Interstitial Cystitis Clinical Trials Group Randomized Controlled Trial #1 – ICCTG RCT #1 – Elmiron (pentosan polysulfate) and Hydroxyzine Study Data Archive

The ICCTG-RCT#1 data archive contains the study protocol and related descriptive documentation; study data forms (data entry and administrative forms); data files prepared for the repository, analysis file, and data integrity check.

The files in the archive are organized into the following directories:

- Documentation
- Data Forms (PDF)
- Datasets
- Data Integrity Check

Documentation Directory

The Documentation directory includes the following folders and files:

- **Manual of Operations.** Manual of procedures, mop.pdf, version 2, dated 31 January 2000. 110 pgs, includes chapters on Study Design, Objectives and Endpoints, Study Organization, Participant Enrollment, Data and Administrative Forms, Laboratory Tests and General Procedures, Treatment Procedures, Risks and Benefits to Participants, Data Management System User Guide, and Data Coordinating Center Responsibilities. The four appendices were not provided by the DCC.
- **Overview.** Overview of ICCTG ComElmironHydroxyzine Study.pdf (revised version) provides documentation of the files provided to the archive including: brief overview of study design, eligibility criteria, participant randomization flowchart, list and description of SAS datasets.
- **Protocol.** This directory includes 2 files and a folder of protocol appendices.

Protocol.doc describes the study protocol for RCT #1: A randomized, multicenter clinical trial to evaluate the efficacy of oral elmiron, oral hydroxyzine and the combination of oral elmiron and oral hydroxyzine in patients with interstitial cystitis (IC), Second edition, effective April 12, 1999. The document includes 15 chapters, reference list, Appendices A-I, and a directory of project collaborators. *C*hapter 1: Introduction, 2: Study Design and Objectives, 3: Study Background and Prior Clinical Studies, 4: Study Organization, 5: Participant Criteria, 6: Participant Recruitment, Consent, and Confidentiality, 7: Endpoints, 8: Treatment Procedures, 9: Concomitant Medications, 10: RCT Tests, Procedures, and Participant Withdrawal, 11: Risks and Benefits to Participants, 12: Adverse Events and Participant Withdrawals, 13: Administrative Aspects, 14: Data Management and Analysis, and 15: Statistical Considerations. Appendices are provided in a separate document (see below).

Appendices to protocol:

Appendix A: Criteria for IC Diagnosis, *appaniddk.doc*
Appendix B: Recruitment Sites, *appen b recruitment site drawing 981115.doc*
Appendix C: Working Group Directives, *appendixc.doc*
Appendix D: Study brochure, *appendixdpatbrochure.pdf*
Appendix E: Consent Form, *appeconsenform.doc*
Appendix F: Exclusionary and Restricted Medications, *restricted_exclusionary_meds_appendix_060899.pdf*
Appendix G: Study Visit Schedule (weeks), *appendixgpatvisit.doc*
Appendix H: Urine Specimen (Banking) Protocol, *appendixhurinebanking.doc*
Appendix I: Specimen Flow (chart), *appendixi-specimen flow.doc*

Summary Amendments. The document *SummaryAMENDMENTS ICCTG RCT1.pdf* describes amendments to the ICCTG study protocol (amendments 1A through 18).

- **Publications.**

Sant GR, Propert KJ, Hanno PM, Burks D, Culkin D, Diokno AC, Hardy C, Landis JR, Mayer R, Madigan R, Messing EM, Peters K, Theoharides TC, Warren J, Wein AJ, Steers W, Kusek JW, Nyberg LM and the Interstitial Cystitis Clinical Trials Group. 2003. A pilot clinical trial of oral pentosan polysulfate and oral hydroxyzine in patients with interstitial cystitis. *The Journal of Urology* 170:810-815.

Data Forms_PDF Directory

The Data Forms directory contains the study (FORMS directory) and administrative (ADMIN FORMS directory) case report forms, or CRFs, used for data collection. All the paper forms are provided in Adobe PDF format. Users should note that annotated versions of the forms, which include the variable names, are not provided. The complete listing of data forms and their associated datasets are noted in the table below.

In addition, a summary file listing all CRFs (*crfver.pdf)* is included in the Data Forms Directory. The weekly visit schedule for form administration is shown in *vtsch.pdf* and *delist.pdf* lists form data entry schedule by contact number, i.e., baseline/randomization (contact 0) through follow-up (contact 36).

Datasets Directory

The Datasets directory contains 16 individual SAS data files (.sas7bdat files) that correspond to a select number of data forms, or CRFs. A summary of the individual datasets, their associated case report forms and SAS datasets (if applicable) is appended below. Users will note that not all PDF forms are associated with SAS data files and not all variables on the forms are included in the datasets.

A single Primary Analysis Dataset, icctgrct1.sas7bdat, includes variables (demographics, primary endpoint, and secondary endpoint variables) for the primary manuscript (Sant et al., 2003). These variables have been selected from various CRFs and recoded for the analysis presented in the manuscript. The analysis dataset includes 121 observations and 49 variables.

A subdirectory, **SAS Program and Results,** includes four files:

Proc Contents for Datasets.doc provides output from SAS ProcContents for each of the 17 (16 individual + 1 analysis) datasets. Variables are listed in alphabetical order. Variable attributes identified include name, type, length, format, and label.

Primary Endpoint Analysis.doc and ***Anal.SAS*** list output from StatXact and SAS code for the estimation and testing of odds ratios comparing the hydroxyzine (drug v placebo) and pentosan polysulfate (drug v placebo) main treatment comparisons.

Format SAS specifies the SAS variable format statements for select variables in the analysis and adverse events files.

ICCTG RCT#1 Case Report Forms and Associated SAS files (if provided)

CRF	Abbrev. Name	PDF {and link}	SAS dataset name	No. of observations	No. of variables
Adverse Event/Serious Adverse Event	AESAE	...FORMS\aesae.pdf	aelog.sas7bdat	1488	17
Baseline Symptom 1	BSYM1	...FORMS\bsym1.pdf	basesymp.sas7bdat	121	33
Baseline Symptom 2	BSYM2	...FORMS\bsym2.pdf			
Blood: LFTs, Coagulation, Platelets	LAB	...FORMS\lab.pdf	--		
Clinical Center Stop	STOP	...FORMS\stop.pdf	stopsg.sas7bdat	160	16
Cross Check	CRSCK	...FORMS\crsck.pdf	--		
Demographics	DEMO	...FORMS\demo.pdf	demopk.sas7bdat	121	18
Eligibility Confirmation and Randomization	ELIG	..FORMS\elig.pdf	--		
Follow-up Symptoms	FUSYM	..FORMS\fusymp.pdf	fusympk.sas7bdat	496	12
Health Status Questionnaire	SF36	...FORMS\sf36.pdf	sf36pk.sas7bdat	219	42
IC Symptom and Problem Index	SYMPROB	...FORMS\symprob.pdf	symprop.sas7bdat	617	16
Medical History	MED	...FORMS\med.pdf	--		
Medication Diary Record	DIARYREC	...FORMS\diaryrec.pdf	diarylog.sas7bdat	4207	18
MOS Sexual functioning Scale	MOS	..FORMS\mos.pdf	--		
Patient Close-Out	PTCLOSE	...FORMS\ptclose.pdf	ptclssg.sas7bdat	135	11
Physical Examination	EXAM				
Run-In Med Dispensing Log	RUNMED	...FORMS\runinmed.pdf	--		
Standard Visit Inventory	STVISIT	...FORMS\stvisit.pdf	stvispk.sas7bdat	496	34
Study Close-Out	STCLOSE	..FORMS\stclose.pdf	--		
Symptom ranking Cards	CARDS	..FORMS\cards.pdf	--		
Telephone Contact	PHONE	..FORMS\phone.pdf	phonepk.sas7bdat	669	32
Univ of Wisconsin Symptom Survey	UNWIS	..\FORMS\univwis.pdf	univwpk.sas7bdat	617	31
Unmasking	UNMASK	..FORMS\unmask.pdf	unmasksg.sas7bdat*	8	15
Urine Screening: UA and Culture	URINE	...FORMS\urine.pdf	urinepk.sas7bdat	121	16
Urine: Residual Volume (men only)	URINE				
Voiding Diary	VOID	..FORMS\void.pdf	voidlog.sas7bdat	10364	7
Clinic Visit Contact Sheet	VCHK	..ADMIN FORMS\vchk.pdf	--		
Data Processing Cover Sheet	DPCS	..ADMIN FORMS\dpcs.pdf	--		
Deferral Criteria	DEF	..ADMIN FORMS\def.pdf	--		
Exclusion Criteria	EXCL	..ADMIN FORMS\excl.pdf	--		
Inclusion Criteria	INCL	..ADMIN FORMS\incl.pdf	--		
Patient Contact Information	PTCONT	..ADMIN FORMS\ptcont.pdf	--		
Patient Refusal Log	REF	..ADMIN FORMS\ref.pdf	--		
Patient Transfer	TRANS	..ADMIN FORMS\trans.pdf	--		
Phone Contact Checklist	PCHK	..ADMIN FORMS\pchk.pdf	--		
Run-In Dosage Record	RUNIN	..ADMIN FORMS\runin.pdf	--		
Schedule	SCHEDULE	..vtsch.pdf	--		

CRF	Abbrev. Name	PDF {and link}	SAS dataset name	No. of observations	No. of variables
Screening Contact Checklist	SCHK	..ADMIN FORMS\schk.pdf	--		
Study Med Tracking Log	MEDTRAC	..ADMIN FORMS\medtrac.pdf			
Urine Sample Tracking	UTRAC	..ADMIN FORMS\utrac.pdf	--		
Urine Sample Tracking Log	ULOG	..ADMIN FORMS\ulog.pdf	--		
Patient's Daily Medication Diary	PTDIARY	..ADMIN FORMS\ptdiary.pdf	--		
Serum Pregnancy Test	---				
[Medication Code List]	---		drugdic2.sas7bat	16391	2

Note: * Datafile contains 0 observations

4. Data Integrity Check

The Data Integrity Check for the ICCTG RCT#1 (Pentosan polysulfate and oral hydroxyzine study*)* is a report of an examination of the data provided to the repository. This report examines data completeness by statisticians and quality control specialists at the repository and compares the published data from the ICCTG RCT#1 study (see Sant et al. publication above) to values tabulated from the ICCTG RCT#1 analysis file provided to the NIDDK repository.