

## MTOPS Data Archive

The MTOPS Archive distributed on this CD-ROM contains the study protocol, manual, procedures, and other descriptive documentation; study forms; data collected by the study; and analysis files.

The files are organized into the following directories:

- Forms
- Manual of Operations (MOOP)
- SAS files

The MTOPS data archive contains 33 data collection forms. Each data collection form is designated by a code comprising one letter and two numbers (B01 through T03). The data files for each data collection form, documentation of contents of data files, and SAS data files are named using these codes. For example, the “Eligibility and Exclusion Inventory” is form “B011.PDF” for the first version of the form and “B012.PDF” for the second version. The SAS datasets from this form are “b011.sas7bdat” and “sasb012.sas7bdat.”

### MTOPS Forms

The MTOPS Forms directory contains two subdirectories:

- The MTOPS Forms by Folder subdirectory contains 68 forms in PDF formats. These are the original 34 forms and subsequent versions.
- The MTOPS Forms by Name contains the same 68 forms in a single subdirectory. They have also been given descriptive names so that B011.pdf has been renamed B011\_Eligibility\_Exclusion.pdf.

There are multiple versions for some forms in the data archive. For the 33 original forms, there are a total 68 documents. One of the major differences between the first version of a form and subsequent versions is that later versions collect information about Viagra use.

### MTOPS MOOP

The MTOPS MOOP directory contains 3 files:

- The Manual of Operations (MOOP) for the PS dataset is MTOPS\_MOOP.pdf (238 pages)
- The MTOPS\_Overview.pdf file is a two page overview of the MTOPS data (2 pages)
- The MTOPS\_Protocol.pdf - objectives, randomization, procedures, data processing, statistics (58 pages)

The original MTOPS\_Overview.pdf lists 37 forms, including four forms not included in the data archive

- P01 TRUS and Biopsy (discontinued ancillary study)
- P03 Biopsy Complications (not implemented in full-scale trial)
- R05 Request for Randomization Exception
- T01 patient Tracking Info

**MTOPS SAS Files**

The MTOPS SAS Files subdirectory contains (4) folders

- SAS7bdat Data Files - 67 SAS7bdat files, corresponding to the various version of the 34 forms. There are also baseline.SAS7bdat and clinic.SAS7bdat files.
- SAS Contents and Xpt - Original subdirectory
- SAS Contents PDF - contains files in .PDF format for 34 data files from forms, the baseline dataset, and a SAS FORMAT file in PDF format.
- SAS Xpt Files - 34 SAS .XPT files

Seven of the original SAS data sets have been omitted from this data archive because data are either no longer being collected or because the data are confidential.

- P02, P03
- R01, R03, R05
- T01, T03

MTOps Forms and Data Sets								
Form	Title	Form	Description	SAS sas7bdat	Records	SAS Content .PDF	SAS XPT	SAS Format
	Baseline			baseline.sas7bdat	3047	+	+	+
	Clinic			clinic.sas7bdat	3047		+	
B01	Eligibility and Exclusion Inventory	B011.PDF		b011.sas7bdat	125	+	+	
		B012.PDF		b012.sas7bdat	3032			
B02	Screening Visit 1 Inventory	B021.PDF	History, clinical data	b021.sas7bdat	125	+	+	
		B021a.PDF	Addendum					
		B022.PDF		b022.sas7bdat	3033			
B03	Screening Visit 2 Inventory	B031.PDF		b031.sas7bdat	116	+	+	
		B032.PDF		b032.sas7bdat	2955			
B04	Randomization Information	B041.PDF	BP, uroflow	b041.sas7bdat	116	+	+	
		B042.PDF		b042.sas7bdat	2934			
B05	Medication Run-In Information	B052.PDF	Doxazosin, Finasteride compliance	b052.sas7bdat	2942	+	+	
D01		N/A	PSA LH DHT Testosterone	d011.sas7bdat d012.sas7bdat	345 16875	+	+	
D02		N/A	Biopsy baseline	d021.sas7bdat	1207	+	+	
D03		N/A	Follow-up biopsy	d031.sas7bdat	2009	+	+	
D05		N/A	PSA	d051.sas7bdat	677	+	+	
E01	AUA Symptom Score Event Report	E011.PDF		e011.sas7bdat	36	+	+	
		E012.PDF		e012.sas7bdat	1017			
E02	Creatinine Rise Event Report	E021.PDF		e021.sas7bdat	2	+	+	
		E022.PDF		e022.sas7bdat	86			
E03	Urinary Event Report	E031.PDF		e031.sas7bdat	3	+	+	
		E032.PDF		e032.sas7bdat	0			
		E033.PDF		e033.sas7bdat	113			
E04	Adverse Event Report	E041.PDF		e041.sas7bdat	163	+	+	
		E042.PDF		e042.sas7bdat	502			
		E043.PDF		e043.sas7bdat	1527			
E05	Adverse Event Report	E051.PDF		e051.sas7bdat	15709	+	+	
E06	Serious Adverse Event Report	E061.PDF		e061.sas7bdat	2431	+	+	
F01	Standard Follow-Up Visit	F011.PDF		f011.sas7bdat	995	+	+	
		F012.PDF		f012.sas7bdat	247			

	Inventory	F013.PDF		f013.sas7bdat	29588				
		F014.PDF		f014.sas7bdat	18958				
F02	Major Follow-Up Visit Inventory	F021.PDF		f021.sas7bdat	203	+	+		
		F022.PDF		f022.sas7bdat	12749				
F03	Interim Visit Checklist	F031.PDF		f031.sas7bdat	106	+	+		
		F032.PDF		f032.sas7bdat	2999				
		F033.PDF		f033.sas7bdat	613				
		F034.PDF		f034.sas7bdat	735				
F04	Missed follow-Up Visit Report	F041.PDF		f041.sas7bdat	78	+	+		
		F042.PDF		f042.sas7bdat	30				
		F043.PDF		f043.sas7bdat	5565				
F06	Titration Visit Inventory	F061.PDF		f061.sas7bdat	6466	+	+		
		F062.PDF		f062.sas7bdat	186				
F07	Post End-of-Study Visit Inventory	F071.PDF		f071.sas7bdat	3728	+	+		
P01	TRUS and Biopsy Information	P011.PDF		p011.sas7bdat	210	+	+		
		P012.PDF		p012.sas7bdat	4189				
		P013.PDF		p013.sas7bdat	2513				
P04	Non-Scheduled Biopsy Information	P041.PDF		p041.sas7bdat	242	+	+		
		P042.PDF		p042.sas7bdat	135				
Q01	AUA Symptom Questionnaire	Q011.PDF		q011.sas7bdat	1390	+	+		
		Q012.PDF		q012.sas7bdat	56511				
		Q012s.PDF	(Spanish)						
Q02	Sexual Function Questionnaire	Q021.PDF		q021.sas7bdat	325	+	+		
		Q022.PDF		q022.sas7bdat	15709				
		Q022s.PDF	(Spanish)						
Q03	Health Survey Questionnaire	Q031.PDF		q031.sas7bdat	15861	+	+		
		Q031i.PDF	Interviewer Script						
Q04	Prostatitis Questionnaire	Q041.PDF		q041.sas7bdat	13572	+	+		
		Q041s.PDF	(Spanish)						
R01	Clinic Laboratory Normal Range Report	R012.pdf				N/A	N/A		
R02	Clinical Review Committee Report	R021.pdf		r021.sas7bdat	3	+	+		
		R022.pdf		r022.sas7bdat	36				
		R023.pdf		r023.sas7bdat	82				
		R024.pdf		r024.sas7bdat	62				
		R025.pdf		r025.sas7bdat	2266				
R03	Dispense Label Report Medication Run-In	R032.pdf				N/A	N/A		
R06	Missed Biopsy Report	R061.pdf		r061.sas7bdat	503	+	+		
R07	PSA Collection Report	R071.pdf		r071.sas7bdat	8778	+	+		
		R072.pdf		r072.sas7bdat	3661				
R08	Prostate Cancer Registry Report	R081.pdf		r081.sas7bdat	223	+	+		

NIDDK Data Repository

06/10/2006

R09	Prior Use Of Viagra Report	R091.pdf		r091.sas7bdat	2765	+	+		
R10	Final Status Report For Inactive Patients	R101.pdf		r0101.sas7bdat	404	+	+		
T02	Recruitment Source Tracking Information	T021.pdf		t021.sas7bdat	3033	+	+		
T03	Patient Relocation Tracking Information	T031.pdf		t031.sas7bdat		N/A	N/A		