

## **PECARN FLUID Trial**

### **Overview of Public Use Datasets**

This document provides an overview of the general principles used in creating the public use datasets for the PECARN FLUID trial. There are a total of 40 datasets available as both CSV and SAS® (.SAS7BDAT) files (with formats and labels). Accompanying documentation and resources provided include the study protocol, protocol summary, the annotated CRF, Manual of Operations (MOO), other essential documents, 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 Research Data Use Agreement (RDUA) for a description of intended use and disclaimer.

#### **GENERAL PRINCIPLES FOR CREATION OF DATASET**

1. The population for the public use dataset is all randomized subjects. See the protocol for a detailed list of inclusion/exclusion criteria and for additional details of study conduct.
2. The datasets are based on raw data as collected by the clinical sites.
3. Open text fields and other variables have been reviewed for sensitive or identifying information and modified as needed. Dates were modified to be the number of days since date of randomization.

#### **LIST OF PUBLIC USE DATASETS AVAILABLE**

##### **FLUID DKA study**

1. Adverse Event Log (AELog)
2. Caregiver Information (CaregiverInfo)
3. CBCL & Cognitive Testing Scores (Cbclcogn)
4. Cerebral Edema Adjudication (CEAdjud)
5. Cerebral Edema Treatment (CETreatment)
6. Concomitant Medication Log (ConMeds)
7. Demographics (Demog)
8. Diabetes History (DiabetesHist)
9. Diabetes History HbA1c (DiabetesHist\_HbA1c)
10. Discharge Data (Discharge)
11. Fluid Administration (FluidAdmin)
12. 3-Month Follow-up Status (FollowUp)
13. 3-Month Follow-up, Medical Treatment Details (FollowUp\_Medical)
14. 3-Month Follow-up Visit (FollowUpVisit)
15. GCS & Digit Span Log (GCSLog)
16. Digit Span Recall Log (GCSLog\_Digitspan)

17. GCS Log (GCSLog\_GCS)
18. Height and Type I or II Diabetes (HeightandType)
19. Imaging Reports (Imaging)
20. Randomized Patients Later Found to be Ineligible (Ineligibility)
21. Laboratory Data & Vital Signs Log (LabVital)
22. Blood Gases Log (LabVital\_BloodGas)
23. Blood Chemistry Log (LabVital\_Chemistry)
24. Electrolytes Log (LabVital\_Electrolyte)
25. Glucose Log (LabVital\_Glucose)
26. Vital Signs Log (LabVital\_VitalSign)
27. Memory Score Data (Memory)
28. NonDKA enrollments that were later enrolled in the DKA study (nonDKA)
29. Physical Examination (PhysExam)
30. Screening (Screening)
31. Physician Treatment Initiation (TrtInitiation)
32. Withdrawn Consent (Withdrawn)

### **Non-DKA Controls**

- 33.** Caregiver Information (ndkaCaregiver)
34. CBCL & Cognitive Testing Scores (ndkaCbclcogn)
35. Demographics (ndkaDemographics)
36. Diabetes History (ndkaDiabHx)
37. Diabetes History HbA1c (ndkaDiabHx\_HbA1c)
38. Memory Score Data (ndkaMemory)
39. Neurocognitive Testing (ndkaNeurocogn)
40. Screening (ndkaScreening)