Collaborative Pediatric Critical Care Research Network iNO 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) iNO Study. There are 26 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, a SAS format file is provided. The annotated CRF should be referenced frequently during analysis, as this is the most complete reference of all variables included in each dataset.

GENERAL PRINCIPLES FOR CREATION OF DATASETS

- The population for the public use dataset is all enrolled subjects with a 'Nitric Oxide Initiation Information' form.
- The datasets are primarily based on raw data as collected by the clinical sites. In addition, we have included two derived data sets, RESPONSIVENESS and FUNDAMENTALCARDIACDX. 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 iNO initiation (iNOStartDate). 'Date' in variable names and labels are changed to 'Day' throughout. For example, the variable ScreenDate will be called ScreenDay and the label will change from "Screening date" to "Screening day (relative to iNO initiation)". 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.

LIST OF PUBLIC USE DATASETS AVAILABLE

1) (DAILY) Day 1 - Day 28 or ICU discharge clinical information
2) (DAY0) Day 0 (iNO initiation to 2359) clinical information
3) (DAY28FSS) Function Status Scale on study day 28 or at ICU discharge
4) (DEMOGRAPHICS) Demographics
5) (DIAGNOSIS) Acute diagnosis information
6) (DIAGNOSIS_AHDX) Acquired heart disease
7) (DIAGNOSIS_CHDDX) Congential heart disease information
8) (DIAGNOSIS_CHRONICDX) Chronic diagnosis information
9) (ECHOABSTRACT_ECHO) Abstracted information from PI reviewed echocardiograms
10) (ELIGIBILITY) Study enrollment requirements
11) (FSS) Function Status Scale at time of ICU admission

12) (FUNDAMENTALCARIDIACDX) Fundamental cardiac diagnosis
13) (HOSPSUMMARY) Hospital summary information from admission to discharge
14) (INITIATION) Nitric oxide information at iNO initiation
15) (MECHVENT) Chronic mechanical ventilation
16) (MECHVENT_MECHVENTLOG) Mechanical ventilation intubations and extubations
17) (NITRICOXIDE_INOLOG) All iNO dose changes through 48 hours of study participation
18) (OR) Operating room admission
19) (OR_ORLOG) Operating room admission(s) start and stop day and times
20) (RESPIRATORY) Type of ventilation support just prior to iNO
21) (RESPIRATORY_ABGLOG) Artierial blood gases changes (the first 48 hours of iNO use)
22) (RESPIRATORY_HFOVLOG) High frequency oscillatory ventilation changes (the first 48 hours of iNO use)
23) (RESPIRATORY_PULSELOG) Pulse oximeter saturation (at top of every hour for first 48 hours of iNO use)
24) (RESPIRATORY_VENTLOG) Convential ventilation (the first 48 hours of iNO use)
25) (RESPONSIVENESS) Oxygenation improvement and clinician responsiveness to improvement
26) (TECHDEPEND) Technology dependence prior to hospitalization