

AS167: Sex Hormones, Risk Factors, and Risk of ER+ and ER- Breast Cancer Summary of Case-Cohort Selection

April 16, 2007

Study Population:

All centrally adjudicated cases of breast cancer assessed for estrogen receptor status as of April 8, 2005 were selected as potential cases. All WHI Observational Study participants were considered for the cohort. A total of 2723 cases out of a cohort of 93,676 were initially eligible.

Potential cases and controls were excluded based on the following hierarchical criteria:

	<i>Eligible ER+ Cases</i>	<i>Eligible ER- Cases</i>	<i>Eligible Cohort</i>
No exclusions	2309	414	93,676
1) Lack of available plasma EDTA (1.0 mL)	2205	394	89,552
2) History of breast cancer at baseline	2052	355	84,377
3) Hormone therapy use at baseline	831	171	42,022
4) Hormone therapy use \leq 2 years prior to baseline	778	159	39,616
5) Androgen, DHEA, or Raloxifene use at baseline	778	159	39,536
6) Hormone therapy use during study	656	134	32,201
7) Androgen, DHEA, or Raloxifene use during study	629	127	30,115
8) No outcomes forms after baseline	629	127	29,806
9) Unknown race/ethnicity on Form 2	622	126	29,301
10) ER+ cases before date of last ER- case (8/31/04)	617	NA	NA

Case and Cohort Selection summary:

Out of the original 2723 cases and 93,676 participants, 617 ER+ and 126 ER- cases and 29,301 participants met the eligibility criteria and were available for case or cohort selection. A set of 200 out of the 617 eligible ER+ cases and 600 out of the 29,301 eligible cohort were chosen by simple random sampling. All 126 ER- cases were included.

There will be 326 cases and 600 cohort members for a total of 920 women in the study population. The age and ethnicity frequencies for each of the groups is summarized below. The average follow-up time for ER+ and ER- cases and cohort members from enrollment to the minimum of the last follow-up date or date of the last ER- case on August 31, 2004 was 7.7 (SD = 1.3), 7.4 (SD = 1.5), and 7.3 (SD = 1.5) years, respectively.

<i>Variable</i>	<i>Level</i>	<i>ER+</i> <i>Cases %</i>	<i>ER-</i> <i>Cases %</i>	<i>Cohort</i> <i>%</i>
Age category	50-54	5.5	8.7	7.3
	55-59	9.5	19.1	13.0
	60-64	21.5	20.6	22.3
	65-69	29.0	24.6	23.5
	70-74	24.5	18.3	24.2
	75-79	10.0	8.7	9.7
Ethnicity	White	86.0	79.4	82.3
	Black	8.0	15.1	11.2
	Hispanic	4.5	2.4	2.8
	Am. Indian	0.0	0.8	0.3
	Asian / Pacific Isl.	1.5	2.4	3.3