Collaborative Pediatric Critical Care Research Network PHENOMS 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) PHENOMS Study. There are 22 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 PHENOMS Research Data Use Agreement V3* 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 permission.
- The datasets are primarily based on raw data as collected by the clinical sites. In addition, we have included a derived data set, STUDYLABS. Variable descriptions are 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.
- Forms capturing clinical data on onset of sepsis induced organ failure (Day 0) are combined with matching forms filled out on subsequent study days, e.g Day0Intervent and DailyIntervent data are combined to form the Intervent data set (see data sets indicated with an * below).

LIST OF PUBLIC USE DATASETS AVAILABLE

1) (ANTIMICROMEDS_ANTIMICROBIAL) Systemic antibiotic, antifugal and/or antiviral medications for Days 0-28 post onset of sepsis induced organ failure.
2) (ASSENT) Assent for study participation
3) (ATYPICALLABS) Indicates whether results from C-reative Protein (CRP), Ferritin or Free Hemoglobin tests were obtained on on study.
4) (ATYPICALLABS_CRP) Results from C-reative Protein (CRP), Ferritin or Free Hemoglobin.
5) (ATYPICALLABS_GENO) Results from Bone Marrow, Genotyping, Natural Killer Cells or sCD25.

6) (BASECLINICAL) Subject status at time of hospitalization.
7) (BIOSAMPLING) Indicates if IRB blood limits were reached or a parent sample was collected.
8) (BIOSAMPLING_BLOODDRAW) Study blood draw day and times for study subjects.
9) (CONTINUEDCONSENT) Consent for continued participatiion for subjects that turn 18 during the study.
10) (DATES) Hospital summary information.
11) (DIAGNOSES) Primary diagnosis information at ICU admission.
12) (DIAGNOSES_SECONDDX) Secondary diagnoses at ICU admission.
13) (ELIGIBILITY) Eligibility criteria at study screening.
14) (IMMUNEMEDS) Indicates if steroids immunosuppressive drugs, chemotherapy, and immune-modulating drugs were given on study.
15) (IMMUNEMEDS_IMMUNEMEDS) Steroids, immunosuppressive drugs, chemotherapy, and immune-modulating drugs given on study.
16) (*INTERVENT) ICU interventions and/or findings by study day.
17) (*LABS) Lowest/highest lab results by study day.
18) (MICROBIOLOGY_MICROBIOLOGY) Microbiology results from Day 0 - Day 28 or ICU discharge whichever occurred first. Microbiology results prior to Day 0 are included if relevant to the study-qualifying episode of infection.
19) (*ORGANFAIL) Organ failures by study day.
20) (PRISM) PRISM component values obtained in the following modified window: 2 hours prior to ICU admission through 4 hours post admission.
21) (STUDYLABS) Contains RBC lab results from study blood samples.
22) (WITHDRAWALOFCONSENT) Data documenting withdrawal of study participation.