

Adverse Events (AE1)
Participant: 00106

Obs	Protocol	Project ID	Center	Adverse event number	Event diagnosis	Special interest	Outcome	Severity	Causality	Action taken	Action taken other	Treatment none	Treatment medication
30	MER02	00106	9	01	PRESUMED SEPSIS	0	Resolved	Moderate	Unrelated	None			Medication/Therapy r

Obs	Treatment procedure	Other treatment	Tx required other specify	Event seizure	Event level II	Event SAE	Death	Lift threatening	Disability	Hospitalization	Important medical event	Comments
30												

Obs	VERBATIM4	Project code	Preferred Term	System Organ Class	VERSION4	LLT4	HLT4	HLGT4	Adverse event onset day	Adverse Event End day
30	PRESUMED SEPSIS	BPC	Sepsis	Infections and infestations	MedDRA V12.1	Sepsis NOS	Sepsis, bacteraemia, viraemia and fungaemia NEC	Infections - pathogen unspecified	1	3

No SAE reported for this participant.

No AES reported for this participant.

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No CSA reported for this participant.

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Demography (DEM)
Participant: 00106

Obs	Protocol	Project ID	Center	Gender	Ethnicity	Amer Indian or Alaskan	Asian	Black or African American
21	MER02	00106	9	Female	Not Hispanic or Latino	No	No	No

Obs	Hawaiian or Pacific Islnd	White or Caucasian	Not reported	Other race	Other race specify	Comments	Age (in days)
21	No	White or Caucasian	No	No			33

Study Completion/ET (DSS)

Participant: 00106

Obs	Protocol	Project ID	Center	Subject complete study	Early termination reason	Other reason specify	Investigator judgment	Protocol non compliance	Comments	Day of study completion/early termination	Day of Death	Day of discharge
21	MER02	00106	9	Yes						27	.	.

Study Drug Administration (EXA)
Participant: 00106

Obs	Protocol	Project ID	Segment	Center	Visit number	Dose number	Administration start time	Administration stop time	Body weight actual	Body weight dosing
38	MER02	00106	A	9	01		12:00	12:30	1261	1261
39	MER02	00106	A	9	02	5	20:00	20:30	1250	1261

Obs	Dosing level	Dosing frequency	Other frequency specify	Dose	Deviation timepoint	Deviation	Comments	Start day of administration	Stop day of administration
38	Low	q8h		25.2				0	0
39	Low	q8h		25.2				1	1

Dose Adjustment (EXD)

Participant: 00106

Obs	Protocol	Project ID	Segment	Center	Visit number	Dose adjustment performed	Dose per kilogram	Body weight	Dose frequency	Other frequency specify	Dose in mg	Comments
40	MER02	00106	A	9	02	Not applicable	.	.			.	
41	MER02	00106	A	9	03	Not applicable	.	.			.	

Study Drug Administration Log (EXS)
Participant: 00106

Obs	Protocol	Project ID	Center	Study drug admin number	Dose start time	Dose in mg	Comments	Dose start day
251	MER02	00106	9	01	12:00	25.2		0
252	MER02	00106	9	02	08:20	25.2		0
253	MER02	00106	9	03	04:00	25.2		1
254	MER02	00106	9	04	12:00	25.2		1
255	MER02	00106	9	05	20:00	25.2		1
256	MER02	00106	9	06	04:00	25.2		2
257	MER02	00106	9	07	12:15	25.2		2
258	MER02	00106	9	08	20:00	25.2		2
259	MER02	00106	9	09	04:00	25.2		3
260	MER02	00106	9	10	12:00	25.2		3
261	MER02	00106	9	11	20:00	25.2		3
262	MER02	00106	9	12	04:00	25.2		4
263	MER02	00106	9	13	12:00	25.2		4
264	MER02	00106	9	14	20:00	25.2		4
265	MER02	00106	9	15	04:00	25.2		5
266	MER02	00106	9	16	12:00	25.2		5
267	MER02	00106	9	17	20:00	25.2		5

MER02A (ENR)
Participant: 00106

Obs	Protocol	Project ID	Gestational age	Birth weight	NEC grade II	Hirschsprungs disease	Spontaneous perforation	Meconium ileus	Bowel obstruction	Stage 1 NEC	Standard of care
21	MER02	00106	27.5	1110						Yes	

Obs	Peritonitis	Other indication	Other indication specify	Inclusion criteria met	Inclusion criteria one	Inclusion criteria two	Inclusion criteria three	Inclusion criteria four	Inclusion criteria five	Exclusion criteria met	Exclusion criteria one	Exclusion criteria two
21				Yes						No		

Obs	Exclusion criteria three	Exclusion criteria four	Exclusion criteria five	Waiver granted	Dosing group assignment	Under 32 weeks strata	Over 32 weeks stratum	Comments	Age (in days) when Informed consent signed	Age (in days) when HIPAA authorization signed	Age (in days) when waiver granted
21				No	Low	>=2 week PNA: 20mg/kg q 8hr			32	32	.

**Abdominal Radiography Log (IML)
 Participant: 00106**

Obs	Protocol	Project ID	Center	Radiography number	Indication	Time performed	Exam performed	Other exam specify	Normal	Asymmetric bowel	Air fluid levels	Non specific bowel dilat	Mild dilatation
117	MER02	00106	9	01	Redacted	08:25	X-ray						
118	MER02	00106	9	02	Redacted	16:50	X-ray						

Obs	Moderate dilatation	Severe dilatation	Focal distension	Diffuse gas distension	Bowel wall thickening	Separation of bowel loops	Featureless loops	Bubbly lucencies	Possible pneumatosis	Persistent loop	Pneumatosis intestinalis	Portal venous gas
117												
118				Yes								

Obs	Free air	Dilated bowel loops	Portal gas	Other	Other specify	Interpretation	Comments	Day performed
117				Yes	MODERATE BOWEL DISTENTION	Abnormal - Clinically significant		1
118						Abnormal - Clinically significant		1

**Abdominal Radiography Log (IML)
 Participant: 00106**

Obs	Protocol	Project ID	Center	Radiography number	Indication	Time performed	Exam performed	Other exam specify	Normal	Asymmetric bowel	Air fluid levels	Non specific bowel dilat	Mild dilatation
119	MER02	00106	9	03	Redacted	04:20	X-ray						
120	MER02	00106	9	04	Redacted	04:00	X-ray						

Obs	Moderate dilatation	Severe dilatation	Focal distension	Diffuse gas distension	Bowel wall thickening	Separation of bowel loops	Featureless loops	Bubbly lucencies	Possible pneumatosis	Persistent loop	Pneumatosis intestinalis	Portal venous gas
119												
120												

Obs	Free air	Dilated bowel loops	Portal gas	Other	Other specify	Interpretation	Comments	Day performed
119				Yes	INTERVAL DECOMPRESSION OF PREVIOUSLY SEEN GASEOUS DISTENTION	Abnormal - Clinically significant		2
120				Yes	DIFFUSE NON DILATED AIR FILLED LOOPS OF BOWEL	Abnormal - Clinically significant		3

Abdominal Radiography Log (IML)
Participant: 00106

Obs	Protocol	Project ID	Center	Radiography number	Indication	Time performed	Exam performed	Other exam specify	Normal	Asymmetric bowel	Air fluid levels	Non specific bowel dilat	Mild dilatation
121	MER02	00106	9	05	Redacted	17:35	X-ray						

Obs	Moderate dilatation	Severe dilatation	Focal distension	Diffuse gas distension	Bowel wall thickening	Separation of bowel loops	Featureless loops	Bubbly lucencies	Possible pneumatosis	Persistent loop	Pneumatosis intestinalis	Portal venous gas
121				Yes								

Obs	Free air	Dilated bowel loops	Portal gas	Other	Other specify	Interpretation	Comments	Day performed
121						Abnormal - Clinically significant		5

Radiography - Plain Film (IMR)
Participant: 00106

Obs	Protocol	Project ID	Center	Abdominal X_rays taken	Projection	Normal	Asymmetric bowel	Air fluid levels	Non specific bowel dilat	Mild dilatation	Moderate dilatation	Severe dilatation
21	MER02	00106	9	Yes	Both A-P and Lateral							

Obs	Focal distension	Diffuse gas distension	Bowel wall thickening	Separation of bowel loops	Featureless loops	Bubbly lucencies	Possible pneumatosis	Persistent loop	Pneumatosis intestinalis	Portal venous gas
21	Yes									

Obs	Free air	Dilated bowel loops	Portal gas	Other	Other specify	Comments	Day performed
21							-6

Clinical Laboratory Tests (LBM)
Participant: 00106

Obs	Protocol	Project ID	Segment	Center	Visit number	Hematology sample colctd	Hematology sample time	Hematology laboratory	WBC test result	WBC test assessment	WBC test comments	RBC test result	RBC test assessment
76	MER02	00106	A	9	00	No			.			.	
77	MER02	00106	A	9	02	Yes	04:00		17.3	ABN, NCS		3.59	ABN, NCS
78	MER02	00106	A	9	03	Yes	07:20		13.0	WNL		3.23	ABN, NCS
79	MER02	00106	A	9	04	Yes	06:31		.		Redacted	.	
80	MER02	00106	A	9	05	Yes	05:53		10.9	WNL		2.79	ABN, CS

Clinical Laboratory Tests (LBM)
Participant: 00106

Obs	RBC test comments	HGB test result	HGB test assessment	HGB test comments	HCT test result	HCT test assessment	HCT test comments	Platelet count result	Platelet count assessment	Platelet count comments	Neutrophils result	Neutrophils assessment
76		
77		10.4	WNL		30.0	ABN, NCS		411	ABN, NCS		52.0	ABN, NCS
78		9.5	ABN, NCS		27.0	ABN, NCS		653	ABN, NCS		18.0	ABN, NCS
79	Redacted	.		Redacted	25.0	ABN, NCS		.		Redacted	.	
80	Redacted	8.0	ABN, CS	Redacted	24.0	ABN, CS	Redacted	562	ABN, CS	Redacted	.	

Clinical Laboratory Tests (LBM)
Participant: 00106

Obs	Neutrophils comments	Lymphocytes result	Lymphocytes assessment	Lymphocytes comments	Monocytes result	Monocytes assessment	Monocytes comments	Eosinophils result	Eosinophils assessment	Eosinophils comments
76		.			.			.		
77		35.0	ABN, NCS		8.0	WNL		4.0	WNL	
78		68.0	WNL		12.0	WNL		2.0	WNL	
79	Redacted	.		Redacted	.		Redacted	.		Redacted
80	Redacted	.		Redacted	.		Redacted	.		Redacted

Clinical Laboratory Tests (LBM)
Participant: 00106

Obs	Basophils result	Basophils assessment	Basophils comments	Bands result	Bands assessment	Bands comments	Chemistry sample collctd	Chemistry sample time	Chemistry laboratory	Glucose result	Glucose assessment	Glucose comments
76	.			.			Yes	04:30	Redacted	106	WNL	
77	0.0	WNL		1.0	WNL		Yes	04:00		118	WNL	
78	0.0	WNL		0.0	ABN, NCS		Yes	07:20		82	WNL	
79	.		Redacted	.		Redacted	Yes	06:31		92	WNL	
80	.		Redacted	.		Redacted	Yes	21:08		93	WNL	

Clinical Laboratory Tests (LBM)
Participant: 00106

Obs	Creatinine result	Creatinine assessment	Creatinine comments	BUN result	BUN assessment	BUN comments	AST result	AST assessment	AST comments	ALT result	ALT assessment	ALT comments
76	0.8	ABN, NCS		14	WNL		18	ABN, NCS		12	WNL	
77	0.5	WNL		10	WNL		19	ABN, NCS		12	WNL	
78	0.6	WNL		8	WNL		29	ABN, NCS		17	WNL	
79	0.3	WNL		4	ABN, NCS		28	ABN, NCS		21	WNL	
80	0.3	WNL		4	ABN, NCS		.		Redacted	.		Redacted

Clinical Laboratory Tests (LBM)
Participant: 00106

Obs	Alk phosphatase result	Alk phosphatase assess	Alk phosphatase comments	Total bilirubin result	Total bilirubin assess	Total bilirubin comments	Direct bilirubin result	Direct bilirubin assess	Direct bilirubin comments	Sodium result	Sodium assessment	Sodium comments
76	156	WNL		1.0	WNL		.		Redacted	134	WNL	
77	188	WNL		0.9	WNL		.		Redacted	134	WNL	
78	334	ABN, NCS		1.1	WNL		.		Redacted	132	ABN, NCS	
79	461	ABN, NCS		0.9	WNL		.		Redacted	133	ABN, NCS	
80	.		Redacted	.		Redacted	.		Redacted	142	WNL	

Clinical Laboratory Tests (LBM)
Participant: 00106

Obs	Potassium result	Potassium assessment	Potassium comments	Chloride result	Chloride assessment	Chloride comments	Calcium result	Calcium assessment	Calcium comments	Magnesium result	Magnesium assessment
76	3.5	ABN, NCS		102	WNL		10.0	WNL		1.8	ABN, NCS
77	3.3	ABN, NCS		89	ABN, NCS		10.3	WNL		2.1	WNL
78	3.6	ABN, NCS		95	ABN, NCS		9.5	WNL		2.0	WNL
79	4.6	WNL		101	WNL		10.3	WNL		2.1	WNL
80	4.3	WNL		112	ABN, NCS		9.9	WNL		.	

Clinical Laboratory Tests (LBM)
Participant: 00106

Obs	Magnesium comments	Total protein result	Total protein assessment	Total protein comments	Albumin result	Albumin assessment	Albumin comments	Comments	Day blood sample collected	Day blood sample collected
76		.		Redacted	.		Redacted		.	-1
77		.		Redacted	.		Redacted		2	2
78		.		Redacted	.		Redacted		8	8
79		.		Redacted	.		Redacted		14	14
80	Redacted	.		Redacted	.		Redacted		22	26

No LBS reported for this participant.

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Microbiology Cultures (MBC)
Participant: 00106

Obs	Protocol	Project ID	Center	Microbiology culture num	Time sample collected	Laboratory name	Culture	Method of acquisition	Other metho specify	Culture results	Bacteria findings A	Candida findings A	Bacteria findings B
80	MER02	00106	9	01	23:45	Redacted	Blood	Peripheral		Positive	Klebsiella sp.		
81	MER02	00106	9	02	00:10	Redacted	Urine	Catheterization		Negative			
82	MER02	00106	9	03	00:35	Redacted	Blood	Peripheral		Negative			
83	MER02	00106	9	04	01:30	Redacted	Cerebrospinal fluid	Lumbar puncture		Negative			
84	MER02	00106	9	05	08:20	Redacted	Blood	Peripheral		Negative			
85	MER02	00106	9	06	10:40	Redacted	Urine	Catheterization		Negative			

Obs	Candida findings B	Bacteria findings C	Candida findings C	Bacteria findings D	Candida findings D	Bacteria findings E	Candida findings E	Bacteria findings F	Candida findings F	Other findings specify	Comments	Day sample collected:
80												-6
81												-5
82												-4
83												-4
84												1
85												1

Prior and Concomitant Medications (ME1)
Participant: 00106

Obs	Protocol	Project ID	Center	Medication name	Sequence number	Med ongoing	Comments	Medication start day	Medication end day
217	MER02	00106	9	CAFFEINE CITRATE	01	Yes		-3	.
218	MER02	00106	9	FLUCONAZOLE	01	Yes		-5	.
219	MER02	00106	9	FUROSEMIDE	01	Yes		-3	.
220	MER02	00106	9	GENTAMICIN	01			-5	5
221	MER02	00106	9	GLYCERIN CHIP	01	Yes		4	.
222	MER02	00106	9	HEPARIN	01	Yes		1	.
223	MER02	00106	9	NYSTATIN	01	Yes		3	.
224	MER02	00106	9	PIPERACILLIN + TAZOBACTUM	01			-4	-1
225	MER02	00106	9	POTASSIUM CHLORIDE	01	Yes		1	.
226	MER02	00106	9	VANCOMYCIN	01			1	3

Medical History (MHM)
Participant: 00106

Obs	Protocol	Project ID	Center	Body system	Medical or surgical hx	Condition A	Condition A active	Onset date A unknown	Condition B	Condition B active	Onset date B unknown
113	MER02	00106	9	Respiratory system	Yes	APNEA OF PREMATURITY	Yes		RESPIRATORY DISTRESS	Yes	
114	MER02	00106	9	Cardiovascular system	Yes	PATENT DUCTUS ARTERIOSUS	No		HYPOTENSION	No	
115	MER02	00106	9	Gastrointestinal system	Yes	FEEDING INTOLERANCE	No				
116	MER02	00106	9	Urinary system	Yes	OLIGURIA	No		RENAL INSUFFICIENCY	Yes	
117	MER02	00106	9	Blood & Lymphatic system	Yes	HYPERLIPIDEMIA	Yes		INDIRECT HYPERBILIRUBINEMIA	No	

Medical History (MHM)
Participant: 00106

Obs	Condition C	Condition C active	Onset date C unknown	Condition D	Condition D active	Onset date D unknown	Condition E	Condition E active	Onset date E unknown	Condition F	Condition F active
113	PULMONARY EDEMA	Yes									
114	PATENT FORAMEN OVALE	Yes		SECUNDUM ASD ATRIAL SEPTAL DEFECT	No		TACHYCARDIA	Yes			
115											
116											
117	ANEMIA OF PREMATURITY	Yes		KLEBSIELLA SEPSIS	No		ELECTROLYTE IMBALANCES	Yes		ELEVATED BUN	No

Medical History (MHM)

Participant: 00106

Obs	Onset date F unknown	Condition G	Condition G active	Onset date G unknown	Condition H	Condition H active	Onset date H unknown	Condition I	Condition I active	Onset date I unknown
113										
114										
115										
116										
117		ELEVATED CREATININE	No		PRESUMED SEPSIS	No		THROMBOCYTOPENIA	No	

Medical History (MHM)

Participant: 00106

Obs	Condition J	Condition J active	Onset date J unknown	Condition K	Condition K active	Onset date K unknown	Condition L	Condition L active	Onset date L unknown	Condition M	Condition M active
113											
114											
115											
116											
117	INTERMITTENT THROMBOCYTOSIS	Yes									

Medical History (MHM)

Participant: 00106

Obs	Onset date M unknown	Condition N	Condition N active	Onset date N unknown	Condition O	Condition O active	Onset date O unknown	Condition P	Condition P active	Onset date P unknown	Condition Q	Condition Q active
113												
114												
115												
116												
117												

Medical History (MHM)

Participant: 00106

Obs	Onset date Q unknown	Condition R	Condition R active	Onset date R unknown	Condition S	Condition S active	Onset date S unknown	Condition T	Condition T active	Onset date T unknown	Condition U	Condition U active
113												
114												
115												
116												
117												

Medical History (MHM)
Participant: 00106

Obs	Onset date U unknown	Condition V	Condition V active	Onset date V unknown	Comments	Day of assessment	Condition A onset day	Condition B onset day	Condition C onset day	Condition D onset day	Condition E onset day	Condition F onset day
113						.	-31	-33	-12	.	.	.
114						.	-30	-10	-27	-30	-15	.
115						.	-11
116						.	-29	-12
117						.	-3	-32	-14	-5	-17	-27

Medical History (MHM)

Participant: 00106

Obs	Condition G onset day	Condition H onset day	Condition I onset day	Condition J onset day	Condition K onset day	Condition L onset day	Condition M onset day	Condition N onset day	Condition O onset day	Condition P onset day	Condition Q onset day	Condition R onset day
113
114
115
116
117	-27	-26	-11	-26

Medical History (MHM)
Participant: 00106

Obs	Condition S onset day	Condition T onset day	Condition U onset day	Condition V onset day
113
114
115
116
117

PK Blood Collection: Dose 1 - Even (PCE)
Participant: 00106

Obs	Protocol	Project ID	Segment	Center	Visit number	Sample 1 collected	Sample 1 time	Sample 1 accession num	Sample 1 specimen type	Sample 2 collected
5	MER02	00106	A	9	01	Yes	11:55	74D	Heel stick	Yes

Obs	Sample 2 time	Sample 2 accession num	Sample 2 specimen type	Sample 3 collected	Sample 3 time	Sample 3 accession num	Sample 3 specimen type	Sample 4 time point	Sample 4 collected	Sample 4 time
5	14:30	75D	Heel stick	Yes	16:45	76D	Heel stick			

Obs	Sample 4 accession num	Sample 4 specimen type	Deviation time point	Deviation reason	Comments	Sample 1 day of Collection	Sample 2 day of Collection	Sample 3 day of Collection	Sample 4 day of Collection
5						0	0	0	.

No PCO reported for this participant.

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PK Blood Collection: Steady State (PCS)
Participant: 00106

Obs	Protocol	Project ID	Segment	Center	Visit number	Sample 1 collected	Sample 1 time	Sample 1 accession num	Sample 1 specimen type	Sample 2 collected	Sample 2 time	Sample 2 accession num
19	MER02	00106	A	9	02	Yes	17:00	77D	Heel stick	Yes	20:45	78D

Obs	Sample 2 specimen type	Sample 3 collected	Sample 3 time	Sample 3 accession num	Sample 3 specimen type	Deviation time point	Deviation reason	Comments	Sample 1 day of Collection	Sample 2 day of Collection	Sample 3 day of Collection
19	Heel stick	No							1	1	.

Protocol Deviation/Waiver (PDW)
Participant: 00106

Obs	Protocol	Project ID	Center	Dev or waiver seq num	Personnel reporting dev	Time deviation occurred	Participant dose regimen	Dev from IE criteria	Dev from IE criteria spec	Deviation details
9	MER02	00106	9	1						Redacted
10	MER02	00106	9	1						Redacted

Obs	Response to deviation	Partic continue in study	Waiver granted	Comments	Day of dev or waiver	Day deviation reported
9					0	0
10					1	1

Physical Examination (PED)

Participant: 00106

Obs	Protocol	Project ID	Segment	Center	Visit number	New abnormal findings	Abnormal findings	Body system 1	Condition 1	Abnormality 1	Body system 2	Condition 2
41	MER02	00106	A	9	00		No					
42	MER02	00106	A	9	05	No						

Physical Examination (PED)

Participant: 00106

Obs	Abnormality 2	Body system 3	Condition 3	Abnormality 3	Body system 4	Condition 4	Abnormality 4	Body system 5	Condition 5	Abnormality 5	Body system 6
41											
42											

Physical Examination (PED)

Participant: 00106

Obs	Condition 6	Abnormality 6	Body system 7	Condition 7	Abnormality 7	Body system 8	Condition 8	Abnormality 8	Body system 9	Condition 9	Abnormality 9
41											
42											

Physical Examination (PED)

Participant: 00106

Obs	Body system 10	Condition 10	Abnormality 10	Body system 11	Condition 11	Abnormality 11	Body system 12	Condition 12	Abnormality 12	Body system 13	Condition 13
41											
42											

Physical Examination (PED)

Participant: 00106

Obs	Abnormality 13	Body system 14	Condition 14	Abnormality 14	Body system 15	Condition 15	Abnormality 15	Comments	Additional abnormalities	Day performed
41										0
42										.

No SGH reported for this participant.

No SGI reported for this participant.

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No SZA reported for this participant.

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Vital Signs (VSS)
Participant: 00106

Obs	Protocol	Project ID	Segment	Center	Visit number	Head circumference	Length	Body weight	Pulse	Respiration rate
95	MER02	00106	A	9	00	.	.	1261	167	42
96	MER02	00106	A	9	02	.	.	1379	.	.
97	MER02	00106	A	9	02A	28.0	40.0	1250	154	43
98	MER02	00106	A	9	03	.	.	1379	.	.
99	MER02	00106	A	9	04	.	.	1375	.	.
100	MER02	00106	A	9	05	.	.	1261	138	44
101	MER02	00106	A	9	05A	31.0	42.0	1641	165	62

Obs	Respiration rate type	Systolic blood pressure	Diastolic blood pressure	Comments	Day of assessment
95	Spontaneous	70	43		.
96		.	.		.
97	Spontaneous	68	43		1
98		.	.		.
99		.	.		.
100	Spontaneous	90	66		.
101	Spontaneous	88	48		22