

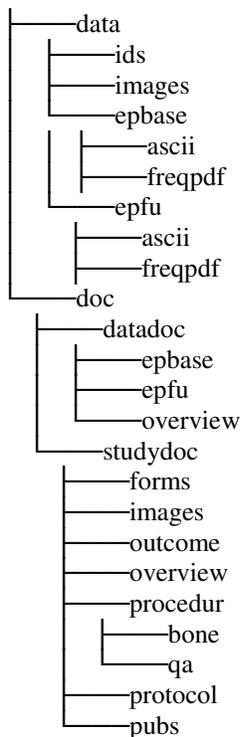
Women's Health Initiative Clinical Trial Limited Access Data Release Overview

This CD contains documentation and data comprising the Limited Access Data Release for the Estrogen plus Progesterone (E+P) component of the Women's Health Initiative (WHI) Hormone Therapy Trial (HT). Recruitment for the Women's Health Initiative Hormone Therapy Trials ended in October 1998. The data presented in this data release are for baseline and follow-up. The E+P baseline data is as of August 25, 1999. The E+P follow-up data is as of January 22, 2003 and reflects data collected through July 7, 2002. On July 8, 2002 the E+P trial was stopped early following a WHI Data and Safety Monitoring Board (DSMB) review of the cumulative data. The DSMB determined that combined estrogen plus progestin was associated with an increased risk of breast cancer, some increased risk of cardiovascular disease, and more harm than benefit overall.

The information on this CD is divided into two parts: Documentation and Data. The DOC directory contains the study and data documentation. The DOC directory is intended to contain all the content that should go up on the NHLBI Limited Access Data Sets web site. The DATA directory contains the raw ASCII data files and the PDFs that present variable descriptions and frequencies. The contents of the DATA directory are only intended for users formally requesting the data.

Currently the WHI commercial purpose data set is the same as the non-commercial data set, so only one data set is provided. A list of participant identification numbers used in the E+P data sets is provided in the **data\ids** directory in a file called **whi_ep_ppt_ids.dat**. The ids provided in this data set are not the original WHI participant ids, but new ids designed for use in the WHI limited access data releases.

CD Directory Structure



Contents of the DOC Directory

The DOC directory is intended to contain all the content that should go up on the NHLBI Limited Access Data Sets web site.

At the root of the DOC directory is an **index.html** file that provides entry into a web interface for accessing the documentation. The subdirectory DATADOC\EPBASE contains the data documentation for the E+P baseline data. The subdirectory DATADOC\EPFU contains the data documentation for the E+P follow-up data. Data documentation is in PDF format and describes the variables contained in each data set. The subdirectories under STUDYDOC contain the study documentation which consists of WHI forms in PDF format and sections of the WHI Manual of Operations in PDF format.

Contents of the DATA Directory

The contents of the DATA directory are only intended for users formally requesting the data.

The data sets are available as ASCII raw data files. In ASCII format each data set is provided as a separate fixed length space-delimited ASCII file. The code needed to create a SAS data set from the ASCII file is also provided. The baseline data can be found in the DATA\EPBASE\ASCII directory. The follow-up data can be found in the DATA\EPFU\ASCII directory. Each data set is zipped up into a .ZIP file that includes the .DAT raw data file, and the .SAS code file to create the SAS data set. To read the ASCII file into any other statistical program, refer to the INFILE statement in the SAS code file for the order of the variables and to the PROC FORMAT section for the values of all categorical variables.

The DATA\EPBASE\FREQPDF directory contains a PDF related to each baseline data set. The DATA\EPFU\FREQPDF directory contains a PDF related to each follow-up data set. Each PDF presents a description and frequency output for each variable in the related data set. A document called **data_prep.pdf** exists in the root of the DATA directory. This PDF document explains some of the issues regarding preparation and analysis of the data.

Women's Health Initiative Overview

The Women's Health Initiative (WHI) is a long-term national health study that focuses on strategies for preventing heart disease, breast and colorectal cancer and osteoporosis in postmenopausal women. These chronic diseases are the major causes of death, disability and frailty in older women of all races and socioeconomic backgrounds.

This multi-million dollar, 15-year project, sponsored by the National Institutes of Health (NIH), National Heart, Lung, and Blood Institute (NHLBI), involves over 161,000 women aged 50-79, and is one of the most definitive, far reaching clinical trials of women's health ever undertaken in the U.S. The WHI Clinical Trial and Observational Study is attempting to address many of the inequities in women's health research and provide practical information to women and their physicians about hormone replacement therapy, dietary patterns and calcium/vitamin D supplements, and their effects on the prevention of heart disease, cancer and osteoporosis.

The WHI study has three components: a randomized clinical trial, an observational study and a community prevention study.

The randomized controlled clinical trial (CT) has enrolled over 68,000 postmenopausal women between the ages of 50-79. The clinical trial has three study components. If eligible, women could choose to enroll in one, two, or all three of the components. The components are:

- **Hormone Replacement Therapy (HRT):** This component will examine the effect of HRT on the prevention of heart disease and osteoporosis, and any associated risk for breast cancer. Women participating in this component take hormone pills or a placebo (inactive pill).

- **Dietary Modification:** The Dietary Modification component will evaluate the effect of a low-fat, high fruit, vegetable and grain diet on the prevention of breast and colorectal cancer and heart disease. Study participants follow either their usual eating pattern or a low-fat eating program.
- **Calcium/Vitamin D:** This component started up to 2 years after a woman joined one or both of the other studies. It will evaluate the effect of calcium and vitamin D supplementation on the prevention of osteoporosis-related fractures and colorectal cancer. Women in this component take calcium and vitamin D pills or a placebo.

The **Observational Study (OS)** will examine the relationship between lifestyle, health and risk factors and specific disease outcomes. This component is tracking the medical history and health habits of over 93,000 women. Recruitment for the observational study was completed in 1998 and participants will be followed for 8 to 12 years.

The WHI clinical trial and observational study is being conducted at 40 clinical centers nationwide. The Fred Hutchinson Cancer Research Center in Seattle, WA serves as the WHI Clinical Coordinating Center for data collection, management, and analysis. Recruitment began in September 1993 and continued through July 1998. The CT enrolled through October 1998. The OS enrolled through December 1998.

The community prevention study (CPS) is a unique collaborative venture between the Centers for Disease Control and Prevention (CDC), and the National Institutes of Health. Eight University-based Prevention Centers underwritten by CDC will conduct and evaluate health programs that encourage women of all races and socioeconomic backgrounds to adopt healthful behaviors such as improved diet, nutritional supplementation, smoking cessation, exercise and early detection of treatable health problems. The goal of the community prevention study is to develop carefully evaluated, model programs that can be implemented in a wide range of communities throughout the U.S.

Hormone Therapy Trial: Estrogen + Progesterone Baseline and Follow-Up Data Release

Recruitment for the Women's Health Initiative Hormone Therapy Trials ended in October 1998. The baseline data presented in this data release are as of August 25, 1999. The follow-up data is as of January 22, 2003 and reflects data collected through July 7, 2002.

E+P Baseline Data Sets

Data Set	Frequencies (located in directory data\epbase\freqpdf)	ASCII Files (located in directory data\epbase\ascii)
Demographics and Study Membership	dem_ep_base_pub2.pdf	dem_ep_base_pub.zip
Form 2 - Eligibility Screening	f2_ep_base_pub2.pdf	f2_ep_base_pub.zip
Form 4 - HRT Washout	f4_ep_base_pub2.pdf	f4_ep_base_pub.zip
Form 20 - Personal Information	f20_ep_base_pub2.pdf	f20_ep_base_pub.zip
Form 30 - Medical History	f30_ep_base_pub2.pdf	f30_ep_base_pub.zip
Form 31 - Reproductive History	f31_ep_base_pub2.pdf	f31_ep_base_pub.zip
Form 32 - Family History	f32_ep_base_pub2.pdf	f32_ep_base_pub.zip
Form 34 - Personal Habits	f34_ep_base_pub2.pdf	f34_ep_base_pub.zip
Form 37 - Thoughts and Feelings	f37_ep_base_pub2.pdf	f37_ep_base_pub.zip
Form 39 - Cognitive Assessment	f39_ep_base_pub2.pdf	f39_ep_base_pub.zip
Form 43 - Hormone Use	f43_ep_base_pub2.pdf	f43_ep_base_pub.zip
Form 45a - Average Daily Nutrients from Supplements	f45a_ep_base_pub2.pdf	f45a_ep_base_pub.zip
Form 45b - Types of Supplements	f45b_ep_base_pub2.pdf	f45b_ep_base_pub.zip
Form 60a - Energy, Macronutrients, Cholesterol, Caffeine, Fiber, Fruits, Vegetables, Glycemic Load	f60a_ep_base_pub2.pdf	f60a_ep_base_pub.zip
Form 60b - Vitamins, Minerals and Carotenoids	f60b_ep_base_pub2.pdf	f60b_ep_base_pub.zip
Form 60c - Individual Starches, Sugars and Amino Acids, Oxalic and Phytic Acid, Ash	f60c_ep_base_pub2.pdf	f60c_ep_base_pub.zip
Form 60d - Individual Fatty Acids & Isoflavones	f60d_ep_base_pub2.pdf	f60d_ep_base_pub.zip
Form 80 - Physical Measurements	f80_ep_base_pub2.pdf	f80_ep_base_pub.zip
Form 81 - Pelvic Exam	f81_ep_base_pub2.pdf	f81_ep_base_pub.zip
Form 82 - Endometrial Aspiration	f82_ep_base_pub2.pdf	f82_ep_base_pub.zip
Form 83 - Transvaginal Uterine Ultrasound	f83_ep_base_pub2.pdf	f83_ep_base_pub.zip
Form 84 - Clinical Breast Exam	f84_ep_base_pub2.pdf	f84_ep_base_pub.zip
Form 85 - Mammogram	f85_ep_base_pub2.pdf	f85_ep_base_pub.zip
Form 90 - Functional Status	f90ep_base_pub2.pdf	f90_ep_base_pub.zip
Form 92 - Pap Smear	f92_ep_base_pub2.pdf	f92_ep_base_pub.zip
Bone Densitometry (BMD) Hip Scan	bmdhip_ep_base_pub2.pdf	bmdhip_ep_base_pub.zip
Bone Densitometry (BMD) Spine Scan	bmdspine_ep_base_pub2.pdf	bmdspine_ep_base_pub.zip
Bone Densitometry (BMD) Whole Body Scan	bmdwbody_ep_base_pub2.pdf	bmdwbody_ep_base_pub.zip
Electrocardiogram (ECG) Results	ecg_ep_base_pub2.pdf	ecg_ep_base_pub.zip
Complete Blood Count (CBC) Results	cbc_ep_base_pub2.pdf	cbc_ep_base_pub.zip
Core Analyte (Blood) Results	core_ep_base_pub2.pdf	core_ep_base_pub.zip

E+P Follow-Up Data Sets

Data Set	Frequencies (located in directory data\epfu\freqpdf)	ASCII Files (located in directory data\epfu\ascii)
Form 10 & 50 HRT Management and Safety Interview, Report of Vaginal Bleeding	f10_50_ep_fu_pub2.pdf	f10_50_ep_fu_pub.zip
Form 33 – Medical History Update	f33_ep_fu_pub2.pdf	f33_ep_fu_pub.zip
Form 35 - Personal Habits Update	f35_ep_fu_pub2.pdf	f35_ep_fu_pub.zip
Form 38 – Daily Life	f38_ep_fu_pub2.pdf	f38_ep_fu_pub.zip
Form 39 – Cognitive Assessment	f39_ep_fu_pub2.pdf	f39_ep_fu_pub.zip
Form 45a - Average Daily Nutrients from Supplements	f45a_ep_fu_pub2.pdf	f45a_ep_fu_pub.zip
Form 45b - Types of Supplements	f45b_ep_fu_pub2.pdf	f45b_ep_fu_pub.zip
Form 80 - Physical Measurements	f80_ep_fu_pub2.pdf	f80_ep_fu_pub.zip
Form 81 – Pelvic Exam	f81_ep_fu_pub2.pdf	f81_ep_fu_pub.zip
Form 82 – Endometrial Aspiration	f82_ep_fu_pub2.pdf	f82_ep_fu_pub.zip
Form 83 - Transvaginal Uterine Ultrasound	f83_ep_fu_pub2.pdf	f83_ep_fu_pub.zip
Form 84 – Clinical Breast Exam	f84_ep_fu_pub2.pdf	f84_ep_fu_pub.zip
Form 85 – Mammogram	f85_ep_fu_pub2.pdf	f85_ep_fu_pub.zip
Form 90 – Functional Status	f90ep_fu_pub2.pdf	f90_ep_fu_pub.zip
Form 92 – Pap Smear	f92_ep_fu_pub2.pdf	f92_ep_fu_pub.zip
Bone Densitometry (BMD) Hip Scan	bmdhip_ep_fu_pub2.pdf	bmdhip_ep_fu_pub.zip
Bone Densitometry (BMD) Spine Scan	bmdspine_ep_fu_pub2.pdf	bmdspine_ep_fu_pub.zip
Bone Densitometry (BMD) Whole Body Scan	bmdwbody_ep_fu_pub2.pdf	bmdwbody_ep_fu_pub.zip
Electrocardiogram (ECG) Results	ecg_ep_fu_pub2.pdf	ecg_ep_fu_pub.zip
Core Analyte (Blood) Results	core_ep_fu_pub2.pdf	core_ep_fu_pub.zip
HRT Study Medication Adherence	ht_adh_ep_fu_pub2.pdf	ht_adh_ep_fu_pub.zip
Outcomes – Cancers (Forms 122, 130)	ocan_ep_fu_pub2.pdf	ocan_ep_fu_pub.zip
Outcomes – CVD (Forms 121, 126, 132)	ocvd_ep_fu_pub2.pdf	ocvd_ep_fu_pub.zip
Outcomes – Fractures (Form 123)	ofrc_ep_fu_pub2.pdf	ofrc_ep_fu_pub.zip
Outcomes – Other (Forms 33, 33D, 124)	ooth_ep_fu_pub2.pdf	ooth_ep_fu_pub.zip

Using the Data Files

Refer to the document **data\data_prep.pdf** for information regarding using the data sets. To use the data you will first need to unzip the .ZIP file for the version of the data set you wish to use. Unzipping the data set will extract two files, a data file in ASCII format and a SAS code file.

Resources

The following resources are available on this CD. The best way to view these resources is through a web browser by opening the **welcome.html** file located at the root of the CD.

Resource	File(s)	Format
WHI HT overview	Doc\studydoc\overview\whihtov.pdf	PDF
WHI forms, frequency of data collection, baseline and follow-up variables	Doc\studydoc\forms*.pdf	PDF
WHI protocol	Doc\studydoc\protocol	PDF
WHI procedures	Doc\studydoc\procedur	PDF
WHI outcomes	Doc\studydoc\outcome	PDF
WHI publications	Doc\studydoc\pubs\whipubs.pdf	PDF
E+P baseline variable frequencies	Data\epsbase\freqpdf*.pdf	PDF
E+P baseline ASCII data files	Data\epbase\ascii*.zip	ZIP (dat)
E+P follow-up variable frequencies	Data\epfu\freqpdf*.pdf	PDF
E+P follow-up ASCII data files	Data\epfu\ascii*.zip	ZIP (dat)
E+P data preparation/use guide	Data\data_prep.pdf	PDF