13 April 2010

ATN Data Archive

The ATN data archive contains the study protocol and related descriptive documentation; study forms; data collected by the study (main study and observational study); and analysis files.

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

1. Documentation
2. Forms
3. Data

In addition to these three directories, the document 'Basic Information for Analysts' is included as a brief reference guide for analysts of the ATN data with linkages to several data and documentation files.

1. Documentation Directory

The Documentation directory contains two files, an Executive Summary and Manual of Operations:

- **Executive Summary/Abstract**, 6 pgs, including a Figure of overall study design (Executive summary.pdf)
- **Manual of Operations**, version 4, September 15, 2006, 452 pgs, a manual for the day-to-day operations of the study. Includes instructions for completing each of the data collection forms, study overview and protocol. (Operations Manual Ver 4.0.pdf).

2. Forms Directory

The Forms directory contains the forms used for data collection. The ATN study included the 'main study' in which patients were randomized to either the intensive or conventional renal support and an 'observational study' of patients who were eligible for the main study, but did not enroll (see Operations Manual, section XV). All the paper forms are provided in Adobe PDF format. Annotated versions of the forms, which include the variable names, are included in the subdirectory, Annotated Forms. A listing of the forms and their associated datasets is provided in Appendix A.

Main Study: Screening Forms

- Form 01 Screening/Eligibility (Ann_530Form01.pdf) – Inclusion and exclusion criteria for patient randomization, surrogate consent. 5 pgs
- Form 02R Patient Re-consent Form Cover Sheet (Ann_530Form02R.pdf) – Cover sheet to be sent to West Haven Cooperative Studies Program Coordinating Center (WHCSPCC) after receiving signed re-consent form. 1 pg.
- Form 02T Consent Transmittal Form (Ann_530Form02T.pdf) – Cover sheet to be sent to WHCSPCC when submitting signed consent form. 1 pg.
- Form 03 Randomization (Ann_530Form03.pdf) – Patient randomization form, including SOFA, indicator of oliguria, and treatment assignment. 1 pg.

- Form 04 Baseline Form (Ann_530Form04.pdf) – Primary diagnosis and treatment, ARF information, hospitalization history, demographic, military, and medical history, physical exam, and nutrition management. 4 pgs.
- Form 05 Patient Contact Information (annotated version not available) – Patient and contact information. Data not included in NIDDK repository. 3 pgs.
- Form 06 Baseline Scores and Laboratory Values (Ann_530Form06.pdf) – Completed prior to initiation of first protocol treatment. Vital signs, mechanical ventilation support, hemodynamic monitoring, Glasgow coma score, hematology, coagulation, renal function, chemistry, pressors (1 hr or more), hemodialysis, glucose management, glucocorticoid therapy, and gastrointestinal complications. 6 pgs.

Main Study: Post-randomization Forms

- Form 07 Study Day Scores and Laboratory Values (Ann_530Form07.pdf) – To be completed on Days 01-14, 21, and 28 during which the patient is on study protocol therapy. Vital signs, fluid intake and output, mechanical ventilation, tracheostomy, arterial blood gas, hemodynamic monitoring, Glasgow coma score, hematology, renal function, chemistry, pressors, nutrition management, glucose management, and glucocorticoid therapy. 5 pgs.
- Form 08 Medications Form (Ann_530Form08.pdf) – Specify all drugs/medications taken from 1) randomization through day 7 post-randomization and 2) days 8 through 28 post-randomization. 1 pg
- Form 09 Renal Replacement Therapy, Each Treatment (Ann_530Form09.pdf) – To be completed on each study day (day 1 through 28) the patient receives RRT. Time, day, and type of treatment, isolated ultrafiltration, hemodialysis or SLED, CVVHDF, complications. 3 pgs.
- Form 10 Discontinuation of Study Therapy (Ann_530form10.pdf) – To be completed immediately after discontinuation of study therapy. Collects information on indications for discontinuing therapy. 1 pg
- Form 11 Day 28 Post-Randomization Status (Ann_530form11.pdf) – Vital status, renal function assessment, hospitalization. 2 pgs.
- Form 12 Day 60 Post-Randomization Status (Ann_530form12.pdf) – Vital status, renal function assessment, hospitalization. 2 pgs.
- Form 13 Study Exit (Ann_530form13.pdf) – Reason for exit. 1 pg.
- Form 14 Release of Information (annotated version not available). Data not included in NIDDK repository. Disclosure of health information. 1 pg.
- Form 15 Dialysis Catheter Insertion Form (Ann_530form 15.pdf) – to be completed for each dialysis catheter insertion or change. Catheter number, time, location, and type, insertion complications, later complications, reason for removal, cultures obtained. 4 pgs.
- Form 16 Serious Adverse Event Form (Ann_530form16.pdf) – to be completed for SAEs occurring within 30 days of randomization. Type of SAE, description, actions taken, relationship to study intervention, final outcome. 2 pgs.
- Form 17N 60 Day Follow-up for Non-VA Patients (Ann_530form17N.pdf) – hospitalization, admission to nursing home, medical appointments, kidney dialysis, home health care. Phone survey. 6 pgs.

- Form 17V 60 Day Follow-up for VA Patients (Ann_530form17V.pdf) See Form 17N above. Phone survey. 6 pgs.
- Form 18N 12 Month Follow-up for Non-VA Patients (Ann_530form18N.pdf) – See Form 17N above. Phone survey. 6 pgs.
- Form 18V 12 Month Follow-up for VA Patients (Ann_530form18V.pdf) – See Form 17N above. Phone survey. 6 pgs.
- Form 19S Health Utilities Index, Self Assessed (Ann_530form19S.pdf) – To be completed by subject on Day 60 and at 12 months after enrollment. Vision, hearing, speech, locomotion, hands and fingers, feelings, memory, thinking, pain. Phone survey. 8 pgs.
- Form 19P Health Utilities Index, Proxy Assessed (Ann_530form19P.pdf) – To be administered by proxy subject, only if subject unable to complete Form 19S on his/her own. Phone survey. 8 pgs.
- Form 20N Patient Diary for Non-VA Patients to Record Healthcare Outside the Study Hospital (annotated version not available) Data not included in NIDDK repository.
- Form 20V Patient Diary for VA Patients to Record Healthcare Outside the VA System (annotated version not available) Data not included in NIDDK repository.
- Form 21 Biorepository Specimen Confirmation (Ann_530form21.pdf) – To be completed when biospecimens are shipped to the laboratory. If no specimens are collected from patient, to be completed on Day 8 or at study exit, whichever comes first. 2 pgs.

Observational Study

- Form 22 Entry Form (Ann_530form22.pdf) – to be administered to patients meeting criteria for ATN study with the exception of informed consent in the intervention trial. Demographics and provision of RRT. 2 pgs.
- Form 23 Renal Replacement Therapy, each treatment (Ann_530form23.pdf) – To be completed for each treatment on days 1 to 14. RRT, isolated ultrafiltration, hemodialysis, CRRT, complications of therapy. 3 pgs.

3. Data Directory

The Data directory contains three subdirectories: Data_from_Forms, Analysis_Data_Sets, and Data Documentation.

The **Data_from_Forms** subdirectory contains the data collected on forms. There are 21 SAS v7 data files (.sas7bdat files) that correspond to the main study screening, post-randomization, and observational study forms described above. (Note: Data files are not associated with Forms 5 and 14 and data for both versions of Forms 17 through 20 are included in single data files).

The **Analysis_Data_Sets** subdirectory includes 10 SAS v7 format datasets (see Table 1 for a listing). Seven of these datasets are analysis files and three datasets provide listings of patient IDs (de-identified) for DNA bank patients, patients providing biorepository specimens, and patient randomization information.

Table 1: Analysis Datasets

File Name	Records	Brief Description
Analobsalltreatmentdays.sas7bdat	1671	Observational study: Treatment/days in therapy
Analobstherapy.sas7bdat	1698	Observational study: Treatment summary data
Analobstherapycounts.sas7bdat	230	Observational study: days in therapy
AnalysisDemo.sas7bdat	1354	Demographic data, main and observational studies
AnalysisMortality.sas7bdat	1124	Mortality data, main study
AnalysisSafety.sas7bdat	6290	RRT complication data, catheter insertion, SAE data
AnalysisTherapy.sas7bdat	14,109	RRT, daily laboratory scores/values, protocol deviation data
Atndnaids.sas7bdat	138	IDs of DNA bank patients
Biorepositoryids.sas7bdat	827	IDs of biorepository patients
Randfile.sas7bdat	1124	Randomization data – date, time, treatment, etc

The **Data Documentation** subdirectory includes a **SAS formats file**, two ***Proc Contents*** folders (***Proc Contents_forms*** and ***Proc Contents_analysisfiles***), and a ***Data Dictionary_Analysis files*** folder.

- ***Formats.sas7bcat*** is a SAS formats library for the forms data files.
- ***Proc Contents_forms*** contains two files. **CSP530AllFormsContents.pdf** provides output from SAS Proc CONTENTS for each of the 21 data files. Variables are listed in alphabetical order and by position on each form with several variable attributes (type, length, position, format, and label). The second file, **CSP530FormatsListing.pdf** specifies the variable format for categorical variables. Variable formats are listed in alphabetical order.
- ***Proc Contents_analysisfiles*** contains the file **CSP530AnalysisContents.pdf** which lists the output from SAS Proc CONTENTS for the seven analysis files. Variables are listed in alphabetical order and by position in the datafile.
- ***Data Dictionary_Analysis files*** includes four files that describe the variables in four analysis files:
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    - **Data Dictionary_AnalysisDemo.xls** contains demographic and basic data for all patients enrolled in the main study (1124 patients in the conventional and intensive groups combined) as well as the Observational study (230 patients). There is one record per patient.

    - **Data Dictionary_AnalysisMortality.xls** contains mortality data for all patients enrolled in the main study (1124 patients randomized to either the conventional or intensive group). There is one record per patient.

    - **Data Dictionary_AnalysisSafety.xls** contains three types of safety-related data: 1) renal replacement therapy complication data (safety_type=1, 2) dialysis catheter insertion and catheter insertion complication data (safety_type=2, and 3) serious adverse event (SAE) data (safety_type=3). There may be multiple records for each patient.

- **Data Dictionary_AnalysisTherapy.xls** contains renal replacement therapy, daily scores/laboratory values and protocol deviation data for all patients enrolled in the main study. There may be multiple records per patient. There is one record for every renal replacement treatment the patient received (case report Form 09) or the recording of scores or laboratory values (case report Form 07). In the event both forms were submitted for a given study day, the data for both forms will reside on one record.

Appendix A. VA/NIH Acute Renal Failure Trial Network (ATN) Study

Form	Form Name	Annotated Form File Name	Time of Administration	SAS Data File Name
01	Screening/Eligibility	Ann_530Form01.pdf	Screening	form01.sas7bdat
02R	Patient Re-consent Cover Sheet	Ann_530Form02R.pdf	Randomization	form02r.sas7bdat
02T	Consent Transmittal Form	Ann_530Form02T.pdf	Randomization	form02t.sas7bdat
03	Randomization	Ann_530Form03.pdf	Randomization	form03.sas7bdat
04	Baseline Data	Ann_530Form04.pdf	Randomization	form04.sas7bdat
05	Subject Contact Information	530Form05.pdf	Data/annotated form not included in repository	
06	Baseline Scores and Laboratory Values	Ann_530Form06.pdf	Randomization	form06.sas7bdat
07	Study Day Scores and Laboratory Values	Ann_530Form07.pdf	Days 1-14, 21, 28	form07.sas7bdat
08	Medications Form	Ann_530Form08.pdf	Days 8, 28 [a]	form08.sas7bdat
09	Renal Replacement Therapy - each treatment	Ann_530Form09.pdf	Each day patient receives RRT	form09.sas7bdat
10	Discontinuation of Study Therapy	Ann_530Form10.pdf	Day RRT is discontinued	form10.sas7bdat
11	Day 28 Post-Randomization Status	Ann_530Form11.pdf	Day 28 [b]	form11.sas7bdat
12	Day 60 Post-Randomization Status	Ann_530Form12.pdf	Day 60 [c]	form12.sas7bdat
13	Study Exit	Ann_530Form13.pdf	Day 60 [c]	form13.sas7bdat
14	Release of Information	530Form15.pdf	Data/annotated form not included in repository	
15	Dialysis Catheter Insertion Form	Ann_530Form15.pdf	Each day catheter is inserted/removed	form15.sas7bdat
16	Serious Adverse Event	Ann_530Form16.pdf	For each SAE	form16.sas7bdat
17N	60 Day Follow-up for Non-VA Subjects	Ann_530Form17N.pdf	Day 60	form17.sas7bdat
17V	60 Day Follow-up for VA Subjects	Ann_530Form17V.pdf	Day 60	form17.sas7bdat
18N	12 Month Follow-up for Non-VA Subjects	Ann_530Form18N.pdf	1 Year	form18.sas7bdat
18V	12 Month Follow-up for VA Subjects	Ann_530Form18V.pdf	1 Year	form18.sas7bdat
19S	Health Utilities Index Form - Self assessed	Ann_530Form19S.pdf	Day 60, 1 year	form19.sas7bdat

Form	Form Name	Annotated Form File Name	Time of Administration	SAS Data File Name
19P	Health Utilities Index Form - Proxy assessed	Ann_530Form19P.pdf	Day 60, 1 year	form19.sas7bdat
20N	Subject Use Only - Subject Diary - Not a CRF	530Form20N.pdf	Data/annotated form not included in repository	
20V	Subject Use Only - Subject Diary - Not a CRF	530Form20V.pdf	Data/annotated form not included in repository	
21	Biorepository Specimen Confirmation	Ann_530Form21.pdf	Day 8 [d]	form21.sas7bdat
22	Observational Study: Entry Form	Ann_530Form22.pdf	Observational Study	form22.sas7bdat
23	Observational Study: Renal Replacement Therapy - each treatment	Ann_530Form23.pdf	Observational Study	form23.sas7bdat

Notes:

Annotated forms include variable names. Unannotated forms are also included in the ATN repository files.

[a] If patient exits study prior to day 8, form should be completed at study exit. If patient exits study between day 8 and 28, form should be completed on Day 8 and at study exit.

[b] If patient exits study prior to day 28, form should be completed on that day

[c] If patient exits study prior to day 60, form should be completed on that day

[d] Form should be completed on day 8 or at study exit, whichever comes first, if no biorepository specimens were collected from the patient. If biorepository specimens were collected, form should be completed at time of shipping specimens.

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