Chronic Prostatitis Collaborative Research Network 2 (CPCRN2) - Pregabalin Study

The full trial name is "A Randomized, Placebo-Controlled Multi-center Clinical Trial to Evaluate the Efficacy & Safety of Pregabalin for the Treatment of Chronic Prostatitis/Chronic Pelvic Pain Syndrome (CP/CPPS)".

The archive is organized in four directories:

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

The archive also contains this study Roadmap document that describes the content of the archive.

1. Documentation

The Documentation directory includes:

- MOP_Version1.0_February2006.pdf - the manual of procedures for data collection
- Pregabalin Protocolv3.0_20060816.Amend1&2.pdf - the Pregabalin study protocol including amendments
- Pregabalin(CP02)_Data_Dictionary.xls– the codebook for variables collected on the study data forms

2. Forms

The Forms directory holds a single PDF file (CP02_final_CRFs_noncopyright.pdf) that contains 24 of the forms used in the study. The forms appear in the PDF in no specific order. The 24 forms include 21 forms used to collect actual data for analysis and 3 forms that were administrative, used to manage the study. The form set originally contained 25 data collection forms (+3 adminisrative forms) but 4 were copyrighted instruments: Hospital Anxiety Depression Scale; McGill Pain Questionnaire; SF12 Health Status Questionnaire; The Sexual Health Inventory for Men. These forms are not contained in the file for distribution since their display, distribution and use requires permission from the copyright holders.

The table below lists all forms including the copyrighted forms (rows highlighted in grey). Administrative forms are categorized separately from data forms. Of the 25 data collection forms listed all but 2 (McGill Pain Questionnaire and The Sexual Health Inventory for Men are the same forms used to collect data on RCT #1 (Alfuzosin Efficacy Study, the other clinical trial conducted under CPCRN2).

The forms used for RCT #2 are described in **Table 1: Study Forms**.

ABBREV	Full Form Name	Visit # Used	Completed By	Purpose
Administrative Forms				
AE Legend	Adverse Events and Serious Adverse Events Legend	NA	NA	Code list of adverse events
PRESCR	Pre-screening Summary	NA	Site Coordinator	Monthly reporting form
SCHEDULE	Forms and Visit Schedule	NA	NA	Procedural checklist
Data Forms				
CPSI	NIH – Chronic Prostatitis Symptom Index (standardized)	1-10	Self admin-in person RC-phone	Measure of symptoms
DEMO	Demographics	1	Self admin	Characteristics of subject
DISP	Dispensing Log	2,5,9	Site Coordinator	Notation of drugs given to subject
DCOMP	Drug Compliance	3,4,5,7,8,9	Site Coordinator	Notation of quantity of drugs taken by subject
ELIG	Eligibility Checklist	1,2	Site Coordinator	Confirms study criteria
EUT	EPS and Urine Testing	1,5	Site Coordinator	Lab report of urine sample
AE	Adverse Events and Serious Adverse Events	2,3,4,5,6,7,8, 9,10- PRN	v	Reports adverse events during study
HADS	Hospital Anxiety and Depression Scale©	2,5,9	Self admin	Measure of anxiety levels
CMED	Concomitant Medications	2-10	Site Coordinator	Report of other meds usage
LABS	Clinical Lab Results	1	Site Coordinator	Baseline lab test results for creatinine and platelets
MEDHX	Medical History	1	Site Coordinator + subject	Medical record abstract
MCGILL	McGill Pain Questionnaire® (MPQ)	2,5,9	Site Coordinator + subject	Measure of pain levels
EXP	Participant Expectations Questionnaire	2,5	Self admin	Report of subject attitude toward study participation
PAIN	Pain Medication Questionnaire	2,5	Self admin	Report on pain med usage in past week
EXAM	Physical Exam	1	Site Coordinator	Medical record abstract for visit
RAND	Randomization	2	Site Coordinator	Confirms eligibility/assigns subject to drug/placebo
SF12	SF12 – Health Status Questionnaire®	2,5,9	Self admin	Measure of current health
SHIM	The Sexual Health Inventory for Men®	2,5,9	Self admin	Measure of sexual functioning
SSTOP	Study Stop Point	PRN (1-9)	Site Coordinator /PI	Information related to subject termination form study
SYM	Symptom Assessment	1-10	Self admin	Rating scale for specific symptoms
TSTOP	Treatment Stop Point	PRN (1-9)	Site Coordinator	Information related to subject termination of treatment
UNMASK	Unmasking Record	PRN (1-6)	Site Coordinator /PI	Information on unmasking of study product assigned
PHASE I	Phase I - Participant Close Out	5	Site Coordinator	ONLY if goes to Phase II- R guess of which med in Phase I

ABBREV	Full Form Name	Visit # Used	Completed By	Purpose
URINE	Urine Screening	1	Site Coordinator	Pre-randomization dipstick analysis of urine
STCONT	Standard Telephone and Clinic Contact Summary	3-10	Site Coordinator	Questions about med usage since last visit

3. Data

The Data folder contains two subdirectories. The subdirectory called Analysis Files and Results contains analysis and program files used for evaluating study results. The subdirectory called Raw contains SAS data files of the study data forms.

3.1 Raw - subdirectory contains **19** SAS data files of data. Not all forms shown in Table 1 have associated data files in Table 2 since some forms were administrative in nature and others included data that was incorporated into the analysis files. "Study Form" column of Table 2 shows the form associated with the listed data file.

Table 2: Study Data Forms with Associated Files

#	Data file	Study Form	Description	Record Count
1	Ae.sas7bdat	AE	Listing of all visits, visit dates and occurrence (If any) of adverse events for all subjects	2139
2	Aelog.sas7bdat	AE	Listing of adverse events only-contents of Adverse Events Form	1971
3	cpsi.sas7bdat	CPSI	NIH – Chronic Prostatitis Symptom Index; forms contents for all visits; all subjects	2461
4	Demo.sas7bdat	DEMO	Demographic data for 319 subjects evaluated at conclusion of study	319
5	Disp.sas7bdat	DISP	Dispensing Log; drugs given; visits 2/3 to ___ subjects	668
6	Dcomp.sas7bdat	DCOMP	Drug Compliance Log; record of drugs used; visits 3,4,5,7,8,9; compliance rate	1579
7	Phase 1.sas7bdat	PHASE1	Phase 1 Close Out Form -ONLY for subjects who continue to Phase II	191
8	Hads.sas7bdat	HADS	Hospital Anxiety and Depression Scale©	847
9	Shim.sas7bdat	SHIM	The Sexual Health Inventory for Men®	838
10	Medhx.sas7bdat	MEDHX	Medical History	320
11	Mcgill.sas7bdat	MCGILL	McGill Pain Questionnaire® (MPQ)	845
12	Randomization.sas7bdat	NA	Assigns Rand_ID to randomization number	720
13	Rand.sas7bdat	RAND	Randomization of subjects to arm A or B	324
14	Random_arm.sas7bdat	NA	Tracking of ARM study subject assigned (A/B)	720
15	Sf12.sas7bdat	SF12	SF12 – Health Status Questionnaire®	849

16	Sstop.sas7bdat	SSTOP	Study Stop Point	323
17	Sym.sas7bdat	SYM	Symptom Assessment	2452
18	Tstop.sas7bdat	TSTOP	Treatment Stop Point	315
19	Stcont.sas7bdat	STCONT	Standard Telephone and Clinic Contact Summary	1811

3.2 Analysis Files and Results -- this subdirectory contains 9 SAS and Stata programs, data files, and output files.

The following files were used in the analysis of the primary manuscript to document: 1) analyses conducted for the manuscript, 2) calculation of study center-adjusted 95% CIs for differences in the CPSI primary endpoint by treatment, and 3) calculation of study-center adjusted 95% CIs for the GRA response measure (as published in the article by Pontari et al [1] in the *Archives of Internal Medicine* in September 2010).

cp02_long.sas7bdat – Final longitudinal dataset with baseline, primary endpoint, secondary endpoints and other major information in main manuscripts.

primary manuscript_revised011811.sas – SAS program file to reproduce tables published in primary manuscript.

format.sas - SAS program file providing variable format library for categorical variables in primary analysis file.

cpsiresp_metan.dta- Stata calculation (using the *metan* procedure) of 95% CI for CPSI primary endpoint.

cpsimetan.log – Output from Stata *metan* procedure for CPSI primary endpoint analysis

cpsimetan.txt – Stata code for calculation of center-adjusted 95% CI, CPSI primary endpoint.

graresp_metan.dta–Stata calculation (using the *metan* procedure) of 95% CI for GRA response measure

grametan.log – Output from Stata *metan* procedure for GRA response outcome measure

grametan.txt – Stata code for calculation of center-adjusted 95% CI, GRA response outcome measure

4. DSIC (Data Set Integrity Check)

As a partial check of the integrity of the CPCRN2-Pregabalin 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 Pontari et al [1] in the *Archives of Internal Medicine* in September 2010. Complete results are presented in the DSIC directory.