

## **The RIVUR Study Data Archive**

The RIVUR 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 RIVUR Documents directory contains:

- RIVUR MOP.pdf – RIVUR protocol and manual of operations
- RIVUR Publications.docx – Bibliography of all study publications

### **Forms**

The RIVUR Forms directory contains the following:

- All Forms annotated.pdf – Annotated version of all forms used in the RIVUR protocol
- ALL QxQ.pdf – Question by question instructions for all forms used in the RIVUR protocol

## **RIVUR Data**

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

- ad\_derv\_niddk1.sas7bdat – This dataset contains 1,563 observations from the UTI Endpoints Classification and Adjudication Form (ADJ).
- aef\_niddk1.sas7bdat – This dataset contains 876 observations from the Adverse Events Form (AEF). Data includes all reported study medication side effects, adverse events, or serious adverse events
- bdfa\_niddk1.sas7bdat - This dataset contains 604 observations from the Baseline Demographic Form (BDF). Data includes demographic variables and socio-economic factor. Interview was completed during the Baseline visit.
- blind\_id\_niddk1.sas7bdat - This dataset contains 607 observations. It is the link between the subject ID and the blinded ID.
- bmha\_niddk1.sas7bdat - This dataset contains 605 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 607 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 2,450 observation from the Blood Specimen Results Form (BSR). Data includes laboratory results of the participant’s blood specimen.
- clrb\_niddk1.sas7bdat – This dataset contains 909 observations from the Central Lab Blood Results Form (CLR). Data includes laboratory results of the participant’s blood specimen, which include the levels of creatinine, cystatin-C, and high sensitivity c reactive protein (hs-CRP).
- cmf\_niddk1.sas7bdat – This dataset contains 7,584 observations from the Concomitant Medication Form (CMF). Data includes all medications being used by the participant including the RIVUR treatment.
- ddfa\_niddk1.sas7bdat – This dataset contains 102 observations from the Drug Discontinuation Form (DDF) and includes data about all temporary and permanent discontinuations for the study drug.
- derv\_niddk1.sas7bdat – This dataset contains 607 observations and contains derived, recoded, or adjusted variables from multiple forms
- diag\_niddk1.sas7bdat – This dataset contains 5,064 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 1,500 observations of adjudicated results from the DMSA Results Form (DMF).
- dsfa\_niddk1.sas7bdat – This dataset contains 1,512 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 223 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 630 observations from the Dysfunctional Voiding Questionnaire (DVQ). Data includes urine and bowel behaviors for participants who are toilet-trained.
- erf\_niddk1.sas7bdat – This dataset contains 607 observations from the Eligibility and Randomization Form (ERF) and contains data about the participants’ eligibility.
- exf\_niddk1.sas7bdat – This dataset contains 536 observations from the Exit Form (EXF). Data includes future VUR treatment plans.
- fup\_niddk1.sas7bdat – This dataset contains 7,047 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 1,043 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 1,581 observations from the Life Impact Assessment Questionnaire (LIQ). Data includes the participant’s recent health and mood, the parent’s quality of life in relation to the child’s VUR, and the child’s level of discomfort with symptoms and tests.
- mca\_niddk1.sas7bdat – This dataset contains 3,009 observations from the Medical Care Abstraction Form (MCA) and includes data about a participant’s medical care visits.
- mcn\_niddk1.sas7bdat – This dataset contains 3,009 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.
- mdd\_niddk1.sas7bdat – This dataset contains 2,069 observations from the Medication Dispensing and Dosing Form (MDD). Data includes the dosage and the bottle codes for the study medication given to the participant.
- mrfa\_niddk1.sas7bdat – This dataset contains 1,535 observations from the Medication Return

Form (MRF) and contains data about the return of the study drug.

- `outcomes_manuscript.sas7bdat` – This dataset contains 607 observations. It was created to run analysis for the Antimicrobial Prophylaxis for Children with Vesicoureteral Reflux manuscript which appears in The New England Journal of Medicine, June 19, 2014.
- `pef_niddk1.sas7bdat` – This dataset contains 2,499 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 10,756 observations from the Participant Screening Log (PSL) which documents the initial eligibility of patients.
- `rffa_niddk1.sas7bdat` – This dataset contains 65 observations from the RIVUR Hard to Reach Follow-up Form (RFF). This questionnaire form is mailed to the participant if the RIVUR staff cannot reach the participant after several attempts. Data is similar to the Follow-up Form (FUP).
- `rsr_derv_niddk1.sas7bdat` – This dataset contains 1,801 observations from the Rectal Swab Results Form (RSR) and contains the Central Rectal Swab Laboratory results of the participant’s rectal swab specimens.
- `scfa_niddk1.sas7bdat` – This dataset contains 2,543 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 18,368 observations. Data includes all antimicrobial sensitivity information from the `sens_primary` and `sens_secondary` datasets.
- `sens_primary_index_niddk1.sas7bdat` – This dataset contains 607 observations. Data includes all microbial sensitivity information for the primary UTI organism.
- `sens_secondary_index_niddk1.sas7bdat` - This dataset contains 607 observations. Data includes all microbial sensitivity information for the secondary UTI organism.
- `tffa_niddk1.sas7bdat` – This dataset contains 41 observations from the Treatment Failure Form (TFF). Data includes treatment failures.
- `ur_derv_niddk1.sas7bdat` – This dataset contains 608 observations of the adjudicated results from the Ultrasound Results Form (URF).
- `usr_derv_niddk1.sas7bdat` – This dataset contains 2,777 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).
- `vr_derv_niddk1.sas7bdat` – This dataset contains 1,058 observations of the adjudicated VCUg Results form (VRF).
- `vsfa_niddk1.sas7bdat` – This dataset contains 1,068 observations from the VCUg Sedation Form (VSF). Data includes sedation usage during a participant’s VCUg procedure.

## **RIVUR\Data\Contents**

- RIVUR Data Dictionary FINAL.pdf —Variable listing, formats, and values from each dataset.
- Proc contents for Outcomes manuscript dataset.xlsx— SAS proc contents output for the variables in the SAS Outcomes\_manuscript data set.

## **RIVUR DSIC**

The RIVUR Data Integrity Check (DSIC) directory contains:

- A report of an examination of the RIVUR Outcomes Manuscript dataset for completeness by statisticians and quality control specialists at the Repository. This dataset was used to replicate Tables 1 and 2 and Figure 3 in the paper “Antimicrobial Prophylaxis for Children with Vesicoureteral Reflux” published by The RIVUR Trial investigators in The New England Journal of Medicine, June 19, 2014. Published results from the RIVUR data were compared to values recalculated from the RIVUR archived analysis datasets in the NIDDK repository.