



## Medical Therapy of Prostatic Symptoms

### Notes on MTOPS Case Report Form (CRF) Databases

#### 1. MTOPS CRFs are classified as follows:

- Baseline visits (B Forms)
  - B01 Eligibility and Exclusion
  - B02 Screening Visit 1
  - B03 Screening Visit 2
  - B04 Randomization
  - B05 Medication Run-in
- Pre-Defined Events (E Forms)
  - E01 AUA Symptom Score Event
  - E02 Creatinine Rise
  - E03 Urinary Event
  - E04 Adverse Event (Initial reporting system)
  - E05 Adverse Event (Refined/subsequent reporting system)
  - E06 Serious Adverse Event
- Follow-up visits (F Forms)
  - F01 Standard Follow-Up Visit (Quarterly)
  - F02 Major Follow-Up Visit (Annual)
  - F03 Interim Visit
  - F04 Missed Follow-Up Visit
  - F06 Titration Visit
  - F07 Post End-of-Study Visit Inventory
- Special Procedures (P Forms)
  - P01 TRUS and Biopsy
  - P02 Urodynamics (discontinued ancillary study)
  - P03 Biopsy Complications (not implemented in the full-scale trial)
  - P04 Non-Scheduled Biopsy Info
- Self-Administered Questionnaires (Q Forms)
  - Q01 AUA Symptom
  - Q02 Sexual Function
  - Q03 SF-36 Health Survey
  - Q04 Prostatitis
- Misc Reports (R Forms)
  - R01 Local Lab Normal Range Report (clinic data, not participant specific)
  - R02 CRC Report (Outcome information)
  - R03 Dispense Label Report
  - R05 Request for Randomization Exception
  - R06 Missed Biopsy
  - R07 PSA collection
  - R08 Prostate Cancer Registry Report
  - R09 Prior Use of Viagra Report
  - R10 Final Status Report for Inactive Patients
- Patient Tracking Info (T forms)
  - T01 Patient Tracking info
  - T02 Recruitment Source Tracking Info
  - T03 Patient Relocation Tracking Info

2. Copies of CRFs are in the subdirectory named \CRF. Each item in the CRFs is annotated with the corresponding variable name of that item in the SAS database. These annotated CRFs serve as the documentation of the variables in the SAS databases.

3. SAS databases in transport format (with extension XPT) are located in the subdirectory named \SAS db. These transport files were created using SAS PROC CPORT and can be converted back to SAS databases using SAS PROC CIMPORT.

4. Baseline values used by the MTOPS coordinating center in all statistical analyses conducted so far are contained in the BASELINE.XPT transport file. Definition of formats used in this baseline database is in \SAS db\Baseline\Formats.PDF. There is no CRF file corresponding to this database.

5. *PSA, hormone and biopsy tissue data from the Diagnostic Center.* Diagnostic center data were keyed in electronic forms. Forms D011 and D012 contain PSA (ng/ml), LH (mIU/mL), testosterone (ng/dL) and DHT data. Form D051 contains % Free PSA data and its matching total PSA. Form D021 contains the baseline biopsy data and D031 contains the follow-up biopsy data. No CRF for these D-Forms is included in this disk. Variables in the transport files are properly labeled and should be self explanatory. The biopsy data is graded on a scale of 0-3 based on quantity.

6. SAS databases corresponding to the following CRFs were not included in this disk due to one of the following reasons: a) the information for which the CRFs were created were no longer being captured during the MTOPS full-scale phase; b) the information captured in the CRF are confidential and only accessible to the MTOPS clinics and not the data coordinating center; c) the information captured in the CRF are potential personal identifying information (PID) as defined by HIPAA; d) information captured in the CRF are clinic specific data, not participant specific (i.e. lab value normal ranges).

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

7. All endpoints for analysis can be obtained by the documented events on the Forms R02 (CRC Report). The Clinical Review Committee adjudicated all study events and documented them on Form R02.

8. The following patient identification variables captured at the front page, top portion of MTOPS CRFs are potential PID as defined by HIPAA, and therefore were not included in the SAS transport databases:

- Patient number (PATID)
- Patient initials (INITS)
- Clinic number (CLINIC)
- Screening number (SCREEN)
- Date of Birth (DOB)

9. All SAS databases contained in this disk may be merged together using the (sort key) variable IDNUM. This variable is NOT the MTOPS participant ID number.