

The CUTIE Study Data Archive

The CUTIE Archive contains the Protocol, Manual of Procedures, Forms, Study data, published papers, and Dataset Integrity Check.

Archive files are organized into the following directories:

- Documents
- Forms
- Data
- Dataset Integrity Check (DSIC)

Documents

The CUTIE Documents directory contains:

- CUTIE MOP.pdf – CUTIE protocol, Manual of Operations, and Data Management System User’s Guide
- CUTIE Publications.docx – Bibliography of all study publications
- CUTIE outcome manuscript.pdf – a copy of the study publication “Risk Factors for Recurrent Urinary Tract Infection and Renal Scarring.” Published in *Pediatrics* July 2015.

Forms

The CUTIE Forms directory contains the following:

- All CUTIE Forms Annotated.pdf – Annotated version of all forms used in the CUTIE protocol

Data

The CUTIE data directory contains the following raw datasets in SAS format:

- aef_niddk1.sas7bdat – This dataset contains 281 observations from the Adverse Events Form (AEF). Data includes all reported study adverse events or serious adverse events
- bdfa_niddk1.sas7bdat - This dataset contains 195 observations from the Baseline Demographic Form (BDF). Data includes demographic variables and socio-economic factor. Interview was completed during the baseline clinic visit.
- blind_id_niddk1.sas7bdat - This dataset contains 195 observations. It is the link between the subject ID and the blinded ID.
- bmha_niddk1.sas7bdat - This dataset contains 195 observations from the Baseline Medical History Form (BMH). Data includes a participant's natal history, medication history, voiding and bowel history and family medical history.
- bp_derv_niddk1.sas7bdat - This dataset contains 195 observations and includes data about z-scores and percentiles for the BMI, height, weight, and blood pressure measured on the Physical Exam Form (PEF).
- bsra_niddk1.sas7bdat - This dataset contains 351 observation from the Blood Specimen Results Form (BSR). Data includes laboratory results of the participant's blood specimen.
- cee_niddk1.sas7bdat – This dataset contains 195 observations from the CUTIE Eligibility and Enrollment Form. Data includes age, history of UTIs, timing of index UTI.
- cmf_niddk1.sas7bdat – This dataset contains 2520 observations from the Concomitant Medication Form (CMF). Data includes all medications being used by the participant.
- cutie_outcomes_manuscript.sas7bdat – This dataset contains 500 observations. It was created to run analysis for the primary study publication.
- diag_niddk1.sas7bdat – This dataset contains 1097 observations. Data includes recoded ICD diagnosis text descriptions and/or corrected ICD9 codes for each medical care visit form (MCA/MCN).
- dm_derv_niddk1.sas7bdat – This dataset contains 339 observations of adjudicated results from the DMSA Results Form (DMF).
- dsfa_niddk1.sas7bdat – This dataset contains 340 observations from the DMSA Sedation Form (DSF) and includes data about sedation usage during a participant's DMSA procedure and basic information about the DMSA imaging.
- dtfa_niddk1.sas7bdat – This dataset contains 68 observations from the DES (Dysfunctional Elimination Syndrome; Bladder and Bowel Dysfunction) Treatment Form (DTF). Data includes

DES treatment based on the DVQ form.

- dvqa_niddk1.sas7bdat – This dataset contains 204 observations from the Dysfunctional Voiding Questionnaire (DVQ). Data includes urine and bowel behaviors for participants who are toilet-trained.
- enr1_niddk1.sas7bdat – This dataset contains 195 observations. Data includes derived variables from the baseline, follow-up, and outcome data.
- fup_niddk1.sas7bdat – This dataset contains 2326 observations from the Protocol Scheduled Follow-up Contact Form (FUP). Data includes side effects/serious adverse events, medical care history, study medication status, interim voiding history, and interim bowel history for each scheduled follow-up contact.
- ict_niddk1.sas7bdat – This dataset contains 402 observations from the Informed Consent Tracking Form (ICT) and contains data about the initial level of consent for the use of study data, specimens, and medical records.
- liqa_niddk1.sas7bdat – This dataset contains 444 observations from the Life Impact Assessment Questionnaire (LIQ). Data includes the participant’s recent health and mood and the level of discomfort with symptoms and tests.
- mca_niddk1.sas7bdat – This dataset contains 682 observations from the Medical Care Abstraction Form (MCA) and includes data about a participant’s medical care visits.
- mcn_niddk1.sas7bdat – This dataset contains 682 observations from the Medical Care Notification Form (MCN) and includes data about a participant’s medical care reported/received since the last contact. Linked to the MCA dataset.
- pef_niddk1.sas7bdat – This dataset contains 629 observations from the Physical Exam Form (PEF). Data includes the results of a participant’s physical exam by a study physician.
- psl_niddk1.sas7bdat – This dataset contains 2355 observations from the Participant Screening Log (PSL) which documents the initial eligibility determination of patients screened as potential CUTIE participants.
- scfa_niddk1.sas7bdat – This dataset contains 356 observations from the Specimen Collection Form and contains data about the collection and shipping status of specimens.
- sens_long_index_niddk1.sas7bdat – This dataset contains 9968 observations. Data includes all antimicrobial sensitivity information from the sens_primary and sens_secondary datasets (multiple entries per Subject ID).
- sens_primary_index_niddk1.sas7bdat – This dataset contains 195 observations. Data includes all microbial sensitivity information for the primary UTI organism.
- sens_secondary_index_niddk1.sas7bdat - This dataset contains 195 observations. Data includes all microbial sensitivity information for the secondary UTI organism.

- ur_derv_niddk1.sas7bdat – This dataset contains 191 observations of the adjudicated results from the Ultrasound Results Form (URF).
- usr_derv_niddk1.sas7bdat – This dataset contains 685 observations. Data includes the results of the urinalysis and urine culture from the baseline and end-of-study visits as well as at any point during the study as reported on the Urine Specimen Results Form (USR).

CUTIE\ Data\Contents

- CUTIE DD final.pdf —Data dictionary and analysis file which contains variable listings, formats, and values from each dataset.
- proc contents for Outcome manuscript dataset.xlsx— SAS proc contents output for the variables in the SAS cutie_outcomes_manuscript data set.

DSIC

The CUTIE Data Integrity Check (DSIC) directory contains:

- A report of an examination of the CUTIE Outcomes Manuscript dataset for completeness by statisticians and quality control specialists at the Repository. This dataset was used to replicate Tables 1 and 2 in the paper “Risk Factors for Recurrent Urinary Tract Infection and Renal Scarring” published in *Pediatrics*, July 2015. Published results from the CUTIE data were compared to values recalculated from the CUTIE archived analysis datasets in the NIDDK repository.