CPCCRN PEACE
Overview of Public Use Datasets

This document provides an overview of the general principles used in creating the public use datasets for the CPCCRN PEACE Study. There are a total of 18 datasets 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, an HTML 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 PEACE Research Data Use Agreement V3 for a description of intended use and disclaimer.

GENERAL PRINCIPLES FOR CREATION OF DATASET

1. The population for the public use dataset is the 17 consented subjects. See the protocol for a detailed list of inclusion/exclusion criteria and for additional details of study conduct.

2. The datasets are primarily based on raw data as collected by the clinical sites. In addition, we have included pharmacokinetic results. All variables are described in the annotated CRF.

3. Open text fields and other variables have been reviewed for sensitive or identifying information and modified as needed. Dates were recoded to be the number of days since consent date.

4. 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. For datasets with multiple records per subject, PUDID and ItemGroupRepeatKey uniquely identify records.

LIST OF PUBLIC USE DATASETS AVAILABLE
- Indication for Cefepime (CEFEPIMEINDICATION)
- Diagnoses (DIAGNOSES)
- Chronic Diagnoses (DIAGNOSES_CHRONICDX)
- Pharmacokinetic Results (PK)
- Concomitant Medications (PKCONMEDS_CONMEDS)
- Demographics (PKDEMOG)
- ECMO Information (PKECMO)
- Daily Fluid Intake (PKFLUID_INTAKE)
- Daily Fluid Output (PKFLUID_OUTPUT)
- Renal and Hepatic Function Labs (PKLABS_LABS)
- Renal Replacement Therapy (PKRRT_RRTLOG)
- Antibiotic and PK Sampling (PKSAMPLE)
- Cefepime Administration (PKSAMPLE_ANTIBIOTIC)

- First PK Sampling Period Blood Product Transfusions (PKSAMPLE_BLOODONE)
- Second PK Sampling Period Blood Product Transfusions (PKSAMPLE_BLOODTWO)
- First PK Sampling Period Samples (PKSAMPLE_ONE)
- Second PK Sampling Period Samples (PKSAMPLE_TWO)
- Shipping Log (PKSHIP_SHIP)