

Cross-Network Pregnancy Data Standards Version 1.0 Revision History

Variable Status	SDMC	Form Title / Form Name	FormOID / Form OID	Field OID Standard (SCHARP convention)	FieldOID / Field OID	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											
	FSTRF	LBW10005: Pregnancy Test	LBW10005		LPPERF	Was a pregnancy test performed?	LBSTAT	YesNo	DropDownList		
	HPTN LBPREG	Pregnancy Test Results	LBPREG		LBYN_HCG	Was a pregnancy test done?		LBYN	RadioButton	Y=Yes; N=No; NRP= Not of reproductive potential; PP=Participant is pregnant	
	HVTN LBPREG	Pregnancy Test Results	LBPREG		LBYN_HCG	Was a pregnancy test done?		LBYN	RadioButton	Y=Yes; N=No	
Consensus		Pregnancy Test		LPPERF	LPPERF	Was a pregnancy test performed?		YesNo	DropDownList	Y N	
	FSTRF	LBW10005: Pregnancy Test	LBW10005		LBREASND_ALL	If No, specify reason not done [200]:	LBREASND		LongText		
	HVTN LBPREG	Pregnancy Test Results	LBPREG			If no, why? Add details to Comments. (add CCG language)				1=Not of reproductive potential; 2=Participant is pregnant; 3=Other	
FSTRF-only		Pregnancy Test		LBREASND_ALL	LBREASND_ALL	If No, specify reason not done [200]:	LBREASND		LongText		
SCHARP-only		Pregnancy Test		LBREASND	LBREASND	If No, specify reason not done:			DropDownList	1=Not of reproductive potential; 2=Participant is pregnant; 3=Other	
SCHARP-only		Pregnancy Test		LBREASND_OSP	LBREASND_OSP	If Other, specify [70]:			LongText		
	FSTRF	LBW10005: Pregnancy Test	LBW10005		LBORRESPREG	Test result:	LBORRES	LBORRESPREG	DropDownList		
	HPTN LBPREG	Pregnancy Test Results	LBPREG		LBORRES_HCG	Pregnancy test result		POS/NEG	RadioButton	1=Positive; 2=Negative	
	HVTN LBPREG	Pregnancy Test Results	LBPREG		LBORRES_HCG	Pregnancy test result		POS/NEG	RadioButton	1=Positive; 2=Negative	
Consensus		Pregnancy Test		HCG_LBORRES	LBORRESPREG	Test result:	LBORRES	LBORRESPREG	DropDownList	NEGATIVE POSITIVE	
	FSTRF	LBW10005: Pregnancy Test	LBW10005		LBDAT	Specimen date:	LBDC		DateTime		
	HPTN LBPREG	Pregnancy Test Results	LBPREG		LBDAT_HCG	Collection date			DateTime		
	HVTN LBPREG	Pregnancy Test Results	LBPREG		LBDAT_HCG	Collection date			DateTime		
Consensus		Pregnancy Test		HCG_LBDAT	LBDAT	Specimen date:	LBDC		DateTime		
	FSTRF	LBW10005: Pregnancy Test	LBW10005		LBSPECPREG	Specimen type:	LBSPEC	LBSPECPREG	DropDownList		
Consensus		Pregnancy Test		HCG_LBSPEC	LBSPECPREG	Specimen type:	LBSPEC	LBSPECPREG	DropDownList	SERUM URINE	
	HPTN LBPREG	Pregnancy Test Results	LBPREG		LBTIM_HCG	Collection time			DateTime		
	HVTN LBPREG	Pregnancy Test Results	LBPREG		LBTIM_HCG	Collection time			DateTime		
Consensus		Pregnancy Test		HCG_LBTIM	LBTIM_HCG	Collection time			DateTime		Optional
Pregnancy Outcome											
	FSTRF	EVW10051: Pregnancy Outcome Log	EVW10051		INFUSUBJID	Infant PID number:	FASPID		Text		
Consensus		Pregnancy Outcome		INFUSUBJID	INFUSUBJID	Infant PID number:	FASPID		Text		
	FSTRF	EVW10051: Pregnancy Outcome Log	EVW10051		APDM_APID_NA	Indicate which fetus/infant this is being completed for:	FASPID	INFANT A/B/C/Not applicable	DropDownList		
Consensus		Pregnancy Outcome		APDM_APID_NA	APDM_APID_NA	Indicate which fetus/infant this is being completed for:	FASPID	INFANT A/B/C/Not applicable	DropDownList		
	FSTRF	EVW10001: Pregnancy Outcome Log	EVW10001		PREGOUT_MULTI	Number of fetuses/infants: □ </br> □ NOTE: If molar pregnancy or false positive, select '0'.		Numbers (0-3)	DropDownList		
	FSTRF	EVW10051: Pregnancy Outcome Log	EVW10051		PREGOUT_MULTI	Number of fetuses/infants: □ </br> □ NOTE: If molar pregnancy or false positive, select '0'.	FAORRES when FATESTCD = FETUSN	Numbers (0-3)	DropDownList		
	HPTN PO	Pregnancy Outcome Log	PO		PONUMPG	How many pregnancy outcomes resulted from this reported pregnancy?			Text		
	HVTN PO	Pregnancy Outcome Log	PO		PONUMPG	How many pregnancy outcomes resulted from this reported pregnancy?			Text		
Consensus		Pregnancy Outcome		FETUSN_FAORRES	PREGOUT_MULTI	Number of fetuses/infants: □ </br> □ NOTE: If molar pregnancy or false positive, select '0'.	FAORRES when FATESTCD = FETUSN	Numbers (0-3)	DropDownList		
	FSTRF	EVW10001: Pregnancy Outcome Log	EVW10001		FAORRES_PREGOUT	Indicate outcome:		PREGOUT	DropDownList		
	FSTRF	EVW10051: Pregnancy Outcome Log	EVW10051		FAORRES_PREGOUT	Indicate outcome:	CETERM	PREGOUT	DropDownList		
	HPTN PO	Pregnancy Outcome Log	PO		POOUTYN	Is the outcome of this pregnancy obtainable? If "No", end of form.		Yes/No	RadioButton	Y=Yes; N=No	

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	HPTN PO	Pregnancy Outcome Log	PO		POOUT	Specify outcome If "Stillbirth/intrauterine fetal demise", "Spontaneous abortion", "Ectopic pregnancy" or "Therapeutic/elective abortion" is chosen, go to "Provide a brief narrative of the circumstances.". If "Full term live birth", go to "Were there any complications related to the pregnancy outcome?".		POOUTCOME	DropDownList	1=Full term live birth (greater than or equal to 37 weeks); 2=Premature live birth (less than 37 weeks); 3=Stillbirth/intrauterine fetal demise (greater than or equal to 20 weeks); 4=Spontaneous abortion (less than 20 weeks); 5=Ectopic pregnancy; 6=Therapeutic/elective abortion; 99=Other	
	HPTN PO	Pregnancy Outcome Log	PO		POOUTOSP	If "Other", specify:			LongText		
	HVTN PO	Pregnancy Outcome Log	PO		POOUTYN	Is the outcome of this pregnancy obtainable? If "No", end of form and specify in comments.		Yes/No	RadioButton	Y=Yes; N=No	
	HVTN PO	Pregnancy Outcome Log	PO		POOUT	Specify outcome If "Full term live birth (greater than or equal to 37 weeks)" or "Premature live birth (less than 37 weeks)" is selected go to Method.		POOUTCOME	DropDownList	1=Full term live birth (greater than or equal to 37 weeks); 2=Premature live birth (less than 37 weeks); 3=Stillbirth/intrauterine fetal demise (greater than or equal to 20 weeks); 4=Spontaneous abortion (less than 20 weeks); 5=Ectopic pregnancy; 6=Therapeutic/elective abortion; 99=Other	
Consensus		Pregnancy Outcome		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		Pregnancy Outcome		POOUTYN	POOUTYN	Is the outcome of this pregnancy obtainable? If "No", end of form and specify in comments.		Yes/No	RadioButton	Y N	Available for non-perinatal studies. If pregnancy is a primary or secondary outcome, this question should not be used.
	FSTRF	EVW10001: Pregnancy Outcome Log	EVW10001		CEENDAT	Provide date of outcome:			DateTime		
	FSTRF	EVW10051: Pregnancy Outcome Log	EVW10051		CEENDAT	Provide date of outcome:	CEENDTC		DateTime		
	HPTN PO	Pregnancy Outcome Log	PO		POENDAT	Outcome date			DateTime		
	HVTN PO	Pregnancy Outcome Log	PO		POENDAT	Outcome date			DateTime		
Consensus		Pregnancy Outcome		CEENDAT	CEENDAT	Provide date of outcome:	CEENDTC		DateTime		
	FSTRF	EVW10001: Pregnancy Outcome Log	EVW10001		COVAL_PREGOUT	Provide a brief narrative of circumstances [200]:			LongText		
	FSTRF	EVW10051: Pregnancy Outcome Log	EVW10051		COVAL_PREGOUT	Provide a brief narrative of circumstances [200]:	COVAL		LongText		
	HPTN PO	Pregnancy Outcome Log	PO		PONARR	Provide a brief narrative of the circumstances (max. 400 characters).			LongText		
Consensus		Pregnancy Outcome		PO COVAL	COVAL_PREGOUT	Provide a brief narrative of circumstances:	COVAL		LongText		
	FSTRF	EVW10051: Pregnancy Outcome Log	EVW10051		CONGENITAL_IDENTYN	At the time of the pregnancy outcome, were any congenital anomalies identified?	Not Submitted	Yes/No/Unknown	DropDownList		
	HPTN PO	Pregnancy Outcome Log	PO		POCABIND	Were any fetal/infant congenital anomalies identified? Mark all that apply. If "No" or "Unknown", go to "Complete the infant items below for live births only."		Yes/No/NS/UNK	DropDownList	Y=Yes; N=No; NS=Not assessed; UNK=Unknown	
	HPTN PO	Pregnancy Outcome Log	PO		FACNSFAC	Central nervous system, cranio-facial			CheckBox		
	HPTN PO	Pregnancy Outcome Log	PO		FACNSSPI	Central nervous system, spinal			CheckBox		
	HPTN PO	Pregnancy Outcome Log	PO		FACARDIO	Cardiovascular			CheckBox		
	HPTN PO	Pregnancy Outcome Log	PO		FARENAL	Renal			CheckBox		
	HPTN PO	Pregnancy Outcome Log	PO		FAGASTRO	Gastrointestinal			CheckBox		

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	HPTN_PO	Pregnancy Outcome Log	PO		FAPULMO	Pulmonary			CheckBox		
	HPTN_PO	Pregnancy Outcome Log	PO		FAMUSCUL	Musculoskeletal/extremities			CheckBox		
	HPTN_PO	Pregnancy Outcome Log	PO		FAPHYSIC	Physical defect			CheckBox		
	HPTN_PO	Pregnancy Outcome Log	PO		FASKIN	Skin			CheckBox		
	HPTN_PO	Pregnancy Outcome Log	PO		FAGENITO	Genitourinary			CheckBox		
	HPTN_PO	Pregnancy Outcome Log	PO		FACHROMO	Chromosomal			CheckBox		
	HPTN_PO	Pregnancy Outcome Log	PO		FACRANIO	Cranio-facial (structural)			CheckBox		
	HPTN_PO	Pregnancy Outcome Log	PO		FAHEMAT	Hematologic			CheckBox		
	HPTN_PO	Pregnancy Outcome Log	PO		FAINFECT	Infectious			CheckBox		
	HPTN_PO	Pregnancy Outcome Log	PO		FAMETAB	Endocrine/metabolic			CheckBox		
	HPTN_PO	Pregnancy Outcome Log	PO		FAANOOOTH	Other			CheckBox		
	HPTN_PO	Pregnancy Outcome Log	PO		FAAEDESC	Describe congenital anomaly/defect (max. 200 characters).			LongText		
	HPTN_PO	Pregnancy Outcome Log	PO		POAE	Specify congenital anomaly/defect AE. Complete AE Log and EAE Reporting form.			Dynamic SearchList		
	HVTN_PO	Pregnancy Outcome Log	PO		POCABIND	Were any fetal/infant congenital anomalies identified?	Yes/No/NS		DropDownList	Y=Yes; N=No; NS=Not assessed	
	HVTN_PO	Pregnancy Outcome Log	PO		POAE	If "Yes", select adverse event and update Adverse Event log and complete EAE Reporting form, if applicable.			Dynamic SearchList		
	HVTN_PO	Pregnancy Outcome Log	PO		POCOMM	Comments (max. 450 characters):			LongText		
Consensus		Pregnancy Outcome		CONAB_IDENTYN	CONGENITAL_IDENTYN	At the time of the pregnancy outcome, were any congenital anomalies identified?		YesNoUnknown	DropDownList	Y N U	
Consensus		Pregnancy Outcome		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

	FSTRF	EVW10003: Pregnancy Record	EVW10003		CESTDTC	What is the estimated date of conception?	CESTDTC when CETERM = Pregnancy		DateTime		
	FSTRF	EVW10003: Pregnancy Record	EVW10003		FAORRES_DETR	How was the estimated date of conception determined?	FAORRES when FATESTCD = DETR (FAOBJ = Estimated Date of Conception)	Conception	DropDownList		
	FSTRF	EVW10003: Pregnancy Record	EVW10003		FAORRES_DETROTH	If Other, specify [70]:	FAORRES when FATESTCD = DETR		LongText		
	HVTN_RPRPT	Pregnancy Report	RPRPT		RPDAT_PGRPT	Date pregnancy reported to site			DateTime		
	HVTN_RPRPT	Pregnancy Report	RPRPT		RPVISIT	Visit at which this pregnancy was reported		VISIT	DropDownList		
	HVTN_RPRPT	Pregnancy Report	RPRPT		INTERIMCD	If "Interim visit", specify Interim visit code			Text		
	HVTN_RPRPT	Pregnancy Report	RPRPT		RPORRES_LMPSTDTC	Date of onset of last menstrual period			DateTime		
	HVTN_RPRPT	Pregnancy Report	RPRPT		RPORRES_EDLVRDTC	Estimated date of delivery			DateTime		
	HVTN_RPRPT	Pregnancy Report	RPRPT		RPORRES_FPREGST	Is this the participant's first pregnancy since enrollment in this study?		Yes/No	RadioButton	Y=Yes; N=No	
	HVTN_RPRPT	Pregnancy Report	RPRPT		LABEL	If "Yes", complete Pregnancy History form.			Text		
Consensus		Pregnancy Record		CESTDAT	CESTDTC	What is the estimated date of conception?	CESTDTC when CETERM = Pregnancy		DateTime		
Consensus		Pregnancy Record		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		Pregnancy Record		DETROSP_FAORRES	FAORRES_DETROTH	If Other, specify [70]:	FAORRES when FATESTCD = DETR		LongText		

Pregnancy History

	HPTN_RPHIST	Pregnancy History	RPHIST		RPDAT_PRGHIST	Date pregnancy history collected			DateTime	0	
	HPTN_RPRPT	Pregnancy History	RPHIST		RPDAT_PRGHIST	Date pregnancy history collected			DateTime	0	
	HVTN_RPHIST	Pregnancy History	RPHIST		RPDAT_PRGHIST	Date pregnancy history collected			DateTime	0	
	HPTN_RPHIST	Pregnancy History	RPHIST		RPORRES_PRVPREG	Has the participant ever been pregnant before?		Yes/No	RadioButton	Y=Yes; N=No	
	HPTN_RPHIST	Pregnancy History	RPHIST		LABEL	If "No", end of form.			Text		

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	HVTN RPHIST	Pregnancy History	RPHIST		RPORRES_PRIVPREG	Has the participant ever been pregnant before?		Yes/No	RadioButton	Y=Yes; N=No	
	HVTN RPHIST	Pregnancy History	RPHIST		LABEL	If "No", end of form.			Text		
	HPTN RPRPT	Pregnancy History	RPHIST		RPORRES_PRIVPREG	Has the participant ever been pregnant before?		Yes/No	RadioButton	Y=Yes; N=No	
	HPTN RPRPT	Pregnancy History	RPHIST		LABEL	If "No", end of form.			Text		
	HPTN RPHIST	Pregnancy History	RPHIST		RPORRES_FULLTRMN	Number of full term live births (>=37 weeks)			Text		
	HPTN RPRPT	Pregnancy History	RPHIST		RPORRES_FULLTRMN	Number of full term live births (>=37 weeks)			Text		
	HVTN RPHIST	Pregnancy History	RPHIST		RPORRES_FULLTRMN	Number of full term live births (>=37 weeks)			Text		
	HPTN RPHIST	Pregnancy History	RPHIST		RPORRES_ERLYTRMN	Number of premature live births (Less than 37 weeks)			Text		
	HPTN RPRPT	Pregnancy History	RPHIST		RPORRES_ERLYTRMN	Number of premature live births (Less than 37 weeks)			Text		
	HVTN RPHIST	Pregnancy History	RPHIST		RPORRES_ERLYTRMN	Number of premature live births (Less than 37 weeks)			Text		
	HPTN RPHIST	Pregnancy History	RPHIST		RPORRES_FETLDTHN	Number of spontaneous fetal deaths and/or still births (>=20 weeks)			Text		
	HPTN RPRPT	Pregnancy History	RPHIST		RPORRES_FETLDTHN	Number of spontaneous fetal deaths and/or still births (>=20 weeks)			Text		
	HVTN RPHIST	Pregnancy History	RPHIST		RPORRES_FETLDTHN	Number of spontaneous fetal deaths and/or still births (>=20 weeks)			Text		
	HPTN RPRPT	Pregnancy History	RPHIST		RPORRES_SPABORTN	Number of spontaneous abortions (Less than 20 weeks)			Text		
	HPTN RPHIST	Pregnancy History	RPHIST		RPORRES_SPABORTN	Number of spontaneous abortions (Less than 20 weeks)			Text		
	HVTN RPHIST	Pregnancy History	RPHIST		RPORRES_SPABORTN	Number of spontaneous abortions (Less than 20 weeks)			Text		
	HPTN RPHIST	Pregnancy History	RPHIST		RPORRES_ABORTN	Number of therapeutic/elective abortions			Text		
	HPTN RPRPT	Pregnancy History	RPHIST		RPORRES_ABORTN	Number of therapeutic/elective abortions			Text		
	HVTN RPHIST	Pregnancy History	RPHIST		RPORRES_ABORTN	Number of therapeutic/elective abortions			Text		
	HPTN RPHIST	Pregnancy History	RPHIST		RPORRES_ECTPREGN	Number of ectopic pregnancies			Text		
	HPTN RPRPT	Pregnancy History	RPHIST		RPORRES_ECTPREGN	Number of ectopic pregnancies			Text		
	HVTN RPHIST	Pregnancy History	RPHIST		RPORRES_ECTPREGN	Number of ectopic pregnancies			Text		
	HPTN RPHIST	Pregnancy History	RPHIST		RPORRES_HCOMP	Does the participant have a history of pregnancy complications or fetal/infant congenital anomalies?		Yes/No	RadioButton	Y=Yes; N=No	
	HPTN RPHIST	Pregnancy History	RPHIST		RPORRES_HCOMP	Does the participant have a history of pregnancy complications or fetal/infant congenital anomalies?			LongText		
	HPTN RPRPT	Pregnancy History	RPHIST		RPORRES_HCOMP	Does the participant have a history of pregnancy complications or fetal/infant congenital anomalies?		Yes/No	RadioButton	Y=Yes; N=No	
	HPTN RPRPT	Pregnancy History	RPHIST		RPORRES_HCOMP	Does the participant have a history of pregnancy complications or fetal/infant congenital anomalies?			LongText		
	HVTN RPHIST	Pregnancy History	RPHIST		RPORRES_HCOMP	Does the participant have a history of pregnancy complications or fetal/infant congenital anomalies before enrollment?		Yes/No	RadioButton	Y=Yes; N=No	
	HVTN RPHIST	Pregnancy History	RPHIST		RPORRES_HCOMP	Does the participant have a history of pregnancy complications or fetal/infant congenital anomalies before enrollment?			LongText		
	FSTRF	LGW10001: IMPAACT 2010 Prior Pregnancy Outcome Log	LGW10001		INSTRUCTIONS01	INSTRUCTIONS: Complete a log line for each prior pregnancy.			Text		
	FSTRF	LGW10001: IMPAACT 2010 Prior Pregnancy Outcome Log	LGW10001		OUTCOMEDATKNO	Is the outcome date known?		Yes/No	RadioButton		
	FSTRF	LGW10001: IMPAACT 2010 Prior Pregnancy Outcome Log	LGW10001		CEENDAT_PRIOR	Outcome date of prior pregnancy			DateTime		
	FSTRF	LGW10001: IMPAACT 2010 Prior Pregnancy Outcome Log	LGW10001		CESTRPT_OUTCOME	Estimate of when prior pregnancy outcome occurred		REFERENCEPERIOD	DropDownList		
	FSTRF	LGW10001: IMPAACT 2010 Prior Pregnancy Outcome Log	LGW10001		CESTRPT_OUTCOMEYR	Estimate year when prior pregnancy outcome occurred			DateTime		
	FSTRF	LGW10001: IMPAACT 2010 Prior Pregnancy Outcome Log	LGW10001		FAORRES_PRIOROUT	Indicate outcome of prior pregnancy		PREGOUT	DropDownList		

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	FSTRF	LGW10001: IMPAACT 2010 Prior Pregnancy Outcome Log	LGW10001		FAORRES_NEONAT	Did neonatal death occur before 28 days of age?		YesNo	RadioButton		
Consensus		Pregnancy History		INSTRUCTIONS01	INSTRUCTIONS01	INSTRUCTIONS: Complete a log line for each prior pregnancy.			Text		
Consensus		Pregnancy History		OUTCOMEDATKNO	OUTCOMEDATKNO	Is the outcome date known?		YesNo	RadioButton	Y N	
Consensus		Pregnancy History		PRIOR_CEENDAT	CEENDAT_PRIOR	Outcome date of prior pregnancy			DateTime		
Consensus		Pregnancy History		OUTCOME_CESTRTPT	CESTRTP_T_OUTCOME	Estimate of when prior pregnancy outcome occurred		REFERENCEPERIOD	DropDownList	BEFORE AFTER UNKNOWN	
Consensus		Pregnancy History		OUTCOMEYR_CESTTPT	CESTTPT_OUTCOMEYR	Estimate year when prior pregnancy outcome occurred			DateTime		
Consensus		Pregnancy History		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											
	FSTRF	EVW10009: Delivery Record (Infant Enrolled)	EVW10009		FAORRES_DELIVLOC	Delivery location:		CESETTING in SUPPCE	DELIVLOC	DropDownList	
	FSTRF	EVW10009: Delivery Record (Infant Enrolled)	EVW10009		FAORRES_DELIVLOCOTH	If Other, specify [70]:		CESETTING in SUPPCE		LongText	
	HPTN PO	Pregnancy Outcome Log	PO		POOUTPLC	Place of delivery/outcome			POPLACE	DropDownList	1=Home; 2=Hospital; 3=Clinic; 4=Unknown; 99=Other
	HPTN PO	Pregnancy Outcome Log	PO		POOUTPLCOSP	If "Other", specify:				LongText	
Consensus		Delivery Record		DELIVLOC_CESSETTING	FAORRES_DELIVLOC	Delivery location:		CESETTING in SUPPCE	DELIVLOC	DropDownList	Home Hospital Clinic En route Other
Consensus		Delivery Record		DELIVLOCOSP_CESSETTING	FAORRES_DELIVLOCOTH	If Other, specify [70]:		CESETTING in SUPPCE		LongText	
	FSTRF	EVW10009: Delivery Record (Infant Enrolled)	EVW10009		FAORRES_DELIVTYP	Type of delivery:		CETERM, PRTRT, PRUGENCY in SUPPPR	DELIVTYPE	DropDownList	
	HPTN PO	Pregnancy Outcome Log	PO		PODELIVTYP	Method			PODELIVTYP	DropDownList	1=C-section; 2=Standard vaginal; 3=Operative vaginal; 4=Vaginal
	HVTN PO	Pregnancy Outcome Log	PO		PODELIVTYP	Method			PODELIVTYP	DropDownList	1=C-section; 4=Vaginal
Consensus		Delivery Record		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											
	FSTRF	EVW10044: Newborn Exam	EVW10044		GESTAGEXAMAVAILYN	Is the infant's gestational age by infant exam available?	Not Submitted	YesNo	RadioButton		
	FSTRF	EVW10044: Newborn Exam	EVW10044		QSORRES_GESTAGEWK	Weeks [nn]:	SCORRES when SCTESTCD = EGESTAGE			Text	
	FSTRF	EVW10044: Newborn Exam	EVW10044		QSORRES_GESTAGEDY	Days [n]:	SCORRES when SCTESTCD = EGESTAGE			Text	
	HPTN PO	Pregnancy Outcome Log	PO		FAGESAGEW	Infant gestational age by examination in weeks				Text	
	HPTN PO	Pregnancy Outcome Log	PO		FAGESAGED	Infant gestational age by examination in days				Text	
	HPTN PO	Pregnancy Outcome Log	PO		FAGESAGEUN	Infant gestational age by examination unavailable If unavailable, end of form.				CheckBox	
Consensus		Newborn Exam		EGESTAGEYN	GESTAGEYN	Is the infant's gestational age by infant exam available?	Not Submitted	YesNo	RadioButton	Y N	

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Consensus		Newborn Exam		EGESTAGEWK_SCORRES	SCORRES_GESTAGEWK	Weeks [nn]:	SCORRES when SCTESTCD = EGESTAGE		Text		Optional: If used, SDTM needs to be converted to days.
Consensus		Newborn Exam		EGESTAGEDY_SCORRES	SCORRES_GESTAGEDY	Days [n]:	SCORRES when SCTESTCD = EGESTAGE		Text		
	FSTRF	EVW10044: Newborn Exam	EVW10044		QSORRES_EXAMTYP	What is the type of exam used to determine the infant's gestational age:	SCMETHOD when SCTESTCD = EGESTAGE	TypeofExam	DropDownList		
	FSTRF	EVW10044: Newborn Exam	EVW10044		QSORRES_EXAMTYPOTH	If Other, specify [70]:	SCMETHOD when SCTESTCD = EGESTAGE		LongText		
	HPTN PO	Pregnancy Outcome Log	PO		FAGESAGETYP	Method used to determine gestational age		FAGESAGETYP	DropDownList	1=Ballard; 2=Dubowitz; 99=Other	
	HPTN PO	Pregnancy Outcome Log	PO		FAGESAGETYPSP	If "Other", specify (max. 200 characters):			LongText		
Consensus		Newborn Exam		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		Newborn Exam		EXAMTYPOSP_SCMETHOD	SCORRES_EXAMTYPOSP	If Other, specify [70]:	SCMETHOD when SCTESTCD = EGESTAGE		LongText		
	FSTRF	EVW10044: Newborn Exam	EVW10044		VSORRES_WEIGHT	Weight [nnn.nn]:	VSORRES when VSTESTCD = WEIGHT		Text		
	FSTRF	EVW10044: Newborn Exam	EVW10044		VSORRESU_WEIGHT	Unit:	VSORRESU when VSTESTCD = WEIGHT	Weight	RadioButton (Vertical)		
	HPTN PO	Pregnancy Outcome Log	PO		FAIWGHT	Infant birth weight			Text		
	HPTN PO	Pregnancy Outcome Log	PO		FAIWGHTUN	Infant birth weight unavailable			CheckBox		
Consensus		Newborn Exam		WEIGHT_VSORRES	VSORRES_WEIGHT	Weight [nnn.nn]:	VSORRES when VSTESTCD = WEIGHT		Text		
Consensus		Newborn Exam		WEIGHT_VSORRESU	VSORRESU_WEIGHT	Unit:	VSORRESU when VSTESTCD = WEIGHT	Weight	RadioButton (Vertical)	g kg LB	
Consensus		Newborn Exam		VSWEIGHTYN	FAIWGHTYN	Infant birth weight available?		YesNo	RadioButton	Y N	Available for non-perinatal studies.
	FSTRF	EVW10044: Newborn Exam	EVW10044		VSORRES_LENGTH	Length [nnn.nn]:	VSORRES when VSTESTCD = BODLNPTH		Text		
	FSTRF	EVW10044: Newborn Exam	EVW10044		VSORRESU_LENGTH	Unit:	VSORRESU when VSTESTCD = BODLNPTH	Height	RadioButton (Vertical)		
	HPTN PO	Pregnancy Outcome Log	PO		FAILGTH	Infant birth length			Text		
	HPTN PO	Pregnancy Outcome Log	PO		FAILGTHUN	Infant birth length unavailable			CheckBox		
Consensus		Newborn Exam		LENGTH_VSORRES	VSORRES_LENGTH	Length [nnn.nn]:	VSORRES when VSTESTCD = BODLNPTH		Text		
Consensus		Newborn Exam		LENGTH_VSORRESU	VSORRESU_LENGTH	Unit:	VSORRESU when VSTESTCD = BODLNPTH	Height	RadioButton (Vertical)	cm in	
Consensus		Newborn Exam		VSLNGTHYN	FAILGTHYN	Infant birth length available?		YesNo	RadioButton	Y N	Available for non-perinatal studies.
	FSTRF	EVW10044: Newborn Exam	EVW10044		VSORRES_HDCIRC	Head Circumference [nn.n]:	VSORRES when VSTESTCD = HDCIRC		Text		
	FSTRF	EVW10044: Newborn Exam	EVW10044		VSORRESU_HDCIRC	Unit:	VSORRESU when VSTESTCD = HDCIRC	Height	RadioButton (Vertical)		
	HPTN PO	Pregnancy Outcome Log	PO		FAIHC	Infant birth head circumference			Text		
	HPTN PO	Pregnancy Outcome Log	PO		FAIHCUN	Infant birth head circumference unavailable			CheckBox		
Consensus		Newborn Exam		HDCIRC_VSORRES	VSORRES_HDCIRC	Head Circumference [nn.n]:	VSORRES when VSTESTCD = HDCIRC		Text		
Consensus		Newborn Exam		HDCIRC_VSORRESU	VSORRESU_HDCIRC	Unit:	VSORRESU when VSTESTCD = HDCIRC	Height	RadioButton (Vertical)	cm in	
Consensus		Newborn Exam		VSHDCIRCYN	FAIHCYN	Infant birth head circumference available?		YesNo	RadioButton	Y N	Available for non-perinatal studies.
	FSTRF	EVW10044: Newborn Exam	EVW10044		PERES_GENACT	General Activity:	PEORRES when PETESTCD = INFACIV	NewbornActivity	RadioButton (Vertical)		
	FSTRF	EVW10044: Newborn Exam	EVW10044		PERES_GENACT_ABN	If Abnormal, specify [70]:	PEORRES when PETESTCD = INFACIV		LongText		
Consensus		Newborn Exam		INFACIV_PEORRES	PERES_GENACT	General Activity:	PEORRES when PETESTCD = INFACIV	NewbornActivity	RadioButton (Vertical)	Normal Abnormal Unknown	Available for perinatal studies

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Consensus		Newborn Exam		INFACTABN_PEORRES	PERES_GENACT_ABN	If Abnormal, specify [70]:	PEORRES when PETESTCD = INFACTIV		LongText		Available for perinatal studies
	FSTRF	EVW10044: Newborn Exam	EVW10044		PERES_PHYSEXAM	Physical Exam:	PEORRES when PETESTCD = NEWBRNEX	NewbornActivity	RadioButton (Vertical)		
	FSTRF	EVW10044: Newborn Exam	EVW10044		PERES_PHYSEXAM_AB N	If Abnormal, specify [70]:	PEORRES when PETESTCD = NEWBRNEX		LongText		
Consensus		Newborn Exam		NEWBRNEX_PEORRES	PERES_PHYSEXAM	Physical Exam:	PEORRES when PETESTCD = NEWBRNEX	NewbornActivity	RadioButton (Vertical)	Normal Abnormal Unknown	Available for perinatal studies
Consensus		Newborn Exam		NEWBRNEXABN_PEORRES	PERES_PHYSEXAM_AB N	If Abnormal, specify [70]:	PEORRES when PETESTCD = NEWBRNEX		LongText		Available for perinatal studies
	FSTRF	EVW10044: Newborn Exam	EVW10044		APGAVAILYN	Are any of the infant's Apgar scores available?	Not Submitted	YesNo	RadioButton		
	FSTRF	EVW10044: Newborn Exam	EVW10044		APGAR1YN	At 1 minute?	Not Submitted	YesNo	RadioButton		
	FSTRF	EVW10044: Newborn Exam	EVW10044		RSORRES_APGAR1	Score at 1 minute [nn]:	RSORRES when RSTESTCD = APGAR and RSTPT = 1 MINUTE		Text		
	FSTRF	EVW10044: Newborn Exam	EVW10044		APGAR5YN	At 5 minutes?	Not Submitted	YesNo	RadioButton		
	FSTRF	EVW10044: Newborn Exam	EVW10044		RSORRES_APGAR5	Score at 5 minutes [nn]:	RSORRES when RSTESTCD = APGAR and RSTPT = 5 MINUTE		Text		
	FSTRF	EVW10044: Newborn Exam	EVW10044		APGAR10YN	At 10 minutes?	Not Submitted	YesNo	RadioButton		
	FSTRF	EVW10044: Newborn Exam	EVW10044		RSORRES_APGAR10	Score at 10 minutes [nn]:	RSORRES when RSTESTCD = APGAR and RSTPT = 10 MINUTE		Text		
Consensus		Newborn Exam		APGAVAILYN	APGAVAILYN	Are any of the infant's Apgar scores available?	Not Submitted	YesNo	RadioButton	Y N	Available for perinatal studies
Consensus		Newborn Exam		APGAR1YN	APGAR1YN	At 1 minute?	Not Submitted	YesNo	RadioButton	Y N	Available for perinatal studies
Consensus		Newborn Exam		APGAR1_RSORRES	RSORRES_APGAR1	Score at 1 minute [nn]:	RSORRES when RSTESTCD = APGAR and RSTPT = 1 MINUTE		Text		Available for perinatal studies
Consensus		Newborn Exam		APGAR5YN	APGAR5YN	At 5 minutes?	Not Submitted	YesNo	RadioButton	Y N	Available for perinatal studies
Consensus		Newborn Exam		APGAR5_RSORRES	RSORRES_APGAR5	Score at 5 minutes [nn]:	RSORRES when RSTESTCD = APGAR and RSTPT = 5 MINUTE		Text		Available for perinatal studies
Consensus		Newborn Exam		APGAR10YN	APGAR10YN	At 10 minutes?	Not Submitted	YesNo	RadioButton	Y N	Available for perinatal studies
Consensus		Newborn Exam		APGAR10_RSORRES	RSORRES_APGAR10	Score at 10 minutes [nn]:	RSORRES when RSTESTCD = APGAR and RSTPT = 10 MINUTE		Text		Available for perinatal studies
	FSTRF	EVW10044: Newborn Exam	EVW10044		GESTATAVAILYN	Is the classification of the newborn by intrauterine growth and gestational age available?	Not Submitted	YesNo	RadioButton		
	FSTRF	EVW10044: Newborn Exam	EVW10044		QSORRES_GESTCLASS	Indicate the classification:	SCORRES when SCTESTCD = GSTCLASS	GESTAGECLASS	DropDownList		
Consensus		Newborn Exam		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		Newborn Exam		GSTCLASS_SCORRES	QSORRES_GESTCLASS	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
	FSTRF	EVW10044: Newborn Exam	EVW10044		VSPERF_ALL	Were vital signs/measurements collected at birth?	Not Submitted	YesNo	RadioButton		
Consensus		Newborn Exam		VSPERF_ALL	VSPERF_ALL	Were vital signs/measurements collected at birth?	Not Submitted	YesNo	RadioButton	Y N	Available for perinatal studies
	FSTRF	EVW10044: Newborn Exam	EVW10044		VSORRES_TEMP	Temperature [nn.n]:	VSORRES when VSTESTCD = TEMP		Text		
	FSTRF	EVW10044: Newborn Exam	EVW10044		VSORRESU_TEMP	Unit:	VSORRESU when VSTESTCD = TEMP	Temperature	RadioButton (Vertical)		
	FSTRF	EVW10044: Newborn Exam	EVW10044		VSMETHOD_TEMP	What method was used to obtain the temperature?	VSLOC when VSTESTCD = TEMP	VSLOCTEMP	DropDownList		
Consensus		Newborn Exam		TEMP_VSORRES	VSORRES_TEMP	Temperature [nn.n]:	VSORRES when VSTESTCD = TEMP		Text		Available for perinatal studies
Consensus		Newborn Exam		TEMP_VSORRESU	VSORRESU_TEMP	Unit:	VSORRESU when VSTESTCD = TEMP	Temperature	RadioButton (Vertical)	C F	Available for perinatal studies

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Consensus		Newborn Exam		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
	FSTRF	EVW10044: Newborn Exam	EVW10044		VSORRES_PULSE	Pulse Rate (beats/min) [nnn]:	VSORRES when VSTESTCD = PULSE		Text		
Consensus		Newborn Exam		PULSE_VSORRES	VSORRES_PULSE	Pulse Rate (beats/min) [nnn]:	VSORRES when VSTESTCD = PULSE		Text		Available for perinatal studies
	FSTRF	EVW10044: Newborn Exam	EVW10044		VSORRES_RESP	Respirations (breaths/min) [nnn]:	VSORRES when VSTESTCD = RESP		Text		
Consensus		Newborn Exam		RESP_VSORRES	VSORRES_RESP	Respirations (breaths/min) [nnn]:	VSORRES when VSTESTCD = RESP		Text		Available for perinatal studies
	FSTRF	EVW10044: Newborn Exam	EVW10044		BLOODPRESSYN	Was blood pressure measurement obtained?	Not Submitted	YesNo	RadioButton		
	FSTRF	EVW10044: Newborn Exam	EVW10044		VSORRES_SYSBP	Systolic Blood Pressure (mmHg) [nnn]:	VSORRES when VSTESTCD = SYSBP		Text		
	FSTRF	EVW10044: Newborn Exam	EVW10044		VSORRES_DIABP	Diastolic Blood Pressure (mmHg) [nnn]:	VSORRES when VSTESTCD = DIABP		Text		
Consensus		Newborn Exam		BLOODPRESSYN	BLOODPRESSYN	Was blood pressure measurement obtained?	Not Submitted	YesNo	RadioButton	Y N	Available for perinatal studies
Consensus		Newborn Exam		SYSBP_VSORRES	VSORRES_SYSBP	Systolic Blood Pressure (mmHg) [nnn]:	VSORRES when VSTESTCD = SYSBP		Text		Available for perinatal studies
Consensus		Newborn Exam		DIABP_VSORRES	VSORRES_DIABP	Diastolic Blood Pressure (mmHg) [nnn]:	VSORRES when VSTESTCD = DIABP		Text		Available for perinatal studies
	FSTRF	EVW10044: Newborn Exam	EVW10044		PRINFANTLABORYN	Were any of the following procedures performed on the infant during labor and delivery? If Yes, check all that apply: 	Not Submitted	YesNoUnknown	RadioButton (Vertical)		
	FSTRF	EVW10044: Newborn Exam	EVW10044		PRTRT_SCALPBLOOD	Sampling of fetal scalp blood:	PROCCUR when PRTRT = SCALP BLOOD SAMPLING		CheckBox		
	FSTRF	EVW10044: Newborn Exam	EVW10044		PRTRT_ELECTRODE	Scalp electrode:	PROCCUR when PRTRT = SCALP ELECTRODE		CheckBox		
	FSTRF	EVW10044: Newborn Exam	EVW10044		PRTRT_OTHER	Other:	PROCCUR		CheckBox		
	FSTRF	EVW10044: Newborn Exam	EVW10044		PRTRT_OTH	If Other, specify [70]:	PRTRT		LongText		
Consensus		Newborn Exam		PRINFANTLABORYN	PRINFANTLABORYN	Were any of the following procedures performed on the infant during labor and delivery? If Yes, check all that apply: 	Not Submitted	YesNoUnknown	RadioButton (Vertical)	Y N U	Available for perinatal studies
Consensus		Newborn Exam		SCALPBLOOD_PRTRT	PRTRT_SCALPBLOOD	Sampling of fetal scalp blood:	PROCCUR when PRTRT = SCALP BLOOD SAMPLING		CheckBox		Available for perinatal studies
Consensus		Newborn Exam		ELECTRODE_PRTRT	PRTRT_ELECTRODE	Scalp electrode:	PROCCUR when PRTRT = SCALP ELECTRODE		CheckBox		Available for perinatal studies
Consensus		Newborn Exam		OTH_PRTRT	PRTRT_OTHER	Other:	PROCCUR		CheckBox		Available for perinatal studies
Consensus		Newborn Exam		OSP_PRTRT	PRTRT_OTH	If Other, specify [70]:	PRTRT		LongText		Available for perinatal studies
	FSTRF	EVW10044: Newborn Exam	EVW10044		AEYN_INFANTLABOR	Were any adverse events experienced by the infant at the time of delivery?	Not Submitted	YesNoUnknown	RadioButton (Vertical)		
Consensus		Newborn Exam		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
	FSTRF	EVW10044: Newborn Exam	EVW10044		AEYN_INFANTLABOR_C ONGEN	Were any congenital anomalies identified at the time of delivery?	Not Submitted	YesNoUnknown	RadioButton (Vertical)		
Consensus		Newborn Exam		ILAEYN_CONABN	AEYN_INFANTLABOR_C ONGEN	Were any congenital anomalies identified at the time of delivery?	Not Submitted	YesNoUnknown	RadioButton (Vertical)	Y N U	Available for perinatal studies

Variables not used

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

	HVTN LBPREG	Pregnancy Test Results	LBPREG		LABEL	If "Positive" at study product administration visit, do not administer study product. Complete Pregnancy Report and Pregnancy History forms, if applicable.			Text		
	HVTN LBPREG	Pregnancy Test Results	LBPREG		LBCOMM	Comments (max. 450 characters):			LongText		

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	HPTN PO	Pregnancy Outcome Log	PO		POCOMPYN	Were there any complications related to the pregnancy outcome? If "No", skip to "Were any fetal/infant congenital anomalies identified?".		Yes/No	RadioButton	Y=Yes; N=No	
	HPTN PO	Pregnancy Outcome Log	PO		PODCN	Delivery-related complications. Mark "None" or all that apply. None			CheckBox		
	HPTN PO	Pregnancy Outcome Log	PO		PODCIH	Intrapartum hemorrhage			CheckBox		
	HPTN PO	Pregnancy Outcome Log	PO		PODCPH	Postpartum hemorrhage			CheckBox		
	HPTN PO	Pregnancy Outcome Log	PO		PODCNRF5	Non-reassuring fetal status			CheckBox		
	HPTN PO	Pregnancy Outcome Log	PO		PODCHOR	Chorioamnionitis			CheckBox		
	HPTN PO	Pregnancy Outcome Log	PO		PODCOTH	Other			CheckBox		
	HPTN PO	Pregnancy Outcome Log	PO		PODCOSP	If "Other", specify:			LongText		
	HPTN PO	Pregnancy Outcome Log	PO		PONDCN	Non-delivery related complications. Mark "None" or all that apply. None			CheckBox		
	HPTN PO	Pregnancy Outcome Log	PO		PONDCHDP	Hypertensive disorders of pregnancy			CheckBox		
	HPTN PO	Pregnancy Outcome Log	PO		PONDCGD	Gestational diabetes			CheckBox		
	HPTN PO	Pregnancy Outcome Log	PO		PONDCOTH	Other			CheckBox		
	HPTN PO	Pregnancy Outcome Log	PO		PONDCOSP	If "Other", specify:			LongText		
	HPTN PO	Pregnancy Outcome Log	PO		FAIAC	Infant birth abdominal circumference Or			Text		
	HPTN PO	Pregnancy Outcome Log	PO		FAIACUN	Infant birth abdominal circumference unavailable			CheckBox		

