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Section 5

DATA MONITORING

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INTRODUCTION

Monitoring data is done by both the Clinical Coordinating Center (CCC) and Clinical Centers (CCs) to monitor CC performance on a wide variety of activities from meeting goals in recruitment, adherence and retention to appraising the quality of data collected. The primary method used to monitor data quality is the production and review of general and specific reports. The type, frequency, and detail of these monitoring reports and other activities is largely dictated by the priorities as outlined in *Section 1.1 - QA Focus and Priorities*, with more attention given to items with higher priority.

Due to the size and complexity of the Women's Health Initiative (WHI), monitoring the quality of WHI study data can generate a large number of reports. Both the CCC and CCs can generate a variety of reports to monitor individual performance and to help identify issues and procedures that need review. The frequency of generating the reports is determined by balancing the CC's need for prompt and frequent monitoring with the available resources to produce such reports.

This section includes:

- A summary of CCC and CC activities to monitor:

    - Study progress in recruitment, adherence, and retention

    - Completeness of WHI specified tasks and associated data collection

    - Validity, or accuracy, of the data collected

    - Timeliness of data collection

    - Reliability of data collection

- A schedule of reports to be run at the CCs

5.1   Database Reports

To provide prompt feedback, CCs have the ability to produce many specific monitoring reports from their own database. Using these CC-produced reports, CCs can evaluate many aspects of their operations, compare their performance to study wide goals (as shown in *Section 6.1 - Performance Goals)*, identify issues and procedures that need review, and monitor individual staff performance. The reports also allow the CCs to take corrective action without needing to wait for monthly reports from the CCC. *Vol. 5 - Data System*, *Appendix D - WHILMA Reports* provides a list of reports CCs can run, giving the report name and number and a description of the report. The report menus in WHILMA are organized by report topic and provide a complete list of reports available at the CCs.

On a regular basis, the CCC prepares the monitoring reports described below from the quarterly consolidated database. These reports show quarterly and cumulative data by CC, allowing comparisons among CCs. The CCC distributes these reports to the Project Office, Contract Office, CC Principal Investigators (PIs), and CCC subcontractors (see *Table 5.1 -Distribution of Routine CCC Reports*). Using the CCC reports, CCs can compare their performance to that of other CCs. Clinical Centers with good performance are encouraged to share their strategies for achieving this with other CCs on their routine staff group conference calls. Clinical Centers performing below the performance goals are encouraged to discuss strategies for improving their performance with other CCs and with the CCC.

Appendix D - CC and CCC Reports includes all the reports available to the CCs in WHILMA and from the CCC (as of March 1997). Included is a list of routine CCC activity reports and a list of CCC subcontractor reports. Both lists give the report number, name, and a short description of intended use. A third list combining all WHILMA reports and CCC reports is included, sorted by WHIP number and by topic. The PMC report is also included in the listing when the PMC report is the only current source for the data. This list is also available in electronic format (see *Section 2.3 Electronic Files*).

5.1.1   Quarterly Activity Reports

The CCC prepares a set of quarterly reports showing data for activities such as, follow-up, adherence and retention, and outcomes. The reports are prepared from the quarterly consolidated database and show quarterly and cumulative data by CC, allowing comparisons between CCs.

Examples of currently distributed quarterly reports include:

- DM Intervention performance

- Retention and follow-up status for all components

- Outcomes processing

- Subcontractor data including ECG, blood and urine collection and processing, and bone densitometry collection and processing

Quarterly consolidation of CC data occurs at the end of February, May, August, and November. The CCC runs and distributes the reports in the weekly mailings to the CCs as soon as they are available, generally 3-6 weeks after consolidations.

The set of reports included each quarter changes as the study proceeds, with new reports added as new stages in the study occur, and other reports are dropped as activities stop (e.g., recruitment). The production of selected reports may be reduced to a semi-annual basis as activities stabilize and require less frequent monitoring. See *Appendix D.1 – CCC Routine Activity Reports* and *D.2 – CCC Subcontractor Reports* for a list of reports as of June 1998.

5.1.2   Performance Monitoring Committee (PMC) Quarterly Report Packet:

The CCC prepares the PMC Summary Report packet each quarter, with the schedule corresponding to the DSMB and Annual Progress report schedule (*Section 5.1.3 – Data and Safety Monitoring Board [DSMB] Report*). The CCC and PMC use the report to monitor CC performance. The tables in the report summarize some data from the quarterly activity reports as well as provide additional data on adherence. Footnotes on each table indicate the routine reports used to create the summary tables. Topics covered in the report are:

- DM C-I

- HRT and CaD pill collection, adherence and retention

- OS Year 3 Visit Completeness

- Outcomes processing

- Task completeness for all required tasks

Within each table, the performance of each clinic is detailed for key activities related to the listed category. Tables also includes a percent of goal over a previous time period to allow easy monitoring of trends within each clinic.

The CCC distributes a hard copy of the PMC report to the Project Office, the PMC, and CC Principal Investigators (PIs) and Clinic Managers. The report is included in the semi-annual DSMB report, the Annual Progress Report, and in Public Folders.

5.1.3   Data and Safety Monitoring Board (DSMB) Report

The CCC produces the DSMB Report every six months from the August 31st and Feb. 28th consolidated databases. It includes all the information in the Annual Progress Report and also displays data by treatment assignment. As a result, it is a confidential report that the CCC distributes only to the DSMB. The DSMB uses this report to monitor study progress and make decisions about continuing or stopping the study.

5.1.4   Semi-Annual Progress Report

The CCC produces a Semi-Annual Progress Report from the consolidated database on February 28th and August 31st. The report summarizes study progress in all areas to date, including details of enrollment; participant baseline characteristics; follow-up and retention; HRT, DM, and CaD interventions; outcomes; and clinic performance monitoring. Many of the reports included in the Annual Progress Report are the same as the quarterly activity reports and other reports the CCC routinely circulates to the CCs.

5.1.5   Periodic Monitoring

The CCC monitors various activities on a periodic basis and provides reports of these activities to the Steering Committee for review. These include:

- Outcome event rates: The CCC plans to provide comparisons of outcome event rates to external sources of event reports (e.g., HCFA, NDI, SEER registry tapes).

Table 5.1
Distribution of Routine CCC Reports

Reports	Project Office	DSMB	CC PIs	CM	Lead Staff	CCC Subcon-tractors*	Frequency	Distributed as
Activity Reports	X		X	X		X	quarterly	hard copy or electronic copy (if available)
PMC Summary Report	X		X	X	X		quarterly	hard copy and electronic copy
DSMB Report	X	X					twice per year	hard copy
Semi-Annual Report	X	X	X			X	Twice per year	hard copy

* CCC Subcontractors include EPICARE (for ECGs), McKesson BioServices (for blood and urine aliquots and all study medications), Bone Density Center at UCSF, Univ. of Minn., and Univ. of Washington.

5.2 **Completeness of Data Collection**

Monitoring completeness of data collection is done on two levels:

- Monitoring that contacts and specific tasks are completed at designated times

- Monitoring missing data associated with specific tasks

Table 5.2 - A. CC Schedule for Data Monitoring - Required summarizes the schedule and data monitoring activities CCs are required to perform. The table lists the activity, report number, action to take, and the frequency of the activity. Clinical Centers may perform the activity more frequently. *Table 5.2 - B. CC Schedule for Data Monitoring - Recommended* gives a schedule for running and reviewing other recommended CC reports.

5.2.1 **Conducting Tasks at Designated Times**

Clinical Centers (CCs) are responsible for ensuring they conduct contacts with participants at specified times. Due to the complexity and size of WHI and to conserve study resources, some tasks are performed at a limited number of visits and/or on a subsample of participants. (See *Vol. 1, Appendix A.1-1 - Participant Contact Schedule* for the schedule of routine contacts and tasks.) While the schedule of contacts reduces the overall data collection burden, it increases the complexity of data collection at the CCs and increases the importance of careful tracking by CCs.

To facilitate the scheduling of appropriate contacts and tasks, WHILMA provides various task reminder and completeness reports. *Section 6.1 - Performance* Goals gives specific goals for completion of both CT and OS contacts.

5.2.1.1 **Task Reminders**

Task reminder reports list participants due to complete a specific task within a date range and/or for a specific visit and year, including reports listing participants selected to be in different subsamples. A Visit Plan report lists tasks to be completed for a specific participant at a specific visit. Clinical Centers are encouraged to run and use the reports on a regular basis to help ensure contacts are made as needed, and to perform the appropriate tasks at the contacts.

5.2.1.2 **Task Completeness**

To help identify tasks that have not been completed when due, reports for overdue contacts are available for many different contacts and tasks. Clinical Centers are encouraged to run these reports on a regular basis to identify tasks that still need to be completed.

Note that tasks will be included on the overdue reports only if they were completed and data entered. Tasks may be included in the overdue reports if there is a delay in data entry. A delay in data entry may be due to normal processing time or to filing the form in the participant file before data entry is done.

Task completeness reports list participants who are missing one or more tasks for a specific contact and include summary reports indicating the percentage of participants who have completed all tasks. Clinical Centers are encouraged to use these reports regularly to help identify the following types of problems:

- Particular tasks that were omitted on specific participants

- Consistent omissions in performing procedures due to misunderstandings of when the procedures need to be completed (e.g., mammogram every year for HRT participants and every other year for DM participants)

- Forms that have not yet been data entered

5.2.2   Missing Data

Clinical Centers are responsible for collecting all data associated with contacts and tasks. These responsibilities include completing data collection forms, submitting data and specimens (e.g., ECG readings, blood and urine samples, and bone density scans) to the appropriate subcontractors, and completing corresponding data entry.

5.2.2.1   Form Completion and Review (Required)

Clinical Center staff are responsible for completing all applicable items on clinic-administered forms. Instructions for completing forms are located in other sections of the WHI Manuals:

- *Vol. 3 - Forms* includes all WHI forms and instructions for completing all non-outcome forms and *Vol. 8, Appendix A - Outcomes Forms and Instructions* includes all outcomes forms and instructions.

- *Vol. 2, Section 18.2 - Data Collection* includes general instructions for completing forms, including how to record "unknown" responses on both key-entered and mark-sense forms.

Clinical Center staff are also responsible for reviewing participant self-administered forms for completeness by briefly reviewing the forms to assure the participant has not skipped entire pages. No other review of the self-administered forms is required. For example, CCs do not need to review each question on the form for completion, skip patterns, and consistency of responses between questions and other forms. Specific procedures for review of the Food Frequency Questionnaire (FFQ) and Four-Day Food Record (4DFR) are described in their corresponding form instructions and *Vol. 2, Section 6.1.6 - DM Eligibility, 10.1 - The Four-Day Food Record,* and *10.2 - The FFQ.*

CCs are required to run and use the following report checklist:

- *Encounters without Data* (*WHIP 0794*): Use this report to identify forms that need data entry.

CCs are encouraged to use other reports as needed.

5.2.2.2   Medications, Data, and Specimens Sent to and from Subcontractors (Required)

- Medications

  CCs are responsible for maintaining medication inventory, selection, and adherence records for all HRT and CaD medication bottles received from McKesson. CCs are required to run and use the following report:

  - *Drug Inventory* (*WHIP 32*): Use the report to compare the CC HRT and CaD inventory with the records in WHILMA. Follow-up on any discrepancies using the procedures described in *Vol. 2, Section 15.3 - Study Pill Inventory Maintenance.*

- ECGs, Blood and Urine, and Bone Density Data

  The CCC prepares monthly CC-specific reports for data and samples that CCs routinely send to subcontractors. These reports include data on ECG data sent to EPICARE; frozen blood and urine specimens sent to the central repository at McKesson; and bone densitometry results sent to the Bone Density Center at UCSF. The CCC, CCs, and subcontractors use these reports monitor and track the collection and submission of data and specimens. *Appendix D.2 - CCC Subcontractor Reports* lists the ECG reports, giving the report WHIP number, the report name, description of the report, and how to use the reports and actions to take.

EPICARE and the Bone Density Center at UCSF are responsible for reviewing the reports in their respective areas and recommending or implementing corrective action as needed. Problems identified by these two centers are communicated to the CCs and CCC directly for correction.

- ECG Data

    Clinical Centers perform ECGs on participants, submit the data electronically to EPICARE using features in the ECG machine (MAC-PC), and complete *Form 86 - ECG* for each ECG sent to EPICARE. EPICARE processes the ECG data and sends the data to the CCC electronically. The CCC provides both the CCs and EPICARE with summary and detail ECG reports using data received from both the CCs and EPICARE.

    The CCC sends copies of the two summary reports (*WHIP 1021* and *WHIP 1022*) showing the matching rates for VCCs and NCCs by CC to all CCs. The two detail reports (*WHIP 921* and *WHIP 922*) list the details of the unmatched data for each CC, and these reports are sent to the respective CCs. CCs can use these reports to identify mismatches and investigate the reasons for mismatched data as described in *Appendix D.2 - CCC Subcontractor Reports*.

- Blood and Urine Specimens

    Clinical Centers collect blood and urine specimens on participants, process the specimens into aliquots, and ship the specimens to the central repository at McKesson at least once each month as described in *Vol. 2, Section 11 - Blood Collection, Processing, and Shipment*. Clinical Centers document the collection and processing of the specimens on *Form 100 - Blood Collection and Processing* and *Form 101 - Urine Collection and Processing.* EPICARE records the receipt of the aliquots, stores the aliquots, and sends corresponding storage data to the CCC.

    The CCC provides both the CCs and EPICARE with summary and detail blood and urine tracking reports. Two summary reports (*WHIP 1041* and *WHIP 1042* for blood specimens and *WHIP 1047* and *WHIP 922* for urine specimens) showing the matching rates for VCCs and NCCs by CC to all CCs. The two detail CC-specific reports (*WHIP 0941* and *WHIP 0942*) list the details of the unmatched data for each CC are sent to the respective CCs. CCs can use these reports to identify mismatches and investigate reasons for the mismatched data as described in *Appendix D.2 - CCC Subcontractor Reports.*

- Bone Density Scans

    The three Bone Density CCs perform bone densitometry scans on participants, submit the data electronically to the Bone Density Center at the University of California at San Francisco (UCSF), and complete *Form 87 - Bone Density* for each participant. University of California at San Francisco processes the bone density data and sends the data to the CCC. The CCC provides both the CCs and the Bone Density Center with summary and detail reports using data received from both the CCs and UCSF.

    The CCC sends copies of two summary reports (*WHIP 1057* and *WHIP 1052)* showing the matching rates for VCCs and NCCs by CC to all Bone Density sites. The two detail reports (*WHIP 951* and *WHIP 952*) list the details of the unmatched data for each CC, and these reports are sent to the respective CCs. Clinical Centers can use these reports to investigate reasons for nonmatches as described in *Appendix D.2 - CCC Subcontractor Reports*.

5.2.2.3   Data Loss

The CCC provides daily back-up of all CC data to protect each CC from data loss as a result of a CC file server failure. This backup frees the CCs from this responsibility and ensures that a full back-up is done on a regular basis. Note that only files on the file server are backed-up by the CCC. Clinical Centers are required to back-up any files they choose to store on workstation hard drives.

If a file server failure occurs resulting in data loss:

- The CCC will restore the CCs data from the time of the last back-up.

  To prevent possible loss of randomization data, CCs are required to record all randomization's/enrollments on *Form 8 - Randomization Log* as they are completed. The CCC uses this log to reconstruct the randomization in the database if a failure of a CC file server causes the loss of randomization data.

- The CC is responsible for the data entry of any data entered from forms into WHILMA since the last back-up. The CCC will work with the CC to re-enter any medication dispensing data lost.

5.3   Validity of Data

Table 5.2 - CC Schedule for Data Monitoring summarizes the reports that CCs are required to run. The table lists the report name, report number, action to take, and the frequency of the activity. Clinical Centers may run the report more frequently. It also gives a schedule for running and reviewing other recommended CC reports.

5.3.1   Form Features

Assuring accuracy of data collection begins with good forms design. Well-designed forms can help prevent errors in data collection such as marking the form incorrectly or not following instructions correctly. These types of errors are difficult to find and costly and time consuming to correct. WHI forms use many features to reduce data collection errors. Clinical Centers are encouraged to adapt similar guidelines in developing participant materials (see also *Vol. 2*, *Section 3.1.6 - Participant Material Review Recommendations and Guidelines).*

When time allows, CCs are asked to pilot-test newly developed self-administered forms on age-eligible women. New forms are monitored for problems and minor changes are made if needed at the time of WHILMA upgrades. The Steering Committee approves all major form changes before implementation.

In general, changes in forms are scheduled to occur with the WHILMA upgrade scheduled for each November. All changes in forms are documented with a change in the form version number and date. For major form changes, the form number increases by a whole number (e.g., from 1 to 2) and for minor changes, the form version number increases in decimal increments (e.g., from 1.0 to 1.1). Note that in WHILMA, forms are identified by whole number only, for example, "1.1" is entered as "1".

5.3.2   Duplication

Duplicate data collection is completed for specific data items to help ensure their accuracy and consistency. The following duplicate measures are collected:

•   Duplicate blood pressure measurements

•   Duplicate functional measures: hand grip dynamometer, chair stand, and timed-walk

•   Duplicate measures of bone densitometry showing high bone loss

•   Review of the abstracting of lab reports for mammogram, Pap smear, endometrial aspiration and transvaginal uterine ultrasound results onto corresponding data entry forms during QA Visit participant file audit

•   Blind duplicate measures of selected blood analysis

•   Comparisons between local and central diagnosis of centrally adjudicated events and comparisons with internal data sources (e.g., mammography, Pap smear, endometrial aspiration, ECG, new medications)

5.3.3   Data Entry

Various features are built into WHILMA to help ensure the entered data are valid. See *Table 5.4 - WHILMA Data Entry Features* for a list of these features. These checks serve to prevent the data entry errors made by data entry staff and also to catch errors made by staff recording incorrect data on the forms. Key-entry staff can make corrections to key-entry errors at the time of key-entry. If there is an error in how the data is recorded on the form, data entry staff must return the form to the appropriate CC staff person completing the form for review and correction. (See *Vol. 2, Section 18.2.4 - Editing Forms* for procedures for making corrections to forms.)

CCs are required to run and use the following reports to identify existing data entry errors and inconsistencies in existing WHILMA data.

- *Encounters without data (WHIP0749)*: Use this report to identify encounters without data. Key-enter the data as needed or delete encounters with no data.

- *Duplicate encounters (WHIP1949)*: Use this report to identify encounters that are entered more than once. Duplicate data entry may occur when the data entry staff are interrupted during key-entry of forms. To avoid duplicate data entry, review key-entry procedures with data entry staff and establish procedures for ensuring forms are not key-entered more than once. For example, indicate on the form when only the encounter data has been key-entered and when the entire form has been key-entered.

5.3.4   Data Verification

Verification of data entry is periodically performed by the CCC, and the CCC may request the CC to verify selected participant forms. Clinical Coordinating Center Data Coordinator staff performed data entry verification on selected forms as part of the participant file audit for the initial QA Visits to CCs. Verification may be performed on subsequent file audits on a selected basis for annual QA visits. After verification, a detailed discrepancy report is produced for the QA Visit report and includes a list of the following types of discrepancies:

- A form in the participant file is not key-entered into WHILMA

- Data in WHILMA are not documented on the participant forms

- Data in WHILMA do not match data recorded on the form

5.3.5   Data Cross Checks

Inconsistencies in data are monitored for the following areas. CCs are required to investigate and correct the inconsistencies in these data.

- Baseline and Follow-up Hysterectomy Status in HRT Participants

    Data related to a participant's hysterectomy status may be collected on several different baseline forms. The eligibility determination in WHILMA compares these data items for consistency. If a discrepancy is found, the eligibility determination in WHILMA returns a result of INFO to indicate that there is a discrepancy and indicates the problem data items. The CC must resolve the discrepancy and key-enter changes into WHILMA before the participant can be randomized/enrolled.

- Medication Dispensing

    A participant's current hysterectomy status is monitored during each HRT medication selection. WHILMA will give a warning message on the screen during HRT medication dispensation if the participant's hysterectomy status and medication assignment are inconsistent. CCs are required to investigate these inconsistencies, to ensure the message is valid (i.e., is appearing because the participant has had a hysterectomy and not because a form indicating this has been incorrectly entered in WHILMA). If the message is appearing due to a key-entered error, make appropriate corrections in the database. If the message is appearing because the participant has, in fact, had a hysterectomy, contact the CCC for resolution.

5.3.6   Data Corrections

Investigating and correcting data errors can be time consuming and difficult. The large number of data items in WHI makes it impractical to identify and correct all possible data errors. Many of the steps described above, particularly the data entry features in WHILMA, were developed to reduce the chance of data errors at the point of data entry.

CC activities for identifying data errors include:

- Review forms before data entry (see *Section 5.2.2.1 – Form Completion and Review*).

- Identify data problems at the time of data entry by responding to error messages in WHILMA

- Review various reports to identify problem areas and review the issues with CC staff to help prevent future errors. For example, recording incorrect visit type and/or dates can lead to inaccurate reporting of timeliness and completeness of data collection.

CC activities for monitoring appropriate data corrections includes:

- Follow standard procedures for documenting data corrections. (See *Vol. 2*, *Section 18.2.4 – Editing Forms.)*

- Review forms for correct documentation of data corrections, as part of the participant file audit performed with QA Visits. (See *Section 4.3.3 – Participant File Audit*.)

Data requiring regular review and corrections have been identified based on study priorities, and include:

- Discrepancies between the date the participant signed the informed consent forms and the date recorded on *Form 11 – Consent Status* (including *Forms 11, 12, 13, 14,* and *15*) and data entered into WHILMA. Correct the *Form 11*. You do not need to correct *Forms 11-14* in WHILMA. However, you should correct Form 15 – CaD Consent in WHILMA if it is incorrect.

- Discrepancies in data on an HRT participant's hysterectomy status. Correct any discrepancies to ensure participants receive the appropriate HRT study medication based on current hysterectomy status. Correct any data discrepancies in hysterectomy status on the appropriate form and in WHILMA. Discrepancies may occur on the following forms:
    - *Form 2/3 - Eligibility Screen*
    - *Form 10 - HRT Management and Safety Interview*
    - *Form 33D - Medical History Update (Detail)*
    - *Form 81 - Pelvic Exam*
    - *Form 82 - Endometrial Aspiration*
    - *Form 131 - Report of Hysterectomy (HRT)*
- Discrepancies between an HRT participant's hysterectomy status and her medication assignment

- Errors in transcription of test and lab results found during participant file audits

- Incorrect or incomplete participant addresses or names

5.3.7   Quality of Data Collection

The CCC provides the following reports to monitor the quality of several procedures for which performance goals are defined in *Section 6.1 - Performance Goals*. If the performance at your CC is below the performance goals, review procedures to help identify ways to improve performance.

- ECG quality grades *(WHIP 1023)* included in the set of the CCC quarterly subcontractor reports.\

- PMC Report (Quarterly packet)

5.3.8   Measurement Reliability

The Observational Study Measurement Precision Study (OS-MPS) was designed to test the reliability of certain measures, including selected self-administered baseline forms and blood analysis. See *Vol. 2, Section 8.4* for details.

5.4   Timeliness

Timely collection of data and data entry are necessary for good data monitoring and facilitates data analyses. Collection of data at follow-up contacts within the specified window and timely processing of data, such as outcomes processing and data entry facilitates prompt review and evaluation of the data. The following types of data are monitored for timeliness and completeness:

- Follow-up contacts performed in the appropriate time window (see *Vol. 2, Section 16, Table 16.1 – Time Limits for Collection Tasks*).

- Data entered into the database within 2 weeks of data collection.

- Timeliness of various outcomes processes, including collection of *Form 33 - Medical History Update* and *Form 33D - Medical History Update - Detail* in window, assembly of outcomes packets and assignment to local adjudicator, local adjudication, and total time to close out a case.

Table 5.2

A. CC Schedule for Data Monitoring - Required

WHIP #	Report Name	How often	How to use/Comments
	Required		
33	Medication Inventory Activity	Quarterly	Use to confirm that HRT (including open-label) and CaD dispensations are being entered correctly in WHILMA.
			Compare report with actual bottles in medication cartons. Verify that bottles listed as dispensed are not in cartons and bottles missing from carton are listed as dispensed on the report. See *Vol. 2, Section 15 - Study Pill Inventory Maintenance* for directions for making corrections.
101	Participants Requiring Follow-up for Management, Change of Medications or Adherence	Monthly	Use to identify participants who need re-contact as recorded on *Form 10 – HRT Safety Interview*, *Form 17 – CaD Safety Interview*, *Form 24 – Adherence and Retention Worksheet*, and *Form 54 – Change of Medications*.
144	Tasks Required at Visit	As needed before F/U visits	To identify the tasks that need to be completed for a participant at a given follow-up visit. Can be used as a visit checklist.
			This report can be run in batch mode (instead of individually by participant) using the WHILMA batch reporting feature. Note: *The Follow-up Visit Information Report (WHIP0148)* can be used instead of *WHIP0144*.
230	Outstanding HRT/CaD bottles	Monthly	Remind participant to return bottles
405	DM Intervention Year Summary	Quarterly	Use to monitor session participantion based on length of time in the intervention.
419	DM Session Adherence Summary Report	Quarterly	Use to track overall DM intervention progress for all groups combined. Compare to study-wide data reflected in Quarterly Activity Reports from the CCC.
427	Session Attendance and Make-up Activities	Quarterly	Use to monitor overall DM intervention progress for each DM intervention group. Alternatively, the LN may run the Overall Progress reports for Group Attendance (426), Session Completion (421), Home Activity Completed (422) and Fat, Fruit/Veg, Grain Scores (423).
432	Unassigned DM members	Quarterly	Use to confirm that participants are not removed from groups after having started intervention. There should be no participants listed in the "Currently Unassigned - Have Previously Started" section.
436	Group Session Performance	Year 1: after sessions 8,12, 16 Years 2+: every 6 months	Use to ensure thorough and accurate DM Intervention data collection and key-entry: • Track makeup completion • Track score collection • Verify accuracy of key-entry. [Note: Strongly recommended that this report be run after every session]

Table 5.2

A. CC Schedule for Data Monitoring – Required (Continued)

WHIP #	Report Name	How often	How to use/Comments
	Required		
444	IIP Triage & Tracking	Quarterly	• Use to track participation in DM intervention activities (attendance, completion, self-monitoring) • Use to identify and track participants having Interrupted DM Intervention Participation (Level 4). • Use to identify and track inactive DM Intervention participants, e.g., stopped DM Intervetntion, stopped follow-up (no follow-up and absolutely no follow-up), lost to follow-up, and deceased.
476	Mammograms Requiring 6-Month Follow-up	Monthly	To identify participants for whom a 6-month follow-up mammogram is needed. Required for participant safety.
611	Members with Incomplete Address or Long Name/Address	Quarterly	To identify addresses that are incomplete or too long to fit on a mailing label. Review and correct addresses as necessary, giving priority to randomized/enrolled participants. Note that there are two lines for street address -- please use both lines for long addresses.
618	Tasks Not Completed at Member Follow-up Visit	Monthly	To identify tasks that were not done for participants at a specified follow-up visit due during a specified period of time, or that were done out of window. This report can be run in batch mode (instead of individually by participant) using the WHILMA query batch reporting feature. Use expanded windows.
621	Members with Outcome screening Actions required	Monthly	Use to identify *Form 33*s that are incomplete or have inconsistent information.
622	Members with Potential outcomes	Monthly	Use to identify participants who need a *Form 33D* based on *Form 33* responses.
782	Members with Missing Labs	Monthly	To identify participants whose lab/test results (*Form 82, 83, 85, 92*) have not been received and/or entered in WHILMA
783	Members with Missing Bloods	Monthly	To identify participants whose CBC and triglyceride results have not been received and/or entered in WHILMA. This report identifies participants for whom a *Form 100* is entered, but results are not. It only works for *Form 100s* that you enter as soon as they are initiated (i.e. as soon as blood is drawn and processed) and have Cryovial #16 entered.

Table 5.2

A. CC Schedule for Data Monitoring – Required (Continued)

WHIP #	Report Name	How often	How to use/Comments
	Required		
794	Encounters without data	Monthly	Review report and delete any tasks that were entered in error. Clean up data for randomized or enrolled participants. Do not clean up screening data. This report will not show encounters without data for the following tasks: 43, 44, 45, 64, 910, 920, 950, 951, and 955.
985	Outcome Conditions Requiring Providers	Monthly	Use to identify conditions that are not linked to provider visits.
987	Member Visits Requiring adjudication	Monthly	Use to identify provider visits not yet in an adjudication case for which documentation has been received.
988	Investigation Document Summary	As needed	Print for each case assigned to an adjudicator.
1124	Members with a Temporary Change of Study Medication	Monthly or as needed	To identify HRT/CaD participants who have temporarily stopped or modified their dose per *Form 54* and whose "review date" on *Form 54* has passed.
1206	OS Members needing clinic F/U	Monthly	Use to identify OS participants who have not returned their most recent forms packet. Contact the participants and administer *Form 33*.
1211	Members With Undeliverable Addresses	Monthly	To identify participants with the "undeliverable address" flag in the member data screen set to "Y" You must manually delete the undeliverable address flag of the "Y" when an address has been corrected in WHILMA
1213	Outcome visits requiring requests Summary	Monthly	Use to identify open outcomes cases that have unreceived documents.
1215	Member Outcome Status Report	As needed	Print one copy for each case packet.
1222	Duplicate Outcomes	Monthly	Use to identify possible duplicate outcomes reported in the same adjudication case.
1225	Unresolved Death	Monthly	Use to identify deceased participants for whom outcomes information is incomplete.
1227	Referral Follow-up	Monthly	To identify participants who have abnormal lab/test results and/or who have been referred for follow-up, but do not have follow-up data entered
1229	Inconsistent Medications	Monthly	To identify women whose HRT medication assignment is inconsistent with current hysterectomy status Check accuracy of hysterectomy information as entered from *Form 10*, *Form 33D,* and *Form 131*. Contact CCC if medication assignment needs to be changed based on hysterectomy status.
1265	HRT/CaD Adherence	Quarterly	Use to identify participants who are below 80% adherent on HRT or CaD.

Table 5.2

A. CC Schedule for Data Monitoring – Required (Continued)

WHIP #	Report Name	How often	How to use/Comments
	Required		
1316	Non-routine EA Showing Failure to Enter with No Follow-up	Quarterly	Use to identify participants for whom a *Form 82 – Endometrial Aspiration* has been entered indicating "failure to enter" but for whom no ultrasound (*Form 83 – Transvaginal Ultrasound*) has been entered or for whom the follow-up questions on the *Form 83* are incomplete.
1400	HRT Participants reporting bleeding on *Form 10*	Monthly	Use to identify participants who may need follow-up of reported bleeding.
1441	HRT/CaD Safety Events	Monthly	Use to identify participants who have reported an event on *Form 10* or *Form 33* that may warrant discontinuation of HRT study pills. Review each case that appears on the report. Follow up with the participant if necessary. Complete *Form 7* and/or *Form 54* if appropriate.
1445	Task Completeness	Quarterly	Use to identify tasks that are not being collected at follow-up visits or that are being collected out of window. Run using the default parameters for study, visit type, and visit year. Enter a date range for the past 3 to 6 months.
1591	Participants who are Lost to Follow-up	Monthly	Use to identify CT participants who have not had a *Form 33* or a contact recorded on *Form 23* for 18 months (24 months for OS participants). Contact participants to determine vital status and collect *Form 33* if possible.
1612	HRT Mammogram Safety Monitoring	Monthly	Use to identify participants who were dispensed HRT when their most recent mammogram was over 18 months old.
1613	Participants Dispensed HRT/CaD Pills After a Definitive Clinical Safety Event was Reported	Monthly	Use to identify participants who have a study pill dispensation date that is after the date of a potential safety event. Run the *Safety Condition Criteria Report (WHIP1443)* to view responses on forms that are considered "safety events".
1949	Participants with Duplicate Encounters	Monthly	Use to identify encounters for a participant that have the same task ID and date. Delete any duplicate follow-up (non-screening) encounters.

Table 5.2

B. CC Schedule for Data Monitoring - Recommended

WHIP #	Report Name	How often	How to use/Comments
428	Individual Progress	Year 1: after sessions 8,12, 16 Years 2+: every 6 months	Use to monitor individual progress. May be given to participants as progress update.
478	Latest Participation Status of Members	Quarterly	Use to track any follow up or intervention status for all participants.
793	Mammogram Due	Monthly	To identify participants who are due for a mammogram.
787	Post-Randomization Contact Reminder	Monthly	To identify participants due for a follow-up contact in a specified time period
1144	Members needing an HRT or CaD Dispensation	Monthly	To identify participants who may need to have HRT or CaD dispensation
1410	Members in Subsample	Monthly	To identify participants who need subsample tasks done at follow-up visits. Will only show subsamples for visits up to 18 months in the future.
1947	Member Addresses with Characters that Interfere with Label Printing	Monthly	Use to identify characters in the database that may interfere with the printing of the Personal Information Update report or the address labels. In WHILMA, review the address and contact information for each participant on the report. Delete any backslashes and any parentheses that appear in these fields (except that parentheses around the area code in the phone number may remain).

Table 5.3
WHI Form Features

- Clean design with effective use of blank space so that questions are easy to read but form does not seem too long
- Font and size (at least 12 point) of print on self-administered forms that is easy to read
- Mixed-case rather than all capitals letters
- Standardization of format, questions, and forms
- Simple vocabulary and sentence structure
- Response fields close to the questions
- Logical sequencing, physical alignment, and indentation of questions
- Directional arrow for skip patterns
- Check boxes rather than blank lines for recording responses, whenever possible
- Necessary diagrams included on the form
- Physical alignment of response fields whenever possible
- Consistency of coding within and between forms
- Mutually exclusive responses
- Numerical or discrete codes wherever possible
- An indication of the number of digits allowed for a response and placement of a decimal point for values
- Units of measure for a response printed next to the response field
- Questions numbered for easy reference
- Each version of the form numbered and dated
- Space for identification of the participant on each required form

Table 5.4

WHILMA Data Entry Features

- Checks for valid values to prevent entry of invalid data. In general, error messages are of two types: "fatal" and "warning". A fatal error prevents the user from entering a certain item - it must be changed to an acceptable response or deleted before the user can mover to the next field. A warning message tells the user that a value is out of the expected range for that item, but is still acceptable. These checks include:

  - Valid value checks for categorical variables, allowing entry of only valid codes as indicated on the forms.

  - Range checks for continuous variables, such as age, weight, blood pressure, to prevent entry of out-of range values and to warn of data that are outside the usual expected range.

  - Checks for valid date variables, such as future or past dates when not applicable.

- Repeat verification of participant ID number before encounter data can be committed.

- Check-digits on unique identifiers (participant ID number; blood, urine, and endometrial aspiration sample numbers; and study medication study boxes) to help ensure that they are entered correctly. Each unique number has preprinted labels to eliminate the need for transcribing the numbers to forms and bottles. Each preprinted label also contains a bar-code to allow for scanning rather than key-entry of the unique number.

- Automated skip patterns that follow the form skip patterns to enhance efficiency of data entry.

- List-of-value feature enables user to look up and select from allowable codes to enter in a field.

- Automated, rather than hand, calculation of values where feasible(e.g., BMI, average BP, adherence percent).

- Required entry of form identifiers such as form and version number.

- Automated eligibility determinations. Each protocol-defined exclusion criteria has associated data items that must be entered into the database. A few exclusion criteria require CC discretion to evaluate (e.g., expected survival less than three years), but in all cases these must be documented in the database. All of these items are assessed by an automated database function, and the woman's eligibility is ensured before she can be randomized or enrolled. The CCs have no ability to circumvent this requirement without changing previously recorded values. Clinical Center staff should not change previous recorded data except to update eligibility information or correct errors.

- The randomization function in WHILMA enforces the randomization of a participant into HRT and DM on the same day.

- All records entered into the database stamped with date, time of entry, and employee identification number of user logged into WHILMA.

- Use of mark-sense forms where possible to reduce key-entry errors.

- Medication dispensing controlled by requiring data entry of both the participant ID number and bottle number and repeat verification of participant ID number before committing bottle selection.

- Use of commercial medication database (Medi-Span) to ensure accurate entry of current medications.

- Restrictions on ability to change or delete critical data items.

- WHILMA enforces a time limit on randomization of 6 months from the earliest SV1 date.

- WHILMA does not allow CCs to delete the final eligibility determination encounter for a randomized participant.

- To change eligibility data after randomization, WHILMA requires CCs to document in the database the reason for the change. WHILMA maintains an electronic record of eligibility data updated after randomization.

- WHILMA requires the data entry of all eligibility data and baseline forms before CCs can randomize or enroll a participant.

- WHILMA provides automated enrollment into an ancillary study.

Section 5
Data Monitoring

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