

Public Use Dataset Annotated eCRF

Fluid Therapy and Cerebral Injury in Pediatric Diabetic Ketoacidosis (Fluid in DKA) PECARN Protocol 026

Pediatric Emergency Care Applied Research Network

Fluid Therapy in DKA Protocol Version: 4.00

Version Date: June 27, 2013

Memory in Diabetes Protocol Version: 1.00

Version Date: March 9, 2011

PUD Annotated eCRF Version 1.0

Version Date: February 28, 2020

Table of Contents

Annotations key:	4
Notes:	5
FLUID Demographics v1.0.....	6
FLUID Screening & Enrollment All Sites CURRENT v5.0.....	7
FLUID Ineligibility	13
FLUID Physician Treatment Initiation v1.0.....	16
FLUID Physical Examination v1.0.....	21
FLUID Diabetes History v1.0	26
FLUID HeightandType	28
FLUID Caregiver Information v1.0	29
FLUID GCS & Digit Span Log v1.0	32
FLUID Laboratory Data & Vital Signs Log v1.0.....	35
FLUID Fluid Administration v2.0	41
FLUID Discharge Data v1.0	42
FLUID Cerebral Edema Treatment Log v1.0	43
FLUID Imaging Reports v1.0	44
FLUID Concomitant Medication Log v1.0	45
FLUID Adverse Event Log v1.0	46
FLUID 3-Month Follow-up Status & History v1.0.....	48
FLUID 3-Month Follow-up Visit v1.0	51
FLUID CBCL & Cognitive Testing Scores v1.0	56
Memory.....	60
NonDKA.....	62
FLUID Withdrawn Consent v1.0.....	63
FLUID CE Adjudication v1.0	64
Non-DKA Demographics v1.0.....	65
Non-DKA Screening & Enrollment v1.0	66
Non-DKA Diabetes History Form v1.0	68
Non-DKA Caregiver Information v1.0.....	70
Non-DKA Neurocognitive Testing v1.0	73

Non-DKA CBCL & Cognitive Testing Scores v1.0	76
NDKAMemory	80

Annotations key:

Table name

Column name followed by: # or \$N
= numeric
\$N = character N = length

Format (name)
Code list

Calculated / Derived variable

Value not provided

Table name_Child table name

Variable in question group

Notes:

This dataset includes all enrolled (i.e. Randomized) DKA episodes and all patients enrolled (i.e. consented/permission given and testing performed) in the Non-DKA control cohort.

PUDID is a randomly generated ID number that uniquely identifies enrollment DKA episodes and Non-DKA controls across datasets. It does not contain information about original site or medical record number. Occurrence and ItemGroupRepeatKey are identifiers used to identify repeating forms and repeating questions within a form (e.g. adverse events in an adverse event log). PUDID, Occurrence, and ItemGroupRepeatKey are unique identifiers in all datasets and are not annotated on most forms.

The study protocol allowed patients to enroll twice for DKA. Use PrevSubjectID on the screening form to identify and link repeat enrollers. Some Non-DKA controls were later enrolled as DKA cases; use NonDKAID on the NonDKA form to identify those patients.

A StudyEvent variable is included in many datasets. StudyEvent was used to clarify data-entry workflow and is included for your information. StudyEvent is a dataset-level character variable; all rows in a dataset have the same value, and this variable is not annotated on most forms.

Date variables are replaced with the number of days after randomization; 0 indicates the same day as randomization and negative days indicates days prior to randomization. Times are unchanged, and are character variables formatted as HHMM.

Open text fields were reviewed and any sensitive or identifying information redacted.

This dataset contains raw study data and will require cleaning and outcome derivation.

FLUID Annotated eCRF

Demog (1 of 1)

FLUID Demographics v1.0

Demogra...(0/4) -- Select to Jump --

Title: Demographics

Instructions: This form is to be completed for all patients entered into OpenClinica, i.e. Enrolled, Not Enrolled, and Missed Eligibles. Answer all questions. ONLY if your IRB does not allow you to enter Date of Birth on Not Enrolled, you may leave it blank. If Race and Ethnicity cannot be found in the medical record, select Unknown.

Date of Birth: Value not provided (DD-MMM-YYYY)

Sex: Sex, INT

Race: American Indian or Alaska Native (select all that apply)
 Asian
 Black or African American
 Native Hawaiian or Other Pacific Islander
 White
 Unknown

Ethnicity: Ethnicity, INT

Sex
1 = Male
2 = Female

Race1, INT (American Indian or Alaska Native)
 Race2, INT (Asian)
 Race3, INT (Black or African American)
 Race4, INT (Native Hawaiian or Other Pacific Islander)
 Race5, INT (White)
 Race92, INT (Unknown or Not Reported)

Ethnic
1 = Hispanic or Latino
2 = Not Hispanic or Latino
92 = Unknown

YN
1 = Yes
0 = No

Variable	Format	Type	Label	Algorithm / Notes
AgeInYears		REAL	Age in years	Calculated as the difference in years between Date of birth and ScreenDay (Screening Form). Continuous variable, so that 12 years and 1 day is 12.003.

FLUID Screening & Enrollment All Sites CURRENT v5.0

◀ **Screeni...(0/3)** Eligibi...(0/13) Permiss...(0/6) ▶ -- Select to Jump -- ▾

Title: Screening Date & Time

Instructions:
Answer all questions on this tab. If Screening Date and/or Time is left blank on paper worksheet, use best estimate based on ED Evaluation Time and enrolling physician consultation (see MOO for details)..

Screening Date and Time

Date: * DD-MMM-YYYY Time: * HHMM

Patient's Total GCS at time of ED Evaluation

* (3-15)

FLUID Annotated eCRF

Screening_v4 (2 of 6)

Screeni...(0/3) Eligibi...(0/13) Permiss...(0/6) -- Select to Jump --

Title: Inclusion & Exclusion Criteria

Instructions:
Answer each inclusion and exclusion criteria. In order to be entered as a patient in this study, each Inclusion Criteria should be answered Yes. If any Exclusion Criteria are met, i.e. answered Yes, data entry on the remaining sections of the form should be skipped.

Inclusion Criteria

1. Is patient less than 18 years of age?
 Yes No * Inclusion1, INT

2. Does patient have a diagnosis of DKA?
 Yes No * Inclusion2, INT

3. Is patient's serum glucose or finger stick glucose concentration > 300 mg/dL?
 Yes No * Inclusion3, INT

4. Is patient's venous pH < 7.25 or serum bicarbonate concentration < 15 mmol/L?
 Yes No * Inclusion4, INT

YN
1 = Yes
0 = No

Exclusion Criteria

1. Does patient have a pre-existing neurological disease that substantially impacts mental status or neurocognitive exam (e.g. cerebral palsy with developmental delay or autism)?

Yes No *

Exclusion1, INT

2. Does patient present with concomitant alcohol or drug use, head trauma, meningitis or other conditions which might affect neurological function?

Yes No *

Exclusion2, INT

3. Has patient been transferred after initiation of DKA treatment more than one 10 mL/kg intravenous bolus?

Yes No *

Exclusion3, INT

4. Is patient known to be pregnant?

Yes No *

Exclusion4, INT

5. Has patient been enrolled in this study twice previously? (per parent/patient recollection)

Yes No *

Exclusion5, INT

6. Has patient been receiving IV fluids at a maintenance rate or greater for more than two hours prior to arrival at the study center hospital? (maintenance per the 4-2-1 rule)

Yes No *

Exclusion6, INT

7. Has it been more than four hours since patient started DKA therapy prior to arrival at the study center hospital (IV fluids, bolus, or insulin)?

Yes No *

Exclusion7, INT

8. Has the patient been given hyperosmolar therapy (i.e. mannitol or 3% normal saline) prior to or since arriving at your site?

Yes No *

Exclusion9, INT

9. Does the treating physician intend to immediately administer hyperosmolar therapy (i.e. mannitol or 3% normal saline) to the patient?

Yes No *

Exclusion10, INT

10. Is the patient's baseline GCS 11 or less?

Yes No *

Exclusion11, INT

Is patient eligible to be approached for participation in this study?

Yes No *

Eligible, INT

YN
1 = Yes
0 = No

FLUID Annotated eCRF

Screening_v4 (4 of 6)

Eligibi...(0/12) **Permiss...(0/6)** Final C...(0/2) -- Select to Jump --

Title: Parental Permission

Instructions:
Answer whether parent/guardian was approached and if applicable, whether permission was given. If the answer to either of these questions is No, data entry on the remaining sections of the form should be skipped.

If eligible, was parent/guardian approached for permission?

Approached, INT If No, enter the reason below, then STOP (skip rest of the form).

If not approached, provide reason: Value not provided

If "Other", please describe: Value not provided STOP (skip rest of the form).

If parent/guardian was approached, was permission given?

Permission, INT If No, STOP (skip rest of the form).

Permission Signed Date and Time

Date: PermissionDay, INT DD-MMM-YYYY Time: PermissionTime, ST HHMM

YesNo
1 = Yes
0 = No

FLUID Annotated eCRF

Screening_v4 (5 of 6)

◀ Permiss...(0/6) Final C...(0/2) Randomi...(0/8) ▶ -- Select to Jump -- ▾

Title: Final Eligibility Re-check

Instructions:
Answer both questions. If the answer to either of these questions is No, data entry on the remaining section of the form should be skipped because patient is no longer eligible for the study.

Was informed consent (parental permission) obtained within 2 hours of IV fluid initiation (of maintenance rate or greater)?

Recheck1, INT

Was informed consent (parental permission) obtained within 4 hours of DKA treatment initiation (IV bolus, IV insulin, IV fluids)?

Recheck2, INT

YesNo
1 = Yes
0 = No

FLUID Annotated eCRF

Screening_v4 (6 of 6)

← **Permiss...(4/6)** **Final C...(2/2)** **Randomi...(7/8)** ▶ -- Select to Jump -- ▾

Title: Randomization

If parental permission given, was the patient randomized?

YesNo
1 = Yes
0 = No

Randomized, INT If No, enter the reason below.

If not randomized, explain: STOP (skip rest of the form).

Randomization Number (##-####)

Treatment Arm

RxGroup, INT

RxGroup
1 = A1:Additional bolus of 10 ml/kg; 0.45% NS for assumed 10% body weight deficit
2 = A2:Additional bolus of 10 ml/kg; 0.9% NS for assumed 10% body weight deficit
3 = B1:No additional bolus; 0.45% NS for assumed 5% body weight deficit
4 = B2:No additional bolus; 0.9% NS for assumed 5% body weight deficit

Randomization Date and Time

Date: **RandDay, INT** DD-MMM-YYYY Time: **RandTime, ST** HHMM

Has this patient been enrolled in this study previously?

PrevEnrolled, INT If Yes, enter previous Study Subject ID and patient's date of birth.

If yes, what was the patient's previous Study Subject ID?

PrevSubjectID, INT (5 or 6 digit OpenClinica Study Subject ID)

YesNo
1 = Yes
0 = No

FLUID Ineligibility

Variable	Format	Type	Label	Algorithm / Notes
StudyEvent		ST	StudyEvent	
IneligibleInclusion1	YNR 1=Yes 0=No	INT	Is patient less than 18 years of age?	
IneligibleInclusion2	YNR 1=Yes 0=No	INT	Does patient have a diagnosis of DKA?	
IneligibleInclusion3	YNR 1=Yes 0=No	INT	Is patient's serum glucose or finger stick glucose concentration > 300 mg/dL?	
IneligibleInclusion4	YNR 1=Yes 0=No	INT	Is patient's venous pH < 7.25 or serum bicarbonate concentration < 15 mmol/L?	
IneligibleExclusion1	YNR 1=Yes 0=No	INT	Does patient have a pre-existing neurological disease that substantially impacts mental status or neurocognitive exam?	
IneligibleExclusion2	YNR 1=Yes 0=No	INT	Does patient present with concomitant alcohol or drug use, head trauma, meningitis or other conditions which might affect neurological function?	

FLUID Annotated eCRF

IneligibleExclusion3	YNR 1=Yes 0=No	INT	Has patient been transferred after initiation of DKA treatment more than one 10 mL/kg intravenous bolus?	
IneligibleExclusion4	YNR 1=Yes 0=No	INT	Is patient known to be pregnant?	
IneligibleExclusion5	YNR 1=Yes 0=No	INT	Has patient been enrolled in this study twice previously?	
IneligibleExclusion6	YNR 1=Yes 0=No	INT	Has patient been receiving IV fluids at a maintenance rate or greater for more than two hours prior to arrival at the study center hospital?	
IneligibleExclusion7	YNR 1=Yes 0=No	INT	Has it been more than four hours since patient started DKA therapy prior to arrival at the study center hospital?	
IneligibleExclusion9	YNR 1=Yes 0=No	INT	Has the patient been given hyperosmolar therapy (i.e. mannitol or 3% normal saline) prior to or since arriving at your site?	

FLUID Annotated eCRF

IneligibleExclusion10	YNR 1=Yes 0=No	INT	Does the treating physician intend to immediately administer hyperosmolar therapy (i.e. mannitol or 3% normal saline) to the patient?	
IneligibleExclusion11	YNR 1=Yes 0=No	INT	Is the patient's baseline GCS 11 or less?	
INELIGIBLEDAY		INT	Day ineligibility discovered (relative to randomization)	

TrtInitiation (1 of 5)

FLUID Physician Treatment Initiation v1.0

MD Eval (9/9) Weight (3/3) Pre Bol...(4/4) -- Select to Jump --

Title: ED Physician Evaluation

Instructions:
Answer all bolded questions and the non-bolded questions when applicable. If the Enrolling Physician did not answer a clinical evaluation question and attempts to find the answer are unsuccessful, Not Documented may be selected.

ED Evaluation Date and Time

Date: DD-MMM-YYYY Time: HHMM

Did patient complain of headache at ED presentation?

*

If Yes, indicate headache severity:

Were patient's peripheral pulses evaluated at ED presentation?

*

If Yes, indicate assessment:

Was patient's capillary refill evaluated at ED presentation?

*

If Yes, indicate refill time:

Has patient been previously diagnosed with diabetes?

If Yes, enter Diabetes History CRF.

HeadSev
1 = Mild
2 = Moderate
3 = Severe
92 = Unknown
94 = Not Documented

PeriPuls
1 = Bounding
2 = Increased
3 = Normal
4 = Weak
5 = Absent or Nonpalpable
94 = Not Documented

RefillTm
1 = < 2 seconds
2 = 2 - 5 seconds
3 = > 5 seconds
94 = Not

YesNoND
1 = Yes
0 = No
94 = Not Documented

YesNo
1 = Yes
0 = No

FLUID Annotated eCRF

TrtInitiation (2 of 5)

MD Eval (9/9) Weight (3/3) Pre Bol...(4/4) -- Select to Jump --

Title: Study Starting Weight

Instructions:
Record the actual weight (done in pjs or gown, no shoes) in kilograms used for the study fluid rate calculations. This should not be an estimated weight. Weights may be entered using up to 2 decimal places and should be between 0.00 and 100.00 kg, as any weight above 100 kgs should be recorded as 100.

What is the patient's actual weight (in kilograms)?

Weight: (kg)

Actual Weight Date and Time

Date: DD-MMM-YYYY Time: HHMM

FLUID Annotated eCRF

TrtInitiation (3 of 5)

◀ **Weight (3/3)** **Pre Bol...(4/4)** **Post Bo...(4/4)** ▶ -- Select to Jump -- ▾

Title: Pre-Randomization Fluid Bolus

Instructions:
Answer all bolded questions and the non-bolded questions when applicable. These questions pertain to any boluses received prior to randomization. If no boluses received prior to randomization, answer No and skip to the next tab.

Did patient receive any IV fluid boluses BEFORE randomization? (> 10 ml/kg over one hour or less)

IVBolus, INT * If No, skip to next section tab. **YesNo**
1 = Yes
0 = No

If any IV bolus received, what was the total amount received?

IVBolusAmt, INT (ml/kg)

Initial IV Bolus Date and Time

Date: **IVBolusDay, INT** DD-MMM-YYYY Time: **IVBolusTime, ST** HHMM

FLUID Annotated eCRF

TrttInitiation (4 of 5)

Pre Bol...(4/4) Post Bo...(4/4) Fluid C...(3/3) -- Select to Jump --

Title: Post-Randomization Fluid Bolus

Instructions:
Answer all bolded questions and the non-bolded questions when applicable. These questions pertain to any boluses received after randomization. If no boluses received after randomization, answer No and skip to the next tab.

Did patient receive additional IV bolus AFTER randomization (including that received as part of treatment arms A1 or A2)?

AddIVBolus, INT * If No, skip to next section tab.

If additional IV bolus received, what was the total amount received?

AddIVBolusAmt, INT (ml/kg)

Additional IV Bolus Date and Time

Date: AddIVBolusDay, INT DD-MMM-YYYY Time: AddIVBolusTime, ST HHMM

YesNo
1 = Yes
0 = No

FLUID Annotated eCRF

TrttInitiation (5 of 5)

◀ Pre Bol...(4/4) Post Bo...(4/4) **Fluid C...(3/3)** ▶ -- Select to Jump -- ▼

Title: Fluid Replacement Calculations

Instructions:
Enter the IV fluid rate(s) for EITHER Arm A or Arm B (whichever patient was assigned to), but not both Arms. If Arm A was assigned, enter both the First 12 Hour Rate and the Following 24 Hour Rate, skipping the Treatment Arm B rate. If Arm B was assigned, leave Treatment Arm A rates blank and enter Arm B 48 Hour Fluid Rate.

Treatment Arm A

First 12 Hour IV Fluid Rate: (ml/hr)

Following 24 Hour IV Fluid Rate: (ml/hr)

Treatment Arm B

48 Hour IV Fluid Rate: (ml/hr)

FLUID Annotated eCRF

PhysExam (1 of 5)

FLUID Physical Examination v1.0

Body Sy...(0/34) -- Select to Jump --

Title: Body System/Site

Instructions:
For each system, an answer of either Normal, Abnormal or Unknown is required. In addition to if the physician selected Unknown, this choice can be selected if physician did not answer the question and a thorough review of medical record does not find documentation of that particular body system history. If "Abnormal" is selected for any system, a description must be provided. This form may be updated to included medical conditions discovered during hospitalization that are reflective of the patient's baseline (prior to randomization).

Review Date and Time

Date: DD-MMM-YYYY Time: HHMM

HEENT Review

HEENT: Description: (Required if Abnormal)

Cardiovascular Review

Cardiovascular: Description: (Required if Abnormal)

Respiratory/Pulmonary Review

Respiratory/Pulmonary: Description: (Required if Abnormal)

PEExam
1 = Normal
2 = Abnormal
99 = Not Assessed

FLUID Annotated eCRF

PhysExam (2 of 5)

Gastrointestinal Review		
Gastrointestinal:	PEGI, INT	Description: PEGIDesc, ST (Required if Abnormal)
Hepatic Review		
Hepatic:	PEHepatic, INT	Description: PEHepaticDesc, ST (Required if Abnormal)
Genitourinary Review		
Neurologic:	PEGU, INT	Description: PEGUDesc, ST (Required if Abnormal)
Renal Review		
Renal:	PERenal, INT	Description: PERenalDesc, ST (Required if Abnormal)

PEExam
1 = Normal
2 = Abnormal
99 = Not Assessed

FLUID Annotated eCRF

PhysExam (3 of 5)

Neurologic Review		
Neurologic:	PENeuro, INT	Description: PENEuroDesc, ST (Required if Abnormal)
Psychiatric/Behavioral Review		
Psychiatric/Behavioral:	PEPsych, INT	Description: PEPsychDesc, ST (Required if Abnormal)
Endocrine Review		
Endocrine:	PEEndo, INT	Description: PEEndoDesc, ST (Required if Abnormal)
Hematologic Review		
Hematologic:	PEHema, INT	Description: PEHemaDesc, ST (Required if Abnormal)

PEExam
1 = Normal
2 = Abnormal
99 = Not Assessed

FLUID Annotated eCRF

PhysExam (4 of 5)

Musculoskeletal Review		
Musculoskeletal:	PEMusculo, INT	Description: PEMusculoDesc, ST (Required if Abnormal)
Dermatologic Review		
Dermatologic:	PEDerm, INT	Description: PEDermDesc, ST (Required if Abnormal)
Allergies Review		
Allergies:	PEAllergies, INT	Description: PEAllergiesDesc, ST (Required if Abnormal)

PEExam
1 = Normal
2 = Abnormal
99 = Not Assessed

FLUID Annotated eCRF

PhysExam (5 of 5)

Immunology Review	
Immunology: PEImmune, INT	Description: PEImmuneDesc, ST (Required if Abnormal)
Alcohol/Drug Abuse Review	
Alcohol/Drug Abuse: PEAlcohol, INT	Description: PEAlcoholDesc, ST (Required if Abnormal)

PEExam
1 = Normal
2 = Abnormal
99 = Not Assessed

FLUID Diabetes History v1.0

Diabete...(0/5) HbA1c (0/3) -- Select to Jump --

Title: Diabetes History

Instructions:
This form is only required for patients who have been previously diagnosed with diabetes (i.e. answer on Physician Treatment Initiation Form to question "Has patient been previously diagnosed with diabetes?" is Yes). Answer all bolded questions and the non-bolded questions when applicable.

What was the year of patient's first diabetes diagnosis?

Value not provided (YYYY)

Has patient ever had a severe hypoglycemic episode with loss of consciousness or seizures?

HypoEpisode, INT

If Yes, indicate the number of severe hypoglycemic episodes:

HypoEpisodeNum, INT

Has patient ever been previously diagnosed with diabetic ketoacidosis (DKA)?

DKADx, INT

If Yes, indicate the number of times patient has been previously diagnosed with DKA:

DKADxNum, INT

Episodes
1 = 1-2
2 = >2
93 = Unable to Determine

YesNoUD
1 = Yes
0 = No
93 = Unable to Determine

Variable	Format	Type	Label	Algorithm / Notes
AgeAtOnset		INT	Age at Onset	Calculated as the difference in years, rounded down, between DOB and either screening day (for new onsets) or July 1, of the year of patient's first diabetes diagnosis.

FLUID Annotated eCRF

Diabete...(0/5) HbA1c (0/3) -- Select to Jump -- DiabetesHist (2 of 2)

Title: HbA1c

Instructions:
At least one HbA1c lab result should be obtained. Wait to mark the form Complete until after at least one HbA1c lab result has been recorded.

Does the patient receive regular diabetes care within your hospital system?

SystemProvider, INT YesNo
1 = Yes
0 = No

HbA1c 12 Month History
Instructions: *ONLY enter HbA1c lab results within the past 12 months.

HbA1c Date (DD-MMM-YYYY)	HbA1c Level	
HbA1cDay, INT	HbA1c, REAL (%)	X

ADD

DiabetesHist_HBA1C

HeightAndtype (1 of 1)

FLUID HeightandType

Variable	Format	Type	Label	Algorithm / Notes
Heightincm		REAL	Height (cm)	
Diagnosis		ST	Type II DM Diagnosis	Yes, No, Unable to determine.

CaregiverInfo (1 of 3)

FLUID Caregiver Information v1.0

-- Select to Jump --

Title: Caregiver-CBCL Respondent

Instructions:
 This information pertains to the caregiver who completes the CBCL, referred to in the study worksheets as "Caregiver A". Choose Not Provided for any question left blank by the caregiver(s). The completed de-identified CBCL should be uploaded on this tab.

Caregiver's sex:

CareSex, INT Sex
1 = Male
2 = Female

Caregiver's relationship to the patient:

CareRelationship, INT If other, describe: Value not provided

Caregiver's highest education received:

CareEducation, INT CareEdu
1 = No education
2 = Some high school or less
3 = High school graduate or GED
4 = Vocational school or some college
5 = College degree
6 = Master's or doctoral degree
97 = Not Provided

Child Behavior Checklist

Was CBCL completed by this parent? CBCL, INT If Yes, upload here--> Upload: Value not provided Click to upload file Before uploading, remove patient and family PHI and replace with Study Subject ID.

CareRel
1 = Biological parent
2 = Adoptive parent
3 = Step parent
4 = Foster parent
5 = Grandparent
6 = Other legal guardian
90 = Other (specify)
97 = Not Provided

YesNo
1 = Yes
0 = No

FLUID Annotated eCRF

CaregiverInfo (2 of 3)

FLUID Caregiver Information v1.0

Title: Caregiver-Additional Caregiver

Instructions:
This information pertains to an additional caregiver (if available), referred to in the study worksheets as "Caregiver B". Choose Not Provided for any question left blank by the caregiver(s).

Was Additional Caregiver data available?

AddCareAvailable, INT YesNo
1 = Yes
0 = No

Caregiver's sex:

AddCareSex, INT Sex
1 = Male
2 = Female

Caregiver's relationship to the patient:

AddCareRelationship, INT If other, describe: Value not provided

Caregiver's highest education received:

AddCareEducation, INT

CareRel

- 1 = Biological parent
- 2 = Adoptive parent
- 3 = Step parent
- 4 = Foster parent
- 5 = Grandparent
- 6 = Other legal guardian
- 90 = Other (specify)
- 97 = Not Provided

CareEdu

- 1 = No education
- 2 = Some high school or less
- 3 = High school graduate or GED
- 4 = Vocational school or some college
- 5 = College degree
- 6 = Master's or doctoral degree
- 97 = Not Provided

FLUID Caregiver Information v1.0

◀ CBCL Re...(6/6) Additio...(5/5) **Income (1/1)** ▶ -- Select to Jump -- ▼

Title: Household Income

Instructions:
This answer should reflect the entire household's income where the patient lives most of the time. Choose Not Provided if this question is left blank by the caregiver(s).

What is the annual household income of the patient's family?

HouseholdIncome, INT

- Income
- 1 = Less than \$20,000
 - 2 = \$20,000 to \$39,999
 - 3 = \$40,000 to \$59,999
 - 4 = \$60,000 to \$79,999
 - 5 = \$80,000 to \$99,999
 - 6 = \$100,000 to \$119,999
 - 7 = \$120,000 to \$149,999
 - 8 = \$150,000 to \$199,999
 - 9 = \$200,000 or more
 - 97 = Not Provided

FLUID GCS & Digit Span Log v1.0

◀ Hour 12...(3/3) GCS (45/46) Digit S...(12/17) ▶ -- Select to Jump -- ▼


Title: Hour 12 Weight

Instructions:
Record the actual weight (done in pjs or gown, no shoes) in kilograms measured at Study Hour 12. This should not be an estimated weight.

Study Hour 12 Weight

Weight: (kg)

Study Hour 12 Weight Date and Time

Date:  DD-MMM-YYYY Time: HHMM

FLUID Annotated eCRF

GCSLog (2 of 3)

FLUID GCS & Digit Span Log v1.0

Hour 12...(3/3) GCS (45/46) Digit S...(12/17) -- Select to Jump --

Title: GCS Log

Instructions:
Upload the GCS Log and record all GCS scores obtained (every hour).

GCS Log Upload

Upload GCS Log Before uploading, remove patient PHI and replace with Study Subject ID.

GCS

Date (DD-MMM-YYYY)	Time (HHMM)	GCS Total Score	
<input type="text" value="GCSDay, INT"/> <input type="button" value="Calendar"/>	<input type="text" value="GCSTime, ST"/>	<input type="text" value="GCSTotal, INT"/> (3-15)	<input type="button" value="X"/>
<input type="button" value="ADD"/> <input type="text" value="GCSLog_GCS"/>			

FLUID Annotated eCRF

GCSLog (3 of 3)

FLUID GCS & Digit Span Log v1.0

Hour 12...(3/3) GCS (45/46) Digit S...(12/17) -- Select to Jump --

Title: Digit Span Log

Instructions:
Digit Span testing is only to be done on patients 3 years of age and older at the time of testing. For these patients, upload the Digit Span packets and record all scores obtained (every four hours).
IMPORTANT NOTE: DO NOT MARK THE FORM COMPLETE UNTIL ALL GCS AND DIGIT SPAN SCORES HAVE BEEN RECORDED ON THIS FORM.

Digit Span Recall Packet Upload

Upload Digit Span Packet Before uploading, remove patient PHI and replace with Study Subject ID.

Digit Span Recall

Date (DD-MMM-YYYY)	Time (HHMM)	Total Score Forward	Total Score Backward	
<input type="text" value="RecallDay, INT"/> <input type="button" value="Calendar"/>	<input type="text" value="RecallTime, ST"/>	<input type="text" value="RecallForward, INT"/> (0-16)	<input type="text" value="RecallBackward, INT"/> (0-16)	<input type="button" value="X"/>

FLUID Laboratory Data & Vital Signs Log v1.0

-- Select to Jump --

Title: Ketones

Instructions:
 For the first ketone test done, record whether or not it was a positive and, if applicable, the date and time of the positive ketone test.
 The Ketone Test Date and Time should be the date and time of the first ketone test done (in the ED or hospital).

Was the patient positive for ketones (by any test, blood or urine)?

If Yes, Ketone Test Date and Time

Date:
 Time:

Ketones

1 = Yes

0 = No

95 = Not Done

FLUID Annotated eCRF

LabVital (2 of 6)

FLUID Laboratory Data & Vital Signs Log v1.0

◀ Ketones (0/3) **Glucose (0/3)** Vital S...(0/6) ▶ -- Select to Jump -- ▾

Title: Glucose Log

Instructions:
Enter all glucose values obtained through hospital discharge (even if this is after IV insulin has been discontinued, or after the 24 hour study period).
Record a glucose every hour. If both serum and point-of-care glucose values are available from the same date and time, enter the lab serum result as the study-preferred result.
If the only result at that date and time is from a point-of-care test and it is a value, it can be recorded. However, if the result is not an actual value, but rather reads "HIGH", for example, don't enter a record for this measurement, i.e. no date, time, or value.

Date (DD-MMM-YYYY)	Time (HHMM)	Glucose	
GlucoseDay, INT <input type="text"/> <input type="text"/>	GlucoseTime, ST <input type="text"/>	Glucose, INT <input type="text"/> (mg/dL)	X
ADD			
LabVital_Glucose			

FLUID Annotated eCRF

LabVital (3 of 6)

FLUID Laboratory Data & Vital Signs Log v1.0

Navigation: Glucose (0/3) Vital S...(0/6) Electro...(0/8) -- Select to Jump --

Title: Vital Signs Log

Instructions:
Enter all vital signs obtained during the 24 hour study period only.
For a set vital signs obtained in the same evaluation, enter all of the obtained values on a single row with the same date and time.
Any vital signs not evaluated or not available at that time, should be left blank on that row.
Add a new row for each hourly evaluation where vital signs were obtained.

Date (DD-MMM-YYYY)	Time (HHMM)	Systolic Blood Pressure	Diastolic Blood Pressure	Respiratory Rate	Heart Rate
VitalDay, INT	VitalTime, ST	SBP, INT (mm Hg)	DBP, INT (mm Hg)	RR, INT (breaths/min)	HR, INT (beats/min)

LabVital_VitalSign

FLUID Annotated eCRF

LabVital (4 of 6)

FLUID Laboratory Data & Vital Signs Log v1.0

Vital S...(0/6)
Electro...(0/8)
Ca,Mg,P (0/5)
-- Select to Jump --

Title: Serum Electrolytes Log

Instructions:
 Enter all electrolyte values obtained through hospital discharge (even if this is after IV insulin has been discontinued, or after the 24 hour study period).
 For a set of lab results obtained from the same sample/evaluation, enter all of the obtained values on a single row with the same date and time.
 Any lab values not obtained or not available from that sample/evaluation, should be left blank on that row.
 Add a new row for each set of lab results.

Date (DD-MMM-YYYY)	Time (HHMM)	Sodium	Potassium
ElectrolyteDay, INT <input type="text"/>	ElectrolyteTime, ST <input type="text"/>	SerumNa, INT <input type="text"/> (mEq/L)	SerumK, REAL <input type="text"/> (mEq/L)
Chloride	Bicarbonate	BUN	Creatinine
SerumCl, INT <input type="text"/> (mEq/L)	SerumBicarb, INT <input type="text"/> (mEq/L)	SerumUrea, INT <input type="text"/> (mg/dL)	SerumCreat, REAL <input type="text"/> (mg/dL) <input type="button" value="X"/>

LabVital_Electrolyte

FLUID Annotated eCRF

LabVital (5 of 6)

FLUID Laboratory Data & Vital Signs Log v1.0

Electro...(0/8) Ca,Mg,P (0/5) Blood G...(0/5) -- Select to Jump --

Title: Serum Ca,Mg,P Log

Instructions:
Enter all calcium, magnesium and phosphate values obtained through hospital discharge (even if this is after IV insulin has been discontinued, or after the 24 hour study period).
For a set of lab results obtained from the same sample/evaluation, enter all of the obtained values on a single row with the same date and time.
Any lab values not obtained or not available from that sample/evaluation, should be left blank on that row.
Add a new row for each set of lab results.

Date (DD-MMM-YYYY)	Time (HHMM)	Serum Calcium	Serum Magnesium	Serum Phosphate	
ChemistryDay, INT <input type="text"/>	ChemistryTime, ST <input type="text"/>	SerumCa, REAL <input type="text"/> (mg/dL)	SerumMg, REAL <input type="text"/> (mEq/L)	SerumPhos, REAL <input type="text"/> (mg/dL)	<input type="button" value="X"/>
<input type="button" value="ADD"/>					
LabVital_Chemistry					

FLUID Annotated eCRF

LabVital (6 of 6)

FLUID Laboratory Data & Vital Signs Log v1.0

Electro...(0/8) Ca,Mg,P (0/5) Blood G...(0/5) -- Select to Jump --

Title: Blood Gases Log

Instructions:
Enter blood gas values obtained through hospital discharge (even if this is after IV insulin has been discontinued, or after the 24 hour study period), as well as the route the sample was obtained.
For a set of lab results obtained from the same sample/evaluation, enter all of the obtained values on a single row with the same date and time.
Any lab values not obtained or not available from that sample/evaluation, should be left blank on that row.
Add a new row for each set of lab results.
IMPORTANT NOTE: DO NOT MARK THE FORM COMPLETE UNTIL ALL LABORATORY AND VITAL SIGN DATA HAVE BEEN RECORDED ON THIS FORM.

Date (DD-MMM-YYYY)	Time (HHMM)	pH	pCO2	Route
BloodGasDay, INT <input type="text"/>	BloodGasTime, ST <input type="text"/>	pH, REAL <input type="text"/>	CO2, INT <input type="text"/> (mm Hg)	BloodGasRoute, INT <input type="text"/>
ADD				
LabVital_BloodGas				

Route
1 = Venous
2 = Arterial

FLUID Annotated eCRF

FluidAdmin (1 of 1)

FLUID Fluid Administration v2.0

Fluid A...(0/18) -- Select to Jump --

Title: Fluid Administration

Instructions:
 Enter the date and time the first IV fluid began on the patient (either at an outside or PECARN hospital) as the IV Start Date and Time.
 Enter the date and time the study calculated IV fluid rate began as the Study Treatment Start Date and Time.
 Enter the date and time the insulin drip was discontinued as the Insulin Drip End (or DKA Resolution) Date and Time.
 For Fluid Calculations, from the medical record, calculate the TOTAL amount of 0.45% NS, 0.9% NS, and all other fluids besides those that contain half and normal saline received from IV Fluid Start until the end of each of three study defined time points, making sure to include all boluses received.
 These ending time points are defined as: 1) DKA resolution=when IV insulin is discontinued, 2) Study Hour 12=randomization + 12 hours, and 3) Study Hour 24=randomization + 24 hours.
 Once saved, the total fluid received for all three time periods will be calculated.

IV Fluid Start Date and Time

Date: FluidStartDay, INT DD-MMM-YYYY Time: FluidStartTime, ST HHMM

Study Treatment (Study Calculated IV Fluid Rate) Start Date and Time

Date: TreatmentStartDay, INT MM-YYYY Time: TreatmentStartTime, ST

Insulin Drip End (DKA Resolution) Date and Time

Date: InsulinEndDay, INT DD-MMM-YYYY Time: InsulinEndTime, ST HHMM

Fluid Calculations

Fluid from IV Fluid Start to DKA Resolution

0.45% NS:	DKAHalfNS, INT (mL)	0.9% NS:	DKANS, INT (mL)	Other Fluid:	DKAOtherFluid, INT (mL)	Total IV Fluid:	DKATotal, INT (mL)
-----------	---	----------	---	--------------	---	-----------------	--

Fluid from IV Start to Study Hour 12

0.45% NS:	Hour12HalfNS, INT (mL)	0.9% NS:	Hour12NS, INT (mL)	Other Fluid:	Hour12OtherFluid, INT (mL)	Total IV Fluid:	Hour12Total, INT (mL)
-----------	--	----------	--	--------------	--	-----------------	---

Fluid from IV Start to Study Hour 24

0.45% NS:	Hour24HalfNS, INT (mL)	0.9% NS:	Hour24NS, INT (mL)	Other Fluid:	Hour24OtherFluid, INT (mL)	Total IV Fluid:	Hour24Total, INT (mL)
-----------	--	----------	--	--------------	--	-----------------	---

FLUID Discharge Data v1.0

Dischar...(6/7) -- Select to Jump --

Title: Discharge Data

Instructions:
 Answer all questions. On Yes or No questions, any information not documented should be answered No. Data should be collected upon discharge (regardless of when discharge occurs).
 3-Month Follow-up Visit Scheduled Date may be left blank until the visit has been scheduled, however DO NOT MARK THE FORM COMPLETE UNTIL ALL QUESTIONS HAVE BEEN ANSWERED.

Did patient have clinically-overt cerebral edema?
 Clinically-overt cerebral edema is identified for study purposes as "Neurological impairment in association with administration of (1) mannitol or (2) hypertonic saline, or (3) endotracheal intubation".

CerebralEdema, INT If Yes, a Cerebral Edema Treatment Log CRF must be entered.

Did patient die during hospitalization?

Death, INT If Yes, a Serious Adverse Event (SAE) Report CRF must be entered.

Hospital Discharge Date and Time

Date: DischargeDay, INT DD-MMM-YYYY Time: DischargeTime, ST HHMM

What was patient's measured (actual) weight at hospital discharge?

DischargeWeight, REAL (kg)

3-Month Follow-up Visit Scheduled Date:

Date: Value not provided DD-MMM-YYYY

Did patient's parent/guardian consent to be contacted for possible future studies?

FurtherContact, INT

YesNo
 1 = Yes
 0 = No

FLUID Cerebral Edema Treatment Log v1.0

Cerebra...(9/15) -- Select to Jump --

Title: Clinically-overt Cerebral Edema

Instructions:
 This form is only required for patients who have study-defined clinically-overt cerebral edema (i.e. answer on Discharge Data Form to question "Did patient have clinically-overt cerebral edema?" is Yes).
 Create and enter a record for each clinically-overt cerebral edema qualifying treatment received.
 IMPORTANT NOTE: DO NOT MARK THE FORM COMPLETE UNTIL ALL DATA REGARDING EACH TREATMENT HAS BEEN RECORDED.

Clinically-overt Cerebral Edema Treatment Log

Treatment Received	Treatment Start Date (DD-MMM-YYYY)	Treatment Start Time (HHMM)	Treatment Stop Date (DD-MMM-YYYY)	Treatment Stop Time (HHMM)	
CETreatment, INT	CETreatmentStartDay, INT	CETreatmentStartTime, ST	CETreatmentStopDay, INT	CETreatmentStopTime, ST	X
<input type="button" value="ADD"/>	CETreatment				

Treat
 1 = Mannitol
 2 = Hypertonic Saline
 3 = Endotracheal Intubation

FLUID Annotated eCRF

Imaging (1 of 1)

FLUID Imaging Reports v1.0

Imaging...(0/4) -- Select to Jump --

Title: Imaging Reports

Instructions: For each head CT or MRI that was performed on the patient during this ED/Hospital encounter, enter a record indicating the date and time and type of study (CT or MRI) performed and upload the de-identified CT or MRI report.
Before uploading, remove patient & physician PHI, and replace with Study Subject ID.
IMPORTANT NOTE: DO NOT MARK THE FORM COMPLETE UNTIL ALL IMAGING REPORTS HAVE BEEN UPLOADED AND INFORMATION PERTAINING TO EACH ONE HAS BEEN COMPLETED.

Imaging Reports

Date (DD-MMM-YYYY)	Time (HHMM)	Image Type	Upload Image Report	
ImageDay, INT <input type="text"/>	ImageTime, ST <input type="text"/>	ImageType, INT <input type="text"/>	Value not provided	Click to upload file <input type="button" value="X"/>
<input type="button" value="ADD"/> ImagingReports				

Imaging
1 = CT
2 = MRI

FLUID Annotated eCRF

ConMeds (1 of 1)

FLUID Concomitant Medication Log v1.0

Con Meds (0/8) -- Select to Jump --

Title: Concomitant Medications Log

Instructions:
Record concomitant medications administered from the time of randomization through hospital discharge. All pharmacological agents, except insulin and IV fluids should be recorded.
IMPORTANT NOTE: DO NOT MARK THE FORM COMPLETE UNTIL ALL CONCOMITANT MEDICATION DATA HAVE BEEN RECORDED ON THIS FORM.

Concomitant Medications

Medication Name	Start Date (DD-MMM-YYYY)	Start Time (HHMM)	Continuing? (Yes or No)
MedName, ST	MedStartDay, INT	MedStartTime, ST	MedContinue, INT
Stop Date (DD-MMM-YYYY)	Stop Time (HHMM)	Was the medication given in relation to an adverse event? (Yes or No)	If yes, provide reason
MedStopDay, INT	MedStopTime, ST	MedRelatedAE, INT	Value not provided

ADD ConMeds

YesNo
 1 = Yes
 0 = No

YesNo
 1 = Yes
 0 = No

Variable	Format	Type	Label	Algorithm / Notes
RXAU1		INT	RxNorm atom unique identifier	See the online RxNorm overview documentation
RXCUI		INT	RxNorm concept unique identifier	See the online RxNorm overview documentation
STR		ST	RxNorm String	See the online RxNorm overview documentation
TTY		ST	RxNorm Term Type	See the online RxNorm overview documentation

FLUID Annotated eCRF

AELog (1 of 2)

FLUID Adverse Event Log v1.0

Relation
 1 = Not Related
 2 = Possibly Related
 3 = Probably Related

AEs (9/18) -- Select to Jump --

Title: Adverse Event Log

Instructions:
 Adverse events (AE) that occur between the time of randomization and hospital discharge should be recorded on this log. Abnormal lab results already collected for the study (glucose, Na, K, Cl, HCO3, BUN, Cr, pH, pCO2, Serum Ca, Mg, Phos, HbA1c) should not be included as an adverse event unless they are considered to be a Serious Adverse Event by the site PI. Abnormal lab results not already collected for the study should be recorded as AEs if the severity a grade 2 or higher on the CTCAE.
For every AE that is considered Serious, a corresponding SAE Report CRF must be completed.
 IMPORTANT NOTE: DO NOT MARK THE FORM COMPLETE UNTIL ALL ADVERSE EVENT DATA HAVE BEEN RECORDED ON THIS FORM.

Adverse Event Log

Adverse Event (AE)	Start Date (DD-MMM-YYYY)	End Date (DD-MMM-YYYY)	Relationship to Study Intervention	Action Taken
AEName, ST	AESTartDay, INT	AEEndDay, INT	AERelation, INT	AEAction, INT
Other Action (Describe)	Outcome	Expectedness	Intensity	Is this AE a Serious Adverse Event (SAE)? If "yes", complete SAE Report eCRF.
Value not provided	AEOutcome, INT	AEEExpected, INT	AEIntensity, INT	AE Serious, INT

ADD AELog

YesNo
 1 = Yes
 2 = No

Outcome
 1 = Recovered (returned to baseline)
 2 = Recovered with sequelae
 3 = Symptom(s) persist(s)
 4 = Death

Expect
 1 = Expected
 2 = Unexpected

Intense
 1 = Mild
 2 = Moderate
 3 = Severe

AEAct
 91 = None
 1 = Intervention: Surgery or Procedure
 2 = Med Initiation, Change, or Discontinue

FLUID Annotated eCRF

AELog (2 of 2)

Variable	Format	Type	Label	Algorithm / Notes
hlgt_name		STR	MedDRA High Level Group Term	Verbatim terms were coded using MedDRA version 20.1
hlt_name		STR	MedDRA high Level Term	Verbatim terms were coded using MedDRA version 20.1
llt_code		INT	MedDRA Lowest Level Term ID Number	Verbatim terms were coded using MedDRA version 20.1
llt_name		STR	MedDRA Lowest Level Term	Verbatim terms were coded using MedDRA version 20.1
pt_name		STR	MedDRA Preferred Term	Verbatim terms were coded using MedDRA version 20.1
soc_name		STR	MedDRA System Organ Class	Verbatim terms were coded using MedDRA version 20.1

FollowUp (1 of 3)

FLUID 3-Month Follow-up Status & History v1.0

Title: Patient Status

Instructions:
 For all patients, answer if a 3-month patient history is gathered (whether by medical record review, phone call or in-person follow-up visit). If patient will be 3 years or older at the date which is 3 months from hospital discharge (3-month follow-up visit) answer whether patient completed 3-month follow-up visit.

Was a patient history obtained at 3 months?

FUStatus, INT	If Yes, complete History questions on next tab.	If No, Reason 3-Month History Not Obtained:	Value not provided	Skip the History questions on the next tab and mark this form Complete.
---------------	---	---	--------------------	---

Will patient be 3 years or older at time of 3-month follow-up visit?

Value not provided	* If No, this patient is not eligible for a follow-up neurocognitive testing visit at 3 months. DO NOT enter a 3-Month Follow-up Visit form.
--------------------	--

For patients 3 years or older at time of 3-month follow-up visit:

Did patient complete in-person 3-Month Follow-up visit?

FUVisit, INT	If Yes, complete a 3-Month Follow-up Visit form.	If No, Reason 3-Month Follow-up Visit Not Done:	Value not provided	Do not enter a 3-Month Follow-up Visit form.
--------------	--	---	--------------------	--

YesNo
 1 = Yes
 0 = No

FLUID Annotated eCRF

FollowUp (2 of 3)

FLUID 3-Month Follow-up Status & History v1.0

Status (4/4) History (11/11) -- Select to Jump --

Title: Follow-up History

Instructions:
 Complete this section (tab) for patients 3 years or older at date of 3-month follow-up. This information should reflect the patient's vital status and relevant medical encounters at the 3-month time point (plus or minus 1 month if visit is scheduled 1 month earlier or later). Do not include information learned after the 3-month time point.

Follow-up History Collection Date

Follow-up History Collection Date: FUHistoryDay, INT DD-MMM-YYYY

What is patient's vital status at time of 3-month follow-up visit?

FUVitalStatus, INT If Dead, indicate the cause (if known). FUDeathCause, ST

Status
 1 = Alive
 2 = Dead
 92 = Unknown

Has patient seen a medical care provider for anything other than usual diabetes care since study DKA episode?

FUMedTreat, INT

YesNoUnk
 1 = Yes
 0 = No
 92 = Unknown

If Yes, enter the date(s), treatment indication(s), and whether or not treatment included hospitalization in table below.

Medical Treatment Date (DD-MMM-YYYY)	Indication (Reason) for Medical Treatment	Hospitalization Required? (Yes/No/Unknown)
FUMedTreatDay, INT	Value not provided	FUMedTreatHospitalization, INT

ADD

FollowUp_Medical

FLUID Annotated eCRF

FollowUp (3 of 3)

FLUID 3-Month Follow-up Status & History v1.0

Since the hospital discharge from the DKA episode, has the patient experienced thrombosis?

FUThrombosis, INT

If Yes, enter the date(s) of thrombosis events below.

Thrombosis Event Date (DD-MMM-YYYY)	
Value not provided	X
ADD	

YesNoUnk
1 = Yes
0 = No
92 = Unknown

Value not provided

FLUID 3-Month Follow-up Visit v1.0

Screeni...(0/3) Digit S...(0/4) Memory ...(2/6) -- Select to Jump --

Title: Follow-up Screening

Instructions:
Follow-up is only to be completed for kids ages 3-18 (at the time of follow-up visit). Only enter the screening data that pertains to the visit in which the patient was able to complete follow-up testing (i.e. if glucose was too low and visit was rescheduled, that visit's information should not be recorded here).

Follow-up Visit Date

Date: DD-MMM-YYYY

How old was the patient at the time of the follow-up visit?

Age:
 age
 1 = 3 through 5 years of age
 2 = 6 through 17 years of age
 3 = 18 years of age

Glucose screening (via patient's meter)

Glucose: (mg/dL)

Since hospital discharge from study DKA episode:

Has patient had a severe hypoglycemic episode with loss of consciousness or seizures?

If Yes, indicate number of severe hypoglycemic episodes since discharge:
 Episode
 1 = 1
 2 = 2
 3 = >2
 93 = Unable to Determine

Has patient had an additional DKA episode?

If Yes, indicate number of DKA episodes since discharge:

YesNoUnk
 1 = Yes
 0 = No
 92 = Unknown

FLUID Annotated eCRF

FollowUpVisit (2 of 5)

FLUID 3-Month Follow-up Visit v1.0

Screeni...(0/3) Digit S...(0/4) Memory ...(2/6) -- Select to Jump --

Title: Follow-up Digit Span Recall Testing

Was a Digit Span Recall test completed?

FUDigitSpan, INT If No, why was test not completed?

Value not provided

YesNo
1 = Yes
0 = No

Digit Span Recall Forward: FURecallForward, INT

Digit Span Recall Backward: FURecallBackward, INT

FLUID Annotated eCRF

FollowUpVisit (3 of 5)

FLUID 3-Month Follow-up Visit v1.0

Digit S...(4/4) Memory ...(6/6) WASI/WP...(3/3) -- Select to Jump --

Title: Follow-up Memory Testing

Instructions:
Answer whether each memory task was completed, providing a reason if not completed, and upload memory test results (.csv file) and memory test notes, if applicable.

Was a Memory-Color Position Task completed?

FUMemColor, INT If No, why was test not completed? Value not provided

Was a Memory-Spatial Position Task completed?

FUMemSpatial, INT If No, why was test not completed? Value not provided

Upload Memory Test Results: (.csv file) Value not provided Click to upload file Before uploading, remove patient PHI and replace with Study Subject ID.

Upload Memory Test Notes: Value not provided Click to upload file Before uploading, remove patient PHI and replace with Study Subject ID.

YesNo
1 = Yes
0 = No

FLUID Annotated eCRF

FollowUpVisit (4 of 5)

FLUID 3-Month Follow-up Visit v1.0

Memory ... (6/6) WASI/WP... (3/3) CBCL (3/3) -- Select to Jump --

Title: Follow-up WASI or WPSSI Testing

Instructions:
Answer whether WASI or WPSSI test was completed, providing a reason if not completed, and upload WASI/WPSSI test results.

Was either a WASI/WPSSI Test Completed?

Value not provided	If No, why was test not completed?	Value not provided
--------------------	------------------------------------	--------------------

Upload WASI/WPSSI Test Results: Value not provided [Click to upload file](#) Before uploading, remove patient PHI and replace with Study Subject ID.

FLUID Annotated eCRF

FollowUpVisit (5 of 5)

FLUID 3-Month Follow-up Visit v1.0

Memory ...(6/6) WASI/WP...(3/3) CBCL (3/3) -- Select to Jump --

Title: Follow-up Child Behavioral Checklist

Instructions:
Answer whether CBCL was completed, providing a reason if not completed, and upload CBCL results.

Was a CBCL completed by parent?

<input type="text" value="Value not provided"/>	If no, why was it not completed?	<input type="text" value="Value not provided"/>
---	----------------------------------	---

Upload CBCL: Before uploading, remove patient PHI and replace with Study Subject ID.

FLUID CBCL & Cognitive Testing Scores v1.0

Subject...(0/1)
CBCL In...(0/7)
CBCL Fo...(0/7)
-- Select to Jump --

Title: Original Subject ID

Original Subject ID: Value not provided

Subject...(0/1)
CBCL In...(0/7)
CBCL Fo...(0/7)
-- Select to Jump --

Title: Child Behavior Checklist - Inpatient

Instructions:
INPATIENT CBCL

Patient's Age in ED

AgeYearsCBCL, INT (Years)

AgeMonthsCBCL, INT (Months)

Inpatient CBCL Uploads

CBCL to Simona: Value not provided [Click to upload file](#)

CBCL Scored from Simona: Value not provided [Click to upload file](#)

Inpatient CBCL Score

Internalizing T Score: InternalScore, INT 0-100

Externalizing T Score: ExternalScore, INT 0-100

Total T Score: TotalScore, INT 0-100

FLUID Annotated eCRF

CBCLCogn (2 of 4)

FLUID CBCL & Cognitive Testing Scores v1.0

◀ CBCL In...(0/7) CBCL Fo...(0/7) Memory ...(0/5) ▶ -- Select to Jump -- ▾

Title: Child Behavior Checklist - Follow-up

Instructions:
FOLLOW-UP CBCL

Patient's Age at CBCL Administration

FUAgeYearsCBCL, INT (Years)

FUAgeMonthsCBCL, INT (Months)

Follow-up CBCL Uploads

CBCL for Simona: Value not provided

CBCL Scored from Simona: Value not provided

Follow-up CBCL Score

Internalizing T Score: FUInternalScore, INT 0-100

Externalizing T Score: FUExternalScore, INT 0-100

Total T Score: FUTotalScore, INT 0-100

FLUID Annotated eCRF

CBCLCogn (3 of 4)

FLUID CBCL & Cognitive Testing Scores v1.0

Navigation: CBCL Fo...(0/7) | Memory ...(0/5) | WASI or...(0/7) | -- Select to Jump --

Title: Memory Tests

Patient's Age at Memory Test Administration

AgeYearsMemory, INT (Years)	
AgeMonthsMemory, INT (Months)	
Memory Test to Simona: (.csv file) Value not provided Click to upload file	Memory Test Notes to Simona: Value not provided Click to upload file
Scored Memory Test from Simona: Value not provided Click to upload file	

FLUID CBCL & Cognitive Testing Scores v1.0

CBCL Fo...(0/7) Memory ...(0/5) WASI or...(0/7) -- Select to Jump --

Title: WASI or WPSSI Tests

Patient's Age at WASI/WPSSI Administration

AgeYearsWASI, INT	(Years)
AgeMonthsWASI, INT	(Months)

WASI/WPSSI Test to Simona: Value not provided [Click to upload file](#)

ScoredWASI/WPSSI Test from Simona: Value not provided [Click to upload file](#)

IQ Scores

Verbal IQ: VerbalIQ, INT	50-150
Performance IQ: PerformancelQ, INT	0-150
Full Scale IQ: FullIQ, INT	50-150

FLUID Annotated eCRF

Memory (1 of 2)

Memory

Variable	Format	Type	Label	Algorithm / Notes
S_Hit_Rate		REAL	S_Hit_Rate	
S_FalseAlarm_Rate		REAL	S_FalseAlarm_Rate	
Item_Space_Rate		REAL	Item_Space_Rate	
S_Dprime		REAL	S_Dprime	
S_Bias_c		REAL	S_Bias_c	
C_Hit_Rate		REAL	C_Hit_Rate	
C_FalseAlarm_Rate		REAL	C_FalseAlarm_Rate	
Item_Color_Rate		REAL	Item_Color_Rate	
C_Dprime		REAL	C_Dprime	
C_Bias_c		REAL	C_Bias_c	
S_Hit_Rate_1st_Half		REAL	S_Hit_Rate_1st_Half	
S_FalseAlarm_Rate_1st_Half		REAL	S_FalseAlarm_Rate_1st_Half	
Item_Space_Rate_1st_Half		REAL	Item_Space_Rate_1st_Half	
S_Dprime_1st_Half		REAL	S_Dprime_1st_Half	
S_Bias_c_1st_Half		REAL	S_Bias_c_1st_Half	
C_Hit_Rate_1st_Half		REAL	C_Hit_Rate_1st_Half	
C_FalseAlarm_Rate_1st_Half		REAL	C_FalseAlarm_Rate_1st_Half	
Item_Color_Rate_1st_Half		REAL	Item_Color_Rate_1st_Half	
C_Dprime_1st_Half		REAL	C_Dprime_1st_Half	
C_Bias_c_1st_Half		REAL	C_Bias_c_1st_Half	
S_Hit_Rate_2nd_Half		REAL	S_Hit_Rate_2nd_Half	
S_FalseAlarm_Rate_2nd_Half		REAL	S_FalseAlarm_Rate_2nd_Half	
Item_Space_Rate_2nd_Half		REAL	Item_Space_Rate_2nd_Half	

FLUID Annotated eCRF

Memory (2 of 2)

S_Dprime_2nd_Half		REAL	S_Dprime_2nd_Half	
S_Bias_c_2nd_Half		REAL	S_Bias_c_2nd_Half	
C_Hit_Rate_2nd_Half		REAL	C_Hit_Rate_2nd_Half	
C_FalseAlarm_Rate_2nd_Half		REAL	C_FalseAlarm_Rate_2nd_Half	
Item_Color_Rate_2nd_Half		REAL	Item_Color_Rate_2nd_Half	
C_Dprime_2nd_Half		REAL	C_Dprime_2nd_Half	
C_Bias_c_2nd_Half		REAL	C_Bias_c_2nd_Half	
S_Hits_Raw		REAL	S_Hits_Raw	
S_False_Alarm_Raw		INT	S_False_Alarm_Raw	
S_Item_Location_Raw		INT	S_Item_Location_Raw	
S_Item_Location_Inc_but_Corr_Lef		INT	S_Item_Location_Inc_but_Corr_LeftRight_RAW	
S_Item_Location_Inc_but_Corr_Top		INT	S_Item_Location_Inc_but_Corr_TopBottom_RAW	
Spatial_Src_Inc_and_OppositeCorn		INT	Spatial_Src_Inc_and_OppositeCorner_RAW	
TRsourcehit		INT	TRsourcehit	
TLsourcehit		INT	TLsourcehit	
BLsourcehit		INT	BLsourcehit	
BRsourcehit		INT	BRsourcehit	
Spatial_number_Old_Raw		INT	Spatial_number_Old_Raw	
Spatial_number_New_Raw		INT	Spatial_number_New_Raw	
Spatial_Hit_Raw		INT	Spatial_Hit_Raw	
numFalseAlarmsRaw		INT	numFalseAlarmsRaw	
TLhit		INT	TLhit	
TRdehit		INT	TRdehit	
BLhit		INT	BLhit	
BRhit		INT	BRhit	
Color_Hit_Raw		INT	Color_Hit_Raw	
Color_FalseAlarm_Raw		INT	Color_FalseAlarm_Raw	
Color_Source_Raw		INT	Color_Source_Raw	
Color_num_Old_raw		INT	Color_num_Old_raw	
Color_num_New_Raw		INT	Color_num_New_Raw	

NonDKA (1 of 1)

NonDKA

Variable	Format	Type	Label	Algorithm / Notes
StudyEvent		INT	StudyEvent	
NonDkaID		INT	PUDID of Non-DKA subjects later enrolled in the FLUID DKA study cohort	Some participants in the Non-DKA cohort were later enrolled in the DKA cohort during a DKA episode. This data provides a list of those participants.

FLUID Withdrawn Consent v1.0

◀ Withdra...(2/5) ▶ -- Select to Jump -- ▾

Title: Withdrawn

Instructions:
Answer all questions regarding withdrawal of consent.

Consent Withdrawal Date and Time

Date: * DD-MMM-YYYY Time: HHMM

During which phase of the study was parental/patient permission withdrawn?

Why was the patient withdrawn?

Reason
1 = Parental preference
2 = Child's preference

Please describe withdrawal (for any reason):

Withdraw

- 1 = Intervention Phase (includes time from randomization through the end of intervention)
- 2 = Post-intervention/Pre-discharge
- 3 = Prior to Month 3 Follow-up after hospital discharge (prior to neurocognitive assessment phase)

CEAdjud (1 of 1)

FLUID CE Adjudication v1.0

CE Adju...(0/3)

Title: Cerebral Edema Adjudication

Date of Adjudication (DD-MMM-YYYY)

Does this patient have clinically overt cerebral edema?

*

Comments: Value not provided

YesNo
1 = Yes
0 = No

NDKADemographics (1 of 1)

Non-DKA Demographics v1.0

Demogra...(0/4) -- Select to Jump --

Title: Demographics

Date of Birth: Value not provided

Sex: Sex, INT

Race: (select all that apply)

- American Indian or Alaska Native
- Asian
- Black or African American
- Native Hawaiian or Other Pacific Islander
- White
- Unknown

Ethnicity: Ethnicity, INT

Sex Legend:

- 1 = Male
- 2 = Female

Race Legend:

- Race1, INT (American Indian or Alaska Native)
- Race2, INT (Asian)
- Race3, INT (Black or African American)
- Race4, INT (Native Hawaiian or Other Pacific Islander)
- Race5, INT (White)
- Race92, INT (Unknown or Not Reported)

Ethnic Legend:

- 1 = Hispanic or Latino
- 2 = Not Hispanic or Latino
- 92 = Unknown

YN Legend:

- 1 = Yes
- 0 = No

Variable	Format	Type	Label	Algorithm / Notes
AgeInYears		REAL	Age in years	Calculated as the difference in years between date of birth and NonDKA screening date. Continuous variable, so that 12 years and 1 day is 12.003.

NDKAScreening (1 of 2)

Non-DKA Screening & Enrollment v1.0

Screeni...(0/8) Permiss...(0/9) -- Select to Jump --

Title: Inclusion & Exclusion Criteria

Inclusion Criteria

1. Is the patient more than 3 years of age?
 Yes No * Inclusion1, INT

2. Is patient less than 18 years plus 3 months of age?
 Yes No * Inclusion2, INT

3. Does patient have a diagnosis of type I diabetes?
 Yes No * Inclusion3, INT

Exclusion Criteria

1. Does the patient have a history of any diabetic ketoacidosis (DKA)?
 Yes No * Exclusion1, INT

2. Does the patient have a pre-existing neurological disease that substantially impacts mental status or neurocognitive exam (e.g. cerebral palsy with developmental delay or autism)?
 Yes No * Exclusion2, INT

Eligibility

Is patient eligible to be approached for participation in this study?
 Yes No * Eligible, INT

Screening Date and Time

Date: * DD-MMM-YYYY Time: * HHMM

YN
1 = Yes
0 = No

FLUID Annotated eCRF

NDKAScreening (2 of 2)

Screeni...(0/8) Permiss...(0/7) -- Select to Jump --

Title: Parental Permission and Consent Signed

Instructions: Patients under 18 years of age should have parental permission completed & the Parental Permission section entered. Patients over 18 years of age should have informed consent completed & the Informed Consent section entered.

Is the patient less than 18 years of age?

PermissionAge, INT

Parental Permission

If "Yes," was parental permission given?

Permission, INT If "Yes," provide the permission date and time

Parental Permission Signed Date and Time

Date: PermissionDay, INT DD-MMM-YYYY Time: PermissionTime, ST HHMM

Informed Consent

If "No," was informed consent given?

Consent, INT If "Yes," provide the consent date and time

Informed Consent Signed Date and Time

Date: ConsentDay, INT DD-MMM-YYYY Time: ConsentTime, ST HHMM

YN
1 = Yes
0 = No

Non-DKA Diabetes History Form v1.0

Diabete...(0/5) HbA1c (0/2) -- Select to Jump --

Title: Diabetes History

Diabetes History

What was the year of patient's first diabetes diagnosis?

* YYYY

Is this "new onset" diabetes (diagnosed within the last 3 months)?

YN
1=Yes
0=No

YesNo
1=Yes
0=No

Has patient ever been previously diagnosed with diabetic ketoacidosis (DKA)?

* If "Yes," STOP (Patient is not eligible for study)

Has patient ever had a severe hypoglycemic episode with loss of consciousness or seizures?

If Yes, indicate the number of severe hypoglycemic episodes:

YesNoUD
1=Yes
0=No
93=Unable to Determine

NDEpi
1=One-two (1-2)
2=More than two (>2)
93=Unable to Determine

Variable	Format	Type	Label	Algorithm / Notes
AgeAtOnset		INT	Age at Onset	Calculated as the difference in years, rounded down, between DOB and the testing visit date (for new onsets) or July 1 of the year of patient's first diabetes diagnosis (for those previously diagnosed).

FLUID Annotated eCRF

NDKADiabHx (2 of 2)

Diabete...(0/5) HbA1c (0/2) -- Select to Jump --

Title: HbA1c

HbA1c 12 Month History

Instructions: *ONLY enter HbA1c lab results within the past 12 months.

HbA1c History- Do not collect beyond the past 12 months.		HbA1c	
HbA1cDay, INT		HbA1c, ST	
ADD	NDKADiabHx_HbA1c		

Non-DKA Caregiver Information v1.0

Caregiv...(0/4)
Additio...(0/5)
Income (0/1)
-- Select to Jump --

Title: Caregiver A

Caregiver's sex:

CareSex, INT

Sex
1 = Male
2 = Female

Caregiver's relationship to the patient:

CareRelationship, INT

If other, specify: Value not provided

Caregiver's highest education received:

(se) CareEducation, INT

CareRel
1=Biological parent
2=Adoptive parent
3=Step parent
4=Foster parent
5=Grandparent
6=Other legal guardian
90=Other (specify)
97=Not Provided

CareEdu
1=No education
2=Some high school or less
3=High school graduate or GED
4=Vocational school or some college
5=College degree
6=Master's or doctoral degree
97=Not Provided

FLUID Annotated eCRF

NDKACaregiver (2 of 2)

Caregiv...(0/4) Additio...(0/5) Income (0/1) -- Select to Jump --

Title: Caregiver-Additional Caregiver

Was Additional Caregiver data available?

AddCareAvailable, INT *

Caregiver's sex:

AddCareSex, INT

Caregiver's relationship to the patient:

AddCareRelationship, INT If other, specify:

Caregiver's highest education received:

AddCareEducation, INT

YesNo
1 =Yes
0=No

Sex
1 = Male
2=Female

CareRel
1=Biological parent
2=Adoptive parent
3=Step parent
4=Foster parent
5=Grandparent
6=Other legal guardian
90=Other (specify)
97=Not Provided

CareEdu
1=No education
2=Some high school or less
3=High school graduate or GED
4=Vocational school or some college
5=College degree
6=Master's or doctoral degree
97=Not Provided

FLUID Annotated eCRF

Caregiv...(0/4) Additio...(0/5) **Income (0/1)**

Title: Household Income

What is the annual household income of the patient's family?

Income, INT

- Income
- 1=Less than \$20,000
- 2=\$20,000 to \$39,999
- 3=\$40,000 to \$59,999
- 4=\$60,000 to \$79,999
- 5=\$80,000 to \$99,999
- 6=\$100,000 to \$119,999
- 7=\$120,000 to \$149,999
- 8=\$150,000 to \$199,999
- 9=\$200,000 or more
- 97=Not Provided

FLUID Annotated eCRF

NDKANeuroCogn (1 of 3)

Non-DKA Neurocognitive Testing v1.0

This dataset is used to identify subjects to include in the PUD Non-DKA cohort. We include all with a non-missing VisitDate.

Navigation: Visit S...(0/3) | Digit S...(0/2) | Memory ...(0/6) | -- Select to Jump --

Title: Visit Screening

Neurocognitive Testing

Visit Date: * MM-DD-YYYY

How old was the patient on the day of the neurocognitive visit?

Glucose Screening (via patient's meter)

Glucose: (mg/dL)

NDAge
1=3 through 5 years of age (Age appropriate testing: WPSSI, CBCL)
2=6 through 17 years of age (Age appropriate testing: WASI, CBCL)
3=18 years of age (Informed consent needed, perform WASI, CBCL)

Navigation: Visit S...(0/3) | Digit S...(0/2) | Memory ...(0/6) | -- Select to Jump --

Title: Digit Span

Digit Span

Digit Span Recall Total Forward (0-16) Digit Span Recall Total Backward (0-16)

FLUID Annotated eCRF

NDKANEuroCogn (2 of 3)

Digit S...(0/2) **Memory ... (0/6)** WASI/WP...(0/4) -- Select to Jump --

Title: Memory Test

Memory Test

Was the memory-color position task completed?

MemColor, INT If "No," why not? Value not provided

Was the memory- spatial position task completed?

MemSpatial, INT If "No," why not? Value not provided

Upload Memory Test results

Memory Test Upload Value not provided Click to upload file Memory Test Notes Upload Value not provided Click to upload file

YesNo
1=Yes
0=No

FLUID Annotated eCRF

NDKANeuroCogn (3 of 3)

Memory ... (0/6) WASI/WP... (0/4) CBCL (0/4) -- Select to Jump --

Title: WASI/WPPSI

WASI/WPPSI Test

Was a WASI or WPPSI test completed?

YesNo
1=Yes
0=No

WASI, INT

If "No," why not?

Value not provided

Test
1=WPPSI
2=WASI

Which test was completed?

TestComp, INT

WASI/WPPSI Upload

Value not provided

Click to upload file

Variable	Format	Type	Label	Algorithm / Notes
CBCL	YesNo 1=Yes 0=No	INT	CBCL completed	
CBCLComp	CBCL 1=3-5 2=6-18		Which CBCL was completed	Parents of patients aged 3 through 5 years old completed the preschool CBCL. Parents of patients aged 6 years through 18 completed the older age CBCL.

Non-DKA CBCL & Cognitive Testing Scores v1.0

◀ Subject...(0/1) CBCL In...(0/7) CBCL Fo...(0/7) ▶

Title: Original Subject ID

Original Subject ID:

FLUID Annotated eCRF

NDKACognCBCL (2 of 4)

◀ Subject...(0/1) CBCL (0/7) Memory ...(0/5) ▶ -- Select to Jump -- ▼

Title: Child Behavior Checklist	
Instructions: CBCL	
Patient's Age in ED	
AgeYearsCBCL, INT	(Years)
AgeMonthsCBCL, INT	(Months)
CBCL Uploads	
CBCL to Simona:	Value not provided Click to upload file
CBCL Scored from Simona:	Value not provided Click to upload file
CBCL Score	
Internalizing T Score:	InternalScore, INT 0-100
Externalizing T Score:	ExternalScore, INT 0-100
Total T Score:	TotalScore, INT 0-100

FLUID Annotated eCRF

NDKACognCBCL (3 of 4)

◀ CBCL Fo...(0/7) **Memory ... (0/5)** WASI or...(0/7) ▶ -- Select to Jump -- ▾

Title: Memory Tests

Patient's Age at Memory Test Administration

AgeYearsMemory, INT	(Years)				
AgeMonthsMemory, INT	(Months)				
Memory Test to Simona: (.csv file)	Value not provided	Click to upload file	Memory Test Notes to Simona:	Value not provided	Click to upload file
Scored Memory Test from Simona:	Value not provided	Click to upload file			

FLUID Annotated eCRF

NDKACognCBCL (4 of 4)

CBCL Fo...(0/7) Memory ...(0/5) WASI or...(0/7) -- Select to Jump

Title: WASI or WPSSI Tests

Patient's Age at WASI/WPSSI Administration

AgeYearsWASI, INT (Years)

AgeMonthsWASI, INT (Months)

WASI/WPSSI Test to Simona: Value not provided [Click to upload file](#)

ScoredWASI/WPSSI Test from Simona: Value not provided [Click to upload file](#)

IQ Scores

Verbal IQ: VerballIQ, INT 50-150

Performance IQ: PerformancelQ, INT 50-150

Full Scale IQ: FullIQ, INT 50-150

FLUID Annotated eCRF

NDKAMemory (1 of 2)

NDKAMemory

Variable	Format	Type	Label	Algorithm / Notes
S_Hit_Rate		REAL	S_Hit_Rate	
S_FalseAlarm_Rate		REAL	S_FalseAlarm_Rate	
Item_Space_Rate		REAL	Item_Space_Rate	
S_Dprime		REAL	S_Dprime	
S_Bias_c		REAL	S_Bias_c	
C_Hit_Rate		REAL	C_Hit_Rate	
C_FalseAlarm_Rate		REAL	C_FalseAlarm_Rate	
Item_Color_Rate		REAL	Item_Color_Rate	
C_Dprime		REAL	C_Dprime	
C_Bias_c		REAL	C_Bias_c	
S_Hit_Rate_1st_Half		REAL	S_Hit_Rate_1st_Half	
S_FalseAlarm_Rate_1st_Half		REAL	S_FalseAlarm_Rate_1st_Half	
Item_Space_Rate_1st_Half		REAL	Item_Space_Rate_1st_Half	
S_Dprime_1st_Half		REAL	S_Dprime_1st_Half	
S_Bias_c_1st_Half		REAL	S_Bias_c_1st_Half	
C_Hit_Rate_1st_Half		REAL	C_Hit_Rate_1st_Half	
C_FalseAlarm_Rate_1st_Half		REAL	C_FalseAlarm_Rate_1st_Half	
Item_Color_Rate_1st_Half		REAL	Item_Color_Rate_1st_Half	
C_Dprime_1st_Half		REAL	C_Dprime_1st_Half	
C_Bias_c_1st_Half		REAL	C_Bias_c_1st_Half	
S_Hit_Rate_2nd_Half		REAL	S_Hit_Rate_2nd_Half	
S_FalseAlarm_Rate_2nd_Half		REAL	S_FalseAlarm_Rate_2nd_Half	
Item_Space_Rate_2nd_Half		REAL	Item_Space_Rate_2nd_Half	
S_Dprime_2nd_Half		REAL	S_Dprime_2nd_Half	

FLUID Annotated eCRF

S_Bias_c_2nd_Half		REAL	S_Bias_c_2nd_Half	NDKAMemory (2 of 2)
C_Hit_Rate_2nd_Half		REAL	C_Hit_Rate_2nd_Half	
C_FalseAlarm_Rate_2nd_Half		REAL	C_FalseAlarm_Rate_2nd_Half	
Item_Color_Rate_2nd_Half		REAL	Item_Color_Rate_2nd_Half	
C_Dprime_2nd_Half		REAL	C_Dprime_2nd_Half	
C_Bias_c_2nd_Half		REAL	C_Bias_c_2nd_Half	
S_Hits_Raw		REAL	S_Hits_Raw	
S_False_Alarm_Raw		INT	S_False_Alarm_Raw	
S_Item_Location_Raw		INT	S_Item_Location_Raw	
S_Item_Location_Inc_but_Corr_Lef		INT	S_Item_Location_Inc_but_Corr_LeftRight_RAW	
S_Item_Location_Inc_but_Corr_Top		INT	S_Item_Location_Inc_but_Corr_TopBottom_RAW	
Spatial_Src_Inc_and_OppositeCorn		INT	Spatial_Src_Inc_and_OppositeCorner_RAW	
TRsourcehit		INT	TRsourcehit	
TLsourcehit		INT	TLsourcehit	
BLsourcehit		INT	BLsourcehit	
BRsourcehit		INT	BRsourcehit	
Spatial_number_Old_Raw		INT	Spatial_number_Old_Raw	
Spatial_number_New_Raw		INT	Spatial_number_New_Raw	
Spatial_Hit_Raw		INT	Spatial_Hit_Raw	
numFalseAlarmsRaw		INT	numFalseAlarmsRaw	
TLhit		INT	TLhit	
TRdehit		INT	TRdehit	
BLhit		INT	BLhit	
BRhit		INT	BRhit	
Color_Hit_Raw		INT	Color_Hit_Raw	
Color_FalseAlarm_Raw		INT	Color_FalseAlarm_Raw	
Color_Source_Raw		INT	Color_Source_Raw	
Color_num_Old_raw		INT	Color_num_Old_raw	
Color_num_New_Raw		INT	Color_num_New_Raw	