Pre-Screening

Patient ID

_____

RAFT Renal Anhydramnios Fetal Therapy

Pre-screening date

_____

Pre-screening type

◯ Phone ◯ In-person

Referral source

◯ Study information sheet
◯ RAFT-trial.org
◯ ClinicalTrials.gov
◯ Physician referral
◯ Personal referral
◯ Social media
◯ Internet search
◯ Other

If other, please specify

_____

Maternal and Pregnancy Information

Gravida

_____

Para

_____
(Format: T-P-A-L (with dash between numbers))

Estimated Date of Delivery

_____

Current gestational age (weeks)

_____
(Hidden, do not complete)

Current gestational age (days)

_____
(Hidden, do not complete)

Calculated gestational age (weeks)

_____
(Weeks, calculated based on EDD)

Calculated gestational age (days)	_____ (Days, calculated based on EDD)
Diagnosis	_____
Maternal height (cm)	_____ (cm)
Reported maternal weight (kg)	_____ (kg)
Maternal BMI (kg/m2)	_____ (kg/m2, calculated field)

Genetic Test

Did the referring physician complete any genetic testing?	◯ No ◯ Yes
.... If yes, check all that apply	☐ cfDNA ☐ CVS ☐ Amniocentesis ☐ Other
cfDNA test date	_____
cfDNA test result	◯ Normal ◯ Abnormal ◯ Pending
.... If cfDNA result is abnormal, specify	_____
CVS test date	_____
CVS test result	◯ Normal ◯ Abnormal ◯ Pending
.... If CVS result is abnormal, specify	_____
Amniocentesis test date	_____
Amniocentesis test result	◯ Normal ◯ Abnormal ◯ Pending
.... If amniocentesis result is abnormal, specify	_____

.... If other, test date

_____

.... If other, specify test name and result

_____

Pregnancy and fetal complications?

Shortened cervix ◯ No ◯ Yes

Vaginal bleeding ◯ No ◯ Yes

Leakage of fluid ◯ No ◯ Yes

Known additional congenital anomalies ◯ No ◯ Yes

Medical records received date

_____

Medical records review date

_____

Proceed to screening visit ◯ No ◯ Yes

.... If no, specify

_____

Select up to four reasons for pre-screen failure

Primary reason for pre-screen failure

◯ Significant maternal co-morbid factors
◯ Amniotic fluid present after 22 weeks
◯ PPROM
◯ Unable to travel or unwilling to relocate
◯ Multiple congenital anomalies of the fetus
◯ Unable to get insurance authorization
◯ Unable to recruit due to COVID-19
◯ Referral came too close to 26w GA to complete screening
◯ Pursuing termination
◯ Multiple gestation
◯ Suspect genetic abnormality
◯ Evidence of pre-term labor
◯ Evidence of infection
◯ Evidence of abruption placentae
◯ Maternal depression
◯ Maternal age < 18 years
◯ Membrane separation
◯ Referred to another RAFT site
◯ Participant declined participation
◯ Other

If multiple congenital anomalies of the fetus is selected, please specify

◯ Cardiac
◯ Brain
◯ Musculoskeletal
◯ Other

If other, please specify	_____
If other, please specify	_____
Second reason for pre-screen failure	◯ Significant maternal co-morbid factors ◯ Amniotic fluid present after 22 weeks ◯ PPROM ◯ Unable to travel or unwilling to relocate ◯ Multiple congenital anomalies of the fetus ◯ Unable to get insurance authorization ◯ Unable to recruit due to COVID-19 ◯ Referral came too close to 26w GA to complete screening ◯ Pursuing termination ◯ Multiple gestation ◯ Suspect genetic abnormality ◯ Evidence of pre-term labor ◯ Evidence of infection ◯ Evidence of abruption placentae ◯ Maternal depression ◯ Maternal age < 18 years ◯ Membrane separation ◯ Referred to another RAFT site ◯ Participant declined participation ◯ Other
If multiple congenital anomalies of the fetus is selected, please specify	◯ Cardiac ◯ Brain ◯ Musculoskeletal ◯ Other
If other, please specify	_____
If other, please specify	_____

Third reason for pre-screen failure	◯ Significant maternal co-morbid factors ◯ Amniotic fluid present after 22 weeks ◯ PPROM ◯ Unable to travel or unwilling to relocate ◯ Multiple congenital anomalies of the fetus ◯ Unable to get insurance authorization ◯ Unable to recruit due to COVID-19 ◯ Referral came too close to 26w GA to complete screening ◯ Pursuing termination ◯ Multiple gestation ◯ Suspect genetic abnormality ◯ Evidence of pre-term labor ◯ Evidence of infection ◯ Evidence of abruption placentae ◯ Maternal depression ◯ Maternal age < 18 years ◯ Membrane separation ◯ Referred to another RAFT site ◯ Participant declined participation ◯ Other
If multiple congenital anomalies of the fetus is selected, please specify	◯ Cardiac ◯ Brain ◯ Musculoskeletal ◯ Other
If other, please specify	_____
If other, please specify	_____
Forth reason for pre-screen failure	◯ Significant maternal co-morbid factors ◯ Amniotic fluid present after 22 weeks ◯ PPROM ◯ Unable to travel or unwilling to relocate ◯ Multiple congenital anomalies of the fetus ◯ Unable to get insurance authorization ◯ Unable to recruit due to COVID-19 ◯ Referral came too close to 26w GA to complete screening ◯ Pursuing termination ◯ Multiple gestation ◯ Suspect genetic abnormality ◯ Evidence of pre-term labor ◯ Evidence of infection ◯ Evidence of abruption placentae ◯ Maternal depression ◯ Maternal age < 18 years ◯ Membrane separation ◯ Referred to another RAFT site ◯ Participant declined participation ◯ Other
If multiple congenital anomalies of the fetus is selected, please specify	◯ Cardiac ◯ Brain ◯ Musculoskeletal ◯ Other

If other, please specify

_____

If other, please specify

_____

Physician and Insurance Information

Referring physician contact information, if available
(name, state, hospital/practice name, phone number)

_____

Insurance

◯ Medicaid
◯ Private Insurance
◯ Other

.... If other, specify

_____

Demographics

Race	◯ White ◯ Black or African American ◯ American Indian or Alaska Native ◯ Asian ◯ Native Hawaiian or Other Pacific Islander ◯ Other ◯ Not Reported ◯ Unknown
Ethnicity	◯ Hispanic or Latino ◯ Not Hispanic or Latino
Highest level of education	◯ High School/GED ◯ Associates ◯ Bachelors ◯ Master's ◯ Doctorate ◯ Unknown

Medical History

Medical History	
Does the subject have any relevant Medical History to report?	◯ No ◯ Yes
Date of medical history collection	_____
For mother or child?	◯ Mother ◯ Child
Medical History Category	◯ Genetic ◯ Endocrine/Metabolic ◯ Allergy/Immune ◯ Head/Ear/Nose/Throat ◯ Rheumatologic ◯ Hematologic ◯ Neurologic ◯ Cardiovascular ◯ Pulmonary/Respiratory ◯ Renal ◯ Gastrointestinal ◯ Genitourinary ◯ Urinary ◯ Orthopedic ◯ Muscular ◯ Psychiatric ◯ Obstetrical ◯ Ocular ◯ Other
Term of the medical condition or event	_____
Ongoing	◯ No ◯ Yes
Is start year, month or day available?	◯ No ◯ Yes
Start Year	_____ (For example: 2018)
Start Month	◯ January ◯ February ◯ March ◯ April ◯ May ◯ June ◯ July ◯ August ◯ September ◯ October ◯ November ◯ December
Start Day	_____

Is end year, month or day available?	◯ No ◯ Yes
End Year (For example, 2018)	_____ (For example: 2018)
End Month	◯ January ◯ February ◯ March ◯ April ◯ May ◯ June ◯ July ◯ August ◯ September ◯ October ◯ November ◯ December
End Day	_____

Screening

Visit date	_____
Gestational age (weeks)	_____
Gestational age (days)	_____
Calculated gestational age (weeks)	_____ (Weeks, calculated based on EDD)
Calculated gestational age (days)	_____ (Days, calculated based on EDD)
Measured maternal height (cm)	_____ (cm)
Measured maternal weight (kg)	_____ (kg)
Maternal BMI (kg/m2)	_____ (kg/m2, calculated field)
Congenial Bilateral Renal Agenesis (CoBRA) or Fetal Renal Failure (FRF)?	◯ CoBRA ◯ FRF ◯ Neither
Ultrasound Date	_____ (Hidden, do not complete)
Upload de-identified ultrasound report	
If CoBRA is yes	
Anhydramnios in the absence of ruptured membranes on ultrasound imaging, prior to 22 weeks 0 days gestation.	◯ No ◯ Yes
No demonstration of renal tissue on grey scale during ultrasound imaging	◯ No ◯ Yes
No demonstration of renal vessels on color Doppler, B flow and power Doppler	◯ No ◯ Yes
< 26 weeks 0 days gestation at time of diagnostic amnioinfusion	◯ No ◯ Yes

Minimal fluid in the absence of ruptured membranes on ultrasound imaging	◯ No ◯ Yes
No significant bladder filling on ultrasound	◯ No ◯ Yes
If FRF is yes	
Anhydramnios in the absence of ruptured membranes on ultrasound imaging, prior to 22 weeks 0 days gestation.	◯ No ◯ Yes
< 26 weeks 0 days gestation at time of diagnostic amnioinfusion	◯ No ◯ Yes
Minimal fluid in the absence of ruptured membranes on ultrasound imaging	◯ No ◯ Yes
No significant bladder filling on ultrasound	◯ No ◯ Yes

Amnioinfusion

Amnioinfusion	
Intervention Amnioinfusion Visit Number: [current-instance]	
Date of visit	_____
Visit type	◯ Diagnostic ◯ Therapeutic Intervention
Gestational age (weeks) of first amnioinfusion visit [Collected at first amnioinfusion visit and used for future GA calculations]	_____ (Weeks)
Gestational age (days) of first amnioinfusion visit [Collected at first amnioinfusion visit and used for future GA calculations]	_____ (Days)
Gestational age (weeks) [Calculated from GA recorded at first amnioinfusion visit]	_____ (Weeks, calculated field)
Gestational age (days) [Calculated from GA recorded at first amnioinfusion visit]	_____ (Days, calculated field)
Maternal weight (kg)	_____ (kg)
Maternal BMI (kg/m2)	_____ (kg/m2, calculated field)
BP Systolic	_____
BP Diastolic	_____
Cervical length (mm)	_____ (Code 999 if not collected at this visit)
Ultrasound type	☐ Transbdominal ☐ Transvaginal

Amnioinfusion

Amnioinfusion completed	◯ No ◯ Yes
.... If no, specify	_____
Performed by	_____
Start time	_____
End time	_____
Needle gauge	◯ 18g ◯ 20g ◯ 22g
Number of attempts	_____
If more than one attempt, specify why	_____
Volume infused (mL)	_____ (mL)
Indigo carmine	◯ No ◯ Yes
Isotonic fluid infused	◯ Normal Saline ◯ Lactated Ringers
Antibiotic infused	◯ Clindamycin ◯ Oxacillin ◯ Nafacillin ◯ No antibiotic used
Start Maximum vertical pocket (MVP) in cm	_____ (cm)
End Maximum vertical pocket (MVP) in cm	_____
Start Amniotic Fluid Index (AFI)	◯ Normal without value ◯ Abnormal without value ◯ Have a value ◯ Not documented
Enter a value for Start Amniotic Fluid Index (AFI) in cm	_____ (cm)

End Amniotic Fluid Index (AFI)	◯ Normal without value ◯ Abnormal without value ◯ Have a value ◯ Not documented
Enter a value for End Amniotic Fluid Index (AFI) in cm	_____ (cm)
Tocolytics used	◯ No ◯ Yes
Tocolytics (check all that apply)	☐ Indomethacin ☐ Magnesium sulfate ☐ Nifedipine ☐ Nitroglycerin ☐ Terbutaline ☐ Other
.... If other, specify	_____
Analgesia	◯ No ◯ Lidocaine ◯ Other
.... If other, specify	_____
Sedation	◯ No ◯ Ativan ◯ Versed ◯ Other
.... If yes, specify	_____
Contractions on Non Stress Test (NST)	◯ No ◯ Yes ◯ Irritability ◯ Not performed
Fetal movement	◯ No ◯ Yes

Did any of the following events occurred after the diagnostic amnioinfusion?

Adverse Events of Interest

If applicable, complete separate adverse event, protocol deviation, and/or unscheduled visit form for these AEs of interest.

Placental abruption	◯ No ◯ Yes
Contractions perceived	◯ No ◯ Yes
Leakage of fluid	◯ No ◯ Yes
Vaginal bleeding	◯ No ◯ Yes

Chorioamnion separation	◯ No ◯ Yes
Biospecimen Collection	
Amniotic fluid collected?	◯ No ◯ Yes
.... If yes, contamination of specimen possible?	◯ No ◯ Yes
.... If yes, contamination with:	☐ Fetal blood ☐ Maternal blood ☐ Other
..... If other, please specify	_____

Fetal Assessment

Fetal demise	◯ No ◯ Yes
Fetal biometry assessed	◯ No ◯ Yes
Biparietal Diameter (BPD, mm)	_____ (Code 999 if not collected at this visit)
Occipito-fronto diameter (OFD, mm)	_____ (Code 999 if not collected at this visit)
Head Circumference (HC, mm)	_____ (Code 999 if not collected at this visit)
Abdominal Circumference (AC, mm)	_____ (Code 999 if not collected at this visit)
Femur Length (FL, mm)	_____ (Code 999 if not collected at this visit)
Humerus Length (HL, mm)	_____ (Code 999 if not collected at this visit)
Estimated Fetal Weight (EFW, grams)	_____ (Code 999 if not collected at this visit)
Umbilical Artery Doppler	◯ Normal ◯ Absence of end-diastolic velocities ◯ Reversal of end-diastolic flow velocity ◯ Not Documented

Umbilical Artery Pulsatility Index (PI)

_____
(Code 999 if not collected at this visit)

Umbilical Artery Resistance Index (RI)

_____
(Code 999 if not collected at this visit)

Umbilical Artery Systolic/Diastolic Ratio of Flow Velocities (S/D Ratio)

_____
(Code 999 if not collected at this visit)

Pulmonary Artery Doppler

◯ Pre-Amnioinfusion
◯ Post-Amnioinfusion
◯ Not Documented

Pulmonary Artery Doppler: Pulsatility Index (PI)

_____
(Code 999 if not collected at this visit)

Pulmonary Artery Doppler: PS

_____
(Code 999 if not collected at this visit)

Pulmonary Artery Doppler: EDV

_____
(Unit: cm/sec. Code 999 if not collected at this visit)

Pulmonary Artery Doppler: TAmax

_____
(Code 999 if not collected at this visit)

Pulmonary Artery Doppler: TAmean

_____
(Code 999 if not collected at this visit)

Pulmonary Artery Doppler: Acceleration Time

_____
(Code 999 if not collected at this visit)

Biophysical profile score (For example: 8/10)

_____
(Code 999 if not collected at this visit)

Cardio/Thoracic Ratio [Pre-Amnioinfusion]

_____
(Code 999 if not collected at this visit)

Cardio/Thoracic Ratio [Post-Amnioinfusion]

_____
(Code 999 if not collected at this visit)

Cardio/Thoracic Ratio (No Indicated)

_____
(Code 999 if not collected at this visit)

Observed to Expected Lung to Head Ratio (O/E LHR) Right [Post-Amnioinfusion]	_____ (Code 999 if not collected at this visit)
Observed to Expected Lung to Head Ratio (O/E LHR) Left [Post-Amnioinfusion]	_____ (Code 999 if not collected at this visit)
Fetal Heart Rate (FHR, bpm) [Pre-Amnioinfusion]	_____ (Code 999 if not collected at this visit)
Fetal Heart Rate (FHR, bpm) [Post-Amnioinfusion]	_____ (Code 999 if not collected at this visit)
Fluid in the bladder	◯ No ◯ Yes
Vesicocentesis performed	◯ No ◯ Yes
Volume of fluid removed (mL)	_____ (Code 999 if not collected at this visit)

Source Docs

Upload US report	
Upload NST document	
Upload additional supporting documentation not included in the US report	

Post Amnioinfusion Ultrasound

Post Amnioinfusion Visit Number: [current-instance]	
Date of visit	_____
Gestational age (weeks) [Calculated from GA recorded at first amnioinfusion visit]	_____ (Weeks, calculated field)
Gestational age (days) [Calculated from GA recorded at first amnioinfusion visit]	_____ (Days, calculated field)
Follow-up visit type	◯ Post Diagnostic ◯ Post Intervention
Select the corresponding Intervention Amnioinfusion Visit Number	◯ 1 ◯ 2 ◯ 3 ◯ 4 ◯ 5 ◯ 6 ◯ 7 ◯ 8 ◯ 9 ◯ 10 ◯ 11 ◯ 12 ◯ 13 ◯ 14 ◯ 15 ◯ 16 ◯ 17 ◯ 18 ◯ 19 ◯ 20 ◯ 21 ◯ 22 ◯ 23 ◯ 24 ◯ 25 ◯ 26 ◯ 27 ◯ 28 ◯ 29 ◯ 30

Maternal Assessment

Temperature (C)	_____ (Code 999 if not collected at this visit)
BP Systolic	_____ (Code 999 if not collected at this visit)
BP Diastolic	_____ (Code 999 if not collected at this visit)
Maximum vertical pocket (MVP, cm)	_____ (Code 999 if not collected at this visit)
Amniotic Fluid Index (AFI)	◯ Normal without value ◯ Abnormal without value ◯ Have a value ◯ Not documented
Enter a value for Amniotic Fluid Index (AFI) in cm	_____ (cm)
Cervical length (mm)	_____ (Code 999 if not collected at this visit)
Ultrasound type	☐ Transbdominal ☐ Transvaginal
Fetal movement	◯ No ◯ Yes
Contractions on Non Stress Test (NST)	◯ No ◯ Yes ◯ Not performed
Premature Rupture of Membranes (PPROM) (Complete AE form if yes)	◯ No ◯ Yes
.... If yes, resealed membranes?	◯ No ◯ Yes
Placental abruption (Complete AE form if yes)	◯ No ◯ Yes
Contractions perceived	◯ No ◯ Yes
Leakage of fluid (Complete AE form if yes)	◯ No ◯ Yes
Vaginal bleeding (Complete AE form if yes)	◯ No ◯ Yes
Chorioamnion separation (Complete AE form if yes)	◯ No ◯ Yes

Fetal Assessment

Fetal demise (Complete AE form if yes)	◯ No ◯ Yes
Fetal Heart Rate (FHR, bpm)	_____ (bpm)
Fetal biometry assessed	◯ No ◯ Yes
Biparietal Diameter (BPD, mm)	_____ (Code 999 if not collected at this visit)
Occipito-fronto diameter (OFD, mm)	_____ (Code 999 if not collected at this visit)
Head Circumference (HC, mm)	_____ (Code 999 if not collected at this visit)
Abdominal Circumference (AC, mm)	_____ (Code 999 if not collected at this visit)
Femur Length (FL, mm)	_____ (Code 999 if not collected at this visit)
Humerus Length (HL, mm)	_____ (Code 999 if not collected at this visit)
Estimated Fetal Weight (EFW, grams)	_____ (Code 999 if not collected at this visit)
Umbilical Artery Doppler	◯ Normal ◯ Absence of end-diastolic velocities ◯ Reversal of end-diastolic flow velocity ◯ Not Documented
Umbilical Artery Pulsatility Index (PI)	_____ (Code 999 if not collected at this visit)
Umbilical Artery Resistance Index (RI)	_____ (Code 999 if not collected at this visit)
Umbilical Artery Systolic/Diastolic Ratio of Flow Velocities (S/D Ratio)	_____ (Code 999 if not collected at this visit)
Pulmonary Artery Doppler	◯ Documented ◯ Not Documented

Pulmonary Artery Doppler: Pulsatility Index (PI)

_____
(Code 999 if not collected at this visit)

Pulmonary Artery Doppler: PS

_____
(Code 999 if not collected at this visit)

Pulmonary Artery Doppler: EDV

_____
(Unit: cm/sec. Code 999 if not collected at this visit)

Pulmonary Artery Doppler: TAmax

_____
(Code 999 if not collected at this visit)

Pulmonary Artery Doppler: TAmean

_____
(Code 999 if not collected at this visit)

Pulmonary Artery Doppler: Acceleration Time

_____
(Code 999 if not collected at this visit)

Biophysical profile score (For example: 8/10)

_____
(Code 999 if not collected at this visit)

Cardio/Thoracic Ratio

_____
(Code 999 if not collected at this visit)

Observed to Expected Lung to Head Ratio (O/E LHR) Right
(Use trace method and TOTAL calculator)

_____
(Code 999 if not collected at this visit)

Observed to Expected Lung to Head Ratio (O/E LHR) Left
(Use trace method and TOTAL calculator)

_____
(Code 999 if not collected at this visit)

Fluid in the bladder

◯ No ◯ Yes

Estimated volume of fluid in the bladder (mL)

_____
(Code 999 if not collected at this visit)

Source Docs
Upload US report
Upload NST document
Upload additional supporting documentation not included in the US report
Please complete a separate form if there are any adverse events, protocol deviation or unscheduled visit.

Genetic Tests

Check all tests that were completed at your site as part of the subject's screening into the trial	☐ cfDNA ☐ CVS ☐ Amniocentesis ☐ Other
cfDNA test date	_____
cfDNA test result	◯ Normal ◯ Abnormal ◯ Pending
.... If cfDNA result is abnormal, specify	_____
Upload cfDMA source document	
CVS test date	_____
CVS test result	◯ Normal ◯ Abnormal ◯ Pending
.... If CVS result is abnormal, specify	_____
Upload CVS source document	
Amniocentesis test date	_____
Amniocentesis test result	◯ Normal ◯ Abnormal ◯ Pending
.... If amniocentesis result is abnormal, specify	_____
Upload amniocentesis source document	
If other, specify test date	_____
If other, specify test name	_____
If other, specify test result	_____
Upload source document for other test	

Enrollment

Enrollment	
Inclusion Criteria	
1. Confirmed anhydramnios before 22 weeks GA for patients with FRF or confirmed diagnosis of CoBRA	◯ No ◯ Yes
2. Consent is signed and first therapeutic amnioinfusion can and does occur before 26 weeks and 0 days GA	◯ No ◯ Yes
3. Confirmation that the expectant mother does not wish to undergo termination of the pregnancy	◯ No ◯ Yes
4. Age 18 years of age or older for expectant mothers	◯ No ◯ Yes
5. Willingness to be followed and deliver at a RAFT center	◯ No ◯ Yes
6. Willingness for postnatal care to be performed at a RAFT center until discharge	◯ No ◯ Yes
7. Completed consults with Pediatric Nephrology, Neonatology, Transplant Surgery, Pediatric surgery, Maternal-Fetal Medicine Specialist, and Licensed Clinical Social Worker and a Genetic Counselor	◯ No ◯ Yes
Consultations	
Maternal-Fetal Medicine	◯ No ◯ Yes
Maternal-Fetal Medicine consultation date	_____ (Hidden, do not complete)
Genetic Counseling	◯ No ◯ Yes
Genetic Counseling Date	_____ (Hidden, do not complete)
Neonatology	◯ No ◯ Yes
Neonatology consultation date	_____ (Hidden, do not complete)
Nephrology	◯ No ◯ Yes
Nephrology consultation date	_____ (Hidden, do not complete)

General Pediatric Surgery	◯ No ◯ Yes
General Pediatric Surgery consultation date	_____ (Hidden, do not complete)
Transplant Surgery	◯ No ◯ Yes
Transplant Surgery consultation date	_____ (Hidden, do not complete)
Licensed Clinical Social Worker	◯ No ◯ Yes
Licensed Clinical Social Worker consultation date	_____ (Hidden, do not complete)
Confounding social issues as noted by Social Work	◯ No ◯ Yes
Exclusion Criteria	
1. Cervix less than 2.5 cm in length	◯ No ◯ Yes
2. Significant pathogenic or likely significant pathogenic findings on Karyotype or Microarray	◯ No ◯ Yes
3. Other significant congenital anomalies in the fetus	◯ No ◯ Yes
Diagnosis:	☐ Significant abdominal wall abnormality ☐ Significant cardiac abnormality ☐ Significant gastrointestinal abnormality ☐ Significant neurologic abnormality ☐ Significant limb abnormality ☐ Other
.... If other, specify	_____
4.1. Evidence of chorioamnioitis	◯ No ◯ Yes
4.2. Evidence of abruption placentae	◯ No ◯ Yes
5.1. Evidence of rupture of membranes	◯ No ◯ Yes
5.2. Evidence of choriamniotic separation	◯ No ◯ Yes
6. Evidence of preterm labor	◯ No ◯ Yes
7. Multiple gestation	◯ No ◯ Yes
8. Severe maternal medical condition in pregnancy	◯ No ◯ Yes

Severe maternal medical condition in pregnancy (check all that apply)	☐ Amniotic fluid embolism ☐ Anemia ☐ Cancer ☐ Cardiac disease ☐ Cholestasis ☐ Deep venous thrombosis (DVT) ☐ Diabetes, gestational ☐ Diabetes ☐ Hyperemesis gravidarum ☐ Hypertension, uncontrolled ☐ Infection ☐ Kidney disease ☐ Neurologic disease ☐ Placental abruption ☐ Placenta accreta ☐ Placenta percreta ☐ Placenta previa ☐ Preeclampsia ☐ Pulmonary embolism ☐ Rh Factor negative ☐ Status post organ transplant ☐ Vascular disease ☐ Other
.... If cancer, specify	_____
.... If infection, specify	_____
.... If other, specify	_____
9. Maternal depression score as assessed by Beck Depression Inventory > 17	◯ No ◯ Yes
Maternal depression score as assessed by Beck Depression Inventory	_____
10. Technical limitations precluding Amnioinfusion	☐ No ☐ Maternal body habitus ☐ Placental location ☐ Other
.... If other, specify	_____
Conclusion of Screening Process	
Confirmed fetal diagnosis	◯ CoBRA ◯ FRF

Enrollment

Warming: Not all INCLUSION criteria are met

Warming: Not all EXCLUSION criteria are met

Study inclusion offered

◯ No
◯ Yes
◯ Other

.... Comment

_____

Consent signed

◯ No ◯ Yes

.... If not consented, specify

_____

Consent date

_____

Upload signed consent form of parents

Study group

◯ Intervention Group
◯ Expectant Management Group

Assigned Subject ID

_____

Participant's date of birth

_____

MRI

MRI

Date of MRI
Initial Diagnostic Amnioinfusion Date:
[screening_arm_1][amn_visdat][first-instance]

Strength of the machine
◯ 1.5T ◯ 3T

Manufacturer of the machine
◯ Siemens
◯ GE
◯ Avanto
◯ Aero
◯ Other

.... If other, specify

Lungs

Ratio of observed versus expected fetal lung volume (O/E)

Left - ADC value

Right - ADC value

Brain

Which side of brain are the measurements for?
(Check all that apply)
☐ Left ☐ Right

Left - Basal ganglia ADC

Left - Thalamus ADC

Left - Frontal and temporal and occipital and posterior white matter ADC

Left - Brainstem ADC

Left - Cerebellum ADC

Left - Centrum semiovale ADC

Left - Lateral ventricle

_____ (mm)

Left - Third ventricle

_____ (mm)

Left - Fourth ventricle

_____ (mm)

Right - Basal ganglia ADC

_____

Right - Thalamus ADC

_____

Right - Frontal and temporal and occipital and posterior white matter ADC

_____

Right - Brainstem ADC

_____

Right - Cerebellum ADC

_____

Right - Centrum semiovale ADC

_____

Right - Lateral ventricle

_____ (mm)

Right - Third ventricle

_____ (mm)

Right - Fourth ventricle

_____ (mm)

Upload Source Documents

Upload MRI source documentation

Delivery and Neonatal Status

Delivery and Neonatal Status

Delivery data within the first 24 hours of life

Spontaneous rupture of the membranes	◯ No ◯ Yes
Date of rupture of membranes [Definitive ruptured membrane such that subsequent amnioinfusion is not possible]	_____
Date of birth	_____
Time of birth	_____
Live birth	◯ No ◯ Yes
Gestational age (weeks)	_____ (Weeks, calculated field)
Gestational age (days)	_____ (Days, calculated field)
Gender	◯ M ◯ F ◯ Ambiguous
Birthweight (grams)	_____ (Grams)
Length (cm)	_____ (cm)
Head circumference (cm)	_____ (cm)
APGAR scores (at 1 minute)	_____ (at 1 minute)
APGAR scores (at 5 minute)	_____ (at 5 minute)
APGAR scores (at 10 minute)	_____ (at 10 minute)

Method of delivery	◯ Vaginal (spontaneous) ◯ Vaginal (induced) ◯ Cesarean section (elective) ◯ Cesarean section (urgent) ◯ Forceps delivery ◯ Vacuum extraction
Neonatal resuscitation approach	◯ Comfort measures only ◯ Any resuscitation attempted ◯ Other ◯ Routine resuscitation
If other, specify	_____
CPR in delivery room	◯ No ◯ Yes

Maternal Corticosteroids

Number of corticosteroids courses	◯ 0 ◯ 1 ◯ 2 ◯ 3
Course 1 2 3 Corticosteroids Type _____ _____ _____ If other, specify _____ _____ _____ # of Doses _____ _____ _____ Date of Dose #1 _____ _____ _____ Date of Dose #2 _____ _____ _____	

Empirical Antibiotics Given to the Baby

Ampicillin courses	◯ Not Used ◯ 1 ◯ 2 ◯ 3
Course 1 start date	_____
Course 1 end date	_____
Course 2 start date	_____
Course 2 end date	_____
Course 3 start date	_____
Course 3 end date	_____
Amoxicillin courses	◯ Not Used ◯ 1 ◯ 2 ◯ 3
Course 1 start date	_____

Course 1 end date	_____
Course 2 start date	_____
Course 2 end date	_____
Course 3 start date	_____
Course 3 end date	_____
Ancef courses	◯ Not Used ◯ 1 ◯ 2 ◯ 3
Course 1 start date	_____
Course 1 end date	_____
Course 2 start date	_____
Course 2 end date	_____
Course 3 start date	_____
Course 3 end date	_____
Gentamicin courses	◯ Not Used ◯ 1 ◯ 2 ◯ 3
Course 1 start date	_____
Course 1 end date	_____
Course 2 start date	_____
Course 2 end date	_____
Course 3 start date	_____

Course 3 end date	_____
Cefotaxime courses	◯ Not Used ◯ 1 ◯ 2 ◯ 3
Course 1 start date	_____
Course 1 end date	_____
Course 2 start date	_____
Course 2 end date	_____
Course 3 start date	_____
Course 3 end date	_____
Cetriaxone courses	◯ Not Used ◯ 1 ◯ 2 ◯ 3
Course 1 start date	_____
Course 1 end date	_____
Course 2 start date	_____
Course 2 end date	_____
Course 3 start date	_____
Course 3 end date	_____
Ceftazidime courses	◯ Not Used ◯ 1 ◯ 2 ◯ 3
Course 1 start date	_____
Course 1 end date	_____

Course 2 start date	
Course 2 end date	
Course 3 start date	
Course 3 end date	
Cefepime courses	◯ Not Used ◯ 1 ◯ 2 ◯ 3
Course 1 start date	
Course 1 end date	
Course 2 start date	
Course 2 end date	
Course 3 start date	
Course 3 end date	
Vancomycin courses	◯ Not Used ◯ 1 ◯ 2 ◯ 3
Course 1 start date	
Course 1 end date	
Course 2 start date	
Course 2 end date	
Course 3 start date	
Course 3 end date	

Other antibiotics courses	◯ Not Used ◯ 1 ◯ 2 ◯ 3
Specify antibiotics name	_____
Course 1 start date	_____
Course 1 end date	_____
Course 2 start date	_____
Course 2 end date	_____
Course 3 start date	_____
Course 3 end date	_____

Umbilical Cord Blood Gas Values - Arterial

pH	_____ (Reference Range: 7.35-7.45)
PO2	_____ (Reference Range: 45-70)
PCO2	_____ (Reference Range: 35-45)
HCO3	_____ (Reference Range: 22-26)
Base excess	_____

Umbilical Cord Blood Gas Values - Venous

pH	_____ (Reference Range: 7.35-7.45)
PO2	_____ (Reference Range: 45-70)

PCO2

_____
(Reference Range: 35-45)

HCO3

_____
(Reference Range: 22-26)

Base excess

_____

Neonate Initial Arterial Blood Gas values

pH

_____
(Reference Range: 7.35-7.45)

PO2

_____
(Reference Range: 45-70)

PCO2

_____
(Reference Range: 35-45)

HCO3

_____
(Reference Range: 22-26)

Base excess

_____

Neonate Initial Capillary Blood Gas values: (If arterial BG is not available)

pH

_____
(Reference Range: 7.35-7.45)

PO2

_____
(Reference Range: 45-70)

PCO2

_____
(Reference Range: 35-45)

HCO3

_____
(Reference Range: 22-26)

Base excess

_____

Pneumothorax

◯ No ◯ Yes

Pulmonary Hypertension	◯ No ◯ Yes

Treatment of Pulmonary Hypertension

Inhaled Nitric Oxide	◯ No ◯ Yes
.... If applicable, maximum dose (ppm)	_____
Sildenafil	◯ No ◯ Yes
.... If applicable	◯ Oral ◯ IV
Endothelial Receptor Blockade	◯ No ◯ Yes
Prostacyclin	◯ No ◯ Yes
Alprostadil (PGE1)	◯ No ◯ Yes
Milrinone	◯ No ◯ Yes
Other	◯ No ◯ Yes
.... If other, specify	_____
Highest PaO2 ___ mmHg	_____
Type of PaO2	◯ Capillary ◯ Arterial
Highest SpO2 value available on ___ (select all that apply)	☐ Pre-ductal ☐ Post-ductal ☐ Not specified
Highest pre-ductal SpO2 ___ %	_____
Highest post-ductal SpO2 ___ %	_____
Highest SpO2 ___ % (unspecified location)	_____
Pressor medications	☐ Dopamine ☐ Dobutamine ☐ Epinephrine ☐ Other
.... If other, specify	_____
Pressor medication date for Dopamine	_____

Pressor medication time for Dopamine	_____
Pressor medication date for Dobutamine	_____
Pressor medication time for Dobutamine	_____
Pressor medication date for Epinephrine	_____
Pressor medication time for Epinephrine	_____
Pressor medication date for other	_____
Pressor medication time for other	_____

Postnatal Cardiac Finding

Atrial Septal Defect (ASD)	◯ No ◯ Yes
Ventricular Septal Defect (VSD)	◯ No ◯ Yes
Patent ductus arteriosus (PDA)	◯ No ◯ Yes
Patent foramen ovale (PFO)	◯ No ◯ Yes

Consent for Baby

Consent for baby signed	◯ No ◯ Yes
Consent date	_____
Upload signed postnatal consent form	

Source Docs

Upload scanned form
Upload source documentation 1
Upload source documentation 2
Upload source documentation 3
Upload source documentation 4
Upload source documentation 5

Neonatal Survival

Neonatal Survival

Neonate Survival Status

Visit Date

_____

Did neonate survive to this event?
Event: [event-label]

◯ No ◯ Yes

Empirical Antibiotics Given

The day of delivery is considered day 0.For Survival 15 Day followup, record new course of antibiotics from Day 1 to Day 15.For Survival 30 Day followup, record new course of antibiotics from Day 16 to Day 30.For Survival 60 Day followup, record new course of antibiotics from Day 31 to Day 60.For Survival 90 Day followup, record new course of antibiotics from Day 61 to Day 90.

Ampicillin courses

◯ Not Used ◯ 1 ◯ 2 ◯ 3

Course 1 start date

_____

Course 1 end date

_____

Course 2 start date

_____

Course 2 end date

_____

Course 3 start date

_____

Course 3 end date

_____

Amoxicillin courses

◯ Not Used ◯ 1 ◯ 2 ◯ 3

Course 1 start date

_____

Course 1 end date

_____

Course 2 start date

_____

Course 2 end date

_____

Course 3 start date	_____
Course 3 end date	_____
Ancef courses	◯ Not Used ◯ 1 ◯ 2 ◯ 3
Course 1 start date	_____
Course 1 end date	_____
Course 2 start date	_____
Course 2 end date	_____
Course 3 start date	_____
Course 3 end date	_____
Gentamicin courses	◯ Not Used ◯ 1 ◯ 2 ◯ 3
Course 1 start date	_____
Course 1 end date	_____
Course 2 start date	_____
Course 2 end date	_____
Course 3 start date	_____
Course 3 end date	_____
Cefotaxime courses	◯ Not Used ◯ 1 ◯ 2 ◯ 3
Course 1 start date	_____

Course 1 end date	_____
Course 2 start date	_____
Course 2 end date	_____
Course 3 start date	_____
Course 3 end date	_____
Cetriaxone courses	◯ Not Used ◯ 1 ◯ 2 ◯ 3
Course 1 start date	_____
Course 1 end date	_____
Course 2 start date	_____
Course 2 end date	_____
Course 3 start date	_____
Course 3 end date	_____
Ceftazidime courses	◯ Not Used ◯ 1 ◯ 2 ◯ 3
Course 1 start date	_____
Course 1 end date	_____
Course 2 start date	_____
Course 2 end date	_____
Course 3 start date	_____

Course 3 end date	_____
Cefepime courses	◯ Not Used ◯ 1 ◯ 2 ◯ 3
Course 1 start date	_____
Course 1 end date	_____
Course 2 start date	_____
Course 2 end date	_____
Course 3 start date	_____
Course 3 end date	_____
Vancomycin courses	◯ Not Used ◯ 1 ◯ 2 ◯ 3
Course 1 start date	_____
Course 1 end date	_____
Course 2 start date	_____
Course 2 end date	_____
Course 3 start date	_____
Course 3 end date	_____
Other antibiotics courses	◯ Not Used ◯ 1 ◯ 2 ◯ 3
Specify antibiotics name	_____
Course 1 start date	_____

Course 1 end date	_____
Course 2 start date	_____
Course 2 end date	_____
Course 3 start date	_____
Course 3 end date	_____

Treatment of Pulmonary Hypertension

Inhaled Nitric Oxide	◯ No ◯ Yes
.... If applicable, maximum dose (ppm)	_____
Sildenafil	◯ No ◯ Yes
.... If applicable, specify	◯ Oral ◯ IV
Endothelial Receptor Blockade	◯ No ◯ Yes
Prostacyclin	◯ No ◯ Yes
Alprostadil (PGE1)	◯ No ◯ Yes
Milrinone	◯ No ◯ Yes
Other	◯ No ◯ Yes
.... If other, specify	_____
Neonate extubated?	◯ No ◯ Yes ◯ Not applicable
Extubation date	_____
Extubation time	_____
Pressor medications	☐ Dopamine ☐ Dobutamine ☐ Epinephrine ☐ Other
Pressor medication date	_____

Pressor medication time

_____

Dopamine start date and time

_____

Dopamine end date and time

_____

Dobutamine start date and time

_____

Dobutamine end date and time

_____

Epinephrine start date and time

_____

Epinephrine end date and time

_____

Other pressor medication name

_____

Other pressor medication start date and time

_____

Other pressor medication end date and time

_____

Aquadex

Aquadex catheter placement

◯ No ◯ Yes

Start Date Ongoing End Date
1 _____ _____ _____
2 _____ _____ _____
3 _____ _____ _____

Dialysis

Dialysis catheter placement

◯ No ◯ Yes

Type of current dialysis

◯ Hemodialysis
◯ Peritoneal Dialysis - Fluid Instilled
◯ Peritoneal Dialysis - Drainage Only

Hemodialysis start date

_____

Current catheter

◯ Single cuff
◯ Double cuff
◯ Non-cuffed

Tunneled	◯ No ◯ Yes
Was current dialysis catheter used for at least 15 days	◯ No ◯ Yes
Is dialysis currently ongoing?	◯ No ◯ Yes
Is this the same device that is being used from last event?	◯ No ◯ Yes
Type of last dialysis	◯ No Dialysis ◯ Hemodialysis ◯ Peritoneal Dialysis - Fluid Instilled ◯ Peritoneal Dialysis - Drainage Only
Last hemodialysis start date	_____
Last catheter	◯ Single cuff ◯ Double cuff ◯ Non-cuffed
Tunneled (for last event)	◯ No ◯ Yes

Peritoneal Dialysis Complications of Interest

Leakage	◯ No ◯ Yes
Is the leakage ongoing	◯ No ◯ Yes
Leakage resolution date	_____
Peritonitis	◯ No ◯ Yes
Culture site	_____
Culture date	_____
Culture result	_____
Antibiotics used	◯ No ◯ Yes
.... If yes, check all that apply	☐ Cefazolin ☐ Cefepime ☐ Fluconazole ☐ Vancomycin ☐ Nystatin ☐ Other
.... If other, specify	_____

Revision	◯ No ◯ Yes
Number of revisions to date For Survival 15 Day followup, record number of revisions from Day 1 to Day 15.For Survival 30 Day followup, record number of revisions from Day 16 to Day 30.For Survival 60 Day followup, record number of revisions from Day 31 to Day 60.For Survival 90 Day followup, record number of revisions from Day 61 to Day 90.	_____
Sepsis	◯ No ◯ Yes
Number of episodes	_____
Occlusion	◯ No ◯ Yes
TPA administered	◯ No ◯ Yes

Hemodialysis Complications

Malfunction	◯ No ◯ Yes
Clotting	◯ No ◯ Yes
Infection	◯ No ◯ Yes
Culture site	_____
Culture date	_____
Culture result	_____

Source Docs

Upload source documentation #1	
Upload source documentation #2	

Neonatal Respiratory Status

Neonate Respiratory Status
For Delivery: Please enter the initial respiratory status.
For Survival Timepoint Day 15, 30, 60 or 90: Please capture the respiratory status on the day of follow up.

Current Event: [event-label]

Surfactant administered after delivery	◯ No ◯ Yes
Where was surfactant administered?	◯ Delivery Room ◯ Neonatal ICU
Ventilation status on day of visit (For delivery, record the initial mode of ventilation.)	◯ Room Air ◯ Oxyhood ◯ Low Flow Nasal Cannula ◯ High Flow Nasal Cannula (heated, high humidity) ◯ Continuous Positive Airway Pressure (CPAP) ◯ SiPAP ◯ NIPPV ◯ VapoTherm ◯ Conventional ventilator ◯ High frequency JET ventilation (HFJV) ◯ High Frequency Oscillatory Ventilation (HFOV) ◯ High Frequency Percussive Ventilation (HFPV; Bronchotron) ◯ Airway pressure release ventilaton (APRV) ◯ Other
Ventilation start date	_____
Ventilation start time	_____
.... If CPAP, specify	◯ Bubble ◯ Standard
Did intubation start at any time since last visit? For survival timepoint, please answer yes or no since last data collection timepoint? - Day 0 , Day of delivery - Day 1-15 - Day 16-30 - Day 31-60 - Day 61-90	◯ No ◯ Yes
Intubation date	_____
Intubation time	_____

Volume modes (check all that apply)	☐ Assist-Control Ventilation (ACV) ☐ Synchronized Intermittent-Mandatory Ventilation (SIMV) ☐ Pressure-Controlled Ventilaton (PCV) ☐ Pressure Support Ventilation (PSV) ☐ Pressure Controlled Inverse Ratio Ventilation (PCIRV) ☐ Airway Pressure Release Ventiation (APRV) ☐ Pressure Regulated Volume Control (PRVC) ☐ Proportional Assist Ventilation (PAV) ☐ Pressure Support (PS)
Maximum Peak Inspiratory Pressure (PIP)	_____
Maximum Positive End-Expiratory Pressure (PEEP)	_____
Maximum Respiratory Rate (per minute)	_____
Maximum Ventilator Rate (per minute)	_____
Maximum Inflation Times (seconds)	_____
Maximum Mean Airway Pressure (MAP)	_____
Maximum Amplitude (delta P)	_____
Maximum Frequency (Hz)	_____
Maximum P high	_____
Maximum T high	_____
Maximum T peep	_____
Maximum FiO2 (%)	_____
Maximum Tidal Volume (TV, ml)	_____
Maximum Temperature (C)	_____
Maximum Liters/minute (LPM)	_____

Maximum Inspiratory Time

_____

Maximum Synchronized or Non-synchronized breaths

_____

.... If other, specify the mode of ventilaton

_____

.... If other, specify settings

_____

Extubation

Was the patient extubated? ◯ No ◯ Yes

Extubation date

_____

Extubation time

_____

Mode of ventilation

◯ Room Air
◯ Oxyhood
◯ Low Flow Nasal Cannula
◯ High Flow Nasal Cannula (heated, high humidity)
◯ Continuous Positive Airway Pressure (CPAP)
◯ SiPAP
◯ NIPPV
◯ VapoTherm
◯ Other

.... If other, specify the mode of ventilaton

_____

.... If other, specify settings

_____

Source Docs

Upload source documentation 1

Upload source documentation 2

Hospital Discharge and Transfer

Death before initial hospital discharge (If yes, please complete the death section on Final Status form.)	◯ No ◯ Yes
Discharge Date	_____
Enrolled in NAPRTCS	◯ No ◯ Yes ◯ Unsure
NAPRTCS registration number	_____
Discharge disposition	◯ Discharge to home ◯ Transfer to stepdown from ICU ◯ Transfer to another hospital ◯ Other
.... If other, specify	_____

Measurements

Weight (grams)	_____
Length (cm)	_____
Head circumference (cm)	_____

Exams at Discharge /Transfer

Hearing test	◯ No ◯ Yes
Right ear	◯ Pass ◯ Fail
Left ear	◯ Pass ◯ Fail
Eye exam	◯ No ◯ Yes
Retinopathy of prematurity	◯ No ◯ Yes
Right eye grade	◯ I ◯ II ◯ III ◯ IV
Left eye grade	◯ I ◯ II ◯ III ◯ IV

Native Renal Function

Urine output prior to dialysis cath placement	◯ No ◯ Yes
Urinary diversion	◯ No ◯ Yes
Urostomy	◯ No ◯ Yes
Suprapubic catheter	◯ No ◯ Yes

Feeding

Date initiated	_____
Formula or breastmilk?	◯ Formula ◯ Breastmilk
Supplements (check all that apply)	☐ No ☐ Vitamin D ☐ Ferrous Sulfate ☐ Iron Sucrose (Venofer) ☐ Epoetin Alfa (Epogen) ☐ ADEK vitamin (AquADEK) ☐ Calcium and Phosphate (Tri-basic) ☐ Sodium Citrate-Citric Acid (Bicitra) ☐ Sodium Polystyrene Sulfonate (Kayexalate)
IU if vitamin D	_____
mg/kg if Ferrous Sulfate	_____
mg/kg if Iron Sucrose (Venofer)	_____
units/kg if Epoetin Alfa (Epogen)	_____
mL if ADEK vitamin (AquADEK)	_____
mg if Sodium Citrate-Citric Acide (Bicitra)	_____
.... If Sodium Polystyrene Sulfonate (Kayexalate)	◯ PO ◯ Formula/Expressed breastmilk pretreatment
Is fortifier used?	◯ No ◯ Yes
Fortifier brand and recipe	_____

Formula brand and product type	☐ No ☐ Similac - Special Care /HP ☐ Similac - Neosure ☐ Similac - Advance (standard term formula) ☐ Similac - Sensitive ☐ Similac - Total comfort ☐ Similac - Alimentum ☐ Similac - PM 60/40 ☐ Similac - Isomil ☐ Enfamil - Premature ☐ Enfamil - Enfacare ☐ Enfamil - Infant (standard term formula) ☐ Enfamil - GentleEase ☐ Enfamil - Sensitive ☐ Enfamil - Pregestimil ☐ Enfamil - Nutramigen ☐ Enfamil - Enfaport ☐ Enfamil - ProSobee ☐ Gerber - GoodStart GentlePro ☐ Gerber - GoodStart SoothePro ☐ Gerber - Extensive HA ☐ Gerber - GoodStart Soy ☐ Breastmilk ☐ Donor breastmilk ☐ Fortification ☐ Other
.... If other, specify	_____
Gastrostomy tube	◯ No ◯ Yes
Gastrostomy tube placement date	_____
Date of full external feeds	_____
Medications at time of discharge/transfer	

Respiratory Medications

Respiratory medications	◯ No ◯ Yes
Diuretics	◯ No ◯ Yes
.... If Diuretics, check all that apply	☐ Bumetanide ☐ Chlorthiazide ☐ Furosemide ☐ Hydrochlorothiazide ☐ Spironolactone ☐ Metolazone ☐ Other
.... If other, specify	_____
Inhaled bronchodilators	◯ No ◯ Yes

.... If inhaled bronchodilators, check all that apply	☐ Albuterol ☐ Levalbuterol ☐ Formoterol ☐ Metaproterenol ☐ Pirbuterol ☐ Salmeterol ☐ Other
.... If other, specify	_____
Inhaled steroids	◯ No ◯ Yes
.... If inhaled steroids, check all that apply	☐ Beclomethasone dipropionate (Qvar) ☐ Budesonide (Pulmicort) ☐ Budesonide/Formoterol (Symbicort) ☐ Fluticasone (Flovent) ☐ Fluticasone/Salmeterol (Advair) ☐ Mometasone (Asmanex) ☐ Mometasone/formoterol (Dulera) ☐ Other
.... If other, specify	_____
Inhalational Nitric Oxide (iNO)	◯ No ◯ Yes
Prostacyclin	◯ No ◯ Yes
Sildenafil	◯ No ◯ Yes
Bosentan	◯ No ◯ Yes
Treprostinil	◯ No ◯ Yes
Other respiratory medications	◯ No ◯ Yes
.... If other, specify	_____

Gastrointestinal Medications

Gastrointestinal medications	◯ No ◯ Yes
Prokinetic agents	◯ No ◯ Yes
. If prokinetic agents, check all that apply	☐ Metoclopramide ☐ Erythromycin (ees) ☐ Other
.... If other, specify	_____
Antacids	◯ No ◯ Yes

. If antacids, check all that apply	☐ Simethicone ☐ Pantoprazole (Protonix) ☐ Lansoprazole (Prevacid) ☐ Ranitidine (Zantac) ☐ Other
.... If other, specify	_____
Erythromycin	◯ No ◯ Yes
TPN	◯ No ◯ Yes
Other	◯ No ◯ Yes
.... If other, specify	_____

Cardiac Medications

Cardiac medications	◯ No ◯ Yes
Digoxin	◯ No ◯ Yes
Captopril	◯ No ◯ Yes
Aspirin	◯ No ◯ Yes
Other	◯ No ◯ Yes
.... If other, specify	_____

Neonate Diagnosis

All neonate diagnoses at time of discharge/transfer	◯ ESRD - chronic peritoneal dialysis dependent ◯ ESRD - chronic hemodialysis dependent ◯ Other
.... If other, specify	_____
Comments	_____

Source Docs

Upload hospital discharge form

Final Status

Final Status	
Did the patient switch from treatment group to expectant management group?	◯ No ◯ Yes
.... If yes, date of switch	_____
Reason to swtich	◯ Adverse Event ◯ Protocol Deviation ◯ Other
.... If other, specify	_____
Maternal Final Status	
Date of study completion or early termination	_____
Maternal final status	◯ Study Activities Completed ◯ Withdrawal by subject ◯ Withdrawal by Investigator ◯ Discontinued due to adverse event ◯ Discontinued due to protocol deviation ◯ Terminated by sponsor ◯ Death ◯ Lost to follow-up ◯ Other
.... If other, specify	_____
Patient Death Section	
Patient's date of death	_____
Patient's time of death (24 hr format)	_____
Specify primary cause of death as judged by the site PI	_____
Contributing cause(s) of death as judged by the site PI	_____

Data used to document cause of death (check all that apply)	☐ Medical record ☐ Physician letter ☐ Death certificate ☐ Autopsy ☐ Other, specify:
.... If other, specify	_____
Was the death related to a study procedure?	◯ Yes ◯ No ◯ N/A ◯ Unknown
Was an autopsy performed?	◯ Yes, available ◯ Yes, not available ◯ No ◯ Unknown
Please upload autopsy document	
Please upload death note	
Please give a brief narrative of circumstances surrounding death and attach the appropriate documentation (e.g. MD's note at death, resuscitation record, discharge summary, specific location(s) where the event took place) Please complete an Adverse Event form and Hospital Discharge/Transfer form. Please submit all source documents to the CCC/DCC as soon as data are obtained.	_____
Child's Final Status Hospital transfer or discharge is recorded on "Hospital Discharge and Transfer" form. Please complete the child's final status when the subject is permanently off study.	
Date of study completion or early termination	_____
Child's final status (Reminder: Please make sure Hispital Discharge and Transfer form is completed.)	◯ Study Activities Completed ◯ Withdrawal by subject ◯ Withdrawal by parent ◯ Withdrawal by Investigator ◯ Discontinued due to adverse event ◯ Discontinued due to protocol deviation ◯ Terminated by sponsor ◯ Fetal death ◯ Death ◯ Lost to follow-up ◯ Kidney transplant ◯ Other
.... If other, specify	_____
Child Death Section	

Child's date of death	_____
Child's time of death (24 hr format)	_____
Specify primary cause of death as judged by the site PI	_____
Contributing cause(s) of death as judged by the site PI	_____
Data used to document cause of death (check all that apply)	☐ Medical record ☐ Physician letter ☐ Death certificate ☐ Autopsy ☐ Other, specify:
.... If other, specify	_____
Was the death related to a study procedure?	◯ Yes ◯ No ◯ N/A ◯ Unknown
Was an autopsy performed?	◯ Yes, available ◯ Yes, not available ◯ No ◯ Unknown
Please upload autopsy document	
Please upload death note	
Please give a brief narrative of circumstances surrounding death and attach the appropriate documentation (e.g. MD's note at death, resuscitation record, discharge summary, specific location(s) where the event took place) Please complete an Adverse Event form and Study Termination/Closeout form. Please submit all source documents to the CCC/DCC as soon as data are obtained.	_____

PI Attestation

As Principal Investigator of the RAFT Trial at my institution, I certify that I have reviewed and agree with all data that is contained in this database. To the best of my knowledge, all information is consistent and accurate.

◯ I do not agree
◯ I agree

Principal investigator's signature

_____

Date of PI signature

_____

Source Docs

Upload source documentation

Unscheduled Visit

Date of visit	_____
Gestational age (weeks)	_____ (Weeks, calculated field)
Gestational age (days)	_____ (Days, calculated field)
Presenting complaint	_____
Final diagnosis	_____
Treatment	_____
Were any adverse events diagnosed at this visit? If yes, please complete a separate Adverse Event CRF.	◯ No ◯ Yes
Do any of these meet the definition of a serious adverse event? If yes, please complete a separate Adverse Event CRF.	◯ No ◯ Yes

Source Docs

Please attach source documentation of diagnostic tests performed wherever appropriate.

Upload de-identified ultrasound report

Please complete a separate form if there are any adverse events or protocol deviations..

Fetal Echocardiogram

Fetal Echocardiogram

The first section should be completed by study coordinator. The second section should be completed by central cardiac reader.

Type of Visit
◯ Fetal Echocardiogram at enrollment
◯ Fetal Echocardiogram with Hyperoxia test after 32 weeks gestation
◯ Fetal Echocardiogram with Hyperoxia test

Date of fetal echo
_____

Gestational age (weeks)
[Calculated from GA recorded at first amnioinfusion visit]
_____
(Weeks, calculated field)

Gestational age (days)
[Calculated from GA recorded at first amnioinfusion visit]
_____
(Days, calculated field)

Date uploaded to Trice
_____

Upload site echo report

Comment
_____

The section below should be completed by central cardiac reader.

Femur Length
_____
(FL, mm)

Head circumference
_____
(cm)

Ultrasound done on same day as fetal echo?
◯ No ◯ Yes

Estimate Fetal Weight grams (OB Ultrasound)
_____
(Gram)

Middle cerebral artery (MCA) peak systolic velocity
_____
(cm/sec (valid range 10-200))

Middle cerebral artery (MCA) end-diastolic velocity
_____
(cm/sec (valid range 0-50))

Middle cerebral artery (MCA) time averaged velocity	_____ (cm/sec)
Middle cerebral artery (MCA) pulsatility index (PI)	_____
Umbilical artary pulsatility index (UA PI)	_____
Umbilical vein (UV)	◯ normal ◯ pulsatility ◯ severe notching ◯ not available
Ductus venosus	◯ normal ◯ 'a' wave at baseline ◯ 'a' wave reversal ◯ not available
DV peak S	_____ (cm/sec (valid range 10-100))
DV peak a	_____ (cm/sec, only if present (valid range 0.001-50))
Pulmonary vein forward velocity-time integral (VTI)	_____ (cm)
Pulmonary vein reverse velocity-time integral (VTI)	_____ (cm)
Pulmonary vein forward: reverse velocity-time integral (VTI)	_____
Branch pulmonary artery (PA) peak systolic velocity	_____ (cm/sec, pick only one PA (left or right))
Branch pulmonary artery (PA) end-diastolic velocity	_____ (cm/sec)
Branch pulmonary artery (PA) time averaged velocity	_____ (cm/sec)
Branch PA PI	_____
Aortic annulus measurement	_____ (cm (valid range 0.1-1.5))

Aortic valve velocity-time integral (VTI)

_____
(cm (valid range 0.3-29))

R-R interval for Aortic velocity

_____
(msec (valid range 325-550))

Pulmonary valve annulus

_____
(cm (valid range 0-3))

Pulmonary valve velocity-time integral (VTI)

_____
(cm (valid range 0.3-29))

R-R interval for Pulmonary velocity

_____
(msec (valid range 325-550))

Pulmonary Cardiac Output

_____
(cc/min)

Aortic Cardiac Output

_____
(cc/min)

Combined cardiac output (CCO)

_____
(cc/min)

Combined cardiac output indexed

_____
(If fetal weight available, cc/kg/min)

Maternal Hyperoxia

Middle cerebral artery (MCA) peak systolic velocity MH

_____
(cm/sec (valid range 10-200))

Middle cerebral artery (MCA) end-diastolic velocity MH

_____
(cm/sec (valid range 0-50))

Middle cerebral artery (MCA) time averaged velocity MH

_____
(cm/sec)

Middle cerebral artery (MCA) pulsatility index (PI) MH

_____

Umbilical artary pulsatility index (UA PI) MH

_____

Umbilical vein (UV) MH	◯ normal ◯ pulsatility ◯ severe notching ◯ not available
Ductus venosus MH	◯ normal ◯ 'a' wave at baseline ◯ 'a' wave reversal ◯ not available
DV peak S MH	_____ (cm/sec (valid range 10-100))
DV peak a MH	_____ (cm/sec, only if present (valid range 0.001-50))
Pulm Vein forward velocity-time integral (VTI) MH	_____
Pulmonary vein reverse velocity-time integral (VTI) MH	_____
Pulmonary vein forward: reverse velocity-time integral (VTI) MH	_____
Branch pulmonary artery (PA) peak systolic velocity MH	_____ (Same PA used for baseline (right or left))
Branch pulmonary artery (PA) end-diastolic velocity MH	_____ (Same PA used for baseline (right or left))
Branch pulmonary artery (PA) time averaged velocity MH	_____ (Same PA used for baseline (right or left))
Branch pulmonary artery (PA) PI MH	_____
Aortic valve velocity-time integral (VTI) MH	_____ (cm (valid range 0.3-29))
R-R interval for Aortic velocity MH	_____ (msec (valid range 325-550))
Pulmonary valve velocity-time integral (VTI) MH	_____ (cm (valid range 0.3-29))
R-R interval for Pulmonary velocity MH	_____ (msec (valid range 325-550))

Pulmonary Cardiac Output MH

_____
(cc/min)

Aortic Cardiac Output MH

_____
(cc/min)

Combined cardiac output (CCO) MH

_____
(cc/min)

Combined cardiac output indexed MH

_____
(If fetal weight available, cc/kg/min)

Concomitant Medications

Concomitant Medications
Instructions: Enter one medication per form. Please enter ALL medications.

Date of data entry

_____

Medication name (trade or generic name)

_____

Indication (if given for AE, enter exact term from AE form)

_____

Dose

_____

Dose Units

- ◯ %
- ◯ AU
- ◯ AU/mL
- ◯ bar
- ◯ BAU
- ◯ BAU/mL
- ◯ bead
- ◯ BU
- ◯ capsule
- ◯ CCID_50
- ◯ cellular sheet
- ◯ Ci
- ◯ cloth
- ◯ cm^2
- ◯ D'ag'U
- ◯ disc
- ◯ dL
- ◯ douche
- ◯ drop
- ◯ FFU
- ◯ g
- ◯ globule
- ◯ granule
- ◯ gum
- ◯ hp_C
- ◯ hp_M
- ◯ hp_Q
- ◯ hp_X
- ◯ IU
- ◯ IU/L
- ◯ IU/mL
- ◯ kp_C
- ◯ L
- ◯ Lf
- ◯ LfU/mL
- ◯ lozenge
- ◯ mcg/actuat
- ◯ mCi
- ◯ mCi/mL
- ◯ mEq
- ◯ mg
- ◯ mg/actuat
- ◯ mg/hr
- ◯ mg/mg
- ◯ mg/mL
- ◯ mL
- ◯ mmol
- ◯ mol
- ◯ mU
- ◯ ng
- ◯ nmol
- ◯ organisms
- ◯ pastille
- ◯ patch
- ◯ pellet
- ◯ PFU
- ◯ pill
- ◯ PNU
- ◯ PNU/mL
- ◯ pouch
- ◯ puff
- ◯ ring
- ◯ salve
- ◯ stick
- ◯ strip
- ◯ suppository
- ◯ swab
- ◯ tablet
- ◯ tampon

◯ tape
◯ tbsp
◯ TCID_50
◯ tsp
◯ U
◯ uCi
◯ ug
◯ ug/mL
◯ uL
◯ umol
◯ unt
◯ unt/mL
◯ USP'U
◯ vial
◯ wafer

Frequency of the medication

◯ Once per day
◯ Twice per day
◯ Three times per day
◯ Four times per day
◯ More than four times per day
◯ Once a month
◯ As needed
◯ Continuous
◯ More than three times per week
◯ Other

.... If other, specify

_____

Route of administration

◯ Oral
◯ Topical
◯ Subcutaneous
◯ Intradermal
◯ Transdermal
◯ Intraocular
◯ Intramuscular
◯ Inhalation
◯ Intravenous
◯ Intraperitoneal
◯ Nasal
◯ Vaginal
◯ Rectal
◯ Other
◯ Unknown

.... If other, specify

_____

Ongoing? ◯ No ◯ Yes

Medication start date

_____

Medication end date

_____

Baseline medication? ◯ Yes ◯ No

If related to AE, enter corresponding Adverse Event ID

_____

Adverse Event (Outdated)

OUTDATED
Adverse Events and Other Reportable Events Form
Includes non-serious Adverse Events (AEs), Serious Adverse Events (SAEs) and other events reportable to the IRB

Instructions: Complete this form for any new Adverse Events, Serious Adverse Events (SAE), or other events reportable to the IRB. Do not duplicate an ongoing AE, SAE, or other reportable event. Report updates to an ongoing reportable event on the inititial eCRF on which the event was documented.

This form is outdated. Please use the one titled "Adverse Events".

Date of this report

_____

Adverse event term

_____

AE code (CTCAE 5.0)

CTCAE Reference

- ◯ Abdominal distension
- ◯ Abdominal pain
- ◯ Acidosis
- ◯ Acoustic nerve disorder NOS
- ◯ Activated partial thromboplastin time prolonged
- ◯ Adrenal insufficiency
- ◯ Adult respiratory distress syndrome
- ◯ Agitation
- ◯ Akathisia
- ◯ Alanine aminotransferase increased
- ◯ Alcohol intolerance
- ◯ Alkaline phosphatase increased
- ◯ Alkalosis
- ◯ Allergic reaction
- ◯ Allergic rhinitis
- ◯ Alopecia
- ◯ Amenorrhea
- ◯ Amnesia
- ◯ Anal fissure
- ◯ Anal fistula
- ◯ Anal pain
- ◯ Anal stenosis
- ◯ Anal ulcer
- ◯ Anaphylaxis
- ◯ Anemia
- ◯ Ankle fracture
- ◯ Anorexia
- ◯ Anorgasmia
- ◯ Anosmia
- ◯ Anxiety
- ◯ Aortic injury
- ◯ Aphonia
- ◯ Apnea
- ◯ Appendicitis
- ◯ Appendicitis perforated
- ◯ Arachnoiditis
- ◯ Arterial injury
- ◯ Arthralgia
- ◯ Arthritis
- ◯ Ascites
- ◯ Aspartate aminotransferase increased
- ◯ Aspiration
- ◯ Asystole
- ◯ Ataxia
- ◯ Atelectasis
- ◯ Atrial fibrillation
- ◯ Atrial flutter
- ◯ Atrioventricular block complete
- ◯ Atrioventricular block first degree
- ◯ Azoospermia
- ◯ Back pain
- ◯ Bacteremia
- ◯ Belching
- ◯ Biliary fistula
- ◯ Bladder infection
- ◯ Bloating
- ◯ Blood and lymphatic system disorders - Other, specify
- ◯ Blood antidiuretic hormone abnormal
- ◯ Blood bicarbonate decreased
- ◯ Blood bilirubin increased
- ◯ Blood corticotrophin decreased
- ◯ Blood gonadotrophin abnormal
- ◯ Blood lactate dehydrogenase increased
- ◯ Blood prolactin abnormal
- ◯ Blurred vision
- ◯ Body odor
- ◯ Bone pain
- ◯ Breast atrophy

◯ Breast infection
◯ Breast pain
◯ Bronchial fistula
◯ Bronchial obstruction
◯ Bronchospasm
◯ Bruising
◯ Budd-Chiari syndrome
◯ Bullous dermatitis
◯ Burn
◯ Capillary leak syndrome
◯ Cardiac arrest
◯ Cardiac disorders - Other, specify
◯ Cardiac troponin I increased
◯ Cardiac troponin T increased
◯ Cataract
◯ Catheter related infection
◯ CD4 lymphocytes decreased
◯ Cerebrospinal fluid leakage
◯ Cervicitis infection
◯ Cheilitis
◯ Chest pain - cardiac
◯ Chest wall pain
◯ Chills
◯ Cholecystitis
◯ Cholesterol high
◯ Chylous ascites
◯ Cognitive disturbance
◯ Colitis
◯ Colonic fistula
◯ Colonic hemorrhage
◯ Colonic obstruction
◯ Colonic perforation
◯ Colonic stenosis
◯ Colonic ulcer
◯ Concentration impairment
◯ Conduction disorder
◯ Confusion
◯ Congenital, familial and genetic disorders - Other, specify
◯ Conjunctivitis
◯ Conjunctivitis infective
◯ Constipation
◯ Cough
◯ CPK increased
◯ Creatinine increased
◯ Cushingoid
◯ Cyanosis
◯ Death neonatal
◯ Death NOS
◯ Dehydration
◯ Delayed puberty
◯ Delirium
◯ Delusions
◯ Dental caries
◯ Depressed level of consciousness
◯ Depression
◯ Diarrhea
◯ Disseminated intravascular coagulation
◯ Dizziness
◯ Dry eye
◯ Dry mouth
◯ Dry skin
◯ Duodenal fistula
◯ Duodenal obstruction
◯ Duodenal perforation
◯ Duodenal ulcer
◯ Dysarthria
◯ Dysgeusia
◯ Dysmenorrhea
◯ Dyspareunia
◯ Dyspepsia

◯ Dysphagia
◯ Dysphasia
◯ Dyspnea
◯ Dysuria
◯ Ear and labyrinth disorders - Other, specify
◯ Ear pain
◯ Eczema
◯ Edema cerebral
◯ Edema face
◯ Ejaculation disorder
◯ Electrocardiogram QT corrected interval prolonged
◯ Encephalitis infection
◯ Encephalomyelitis infection
◯ Encephalopathy
◯ Endocarditis infective
◯ Endocrine disorders - Other, specify
◯ Endophthalmitis
◯ Enterocolitis
◯ Eosinophilia
◯ Epistaxis
◯ Epstein-Barr virus infection reactivation
◯ Erythema multiforme
◯ Erythroderma
◯ Esophageal hemorrhage
◯ Esophageal obstruction
◯ Esophageal pain
◯ Esophageal stenosis
◯ Esophageal ulcer
◯ Esophageal varices hemorrhage
◯ Esophagitis
◯ Euphoria
◯ Exostosis
◯ Extraocular muscle paresis
◯ Extrapyramidal disorder
◯ Eye disorders - Other, specify
◯ Eye infection
◯ Eye pain
◯ Facial pain
◯ Fall
◯ Fat atrophy
◯ Fatigue
◯ Febrile neutropenia
◯ Fecal incontinence
◯ Fever
◯ Fibrinogen decreased
◯ Flank pain
◯ Flashing lights
◯ Flatulence
◯ Floaters
◯ Flu like symptoms
◯ Flushing
◯ Folliculitis
◯ Forced expiratory volume decreased
◯ Fracture
◯ Fungemia
◯ Gait disturbance
◯ Gallbladder fistula
◯ Gallbladder obstruction
◯ Gallbladder pain
◯ Gallbladder perforation
◯ Gastric hemorrhage
◯ Gastric perforation
◯ Gastric ulcer
◯ Gastritis
◯ Gastrointestinal fistula
◯ Gastrointestinal disorders - Other, specify
◯ Gastrointestinal pain
◯ Gastroparesis
◯ General disorders and administration site conditions - Other, specify
◯ Generalized edema

◯ Genital edema
◯ Gingival pain
◯ Glaucoma
◯ Growth accelerated
◯ Growth hormone abnormal
◯ Growth suppression
◯ Guillain-Barre syndrome
◯ Gum infection
◯ Gynecomastia
◯ Hair texture abnormal
◯ Hallucinations
◯ Haptoglobin decreased
◯ Headache
◯ Hearing impaired
◯ Heart failure
◯ Hematoma
◯ Hematuria
◯ Hemoglobinuria
◯ Hemolysis
◯ Hemolytic uremic syndrome
◯ Hemorrhoids
◯ Hepatic failure
◯ Hepatic hemorrhage
◯ Hepatic necrosis
◯ Hepatic pain
◯ Hepatitis viral
◯ Hepatobiliary disorders - Other, specify
◯ Hiccups
◯ Hip fracture
◯ Hirsutism
◯ Hoarseness
◯ Hot flashes
◯ Hydrocephalus
◯ Hypercalcemia
◯ Hyperglycemia
◯ Hyperhidrosis
◯ Hyperkalemia
◯ Hyperkeratosis
◯ Hyperlipidemia
◯ Hypermagnesemia
◯ Hypernatremia
◯ Hyperparathyroidism
◯ Hyperphosphatemia
◯ Hypersomnia
◯ Hypertension
◯ Hyperthyroidism
◯ Hypertrichosis
◯ Hypertriglyceridemia
◯ Hyperuricemia
◯ Hypoalbuminemia
◯ Hypocalcemia
◯ Hypoglycemia
◯ Hypohidrosis
◯ Hypokalemia
◯ Hypomagnesemia
◯ Hyponatremia
◯ Hypoparathyroidism
◯ Hypophosphatemia
◯ Hypopituitarism
◯ Hypotension
◯ Hypothermia
◯ Hypothyroidism
◯ Hypoxia
◯ Ileal perforation
◯ Ileal stenosis
◯ Ileal ulcer
◯ Ileus
◯ Immune system disorders - Other, specify
◯ Infections and infestations - Other, specify
◯ Infective myositis
◯ Injection site reaction

◯ Injury, poisoning and procedural complications - Other, specify
◯ Injury to carotid artery
◯ Injury to inferior vena cava
◯ Injury to superior vena cava
◯ INR increased
◯ Insomnia
◯ Intracranial hemorrhage
◯ Investigations - Other, specify
◯ Irregular menstruation
◯ Irritability
◯ Ischemia cerebrovascular
◯ Jejunal perforation
◯ Jejunal stenosis
◯ Jejunal ulcer
◯ Joint effusion
◯ Joint infection
◯ Keratitis
◯ Kidney infection
◯ Kyphosis
◯ Laryngeal edema
◯ Laryngeal stenosis
◯ Laryngitis
◯ Laryngospasm
◯ Lethargy
◯ Leukocytosis
◯ Leukoencephalopathy
◯ Libido decreased
◯ Libido increased
◯ Lip pain
◯ Lipase increased
◯ Lordosis
◯ Lymph node pain
◯ Lymphedema
◯ Lymphocyte count decreased
◯ Lymphocyte count increased
◯ Malabsorption
◯ Malaise
◯ Mania
◯ Memory impairment
◯ Meningismus
◯ Meningitis
◯ Menorrhagia
◯ Metabolism and nutrition disorders - Other, specify
◯ Methemoglobinemia
◯ Mobitz (type) II atrioventricular block
◯ Mobitz type I
◯ Movements involuntary
◯ Mucositis oral
◯ Multi-organ failure
◯ Muscle cramp
◯ Musculoskeletal and connective tissue disorder - Other, specify
◯ Myalgia
◯ Myasthenia gravis
◯ Myelitis
◯ Myelodysplastic syndrome
◯ Myocardial infarction
◯ Myocarditis
◯ Myositis
◯ Nail changes
◯ Nail discoloration
◯ Nasal congestion
◯ Nausea
◯ Neck pain
◯ Neoplasms benign, malignant and unspecified (incl cysts and polyps) - Other, specify
◯ Nephrotic syndrome
◯ Nervous system disorders - Other, specify
◯ Neuralgia
◯ Neutrophil count decreased

◯ Night blindness
◯ Nystagmus
◯ Obesity
◯ Obstruction gastric
◯ Oligospermia
◯ Oral hemorrhage
◯ Oral pain
◯ Osteonecrosis
◯ Osteoporosis
◯ Otitis externa
◯ Otitis media
◯ Ovarian rupture
◯ Ovulation pain
◯ Pain
◯ Pain in extremity
◯ Pain of skin
◯ Palpitations
◯ Pancreatic hemorrhage
◯ Pancreatitis
◯ Papilledema
◯ Paresthesia
◯ Paronychia
◯ Paroxysmal atrial tachycardia
◯ Pelvic pain
◯ Penile pain
◯ Perforation bile duct
◯ Pericardial effusion
◯ Pericarditis
◯ Periodontal disease
◯ Peripheral ischemia
◯ Peripheral motor neuropathy
◯ Peripheral sensory neuropathy
◯ Personality change
◯ Pharyngeal fistula
◯ Pharyngitis
◯ Pharyngolaryngeal pain
◯ Phlebitis
◯ Photophobia
◯ Photosensitivity
◯ Platelet count decreased
◯ Pleural effusion
◯ Pleuritic pain
◯ Pneumonitis
◯ Pneumothorax
◯ Portal hypertension
◯ Portal vein thrombosis
◯ Postnasal drip
◯ Pregnancy, puerperium and perinatal conditions - Other, specify
◯ Premature delivery
◯ Premature menopause
◯ Presyncope
◯ Proctitis
◯ Productive cough
◯ Prostatic pain
◯ Proteinuria
◯ Pruritus
◯ Psychiatric disorders - Other, specify
◯ Psychosis
◯ Pulmonary edema
◯ Pulmonary fibrosis
◯ Pulmonary hypertension
◯ Purpura
◯ Radiation recall reaction (dermatologic)
◯ Rash acneiform
◯ Rash maculo-papular
◯ Rash pustular
◯ Rectal fistula
◯ Rectal hemorrhage
◯ Rectal pain
◯ Rectal perforation

◯ Rectal stenosis
◯ Rectal ulcer
◯ Recurrent laryngeal nerve palsy
◯ Renal and urinary disorders - Other, specify
◯ Renal calculi
◯ Renal colic
◯ Renal hemorrhage
◯ Reproductive system and breast disorders - Other, specify
◯ Respiratory failure
◯ Respiratory, thoracic and mediastinal disorders - Other, specify
◯ Restlessness
◯ Restrictive cardiomyopathy
◯ Retinal detachment
◯ Retinal tear
◯ Retinal vascular disorder
◯ Retinoic acid syndrome
◯ Retinopathy
◯ Retroperitoneal hemorrhage
◯ Rhabdomyolysis
◯ Rhinorrhea
◯ Rotator cuff injury
◯ Salivary gland fistula
◯ Salivary gland infection
◯ Scoliosis
◯ Scrotal pain
◯ Seizure
◯ Sepsis
◯ Seroma
◯ Serum amylase increased
◯ Serum sickness
◯ Shingles
◯ Sick sinus syndrome
◯ Sinus bradycardia
◯ Sinus pain
◯ Sinus tachycardia
◯ Sinusitis
◯ Skin and subcutaneous tissue disorders - Other, specify
◯ Skin atrophy
◯ Skin hyperpigmentation
◯ Skin hypopigmentation
◯ Skin infection
◯ Skin papilloma
◯ Skin ulceration
◯ Sleep apnea
◯ Small intestinal obstruction
◯ Small intestinal perforation
◯ Small intestine ulcer
◯ Sneezing
◯ Social circumstances - Other, specify
◯ Somnolence
◯ Sore throat
◯ Spasticity
◯ Spinal cord compression
◯ Spinal fracture
◯ Stevens-Johnson syndrome
◯ Stomach pain
◯ Stomal ulcer
◯ Stridor
◯ Stroke
◯ Subcutaneous emphysema
◯ Sudden death NOS
◯ Suicidal ideation
◯ Suicide attempt
◯ Superficial thrombophlebitis
◯ Superior vena cava syndrome
◯ Supraventricular tachycardia
◯ Surgical and medical procedures - Other, specify
◯ Syncope

◯ Telangiectasia
◯ Tendon reflex decreased
◯ Testicular disorder
◯ Testicular pain
◯ Thromboembolic event
◯ Thrombotic thrombocytopenic purpura
◯ Thrush
◯ Thyroid stimulating hormone increased
◯ Tinnitus
◯ Tooth development disorder
◯ Tooth discoloration
◯ Toothache
◯ Toxic epidermal necrolysis
◯ Tracheal obstruction
◯ Tracheitis
◯ Transient ischemic attacks
◯ Tremor
◯ Trismus
◯ Tumor lysis syndrome
◯ Tumor pain
◯ Typhlitis
◯ Upper respiratory infection
◯ Urinary frequency
◯ Urinary incontinence
◯ Urinary retention
◯ Urinary tract infection
◯ Urinary urgency
◯ Urine discoloration
◯ Urticaria
◯ Uterine hemorrhage
◯ Uterine pain
◯ Uterine perforation
◯ Uveitis
◯ Vaccination complication
◯ Vaginal discharge
◯ Vaginal dryness
◯ Vaginal hemorrhage
◯ Vaginal infection
◯ Vaginal inflammation
◯ Vaginal pain
◯ Vascular disorders - Other, specify
◯ Vasculitis
◯ Vasovagal reaction
◯ Venous injury
◯ Ventricular arrhythmia
◯ Ventricular fibrillation
◯ Ventricular tachycardia
◯ Vertigo
◯ Vestibular disorder
◯ Virilization
◯ Vision decreased
◯ Vital capacity abnormal
◯ Vitreous hemorrhage
◯ Voice alteration
◯ Vomiting
◯ Watering eyes
◯ Weight gain
◯ Weight loss
◯ Wheezing
◯ Wound dehiscence
◯ Wound infection
◯ Wrist fracture
◯ Leukemia secondary to oncology chemotherapy
◯ Corneal ulcer
◯ Bone marrow hypocellular
◯ Lymphocele
◯ Buttock pain
◯ Joint range of motion decreased
◯ Tooth infection
◯ Chest wall necrosis
◯ Bladder spasm

◯ Scalp pain
◯ White blood cell decreased
◯ Pancreatic fistula
◯ Nail loss
◯ Intestinal stoma site bleeding
◯ Treatment related secondary malignancy
◯ Pharyngeal stenosis
◯ Edema limbs
◯ Duodenal stenosis
◯ Electrocardiogram T wave abnormal
◯ Pancreatic anastomotic leak
◯ Biliary anastomotic leak
◯ Ejection fraction decreased
◯ Prostate infection
◯ Tracheal stenosis
◯ Lymph gland infection
◯ Chylothorax
◯ Facial muscle weakness
◯ Bile duct stenosis
◯ Periorbital infection
◯ Pancreas infection
◯ Lower gastrointestinal hemorrhage
◯ Infusion related reaction
◯ Skin induration
◯ Gastric necrosis
◯ Cytokine release syndrome
◯ Urethral infection
◯ Glucose intolerance
◯ Bronchopleural fistula
◯ Vaginal stricture
◯ Pericardial tamponade
◯ Oculomotor nerve disorder
◯ Abducens nerve disorder
◯ Wound complication
◯ Feminization acquired
◯ Neck edema
◯ Oral dysesthesia
◯ Palmar-plantar erythrodysesthesia syndrome
◯ Periorbital edema
◯ Viremia
◯ Visceral arterial ischemia
◯ Fetal growth retardation
◯ Ovarian infection
◯ Prostatic obstruction
◯ Bronchial infection
◯ Anal hemorrhage
◯ Duodenal hemorrhage
◯ Ileal hemorrhage
◯ Intra-abdominal hemorrhage
◯ Intraoperative hemorrhage
◯ Jejunal hemorrhage
◯ Pharyngeal hemorrhage
◯ Pleural hemorrhage
◯ Postoperative hemorrhage
◯ Prostatic hemorrhage
◯ Testicular hemorrhage
◯ Tumor hemorrhage
◯ Upper gastrointestinal hemorrhage
◯ Esophageal perforation
◯ Hair color changes
◯ Hemoglobin increased
◯ Phantom pain
◯ Mediastinal hemorrhage
◯ Olfactory nerve disorder
◯ Abdominal infection
◯ Hepatic infection
◯ Phlebitis infective
◯ Salivary duct inflammation
◯ Postoperative thoracic procedure complication
◯ GGT increased
◯ Delayed orgasm

◯ Peritoneal infection
◯ Mediastinal infection
◯ Precocious puberty
◯ Pancreatic necrosis
◯ Right ventricular dysfunction
◯ Cytomegalovirus infection reactivation
◯ Pelvic infection
◯ Edema trunk
◯ Esophageal infection
◯ Hepatitis B reactivation
◯ Enterocolitis infectious
◯ Intestinal stoma obstruction
◯ Intestinal stoma leak
◯ Gallbladder necrosis
◯ Laryngeal obstruction
◯ Rhinitis infective
◯ Urine output decreased
◯ Hematosalpinx
◯ Hemorrhoidal hemorrhage
◯ Trigeminal nerve disorder
◯ Accessory nerve disorder
◯ Bone infection
◯ Dermatitis radiation
◯ Eyelid function disorder
◯ Glossopharyngeal nerve disorder
◯ Hypoglossal nerve disorder
◯ Lung infection
◯ Lactation disorder
◯ Nail infection
◯ Optic nerve disorder
◯ Perineal pain
◯ Pleural infection
◯ Tricuspid valve disease
◯ Vagus nerve disorder
◯ Facial nerve disorder
◯ Erectile dysfunction
◯ Scleral disorder
◯ Mitral valve disease
◯ Pulmonary valve disease
◯ Urinary tract obstruction
◯ Aortic valve disease
◯ Anorectal infection
◯ Autoimmune disorder
◯ Biliary tract infection
◯ Corneal infection
◯ Disease progression
◯ Penile infection
◯ Radiculitis
◯ Gastric stenosis
◯ Splenic infection
◯ Scrotal infection
◯ Vascular access complication
◯ Urinary tract pain
◯ Uterine infection
◯ Sinus disorder
◯ Soft tissue infection
◯ Small intestinal stenosis
◯ Nail ridging
◯ Lipohypertrophy
◯ Localized edema
◯ Non-cardiac chest pain
◯ Tracheal hemorrhage
◯ Enterovesical fistula
◯ Generalized muscle weakness
◯ Gallbladder infection
◯ Pancreatic enzymes decreased
◯ Laryngopharyngeal dysesthesia
◯ Hypophysitis
◯ Dysesthesia
◯ Cystitis noninfective
◯ Rectal mucositis

◯ Bronchial stricture
◯ Bladder perforation
◯ Pyramidal tract syndrome
◯ Sinusoidal obstruction syndrome
◯ Reversible posterior leukoencephalopathy syndrome
◯ Pelvic floor muscle weakness
◯ Stoma site infection
◯ Osteonecrosis of jaw
◯ Device related infection
◯ Infusion site extravasation
◯ Chronic kidney disease
◯ Rectal fissure
◯ Urinary fistula
◯ Brachial plexopathy
◯ Pancreatic duct stenosis
◯ Peritoneal necrosis
◯ Pharyngeal anastomotic leak
◯ Pharyngeal necrosis
◯ Rectal obstruction
◯ Rectal necrosis
◯ Small intestinal mucositis
◯ Gastrointestinal stoma necrosis
◯ Gastric fistula
◯ Jejunal fistula
◯ Oral cavity fistula
◯ Anal mucositis
◯ Anal necrosis
◯ Esophageal necrosis
◯ Ileal fistula
◯ Ileal obstruction
◯ Jejunal obstruction
◯ Laryngeal inflammation
◯ Unequal limb length
◯ Arteritis infective
◯ Prolapse of intestinal stoma
◯ Bronchopulmonary hemorrhage
◯ Cecal hemorrhage
◯ Urostomy site bleeding
◯ Tracheostomy site bleeding
◯ Duodenal infection
◯ Lip infection
◯ Laryngeal hemorrhage
◯ Cecal infection
◯ Spermatic cord hemorrhage
◯ Ovarian hemorrhage
◯ Mucosal infection
◯ Cranial nerve infection
◯ Peripheral nerve infection
◯ Small intestine infection
◯ Vulval infection
◯ Lymph leakage
◯ Abdominal soft tissue necrosis
◯ Muscle weakness lower limb
◯ Soft tissue necrosis lower limb
◯ Soft tissue necrosis upper limb
◯ Head soft tissue necrosis
◯ Muscle weakness left-sided
◯ Neck soft tissue necrosis
◯ Musculoskeletal deformity
◯ Central nervous system necrosis
◯ External ear pain
◯ Laryngeal fistula
◯ Tracheal fistula
◯ Fallopian tube anastomotic leak
◯ Fallopian tube obstruction
◯ Fallopian tube perforation
◯ Pelvic soft tissue necrosis
◯ Muscle weakness right-sided
◯ Muscle weakness trunk
◯ Joint range of motion decreased cervical spine
◯ Superficial soft tissue fibrosis

◯ Fibrosis deep connective tissue
◯ Joint range of motion decreased lumbar spine
◯ Bladder anastomotic leak
◯ Kidney anastomotic leak
◯ Spermatic cord obstruction
◯ Uterine fistula
◯ Vaginal fistula
◯ Ureteric anastomotic leak
◯ Urethral anastomotic leak
◯ Vaginal obstruction
◯ Vaginal perforation
◯ Prolapse of urostomy
◯ Nipple deformity
◯ Intraoperative gastrointestinal injury
◯ Intraoperative arterial injury
◯ Intraoperative hepatobiliary injury
◯ Intraoperative urinary injury
◯ Intraoperative musculoskeletal injury
◯ Intraoperative neurological injury
◯ Intraoperative breast injury
◯ Intraoperative respiratory injury
◯ Intraoperative endocrine injury
◯ Middle ear inflammation
◯ Intraoperative reproductive tract injury
◯ Intraoperative ocular injury
◯ Intraoperative head and neck injury
◯ Intraoperative cardiac injury
◯ Intraoperative ear injury
◯ Intraoperative renal injury
◯ Intraoperative splenic injury
◯ Intraoperative venous injury
◯ Injury to jugular vein
◯ Esophageal fistula
◯ Pulmonary fistula
◯ Gastrointestinal anastomotic leak
◯ Laryngeal mucositis
◯ Pharyngeal mucositis
◯ Urostomy leak
◯ Urostomy obstruction
◯ Urostomy stenosis
◯ Uterine anastomotic leak
◯ Vaginal anastomotic leak
◯ Vas deferens anastomotic leak
◯ Large intestinal anastomotic leak
◯ Small intestinal anastomotic leak
◯ Gastric anastomotic leak
◯ Rectal anastomotic leak
◯ Muscle weakness upper limb
◯ Spermatic cord anastomotic leak
◯ Stenosis of gastrointestinal stoma
◯ Tracheal mucositis
◯ Carbon monoxide diffusing capacity decreased
◯ Uterine obstruction
◯ Esophageal anastomotic leak
◯ Iron overload
◯ Avascular necrosis
◯ Gastroesophageal reflux disease
◯ Testosterone deficiency
◯ Oropharyngeal pain
◯ Glucosuria
◯ Papulopustular rash
◯ Acute kidney injury
◯ Vaccination site lymphadenopathy
◯ Left ventricular systolic dysfunction
◯ Pregnancy loss
◯ Arterial thromboembolism
◯ Trochlear nerve disorder
◯ Herpes simplex reactivation
◯ Other

If other, please choose a MedDRA System Organ Class (SOC)	◯ Hematopoietic and Lymphoid System Disorder ◯ Cardiac disorders ◯ Congenital, Familial and Genetic Disorder Class ◯ Ear and Labyrinth Disorder Class ◯ Endocrine Disorder ◯ Eye Disorder ◯ Gastrointestinal Disorder ◯ General Disorders and Administration Site Conditions Class ◯ Liver and Biliary Tract Disorder ◯ Immune System Disorder ◯ Infection and infestation ◯ Injury, Poisoning and Procedural Complication Class ◯ Investigation ◯ Metabolism and Nutrition Disorder Class ◯ Connective and Soft Tissue Disorder ◯ Neoplasm ◯ Nervous System Disorder ◯ Pregnancy, Puerperium and Perinatal Condition Class ◯ Psychiatric Disorder ◯ Urinary Tract Disorder ◯ Reproductive System and Breast Disorder Class ◯ Respiratory and Thoracic Disorder ◯ Skin Disorder ◯ Social Circumstances ◯ Intervention or Procedure ◯ Vascular Disorder
Severity Mild: Events require minimal or no treatment and do not interfere with the participant's daily activities. Moderate: Events result in a low level of inconvenience or concern with the therapeutic measures. Moderate events may cause some interference with functioning. Severe: Events interrupt a participant's usual daily activity and may require systemic drug therapy or other treatment. Severe events are usually potentially life-threatening or incapacitating. Of note, the term "severe" does not necessarily equate to "serious."	◯ Mild ◯ Moderate ◯ Severe
Is this a Serious Adverse Event (SAE) 1) Death 2) Life-threatening event 3) Inpatient hospitalization > 7 days / Prolongation of existing hospitalization 4) Persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions 5) Congental anomoly/birth defect	◯ No ◯ Yes

If serious, select reason:	◯ Death ◯ Life-threatening event ◯ Inpatient hospitalization > 7 days / Prolongation of existing hospitalization ◯ Persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions ◯ Congental anomoly/birth defect
Relationship to study treatment	◯ Not Related ◯ Unlikely to be Related ◯ Potentially Related ◯ Probably Related ◯ Definitely Related
AE action taken with study intervention	◯ None ◯ Study intervention interrupted ◯ Study intervention discontinued ◯ Study intervention modified
Other action taken	◯ None ◯ Moved to the expectant management group ◯ Non-study treatment required
.... If non-study treatment is selected, please specify	_____
Unanticipated or unexpected AE?	◯ No ◯ Yes
AE start date	_____
Date site became aware of the adverse event (if Unanticipated, Unexpected, or Severe only)	_____
AE stop date	_____
Outcomes attributed to the event	◯ Recovered/Resolved ◯ Recovered/Resolved with sequelae ◯ Recovering/resolving ◯ Not recovered/not resolved ◯ Fatal ◯ Unknown
... If not yet recovered, enter date of last patient status update:	_____
Who was involved? (e.g. Mother/Fetus/Neonate, study team members, family members, etc.)	_____
Specific location(s) where event took place (e.g. in the emergency room, the NICU, the participant's home, etc.)	_____

Describe the event, including the timing of any related study interventions, relevant tests, and/or history	_____
IRB notified?	◯ No ◯ Yes
Which IRB did you report to?	◯ JHMIRB ◯ Local IRB
Date reported to IRB	_____

Complete this section if reporting an Adverse Events of Interest

Preterm Premature Rupture of Membranes (PPROM)	◯ No ◯ Yes
.... If yes, resealed membranes?	◯ No ◯ Yes
Preterm labor (after 20, but before 37 weeks gestation)	◯ No ◯ Yes
Chorioamnionitis	◯ No ◯ Yes
Bleeding with hemoperitoneum	◯ No ◯ Yes
Placental abruption	◯ No ◯ Yes
Uterine rupture	◯ No ◯ Yes
Bleeding in absence of placental abruption	◯ No ◯ Yes
Amniotic fluid embolism	◯ No ◯ Yes
Fetal death	◯ No ◯ Yes
Hydrops Fetalis	◯ No ◯ Yes
Severe maternal illness	◯ No ◯ Yes
Maternal death	◯ No ◯ Yes, within 30 days of study intervention ◯ Yes, more than 30 days after leaving the study
Upload de-identified maternal autopsy report	
Local Wound infection	◯ No ◯ Yes
Fetal injury	◯ No ◯ Yes
Chorioamniotic separation	◯ No ◯ Yes
Amniotic band syndrome	◯ No ◯ Yes

Failure of procedure	◯ No ◯ Yes
A consent error	◯ No ◯ Yes

Review and Source Documents

Upload source document(s) relating to this event	
CCC/DCC review date	_____
CCC/DCC review comments	_____

Medical Monitor Review

Relationship to study treatment	◯ Not Related ◯ Unlikely to be Related ◯ Potentially Related ◯ Probably Related ◯ Definitely Related
Comments	_____
Medical monitor name	_____
Signature	_____
Signature date	_____
Name	_____
Signature date	_____

Adverse Events

Adverse Events and Other Reportable Events Form
Includes non-serious Adverse Events (AEs), Serious Adverse Events (SAEs) and other events reportable to the IRB

Instructions:
Complete this form for any new Adverse Events.After the birth of the baby, do not include any events related to the neonate. After birth, report only Adverse Events or other events involving the mother until hospital discharge.Do not duplicate an ongoing AE, SAE, or other reportable event. Report updates to an ongoing reportable event on the form on which the event was initially documented.

Date of this report

_____

Indicate which adverse event occurred

- ◯ Amniotic fluid embolism
- ◯ Bleeding with hemoperitoneum
- ◯ Bleeding in absence of placental abruption
- ◯ Chorioamnionitis
- ◯ Fetal death
- ◯ Hydrops fetalis
- ◯ Maternal death
- ◯ Placental abruption
- ◯ Preterm Premature Rupture of Membranes (PPROM)
- ◯ Preterm labor (after 20, but before 37 weeks gestation)
- ◯ Severe maternal illness
- ◯ Uterine rupture
- ◯ Amniotic band syndrome
- ◯ Chorioamniotic separation
- ◯ Fetal injury
- ◯ Local wound infection
- ◯ Failure of procedure
- ◯ Other

This is an adverse event that may lead to premature discontinuation from the study intervention. Please contact the lead PI.

PPROM is no longer considered an SAE but rather an expected event to be recorded.

.... If PPROM, resealed membranes? ◯ No ◯ Yes

.... If maternal death, specify

- ◯ Maternal death within 30 days of study intervention
- ◯ Maternal death more than 30 days after leaving the study

Adverse event term (CTCAE 5.0)

CTCAE Reference

- ◯ Abdominal distension
- ◯ Abdominal pain
- ◯ Acidosis
- ◯ Acoustic nerve disorder NOS
- ◯ Activated partial thromboplastin time prolonged
- ◯ Adrenal insufficiency
- ◯ Adult respiratory distress syndrome
- ◯ Agitation
- ◯ Akathisia
- ◯ Alanine aminotransferase increased
- ◯ Alcohol intolerance
- ◯ Alkaline phosphatase increased
- ◯ Alkalosis
- ◯ Allergic reaction
- ◯ Allergic rhinitis
- ◯ Alopecia
- ◯ Amenorrhea
- ◯ Amnesia
- ◯ Anal fissure
- ◯ Anal fistula
- ◯ Anal pain
- ◯ Anal stenosis
- ◯ Anal ulcer
- ◯ Anaphylaxis
- ◯ Anemia
- ◯ Ankle fracture
- ◯ Anorexia
- ◯ Anorgasmia
- ◯ Anosmia
- ◯ Anxiety
- ◯ Aortic injury
- ◯ Aphonia
- ◯ Apnea
- ◯ Appendicitis
- ◯ Appendicitis perforated
- ◯ Arachnoiditis
- ◯ Arterial injury
- ◯ Arthralgia
- ◯ Arthritis
- ◯ Ascites
- ◯ Aspartate aminotransferase increased
- ◯ Aspiration
- ◯ Asystole
- ◯ Ataxia
- ◯ Atelectasis
- ◯ Atrial fibrillation
- ◯ Atrial flutter
- ◯ Atrioventricular block complete
- ◯ Atrioventricular block first degree
- ◯ Azoospermia
- ◯ Back pain
- ◯ Bacteremia
- ◯ Belching
- ◯ Biliary fistula
- ◯ Bladder infection
- ◯ Bloating
- ◯ Blood and lymphatic system disorders - Other, specify
- ◯ Blood antidiuretic hormone abnormal
- ◯ Blood bicarbonate decreased
- ◯ Blood bilirubin increased
- ◯ Blood corticotrophin decreased
- ◯ Blood gonadotrophin abnormal
- ◯ Blood lactate dehydrogenase increased
- ◯ Blood prolactin abnormal
- ◯ Blurred vision
- ◯ Body odor
- ◯ Bone pain
- ◯ Breast atrophy

◯ Breast infection
◯ Breast pain
◯ Bronchial fistula
◯ Bronchial obstruction
◯ Bronchospasm
◯ Bruising
◯ Budd-Chiari syndrome
◯ Bullous dermatitis
◯ Burn
◯ Capillary leak syndrome
◯ Cardiac arrest
◯ Cardiac disorders - Other, specify
◯ Cardiac troponin I increased
◯ Cardiac troponin T increased
◯ Cataract
◯ Catheter related infection
◯ CD4 lymphocytes decreased
◯ Cerebrospinal fluid leakage
◯ Cervicitis infection
◯ Cheilitis
◯ Chest pain - cardiac
◯ Chest wall pain
◯ Chills
◯ Cholecystitis
◯ Cholesterol high
◯ Chylous ascites
◯ Cognitive disturbance
◯ Colitis
◯ Colonic fistula
◯ Colonic hemorrhage
◯ Colonic obstruction
◯ Colonic perforation
◯ Colonic stenosis
◯ Colonic ulcer
◯ Concentration impairment
◯ Conduction disorder
◯ Confusion
◯ Congenital, familial and genetic disorders - Other, specify
◯ Conjunctivitis
◯ Conjunctivitis infective
◯ Constipation
◯ Cough
◯ CPK increased
◯ Creatinine increased
◯ Cushingoid
◯ Cyanosis
◯ Death neonatal
◯ Death NOS
◯ Dehydration
◯ Delayed puberty
◯ Delirium
◯ Delusions
◯ Dental caries
◯ Depressed level of consciousness
◯ Depression
◯ Diarrhea
◯ Disseminated intravascular coagulation
◯ Dizziness
◯ Dry eye
◯ Dry mouth
◯ Dry skin
◯ Duodenal fistula
◯ Duodenal obstruction
◯ Duodenal perforation
◯ Duodenal ulcer
◯ Dysarthria
◯ Dysgeusia
◯ Dysmenorrhea
◯ Dyspareunia
◯ Dyspepsia

◯ Dysphagia
◯ Dysphasia
◯ Dyspnea
◯ Dysuria
◯ Ear and labyrinth disorders - Other, specify
◯ Ear pain
◯ Eczema
◯ Edema cerebral
◯ Edema face
◯ Ejaculation disorder
◯ Electrocardiogram QT corrected interval prolonged
◯ Encephalitis infection
◯ Encephalomyelitis infection
◯ Encephalopathy
◯ Endocarditis infective
◯ Endocrine disorders - Other, specify
◯ Endophthalmitis
◯ Enterocolitis
◯ Eosinophilia
◯ Epistaxis
◯ Epstein-Barr virus infection reactivation
◯ Erythema multiforme
◯ Erythroderma
◯ Esophageal hemorrhage
◯ Esophageal obstruction
◯ Esophageal pain
◯ Esophageal stenosis
◯ Esophageal ulcer
◯ Esophageal varices hemorrhage
◯ Esophagitis
◯ Euphoria
◯ Exostosis
◯ Extraocular muscle paresis
◯ Extrapyramidal disorder
◯ Eye disorders - Other, specify
◯ Eye infection
◯ Eye pain
◯ Facial pain
◯ Fall
◯ Fat atrophy
◯ Fatigue
◯ Febrile neutropenia
◯ Fecal incontinence
◯ Fever
◯ Fibrinogen decreased
◯ Flank pain
◯ Flashing lights
◯ Flatulence
◯ Floaters
◯ Flu like symptoms
◯ Flushing
◯ Folliculitis
◯ Forced expiratory volume decreased
◯ Fracture
◯ Fungemia
◯ Gait disturbance
◯ Gallbladder fistula
◯ Gallbladder obstruction
◯ Gallbladder pain
◯ Gallbladder perforation
◯ Gastric hemorrhage
◯ Gastric perforation
◯ Gastric ulcer
◯ Gastritis
◯ Gastrointestinal fistula
◯ Gastrointestinal disorders - Other, specify
◯ Gastrointestinal pain
◯ Gastroparesis
◯ General disorders and administration site conditions - Other, specify
◯ Generalized edema

◯ Genital edema
◯ Gingival pain
◯ Glaucoma
◯ Growth accelerated
◯ Growth hormone abnormal
◯ Growth suppression
◯ Guillain-Barre syndrome
◯ Gum infection
◯ Gynecomastia
◯ Hair texture abnormal
◯ Hallucinations
◯ Haptoglobin decreased
◯ Headache
◯ Hearing impaired
◯ Heart failure
◯ Hematoma
◯ Hematuria
◯ Hemoglobinuria
◯ Hemolysis
◯ Hemolytic uremic syndrome
◯ Hemorrhoids
◯ Hepatic failure
◯ Hepatic hemorrhage
◯ Hepatic necrosis
◯ Hepatic pain
◯ Hepatitis viral
◯ Hepatobiliary disorders - Other, specify
◯ Hiccups
◯ Hip fracture
◯ Hirsutism
◯ Hoarseness
◯ Hot flashes
◯ Hydrocephalus
◯ Hypercalcemia
◯ Hyperglycemia
◯ Hyperhidrosis
◯ Hyperkalemia
◯ Hyperkeratosis
◯ Hyperlipidemia
◯ Hypermagnesemia
◯ Hypernatremia
◯ Hyperparathyroidism
◯ Hyperphosphatemia
◯ Hypersomnia
◯ Hypertension
◯ Hyperthyroidism
◯ Hypertrichosis
◯ Hypertriglyceridemia
◯ Hyperuricemia
◯ Hypoalbuminemia
◯ Hypocalcemia
◯ Hypoglycemia
◯ Hypohidrosis
◯ Hypokalemia
◯ Hypomagnesemia
◯ Hyponatremia
◯ Hypoparathyroidism
◯ Hypophosphatemia
◯ Hypopituitarism
◯ Hypotension
◯ Hypothermia
◯ Hypothyroidism
◯ Hypoxia
◯ Ileal perforation
◯ Ileal stenosis
◯ Ileal ulcer
◯ Ileus
◯ Immune system disorders - Other, specify
◯ Infections and infestations - Other, specify
◯ Infective myositis
◯ Injection site reaction

◯ Injury, poisoning and procedural complications - Other, specify
◯ Injury to carotid artery
◯ Injury to inferior vena cava
◯ Injury to superior vena cava
◯ INR increased
◯ Insomnia
◯ Intracranial hemorrhage
◯ Investigations - Other, specify
◯ Irregular menstruation
◯ Irritability
◯ Ischemia cerebrovascular
◯ Jejunal perforation
◯ Jejunal stenosis
◯ Jejunal ulcer
◯ Joint effusion
◯ Joint infection
◯ Keratitis
◯ Kidney infection
◯ Kyphosis
◯ Laryngeal edema
◯ Laryngeal stenosis
◯ Laryngitis
◯ Laryngospasm
◯ Lethargy
◯ Leukocytosis
◯ Leukoencephalopathy
◯ Libido decreased
◯ Libido increased
◯ Lip pain
◯ Lipase increased
◯ Lordosis
◯ Lymph node pain
◯ Lymphedema
◯ Lymphocyte count decreased
◯ Lymphocyte count increased
◯ Malabsorption
◯ Malaise
◯ Mania
◯ Memory impairment
◯ Meningismus
◯ Meningitis
◯ Menorrhagia
◯ Metabolism and nutrition disorders - Other, specify
◯ Methemoglobinemia
◯ Mobitz (type) II atrioventricular block
◯ Mobitz type I
◯ Movements involuntary
◯ Mucositis oral
◯ Multi-organ failure
◯ Muscle cramp
◯ Musculoskeletal and connective tissue disorder - Other, specify
◯ Myalgia
◯ Myasthenia gravis
◯ Myelitis
◯ Myelodysplastic syndrome
◯ Myocardial infarction
◯ Myocarditis
◯ Myositis
◯ Nail changes
◯ Nail discoloration
◯ Nasal congestion
◯ Nausea
◯ Neck pain
◯ Neoplasms benign, malignant and unspecified (incl cysts and polyps) - Other, specify
◯ Nephrotic syndrome
◯ Nervous system disorders - Other, specify
◯ Neuralgia
◯ Neutrophil count decreased

◯ Night blindness
◯ Nystagmus
◯ Obesity
◯ Obstruction gastric
◯ Oligospermia
◯ Oral hemorrhage
◯ Oral pain
◯ Osteonecrosis
◯ Osteoporosis
◯ Otitis externa
◯ Otitis media
◯ Ovarian rupture
◯ Ovulation pain
◯ Pain
◯ Pain in extremity
◯ Pain of skin
◯ Palpitations
◯ Pancreatic hemorrhage
◯ Pancreatitis
◯ Papilledema
◯ Paresthesia
◯ Paronychia
◯ Paroxysmal atrial tachycardia
◯ Pelvic pain
◯ Penile pain
◯ Perforation bile duct
◯ Pericardial effusion
◯ Pericarditis
◯ Periodontal disease
◯ Peripheral ischemia
◯ Peripheral motor neuropathy
◯ Peripheral sensory neuropathy
◯ Personality change
◯ Pharyngeal fistula
◯ Pharyngitis
◯ Pharyngolaryngeal pain
◯ Phlebitis
◯ Photophobia
◯ Photosensitivity
◯ Platelet count decreased
◯ Pleural effusion
◯ Pleuritic pain
◯ Pneumonitis
◯ Pneumothorax
◯ Portal hypertension
◯ Portal vein thrombosis
◯ Postnasal drip
◯ Pregnancy, puerperium and perinatal conditions - Other, specify
◯ Premature delivery
◯ Premature menopause
◯ Presyncope
◯ Proctitis
◯ Productive cough
◯ Prostatic pain
◯ Proteinuria
◯ Pruritus
◯ Psychiatric disorders - Other, specify
◯ Psychosis
◯ Pulmonary edema
◯ Pulmonary fibrosis
◯ Pulmonary hypertension
◯ Purpura
◯ Radiation recall reaction (dermatologic)
◯ Rash acneiform
◯ Rash maculo-papular
◯ Rash pustular
◯ Rectal fistula
◯ Rectal hemorrhage
◯ Rectal pain
◯ Rectal perforation

◯ Rectal stenosis
◯ Rectal ulcer
◯ Recurrent laryngeal nerve palsy
◯ Renal and urinary disorders - Other, specify
◯ Renal calculi
◯ Renal colic
◯ Renal hemorrhage
◯ Reproductive system and breast disorders - Other, specify
◯ Respiratory failure
◯ Respiratory, thoracic and mediastinal disorders - Other, specify
◯ Restlessness
◯ Restrictive cardiomyopathy
◯ Retinal detachment
◯ Retinal tear
◯ Retinal vascular disorder
◯ Retinoic acid syndrome
◯ Retinopathy
◯ Retroperitoneal hemorrhage
◯ Rhabdomyolysis
◯ Rhinorrhea
◯ Rotator cuff injury
◯ Salivary gland fistula
◯ Salivary gland infection
◯ Scoliosis
◯ Scrotal pain
◯ Seizure
◯ Sepsis
◯ Seroma
◯ Serum amylase increased
◯ Serum sickness
◯ Shingles
◯ Sick sinus syndrome
◯ Sinus bradycardia
◯ Sinus pain
◯ Sinus tachycardia
◯ Sinusitis
◯ Skin and subcutaneous tissue disorders - Other, specify
◯ Skin atrophy
◯ Skin hyperpigmentation
◯ Skin hypopigmentation
◯ Skin infection
◯ Skin papilloma
◯ Skin ulceration
◯ Sleep apnea
◯ Small intestinal obstruction
◯ Small intestinal perforation
◯ Small intestine ulcer
◯ Sneezing
◯ Social circumstances - Other, specify
◯ Somnolence
◯ Sore throat
◯ Spasticity
◯ Spinal cord compression
◯ Spinal fracture
◯ Stevens-Johnson syndrome
◯ Stomach pain
◯ Stomal ulcer
◯ Stridor
◯ Stroke
◯ Subcutaneous emphysema
◯ Sudden death NOS
◯ Suicidal ideation
◯ Suicide attempt
◯ Superficial thrombophlebitis
◯ Superior vena cava syndrome
◯ Supraventricular tachycardia
◯ Surgical and medical procedures - Other, specify
◯ Syncope

◯ Telangiectasia
◯ Tendon reflex decreased
◯ Testicular disorder
◯ Testicular pain
◯ Thromboembolic event
◯ Thrombotic thrombocytopenic purpura
◯ Thrush
◯ Thyroid stimulating hormone increased
◯ Tinnitus
◯ Tooth development disorder
◯ Tooth discoloration
◯ Toothache
◯ Toxic epidermal necrolysis
◯ Tracheal obstruction
◯ Tracheitis
◯ Transient ischemic attacks
◯ Tremor
◯ Trismus
◯ Tumor lysis syndrome
◯ Tumor pain
◯ Typhlitis
◯ Upper respiratory infection
◯ Urinary frequency
◯ Urinary incontinence
◯ Urinary retention
◯ Urinary tract infection
◯ Urinary urgency
◯ Urine discoloration
◯ Urticaria
◯ Uterine hemorrhage
◯ Uterine pain
◯ Uterine perforation
◯ Uveitis
◯ Vaccination complication
◯ Vaginal discharge
◯ Vaginal dryness
◯ Vaginal hemorrhage
◯ Vaginal infection
◯ Vaginal inflammation
◯ Vaginal pain
◯ Vascular disorders - Other, specify
◯ Vasculitis
◯ Vasovagal reaction
◯ Venous injury
◯ Ventricular arrhythmia
◯ Ventricular fibrillation
◯ Ventricular tachycardia
◯ Vertigo
◯ Vestibular disorder
◯ Virilization
◯ Vision decreased
◯ Vital capacity abnormal
◯ Vitreous hemorrhage
◯ Voice alteration
◯ Vomiting
◯ Watering eyes
◯ Weight gain
◯ Weight loss
◯ Wheezing
◯ Wound dehiscence
◯ Wound infection
◯ Wrist fracture
◯ Leukemia secondary to oncology chemotherapy
◯ Corneal ulcer
◯ Bone marrow hypocellular
◯ Lymphocele
◯ Buttock pain
◯ Joint range of motion decreased
◯ Tooth infection
◯ Chest wall necrosis
◯ Bladder spasm

◯ Scalp pain
◯ White blood cell decreased
◯ Pancreatic fistula
◯ Nail loss
◯ Intestinal stoma site bleeding
◯ Treatment related secondary malignancy
◯ Pharyngeal stenosis
◯ Edema limbs
◯ Duodenal stenosis
◯ Electrocardiogram T wave abnormal
◯ Pancreatic anastomotic leak
◯ Biliary anastomotic leak
◯ Ejection fraction decreased
◯ Prostate infection
◯ Tracheal stenosis
◯ Lymph gland infection
◯ Chylothorax
◯ Facial muscle weakness
◯ Bile duct stenosis
◯ Periorbital infection
◯ Pancreas infection
◯ Lower gastrointestinal hemorrhage
◯ Infusion related reaction
◯ Skin induration
◯ Gastric necrosis
◯ Cytokine release syndrome
◯ Urethral infection
◯ Glucose intolerance
◯ Bronchopleural fistula
◯ Vaginal stricture
◯ Pericardial tamponade
◯ Oculomotor nerve disorder
◯ Abducens nerve disorder
◯ Wound complication
◯ Feminization acquired
◯ Neck edema
◯ Oral dysesthesia
◯ Palmar-plantar erythrodysesthesia syndrome
◯ Periorbital edema
◯ Viremia
◯ Visceral arterial ischemia
◯ Fetal growth retardation
◯ Ovarian infection
◯ Prostatic obstruction
◯ Bronchial infection
◯ Anal hemorrhage
◯ Duodenal hemorrhage
◯ Ileal hemorrhage
◯ Intra-abdominal hemorrhage
◯ Intraoperative hemorrhage
◯ Jejunal hemorrhage
◯ Pharyngeal hemorrhage
◯ Pleural hemorrhage
◯ Postoperative hemorrhage
◯ Prostatic hemorrhage
◯ Testicular hemorrhage
◯ Tumor hemorrhage
◯ Upper gastrointestinal hemorrhage
◯ Esophageal perforation
◯ Hair color changes
◯ Hemoglobin increased
◯ Phantom pain
◯ Mediastinal hemorrhage
◯ Olfactory nerve disorder
◯ Abdominal infection
◯ Hepatic infection
◯ Phlebitis infective
◯ Salivary duct inflammation
◯ Postoperative thoracic procedure complication
◯ GGT increased
◯ Delayed orgasm

◯ Peritoneal infection
◯ Mediastinal infection
◯ Precocious puberty
◯ Pancreatic necrosis
◯ Right ventricular dysfunction
◯ Cytomegalovirus infection reactivation
◯ Pelvic infection
◯ Edema trunk
◯ Esophageal infection
◯ Hepatitis B reactivation
◯ Enterocolitis infectious
◯ Intestinal stoma obstruction
◯ Intestinal stoma leak
◯ Gallbladder necrosis
◯ Laryngeal obstruction
◯ Rhinitis infective
◯ Urine output decreased
◯ Hematosalpinx
◯ Hemorrhoidal hemorrhage
◯ Trigeminal nerve disorder
◯ Accessory nerve disorder
◯ Bone infection
◯ Dermatitis radiation
◯ Eyelid function disorder
◯ Glossopharyngeal nerve disorder
◯ Hypoglossal nerve disorder
◯ Lung infection
◯ Lactation disorder
◯ Nail infection
◯ Optic nerve disorder
◯ Perineal pain
◯ Pleural infection
◯ Tricuspid valve disease
◯ Vagus nerve disorder
◯ Facial nerve disorder
◯ Erectile dysfunction
◯ Scleral disorder
◯ Mitral valve disease
◯ Pulmonary valve disease
◯ Urinary tract obstruction
◯ Aortic valve disease
◯ Anorectal infection
◯ Autoimmune disorder
◯ Biliary tract infection
◯ Corneal infection
◯ Disease progression
◯ Penile infection
◯ Radiculitis
◯ Gastric stenosis
◯ Splenic infection
◯ Scrotal infection
◯ Vascular access complication
◯ Urinary tract pain
◯ Uterine infection
◯ Sinus disorder
◯ Soft tissue infection
◯ Small intestinal stenosis
◯ Nail ridging
◯ Lipohypertrophy
◯ Localized edema
◯ Non-cardiac chest pain
◯ Tracheal hemorrhage
◯ Enterovesical fistula
◯ Generalized muscle weakness
◯ Gallbladder infection
◯ Pancreatic enzymes decreased
◯ Laryngopharyngeal dysesthesia
◯ Hypophysitis
◯ Dysesthesia
◯ Cystitis noninfective
◯ Rectal mucositis

◯ Bronchial stricture
◯ Bladder perforation
◯ Pyramidal tract syndrome
◯ Sinusoidal obstruction syndrome
◯ Reversible posterior leukoencephalopathy syndrome
◯ Pelvic floor muscle weakness
◯ Stoma site infection
◯ Osteonecrosis of jaw
◯ Device related infection
◯ Infusion site extravasation
◯ Chronic kidney disease
◯ Rectal fissure
◯ Urinary fistula
◯ Brachial plexopathy
◯ Pancreatic duct stenosis
◯ Peritoneal necrosis
◯ Pharyngeal anastomotic leak
◯ Pharyngeal necrosis
◯ Rectal obstruction
◯ Rectal necrosis
◯ Small intestinal mucositis
◯ Gastrointestinal stoma necrosis
◯ Gastric fistula
◯ Jejunal fistula
◯ Oral cavity fistula
◯ Anal mucositis
◯ Anal necrosis
◯ Esophageal necrosis
◯ Ileal fistula
◯ Ileal obstruction
◯ Jejunal obstruction
◯ Laryngeal inflammation
◯ Unequal limb length
◯ Arteritis infective
◯ Prolapse of intestinal stoma
◯ Bronchopulmonary hemorrhage
◯ Cecal hemorrhage
◯ Urostomy site bleeding
◯ Tracheostomy site bleeding
◯ Duodenal infection
◯ Lip infection
◯ Laryngeal hemorrhage
◯ Cecal infection
◯ Spermatic cord hemorrhage
◯ Ovarian hemorrhage
◯ Mucosal infection
◯ Cranial nerve infection
◯ Peripheral nerve infection
◯ Small intestine infection
◯ Vulval infection
◯ Lymph leakage
◯ Abdominal soft tissue necrosis
◯ Muscle weakness lower limb
◯ Soft tissue necrosis lower limb
◯ Soft tissue necrosis upper limb
◯ Head soft tissue necrosis
◯ Muscle weakness left-sided
◯ Neck soft tissue necrosis
◯ Musculoskeletal deformity
◯ Central nervous system necrosis
◯ External ear pain
◯ Laryngeal fistula
◯ Tracheal fistula
◯ Fallopian tube anastomotic leak
◯ Fallopian tube obstruction
◯ Fallopian tube perforation
◯ Pelvic soft tissue necrosis
◯ Muscle weakness right-sided
◯ Muscle weakness trunk
◯ Joint range of motion decreased cervical spine
◯ Superficial soft tissue fibrosis

◯ Fibrosis deep connective tissue
◯ Joint range of motion decreased lumbar spine
◯ Bladder anastomotic leak
◯ Kidney anastomotic leak
◯ Spermatic cord obstruction
◯ Uterine fistula
◯ Vaginal fistula
◯ Ureteric anastomotic leak
◯ Urethral anastomotic leak
◯ Vaginal obstruction
◯ Vaginal perforation
◯ Prolapse of urostomy
◯ Nipple deformity
◯ Intraoperative gastrointestinal injury
◯ Intraoperative arterial injury
◯ Intraoperative hepatobiliary injury
◯ Intraoperative urinary injury
◯ Intraoperative musculoskeletal injury
◯ Intraoperative neurological injury
◯ Intraoperative breast injury
◯ Intraoperative respiratory injury
◯ Intraoperative endocrine injury
◯ Middle ear inflammation
◯ Intraoperative reproductive tract injury
◯ Intraoperative ocular injury
◯ Intraoperative head and neck injury
◯ Intraoperative cardiac injury
◯ Intraoperative ear injury
◯ Intraoperative renal injury
◯ Intraoperative splenic injury
◯ Intraoperative venous injury
◯ Injury to jugular vein
◯ Esophageal fistula
◯ Pulmonary fistula
◯ Gastrointestinal anastomotic leak
◯ Laryngeal mucositis
◯ Pharyngeal mucositis
◯ Urostomy leak
◯ Urostomy obstruction
◯ Urostomy stenosis
◯ Uterine anastomotic leak
◯ Vaginal anastomotic leak
◯ Vas deferens anastomotic leak
◯ Large intestinal anastomotic leak
◯ Small intestinal anastomotic leak
◯ Gastric anastomotic leak
◯ Rectal anastomotic leak
◯ Muscle weakness upper limb
◯ Spermatic cord anastomotic leak
◯ Stenosis of gastrointestinal stoma
◯ Tracheal mucositis
◯ Carbon monoxide diffusing capacity decreased
◯ Uterine obstruction
◯ Esophageal anastomotic leak
◯ Iron overload
◯ Avascular necrosis
◯ Gastroesophageal reflux disease
◯ Testosterone deficiency
◯ Oropharyngeal pain
◯ Glucosuria
◯ Papulopustular rash
◯ Acute kidney injury
◯ Vaccination site lymphadenopathy
◯ Left ventricular systolic dysfunction
◯ Pregnancy loss
◯ Arterial thromboembolism
◯ Trochlear nerve disorder
◯ Herpes simplex reactivation
◯ Other

... If other, please enter your adverse event term

_____

.... If other, please choose a MedDRA System Organ Class (SOC)

- ◯ Hematopoietic and Lymphoid System Disorder
- ◯ Cardiac disorders
- ◯ Congenital, Familial and Genetic Disorder Class
- ◯ Ear and Labyrinth Disorder Class
- ◯ Endocrine Disorder
- ◯ Eye Disorder
- ◯ Gastrointestinal Disorder
- ◯ General Disorders and Administration Site Conditions Class
- ◯ Liver and Biliary Tract Disorder
- ◯ Immune System Disorder
- ◯ Infection and infestation
- ◯ Injury, Poisoning and Procedural Complication Class
- ◯ Investigation
- ◯ Metabolism and Nutrition Disorder Class
- ◯ Connective and Soft Tissue Disorder
- ◯ Neoplasm
- ◯ Nervous System Disorder
- ◯ Pregnancy, Puerperium and Perinatal Condition Class
- ◯ Psychiatric Disorder
- ◯ Urinary Tract Disorder
- ◯ Reproductive System and Breast Disorder Class
- ◯ Respiratory and Thoracic Disorder
- ◯ Skin Disorder
- ◯ Social Circumstances
- ◯ Intervention or Procedure
- ◯ Vascular Disorder

Severity

Mild: Events require minimal or no treatment and do not interfere with the participant's daily activities.

Moderate: Events result in a low level of inconvenience or concern with the therapeutic measures. Moderate events may cause some interference with functioning.

Severe: Events interrupt a participant's usual daily activity and may require systemic drug therapy or other treatment. Severe events are usually potentially life-threatening or incapacitating. Of note, the term "severe" does not necessarily equate to "serious."

- ◯ Mild
- ◯ Moderate
- ◯ Severe

Is this a Serious Adverse Event (SAE)

1) Death
2) Life-threatening event
3) Inpatient hospitalization > 7 days / Prolongation of existing hospitalization
4) Persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions
5) Congental anomoly/birth defect

◯ No ◯ Yes

When severity is severe, it should be a serious adverse event.

If serious, select reason:	◯ Death ◯ Life-threatening event ◯ Inpatient hospitalization > 7 days / Prolongation of existing hospitalization ◯ Persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions ◯ Congental anomoly/birth defect
Relationship to study treatment	◯ Not Related ◯ Unlikely to be Related ◯ Potentially Related ◯ Probably Related ◯ Definitely Related
AE action taken with study intervention	◯ None ◯ Study intervention interrupted ◯ Study intervention discontinued ◯ Study intervention modified
Other action taken	◯ None ◯ Moved to the expectant management group ◯ Non-study treatment required
.... If non-study treatment is selected, please specify	_____
Unanticipated or unexpected AE?	◯ No ◯ Yes
AE start date	_____
Date site became aware of the adverse event (if Unanticipated, Unexpected, or Severe only)	_____
AE stop date	_____
Outcomes attributed to the event	◯ Recovered/Resolved ◯ Recovered/Resolved with sequelae ◯ Recovering/resolving ◯ Not recovered/not resolved ◯ Fatal ◯ Unknown
... If not yet recovered, enter date of last patient status update:	_____
Who was involved? (e.g. Mother/Fetus/Neonate, study team members, family members, etc.)	_____
Specific location(s) where event took place (e.g. in the emergency room, the NICU, the participant's home, etc.)	_____

Describe the event, including the timing of any related study interventions, relevant tests, and/or history	_____
IRB notified?	◯ No ◯ Yes
Which IRB did you report to?	◯ JHMIRB ◯ Local IRB
Date reported to IRB	_____

Review and Source Documents

Upload source document(s) relating to this event	
CCC/DCC review date	_____
CCC/DCC review comments	_____

Medical Monitor Review

Relationship to study treatment	◯ Not Related ◯ Unlikely to be Related ◯ Potentially Related ◯ Probably Related ◯ Definitely Related
Comments	_____
Medical monitor name	_____
Signature	_____
Signature date	_____
Name	_____
Signature date	_____

Protocol Deviation

Protocol Deviations	
Date of this report	_____
Deviation date	_____
Is the event reported for mother or child?	◯ Mother ◯ Child
Deviation category Choose primary category. Choose "Other" only if the deviation cannot be classified as any of the given category choices.	◯ Required event or procedure not performed ◯ Required event or proceure performed outside of scheduled window ◯ Required event or procedure performed incorrectly/not according to protocol ◯ Deviation relates to subject eligibility ◯ Deviation relates to informed consent process ◯ Deviation relates to patient confidentiality or privacy ◯ Deviation relates to general study operations or procedures ◯ Other
.... If other, specify:	_____
This deviation is being reported because it could result in harm to the patient or has more than a 50% likelihood of harming future patients.	◯ No ◯ Yes
Did the deviation result in an Adverse Event? If yes, complete an AE/SAE form	◯ No ◯ Yes
Did the deviation lead to early withdrawal from the study or switch to control group? If yes, please complete the final status form.	◯ No change ◯ Early withdrawal ◯ Switch to control group
Brief deviation description:	_____
Reason for deviation Choose primary reason. Choose "Other" only if the deviation reason cannot be classified as any of the given choices.	◯ Subject/Parent/Legal Guardian unable to comply ◯ Subject/Parent/Legal Guardian illness ◯ Subject/Parent/Legal Guardian refusal ◯ Study team error ◯ Investigator/study decision ◯ To eliminate an apparent immediate hazard ◯ Other
.... If other, specify:	_____

Describe steps taken to resolve or avoid recurrence of the deviation

Source Documents and Review

Upload any source related to the deviation

DCC/CCC review date

DCC/CCC review comments

Other Uploads

Other Uploads	
Document Type	◯ Visit Notes ◯ Note to File ◯ Other
Descriptions	_____
Document Date	_____
Upload documents	
Comments	_____
Upload Date	_____

Patient Transfer

Patient Transfer

Instructions:

Site should notify the CC as soon as they know a patient is going to be transferred. The CC will alert Sarah to monitor the originating site data before the transfer.
The original site should enter all collected data, upload echo tracing(s) and finalize the forms. All queries need to be answered. All source documents should be uploaded.
The original site PI completes and signs the first section of the Patient Transfer form in REDCap under the "Repeating Events" section.
The record will be moved from the original site to the new site by DCC. The original site will NOT have access to the patient data after the move. The patient will keep the original screening ID and subject ID.
After the transfer, the new site should complete and sign the Patient Transfer form as soon as possible. The new site is responsible for completing the rest of the CRFs.

Transfer Date

_____

Signature from the Original Site

Transfer From

- ◯ 000 - Johns Hopkins University
- ◯ 067 - Stanford University
- ◯ 096 - University of Southern California
- ◯ 282 - Children's Hospital of Philadelphia
- ◯ 283 - Mayo Clinic
- ◯ 284 - University of California San Francisco
- ◯ 285 - Columbia University
- ◯ 286 - University of Colorado

PI's signature from the original site

Investigator must login from his/her own REDCap account and sign here.

_____

Signature from the New Site

Transfer To

- ◯ 000 - Johns Hopkins University
- ◯ 067 - Stanford University
- ◯ 096 - University of Southern California
- ◯ 282 - Children's Hospital of Philadelphia
- ◯ 283 - Mayo Clinic
- ◯ 284 - University of California San Francisco
- ◯ 285 - Columbia University
- ◯ 286 - University of Colorado

PI's signature from the new site

Investigator must login from his/her own REDCap account and sign here.

_____

Consent at the New Site

Is consent obtained at the new site?	◯ Yes ◯ No
If no, explain	_____
New Consent Date	_____
Upload signed consent	

Additional Comments

Comments	_____