rodabough, Bragg, Brewer, Freed, Kinzel, Pedersen, Soule, Vosburg	12	CT	J Am Diet Assoc. 2004 Jan;104(1):76-85	
135	Radiographic measurements, bone mineral density, and the Singh Index in the proximal femur of white and black postmenopausal women	**Barondess**, Singh, Hendrix, Nelson	12	Gen	Dis Mon. 2002 Oct;48(10):637-46	
137	Recruitment of hispanic women to the Women's Health Initiative: The case of Embajadoras in Arizona	**Larkey**, Staten, Ritenbaugh, Hall, Buller, Bassford, Altimari	12	Gen	Control Clin Trials. 2002 Jun;23(3):289-98	
138	Baseline experience with Modified Mini Mental State Exam: The Women's Health Initiative Memory Study (WHIMS) [WHIMS]	**Rapp**, Espeland, Hogan, Jones, Dugan, The WHIMS Investigators	12	WHIMS	Aging Ment Health. 2003 May;7(3):217-23	AS39
139	Cholesteryl ester transfer protein and lecithin:cholesterol acyltransferase activities in hispanic and anglo postmenopausal women: Associations with total and regional body fat	**Greaves**, Going, Fernandez, Milliken, Lohman, Bassford, McNamara	12	OS	Metabolism. 2003 Mar;52(3):282-9	
140	Usefulness of prior hysterectomy as an independent predictor of Framingham risk score (The Women's Health Initiative)	**Hsia**, Barad, Margolis, Rodabough, McGovern, Limacher, Oberman, Wassertheil-Smoller, Women's Health Initiative Research Group	12	Gen	Am J Cardiol. 2003 Aug 1;92(3):264-9	
142	Coronary artery calcification in black women and white women	**Khurana**, Rosenbaum, Howard, Adams-Campbell, Detrano, Klouj, Hsia	12	OS	Am Heart J. 2003 Apr;145(4):724-9	
144	Risk of cardiovascular disease by hysterectomy status, with and without oophorectomy: The Women's Health Initiative Observational Study	**Howard**, Kuller, Langer, Manson, Allen, Assaf, Cochrane, Larson, Lasser, Rainford, VanHorn, Stefanick, Trevisan	12	OS	Circulation. 2005 Mar 29;111(12):1462-70. Epub 2005 Mar 21	
145	Breast cancer and nonsteroidal anti-inflammatory drugs: Prospective results from the Women's Health Initiative	**Harris**, Chlebowski, Jackson, Frid, Ascensao, Anderson, Loar, Rodabough, White, McTiernan	12	OS	Cancer Res. 2003 Sep 15;63(18):6096-101	
148	Incidence of cervical cytological abnormalities with aging in the Women's Health Initiative: A randomized controlled trial	**Yasmeen**, Romano, Pettinger, Johnson, Hubbell, Lane, Hendrix	12	CT	Obstet Gynecol. 2006 Aug;108(2):410-9	

Table 11.2 (continued)
Publications – Stages 3 through 12

Ms ID	Title	Authors	Status	Data Focus	Reference	Study
149	A community-based study of postmenopausal white women with back and leg pain: Health status and limitations in physical activity	**Vogt**, Lauerman, Chirumbole, Kuller	12	OS	J Gerontol A Biol Sci Med Sci. 2002 Aug;57(8):M544-50	
155	Changes in food sources of dietary fat in response to an intensive low-fat dietary intervention: Early results from the Women's Health Initiative	**Patterson**, Kristal, Rodabough, Caan, Lillington, Mossavar-Rahmani, Simon, Snetselaar, VanHorn	12	CT	J Am Diet Assoc. 2003 Apr;103(4):454-60	
163	Ethnicity and breast cancer: Factors influencing differences in incidence and outcome	**Chlebowski**, Chen, Anderson, Rohan, Aragaki, Lane, Dolan, Paskett, McTiernan, Hubbell, Adams-Campbell, Prentice	12	OS	J Natl Cancer Inst. 2005 Mar 16;97(6):439-48	AS144
164	Leukocyte count as a predictor of cardiovascular events and mortality in postmenopausal women: The Women's Health Initiative Observational Study	**Margolis**, Manson, Greenland, Rodabough, Bray, Safford, Grimm, Howard, Assaf, Prentice, Women's Health Initiative Research Group	12	OS	Arch Intern Med. 2005 Mar 14;165(5):500-8	
166	Habitual tea consumption and risk of osteoporosis: A prospective study in the Women's Health Initiative observational cohort	**Chen**, Pettinger, Ritenbaugh, LaCroix, Robbins, Caan, Barad, Hakim	12	OS	Am J Epidemiol. 2003 Oct 15;158(8):772-81	
169	Reliability and validity of the Women's Health Initiative Insomnia Rating Scale	**Levine**, Kripke, Kaplan, Lewis, Naughton, Bowen, Shumaker	12	Gen	Psychol Assess. 2003 Jun;15(2):137-48	
171	Prevalence and correlates of panic attacks in postmenopausal women: Results from an ancillary study to the Women's Health Initiative	**Smoller**, Pollack, Wassertheil-Smoller, Barton, Hendrix, Jackson, Dicken, Oberman, Sheps, Women's Health Initiative Investigators	12	Gen	Arch Intern Med. 2003 Sep 22;163(17):2041-50	AS70
173	A prospective study of the effect of hypertension and baseline blood pressure on cognitive decline and dementia in postmenopausal women: The Women's Health Initiative Memory Study [WHIMS]	**Johnson**, Margolis, Espeland, Colenda, Fillit, Manson, Masaki, Mouton, Prineas, Robinson, Wassertheil-Smoller, for the Women's Health Initiative Memory Study and Women's Health Initiative Investigators	12	WHIMS	J Am Geriatr Soc. 2008 Jul 15. [Epub ahead of print]	AS39

Table 11.2 (continued)
Publications – Stages 3 through 12

Ms ID	Title	Authors	Status	Data Focus	Reference	Study
174	Statin use and breast cancer: Prospective results from the Women's Health Initiative	**Cauley**, McTiernan, Rodabough, LaCroix, Bauer, Margolis, Paskett, Vitolins, Furberg, Chlebowski, Women's Health Initiative Research Group	12	OS	J Natl Cancer Inst. 2006 May 17;98(10):700-7	
176	Predicting risk of breast cancer in postmenopausal women by hormone receptor status	**Chlebowski**, Anderson, Lane, Aragaki, Rohan, Yasmeen, Sarto, Rosenberg, Hubbell, Women's Health Initiative Investigators	12	Gen	J Natl Cancer Inst. 2007 Nov 21;99(22):1695-705. Epub 2007 Nov 13	
177	Validity of self-report for fractures among a multiethnic cohort of postmenopausal women: Results from the Women's Health Initiative observational study and clinical trials	**Chen**, Kooperberg, Pettinger, Bassford, Cauley, LaCroix, Lewis, Kipersztok, Borne, Jackson	12	Gen	Menopause. 2004 May-Jun;11(3):264-74	
179	Progression and remission of pelvic organ prolapse: A longitudinal study of menopausal women	**Handa**, Garret, Hendrix, Gold, Robbins	12	CT	Am J Obstet Gynecol. 2004 Jan;190(1):27-32	
181	Alcohol and folate intake and breast cancer risk in the WHI Observational Study	**Duffy**, Assaf, Cyr, Burkholder, Coccio, Rohan, McTiernan, Paskett, Lane, Chetty	12	OS	Breast Cancer Res Treat. 2008 Sep 11. [Epub ahead of print]	
183	Panic attacks, daily life ischemia, and chest pain in postmenopausal women	**Smoller**, Pollack, Wassertheil-Smoller, Brunner, Curb, Torner, Oberman, Hendrix, Hsia, Sheps	12	Gen	Psychosom Med. 2006 Nov-Dec;68(6):824-32. Epub 2006 Nov 13	AS70
186	Physical activity and diabetes risk in postmenopausal women	**Hsia**, Wu, Allen, Oberman, Lawson, Torrens, Safford, Limacher, Howard, Women's Health Initiative Research Group	12	Gen	Am J Prev Med. 2005 Jan;28(1):19-25	
187	Postmenopausal hormone therapy and cardiovascular disease	**Rossouw**	12	OS	In: Yusuf S, ed. Evidence based cardiology. 2nd ed. London: BMJ Books,2002:244-58	
188	Electrocardiographic abnormalities that predict coronary heart disease events and mortality in postmenopausal women: The Women's Health Initiative	**Rautaharju**, Kooperberg, Larson, LaCroix	12	CT	Circulation. 2006 Jan 31;113(4):473-80	

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Ms ID	Title	Authors	Status	Data Focus	Reference	Study
189	Dietary adherence in the Women's Health Initiative Dietary Modification Trial	**The Women's Health Initiative Study Group**	12	CT	J Am Diet Assoc. 2004 Apr;104(4):654-8	
190	Prevalence and determinants of electrocardiographic left ventricular hypertrophy among a multiethnic population of postmenopausal women (The Women's Health Initiative)	**Oberman**, Prineas, Larson, LaCroix, Lasser	12	CT	Am J Cardiol. 2006 Feb 15;97(4):512-9. Epub 2006 Jan 4	
192	Bone mineral density of American Indian and Alaska Native women compared with non-Hispanic white women: Results from the Women's Health Initiative Study	**Wampler**, Chen, Jacobsen, Henderson, Howard, Rossouw	12	Gen	Menopause. 2005 Sep-Oct;12(5):536-44. Epub 2005 Sep 1	
196	Predictors of dietary change and maintenance in the Women's Health Initiative Dietary Modification Trial	**Tinker**, Rosal, Young, Perri, Patterson, VanHorn, Assaf, Bowen, Ockene, Hays, Wu	12	CT	J Am Diet Assoc. 2007 Jul;107(7):1155-65	
197	Predictors of angina pectoris versus myocardial infarction from the Women's Health Initiative Observational Study	**Hsia**, Aragaki, Bloch, LaCroix, Wallace, Women's Health Initiative Investigators.	12	OS	Am J Cardiol. 2004 Mar 15;93(6):673-8	
198	The Women's Health Initiative: Aspects of the management and coordination	**Cochrane**, Lund, Anderson, Prentice	12	Gen	In: Hawkins JW, Haggerty LA, eds. Diversity in health care research: strategies for multisite, multidisciplinary, and multi-ethnic projects. New York: Springer,2003:181-207	
200	Expression and ambivalence over expression of negative emotion: Psychometric analysis in the Women's Health Initiative	**Michael**, Perrin, Bowen, Cochrane, Wisdom, Brzyski, Ritenbaugh	12	Gen	J Women Aging. 2005;17(1-2):5-18	
201	Normal standards for QT and QT subintervals derived from a large ethnically diverse population of women aged 50 to 79 years (the Women's Health Initiative [WHI])	**Rautaharju**, Prineas, Kadish, Larson, Hsia, Lund	12	Gen	Am J Cardiol. 2006 Mar 1;97(5):730-7. Epub 2006 Jan 11	

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Ms ID	Title	Authors	Status	Data Focus	Reference	Study
202	Depressive symptoms and heart rate variability in postmenopausal women	**Kim**, McGorray, Bartholomew, Marsh, Dicken, Wassertheil-Smoller, Curb, Oberman Barton, McMahon, Hsia, Gardin, Wong, Barton	12	Gen	Arch Intern Med. 2005 Jun 13;165(11):1239-44	
203	Influence of estrogen plus progestin on breast cancer and mammography in healthy postmenopausal women: The Women's Health Initiative Randomized Trial	**Chlebowski**, Hendrix, Langer, Stefanick, Gass, Lane, Rodabough, Gilligan, Cyr, Thomson, Khandekar, Petrovich, McTiernan, Women's Health Initiative Investigators	12	CT	JAMA. 2003 Jun 25;289(24):3243-53	
204	Effect of estrogen plus progestin on stroke in postmenopausal women: the Women's Health Initiative: A randomized trial	**Wassertheil-Smoller**, Hendrix, Limacher, Heiss, Kooperberg, Baird, Kotchen, Curb, Black, Rossouw, Aragaki, Safford, Stein, Laowattana, Mysiw	12	CT	JAMA. 2003 May 28;289(20):2673-84	W1, W6
206	Fracture risk among breast cancer survivors: Results from the Women's Health Initiative Observational Study	**Chen**, Maricic, Bassford, Pettinger, Ritenbaugh, Lopez, Barad, Gass, LeBoff	12	Gen	Arch Intern Med. 2005 Mar 14;165(5):552-8	
208	Effects of estrogen plus progestin on risk of fracture and bone mineral density: The Women's Health Initiative randomized trial	**Cauley**, Robbins, Chen, Cummings, Jackson, LaCroix, LeBoff, Lewis, McGowan, Neuner, Pettinger, Stefanick, Wactawski-Wende, Watts, Women's Health Initiative Investigators	12	CT	JAMA. 2003 Oct 1;290(13):1729-38	
209	Obesity, hormone therapy, estrogen metabolism and risk of postmenopausal breast cancer	**Modugno**, Kip, Cochrane, Kuller, Klug, Rohan, Chlebowski, Lasser, Stefanick	12	OS	Int J Cancer. 2006 Mar 1;118(5):1292-301	AS134
210	Estrogen plus progestin and the risk of coronary heart disease	**Manson**, Hsia, Johnson, Rossouw, Assaf, Lasser, Trevisan, Black, Heckbert, Detrano, Strickland, Wong, Crouse, Stein, Cushman	12	CT	N Engl J Med. 2003 Aug 7;349(6):523-34	W1, W6

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Ms ID	Title	Authors	Status	Data Focus	Reference	Study
211	Effects of estrogen plus progestin on health-related quality of life	**Hays**, Ockene, Brunner, Kotchen, Manson, Patterson, Aragaki, Shumaker, Brzyski, LaCroix, Granek, Valanis, Women's Health Initiative Investigators	12	CT	N Engl J Med. 2003 May 8;348(19):1839-54. Epub 2003 Mar 17	
212	Effect of oestrogen plus progestin on the incidence of diabetes in postmenopausal women: Results from the Women's Health Initiative Hormone Trial	**Margolis**, Bonds, Rodabough, Tinker, Phillips, Allen, Bassford, Burke, Torrens, Howard, Women's Health Initiative Investigators	12	CT	Diabetologia. 2004 Jul;47(7):1175-87. Epub 2004 Jul 14	
216	Effects of combination estrogen plus progestin hormone treatment on cognition and affect [WHISCA]	**Resnick**, Maki, Rapp, Espeland, Brunner, Coker, Granek, Hogan, Ockene, Shumaker, Women's Health Initiative Study of Cognitive Aging Investigators	12	CT	J Clin Endocrinol Metab. 2006 May;91(5):1802-10. Epub 2006 Mar 7	AS103
220	The Women's Health Initiative: Implications for practice	**Furniss**	12	CT	Adv Nurse Pract. 2002 Nov;10(11):53-5	
221	Effects of estrogen plus progestin on gynecologic cancers and associated diagnostic procedures: The Women's Health Initiative randomized trial	**Anderson**, Judd, Kaunitz, Barad, Beresford, Pettinger, Liu, McNeeley, Lopez, Women's Health Initiative Investigators	12	CT	JAMA. 2003 Oct 1;290(13):1739-48	
222	Estrogen plus progestin and risk of venous thrombosis	**Cushman**, Kuller, Prentice, Rodabough, Psaty, Stafford, Sidney, Rosendaal, Women's Health Initiative Investigators	12	CT	JAMA. 2004 Oct 6;292(13):1573-80	W1, W6
224	Estimation of dependence between paired correlated failure times in the presence of covariate measurement error	**Gorfine**, Hsu, Prentice	12	OS	J R Stat Soc [Ser B]. 2003;65(3):633-61	
225	Estrogen plus progestin and the incidence of dementia and mild cognitive impairment in postmenopausal women: the Women's Health Initiative Memory Study: A randomized controlled trial [WHIMS]	**Shumaker**, Legault, Rapp, Thal, Wallace, Ockene, Hendrix, Jones, Assaf, Jackson, Kotchen, Wassertheil-Smoller, Wactawski-Wende, The WHIMS Investigators	12	CT	JAMA. 2003 May 28;289(20):2651-62	AS39

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Publications – Stages 3 through 12

Ms ID	Title	Authors	Status	Data Focus	Reference	Study
226	Effect of estrogen plus progestin on global cognitive function in postmenopausal women: the Women's Health Initiative Memory Study: A randomized controlled trial [WHIMS]	**Rapp**, Espeland, Shumaker, Henderson, Brunner, Manson, Gass, Stefanick, Lane, Hays, Johnson, Coker, Dailey, Bowen, The WHIMS Investigators	12	CT	JAMA. 2003 May 28;289(20):2663-72	AS39
229	Menopausal symptoms and treatment-related effects of estrogen and progestin in the Women's Health Initiative	**Barnabei**, Cochrane, Aragaki, Nygaard, Williams, McGovern, Young, Wells, O'Sullivan, Chen, Schenken, Johnson, Women's Health Initiative Investigators	12	CT	Obstet Gynecol. 2005 May;105(5 Pt 1):1063-73	
230	Use of electric blankets and association with prevalence of endometrial cancer	**Abel**, Hendrix, McNeeley, O'Leary, Mossavar-Rahmani, Johnson, Kruger	12	OS	Eur J Cancer Prev. 2007 Jun;16(3):243-50	
232	Women's Health Initiative: Statistical aspects and selected early results	**Prentice**, Anderson	12	Gen	In: Armitage P, Colton T, eds. Encyclopedia of biostatistics. 2nd ed. Wiley,2005	
233	Estrogen plus progestin and colorectal cancer in postmenopausal women	**Chlebowski**, Wactawski-Wende, Ritenbaugh, Hubbell, Ascensao, Rodabough, Rosenberg, Taylor, Harris, Chen, Adams-Campbell, White, Women's Health Initiative Investigators	12	CT	N Engl J Med. 2004 Mar 4;350(10):991-1004	
234	Postmenopausal hormone therapy and body composition: A substudy of the estrogen plus progestin trial of the Women's Health Initiative	**Chen**, Bassford, Green, Cauley, Jackson, LaCroix, LeBoff, Stefanick, Margolis	12	CT	Am J Clin Nutr. 2005 Sep;82(3):651-6	
235	Hormone replacement therapy and risk of cardiovascular disease: Implications of the results of the Women's Health Initiative	**Kuller**	12	CT	Arterioscler Thromb Vasc Biol. 2003 Jan 1;23(1):11-6	
237	The Women's Health Initiative Study of Cognitive Aging (WHISCA): A randomized clinical trial of the effects of hormone therapy on age-associated cognitive decline [WHISCA]	**Resnick**, Coker, Maki, Rapp, Espeland, Shumaker	12	CT	Clin Trials. 2004;1(5):440-50	AS103

Table 11.2 (continued)
Publications – Stages 3 through 12

Ms ID	Title	Authors	Status	Data Focus	Reference	Study
240	Risks and benefits of estrogen plus progestin in healthy postmenopausal women: Principal results From the Women's Health Initiative randomized controlled trial	**Rossouw**, Anderson, Prentice, LaCroix, Kooperberg, Stefanick, Jackson, Beresford, Howard, Johnson, Kotchen, Ockene, The Writing Group for the Women's Health Initiative Investigators	12	CT	JAMA. 2002 Jul 17;288(3):321-33	W1
242	Estrogen deficiency symptom management in breast cancer survivors in the changing context of menopausal hormone therapy	**Chlebowski**, Kim, Col	12	CT	Semin Oncol. 2003 Dec;30(6):776-88	
243	Combined postmenopausal hormone therapy and cardiovascular disease: Toward resolving the discrepancy between observational studies and the Women's Health Initiative clinical trial	**Prentice**, Langer, Stefanick, Howard, Pettinger, Anderson, Barad, Curb, Kotchen, Kuller, Limacher, Wactawski-Wende, Women's Health Initiative Investigators	12	CT	Am J Epidemiol. 2005 Sep 1;162(5):404-14. Epub 2005 Jul 20	
246	WHI response to Goodman, Goldzieher and Ayala's critique of the Women's Health Initiative report on the risks and benefits of estrogen plus progestin	**Hendrix**, Prentice	12	CT	Menopausal Medicine. 2003;11:1-4	
248	Progression of coronary calcification in healthy postmenopausal women	**Hsia**, Klouj, Prasad, Burt, Adams-Campbell, Howard	12	OS	BMC Cardiovasc Disord. 2004 Dec 1;4:21	
249	Effects of estrogen with and without progestin on urinary incontinence	**Hendrix**, Cochrane, Nygaard, Handa, Barnabei, Iglesia, Aragaki, Naughton, Wallace, McNeeley	12	CT	JAMA. 2005 Feb 23;293(8):935-48	
250	Hormone therapy and age-related macular degeneration: The Women's Health Initiative Sight Exam Study [WHISE]	**Haan**, Klein, Klein, Deng, Blythe, Seddon, Musch, Kuller, Hyman, Wallace	12	CT	Arch Ophthalmol. 2006 Jul;124(7):988-92	AS62
253	Cardiovascular disease, its risk factors and treatment, and age-related macular degeneration: Women's Health Initiative Sight Exam ancillary study [WHISE]	**Klein**, Deng, Klein, Hyman, Seddon, Frank, Wallace, Hendrix, Kuppermann, Langer, Kuller, Brunner, Johnson, Thomas, Haan	12	CT	Am J Ophthalmol. 2007 Mar;143(3):473-83. Epub 2007 Jan 10	AS62
265	Comparing SF-36 scores across three groups of women with different health profiles	**Yost**, Haan, Levine, Gold	12	Gen	Qual Life Res. 2005 Jun;14(5):1251-61	

Table 11.2 (continued)
Publications – Stages 3 through 12

Ms ID	Title	Authors	Status	Data Focus	Reference	Study
271	Factors associated with treatment initiation after osteoporosis screening	**Brennan**, Wactawski-Wende, Crespo, Dmochowski	12	CT	Am J Epidemiol. 2004 Sep 1;160(5):475-83	AS98
272	Effect of estrogen therapy on gallbladder disease	**Cirillo**, Wallace, Rodabough, Greenland, LaCroix, Limacher, Larson	12	CT	JAMA. 2005 Jan 19;293(3):330-9	
273	Effects of conjugated equine estrogen in postmenopausal women with hysterectomy. The Women's Health Initiative randomized controlled trial	**Anderson**, Limacher, Assaf, Bassford, Beresford, Black, Bonds, Brunner, Brzyski, Caan, Chlebowski, Curb, Gass, Hays, et al	12	CT	JAMA. 2004 Apr 14;291(14):1701-12	W1, W6
274	Association between reported alcohol intake and cognition: Results from the Women's Health Initiative Memory Study [WHIMS]	**Espeland**, Gu, Masaki, Langer, Coker, Stefanick, Ockene, Rapp	12	CT	Am J Epidemiol. 2005 Feb 1;161(3):228-38	AS39
277	Estrogen plus progestin and the risk of peripheral arterial disease: The Women's Health Initiative	**Hsia**, Criqui, Rodabough, Langer, Resnick, Phillips, Allison, Bonds, Masaki, Caralis, Kotchen, Women's Health Initiative Investigators	12	CT	Circulation. 2004 Feb 10;109(5):620-6	
279	Symptom experience after discontinuing use of estrogen plus progestin	**Ockene**, Barad, Cochrane, Larson, Gass, Wassertheil-Smoller, Manson, Barnabei, Lane, Brzyski, Rosal, Wylie-Rosette, Hays	12	CT	JAMA. 2005 Jul 13;294(2):183-93	
280	Relation of BMI and physical activity to sex hormones in postmenopausal women	**McTiernan**, Wu, Chen, Chlebowski, Mossavar-Rahmani, Modugno, Perri, Stanczyk, VanHorn, Wang, Women's Health Initiative Investigators	12	CT	Obesity (Silver Spring). 2006 Sep;14(9):1662-77	W5
282	Improving dietary self-monitoring and adherence with hand-held computers: A pilot study	**Glanz**, Murphy, Moylan, Evensen, Curb	12	CT	Am J Health Promot. 2006 Jan-Feb;20(3):165-70	
285	Estrogen-plus-progestin use and mammographic density in postmenopausal women: Women's Health Initiative randomized trial	**McTiernan**, Martin, Peck, Aragaki, Chlebowski, Pisano, Wang, Brunner, Johnson, Manson, Lewis, Kotchen, Hulka, Women's Health Initiative Mammogram Density Study Investigators	12	CT	J Natl Cancer Inst. 2005 Sep 21;97(18):1366-76	AS36

Table 11.2 (continued)
Publications – Stages 3 through 12

Ms ID	Title	Authors	Status	Data Focus	Reference	Study
287	Prior hormone therapy and breast cancer risk in the Women's Health Initiative randomized trial of estrogen plus progestin	**Anderson**, Chlebowski, Rossouw, Rodabough, McTiernan, Margolis, Aggerwal, Curb, Hendrix, Hubbell, Khandekar, Lane, Lasser, Lopez, Potter	12	CT	Maturitas. 2006 Sep 20;55(2):103-15. Epub 2006 Jul 11	
288	Insulin, physical activity, and caloric intake in postmenopausal women: Breast cancer implications	**Chlebowski**, Pettinger, Stefanick, Howard, Mossavar-Rahmani, McTiernan	12	Gen	J Clin Oncol. 2004 Nov 15;22(22):4507-13	
289	Cutaneous melanoma in postmenopausal women following nonmelanoma skin carcinoma: The Women's Health Initiative Observational Study	**Rosenberg**, Khandekar, Greenland, Rodabough, McTiernan	12	OS	Cancer. 2006 Feb 1;106(3):654-63	
292	Menopausal hormone therapy informed consent	**Hendrix**	12	Gen	Am J Obstet Gynecol. 2003 Oct;189(4 Suppl):S31-2; discussion S32-6	
294	Weighted estimators for proportional hazards regression with missing covariates	**Qi**, Wang, Prentice	12	OS	J Am Stat Assoc. 2005;100:1250-63	
298	The association between aspirin use and the incidence of colorectal cancer in women	**Allison**, Garland, Chlebowski, Criqui, Langer, Wu, Roy, McTiernan, Kuller, Women's Health Initiative Investigators	12	OS	Am J Epidemiol. 2006 Sep 15;164(6):567-75. Epub 2006 Jul 17	
302	Frailty: Emergence and consequences in women aged 65 and older in the Women's Health Initiative Observational Study	**Woods**, LaCroix, Gray, Aragaki, Cochrane, Brunner, Masaki, Murray, Newman	12	Gen	J Am Geriatr Soc. 2005 Aug;53(8):1321-30	AS179
303	Statin use and incident frailty in women aged 65 years or older: Prospective findings from the Women's Health Initiative Observational Study	**LaCroix**, Gray, Aragaki, Cochrane, Newman, Kooperberg, Black, Curb, Greenland, Woods	12	Gen	J Gerontol A Biol Sci Med Sci. 2008 Apr;63(4):369-75	AS179
307	Predictors of optical density of lutein and zeaxanthin in retinas of older women in the Carotenoids in Age-Related Eye Disease Study, an ancillary study of the Women's Health Initiative [CAREDS]	**Mares-Perlman**, LaRowe, Snodderly, Moeller, Gruber, Klein, Wooten, Johnson, Chappel, CAREDS Macular Pigment Study Group and Investigators	12	OS	Am J Clin Nutr. 2006 Nov;84(5):1107-22	AS105
316	Daily coffee consumption and prevalence of nonmelanoma skin cancer in Caucasian women	**Abel**, Hendrix, McNeeley, Johnson, Rosenberg, Mossavar-Rahmani, Vitolins, Kruger	12	OS	Eur J Cancer Prev. 2007 Oct;16(5):446-452	

Table 11.2 (continued)
Publications – Stages 3 through 12

Ms ID	Title	Authors	Status	Data Focus	Reference	Study
317	Pelvic organ prolapse in older women: Prevalence and risk factors	**Nygaard**, Bradley, Brandt, Women's Health Initiative	12	CT	Obstet Gynecol. 2004 Sep;104(3):489-97	AS135
318	Depressive symptoms, bone loss, and fractures in postmenopausal women	**Spangler**, Scholes, Brunner, Robbins, Reed, Newton, Melville, LaCroix	12	OS	J Gen Intern Med. 2008 May;23(5):567-74. Epub 2008 Feb 20	AS173
322	Postmenopausal hormone therapy and risk of cardiovascular disease by age and years since menopause	**Rossouw**, Prentice, Manson, Wu, Barad, Barnabei, Ko, LaCroix, Margolis, Stefanick	12	CT	JAMA. 2007 Apr 4;297(13):1465-77	
323	Vaginal wall descensus and pelvic floor symptoms in older women	**Bradley**, Nygaard	12	OS	Obstet Gynecol. 2005 Oct;106(4):759-66	AS135
324	Mortality and cardiac and vascular outcomes in extremely obese women	**McTigue**, Larson, Valoski, Burke, Kotchen, Lewis, Stefanick, VanHorn, Kuller	12	OS	JAMA. 2006 Jul 5;296(1):79-86	
325	Association between alcohol intake and domain-specific cognitive function in older women [WHISCA]	**Espeland**, Coker, Wallace, Rapp, Resnick, Limacher, Powell, Messina, Women's Health Initiative Study of Cognitive Aging	12	CT	Neuroepidemiology. 2006;27(1):1-12. Epub 2006 May 24	AS103
326	The association between osteoporosis and alveolar crestal height in postmenopausal women	**Wactawski-Wende**, Hausmann, Hovey, Trevisan, Grossi, Genco	12	CT	J Periodontol. 2005 Nov;76(11 Suppl):2116-24	AS98
327	Low-fat dietary pattern and weight change over 7 years: The Women's Health Initiative Dietary Modification Trial	**Howard**, Manson, Stefanick, Beresford, Frank, Jones, Rodabough, Snetselaar, Thomson, Tinker, Vitolins, Prentice	12	CT	JAMA. 2006 Jan 4;295(1):39-49	
328	Prospective study of leukocyte count as a predictor of incident breast, colorectal, endometrial, and lung cancer and mortality in postmenopausal women	**Margolis**, Rodabough, Thomson, Lopez, McTiernan, for the Women's Health Initiative Research Group	12	OS	Arch Intern Med. 2007 Sep 24;167(17):1837-44	
330	Effects of estrogen with and without progestin and obesity on symptomatic gastroesophageal reflux	**Zheng**, Margolis, Liu, Tinker, Ye, Women's Health Initiative Investigators	12	CT	Gastroenterology. 2008 Jul;135(1):72-81. Epub 2008 Mar 25	
331	Pelvic floor symptoms and lifestyle factors in older women	**Bradley**, Kennedy, Nygaard	12	CT	J Womens Health (Larchmt). 2005 Mar;14(2):128-36	AS135

Table 11.2 (continued)
Publications – Stages 3 through 12

Ms ID	Title	Authors	Status	Data Focus	Reference	Study
332	Conjugated equine estrogens and global cognitive function in postmenopausal women: Women's Health Initiative Memory Study [WHIMS]	**Espeland**, Rapp, Shumaker, Brunner, Manson, Sherwin, Hsia, Margolis, Hogan, Wallace, Dailey, Freeman, Hays	12	WHIMS	JAMA. 2004 Jun 23;291(24):2959-68	AS39
336	Conjugated equine estrogens and incidence of probable dementia and mild cognitive impairment in postmenopausal women: Women's Health Initiative Memory Study [WHIMS]	**Shumaker**, Legault, Kuller, Rapp, Thal, Lane, Fillit, Stefanick, Hendrix, Lewis, Masaki, Coker	12	WHIMS	JAMA. 2004 Jun 23;291(24):2947-58	AS39
337	Estrogen plus progestin therapy and breast cancer in recently postmenopausal women	**Prentice**, Chlebowski, Stefanick, Manson, Pettinger, Hendrix, Kooperberg, Kuller, Lane, McTiernan, O'Sullivan, Rossouw, Anderson	12	Gen	Am J Epidemiol. 2008 May 15;167(10):1207-16. Epub 2008 Mar 27	
339	Validity of diabetes self-reports in the Women's Health Initiative: comparison with medication inventories and fasting glucose measurements	**Margolis**, Qi, Brzyski, Bonds, Howard, Kempainen, Liu, Robinson, Safford, Tinker, Phillips	12	Gen	Clin Trials. 2008;5(3):240-7	AS132
340	Hormone therapy improves femur geometry among ethnically diverse postmenopausal participants in the Women's Health Initiative Hormone Intervention Trials	**Chen**, Beck, Cauley, Lewis, LaCroix, Bassford, Wu, Sherrill, Going	12	CT	J Bone Miner Res. 2008 Jul 29. [Epub ahead of print]	AS153
341	Race/ethnicity, socioeconomic status, and lifetime morbidity burden in the Women's Health Initiative: A cross-sectional analysis	**Gold**, Michael, Whitlock, Hubbell, Mason, Rodriguez, Safford, Sarto	12	Gen	J Womens Health (Larchmt). 2006 Dec;15(10):1161-73	
342	Body mass index is not a good predictor of bone density: Results from WHI, CHS, and EPIDOS	**Robbins**, Schott, Azari, Kronmal	12	OS	J Clin Densitom. 2006 Jul-Sep;9(3):329-34	
343	Effects of conjugated equine estrogens on breast cancer and mammography screening in postmenopausal women with hysterectomy	**Stefanick**, Anderson, Margolis, Hendrix, Rodabough, Paskett, Lane, Hubbell, Assaf, Sarto, Schenken, Yasmeen, Lessin, Chlebowski, Women's Health Initiative Investigators	12	CT	JAMA. 2006 Apr 12;295(14):1647-57	
344	Elderly women diagnosed with nonspecific chest pain may be at increased cardiovascular risk	**Robinson**, Wallace, Limacher, Sato, Cochrane, Wassertheil-Smoller, Ockene, Blanchette, Ko	12	Gen	J Womens Health (Larchmt). 2006 Dec;15(10):1151-60	

Table 11.2 (continued)
Publications – Stages 3 through 12

Ms ID	Title	Authors	Status	Data Focus	Reference	Study
345	Conjugated equine estrogens and coronary heart disease: The Women's Health Initiative	**Hsia**, Langer, Manson, Kuller, Johnson, Hendrix, Pettinger, Heckbert, Greep, Crawford, Eaton, Kostis, Caralis, Prentice, Women's Health Initiative Investigators	12	CT	Arch Intern Med. 2006 Feb 13;166(3):357-65	W1, W6
346	Estrogen plus progestin and breast cancer detection by means of mammography and breast biopsy	**Chlebowski**, Anderson, Pettinger, Lane, Langer, Gilligan, Walsh, Chen, McTiernan	12	CT	Arch Intern Med. 2008 Feb 25;168(4):370-377	
347	Effects of conjugated equine estrogen on stroke in the Women's Health Initiative	**Hendrix**, Wassertheil-Smoller, Johnson, Howard, Kooperberg, Rossouw, Trevisan, Aragaki, Baird, Bray, Buring, Criqui, Herrington, Lynch, Rapp	12	CT	Circulation. 2006 May 23;113(20):2425-34. Epub 2006 May 15	W1, W6
348	Effects of conjugated equine estrogen on health-related quality of life in postmenopausal women with hysterectomy: Results from the Women's Health Initiative randomized clinical trial	**Brunner**, Gass, Aragaki, Hays, Granek, Woods, Mason, Brzyski, Ockene, Assaf, LaCroix, Matthews, Wallace, Women's Health Initiative Investigators	12	CT	Arch Intern Med. 2005 Sep 26;165(17):1976-86	
350	Venous thrombosis and conjugated equine estrogen in women without a uterus	**Curb**, Prentice, Bray, Langer, VanHorn, Barnabei, Bloch, Cyr, Gass, Lepine, Rodabough, Sidney, Uwaifo, Rosendaal	12	CT	Arch Intern Med. 2006 Apr 10;166(7):772-80	W1, W6
352	Body size, weight cycling, and risk of renal cell carcinoma among postmenopausal women: The Women's Health Initiative (United States)	**Luo**, Margolis, Adami, Lopez, Lessin, Ye, Women's Health Initiative Investigators	12	Gen	Am J Epidemiol. 2007 Oct 1;166(7):752-9. Epub 2007 Jul 5	
354	Effects of conjugated equine estrogen on risk of fractures and BMD in postmenopausal women with hysterectomy: Results from the women's health initiative randomized trial	**Jackson**, Wactawski-Wende, LaCroix, Pettinger, Yood, Watts, Robbins, Lewis, Beresford, Ko, Naughton, Satterfield, Bassford, Women's Health Initiative Investigators	12	CT	J Bone Miner Res. 2006 Jun;21(6):817-28	

Table 11.2 (continued)
Publications – Stages 3 through 12

Ms ID	Title	Authors	Status	Data Focus	Reference	Study
357	The effect of conjugated equine oestrogen on diabetes incidence: The Women's Health Initiative randomised trial	**Bonds**, Lasser, Qi, Brzyski, Caan, Heiss, Limacher, Liu, Mason, Oberman, O'Sullivan, Phillips, Prineas, Tinker	12	CT	Diabetologia. 2006 Mar;49(3):459-68. Epub 2006 Jan 27	
359	Risk of fracture in women with type 2 diabetes: The Women's Health Initiative Observational Study	**Bonds**, Larson, Schwartz, Strotmeyer, Robbins, Rodriguez, Johnson, Margolis	12	OS	J Clin Endocrinol Metab. 2006 Sep;91(9):3404-10. Epub 2006 Jun 27	
361	Effect of hormone therapy on risk of hip and knee joint replacement in the Women's Health Initiative	**Cirillo**, Wallace, Wu, Yood	12	CT	Arthritis Rheum. 2006 Oct;54(10):3194-204	
362	Effects of postmenopausal hormone therapy on rheumatoid arthritis: The Women's Health Initiative randomized controlled trials	**Walitt**, Pettinger, Weinstein, Katz, Torner, Wasko, Howard, Women's Health Initiative Investigators	12	CT	Arthritis Rheum. 2008 Mar 15;59(3):302-10. Epub 2008 Feb 28	
363	Long-term exposure to air pollution and incidence of cardiovascular events in women	**Miller**, Siscovick, Sheppard, Shepherd, Sullivan, Anderson, Kaufman	12	CT	N Engl J Med. 2007 Feb 1;356(5):447-58	AS150
367	The Women's Health Initiative: A potential resource for future studies of autoimmune diseases	**Howard**	12	Gen	Autoimmunity. 2004 Jun;37(4):265-8	
368	Postmenopausal hormone therapy in relation to cardiovascular disease and cognition	**Prentice**	12	CT	Proceedings of the Forty Seventh Study Group of the Royal College of Obstetricians and Gynecologists. 2004	
369	A prospective study of inflammatory cytokines and diabetes mellitus in a multiethnic cohort of postmenopausal women	**Liu**, Tinker, Song, Rifai, Bonds, Cook, Heiss, Howard, Hotamisligil, Hu, Kuller, Manson	12	OS	Arch Intern Med. 2007 Aug 13-27;167(15):1676-85	AS132
370	Benchmarks for designing two-stage studies using modified mini-mental state examinations: Experience from the Women's Health Initiative Memory Study [WHIMS]	**Espeland**, Rapp, Robertson, Granek, Murphy, Albert, Bassford	12	CT	Clin Trials. 2006;3(2):99-106	AS39
371	Associations between intermediate age-related macular degeneration and lutein and zeaxanthin in the Carotenoids in Age-related Eye Disease Study (CAREDS): Ancillary study of the Women's Health Initiative [CAREDS]	**Moeller**, Parekh, Tinker, Ritenbaugh, Blodi, Wallace, Mares-Perlman	12	OS	Arch Ophthalmol. 2006 Aug;124(8):1151-62	AS105

Table 11.2 (continued)
Publications – Stages 3 through 12

Ms ID	Title	Authors	Status	Data Focus	Reference	Study
372	Factors associated with 5-year risk of hip fracture in postmenopausal women	**Robbins**, Aragaki, Kooperberg, Watts, Wactawski-Wende, Jackson, LeBoff, Lewis, Chen, Stefanick, Cauley	12	OS	JAMA. 2007 Nov 28;298(20):2389-98	
373	Conjugated equine estrogens and peripheral arterial disease risk: The Women's Health Initiative	**Hsia**, Criqui, Herrington, Manson, Wu, Heckbert, Allison, McDermott, Robinson, Masaki, Women's Health Initiative Research Group	12	CT	Am Heart J. 2006 Jul;152(1):170-6	
376	Circulating levels of endothelial adhesion molecules and risk of diabetes in an ethnically diverse cohort of women	**Song**, Manson, Tinker, Rifai, Cook, Hu, Hotamisligil, Ridker, Rodriguez, Margolis, Oberman, Liu	12	OS	Diabetes. 2007 Jul;56(7):1898-904. Epub 2007 Mar 27	AS132
378	Expression and ambivalence over expression of negative emotion: Cross-sectional associations with psychosocial factors and health-related quality of life in postmenopausal women	**Michael**, Wisdom, Perrin, Bowen, Cochrane, Brzyski, Ritenbaugh	12	Gen	J Women Aging. 2006;18(2):25-40	
385	Development of a glycemic index database for food frequency questionnaires used in epidemiologic studies	**Neuhouser**, Tinker, Thomson, Caan, VanHorn, Snetselaar, Parker, Patterson, Robinson, Beresford, Shikany	12	CT	J Nutr. 2006 Jun;136(6):1604-9	AS111
387	Major and minor ECG abnormalities in asymptomatic women and risk of cardiovascular events and mortality	**Denes**, Larson, Lloyd-Jones, Prineas, Greenland	12	CT	JAMA. 2007 Mar 7;297(9):978-85	
388	Accuracy of commercial geocoding: Assessment and implications	**Whitsel**, Quibrera, Smith, Catellier, Liao, Henley, Heiss	12	CT	Epidemiol Perspect Innov. 2006 Jul 20;3:8	AS140
394	Association between cigarette smoking and colorectal cancer in the Women's Health Initiative	**Paskett**, Reeves, Rohan, Allison, Williams, Messina, Whitlock, Sato, Hunt	12	Gen	J Natl Cancer Inst. 2007 Nov 21;99(22):1729-35. Epub 2007 Nov 13	
398	Osteoporosis and rate of bone loss among postmenopausal survivors of breast cancer	**Chen**, Maricic, Pettinger, Ritenbaugh, Lopez, Barad, Gass, LeBoff, Bassford	12	OS	Cancer. 2005 Oct 1;104(7):1520-30	
401	Are depressive symptoms associated with cancer screening and cancer stage at diagnosis among postmenopausal women? The Women's Health Initiative Observational Cohort	**Aggarwal**, Freund, Sato, Adams-Campbell, Lopez, Lessin, Ockene, Wallace, Williams, Bonds	12	OS	J Womens Health (Larchmt). 2008 Sep 14. [Epub ahead of print]	

Table 11.2 (continued)
Publications – Stages 3 through 12

Ms ID	Title	Authors	Status	Data Focus	Reference	Study
404	Fracture risk increases after diagnosis of breast or other cancers in postmenopausal women: Results from the Women's Health Initiative	**Chen**, Maricic, Aragaki, Mouton, Arendell, Lopez, Bassford, Chlebowski	12	Gen	Osteoporos Int. 2008 Sep 3. [Epub ahead of print]	
409	Clinical risk factors for fractures in multi-ethnic women: The Women's Health Initiative	**Cauley**, Wu, Wampler, Barnhart, Allison, Chen, Jackson, Robbins	12	OS	J Bone Miner Res. 2007 Nov;22(11):1816-26	
414	Prehypertension and cardiovascular disease risk in the Women's Health Initiative	**Hsia**, Margolis, Eaton, Wenger, Allison, Wu, LaCroix, Black, Women's Health Initiative Investigators	12	CT	Circulation. 2007 Feb 20;115(7):855-60	
415	GIS approaches for the estimation of residential-level ambient PM concentrations	**Liao**, Peuquet, Duan, Whitsel, Dou, Smith, Lin, Chen, Heiss	12	CT	Environ Health Perspect. 2006 Sep;114(9):1374-80	AS140
417	Impact of cyclooxygenase inhibitors in the Women's Health Initiative Hormone Trials: Secondary analysis of a randomized trial	**Hsia**, Manson, Kuller, Pettinger, Choe, Langer, Limacher, Oberman, Ockene, O'Sullivan, Robinson	12	CT	PLoS Clin Trials. 2006 Sep 29;1(5):e26	
418	Linear measurement error models with restricted sampling	**Gorfine**, Lipshtat, Freedman, Prentice	12	CT	Biometrics. 2007 Mar;63(1):137-42	
421	Serum alpha-tocopherol, concurrent and past vitamin E intake, and mild cognitive impairment	**Dunn**, Weintraub, Stoddard, Banks	12	Gen	Neurology. 2007 Feb 27;68(9):670-6	AS84
423	Combined analysis of Women's Health Initiative observational and clinical trial data on postmenopausal hormone treatment and cardiovascular disease	**Prentice**, Langer, Stefanick, Howard, Pettinger, Anderson, Barad, Curb, Kotchen, Kuller, Limacher, Wactawski-Wende, Women's Health Initiative Investigators	12	Gen	Am J Epidemiol. 2006 Apr 1;163(7):589-99. Epub 2006 Feb 16	
428	Association of pelvic organ prolapse and fractures in postmenopausal women: Analysis of baseline data from the Women's Health Initiative Estrogen plus Progestin Trial	**Pal**, Hailpern, Santoro, Freeman, Barad, Kipersztok, Barnabei, Wassertheil-Smoller	12	Gen	Menopause. 2008 Jan-Feb;15(1):59-66; 2007 Aug 9 [Epub ahead of print]	
429	Can biomarkers identify women at increased stroke risk? The Women's Health Initiative Hormone Trials	**Kooperberg**, Cushman, Hsia, Robinson, Aragaki, Lynch, Baird, Johnson, Kuller, Beresford, Rodriguez	12	Gen	PLoS Clin Trials. 2007 Jun 15;2(6):e28	W6

Table 11.2 (continued)
Publications – Stages 3 through 12

Ms ID	Title	Authors	Status	Data Focus	Reference	Study
430	Sleep duration and risk of ischemic stroke in postmenopausal women	**Chen**, Brunner, Ren, Wassertheil-Smoller, Larson, Levine, Allison, Naughton, Stefanick	12	Gen	Stroke. 2008 Jul 17. [Epub ahead of print]	AS140
438	Walking speed and risk of incident ischemic stroke among postmenopausal women	**McGinn**, Kaplan, Verghese, Rosenbaum, Psaty, Baird, Lynch, Wolf, Kooperberg, Larson, Wassertheil-Smoller	12	Gen	Stroke. 2008 Apr;39(4):1233-9. Epub 2008 Feb 21	
440	Monitoring and reporting of the Women's Health Initiative randomized hormone therapy trials	**Anderson**, Kooperberg, Gellar, Rossouw, Pettinger, Prentice	12	CT	Clin Trials. 2007;4(3):207-17	
441	Calcium plus vitamin D supplementation and the risk of postmenopausal weight gain	**Caan**, Neuhouser, Aragaki, Lewis, Jackson, LeBoff, Margolis, Powell, Uwaifo, Whitlock, Wylie-Rosette, LaCroix	12	CT	Arch Intern Med. 2007 May 14;167(9):893-902	
444	Associations between age-related nuclear cataract and lutein and zeaxanthin in the diet and serum in the Carotenoids in the Age-Related Eye Disease Study, an Ancillary Study of the Women's Health Initiative [CAREDS]	**Moeller**, Voland, Tinker, Blodi, Klein, Gehrs, Johnson, Snodderly, Wallace, Chappell, Parekh, Ritenbaugh, Mares	12	OS	Arch Ophthalmol. 2008 Mar;126(3):354-364	AS105
445	Usefulness of baseline lipids and C-reactive protein in women receiving menopausal hormone therapy as predictors of treatment-related coronary events	**Bray**, Larson, LaCroix, Manson, Limacher, Rossouw, Lasser, Lawson, Stefanick, Langer, Margolis	12	Gen	Am J Cardiol. 2008 Jun 1;101(11):1599-1605. Epub 2008 Apr 2	W6
447	Low-fat dietary pattern and risk of cardiovascular disease: The Women's Health Initiative Randomized Controlled Dietary Modification Trial	**Howard**, VanHorn, Hsia, Manson, Stefanick, Wassertheil-Smoller, Kuller, LaCroix, Langer, Lasser, Lewis, Limacher, Margolis, Mysiw, et al	12	CT	JAMA. 2006 Feb 8;295(6):655-66	W1
448	Low-fat dietary pattern and risk of invasive breast cancer: The Women's Health Initiative Randomized Controlled Dietary Modification Trial	**Prentice**, Caan, Chlebowski, Patterson, Kuller, Ockene, Margolis, Limacher, Manson, Parker, Paskett, Phillips, Robbins, Rossouw, et al	12	CT	JAMA. 2006 Feb 8;295(6):629-42	W1, W33

Table 11.2 (continued)
Publications – Stages 3 through 12

Ms ID	Title	Authors	Status	Data Focus	Reference	Study
449	Low-fat dietary pattern and risk of colorectal cancer: The Women's Health Initiative Randomized Controlled Dietary Modification Trial.	**Beresford**, Johnson, Ritenbaugh, Lasser, Snetselaar, Black, Anderson, Assaf, Bassford, Bowen, Brunner, Brzyski, Caan, Chlebowski, et al	12	CT	JAMA. 2006 Feb 8;295(6):643-54	W1
450	Calcium plus vitamin D supplementation and the risk for fractures	**Jackson**, LaCroix, Gass, Wallace, Robbins, Lewis, Bassford, Beresford, Black, Blanchette, Bonds, Brunner, Brzyski, Caan, et al	12	CT	N Engl J Med. 2006 Feb 16;354(7):669-83	W15
451	Calcium plus vitamin D supplementation and the risk of colorectal cancer	**Wactawski-Wende**, Kotchen, Anderson, Assaf, Brunner, O'Sullivan, Margolis, Ockene, Phillips, Pottern, Prentice, Robbins, Rohan, Sarto, et al	12	CT	N Engl J Med. 2006 Feb 16;354(7):684-96	W15
452	Macular pigment density and age-related maculopathy in the Carotenoids in Age-Related Eye Disease Study. An ancillary study of the Women's Health Initiative [CAREDS]	**LaRowe**, Mares-Perlman, Snodderly, Klein, Wooten, Chappell, CAREDS Macular Pigment Study Group	12	CT	Ophthalmology. 2008 May;115(5):876-883.e1. Epub 2007 Sep 14	AS105
456	Dual-energy X-ray absorptiometry is a valid tool for assessing skeletal muscle mass in older women	**Chen**, Wang, Lohman, Heymsfield, Outwater, Nicholas, Bassford, LaCroix, Sherrill, Punyanitya, Wu, Going	12	Gen	J Nutr. 2007 Dec;137(12):2775-80	AS153
459	A prospective evaluation of insulin and insulin-like growth factor-I as risk factors for endometrial cancer	**Gunter**, Hoover, Yu, Wassertheil-Smoller, Manson, Li, Harris, Rohan, Xue, Ho, Einstein, Kaplan, Burk, Wylie-Rosette, Pollak	12	OS	Cancer Epidemiol Biomarkers Prev. 2008 Apr;17(4):921-9	AS129
460	Insulin, insulin-like growth factor-I, endogenous estradiol, and risk of colorectal cancer in postmenopausal women	**Gunter**, Hoover, Yu, Wassertheil-Smoller, Rohan, Manson, Howard, Wylie-Rosette, Anderson, Ho, Kaplan, Li, Xue, Harris, Burk	12	OS	Cancer Res. 2008 Jan 1;68(1):329-37	AS129
464	Use of recovery biomarkers to calibrate nutrient consumption self-reports in the Women's Health Initiative [NBS]	**Neuhouser**, Tinker, Shaw, Schoeller, Bingham, VanHorn, Beresford, Caan, Thomson, Satterfield, Kuller, Heiss, et al.	12	CT	Am J Epidemiol. 2008 May 15;167(10):1247-59. Epub 2008 Mar 15	W8

Table 11.2 (continued)
Publications – Stages 3 through 12

Ms ID	Title	Authors	Status	Data Focus	Reference	Study
469	Low-fat dietary pattern and cancer incidence in the Women's Health Initiative Dietary Modification Randomized Controlled Trial	**Prentice**, Thomson, Caan, Hubbell, Anderson, Beresford, Pettinger, Lane, Lessin, Yasmeen, Singh, Khandekar, Shikany, Satterfield, Chlebowski	12	CT	J Natl Cancer Inst. 2007 Oct 17;99(20):1534-43. Epub 2007 Oct 9	W31
471	Calcium/vitamin D supplementation and cardiovascular events	**Hsia**, Heiss, Ren, Allison, Dolan, Greenland, Heckbert, Johnson, Manson, Sidney, Trevisan, Women's Health Initiative Investigators	12	CT	Circulation. 2007 Feb 20;115(7):846-54	
475	Calcium, vitamin D supplementation, and physical function in the Women's Health Initiative	**Brunner**, Cochrane, Jackson, Larson, Lewis, Limacher, Rosal, Shumaker, Wallace, Women's Health Initiative Investigators	12	CT	J Am Diet Assoc. 2008 Sep;108(9):1472-9	
481	Associations of serum sex hormone-binding globulin and sex hormone concentrations with hip fracture risk in postmenopausal women	**Lee**, LaCroix, Wu, Cauley, Jackson, Kooperberg, LeBoff, Robbins, Lewis, Bauer, Cummings	12	OS	J Clin Endocrinol Metab. 2008 May;93(5):1796-803. Epub 2008 Mar 11	AS90
482	Plasma folate, vitamin B6, vitamin B12, and homocysteine and pancreatic cancer risk in four large cohorts	**Schernhammer**, Wolpin, Rifai, Cochrane, Manson, Ma, Giovannucci, Thomson, Stampfer, Fuchs	12	OS	Cancer Res. 2007 Jun 1;67(11):5553-60	AS146
483	Prediagnostic plasma C-peptide and pancreatic cancer risk in men and women	**Michaud**, Wolpin, Giovannucci, Liu, Cochrane, Manson, Pollak, Ma, Fuchs	12	OS	Cancer Epidemiol Biomarkers Prev. 2007 Oct;16(10):2101-9. Epub 2007 Sep 28	AS146
484	Circulating insulin-like growth factor axis and the risk of pancreatic cancer in four prospective cohorts	**Wolpin**, Michaud, Giovannucci, Schernhammer, Stampfer, Manson, Cochrane, Rohan, Ma, Pollak, Fuchs	12	OS	Br J Cancer. 2007 Jul 2;97(1):98-104. Epub 2007 May 29	AS146
486	Insulin sensitivity and insulin secretion determined by homeostasis model assessment and risk of diabetes in a multiethnic cohort of women: The Women's Health Initiative Observational Study	**Song**, Manson, Tinker, Howard, Kuller, Nathan, Rifai, Liu	12	OS	Diabetes Care. 2007 Jul;30(7):1747-52. Epub 2007 Apr 27	AS132

Table 11.2 (continued)
Publications – Stages 3 through 12

Ms ID	Title	Authors	Status	Data Focus	Reference	Study
492	Cardiovascular risk in women with non-specific chest pain (from the Women's Health Initiative Hormone Trials)	**Robinson**, Wallace, Limacher, Ren, Cochrane, Wassertheil-Smoller, Ockene, Blanchette, Ko	12	CT	Am J Cardiol. 2008 Sep 15;102(6):693-9. Epub 2008 Jul 2	
493	Panic attacks and risk of Incident cardiovascular events among postmenopausal women in the Women's Health Initiative observational study	**Smoller**, Pollack, Wassertheil-Smoller, Jackson, Oberman, Wong, Sheps	12	OS	Arch Gen Psychiatry. 2007 Oct;64(10):1153-60	
495	Natural history of pelvic organ prolapse in postmenopausal women	**Bradley**, Zimmerman, Qi, Nygaard	12	CT	Obstet Gynecol. 2007 Apr;109(4):848-54	AS135
496	Hip bone density predicts breast cancer risk independently of Gail score: Results from the Women's Health Initiative	**Chen**, Arendell, Aickin, Cauley, Lewis, Chlebowski	12	Gen	Cancer. 2008 Sep 1;113(5):907-15. Epub 2008 Jul 29	
501	Health risks and benefits 3 years after stopping randomized treatment with estrogen and progestin	**Heiss**, Wallace, Anderson, Aragaki, Beresford, Brzyski, Chlebowski, Gass, LaCroix, Manson, Prentice, Rossouw, Stefanick, Women's Health Initiative Investigators	12	CT	JAMA. 2008 Mar 5;299(9):1036-45	
503	Oophorectomy, hormone therapy, and subclinical coronary artery disease in women with hysterectomy: the Women's Health Initiative coronary artery calcium study [WHI-CACS]	**Allison**, Manson, Langer, Carr, Rossouw, Pettinger, Phillips, Cochrane, Eaton, Greenland, Hendrix, Hsia, Hunt, Jackson, Johnson	12	CT	Menopause. 2008 Jul-Aug;15(4 Pt 1):639-47. Epub 2008 May 2	W25
504	A comparison of two dietary instruments for evaluating the fat-breast cancer relationship	**Freedman**, Potischman, Kipnis, Midthune, Schatzkin, Thompson, Troiano, Prentice, Patterson, Carroll, Subar	12	CT	Int J Epidemiol. 2006 Aug;35(4):1011-21. Epub 2006 May 3	
506	Estrogen therapy and coronary-artery calcification [WHI-CACS]	**Manson**, Allison, Rossouw, Carr, Langer, Hsia, Kuller, Cochrane, Hunt, Ludlam, Pettinger, Gass, Margolis, Nathan, et al	12	CT	N Engl J Med. 2007 Jun 21;356(25):2591-602	W25
508	Alcohol and folate consumption and risk of benign proliferative epithelial disorders of the breast [Benign breast disease study]	**Cui**, Page, Chlebowski, Beresford, Hendrix, Lane, Rohan	12	CT	Int J Cancer. 2007 Sep 15;121(6):1346-51	AS130

Table 11.2 (continued)
Publications – Stages 3 through 12

Ms ID	Title	Authors	Status	Data Focus	Reference	Study
509	Cigarette smoking and risk of benign proliferative epithelial disorders of the breast in the Women's Health Initiative [Benign breast disease study]	**Cui**, Page, Chlebowski, Hsia, Hubbell, Johnson, Rohan	12	CT	Cancer Causes Control. 2007 May;18(4):431-8. Epub 2007 Feb 24	AS130
514	Selected antioxidants and risk of hormone receptor–defined invasive breast cancers among postmenopausal women in the Women's Health Initiative Observational Study	**Cui**, Shikany, Liu, Yasmeen, Rohan	12	OS	Am J Clin Nutr. 2008 Apr;87(4):1009-18	
518	Baseline monograph - foreword	**Rossouw**, Anderson, Oberman	12	Gen	Ann Epidemiol. 2003 Oct;13:S1-S4	
519	Implementation of the Women's Health Initiative study design	**Anderson**, Manson, Wallace, Lund, Hall, Davis, Shumaker, Wang, Stein, Prentice	12	Gen	Ann Epidemiol. 2003 Oct;13(9 Suppl):S5-17	
520	The Women's Health Initiative recruitment methods and results	**Hays**, Hunt, Hubbell, Anderson, Limacher, Allen, Rossouw	12	OS	Ann Epidemiol. 2003 Oct;13(9 Suppl):S18-77	W1
521	The Women's Health Initiative postmenopausal hormone trials: Overview and baseline characteristics of participants	**Stefanick**, Cochrane, Hsia, Barad, Liu, Johnson	12	Gen	Ann Epidemiol. 2003 Oct;13(9 Suppl):S78-86	W1
522	The Women's Health Initiative Dietary Modification trial: Overview and baseline characteristics of participants	**Ritenbaugh**, Patterson, Chlebowski, Caan, Tinker, Howard, Ockene	12	Gen	Ann Epidemiol. 2003 Oct;13(9 Suppl):S87-97	
523	The Women's Health Initiative calcium-vitamin D trial: Overview and baseline characteristics of participants	**Jackson**, LaCroix, Cauley, McGowan	12	Gen	Ann Epidemiol. 2003 Oct;13(9 Suppl):S98-106	
524	The Women's Health Initiative Observational Study: Baseline characteristics of participants and reliability of baseline measures	**Langer**, White, Lewis, Kotchen, Hendrix, Trevisan	12	OS	Ann Epidemiol. 2003 Oct;13(9 Suppl):S107-21	W1, W2
525	Outcomes ascertainment and adjudication methods in the Women's Health Initiative	**Curb**, McTiernan, Heckbert, Kooperberg, Stanford, Nevitt, Johnson, Proulx-Burns, Pastore, Criqui, Daugherty, WHI Morbidity and Mortality Committee	12	Gen	Ann Epidemiol. 2003 Oct;13(9 Suppl):S122-8	
527	Predictors of change in calcium intake in postmenopausal women after osteoporosis screening	**McLeod**, McCann, Horvath, Wactawski-Wende	12	OS	J Nutr. 2007 Aug;137(8):1968-73	AS98

Table 11.2 (continued)
Publications – Stages 3 through 12

Ms ID	Title	Authors	Status	Data Focus	Reference	Study
535	Lipoprotein particle concentrations may explain the absence of coronary protection in the Women's Health Initiative Hormone Trials	**Hsia**, Otvos, Rossouw, Wu, Wassertheil-Smoller, Hendrix, Robinson, Lund, Kuller, for the Women's Health Initiative Research Group	12	CT	Arterioscler Thromb Vasc Biol. 2008 Sep;28(9):1666-71. Epub 2008 Jul 3	
536	Sexual satisfaction and cardiovascular disease: The Women's Health Initiative	**McCall-Hosenfeld**, Freund, Legault, Jaramillo, Cochrane, Manson, Wenger, Eaton, McNeeley, Rodriguez, Bonds	12	OS	Am J Med. 2008 Apr;121(4):295-301	
538	Electrocardiographic predictors of incident congestive heart failure and all-cause mortality in postmenopausal women: The Women's Health Initiative	**Rautaharju**, Kooperberg, Larson, LaCroix	12	CT	Circulation. 2006 Jan 31;113(4):481-9	
541	Low-fat dietary pattern and risk of treated diabetes mellitus in postmenopausal women: the Women's Health Initiative randomized controlled dietary modification trial	**Tinker**, Bonds, Margolis, Manson, Howard, Larson, Perri, Beresford, Robinson, Rodriguez, Safford, Wenger, Stevens, Parker	12	CT	Arch Intern Med. 2008 Jul 28;168(14):1500-11	
542	Enrollment in a brain magnetic resonance study: Results from the Women's Health Initiative Memory Study Magnetic Resonance Imaging Study (WHIMS-MRI) [WHIMS-MRI]	**Jaramillo**, Felton, Andrews, Desiderio, Hallarn, Jackson, Coker, Robinson, Ockene, Espeland, Women's Health Initiative Memory Study Research Group	12	WHIMS	Acad Radiol. 2007 May;14(5):603-12	AS183
544	Menstrual and reproductive history, postmenopausal hormone use, and risk of benign proliferative epithelial disorders of the breast: A cohort study [Benign breast disease study]	**Cui**, Page, Lane, Rohan	12	CT	Breast Cancer Res Treat. 2008 Mar 22 [Epub ahead of print]	AS130
550	Common genetic variation in calpain-10 gene (CAPN10) and diabetes risk in a multi-ethnic cohort of American postmenopausal women	**Song**, You, Hsu, Sul, Wang, Tinker, Eaton, Liu	12	OS	Hum Mol Genet. 2007 Dec 1;16(23):2960-71. Epub 2007 Sep 12	AS132
554	Genetic variants in the UCP2-UCP3 gene cluster and risk of diabetes in the Women's Health Initiative Observational Study	**Hsu**, Niu, Song, Tinker, Kuller, Liu	12	OS	Diabetes. 2008 Apr;57(4):1101-7. Epub 2008 Jan 25	AS132

Table 11.2 (continued)
Publications – Stages 3 through 12

Ms ID	Title	Authors	Status	Data Focus	Reference	Study
563	Cystatin-C, renal function, and incidence of hip fracture in postmenopausal women	**LaCroix**, Lee, Wu, Cauley, Shlipak, Ott, Robbins, Curb, LeBoff, Bauer, Jackson, Kooperberg, Cummings	12	OS	J Am Geriatr Soc. 2008 Jul 24. [Epub ahead of print]	AS90
565	Self-reported osteoarthritis, ethnicity, body mass index, and other associated risk factors in postmenopausal women: Results from the Women's Health Initiative	**Wright**, Kershner Riggs, Lisse, Chen	12	Gen	J Am Geriatr Soc. 2008 Jul 17. [Epub ahead of print]	
576	Circulating insulin-like growth factor binding protein-1 and the risk of pancreatic cancer	**Wolpin**, Michaud, Giovannucci, Schernhammer, Stampfer, Manson, Cochrane, Rohan, Ma, Pollak, Fuchs	12	OS	Cancer Res. 2007 Aug 15;67(16):7923-8	AS146
585	Low-fat dietary pattern and risk of benign proliferative breast disease: A randomized, controlled dietary modification trial [Benign breast disease study]	**Rohan**, Negassa, Caan, Chlebowski, Curb, Ginsberg, Lane, Neuhouser, Shikany, Wassertheil-Smoller, Page	12	CT	Cancer Prev Research. 2008 Jul 9. [Epub ahead of print]	AS130
586	Conjugated equine estrogen and risk of benign proliferative breast disease: A randomized controlled trial [Benign breast disease study]	**Rohan**, Negassa, Chlebowski, Habel-Oakland, McTiernan, Ginsberg, Wassertheil-Smoller, Page	12	CT	J Natl Cancer Inst. 2008 Apr 16;100(8):563-71. Epub 2008 Apr 8	AS130
587	Estrogen plus progestin and risk of benign proliferative breast disease [Benign breast disease study]	**Rohan**, Negassa, Chlebowski, Lasser, McTiernan, Schenken, Wassertheil-Smoller, Page	12	CT	Cancer Epidemiol Biomarkers Prev. 2008 Sep;17(9):2337-43. Epub 2008 Aug 25	AS130
591	Association between different measures of blood pressure and coronary artery calcium in postmenopausal women [WHI-CACS]	**Allison**, Manson, Langer, Aragaki, Wassertheil-Smoller, Lewis, Thomas, Lawson, Cochrane, Hsia, Hunt, Robinson	12	CT	Hypertension. 2008 Sep 15. [Epub ahead of print]	W25
592	Vaginal descent and pelvic floor symptoms in postmenopausal women: A longitudinal study	**Bradley**, Zimmerman, Wang, Nygaard	12	CT	Obstet Gynecol. 2008 May;111(5):1148-53	AS135
594	Association between dietary fiber and markers of systemic inflammation in the Women's Health Initiative Observational Study	**Ma**, Hebert, Li, Bertone-Johnson, Olendzki, Pagoto, Tinker, Rosal, Ockene, Ockene, Griffith, Liu	12	OS	Nutrition. 2008 Oct;24(10):941-9. Epub 2008 Jun 18	AS132

Table 11.2 (continued)
Publications – Stages 3 through 12

Ms ID	Title	Authors	Status	Data Focus	Reference	Study
603	Lipoprotein-associated phospholipase A2, hormone use, and the risk of ischemic stroke in postmenopausal women	**Wassertheil-Smoller**, Kooperberg, McGinn, Kaplan, Hsia, Hendrix, Manson, Berger, Kuller, Allison, Baird	12	OS	Hypertension. 2008 Apr;51(4):1115-22. Epub 2008 Feb 7	AS126
613	Obesity and risk of pancreatic cancer among postmenopausal women: the Women's Health Initiative (United States)	**Luo**, Margolis, Adami, LaCroix, Ye, Women's Health Initiative Investigators	12	Gen	Br J Cancer. 2008 Aug 5;99(3):527-31. Epub 2008 Jul 15	
614	Incidence of fractures compared to cardiovascular disease and breast cancer: The Women's Health Initiative Observational Study	**Cauley**, Wampler, Barnhart, Wu, Allison, Chen, Hendrix, Robbins, Jackson	12	OS	Osteoporos Int. 2008 Jul 16. [Epub ahead of print]	
618	Dietary carbohydrate, glycemic index, and glycemic load in relation to colorectal cancer risk in the Women's Health Initiative	**Kabat**, Shikany, Beresford, Caan, Neuhouser, Tinker, Rohan	12	CT	Cancer Causes Control. 2008 Jul 10. [Epub ahead of print]	
620	Calcium plus vitamin D supplementation and the risk of incident diabetes in the Women's Health Initiative	**DeBoer**, Tinker, Connelly, Curb, Howard, Kestenbaum, Larson, Manson, Margolis, Siscovick, Weiss, Women's Health Initiative Investigators	12	CT	Diabetes Care. 2008 Apr;31(4):701-7. Epub 2008 Jan 30	
631	Body mass index and waist circumference in relation to lung cancer risk in the Women's Health Initiative	**Kabat**, Kim, Hunt, Chlebowski, Rohan	12	Gen	Am J Epidemiol. 2008 Jul 15;168(2):158-69. Epub 2008 May 15	
632	Clinical attachment loss, systemic bone density, and subgingival calculus in postmenopausal women	**Brennan**, Genco, Hovey, Trevisan, Wactawski-Wende	12	OS	J Periodontol. 2007 Nov;78(11):2104-11	AS98
634	Serum 25-hydroxyvitamin D concentrations and risk for hip fractures	**Cauley**, LaCroix, Wu, Horwitz, Danielson, Bauer, Lee, Jackson, Robbins, Stanczyk, LeBoff, Wactawski-Wende, Sarto, Ockene, Cummings	12	OS	Ann Intern Med. 2008 Aug 19;149(4):242-50	AS181
635	Validation of self-report of rheumatoid arthritis and systemic lupus erythematosus: The Women's Health Initiative	**Walitt**, Constantinescu, Katz, Weinstein, Wang, Hernandez, Hsia, Howard	12	OS	J Rheumatol. 2008 May;35(5):811-8. Epub 2008 Apr 1	AS217

Table 11.2 (continued)
Publications – Stages 3 through 12

Ms ID	Title	Authors	Status	Data Focus	Reference	Study
652	Osteoporosis and oral infection: Independent risk factors for oral bone loss	**Brennan-Calanan**, Genco, Wilding, Hovey, Trevisan, Wactawski-Wende	12	OS	J Dent Res. 2008 Apr;87(4):323-7	AS98
664	FTO polymorphisms are associated with obesity but not diabetes risk in postmenopausal women	**Song**, You, Hsu, Howard, Langer, Manson, Nathan, Niu, Tinker, Liu	12	OS	Obesity (Silver Spring). 2008 Sep 11. [Epub ahead of print]	AS132
689	A partial least-square approach for modeling gene-gene and gene-environment interactions when multiple markers are genotyped	**Wang**, Ho, Ye, Strickler, Elston	12	OS	Genet Epidemiol. 2008 Jul 9. [Epub ahead of print]	AS152
701	Statistical issues arising in the Women's Health Initiative	**Prentice**, Pettinger, Anderson	12	Gen	Biometrics. 2005 Dec;61(4):899-911; discussion 911-41	
715	Projecting individualized absolute invasive breast cancer risk in African American women	**Gail**, Costantino, Pee, Bondy, Newman, Selvan, Anderson, Malone, Marchbanks, McCaskill-Stevens, Norman, Simon, Spirtas, Ursin, Bernstein	12	Gen	J Natl Cancer Inst. 2007 Dec 5;99(23):1782-92. Epub 2007 Nov 27	
731	Postmenopausal hormone therapy for disease prevention: Have we learned any lessons from the past?	**Rossouw**	12	Gen	Clin Pharmacol Ther. 2008 Jan;83(1):14-6	
732	The Women's Health Initiative: Be part of the answer!	**Tinker**	12	Gen	J Am Diet Assoc. 1995 Dec;95(12):1375	
733	The Women's Health Initiative Clinical Trial and Observational Study: History and overview	**Assaf**, Carleton	12	Gen	R I Med. 1994 Dec;77(12):424-7	
734	Barriers to black women's participation in cancer clinical trials	**Mouton**, Harris, Rovi, Solorzano, Johnson	12	Gen	J Natl Med Assoc. 1997 Nov;89(11):721-7	
735	Evaluation of a simplified vitamin supplement inventory developed for the Women's Health Initiative	**Patterson**, Levy, Tinker, Kristal	12	Gen	Public Health Nutr. 1999 Sep;2(3):273-6	
736	Meeting the challenges of recruiting and retaining participants in clinical trials	**Vozenilek**	12	CT	J Am Diet Assoc. 1999 Oct;99(10):1190, 1192	
737	Commentary on the Women's Health Initiative	**McGowan**, Pottern	12	Gen	Maturitas. 2000 Feb 15;34(2):109-12	

Table 11.2 (continued)
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Ms ID	Title	Authors	Status	Data Focus	Reference	Study
738	Individually randomized intervention trials for disease prevention and control	**Anderson**, Prentice	12	CT	Stat Methods Med Res. 1999 Dec;8(4):287-309	
739	Effect of postmenopausal hormone therapy on cardiovascular risk	**Rossouw**	12	CT	J Hypertens Suppl. 2002 May;20(2):S62-5	
740	Hormone replacement therapy: Applying the results of the Women's Health Initiative	**Johnson**	12	CT	Cleve Clin J Med. 2002 Sep;69(9):682, 685	
741	Participant characteristics associated with errors in self-reported energy intake from the Women's Health Initiative food-frequency questionnaire	**Horner**, Patterson, Neuhouser, Lampe, Beresford, Prentice	12	Gen	Am J Clin Nutr. 2002 Oct;76(4):766-73	
742	Risks, fears and choices: Unexpected lessons from the Women's Health Initiative	**Jeffcoat**	12	Gen	J Am Dent Assoc. 2002 Oct;133(10):1314, 1316, 1318	
743	The Women's Health Initiative estrogen plus progestin trial: The study and how it changes our practice	**Hendrix**	12	CT	J Am Osteopath Assoc. 2003 Feb;103(2 Suppl 2):S3-5	
744	Treatment of menopause: Recommendations for hormonal and non-hormonal therapy	**Johnson**	12	Gen	J Okla State Med Assoc. 2003 Mar;96(3):140-2	
745	Hormone therapy: Evolving concepts	**Hendrix**	12	CT	Curr Opin Rheumatol. 2003 Jul;15(4):464-8	
746	Impact of WHI conclusions and ACOG guidelines on clinical practice	**Gass**	12	Gen	Int J Fertil Womens Med. 2003 May-Jun;48(3):106-10; discussion 137-8	
747	HT and breast cancer risk	**Geller**, Chlebowski	12	Gen	Fertil Steril. 2003 Oct;80 Suppl 4:5-9; quiz 54-5	
748	Estrogen with and without progestin: Benefits and risks of short-term use	**LaCroix**	12	Gen	Am J Med. 2005 Dec 19;118 Suppl 12B:79-87	
749	Ethnicity, sleep, mood, and illumination in postmenopausal women	**Kripke**, Jean-Louis, Elliott, Klauber, Rex, Tuunainen, Langer	12	CT	BMC Psychiatry. 2004 Apr 7;4:8	AS11
750	Women's cognitive health: Postmenopausal dementia and the Women's Health Initiative Memory Study [WHIMS]	**Klein**, Rapp	12	CT	Womens Health Issues. 2004 May-Jun;14(3):71-4	AS39
751	Concerns about published data from the estrogen-progestin (HT) arm of the WHI	**Gass**, Anderson, Barad	12	CT	Am J Obstet Gynecol. 2005 Jan;192(1):333; author reply 334	

Table 11.2 (continued)
Publications – Stages 3 through 12

Ms ID	Title	Authors	Status	Data Focus	Reference	Study
752	Validation of the Women's Health Initiative Insomnia Rating Scale in a multicenter controlled clinical trial	**Levine**, Dailey, Rockhill, Tipping, Naughton, Shumaker	12	CT	Psychosom Med. 2005 Jan-Feb;67(1):98-104	
753	Menopausal hormone therapy: Currently no evidence for cardiac protection	**Wenger**	12	Gen	Pediatr Blood Cancer. 2005 Jun 15;44(7):625-9	
754	Postmenopausal hormone therapy: Critical reappraisal and a unified hypothesis	**Phillips**, Langer	12	CT	Fertil Steril. 2005 Mar;83(3):558-66	
755	Reanalysis of the Women's Health Initiative oral contraceptive data reveals no evidence of delayed cardiovascular benefit	**Stefanick**, Prentice, Anderson, Gass, Manson, Hendrix, Vista-Deck, McNeeley, Women's Health Initiative Steering Committee	12	Gen	Fertil Steril. 2005 Apr;83(4):853-4	
756	Abnormal mammographic findings with short-interval follow-up recommendation	**Chlebowski**, Khalkhali	12	Gen	Clin Breast Cancer. 2005 Aug;6(3):235-9	
757	Estrogens and progestins: Background and history, trends in use, and guidelines and regimens approved by the US Food and Drug Administration	**Stefanick**	12	Gen	Am J Med. 2005 Dec 19;118 Suppl 12B:64-73	
758	Aspects of the design and analysis of high-dimensional SNP studies for disease risk estimation	**Prentice**, Qi	12	Gen	Biostatistics. 2006 Jul;7(3):339-54. Epub 2006 Jan 27	
759	Observational studies and clinical trials of menopausal hormone therapy: Can they both be right?	**Allison**, Manson	12	Gen	Menopause. 2006 Jan-Feb;13(1):1-3	
760	Postmenopausal hormone therapy: New questions and the case for new clinical trials	**Manson**, Bassuk, Harman, Brinton, Cedars, Lobo, Merriam, Miller, Naftolin, Santoro	12	Gen	Menopause. 2006 Jan-Feb;13(1):139-47	
761	Re: "combined postmenopausal hormone therapy and cardiovascular disease: toward resolving the discrepancy between observational studies and the women's health initiative clinical trial"	**Willett**, Manson, Grodstein, Stampfer, Colditz	12	Gen	Am J Epidemiol. 2006 Jun 1;163(11):1067-8; author reply 1068-9..Epub 2006 Apr 26	
762	Is estrogen for you?	**Manson**, Bassuk	12	Gen	Newsweek. 2006 Apr 24;147(17):72-3	
763	The Women's Health Initiative	**Nabel**	12	Gen	Science. 2006 Sep 22;313(5794):1703	

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Ms ID	Title	Authors	Status	Data Focus	Reference	Study
764	Hot flashes and hormones	**Manson**, Bassuk	12	Gen	Newsweek. 2007 Jan 15;149(3):56-7	
765	Implications of recent clinical trials of postmenopausal hormone therapy for management of cardiovascular disease	**Rossouw**	12	CT	Ann N Y Acad Sci. 2006 Nov;1089:444-53	
766	Prevalence, clinical significance, and management of peripheral arterial disease in women: Is there a role for postmenopausal hormone therapy?	**Mazhari**, Hsia	12	Gen	Vasc Health Risk Manag. 2005;1(2):111-7	
767	Dietary fat and cardiovascular disease: Putting the Women's Health Initiative in perspective	**Howard**	12	Gen	Nutr Metab Cardiovasc Dis. 2007 Mar;17(3):171-4. Epub 2007 Feb 21	
768	The decrease in breast-cancer incidence in 2003 in the United States	**Ravdin**, Cronin, Howlader, Berg, Chlebowski, Feuer, Edwards, Berry	12	Gen	N Engl J Med. 2007 Apr 19;356(16):1670-4	
769	How the Women's Health Initiative (WHI) influenced physicians' practice and attitudes	**Bush**, Bonomi, Nekhlyudov, Ludlam, Reed, Connelly, Grothaus, LaCroix, Newton	12	Gen	J Gen Intern Med. 2007 Sep;22(9):1311-6. Epub 2007 Jul 18	
770	Invited commentary: Hormone therapy and risk of coronary heart disease - why renew the focus on the early years of menopause?	**Manson**, Bassuk	12	Gen	Am J Epidemiol. 2007 Sep 1;166(5):511-7. Epub 2007 Jul 23	
771	The Women's Health Initiative and hormone therapy, 5 years later	**Johnson**	12	Gen	Cleve Clin J Med. 2007 Oct;74(10):755-6	
772	Observational studies, clinical trials, and the Women's Health Initiative	**Prentice**	12	Gen	Lifetime Data Anal. 2007 Dec;13(4):449-62. Epub 2007 Oct 18	
773	Do diet, folic acid, and vitamins matter? What did we learn from the Women's Health Initiative, the Women's Health Study, the Women's Antioxidant and Folic Acid Cardiovascular Study, and other clinical trials?	**Wenger**	12	Gen	Cardiol Rev. 2007 Nov-Dec;15(6):288-90	
774	BMI and headache among women: Results from 11 epidemiologic datasets	**Keith**, Wang, Fontaine, Cowan, Allison	12	Gen	Obesity (Silver Spring). 2008 Feb;16(2):377-83	

Table 11.2 (continued)
Publications – Stages 3 through 12

Ms ID	Title	Authors	Status	Data Focus	Reference	Study
775	Risks and benefits of therapy with menopausal hormones versus selective estrogen-receptor modulators in peri- and postmenopausal women at increased breast cancer risk	**Col**, Chlebowski	12	CT	Menopause. 2008 Jul-Aug;15(4 Suppl):804-9	
777	Coronary heart disease and stroke with aromatase inhibitor, tamoxifen and menopausal hormone therapy use	**Chlebowski**, Anderson, Geller, Col	12	CT	Clin Breast Cancer. 2006;6(suppl 2):S58-64	
778	Menopausal hormone therapy and breast cancer: Where we are after the WHI	**Chlebowski**	12	Gen	ASBD Advisor. 2003;2:7-10	
779	The Women's Health Initiative: Implications for clinicians	**VanHorn**, Manson	12	Gen	Cleve Clin J Med. 2008 May;75(5):385-90	
780	Risks and benefits of estrogen plus progestin in healthy postmenopausal women: The Women's Health Initiative	**Manson**, Bassuk	12	Gen	In: Braunwald E et al, eds. Harrison's principles of internal medicine online: Clinical trial update. McGraw-Hill,2002	
781	Clinical practice. Postmenopausal hormone-replacement therapy	**Manson**, Martin	12	Gen	N Engl J Med. 2001 Jul 5;345(1):34-40	
782	Understanding the divergent data on postmenopausal hormone therapy	**Grodstein**, Clarkson, Manson	12	Gen	N Engl J Med. 2003 Feb 13;348(7):645-50	
783	Postmenopausal hormone therapy. A reversal of fortune	**Michels**, Manson	12	Gen	Circulation. 2003 Apr 15;107(14):1830-3	
784	The menopause transition and postmenopausal hormone therapy	**Manson**, Bassuk	12	Gen	In: Kasper DL et al, eds. Harrison's principles of internal medicine. 16th ed. New York: McGraw-Hill,2004:2209-13	
785	Is age at initiation of hormone therapy a key determinant of coronary heart disease outcomes?	**Allison**, Manson	12	Gen	Johns Hopkins Adv Stud in Med. 2006;6(7):329-30	

Table 11.2 (continued)
Publications – Stages 3 through 12

Ms ID	Title	Authors	Status	Data Focus	Reference	Study
786	Postmenopausal hormone therapy: Observational studies to clinical trials	**Bassuk**, Manson	12	Gen	In: Liu JH, Gass MLS, eds. Management of the perimenopause (Practical pathways in obstetrics and gynecology). New York: McGraw Hill,2006:377-408	
787	Menopausal hormone therapy and the risk of coronary heart disease. Does the relation vary by age or time since menopause? The investigator's perspective	**Manson**, Bassuk	12	Gen	The Monitor. 2007 Oct:17-22	
788	Hormone replacement therapy	**Allison**, Manson	12	Gen	In: Encyclopedia of Epidemiology. Thousand Oaks, CA: Sage Publications,2007:503-10	
799	Women's Ischemic Syndrome Evaluation: current status and future research directions: Report of the National Heart, Lung and Blood Institute workshop: October 2-4, 2002 : Section 4: lessons from hormone replacement trials	**Waters**, Gordon, Rossouw, Cannon, Collins, Herrington, Hsia, Langer, Mosca, Ouyang, Sopko, Stefanick	12	Gen	Circulation. 2004 Feb 17;109(6):e53-5	
800	The rise and fall of menopausal hormone therapy	**Barrett-Connor**, Grady, Stefanick	12	Gen	Annu Rev Public Health. 2005;26:115-40	
801	Estrogen therapy: Prevention and treatment of osteoporosis	**McGowan**, Stefanick	12	Gen	In: Marcus R et al, eds. Osteoporosis. 3rd ed. San Diego, CA: Elsevier Academic Press,2008:1687-704	
802	Reply: Reanalysis of the data--science at its best and always informative	**Barad**, Stefanick, Manson, Gass, Anderson	12	CT	Fertil Steril. 2006 June;85(6): author reply e14. Epub 2006 May 4	
803	Risk-benefit profiles of raloxifene for women	**Stefanick**	12	CT	N Engl J Med. 2006 Jul 13;355(2):190-2	
810	The Women's Health Initiative: Lessons learned	**Prentice**, Anderson	12	Gen	Annu Rev Public Health. 2008;29:131-50	

Table 11.2 (continued)
Publications – Stages 3 through 12

Ms ID	Title	Authors	Status	Data Focus	Reference	Study
813	Bacterial species in subgingival plaque and oral bone loss in postmenopausal women	**Brennan**, Genco, Wilding, Hovey, Trevisan, Wactawski-Wende	12	OS	J Periodontol. 2007 Jun;78(6):1051-61	AS98
825	Conjugated equine estrogens and breast cancer risk in the Women's Health Initiative clinical trial and observational study	**Prentice**, Chlebowski, Stefanick, Manson, Langer, Pettinger, Hendrix, Hubbell, Kooperberg, Kuller, Lane, McTiernan, O'Sullivan, Rossouw, Anderson	12	Gen	Am J Epidemiol. 2008 Jun 15;167(12):1407-15. Epub 2008 Apr 29	
826	The role of hormone therapy and calcium plus vitamin D for reduction of bone loss and risk for fractures: Lessons learned from the Women's Health Initiative	**Jackson**, Shidham	12	Gen	Curr Osteoporos Rep. 2007 Dec;5(4):153-9	
837	Women's Health Iinitiative studies of postmenopausal breast cancer	**Prentice**	12	Gen	Adv Exp Med Biol. 2008;617:151-60	
845	Colorectal cancer in women after stopping postmenopausal hormone therapy—reply	**Chlebowski**	12	CT	JAMA. 2008; 299(23):2744-5	
74	Breast cancer survivors' health-related quality of life: Racial differences and comparisons to non-cancer controls	**Paskett**, Alfano, Davidson, Andersen, Naughton, Sherman, McDonald, Hays	11	OS	In press, Cancer	
195	Predictors of adherence in the Women's Health Initiative Calcium/Vitamin D Trial	**Brunner**, Wu, Rosal, Wactawski-Wende, Granek, Shumaker, Ockene, Dunbar-Jacob, Cauley, Cochrane, Tinker, Jackson, Snetselaar, LeBoff, Bowen	11	CT	In press, Behav Med	
215	Influence of stressors on breast cancer incidence in the Women's Health Initiative	**Michael**, Carlson, Chlebowski, Aickin, Weihs, Ockene, Bowen, Ritenbaugh	11	OS	In press, Health Psychol	
319	The relationship between religion and cardiovascular outcomes and all-cause mortality in the Women's Health Initiative Observational Study	**Schnall**, Wassertheil-Smoller, Swencionis, Zemon, Tinker, O'Sullivan, VanHorn, Goodwin	11	OS	In press, Psychol Health	
353	Conjugated equine estrogens and colorectal cancer incidence and survival: The Women's Health Initiative Randomized Clinical Trial	**Ritenbaugh**, Stanford, Ascensao, Chlebowski, Frank, Garland, Lane, Mason, McNeeley, Shikany, Stefanick, Taylor, Wu	11	CT	In press, Cancer Epidemiol Biomarkers Prev	

Table 11.2 (continued)
Publications – Stages 3 through 12

Ms ID	Title	Authors	Status	Data Focus	Reference	Study
386	The role of antioxidants and Vitamin A in ovarian cancer: Results from the Women's Health Initiative	**Thomson**, Neuhouser, Shikany, Caan, Monk, Mossavar-Rahmani, Sarto, Parker, Modugno, Anderson	11	Gen	In press, Nutr Cancer	
416	Influence of testosterone supplementation on breast cancer	**Ness**, Albano, McTiernan, Cauley	11	OS	In press, Arch Intern Med	
442	Test-retest reliability of the Women's Health Initiative physical activity questionnaire	**Meyer**, Evenson, Morimoto, Siscovick, White	11	OS	In press, Med Sci Sports Exerc	W2
468	Effect of calcium and vitamin D supplementation on blood pressure in postmenopausal women: Results from the Women's Health Initiative Clinical Trial	**Margolis**, Ray, VanHorn, Manson, Allison, Black, Beresford, Connelly, Curb, Grimm, Kotchen, Kuller, Wassertheil-Smoller, Thomson, Torner	11	CT	In press, Hypertension	
526	Inflammatory, lipid, thrombotic, and genetic markers of coronary heart disease risk in the Women's Health Initiative trials of hormone therapy	**Rossouw**, Cushman, Greenland, Lloyd-Jones, Bray, Kooperberg, Pettinger, Robinson, Hendrix, Hsia	11	CT	In press, Arch Intern Med	W6
560	Loop diuretic use and fracture in postmenopausal women: Findings from the Women's Health Initiative (WHI)	**Carbone**, Johnson, Bush, Robbins, Weber, LaCroix, Thomas, Larson	11	CT	In press, Arch Intern Med	
583	Multivitamin use and risk of cancer and cardiovascular disease risk in the Women's Health Initiative cohorts	**Neuhouser**, Wassertheil-Smoller, Thomson, Aragaki, Anderson, Manson, Patterson, Rohan, VanHorn, Shikany, Thomas, LaCroix, Prentice	11	CT	In press, Arch Intern Med	
602	Inflammation and hemostasis biomarkers for predicting risk of ischemic stroke in postmenopausal women: The Women's Health Initiative Observational Study	**Kaplan**, McGinn, Baird, Hendrix, Kooperberg, Lynch, Rosenbaum, Johnson, Strickler, Wassertheil-Smoller	11	OS	In press, J Stroke Cerebrovasc Dis	AS126
625	Postmenopausal hormone therapy and subclinical cerebrovascular disease: The WHIMS-MRI Study [WHIMS-MRI]	**Coker**, Hogan, Bryan, Kuller, Margolis, Betterman, Wallace, Lao, Freeman, Stefanick, Shumaker	11	WHIMS	In press, Neurology	AS183

Table 11.2 (continued)
Publications – Stages 3 through 12

Ms ID	Title	Authors	Status	Data Focus	Reference	Study
626	Effects of postmenopausal hormone therapy on regional brain volumes in older women: The Women's Health Initiative Magnetic Resonance Imaging Study [WHIMS-MRI]	**Resnick**, Espeland, Jaramillo, Hirsch, Stefanick, Murray, Ockene, Davatzikos	11	WHIMS	In press, Neurology	AS183
645	Aortic aneurysm in postmenopausal women: Findings from the Women's Health Initiative	**Lederle**, Larson, Margolis, Allison, Freiberg, Cochrane, Graettinger, Curb	11	Gen	In press, Br Med J	
677	Calcium plus vitamin D supplementation and the risk of breast cancer	**Chlebowski**, Johnson, Kooperberg, Pettinger, Wactawski-Wende, Rohan, Lane, O'Sullivan, Yasmeen, Hiatt, Shikany, Vitolins, Khandekar, Hubbell, Rossouw	11	CT	In press, J Natl Cancer Inst	
700	Women's Health Initiative dietary modification randomized controlled trial	**Mossavar-Rahmani**, Tinker	11	CT	In press, article in Wiley Encyclopedia of Clinical Trials	
727	Women's Health Initiative Memory Study (WHIMS) Program: Emerging findings [WHIMS]	**Espeland**, Shumaker, Hogan, Resnick, Henderson, Hogervorst	11	CT	In press, chapter in Hormones, cognition and dementia: State of the art and emergent therapeutic strategies; Cambridge University Press	AS39, AS183
865	Menopausal hormone therapy in BRCA1 mutation carriers: Uncertainty and caution	**Chlebowski**, Prentice	11	Gen	In Press, J Nat Cancer Inst	
873	Understanding the effects of menopausal hormone therapy: Using the Women's Health Initiative randomized trials and observational study to improve inference	**Anderson**, Prentice	11	Gen	In press, article in APA book	
154	The role of dietary proteins in the disposition to fractures: A prospective analysis of postmenopausal women from the Women's Health Initiative observational study	**Barzel**, Aragaki, Ritenbaugh, LeBoff, Wylie-Rosette	10	OS	Submitted, J Nutr	
172	The association of glycemic load with cardiovascular disease risk factors in the Women's Health Initiative observational study	**Shikany**, Tinker, Neuhouser, Ma, Patterson, Phillips, Liu, Redden	10	Gen	Submitted, J Nutr	AS111

Table 11.2 (continued)
Publications – Stages 3 through 12

Ms ID	Title	Authors	Status	Data Focus	Reference	Study
218	Psychosocial effects of physical and verbal abuse among postmenopausal women	**Mouton**, Rodabough, Rovi, Brzyski, Katerndahl	10	OS	Submitted, J Gerontol	
308	Association between dietary fats and age-related macular degeneration (AMD) in the Carotenoids in Age-Related Eye Disease Study (CAREDS), an ancillary study of the Women's Health Initiative [CAREDS]	**Parekh**, Moeller, Blodi, Ritenbaugh, Chappel, Wallace, Mares-Perlman	10	OS	Submitted, Am J Clin Nutr	AS105
310	Relationship of body fat level and distribution to age-related maculopathy in the Carotenoids in Age related Eye Disease Study [CAREDS]	**LaRowe**, Wallace, Gehrs, Chappel, Mares-Perlman	10	OS		AS105
312	Accuracy of food portion estimation among postmenopausal women	**Coy**, Frank, Lee, Meyskens	10	CT	Submitted, Am J Clin Nutr	AS118
356	The cross-sectional relationship between body weight, obesity and cognitive function in postmenopausal women enrolled in the Women's Health Initiative (WHI)	**Kerwin**, Zhang, Kotchen, Espeland, VanHorn, McTigue, Robinson, Powell, Kooperberg, Coker, Hoffman	10	CT	Submitted, JAMA	
375	Intentional weight loss as a possible risk factor for B-cell lymphomas	**DeRoos**, Ulrich, Ray, Mossavar-Rahmani, Rosenberg, Caan, Thomson, McTiernan, LaCroix	10	OS	Submitted, Cancer Epidemiol Biomarkers Prev	
390	Identifying risk factors for cognitive change in the Women's Health Initiative Memory Study: A neural networks approach [WHIMS]	**Bandelow**, Espeland, Coker, Henderson, Hogervorst, Resnick, Wallace	10	WHIMS	Submitted, Cambridge University Press	AS39
426	Incident invasive breast cancer, geographic location of residence, and reported average time spent outside	**Millen**, Pettinger, Freudenheim, Langer, Rosenberg, Mossavar-Rahmani, Duffy, Lane, McTiernan, Kuller, Lopez, Wactawski-Wende	10	OS	Submitted, Cancer Epidemiol Biomarkers Prev	
433	Serum estradiol and fracture reduction during treatment with hormone therapy: The Women's Health Initiative randomized trial	**Cauley**, LaCroix, Robbins, Larson, Wallace, Wactawski-Wende, Chen, Bauer, Cummings, Jackson	10	CT		W9
453	Relationship between degree of obesity and quality of life and functioning in women of diverse racial-ethnic backgrounds	**McTigue**, Adams-Campbell, Bost, Hays, Kuller, Lynch, Manson, Sarto, Tinker, Vitolins	10	Gen	Submitted, Am J Public Health	

Table 11.2 (continued)
Publications – Stages 3 through 12

Ms ID	Title	Authors	Status	Data Focus	Reference	Study
461	Insulin, insulin-like growth factor-I, and risk of breast cancer in postmenopausal women	**Gunter**, Hoover, Yu, Wassertheil-Smoller, Rohan, Manson, Li, Ho, Xue, Anderson, Kaplan, Harris, Howard, Wylie-Rosette, Burk	10	OS	Submitted, J Nat Cancer I	AS129
467	Low fat dietary pattern, fractures, and bone density: The Women's Health Initiative Dietary Modification Clinical Trial	**McTiernan**, Wactawski-Wende, Wu, Watts, Tylavsky, Freeman, Hendrix, Jackson	10	CT	Submitted, Am J Clin Nutr	
470	Calcium plus vitamin D and exogenous estrogen influence on joint symptoms	**Chlebowski**, Johnson, Wactawski-Wende, Cummings, Kooperberg, Hubbell, Hiatt, Vitolins, Lane, Yasmeen, Shikany, Khandekar, O'Sullivan, Rohan	10	CT	Submitted, J Clin Oncol	W24
472	Calcium plus vitamin D supplementation and risk of death in postmenopausal women: The WHI Calcium-Vitamin D Randomized Controlled Trial	**LaCroix**, Kotchen, Anderson, Brzyski, Cauley, Cummings, Gass, Johnson, Ko, Larson, Manson, Stefanick, Wactawski-Wende	10	CT	Submitted, Ann Intern Med	
479	Homocysteine levels and risk of hip fracture in postmenopausal women	**LeBoff**, Narweker, LaCroix, Wu, Jackson, Lee, Bauer, Cauley, Kooperberg, Lewis, Thomas, Cummings	10	OS	Submitted, J Bone Min Res	AS90
489	Does obesity really make the femur stronger? Bone Mineral Density, geometry and fracture incidence in the Women's Health Initiative - Observational Study	**Beck**, Chen, Petit, Wu, LeBoff	10	OS	Submitted, J Bone Min Res	AS153
507	Hematopoietic prostaglandin D synthase variant (Val187Ile) in African Americans: enzyme characterization, urine PGD2 metabolites, and case-control analyses of colorectal neoplasia in four studies	**Tippen**, Levine, Materi, Park, Song, Keku, Dai, Huang, Zhou, Frankl, Hardy, Patterson, Chlebowski, Henderson, Kolonel	10	OS	Submitted, J Biol Chem	AS108
529	Short–term exposure to ambient fine particulate matter and electrocardiographic measures of myocardial ischemia in women: The environmental epidemiology of arrhythmogenesis in the Women's Health Initiative	**Zhang**, Whitsel, Quibrera, Smith, Liao, Anderson, Prineas	10	CT	Submitted, Circulation	AS140

Table 11.2 (continued)
Publications – Stages 3 through 12

Ms ID	Title	Authors	Status	Data Focus	Reference	Study
551	Antidepressant use and risk of incident cardiovascular morbidity and mortality among post-menopausal women in the Women's Health Initiative Study	**Smoller**, Allison, Cochrane, Curb, Perlis, Robinson, Rosal, Wang, Wenger, Wassertheil-Smoller	10	OS	Submitted, JAMA	
567	New-onset breast tenderness after initiation of estrogen plus progestin hormone therapy and future breast cancer risk: The Women's Health Initiative Estrogen Plus Progestin Trial	**Crandall**, Aragaki, Chlebowski, McTiernan, Anderson, Hendrix, Cochrane, Langer, Kuller, Cauley	10	CT	Submitted, Ann Intern Med	
570	Calcium/vitamin D supplementation and coronary artery calcification [WHI-CACS]	**Manson**, Allison, Carr, Langer, Cochrane, Hendrix, Hsia, Hunt, Lewis, Margolis, Robinson, Rodabough, Thomas	10	CT	Submitted, JAMA	W25
577	Effect of a long-term, low-fat, high fruit and vegetable diet on retinal carotenoids in the Women's Health Initiative	**Moeller**, Voland, Sarto, Gobel, Streicher, Mares-Perlman	10	CT	Submitted, J Nutr Sci	AS219
590	Impact of duration of lactation on risk factors for cardiovascular disease	**Schwarz**, Ray, Stuebe, Allison, Ness, Freiberg, Cauley	10	Gen	Submitted, JAMA	
609	Ambient particulate air pollution and ectopy: The environmental epidemiology of arrhythmogenesis in WHI (EEAWHI), 1999-2004	**Liao**, Whitsel, Duan, Lin, Quibrera, Smith, Peuquet, Prineas, Zhang, Anderson	10	CT	Submitted, Environ Health Perspect	AS140
610	Prostaglandin H synthase 2 Val511Ala variant in African Americans: Suggestion of lower risk for colorectal cancer in four case-control studies	**Lin**, Levine, Materi, Park, Patterson, Goodman, Chlebowski, Sansbury, Keku, Henderson, Kolonel Harris, Sandler, Haile	10	OS		AS108
624	Biomarker-calibrated energy and protein consumption and increased cancer risk among postmenopausal women [NBS]	**Prentice**, Shaw, Bingham, Beresford, Caan, Neuhouser, Patterson, Stefanick, Satterfield, Thomas, Snetselaar, Thomson, Tinker	10	Gen	Submitted, J Nat Cancer I	W8
628	Benefits and risks of postmenopausal hormone therapy when initiated soon after the menopause	**Prentice**, Manson, Langer, Anderson, Pettinger, Jackson, Johnson, Kuller, Lane, Wactawski-Wende, Brzyski, Allison, Ockene, Sarto, Rossouw	10	Gen	Submitted, Am J Epidemiol	

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Ms ID	Title	Authors	Status	Data Focus	Reference	Study
636	Effect of weight change on natural history of pelvic organ prolapse	**Kudish**, Cochrane, Hendrix, Iglesia, McNeeley, Petrovich, Richter, Sokol	10	CT	Submitted, J Obstet Gynaecol	
641	Resting heart rate: A low-tech measure of cardiovascular risk in women	**Hsia**, Larson, Ockene, Sarto, Allison, Hendrix, Robinson, LaCroix, Manson	10	Gen	Submitted, Br Med J	
651	Alcohol consumption, hypertension, and total mortality among African American and Caucasian post-menopausal women: Results from the Women's Health Initiative	**Freiberg**, Chang, Kraemer, Robinson, Adams-Campbell, Kuller	10	OS	Submitted, JAMA	
676	The interaction of vasomotor symptoms, low-fat dietary pattern and risk of invasive breast cancer: A secondary analyses of the Women's Health Initiative Randomized Controlled Dietary Modification Trial	**Caan**, Aragaki, Thomson, Chlebowski, Stefanick, Hubbell, Tinker, Vitolins, Rajkovic, Bueche	10	CT		
683	Influence of educational attainment and occupation on relationships between neuropathology and cognitive function: The Women's Health Initiative Memory Study [WHIMS]	**Rapp**, Espeland, Manson, Resnick, Wassertheil-Smoller, Coker, Phillips, Stefanick, Sarto, Bryan, Women's Health Initiative Memory Study Research Group	10	WHIMS	Submitted, J Am Geriatrics As	AS39, AS183
723	Breast cancer after stopping estrogen plus progestin in postmenopausal women	**Chlebowski**, Kuller, Prentice, Stefanick, Manson, Gass, Aragaki, Ockene, Lane, Sarto, Rajkovic, Schenken, Hendrix, Ravdin, Rohan	10	CT		
728	Estrogen alone and breast cancer detection by means of mammography and breast biopsy	**Chlebowski**, Anderson, Manson, Pettinger, Yasmeen, Lane, Langer, Hubbell, McTiernan, Hendrix, Schenken, Stefanick	10	CT	Submitted, Arch Intern Med	
794	Regional brain and ischemic lesion volumes in women with cognitive impairment following exposure to conjugated equine estrogen therapies: The Women's Health Initiative Magnetic Resonance Imaging Study (WHIMS-MRI)	**Espeland**, Tindle, Bushnell, Jaramillo, Kuller, Margolis, Mysiw, Maldjian, Melman, Resnick	10	CT	Submitted, Lancet Neurol	AS183

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Ms ID	Title	Authors	Status	Data Focus	Reference	Study
850	Heart rate variability, ambient particulate matter air pollution and glucose homeostasis: The Environmental Epidemiology of Arrhythmogenesis in the Women's Health Initiative	**Whitsel**, Quibrera, Christ, Liao, Anderson, Prineas, Heiss	10	CT	Submitted, Am J Epidemiol	AS140
87	Predictors of total hip replacement in a cohort of older women: Result from the WHI observational study	**Wallace** Chang, Nevitt, LaCroix, Kaplan Sturm	9	Gen		
127	Homocysteine and incident coronary heart disease: Prospective analysis from the Women's Health Initiative observational study	**Siscovick**, Manson, Trevisan, Wallace, Howard, Burke, Ridker	9	OS		AS83
147	Association of hormone replacement therapy with body fat distribution in postmenopausal women	**Mayo**, Heimburger, Gower, Goran, Fouad, Redden, Oberman, Lewis, McGwin	9	CT		
153	Hostility in relation to incident diabetes and increase in metabolic syndrome characteristics in postmenopausal women	**Wylie-Rosette**, Aragaki, Cochrane, Perri, Rosal, Rapp	9	CT		
301	Angiotensin-converting enzyme inhibitor use and incident frailty in women ages 65 and older: Prospective findings from the Women's Health Initiative Observational Study	**Gray**, LaCroix, Aragaki, McDermott, Cochrane, Kooperberg, Murray, Black, Rodriguez, Woods	9	Gen		AS179
314	The effect of aspirin treatment and dose on all-cause mortality and cardiovascular events in postmenopausal women with stable cardiovascular disease: The Women's Health Initiative Observational Study	**Berger**, Brown, Burke, Oberman, Kostis, Langer, Wong, Wassertheil-Smoller	9	OS		
389	Hierarchical models for the effect of spatial interpolation error on the inferred relationship between ambient particulate matter exposure and cardiovascular health	**Crooks**, Whitsel, Catellier, Liao, Quibrera, Smith	9	CT		AS140
392	Family history of myocardial infarction predicts incident coronary heart disease in postmenopausal women with diabetes: The Women's Health Initiative Observational Study	**Li**, Johnson, O'Sullivan, Robinson, Safford, Curb	9	OS		AS180

Table 11.2 (continued)
Publications – Stages 3 through 12

Ms ID	Title	Authors	Status	Data Focus	Reference	Study
510	Alcohol consumption and the risk of coronary heart disease in women with diabetes: Results from the Women's Health Initiative observational study	**Rajpathak**, Freiberg, Wang, Wylie-Rosette, Wildman, Rohan, Robinson, Liu, Wassertheil-Smoller	9	OS		
532	Incidence of urinary incontinence in postmenopausal women with diabetes: The Women's Health Initiative Observational Study	**Bonds**, Hogan, Cochrane, Hendrix, Masaki, Sarto	9	OS		
534	Menopausal symptom experience before and after stopping estrogen therapy in The Women's Health Initiative Randomized Placebo-Controlled Trial	**Brunner**, Aragaki, Barnabei, Gass, Hendrix, Lane, Ockene, Yasmeen, Woods, Stefanick	9	CT		
549	Semiparametric regression exploiting covariate independence in two-phase sampling	**Dai**, LcBlanc, Kooperberg	9	Gen		
553	Association of dopamine genotypes with physical activity and body habitus in post-menopausal women	**Leddy**, Hovey, Salis, Brennan, Epstein, Wactawski-Wende	9	OS		AS15
558	The relationship between cognitive function and physical performance in older women: Results from the Women's Health Initiative Memory Study [WHIMS]	**Atkinson**, Rapp, Williamson, Lovato, Absher, Gass, Henderson, Johnson, Kostis, Mouton, Ockene, Stefanick, Lane, Espeland	9	WHIMS		AS39
584	A randomized controlled trial of calcium plus vitamin D supplementation and risk of benign proliferative breast disease [Benign breast disease study]	**Rohan**, Negassa, Chlebowski, Ceria, Cochrane, Lane, Wassertheil-Smoller, Page	9	CT		AS130
633	Vitamin A and retinol intake and the risk of fractures among participants of the Women's Health Initiative Observational Study	**Caire-Juvera**, Ritenbaugh, Wactawski-Wende, Snetselaar, Chen	9	OS		AS153
657	Correlates of sexual satisfaction among sexually active women in the Women's Health Initiative-Observational Study (WHI-OS)	**McCall-Hosenfeld**, Jaramillo, Legault, Freund, Cochrane, Manson, Wenger, Eaton, Rodriguez, McNeeley, Bonds	9	OS		

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Publications – Stages 3 through 12

Ms ID	Title	Authors	Status	Data Focus	Reference	Study
696	Relationship of HTN, blood pressure (BP) and BP control with magnetic resonance imaging (MRI) outcomes in the Women's Health Initiative Memory Study (WHIMS) MRI Study [WHIMS-MRI]	**Kuller**, Margolis, Jaramillo, Bryan, Kerwin, Limacher, Moonis, Wassertheil-Smoller, Williamson, Robinson	9	CT		AS183
697	Life outlook, incident coronary heart disease, and total mortality in the Women's Health Initiative	**Tindle**, Kuller, Matthews, Hunt, Robinson, Rosal, Manson	9	Gen		
716	Migraines, ST depression and risk for cardiac events: Results from the MIMS Study	**York**, Li, Hassan, Ephross, Brunner, Limacher, Wassertheil-Smoller, Sheps	9	OS		AS70
871	Data analysis methods and the reliability of analytic epidemiologic research	**Prentice**	9	Gen		
879	Epidemiology of fracture risk in the Women's Health Initiative	**Jackson**, Donepudi, Mysiw	9	Gen		
228	Past hysterectomy as a risk factor for hypertension in the Women's Health Initiative observational study participants	**Barad**	8	OS		
358	Conjugated equine estrogen influence on mammographic density in postmenopausal women: The Women's Health Initiative Randomized Trial	**McTiernan**, Martin, Peck, Aragaki, Pisano, Wang, Chlebowski, Heiss, Wallace, Johnson, Vitolins, Manson	8	CT		AS36
436	Health characteristics of postmenopausal women With breast implants many years ago	**Rubin**, Song, Shestak, Lane, Valoski, Chang, Kuller	8	Gen		
476	Associations between dietary fat intake and Age Related Macular Degeneration (ARM) For the Women's Health Initiative-Sight Exam (WHI-SE) Study participants [WHISE]	**Kannan**, Haan, Blythe, Moore, Hazzouri, Deng, Tong	8	CT		AS62
539	Estrogen use and mild cognitive impairment: Baseline and retrospective data from the Cognitive Change in Women WHI Ancillary Study	**Dunn**, Stoddard, Harty, Gavett, Weintraub	8	CT		AS84

Table 11.2 (continued)
Publications – Stages 3 through 12

Ms ID	Title	Authors	Status	Data Focus	Reference	Study
579	Relative effects of Tamoxifen, Raloxifene, and conjugated equine estrogens on cognition: Results from the Women's Health Initiative Memory Study (WHIMS) and the Cognition in the Study of Tamoxifen and Raloxifene (CoSTAR) Clinical Trials [WHISCA]	**Espeland**, Shumaker, Limacher, Rapp, Bevers, Barad, Coker, Jaramillo, Stefanick, Lane, Maki, Resnick	8	WHIMS		AS103
600	Reading ability and race-ethnic differences in cognitive testing: The Cognitive Change in Women ancillary study to the Women's Health Initiative	**Dunn**, Harty, Stoddard, Gavett, Weintraub	8	OS		AS84
619	Dietary fish intake and incident atrial fibrillation: Findings from the Women's Health Initiative	**Berry**, Passman, Prineas, VanHorn, Larson, Goldberger, Snetselaar, Tinker, Liu, Lloyd-Jones	8	CT		
660	Relation of genetic variation in the gene coding for c-reactive protein with its plasma protein levels: Findings from the Women's Health Initiative observational cohort	**Lee**, You, Song, Hsu, Manson, Nathan, Tinker, Liu	8	OS		AS132
875	Cigarette smoking and pancreatic cancer: A pooled analysis from the Pancreatic Cancer Cohort Consortium (PanScan)	**Kooperberg**, Johnson, Messina, Luo, Tong	8	Gen		M4 -
81	The prevalence of urinary incontinence in WHI women	**Hendrix**, Clark, Ling, Dugan, Salmieri, Hurtado, McNeeley, Laube, McTiernan, Francis	7	Gen		
152	The impact of magnesium intake on bone mass and risk of fracture in the Women's Health Initiative observational study	**Jackson**, LaCroix, Lewis, Wactawski-Wende, Cauley, Chen, Bassford	7	OS		
159	Endogenous sex steroid hormone and risk of coronary heart disease in postmenopausal women	**Rexrode**, Manson, Kuller, McTiernan, Stefanick, Heckbert, White	7	OS		AS110
175	The effect of nutrient intake on blood pressure in the Women's Health Initiative at baseline	**Kotchen**, Kotchen	7	Gen		
194	Predictors of adherence to the hormone replacement therapy clinical trial in the Women's Health Initiative	**Cochrane**, Stefanick, Wallace, Granek, Lillington, Anderson, Woods, Naughton	7	CT		

Table 11.2 (continued)
Publications – Stages 3 through 12

Ms ID	Title	Authors	Status	Data Focus	Reference	Study
223	Physical activity and fracture in the Women's Health Initiative observational study	**Wactawski-Wende**, Cauley, Jackson, LeBoff, Chen, Robbins, Ockene, Rodriguez, LaCroix	7	OS		
334	Sexual function and the effect of discontinuation of E+P therapy among participants in WHI	**Gass**, Cochrane, Barad, Barnabei, Brzyski, Lane, LaValleur, Manson, Mouton, Ockene	7	CT		
360	Body mass index, waist-hip ratio, and cognitive decline in postmenopausal women: Results from the WHIMS [WHIMS]	**Kerwin**, Jaramillo, Chlebowski, Coker, Hoffman, Espeland, Kotchen, Kuller, Nicklas, Rainford, Vitolins	7	WHIMS		AS39
374	Tamoxifen and coronary heart disease (CHD) risk	**Chlebowski**, Allison, Brzyski, Greep, Kooperberg, O'Sullivan, Robinson	7	Gen		
377	Medication utilization for the secondary prevention of cardiovascular disease in older women	**Robinson**, Wallace, Cochrane, Black, Ko, Masaki, O'Sullivan, Petrovich	7	Gen		
380	Coagulation factors, postmenopausal hormone replacement therapy and the risk of venous thrombosis: The Women's Health Initiative clinical trials of postmenopausal hormone therapy	**Cushman**, Rosendaal, Baird, Bray, Curb, Eaton, Heckbert, Howard, Phillips, Stafford	7	CT		W6
406	Effect of estrogen and estrogen plus progestin replacement therapy on the incidence of stroke in older women with atrial fibrillation	**Konety**, Robinson, Black, Frishman, Oberman, Sarto, Williams, Wallace, Wassertheil-Smoller	7	CT		
473	Adverse effects of Calcium/Vitamin D supplementation	**Wallace**, O'Sullivan, Wactawski-Wende, Masaki, Cochrane, Gass, Whitlock	7	CT		
528	Ambient air pollution and ventricular repolarization: Environmental epidemiology of arrhythmogenesis in WHI,1999-2001	**Whitsel**, Anderson, Catellier, Chen, Crooks, Liao, Peuquet, Prineas, Quibrera, Smith	7	CT		AS140
543	Insulin-like growth hormone-1, risk factors, and risk for hip fracture in postmenopausal women	**Jackson**, Lee, Cummings	7	OS		AS90

Table 11.2 (continued)
Publications – Stages 3 through 12

Ms ID	Title	Authors	Status	Data Focus	Reference	Study
546	Predictors of incident dementia in postmenopausal women enrolled in a trial of hormone therapy: The Women's Health Initiative Memory Study [WHIMS]	**Coker**, Legault, Colenda, Greep, Limacher, Murray, Rainford, Vitolins, Wallace	7	WHIMS		AS39
595	Quality assurance and training in a low event long-term clinical trial [WHIMS]	**Dailey**, Felton, Summerville, Coker, Nance, Kidd	7	WHIMS		AS39
598	Effects of conjugated equine estrogens on cognition and affect in surgically menopausal women [WHISCA]	**Resnick**, Espeland, An, Coker, Jackson, Maki, Stefanick, Wallace	7	CT		AS103
616	Subjective and informant-reported memory complaints and cognitive function in non-demented older women	**Gavett**, Dunn, Harty, Stoddard, Weintraub	7	OS		AS84
639	Psychiatric disorders and co-morbid adjudicated cognitive dysfunction among postmenopausal women: Results from the Women's Health Initiative Memory Study [WHIMS]	**Colenda**, Legault, DeBon, Hershey, Ockene, Phillips, Rapp, Sarto, Wallace, Whitmer	7	WHIMS		AS39
647	2007 AHA Cardiovascular (CV) Prevention Guidelines for Women: CV event rates in 'high risk', 'at risk' and 'optimal risk' women	**Hsia**, Cochrane, Freiberg, Graettinger, Howard, Liu, Lloyd-Jones, Manson, Robinson, Rosal, Wong	7	Gen		
722	Bisphosphonates and breast cancer outcome in the WHI	**Chlebowski**, Cauley, Chen, Lane, McTiernan, Safford, Wallace, O'Sullivan, Yasmeen, Snetselaar, Manson, Hendrix	7	Gen		
117	Correlates of session completion and self-monitoring of food intake among minority participants enrolled in the Women's Health Initiative (WHI) dietary modification intervention during the first year of intervention	**Rosal**, Ockene, Mossavar-Rahmani, Margolis, Paskett, Thomson	6	CT		AS75
251	Reproductive history and age-related maculopathy in the Women's Health Initiative Sight Exam Study [WHISE]	**Haan**, Wallace, Hendrix, Seddon, Klein, Klein, Musch, Langer, Brunner, Wactawski-Wende	6	CT		AS62

Table 11.2 (continued)
Publications – Stages 3 through 12

Ms ID	Title	Authors	Status	Data Focus	Reference	Study
266	Correlation of endogenous sex steroid hormones with fasting glucose and insulin levels, HOMA indices, and incident diabetes mellitus in postmenopausal women	**Weinstein**, Rexrode, Ridker, Manson, Kuller, Hankinson, Cochrane	6	OS		AS110
304	The effect of E+P discontinuation on risk for fracture: The WHI	**Jackson**, Watts, Lewis, Chen, Neuner, Caulcy, Mouton, Robbins, Greep, LaCroix, Stefanick, Caralis, O'Sullivan	6	Gen		
305	Serum sex hormone levels and risk of hypertension in postmenopausal women	**Joffe**, Rexrode, Cochrane, Allison, Kotchen, O'Sullivan, Safford	6	OS		AS110
366	Association of vasomotor symptoms with cardiovascular outcomes	**Barad**, Allison, Barnabei, Brunner, Cochrane, Gass, Manson, Ockene, Robinson, Schatz, Stefanick, Woods, Rossouw	6	CT		
395	Hormone therapy, lean mass, falling and fracture risk among postmenopausal women: Results from the Women's Health Initiative hormone trials	**Bea**, Bassford, Caulcy, Jackson, LaCroix, Lewis, Chen	6	CT		
399	Subtypes of mild cognitive impairment: Prevalence, course, and effect of hormone therapy [WHIMS]	**Rapp**, Legault, Absher, Brunner, Henderson, Jones, Masaki, Thal	6	WHIMS		AS39
410	Stress as a factor contributing to advanced breast cancer stage at the time of diagnosis in underserved minority women	**Moshesh**, Eaton, Hunt, Paskett, Woods	6	Gen		
420	Postmenopausal hormone use and the risk of nephrolithiasis: Results from the Women's Health Initiative	**Maalouf**, Welch, Robbins, Cochrane, Moe, Sakhaee	6	CT		
547	CaD and hip geometry	**Chen**	6	Gen		AS153
562	Anemia and fracture risk	**Chen**, Bassford, Thomson	6	Gen		
608	Ambient air pollution, atrioventricular / ventricular conduction and their abnormalities: The environmental epidemiology of arrhythmogenesis in WHI, 1999-2003	**Liao**, Anderson, Duan, Lin, Peuquet, Prineas, Quibrera, Smith, Whitsel	6	CT		AS140

Table 11.2 (continued)
Publications – Stages 3 through 12

Ms ID	Title	Authors	Status	Data Focus	Reference	Study
621	Factors associated with 3-year change in cognitive function in older women	**Dunn**, Gavett, Harty, Stoddard, Weintraub	6	OS		AS84
673	Abuse, frailty, and mortality in older women	**Baker**, LaCroix, Cochrane, Wallace, Woods	6	Gen		
685	Diet and the risk for clinical cardiovascular disease in the Women's Health Initiative Observational Study	**Belin**, VanHorn, Greenland, Lloyd-Jones, Tinker, Howard, Allison, Shikany, Martin	6	OS		
710	Insomnia and risk of cardiovascular diseases in postmenopausal women	**Chen**, Wassertheil-Smoller, Allison, Kotchen, Mellman, Sarto, Stefanick, Brunner, Naughton, Levine, Ren	6	Gen		AS140
795	Effect of postmenopausal hormone therapy on circulating estrogens and sex hormone binding globulin: Findings of the Women's Health Initiative	**Edlefsen**, Jackson, Anderson, Prentice, Rajkovic, O'Sullivan, Janssen	6	CT		W18
18	The association between dietary phytoestrogens and breast cancer risk in postmenopausal women	**Assaf**, Cyr, Coccio, Hixson	5	CT		
118	Association between depressive symptomatology and physical activity in postmenopausal women	**Rosal**, Ockene, Haan, Brunner, Mouton, Lopez, Perri, Cochrane, Matthews, Jackson, Sato	5	Gen		
141	The association of food and nutrient intake with the incidence of stroke in the WHI observational study	**Beresford**, Shikany, St. Jeor, Torrens, Mossavar-Rahmani, Heiss, Patterson, VanHorn	5	Gen		
160	Correlation of endogenous sex steroid hormones with inflammatory and thrombotic markers in postmenopausal women	**Rexrode**, Manson, Ridker, Cochrane, Ockene, Kotchen, Margolis, McGovern	5	OS		AS110
180	Alcohol use and the risk of endometrial cancer in the Women's Health Initiative observational study	**Assaf**, Beresford, Ockene, Chen, Cyr, Coccio, Moulton, Duffy, Burkholder	5	OS		
182	The effect of moderate alcohol consumption on the incidence of ovarian cancer	**Assaf**, Coccio, Anderson, Caan, Kaunitz, DeSantis, Duffy, Burkholder	5	OS		
245	Factors associated with self-reported severity of constipation in the Women's Health Initiative	**Morse**, Ockene, Nygaard, Crawford	5	Gen		

Table 11.2 (continued)
Publications – Stages 3 through 12

Ms ID	Title	Authors	Status	Data Focus	Reference	Study
276	Social support and cognitive functioning in post-menopausal women [WHIMS]	**Messina**, Espeland, Jaramillo, Coker, Lane, Masaki, Phillips, Powell, Rosal, Shumaker	5	WHIMS		AS39
297	Racial/ethnic differences in menopausal symptoms in minority vs. White women in the observational study cohort of WHI at baseline	**Potter**, Cochrane, Brzyski, Schenken, Murphy, O'Sullivan, Mossavar-Rahmani, Kempainen	5	OS		
309	Correlates of dietary patterns in older women in the Carotenoids in Age related eye Disease Study [CAREDS]	**Moeller**, Ritenbaugh, Tinker, Moeller, Blodi, Chappel	5	OS		AS105
381	Estimating ovarian cancer risk	**Anderson**, Chlebowski, Johnson, Kaunitz Sato Monk	5	Gen		AS97
384	Frailty in WHI clinical trials participants: Comparison of self-report and physical performance measures	**Woods**, LaCroix, Brunner, Cochrane, O'Sullivan, Wallace	5	CT		
422	The occurrence of postmenopausal breast cancer following nonmelanoma skin cancer – A prospective observational study from the Women's Health Initiative	**Rosenberg**, Greenland, Khandekar, McTiernan, Rodabough, Sharma	5	Gen		
435	Association of diabetes-related phenotypes with genetic variants in the estrogen and progesterone receptor genes	**Mychaleckyj**, Bonds, Rodabough	5	CT		W11
458	BMI and prognostic features of endometrial cancer	**Paskett**, Cunyun, Lane, McNeeley, Reeves	5	Gen		
463	Glycemic load and risk of coronary heart disease in the Women's Health Initiative observational study	**Shikany**, Tinker, Liu, Allison, Hsia, Ma, Neuhouser, Uwaifo, VanHorn	5	OS		AS111
466	Dietary modification, quality of life, and depression	**Assaf**, Beresford, Brunner, Bowen, Naughton, Petrovich, Granek, Whitlock, Phillips, Haines, DeCosimo, Robinson-O'Brien, Rosal, Wenger, Snetselaar	5	CT		
478	Correlates of medication utilization for the secondary prevention of coronary heart disease in older women	**Robinson**, Wallace, Cochrane, Johnson, Safford	5	CT		

Table 11.2 (continued)
Publications – Stages 3 through 12

Ms ID	Title	Authors	Status	Data Focus	Reference	Study
480	Thyroid disease and risk for hip fracture in postmenopausal women	**Cummings**, Bauer, Cauley, Jackson, Kooperberg, LaCroix, LeBoff, Lee, Lewis, Thomas, Wu	5	OS		AS90
487	Body composition and physical function in a cohort of multiethnic older women: The WHI observational study and clinical trials	**Chen**, Bassford, Lohman, Nicholas, Wu, Wright, Wang, Going, LaCroix, Sherrill, Heymsfield	5	OS		AS153
494	The effect of lipid-lowering agents on the development of malignant melanoma: A prospective study from the Women's Health Initiative	**Rosenberg**, Levy, Greenland, McTiernan	5	Gen		
498	The effect of vitamin E intake on serum tocopherol concentrations: changes with age [CAREDS]	**Johnson**, Bragg	5	OS		AS105
499	Prospective analysis of association between use of statins or other lipid lowering agents and colorectal cancer risk	**Rosenberg**, Roy, Khandekar, Cauley, Greenland, Lane, Ockene	5	Gen		
502	Menopausal hormone therapy and risk of ovarian cancer	**Anderson**, Barnabei, Brzyski, Chlebowski, Hendrix, Lane, Monk, Ockene, Rodriguez, Sarto	5	CT		
566	Ethnicity and cross-sectional geometry of the hip	**Nelson**, Chen, Going	5	Gen		AS153
575	Effect of hormone therapy on physical performance in the Women's Health Initiative	**Michael**, Brzyski, Cochrane, Gold, Manson, McNeeley, Wallace, Woods	5	CT		
578	Depression and the risk of peripheral arterial disease: Results from the Women's Health Initiative observational study	**Cherr**, Wassertheil-Smoller, Trevisan, Wactawski-Wende, Allison, Johnson, Hsia, Hunt	5	OS		
581	Correlations between serum vitamin D, total vitamin D Intake, and estimates of sunlight exposure in the Women's Health Initiative nested case-control studies	**Millen**, Jackson, LaCroix, LeBoff, Liu, Mares-Perlman, Melamed, Robbins, Tylavsky, Wactawski-Wende	5	CT		W15
597	Prevalence of anticholinergic drug use and impact on cognition and function in older women [WHIMS]	**Sink**, Espeland, Gass, Goff, Rapp, Sherwin, Thomas	5	WHIMS		AS39

Table 11.2 (continued)
Publications – Stages 3 through 12

Ms ID	Title	Authors	Status	Data Focus	Reference	Study
611	Blood pressure response to dietary modification in postmenopausal women: Results from the Women's Health Initiative Clinical Trial	**VanHorn**, Margolis, Thomson, Kotchen, Allison, Beresford, Black, Cantey, Curb, Frank, Grimm, Kuller, O'Sullivan, Wassertheil-Smoller, Torner	5	CT		
630	Postmenopausal hormone therapy and colorectal cancer in the WHI CT and OS	**Prentice**, Beresford, Chlebowski, Hubbell, Liu, Wactawski-Wende	5	Gen		
646	The association of calibrated nutrient biomarkers, dietary assessment and cardiovascular disease risk: The Women's Health Intiative Nutrient Biomarker Study [NBS]	**Johnson**, Prentice, Hsia, Kuller, Liu, Ockene, Sarto, Stefanick, Tinker, VanHorn	5	OS		W8
649	Effects of low-fat dairy products and yogurt on diabetes incidence in post-menopausal women	**Margolis**, DeBoer, Howard, Liu, Manson, Mossavar-Rahmani, Phillips, Safford, Shikany, Tinker, Wei	5	OS		
650	Proton pump inhibitor use, hip fracture and change in bone density in postmenopausal women: Results from the Women's Health Initiative	**LaCroix**, Cauley, Chen, Gray, Manson, Robbins	5	Gen		
665	Ascertaining dementia related outcomes for deceased or proxy-dependent participants: An overview of WHIMS supplemental case ascertainment protocol (WHIMS-SCAP) [WHIMS]	**Jaramillo**, Rapp, Absher, Espeland, Jones	5	WHIMS		AS39
667	Vasomotor symptoms and incident cardiovascular disease in postmenopausal women	**Szmuilowicz**, Manson, Seely, Howard, Rodriguez, Grobbee, Sarto, Rossouw, Ockene, Johnson, Margolis, Vitolins, Stefanick, O'Sullivan, Greep	5	OS		
670	Long-term neurocognitive effects of sleep disturbance: Impacts on cognitive declines, and incidence of mild cognitive impairment and dementia [WHIMS]	**Chen**, Espeland, Lovato, Brunner, Johnson, Kotchen, Manson, Mysiw, Phillips, Robinson, Sarto, Stefanick, Wallace	5	WHIMS		AS39

Table 11.2 (continued)
Publications – Stages 3 through 12

Ms ID	Title	Authors	Status	Data Focus	Reference	Study
680	Mixed distribution risk factors models for ischemic lesion prevalence and extent: The Women's Health Initiative Magnetic Resonance Imaging Study [WHIMS-MRI]	**Espeland**, Resnick, Tooze, An, Bryan, Coker, Robinson	5	WHIMS		AS183
681	Bone turnover and the risk of hip fracture: The Women's Health Initiative	**Bauer**, Cauley, LeBoff, LaCroix, Robbins, Jackson, Greep	5	OS		AS181
694	Dietary vitamin D and calcium intake and mammographic density	**Bertone-Johnson**, McTiernan, Thomson, Sarto, Wactawski-Wende, Manson, Rexrode, Chlebowski, Tamimi, Rohan, Pisano	5	CT		AS36
706	Vasomotor symptoms and cardiovascular risk markers in postmenopausal women	**Szmuilowicz**, Seely, Manson, Vaidean, Rossouw, Vitolins, Stefanick, O'Sullivan, Greep	5	OS		
713	World Health Organization (WHO) absolute fracture risk score: How well does it predict fractures in minority women	**Cauley**, Robbins, LaCroix, Lewis, Wactawski-Wende, Masaki, Johnson, O'Sullivan, Jackson, Hendrix	5	Gen		
714	Inflammatory markers and the risk of hip fracture: The Women's Health Initiative	**Cauley**, Jackson, LaCroix, Lee, Robbins, Allison, Greep, Cummings, Wallace	5	OS		AS181
718	Anticonvulsant use and osteoporosis: Findings from the WHI	**Carbone**, Johnson, Robbins, LaCroix, Curb, Gass, Watson	5	Gen		
720	Association between non-melanoma skin cancer and subsequent hematolymphoid malignancy by WHO diagnostic subtype, implications for subclinical immunosuppression and relationship to disease-specific and all-cause mortality	**Edlefsen**, DeRoos, LaCroix, Cherian, Rosenberg, Kotchen	5	Gen		
724	Low-fat dietary pattern and lipoprotein risk factors: The Women's Health Initiative Randomized Controlled Dietary Modification Trial	**Howard**, Curb, Eaton, Kooperberg, Ockene, Kostis, Rajkovic, Robinson, Rossouw, Sarto, Shikany, VanHorn	5	CT		

Table 11.2 (continued)
Publications – Stages 3 through 12

Ms ID	Title	Authors	Status	Data Focus	Reference	Study
729	Do changes within specific nutrients or food groups within the WHI dietary intervention explain a reduction in breast cancer incidence?	**Caan**, Thomson, Hubbell, Lane, Curb, Johnson, Kuller, VanHorn, Gass, Prentice, Chlebowski, Yasmeen, Beresford, Mossavar-Rahmani	5	CT		
849	Effect of a low-fat dietary pattern on glucose and insulin resistance in the Women's Health Initiative Dietary Modification Trial	**Margolis**, Shikany, Beresford, Brzyski, Jackson, Limacher, Liu, Phillips, Tinker	5	CT		
861	25(OH)vitamin D levels and incident cardiovascular events in the WHI	**Manson**, Margolis	5	Gen		W15, W24, AS181
205	Risk factors for sarcopenia among a multiethnic cohort of postmenopausal women	**Chen**, Cauley, Lewis, Phillips, VanHorn, Wallace	4	Gen		
267	Adherence to dietary modification: A theoretical framework	**Rosal**, Ockene, Fletcher, Lasser, Tinker	4	CT		AS75
281	Prevalence of ST segment depression on Holtor monitoring in women in the observational study relationship to HRT	**Sheps**, Smoller, Wassertheil-Smoller, Oberman, Hsia, Wong, Heiss, Ephross, McGorray	4	OS		AS70
427	Statin use and cognition in postmenopausal women:The Women's Health Initiative Memory Study [WHIMS]	**Legault**, Fillit, Hsia, Limacher, Manson, Ockene, Robinson, Sherwin, Sink	4	CT		AS39
434	The effect of physical activity frequency, duration, and intensity on cardiovascular outcomes in WHI observational study	**Meyer**, Evenson, Heiss, Manson	4	OS		
446	Hormone exposure and risk of Parkinson's disease	**Saunders-Pullman**, Bressman, Chiu, Derby, Lipton, Santoro, Wassertheil-Smoller	4	OS		
491	Cause of death in women who die after hip fracture: WHI experience	**Robbins**, Pastore	4	OS		
513	Alcohol consumption and the risk of cardiovascular disease among black and white women: The effects of current and lifetime patterns of alcohol consumption among participants from the Women's Health Initiative	**Freiberg**, Adams-Campbell, Allison, Beresford, Curb, Hunt, Kraemer, Kuller, Safford, Trevisan, Robinson	4	OS		

Table 11.2 (continued)
Publications – Stages 3 through 12

Ms ID	Title	Authors	Status	Data Focus	Reference	Study
582	Prediction and risk stratification of clinical diabetes in postmenopausal women	**Chao**, Liu, Bonds, Chen, Eaton, Margolis, Phillips, Rodriguez, Song, Tinker	4	OS		AS132
588	Non-steroidal anti-inflammatory drugs and cognitive function in older women	**Dunn**, Gavett, Harty, Stoddard, Weintraub	4	Gen		AS84
593	Effect of genetic polymorphisms on coronary cardiac events among women in the Women's Health Initiative (WHI) study	**Bray**, Afshar-Kharghan, Hays, Hendrix, Herrington, Howard, Johnson, Kuller, LaCroix, Langer, Leal	4	OS		AS137
644	Association between reproductive history, adult weight stability and postmenopausal BMI and body composition	**Rosal**, Crawford, Bodenlos, Brzyski, Hardy, Hays, Hunt, Liu, Masaki, McNeeley, Moore-Simas, Phillips, Thomson, VanHorn	4	Gen		
686	Fish, omega-3 fat, and trans fat intake and the risk for incident congestive heart failure in the Women's Health Initiative	**Belin**, VanHorn, Greenland, Lloyd-Jones, Tinker, Robinson, Oberman, Martin	4	OS		
806	The effect of treatment with conjugated equine estrogen on the presence and extent of subclinical atherosclerosis in the thoracic aorta of women 50 – 59 years of age at enrollment in the Women's Health Initiative [WHI-CACS]	**Carr**, Allison, Manson, Lewis, Curb, Johnson, Kuller, Martin, Trevisan, Woods, O'Sullivan, Langer, Wallace, Terry, Cochrane	4	CT		W25
90	Passive smoke exposure in childhood and adulthood and prevalent coronary heart disease in women enrolled in the WHI	**Frishman**, Wagenknecht, Wong, Ockene	3	OS		
157	Type 2 diabetes and change in cognitive functioning in WHIMS: The effects of diabetic risk factors and treatment for diabetes and hypertension [WHIMS]	**Coker**, Hogan, Hall, Mount, Ockene, Wallace	3	WHIMS		AS39
170	Non-steroidal anti-inflammatory drugs (NSAID) as potential preventive factors for the development of gallstone disease in older women	**Wallace**	3	OS		
364	Hormone replacement therapy and chronic heart failure incidence and outcomes in post-menopausal women	**Greenland**, Klein, Lloyd-Jones, LaCroix, Limacher, Robinson, Wong, Howard, Chae, Gulati, Sueta	3	CT		AS196

Table 11.2 (continued)
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Ms ID	Title	Authors	Status	Data Focus	Reference	Study
412	Validation of WHO model for absolute risk of fracture	**Cauley**, Watts, Chen, Cummings, Jackson, LeBoff, McGowan, O'Sullivan, Robbins, Wactawski-Wende	3	Gen		
432	Racial/ethnic-specific patterns of extreme obesity, mortality, and cardiovascular risk in the Women's Health Initiative	**McTigue**, Valoski, Kuller, Johnson, Robinson, Lewis, Garcia, Liu, Eaton, Rosal	3	Gen		
439	The effect of intentional and unintentional weight loss on stroke risk in the Women's Health Initiative observational study	**Ostfeld**, Bobra, Kaplan, Kooperberg, Lo, Myrskyla, Mysiw, Rosenbaum, Wassertheil-Smoller	3	OS		
443	Statin use and lung cancer risk in non-smoking postmenopausal women	**Schlecht**, Wassertheil-Smoller, Johnson, Kamensky	3	OS		
457	Elevated blood pressure and kidney cancer	**Kuller**, Chang, Curb, Fried, Liu, Tevisan	3	OS		
485	Caffeine and risk of Parkinson's disease in women	**Wassertheil-Smoller**, Santoro, Derby, Saunders-Pullman	3	OS		
497	Extreme obesity and incident hypertension and diabetes: Racial and ethnic patterns in the WHI study	**McTigue**, Kuller, Valoski, Safford	3	Gen		
500	Results from the long term stability, standardization and quality control for the core analytes at the central laboratory for the WHI program	**Stein** Chen, LaCroix, Lund, Rossouw, Miller	3	Gen		
505	Body image satisfaction in postmenopausal women	**Ginsberg**, Margolis, Gray, Tinker, Rosal, Manson, Sangi-Haghpeykar	3	OS		
540	Interaction between family history of cardiovascular disease and diabetes for the risk of coronary heart disease and stroke in postmenopausal women without diabetes at baseline: The WHI observational study	**Li**, Johnson, Curb, Robinson, Snetselaar, Allison, Safford, Liu	3	OS		
555	Genetic variation in the peroxisome proliferator-activated receptor y is associated with type 2 diabetes mellitus in the Women's Health Initiative observational study	**Song**, Manson, Tinker, Howard, Kuller, Nathan, Rifai, Liu	3	OS		AS132

Table 11.2 (continued)
Publications – Stages 3 through 12

Ms ID	Title	Authors	Status	Data Focus	Reference	Study
557	Characteristics of the built environment in Seattle and weight change over time	**Littman**, Beresford	3	CT		
559	Tagging SNPs and haplotypes in 9 genes involved in insulin and IGF-I signaling and their associations with breast cancer risk	**Ho**	3	OS		AS152
564	Assessing the relationship between rheumatoid arthritis and fracture risk	**Wright**, Lisse, Chen, Eaton, Walitt	3	OS		
569	Hip geometry and fracture risk in postmenopausal women	**Chen**	3	CT		AS153
571	Cause of death in women who die after hip fracture: WHI	**Robbins**, Pastore, Masaki, Stefanick, Gass, Carbone, LaCroix	3	Gen		
572	Genetic variation in the adiopocyte fatty acid binding protein (aP2 or FABP4) gene is associated with type 2 diabetes in the WHI OS	**Liu**, Hsu, Papps, Song, Tinker	3	OS		AS132
573	Common genetic variation in the endothelial nitric oxide synthase (NOS3) gene and type 2 diabetes in an ethnically diverse cohort of women	**Liu**, Hsu, Papps, Tinker	3	OS		AS132
574	Dietary glycemic index/glycemic load and risk of breast cancer in the Women's Health Initiative observational study	**Shikany**, Chlebowski, Lane, Liu, Neuhouser, Rohan, Simon, Tinker	3	OS		AS111
596	Family history of non-early-onset breast cancer and the incidence of breast cancer among women with breast-healthy lifestyles	**Gramling**, Assaf, Lash, Cabral, Eaton, Harrigan, Hunt, Rothman, Stefanick	3	OS		
599	Estrogen and progesterone and the risk of Parkinson's disease in the clincial trial	**Saunders-Pullman**, Lipton, Wassertheil-Smoller, Tanner, Derby, Santoro	3	CT		
601	Relationship between aspirin use, dose and inflammatory markers in postmenopausal women	**Berger**, Wassertheil-Smoller, Baird, Kaplan, Lynch, McGinn, Rosenbaum, Phillips, Wactawski-Wende, Johnson	3	OS		AS126
604	Metabolic syndrome and incident stroke	**McGinn**, Wassertheil-Smoller, Wolf, Allison, Baird, Berger, Hsia, Kaplan, Kooperberg, Kuller, Rexrode, Rosenbaum	3	OS		AS126

Table 11.2 (continued)
Publications – Stages 3 through 12

Ms ID	Title	Authors	Status	Data Focus	Reference	Study
605	Glycemic index, glycemic load, and risk of pancreatic cancer among postmenopausal women	**Cui**, Liu, Neuhouser, Rohan, Shikany, Simon, Nirmal, Abrams	3	Gen		
607	Race, psychosocial stress, and mammography: Prospective analysis in the Women's Health Initiative	**Michael**, Bowen, Carson, Chlebowski, Hubbell, Lane, Yasmeen	3	OS		
.622	Sex hormones, risk factors and risk of ER-positive and ER-negative breast cancers in postmenopausal women: Women's Health Initiative Observational Study	**Cummings**, Lee, Cauley, Rohan, Vitolins, Chlebowski, Manson, Lane, Sarto, Yasmeen, Hubbell, Cochrane, Hankinson, Crandall	3	OS		AS167
623	Factors associated with life satisfaction and health in postmenopausal women	**Ceballos**, Beresford, Tinker, O'Sullivan, Brunner, Hunt, Manson	3	OS		
627	Neighborhood environment and the risk of coronary heart disease in WHI participants	**Li**, Crawford, Ma, Ockene	3	Gen		
629	Dietary potassium intake and the risk of incident stroke and mortality	**Rajpathak**, Wassertheil-Smoller	3	OS		
642	Thiazolidinedione (TZD) use and fracture risk in postmenopausal women with diabetes	**Schwartz**, Bonds, Cummings, Liu, Margolis, Palermo, Phillips, Vittinghoff	3	Gen		
654	Plasma adiponectin, gene polymorphisms on the adiponectin gene, and risk of hypertension in White and Black women	**Sesso**, Manson, Wang, Brunner, Cochrane, Cook, Kwiatkowski, Liu, Miller	3	OS		AS133
655	Plasma inflammatory markers and the risk of developing hypertension in white and black women	**Sesso**, Cochrane, Cook, Gaziano, Liu, Manson, Ridker, Rifai, Wang	3	OS		AS133
656	Multi-marker risk assessment will yield a better assessment of cardiovascular risk in the Women's Health Initiative compared to a standard risk assessment incorporating major traditional risk factors alone	**Greenland**, Cochrane, Lasser, Limacher, Lloyd-Jones, Manson, Margolis, Robinson, Rossouw	3	OS		
658	The relationship between self-reported rheumatoid arthritis, BMD and hip geometry	**Wright**, Chen, Lisse	3	Gen		AS153
659	Coronary heart disease (CHD) risk perception and its relation to health behaviors in the Women's Health Initiative	**Barnhart**, Walker, Wassertheil-Smoller	3	OS		AS127

Table 11.2 (continued)
Publications – Stages 3 through 12

Ms ID	Title	Authors	Status	Data Focus	Reference	Study
661	Racial differences in Vitamin D levels: Results from the WHI	**Melamed**, Cauley, Chlebowski, Jacobs, LaCroix, LeBoff, Liu, Millen, Robbins, Tylavsky, Wactawski-Wende, Wassertheil-Smoller, Wylie-Rosette	3	CT		
662	Inflammatory biomarkers and risk of incident frailty in postmenopausal women	**LaCroix**, Cauley, Cochrane, Gray, Liu, Reiner, Tinker, Wactawski-Wende, Woods	3	OS		AS179
663	Thrombosis biomarkers and risk of incident frailty in postmenopausal women	**Reiner**, Cochrane, Gray, LaCroix, Woods	3	OS		AS179
668	Dietary antioxidants, inflammation and diabetes mellitus in a multi-ethnic cohort of postmenopausal women	**Rodriguez**, Liu, Manson, Song, Nathan, Phillips, Mouton, Li, Shikany, Curb, Yasmeen, Bonds, Tinker, Rosal,	3	OS		AS132
672	Obesity subtypes and inflammation	**Wildman**, Wassertheil-Smoller, Kaplan, Connelly, Rajkovic, Mackey, Curb, Eaton, Manson, Tinker	3	OS		AS126
679	Physical activity, incident ischemic stroke and cardiovascular biomarkers	**McGinn**, Wassertheil-Smoller, Kaplan, Johnson, Phillips, Robinson, Lee, Beresford, Kooperberg, Stefanick	3	OS		AS126
682	Effect of migraine on stroke risk associated with hormone therapy in post-menopausal women in the Women's Health Initiative	**Schumacher**, Wassertheil-Smoller, Gass, Mysiw, Rossouw, O'Sullivan, Oberman, Manson	3	CT		
687	Associations between body composition and hip geometry in postmenopausal women in the Women's Health Initiative	**Going**, Chen	3	Gen		AS153
688	Relation of dietary vitamin D, calcium, and magnesium intake to inflammatory markers in postmenopausal women	**Chacko**, Liu, Nathan, DeBoer, Tinker, Tylavsky, Wallace	3	OS		AS132
690	Hip geometric structure is weaker in anemic women: Results from the Women's Health Initiative Observational Study	**Wu**, Chen	3	OS		AS153

Table 11.2 (continued)
Publications – Stages 3 through 12

Ms ID	Title	Authors	Status	Data Focus	Reference	Study
691	Changes in Hip Geometric Structures with Aging--Longitudinal Data Analysis from the Women's Health Initiative Observational Study	**Chen**	3	OS		AS153
692	Change in dietary intake in response to the DM Intervention is associated with change in physical activity among postmenopausal women in the Women's Health Initiative	**Russell**, Beresford, Bowen, Shikany, Snetselaar, Curb, Limacher, Parker	3	CT		
693	Effects of sweetened beverages on diabetes incidence in post-menopausal women	**Margolis**, Tinker, Shikany, Manson, Howard, Ritenbaugh, Wei, Johnson, Snetselaar, VanHorn, Stefanick, Rosal, Liu, Plodkowski	3	OS		
695	Application of hidden Markov models to longitudinal measures of cognition collected by the Women's Health Initiative Study of Cognitive Aging [WHISCA]	**Ip**, Rapp, Zhang, Legault, Snow-Jones	3	CT		AS103
698	Distribution and correlates of adiponectin, leptin, ghrelin and lipoprotein subclasses among black and white postmenopausal women across a range of BMI	**Mackey**, Kuller, Evans, Tinker, Howard, Barinas-Mitchell, Robinson, Manson, McTigue, Phillips, Stefanick, Allison, Rosal, Beresford, Liu	3	OS		AS189
699	Metabolically healthy obese phenotype among black and white postmenopausal women: Definition and risk of incident CHD	**Mackey**, Kuller, Evans, Tinker, Kulick, Howard, Lewis, Wildman, Phillips, Liu, Curb, Stefanick, Barinas-Mitchell, McTigue, Manson	3	OS		AS189
703	Street connectivity, urban sprawl and incident CHD in women	**Eibner**, Bird, Griffin, Margolis, Whitsel, Lurie, Allison, Hunt	3	Gen		AS220b
704	Neighborhood SES and incident CHD in women	**Bird**, Eibner, Griffin, Margolis, Whitsel, Hunt, Mouton, Li	3	OS		AS220b
705	Clustering of mortality in the Women's Health Initiative observational study and clinical trials	**Griffin**, Whitsel, Escarce, Eibner, Bird, Hunt	3	Gen		AS220b

Table 11.2 (continued)
Publications – Stages 3 through 12

Ms ID	Title	Authors	Status	Data Focus	Reference	Study
707	Animal fat intake and ovarian cancer incidence	**Freedman**, Prentice, Lessin, VanHorn, Rajkovic, O'Sullivan, Chlebowski, Manson, Thomson, Smith, Tinker, Lubin, Chetrit, Oberman	3	CT		
708	Comparison of methods used for correcting dietary data for underreporting [NBS]	**Schoeller**, Neuhouser, Bingham, Tylavsky, Tinker, Parker, Snetselaar, Vitolins, Beresford, Liu, LaRowe, Alvig	3	Gen		W8
709	Diet-gene interaction and the risk of diabetes in postmenopausal women	**Ma**, Ockene, Liu, Ockene, Olendzki, Pagoto, Li, Niu, Song, Eaton, Rajkovic, Phillips, Tinker, Plodkowski, Wallace	3	OS		AS132
712	Evidence that women with a history of fracture have reduced mechanosensitivity compared to those who have never fractured	**Beck**, Jackson, Going, Chen, LeBoff, Cauley, Wu, LaCroix, Khaled	3	OS		AS153
717	Dietary omega 3 fatty acids, the omega 6/omega 3 ratio, bone mineral density and fractures in the Women's Health Initiative	**Jackson**, Orchard, Frank, Snetselaar, Lee, Wactawski-Wende, Neuhouser, Robinson, Cauley, Tylavsky	3	Gen		
719	Depression and risk of type 2 diabetes in postmenopausal women	**Ma**, Pagoto, Schneider, Liu, Rodriguez, Ockene, Carnethon, Rosal, Safford, Culver, Sepavich, Tinker, Olendzki	3	OS		AS132
725	Air pollution components and cardiovascular disease in women	**Miller**, Vedal, Kaufman, Anderson, Siscovick, Sheppard, Larson, Eaton, Manson, Kuller	3	OS		AS150
726	The association between neighborhood retail food environment, obesity, blood pressure and Framingham Risk Score	**Fernandes**, Escarce, Ghosh-Datsidar, Margolis, Eibner, Bird, Whitsel, Li, Michael, Manson, Hunt	3	CT		AS220b
730	Changes in dietary intake associated with the WHI dietary modification intervention and colorectal cancer incidence	**Vitolins**, Beresford, Caan, Shikany, Kotchen, Hunt, Parker, Adams-Campbell, Perri	3	CT		

Table 11.2 (continued)
Publications – Stages 3 through 12

Ms ID	Title	Authors	Status	Data Focus	Reference	Study
776	Insulin-resistance associated TCF7L2 polymorphisms and risk of insulin-related cancers	**Ho**, Chen, Anderson, Chlebowski, Rajkovic	3	OS		AS152
789	Tagging SNPs and haplotypes in genes involved in insulin and IGF-I signaling and their associations with colorectal cancer risk	**Ho**, Adams-Campbell, Chlebowski, Peters	3	OS		AS152
790	Tagging SNPs and haplotypes in genes involved in insulin and IGF-I signaling and their associations with endometrial cancer risk	**Ho**, Chen, Rajkovic	3	OS		AS152
791	Polymorphisms of genes involved in insulin and IGF-I signaling and serum biomarkers in the IGF/insulin axis	**Ho**, Chen, Tinker	3	OS		AS152
792	Comparative value of current ECG codes for myocardial infarction/ischemia in predicting incident fatal and nonfatal cardiac events and total mortality in the Women's Health Initiative (WHI)	**Zhang**, Prineas, Eaton	3	CT		
793	Patient-level analysis of vitamin D fracture trials	**Abrahamson**, Robbins, LaCroix, Jackson, Wactawski-Wende	3	CT		
804	Trajectories of physical activity in post-menopausal women: Influence of demographic characteristics, lifestyle behaviors and health status	**Nguyen**, LaCroix, Perry, Herting, Kohen, Tinker, Beresford, Adams-Campbell, Eaton	3	Gen		
805	B adrenergic inhibitors (ß Blockers) and risk for melanoma, multiple myeloma and nasopharyngeal cancer	**Glaser**, Jackson, Saltz, Lemeshow, Benson, Hofmeister, Yang, Rajkovic, Simon	3	Gen		
807	Repeat measurements of serum glucose and insulin levels in relation to breast cancer risk among postmenopausal women	**Kabat**, Kim, Rohan, Rodriguez, Strickler, Shikany, Adams-Campbell, Vitolins, Gunter, Chlebowski, Caan, Aroda	3	CT		
808	Repeat measurements of serum levels of carotenoids, retinol, and vitamin E in relation to breast cancer risk among postmenopausal women	**Kabat**, Kim, Rohan, Shikany, Adams-Campbell, Neuhouser, Chlebowski, Caan	3	CT		

Table 11.2 (continued)
Publications – Stages 3 through 12

Ms ID	Title	Authors	Status	Data Focus	Reference	Study
809	Physical activity and mortality in breast cancer survivors: Results from the Women's Health Initiative	**Irwin**, McTiernan, Chlebowski, Wactawski-Wende, Stefanick, Craft, Lane, Sternfeld, Thomson, Manson, Martin	3	Gen		
811	The effect of calcium plus vitamin D on risk for invasive cancer: Results of the Women's Health Initiative calcium plus vitamin D randomized clinical trial	**Brunner**, Wactawski-Wende, Millen, LaCroix, Cochrane, Caan, Wallace, Lane, Jacobs, Sarto, Margolis, Vitolins, Gass, Chlebowski	3	CT		
814	Variation in the selenoenzyme genes and risk of colorectal cancer	**Peters**, Hutter, Hsu, Prentice, Rajkovic, Marshall, Beresford, Caan, Potter, Duggan, Slattery, Ulrich, Foster, Diamond, Davis	3	OS		AS206
815	Genetic variation in chromosomal regions 8q24 and 9p24 and colorectal cancer risk	**Peters**, Hutter, Potter, Prentice, Rajkovic, Sarto, Marshall, Hammad, Wallace, Beresford, Caan, Potter, Duggan, Slattery, Makar	3	OS		AS206
816	Vasomotor symptoms and coronary artery calcium in postmenopausal women [WHI-CACS]	**Allison**, Manson, Rossouw, Sarto, Curb, Barnhart, Johnson, Phillips, Martin, Stefanick, Gass, Trevisan, Woods, O'Sullivan, Langer	3	CT		W25
819	Genetic and epidemiologic factors associated with AMD among women in the WHI-SE study [WHISE]	**Seddon**, Haan, Peter, Wactawski-Wende, Johnson, Hyman	3	Gen		AS62
822	Low-fat dietary pattern and risk of metabolic syndrome	**Neuhouser**, Thomson, Stefanick, Howard, Tinker, Rohan, Caan, VanHorn	3	CT		
824	Economic and racial/ethnic segregation and incident CHD in women	**Shih**, Bird, Eibner, Escarce, Griffin, Lurie, Michael, Eaton, Gold, Sarto, Allison, Masaki, Rosal, Safford, Manson	3	Gen		AS220b
827	Is social support related to cardiovascular disease in the Women's Health Initiative observational study cohort?	**Freeborne**, Katz, Simmens	3	OS		

Table 11.2 (continued)
Publications – Stages 3 through 12

Ms ID	Title	Authors	Status	Data Focus	Reference	Study
828	Serum selenium concentration and risk of colorectal cancer in postmenopausal women	**Peters**, Takata, Hsu, Prentice, Langer, Petrovich, Shikany, Diamond, Foster, Davis, King, Song, Duggan	3	OS		AS206
829	Lipoprotein particle concentration and size as predictors of ischemic stroke in postmenopausal women	**Berger**, Wassertheil-Smoller, Howard, Eaton, Kuller, Curb, Manson, Otvos, Kaplan, McGinn, Lynch, Rosenbaum	3	OS		AS126
830	The association of consumption of whole grains and fiber with incident diabetes	**Parker**, Margolis, Tinker, Eaton, VanHorn, Rodriguez, Shikany, Liu, Wei	3	OS		
831	Association between protein intake and incident frailty in the Women's Health Initiative Observational Study [NBS]	**Beasley**, LaCroix, Neuhouser, Prentice, Huang, Tinker, Michael, Woods, Curb	3	OS		W8
832	Effect of long-term calcium plus vitamin D supplementation on change in the circulating levels of lipids	**Rajpathak**, Xue, Rohan, Wassertheil-Smoller, Robinson, VanHorn, Allison, Liu, Martin	3	CT		
833	Effect of long-term low-fat dietary intervention on change in the circulating levels of hemostatic factors	**Rajpathak**, Xue, Rohan, Wassertheil-Smoller, Snetselaar, VanHorn, Martin	3	CT		
834	Reproductive history, estrogen use and lung cancer risk in the Women's Health Initiative Clinical Trial and Observational Study	**Schwartz**, Simon, Hubbell, Kooperberg, Chen, Wakelee, Wactawski-Wende, Manson, Abrams, Stefanick, O'Sullivan, Cote, Sokol, Chlebowski, Hendrix	3	Gen		
835	Determinants of serum 25-hydroxyvitamin D in the Carotenoids in Age-Related Eye Disease Study [CAREDS]	**Millen**, Mares, Sarto, Snetselaar	3	OS		AS105
836	Nutrient intake and anemia risk in the WHI Observational trial	**Thomson**, Chen, Aickin, Neuhouser, Snetselaar, Stefanick, Arendell	3	OS		
838	Biomarker-calibrated protein intake and bone health in the Women's Health Initiative Clinical Trial and Observational Study	**Beasley**, LaCroix, Neuhouser, Snetselaar, Tinker, Johnson, Eaton, Jackson, Bingham, Prentice, Huang	3	Gen		

Table 11.2 (continued)
Publications – Stages 3 through 12

Ms ID	Title	Authors	Status	Data Focus	Reference	Study
840	The relationship between migraine and breast cancer risk	**Li**, Mathes, Prentice, Stefanick, Chlebowski, Michael, O'Sullivan, Cavanagh, Bluhm, Caan	3	OS		
841	Serum 25 hydroxyvitamin 25(OH)D and parathyroid hormone (PTH) and fracture risk in multi-ethnic women: The Women's Health Initiative	**Cauley**, Danielson, Boudreau, Jackson, Bauer, Ensrud	3	OS		BAA9
843	Comprehensive serum proteome analysis of post-menopausal estrogen replacement therapy reveals multiple molecular changes in coagulation and metabolic pathways	**Hanash**, Prentice, Paczesny, Jackson, Chlebowski, Manson, Hsia, Rossouw	3	OS		W19
844	Environmental determinants of sleep disturbance in postmenopausal women	**Chen**, Levine, Cai, Kaufmann, Rudra, Rosal, Hunt, Brunner, Michael, O'Sullivan, Wassertheil-Smoller, Kravitz, Serre	3	CT		AS226
846	Genotype as a modifier of intervention effects on breast cancer in the Women's Health Initiative Clinical Trial	**Prentice**, Ballinger, Peters, Huang	3	CT		BAA2
847	Evaluation of dietary fiber, whole grains, and dietary fat in relation to colorectal cancer using different dietary assessment methods: Food Frequency Questionnaire vs. 4-day food record	**Park**, Schatzkin, Prentice, Neuhouser, Tinker, Caan, Subar, Kipnis, Thompson	3	OS		
848	Lung cancer outcome and estrogen use in postmenopausal women	**Chlebowski**, Schwartz, Hubbell, Chen, Anderson, Kotchen, Wactawski-Wende, Manson, Ockene, Johnson, Stefanick, Gass, O'Sullivan, Wakelee	3	CT		
863	Renal function and fracture risk in multi-ethnic women: The Women's Health Initiative	**Ensrud**, Cauley, Danielson, Boudreau, Jackson, Bauer, Canales, LaCroix	3	OS		BAA9
874	C-GEMS collaborative paper - Genotype associations and breast cancer risk	**Prentice**, Jackson, Chlebowski, Kooperberg	3	Gen		M3

Appendix A

Women's Health Initiative Memory Study (WHIMS)

October 2008

Table of Contents

Introduction

This report has been prepared to support the Observational Study Monitoring Board in its review of the Women's Health Initiative Memory Program. The current major initiatives in this Program are the:

- Women's Health Initiative Memory Study (WHIMS) Extension – this is transitioning into the WHIMS Epidemiology of Cognitive Health Outcomes (WHIMS-ECHO)
- Women's Health Initiative Memory Study of Cerebral Magnetic Resonance Imaging (WHIMS-MRI) – this is transitioning to collect a second MRI scan on women (WHIMS-MRI2)
- Women's Health Initiative Study of Cognitive Aging (WHISCA) Extension

These three studies include intersecting cohorts of women, all of whom were participants in the Women's Health Initiative Hormone Trials (WHI-HT), and intersecting subsets of WHI clinical sites. The studies' Coordinating Center is located in the Division of Public Health Sciences at Wake Forest University School of Medicine.

Materials are drawn from study databases and records in September, 2008 to provide an up-to-date accounting. Live study databases were accessed at time points spanning several weeks so that minor discrepancies may exist across exhibits.

We organized this report into sections to describe each of the three initiatives listed above. The WHIMS Extension (Section 2) this month ends its enrollment and surveillance of the original WHIMS cohort to identify incident cases of probable dementia (PD) and mild cognitive impairment (MCI). We describe the cohort and provide data on the post-trial incidence of study endpoints according to women's original treatment assignments. The WHIMS-MRI study (Section 3) completed central reading of images. We describe findings from this study, which from publications that are in press or under review. The WHISCA Extension (Section 4) enrolled women to continue the annual administration of a battery of cognitive tests. Section 5 lists the current study bibliography.

We are in the process of launching studies that build on the WHIMS studies described above. These include the WHIMS Epidemiology of Cognitive Health Outcomes (WHIMS-ECHO), obtaining a follow-up MRI scan (WHIMS-MRI2), and cognitive assessment of younger WHI women (WHIMS-Y). Section 6 summarizes our progress.

WHIMS Coordinating Center
September 22, 2008

Section 1.

Overview of Suite of Studies

The Women's Health Initiative Memory Study (WHIMS)

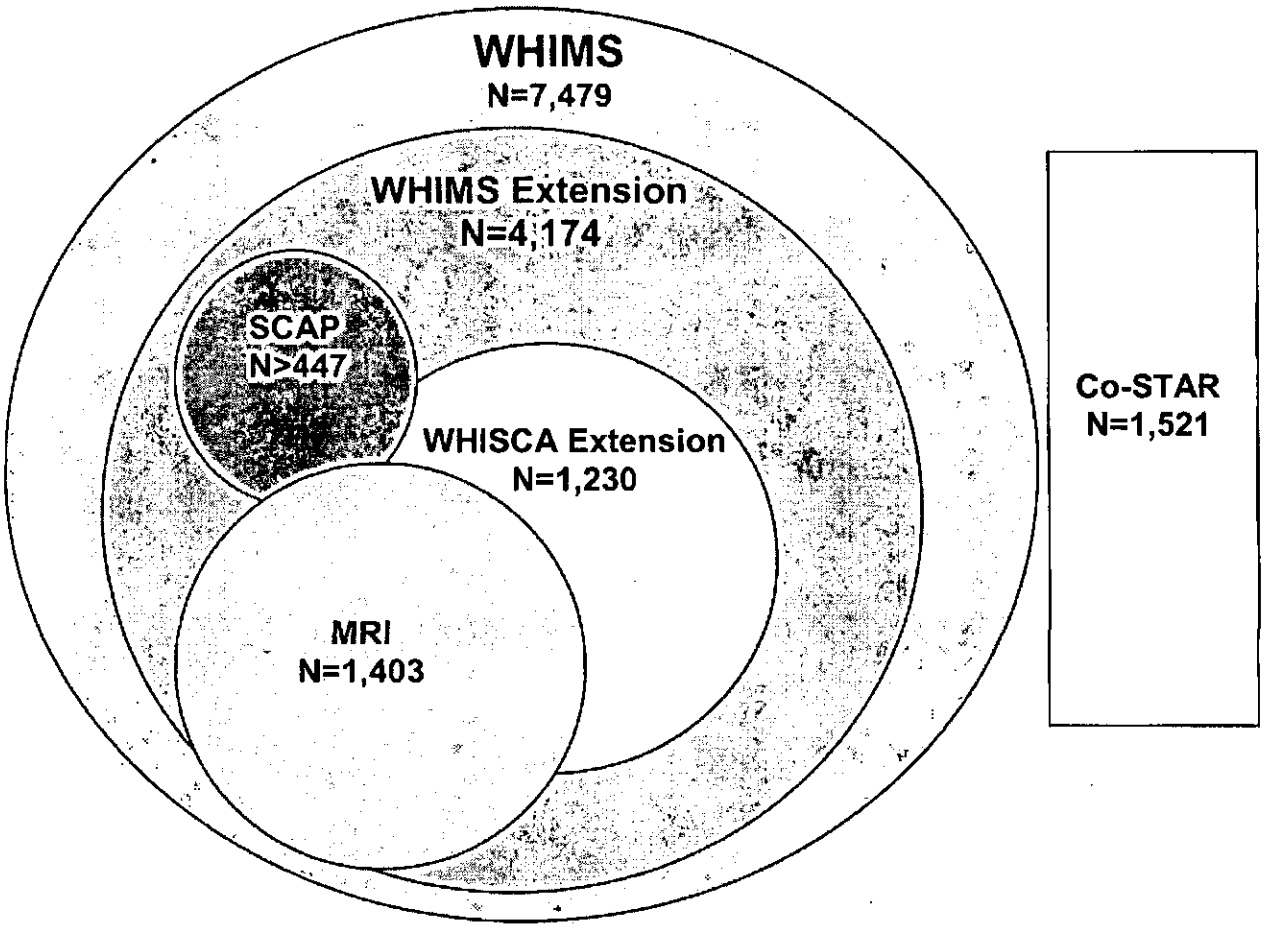
The WHIMS Supplemental Case Ascertainment Protocol (SCAP)

The Women's Health Initiative Memory Study of Cerebral Magnetic Resonance Imaging (WHIMS-MRI)

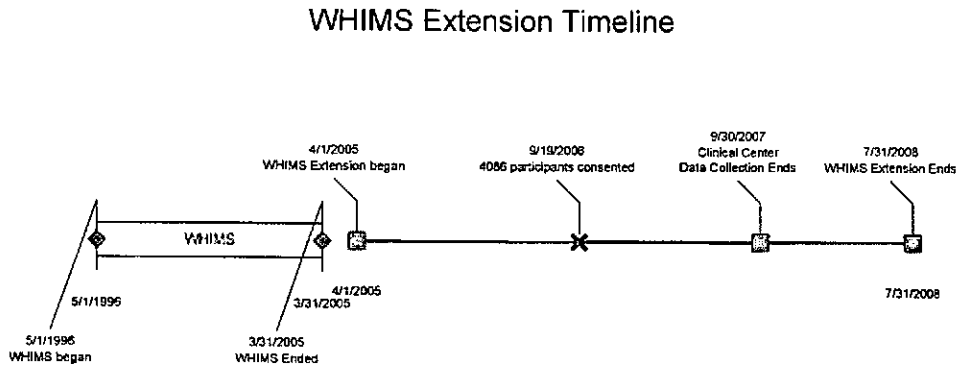
The Women's Health Initiative Study of Cognitive Aging (WHISCA)

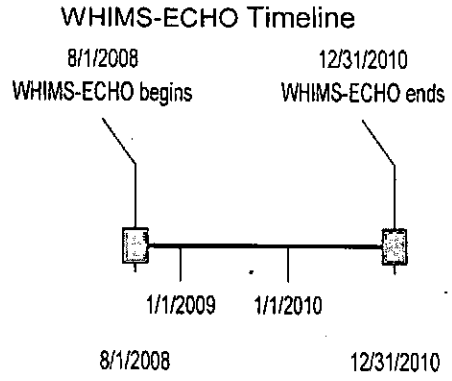
Cognition in the Study of Tamoxifen and Raloxifene (Co-STAR)

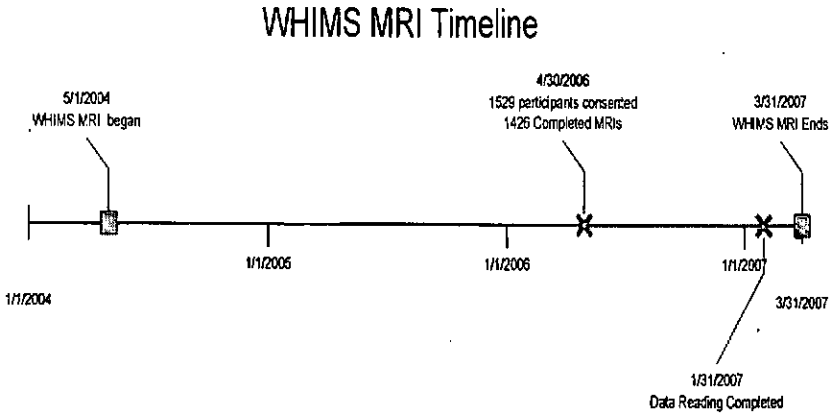
1.1 Intersection of the WHIMS, SCAP, WHIMS-MRI, WHISCA, and Co-STAR Study Cohorts

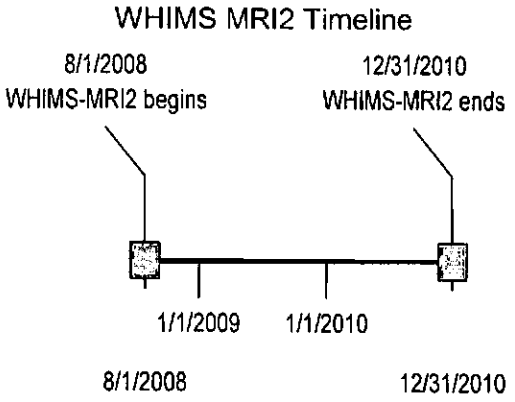


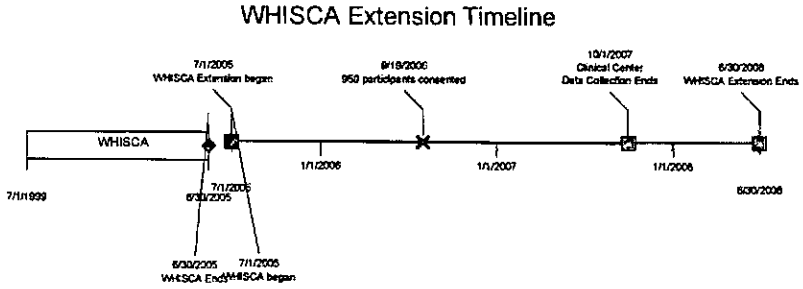
1.2 Timelines for the WHIMS, WHIMS Extension, WHIMS-ECHO, WHIMS-MRI, WHIMS-MRI2, WHISCA, WHISCA Extension, and Co-STAR Studies

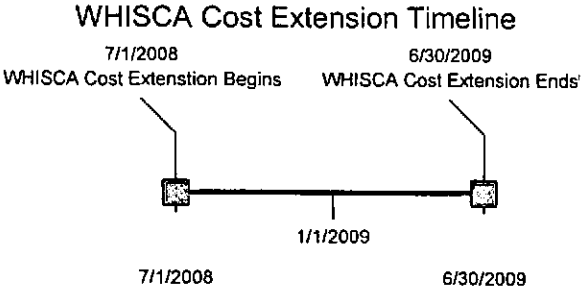


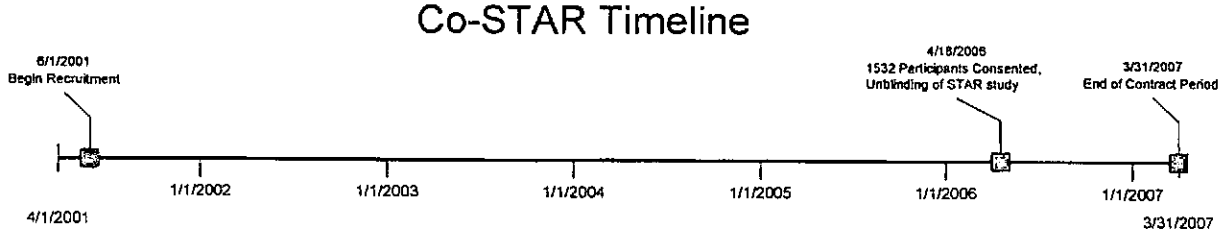












1.3 Study Objectives: Abstracts of Current Studies

1.3.1 Women's Health Initiative Memory Study (WHIMS) Extension

The WHIMS Extension is sponsored by the National Heart, Lung, and Blood Institute (NHLBI) and is an ancillary study to the National Institute of Health (NIH) sponsored Women's Health Initiative. The goal of the WHIMS Extension is to provide post-trial follow-up and surveillance of participants from the completed E+P and E-alone trials to determine whether an increased risk of dementia is sustained following study drug termination.

WHIMS Extension was designed to be conducted during the time period of the safety monitoring extension for the WHI hormone trials. There are no data available from other studies on how the cessation of E+P or E-alone therapy impacts critical cognitive-related outcomes. Given the data derived from the WHI E+P and E-alone trials, and the fact that millions of women decided to stop taking combination hormone therapy following the WHI and WHIMS publications regarding E+P, it is critical that we determine the implications of this decision for postmenopausal women's cognitive health. By continuing the careful ascertainment of probable dementia, MCI, and global cognitive functioning, we increase the power in the surveillance component. This enables us to provide more accurate estimates of cognitive risk associated with prior exposure to E+P or E-alone therapy, as well as more sophisticated and hypothesis-generating sub-analyses. The WHIMS Epidemiology of Cognitive Health Outcomes (WHIMS-ECHO) continues the follow-up of this cohort (see Chapter 6).

The Modified Mini-Mental Status Exam (3MSE) is administered yearly (Phase 1) to the participants by a trained and certified WHIMS technician. Based on the 3MSE score and her education level, the participant could be referred for further neuropsychological testing and functional assessments (Phase 2) and a clinician's examination (Phase 3).

The WHIMS Supplemental Case Ascertainment Protocol is embedded within the WHIMS Extension. In WHIMS, a determination of *probable dementia* (the primary end point) is reached by decision of an adjudication committee. As the study progressed, some participants died and others ceased full follow-up participation without a "determination" of cognitive status at the time of death or conversion to "proxy" status. WHIMS investigators are concerned that among these participants are women who would have been classified as *probable dementia* had they completed the scheduled assessments. In order to capture these possible cases, WHIMS, with the approval of WHI, implemented a supplemental standardized telephone survey to be conducted by trained staff at the WHIMS Central Coordinating Center (CCC). Staff from each clinical center are responsible for contacting the proxy/family member identified at WHIMS enrollment or updated during the study to obtain permission and contact information. Trained and certified CCC staff conduct the SCAP interview. The completed survey is then sent through data entry and adjudication.

The SCAP survey consists of the Dementia Questionnaire, a standardized, validated instrument used to reliably diagnose dementia and specifically Alzheimer's Dementia in deceased persons (Ellis et al, 1998) and can be reliably administered by telephone. It has demonstrated sensitivity

and specificity. The SCAP survey consists of 48 items assessing memory and other cognitive functions, language, daily functioning, insight, and other medical and psychiatric difficulties. Below is the breakdown by arm of the 795 participants eligible for SCAP ***as of 9/15/08***. These counts exclude participants that were previously classified as *probable dementia* or who had the WHI status of "absolutely no follow-up" prior to becoming eligible for SCAP.

SCAP	**Number Eligible**
E+P Trial	458
E-Alone Trial	337
Total	795

1.3.2 The WHIMS Cerebral Magnetic Resonance Imaging (WHIMS-MRI) sub-study

WHIMS-MRI was a cross-sectional substudy of 1,403 women who were enrolled in the WHIMS E+P and E-Alone studies. The primary goal was to assess the impact of hormone therapy on subclinical neuropathological changes (ischemic lesion volume and brain volume) to further our understanding of the processes by which hormone therapy may increase participants' risk for stroke and adverse cognitive findings.

WHIMS-MRI2 will collect a second scan on women who had been enrolled in WHIMS-MRI, an average of 3-5 years after their initial scan (see Chapter 6).

1.3.3 Women's Health Initiative Study of Cognitive Aging (WHISCA) Extension Study

The WHISCA Extension Study, supported by the National Institute on Aging (NIA), was an ancillary study to the WHI and WHIMS Extension Studies. The goal of the original WHISCA study was to measure the effect of E+P or E-Alone versus placebo on age-associated decline in women age 65 and older enrolled in WHIMS. A battery of standardized cognitive tests used in the Baltimore Longitudinal Study of Aging which were sensitive to the effects of age and HT, was used in WHISCA. Following termination of the WHI HT trials, WHISCA participants continued post-trial follow-up and receive annual administration of the full cognitive battery. Of the 2,303 non-demented women at least 65 years old recruited from a cohort of WHIMS participants from the original study, 1,521 remain in the WHIMS Extension Study and are therefore eligible for WHISCA. To date 1,230 of these women enrolled in the WHISCA Extension, and enrollment continues. Data collection ended October 31, 2007, however support for data analysis continues.

1.3.4 Women's Health Initiative Memory Study of Younger Women (WHIMS-Y)

The Women's Health Initiative Memory Study of Younger Women (WHIMS-Y) is designed to assess the long-term impact of random assignment to postmenopausal hormone therapy among the WHI women who were aged 50-54 years at baseline. Hormone therapy continues to be widely prescribed for the treatment of menopausal symptoms. Further, there remains a strong

belief among basic and clinical scientists that hormone therapy begun during the peri- or immediate post-menopausal period bestows cognitive benefits and that the cognitive harm associated with hormone therapy in the post-menopausal woman occurs only when there is some pre-existing, sub-clinical disease and/or the aging brain is more vulnerable to hormones. This specific issue was not addressed within the original WHIMS cohort: whether the adverse effects on cognition of conjugated equine estrogen (CEE) based therapy seen in women aged 65 years and older extend to younger women. As described below, there is some evidence that hormone therapy has beneficial effects on cognition for younger women. Thus, WHIMSY adds critical information on the clinical treatment of peri-menopausal and early post-menopausal women and on potential mechanisms of action for how CEE-based therapy may affect cognition.

1.3.5 Cognition in the Study of Tamoxifen and Raloxifene (Co-STAR)

Co-STAR is an ancillary study to the National Cancer Institute (NCI) sponsored STAR trial. Co-STAR is aimed at measuring age-associated changes in cognitive functioning in women age 65 and older enrolled in STAR and who are at increased risk for developing breast cancer, but otherwise healthy. Co-STAR was sponsored by the NIA and the Coordinating Center is the Division of Public Health Sciences, Wake Forest University School of Medicine.

Co-STAR responds to the unique opportunity afforded by the STAR Trial, coordinated by the National Surgical Adjuvant Breast and Bowel Program (NSABP), to study the effects of two commonly prescribed selective estrogen receptor modulators (SERMS), tamoxifen and raloxifene on cognitive aging in non-demented post-menopausal women. Co-STAR provides critical data for women and their clinicians to make informed choices about the benefits and risks of various hormone therapies.

Co-STAR recruitment was initiated in October 2001, with annual cognitive assessments conducted for 5 years. Recruitment was terminated with the unblinding of the parent STAR Trial on April 17, 2006 with a total enrollment of 1,521 participants. The Co-STAR protocol was amended to allow for post-trial follow-up assessments, which continued until March, 2008.

Several publications are planned that will pool data from WHISCA and Co-STAR: Section 2.8 provides a description of this interface.

2.1 Study Goals

The WHIMS Extension was designed to continue the collection of cognitive outcomes on the original WHIMS cohort. The objectives of the WHIMS Extension included:

- Post-trial follow-up of participants from the E-alone and E+P trials to provide additional statistical power to determine whether an increased risk of dementia is sustained following study drug termination;
- The Supplemental Case Ascertainment Protocol enhances estimates of the incidence of probable dementia and increase overall study power, thereby permitting sub-analyses;
- Continued analytical support for data collected during the WHIMS Follow-up and analytical support for new data collected during the WHIMS Extension; and
- Dissemination of findings from E-alone and E+P post-trial extension.

The following timeline demonstrates the schedule of the WHIMS Follow-up and Extension.

Activity	WHIMS Extension			
	12/03-3/05	4/05-9/07	10/07-3/08	4/08-6/08
WHIMS Follow-up	X			
Development of Extension Protocol / Training	X			
E-alone and E+P Post-Trial Screening		X		
E-alone and E+P Post-Trial Case Ascertainment/Adjudication		X	X	
Post-trial Extension Closeout			X	
Supplemental Case Ascertainment		X		
Supplemental Case Ascertainment Adjudication		X	X	
Analytical Support for Extension Data		X	X	X
Dissemination			X	X

2.2 Enrollment

Enrollment rates for the WHIMS Extension average 80.0% for eligible WHI Extension participants across all sites. Currently, there are 4,174 participants enrolled in the WHIMS Extension. The WHIMS Enrollment Report (Exhibit 2.2.1) shows the cumulative number of participants recruited at each clinical center. Exhibit 2.2.2 presents enrollment data for women grouped by WHI treatment assignment and clinic site. Women from both active and placebo arms of the trials enrolled in the WHIMS Extension at equal rates. Participation rates from the E+P and E-Alone trials are approximately proportional to the sizes of the original trials.

2.3 Adjudication and Case Ascertainment

Cases are identified by two processes in WHIMS. The primary study protocol identifies women who score below education level-specific 3MSE cut-points to return for further clinic assessment (Phase 2). The SCAP was implemented to capture data from women who do not return for further clinic assessment and for whom WHIMS follow-up has ceased.

The WHIMS Adjudicators are an independent panel of experts in dementia who conduct a thorough central review of all participants classified as "probable dementia" (PD). In addition to those classified as PD, at least 50% of those classified as "minor cognitive impairment" (MCI) and 20% of those classified as "no dementia" (ND) as determined by the Phase 3 clinician evaluation are centrally reviewed.

Exhibit 2.3.1 provides a summary of the WHIMS/WHIMS Extension adjudication process. Currently, 1,780 women qualified for work-up towards adjudication based on 3MSE scores below the study cut-points. Of these, 350 proceeded to Phase 2 and were not selected for further adjudication; 534 women qualified for Phase 2 but did not return to the clinic site (and are potentially eligible for SCAP). From Phase 2, 896 women progressed to central adjudication (all locally identified PD cases and subsamples of locally identified MCI and no impairment cases). Of these, adjudication has been completed on 861 (96%) and the remainder are in process.

In addition, as shown in Exhibit 2.3.1, 181 women were adjudicated based on SCAP interviews. Of these, 123 were adjudicated to have no impairment. Of the remaining 58 women, adjudication was completed on 43 to date.

These activities, currently, yielded 217 cases of adjudicated Probable Dementia. They also yielded 518 classifications of MCI (381 of which were based on both central adjudication and local classification and 137 which are based solely on local classification).

The distribution of PD cases remains similar to previous reports. Probable Alzheimer's disease remains the most common classification (51.15%), followed by mixed dementia (16.59%) and probable vascular dementia (13.36%).

Exhibit 2.3.1 details the results of the adjudication process. Of those adjudicated, 263 (30.55%) were classified as ND, 381 (44.25%) as MCI and 217 (25.20%) as PD. As is seen in Section 2.3.2, there was excellent agreement between the field clinicians and the adjudicators (80.14%) overall. Most disagreements on protocols led to a less severe classification. Classification differences primarily involved minor cognitive impairment versus no dementia. In 2.9% of the reviewed protocols, adjudicators identified dementia when it had not been diagnosed by the field clinicians (false negatives). In 4.9% of reviewed protocols, adjudicators did not confirm dementia identified by the field clinicians (false positives).

2.4 Preliminary Results

The exhibits in Section 2.4 describe the current distribution of PD and combined MCI/PD incidence by WHI intervention assignment. The excess hazard (HR=1.77) for PD observed during the HT trials (Exhibit 2.4.1) has largely dissipated following the cessation of the trials (Exhibit 2.4.2). During the post-trial follow-up the current estimated hazard ratio is 1.17, and is no longer statistically significant. Over the entire follow-up (Exhibit 2.4.3), the excess number of probable dementia cases encountered during the trial among women assigned to hormone therapy has been maintained post-trial. Similar findings exist for combined MCI/PD: Exhibit

2.4.4 demonstrates that the post-trial incidence of composite MCI/PD has been parallel for women from the two treatment groups: HR=1.16.

Cases of probable dementia and mild cognitive impairment continue to accrue. Exhibit 2.4.5 demonstrates that the hazard or cases increases markedly with age.

Exhibit 2.4.6 demonstrates that the mean relative decrement in 3MSE scores associated with HT has been maintained throughout post-trial follow-up.

Exhibits 2.4.7 and 2.4.8 portray data from the cohort of WHISCA women: mean test scores from two of its cognitive tests over time. Because WHISCA began after WHIMS enrollment had ceased, no baseline test scores from the WHISCA battery were collected. In the figures in this report, baseline 3MSE scores collected in WHIMS are used as a covariate. Mean Digit Span Test scores (assessments of attention and working memory) tended to be slightly lower over time among women who had been assigned to hormone therapy. A similar trend is seen for scores from the California Verbal Learning Test (a test of verbal memory), however the differences do not reach $p<0.05$.

Exhibit 2.4.9 contrasts the on-trial and post-trial HT-associated decrements in test scores for the 3MSE, digit span, and California Verbal Learning Test. These results appear to suggest that the on-trial decrements of these test scores are largely maintained post-trial.

Exhibit 2.4.10 contrasts the on-trial and post-trial HT-related decrements in 3MS scores between women enrolled in the E-Alone and E+P trials. There appears to be little difference in the effects of the CEE-Alone and CEE+MPA treatments on 3MS scores.

2.5 Safety Protocol

It is important to the overall success of the study that communications about the results of the Phase 2, 3, 4 testing be reported in a consistent, timely and sensitive manner. At the conclusion of the testing, the participant is informed that the interviews and test results will be reviewed centrally by a panel of study clinicians and that the participant will be contacted if follow-up is required.

The classification decision made by the Adjudication Committee is the official study classification. The WHIMS CCC Adjudication Committee sends a letter of notification to the CC for each file that is reviewed. The letter states the adjudicated classification and provides a detailed description of those steps to be taken with the particular participant at the following annual visit.

The Clinical Center PI notifies the participant of the adjudication classification. Accompanying the WHIMS CCC adjudication notice to the clinical center, there is a suggested format for a participant letter of notification. The PI may or may not choose to use the suggested letter format. It is the prerogative and responsibility of the CC PI to determine, establish, and maintain the participant notification process at her or his specific clinic. Since a Clinical Center PI may

not have had any prior interaction with the participant, the certified technician or WHIMS liaison often meets with the PI to provide additional information about the participant and to discuss any unusual circumstances that may require special attention. With the permission of the participant, the clinical center PI communicates the adjudication committee findings to the participant's primary care physician.

2.6 Supplemental Case Ascertainment Protocol (SCAP)

Of the 795 currently eligible SCAP participants, 648 (82%) participant informants were contacted by the WHIMS Clinical Center staff. Of these 648 contacts, 447 (70%) informants agreed to be contacted by certified interviewers at the WHIMS CCC and 201 informants refused contact. Of the 447 informants who agreed to be contacted, 419 (94%) have been attempted to date. Of the 419 attempted contacts, 207 (49%) completed Dementia Questionnaires were obtained. The interviewers conduct a maximum of 4 attempts to reach an informant. The four attempts are tracked through a web-based data entry tracking system, with the results of these attempts listed in Exhibit 2.6.1.

2.7 Interface with WHISCA

WHISCA is complementary to WHIMS in that data derived from WHISCA provide detailed annual assessments of specific cognitive domains. This cognitive detail, coupled with frequency of assessment, allows investigators to explore potential differential effects of hormone therapy (E-alone or E+P) on specific cognitive abilities (e.g. memory, spatial skills). As an ancillary study to WHIMS, WHISCA involves the annual administration of an extensive battery of neuropsychological tests that are sensitive to the effects of estrogen and age. WHISCA relies on WHIMS for data from the 3MSE and for the identification of women with MCI and PD.

2.8 Interface with Co-STAR

The NIA funded Co-STAR examines the relative impact of these two selective estrogen receptor modulators (SERMs) on cognitive aging. It should be noted that STAR (and therefore Co-STAR) does not include a placebo group. By utilizing the same neuropsychological test battery as is used in WHISCA, Co-STAR will provide an important comparison between women taking E+P, E-alone and placebo with women taking these SERMs. This comparison is fully dependent on WHIMS and WHISCA, and represents a unique opportunity to explore the relative value of these two SERMs on normal cognitive aging.

Exhibit 2.2.1 Enrollment

WHIMS Extension Enrollment
Number enrolled by clinic
Generated at 10:12 ET on 15SEP08

				WHI Extension		WHIMS Extension			
		Contacted^^		Enrolled		Enrolled		Denied Consent	
Clinic	Number eligible for Extension^	N	%	N	%	N	%^^^	N	%
ALL CLINICS	6555	6242	95.2%	5217	83.6%	4174	80.0%	1044	20.0%
11=Davenport	38	38	100%	28	73.7%	24	85.7%	4	14.3%
12=Birmingham	151	145	96.0%	114	78.6%	96	84.2%	18	15.8%
13=Greensboro	31	31	100%	26	83.9%	21	80.8%	5	19.2%
14=Boston	191	181	94.8%	156	86.2%	101	64.7%	55	35.3%
15=Buffalo	148	148	100%	133	89.9%	117	88.0%	17	12.8%
16=Chicago	9	9	100%	7	77.8%	5	71.4%	2	28.6%
19=Atlanta	93	93	100%	76	81.7%	70	92.1%	6	7.89%
20=Chicago-Evanston	19	18	94.7%	17	94.4%	13	76.5%	4	23.5%
21=Iowa City	47	45	95.7%	35	77.8%	21	60.0%	14	40.0%
23=Pawtucket	182	182	100%	158	86.8%	109	69.0%	49	31.0%
24=Memphis	90	90	100%	61	67.8%	45	73.8%	16	26.2%
25=Minneapolis	197	197	100%	161	81.7%	126	78.3%	35	21.7%
26=Newark	103	100	97.1%	82	82.0%	74	90.2%	8	9.76%
27=Phoenix	89	88	98.9%	59	67.0%	49	83.1%	10	16.9%
28=Pittsburgh	139	139	100%	125	89.9%	108	86.4%	17	13.6%
29=Tucson	135	127	94.1%	86	67.7%	57	66.3%	29	33.7%

		WHI Extension				WHIMS Extension			
		Contacted^^		Enrolled		Enrolled		Denied Consent	
Clinic	Number eligible for Extension^	N	%	N	%	N	%^^^	N	%
30=Davis	199	194	97.5%	164	84.5%	120	73.2%	44	26.8%
42=Stanford	240	239	99.6%	214	89.5%	193	90.2%	21	9.81%
43=Milwaukee	232	232	100%	193	83.2%	148	76.7%	45	23.3%
44=George Wash.	165	149	90.3%	126	84.6%	116	92.1%	10	7.94%
45=Honolulu	86	71	82.6%	62	87.3%	58	93.5%	4	6.45%
46=Gainesville	134	133	99.3%	128	96.2%	101	78.9%	27	21.1%
47=Houston	109	109	100%	67	61.5%	59	88.1%	8	11.9%
48=Worcester	263	261	99.2%	247	94.6%	197	79.8%	50	20.2%
49=New York	244	239	98.0%	200	83.7%	164	82.0%	36	18.0%
50=Columbus	264	264	100%	213	80.7%	139	65.3%	74	34.7%
51=MedSTAR	149	140	94.0%	126	90.0%	114	90.5%	12	9.52%
53=Oakland	172	172	100%	142	82.6%	116	81.7%	26	18.3%
54=Jacksonville	81	79	97.5%	70	88.6%	62	88.6%	8	11.4%
55=Torrance	56	51	91.1%	40	78.4%	24	60.0%	16	40.0%
56=Madison	143	141	98.6%	125	88.7%	98	78.4%	27	21.6%
57=Stony Brook	231	231	100%	198	85.7%	153	77.3%	45	22.7%
58=Chapel Hill	223	216	96.9%	177	81.9%	147	83.1%	30	16.9%
59/60=Chicago-Rush	131	76	58.0%	76	100%	71	93.4%	5	6.58%
61=Cincinnati	148	148	100%	128	86.5%	118	92.2%	10	7.81%
62=Detroit	111	107	96.4%	75	70.1%	63	84.0%	12	16.0%

				WHI Extension		WHIMS Extension			
		Contacted^^		Enrolled		Enrolled		Denied Consent	
Clinic	Number eligible for Extension^	N	%	N	%	N	%^^^	N	%
63=Irvine	175	152	86.9%	129	84.9%	87	67.4%	42	32.6%
65=Nevada	181	113	62.4%	113	100%	112	99.1%	1	0.88%
66=Portland	179	171	95.5%	150	87.7%	130	86.7%	20	13.3%
67=San Antonio	98	50	51.0%	38	76.0%	38	100%	0	0.00%
68=Los Angeles	209	209	100%	150	71.8%	102	68.0%	48	32.0%
69=Fall River	123	122	99.2%	114	93.4%	96	84.2%	18	15.8%
70=Pauline	42	42	100%	30	71.4%	28	93.3%	2	6.67%
71=Bowman Gray	34	34	100%	23	67.6%	13	56.5%	10	43.5%
72=New Brunswick	185	180	97.3%	149	82.8%	126	84.6%	23	15.4%
73=Des Moines	286	286	100%	226	79.0%	145	64.2%	81	35.8%

^Based on most recent follow up status (Deceased, absolutely no follow-up, and proxy follow-up omitted)

^^Completed WHIMS Extension consent form

^^^Denominator is those participants that enrolled in WHI Extension

Click on link to get clinic specific information for reason for not consenting

Exhibit 2.2.2 Enrollment by original WHI Treatment Assignment

WHIMS Extension Enrollment
By treatment assignment
Generated at 10:14 ET on 15SEP08

	E+P Trial					E alone Trial					Combined				
	Active		Placebo		Total	Active		Placebo		Total	Active		Placebo		Total
Clinic	N	%	N	%	N	N	%	N	%	N	N	%	N	%	N
ALL CLINICS	1279	48.9%	1338	51.1%	2617	779	50.0%	778	50.0%	1557	2058	49.3%	2116	50.7%	4174
11=Davenport	12	66.7%	6	33.3%	18	2	33.3%	4	66.7%	6	14	58.3%	10	41.7%	24
12=Birmingham	29	48.3%	31	51.7%	60	20	55.6%	16	44.4%	36	49	51.0%	47	49.0%	96
13=Greensboro	5	45.5%	6	54.5%	11	5	50.0%	5	50.0%	10	10	47.6%	11	52.4%	21
14=Boston	36	47.4%	40	52.6%	76	11	44.0%	14	56.0%	25	47	46.5%	54	53.5%	101
15=Buffalo	37	54.4%	31	45.6%	68	26	53.1%	23	46.9%	49	63	53.8%	54	46.2%	117
16=Chicago	1	100%	0	0.00%	1	3	75.0%	1	25.0%	4	4	80.0%	1	20.0%	5
19=Atlanta	30	62.5%	18	37.5%	48	8	36.4%	14	63.6%	22	38	54.3%	32	45.7%	70
20=Chicago-Evanston	4	44.4%	5	55.6%	9	4	100%	0	0.00%	4	8	61.5%	5	38.5%	13
21=Iowa City	12	85.7%	2	14.3%	14	5	71.4%	2	28.6%	7	17	81.0%	4	19.0%	21
23=Pawtucket	41	63.1%	24	36.9%	65	23	52.3%	21	47.7%	44	64	58.7%	45	41.3%	109
24=Memphis	15	48.4%	16	51.6%	31	7	50.0%	7	50.0%	14	22	48.9%	23	51.1%	45
25=Minneapolis	46	50.0%	46	50.0%	92	18	52.9%	16	47.1%	34	64	50.8%	62	49.2%	126

	E+P Trial					E alone Trial					Combined				
	Active		Placebo		Total	Active		Placebo		Total	Active		Placebo		Total
Clinic	N	%	N	%	N	N	%	N	%	N	N	%	N	%	N
26=Newark	24	42.9%	32	57.1%	56	7	38.9%	11	61.1%	18	31	41.9%	43	58.1%	74
27=Phoenix	14	46.7%	16	53.3%	30	10	52.6%	9	47.4%	19	24	49.0%	25	51.0%	49
28=Pittsburgh	26	49.1%	27	50.9%	53	27	49.1%	28	50.9%	55	53	49.1%	55	50.9%	108
29=Tucson	19	54.3%	16	45.7%	35	9	40.9%	13	59.1%	22	28	49.1%	29	50.9%	57
30=Davis	36	47.4%	40	52.6%	76	21	47.7%	23	52.3%	44	57	47.5%	63	52.5%	120
42=Stanford	57	44.9%	70	55.1%	127	35	53.0%	31	47.0%	66	92	47.7%	101	52.3%	193
43=Milwaukee	48	52.2%	44	47.8%	92	30	53.6%	26	46.4%	56	78	52.7%	70	47.3%	148
44=George Wash.	39	49.4%	40	50.6%	79	18	48.6%	19	51.4%	37	57	49.1%	59	50.9%	116
45=Honolulu	19	46.3%	22	53.7%	41	10	58.8%	7	41.2%	17	29	50.0%	29	50.0%	58
46=Gainesville	31	50.8%	30	49.2%	61	20	50.0%	20	50.0%	40	51	50.5%	50	49.5%	101
47=Houston	14	37.8%	23	62.2%	37	15	68.2%	7	31.8%	22	29	49.2%	30	50.8%	59
48=Worcester	65	49.2%	67	50.8%	132	34	52.3%	31	47.7%	65	99	50.3%	98	49.7%	197
49=New York	55	51.9%	51	48.1%	106	28	48.3%	30	51.7%	58	83	50.6%	81	49.4%	164
50=Columbus	44	51.2%	42	48.8%	86	25	47.2%	28	52.8%	53	69	49.6%	70	50.4%	139
51=MedSTAR	24	43.6%	31	56.4%	55	31	52.5%	28	47.5%	59	55	48.2%	59	51.8%	114
53=Oakland	37	45.1%	45	54.9%	82	14	41.2%	20	58.8%	34	51	44.0%	65	56.0%	116
54=Jacksonville	17	50.0%	17	50.0%	34	13	46.4%	15	53.6%	28	30	48.4%	32	51.6%	62
55=Torrance	14	66.7%	7	33.3%	21	2	66.7%	1	33.3%	3	16	66.7%	8	33.3%	24

	E+P Trial					E alone Trial					Combined				
	Active		Placebo		Total	Active		Placebo		Total	Active		Placebo		Total
Clinic	N	%	N	%	N	N	%	N	%	N	N	%	N	%	N
56=Madison	28	43.1%	37	56.9%	65	15	45.5%	18	54.5%	33	43	43.9%	55	56.1%	98
57=Stony Brook	44	43.6%	57	56.4%	101	23	44.2%	29	55.8%	52	67	43.8%	86	56.2%	153
58=Chapel Hill	44	47.3%	49	52.7%	93	32	59.3%	22	40.7%	54	76	51.7%	71	48.3%	147
59/60=Chicago-Rush	10	29.4%	24	70.6%	34	17	45.9%	20	54.1%	37	27	38.0%	44	62.0%	71
61=Cincinnati	24	39.3%	37	60.7%	61	30	52.6%	27	47.4%	57	54	45.8%	64	54.2%	118
62=Detroit	18	42.9%	24	57.1%	42	12	57.1%	9	42.9%	21	30	47.6%	33	52.4%	63
63=Irvine	23	43.4%	30	56.6%	53	16	47.1%	18	52.9%	34	39	44.8%	48	55.2%	87
65=Nevada	31	56.4%	24	43.6%	55	28	49.1%	29	50.9%	57	59	52.7%	53	47.3%	112
66=Portland	36	48.6%	38	51.4%	74	25	44.6%	31	55.4%	56	61	46.9%	69	53.1%	130
67=San Antonio	12	60.0%	8	40.0%	20	10	55.6%	8	44.4%	18	22	57.9%	16	42.1%	38
68=Los Angeles	33	46.5%	38	53.5%	71	13	41.9%	18	58.1%	31	46	45.1%	56	54.9%	102
69=Fall River	24	42.9%	32	57.1%	56	21	52.5%	19	47.5%	40	45	46.9%	51	53.1%	96
70=Pauline	8	61.5%	5	38.5%	13	7	46.7%	8	53.3%	15	15	53.6%	13	46.4%	28
71=Bowman Gray	7	58.3%	5	41.7%	12	1	100%	0	0.00%	1	8	61.5%	5	38.5%	13
72=New Brunswick	41	48.8%	43	51.2%	84	24	57.1%	18	42.9%	42	65	51.6%	61	48.4%	126
73=Des Moines	45	51.7%	42	48.3%	87	24	41.4%	34	58.6%	58	69	47.6%	76	52.4%	145

Exhibit 2.3.1 Adjudication Summary

	E+P		E+P Placebo		E-Alone		E-Alone Placebo		E+P and E-Alone		Placebo		Subtotal	
	N	%	N	%	N	%	N	%	N	%	N	%	N	%
WHIMS Phase 2 Protocols	504		384		466		426		970		810		1780	
- - - - Adjudicated Protocols	246	48.81	190	49.48	219	47.00	206	48.36	465	47.94	396	48.89	861	48.37
- - - - Protocols Under Review by Adjudicators	8	1.59	5	1.30	4	0.86	8	1.88	12	1.24	13	1.60	25	1.40
- - - - Participant Refusal/Illness/Deceased/Surgery/Other	145	28.77	117	30.47	139	29.83	133	31.22	284	29.28	250	30.86	534	30.00
- - - - Completed Forms Not Received From Clinic/Forms in Process	2	0.40	4	1.04	3	0.64	1	0.23	5	0.52	5	0.62	10	0.56
- - - - Protocols Not Adjudicated (No Dementia or MCI)	103	20.44	68	17.71	101	21.67	78	18.31	204	21.03	146	18.02	350	19.66
SCAP Phase 2 Protocols	39		57		46		39		85		96		181	
- - - - - Adjudicated Protocols	8	20.51	11	19.30	11	23.91	13	33.33	19	22.35	24	25.00	43	23.76
- - - - - Protocols Under Review by Adjudicators	5	12.82	4	7.02	1	2.17	5	12.82	6	7.06	9	9.38	15	8.29
- - - - - Protocols Not Adjudicated (No Dementia or MCI)	26	66.67	42	73.68	34	73.91	21	53.85	60	70.59	63	65.63	123	67.96

	E+P		E+P Placebo		E-Alone		E-Alone Placebo		E+P and E-Alone		Placebo		Subtotal	
	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Adjudicated Protocols Final Classification	246		190		219		206		465		396		861	
- - - - ND	71	28.86	60	31.58	61	27.85	71	34.47	132	28.39	131	33.08	263	30.55
- - - - MCI	98	39.84	81	42.63	108	49.32	94	45.63	206	44.30	175	44.19	381	44.25
- - - - PD	77	31.30	49	25.79	50	22.83	41	19.90	127	27.31	90	22.73	217	25.20

	E+P		E+P Placebo		E-Alone		E-Alone Placebo		E+P and E-Alone		Placebo		Subtotal	
	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Overall Classification of Protocols (Adjud + Not Adjudicated)	349		258		320		284		669		542		1211	
- - - - ND	141	40.40	95	36.82	115	35.94	125	44.01	256	38.27	220	40.59	476	39.31
- - - - MCI	131	37.54	114	44.19	155	48.44	118	41.55	286	42.75	232	42.80	518	42.77
- - - - PD	77	22.06	49	18.99	50	15.63	41	14.44	127	18.98	90	16.61	217	17.92

	E+P		E+P Placebo		E-Alone		E-Alone Placebo		E+P and E-Alone		Placebo		Subtotal	
	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Classification of Probable Dementia Cases	77		49		50		41		127		90		217	
- - - - Probable Alzheimer's Disease	36	46.75	23	46.94	28	56.00	24	58.54	64	50.39	47	52.22	111	51.15
- - - - Probable Vascular Dementia	13	16.88	9	18.37	4	8.00	3	7.32	17	13.39	12	13.33	29	13.36
- - - - Mixed Dementia (Other A)	13	16.88	8	16.33	9	18.00	6	14.63	22	17.32	14	15.56	36	16.59
- - - - Other Dementia (B-I)	10	12.99	4	8.16	2	4.00	2	4.88	12	9.45	6	6.67	18	8.29
- - - - Dementia, etiology unknown (Other J)	3	3.90	2	4.08	3	6.00	5	12.20	6	4.72	7	7.78	13	5.99
- - - - Classification under review	2	2.60	3	6.12	4	8.00	1	2.44	6	4.72	4	4.44	10	4.61

Exhibit 2.3.2 Adjudicator and Field Clinician Agreement/Disagreement

	Subtotal	
	N	%
Adjudicator and Clinician Agreement/Disagreement on Ajudicated Protocols		
- - - - Protocols Where Adjudicators and Clinician Agree	690	80.14
- - - - Protocols Where Adjudicators and Clinician Disagree	171	19.86
Disagreement		
- - - - Adjudicated with more severe diagnosis	54	31.58
- - - - Changed from ND to MCI	29	53.70
- - - - Changed from MCI to PD	24	44.44
- - - - Changed from ND to PD	1	1.85
- - - - Adjudicated with less severe diagnosis	117	68.42
- - - - Changed from PD to ND	0	0.00
- - - - Changed from PD to MCI	43	36.75
- - - - Changed from MCI to ND	74	63.25

Exhibit 2.4.1 Incidence of Probable Dementia during the WHIMS Trials

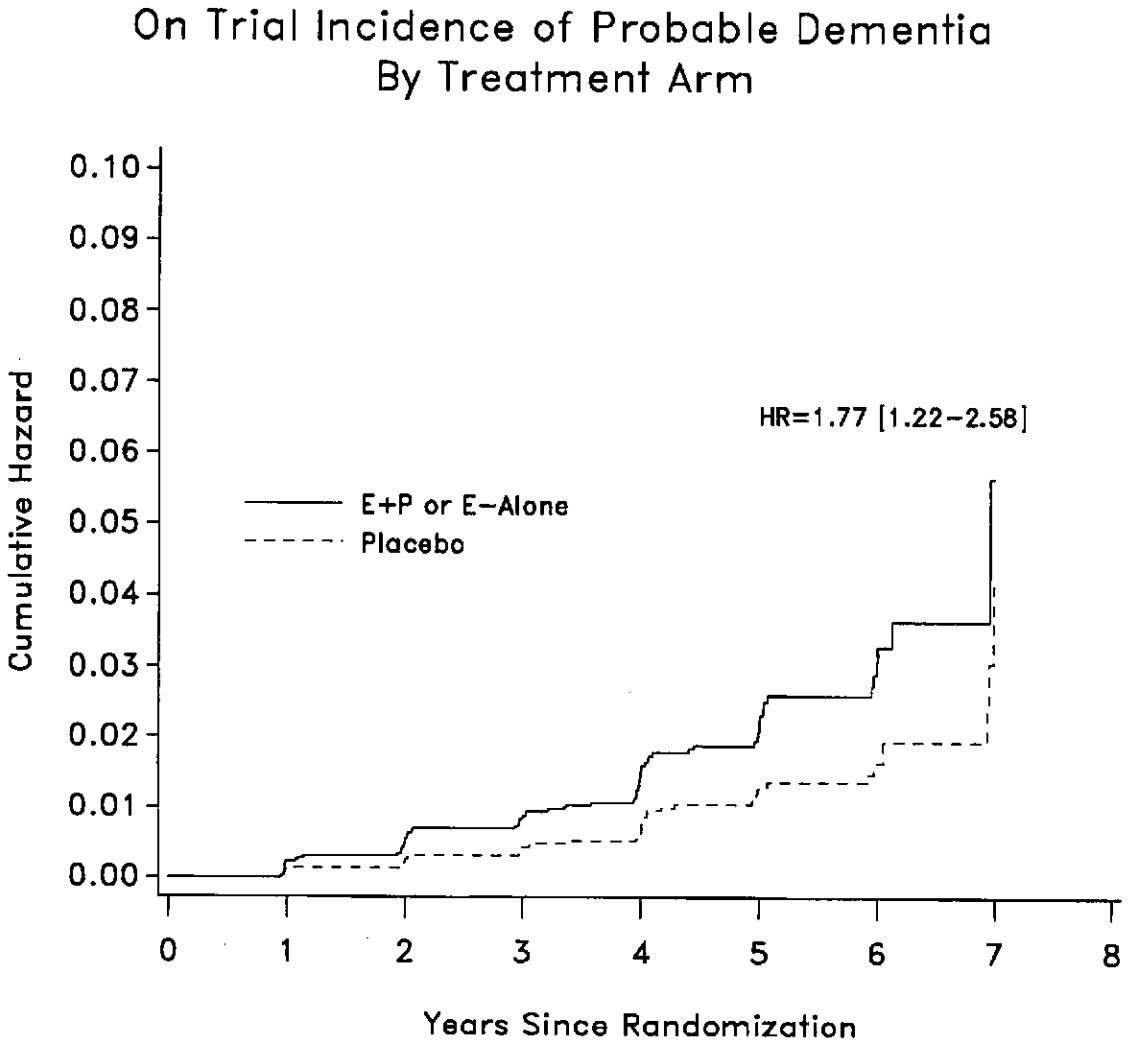
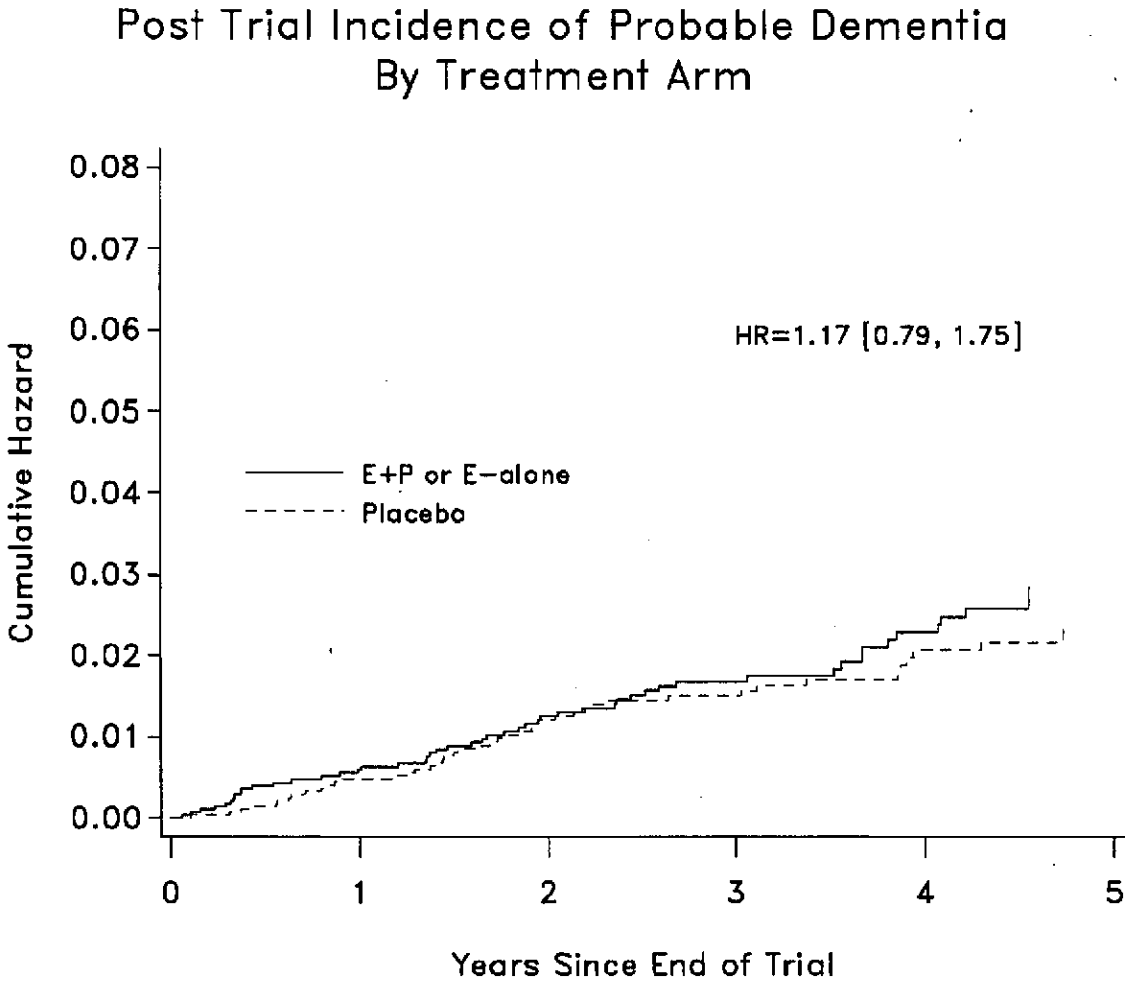


Exhibit 2.4.2 Incidence of Probable Dementia Following the Termination of the WHIMS Trials



Note: participants censored September 2007.

Exhibit 2.4.3 Incidence of the Composite Outcome of Probable Dementia or Mild Cognitive Impairment during the WHIMS Trials

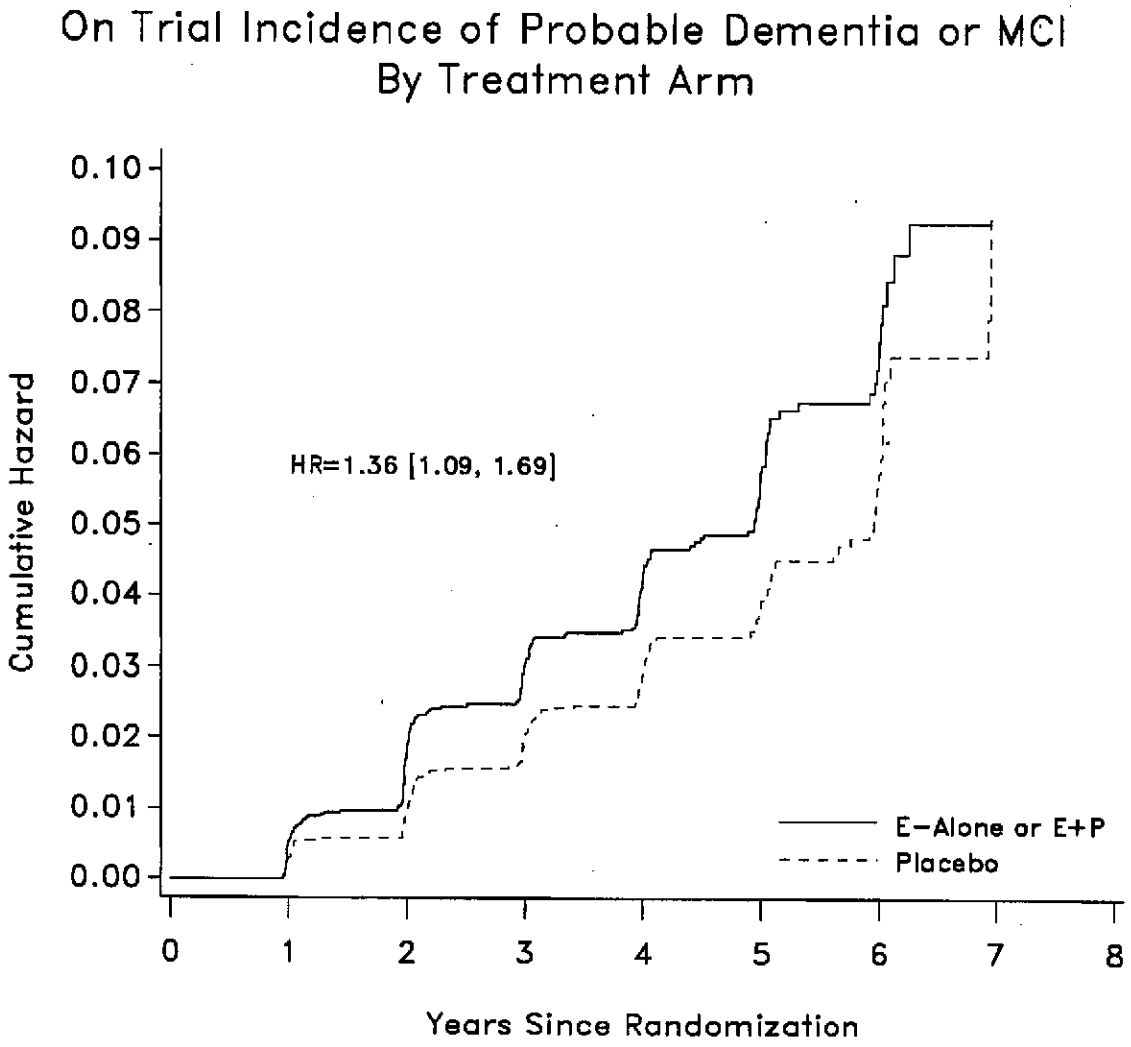
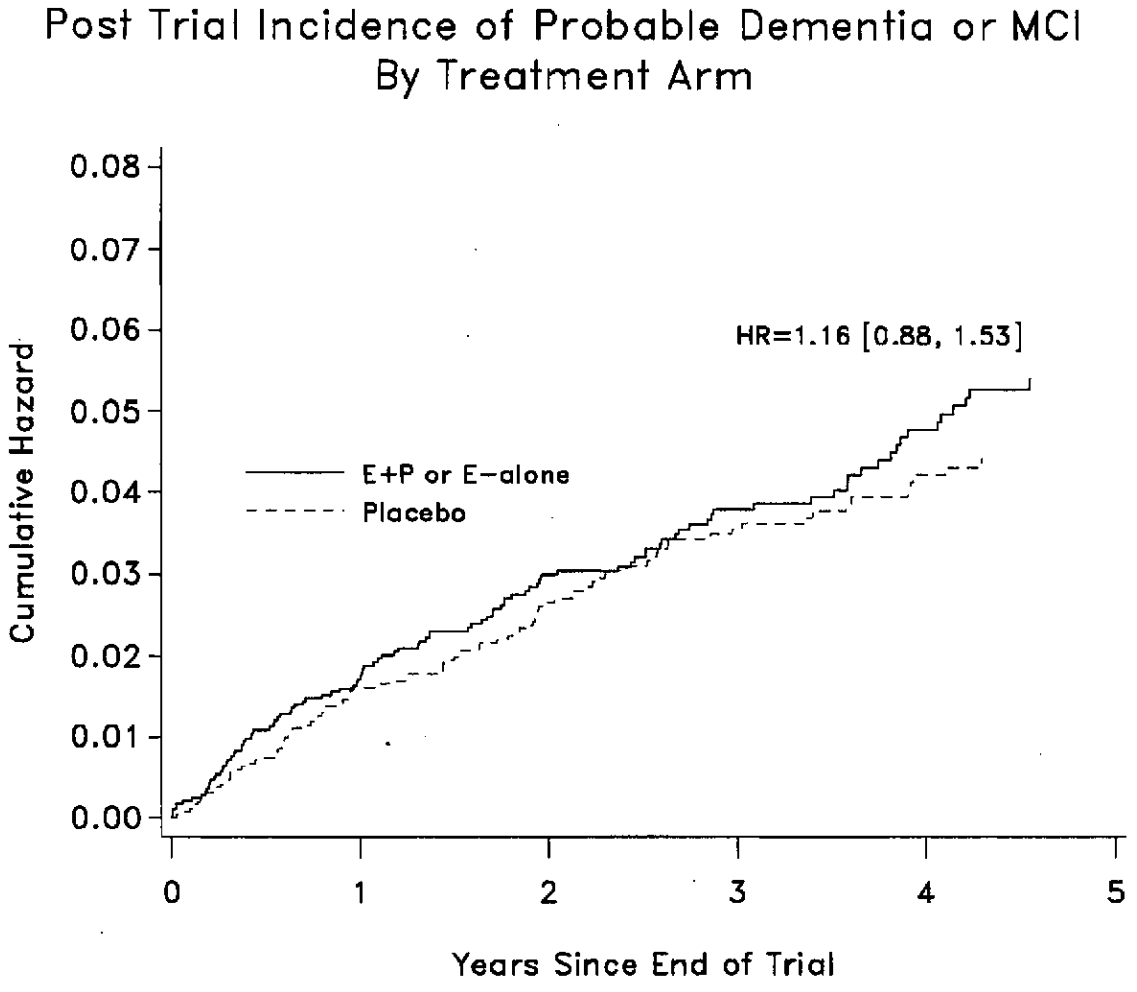


Exhibit 2.4.4 Incidence of the Composite Outcome of Probable Dementia or Mild Cognitive Impairment Following the Termination of the WHIMS Trials



Note: participants censored September 2007.

Exhibit 2.4.5 Current Incidence of Probable Dementia and Any Impairment by Age

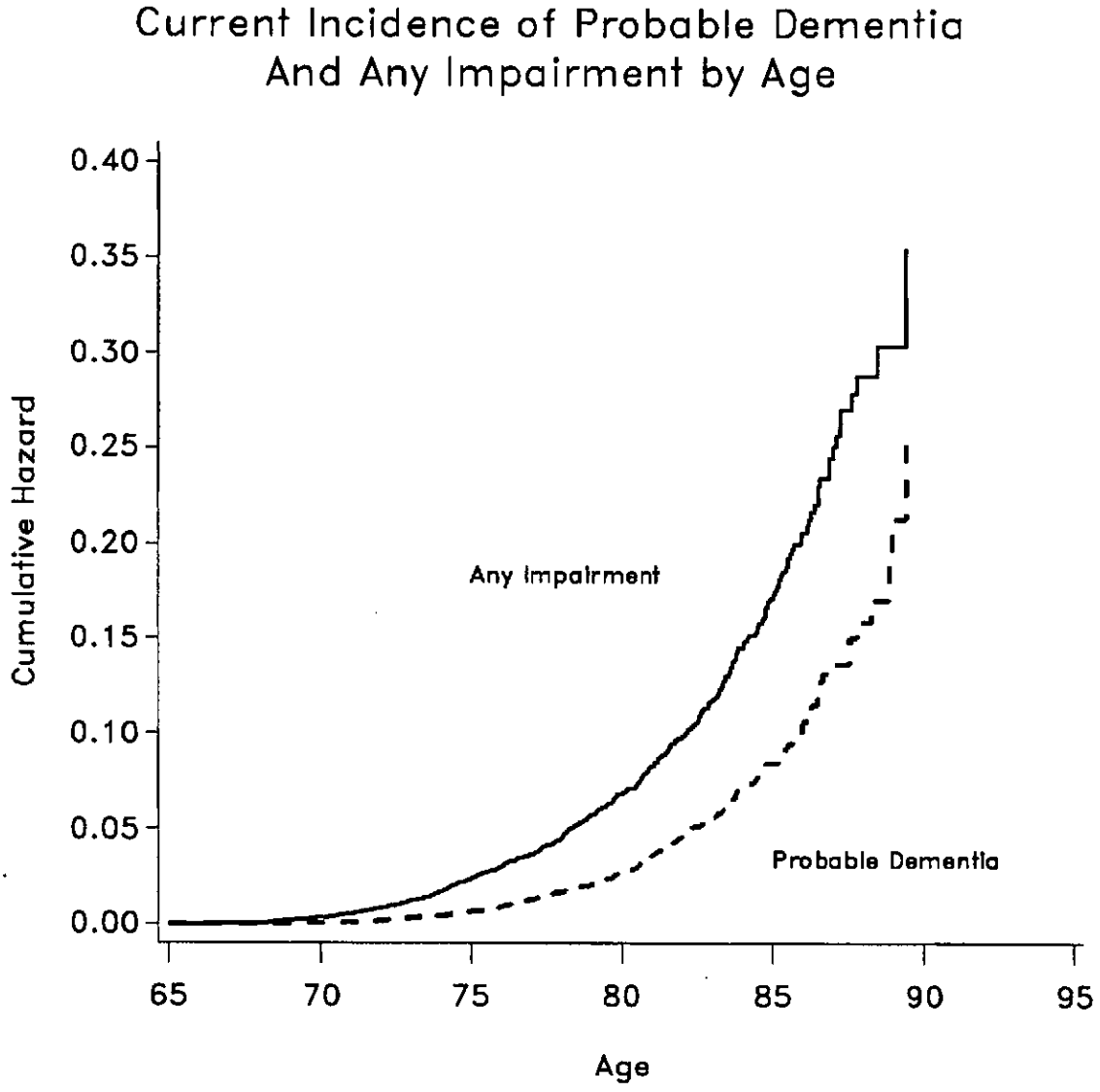


Exhibit 2.4.6 Adjusted mean 3MSE scores (and 95% confidence intervals) Across WHIMS and WHIMS-Extension Follow-up

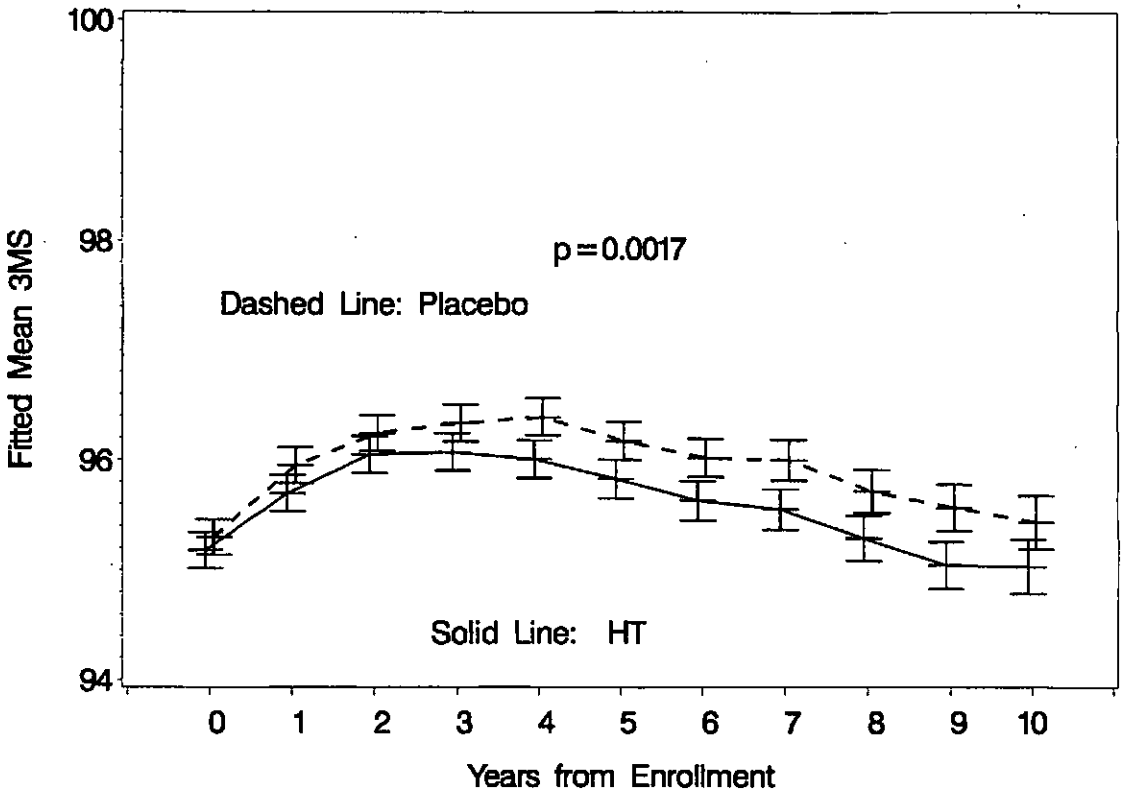


Exhibit 2.4.7 Mean digit span (forward + backward) scores (and 95% confidence intervals) across WHISCA and WHISCA-Extension follow-up with adjustment for baseline 3MSE.

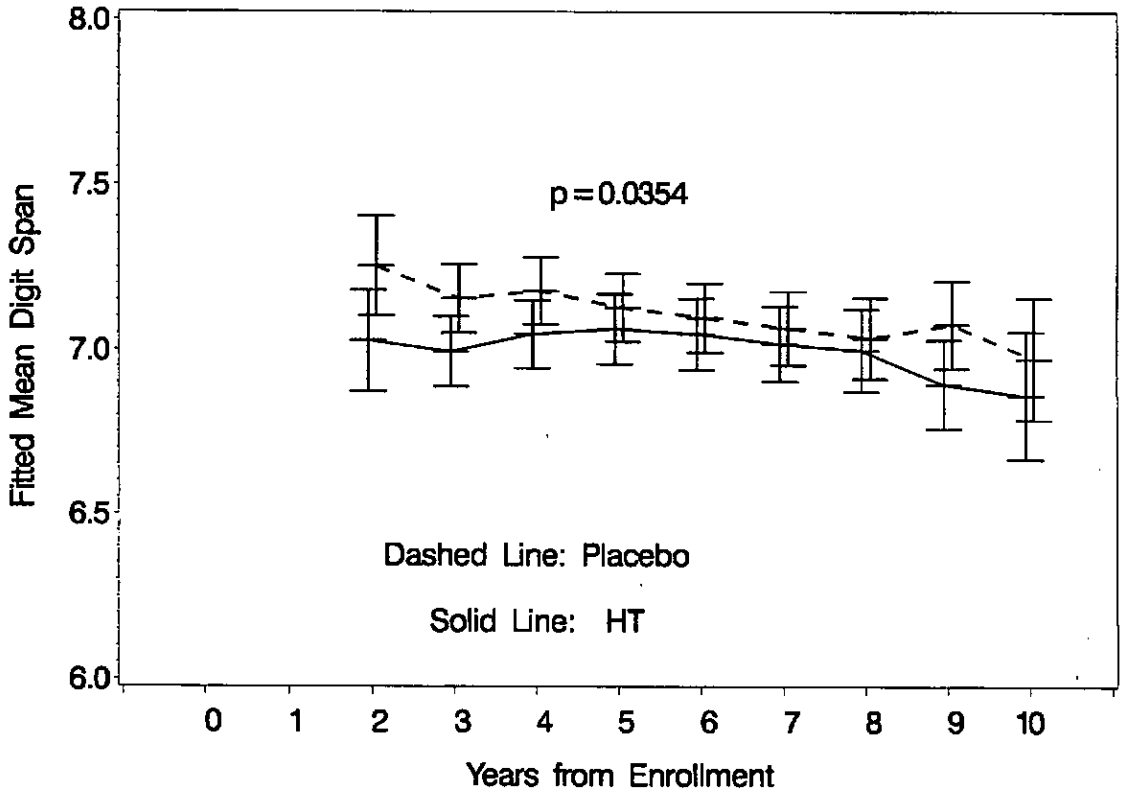


Exhibit 2.4.8 Mean California Verbal Learning Test (A + B) scores (and 95% confidence intervals) across WHISCA and WHISCA-Extension follow-up with adjustment for baseline 3MSE

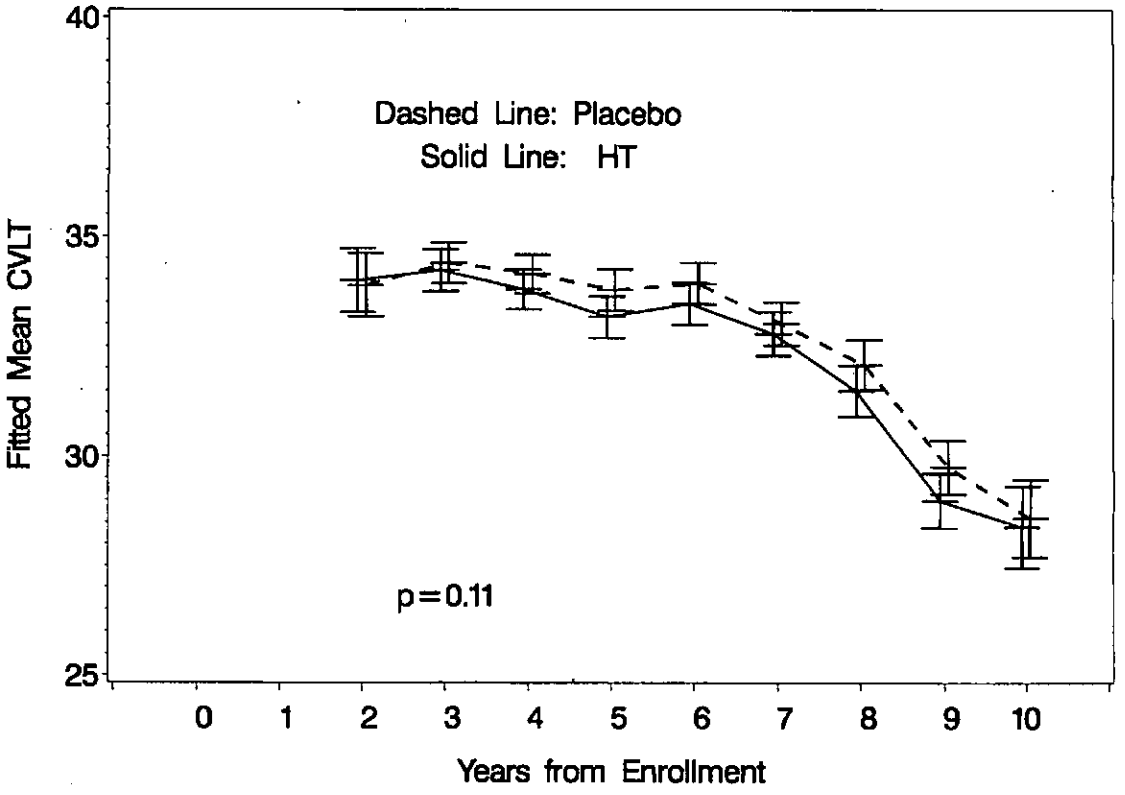


Exhibit 2.4.9 Comparison mean on-trial and post-trial differences between women assigned to hormone therapy versus placebo over time with adjustment for baseline 3MSE.

Cognitive Test	Fitted Mean Difference: HT vs Placebo [95% CI]		Overall Mean (SE) / p-value
	On-Trial	Post-Trial	
Global Cognitive Function 3MSE	-0.23 [-0.39,-0.07]	-0.29 [-0.45,-0.12]	-0.25 (0.08); p=0.0013
Digit Span	-0.13 [-0.25, -0.01]	-0.11 [-0.24, 0.02]	-0.12 (0.06); p=0.035
CVLT	-0.46 [-0.96, 0.05]	-0.43 [-0.99, 0.14]	-0.45 (0.22); p=0.11

Exhibit 2.4.10 Comparison mean on-trial and post-trial differences between women assigned to hormone therapy versus placebo over time with adjustment for baseline 3MSE.

Cognitive Test	E-Alone Relative Effect Adjusted Mean (SE)		E+P Relative Effect Adjusted Mean (SE)		Consistency of E-alone vs E+P Relative Effect p-value	
	On-Trial	Post-Trial	On-Trial	Post-Trial	On-Trial	Post-Trial
Global Cognitive Function 3MSE	-0.27 (0.13)	-0.25 (0.15)	-0.21 (0.10)	-0.30 (0.14)	0.66	0.90

Exhibit 2.6.1 WHIMS SCAP Call Status

Based on Data Entered as of 9/15/08

	Clinical Center Contacts				CCC Contacts							CCC Call Status						
	Eligible	Contacted	Call Outcome		Attempts					Total Contacts								
Clinic	N	N	Agreed	Refused	Not Yet Attempted	1	2	3	4	Participant	Phone	DQ Completed	Declined	No Answer	Phone Disconnected	Unable to Locate	Other	Left a message (4th attempt only)
ALL CLINICS	795	648	447	201	29	139	60	37	183	419	1102	207	19	135	23	6	10	19

Exhibit 2.7 Bibliography

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3.1 WHIMS-MRI Progress Report

The WHIMS-MRI enrolled 1,424 women, which yielded 1,403 MRI scans that were certified by the Central Reading Center for analysis. Exhibit 3.1 describes the enrollment process.

MR Protocol

The MR scanning protocol was developed by investigators at the MRI Quality Control Center (MRIQCC) in the Department of Radiology, University of Pennsylvania, Philadelphia. The scans were conducted at 14 WHIMS clinical sites following informed consent and using a standardized MR protocol. Detailed explanation of the procedure was provided by a WHIMS-MRI technologist, which included measures to enhance participant comfort during the scanning procedure. MR scanning pulse sequences were performed in the following order:

- Series 1 – 3 plane gradient echo localizer for positioning
- Series 2 – Sagittal T1-weighted spin echo (300/0/8/1/5 (TR/TI/TE/slice thickness) mid-slice image to demonstrate anatomical location of the AC/PC for slice angle and slice position
- Series 3- Oblique Axial Spin Density/ T2-weighted spin echo (3200/0/30,120/3) images from the vertex to skull base parallel to the AC/PC plane
- Series 4 - Oblique Axial FLAIR T2- weighted spin echo (8000/2000/100/3) images matching slice positions in Series 3
- Series 5 - Oblique Axial 3D T1 weighted gradient echo (flip angle 30; 21/0/8/1.5) images from the vertex to the skull base parallel to the AC/PC plane, FOV:22cm; matrix: 256 x 256 for series 3, 4, and 5. Series 3, 4, and 5 were used for ischemic lesion analysis
- The WHIMS-MRI technologist immediately reviewed all scans for technical issues, protocol compliance and participant motion. If a series needed to be repeated, it was done before the participant was removed from the scanner. Imaging data were transmitted utilizing an encrypted DICOM image transfer mechanism, to the permanent archive via the Web. MRI data were transmitted from the clinics to the MRIQCC within 3 days from the MRI scan date

WHIMS MRI Primary Outcome Measure

The primary outcome measure for the WHIMS-MRI is total ischemic brain lesion volume, measured in cubic centimeters, as detected from a standardized imaging and reading protocol. Secondarily, ischemic lesion volumes in the basal ganglia and the cerebral white and gray matter outside the basal ganglia were measured (Lao, 2006).

The ischemic lesion volume as defined and identified by this methodology generally corresponds to what has been called leukoareosis, ischemic white matter disease, small vessel ischemia, etc. (Pantoni and Garcia, 1997). Basically unknown before the advent of MRI, this process is now accepted as a non-necrotic, ischemic effect on myelin that is secondary to the effects of aging, hypertension and other small vessel pathologies of the brain (Moody et al., 1990). The earliest reports of this vasculopathy depended on anecdotal observations which were quickly superseded by semi-quantitative, human observer scoring systems such as those used in the Cardiovascular Health Study (Bryan et al., 1994) and the Rotterdam Study (DeGroot et al., 2000, 2002). While these systems are strongly correlated with each other in terms of rank order, their scores are not directly comparable, and these manual systems have limited reproducibility and restricted

dynamic ranges (Bryan et al., 1994; Mantyla, et al., 1997). The methodology for detecting and quantifying ischemic tissue used in this report reflects the evolution in image processing from manual human observer to automatic, quantitative computerized digital image analytical techniques that are not only correlated with human observers and the semi-quantitative scoring systems, but are very reproducible and offer a greater dynamic range (Anbeek et al., 2004; Yoshita, et al., 2006).

Our methodology classifies all brain tissue into either normal or ischemic gray or white matter and assigns the tissue type to one of 92 anatomic regions of interest (ROIs) of the cerebrum that are organized in an anatomically hierarchal system that was collapsed into 3 ROIs for this analysis – cerebral gray and white matter and basal ganglia (gray and white matter). These 3 ROIs form the basis for our secondary outcomes while the sum of the three is the primary outcome.

MRI Training and Quality Control

Prior to conducting scans for study purposes, a central training session conducted by the WHIMS-MRI Coordinating Center and MRIQCC staff was provided to instruct and train all WHIMS-MRI project managers and MRI technologists involved in the study. The following training was provided:

- participant enrollment and preparation prior to the MRI study;
- MRI procedures (test scan protocol, vendor equipment and software platform, participant positioning, MRI protocol, archiving, transfer of image data from MRI scanner to workstation);
- transmission of images via MIRC (Medical Image Resource Consortium) from local workstations to the MRIQCC;
- quality control and correspondence of study data; and
- safety monitoring and reporting.

The WHIMS-MRI quality control program, which was based on the American College of Radiology (ACR) MRI Accreditation Program, involved quarterly analysis of scans of an ACR MRI phantom. Specific tests included slice position accuracy, slice thickness accuracy, geometric accuracy, spatial resolution, image uniformity, ghosting, low contrast detectibility, signal to noise and contrast to noise ratio. All WHIMS-MRI clinics were ACR MR accredited sites. In addition, each clinic sent digital image data of its QC phantom to the MRIQCC for in-house review. Each WHIMS-MRI clinical center was responsible for keeping its WHIMS-MRI scanners within the ACR performance specifications. The MRIQCC documented that each clinical center was in compliance throughout the study.

WHIMS-MRI Preliminary Results

The characteristics of the WHIMS-MRI cohort are displayed in Exhibits 3.2 and 3.3. Good balance was obtained between the groups of women defined by their original treatment assignment.

Exhibit 3.4 portrays the distribution of ischemic brain lesion volumes for women grouped by treatment assignment. No differences between groups reached statistical significance.

Exhibit 3.5 examines the relationships that ischemic lesion volumes had with dementia risk factors. The strongest relationships ($p \leq 0.05$) were for age, smoking status, prior CVD, hypertension, body mass index, Modified Mini-Mental (3MS) score, and prior MCI or PD.

Exhibit 3.6 portrays the mean brain volumes for women grouped by treatment assignment. In analyses with adjustment for age and intracranial volume, women assigned to hormone therapy tended to have smaller frontal lobe volumes ($p=0.004$) and hippocampal volumes ($p=0.05$).

Evidence from the WHIMS trials suggests that the adverse impact of hormone therapy on cognition may be strongest among women with evidence of cognitive deficits. Exhibit 3.7 examines how the relative decrement in brain volume associated with assignment to HT varies according to women's pre-treatment cognitive function, as assessed by baseline 3MS testing. In general, the adverse effects of HT are greatest among women who scored relatively poorly on 3MS at baseline. Exhibit 3.8 groups women according to the level of ischemic lesion volume and examines, within these subgroups, the differences in mean brain volumes according to women's WHI treatment assignment. The adverse impact of prior HT assignment appears to be limited to women who have some level of lesion load.

Exhibit 3.9 examines the relationship between ischemic lesion volume and blood pressure among women grouped by baseline antihypertensive use. Ischemic lesion load tended to have a U-shaped relationship with systolic blood pressure. Exhibit 3.10 portrays region-specific ischemic lesion volumes of women with and without baseline hypertension: the greater levels of ischemic lesions associated with hypertension reach statistical significance in many of the regions.

Exhibit 3.11 portrays the time course of probable dementia/mild cognitive impairment (PD/MCI) incidence for WHIMS-MRI enrollees. At the time of their MRI, approximately 4% were classified as either MCI or PD. Exhibit 3.12 portrays relationships that established dementia risk factors have with PD/MCI: the strongest of these are for age and 3MS score in the WHIMS-MRI cohort. Note that treatment groups are balanced with respect to these risk factors. Exhibit 3.13 portrays mean brain volumes and ischemic lesion volumes for women grouped by treatment assignment and PD/MCI status. PD/MCI cases who had been assigned to HT tended to have smaller total and hippocampal brain volumes than PD/MCI cases who had been assigned to placebo. They also tended to have less (although not significantly less) ischemic lesion volumes than women assigned to placebo. Exhibit 3.14 portrays these relationships graphically: the increases in ischemic lesion volumes associated with PD/MCI is slightly larger among women assigned to placebo versus HT while the increases in brain loss associated with PD/MCI are markedly greater at the hippocampus for women assigned to HT versus placebo. Exhibit 3.15 portrays the cumulative distribution of the ratio of cerebral spinal fluid volume to total intracranial volume (a measure of brain atrophy) among women grouped by treatment assignment and PD/MCI status. Regardless of baseline 3MS level, the distribution of brain atrophy is shifted to larger values for HT women who converted to PD/MCI.

Exhibit 3.1: Enrollment of the WHIMS-MRI cohort

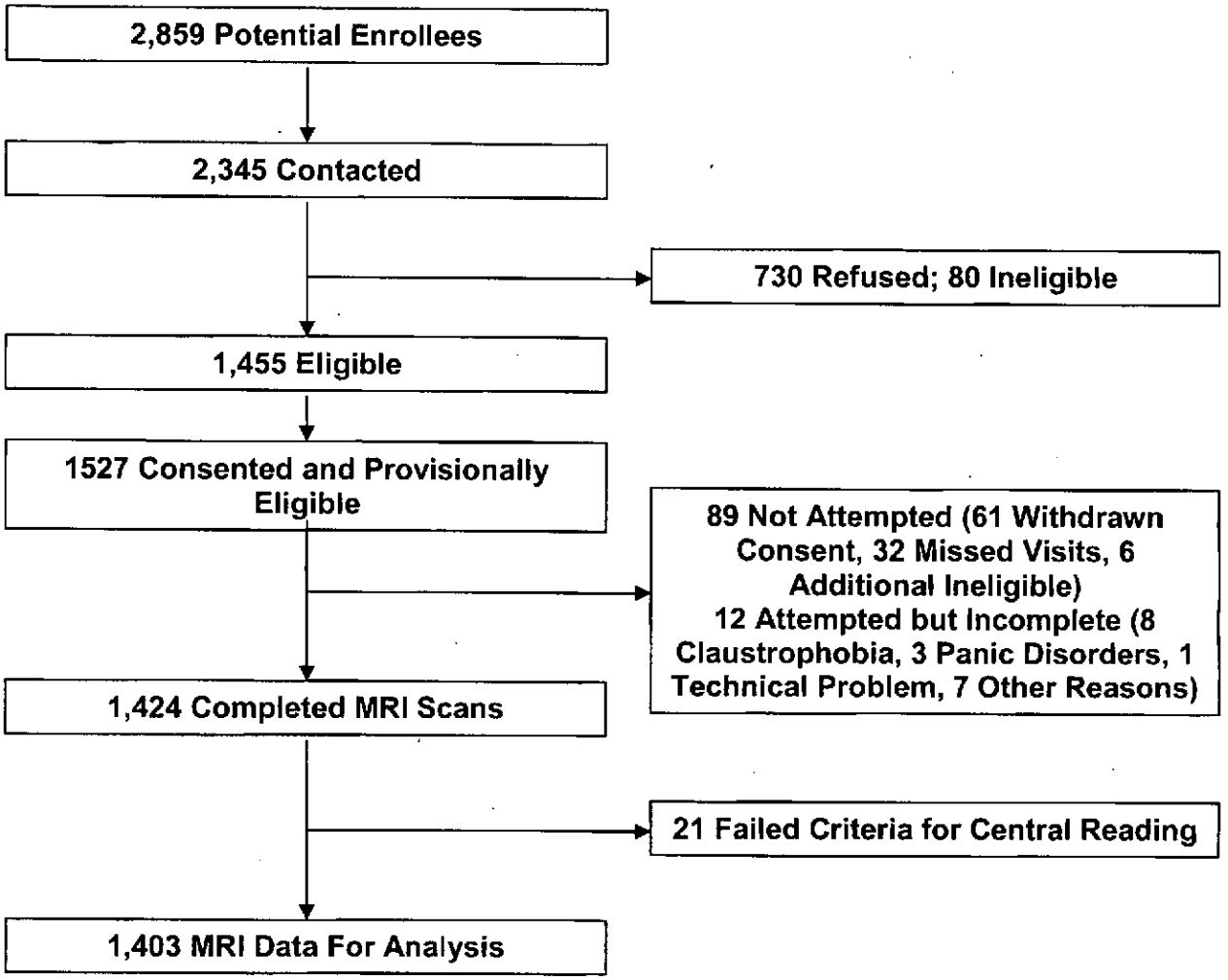


Exhibit 3.2: WHI baseline demographic, socioeconomic status, and lifestyle characteristics of WHIMS-MRI women by treatment assignment: frequency and (percent).

Variable	WHIMS-MRI CEE+MPA (N=883)		WHIMS-MRI CEE-Alone (N=520)		p-values		
	CEE+MPA (N=436)	Placebo (N=447)	CEE-Alone (N=257)	Placebo (N=263)	CEE+MPA vs Placebo	CEE-Alone vs Placebo	HT vs no HT
Age --yrs, No. (%)		231(52)		131(50)			
65-69	229 (53)	153 (34)	124 (48)	92 (35)			
70-74	153 (35)	63 (14)	94 (37)	40 (15)	0.75	0.92	0.81
75+	54 (12)		39 (15)				
Years since menopause, No. (%)							
< 15	92(22)	105(24)	17(8)	29(12)			
15-24	241 (57)	253(58)	79 (36)	88(38)	0.40	0.19	0.18
25+	90 (21)	78 (18)	123(56)	117(50)			
Education, No. (%)							
< High school	16 (4)	22 (5)	16 (6)	9 (3)			
High school/GED	88 (20)	98 (22)	70 (27)	69 (26)	0.54	0.18	0.97
Some college	179 (41)	165 (37)	95 (37)	118 (45)			
College grad	152 (35)	160 (36)	76 (30)	67 (26)			
Ethnicity, No. (%)							
American Indian	1 (0)	0 (0)	3 (1)	0 (0)			
Asian/Pacific Islander	4 (1)	14 (3)	3 (1)	2 (1)			
Black/African American	18(4)	16 (4)	13 (5)	17 (6)	0.39[1]	0.06[1]	0.88[1]
Hispanic/Latina	7 (2)	5 (1)	7 (3)	2 (1)			
White, non-Hispanic	405 (93)	409 (92)	224 (88)	238 (91)			
Other	1 (0)	2 (0)	5 (2)	3 (1)			
Family Income-$/yr, No. (%)							
Less than 19,999	81 (20)	79 (19)	61 (25)	77 (31)			
20,000 to 34,999	115 (28)	145 (34)	87 (36)	76 (30)			
35,000 to 49,999	109 (27)	101 (24)	46 (19)	49 (19)	0.33	0.39	0.46
50,000 to 74,999	71 (17)	61 (14)	35 (14)	29 (12)			
75,000+	35 (9)	40 (9)	15 (6)	21 (8)			
Smoking Status, No. (%)							
Never	257 (59)	252 (57)	149 (59)	148 (56)			
Former	159 (37)	172 (39)	96 (38)	99 (38)	0.77	0.49	0.67
Current	18 (4)	17 (4)	9 (3)	15 (6)			
Alcohol Intake							
None	163 (37)	190 (43)	131 (51)	135 (52)			
<1/day	208 (48)	205 (46)	107 (42)	104 (40)	0.32	0.95[2]	0.55
1-2/day	56 (13)	46 (10)	17 (7)	19 (7)			
3+/day	9 (2)	6 (1)	2 (1)	3 (1)			

[1] Based on collapsing to three categories (Black/African American, White and other).
[2] Based on Fisher's exact test.

Exhibit 3.3: WHI Baseline clinical characteristics of WHIMS-MRI women by treatment assignment: frequency and (percent)

Variable	WHIMS-MRI CEE+MPA		WHIMS-MRI CEE-Alone		p-values		
	CEE+MPA	Placebo	CEE-Alone	Placebo	CFE + MPA vs. Placebo	CFE-Alone vs. Placebo	HT vs No HT
BMI, kg/m^2, No. (%)							
< 25	138 (32)	156 (35)	60 (24)	64 (24)			
25-29	165 (38)	155 (35)	98 (38)	108 (41)	0.71	0.85	0.81
30-34	90 (21)	90 (20)	62 (24)	58 (22)			
35+	42 (10)	45 (10)	35 (14)	32 (12)			
Hypertension status, No. (%)							
None	234 (54)	240 (54)	122 (47)	139 (53)			
Current/controlled[1]	55 (13)	49 (11)	51 (20)	54 (21)	0.71	0.30	0.75
Current/uncontrolled	147 (34)	158 (35)	84 (33)	70 (27)			
Prior CVD , No. (%)							
No	413 (95)	425 (95)	236 (92)	239 (91)			
History of stroke	2 (0)	5 (1)	3 (1)	4 (2)	0.43[3]	0.93[3]	0.56
History of other CVD[2]	21 (5)	17 (4)	18 (7)	20 (8)			
Diabetes, No. (%)							
No	420 (96)	425 (95)	241 (94)	242 (92)	0.36	0.44	0.23
Yes	16 (4)	22 (5)	16 (6)	21 (8)			
Prior use of HT, No. (%)							
No	340 (78)	346 (77)	131 (51)	127 (48)	0.84	0.54	0.59
Yes	96 (22)	101 (23)	126 (49)	136 (52)			
Baseline 3MSE, No. (%)							
<90	22 (5)	19 (4)	20 (8)	19 (7)			
90-94	66 (15)	80 (18)	50 (20)	58 (22)	0.45	0.76	0.36
95-100	347 (80)	341 (78)	185 (73)	184 (71)			
MCI/PD[4], No. (%)							
No	416 (95)	435 (97)	247 (96)	251 (95)	0.13	0.70	0.36
Yes	20 (5)	12 (3)	10 (4)	12 (5)			

[1]Measured to be less than 140/90 mmHg.
[2]Other cardiovascular disease defined as myocardial infarction, angina, percutaneous transluminal angioplasty, or coronary artery bypass grafting.
[3] Based on Fisher's exact test.
[4]Mild cognitive impairment (MCI)/probable dementia (PD)

Exhibit 3.4: Distribution of raw ischemic brain lesion volumes by WHI treatment assignment

Variable	WHIMS-MRI E+P Trial		WHIMS-MRI E-Alone Trial		p-values[1]		
	CEE+MPA N=436	Placebo N=447	CEE-Alone N=257	Placebo N=263	CEE+MPA vs Placebo	CEE-Alone vs Placebo	HT vs No HT
White and gray matter (outside of basal ganglia)							
Mean ± SD	7.57± 9.13	7.29 ± 10.79	7.90 ± 9.53	8.43 ± 12.35	0.24	0.85	0.28
10th percentile	0.7	0.7	0.8	0.8			
25th percentile	1.7	1.6	1.8	1.9			
40th percentile	2.9	2.6	3.2	3.1			
50th percentile	4.1	3.5	4.4	4.6			
60th percentile	5.9	4.9	6.1	5.6			
75th percentile	10.1	8.7	10.3	9.2			
90th percentile	18.9	16.6	19.4	19.2			
Basal ganglia							
Mean ± SD	0.90 ± 1.19	0.87 ± 1.08	0.91 ± 1.19	0.93 ± 1.23	0.92	0.73	0.90
10th percentile	0.0	0.0	0.0	0.0			
25th percentile	0.1	0.1	0.1	0.1			
40th percentile	0.3	0.3	0.3	0.3			
50th percentile	0.4	0.4	0.5	0.4			
60th percentile	0.7	0.7	0.8	0.7			
75th percentile	1.2	1.3	1.2	1.4			
90th percentile	2.2	2.3	2.3	2.4			
Total brain volume							
Mean ± SD	8.47 ± 9.95	8.16 ± 11.5	8.80 ± 10.32	9.36 ± 13.28	0.27	0.87	0.32
10th percentile	0.8	0.7	0.9	0.8			
25th percentile	1.9	1.8	1.9	2.1			
40th percentile	3.3	3.1	3.7	2.6			
50th percentile	4.7	4.2	5.0	4.9			
60th percentile	6.5	5.6	6.8	6.4			
75th percentile	11.8	10.3	11.5	10.8			
90th percentile	20.2	18.7	21.5	21.2			

[1] Based on Wilcoxon rank-sum test.

Exhibit 3.5: Geometric mean (SE) ischemic brain lesion volumes (cc) by demographic; socioeconomic status; lifestyle; and clinical characteristics*

Variable	N (%)	White and Gray Matter (outside of basal ganglia) Mean (SE)	Basal Ganglia Mean (SE)	Total Lesion Volume Mean (SE)
Age, years[1]				
65-69	715 (51)	3.78 (0.12)	0.54 (0.01)	4.21 (0.14)
70-74	492 (35)	5.00 (0.20)	0.74 (0.02)	5.61 (0.22)
75+	196 (14)	6.47 (0.40)	0.98 (0.03)	7.36 (0.47)
p-value		<0.0001	<0.0001	<0.0001
Education				
< High school	63 (5)	3.80 (0.42)	0.56 (0.03)	4.25 (0.48)
High school/GED	325 (23)	4.47 (0.22)	0.66 (0.02)	5.01 (0.25)
Some college	557 (40)	4.54 (0.17)	0.66 (0.01)	5.07 (0.19)
College grad	455 (33)	4.62 (0.19)	0.69 (0.01)	5.19 (0.22)
p-value		0.61	0.62	0.60
Ethnicity				
Black/African American	64 (5)	5.35 (0.61)	0.65 (0.040	5.86 (0.68)
White, non-Hispanic	1276 (91)	4.49 (0.11)	0.69 (0.01)	5.03 (0.13)
Other	59 (4)	4.21 (0.49)	0.65 (0.04)	4.73 (0.56)
p-value		0.40	0.98	0.50
Family income, $/yr				
Less than 19,999	298 (22)	4.86 (0.25)	0.72 (0.02)	5.46 (0.28)
20,000 to 34,999	423 (32)	4.47 (0.19)	0.66 (0.01)	4.99 (0.22)
35,000 to 49,999	305 (23)	4.29 (0.21)	0.66 (0.02)	4.82 (0.24)
50,000 to 74,999	196 (15)	4.36 (0.27)	0.63 (0.02)	4.84 (0.31)
75,000+	111 (8)	4.11 (0.34)	0.60 (0.03)	4.62 (0.39)
p-value		0.58	0.60	0.55
Smoking status				
Never	806 (58)	4.15 (0.13)	0.62 (0.01)	4.65 (0.14)
Former	526 (38)	4.95 (0.19)	0.72 (0.01)	5.53 (0.21)
Current	59 (4)	6.07 (0.69)	0.88 (0.05)	6.88 (0.79)
p-value		0.001	0.004	0.001
Alcohol intake				
None	619 (45)	4.49 (0.16)	0.64 (0.01)	5.01 (0.18)
<1/day	624 (45)	4.56 (0.16)	0.69 (0.01)	5.12 (0.18)
1-2/day	138 (10)	4.53 (0.34)	0.68 (0.03)	5.07 (0.39)
3+/day	20 (1)	3.58 (0.70)	0.71 (0.07)	4.06 (0.81)
p-value		0.81	0.77	0.81
Prior CVD				
No	1313 (94)	4.43 (0.11)	0.66 (0.01)	4.96 (0.12)
History of stroke	14 (1)	5.17 (1.21)	0.62 (0.08)	5.67 (1.35)
History of other CVD[2]	76 (5)	5.99 (0.60)	0.85 (0.04)	6.67 (0.68)
p-value		0.05	0.12	0.05

Variable	N (%)	White and Gray Matter (outside of basal ganglia) Mean (SE)	Basal Ganglia Mean (SE)	Total Lesion Volume Mean (SE)
Hypertension at WHI enrollment				
No	735 (52)	3.97 (0.13)	0.59 (0.01)	4.44 (0.14)
Yes, controlled[3]	209 (15)	4.32 (0.26)	0.62 (0.02)	4.81 (0.30)
Yes, uncontrolled	459 (33)	5.61 (0.23)	0.83 (0.02)	6.31 (0.26)
p-value		<0.0001	<0.0001	<0.0001
History of high cholesterol				
No				
Yes	1153 (84)	4.48 (0.11)	0.65 (0.01)	5.01 (0.13)
p-value	223 (16)	4.91 (0.29)	0.76 (0.02)	5.53 (0.33)
		0.23	0.07	0.19
Diabetes				
No	1328 (95)	4.46 (0.11)	0.67 (0.01)	5.00 (0.12)
Yes	75 (5)	5.43 (0.55)	0.62 (0.03)	6.01 (0.62)
p-value		0.12	0.92	0.14
Body Mass Index, kg/m^2				
<25	418 (30)	4.90 (0.21)	0.72 (0.02)	5.49 (0.24)
25-29	526 (37)	4.63 (0.18)	0.68 (0.01)	5.18 (0.20)
30-34	300 (21)	4.25 (0.21)	0.61 (0.02)	4.76 (0.24)
35+	154 (11)	3.75 (0.27)	0.59 (0.02)	4.20 (0.30)
p-value		0.04	0.12	0.04
Baseline 3 MS				
< 90	80 (6)	4.14 (0.41)	0.65 (0.03)	4.64 (0.47)
90-94	254 (18)	4.64 (0.26)	0.61 (0.02)	5.14 (0.29)
95-100	1057 (76)	4.50 (0.12)	0.68 (0.01)	5.05 (0.14)
p-value		0.71	0.39	0.76
3MS closest to MRI				
< 90	67 (5)	5.60 (0.60)	0.80 (0.04)	6.25 (0.68)
90-94	174 (12)	5.20 (0.35)	0.81 (0.03)	5.86 (0.40)
95-100	1162 (83)	4.36 (0.11)	0.64 (0.01)	4.88 (0.13)
p-value		0.04	0.01	0.03
Change in 3MS (MRI – Baseline)				
≤ -1	450 (32)	4.90 (0.20)	0.77 (0.02)	5.52 (0.23)
> -1 and ≤ 1	432 (31)	4.50 (0.19)	0.63 (0.01)	5.01 (0.21)
≥ 2	509 (37)	4.18 (0.16)	0.60 (0.01)	4.68 (0.19)
p-value		0.08	0.002	0.06
On- or post-trial MCI/PD[4]				
No	1349 (96)	4.44 (0.10)	0.65 (0.01)	4.97 (0.12)
Yes	54 (4)	6.61 (0.79)	0.97 (0.06)	7.34 (0.89)
p-value		0.006	0.006	0.007

*After adjustment for trial, clinical site, age, time from randomization to MR scan, intracranial volume, education, smoking, body mass index, prior cardiovascular disease, hypertension, and diabetes

[1] Not adjusted for age.

[2] Other cardiovascular disease defined as myocardial infarction, angina, percutaneous transluminal angioplasty, or coronary artery bypass grafting.

[3]Measured to be less than 140/90 mmHg.

[4]Mild cognitive impairment (MCI)/probable dementia (PD)

Exhibit 3.6: Mean (SE) volumes by treatment assignment after adjustment for age, time since enrollment, intracranial volume, clinic site, and other potential confounders.

	Total Brain Volume Mean (SE)	Ventricle Volume Mean (SE)	Hippocampal Volume Mean (SE)	Frontal Lobe Volume Mean (SE)
Pooled trials				
HT	798.37 (1.30)	37.62 (0.55)	5.69 (0.04)	282.72 (0.57)
Placebo	801.69 (1.29)	37.15 (0.55)	5.79 (0.04)	285.09 (0.57)
Difference	-3.32 (1.84)	0.47 (0.78)	-0.10 (0.05)	-2.37 (0.81)
p-value	0.07	0.55	0.05	0.004
E+P Trial				
CEE+MPA	800.92 (1.63)	37.84 (0.68)	5.72 (0.04)	283.61 (0.72)
Placebo	803.11 (1.63)	36.53 (0.68)	5.83 (0.04)	285.46 (0.72)
Difference	-2.19 (2.32)	1.31 (0.97)	-0.11 (0.06)	-1.85 (1.03)
p-value	0.35	0.18	0.09	0.07
E-Alone Trial				
CEE-Alone	794.53 (2.21)	37.53 (0.95)	5.63 (0.06)	281.47 (0.95)
Placebo	799.03 (2.16)	37.85 (0.94)	5.75 (0.06)	284.25 (0.94)
Difference	-4.50 (3.13)	-0.33 (1.36)	-0.12 (0.09)	-2.78 (1.36)
p-value	0.15	0.81	0.18	0.04

Consistency of treatment effects of CEE+MPA vs CEE-Alone
Total brain volume: p=0.36
Ventricle volume: p=0.20
Hippocampal volume: p=0.99
Frontal lobe volume: p=0.45
Tissue volumes include gray and white matter but not cerebral spinal fluid volume.

Exhibit 3.7: Fitted mean difference in volumes for women assigned to HT versus placebo, after adjustment for age, time since enrollment, intracranial volume, clinic site, and other potential confounders.

Region	Baseline 3MS			p-value*
	<90 Mean (SE)	90-94 Mean (SE)	95-100 Mean (SE)	
Total brain	-16.93 (7.71)	-7.40 (4.34)	-1.41 (2.10)	0.07
Ventricles	3.19 (3.29)	-0.69 (1.85)	0.52 (0.90)	0.77
Hippocampus	-0.53 (0.21)	-0.21 (0.12)	-0.04 (0.06)	0.02
Frontal	-7.62 (3.40)	-2.59 (1.92)	-1.96 (0.93)	0.43

* p-values are based on interaction terms between treatment effect and baseline 3MS score as a continuous variable.

Exhibit 3.8: Mean (SE) volumes by treatment assignment for women grouped according to total abnormal tissue volumes: <2 cm^3 or ≥ 2 cm^3, after adjustment for age, time since enrollment, intracranial volume, clinic site, and other potential confounders.

	Total Brain Volume Mean (SE)	Ventricle Volume Mean (SE)	Hippocampal Volume* Mean (SE)	Frontal Lobe Volume Mean (SE)
Lesion Volume < 2 cm^3				
HT	788.12 (2.41)	30.90 (0.93)	6.08 (0.07)	278.15 (1.05)
Placebo	785.51 (2.43)	31.71 (0.94)	5.93 (0.07)	278.66 (1.06)
Difference	2.62 (3.52)	-0.81 (1.36)	0.15 (0.10)	-0.51 (1.54)
p-value	p=0.41	p=0.55	p=0.13	p=0.74
Lesion Volume ≥ 2 cm^3				
HT	802.27 (1.55)	39.78 (0.67)	5.57 (0.04)	284.29 (0.69)
Placebo	806.93 (1.54)	39.13 (0.66)	5.73 (0.04)	287.31 (0.68)
Difference	-4.67 (2.20)	0.66 (0.95)	-0.16 (0.06)	-3.01 (0.98)
p-value	p=0.03	p=0.49	p=0.005	p=0.002

*Significant HT*lesion volume interaction, p=0.01

Exhibit 3.9: Abnormal white matter volumes (SE) by hormone therapy (active or placebo) in CEE-Alone or CEE+MPA arm and baseline BP levels (not on antihypertensive drug therapy or on antihypertensive drug therapy at baseline)

	Not On Antihypertensive Drug Therapy				
		Active (n=490)		Placebo (n=519)	
SBP	Overall (n=1009)	CEE-Alone (n=166)	CEE+MPA (n=324)	CEE-Alone (n=181)	CEE+MPA (n=338)
<110 mmHg	4.07 (0.44)	7.48 (2.49)	3.23 (0.70)	7.31 (2.04)	2.64 (0.63)
110-119	4.11 (0.32)	7.00 (1.70)	3.48 (0.62)	6.08 (1.47)	2.95 (0.53)
120-139	3.89 (0.20)	6.31 (1.30)	3.03 (0.42)	6.22 (1.30)	2.95 (0.42)
140+	5.20 (0.33)	9.00 (1.93)	3.73 (0.57)	10.05 (2.25)	3.74 (0.55)
p-value SBP group =0.0043 for overall BP effect, p-value , CEE-Alone compared to CEE+MPA=0.0356, p-value treatment assignment active vs. placebo=NS					
	On Antihypertensive Drug Therapy				
		Active (n=198)		Placebo (n=182)	
SBP	Overall (n=380)	CEE-Alone (n=88)	CEE+MPA (n=110)	CEE-Alone (n=78)	CEE+MPA (n=104)
<110 mmHg	5.42 (1.72)	5.48 (3.66)	-	3.00 (1.63)	28.17 (25.59)
110-119	2.72 (0.56)	1.42 (0.98)	2.77 (1.29)	1.90 (1.07)	4.85 (1.93)
120-139	5.00 (0.40)	3.78 (1.32)	6.85 (1.68)	4.27 (1.39)	4.79 (1.37)
140+	6.12 (0.49)	4.39 (1.56)	7.88 (1.94)	4.66 (1.78)	7.32 (1.84)
p-value SBP group =0.0014 for overall BP effect, p-value, CEE-Alone as compared to CEE+MPA=0.5250, p-value treatment assignment active vs. placebo=NS					

Exhibit 3.10: Mean (SE) abnormal volumes by hypertension status after adjustment for age, race, total cranial volume, time between termination of study and MRI

Analysis	Hypertension N=661	No Hypertension N=728	P-value Hypertension vs No Hypertension
Abnormal left frontal lobe	1.21 (0.05)	0.90 (0.04)	<.0001
Abnormal right frontal lobe	1.31 (0.05)	1.02 (0.04)	<.0001
Abnormal left occipital lobe	0.20 (0.01)	0.19 (0.01)	0.51
Abnormal right occipital lobe	0.20 (0.01)	0.19 (0.01)	0.58
Abnormal left parietal lobe	0.72 (0.04)	0.55 (0.03)	0.0002
Abnormal right parietal lobe	0.66 (0.03)	0.51 (0.03)	0.001
Abnormal left temporal lobe	0.69 (0.03)	0.54 (0.03)	<.0001
Abnormal right temporal lobe	0.62 (0.03)	0.50 (0.02)	0.0005
Abnormal limbic lobe	0.05 (0.00)	0.03 (0.00)	0.005
Abnormal corpus callosum	0.17 (0.01)	0.17 (0.01)	0.67

Exhibit 3.11: Incidence of cognitive impairment in relation to the timing of the MRI scan

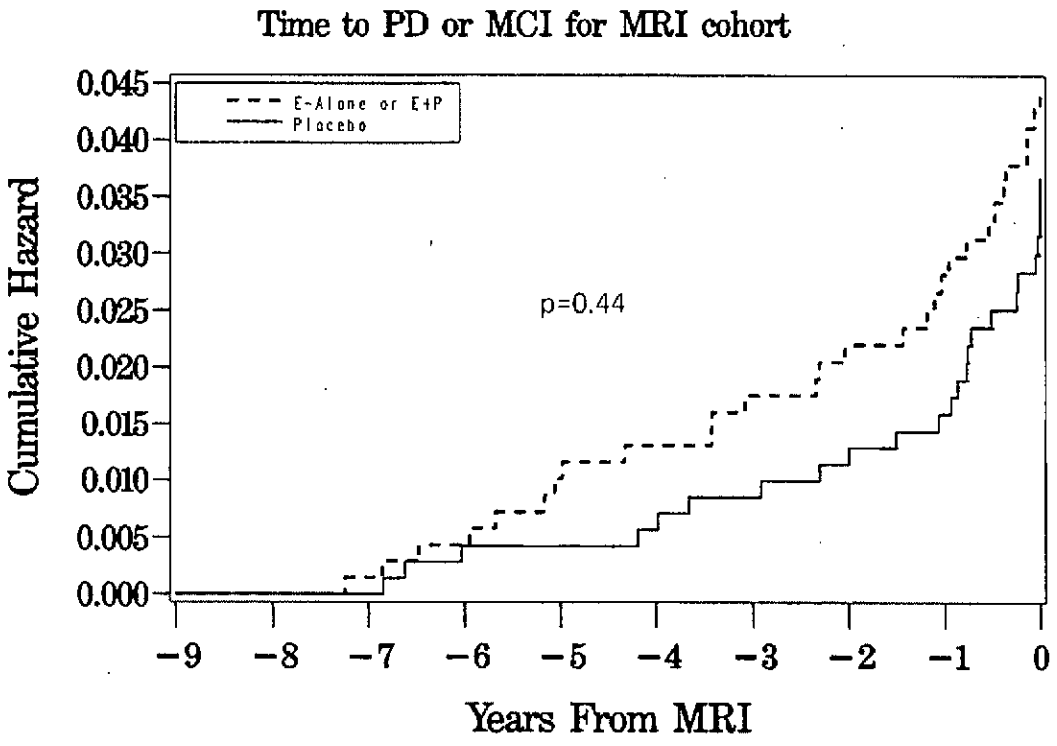


Exhibit 3.12: Selected dementia risk factors of the WHIMS-MRI cohort.

Variable	No Cognitive Impairment		Cognitive Impairment		p-values	
	HT Therapy N=664	Placebo N=686	HT Therapy N=29	Placebo N=24	HT vs No HT	Any CI vs No CI
Age --yrs, No. (%)						
65-69	342 (51.5)	354 (51.6)	11 (37.9)	8 (33.3)		
70-74	239 (36.0)	236 (34.4)	8 (27.6)	9 (37.5)	0.81	<0.001
75+	83 (12.5)	96 (14.0)	10 (34.5)	7 (29.2)		
Education, No. (%)						
< High school	31 (4.7)	29 (4.2)	1 (3.4)	2 (8.3)		
High school/GED	149 (22.5)	160 (23.4)	8 (27.6)	7 (29.2)	0.97	0.78
> High school < 4 yr college	263 (39.7)	275 (40.2)	11 (37.9)	8 (33.3)		
> 4 yr college	219 (33.1)	220 (32.2)	9 (31.0)	7 (29.2)		
Hypertension Status, No. (%)						
No	345 (52.0)	366 (52.3)	11 (37.9)	13 (54.2)	0.45	0.29
Yes	319 (48.0)	320 (46.6)	18 (62.1)	11 (45.8)		
Prior CVD						
None	623 (93.8)	642 (93.6)	26 (89.7)	22 (91.7)		
Stroke	4 (0.6)	9 (1.3)	1 (3.4)	0 (0.0)	0.56	0.33**
Other CVD*	37 (5.6)	35 (5.1)	2 (6.9)	2 (8.3)		
Diabetes, No. (%)						
No	635 (95.6)	645 (94.0)	26 (89.7)	22 (91.7)	0.23	0.18
Yes	29 (4.4)	41 (6.0)	3 (10.3)	2 (8.3)		
Smoking Status, No. (%)						
Never	387 (59.0)	391 (57.7)	19 (59.4)	9 (36.0)		
Former	243 (37.0)	256 (37.8)	12 (37.5)	15 (60.0)	0.67	0.45
Current	26 (4.0)	31 (4.6)	1 (3.1)	1 (4.0)		
METs/week, No. (%)						
≤ 3.5	217 (32.7)	219 (31.9)	4 (13.8)	14 (58.3)		
3.6-12.5	223 (33.6)	228 (33.2)	9 (31.0)	2 (8.3)	0.90	0.12
> 12.6	224 (33.7)	239 (34.8)	16 (55.2)	8 (33.3)		
3MS Score, No. (%)						
<90	31 (4.7)	30 (4.4)	11 (37.9)	8 (33.3)		
90-94	110 (16.6)	130 (19.2)	6 (20.7)	8 (33.3)	0.36	<0.001
95-100	520 (78.7)	518 (76.4)	12 (41.4)	8 (33.3)		

* Other CVD defined as MI, angina, PCTA, or CABG
**Fisher's exact test

Exhibit 3.13: Adjusted mean (SE) regional brain volumes and ischemic lesion volumes among women with cognitive impairment grouped by WHI treatment assignment: adjustment for intracranial volume, age, time since randomization, trial, clinic site, education, race/ethnicity, smoking, BMI, hypertension, prior cardiovascular disease, prior HT, and baseline 3MSE.

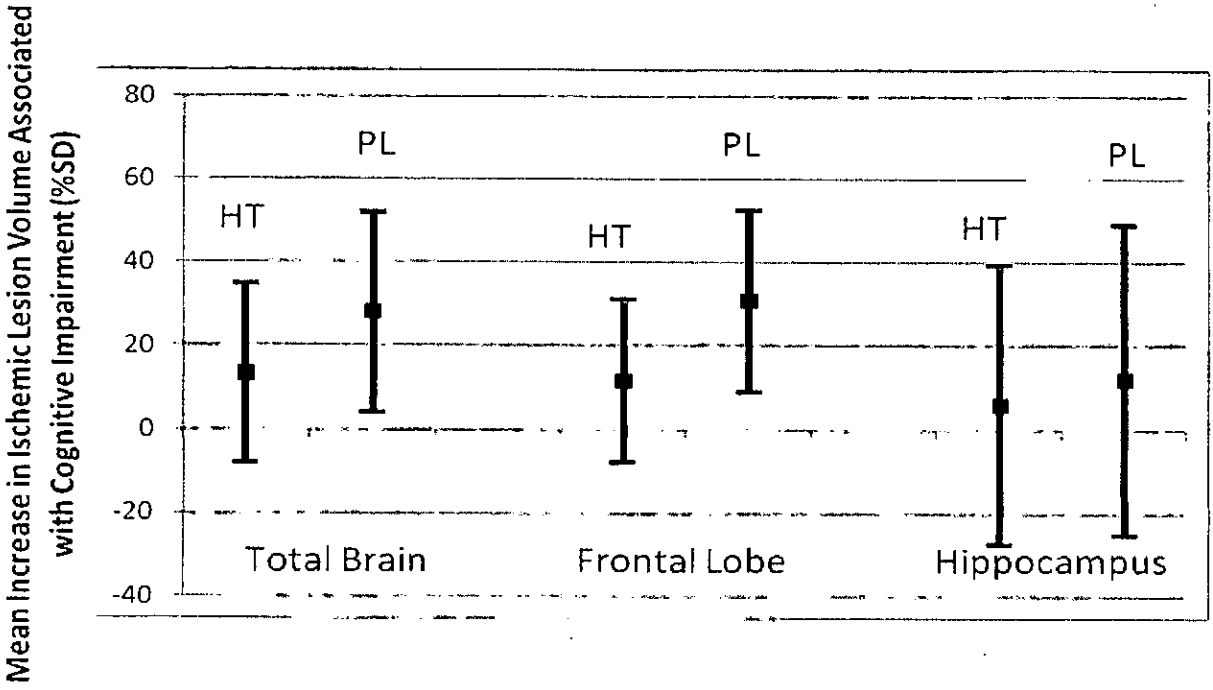
All women

MRI Outcome	MCI and/or PD		No MCI or PD		p-values		
	HT	Placebo	HT	Placebo	HT vs No HT	CI vs No CI	Interaction
Regional brain volumes, cm^3							
Total brain	781.78 (6.52)	804.94 (7.29)	799.11 (1.33)	801.58 (1.31)	0.07	0.10	0.03
Frontal lobe	280.87 (2.88)	287.41 (3.22)	282.80 (0.59)	285.01 (0.58)	0.004	0.94	0.32
Hippocampus	4.40 (0.18)	5.43 (0.20)	5.75 (0.04)	5.80 (0.04)	0.05	<0.001	<0.001
Ischemic lesion volumes, cm^3							
Total brain	6.648 (1.280)	8.029 (1.689)	5.143 (0.210)	4.868 (0.198)	0.39	0.02	0.39
Frontal lobe	2.697 (0.506)	3.576 (0.700)	2.102 (0.087)	2.011 (0.083)	0.55	0.01	0.23
Hippocampus	0.006 (0.005)	0.011 (0.006)	0.004 (0.001)	0.007 (0.001)	0.06	0.55	0.82

Excluding women with pre-enrollment history of stroke

MRI Outcome	MCI and/or PD		No MCI or PD		p-values		
	HT	Placebo	HT	Placebo	HT vs No HT	CI vs No CI	Interaction
Regional brain volumes, cm^3							
Total brain	783.04 (6.63)	805.48 (7.30)	799.77 (1.34)	802.10 (1.32)	0.09	0.13	0.04
Frontal lobe	281.30 (2.93)	287.64 (3.23)	283.08 (0.59)	285.21 (0.59)	0.005	0.99	0.33
Hippocampus	4.37 (0.18)	5.44 (0.20)	5.75 (0.04)	5.81 (0.04)	0.05	<0.001	<0.001
Ischemic lesion volumes, cm^3							
Total brain	6.432 (1.259)	7.996 (1.680)	5.173 (0.211)	4.854 (0.198)	0.34	0.02	0.33
Frontal lobe	2.643 (0.504)	3.558 (0.695)	2.115 (0.087)	1.999 (0.083)	0.45	0.01	0.20
Hippocampus	0.006 (0.006)	0.011 (0.006)	0.004 (0.001)	0.007 (0.001)	0.06	0.53	0.81

Exhibit 3.14: Estimated mean differences in ischemic lesion volumes and untransformed regional brain volumes between women with and without cognitive impairment. Estimates are derived from analyses of covariance with adjustment for intracranial volume and dementia risk factors. To facilitate comparison across brain regions, estimates are divided by the cohort-wide standard deviations of measures and expressed as percentages.



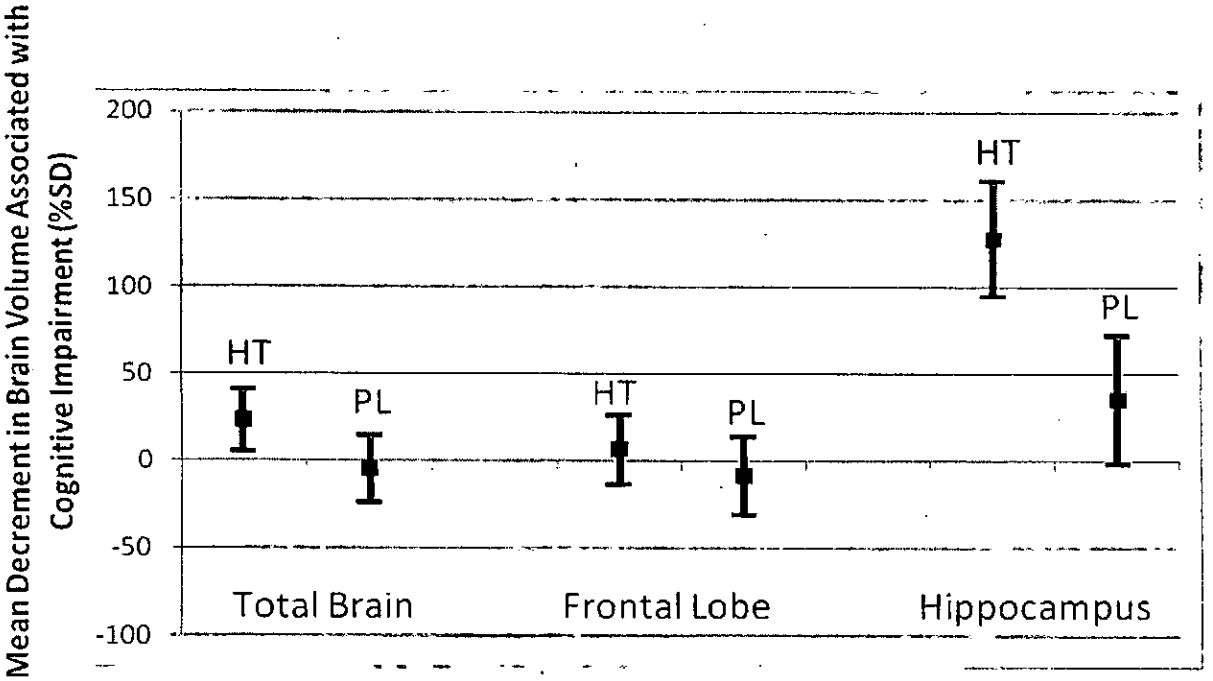
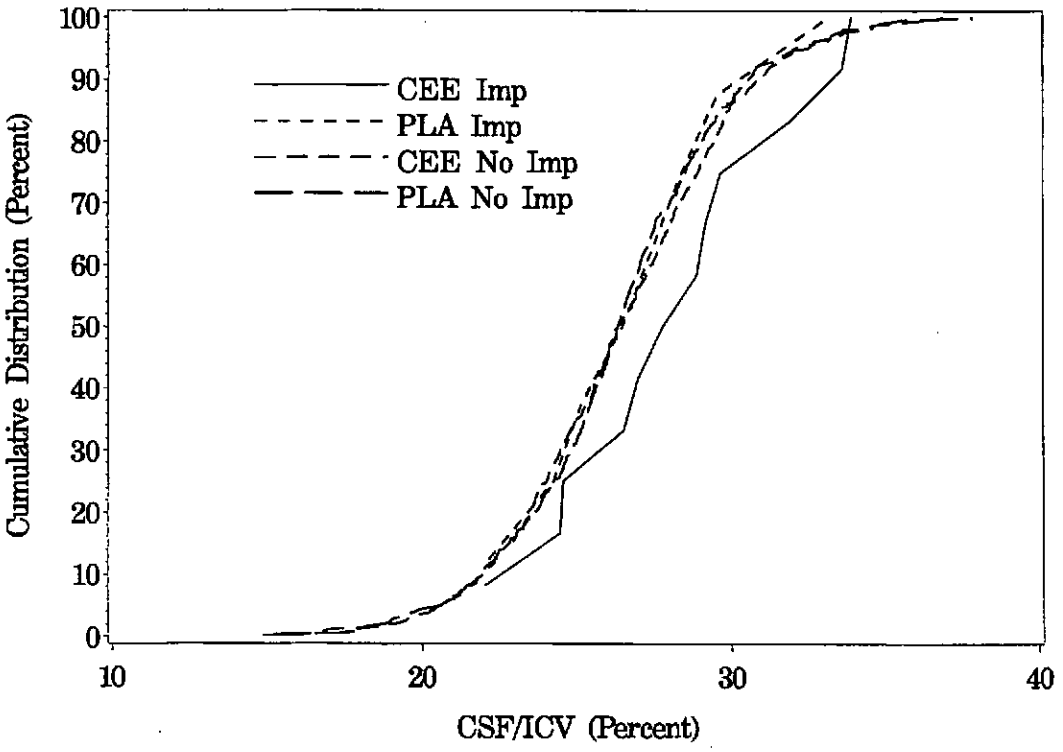
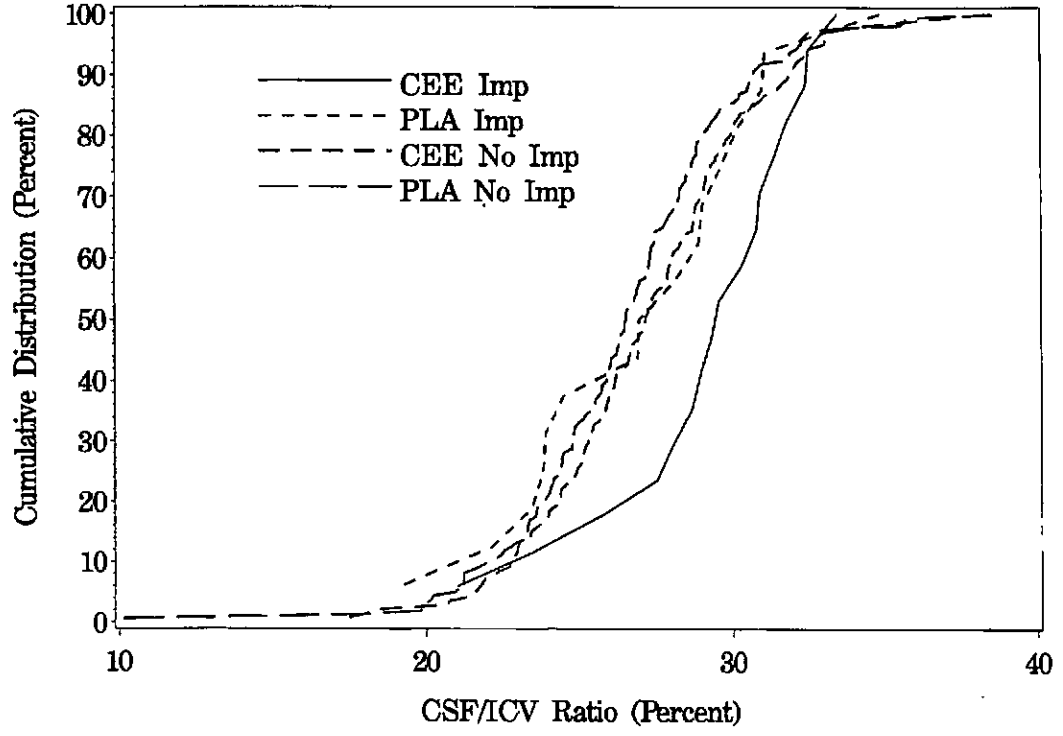


Exhibit 3.15: Cumulative distribution of percent CSF/ICV ratio for women grouped by treatment assignment and by whether they were classified with cognitive impairment.

Baseline 3MS ≥ 95



Baseline 3MS < 95



4.1. Study Goals

The Women's Health Initiative Study of Cognitive Aging (WHISCA) was two, parallel randomized, placebo controlled, clinical trials designed to assess the efficacy of postmenopausal hormone therapy (HT)- conjugated equine estrogen (CEE) 0.625mg/day with or without medroxyprogesterone acetate (MPA) 2.5mg/day compared with placebo on age related changes on domain specific cognitive functions. WHISCA was an ancillary study to the Women's Health Initiative and the WHI Memory Study and enrolled 2,303 women aged 66 to 84 years who did not meet the criteria for dementia. Women with prior history of hysterectomy were randomly assigned by the WHI to CEE-Alone and those with an intact uterus received, CEE+ MPA for an average of three years before the first WHISCA cognitive assessment. WHISCA investigated the effects of hormone therapy on rates of change over time in memory, other aspects of cognition (language, attention, spatial ability), motor function, and mood.

An Extension to WHISCA was funded on July 1, 2005 and provided follow-up cognitive testing off-study medication until October 2007. All of the original 14 clinical sites participated in the Extension study. Annual cognitive testing was conducted with the same standardized neuropsychological (NP) battery used in the original WHISCA study. This NP battery was developed by the National Institute on Aging and designed to be sensitive to the effects of age and HT.

Additional goals addressed by the WHISCA Extension were:

- To determine the long-term effects of HT on changes in memory, other cognitive functions, and affect;
- To determine the effects of discontinuation of HT on changes in memory, other cognitive functions, and affect;
- To determine whether vascular disease and atrophy, measured by MRI, modify the effects of HT on cognitive change;
- To investigate predictors of the transitions between normal aging and mild cognitive impairment and mild cognitive impairment and dementia.

A cost extension began on July 1, 2008 using carry over funds and will continue until June 30, 2009. The goals of the cost extension are:

- Collaborate with the NIA in order to complete scoring of a subset of the WHISCA data and to plan and conduct collaborative analyses.
- To analyze and disseminate findings from WHISCA data through a series of publications and presentation at selected national meetings.
- To offer a visiting scholar program to provide opportunities for investigators, including junior scientists, to conduct scholarly work during brief, intensive, onsite collaborations with WHISCA investigators at WFUHS (Drs. Sally Shumaker, Mark Espeland, Stephen Rapp, Laura Coker) and from the NIA in Baltimore (Drs. Susan Resnick and Alan Zonderman).
- To host a conference for WHISCA principal investigators from each clinical site. This conference will be held in conjunction with another conference to maximize participation.

- To support analyses for apoE status among women enrolled in WHISCA by acquiring extracted DNA for apoE genotyping for up 2305 women enrolled in WHISCA.

Extension of WHISCA will allow the investigators to complete the planned work and to reach the ultimate study goal of providing critical information to clinicians and researchers on the effects of hormone therapy on cognition and aging in a healthy, older cohort of women

4.2 WHISCA Enrollment and Retention

A total of 2,303 women, at least 65 years of age and enrolled in both the WHI and WHIMS studies, were recruited into WHISCA. The mean age at the end of the Extension was 79.9 years of age and the oldest participant was 93 years old. The rate of attrition was projected to be 10% per year over the life of the study. To date 1,844 participants were reported to be at full follow-up status, leaving 266 participants who were alive but were not making clinic visits. There have been 192 participant deaths since the beginning of the study. Enrollment for the Extension was 1,230 women making enrollment at 89% of potential enrollment.

5.1 Current Active Writing Groups

WHIMS/WHIMS-MRI/WHISCA/ WHISCA-CoStar/ WHI Ms#	Title	Convenor	Stage
Ms#8/157	Type 2 diabetes and change in cognitive functioning in the Women's Health Initiative Memory Study: the effects of diabetic risk factors and treatment for diabetes and hypertension (WHIMS)	Coker	2
Ms#11/595	Quality assurance and training in a low event long-term clinical trial: The Women's Health Initiative Memory Study (WHIMS)	Dailey	5
Ms#39/276	Social Support and Cognitive Functioning in Post-Menopausal Women (WHIMS)	Messina	5
Ms#46/360	Body mass index, waist-hip ratio, and cognitive decline in postmenopausal women: results from the Women's Health Initiative Memory Study (WHIMS)	Kerwin	5
Ms#47/546	Predictors of incident dementia in postmenopausal women enrolled in a trial of hormone therapy: The Women's Health Initiative Memory Study (WHIMS)	Coker	5
Ms#49/390	Identifying risk factors for cognitive change in the WHIMS: a neural networks approach ***(Possible submission as book chapter to Cambridge University Press)***	Bandelow	7
Ms#50/399	Subtypes of mild cognitive impairment: prevalence, course and effect of hormone therapy (WHIMS)	Rapp	5
Ms#51/427	Statin use and cognition in postmenopausal women: The Women's Health Initiative Memory Study (WHIMS)	Legault	3
Ms#54/558	Cognitive function and physical performance in the Women's Health Initiative Memory Study (WHIMS) ***(Draft manuscript reviewed and approved by the WHI P&P/PO on their 5/22/08 call ; submitted to the Journal of Gerontology)***	Atkinson	7
Ms#55/4/579	Relative effects of tamoxifen, raloxifene, and estrogen therapy on cognition: results from the Women's Health Initiative Study of Cognitive Aging (WHISCA) and the Cognition in the Study of Tamoxifen and Raloxifene (CoStar) clinical trials ***(Draft manuscript reviewed by WHI P&P/PO on 4/24/08.Reviewers requested copy of CoStar primary paper before finalizing review)***	Espeland	5
Ms#56/6/598	Effects of conjugated equine estrogens on cognition and affect in surgically menopausal women (WHISCA)	Resnick	5
Ms#57/597	Prevalence of Anticholinergic Drug Use and Impact on Cognition and Function in Older Adults (WHIMS)	Sink	5
Ms#60/2/625	Effects of Postmenopausal HT on Volumetric Subclinical Cerebrovascular Disease: the WHIMS-MRI ***(Final manuscript in-press in journal Neurology)***	Coker	8
Ms#61/3/626	Effects of Postmenopausal HT on Regional Brain Volumes: the WHIMS-MRI ***(Final manuscript in-press in journal Neurology)***	Resnick	8
Ms#63/5	Differences in MRI Outcomes Associated with Cognitive Decline, Mild Cognitive Impairment and Probable Dementia: the WHIMS-MRI ***(Awaiting proposal)***	Rapp	1
Ms#64/6/696	Relationship of HTN, BP & BP Control with MRI Outcomes in the WHIMS-MRI ***(Final manuscript reviewed and approved by WHI P&P/PO on 5/22/08. Group***	Kuller & Margolis	6

	has finalized data tables per P&P review. Submission to the journal Stroke to follow acceptance by Neurology of the 2 primary MRI manuscripts)		
Ms#65/7	Do MRI Outcomes Predict Subsequent Declines in Global and Domain Specific Cognition: the WHIMS-MRI ***(Awaiting proposal)***	Resnick	1
Ms#66/639	Psychiatric Co-Morbidity in Subjects Participating in the WHIMS	Colenda	5
Ms#67/670	Long-term Neurocognitive Effects of Sleep Disturbance: Impacts on Cognitive Declines, and Incidence of Mild Cognitive Impairment and Dementia (WHIMS)	Chen	3
Ms#68/665	Ascertaining Dementia Related Outcomes for Deceased or Proxy-dependent Participants: An Overview of WHIMS Supplemental Case Ascertainment Protocol (WHIMS-SCAP)	Jaramillo	3
Ms#69/683	Influence of Educational Attainment on Relationships Between Neuropathology and Cognitive Function: The WHIMS ***(Group exploring potential journals for submission)***	Rapp	7
Ms#70/8/680	Mixed Distribution Risk Factors Models for Ischemic Lesion Prevalence and Extent: The WHIMS-MRI.	Espeland	4
Ms#71/6/695	Application of Hidden Markov Models for Longitudinal Measures of Cognition Collected by the WHISCA.	Ip	2
Ms#72/9/794	Regional Brain & Ischemic Lesion Volumes in Women with Cognitive Impairment Following Exposure to CEET: (WHIMS-MRI) ***(Group exploring potential journals for submission)***	Espeland	7
Ms#73/727	WHIMS Program: Emerging Findings ***(Book chapter approved by WHI P&P/PO 3/08. Submitted to Cambridge University Press for publication in spring of 2009)***	Espeland	8
Ms#74/881	Change in Cognitive Function in Cancer Patients Among WHIMS Participants ***(Manuscript proposal will be reviewed by the WHI P&P on 10/9/08)***	Resnick	1

Section 6.

WHIMS Epidemiology of Cognitive Health Outcomes (WHIMS-ECHO) & WHIMS-MRI2

6.1 Future Opportunities: WHIMS-ECHO and WHIMS-MRI2

6.1.1 Strengths of the WHIMS data and cohort

Given the enormous personal and financial burden associated with cognitive decline and impairment, and the associations between cognitive decline and other critical health risks and behaviors in older adults, a study on older women's health which does not include assessments of cognitive aging represents a serious oversight. The Women's Health Initiative Memory Study (WHIMS) – coupled with the data from the "parent study" the Women's Health Initiative (WHI) – represents a major, cost-effective resource for furthering our understanding of the epidemiology of cognitive health and decline in older women.

Resources embodied in the WHIMS Suite of Studies, include:

- A focus on women's health and aging with up to 10 years of annual assessments of global cognitive function on 7,145 women who have been well-characterized and who were aged 65-80 years at enrollment at a time when it is rare to see annual cognitive assessments and non-existent to see annual assessments over such a long timeframe;
- A large cohort with much broader geographic distribution, and more ethnic and racial diversity than any other study in the field;
- Incidence data on centrally-adjudicated mild cognitive impairment (MCI) and probable dementia (PD) – and with the MCI subtypes – one of the largest datasets to date on this critical issue;
- Detailed risk factor data available on all women over time, extensive medical information in general, and access to banked samples (including DNA) on study participants collected by the WHI;
- Ongoing surveillance of the entire cohort for major cardiovascular clinical events, cancers, and fractures;
- Up to seven years of data from a comprehensive neuro-cognitive test battery collected annually on 2,145 women through the Women's Health Initiative Study of Cognitive Aging (WHISCA);
- Brain magnetic resonance imaging (MRI) on 1,424 of the women through the WHIMS-MRI Study;
- An established research structure to contact women for further follow-up;
- A national network of outstanding scientists associated with the WHI;
- A WHIMS External Advisory Committee of nationally recognized experts in fields related to WHIMS outcomes;
- An experienced and stable multi-disciplinary research team with excellent credentials for conducting the proposed research.

6.1.2 Specific Strengths of the WHIMS-MRI

Between April, 2005 and January, 2006, 1,424 women underwent magnetic resonance imaging (MRI) across 14 WHI centers. These women were enrolled in the WHI Hormone Therapy (HT) randomized controlled clinical trials: from as early as December 1993 until either July, 2002 (when the trial of combination therapy was halted due to an unfavorable risk-to-

benefit ratio of its non-cognitive endpoints) or February, 2004 (when the trial of estrogen-alone therapy was halted due to an increased risk of stroke and embolic events and the lack of any favorable effect on cardiovascular disease) (WHI, 2002, 2004). These women also were participants in the Women's Health Initiative Memory Study (WHIMS), which provided annual cognitive screening for dementia and mild cognitive impairment and documented an increased risk for cognitive impairment among women who were assigned to HT during the WHI trials (Shumaker, 2003, 2004, 2004). In addition, 73% were participants in the Women's Health Initiative Study of Cognitive Aging (WHISCA), which provided more comprehensive annual assessments of cognitive function and mood. Both WHIMS and WHISCA testing continues for these women through the fall of 2007. Collectively, these rich data resources include characterizations, over extended periods of time, of risk factors for neuropathology and cognitive decline and psychometric and clinical assessments of cognitive function and cognitive status.

6.1.3 Summary of WHIMS' Strengths & Specific Aims of WHIMS-ECHO and WHIMS-MRI2

Major scientific advances have been made within the WHIMS program (and within research in other cohorts and clinical trials). However, this area of research is challenging due to the costs associated with the maintenance of cohorts over time, and the sample sizes and length of follow-up needed to address the complex health issues that occur in an aging population with multiple co-morbidities. Thus, a number of critical questions regarding cognition and aging in women remain unanswered. What are the transition patterns from normal cognitive function to mild impairment, and to dementia among aging women? Are there sub-types of cognitive deficits that vary in their trajectories over time? Can these sub-types be identified psychometrically? How well do domain-specific neuro-cognitive tests and brain MRI images predict the subsequent incidence of mild cognitive impairment and probable dementia? What is the association between major clinical events (e.g., cancers, cardiac events, hypertension) and changes in cognitive functioning? By continuing to follow the well-established and clinically characterized WHIMS cohort, and ascertaining additional outcome data on incidence of MCI and PD, the proposed WHIMS **E**pidemiology of **C**ognitive **H**ealth **O**utcomes (WHIMS-ECHO) provides a uniquely powerful and cost-effective mechanism for answering these and other critical questions about women's cognitive aging.

The specific aims of WHIMS-ECHO are to:

1. Model rates and correlates of transitions over time among cognitively normal women and those with MCI or PD;
2. Examine the predictive ability of the domain-specific Women's Health Initiative Study of Cognitive Aging (WHISCA) cognitive battery for subsequent incidence of MCI and PD;
3. Examine the progression of specific subtypes of cognitive deficits and impairments;
4. Model the relationships among risk factors associated with MCI and PD;
5. Examine correlates between cerebral MRI outcomes and subsequent incidence of cognitive impairment;
6. Examine relationships between inter-current clinical events (e.g. CVD, cancer, stroke, depression, hip fractures) and cognitive decline;
7. Further demonstrate the efficiency of centralized versus distributed cognitive assessment methods for cohort studies – a technique that becomes more critical as the population ages and cost-effective methods for assessing cognitive decline and dementia are required.

WHIMS-MRI2 is proposed to collect a second MRI (approximately 4 yrs after the first MRI) from women to assess incident neuropathology and the rate of atrophy. The specific goals are to address:

- What relationships do the longitudinal risk factor data collected by the WHI have with the incidence of infarcts and increases in cerebral ischemic lesion volumes?
- What associations do the longitudinal cognitive test scores collected by the WHIMS have with rates of change in overall and region-specific atrophy?
- Do the smaller brain volumes we currently see among women who had been assigned to WHI HT correspond to a continuing increased rate of atrophy?
- Will the increased atrophy seen among incident PD/MCI cases who had been assigned to HT compare to cases who had been assigned to placebo continue to be evident with longer follow-up?

In addition to the unique resource offered by WHIMS-ECHO and WHIMS MRI2, in combination these studies will provide further information on the most enduring negative consequences of postmenopausal hormone therapy (HT): a relative deficit in cognitive status and smaller brain volumes that remain in the cohort up to five years after the cessation of study-prescribed HT. The differences observed in global cognitive functioning seen at the end of the trials are persisting and increasing over time; we do not know how long this will continue but it presents a clear risk factor for declining to MCI and/or PD. The proposed characterization of subtypes of MCI will help to identify whether vulnerable sub-populations exist.

Transitioning the WHIMS program into an epidemiologic cohort provides an unprecedented opportunity to address these, and other, important questions about the cognitive health of older women, leveraging the remarkable assets and promise of the WHI. We are aware of no other program that can address these important public health issues so comprehensively. We anticipate that WHIMS-ECHO will provide normative data essential to designing future studies aimed at identifying and assessing multiple treatment strategies to promote cognitive health in women.

6.2 Brief Overview of Research Design and Methods

6.2.1 WHIMS-ECHO

WHIMS-ECHO continues the collection of data on cognitive changes and incident MCI and PD in the WHIMS cohort. We have refined data-collection methods to significantly reduce cost and participant strain, while maintaining a demonstrated high level of reliability and validity. WHIMS-ECHO has been reviewed and approved by the WHI Steering Committee. Women currently enrolled in the WHIMS Extension Study will be eligible for participation in WHIMS-ECHO. Cognitive data on consenting women will be obtained through telephone interviews of participants and previously identified proxies. Telephone interviews will be conducted by trained and certified staff at the WHIMS-ECHO Coordinating Center at WFUSM. The proposed telephone-based protocol has been used successfully in other studies and proven to be a valid and cost-effective method for tracking changes in cognitive status, MCI and dementia (Crooks et al., 2005; Jarvenpaa et al., 2002; Lipton et al., 2003). WHIMS-ECHO participants will be contacted

annually for 2 years beyond the WHIMS Extension, which ended its data collection on September 30, 2007.

Approximately 3,600 (86.7%) of the WHIMS Extension participants are currently active. All are eligible to continue in the WHIMS-ECHO study. Fifty-four percent of these women are below the age of 80. To continue in WHIMS-ECHO, participants cannot previously have been adjudicated as having probable dementia (PD), and must pass a hearing screening test.

Further follow-up has already been discussed with potential participants at clinic sites. In addition, WHIMS Extension participants previously provided informed consent that permits further contact. When WHIMS-ECHO begins, mailings will be sent to all WHIMS Extension participants informing them about the study, and noting that they will be contacted by staff at the WHIMS Coordinating Center (WFUSM). Recruitment materials will be developed by the WHIMS-ECHO Steering Committee and final review and approval will follow the standard process within WHI. Based on prior experience, an outstanding recruitment and retention history within WHIMS and the reduced burden from telephone interviews without clinic visits, we anticipate that 90% of women enrolled in the current WHIMS Extension will join WHIMS-ECHO.

Face-to-face clinical assessments of cognitive functioning are expensive in large multi-site studies, and can be burdensome for study participants. Thus, telephone-based protocols have been developed and validated (Ellis et al., 1998). A battery of neuropsychological tests will be administered to all participants and will take, on average, approximately 30 minutes. Included in the battery is the TICS, which will identify participants at risk for dementia or MCI (scores $\leq$ 28). For such participants, additional data will be collected by telephone from a previously identified friend or family member (proxy) using a structured clinical interview – The Dementia Questionnaire (Kawas et al., 1994) – for determining dementia diagnoses. Proxy interviews are expected to be conducted for approximately 4% of participants and will require, on average, about 15 minutes. Together these data will be submitted to the WHIMS Adjudication Committee for final determination of No Dementia, Mild Cognitive Impairment, or Probable Dementia as is currently done in WHIMS. **The proposed protocol differs from the one used in WHIMS and WHIMS-Extension in that all participants receive the full cognitive battery, providing domain specific and global cognitive data on all participants. Consolidating as such eliminates any confusion associated with call-backs and is more cost-effective than the original phased approach.**

Telephone administration of these instruments will be conducted by trained and certified cognitive technicians. As a quality assurance measure, each administration of the cognitive battery will be audio-taped to assist the cognitive technician in scoring. Interviewers will be trained at an initial training session. Certification and re-certification will be required.

6.3.4 Detecting Changes in Cognitive Functioning and Ascertainment of Cases

One of the strengths of WHIMS was our repeated assessments and the availability of longitudinal data to our Adjudication Committee (AC). WHIMS-ECHO retains this strength. The AC will have all the WHIMS data as well as the WHIMS-ECHO data when adjudicating cases. ***The WHIMS-ECHO retains the ability to detect changes in cognitive and behavioral functioning over time necessary for diagnosis of PD and MCI and for some sub-typing.***

The changes proposed in WHIMS-ECHO do not threaten the validity of ascertainment and may actually strengthen it as we are able to conduct more extensive neuropsychological testing in all women as compared to the Phase 1 component of WHIMS. The phone-administered neuro-cognitive test battery will have sub-tests assessing key cognitive domains: verbal memory (East Boston Memory Test, TICS-M word list), language (Verbal Fluency), attention / concentration (portions of TICS-M), and executive function (Digit Span-Backwards) as well as global cognitive functioning (TICS-M). ***The addition of the Dementia Questionnaire (DQ) in WHIMS-ECHO adds an instrument specifically designed for the purpose of making a diagnosis of dementia.*** The DQ includes questions regarding the criteria for diagnosing dementia including the onset and course of varied cognitive and behavioral changes, the number and timing of strokes, hypertension, Parkinson's disease, head injury, seizures, syphilis, diabetes, drinking problems, depression, mania, and family history.

6.3.5 Feasibility of MRI in Longitudinal Studies

A good source of information on the feasibility of MRI for use in longitudinal studies is:

Mueller SG, Schuff N, Weiner MW. Evaluation of treatment effects in Alzheimer's and other neurodegenerative diseases by MRI and MRS. NMR Biomedicine 2006; 19:655-668.

Of the potential MRI-based outcome measures, the authors conclude that volumetric MRI is the "method of choice to monitor drug effects in neurodegenerative diseases," which is what we are proposing for WHIMS-MRI2: changes in brain volume as a measure of atrophy rates. The authors state that the annual rate of global atrophy among 70-80 year old "normal" individuals is 0.3-0.5% per year, while rates range to 2-3% per year in neurodegenerative diseases. Thus, neurodegenerative diseases may increase the rate of atrophy by factors ranging from 4 to 10. Atrophy rates also differ among brain regions and these differences depend on diseases and disease states. We will adopt in our power calculations the annual rate of 0.4 cm^3/yr for our cohort, which may be conservative: a simple regression of total brain volume versus age produces a slope corresponding to about 0.48cm^3/yr, which would be expected to increase with age. We are also, perhaps, conservative in focusing on total brain volume, since we may have larger treatment effects detectable on specific regions, such as the frontal lobe.

The Baltimore Longitudinal Study of Aging found that the standard error of annualized rates of change in total brain volumes in 92 subjects aged 59-85 years was 0.3 cm^3 per year, based on measurements taken 4 years apart. This translates to a standard deviation of about 2.9 cm^3 per year in rates among participants. We use this as the standard deviation we project to obtain for estimating annual rates of change in WHIMS-MRI2.

The mean total brain volume among WHIMS-MRI participants was 799.7 cm^3 and the estimated age-adjusted difference in total brain volume between the women assigned to HT versus placebo was 3.43 cm^3, i.e. equivalent to about 3.43 cm^3/0.4 cm^3/yr = 8+ years of normal aging.

Tabulated below are the mean differences in total brain atrophy rates that we anticipate to detect between women who had been assigned to HT versus placebo. Presented are mean differences in annualized atrophy rates and the factor by which these would result in an increase in annual rates for "normal" women aged 70-80 years. We have, in these calculations, targeted a retention rate of 85%, i.e. that 85% of the original WHIMS-MRI cohort would return for a second scan, which we feel is reasonable (see below).

85% Retention

	Power	
Detectable Differences	80%	90%
Absolute Difference in Annual Rates (cm^3/yr)	0.47 cm^3/yr	0.55 cm^3/yr
Factor by Which Progression is Increased Over 0.4%/yr	2.18	2.38

This table indicates that if we are able to have 85% of our participants re-scanned at 3-4 years after the initial scan, we will have 80% power to detect an increase in the rate of total brain atrophy by a factor of 2.18, i.e. an increase from 0.40 cm^3/yr to 0.40 + 0.47 = 0.87 cm^3/yr. We will have 90% power to detect an increase by a factor of 2.38.

The following table present results from similar calculations if retention is 80%. These indicate that with 80% retention, we still retain 80% power to detect increases in annual atrophy rates by a factor of about 2.2.

80% Retention

	Power	
Detectable Differences	80%	90%
Absolute Difference in Annual Rates (cm^3/yr)	0.48 cm^3/yr	0.57 cm^3/yr
Factor by Which Progression is Increased Over 0.4%/yr	2.21	2.42

Note that the above calculations are based on the MRI techniques adopted in the Baltimore Longitudinal Study of Aging. The WHIMS-MRI reading center investigators (Dr. Bryan and Davatzikos) developed these earlier protocols and are confident that the newer generation of methods adopted in the WHIMS-MRI provide greater precision, and thus the power to detect smaller differences.

In summary, the precision with which we are able to estimate changes based on 3-4 years of follow-up (which we take, in these calculations, to be comparable to that reported by the Baltimore Longitudinal Study of Aging) will provide us adequate statistical power to detect increases in the annual rate of total brain atrophy by a factor of about 2.2, still well short of the increased rates associated with neurodegenerative diseases (which increase the rate of atrophy by factors of 4 to 10).