

Collaborative Pediatric Critical Care Research Network LAPSE Study Overview of Public Use Datasets

This document provides an overview of the general principles used in creating the public use datasets for the *Eunice Kennedy Shriver* National Institute for Child Health and Human Development Collaborative Pediatric Critical Care Research Network (CPCCRN) LAPSE Study. There are 29 data sets available as both CSV and SAS® (.SAS7BDAT) files (with formats and labels). Accompanying documentation and resources provided include the study protocol, the annotated CRF, and for each dataset a PDF document summarizing variables in the associated dataset (i.e., frequency distributions or descriptive statistics). For SAS software users, an example script to set up the SAS library and apply SAS formats is also provided. The annotated CRF should be referenced frequently during analysis, as this is the most complete reference of all variables included in each dataset. Please see the attached *CPCCRN LAPSE Research Data Use Agreement* for a description of intended use and disclaimer.

GENERAL PRINCIPLES FOR CREATION OF DATASETS

- The population for the public use dataset is all enrolled subjects, i.e eligible subjects with guardian consent.
- The datasets are primarily based on raw data as collected by the clinical sites, but to facilitate analyses we have included the following derived data sets in-lieu of the raw tables: DATSTATSURVEYS, MICROABSTRACTION, MICROORGANISMS, MEDICATIONS, DEVICES, and ENROLLEDSUBJECTS. Variable descriptions can be found in the annotated eCRF.
- Open text fields and other variables have been reviewed for sensitive or identifying information and modified as needed.
- All date variables are recoded to be number of days since date of screening (ScreenDate). 'Date' in variable names and labels are changed to 'Day' throughout. For example, the variable HospDisDate will be called HOSPDISDAY and the label will change from "Hospital discharge date" to "Hospital discharge day (relative to screening date)". No actual dates are included.
- Within each dataset, the PUDID is a masked identifier. The annotated CRF provides information as to the structure of each dataset and the unique identifier for each record.
- Functional assessments FSS, PCPC, POPC data sets were combined into one data set titled FSS. These assessments occurred on the day of PICU admission, seven calendar days post PICU admission if subject was still in the hospital on that day (Day 7), and twenty eight calendar days post PICU admission or hospital discharge whichever occurred first (Day 28/Hospital discharge).

LIST OF PUBLIC USE DATASETS AVAILABLE

- 1) (ASSENT) Assent information
- 2) (BASECLINICAL) Baseline clinical information

- 3) (BIOMARKER) Biomarker sample collection information
- 4) (CNS) Neurological insults that occurred.
- 5) (DATES) Hospital summary information
- 6) (DATSTATSURVEYS) Follow-up surveys assessing parent information and HRQL at study time points. These time points include Baseline (representing the month prior PICU admission), Day 7, Day 28, and Months 3, 6, and 12. All time points refer to time since PICU admission.
- 7) (DEMOG) Demographics
- 8) (DEVICES) Research coordinators (RCs) and parents listed devices the child was using at survey time points. The original data was open-text. A physician involved in the project standardized the device names.
- 9) (ELIGIBILITY_V2) Study eligibility criteria
- 10) (ENROLLEDSUBJECTS) Contains medical complexity algorithm categories as determined by ICD-10 codes and calculated by the project lead clinical site for each subject. ICU-10 codes are not included. Vital status at all study time points is also included.
- 11) (FLUID) 24-Hour total fluid volumes
- 12) (FSS) FSS, PCPC, POPC functional assessments at Day 0, Day 7, and Day 28/Hospital discharge whichever occurred first.
- 13) (INTERVENTIONS) Interventions and clinical findings
- 14) (LABS) Highest and lowest daily values from select laboratory results
- 15) (LABS_BONE) Daily bone marrow biopsy information
- 16) (LABS_COMMON) Daily common laboratory results
- 17) (LABS_GENO) Daily genotyping for perforin mutations
- 18) (LABS_NKCELLS) Daily natural killer cell activity information
- 19) (LABS_RARE) Daily rare laboratory results
- 20) (LABS_SCD) sCD25 laboratory result
- 21) (MEDICATIONS) Contains all antimicrobial, immune, and steroid medications given in-hospital up to 28 days post-ICU admission. Medications the subjects were on as reported by RCs and caregivers at study time points are also included.
- 22) (MICROABSTRACTIONS) Contains collection information for each microbiology sample including collection date, sample site, and test result.
- 23) (MICROORGANISMS) Organisms were abstracted from each microbiology sample report and are included in this dataset.
- 24) (PELOD) Pediatric Logistic Organ Dysfunction Score II
- 25) (PRISM) Pediatric Risk of Mortality Index, Version III
- 26) (RESPIRATORY) Respiratory parameter data
- 27) (VIS) Infused vasoactive medications closest to 8AM and 8PM
- 28) (VM) Vital measurements closest 8AM and 8PM
- 29) (WITHDRAWALOFCONSENT) Withdrawal of consent