BPC

Metadata Report

Adverse Event MER02 (AE1 form and dataset)
Version 3.00

Key Field	Field Name	Full Name	Question Text	Type	Length and Decimals	Codelist Values
*	SITE	Center		C	5	
*	PROT	Protocol		C	5	
	PATID	Participant ID		C	15	
*	PROJID	Project ID		C	5	
*	AEOSDT	Adverse event onset date		D	8	
*	AENO	Adverse event number		C	2	01=01, 02=02, 03=03, 04=04, 05=05, 06=06, 07=07, 08=08, 09=09, 10=10, 11=11, 12=12, 13=13, 14=14, 15=15
	AETERM	Event diagnosis	Adverse event:	C	200	
	AESPCL	Special interest	AE of special interest?	C	1	0=No, 1=Yes
	AENDTC	End date	End date:	D	8	
	AEOUT	Outcome	Outcome:	C	2	1=Resolved, 2=Resolved with sequelae, 3=Ongoing,

						4=Death, 77=Unknown
	AESEV	Severity	Severity:	C	1	1=Mild, 2=Moderate, 3=Severe
	AEREL	Causality	Causality:	C	1	1=Unrelated, 2=Possibly related, 3=Probably related, 4=Definitely related
	AEACN	Action taken	Action taken:	C	1	1=None, 2=Discontinued, 3=Interrupted, 4=Other
	AEACNOTH	Action taken other	If "Other," specify:	C	200	
	AETXNONE	Treatment none	None:	C	1	1=Yes
	AETXMED	Treatment medication	Medication/Therapy required:	C	1	1=Yes
	AETXPROC	Treatment procedure	Procedure/Surgery required:	C	1	1=Yes
	AETXOTHY	Other treatment	Other:	C	1	1=Yes
	AETXOTH	Treatment required other	Specify:	C	75	
	AESIEZ	Event seizure	Seizure:	C	1	1=Yes
	AELEVII	Event level II	Level II AE:	C	1	1=Yes
	AESAE	Event SAE	Serious adverse event:	C	1	1=Yes
	AESDTH	Death	Death:	C	1	1=Yes
	AESLIFE	Lift threatening	Life threatening:	C	1	1=Yes
	AESDISAB	Disability	Persistent or significant	C	1	1=Yes

			disability:			
	AESHOSP	Hospitalization	Prolonged hospitalization:	C	1	1=Yes
	AESMIE	Important medical event	Important medical event:	C	1	1=Yes
	AE1COMM	Comments	Comments:	C	1	
	AESDTC	Onset date		D	8	
	VERBATIM4			C	205	
	PROJCODE	Project code		C	3	
	PT4	Preferred Term	MedDRA Preferred Term	C	100	
	SOC4	System Organ Class	MedDRA System Organ Class	C	100	
	VERSION4			C	20	
	LLT4			C	100	
	HLT4			C	100	
	HLGT4			C	100	

Serious Adverse Event MER02 (AE2 form and dataset)
Version 2.01

Key Field	Field Name	Full Name	Question Text	Type	Length and Decimals	Codelist Values
*	SITE	Center		C	5	
*	PROT	Protocol		C	5	
	PATID	Participant ID		C	15	

*	PROJID	Project ID		C	5	
*	AEOSDT	Adverse event onset date		D	8	
*	AENO	Adverse event number		C	2	01=01, 02=02, 03=03, 04=04, 05=05, 06=06, 07=07, 08=08, 09=09, 10=10, 11=11, 12=12, 13=13, 14=14, 15=15
	AE2REPOR	Report prepared by	**Report prepared by:**	C	150	
	AEREPORT	Report sequence	**Report sequence:**	C	2	01=Initial Report, 02=Follow-up Version, 03=Final Report, 99=Other
	AEVERNO	Follow up version number	If "Follow-up Version," indicate the number:	N	4(0)	
	AEOTHSP	Other report sepcify	If "Other," specify:	C	100	
	AEWT	Weight	Weight:	N	8(2)	
	AELENG	Length	Length:	N	8(2)	
	AEPRES	AE still present	Serious adverse event still present?	C	2	00=No, 01=Yes, 87=Unknown
	AEONTIME	Onset time	Time of onset:	T	5	
	AERESDT	Resolved date	Date resolved:	D	8	
	AERESNA	Not resolved		C	2	88=N/A
	AEPIOPN	Investigator opinion	Investigator's opinion of relationship to the investigation	C	1	0=Not, 1=Possible, 2=Probable, 3=Definite

			al product:			
	AETRSTDT	Treatment start date	Start date:	D	8	
	AE1DOSE	Starting dose	Dose:	N	6(1)	
	AE1TIME	Starting times a day	Number of times a day:	N	2(0)	
	AELASDT	Date of last dose	Date of last dose prior to event:	D	8	
	AE2DOSE	Ending dose	Dose:	N	4(1)	
	AE2TIME	Ending times a day	Number of times a day:	N	2(0)	
	AE2SEV	Severity	**Severity:**	C	1	1=Mild, 2=Moderate, 3=Severe
	AEOUTC	Outcome	**Outcome:**	C	2	01=Death, 02=Unresolved, 03=Recovered, 04=Resolved with sequelae, 87=Unknown
	AEOUTDT	Outcome date	Date of outcome:	D	8	
	AETYPE	Type of SAE	**Type of SAE:**	C	1	1=Fatal, 2=Life-Threatening, 3=Hospitalization, 4=Prolonged Hospitalization, 5=Congenital Anomaly, 6=Important Medical Event, 7=Persistent/Significant Disability/Incapacity
	AEACTION	Action taken	**Action taken with study drug:**	C	2	00=None, 01=Study Drug Discontinued, 02=Study Drug Reduced, 03=Study Drug Interrupted, 99=Other

	AEOTACT	Other action	If "Other," specify:	C	100	
	AENAR	Narrative description	**Narrative description :**	C	4	
	AEALAB	Lab results attach	Laboratory results:	C	1	1=Yes
	AEADIAG	Diagnostic tests attach	Diagnostic tests:	C	1	1=Yes
	AEADIS	Discharge attach	Discharge summary:	C	1	1=Yes
	AEACONR	Consultation attach	Consultation reports:	C	1	1=Yes
	AEAHOS	Hospital records attach	Hospital records:	C	1	1=Yes
	AEACRF	CRF pages attach	CRF page(s):	C	1	1=Yes
	AEAAUTO	Autopsy attach	Autopsy / death certificate:	C	1	1=Yes
	AEAOTH	Other attach	Other:	C	1	1=Yes
	AEAOTHSP	Other attach specify	If "Other," specify:	C	100	
	AE2COMM	Comments	Comments:	C	1	
	AEONDATE	Onset date		D	8	

Adverse Event of Special Interest MER02 (AES form and dataset) Version 2.01

Key Field	Field Name	Full Name	Question Text	Type	Length and	Codelist Values

					Decimals	
*	SITE	Center		C	5	
*	PROT	Protocol		C	5	
	PATID	Participant ID		C	15	
*	PROJID	Project ID		C	5	
*	AEOSDT	Adverse event onset date		D	8	
*	AENO	Adverse event number		C	2	01=01, 02=02, 03=03, 04=04, 05=05, 06=06, 07=07, 08=08, 09=09, 10=10, 11=11, 12=12, 13=13, 14=14, 15=15
	AESREPOR	Report prepared by	**Report prepared by:**	C	150	
	AESWT	Weight	Weight:	N	8(2)	
	AESLENGT	Length	Length:	N	8(2)	
	AESBILI	Elevated direct bilirubin	Elevated direct bilirubin:	C	1	1=Yes
	AESIBILI	Elevated indirect bili	Elevated indirect bilirubin:	C	1	1=Yes
	AESAST	Elevated AST	Elevated AST:	C	1	1=Yes
	AESALT	Elevated ALT	Elevated ALT:	C	1	1=Yes
	AESCREAT	Elevated creatinine	Elevated creatinine:	C	1	1=Yes
	AESSEIZ	Seizure	Seizure:	C	1	1=Yes

	AESPRES	AE still present	Adverse event still present?	C	2	00=No, 01=Yes, 87=Unknown
	AESONTM	Onset time	Time of onset:	T	5	
	AESRESDT	Date resolved	Date resolved:	D	8	
	AESRESNA	Date resolved NA		C	2	88=N/A
	AESPIOP	Investigator opinion	Investigator's opinion of relationship to the investigational product:	C	1	0=Not, 1=Possible, 2=Probable, 3=Definite
	AESSTDT	Treatment start date	Start date:	D	8	
	AESSTDOS	Treatment start dose	Start date dose:	N	6(1)	
	AE1TIMES	Start times a day	Times a day:	N	4(0)	
	AESLAST	Date of last dose	Date of last dose prior to event:	D	8	
	AESLADOS	Final dose	Last date dose:	N	6(1)	
	AE2TIMES	End times a day	Times a day:	N	4(0)	
	AESCOMM	Comments	Comments:	C	175	
	AESONDT	Onset date		D	8	

Clinical Signs Assessment (CSA form and dataset)
Version 4.00

Key Field	Field Name	Full Name	Question Text	Type	Length and Decimals	Codelist Values

*	SITE	Center		C	5	
*	PROT	Protocol		C	5	
	PATID	Participant ID		C	15	
*	PROJID	Project ID		C	5	
*	PROTSEG	Segment		C	1	
*	VISNO	Visit number		C	4	
	CSCRSAMP	CRP sample collected	CRP sample collected?	C	1	0=No, 1=Yes
	CSCRPDAY	CRP collection day	Day sample collected:	C	1	3=3, 4=4, 5=5
	CSCRBSDT	CRP sample collect date	Date sample collected:	D	8	
	CSCRBSTM	CRP sample collect time	Time sample collected:	T	5	
	CSCRPLAB	Laboratory name	Laboratory name:	C	75	
	CSMBP	Mean blood pressure		N	4(0)	
	CSMBP1II	Initial BP interpretation		C	1	1=Symptomatic, 2=Asymptomatic
	CSMBP2II	Efficacy BP interpretation		C	1	1=No change, 2=Worsening, 3=Asymptomatic, 4=Improved
	CSBPCOM	BP comments		C	125	
	CSTEMP	Temperature		N	6(1)	
	CSTMP1II	Initial temperature interpretation		C	1	1=Symptomatic, 2=Asymptomatic
	CSTMP2II	Efficacy temperature		C	1	1=No change, 2=Worsening,

		interpretation				3=Asymptomatic, 4=Improved
	CSTEMCOM	Temperature comments		C	125	
	CSOX	O2 percentage		N	7(1)	
	CSOX1II	Initial O2 interpretation		C	1	1=Symptomatic, 2=Asymptomatic
	CSOX2II	Efficacy O2 interpretation		C	1	1=No change, 2=Worsening, 3=Asymptomatic, 4=Improved
	CSOXCOM	O2 comments		C	125	
	CSPAOX	Pa oxygen		N	7(1)	
	CSPOX1II	Initial PaO2 interpretation		C	1	1=Symptomatic, 2=Asymptomatic
	CSPOX2II	Efficacy PaO2 interpretation		C	1	1=No change, 2=Worsening, 3=Asymptomatic, 4=Improved
	CSPAOXCO	Pa oxygen comments		C	125	
	CSSPH	Serum pH		N	6(2)	
	CSPH1II	Initial pH interpretation		C	1	1=Symptomatic, 2=Asymptomatic
	CSPH2II	Efficacy pH interpretation		C	1	1=No change, 2=Worsening, 3=Asymptomatic, 4=Improved
	CSPHCOM	Serum pH comments		C	125	
	CSSEIZ	Seizures present		C	1	0=No, 1=Yes
	CSSZR1II	Initial seizures interpretation		C	1	1=Symptomatic, 2=Asymptomatic

	CSSZR2II	Efficacy seizures interpretation		C	1	1=No change, 2=Worsening, 3=Asymptomatic, 4=Improved
	CSSEICOM	Seizures comments		C	125	
	CSURINE	Urine output		N	6(1)	
	CSUR1II	Initial urine interpretation		C	1	1=Symptomatic, 2=Asymptomatic
	CSUR2II	Efficacy urine interpretation		C	1	1=No change, 2=Worsening, 3=Asymptomatic, 4=Improved
	CSURCOM	Urine comments		C	125	
	CSPRESS	Cardioactive drugs used		C	1	0=No, 1=Yes
	CSPRS1II	Initial cardioactive drugs interpretation		C	1	1=Symptomatic, 2=Asymptomatic
	CSPRS2II	Efficacy cardioactive drugs interpretation		C	1	1=No change, 2=Worsening, 3=Asymptomatic, 4=Improved
	CSPRSCOM	Cardioactive drugs comments		C	125	
	CSCRP	C-reactive Protein		N	7(1)	
	CSCRP1II	Initial CRP interpretation		C	1	1=Symptomatic, 2=Asymptomatic
	CSCRP2II	Efficacy CRP interpretation		C	1	1=No change, 2=Worsening, 3=Asymptomatic, 4=Improved
	CSCRPCOM	C-reactive protein comments		C	125	

	CSABGIRT	Abdominal girth		N	6(1)	
	CSAB1II	Initial girth interpretation		C	1	1=Symptomatic, 2=Asymptomatic
	CSAB2II	Efficacy girth interpretation		C	1	1=No change, 2=Worsening, 3=Asymptomatic, 4=Improved
	CSABCOM	Abdominal girth comments		C	125	
	CSABRAD	Abdominal radiograph		C	1	0=No, 1=Yes
	CSABR1II	Initial radiograph interpretation		C	1	1=Symptomatic, 2=Asymptomatic
	CSABR2II	Efficacy radiograph interpretation		C	1	1=No change, 2=Worsening, 3=Asymptomatic, 4=Improved
	CSABCOMM	Abdominal radiograph comments		C	125	
	CSDOPA	Dopamine	Dopamine used?	C	1	0=No, 1=Yes
	CSDOPDOS	Dopamine dose	Dopamine dose:	N	7(2)	
	CSEPIN	Epinephrine	Epinephrine used?	C	1	0=No, 1=Yes
	CSEPINDO	Epinephrine dose	Epinephrine dose:	N	7(2)	
	CSVASOP	Vasopressin	Vasopressin used?	C	1	0=No, 1=Yes
	CSVASDOS	Vasopressin dose	Vasopressin dose:	N	7(2)	
	CSOTH	Other drug	Other drug used?	C	1	0=No, 1=Yes
	CSOTHSPE	Other drug specify	If "Yes," specify the	C	25	

			drug:			
	CSOTHDOS	Other drug dose	Drug dose:	C	20	
	CS2OTHSP	Other drug 2 specify	If "Yes," specify the drug (if applicable):	C	25	
	CS2OTHDO	Other drug 2 dose	Drug dose:	C	20	
	CSCOMM	Comments	Comments:	C	148	

Demography (DEM form and dataset)
Version 1.00

Key Field	Field Name	Full Name	Question Text	Type	Length and Decimals	Codelist Values
	SITE	Center		C	5	
*	PROJID	Participant ID		C	5	
	DEGENDER	Gender	Gender:	C	1	1=Male, 2=Female
	DEBIRTH	Date of birth	Date of birth:	D	8	
	DEETHNI	Ethnicity	Ethnicity:	C	2	1=Hispanic or Latino, 2=Not Hispanic or Latino, 98=Not reported
	DEAMIND	American Indian or Alaskan	American Indian or Alaska Native:	C	1	0=No, 1=Yes
	DEASIAN	Asian	Asian:	C	1	0=No, 1=Yes

	DEBLACK	Black or African American	Black or African American:	C	1	0=No, 1=Yes
	DEHAWAI	Hawaiian or Pacific Islander	Native Hawaiian or Pacific Islander:	C	1	0=No, 1=Yes
	DEWHITE	White or Caucasian	White or Caucasian:	C	1	0=No, 1=Yes
	DENOTRPT	Not reported	Not reported:	C	1	0=No, 1=Yes
	DEOTHER	Other race	Other:	C	1	0=No, 1=Yes
	DEOTHRSP	Other race specify	If "Other," specify:	C	25	
	DECOMM	Comments	Comments:	C	157	
	PATID	Participant ID		C	15	
	PROT	Protocol		C	5	

Study Completion/ET (DSS form and dataset)
Version 2.00

Key Field	Field Name	Full Name	Question Text	Type	Length and Decimals	Codelist Values
*	SITE	Center		C	5	
*	PROT	Protocol		C	5	
	PATID	Participant ID		C	15	
*	PROJID	Project ID		C	5	
	DSSOCCUR	Subject complete study	Did subject complete the study?	C	1	0=No, 1=Yes
	DSSETDT	Date of	Date of study	D	8	

	C	completion or ET	completion/early termination:			
	DSDECOD	Early termination reason	Early termination reason:	C	2	01=Parent/Guardian withdrew consent, 02=Investigator judgment, 03=Protocol non-compliance (after enrollment), 04=Serious Adverse Event/Adverse Event, 05=Subject death, 06=Subject discharged prior to study day 28 and final assessments were **not** completed, 07=Termination of study or of specific site by sponsor, 99=Other
	DS1DTC	Date of death	If "Subject Death," record date of death:	D	8	
	DS2DTC	Date of discharge	If "Subject discharged prior to study day 28 and final assessments were not completed," record date of discharge:	D	8	
	DSSOTH	Other reason specify	If "Other," specify:	C	75	
	DSSIJSP	Invesitgator judgment	If "Investigator judgment," specify:	C	75	
	DSSPNCP	Protocol non compliance	If "Protocol non-compliance (after	C	75	

			enrollment)," specify:			
	DSSCOM	Comments	Comments:	C	45	

Enrollment (MER02A form ECMER02A dataset)
Version 2.00

Key Field	Field Name	Full Name	Question Text	Type	Length and Decimals	Codelist Values
*	SITE	Center		C	5	
*	PROT	Protocol		C	5	
	PATID	Participant ID		C	15	
*	PROJID	Project ID		C	5	
	ERICDT	Informed consent date	Date informed consent signed:	D	8	
	ERHIPADT	HIPAA authorization date	Date HIPAA authorization signed:	D	8	
	ERGESTAG	Gestational age	Gestational age:	N	6(1)	
	ERBTHWT	Birth weight	Birth weight:	N	6(0)	
	ERNEC	NEC grade II	NEC Grade II or higher by Bell's criteria:	C	1	1=Yes
	ERHIRSCH	Hirschsprungs disease	Hirschsprung's disease with perforation:	C	1	1=Yes
	ERSPON	Spontaneous perforation	Spontaneous perforation:	C	1	1=Yes
	ERMECONI	Meconium ileus	Meconium ileus with perforation:	C	1	1=Yes
	ERBOWEL	Bowel	Bowel	C	1	1=Yes

		obstruction	obstruction with perforation:			
	ERST1NEC	Stage 1 NEC	Infant with Stage I NEC and would receive broad spectrum antibiotics per local standard of care:	C	1	1=Yes
	ERSTCARE	Standard of care	Infant who is otherwise receiving meropenem per local standard of care:	C	1	1=Yes
	ERPERIT	Peritonitis	Peritonitis:	C	1	1=Yes
	EROTHER	Other indication	Other:	C	1	1=Yes
	EROTHSP	Other indication specify	If "Other," specify:	C	125	
	ERINCLU	Inclusion criteria met	Does the subject meet all inclusion criteria?	C	1	0=No, 1=Yes
	ER1INCLU	Inclusion criteria one	Indicate inclusion criteria number(s) not met (as defined on form IEC) and complete waiver question:	C	1	
	ER2INCLU	Inclusion criteria two		C	1	
	ER3INCLU	Inclusion criteria three		C	1	
	ER4INCLU	Inclusion criteria four		C	1	
	ER5INCLU	Inclusion		C	1	

		criteria five				
	EREXCLU	Exclusion criteria met	Does the subject meet any exclusion criteria?	C	1	0=No, 1=Yes
	ER1EXCLU	Exclusion criteria one	Indicate exclusion criteria number(s) met (as defined on form IEC) and complete waiver question:	C	1	
	ER2EXCLU	Exclusion criteria two		C	1	
	ER3EXCLU	Exclusion criteria three		C	1	
	ER4EXCLU	Exclusion criteria four		C	1	
	ER5EXCLU	Exclusion criteria five		C	1	
	ERWAIVER	Waiver granted	Was a waiver granted for any inclusion criteria not met or exclusion criteria met?	C	1	0=No, 1=Yes
	ERWVDT	Date of waiver	Date of waiver:	D	8	
	ERGROUP	Dosing group assignment	Group assignment:	C	1	1=Low, 2=High
	ERLESSTR	Under 32 weeks strata	Infants	C	1	1=<2 week PNA: 20mg/kg q 12hr, 2=≥2 week PNA: 20mg/kg q 8hr, 3=<2 week PNA: 20mg/kg q 8 hr,

						4=≥2 week PNA: 30mg/kg q 8 hr
	ERGRSTR	Over 32 weeks stratum	Infants >= 32 weeks stratum:	C	1	1=<2 week PNA: 20mg/kg q 8hr, 2=≥2 week PNA: 30mg/kg q 8hr, 3=<2 week PNA: 30mg/kg q 8hr, 4=≥2 week PNA: 40mg/kg q 8hr
	STARTDT6	MER02 start date		D	8	
	ERCOMM	Comments	Comments:	C	106	

Study Drug Administration (EXA form and dataset) Version 2.00

Key Field	Field Name	Full Name	Question Text	Type	Length and Decimals	Codelist Values
*	SITE	Center		C	5	
*	PROT	Protocol		C	5	
	PATID	Participant ID		C	15	
*	PROJID	Project ID		C	5	
*	PROTSEG	Segment		C	1	

*	VISNO	Visit number		C	4	
	EXDSNO	Dose number	Dose number:	C	2	4=4, 5=5*, 6=6, 7=7, 8=8, 9=9, 10=10, 13=13
	EXSTDT	Administration start date	Start date of administration:	D	8	
	EXSTTM	Administration start time	Start time of administration:	T	5	
	EXENDTC	Administration stop date	Stop date of administration:	D	8	
	EXENTM	Administration stop time	Stop time of administration:	T	5	
	EXWGT	Body weight actual	Body weight (actual weight):	N	6(0)	
	EXBWGT	Body weight dosing	Body weight (dosing weight):	N	6(0)	
	EXLVL	Dosing level	Dosage level:	C	1	1=Low, 2=High
	EXFRQ	Dosing frequency	Frequency:	C	2	01=q8h, 02=q12h, 99=Other
	EXFRQSP	Other frequency specify	If "Other," specify:	C	25	
	EXDOSE	Dose	Dose:	N	7(1)	
	EXTIMEPT	Deviation timepoint	Time point (specify day and time point deviation occurred):	C	100	
	EXDEV	Deviation	Deviation (provide a reason for any deviations in sampling or sample	C	150	

			processing):			
	EXCOMM	Comments	Comments:	C	200	

Dose Adjustment (EXD form and dataset)
Version 1.01

Key Field	Field Name	Full Name	Question Text	Type	Length and Decimals	Codelist Values
*	SITE	Center		C	5	
*	PROT	Protocol		C	5	
	PATID	Participant ID		C	15	
*	PROJID	Project ID		C	5	
*	PROTSEG	Segment		C	1	
*	VISNO	Visit number		C	4	
	EXNA	Dose adjustment performed	Was a dose adjustment performed?	C	2	01=Yes, 88=Not applicable
	EXDPKG	Dose per kilogram	Dose per kilogram:	N	6(1)	
	EXDPKGU	Body weight	Body weight (dosing weight):	N	6(0)	
	EXDFRQ	Dose frequency	Frequency:	C	2	01=q8h, 02=q12h, 99=Other
	EXINOTH	Other frequency specify	If "Other," specify:	C	25	
	EXDDOSE	Dose in mg	Dose:	N	7(1)	
	EXDCOMM	Comments	Comments:	C	96	

Study Drug Administration Log (EXS form and dataset)
Version 1.01

Key Field	Field Name	Full Name	Question Text	Type	Length and Decimals	Codelist Values
*	SITE	Center		C	5	
*	PROT	Protocol		C	5	
	PATID	Participant ID		C	15	
*	PROJID	Project ID		C	5	
*	SDANO	Study drug admin number		C	2	01=01, 02=02, 03=03, 04=04, 05=05, 06=06, 07=07, 08=08, 09=09, 10=10, 11=11, 12=12, 13=13, 14=14, 15=15, 16=16, 17=17, 18=18, 19=19, 20=20, 21=21, 22=22, 23=23, 24=24, 25=25, 26=26, 27=27, 28=28, 29=29, 30=30, 31=31, 32=32, 33=33, 34=34,

						35=35, 36=36, 37=37, 38=38, 39=39, 40=40, 41=41, 42=42, 43=43, 44=44, 45=45, 46=46, 47=47, 48=48, 49=49, 50=50, 51=51, 52=52, 53=53, 54=54, 55=55, 56=56, 57=57, 58=58, 59=59, 60=60, 61=61, 62=62, 63=63, 64=64, 65=65
	EXSTDTC	Dose start date	Dose start date:	D	8	
	EXSSTTM	Dose start time	Dose start time:	T	5	
	EXSDOSE	Dose in mg	Dose:	N	7(1)	
	EXSCOM	Comments	Comments:	C	200	

Abdominal Radiography Log (IML form and dataset)
Version 1.03

Key Field	Field Name	Full Name	Question Text	Type	Length and Decimals	Codelist Values

*	SITE	Center		C	5	
*	PROT	Protocol		C	5	
	PATID	Participant ID		C	15	
*	PROJID	Project ID		C	5	
*	ARLNO	Radiography number		C	2	01=01, 02=02, 03=03, 04=04, 05=05, 06=06, 07=07, 08=08, 09=09, 10=10, 11=11, 12=12, 13=13, 14=14, 15=15, 16=16, 17=17, 18=18, 19=19, 20=20, 21=21, 22=22, 23=23, 24=24, 25=25, 26=26, 27=27, 28=28, 29=29, 30=30
	IMINDIC	Indication	Indication:	C	100	
	IMLDTC	Date performed	Date performed:	D	8	
	IMLTM	Time performed	Time performed:	T	5	
	IMLCAT	Exam performed	Exam performed:	C	2	01=X-ray, 02=Ultrasound, 03=CT scan, 04=MRI, 99=Other
	IMLCATOT	Other exam specify	If "Other," specify:	C	50	
	IMLNORMA	Normal	Normal:	C	1	1=Yes
	IMLASYM	Asymmetric bowel	Asymmetric bowel pattern:	C	1	1=Yes
	IMLAIR	Air fluid levels	Air fluid levels:	C	1	1=Yes
	IMLNONSP	Non specific bowel dilat	Non-specific bowel dilatation:	C	1	1=Yes
	IMLMILD	Mild dilatation	Mild dilatation:	C	1	1=Yes

	IMLMODER	Moderate dilatation	Moderate dilatation:	C	10	1=Yes
	IMLSEVER	Severe dilatation	Severe dilatation:	C	1	1=Yes
	IMLFOCAL	Focal distension	Focal distension:	C	10	1=Yes
	IMLDIFFU	Diffuse gas distension	Diffuse gaseous distension:	C	1	1=Yes
	IMLWALL	Bowel wall thickening	Bowel wall thickening:	C	1	1=Yes
	IMLSEPAR	Separation of bowel loops	Separation of bowel loops:	C	1	1=Yes
	IMLFEATU	Featureless loops	Featureless loops:	C	1	1=Yes
	IMLBUBB	Bubbly lucencies	Bubbly lucencies:	C	10	1=Yes
	IMLPOSSI	Possible pneumatosis	Possible pneumatosis:	C	1	1=Yes
	IMLPERSI	Persistent loop	Persistent loop:	C	1	1=Yes
	IMLPNEUM	Pneumatosis intestinalis	Pneumatosis intestinalis:	C	1	1=Yes
	IMLPORTV	Portal venous gas	Portal venous gas:	C	1	1=Yes
	IMLFREE	Free air	Free air:	C	1	1=Yes
	IMLDILAT	Dilated bowel loops	Dilated bowel loops:	C	1	1=Yes
	IMLPORTA	Portal gas	Portal gas:	C	1	1=Yes
	IMLOTHER	Other	Other:	C	1	1=Yes
	IMLOTH	Other specify	If "Other," specify:	C	220	
	IMORRES	Interpretation	Investigator interpretation:	C	1	1=Normal, 2=Abnormal - Not clinically significant, 3=Abnormal - Clinically significant

	IMLCOMM	Comments	Comments:	C	102	

Radiography - Plain Film (IMR form and dataset)
Version 1.01

Key Field	Field Name	Full Name	Question Text	Type	Length and Decimals	Codelist Values
*	SITE	Center		C	5	
*	PROT	Protocol		C	5	
	PATID	Participant ID		C	15	
*	PROJID	Project ID		C	5	
	IMSTAT	Abdominal X-rays taken	Were abdominal X-rays taken?	C	1	0=No, 1=Yes
	IMDTC	Date performed	Date performed:	D	8	
	IMPOS	Projection	Projection:	C	1	1=Antero-Posterior (A-P) only, 2=Lateral only, 3=Both A-P and Lateral
	IMNORMAL	Normal	Normal:	C	1	1=Yes
	IMASYM	Asymmetric bowel	Asymmetric bowel pattern:	C	1	1=Yes
	IMAIR	Air fluid levels	Air fluid levels:	C	1	1=Yes
	IMNONSP	Non specific bowel dilat	Non-specific bowel dilatation:	C	1	1=Yes
	IMMILD	Mild dilatation	Mild dilatation:	C	1	1=Yes

	IMMODER	Moderate dilatation	Moderate dilatation:	C	10	1=Yes
	IMSEVERE	Severe dilatation	Severe dilatation:	C	1	1=Yes
	IMFOCAL	Focal distension	Focal distension:	C	10	1=Yes
	IMDIFFUS	Diffuse gas distension	Diffuse gaseous distension:	C	1	1=Yes
	IMWALL	Bowel wall thickening	Bowel wall thickening:	C	1	1=Yes
	IMSEPAR	Separation of bowel loops	Separation of bowel loops:	C	1	1=Yes
	IMFEATU	Featureless loops	Featureless loops:	C	1	1=Yes
	IMBUBB	Bubbly lucencies	Bubbly lucencies:	C	10	1=Yes
	IMPOSSI	Possible pneumatosis	Possible pneumatosis:	C	1	1=Yes
	IMPERSIS	Persistent loop	Persistent loop:	C	1	1=Yes
	IMPNEUM	Pneumatosis intestinalis	Pneumatosis intestinalis:	C	1	1=Yes
	IMPORTVG	Portal venous gas	Portal venous gas:	C	1	1=Yes
	IMFREE	Free air	Free air:	C	1	1=Yes
	IMDILATE	Dilated bowel loops	Dilated bowel loops:	C	1	1=Yes
	IMPORTAL	Portal gas	Portal gas:	C	1	1=Yes
	IMOTHER	Other	Other:	C	1	1=Yes
	IM1OTH	Other specify	If "Other," specify:	C	200	
	IMCOMM	Comments	Comments:	C	75	

Clinical Laboratory Tests (LBM form and dataset)
Version 4.00

Key Field	Field Name	Full Name	Question Text	Type	Length and Decimals	Codelist Values
*	SITE	Center		C	5	
*	PROT	Protocol		C	5	
	PATID	Participant ID		C	15	
*	PROJID	Project ID		C	5	
*	PROTSEG	Segment		C	1	
*	VISNO	Visit number		C	4	
	LBMSTAT	Hematology sample collected	Blood samples collected?	C	1	0=No, 1=Yes
	LBMDTC	Hematology sample date	Date blood sample collected:	D	8	
	LBMTM	Hematology sample time	Time collected:	T	5	
	LBMNAM	Hematology laboratory	Laboratory name:	C	75	
	LBMWBC	WBC test result		N	6(1)	
	LBMWBCAS	WBC test assessment		C	1	1=WNL, 2=ABN, CS, 3=ABN, NCS
	LBMWBCCO	WBC test comments		C	150	
	LBMRBC	RBC test result		N	6(2)	
	LBMRBCAS	RBC test assessment		C	1	1=WNL, 2=ABN, CS, 3=ABN, NCS

	LBMRBCCO	RBC test comments		C	150	
	LBMHGB	HGB test result		N	6(1)	
	LBMHGBAS	HGB test assessment		C	1	1=WNL, 2=ABN, CS, 3=ABN, NCS
	LBMHGBCO	HGB test comments		C	150	
	LBMHCT	HCT test result		N	7(1)	
	LBMHCTAS	HCT test assessment		C	1	1=WNL, 2=ABN, CS, 3=ABN, NCS
	LBMHCTCO	HCT test comments		C	150	
	LBMPLCT	Platelet count result		N	6(0)	
	LBMPLCTA	Platelet count assessment		C	1	1=WNL, 2=ABN, CS, 3=ABN, NCS
	LBMPLCOM	Platelet count comments		C	150	
	LBMNEUT	Neutrophils result		N	7(1)	
	LBMNEUTA	Neutrophils assessment		C	1	1=WNL, 2=ABN, CS, 3=ABN, NCS
	LBMNEUTC	Neutrophils comments		C	150	
	LBMLYMPH	Lymphocytes result		N	7(1)	
	LBMLYMAS	Lymphocytes		C	1	1=WNL,

		assessment				2=ABN, CS, 3=ABN, NCS
	LBMLYMCO	Lymphocytes comments		C	150	
	LBMMONO	Monocytes result		N	7(1)	
	LBMMONAS	Monocytes assessment		C	1	1=WNL, 2=ABN, CS, 3=ABN, NCS
	LBMMONCO	Monocytes comments		C	150	
	LBMEOS	Eosinophils result		N	7(1)	
	LBMEOSAS	Eosinophils assessment		C	1	1=WNL, 2=ABN, CS, 3=ABN, NCS
	LBMEOSCO	Eosinophils comments		C	150	
	LBMBASO	Basophils result		N	7(1)	
	LBMBASOA	Basophils assessment		C	1	1=WNL, 2=ABN, CS, 3=ABN, NCS
	LBMBASOC	Basophils comments		C	150	
	LBMBANDS	Bands result		N	7(1)	
	LBMBANAS	Bands assessment		C	1	1=WNL, 2=ABN, CS, 3=ABN, NCS
	LBMBANCO	Bands comments		C	150	
	LBMCHEM	Chemistry	Blood	C	1	0=No,

		sample collected	samples collected?			1=Yes
	LBMCHEMD	Chemistry sample date	Date blood sample collected:	D	8	
	LBMCHEMT	Chemistry sample time	Time collected:	T	5	
	LBMCHEMN	Chemistry laboratory	Laboratory name:	C	75	
	LBMGLU	Glucose result		N	5(0)	
	LBMGLUAS	Glucose assessment		C	1	1=WNL, 2=ABN, CS, 3=ABN, NCS
	LBMGLUCO	Glucose comments		C	150	
	LBMCREAT	Creatinine result		N	6(1)	
	LBMCRASS	Creatinine assessment		C	1	1=WNL, 2=ABN, CS, 3=ABN, NCS
	LBMCRCOM	Creatinine comments		C	150	
	LBMBUN	BUN result		N	5(0)	
	LBMBUNAS	BUN assessment		C	1	1=WNL, 2=ABN, CS, 3=ABN, NCS
	LBMBUNCO	BUN comments		C	150	
	LBMAST	AST result		N	6(0)	
	LBMASTAS	AST assessment		C	1	1=WNL, 2=ABN, CS, 3=ABN, NCS

	LBMASTCO	AST comments		C	150	
	LBMALT	ALT result		N	6(0)	
	LBMALTAS	ALT assessment		C	1	1=WNL, 2=ABN, CS, 3=ABN, NCS
	LBMALTCO	ALT comments		C	150	
	LBMAP	Alk phosphatase result		N	6(0)	
	LBMAPAS	Alk phosphatase assess		C	1	1=WNL, 2=ABN, CS, 3=ABN, NCS
	LBMAPCO	Alk phosphatase comments		C	150	
	LBMTBILI	Total bilirubin result		N	6(1)	
	LBMTBILA	Total bilirubin assess		C	1	1=WNL, 2=ABN, CS, 3=ABN, NCS
	LBMTBILC	Total bilirubin comments		C	150	
	LBMDBILI	Direct bilirubin result		N	6(1)	
	LBMDBILA	Direct bilirubin assess		C	1	1=WNL, 2=ABN, CS, 3=ABN, NCS
	LBMDBILC	Direct bilirubin comments		C	150	

	LBMSODIU	Sodium result		N	5(0)	
	LBMNAASS	Sodium assessment		C	1	1=WNL, 2=ABN, CS, 3=ABN, NCS
	LBMNACOM	Sodium comments		C	150	
	LBMPOTAS	Potassium result		N	5(1)	
	LBMKASS	Potassium assessment		C	1	1=WNL, 2=ABN, CS, 3=ABN, NCS
	LBMKCOM	Potassium comments		C	150	
	LBMCL	Chloride result		N	5(0)	
	LBMCLASS	Chloride assessment		C	1	1=WNL, 2=ABN, CS, 3=ABN, NCS
	LBMCLCOM	Chloride comments		C	150	
	LBMCALC	Calcium result		N	6(1)	
	LBMCALAS	Calcium assessment		C	1	1=WNL, 2=ABN, CS, 3=ABN, NCS
	LBMCALCO	Calcium comments		C	150	
	LBMMG	Magnesium result		N	5(1)	
	LBMMGAS	Magnesium assessment		C	1	1=WNL, 2=ABN, CS, 3=ABN, NCS

	LBMMGCO	Magnesium comments		C	150	
	LBMPRO	Total protein result		N	6(1)	
	LBMPROAS	Total protein assessment		C	1	1=WNL, 2=ABN, CS, 3=ABN, NCS
	LBMPROCO	Total protein comments		C	150	
	LBMAL	Albumin result		N	5(1)	
	LBMALAS	Albumin assessment		C	1	1=WNL, 2=ABN, CS, 3=ABN, NCS
	LBMALCOM	Albumin comments		C	150	
	LBMCOMM	Comments	Comments:	C	200	

Scavenge/Tissue Samples (LBS form and dataset)
Version 2.01

Key Field	Field Name	Full Name	Question Text	Type	Length and Decimals	Codelist Values
*	SITE	Center		C	5	
*	PROT	Protocol		C	5	
	PATID	Participant ID		C	15	
*	PROJID	Project ID		C	5	
*	TISSUENO	Scavenge/tissue number		C	2	01=01, 02=02, 03=03, 04=04, 05=05,

						06=06, 07=07, 08=08, 09=09, 10=10, 11=11, 12=12, 13=13, 14=14, 15=15
	LBSPEC	Type of sample	Type of sample:	C	1	1=Scavenge plasma, 2=Scavenge whole blood, 3=CSF, 4=Urine, 5=Peritoneal, 6=Pleural, 7=Intestinal tissue
	LBSDTC	Date sample obtained	Date sample obtained from infant:	D	8	
	LBSTM	Time sample obtained	Time sample obtained from infant:	T	5	
	LBREFID	Accession number	Accession number:	C	3	
	LBFRDTC	Date sample frozen	Date sample frozen at -70°C:	D	8	
	LBFRTM	Time sample frozen	Time sample frozen at -70°C:	T	5	
	LBDSDTC	Date of most recent dose	Date of most recent dose:	D	8	
	LBDSTM	Time of most recent dose	Time of most recent dose:	T	5	
	LBSWGT	Most recent body weight	Most recent body weight:	N	6(0)	
	LBSWBC	CSF WBC count		N	6(0)	
	LBSRBC	CSF RBC count		N	7(0)	
	LBSCSFPR	CSF protein		N	6(0)	

	LBSCSFGL	CSF glucose		N	6(0)	
	LBSCSFCR	CSF culture result		C	1	1=Positive, 0=Negative
	LBACCNO	Accession number done	Accession number of corresponding scavenge plasma sample (check yes if collected):	C	1	0=No, 1=Yes
	LBACCNUM	Accession number		C	3	
	LBURINPH	Urine pH		N	6(2)	
	LBURINSG	Urine specific gravity		N	6(0)	
	LBURINCU	Urine culture result		C	1	1=Positive, 0=Negative
	LB2ACCNO	Accession 2 number done	Accession number of corresponding scavenge plasma sample (check yes if collected):	C	1	0=No, 1=Yes
	LB2ACCNU	Accession 2 number		C	3	
	LBSPERPH	Peritoneal pH		N	6(2)	
	LBSPERCU	Peritoneal culture result		C	1	1=Positive, 0=Negative
	LBSPLPH	Pleural pH		N	6(2)	
	LBSPLCU	Pleural culture result		C	1	1=Positive, 0=Negative
	LBSCOM	Comments	Comments:	C	140	

Microbiology Cultures (MBC form and dataset)
Version 1.02

Key Field	Field Name	Full Name	Question Text	Type	Length and Decimals	Codelist Values
*	SITE	Center		C	5	
*	PROT	Protocol		C	5	
	PATID	Participant ID		C	15	
*	PROJID	Project ID		C	5	
*	MBCNO	Microbiology culture num		C	2	01=01, 02=02, 03=03, 04=04, 05=05, 06=06, 07=07, 08=08, 09=09, 10=10, 11=11, 12=12, 13=13, 14=14, 15=15
	MBDTC	Date sample collected	Date sample collected:	D	8	
	MBTM	Time sample collected	Time sample collected:	T	5	
	MBNAM	Laboratory name	Laboratory name:	C	75	
	MBSCAT	Culture	Culture:	C	2	01=Blood, 02=Urine, 03=Cerebrospinal fluid, 4=Peritoneal fluid
	MBMETHOD	Method of acquisition	Method of acquisition:	C	2	01=Peripheral, 02=Central line, 03=Suprapubic aspiration, 04=Catheterization, 05=Lumbar puncture, 06=Ventricular reservoir tap, 99=Other
	MBOTHSPC	Other method specify	If "Other," specify:	C	100	
	MBORRES	Culture results	Culture results:	C	1	1=Positive, 0=Negative
	MBFINDA	Bacteria findings A	Bacteria findings A:	C	2	01=Acinetobacter antiratus, 02=Bacillus

						sp., 03=Bacteroides sp., 04=Citrobacter sp., 05=Clostridia sp., 06=Corynebacterium sp., 07=Enterobacter sp., 08=Enterobacter cloacae, 09=Escherichia coli, 10=Fusobacterium nucleatum, 11=Hemophilus influenzae, 12=Klebsiella sp., 13=Listeria sp., 14=Listeria monocytogenes, 15=Micrococcus sp., 16=Neisseria sp., 17=Neisseria gonorrhoeae, 18=Peptococcus sp., 19=Peptostreptococcus sp., 20=Propionibacterium sp., 21=Proteus sp., 22=Providencia sp., 23=Pseudomonas aeruginosa, 24=Pseudomonas cepacia, 25=Salmonella sp., 26=Serratia marcescens, 27=Shigella sp., 28=Staphylococcus aureus, 29=Staphylococcus epidermidis, 30=Staphylococcus sp. unknown, coag -neg, 31=Streptobacillus sp., 32=Streptococcus viridans, 33=Enterococcus faecum, 34=Enterococcus faecalis
	MBCANDA	Candida findings A	Candida findings A:	C	1	1=Candida albicans, 2=Candida parapsilosis, 3=Candida tropicalis, 4=Candida krusei, 5=Candida glabrata, 6=Candida guillermondi, 7=Candida lusitaniae, 8=Malassezia furfur
	MBFINDB	Bacteria findings B	Bacteria findings B:	C	2	01=Acinetobacter antiratus, 02=Bacillus

						sp., 03=Bacteroides sp., 04=Citrobacter sp., 05=Clostridia sp., 06=Corynebacterium sp., 07=Enterobacter sp., 08=Enterobacter cloacae, 09=Escherichia coli, 10=Fusobacterium nucleatum, 11=Hemophilus influenzae, 12=Klebsiella sp., 13=Listeria sp., 14=Listeria monocytogenes, 15=Micrococcus sp., 16=Neisseria sp., 17=Neisseria gonorrhoeae, 18=Peptococcus sp., 19=Peptostreptococcus sp., 20=Propionibacterium sp., 21=Proteus sp., 22=Providencia sp., 23=Pseudomonas aeruginosa, 24=Pseudomonas cepacia, 25=Salmonella sp., 26=Serratia marcescens, 27=Shigella sp., 28=Staphylococcus aureus, 29=Staphylococcus epidermidis, 30=Staphylococcus sp. unknown, coag -neg, 31=Streptobacillus sp., 32=Streptococcus viridans, 33=Enterococcus faecum, 34=Enterococcus faecalis
	MBCANDB	Candida findings B	Candida findings B:	C	1	1=Candida albicans, 2=Candida parapsilosis, 3=Candida tropicalis, 4=Candida krusei, 5=Candida glabrata, 6=Candida guillermondi, 7=Candida lusitaniae, 8=Malassezia furfur
	MBFINDC	Bacteria findings C	Bacteria findings C:	C	2	01=Acinetobacter antiratus, 02=Bacillus

						sp., 03=Bacteroides sp., 04=Citrobacter sp., 05=Clostridia sp., 06=Corynebacterium sp., 07=Enterobacter sp., 08=Enterobacter cloacae, 09=Escherichia coli, 10=Fusobacterium nucleatum, 11=Hemophilus influenzae, 12=Klebsiella sp., 13=Listeria sp., 14=Listeria monocytogenes, 15=Micrococcus sp., 16=Neisseria sp., 17=Neisseria gonorrhoeae, 18=Peptococcus sp., 19=Peptostreptococcus sp., 20=Propionibacterium sp., 21=Proteus sp., 22=Providencia sp., 23=Pseudomonas aeruginosa, 24=Pseudomonas cepacia, 25=Salmonella sp., 26=Serratia marcescens, 27=Shigella sp., 28=Staphylococcus aureus, 29=Staphylococcus epidermidis, 30=Staphylococcus sp. unknown, coag -neg, 31=Streptobacillus sp., 32=Streptococcus viridans, 33=Enterococcus faecum, 34=Enterococcus faecalis
	MBCANDC	Candida findings C	Candida findings C:	C	1	1=Candida albicans, 2=Candida parapsilosis, 3=Candida tropicalis, 4=Candida krusei, 5=Candida glabrata, 6=Candida guillermondi, 7=Candida lusitaniae, 8=Malassezia furfur
	MBFINDD	Bacteria findings D	Bacteria findings D:	C	2	01=Acinetobacter antiratus, 02=Bacillus

						sp., 03=Bacteroides sp., 04=Citrobacter sp., 05=Clostridia sp., 06=Corynebacterium sp., 07=Enterobacter sp., 08=Enterobacter cloacae, 09=Escherichia coli, 10=Fusobacterium nucleatum, 11=Hemophilus influenzae, 12=Klebsiella sp., 13=Listeria sp., 14=Listeria monocytogenes, 15=Micrococcus sp., 16=Neisseria sp., 17=Neisseria gonorrhoeae, 18=Peptococcus sp., 19=Peptostreptococcus sp., 20=Propionibacterium sp., 21=Proteus sp., 22=Providencia sp., 23=Pseudomonas aeruginosa, 24=Pseudomonas cepacia, 25=Salmonella sp., 26=Serratia marcescens, 27=Shigella sp., 28=Staphylococcus aureus, 29=Staphylococcus epidermidis, 30=Staphylococcus sp. unknown, coag -neg, 31=Streptobacillus sp., 32=Streptococcus viridans, 33=Enterococcus faecum, 34=Enterococcus faecalis
	MBCANDD	Candida findings D	Candida findings D:	C	1	1=Candida albicans, 2=Candida parapsilosis, 3=Candida tropicalis, 4=Candida krusei, 5=Candida glabrata, 6=Candida guillermondi, 7=Candida lusitaniae, 8=Malassezia furfur
	MBFINDE	Bacteria findings E	Bacteria findings E:	C	2	01=Acinetobacter antiratus, 02=Bacillus

						sp., 03=Bacteroides sp., 04=Citrobacter sp., 05=Clostridia sp., 06=Corynebacterium sp., 07=Enterobacter sp., 08=Enterobacter cloacae, 09=Escherichia coli, 10=Fusobacterium nucleatum, 11=Hemophilus influenzae, 12=Klebsiella sp., 13=Listeria sp., 14=Listeria monocytogenes, 15=Micrococcus sp., 16=Neisseria sp., 17=Neisseria gonorrhoeae, 18=Peptococcus sp., 19=Peptostreptococcus sp., 20=Propionibacterium sp., 21=Proteus sp., 22=Providencia sp., 23=Pseudomonas aeruginosa, 24=Pseudomonas cepacia, 25=Salmonella sp., 26=Serratia marcescens, 27=Shigella sp., 28=Staphylococcus aureus, 29=Staphylococcus epidermidis, 30=Staphylococcus sp. unknown, coag -neg, 31=Streptobacillus sp., 32=Streptococcus viridans, 33=Enterococcus faecum, 34=Enterococcus faecalis
	MBCANDE	Candida findings E	Candida findings E:	C	1	1=Candida albicans, 2=Candida parapsilosis, 3=Candida tropicalis, 4=Candida krusei, 5=Candida glabrata, 6=Candida guillermondi, 7=Candida lusitaniae, 8=Malassezia furfur
	MBFINDF	Bacteria findings F	Bacteria findings F:	C	2	01=Acinetobacter antiratus, 02=Bacillus

						sp., 03=Bacteroides sp., 04=Citrobacter sp., 05=Clostridia sp., 06=Corynebacterium sp., 07=Enterobacter sp., 08=Enterobacter cloacae, 09=Escherichia coli, 10=Fusobacterium nucleatum, 11=Hemophilus influenzae, 12=Klebsiella sp., 13=Listeria sp., 14=Listeria monocytogenes, 15=Micrococcus sp., 16=Neisseria sp., 17=Neisseria gonorrhoeae, 18=Peptococcus sp., 19=Peptostreptococcus sp., 20=Propionibacterium sp., 21=Proteus sp., 22=Providencia sp., 23=Pseudomonas aeruginosa, 24=Pseudomonas cepacia, 25=Salmonella sp., 26=Serratia marcescens, 27=Shigella sp., 28=Staphylococcus aureus, 29=Staphylococcus epidermidis, 30=Staphylococcus sp. unknown, coag -neg, 31=Streptobacillus sp., 32=Streptococcus viridans, 33=Enterococcus faecum, 34=Enterococcus faecalis
	MBCANDF	Candida findings F	Candida findings F:	C	1	1=Candida albicans, 2=Candida parapsilosis, 3=Candida tropicalis, 4=Candida krusei, 5=Candida glabrata, 6=Candida guillermondi, 7=Candida lusitaniae, 8=Malassezia furfur
	MBFNDOTH	Other findings	If "Other," specify:	C	100	

		specify				
	MBCOM	Comments	Comments:	C	89	

Prior and Concomitant Medications (ME1 dataset)
Version 4.00

Key Field	Field Name	Full Name	Question Text	Type	Length and Decimals	Codelist Values
*	SITE	Center		C	5	
*	PROT	Protocol		C	5	
	PATID	Participant ID		C	15	
*	PROJID	Project ID		C	5	
*	MEDNAME	Medication name		C	75	
*	MEDSTADT	Medication start date		D	8	
*	M1SEQNUM	Sequence number		C	2	01=1st medication instance for the day, 02=2nd medication instance for the day, 03=3rd medication instance for the day, 04=4th medication instance for the day, 05=5th medication instance for the day, 06=6th medication instance for the day, 07=7th medication instance for the day, 08=8th medication instance for the day, 09=9th medication instance for the day, 10=10th medication instance for the day, 11=11th medication instance for the day, 12=12th medication

						instance for the day, 13=13th medication instance for the day, 14=14th medication instance for the day, 15=15th medication instance for the day, 16=16th medication instance for the day, 17=17th medication instance for the day, 18=18th medication instance for the day, 19=19th medication instance for the day, 20=20th medication instance for the day, 21=21st medication instance for the day, 22=22nd medication instance for the day, 23=23rd medication instance for the day, 24=24th medication instance for the day, 25=25th medication instance for the day
	M1ONGM	Med ongoing	Ongoing (check if Yes):	C	1	1=Yes
	M1ENDDT	Med end date	Medication end date:	D	8	
	M1COMM	Comments	Comments:	C	200	

Medical History (MHM form and dataset)
Version 5.00

Key Field	Field Name	Full Name	Question Text	Type	Length and Decimals	Codelist Values
*	SITE	Center		C	5	
*	PROT	Protocol		C	5	
	PATID	Participant		C	15	

		ID				
*	PROJID	Project ID		C	5	
*	BODY2SYS	Body system		C	2	01=ENT (Ears, Nose, Throat), 02=Eyes, 03=Respiratory system, 04=Cardiovascular system, 05=Gastrointestinal system, 06=Urinary system, 07=Reproductive system, 08=Blood & Lymphatic system, 09=Musculoskeletal system, 10=Dermatologic system, 11=Neurological system, 99=Other
	MMASDT	Date of assessment	Date of assessment:	D	8	
	MMNOHIS	Medical or surgical hx	Does the subject have any relevant medical history (including surgical history) or current medical conditions?	C	1	0=No, 1=Yes
	MMCONA	Condition A		C	100	
	MMOSADT	Onset date A		D	8	
	MMACTVA	Condition A active		C	1	0=No, 1=Yes
	MMODAUNK	Onset date A unknown		C	20	
	MMCONB	Condition B		C	100	
	MMOSBDT	Onset date B		D	8	
	MMACTVB	Condition B active		C	1	0=No, 1=Yes

	MMODBUNK	Onset date B unknown		C	20	
	MMCONC	Condition C		C	100	
	MMOSCDT	Onset date C		D	8	
	MMACTVC	Condition C active		C	1	0=No, 1=Yes
	MMODCUNK	Onset date C unknown		C	20	
	MMCOND	Condition D		C	100	
	MMOSDDT	Onset date D		D	8	
	MMACTVD	Condition D active		C	1	0=No, 1=Yes
	MMODDUNK	Onset date D unknown		C	20	
	MMCONE	Condition E		C	100	
	MMOSEDT	Onset date E		D	8	
	MMACTVE	Condition E active		C	1	0=No, 1=Yes
	MMODEUNK	Onset date E unknown		C	20	
	MMCONF	Condition F		C	100	
	MMOSFDT	Onset date F		D	8	
	MMACTVF	Condition F active		C	1	0=No, 1=Yes
	MMODFUNK	Onset date F unknown		C	20	
	MMCONG	Condition G		C	100	
	MMOSGDT	Onset date G		D	8	
	MMACTVG	Condition G active		C	1	0=No, 1=Yes
	MMODGUNK	Onset date		C	20	

		G unknown				
	MMCONH	Condition H		C	100	
	MMOSHDT	Onset date H		D	8	
	MMACTVH	Condition H active		C	1	0=No, 1=Yes
	MMODHUNK	Onset date H unknown		C	20	
	MMCONI	Condition I		C	100	
	MMOSIDT	Onset date I		D	8	
	MMACTVI	Condition I active		C	1	0=No, 1=Yes
	MMODIUNK	Onset date I unknown		C	20	
	MMCONJ	Condition J		C	100	
	MMOSJDT	Onset date J		D	8	
	MMACTVJ	Condition J active		C	1	0=No, 1=Yes
	MMODJUNK	Onset date J unknown		C	20	
	MMCONK	Condition K		C	100	
	MMOSKDT	Onset date K		D	8	
	MMACTVK	Condition K active		C	1	0=No, 1=Yes
	MMODKUNK	Onset date K unknown		C	20	
	MMCONL	Condition L		C	100	
	MMOSLDT	Onset date L		D	8	
	MMACTVL	Condition L active		C	1	0=No, 1=Yes
	MMODLUNK	Onset date L unknown		C	20	

	MMCONM	Condition M		C	100	
	MMOSMDT	Onset date M		D	8	
	MMACTVM	Condition M active		C	1	0=No, 1=Yes
	MMODMUNK	Onset date M unknown		C	20	
	MMCONN	Condition N		C	100	
	MMOSNDT	Onset date N		D	8	
	MMACTVN	Condition N active		C	1	0=No, 1=Yes
	MMODNUNK	Onset date N unknown		C	20	
	MMCONO	Condition O		C	100	
	MMOSODT	Onset date O		D	8	
	MMACTVO	Condition O active		C	1	0=No, 1=Yes
	MMODOUNK	Onset date O unknown		C	20	
	MMCONP	Condition P		C	100	
	MMOSPDT	Onset date P		D	8	
	MMACTVP	Condition P active		C	1	0=No, 1=Yes
	MMODPUNK	Onset date P unknown		C	20	
	MMCONQ	Condition Q		C	100	
	MMOSQDT	Onset date Q		D	8	
	MMACTVQ	Condition Q active		C	1	0=No, 1=Yes
	MMODQUNK	Onset date Q unknown		C	20	

	MMCONR	Condition R		C	100	
	MMOSRDT	Onset date R		D	8	
	MMACTVR	Condition R active		C	1	0=No, 1=Yes
	MMODRUNK	Onset date R unknown		C	20	
	MMCONS	Condition S		C	100	
	MMOSSDT	Onset date S		D	8	
	MMACTVS	Condition S active		C	1	0=No, 1=Yes
	MMODSUNK	Onset date S unknown		C	20	
	MMCONT	Condition T		C	100	
	MMOSTDT	Onset date T		D	8	
	MMACTVT	Condition T active		C	1	0=No, 1=Yes
	MMODTUNK	Onset date T unknown		C	20	
	MMCONU	Condition U		C	100	
	MMOSUDT	Onset date U		D	8	
	MMACTVU	Condition U active		C	1	0=No, 1=Yes
	MMODUUNK	Onset date U unknown		C	20	
	MMCONV	Condition V		C	100	
	MMOSVDT	Onset date V		D	8	
	MMACTVV	Condition V active		C	1	0=No, 1=Yes
	MMODVUNK	Onset date V unknown		C	20	
	MMCOMM	Comments	Comments:	C	90	

PK Blood Collection: Dose 1 – Even (PCE form and dataset)
Version 1.01

Key Field	Field Name	Full Name	Question Text	Type	Length and Decimals	Codelist Values
*	SITE	Center		C	5	
*	PROT	Protocol		C	5	
	PATID	Participant ID		C	15	
*	PROJID	Project ID		C	5	
*	PROTSEG	Segment		C	1	
*	VISNO	Visit number		C	4	
	PCE1SAMP	Sample 1 collected		C	1	0=No, 1=Yes
	PCE1DTC	Sample 1 date		D	8	
	PCE1TM	Sample 1 time		T	5	
	PCE1ACCN	Sample 1 accession number		C	3	
	PCE1SPTY	Sample 1 specimen type		C	1	1=Arterial, 2=Central venous, 3=Heel stick, 4=Peripheral venous
	PCE2SAMP	Sample 2 collected		C	1	0=No, 1=Yes
	PCE2DTC	Sample 2 date		D	8	
	PCE2TM	Sample 2 time		T	5	

	PCE2ACCN	Sample 2 accession number		C	3	
	PCE2SPTY	Sample 2 specimen type		C	1	1=Arterial, 2=Central venous, 3=Heel stick, 4=Peripheral venous
	PCE3SAMP	Sample 3 collected		C	1	0=No, 1=Yes
	PCE3DTC	Sample 3 date		D	8	
	PCE3TM	Sample 3 time		T	5	
	PCE3ACCN	Sample 3 accession number		C	3	
	PCE3SPTY	Sample 3 specimen type		C	1	1=Arterial, 2=Central venous, 3=Heel stick, 4=Peripheral venous
	PCE4TPT	Sample 4 time point		C	1	1=q8h (7 hrs - 8 hrs), 2=q12h (10 hrs - 12 hrs)
	PCE4SAMP	Sample 4 collected		C	1	0=No, 1=Yes
	PCE4DT	Sample 4 date		D	8	
	PCE4TM	Sample 4 time		T	5	
	PCE4ACCN	Sample 4 accession number		C	3	
	PCE4SPTY	Sample 4 specimen type		C	1	1=Arterial, 2=Central venous, 3=Heel stick, 4=Peripheral venous

	PCEDEV	Deviation time point	Time point (specify day and time point deviation occurred):	C	100	
	PCEDEVRS	Deviation reason	Deviation (provide a reason for any deviations in sampling or sample processing):	C	150	
	PCECOM	Comments	Comments:	C	1	

PK Blood Collection: Dose 1 – Odd (PCO form and dataset) Version 1.01

Key Field	Field Name	Full Name	Question Text	Type	Length and Decimals	Codelist Values
*	SITE	Center		C	5	
*	PROT	Protocol		C	5	
	PATID	Participant ID		C	15	
*	PROJID	Project ID		C	5	
*	PROTSEG	Segment		C	1	
*	VISNO	Visit number		C	4	
	PC1SAMP	Sample 1 collected		C	1	0=No, 1=Yes
	PC1DTC	Sample 1 date		D	8	
	PC1TM	Sample 1 time		T	5	
	PC1ACCNO	Sample 1		C	3	

		accession number				
	PC1SPTYP	Sample 1 specimen type		C	1	1=Arterial, 2=Central venous, 3=Heel stick, 4=Peripheral venous
	PC2SAMP	Sample 2 collected		C	1	0=No, 1=Yes
	PC2DTC	Sample 2 date		D	8	
	PC2TM	Sample 2 time		T	5	
	PC2ACCNO	Sample 2 accession number		C	3	
	PC2SPTYP	Sample 2 specimen type		C	1	1=Arterial, 2=Central venous, 3=Heel stick, 4=Peripheral venous
	PC3SAMP	Sample 3 collected		C	1	0=No, 1=Yes
	PC3DTC	Sample 3 date		D	8	
	PC3TM	Sample 3 time		T	5	
	PC3ACCNO	Sample 3 accession number		C	3	
	PC3SPTYP	Sample 3 specimen type		C	1	1=Arterial, 2=Central venous, 3=Heel stick, 4=Peripheral venous
	PC4TPT	Sample 4 time point		C	1	1=q8h (7 hrs - 8 hrs), 2=q12h (10 hrs - 12 hrs)
	PC4SAMP	Sample 4		C	1	0=No, 1=Yes

		collected				
	PC4DT	Sample 4 date		D	8	
	PC4TM	Sample 4 time		T	5	
	PC4ACCNO	Sample 4 accession number		C	3	
	PC4SPTYP	Sample 4 specimen type		C	1	1=Arterial, 2=Central venous, 3=Heel stick, 4=Peripheral venous
	PCDEV	Deviation time point	Time point (specify day and time point deviation occurred):	C	100	
	PCDEVRS	Deviation reasons	Deviation (provide a reason for any deviations in sampling or sample processing):	C	150	
	PCOCOM	Comments	Comments:	C	75	

PK Blood Collection: Steady State (PCS form and dataset) Version 1.01

Key Field	Field Name	Full Name	Question Text	Type	Length and Decimals	Codelist Values
*	SITE	Center		C	5	
*	PROT	Protocol		C	5	
	PATID	Participant		C	15	

		ID				
*	PROJID	Project ID		C	5	
*	PROTSEG	Segment		C	1	
*	VISNO	Visit number		C	4	
	PCS1SAMP	Sample 1 collected		C	1	0=No, 1=Yes
	PCS1DTC	Sample 1 date		D	8	
	PCS1TM	Sample 1 time		T	5	
	PCS1ACCN	Sample 1 accession number		C	3	
	PCS1SPTY	Sample 1 specimen type		C	1	1=Arterial, 2=Central venous, 3=Heel stick, 4=Peripheral venous
	PCS2SAMP	Sample 2 collected		C	1	0=No, 1=Yes
	PCS2DTC	Sample 2 date		D	8	
	PCS2TM	Sample 2 time		T	5	
	PCS2ACCN	Sample 2 accession number		C	3	
	PCS2SPTY	Sample 2 specimen type		C	1	1=Arterial, 2=Central venous, 3=Heel stick, 4=Peripheral venous
	PCS3SAMP	Sample 3 collected		C	1	0=No, 1=Yes
	PCS3DTC	Sample 3 date		D	8	
	PCS3TM	Sample 3		T	5	

		time				
	PCS3ACCN	Sample 3 accession number		C	3	
	PCS3SPTY	Sample 3 specimen type		C	1	1=Arterial, 2=Central venous, 3=Heel stick, 4=Peripheral venous
	PCSDEV	Deviation time point	Time point (specify day and time point deviation occurred):	C	100	
	PCSDEVRS	Deviation reason	Deviation (provide a reason for any deviations in sampling or sample processing):	C	150	
	PCSCOM	Comments	Comments:	C	1	

Protocol Deviation/Waiver (PDW form and dataset)
Version 2.00

Key Field	Field Name	Full Name	Question Text	Type	Length and Decimals	Codelist Values
*	SITE	Center		C	5	
*	PROT	Protocol		C	5	
	PATID	Participant ID		C	15	
*	PROJID	Project ID		C	5	
*	PDDEVWDT	Date of deviation		D	8	

		or waiver				
*	PDDWSEQN	Deviation or waiver sequence number		C	2	01=1, 02=2, 03=3, 04=4, 05=5, 06=6, 07=7, 08=8, 09=9, 10=10, 11=11, 12=12, 13=13, 14=14, 15=15, 16=16, 17=17, 18=18, 19=19, 20=20, 21=21, 22=22, 23=23, 24=24, 25=25, 26=26, 27=27, 28=28, 29=29, 30=30, 31=31, 32=32, 33=33, 34=34, 35=35, 36=36, 37=37, 38=38, 39=39, 40=40
	PDRPTPER	Personnel reporting deviation	Site personnel reporting deviation (name/title):	C	40	
	PDDRPTDT	Date deviation reported	Date deviation reported:	D	8	
	PDDOCCTM	Time deviation occurred	Time deviation occurred:	T	5	

	PDDOSREG	Participant dose regimen	Participant dosing regimen:	C	2	1=Low, 2=High, 88=N/A
	PDDIEC	Dev from IE criteria	Deviation from inclusion or exclusion criteria:	C	1	0=No, 1=Yes
	PDDIECSP	Dev from IE criteria specify	If "Yes," specify:	C	55	
	PDDEVDET	Deviation details	Deviation details:	C	200	
	PDDRSPND	Response to deviation	Response to deviation:	C	155	
	PDPCONT	Participant continue in study	Participant may continue in the study:	C	1	0=No, 1=Yes
	PDWAIVER	Waiver granted	Waiver granted:	C	2	0=No, 1=Yes, 88=N/A
	PDCOMM	Comments	Comments:	C	133	

Physical Examination (PED form and dataset)
Version 3.00

Key Field	Field Name	Full Name	Question Text	Type	Length and Decimals	Codelist Values
*	SITE	Center		C	5	
*	PROT	Protocol		C	5	
	PATID	Participant ID		C	15	
*	PROJID	Project ID		C	5	
*	PROTSEG	Segment		C	1	

*	VISNO	Visit number		C	4	
	PEDASDT	Date of assessment	Date performed:	D	8	
	PEDABBS	New abnormal findings	Are there any clinically significant abnormal findings that have been newly diagnosed or have worsened since the baseline assessment?	C	1	0=No, 1=Yes
	PEDABNOR	Abnormal findings	Were there any abnormal findings?	C	1	0=No, 1=Yes
	PED1BS	Body system 1		C	2	01=ENT (Ears, Nose, Throat), 02=Eyes, 03=Respiratory system, 04=Cardiovascular system, 05=Gastrointestinal system, 06=Urinary system, 07=Reproductive system, 08=Blood & Lymphatic system, 09=Musculoskeletal system, 10=Dermatologic system, 11=Neurological system, 99=Other
	PED1CON	Condition 1		C	25	
	PED1AB	Abnormality 1		C	200	
	PED2BS	Body system 2		C	2	01=ENT (Ears, Nose, Throat), 02=Eyes, 03=Respiratory system, 04=Cardiovascular system, 05=Gastrointestinal system, 06=Urinary system,

						07=Reproductive system, 08=Blood & Lymphatic system, 09=Musculoskeletal system, 10=Dermatologic system, 11=Neurological system, 99=Other
	PED2CON	Condition 2		C	25	
	PED2AB	Abnormality 2		C	200	
	PED3BS	Body system 3		C	2	01=ENT (Ears, Nose, Throat), 02=Eyes, 03=Respiratory system, 04=Cardiovascular system, 05=Gastrointestinal system, 06=Urinary system, 07=Reproductive system, 08=Blood & Lymphatic system, 09=Musculoskeletal system, 10=Dermatologic system, 11=Neurological system, 99=Other
	PED3CON	Condition 3		C	25	
	PED3AB	Abnormality 3		C	200	
	PED4BS	Body system 4		C	2	01=ENT (Ears, Nose, Throat), 02=Eyes, 03=Respiratory system, 04=Cardiovascular system, 05=Gastrointestinal system, 06=Urinary system, 07=Reproductive system, 08=Blood & Lymphatic system, 09=Musculoskeletal system, 10=Dermatologic system, 11=Neurological system, 99=Other

	PED4CON	Condition 4		C	25	
	PED4AB	Abnormality 4		C	200	
	PED5BS	Body system 5		C	2	01=ENT (Ears, Nose, Throat), 02=Eyes, 03=Respiratory system, 04=Cardiovascular system, 05=Gastrointestinal system, 06=Urinary system, 07=Reproductive system, 08=Blood & Lymphatic system, 09=Musculoskeletal system, 10=Dermatologic system, 11=Neurological system, 99=Other
	PED5CON	Condition 5		C	25	
	PED5AB	Abnormality 5		C	200	
	PED6BS	Body system 6		C	2	01=ENT (Ears, Nose, Throat), 02=Eyes, 03=Respiratory system, 04=Cardiovascular system, 05=Gastrointestinal system, 06=Urinary system, 07=Reproductive system, 08=Blood & Lymphatic system, 09=Musculoskeletal system, 10=Dermatologic system, 11=Neurological system, 99=Other
	PED6CON	Condition 6		C	25	
	PED6AB	Abnormality 6		C	200	
	PED7BS	Body system 7		C	2	01=ENT (Ears, Nose, Throat), 02=Eyes, 03=Respiratory system,

						04=Cardiovascular system, 05=Gastrointestinal system, 06=Urinary system, 07=Reproductive system, 08=Blood & Lymphatic system, 09=Musculoskeletal system, 10=Dermatologic system, 11=Neurological system, 99=Other
	PED7CON	Condition 7		C	25	
	PED7AB	Abnormality 7		C	200	
	PED8BS	Body system 8		C	2	01=ENT (Ears, Nose, Throat), 02=Eyes, 03=Respiratory system, 04=Cardiovascular system, 05=Gastrointestinal system, 06=Urinary system, 07=Reproductive system, 08=Blood & Lymphatic system, 09=Musculoskeletal system, 10=Dermatologic system, 11=Neurological system, 99=Other
	PED8CON	Condition 8		C	25	
	PED8AB	Abnormality 8		C	200	
	PED9BS	Body system 9		C	2	01=ENT (Ears, Nose, Throat), 02=Eyes, 03=Respiratory system, 04=Cardiovascular system, 05=Gastrointestinal system, 06=Urinary system, 07=Reproductive system, 08=Blood & Lymphatic system, 09=Musculoskeletal

						system, 10=Dermatologic system, 11=Neurological system, 99=Other
	PED9CON	Condition 9		C	25	
	PED9AB	Abnormality 9		C	200	
	PED10BS	Body system 10		C	2	01=ENT (Ears, Nose, Throat), 02=Eyes, 03=Respiratory system, 04=Cardiovascular system, 05=Gastrointestinal system, 06=Urinary system, 07=Reproductive system, 08=Blood & Lymphatic system, 09=Musculoskeletal system, 10=Dermatologic system, 11=Neurological system, 99=Other
	PED10CON	Condition 10		C	25	
	PED10AB	Abnormality 10		C	200	
	PED11BS	Body system 11		C	2	01=ENT (Ears, Nose, Throat), 02=Eyes, 03=Respiratory system, 04=Cardiovascular system, 05=Gastrointestinal system, 06=Urinary system, 07=Reproductive system, 08=Blood & Lymphatic system, 09=Musculoskeletal system, 10=Dermatologic system, 11=Neurological system, 99=Other
	PED11CON	Condition 11		C	25	
	PED11AB	Abnormality		C	200	

		11				
	PED12BS	Body system 12		C	2	01=ENT (Ears, Nose, Throat), 02=Eyes, 03=Respiratory system, 04=Cardiovascular system, 05=Gastrointestinal system, 06=Urinary system, 07=Reproductive system, 08=Blood & Lymphatic system, 09=Musculoskeletal system, 10=Dermatologic system, 11=Neurological system, 99=Other
	PED12CON	Condition 12		C	25	
	PED12AB	Abnormality 12		C	200	
	PED13BS	Body system 13		C	2	01=ENT (Ears, Nose, Throat), 02=Eyes, 03=Respiratory system, 04=Cardiovascular system, 05=Gastrointestinal system, 06=Urinary system, 07=Reproductive system, 08=Blood & Lymphatic system, 09=Musculoskeletal system, 10=Dermatologic system, 11=Neurological system, 99=Other
	PED13CON	Condition 13		C	25	
	PED13AB	Abnormality 13		C	200	
	PED14BS	Body system 14		C	2	01=ENT (Ears, Nose, Throat), 02=Eyes, 03=Respiratory system, 04=Cardiovascular system, 05=Gastrointestinal

						system, 06=Urinary system, 07=Reproductive system, 08=Blood & Lymphatic system, 09=Musculoskeletal system, 10=Dermatologic system, 11=Neurological system, 99=Other
	PED14CON	Condition 14		C	25	
	PED14AB	Abnormality 14		C	200	
	PED15BS	Body system 15		C	2	01=ENT (Ears, Nose, Throat), 02=Eyes, 03=Respiratory system, 04=Cardiovascular system, 05=Gastrointestinal system, 06=Urinary system, 07=Reproductive system, 08=Blood & Lymphatic system, 09=Musculoskeletal system, 10=Dermatologic system, 11=Neurological system, 99=Other
	PED15CON	Condition 15		C	25	
	PED15AB	Abnormality 15		C	200	
	PEDCOMM	Comments	Comments:	C	1	
	PEDMOREA	Additional abnormalities		C	1	

Abdominal Surgical History (SGH form and dataset)
Version 3.01

Key Field	Field Name	Full Name	Question Text	Type	Length and Decimals	Codelist Values
*	SITE	Center		C	5	
*	PROT	Protocol		C	5	
	PATID	Participant ID		C	15	
*	PROJID	Project ID		C	5	
*	SURGNUM	Abdominal surgery number		C	2	01=01, 02=02, 03=03, 04=04, 05= 06=06, 07=07, 08=08, 09=09, 10= 11=11, 12=12, 13=13, 14=14, 15= 16=16, 17=17, 18=18, 19=19, 20=
	SGINDC	Surgery indication	Indication:	C	80	
	SGTRT	Procedure	Procedure:	C	2	01=Laparotomy, 02=Bowel resectio (end to end anastomosis), 03=Jejunostomy/ileostomy/colostor 04=Ostomy takedown/reanastomos 05=Peritoneal drain (for NEC), 06=Gastrostomy, 07=Appendectom 08=Fundoplication, 09=T-E fistula/esophageal atresia repair, 10=Gastroschisis/omphalocele repa 11=Diaphragmatic hernia repair, 12=Inguinal hernia repair, 99=Othe
	SGSPEC	Other specify	If "Other," specify:	C	75	
	SGPDTC	Date of procedure	Date of procedure:	D	8	
	SGCOMM	Comments	Comments:	C	200	

Abdominal Surgery Procedure Log (SGI form and dataset)
Version 1.02

Key Field	Field Name	Full Name	Question Text	Type	Length and Decimals	Codelist Values
*	SITE	Center		C	5	

*	PROT	Protocol		C	5	
	PATID	Participant ID		C	15	
*	PROJID	Project ID		C	5	
*	SURGNUM	Abdominal surgery number		C	2	01=01, 02=02, 03=03, 04=04, 05= 06=06, 07=07, 08=08, 09=09, 10= 11=11, 12=12, 13=13, 14=14, 15= 16=16, 17=17, 18=18, 19=19, 20=
	SGIINDC	Indication	Indication:	C	125	
	SGIDTC	Date performed	Date performed:	D	8	
	SGITM	Time performed	Time performed:	T	5	
	SGITRT	Procedure performed	Procedure:	C	2	01=Laparotomy, 02=Bowel resectio (end to end anastomosis), 03=Jejunostomy/ileostomy/colostor 04=Ostomy takedown/reanastomos 05=Peritoneal drain (for NEC), 06=Gastrostomy, 07=Appendectom 08=Fundoplication, 09=T-E fistula/esophageal atresia repair, 10=Gastroschisis/omphalocele repa 11=Diaphragmatic hernia repair, 12=Inguinal hernia repair, 99=Othe
	SGOTHSP	Other procedure specify	If "Other," specify:	C	125	
	SGICOM	Comments	Comments:	C	104	

Seizure Activity (SZA form and dataset)
Version 3.00

Key Field	Field Name	Full Name	Question Text	Type	Length and Decimals	Codelist Values
*	SITE	Center		C	5	
*	PROT	Protocol		C	5	

	PATID	Participant ID		C	15	
*	PROJID	Project ID		C	5	
*	SEIZNUM	Seizure number		C	2	01=Seizure 01, 02=Seizure 02, 03=Seizure 03, 04=Seizure 04, 05=Seizure 05, 06=Seizure 06, 07=Seizure 07, 08=Seizure 08, 09=Seizure 09, 10=Seizure 10, 11=Seizure 11, 12=Seizure 12, 13=Seizure 13, 14=Seizure 14, 15=Seizure 15
	SZDTC	Date of assessment	Date of assessment:	D	8	
	SZTM	Time of assessment	Time of assessment:	T	5	
	SZTYPE	Type of seizure	Type of seizure:	C	2	01=Tonic/clonic, 02=Localized, 03=Multifocal, 04=Generalized, 05=EEG, 06=Seizure-like activity, 99=Other
	SZOTSP	Other seizure specify	If "Other," specify:	C	50	
	SZSTDT	Seizure start date	Seizure start date:	D	8	
	SZSTTM	Seizure start time	Seizure start time:	T	5	
	SZENDT	Seizure stop date	Seizure stop date:	D	8	
	SZENTM	Seizure stop time	Seizure stop time:	T	5	
	SZAEM	Antiepileptics given	Were Anti-eplieptic medications given?	C	1	0=No, 1=Yes

	SZETIOL	Plausible etiology	Plausible etiology (if seizure is not explained by subject's underlying illness):	C	1	1=IVH, 2=Meningitis, 3=Electrolyte abnormality, 4=Genetic/metabolic disorder, 5=Drug withdrawal, 6=Hypoxia-ischemia, 7=Cerebral anomalies
	SZEEGDT	Date EEG performed	Date performed:	D	8	
	SZEEGTM	Time EEG performed	Time performed:	T	5	
	SZEEGRS	EEG result	Result:	C	1	1=Normal, 2=Abnormal - Not clinically significant, 3=Abnormal - Clinically significant
	SZEEGCR	EEG clinical reading	Clinical reading:	C	1	0=No abnormality, 1=Mild abnormality, 2=Moderate abnormality, 3=Severe abnormality
	SZEEGFND	EEG specific findings	Specific findings:	C	2	01=Epileptiform seizures, 02=Worsening of a pre-existing seizure, 03=Diffuse slowing, 04=Widening of the frequency spectrum, 05=Potentiation and disorganization of the background rhythm, 06=Marked slowing, 07=Increased amplitude, 08=Dysrhythmia, 99=Other
	SZFNOTH	EEG findings specify	If "Other," specify:	C	50	
	SZPKDT	Date PK sample collected	Date sample collected:	D	8	
	SZPKTM	Time PK sample collected	Time sample collected:	T	5	
	SZPKACNO	PK accession	Accession	C	3	

		number	number:			
	SZPKTYPE	PK specimen type	Specimen type:	C	1	1=Arterial, 2=Central venous, 3=Heel stick, 4=Peripheral venous
	SZCOM	Comments	Comments:	C	168	

Vital Signs (VSS form and dataset)
Version 2.00

Key Field	Field Name	Full Name	Question Text	Type	Length and Decimals	Codelist Values
*	SITE	Center		C	5	
*	PROT	Protocol		C	5	
	PATID	Participant ID		C	15	
*	PROJID	Project ID		C	5	
*	PROTSEG	Segment		C	1	
*	VISNO	Visit number		C	4	
	VSSDT	Date of assessment	Date of assessment:	D	8	
	VSCIRCUM	Head circumference	Head circumference:	N	6(1)	
	VSLENGTH	Length	Length:	N	6(1)	
	VSBDWGT	Body weight	Body weight (actual weight):	N	6(0)	
	VSSPULSE	Pulse	Pulse:	N	5(0)	
	VSSRR	Respiration rate	Respiration rate:	N	5(0)	
	VSSRRTYP	Respiration rate type	Measurement type:	C	1	1=Spontaneous, 2=Ventilator-supported, 3=NCPAP, 4=High-

						frequency
	VSSBP	Systolic blood pressure	Systolic Blood pressure:	N	5(0)	
	VSDBP	Diastolic blood pressure	Diastolic Blood pressure:	N	5(0)	
	VSSCOMM	Comments	Comments:	C	182	