NATIONAL HEART, LUNG, AND BLOOD INSTITUTE
DIVISION OF EPIDEMIOLOGY AND CLINICAL APPLICATIONS

The Digitalis Study Limited Use Data Sets

The DIGITALIS study consists of 48 files. There are 36 files of three types. These include 12 files which are the data forms (called Baseline.doc, followup.doc, etc.), 11 files of data in SAS data format (called Form01.sd2, Form02.sd2, etc.), and 11 files of data in SAS transport format (called Form01.xpt, Form02.xpt etc.). There are two more .sd2 forms for treatment and status; these two files are also SAS transport files in xpt format. The forms' files are the original data forms used by the DIG investigators and indicate the original data codes. Note that the Follow-Up form file and the Event form file have their data combined into Form02_3.sd2 as well as split into separate files, Form02.sd2 and Form03.sd2. Form02_3.sd2 consists of the data used for the New England Journal of Medicine paper referenced below. Form02.sd2 and Form03.sd2 consist of data that was obtained during post-trial follow-up and so *must be used with caution*.

SAS transport files may be used in different SAS platforms and can be converted to SAS files using SAS program codes.

The remaining three types of files are this "readme.wpd" file and Content.wpd and Forms_to_NHLBI995.wpd. The file Forms_ to_ NHLBI995.wpd is one page should be printed. It gives the correspondence between the .doc files and the .sd2 files. (E.g. Baseline.doc corresponds to Form01.sd2, etc.)

The content.wpd file is a SAS Proc Content output file and indicates all of the recoding that was undertaken to protect patient confidentiality. Thus, for example, race was originally coded as white, black, or other, but has been recoded into white and non-white.

REFERENCES

The Digitalis Investigation Group (1996). Rationale, design, implementation and baseline characteristics of patients in the DIG trial: a large, simple trial to evaluate the effect of digitalis on mortality in heart failure. Controlled Clinical Trials 17:77-97.

The Digitalis Investigation Group (1997). The effect of Digoxin on mortality and morbidity in patients with heart failure. The New England Journal of Medicine 336:525-533.

CONTENTS OF CD ROM

1) 6MINWALD.DOC	Six-minute walk test form in MSWord 6.0/7.0
2) AVBLOCK.DOC	Av-block questionnaire in MSWord 6.0/7.0
3) BASELINE.DOC	Baseline form in MSWord 6.0/7.0
4) CLOSEOUT.DOC	Closeout form in MSWord 6.0/7.0
5) CONTENTS.DOC	Contents of form01 form02 form03 form10 form1 form12 form15 form16 form19 form 25 labdata status trtmt in MSWord 6.0/.7.0
6) CONTENTS.WPD	Contents of form01 form02 form03 form10 form11 form12 form15 form16 form19 form 25 labdata status trtmt in Word Perfect
7) EVENT.DOC	Event form in MSWord 6.0/7.0
8) FOLLOWUP.DOC	Follow-up form in MSWord 6.0/7.0

9)	FORM01.SD2	Baseline data
10)	FORM01.XPT	Baseline data in XPORT format for use with SAS
11)	FORM02_3.SD2	Follow-up AND Event data
12)	FORM02_3.XPT	Follow-up AND Event data in XPORT format for use with SAS
13)	FORM02_3.DOC	Documentation for FORM02_3.SD2 in MSWORD 6.0/7.0
14)	FORM02_3.WPD	Documentation for FORM02_3.SD2 in Word Perfect
15)	FORM02.SD2	Follow-up data
16)	FORM02.XPT	Follow-up data in XPORT format for use with SAS
17)	FORM03.SD2	Event data
18)	FORM03.XPT	Event data in XPORT format for use with SAS
19)	FORM10.SD2	Quality of Life data
20)	FORM10.XPT	Quality of Life data in XPORT format for use with SAS
21)	FORM11.SD2	Quality of Life @ 12 months data
22)	FORM11.XPT	Quality of Life @ 12 months data in XPORT format for use with SAS
23)	FORM12.SD2	Six Minute Walk data
24)	FORM12.XPT	Six Minute Walk data in XPORT format for use with SAS
25)	FORM15.SD2	AV-Block data
26)	FORM15.XPT	AV-Block data in XPORT format for use with SAS
27)	FORM16.SD2	Ventricular Arrhythmia data
28)	FORM16.XPT	Ventricular Arrhythmia data in XPORT format for use with SAS
29)	FORM19.SD2	Close-out data
30)	FORM19.XPT	Close-out data in XPORT format for use with SAS
31)	FORM25.SD2	Stroke data
32)	FORM25.XPT	Stroke data in XPORT format for use with SAS
33)	FORMS_T0_NHLBI.995.DOC	Correspondence between .doc and .sd2 files In MSWord 6.0/7.0
34)	FORMS_T0_NHLBI.995.WPD	Correspondence between .doc and .sd2 files In Word Perfect
35)	LABDATA.DOC	Digoxin Blood Level documentation in MSWord 6.0/7.0
36)	LABDATA.SD2	Digoxin Blood Level data
37)	LABDATA.XPT	Digoxin Blood Level data in XPORT format for use with SAS
38)	QOL.DOC	Quality of Life questionnaire in MSWord 6.0/7.0
39)	QOL12MTH.DOC	Quality of Life questionnaire - twelve month visit in MSWord 6.0/7.0
40)	README.DOC	This document - description of installation in MSWord in 6.0/7.0
41)	README.WPD	This document - description of installation in Word Perfect
42)	STATUS.SD2	Body Mass Index data
43)	STATUS.XPT	Body Mass Index data in XPORT format for use with SAS
44)	STROKE.DOC	Stroke data questionnaire in MSWord 6.0/7.0
45)	TRTMT.DOC	Patient treatment documentation in MSWord 6.0/7.0
46)	TRTMT.SD2	Patient treatment data
47)	TRTMT.XPT	Patient treatment data in XPORT format for use with SAS
48)	VENTARR.DOC	Ventricular Arrhythmia questionnaire in MSWord 6.0/7.0

How to install The Digitalis Study. LABDATA.XPT will be an example for all XPT datasets.

The export file, LABDATA.XPT, is a copy of the Digitalis
data that is designed to be able to reside on any computer's file
system, or to be communicated through any electronic connection between
computers, via e_mail, modem, or ftp. Although it is in a very general,
very transportable format, the export file needs to be converted into a SAS
system file on a local computer before use. We are including instructions on
how to install the data on a PC type system with Windows capability.
These instructions can easily be modified for other systems.

Installation Guidelines

System requirements

1) A CD_ROM drive with these 10 xport data sets, contents and coding manuals require 55 MB of hard drive space.
2) Access to the Statistical Analysis System (SAS) software package for PC or on a mainframe.

In the following instructions, the following is assumed:

1) The CD_ROM drive is assigned the letter D:.
2) The hard drive is assigned the letter C.
3) The directory you want to store the data in is called C:\Digital.

The following program will generate a SAS system file from the
LABDATA XPORT file, assuming it is located on the CD_ROM.:

```
libname in1 xport 'd:\labdata.xpt';
libname out1 'c:\Digital\';
proc copy in=in1  out=out1;                    /*  Create a permanent file    */
```

The following SAS statement will create output which can be compared to the output
included after these instructions.

```
proc freq data=out1.labdata; tables magnes status visit ;
run;
```

At the conclusion of this operation point, you will have copied
and translated 14 files onto your hard drive to a SAS format.

The 1st is a SAS file, of the Digitalis form01 (Baseline) file.
This file (FORM01) contains 7788 observations and 42 variables.

The 2nd is a SAS file, of the Digitalis form02 (Follow-up) file and
form03 (Event) file. This file (FORM02_3) contains 7788 observations
and 38 variables.

The 3rd is a SAS file, of the Digitalis form02 (Follow-up) file.
This file (FORM02) contains 74977 observations and 30 variables.

The 4th is a SAS file, of the Digitalis form03 (Event) file.
This file (FORM03) contains 15661 observations and 34 variables.

The 5th is a SAS file, of the Digitalis form10 (Quality of Life) file.
This file (FORM10) contains 2128 observations and 82 variables.

The 6th is a SAS file, of the Digitalis form11 (Quality of Life @ 12 month) file.
This file (FORM11) contains 406 observations and 6 variables.

The 7th is a SAS file, of the Digitalis form12 (Six minute walk) file.
This file (FORM12) contains 2108 observations and 23 variables.

The 8th is a SAS file, of the Digitalis form15 (AV-Block) file.
This file (FORM15) contains 126 observations and 19 variables.

The 9th is a SAS file, of the Digitalis form16 (Ventricular Arrhythmia) file.
This file (FORM16) contains 104 observations and 24 variables.

The 10th is a SAS file, of the Digitalis form19 (Close-out) file.
This file (FORM19) contains 4240 observations and 7 variables.

The 11th is a SAS file, of the Digitalis form25 (Stroke) file.
This file (FORM25) contains 222 observations and 7 variables.

The 12th is a SAS file, of the Digitalis labdata (Digoxin Blood Level) file.
This file (LABDATA) contains 9889 observations and 12 variables.

The 13th is a SAS file, of the Digitalis status (Body Mass Index, Days til last Followup & status) file.
This file (STATUS) contains 7788 observations and 4 variables.

The 14th is a SAS file, of the Digitalis trtmt (Patient treatment) file.
This file (TRTMT) contains 7788 observations and 2 variables.

Questions about the Digitalis Study files

Please direct any questions or problems to the Division of Epidemiology and Clinical Applications, Epidemiology and Biometry Program, Two Rockledge Centre, 6701 Rockledge Drive, MSC 7934, Bethesda, Maryland 20892-7934, (301) 435-0707 (phone), (301) 480-1667 (fax).

VISIT	Frequency	Percent	Cumulative Frequency	Cumulative Percent
12	1	0.0	1	0.0
12M	3795	38.4	3796	38.4
1M	4706	47.6	8502	86.0
BL	827	8.4	9329	94.4
SDT	558	5.6	9887	100.0

Frequency Missing = 2

STATUS	Frequency	Percent	Cumulative Frequency	Cumulative Percent
A	3938	39.8	3938	39.8
C	331	3.3	4269	43.2
F	5614	56.8	9883	100.0

Frequency Missing = 6

MAGNES	Frequency	Percent	Cumulative Frequency	Cumulative Percent
1.1	1	0.0	1	0.0
1.2	1	0.0	2	0.1
1.3	3	0.1	5	0.2
1.4	6	0.2	11	0.4
1.5	15	0.5	26	0.9
1.6	55	1.8	81	2.7
1.7	120	4.0	201	6.8
1.8	267	9.0	468	15.7
1.9	502	16.9	970	32.6
2	608	20.4	1578	53.0
2.1	582	19.5	2160	72.6
2.2	383	12.9	2543	85.4
2.3	220	7.4	2763	92.8
2.4	116	3.9	2879	96.7
2.5	47	1.6	2926	98.3
2.6	26	0.9	2952	99.2
2.7	12	0.4	2964	99.6
2.8	5	0.2	2969	99.7
2.9	3	0.1	2972	99.8
3	2	0.1	2974	99.9
3.3	2	0.1	2976	100.0
3.4	1	0.0	2977	100.0

Frequency Missing = 6912