CPCRN RCT #1 Roadmap

The official archive for CPCRN RCT#1 (Multicenter, Randomized Clinical Trial to Evaluate the Efficacy of Oral CIPRO Oral FLOMAX and the Combination of Oral CIPRO and Oral FLOMAX for the Treatment of Chronic Prostatitis) contains the study protocol and related descriptive documentation; study forms; and data collected by the study.

The data files are organized into the following four directories:

1. Documentation
2. Forms
3. Data
4. Dataset Integrity Check (DSIC)

1. Documentation

The Documentation directory contains documentation of the CPCRN protocol and descriptive documentation, including:

- MOP: a file containing the Manual of Procedures (MOP)
  - final_cpcrnrct1_mop.pdf - Version #1.0-May 10, 2001- the manual of procedures for the randomized clinical trial conducted under the Chronic Prostatitis Clinical Research Network (CPCRN).
- Protocol: two files constitute the study protocol:
  - Revised CPCRNRCT#1 Protocol01152002.pdf- Version 3.3 – Dec 6, 2001 – includes the amendment #1 (below)
  - Amendment #1.doc - Nov 26, 2001 is date noted on the cover of the protocol: (Incorporates Protocol Amendment #1 – Effective Date: November 26, 2001). However, the “effective date” in the footer of the amendment is 1/11/2001.

2. Forms

The Forms directory holds a single PDF file (cpcrn_rct1_noncopyright_forms.pdf) that contains forms used in the study although the forms in the PDF are in no specific order. Twenty six forms were provided by the DCC but only 25 are included in the archive since one form is proprietary (SF-12). Five forms collect information used to manage the study. **Table 1** describes the forms.

Table 1: Study Forms

Form Code	Form Name	Visit Number	Completed By	Purpose
Administrative Forms				
1. Patient Contact *	NA	1	RC	Info to re-contact subject
2. Visit Checklist*	NA	all	RC	Visit form tracking
3. Study Med Tracking Log*	NA	2,4, 98	RC	Med management
4. Participant Status*	NA	1,2,6	RC	Subject participation tracking
5. Participant ID *	NA	1	RC	Track ID assignment
Data Forms				
6. CPSI	NIH – Chronic Prostatitis Symptom Index (standardized)	1,2,3,4,5,6, 98,99	Self admin	Measure symptoms
7. DEMO	Demographics	1	Self admin	Characteristics of subject
8. DISP	Dispensing Log	2	RC	Notation of drugs given to subject
9. SEMEN	Semen Sample	2,4	RC	Info about semen sample
10. ELIG	Eligibility Checklist	1,2	RC	Confirms study criteria
11. AE	Events and Serious Adverse Events	3,4,5,6	RC	Reports adverse events during study
12. CMED	Concomitant Medications	2,4	RC	Record of other drugs used at start/since start
13. FUP	Follow Up Contacts	3,4,5,6	RC	Track study med use since last contact
14. URO	Uroflow and PVR	2,4 (PVR only)	RC	Info on urine stream and vol
15. VOID	Voiding Log	2,4	RC	Record of voids/pain
16. MED	Medical History	1	RC + subject	Medical record abstract
17. FGTM	Four Glass Test Microscopy	1,4	RC	Record microscopy in samples (e.g. RBC,WBC,etc)
18. FGTC	Four Glass Test Cultures	1,4	RC	Record bacterial type/count in urine/prostatic secretions
19. EXAM	Physical Exam	1,4	RC	Medical record abstract for visit
20. RAND	Randomization	2	RC	Confirms eligibility/assigns subject to drug/placebo
21. SF12®	SF12 – Health Status Questionnaire®	2	Self admin	Measure of current health
22. SSTOP	Study Stop Point	6	RC/PI	Information related to subject termination form study
23. SYM	Symptom Assessment	3,4,5,6,98,99	Self admin	Rating scale for specific symptoms
24. TSTOP	Treatment Stop Point	4 or earlier (98)	RC	Information related to subject termination of treatment
25. UNMASK*	Unmasking Record	SAE and/or PI discretion	RC/PI	Information on unmasking of study product assigned
26. RMED	Rescue Treatment Event	99	RC	Meds/treatments since stop study drug
* These forms do not have an associated data set.				

3. Data Directory

The Data directory contains the CPCRN RCT#1 datasets organized in raw data collected by study Forms, as well as analysis datasets by study phases, and the SAS program files used for generating the analysis datasets:

- **raw:** subdirectory contains 30 data files collected by the study Forms. The data files with their associated forms are described in **Table 2**.

Table 2: Study data files with their associated Forms

Data File	Related Form	Related Form Description
1. cpsi.sas7bdat	CPSI	NIH – Chronic Prostatitis Symptom Index (standardized)
2. demo.sas7bdat	DEMO	Demographics
3. disp.sas7bdat	DISP	Dispensing Log
4. semen.sas7bdat	SEMEN	Semen Sample
5. semen08a.sas7bdat	SEMEN	
6. elig.sas7bdat	ELIG	Eligibility Checklist
7. ae.sas7bdat	AE	Events and Serious Adverse Events
8. aelog.sas7bdat	AE	Events and Serious Adverse Events
9. aesae_code_list	AE	Events and Serious Adverse Events coding
10. cmed.sas7bdat	CMED	Concomitant Medications
11. fup.sas7bdat	FUP	Follow Up Contacts
12. uro.sas7bdat	URO	Uroflow and PVR
13. void.sas7bdat	VOID	Voiding Log
14.voidlog sas7bdat	VOID	Voiding Log
15.med.sas7bdat	MED	Medical History
16.fgtm.sas7bdat	FGTM	Four Glass Test Microscopy
17.fgtc.sas7bdat	FGTC	Four Glass Test Cultures
18.fgtc03a.sas7bdat	FGTC	
19.fgtc05a.sas7bdat	FGTC	
20.fgtc06a.sas7bdat	FGTC	
21.fgtc08a.sas7bdat	FGTC	
22.fgtc10a.sas7bdat	FGTC	
23.exam.sas7bdat	EXAM	Physical Exam
24.rand.sas7bdat	RAND	Randomization
25.random_arm.sas7bdat	RAND	
26.sf12.sas7bdat	SF12®	SF12 – Health Status Questionnaire®
27.sstop.sas7bdat	SSTOP	Study Stop Point
28.sym.sas7bdat	SYM	Symptom Assessment
29.tstop.sas7bdat	TSTOP	Treatment Stop Point
30.rmed.sas7bdat	RMED	Rescue Treatment Event

SAS programs and results are also included in the Data directory. Included are SAS program files used to generate the analysis data files from the raw data collected from the study forms, as well as the analysis files that were generated:

- **program-** a subdirectory containing:

  - mkdata.sas: program to create an analysis dataset for the CPCRN final efficacy analysis for presentation 12/12-12/13/2002.
  - mkdata_cultures.sas: program to create one record per person containing information about growth of all species of bacteria at 5 days.
  - mkdata_void.sas: program to read in voiding data from Oracle and create summaries of total number of voids, total number of nocturia voids, and min, max and avg voiding volumes.
  - primary manuscript.sas: program to reproduce the tables in the primary manuscript for CiproFlomax trial
  - responsiveness.sas: program to reproduce the tables in the responsiveness manuscript for CiproFlomax trial

- **anal.sas7bdat**: file containing the SAS analysis dataset used for primary publication
- **cultures.sas7bdat**: file containing data from cultures performed on biologic samples
- **void.sas7bdat**: file containing data from voiding log submitted by subject

4. Dataset Integrity Check (DSIC)

As a partial check of the integrity of the CPCRN RCT#1-CiproFlomax dataset archived in the NIDDK data repository, a set of tabulations was performed to verify that published results can be reproduced using the archived dataset. Analyses were performed to duplicate selected results for the data published by Alexander et al [1] in the Annals of Internal Medicine in 2004. Descriptive results provided by this DSIC for the baseline measurements and the primary and secondary outcomes were tabulated using an analysis file provided by the DCC to the NIDDK repository. DSIC results either matched exactly or closely agreed with published values in Alexander et al (2004).