

Cross-Network Pregnancy Data Standards Version 1.0

Variable Status	Field OID Standard (SCHARP convention)	Field OID (FSTRF convention)	PreText / Item Text (Field Label)	FS SDTM Annotation / SDTM variables	DataDictionaryName / Data Dictionary	ControlType / Response Type	FS Data Dictionary / Response Options (Dictionary Items)	Recommended Use
Pregnancy Test								
Consensus	LBPERF	LBPERF	Was a pregnancy test performed?		YesNo	DropDownList	Y N	
FSTRF-only	LBREASND_ALL	LBREASND_ALL	If No, specify reason not done [200]:	LBREASND		LongText		
SCHARP-only	LBREASND	LBREASND	If No, specify reason not done:			DropDownList	1=Not of reproductive potential; 2=Participant is pregnant; 3=Other	
SCHARP-only	LBREASND_OSP	LBREASND_OSP	If Other, specify [70]:			LongText		
Consensus	HCG_LBORRES	LBORRESPREG	Test result:	LBORRES	LBORRESPREG	DropDownList	NEGATIVE POSITIVE	
Consensus	HCG_LBDAT	LBDAT	Specimen date:	LBDC		DateTime		
Consensus	HCG_LBSPEC	LBSPEC	Specimen type:	LBSPEC	LBSPEC	DropDownList	SERUM URINE	
Consensus	HCG_LBTIM	LBTIM_HCG	Collection time			DateTime		Optional
Pregnancy Outcome								
Consensus	INFUSUBJID	INFUSUBJID	Infant PID number:	FASPID		Text		
Consensus	APDM_APID_NA	APDM_APID_NA	Indicate which fetus/infant this is being completed for:	FASPID	INFANT A/B/C/Not applicable	DropDownList		
Consensus	FETUSN_FAORRES	PREGOUT_MULTI	Number of fetuses/infants: NOTE: If molar pregnancy or false positive, select '0'.	FAORRES when FATESTCD = FETUSN	Numbers (0-3)	DropDownList		
Consensus	CETERM_PREGOUT	FAORRES_PREGOUT	Indicate outcome:	CETERM	PREGOUT	DropDownList	Full term live birth (greater than or equal to 37 weeks) Premature live birth (less than 37 weeks) Stillbirth/Intrauterine fetal demise Spontaneous abortion Induced abortion Ectopic pregnancy Molar pregnancy False positive/No pregnancy Other	
Consensus	POOUTYN	POOUTYN	Is the outcome of this pregnancy obtainable? If "No", end of form and specify in comments.		YesNo	RadioButton	Y N	Available for non-perinatal studies. If pregnancy is a primary or secondary outcome, this question should not be used.
Consensus	CEENDAT	CEENDAT	Provide date of outcome:	CEENDTC		DateTime		
Consensus	PO_COVAL	COVAL_PREGOUT	Provide a brief narrative of circumstances:	COVAL		LongText		
Consensus	CONAB_IDENTYN	CONGENITAL_IDENTYN	At the time of the pregnancy outcome, were any congenital anomalies identified?		YesNoUnknown	DropDownList	Y N U	
Consensus	PO_AENO	PO_AENO	If "Yes", select adverse event and update Adverse Event log and complete EAE Reporting form, if applicable.			Dynamic SearchList		Available for non-perinatal studies.
Pregnancy Record								
Consensus	CESTDAT	CESTDTC	What is the estimated date of conception?	CESTDTC when CETERM = Pregnancy		DateTime		
Consensus	DETR_FAORRES	FAORRES_DETR	How was the estimated date of conception determined?	FAORRES when FATESTCD = DETR (FAOBJ = Estimated Date of Conception)	Conception	DropDownList	Last menstrual period Initial ultrasound Physical examination Assisted reproduction Other	
Consensus	DETROSP_FAORRES	FAORRES_DETROTH	If Other, specify [70]:	FAORRES when FATESTCD = DETR		LongText		
Pregnancy History								
Consensus	INSTRUCTIONS01	INSTRUCTIONS01	INSTRUCTIONS: Complete a log line for each prior pregnancy.			Text		

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Consensus	OUTCOMEDATKNO	OUTCOMEDATKNO	Is the outcome date known?		YesNo	RadioButton	Y N	
Consensus	PRIOR_CEENDAT	CEENDAT_PRIOR	Outcome date of prior pregnancy			DateTime		
Consensus	OUTCOME_CESTRPT	CESTRPT_OUTCOME	Estimate of when prior pregnancy outcome occurred		REFERENCEPERIOD	DropDownList	BEFORE AFTER UNKNOWN	
Consensus	OUTCOMEYR_CESTTPT	CESTTPT_OUTCOMEYR	Estimate year when prior pregnancy outcome occurred			DateTime		
Consensus	PRIOROUT_FAORRES	FAORRES_PRIOROUT	Indicate outcome of prior pregnancy		PREGOUT	DropDownList	Full term live birth (greater than or equal to 37 weeks) Premature live birth (less than 37 weeks) Stillbirth/Intrauterine fetal demise Spontaneous abortion Induced abortion Ectopic pregnancy Molar pregnancy False positive/No pregnancy Other	
Delivery Record								
Consensus	DELIVLOC_CESSETTING	FAORRES_DELIVLOC	Delivery location:	CESETTING in SUPPCE	DELIVLOC	DropDownList	Home Hospital Clinic En route Other	
Consensus	DELIVLOCOSP_CESSETTING	FAORRES_DELIVLOCOTH	If Other, specify [70]:	CESETTING in SUPPCE		LongText		
Consensus	DELIVTYP_CETERM	FAORRES_DELIVTYP	Type of delivery:	CETERM, PRTRT, PRUGENCY in SUPPPR	DELIVTYPE	DropDownList	Assisted vaginal Unassisted vaginal Unknown vaginal Elective cesarean Emergency cesarean Unknown cesarean	
Newborn Exam								
Consensus	EGESTAGEYN	GESTAGEYN	Is the infant's gestational age by infant exam available?	Not Submitted	YesNo	RadioButton	Y N	
Consensus	EGESTAGEWK_SCORRES	SCORRES_GESTAGEWK	Weeks [nn]:	SCORRES when SCTESTCD = EGESTAGE		Text		Optional: If used, SDTM needs to be converted to days.
Consensus	EGESTAGEDY_SCORRES	SCORRES_GESTAGEDY	Days [n]:	SCORRES when SCTESTCD = EGESTAGE		Text		
Consensus	EXAMTYP_SCMETHOD	SCORRES_EXAMTYP	What is the type of exam used to determine the infant's gestational age:	SCMETHOD when SCTESTCD = EGESTAGE	TypeofExam	DropDownList	Ballard Dubowitz Other Unknown	
Consensus	EXAMTYPOSP_SCMETHOD	SCORRES_EXAMTYPOSP	If Other, specify [70]:	SCMETHOD when SCTESTCD = EGESTAGE		LongText		
Consensus	WEIGHT_VSORRES	VSORRES_WEIGHT	Weight [nnnn.nn]:	VSORRES when VSTESTCD = WEIGHT		Text		
Consensus	WEIGHT_VSORRESU	VSORRESU_WEIGHT	Unit:	VSORRESU when VSTESTCD = WEIGHT	Weight	RadioButton (Vertical)	g kg LB	
Consensus	VSWEIGHTYN	FAIWGHTYN	Infant birth weight available?		YesNo	RadioButton	Y N	Available for non-perinatal studies.
Consensus	LENGTH_VSORRES	VSORRES_LENGTH	Length [nnn.nn]:	VSORRES when VSTESTCD = BODLNPTH		Text		
Consensus	LENGTH_VSORRESU	VSORRESU_LENGTH	Unit:	VSORRESU when VSTESTCD = BODLNPTH	Height	RadioButton (Vertical)	cm in	
Consensus	VSLNGTHYN	FAILGHTYN	Infant birth length available?		YesNo	RadioButton	Y N	Available for non-perinatal studies.
Consensus	HDCIRC_VSORRES	VSORRES_HDCIRC	Head Circumference [nn.n]:	VSORRES when VSTESTCD = HDCIRC		Text		

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Consensus	HDCIRC_VSORRESU	VSORRESU_HDCIRC	Unit:	VSORRESU when VSTESTCD = HDCIRC	Height	RadioButton (Vertical)	cm in	
Consensus	VSHDCIRCYN	FAIHCYN	Infant birth head circumference available?		YesNo	RadioButton	Y N	Available for non-perinatal studies.
Consensus	INFACTIV_PEORES	PERES_GENACT	General Activity:	PEORES when PETESTCD = INFACTIV	NewbornActivity	RadioButton (Vertical)	Normal Abnormal Unknown	Available for perinatal studies
Consensus	INFACTABN_PEORES	PERES_GENACT_ABN	If Abnormal, specify [70]:	PEORES when PETESTCD = INFACTIV		LongText		Available for perinatal studies
Consensus	NEWBRNEX_PEORES	PERES_PHYSEXAM	Physical Exam:	PEORES when PETESTCD = NEWBRNEX	NewbornActivity	RadioButton (Vertical)	Normal Abnormal Unknown	Available for perinatal studies
Consensus	NEWBRNEXABN_PEORES	PERES_PHYSEXAM_ABN	If Abnormal, specify [70]:	PEORES when PETESTCD = NEWBRNEX		LongText		Available for perinatal studies
Consensus	APGAVAILYN	APGAVAILYN	Are any of the infant's Apgar scores available?	Not Submitted	YesNo	RadioButton	Y N	Available for perinatal studies
Consensus	APGAR1YN	APGAR1YN	At 1 minute?	Not Submitted	YesNo	RadioButton	Y N	Available for perinatal studies
Consensus	APGAR1_RSORRES	RSORRES_APGAR1	Score at 1 minute [nn]:	RSORRES when RSTESTCD = APGAR and RSTPT = 1 MINUTE		Text		Available for perinatal studies
Consensus	APGAR5YN	APGAR5YN	At 5 minutes?	Not Submitted	YesNo	RadioButton	Y N	Available for perinatal studies
Consensus	APGAR5_RSORRES	RSORRES_APGAR5	Score at 5 minutes [nn]:	RSORRES when RSTESTCD = APGAR and RSTPT = 5 MINUTE		Text		Available for perinatal studies
Consensus	APGAR10YN	APGAR10YN	At 10 minutes?	Not Submitted	YesNo	RadioButton	Y N	Available for perinatal studies
Consensus	APGAR10_RSORRES	RSORRES_APGAR10	Score at 10 minutes [nn]:	RSORRES when RSTESTCD = APGAR and RSTPT = 10 MINUTE		Text		Available for perinatal studies
Consensus	GESTATAVAILYN	GESTATAVAILYN	Is the classification of the newborn by intrauterine growth and gestational age available?	Not Submitted	YesNo	RadioButton	Y N	Available for perinatal studies
Consensus	GSTCLASS_SCORRES	QSORRES_GSTCLASS	Indicate the classification:	SCORRES when SCTESTCD = GSTCLASS	GESTAGECLASS	DropDownList	Large for Gestational Age > 90% Appropriate for Gestational Age Small for Gestational Age < 10% Intrauterine Growth Retardation <3%	Available for perinatal studies
Consensus	VSPERF_ALL	VSPERF_ALL	Were vital signs/measurements collected at birth?	Not Submitted	YesNo	RadioButton	Y N	Available for perinatal studies
Consensus	TEMP_VSORRES	VSORRES_TEMP	Temperature [nnn.n]:	VSORRES when VSTESTCD = TEMP		Text		Available for perinatal studies
Consensus	TEMP_VSORRESU	VSORRESU_TEMP	Unit:	VSORRESU when VSTESTCD = TEMP	Temperature	RadioButton (Vertical)	C F	Available for perinatal studies
Consensus	TEMP_VSMETHOD	VSMETHOD_TEMP	What method was used to obtain the temperature?	VSLOC when VSTESTCD = TEMP	VSLOCTEMP	DropDownList	ORAL CAVITY AXILLA INGUINAL REGION RECTUM FOREHEAD EAR	Available for perinatal studies
Consensus	PULSE_VSORRES	VSORRES_PULSE	Pulse Rate (beats/min) [nnn]:	VSORRES when VSTESTCD = PULSE		Text		Available for perinatal studies
Consensus	RESP_VSORRES	VSORRES_RESP	Respirations (breaths/min) [nnn]:	VSORRES when VSTESTCD = RESP		Text		Available for perinatal studies

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Consensus	BLOODPRESSYN	BLOODPRESSYN	Was blood pressure measurement obtained?	Not Submitted	YesNo	RadioButton	Y N	Available for perinatal studies
Consensus	SYSBP_VSORRES	VSORRES_SYSBP	Systolic Blood Pressure (mmHg) [nnn]:	VSORRES when VSTESTCD = SYSBP		Text		Available for perinatal studies
Consensus	DIABP_VSORRES	VSORRES_DIABP	Diastolic Blood Pressure (mmHg) [nnn]:	VSORRES when VSTESTCD = DIABP		Text		Available for perinatal studies
Consensus	PRINFANTLABORYN	PRINFANTLABORYN	Were any of the following procedures performed on the infant during labor and delivery? <input type="checkbox"/> If Yes, check all that apply: <input type="checkbox"/> 	Not Submitted	YesNoUnknown	RadioButton (Vertical)	Y N U	Available for perinatal studies
Consensus	SCALPBLOOD_PRTRT	PRTRT_SCALPBLOOD	Sampling of fetal scalp blood:	PROCCUR when PRTRT = SCALP BLOOD SAMPLING		CheckBox		Available for perinatal studies
Consensus	ELECTRODE_PRTRT	PRTRT_ELECTRODE	Scalp electrode:	PROCCUR when PRTRT = SCALP ELECTRODE		CheckBox		Available for perinatal studies
Consensus	OTH_PRTRT	PRTRT_OTHER	Other:	PROCCUR		CheckBox		Available for perinatal studies
Consensus	OSP_PRTRT	PRTRT_OTH	If Other, specify [70]:	PRTRT		LongText		Available for perinatal studies
Consensus	ILAEYN	AEYN_INFANTLABOR	Were any adverse events experienced by the infant at the time of delivery?	Not Submitted	YesNoUnknown	RadioButton (Vertical)	Y N U	Available for perinatal studies
Consensus	ILAEYN_CONABN	AEYN_INFANTLABOR_CONGEN	Were any congenital anomalies identified at the time of delivery?	Not Submitted	YesNoUnknown	RadioButton (Vertical)	Y N U	Available for perinatal studies

*Not included: FS Labor Record, Delivery Record, Birth Outcome

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Data Dictionary

DataDictionaryName	FS CodedData	FS UserDataString
CesareanIndication	Arrest disorder	Arrest disorder
CesareanIndication	Non-reassuring fetal heart rate (FHR)	Non-reassuring fetal heart rate (FHR)
CesareanIndication	Malpresentation	Malpresentation
CesareanIndication	Previous cesarean	Previous cesarean
CesareanIndication	Placenta previa	Placenta previa
CesareanIndication	Placenta abruptio	Placenta abruptio
CesareanIndication	Cephalo-pelvic disproportion (CPD)	Cephalo-pelvic disproportion (CPD)
CesareanIndication	Active or recent vaginal infection/inflammation including STI's	Active or recent vaginal infection/inflammation including STI's
CesareanIndication	Failed induction	Failed induction
CesareanIndication	Prolonged rupture of membranes (PROM)	Prolonged rupture of membranes (PROM)
CesareanIndication	Pre-eclampsia	Pre-eclampsia
CesareanIndication	Eclampsia	Eclampsia
CesareanIndication	Cord prolapse	Cord prolapse
CesareanIndication	Failure to descend	Failure to descend
CesareanIndication	Multiple gestation	Multiple gestation
CesareanIndication	Fetal anomaly	Fetal anomaly
CesareanIndication	Macrosomia	Macrosomia
CesareanIndication	Protraction and/or arrest of labor	Protraction and/or arrest of labor
CesareanIndication	Fetal distress	Fetal distress
CesareanIndication	Reduction of MTCT risk (e.g. detectable maternal HIV RNA)	Reduction of MTCT risk (e.g. detectable maternal HIV RNA)
CesareanIndication	Genital herpes simplex virus (HSV)	Genital herpes simplex virus (HSV)
CesareanIndication	Subject request/desire	Subject request/desire
CesareanIndication	Other maternal indication	Other maternal indication
CesareanIndication	Other infant indication	Other infant indication
Conception	Last menstrual period	Last menstrual period
Conception	Initial ultrasound	Initial ultrasound
Conception	Physical examination	Physical examination
Conception	Assisted reproduction	Assisted reproduction
Conception	Other	Other
DELIVLOC	Home	Home
DELIVLOC	Hospital	Hospital
DELIVLOC	Clinic	Clinic
DELIVLOC	En route	En route
DELIVLOC	Other	Other
DELIVTYPE	Assisted vaginal	Assisted vaginal
DELIVTYPE	Unassisted vaginal	Unassisted vaginal
DELIVTYPE	Unknown vaginal	Unknown vaginal
DELIVTYPE	Elective cesarean	Elective cesarean
DELIVTYPE	Emergency cesarean	Emergency cesarean
DELIVTYPE	Unknown cesarean	Unknown cesarean
GESTAGECLASS	Large for Gestational Age > 90%	Large for Gestational Age (LGA) > 90%

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GESTAGECLASS	Appropriate for Gestational Age	Appropriate for Gestational Age (AGA)
GESTAGECLASS	Small for Gestational Age < 10%	Small for Gestational Age (SGA) < 10%
GESTAGECLASS	Intrauterine Growth Retardation < 3%	Intrauterine Growth Retardation (IUGR) < 3%
GESTAGESRC	Infant exam	Infant exam
GESTAGESRC	Prenatal estimation	Prenatal estimation
GESTAGESRC	Unknown	Unknown
Height	cm	Centimeters (cm)
Height	in	Inches (in)
Induction Indication	Gestational hypertension (e.g. preeclampsia/ eclampsia/ HELLP)	Gestational hypertension (e.g., preeclampsia, eclampsia, HELLP)
Induction Indication	Worsening maternal chronic hypertension	Worsening maternal chronic hypertension
Induction Indication	Other maternal chronic disease (eg. diabetes mellitus/ renal disease/ chronic pulmonary disease)	Other maternal chronic disease (e.g. diabetes mellitus, renal disease, chronic pulmonary disease)
Induction Indication	Chorioamnionitis	Chorioamnionitis
Induction Indication	Post-term pregnancy	Post-term pregnancy
Induction Indication	Fetal growth restriction	Fetal growth restriction
Induction Indication	Oligohydramnios	Oligohydramnios
Induction Indication	Isoimmunization	Isoimmunization
Induction Indication	Abnormal fetal testing	Abnormal fetal testing
Induction Indication	Twin gestation	Twin gestation
Induction Indication	Placental abruption	Placental abruption
Induction Indication	Cholestasis of pregnancy	Cholestasis of pregnancy
Induction Indication	Fetal death	Fetal death
Induction Indication	Prolonged rupture of membranes (PROM)	Prolonged rupture of membranes (PROM)
Induction Indication	Other maternal reason	Other maternal reason
Induction Indication	Other fetal reason	Other fetal reason
Infant A/B/C	A	A
Infant A/B/C	B	B
Infant A/B/C	C	C
INFANT A/B/C/Not applicable	A	A
INFANT A/B/C/Not applicable	B	B
INFANT A/B/C/Not applicable	C	C
INFANT A/B/C/Not applicable	Not applicable	Not applicable
LaborTime	0-<4 hours	0-<4 hours
LaborTime	4-<6 hours	4-<6 hours
LaborTime	6-<12 hours	6-<12 hours
LaborTime	12-24 hours	12-24 hours
LaborTime	>24 hours	>24 hours
LaborTime	Unknown	Unknown
LBORRESPREG	NEGATIVE	Negative

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LBORRESPREG	POSITIVE	Positive
LBSPECPREG	SERUM	Serum
LBSPECPREG	URINE	Urine
MembraneRupture	Spontaneous	Spontaneous
MembraneRupture	Amniotomy	Amniotomy
MembraneRupture	Unknown	Unknown
NewbornActivity	Normal	Normal
NewbornActivity	Abnormal	Abnormal
NewbornActivity	Unknown	Unknown
Numbers (0-3)	0	0
Numbers (0-3)	1	1
Numbers (0-3)	2	2
Numbers (0-3)	3	3
Numbers (1-3)	1	1
Numbers (1-3)	2	2
Numbers (1-3)	3	3
Numbers (1-5)	1	1
Numbers (1-5)	2	2
Numbers (1-5)	3	3
Numbers (1-5)	4	4
Numbers (1-5)	5	5
PREGOUT	Full term live birth (greater than or equal to 37 weeks)	Full term live birth (greater than or equal to 37 weeks)
PREGOUT	Premature live birth (less than 37 weeks)	Premature live birth (less than 37 weeks)
PREGOUT	Stillbirth/Intrauterine fetal demise	Stillbirth/Intrauterine fetal demise (IUCD ≥ 20 weeks)
PREGOUT	Spontaneous abortion	Spontaneous abortion (< 20 weeks)
PREGOUT	Induced abortion	Induced abortion (therapeutic or elective)
PREGOUT	Ectopic pregnancy	Ectopic pregnancy
PREGOUT	Molar pregnancy	Molar pregnancy
PREGOUT	False positive/No pregnancy	False positive/No pregnancy
PREGOUT	Other	Other
Presentation	Vertex	Vertex
Presentation	Breech	Breech
Presentation	Transverse	Transverse
REFERENCEPERIOD	BEFORE	Before
REFERENCEPERIOD	AFTER	After
REFERENCEPERIOD	UNKNOWN	Unknown
SEXATBRTH	M	Male
SEXATBRTH	F	Female
SEXATBRTH	UNDIFFERENTIATED	Ambiguous genitalia/Intersex
SEXATBRTH	U	Unknown
Spontaneous/Induced	Spontaneous	Spontaneous
Spontaneous/Induced	Induced	Induced
Temperature	C	Celsius (C)
Temperature	F	Fahrenheit (F)
TypeofExam	Ballard	Ballard
TypeofExam	Dubowitz	Dubowitz

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TypeofExam	Other	Other
TypeofExam	Unknown	Unknown
VSLOCTEMP	ORAL CAVITY	Oral cavity
VSLOCTEMP	AXILLA	Axilla
VSLOCTEMP	INGUINAL REGION	Inguinal region
VSLOCTEMP	RECTUM	Rectum
VSLOCTEMP	FOREHEAD	Forehead
VSLOCTEMP	EAR	Ear
Weight	g	Grams (g)
Weight	kg	Kilograms (kg)
Weight	LB	Pounds (lb)
YesNo	Y	Yes
YesNo	N	No
YesNoUnknown	Y	Yes
YesNoUnknown	N	No
YesNoUnknown	U	Unknown