

**I.1 Outcomes Reports Schedule (Recommended)**

Outcomes Processes	Definition	WHILMA Reports	Frequency (suggested)	WHIP9000 Series Reports
<b>Identification</b>	Identification of a possible WHI outcome	<b><u>Prior to Form 33D collection and analysis</u></b> <ul style="list-style-type: none"> <li>• <i>WHIP0621 Outcomes Screening Action Required</i> – Shows Form 33s that are incomplete. Does <b>not</b> show Form 33s that need a Form 33D.</li> <li>• <i>WHIP0622 Members Potential Outcomes</i> – Shows Form 33s that need a Form 33D. Shows Form 33s that report an outcome, but are incomplete in some way.</li> </ul>	0621 – Weekly	<i>WHIP9745 – Completed Form 33s Without the Required Form 33D</i>
		<b><u>After Form 33D collection and analysis:</u></b> <ul style="list-style-type: none"> <li>• <i>WHIP0983 Forms to Pull by Analysis Batch</i> – Shows conditions created and “info” errors needed follow up for individual analysis batches. (Print after each batch analysis)</li> </ul>	0622 – Weekly  0983 – After each batch	
<b>Investigation</b>	The process of locating relevant information about a possible WHI outcome	<ul style="list-style-type: none"> <li>• <i>WHIP0980 Request for Medical Information</i> – Lists documentation to be requested from specific providers.</li> <li>• <i>WHIP1213 Outcome Visits Requiring Requests Summary</i> – A summary of all provider visits for which there are documents outstanding (not requested, not received). Visits will come off list when the adjudication case packet is closed.</li> </ul>	0980 – After entering the document request date for a provider visit.  1213 – Weekly	<i>WHIP9747 – WHILMA Analyzed Forms 33 (v. 1&amp;2), 33D and 120, Outcomes Cases Without Medical Records Requested</i>
		<b><u>Suggested reports for QA:</u></b> <ul style="list-style-type: none"> <li>• <i>WHIP0984 Outcome Member Visit Details Requiring Requests</i> – Lists all details for a member’s <u>visit</u> for which there are outstanding documents.</li> <li>• <i>WHIP0985 Outcome Conditions Requiring Providers</i> – Lists conditions that are created by the analyzer or manually inserted and have not been linked to a provider visit.</li> </ul>	0984 – Weekly  0985 - Monthly	
<b>Document-ation</b>	Assembly of required supporting medical records, obtained through investigation of a possible WHI outcome into an adjudication case packet	<b><u>Suggested reports for QA:</u></b> <ul style="list-style-type: none"> <li>• <i>WHIP0987 Member Visits Requiring Adjudication</i> – Lists visits in which all documentation is obtained but not assigned an adjudication case packet.</li> <li>• <i>WHIP1222 Duplicate Outcomes</i> – Lists potential duplicate outcomes in adjudications closed within a specified time period.</li> </ul>	0987 – Bi-monthly  1222 - Monthly	<i>WHIP9749 – Outcomes Cases With Medical Records Response Date Not Yet Assigned to an Adjudicator</i>

Outcomes Processes	Definition	WHILMA Reports	Frequency (suggested)	WHIP9000 Series Reports
<b>Adjudication</b>	Decreases if a WHI outcomes is present or not	<ul style="list-style-type: none"> <li>• <i>WHIP0988 Investigation Documentation Summary (IDS) (Required)</i> – Cover or face sheet for each adjudication case packet.</li> <li>• <i>WHIP1215 Members Outcome Status Report (Required)</i> – Lists member's outcomes history (e.g., confirmed outcomes, pending cases), excluding closed hospitalizations. Print for each case packet assigned to the adjudicator.</li> <li>• <i>WHIP1228 Adjudications by Adjudicator</i> – Lists progress of cases forwarded to adjudicator (pending, returned to OC but still open, closed in WHILMA, sent to CCC).</li> <li>• <i>Adjudication Rules (optional)</i> – Sheet can help monitor for subsequent conditions. Must be updated by the OC. Print with each case packet assigned to the adjudicator.</li> </ul>	<p>0988 &amp; 1215 – Print for each case assigned to the adjudicator</p> <p>1228 – After assigning cases to adjudicator</p>	<i>WHIP9750 – Outcomes Cases Assigned to Adjudicator Not Yet Closed in WHIMA</i>
<b>Death</b>		<ul style="list-style-type: none"> <li>• <i>WHIP1225 Unresolved Deaths</i> – Lists unresolved deaths from all WHILMA sources. This includes members who have one, but not all of, the following: <i>Form 120 – Initial Notification of Death</i>, <i>Form 33/33D</i> (by proxy) or <i>Form 124A/B – Final Report of Death</i>.</li> </ul>	1225 - Monthly	

**I.2 Outcomes Reports**

<u>Menu Path</u>	<u>#</u>	<u>Report</u>	<u>Required/Frequency</u>	<u>Menu Item</u>	<u>Report Description</u>
Reports/ Outcome Reports	0621	Outcomes Screening Action Required	Required/Weekly	Screening Actions Required	<p>Lists participants whose <i>Form 33 v.3</i> or <i>Form 33 v.4</i> contains incomplete or inconsistent information that must be clarified for WHILMA. You choose which participants to include on the report based on the <i>Form 33</i> encounter date.</p> <p>The report output includes the <i>Form 33</i> version, a “Study” field to show if the participant is CT or OS, and the possible outcomes from the <i>Form 33</i> (e.g., “heart”, “stroke”, etc.). Questions for which data is missing are described by codes, such as “ER” and “Tests”. Footnotes detail the exact question number that needs to be updated (based on the Form version). You can choose to apply a filter to the report.</p>
Reports/ Outcome Reports	0622	Members with Potential Outcomes	Required/Weekly	Potential Outcomes	<p>Lists participants for whom a <i>Form 33D - Medical History Update (Detail)</i> is required, based on <i>Form 33, v.3</i> or <i>Form 33, v.4</i> responses. This report is designed to be used as a “call list” for all participants needing a <i>Form 33D</i>. You choose which participants to include on the report based on the <i>Form 33</i> encounter date. Lists <i>Form 33s</i> that report an outcome, but are incomplete in some way (for example, a <i>Form 33</i> that reports a fracture, but is missing a response to the hospitalization).</p> <p>The report output includes the <i>Form 33</i> version, a “study” field to show if the participant is CT or OS and “condition” codes (detailed in footnotes). The participant’s hysterectomy status and the date of her most recent previous <i>Form 33</i> are also included on the report.</p>
Reports/ Outcome Report/ Outcome QA	0624	Errors in Applying Multiple Form 33s to a Single Form 33D	Required/Quarterly	Potential error for <i>Form 33</i> make-up <i>Form 33Ds</i>	<p>This report lists potential errors in using the new “<i>Form 33/33D Make-up Screen</i>”.</p> <p>For example – if a <i>Form 33D</i> is matched to a <i>Form 33</i> in the new screen, and later a <i>Form 33D</i> with the same visit type and year as the <i>Form 33</i> is entered in WHILMA.</p>
Reports/ Outcome Report/ Outcome QA	0625	Form 33 with Possible Matching Form 33D	Required/Quarterly	<i>Form 33s</i> with possible matching <i>Form 33D</i>	<p>Lists <i>Form 33s</i> that are missing a <i>Form 33D</i>, and also lists the <i>Form 33D</i> with the closest date after the date of the <i>Form 33</i>. <i>Form 33Ds</i> on this report must be reviewed to determine whether they actually apply to the <i>Form 33</i> listed.</p>

<u>Menu Path</u>	<u>#</u>	<u>Report</u>	<u>Required/Frequency</u>	<u>Menu Item</u>	<u>Report Description</u>
Reports/ Outcome Reports	0626	Outcome Forms that Require Verification	Required/Monthly	Forms Needing Verification	Lists outcome forms entered after November 19, 2002 that have not yet been verified. Exclude <i>Form 120 and 124A</i> from verification procedure.
Reports/ Outcome Reports	0978	Outcome Member Visit Details	As needed	Outcome <u>M</u> ember Visit Details	Lists for a specified member (and Visit ID, if desired), all reported conditions and the status of all requested documents.
Reports/ Outcome Reports	0980	Request for Medical Information	Recommended/After entering document request date for provider	Outcome <u>R</u> quest	The “cover sheet” that you print and include when requesting provider documentation. It includes your CC’s name and address, the provider’s name and address, the participant’s name and identifying information, and the names of all requested documents.
Reports/ Outcome Reports	0983	Forms to Pull by Outcome Analysis Batch	Recommended/After each batch, minimum weekly	<u>F</u> orms to Pull	For a given analysis batch, lists the analysis result for each encounter that requires follow-up, such as forms that yielded an INFO result by the analyzer, or forms in which conditions were identified.  The current Batch ID is automatically filled-in when you hot-key to the parameter screen for this report from the <i>Analysis Batch</i> or <i>Form Analyses</i> blocks.
Reports/ Outcome Reports	0984	Outcome Member Visit Details Requiring Requests	Recommended/As needed	<u>N</u> eed Requests	Lists all outstanding provider documents requested <i>n</i> or more days ago, but not received at your CC. (The default value for <i>n</i> is 21, but you may change this as needed.) You can run this report for all participants, or a particular member that you specify. You can choose to apply a filter to the report.
Reports/ Outcome Reports	0985	Outcome Conditions Requiring Providers	Required/Monthly	Need Providers	Lists all conditions reported at your CC that have not been linked with a provider visit. You can choose to list only a particular member and/or batch if desired. You can choose to apply a filter to the report. Note: a condition can only be linked to an “open” visit. Visits in a closed adjudication require CCC open case before condition/visit can be linked.
Reports/ Outcome Reports	0987	Member Visits Requiring Adjudication	Required/Monthly	Need <u>A</u> djudication	Lists all provider visits for which all information has been obtained, but have not yet been assigned to an adjudication case packet. You can choose to apply a filter to the report.
Outcomes/ Adjudication/ Run/IDS	0988	Investigation Documentation Summary	Required/When assign case to adjudicator		Contains specific information about the adjudication case packet documents and is completed by the Physician Adjudicator. Note: This report is run from the Outcomes subsystem not the Report system. Go to Outcomes, Adjudications and select IDS (Investigation Document Summary) from the Run menu.

<u>Menu Path</u>	<u>#</u>	<u>Report</u>	<u>Required/Frequency</u>	<u>Menu Item</u>	<u>Report Description</u>
Reports/ Outcome Reports	0992	Provider Details	Recommended/As Needed	Provider Details	Lists provider information, including contact name, address, and fax and phone numbers, for all providers whose information has been entered into your WHILMA database. Comments entered in the Provider Maintenance screen print out on this report.
Reports/ Outcome Reports	1001	Adjudication Rules	Recommended/As needed	Adjudication Rule	Confirmed outcomes of potential outcomes that need to be adjudicated for a particular participant. The OC determines which rules apply to a particular participant or group of participants. The conditions that need to be adjudicated for a participant may vary based on factors such as the study or studies to which she is randomized or enrolled. Assists local Adjudicator to determine which outcomes meet subsequent condition criteria. You can choose to apply a filter to the report.
Reports/ Outcome Reports	1002	Find Outcome Encounters	As Needed	Find Outcomes Encounter	Allows you to print information about outcome encounters and analysis batches that meet specified criteria.  Parameters for the report allow you to find all outcome encounters for a specified participant, all outcome encounters included in a specific batch, all analyzed forms with a specified analysis result (i.e., Y, N, or I), and any combination of the above criteria.
Reports/ Outcome Reports	1213	Outcomes Visits Requiring Requests Summary	Required/Weekly	Need Request Summary	Shows a summary of all provider visits for which there are documents outstanding. “Outstanding” is defined as a document that has not been requested, has been requested, but not received, or has been temporarily denied.
Reports/ Outcome Reports	1214	Outcome Questionnaire Responses	As Needed	Outcome Questions	Prints responses from a specified (by Member ID and adjudication number) Outcomes form. You can choose to apply a filter to the report.
Reports/ Outcome Reports	1215	Members Outcomes Status	Required/When assign case to adjudicator	Outcome Status	Lists all confirmed outcomes, outstanding conditions, and pending adjudications entered in your database, sorted by participant.  You can run this report for a particular participant or for all participants.  <u>Confirmed Outcomes</u> are those that have been confirmed by the adjudicator and closed. The report output lists the outcome type, diagnosis date, adjudication number, and closed date.

<u>Menu Path</u>	<u>#</u>	<u>Report</u>	<u>Required/Frequency</u>	<u>Menu Item</u>	<u>Report Description</u>
Reports/ Outcome Reports (cont.)	1215	Members Outcomes Status	Required/When assign case to adjudicator	<u>Outcome Status</u>	<p><u>Outstanding Conditions</u> are potential outcomes that have been detected by the analyzer. The report output lists the condition type, the provider visit to which the condition is attached (if any), the provider name, the admit date (where applicable) and the encounter date for the <i>Form 33</i>, <i>Form 33D</i>, or <i>Form 120</i> on which the condition was found.</p> <p><u>Pending Adjudications</u> are conditions that require adjudication, have been given an adjudication number and assigned to the adjudicator. The report lists the same information given for outstanding conditions, as well as the adjudication number, the adjudicator ID and the date the adjudication package was assigned.</p> <p>You can “hot-key” to the parameter screen for this report by selecting Member Status from the Run menu in the <i>Form Analyses</i> screen or the <i>Outcome Adjudication</i> screen. When you do, the Member ID of the currently-displayed participant is filled in as the report’s parameters. You can choose to apply a filter to the reports.</p>
Reports/ Outcome Reports	1222	Duplicate Outcomes	Required/Monthly	<u>Duplicate Outcomes</u>	Lists potential duplicate outcomes in adjudications closed within a specified time period. You can choose to apply a filter to the report. Confirmed duplicate report of outcomes remain on this report indefinitely.
Reports/ Outcome Reports	1225	Unresolved Death	Required/Monthly	<u>Unresolved Death</u>	Lists participants missing <i>Form 120</i> , the final date of death or cause of death from <i>Form 124A/B</i> or the Proxy <i>Form 33</i> or <i>33D</i> .
Reports/ Outcome Reports	1228	Adjudications by Adjudicator	Required/After assigning cases to adjudicator	Adjudication <u>By</u> Adjudicator	Lists, by adjudicator ID and name, the status of adjudications meeting specified criteria. You can run this report by adjudicator ID number; for all cases closed on or after a specified date; on Open or Closed adjudications or Both; Adjudications Sent to the CCC or Not sent to the CCC, or Both; and adjudications due within a specified date range. You can choose to apply a filter to the report.
<i>Run/Double Data Entry report while in the Verify Forms screen.</i>	1593	Verify Responses	Required/As Needed	Double data entry report	Lists all of the responses entered and verified on an outcomes form, and identifies discrepancies with a shaded line.

**I.3 Outcomes Study-Wide Reports**

<u>Menu Path</u>	<u>#</u>	<u>Report</u>	<u>Required/Frequency</u>	<u>Menu Item</u>	<u>Report Description</u>
Reports/ Outcome Reports/ Outcome study- wide data reports	0977	Outcomes Conditions	As Needed	<u>C</u> ondition Types	For each outcome of interest, lists the condition type and ID, a detailed description of the condition, the studies for which it is an outcome of interest, and the provider documents to request when this condition is associated with a participant.
Reports/ Outcome Reports/ Outcome study- wide data reports	0981	Outcomes Document Types	As Needed	<u>D</u> ocument Types	Lists all documents that might be requested from a provider with their ID, short name, and description.
Reports/ Outcome Reports/ Outcome study- wide data reports	1212	Questionnaire Responses	As Needed	Outcome Questionnaire	

**I.4 9000 Series Reports (Released September, 1998)**

The 9000 series reports (*WHIP9745-9750*) includes six separate reports developed by the CCC in 1998 in collaboration with the Data and Safety and Monitoring Board [DSMB].

The reports give Outcomes Coordinators a means to track *Form 33 - Medical History Update* and *Form 33D - Medical History Update (Detail)*, provider visits, and adjudication cases through the six steps of the outcomes process, as well as to monitor outcomes processing timeliness. The six steps are outlined as follows:

- Participants with a *Form 33 - Medical History Update* that requires completion of *Form 33D - Medical History Update (Detail)*
- Forms that requiring analysis in the WHILMA database
- Analyzed forms resulting in outcomes cases without medical records requested
- Outcomes cases with medical records requested but no response in the WHILMA database
- Outcomes cases with medical records response date in WHILMA database but not yet assigned to an adjudicator
- Outcomes cases assigned to an adjudicator but not yet closed in the WHILMA database

The CCC distributes the 9000 reports to CCs on a quarterly basis. The report packet includes two sets of reports, one set for Clinical Trial (CT) participants and a second set for Observational Study (OS) participants. Participant information is sorted by one of two processing priorities, with the priority alternating each quarter. Outcome Coordinators are to complete the priority cases listed on each report first. Priorities include;

- Primary endpoints (CT over OS, priority A over B cases). Reports sorted by primary endpoint are typically mailed to CCs in June and December
- *Form 33D - Medical History Update (Detail)* contact dates, with the OC processing and completing the oldest WHI cases by a CCC-established deadline date. Reports formatted by oldest WHI cases are typically mailed in March and September and correspond to DSMB review cycles.

**Summary of Outcomes Reports WHIP9745-9750**

WHIP #	Report Name and Description	CC Action
9745	<p><i>Completed Form 33s Without the Required Form 33D</i></p> <p>This report lists CT participants who have a <i>Form 33 v.3</i> or <i>33 v.4</i> entered in WHILMA on which the participant indicated a visit to a medical provider for hospitalization, cancer, fracture, hysterectomy or PTCA, but whom no corresponding <i>Form 33D</i> with the same visit type and visit year is entered into WHILMA. An asterisk (*) in front of the <i>Form 33</i> Date column indicates forms that CC received more than 15 days before the database date (the “data as of date”).</p>	<ul style="list-style-type: none"> <li>• Contact participants on the list and administer/obtain a <i>Form 33D</i> and a current medical release form. Process older forms (those with an * in the <i>Form 33</i> Date column) first.</li> <li>• Analyze and process the <i>Form 33Ds</i> in WHILMA as usual.</li> </ul>
9746	<p><i>Forms 33, 33D, and 120 Requiring WHILMA Analyzer</i></p> <p>This report lists <i>Form 33 v.1</i> and <i>v.2</i>, <i>Form 33D</i> (all versions) and <i>Form 120</i> (all versions) for which no condition/provider visit links exist in WHILMA. Only <i>Form 33 v.1</i> or <i>v.2</i> that contain a participant self-report are listed. Any forms with a current analyzer result of I (Info) and no condition/provider visit link are also listed. Forms with a most recent analyzer result of Y or N are not listed on the report.</p>	<ul style="list-style-type: none"> <li>• Enter the <i>Form 33</i>, <i>33D</i>, and <i>120</i> that appear on this list into an analyzer batch in WHILMA.</li> <li>• Run the analyzer program in WHILMA. You can analyze Priority A forms and Priority B forms together in the same batch.</li> <li>• Analyze the <i>Form 33 v.1</i> and <i>v.2</i> separately from <i>Form 33D</i> and <i>120</i>. (The analyzer program for the versions 1 and 2 of <i>Form 33</i> will be restored to the WHILMA menu for this purpose [WHEN]).</li> </ul>



WHIP #	Report Name and Description	CC Action
9747	<p><i>For WHILMA Analyzed Forms 33, 33D, and 120, Outcomes Cases Without Medical Records Requested.</i></p> <p>This report lists WHIMA analyzed form that contain at least one outcomes condition/provider visit link, but for which the CC has not requested medication records. The report shows the WHILMA ID number(s) of the provider visit(s) in question. (If the CC requested at least one medical record for a provider visit(s), the provider visit will not appear on this list.)</p>	<ul style="list-style-type: none"> <li>Enter the medical record request dates for the provider visits reported on the form into the Provider Visit screen in WHILMA.</li> <li>Print a document request report (WHIP0980) for each provider visit and send it to the provider (or follow your usual procedure for requesting documents).</li> <li>Process Priority A forms before Priority B forms.</li> </ul>
9748	<p><i>Outcomes Cases With Medical Records Requested But No Response Dates Entered in WHILMA.</i></p> <p>This report lists outcomes forms that have provider visits linked to outcomes conditions and have at least one medical record requested for the visit, but no “received” dates entered into WHILMA. In addition to the form contact date and visit type (e.g. AV1), the report also shows the ID number of the provider visit, the dates the CC requested the medical record(s), and the self-report information from the <i>Form 33D</i>.</p>	<ul style="list-style-type: none"> <li>Follow up with the provider to obtain the missing medical records.</li> <li>Enter a receive date in WHIMA when you obtain the documents.</li> <li>Within Priority A and B forms, focus first on those items marked with an asterisk (*).</li> </ul>
9749	<p><i>Outcomes Cases With Medical Records Response Date Not Yet Assigned to an Adjudicator.</i></p> <p>This report lists forms that have a condition linked to a provider visit for which document response dates have been entered, but the provider visit is not yet assigned to an adjudicator. The provider visit will appear on the report if it has at least one document with a response or “received” date in WHILMA.</p>	<ul style="list-style-type: none"> <li>Determine if the document set is complete enough for adjudication to proceed.</li> <li>If so, put the visit into an adjudication case in WHILMA (if necessary) and assign the case to an adjudicator.</li> <li>If not, contact the provider and obtain the missing documents.</li> </ul>
9750	<p><i>Outcomes Cases Assigned to Adjudicator Not Yet Closed in WHILMA.</i></p> <p>This report lists provider visits that are in adjudication cases that have an assigned date, but that are not yet closed in WHILMA. The report shows both the <i>Form 33D/Form 120</i> information as well as the WHILMA-assigned provider visit ID number(s) and self-report information.</p>	<ul style="list-style-type: none"> <li>Confirm that the case packet has been sent to the adjudicator.</li> <li>Follow up with adjudicator to expedite completion of the case.</li> <li>Enter the outcomes information in WHILMA and close the case.</li> </ul>

- If you feel that you have adequately dealt with an item that appears on one of these reports, then you should close it out with the appropriate closure reason code.
- For any item on the reports that you are unable to close after six months from the date of the form (*Form 33, 33D, or 120*) was received at the CC, document the steps you have taken to process the form, visit or case along with the reason that you are unable to close it, and send the documentation to your CCC Outcomes Liaison.

## I.5 DSMB Reports

The Data and Safety Monitoring Board (DSMB) is an independent board that monitors study progress and intervention safety. The purpose of the DSMB clean-up reports is to provide the most accurate data to the DSMB. The reports are generated from the consolidated data at the CCC and distributed to the clinics via email in December and June. For CT participants, a clean-up deadline is provided and corresponds to a semi-annual data base freeze. (Note OS data clean up is not deadline driven.)

The reports are numbered in priority order and include both CT and OS participants. Instructions for each report are included, although it is very unlikely you will have participants listed on all reports. Please prioritize CT participants over OS, with the goal of having CT data clean-up completed by the database freeze date.

To open and close a case for clean-up:

- The CCC will automatically open CT cases as needed.
- OS cases are not automatically opened, but will be opened upon CC request. Please contact your CCC DC liaison to request an OS case be opened.
- See individual instructions for details on how to re-close a case once you have made corrections.

### 1. Missing death date

- Review *Form 120*:

If the date of death is known, record on *Form 120* and key-enter response.

- Review *Form 124*:

If the date of death is recorded on *Form 124*, key-enter response, and close case with original close date.

If the date of death is blank, forward to your Physician Adjudicator (PA) for date of death confirmation.

Key-enter response, and close case with original close date.

### 2. Missing outcome form date

- Review *Outcomes Form (Forms 120-131)*:

If the date of diagnosis is recorded on form, key-enter the date of diagnosis and close case with original close date.

If the date of diagnosis is missing, forward case to PA for review and confirmation of date of diagnosis.

Key-enter response, and close case with original close date.

### 3. Form 124 with missing "Subclassification of Underlying Cause of Death"

- Review "Subclassification of Underlying Cause of Death" on *Form 124*:
  - If underlying cause of death subclassification is recorded, key-enter response and close case with original close date.
  - If underlying cause of death subclassification is blank, forward case to Physician Adjudicator (PA) for adjudication of death subclassification.
  - Key-enter response, and close case with original close date.
- It is possible a participant with a preliminary report of death (*Form 124, Ver. 3*) is legitimately listed without the death subclassification because it is still under investigation. If this occurs, email the CCC with status of the case.

**4. Completed outcomes form with no related outcome**

Examples include:

- An outcome form has all "no" responses. (See instructions under "A" below.)
- *Form 122* is missing the primary cancer site or other cancer site. (See instructions under "B & C" below.)
- *Form 123* is missing the fracture site. (See instructions under "B & C" below.)

**A) An outcome form has all "no" responses:**

- Review the report with a hard copy of the outcomes form. Verify that the data items are all "no" responses.
  - If the data item "no" is incorrect and a "yes" response should have been marked and/or data entered, edit the hard copy of the completed outcomes form and key-enter the correction, or correct the data entry error.
  - Close the case with the original close date.
- It is possible all responses documented on the form are "no".
  - After verifying all responses are "no", delete the relevant outcome form from the data base.
  - Close the case with the original close date.

**B & C) Form completed but is missing one required field that indicates the outcome type (e.g., fracture site, primary cancer site):**

- Review form and data enter the missing response.
  - Close case with the original close date.

**5. Diagnosis dates before randomization/enrollment**

- Confirm outcome occurred before participant's randomization or enrollment date.
- Do not edit the completed outcomes form. Archive the hard copy in outcomes file.
- Delete the corresponding outcome form in WHILMA, and close case with code "3 – Not adjudicated, documents not required". (If hospitalization date occurred after randomization/enrollment, do not delete *Form 125 – Summary of Hospitalization Diagnosis*.)
- Close the case with the original close date.

**6. Participant with outcome diagnosis date later than the Form 33/33D or 120 date**

- Confirm the date of diagnosis on the completed outcomes form.
- The date of diagnosis should not be later than *Form 33/33D* or *120* encounter date (this is usually due to a data entry error). There are situations where a diagnosis date greater than that on *Form 33/33D* would be appropriate. Contact your CCC liaison if you have any questions.
- Correct the date on the hard copy of the outcomes form (draw a single line through the correction, initial, and date the edit).
- Enter the correction in WHILMA.
- Close the case with the original close date.

**I.6 Outcome Summary Reports**

<u>Menu Path</u>	<u>#</u>	<u>Report</u>	<u>Required/Frequency</u>	<u>Menu Item</u>	<u>Report Description</u>
Reports/Outcome Report/Outcome Summary Reports	1258	Outcomes Analysis Investigation	Recommended/Quarterly	Outcomes <u>A</u> nalysis Investigation	Shows number of outcomes forms to be analyzed and status of the outcomes investigation.  Two recommended report options: <ul style="list-style-type: none"> <li>• Last 12 months</li> <li>• Cumulative</li> </ul>
Reports/Outcome Report/Outcome Summary Reports	1263	Timeliness of Case Packet Assembly and Local Adjudication	Recommended/Quarterly	<u>T</u> imeliness of Outcome Packet by Assembly	Shows number of cases created and timeliness of packet assembly and local adjudication.  Two recommended report options: <ul style="list-style-type: none"> <li>• Last 12 months</li> <li>• Cumulative</li> </ul>
Reports/Outcome Report/Outcome Summary Reports	1264	Timeliness of Outstanding Outcomes Case Packet Assembly and Local Adjudication	Recommended/Quarterly	Timeliness of <u>L</u> ocal Adjudications	Shows number of cases not yet closed and timeliness of packet assembly and local adjudication.  Two recommended report options: <ul style="list-style-type: none"> <li>• Last 12 months</li> <li>• Cumulative</li> </ul>
Reports/Outcome Report/Outcome Summary Reports	2030	Timeliness of Outcomes Processing	Recommended/Quarterly	Timeliness of Outcomes Processing	Shows the number of adjudication cases that are still open at <16 weeks, at 17-26 weeks, and at >26 weeks based upon the <i>Form 33D</i> contact date.  Two recommended report options: <ul style="list-style-type: none"> <li>• Last 12 months</li> <li>• Cumulative</li> </ul>

**APPENDIX I**  
**OUTCOMES REPORTS**  
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