SAE (LURN)

A. SAEs

1

Date of this report:

[ ] [ ] [ ]

Month Day Year

#	Field Name	Lookup Set	Type	Length	Range Checks
1	ReportDate		DATETIME		No range checks

2

Start Date of Event:

[ ] [ ] [ ]

Month Day Year

#	Field Name	Lookup Set	Type	Length	Range Checks
1	EventStartDate		DATETIME		No range checks

3

End Date of Event:

[ ] [ ] [ ]

Month Day Year

#	Field Name	Lookup Set	Type	Length	Range Checks
1	EventEndDate		DATETIME		No range checks

4

ICD-10 Code:

[ ]

#	Field Name	Lookup Set	Type	Length	Range Checks
1	EventICD10ID		NVARCHAR	50	No range checks
2	EventICD10Text		NVARCHAR	255	No range checks

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Severity of event (assessed by PI):
○ Mild
○ Moderate
○ Severe

#	Field Name	Lookup Set	Type	Length	Range Checks
1	EventSeverity	*Name:* EventSeverity *SASFmt:* EventSeverity | Val	Text	Culture Suppression | |---|---|---| | 1 | Mild | | | 2 | Moderate | | | 3 | Severe | |	SMALLINT		No range checks

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Pattern of event:
- ◯ Single episode
- ◯ Intermittent
- ◯ Continuous

#	Field Name	Lookup Set	Type	Length	Range Checks
1	EventPattern	*Name:* EventPattern *SASFmt:* EventPattern | Val	Text	Culture Suppression | |---|---|---| | 1 | Single episode | | | 2 | Intermittent | | | 3 | Continuous | |	SMALLINT		No range checks

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Relatedness of event to study procedure:
- ◯ Unrelated
- ◯ Remote
- ◯ Possible
- ◯ Probable
- ◯ Related

#	Field Name	Lookup Set	Type	Length	Range Checks
1	EventRelatedness	*Name:* EventRelatedness *SASFmt:* EventRelatedness	SMALLINT		No range checks

Val	Text	Culture Suppression
1	Unrelated	
2	Remote	
3	Possible	
4	Probable	
5	Related	

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If related, possible related, probably related, or remotely related, which study procedure?
- ◯ PRO Assessment
- ◯ Clinic Testing (Urine Analysis)
- ◯ Biosample Collection
- ◯ MRI or Neuroimaging
- ◯ Auditory Testing
- ◯ Sensory Testing ("Thumbcrusher")
- ◯ Unknown

#	Field Name	Lookup Set	Type	Length	Range Checks
1	EventRelatedProcedure	*Name:* EventRelatedProcedure *SASFmt:* EventRelatedProcedure Val / Text / Culture Suppression: 1 — PRO Assessment 2 — Clinic Testing (Urine Analysis) 3 — Biosample Collection 4 — MRI or Neuroimaging 5 — Auditory Testing 6 — Sensory Testing ("Thumbcrusher") 97 — Unknown	SMALLINT		No range checks

9   Action(s) taken (check all that apply):

- ☐ None
- ☐ Additional meds
- ☐ Additional therapy
- ☐ Additional lab tests
- ☐ Hospitalization required
- ☐ Prolonged hospitalization required

#	Field Name	Lookup Set	Type	Length	Range Checks
1	ActionsTaken	*Name:* ActionsTaken *SASFmt:* ActionsTaken <table><tr><td>Val</td><td>Text</td><td>Culture Suppression</td></tr><tr><td>0</td><td>None</td><td></td></tr><tr><td>1</td><td>Additional meds</td><td></td></tr><tr><td>2</td><td>Additional therapy</td><td></td></tr><tr><td>3</td><td>Additional lab tests</td><td></td></tr><tr><td>4</td><td>Hospitalization required</td><td></td></tr><tr><td>5</td><td>Prolonged hospitalization required</td><td></td></tr></table>	NVARCHAR	100	No range checks

SAE condition (check all that apply):
- ☐ Death
- ☐ Life-threatening
- ☐ Inpatient/prolonged hospitalization
- ☐ Congenital anomaly or birth defect
- ☐ Persistent/significant disability or incapacity
- ☐ Medically important condition

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#	Field Name	Lookup Set	Type	Length	Range Checks
1	SAECondition	*Name:* SAECondition *SASFmt:* SAECondition <table><tr><td>Val</td><td>Text</td><td>Culture Suppression</td></tr></table>	NVARCHAR	100	No range checks

1	Death	
2	Life-threatening	
3	Inpatient/prolonged hospitalization	
4	Congenital anomaly or birth defect	
5	Persistent/significant disability or incapacity	
6	Medically important condition	

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Is this an expected SAE?
○ No
○ Yes

#	Field Name	Lookup Set	Type	Length	Range Checks
1	ExpectedSAE	*Name:* YesNo *SASFmt:* YesNo 	Val	Text	Culture Suppression
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0	No	
1	Yes			SMALLINT		No range checks

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Has the principal investigator reviewed this report?
○ No
○ Yes

#	Field Name	Lookup Set	Type	Length	Range Checks
1	PIReview	*Name:* YesNo *SASFmt:* YesNo 	Val	Text	Culture Suppression
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0	No	
1	Yes			SMALLINT		No range checks

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Date of PI review:
[   ] [   ] [   ]

Month Day Year

#	Field Name	Lookup Set	Type	Length	Range Checks
1	PIReviewDate		SMALLINT		No range checks

A14

Questionnaire Complete
○ Yes

#	Field Name	Lookup Set	Type	Length	Range Checks
1	CenterComplete	*Name:* QuestComp *SASFmt:* QuestComp 	Val	Text	Culture Suppression
1	Yes			SMALLINT		No range checks