

Study Team Review Guide:

General:

This document is to be used as a database development tool for CDM and the EDC programmer. This document will also serve as an eCRF review tool for the study team during eCRF development. The CDM Lead is the owner of this document. The study team will provide their comments for each eCRF in the appropriate column on the right labeled, "Internal Comments" or "External Comments". Each study member should review those eCRFs that are pertinent to his/her role prior to the Study Orientation Meeting.

Standard CRFs and their respective data specs have $\frac{blue\ tabs}{tabs}$ in the Build Specs Template.

Clinical eCRFs have purple tabs in the Build Spec Template.

Laboratory eCRFs have green tabs in the Build Spec Template.

Administrative eCRFs have brown tabs in the Build Spec Template.

Behavioral eCRFs have yellow tabs in the Build Spec Template - the Behavioral Forms are still pending input from BRWG and content should be reviewed by study team.

Field OID: Variable name in Medidata Rave. If field OID is empty, existing field has not yet been programmed into Rave.

The Following Tabs Should be Ignored During Internal Review (Items will be hidden for External Review):

Implementation Guide

Folders (study folders to be reviewed at a later date)

Dynamics (used for programming purposes only)

Dictionary (used for programming purposes only)

Coding (used by EDC Programmer and Clinical Coding group)

Derivations (data derivations used by EDC Progammer)

Programming Standards:

All date fields will check for future dates and non conformant data

Form Name		• • • • • • • • • • • • • • • • • • • •	Response Options (Dictionary Items)	External Review Comments
Participant Identifier	Participant ID:	Text		
Participant Identifier	NOW	DateTime		

Form Name			Response Options (Dictionary Items)		External Review
	,	, ,	(Dictionary Items)	Help Text	Comments
	Has the participant experienced an adverse event				
Adverse Event Y/N	during the study?	RadioButton	Y=Yes; N=No		
Adverse Event Y/N	If "Yes", update the Adverse Event log.	Text			

					External Review
Form Name	Item Text (Field Label)	Response Type (Control Type)	Response Options (Dictionary Items)	Help Text	Comments
Adverse Event	Date AE reported to site	DateTime	, , , ,		
				Record diagnosis (in	
Adverse Event	Adverse event (AE)	LongText		English), if available.	
Adverse Event	Onset date	DateTime			
			1=Screening 2=Enrollment		
			3=Visit 3		
			4=Visit 4		
			5=Visit 5		
			6=Visit 6		
			7=Visit 7		
			8=Visit 8		
			9=Visit 9		
			10=Visit 10		
			11=Visit 11/Final Contact		
Adverse Event	Visit AE was reported	DropDownList	12=Interim Visit		
Adverse Event	Interim Visit Code	Text			
Adverse Event	Is the AE still ongoing?	RadioButton	Y=Yes; N=No		
Adverse Event	If "No", outcome date	DateTime			
			1=Grade 1 (Mild)		
			2=Grade 2 (Moderate) 3=Grade 3 (Severe) 4=Grade 4 (Potentially		
			life-threatening) 5=Grade 5 (Death)		
Adverse Event	Severity grade	DropDownList	3-Grade 3 (Deatri)		
AUVEISE EVEIIL	Severity grade	DI OPDOWIILIST	1=Related		
Adverse Event	Relationship to study product	RadioButton	2=Not related		
			1=Dose not changed;		
I			2=Dose reduced;		
			3=Dose increased;		
			4=Drug withdrawn;		
			5=Drug interrupted;		
Adverse Event	Action taken with study product	DropDownList	98=Not applicable		
	Other actions				
	Mark "None" or all that apply.				
Adverse Event	None	CheckBox			
Adverse Event	Medication(s)	CheckBox		Report on Concomitant	
Adverse Event	Therapeutic procedure/surgery	CheckBox		Medications Log.	
Adverse Event	Diagnostic procedure	CheckBox			
Adverse Event	Referral	CheckBox			
Adverse Event	Other	CheckBox			
Adverse Event	If "Other", specify (max. 200 characters):	LongText			
	, , , ,		1=Recovered/resolved; 2=Recovering/resolving;		
			3=Recovered/resolved with sequelae;		
			4=Not recovered/not resolved;		
Adverse Event	Status/outcome	DropDownList	5=Fatal; 6=Severity/frequency increased		
	Is this a serious adverse event according to ICH/GCP or				
	protocol guidelines?				
l	If "No", go to "Has or will this AE be reported as an EAE?".	L			
Adverse Event	If "Yes", check all that apply.	RadioButton	Y=Yes; N=No		
Adverse Event	Results in death	CheckBox			1
Adverse Event	Is life-threatening	CheckBox			
Adverse Event	Requires inpatient hospitalization or prolongation of existing hospitalization	CheckBox			
Auverse Everit	CAISTING HOSPITALIZATION	CITCURBUA			
Adverse Event	Results in persistent or significant disability/incapacity	CheckBox			
Adverse Event	Is a congenital anomaly/birth defect	CheckBox			
	7 O				
I	Is another serious important medical event that may				
	jeopardize the patient or require intervention to prevent				
Adverse Event	one of the other outcomes listed above	CheckBox			<u></u>
Adverse Event	SAE onset date	DateTime			
	Has or will this AE be reported as an EAE?				
Adverse Event	If "Yes", provide EAE number below.	RadioButton	Y=Yes; N=No		
	EAE number				
l	Begin number with 4-digit year, followed by 6-digit EAE	L.			
Adverse Event	number (no dashes or spaces).	Text			
Adverse Event	Study agent(s)	LongText			
		l	İ	1	1
Advarsa Frant	Was this AE a worsening of a baseline medical as a divisual	PadioRutton	V-Voc: N-No		
Adverse Event Adverse Event	Was this AE a worsening of a baseline medical condition? Comments (max. 450 characters):	RadioButton LongText	Y=Yes; N=No		

		Response Type	Response Options		External Review
Form Name	Item Text (Field Label)	(Control Type)	(Dictionary Items)	Help Text	Comments
Concomitant Medications					
Y/N	Were any concomitant medications taken?	RadioButton	Y=Yes; N=No		
Concomitant Medications					
Y/N	If "Yes", update the Concomitant Medications log.	Text			

		1			
F N	the section of the se	Response Type (Control	D	Hala Tana	External Review
Form Name Concomitant	Item Text (Field Label)	Туре)	Response Options (Dictionary Items)	Help Text	Comments
Medications	Medication name	LongText			
Concomitant	Medication name	Longrext	+		
Medications	Indication	LangTout			
Concomitant	indication	LongText	+		
Medications	Date started	DateTime			
iviedications	Date stopped	Daterline			
Concomitant	Date stopped				
Medications	Or	DateTime			
Concomitant	OI .	Daterline			
Medications	Ongoing	CheckBox		If Date Stopped is provided, Ongoing should not be selected.	
Concomitant	Oligonia	CHECKBOX		in Date Stopped is provided, Origonia should not be selected.	
Medications	Dose	Text			
Wedleadons	Dose	TEAL	g=Grams		
			ug=Micrograms		
			mg=Milligrams		
			ml=Millileters		
			CAPSULE=Capsules		
			gtt=Drops		
			PUFF=Puffs		
			SACHET=Sachets		
			SUPPOSITORY=Suppository		
			TABLET=Tablets		
			UNIT=Units		
Concomitant			UNKNOWN=Unknown		
Medications	Dose units	DropDownList	OTHER=Other		
Concomitant	Dose units	DropDownEist	OTHER=Other		
Medications	If "Other", specify:	LongText			
Wedleadons	ii Other , specify.	Longrext	PRN=PRN		
			QD=QD		
			BID=BID		
			TID=TID		
			QID=QID		
			QM=QM		
			QH=QH		
Concomitant			ONCE=ONCE		
Medications	Frequency	DropDownList	OTHER=Other		
Concomitant	requelity	propownitist	OTTEN-OUIEI		
Medications	If "Other", specify:	LongText			
iviculcations	ii other , specify.	COURTENT	PO=Oral		
			IM=Intramuscular		
			IV=Intravenous		
			TOP=Topical		
			IHL=Inhalation		
			VAG=Vaginal		
			REC=Rectal		
Concomitant			SC=Subcutaneous		
Medications	Route	DropDownList	OTHER=Other		
Concomitant		S. Oppownicist	omen odici		
Medications	If "Other", specify:	LongText			
Concomitant	ii other , specify.	COURTENT	<u> </u>		
Medications	Taken for a reported AE?	RadioButton	Y=Yes; N=No		
Concomitant	Taken for a reported AL:	naulobutton	1-103, 14-140		
Medications	If "Yes", select adverse event.	Dynamic SearchList			
iviculcations	ii iea , seiect auverse evellt.	Dynamic Searchest	1	<u> </u>	l .

		Response Type	Response Options		External Review
Form Name	Item Text (Field Label)	(Control Type)	(Dictionary Items)	Help Text	Comments
Medical History Y/N	Does the participant have any medical history to report?	RadioButton	Y=Yes; N=No		
Medical History Y/N	If "Yes", update the Medical History log.	Text			

		Response Type	Response Options		External Review
Form Name	Item Text (Field Label)	(Control Type)	(Dictionary Items)	Help Text	Comments
Medical History	Date medical history collected	DateTime			
Medical History	Description of medical history condition/event	LongText			
Medical History	Is condition/event gradable?	RadioButton	Y=Yes; N=No		
			1=Grade 1 (Mild)		
			2=Grade 2 (Moderate)		
			3=Grade 3 (Severe)		
			4=Grade 4 (Potentially life-		
Medical History	Severity grade	DropDownList	threatening)		
Medical History	Start date of medical history condition/event	DateTime			
Medical History	Is the condition ongoing?	RadioButton	Y=Yes; N=No		
Medical History	Date medical history/condition ended/resolved	DateTime			
Medical History	Comments (max. 200 characters):	LongText			

		Response Type			
Form Name	Item Text (Field Label)	(Control Type)	Response Options (Dictionary Items)	Help Text	External Review Comments
Discontinuation of Study Product	Date that study product use ended	DateTime			
			1=Scheduled study product use period completed		
			2=Death;		
			3=Participant refused further participation;		
			4=Participant is unwilling or unable to comply with required study procedures;		
			5=Lost to follow-up		
			6=Investigator decision;		
			7=Participant refused further study product use;		
			9=HIV infection;		
			10=Early study closure;		
			11=Protocol deviation;		
			12=Adverse event;		
			13=Pregnancy or breastfeeding		
			15=Study terminated by sponsor;		
			20=Anogenital STI		
			21=Use of prohibited medications		
Discontinuation of Study Product	Primary reason for ending study product use	DropDownList	99=Other, specify		
Discontinuation of Study Product	If "Other", specify:	LongText			
Discontinuation of Study Product	If "Adverse event", select applicable adverse event.	Dynamic SearchList			

Form Name	Item Text (Field Label)	Response Type(Control Type)	Response Options (Dictionary Items)	Help Text	External Review Comments
Study Termination	Date of study exit	DateTime			
			1=Scheduled exit visit/end of study		
			2=Death		
			3=Participant refused further participation		
			4=Participant is unwilling or unable to comply with required study procedures		
			5=Lost to follow-up		
			6=Investigator decision		
			7=Participant refused further study product use		
			9=HIV infection		
			10=Early study closure		
			11=Protocol deviation		
			12=Adverse event		
			13=Pregnancy		
	Primary reason for		15=Study terminated by sponsor		
Study Termination	completion/discontinuation	DropDownList	99=Other, specify		
Study Termination	If "Other", specify (max. 200 characters):				
Study Termination	If "Death", enter date of death.	DateTime			
	If "Adverse event", select applicable				
Study Termination	adverse event.	Dynamic SearchList		ı	

		Response Type			External Review
Form Name	Item Text (Field Label)	(Control Type)	Response Options (Dictionary Items)	Help Text	Comments
Protocol Deviations Log	Site awareness date	DateTime			
Protocol Deviations Log	Deviation date	DateTime			
	Has or will this deviation be reported to local				
Protocol Deviations Log	IRB/EC?	RadioButton	Y=Yes; N=No		
	Has or will this deviation be reported to DAIDS as a				
Protocol Deviations Log	critical event?	RadioButton	Y=Yes; N=No		
			1=Inappropriate enrollment;		
			2=Failure to follow randomization or blinding procedures;		
			3=Study product management deviation;		
		1	4=Study product dispensing error;		
		1	5=Study product use/non-use deviation;		
		1	6=Study product sharing;		
			7=Study product not returned;		
			8=Conduct of non-protocol procedure;		
			9=Improper AE/EAE;		
			10=Unreported AE;		
			11=Unreported EAE;		
			12=Breach of confidentiality;		
			13=Physical assessment deviation;		
			14=Lab assessment deviation;		
			15=Mishandled lab specimen;		
			16=Staff performing duties that they are not qualified to perform;		
			17=Questionnaire administration deviation;		
			18=Counseling deviation;		
			19=Use of non-IRB/EC-approved materials;		
			20=Use of excluded concomitant medications, devices, or non-study products;		
			21=Informed consent process deviation;		
		1	22=Visit completed outside of window;		1
Protocol Deviations Log	Type of deviation	SearchList	99=Other		
Protocol Deviations Log	Description of deviation	LongText			
Protocol Deviations Log	Plans and/or action taken to address the deviation	LongText			
	Plans and/or action taken to prevent future				
Protocol Deviations Log	occurrences of the deviation	LongText			
Protocol Deviations Log	Deviation reported by	Text			

Form Name	Item Text (Field Label)	Response Type(Control Type)	Response Options (Dictionary Items)	Help Text	External Review Comments
Protocol Deviations Y/N	Have any protocol deviations been reported?	RadioButton	Y=Yes; N=No		
Protocol Deviations Y/N	If "Yes", update the Protocol Deviations log.	Text			

		Response Type			External Review
Form Name	Item Text (Field Label)	(Control Type)	Response Options (Dictionary Items)	Help Text	Comments
Demographics	Date of birth	DateTime		·	
Demographics	Age	Text			
			M=Male		
Demographics	Sex at birth	RadioButton	F=Female		
			1=Hispanic or Latino		
Demographics	Ethnicity	RadioButton (Vertical)	2=Not Hispanic or Latino		
	Race				
Demographics	Mark all that apply.	Text			
Demographics	American Indian or Alaska Native	CheckBox			
Demographics	Asian	CheckBox			
Demographics	Black or African American	CheckBox			
Demographics	Native Hawaiian or other Pacific Islander	CheckBox			
Demographics	White	CheckBox			
Demographics	Other	CheckBox			
Demographics	If "Other", specify:	LongText			
Ŭ '	Gender	Ü			
Demographics	Mark all that apply.	Text			
Demographics	Male	CheckBox			
Demographics	Female	CheckBox			
Demographics	Transgender Male	CheckBox			
Demographics	Transgender Female	CheckBox			
Demographics	Gender Nonconforming/Gender Variant	CheckBox			
Demographics	Self-identify	CheckBox			
Demographics	If "Self-identify", specify:	LongText			
Demographics	Prefer not to answer	CheckBox			
			1=Gay/Lesbian/Homosexual		
			2=Bisexual		
			3=Queer		
			4=Two Spirit		
			5=Straight/Heterosexual		
			6=Additional category		
			7=Not sure		
Demographics	How do you identify your sexual orientation?	DropDownList	8=Prefer not to answer		
Demographics	If "Additional category", specify:	LongText			

Form Name	Item Text (Field Label)		Response Options (Dictionary Items)	External Review Comments
Vital Signs	Were vital signs done?	RadioButton	Y=Yes; N=No	
Vital Signs	Date of assessment	DateTime		
Vital Signs	Height	Text		
Vital Signs	Weight	Text		
Vital Signs	Body temperature	Text		
Vital Signs	Systolic blood pressure	Text		
Vital Signs	Diastolic blood pressure	Text		
Vital Signs	Pulse	Text		
Vital Signs	Rate of respiration	Text		

Form Name	Item Text (Field Label)		Response Options (Dictionary Items Help Text	External Review Comment
Physical Exam	Was a physical exam performed?		Y=Yes; N=No	
Physical Exam	Date of exam	DateTime		
Physical Exam	BODY SYSTEM	Text		
Physical Exam	HEENT	RadioButton	97=Not done; 2=Normal; 3=Abnormal	
Physical Exam	If "Abnormal", specify:	LongText		
Physical Exam	Neck	RadioButton	97=Not done; 2=Normal; 3=Abnormal	
Physical Exam	If "Abnormal", specify:	LongText		
Physical Exam	Lymph Nodes	RadioButton	97=Not done; 2=Normal; 3=Abnormal	
Physical Exam	If "Abnormal", specify:	LongText		
Physical Exam	Heart/Cardiovascular	RadioButton	97=Not done; 2=Normal; 3=Abnormal	
Physical Exam	If "Abnormal", specify:	LongText		
Physical Exam	Lung/Respiratory	RadioButton	97=Not done; 2=Normal; 3=Abnormal	
Physical Exam	If "Abnormal", specify:	LongText		
Physical Exam	Abdomen	RadioButton	97=Not done; 2=Normal; 3=Abnormal	
Physical Exam	If "Abnormal", specify:	LongText		
Physical Exam	Genitourinary	RadioButton	97=Not done; 2=Normal; 3=Abnormal	
Physical Exam	If "Abnormal", specify:	LongText		
Physical Exam	Extremities	RadioButton	97=Not done; 2=Normal; 3=Abnormal	
Physical Exam	If "Abnormal", specify:	LongText		
Physical Exam	Neurological	RadioButton	97=Not done; 2=Normal; 3=Abnormal	
Physical Exam	If "Abnormal", specify:	LongText		
Physical Exam	Skin	RadioButton	97=Not done; 2=Normal; 3=Abnormal	
Physical Exam	If "Abnormal", specify:	LongText		
Physical Exam	Oral Mucosa	RadioButton	97=Not done; 2=Normal; 3=Abnormal	
Physical Exam	If "Abnormal", specify:	LongText		
Physical Exam	General appearance	RadioButton	97=Not done; 2=Normal; 3=Abnormal	
Physical Exam	If "Abnormal", specify:	LongText		
Physical Exam	Other system finding	RadioButton	97=Not done; 2=Normal; 3=Abnormal	
Physical Exam	If "Other system finding", specify:	LongText		
Physical Exam	If "Abnormal", specify:	LongText		

		Response Type			
Form Name	Item Text (Field Label)	(Control Type)	Response Options (Dictionary Items)	Help Text	External Review Comments
Pregnancy Outcome Log	Is the outcome of this pregnancy obtainable? If "No", end of form.	RadioButton	Y=Yes; N=No		
Pregnancy Outcome Log	How many pregnancy outcomes resulted from this reported pregnancy?	Text	1=163, N=140		
Pregnancy Outcome Log	Outcome date	DateTime	4 Hamai		
			1=Home; 2=Hospital;		
			3=Clinic;		
			4=Unknown;		
Pregnancy Outcome Log Pregnancy Outcome Log	Place of delivery/outcome If "Other", specify:	DropdownList LongText	5=Other		
regnancy outcome Log	ii other japeery.	Longrenc			
			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);	If the pregnancy or outcome was associated	
	Specify outcome If "Stillbirth/intrauterine fetal demise", "Spontaneous abortion", "Ectopic pregnancy" or		4=Spontaneous abortion (less than 20 weeks); 5=Ectopic pregnancy;	with maternal complications or symptoms that would otherwise be reported as an AE,	
	"Therapeutic/elective abortion" is chosen, go to "Provide a brief narrative of the circumstances:". If		6=Therapeutic/elective abortion;	report these on the AE Log. Complete an EAE	
Pregnancy Outcome Log	"Full term live birth", go to "Method".	DropdownList	99=Other	reporting form, if applicable.	
Pregnancy Outcome Log	If "Other", specify:	LongText	A. C. continue		
			1=C-section; 2=Standard vaginal;		
	Method		3=Operative vaginal;		
Pregnancy Outcome Log	If "Full term live birth", go to "Were there any complications related to the pregnancy outcome?"	DropdownList	4=Vaginal		
Pregnancy Outcome Log	Provide a brief narrative of the circumstances (max. 400 characters). Were there any complications related to the pregnancy outcome?	LongText			
Pregnancy Outcome Log	If "No", skip to "Were any fetal/infant congenital anomalies identified?".	RadioButton	Y=Yes; N=No	<u> </u>	
	Delivery-related complications. Mark "None" or all that apply.				
	No.	Charles and			
Pregnancy Outcome Log Pregnancy Outcome Log	None Intrapartum hemorrhage	CheckBox CheckBox			
Pregnancy Outcome Log	Postpartum hemorrhage	CheckBox			
Pregnancy Outcome Log	Non-reassuring fetal status	CheckBox			
Pregnancy Outcome Log	Chorioamnionitis	CheckBox			
Pregnancy Outcome Log Pregnancy Outcome Log	Other If "Other", specify:	CheckBox LongText			
	Non-delivery related complications. Mark "None" or all that apply.				
	Name of the second seco	Classic Da			
Pregnancy Outcome Log Pregnancy Outcome Log	None Hypertensive disorders of pregnancy	CheckBox CheckBox			
Pregnancy Outcome Log	Gestational diabetes	CheckBox			
Pregnancy Outcome Log	Other	CheckBox			
Pregnancy Outcome Log	If "Other", specify:	LongText			
	Were any fetal/infant congenital anomalies identified? Mark all that apply.				
Pregnancy Outcome Log Pregnancy Outcome Log	If "No" or "Unknown", go to "Complete the infant items below for live births only." Central nervous system, cranio-facial	DropDownList CheckBox	Y=Yes; N=No; NS=Not assessed; UNK=Unknown		
Pregnancy Outcome Log	Central nervous system, clanic-lacial	CheckBox			
Pregnancy Outcome Log	Cardiovascular	CheckBox			
Pregnancy Outcome Log	Renal	CheckBox			
Pregnancy Outcome Log Pregnancy Outcome Log	Gastrointestinal Pulmonary	CheckBox CheckBox			
Pregnancy Outcome Log	Musculoskeletal/extremities	CheckBox			
Pregnancy Outcome Log	Physical defect	CheckBox			
Pregnancy Outcome Log	Skin Genitourinary	CheckBox CheckBox			
Pregnancy Outcome Log Pregnancy Outcome Log	Chromosomal	CheckBox			
Pregnancy Outcome Log	Cranio-facial (structural)	CheckBox			
Pregnancy Outcome Log	Hematologic	CheckBox			
Pregnancy Outcome Log	Infectious Endocrine/metabolic	CheckBox CheckBox			
Pregnancy Outcome Log Pregnancy Outcome Log	Other	CheckBox			
Pregnancy Outcome Log	Describe congenital anomaly/defect (max. 200 characters).	LongText			
	If "Yes", select adverse event. OR Specify congenital anomaly/defect AE.	D			
Pregnancy Outcome Log	Complete AE Log and EAE Reporting form. Complete the infant items below for live births only. Otherwise, end of form.	Dynamic SearchList		1	
Pregnancy Outcome Log	Infant sex	RadioButton	M=Male; F=Female		
	Infant birth weight				
Pregnancy Outcome Log	Or .	Text			
Pregnancy Outcome Log	Infant birth weight unavailable	CheckBox			
	Infant birth weight unit	Text			
	Infant birth length				
Pregnancy Outcome Log	Or .	Text			
Pregnancy Outcome Log	Infant birth length unavailable	CheckBox			
Pregnancy Outcome Log	Infant birth length unit	Text			
	Infant birth head circumference				
Pregnancy Outcome Log	Or .	Text			
Pregnancy Outcome Log	Infant birth head circumference unavailable	CheckBox			-
Pregnancy Outcome Log	Infant birth head circumference unit	Text			
	Infant birth abdominal circumference				
Pregnancy Outcome Log	Or .	Text		1	
Pregnancy Outcome Log	Infant birth abdominal circumference unavailable	CheckBox			-
Pregnancy Outcome Log Pregnancy Outcome Log	Infant birth abdominal circumference unit Infant gestational age by examination in weeks	Text			
Pregnancy Outcome Log Pregnancy Outcome Log	Infant gestational age by examination in weeks Infant gestational age by examination in weeks Unit	Text Text			
J ,	Infant gestational age by examination in days				
Pregnancy Outcome Log Pregnancy Outcome Log	Or Infant gestational age by examination in Days Unit	Text			
r regnancy Outcome Log	Infant gestational age by examination in Days Unit Infant gestational age by examination unavailable	Text			
Pregnancy Outcome Log	If unavailable, end of form.	CheckBox			
	lead to the terminal to the te	DropDownList	1=Ballard; 2=Dubowitz; 99=Other	1	·
Pregnancy Outcome Log Pregnancy Outcome Log	Method used to determine gestational age If "Other", specify (max. 200 characters):	LongText			

Form Name	Item Text (Field Label)	Response Type(Control Type)	Response Options (Dictionary Items)	Help Text	External Review Comments
Pregnancy Test Results	Was a pregnancy test done?	RadioButton	Y=Yes; N=No		
Pregnancy Test Results	Collection date	DateTime			
Pregnancy Test Results	Pregnancy test result	RadioButton	1=Positive; 2=Negative		

		Response Type (Control	Response Options		External Review
Form Name	Item Text (Field Label)	Type)	(Dictionary Items)	Help Text	Comments
Pregnancy History	Date pregnancy history collected	DateTime			
Pregnancy History	Has the participant ever been pregnant before?	RadioButton	Y=Yes; N=No		
Pregnancy History	If "No", end of form.	Text			
Pregnancy History	Number of full term live births (>=37 weeks)	Text			
Pregnancy History	Number of premature live births (Less than 37 weeks)	Text			
Pregnancy History	Number of spontaneous fetal deaths and/or still births (>=20 weeks)	Text			
Pregnancy History	Number of spontaneous abortions (Less than 20 weeks)	Text			
Pregnancy History	Number of therapeutic/elective abortions	Text			
Pregnancy History	Number of ectopic pregnancies	Text			
	Does the participant have a history of pregnancy complications or fetal/infant				
Pregnancy History	congenital anomalies?	RadioButton	Y=Yes; N=No		
Pregnancy History	If "Yes", specify (max. 200 characters):	LongText			

		Response Type			External Review
Form Name	Item Text (Field Label)	(Control Type)	Response Options (Dictionary Items)	Help Text	Comments
Pregnancy Report	Date pregnancy reported to site	DateTime			
			1=Screening		
			2=Enrollment		
			3=Visit 3		
			4=Visit 4		
			5=Visit 5		
			6=Visit 6		
			7=Visit 7		
			8=Visit 8		
			9=Visit 9		
			10=Visit 10		
			11=Visit 11/Final Contact		
Pregnancy Report	Visit at which this pregnancy was reported	DropDownList	12=Interim Visit		
Pregnancy Report	If "Interim visit", specify Interim visit code	Text			
Pregnancy Report	Date of onset of last menstrual period	DateTime			
Pregnancy Report	Or .	Text			
Pregnancy Report	Amenorrheic for past 6 months	CheckBox			
Pregnancy Report	Estimated date of delivery	DateTime			
			1=Last menstrual period;		
			2=Initial ultrasound <20 weeks;		
			3=Initial ultrasound >= 20 weeks;		
			4= Physical examination;		
			5=Conception date by assisted reproduction;		
Pregnancy Report	What primary information was used to estimate the date of delivery?	DropDownList	99=Other		
Pregnancy Report	If "Other", specify:	LongText			
		1			
Pregnancy Report	Is this the participant's first pregnancy since enrollment in this study?	RadioButton	Y=Yes; N=No		
Pregnancy Report	If "Yes", complete Pregnancy History form.	Text			

		Response Type			External Review
Form Name	Item Text (Field Label)	(Control Type)	Response Options (Dictionary Items)	Help Text	Comments
Anorectal Exam	Was anorectal exam done?	RadioButton	Y=Yes; N=No		
Anorectal Exam	Anorectal exam date	DateTime			
Anorectal Exam	PERIANAL EXAMINATION	Text			
			99=Not done; 2=No abnormal findings;		
Anorectal Exam	Perianal examination findings	DropDownList	3=Abnormal findings		
Anorectal Exam	If "Abnormal findings", select all that apply:	Text	5 Alementus miemęs		
Anorectal Exam	Warts	CheckBox			
Anorectal Exam	Fissure	CheckBox			
Anorectal Exam	Ulceration	CheckBox		-	
Anorectal Exam	Pigmentation	CheckBox			
Anorectal Exam	Hemorrhoids	CheckBox			
Anorectal Exam	Skin tags	CheckBox			
Anorectal Exam	Leukoplakia	CheckBox			
Anorectal Exam	Fistula	CheckBox			
Anorectal Exam	Petechiae (less than 3 mm)	CheckBox			
Anorectal Exam	Purpura (0.3 to 1 cm)	CheckBox			ļ
Anorectal Exam	Ecchymosis (greater than 1 cm)	CheckBox			
Anorectal Exam	Discharge	CheckBox			
Anorectal Exam	Erythema	CheckBox			
Anorectal Exam	Bleeding	CheckBox			
Anorectal Exam	Other abnormal findings	CheckBox			
Anorectal Exam	If "Other abnormal findings", specify:	LongText			
Anorectal Exam	DIGITAL RECTAL EXAMINATION	Text			
			99=Not done; 2=No abnormal findings;		
Anorectal Exam	Digital rectal examination findings	DropDownList	3=Abnormal findings		
Anorectal Exam	If "Abnormal findings", specify:	LongText	5 Alementus miemęs		
Anorectal Exam	ANOSCOPY	Text		-	
Allorectal Exam	ANOSCOFI	TEXT	99=Not done; 2=No abnormal findings;		
	Bootel access findings	December and int			
Anorectal Exam	Rectal mucosa findings	DropDownList	3=Abnormal findings		-
Anorectal Exam	If "Abnormal findings", select all that apply:	Text			
Anorectal Exam	Erythema	CheckBox			
Anorectal Exam	Abnormal vessels	CheckBox			
Anorectal Exam	Ulceration	CheckBox			
Anorectal Exam	Friability	CheckBox			
Anorectal Exam	Bleeding	CheckBox			
Anorectal Exam	Discharge	CheckBox			
Anorectal Exam	Polyps	CheckBox			
Anorectal Exam	Hemorrhoids	CheckBox			
Anorectal Exam	Other abnormal findings	CheckBox			
Anorectal Exam	If "Other abnormal findings", specify:	LongText			
Anorectal Exam	SIGMOIDOSCOPY	Text			
			99=Not done; 2=No abnormal findings;		
Anorectal Exam	Sigmoidoscopy findings	DropDownList	3=Abnormal findings		1
Anorectal Exam	If "Abnormal findings", select all that apply:	Text			1
Anorectal Exam	Erythema	CheckBox		-	
Anorectal Exam	Abnormal vessels	CheckBox		-	
			+	-	-
Anorectal Exam	Ulceration	CheckBox		-	-
Anorectal Exam	Friability	CheckBox			_
Anorectal Exam	Bleeding	CheckBox			.
Anorectal Exam	Discharge	CheckBox			-
Anorectal Exam	Polyps	CheckBox			
Anorectal Exam	Hemorrhoids	CheckBox			ļ
Anorectal Exam	Other abnormal findings	CheckBox			
Anorectal Exam	If "Other abnormal findings", specify:	LongText			
Anorectal Exam	Were any new anorectal AE findings reported at this visit?	RadioButton	Y=Yes; N=No		1
Anorectal Exam	Adverse event #1	Dynamic SearchList			
Allorectal Exam			<u> </u>	_	i .
Anorectal Exam	Adverse event #2	Dynamic SearchList			

		1			
F NI	15 T (Field teles)	Response Type	Barrer (Birtianan Itana)	Hala Tara	External Review
Form Name	Item Text (Field Label)	(Control Type)	Response Options (Dictionary Items)	Help Text	Comments
			99=Not done; 2=No abnormal findings;		
Pelvic Exam	Pelvic exam assessment	DropDownList	3=Abnormal findings		
Pelvic Exam	Pelvic exam date	DateTime			
Pelvic Exam	If "Abnormal findings", select all that apply:	Text			
Pelvic Exam	VULVAR	Text			
Pelvic Exam	Vulvar edema	CheckBox			
Pelvic Exam	Vulvar erythema	CheckBox			
Pelvic Exam	Vulvar rash	CheckBox			
Pelvic Exam	Vulvar tenderness	CheckBox			
Pelvic Exam	Bartholin's or Skene's gland abnormality	CheckBox			
Pelvic Exam	Vulvar ulcer	CheckBox			
Pelvic Exam	Vulvar blister	CheckBox			
Pelvic Exam	Vulvar pustule	CheckBox			
Pelvic Exam	Vulvar peeling	CheckBox			
Pelvic Exam	Vulvar ecchymosis	CheckBox			
Pelvic Exam	VAGINAL	Text			
Pelvic Exam	Vaginal edema	CheckBox			
Pelvic Exam	Vaginal erythema	CheckBox			
Pelvic Exam	Vaginal masses (polyps, myomas, possible malignancy)	CheckBox			
Pelvic Exam	Vaginal abrasions or lacerations	CheckBox		1	
Pelvic Exam	Vaginal tenderness	CheckBox	<u> </u>	1	
Pelvic Exam	Vaginal ulcer	CheckBox		+	
Pelvic Exam	Vaginal dicer	CheckBox		+	
Pelvic Exam	Vaginal dister				
		CheckBox			
Pelvic Exam	Vaginal peeling	CheckBox		-	
Pelvic Exam	Vaginal ecchymosis	CheckBox		-	
Pelvic Exam	Abnormal vaginal discharge	DropDownList	1=Slight; 2=Moderate; 3=Pooling		
Pelvic Exam	CERVICAL	Text			
Pelvic Exam	Cervical edema and/or friability	CheckBox			
Pelvic Exam	Cervical erythema	CheckBox			
Pelvic Exam	Cervical masses (polyps, myomas, possible malignancy)	CheckBox			
Pelvic Exam	Cervical motion tenderness	CheckBox			
Pelvic Exam	Cervical discharge	CheckBox			
Pelvic Exam	Cervical ulcer	CheckBox			
Pelvic Exam	Cervical blister	CheckBox			
Pelvic Exam	Cervical pustule	CheckBox			
Pelvic Exam	Cervical peeling	CheckBox			
Pelvic Exam	Cervical ecchymosis	CheckBox			
Pelvic Exam	GENERAL/OTHER	Text			
Pelvic Exam	Odor (vaginal)	CheckBox			
Pelvic Exam	Condyloma	CheckBox			
Pelvic Exam	If "Condyloma", specify location:	LongText			
I CIVIC EXAIII	in condytonia , specify location.	Longrext			
Pelvic Exam	Adnexal masses (based on bimanual exam; not pregnancy or infection-related)	CheckBox			
Pelvic Exam	Uterine masses (based on bimanual exam; not pregnancy of infection-related)	CheckBox		+	
Pelvic Exam	Uterine tenderness		+	+	
		CheckBox			
Pelvic Exam	Adnexal tenderness	CheckBox		1	
Pelvic Exam	Abnormal blood or bleeding	CheckBox		+	
Pelvic Exam	If "Abnormal blood or bleeding", specify:	LongText		-	
Pelvic Exam	Other abnormal findings	CheckBox		1	
Pelvic Exam	If "Other abnormal findings", specify:	LongText		ļ	
Pelvic Exam	If "Other abnormal findings", specify anatomical location:	LongText			
	Complete or update Baseline Medical Conditions Log or Adverse Event Log, as				
Pelvic Exam	applicable.	Text			
Pelvic Exam	Were any new pelvic finding AEs reported at this visit?	RadioButton	Y=Yes; N=No		
Pelvic Exam	Adverse event #1	Dynamic SearchList			
Pelvic Exam	Adverse event #2	Dynamic SearchList			
Pelvic Exam	Adverse event #3	Dynamic SearchList			
		1	1=0%		
			2=1-25%		
			3=26-50%		
			4=51-75%		
			5=76-100%		
Dobile Fire	Comingliantany (0/)	DranDavinList			
Pelvic Exam	Cervical ectopy (%)	DropDownList	99=Not done	1	<u> </u>

Form Name			Response Options (Dictionary Items)	Help Text	External Review Comments
	Does the participant have any clinical		Yes		
Product Hold Summary	product holds to be applied?	RadioButton	No		
Product Hold Summary	If Yes, complete the Product Hold form	Text			

		Response Type	Response Options (Dictionary		External Review
Form Name	Item Text (Field Label)	(Control Type)	Items)	Help Text	Comments
	Date when study product hold	,,,,,			
Product Hold Log	was intiated:	DateTime	NA		
			1=Reactive rapid HIV test		
			2=Adverse Event		
			3=Reported use of PEP or PrEP		
			4=Pregnancy		
			5=Breastfeeding		
			6=Participant unable/unwilling		
			to comply with the required		
			study procedures, or		
			otherwise might be put at		
			undue risk to their safety and		
			well-being by continuing		
			product use according to the		
			judgment of loR/designee		
	Why is study product being		99=Other		
Product Hold Log	held?	RadioButton			
Product Hold Log	Other, specify:	LongText	NA		
Product Hold Log	Adverse Event:	DynamicSearchList	NA		
Product Hold Log	Concomitant Medication:	DynamicSearchList	NA		
Product Hold Log	Concomitant Medication:	DynamicSearchList	NA		
Product Hold Log	Concomitant Medication:	DynamicSearchList	NA		
Product Hold Log	Concomitant Medication:	DynamicSearchList	NA		
Product Hold Log	Date of last study product use:	DateTime	NA		
	Was the participant instructed				
	to resume study product use?		1=Yes		
			2=No - Hold continuing for		
	If 'no - permanently		another reason		
	discontinued', 'no - early		3=No - Early termination		
	termination' or 'no - hold		4=No - Hold continuing at		
	continuing at scheduled		scheduled PUEV		
	PUEV', complete the Product		5=No - Permanently		
Product Hold Log	Discontinuation form.	DropDown	discontinued		
Product Hold Log	Date study product resumed	DateTime			
	Date study product hold				
Product Hold Log	continuing for another reason	DateTime			

		Response Type	Response Options		
Form Name	Item Text (Field Label)	(Control Type)	(Dictionary Items)	Help Text	External Review Comments
	toon ten (title end of)	(com or type)	(Exercise)		
	Was a pharyngeal sample collected for N.				
STI Tests	gonorrhea and C. trachomatis testing?	RadioButton	Yes N o		
STI Tests	Collection date	DateTime			
STI Tests	N. gonorrhea - Pharyngeal test result	RadioButton	1=Positive; 2=Negative		
STI Tests	C. trachomatis - Pharyngeal test result	RadioButton	1=Positive; 2=Negative		
	Was a pelvic sample collected for N.		, ,		
	gonorrhea, C. trachomatis, and				
STI Tests	trichomonas vaginalis testing?	RadioButton	YesNo		
STI Tests	Collection date	DateTime			
STI Tests	N. gonorrhea - Pelvic test result	RadioButton	1=Positive; 2=Negative		
STI Tests	C. trachomatis - Pelvic test result	RadioButton	1=Positive; 2=Negative		
STI Tests	trichomonas vaginalis - Pelvic test result	RadioButton	1=Positive; 2=Negative		
STI Tests	Was a sample collected for Syphilis testing?	RadioButton	YesNo		
STI Tests	Collection date	DateTime			
			1=Non-reactive		
			2=Reactive		
STI Tests	Syphilis screening test	RadioButton (Horiz	3=Not reported		
STI Tests	Syphilis titer	Text			
			1=Postive		
			2=Negative		
			3=Indeterminate		
STI Tests	Syphilis confirmatory test	DropDownList	4=Not done		
	Was a urine sample collected for N.				
STI Tests	gonorrhea and C. trachomatis testing?	RadioButton	YesNo		
STI Tests	Collection date	DateTime			
STI Tests	N. gonorrhea - URINE test result	RadioButton	1=Positive; 2=Negative		
STI Tests	C. trachomatis - URINE test result	RadioButton	1=Positive; 2=Negative		
	Was a rectal swab sample collected for N.				
STI Tests	gonorrhea and C. trachomatis testing?	RadioButton	YesNo		
STI Tests	Collection date	DateTime			
STI Tests	N. gonorrhea - RECTAL SWAB test result	RadioButton	1=Positive; 2=Negative		
STI Tests	C. trachomatis - RECTAL SWAB test result	RadioButton	1=Positive; 2=Negative		
	Was the participant diagnosed with				
STI Tests	asymptomatic BV?	RadioButton	Yes⊠o		
	Was the participant diagnosed with				
STI Tests	asymptomatic candida?	RadioButton	YesNo		

			Response Options		
Form Name	Item Text (Field Label)	Response Type(Control Type)	(Dictionary Items)	Help Text	External Review Comments
Chemistry Panel	Was a sample collected for serum chemistries?	RadioButton	Y=Yes; N=No	neip rext	Execute Neview Comments
Chemistry Panel	Specimen collection date	DateTime	. 103,11 110		
Chemistry Panel	LIVER FUNCTION TESTS	Text			
Chemistry Panel	AST (SGOT) result	Text			
enemotry runer	not focoty result	Text	1=Grade 1 (Mild); 2=Grade		
			2 (Moderate); 3=Grade 3		
			(Severe); 4=Grade 4		
			(Potentially life-		
			threatening); 95=Not		
Chemistry Panel	AST (SGOT) severity grade	DropDownList	gradable		
chemistry runer	The food of several grade	Diopowness	1=Grade 1 (Mild); 2=Grade		
			2 (Moderate); 3=Grade 3		
			(Severe); 4=Grade 4		
			(Potentially life-		
			threatening); 95=Not		
Chemistry Panel	AST (SGOT) severity grade - calculated	DropDownList	gradable		
Chemistry Panel	AST (SGOT) seventy grade - calculated AST (SGOT) adverse event	Dynamic SearchList	gradable	1	
Chemistry Panel	Not reportable as an adverse event	CheckBox			
Chemistry Panel	ALT (SGPT) result	Text		1	
Chemistry Paner	ALI (3GFI) Tesuit	Text	1=Grade 1 (Mild); 2=Grade		
				=	
			2 (Moderate); 3=Grade 3		
			(Severe); 4=Grade 4		
			(Potentially life-		
			threatening); 95=Not		
Chemistry Panel	ALT (SGPT) severity grade	DropDownList	gradable		
			1=Grade 1 (Mild); 2=Grade	2	
			2 (Moderate); 3=Grade 3		
			(Severe); 4=Grade 4		
			(Potentially life-		
			threatening); 95=Not		
Chemistry Panel	ALT (SGPT) severity grade - calculated	DropDownList	gradable		
Chemistry Panel	ALT (SGPT) adverse event	Dynamic SearchList			
Chemistry Panel	Not reportable as an adverse event	CheckBox			
Chemistry Panel	RENAL FUNCTION TESTS	Text			
Chemistry Panel	Creatinine result	Text			
			1=Grade 1 (Mild); 2=Grade	2	
			2 (Moderate); 3=Grade 3		
			(Severe); 4=Grade 4		
			(Potentially life-		
			threatening); 95=Not		
Chemistry Panel	Creatinine severity grade	DropDownList	gradable		
			1=Grade 1 (Mild); 2=Grade	2	
			2 (Moderate); 3=Grade 3		
			(Severe); 4=Grade 4		
			(Potentially life-		
			threatening); 95=Not		
Chemistry Panel	Creatinine severity grade - calculated	DropDownList	gradable		
Chemistry Panel	Creatinine adverse event	Dynamic SearchList			
Chemistry Panel	Not reportable as an adverse event	CheckBox			
Chemistry Panel	Comments (max. 200 characters):	LongText			

Form Name	Item Text (Field Label)	Response Type (Control Type)	Response Options (Dictionary Items)	Help Text	External Review Comments
Hematology	HEMOGRAM	Text	, , , , , , , , , , , , , , , , , , , ,		
Hematology	Was a hematology sample collected?	RadioButton	Y=Yes; N=No		
Hematology	Hematology collection date⊠	DateTime			
Hematology	Hemoglobin	Text			
, , , , , , , , , , , , , , , , , , ,	•				
			1=Grade 1 (Mild); 2=Grade 2 (Moderate);		
			3=Grade 3 (Severe); 4=Grade 4 (Potentially		
Hematology	Hemoglobin severity grade	DropDownList	life-threatening); 95=Not gradable		
			1=Grade 1 (Mild); 2=Grade 2 (Moderate);		
			3=Grade 3 (Severe); 4=Grade 4 (Potentially		
Hematology	Hemoglobin severity grade - calculated	DropDownList	life-threatening); 95=Not gradable		
Hematology	Hemoglobin adverse event, if applicable	Dynamic SearchList			
Hematology	Not reportable as an adverse event	CheckBox			
Hematology	Hematocrit	Text			
Hematology	MCV	Text			
Hematology	Platelets	Text			
			1=Grade 1 (Mild); 2=Grade 2 (Moderate);		
	Black and		3=Grade 3 (Severe); 4=Grade 4 (Potentially		
Hematology	Platelets severity grade	DropDownList	life-threatening); 95=Not gradable		
			1=Crodo 1 (Mild), 2=C1-2 (Mi-1-1-1)		
			1=Grade 1 (Mild); 2=Grade 2 (Moderate);		
	Districts and a selection	Dana Danisalist	3=Grade 3 (Severe); 4=Grade 4 (Potentially		
Hematology	Platelets severity grade - calculated	DropDownList	life-threatening); 95=Not gradable		
Hematology Hematology	Platelets adverse event, if applicable Not reportable as an adverse event	Dynamic SearchList			
Hematology	WBC	CheckBox Text			
nematology	WBC	Text			
			1=Grade 1 (Mild); 2=Grade 2 (Moderate);		
			3=Grade 3 (Severe); 4=Grade 4 (Potentially		
Hematology	WBC severity grade	DropDownList	life-threatening); 95=Not gradable		
ricinatology	w be severity grade	ргорожных	inc threatening, 33 Not graduate		
			1=Grade 1 (Mild); 2=Grade 2 (Moderate);		
			3=Grade 3 (Severe); 4=Grade 4 (Potentially		
Hematology	WBC severity grade - calculated	DropDownList	life-threatening); 95=Not gradable		
Hematology	WBC adverse event, if applicable	Dynamic SearchList			
Hematology	Not reportable as an adverse event	CheckBox			
Hematology	DIFFERENTIAL	Text			
Hematology	Was a differential done?	RadioButton	Y=Yes; N=No		
Hematology	Differential collection date®	DateTime			
Hematology	Neutrophils	Text			
			1=Grade 1 (Mild); 2=Grade 2 (Moderate);		
			3=Grade 3 (Severe); 4=Grade 4 (Potentially		
Hematology	Neutrophils severity grade	DropDownList	life-threatening); 95=Not gradable		
			1=Grade 1 (Mild); 2=Grade 2 (Moderate);		
[L	3=Grade 3 (Severe); 4=Grade 4 (Potentially		
Hematology	Neutrophils severity grade - calculated	DropDownList	life-threatening); 95=Not gradable		
Hematology	Neutrophils adverse event, if applicable	Dynamic SearchList			
Hematology	Not reportable as an adverse event	CheckBox			
Hematology	Lymphocytes	Text			
			1=Grade 1 (Mild); 2=Grade 2 (Moderate);		
			3=Grade 3 (Severe); 4=Grade 4 (Potentially		
Hematology	Lymphocytes severity grade	DropDownList	life-threatening); 95=Not gradable		
cmatology	cymphocytes severity grade	o.opsownest	catelling), 55-140t grauable		
			1=Grade 1 (Mild); 2=Grade 2 (Moderate);		
			3=Grade 3 (Severe); 4=Grade 4 (Potentially		
Hematology	Lymphocytes severity grade - calculated	DropDownList	life-threatening); 95=Not gradable		
Hematology	Lymphocytes adverse event, if applicable	Dynamic SearchList			
Hematology	Not reportable as an adverse event	CheckBox			
Hematology	Monocytes	Text			
Hematology	Eosinophils	Text			
Hematology	Basophils	Text			
Hematology	Comments (max. 200 characters):	LongText			
	,				

Form Name	Item Text (Field Label)	Response Type (Control Type)	Response Options (Dictionary Items)	Help Text	External Review Comments
HIV Test Results	Rapid HIV test 1	Text			
			Yes		
HIV Test Results	Was Rapid HIV test sample 1 collected for testing?	RadioButton	No		
HIV Test Results	If "No", skip to Rapid HIV test 2.				
			1=AlereTM HIV Combo 2=Oraquick ADVANCE HIV-1/2		
			3=Uni-Gold Recombigen HIV-		
			1/2		
			4=Alere Determine		
HIV Test Results	Rapid HIV test 1 Kit	DropDownList	5=Other		
HIV Test Results	If "Other", specify:	LongText			
HIV Test Results	Rapid HIV test 1 collection date	DateTime			
				If antibody	
				positive, antigen positive, or	
			1=Antibody positive	antibody and	
			2=Antigen positive	antigen positive,	
			3=Antibody and antigen positive		
HIV Test Results	Rapid HIV test 1	DropDownList	4=Negative	Hold form.	
HIV Test Results	Rapid HIV test 2	Text	4-regative	11010 101111.	
		1	Yes		
HIV Test Results	Was Rapid HIV test sample 2 collected for testing?	RadioButton	No		
HIV Test Results	If "No", end of form.				
			1=AlereTM HIV Combo		
			2=Oraquick ADVANCE HIV-1/2		
			3=Uni-Gold Recombigen HIV-		
			1/2		
			4=Alere Determine		
HIV Test Results	Rapid HIV test 2 Kit	DropDownList	5=Other		
HIV Test Results	If "Other", specify:	LongText			
HIV Test Results	Rapid HIV test 2 collection date	DateTime	NA		
				If antibody	
				positive, antigen	
				positive, or	
			1=Antibody positive	antibody and	
			2=Antigen positive	antigen positive,	
			3=Antibody and antigen positive		
HIV Test Results	Rapid HIV test 2	DropDownList	4=Negative	Hold form.	
	If at least one Rapid HIV tests is positive, complete				
HIV Test Results	the HIV Confirmatory Test Result form.	Text			

Form Name	Item Text (Field Label)	Response Type(Control Type)	Response Options (Dictionary Items)	Help Text	External Review Comments
HIV Confirmatory Results	ABSOLUTE CD4+	Text			
HIV Confirmatory Results	Were Absolute CD4+ collected for testing?	RadioButton	Y=Yes; N=No		İ
HIV Confirmatory Results	Specimen collection date	DateTime			İ
HIV Confirmatory Results	Absolute CD4+	Text			
HIV Confirmatory Results	Absolute CD4+ unit	Text			İ
HIV Confirmatory Results	Unable to analyze	CheckBox			
HIV Confirmatory Results	CD4 %	Text			
HIV Confirmatory Results	Specimen collection date	DateTime			
HIV Confirmatory Results	CD4 %	Text			
HIV Confirmatory Results	CD4 % unit	Text			
HIV Confirmatory Results	Unable to analyze	CheckBox			
HIV Confirmatory Results	T CELL SUBSETS	Text			
HIV Confirmatory Results	Were T Cell Subsets collected for testing?	RadioButton	Y=Yes; N=No		
HIV Confirmatory Results	If "No", go to "HIV RNA".	Text			
HIV Confirmatory Results	Specimen collection date	DateTime			
HIV Confirmatory Results	T Cell subsets	RadioButton	1=Positive; 2=Negative		
HIV Confirmatory Results	HIV RNA	Text			
HIV Confirmatory Results	Was HIV RNA PCR testing completed?	RadioButton	Y=Yes; N=No		
HIV Confirmatory Results	Specimen collection date	DateTime			
HIV Confirmatory Results	Operator	RadioButton	1=>; 2=<; 3==		
HIV Confirmatory Results	HIV RNA PCR	Text			
HIV Confirmatory Results	HIV RNA PCR unit	Text			
HIV Confirmatory Results	HIV RNA PCR target not detected	CheckBox			
HIV Confirmatory Results	HIV RNA PCR kit	DropDownList	Depends on the PCR Kit		
HIV Confirmatory Results	HIV RNA PCR kit lower limit of detection	RadioButton	Depends on the PCR Kit		
HIV Confirmatory Results	HIV RNA PCR kit lower limit of detection text	Text			
HIV Confirmatory Results	HIV RNA PCR kit lower limit of detection unit	Text			
HIV Confirmatory Results	GEENIUS HIV-1/2 CONFIRMATORY TEST	Text			
HIV Confirmatory Results	Was Geenius HIV-1/2 confirmatory test collected for testing?	RadioButton	Y=Yes; N=No		
HIV Confirmatory Results	Specimen collection date	DateTime			
			1=HIV negative;		
			2=HIV-1 indeterminate;		
			3=HIV-2 indeterminate;		
ĺ			4=HIV-1 positive;		
			5=HIV-2 positive;		
			6=HIV-2 positive with HIV-1 cross-reactivity;		
HIV Confirmatory Results	Geenius HIV-1/2 result	DropDownList	7=HIV positive undifferentiatied (untypeable)		
HIV Confirmatory Results	Final HIV status	DropDownList	1=HIV uninfected; 2=HIV infected; 3=Pending		

		Response Type			
Form Name	Item Text (Field Label)	(Control Type)	Response Options (Dictionary Items)	Help Text	External Review Comments
			2=Blood for PK;		
			3=Blood for PK - 1 hr;		
			4=Blood for PK - 2 hrs;		
			5=Blood for PK - 4 hrs;		
			6=Blood for PK - 6 hrs;		
			7=CVF for PK;		
			8=CVF for PK - 2 hrs;		
			9=CVF for PK - 4 hrs;		
			10=CVF for PK - 6 hrs;		
			11=CVF for PD;		
			12=CVF for PD - 2 hrs;		
			13=CVF for microflora;		
			14=CVF for microflora - 2 hrs;		
			15=Rectal fluid for PK;		
			16=Rectal fluid for PK - 2 hrs;		
			17=Rectal fluid for PK - 4 hrs;		
			18=Rectal fluid for PK - 6 hrs;		
			19=Rectal fluid for PD;		
			20=Rectal fluid for PD - 2 hrs;		
			21=Rectal fluid for microbiome;		
			22=Rectal fluid for microbiome - 2 hrs;		
			23=Rectal enema prior to biopsy collection;		
			24=Rectal tissue for PK;		
			25=Rectal tissue for PK - 2 hrs;		
			26=Rectal tissue for PD;		
			27=Rectal tissue for PD - 2 hrs;		
Specimen Collection and Storage	Specimen type	DropDown List	28=Rectal tissue for biomarkers;		
Specimen Collection and Storage	Was specimen collected?	RadioButton	Y=Yes; N=No		
	If "No", record reason why sample was				
Specimen Collection and Storage	not collected (max. 200 characters).	LongText			
Specimen Collection and Storage	Specimen collection date	DateTime			
Specimen Collection and Storage	Specimen collection time	DateTime			
Specimen Collection and Storage	Was sample stored?	RadioButton	1=Stored; 2=Not stored		
	If "No", record reason why sample was				
Specimen Collection and Storage	not stored (max. 200 characters).	LongText			

		Response Type			
Form Name	Item Text (Field Label)	(Control Type)	Response Options (Dictionary Items)	Heln Text	External Review Comments
Torm Nume	Text (Field Edder)	(control type)	, , , , , , , ,	ricip rext	External Review Comments
			1=Plasma for archive;		
			2=Blood for PK;		
			3=Blood for PK - 1 hr;		
			4=Blood for PK - 2 hrs;		
			5=Blood for PK - 4 hrs;		
			6=Blood for PK - 6 hrs;		
			7=CVF for PK;		
			8=CVF for PK - 2 hrs;		
			9=CVF for PK - 6 hrs;		
			10=CVF for PD;		
			11=CVF for PD - 2 hrs;		
			12=CVF for microflora;		
			13=CVF for microflora - 2 hrs;		
			14=Rectal fluid for PK;		
			15=Rectal fluid for PK - 2 hrs;		
			16=Rectal fluid for PK - 6 hrs;		
			17=Rectal fluid for PD;		
			18=Rectal fluid for PD - 2 hrs;		
			19=Rectal fluid for microbiome;		
			20=Rectal fluid for microbiome - 2 hrs;		
			21=Rectal enema prior to biopsy collection;		
			22=Rectal tissue for PK;		
			23=Rectal tissue for PK - 2 hrs;		
			24=Rectal tissue for PD;		
			25=Rectal tissue for PD - 2 hrs;		
Specimen Collection and Storage			26=Rectal tissue for biomarkers;		
(Group 1)	Specimen type	DropDown List	27=Rectal tissue for biomarkers - 2 hrs		
Specimen Collection and Storage	зресппен туре	DIOPDOWILLIST	27-Rectal tissue for biofilarkers - 2 fils		
(Group 1)	Was specimen collected?	RadioButton	V-Voc: N-No		
(Group 1)	was specimen collected?	RadioButton	Y=Yes; N=No		
Consistent Callestian and Staves	If "No", record reason why sample was				
Specimen Collection and Storage					
(Group 1)	not collected (max. 200 characters).	LongText			
Specimen Collection and Storage	Consider a collection data	Data Time			
(Group 1)	Specimen collection date	DateTime			
Specimen Collection and Storage					
(Group 1)	Specimen collection time	DateTime			
Specimen Collection and Storage	L				
(Group 1)	Was sample stored?	RadioButton	1=Stored; 2=Not stored		
Specimen Collection and Storage	If "No", record reason why sample was				
(Group 1)	not stored (max. 200 characters).	LongText			

		Response Type			
Form Name	Item Text (Field Label)	(Control Type)	Response Options (Dictionary Items)	Help Text	External Review Comments
			1=Plasma for archive;		
			2=Blood for PK;		
			3=Blood for PK - 1 hr;		
I			4=Blood for PK - 2 hrs;		
I			5=Blood for PK - 4 hrs;		
I			6=Blood for PK - 6 hrs;		
I			7=CVF for PK;		
I			8=CVF for PK - 4 hrs;		
			9=CVF for PD;		
			10=CVF for microflora;		
			11=Rectal fluid for PK;		
			12=Rectal fluid for PK - 4 hrs;		
			13=Rectal fluid for PD;		
			14=Rectal fluid for microbiome;		
			15=Rectal enema prior to biopsy collection;		
			16=Rectal tissue for PK;		
			17=Rectal tissue for PD;		
Specimen Collection and Storage	Specimen type	DropDown List	18=Rectal tissue for biomarkers;		
Specimen Collection and Storage	Was specimen collected?	RadioButton	Y=Yes; N=No		
	If "No", record reason why sample was				
Specimen Collection and Storage	not collected (max. 200 characters).	LongText			
Specimen Collection and Storage	Specimen collection date	DateTime			
Specimen Collection and Storage	Specimen collection time	DateTime			
Specimen Collection and Storage	Was sample stored?	RadioButton	1=Stored; 2=Not stored		
	If "No", record reason why sample was				
Specimen Collection and Storage	not stored (max. 200 characters).	LongText			

		Response Type	Response Options		External Review
Form Name	Item Text (Field Label)	(Control Type)	(Dictionary Items)	Help Text	Comments
Inclusion Exclusion					
Criteria	Did the participant meet all eligibility criteria?	RadioButton	Y=Yes; N=No		
			1=Eligible and enrolled		
			2=Eligible/Not enrolled		
Inclusion Exclusion			3=Ineligible		
Criteria	Eligibility status	DropDownList	4=Incomplete screening		
Inclusion Exclusion	If "Eligible and enrolled", or "Incomplete screening", end of				
Criteria	form.	Text			
Inclusion Exclusion			See data dictionary tab (study		
Criteria	Select reason(s) why participant is ineligible.	DropDownList	build specific)		
Inclusion Exclusion					
Criteria	If "Investigator decision", specify (max. 200 characters):	LongText			
Inclusion Exclusion					
Criteria	If eligible, but participant declined enrollment, specify reason:	LongText			

		Response Type	Response Options		
Form Name	Item Text (Field Label)	(Control Type)	(Dictionary Items)	Help Text	External Review Comments
	Date the participant marked or signed the				
Enrollment	study screening and enrollment consent form	DateTime			
	Did the participant consent to long-term		Yes		
Enrollment	specimen storage and future testing?	RadioButton	No		
			1=Group 1		
Enrollment	Sample Collection Schedule Assignment	RadioButton	2=Group 2		
	Is this a replacement participant?	RadioButton	Yes		
Enrollment			No		
Enrollment	PTID of participant being replaced	Text	NA		

	Item Text	Response Type	Response Options		External Review
Form Name	(Field Label)	(Control Type)	(Dictionary Items)	Help Text	Comments
	Screening visit				
Screening Date of Visit	date	DateTime	NA		

		Response Type	Response Options		
Form Name	Item Text (Field Label)	(Control Type)	(Dictionary Items)	Help Text	External Review Comments
Randomization	Is the participant ready to be randomized?	RadioButton	Y=Yes; N=No		
Randomization	Randomization date and time	DateTime			
Randomization	Randomization date	DateTime			
Randomization	Randomization ID	Text			
Randomization	Regime name	Text			
Randomization	Regime ratio	Text			
Randomization	Stratum name	Text			
Randomization	Blinded	Text			
Randomization	TSDV hidden variable	Text			

		•	Response Options		
Form Name	Item Text (Field Label)	(Control Type)	(Dictionary Items)	Help Text	External Review Comments
	Did the participant		Yes		
Follow-up Visit Y/N	complete this visit?	RadioButton	No		

		Response Type	Response Options		
Form Name	Item Text (Field Label)	(Control Type)	(Dictionary Items)	Help Text	External Review Comments
Follow-up Visit Summa	Visit date:	DateTime			
	Was this a PK/PD Sampling		Yes		
Follow-up Visit Summa	Visit?	RadioButton	No		
	Was study product				
	permanently discontinued				
	(scheduled or early) at this		Yes		
Follow-up Visit Summa	•	RadioButton	No		
·	Did the participant				
	exit/terminate the study at		Yes		
Follow-up Visit Summa	this visit?	RadioButton	No		
	Were any new adverse				
	events (AEs) reported at this		Yes		
Follow-up Visit Summa	visit?	RadioButton	No		
	Is the participant taking any				
	concomitant medications				
	that have not been		Yes		
Follow-up Visit Summa	previously reported?	RadioButton	No		
·	Have any protocol				
	deviations been reported at		Yes		
Follow-up Visit Summa	this visit?	RadioButton	No		
	Were any additional study				
	procedures or forms				
	completed outside of the				
	scheduled study visit per		Yes		
Follow-up Visit Summa	protocol?	RadioButton	No		

		Response Type	Response Options		External Review
Form Name	Item Text (Field Label)	(Control Type)	(Dictionary Items)	Help Text	Comments
Interim Visit Summary	Visit date	DateTime	(Dictionally Items)	Help Text	Comments
Interim Visit Summary		Text			
internii visit summary	interim visit code	TEXT	<u> </u>		
	NA/a a atoudo a mando atoua a a a mando a a atou				
	Was study product use permanently discontinued		Yes		
lasta viva Minit Cooperan		Dadia Dustana			
Interim Visit Summary	(scheduled or early) at this visit?	RadioButton	No	_	
	Bid the condition of a fifth control				
	Did the participant exit/terminate		Yes		
Interim Visit Summary		RadioButton	No		
	Were any new adverse events (AEs)		Yes		
Interim Visit Summary	reported at this visit?	RadioButton	No		
	Is the participant taking any				
	concomitant medications that have		Yes		
Interim Visit Summary	not been previously reported?	RadioButton	No		
	Have any protocol deviations been		Yes		
Interim Visit Summary	reported at this visit?	RadioButton	No		
	Reason for interim visit (Select all				
Interim Visit Summary	that apply.)	Text			
Interim Visit Summary	AE report or follow-up	CheckBox			
	Completion of missed visit				
Interim Visit Summary	procedures	CheckBox			
			1=Visit 3		
			2=Visit 4		
			3=Visit 5		
			4=Visit 6		
			5=Visit 7		
			6=Visit 8		
			7=Visit 9		
	If completion of missed visit		8=Visit 10		
	procedures, for which visit are		9=Visit 11/Final Contact		
Interim Visit Summary		DropDownList	10=Interim Visit		
Interim Visit Summary		CheckBox	20 meenm visie		
	1	LongText			
	What study procedures were				
	completed at this visit? Select all				
Interim Visit Summary	'	Text			
Interim Visit Summary	Vital signs	CheckBox		+	
Interim Visit Summary	·	CheckBox		+	
Interim Visit Summary	Pelvic exam	CheckBox		+	
Interim Visit Summary	Anorectal exam	CheckBox		-	
micerini visit sumillaly	Anorectal exam	CITCORDOX			
Intorim Visit Summer:	Specimen Collection and Store-	ChackBoy			
	Specimen Collection and Storage	CheckBox CheckBox			
Interim Visit Summary					
Interim Visit Summary	<u>. </u>	CheckBox			
· · · · · · · · · · · · · · · · · · ·		CheckBox			
Interim Visit Summary		CheckBox			
		CheckBox		-	
,		CheckBox		-	
Interim Visit Summary	Participant Replacement	Checkbox			1

		Response			
		Type (Control	Response Options		External Review
Form Name	Item Text (Field Label)	Type)	(Dictionary Items)	Help Text	Comments
Additional Study Procedures	Anorectal Exam	Checkbox			
Additional Study Procedures	Behavioral Assessment	Checkbox			
Additional Study Procedures	CASI Tracking	Checkbox			
Additional Study Procedures	Chemistry Panel	Checkbox			
Additional Study Procedures	Demographics	Checkbox			
Additional Study Procedures	Hematology	Checkbox			
Additional Study Procedures	HIV Confirmatory Results	Checkbox			
Additional Study Procedures	Pelvic Exam	Checkbox			
Additional Study Procedures	Physical Examination	Checkbox			
Additional Study Procedures	Pregnancy Test Results	Checkbox			
	Specimen Collection and				
Additional Study Procedures	Storage	Checkbox			
Additional Study Procedures	STI Tests	Checkbox			
Additional Study Procedures	Vital Signs	Checkbox			

Form Name	Item Text (Field Label)	Response Type (Control Type)	Response Options (Dictionary Items)	Help Text	External Review Comments
Missed Visit	Target visit date	DateTime			
Missed Visit	Reason visit was missed	DropDownList	1=Unable to contact participant; 2=Participant unable to schedule visit within window; 3=Participant refused visit; 4=Participant incarcerated; 5=Participant admitted to healthcare facility; 6=Participant withdrew from study; 7=Participant deceased; 99=Other		
Missed Visit	If "Other", specify:	LongText			
Missed Visit	Steps taken to address the missed visit (corrective action plan)	LongText			

		Response Type			External Review
Form Name	Item Text (Field Label)	(Control Type)	Response Options (Dictionary Items)	Help Text	Comments
Participant Replacement Assessment	Date of assessment	Date Time			
	Does this participant meet protocol-	RadioButton	Yes		
Participant Replacement Assessment	specified criteria for replacement?		No		
	Why is this participant being replaced?	Dropdown List	1=None of the doses administered (e.g., due to non-		
			adherence or permanent discontinuation)		
			2=Early termination (e.g., due to participant		
			voluntarily withdrawing from the study, death, lost		
			to follow-up, relocation, or permanent		
			discontinuation)		
			3=Other		
Participant Replacement Assessment					
Participant Replacement Assessment	If other, specify	Text	NA	2	

Form Name		Response	Response Options (Dictionary Items)	External Review Comments
	Was a CASI questionnaire or IDI completed at	(0000000000)	Yes	
Behavioral Assessment	this visit?	RadioButton	No	
Behavioral Assessment	If no, please explain:	LongText		

		Response Type	Response Options (Dictionary		
Form Name	Item Text (Field Label)	(Control Type)	Items)	Help Text	External Review Comments
CASI Tracking	CASI collection date	DateTime			
CASI Tracking	CASI ID	Text			
			1=Visit 2 Baseline CASI		
			2=Visit 4 Follow-Up CASI		
			3=Visit 8 Follow-Up CASI		
CASI Tracking	Which questionnaire was completed?	Dropdown List	4=Visit 10 IDI		
	Were there any problems or issues related to				
	the administration or completion of the				
CASI Tracking	questionnaire?	RadioButton			
CASI Tracking	If yes, please describe	LongText			

		Response Type	Response Options		
Form Name	Item Text (Field Label)	(Control Type)	(Dictionary Items)	Help Text	External Review Comments
	Visit Number	Dropdown List	1=Visit 3		,
Dose Administration		_	2=Visit 7		
	Date gel application	DateTime	NA		
Dose Administration	administered				
	Time gel application	Time	NA		
Dose Administration	administered				
	Dosage Administered	Dropdown List	1=1 TAF/EVG insert		
Dose Administration		_	2=2 TAF/EVG inserts		

		Response Type	Response Options		
Form Name	Item Text (Field Label)	(Control Type)	(Dictionary Items)	Help Text	External Review Comments
	Which visit was study		1=Visit 3		
Pharmacy Dispensation	product dispensed:	DropDown	2=Visit 7		
	Date study product				
Pharmacy Dispensation	dispensed:	DateTime	NA		
			1=1 TAF/EVG insert		
Pharmacy Dispensation	Dosage dispensed	DropDown	2=2 TAF/EVG inserts		

Data Dictionary Name AEACN	Coded Data	User Data String										
AEACN AEACN	2	Dose not changed Dose reduced Dose increased										
AEACN AEACN AEACN	4 5	Drug withdrawn Drug Interrupted Not applicable										
AEACNV AEACNV	2	No change Held										
AEACNV AEOUT	1	Permanently discontinued Not applicable Recovered/resolved										
AEOUT AEOUT	3	Recovering/resolving Recovered/resolved with sequelae Not recovered/not resolved										
AEOUTV AEOUTV	1	Fatal Resolved Recovering/resolving										
AEOUTV AEOUTV	4	Recovered with sequelae Continuing										
AEOUTV AEOUTV AEREL	6 1	Death Severity/frequency increased Related										
AEREL AESEV AESEV	1	Not related Grade 1 (Mild) Grade 2 (Moderate)										
	3 4 5	Grade 3 (Severe) Grade 4 (Potentially life-threatening) Grade 6 (Potentially life-threatening)										
BSSPEC BSSPEC	1 2	Plasma for archive Blood for PK CVF for PK										
BSSPEC BSSPEC BSSPEC	4 5	CVF for PD CVF for microflora										
BSSPEC BSSPEC BSSPEC	7 8	Rectal fluid for PK Rectal fluid for PD Rectal fluid for mycrobiome										
BSSPEC BSSPEC	9 10 11	Rectal enema prior to biopsy collection Rectal issue for PC Rectal tissue for PC										
BSSPEC BSSTORE	12	Rectal tissue for biomarkers Stored										
CMDOSFRQ	QD QD	Not stored PRN QD										
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CMDOSFRQ CMDOSFRQ	QM OH	QM OH										
CMDOSFRQ CMDOSU	OTHER R	ONCE Other Grams										
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CMDOSU CMDOSU	CAPSULE	Capsules Droos Puffs			1						7	
CMDOSU	SACHET SUPPOSITORY	Sachets Suppository										
CMDOSU CMDOSU	UNIT UNKNOWN	Tablets Units Unknown										
CMROUTE	OTHER IHL IM	Other Inhalation Intramuscular										
CMROUTE CMROUTE	IV OTHER	Intermediates										
CMROUTE CMROUTE	REC SC	Rectal Subcutaneous										
	VAG	Topical Vaginal Scheduled exit visit/end of study										
DSTERM DSTERM	3	Death Participant refused further participation Participant is unwilling or unable to comply with required study procedures										
DSTERM DSTERM	5	Lost to follow-up Investigator decision										
DSTERM	9	Participant refused further study product use Unable to contact participant HIV Infection										
DSTERM	12	Early study docure Protocol deviation Adverse event										
DSTERM DSTERM	13 14	Preenancv Withdrawal of consent by participant (remove for HVTN) Study terminated by sponsor										
DSTERM	16	One or more reactive HIV test results or acute HIV infection suspected										
DSTERM DSTERM DSTERM DSTERM	16 17 18 19	One or more reactive HIV feet results of acute HIV TINI Participant relocated, no follow-up planned (RVTN) Participant relocated, no follow-up planned (RVTN) Reactiogenicity symptoms (HVTN) Other, specify										
DSTERM DSTERM DSTERM DSTERM DSTRITTERM DSTRITTERM DSTRITTERM DSTRITTERM	16 17 18 19 99 1 2 3	One or more markles MV test results or accuse MV insert event of Persisteent modes and where the one schedule MVM insert or persisteent modes and where the one schedule MVM in Resistance persistes are personal personal personal Resistance personal personal personal personal Resistance personal personal personal personal personal personal Scheduled study product use period completed Persistant reference personal pers										
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SETTIME STEWN OPTIME	10-12-13-13-13-13-13-13-13-13-13-13-13-13-13-	One or more machine MV feet results or acute MV feet feet feet feet feet feet feet fee										
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DETURN DETURN DETURN OSTERN 16: 16: 16: 16: 16: 16: 16: 16: 16: 16:	City or more machine INV feet investor or acute InV indiction surpreted Articlasent relocation in officer or patients of the Investor of Investor of Investor or Investor of Investor or											
DETURN DETERM	10 10 10 10 10 10 10 10 10 10 10 10 10 1	Circle or micro markine MV feet results or assist MV indiction supported Assistance should be allowed to the situation of MVN Assistance with a second should be allowed to MVN Assistance with a second should be allowed to MVN Assistance with a second should be allowed to MVN Assistance with a second should be allowed to MVN Assistance with a second should be allowed to MVN Participant induced further participation Participant induced further participation Participant induced further study product use funds to solve the solve procedures. Let to follow our benefit of the participation of the solve procedures and the solve procedur										
DETURN DETURN DETURN OSTERN 10 10 10 10 10 10 10 10 10 10 10 10 10 1	One or more machine MV feet results or south 6V index results or south											
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PECECTO	3	26-50%						1	Г						
PECECTO PECECTO	4	51-75% 76-100%													
PECECTO PERES	6	Not done Not done													
PERES	2	Abnormal findings													
PEVGABDX	1	No apnormal findings Slight													
PEVGABDX PEVGABDX	3	Moderate Pooling													
POCABIND POCABIND	2	Yes No													
POCABIND POCABIND	4	Not assessed Unknown													
POMETHOD POMETHOD	2	C-section Standard vacinal													
POMETHOD POMETHOD	3	Operative vaginal Vaginal													
POOUTCOME POOUTCOME	1	Full term live birth (>37 weeks) Premature live birth (<37 weeks)													
POOUTCOME POOUTCOME	3	Stillbirth/intrauterine fetal demise (>=20 weeks)													
POOUTCOME	5	Spontaneous abortion (<20 weeks) Ectopic pregnancy													
POOUTCOME POOUTCOME	7	Therapeutic/elective abortion Other													
POPLACE POPLACE	2	Home Hospital													
POPLACE POPLACE	4	Clinic Unknown													
POPLACE POS/NEG	5	Other Positive													\vdash
POS/NEG POSEX	2 M	Negative Male													
POSEX	F	Female Last menstrual period													
RPEDLVR RPEDLVR	2	Initial ultrasound <20 weeks													
RPEDLVR RPEDLVR	4	Initial ultrasound >=20 weeks Physical examination													
RPEDLVR RPEDLVR	6	Conception date by assisted reproduction Other													
SCSEXORIEN SCSEXORIEN	2	Heterosexual Homosexual													
SCSEXORIEN SCSEXORIEN	4	Bisexual Asexual													\vdash
SCSEXORIEN SCSEXORIEN	5	Additional category, specify Not sure													
SCSEXORIEN SEX	7 M	Not sure Perfer not to answer Male													
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VISIT	2	Screenink Enrollment													
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VISIT	6	Visit 5 Visit 6													
VISIT	7	Visit 7 Visit 8						E	LΞ		LΞ				
VISIT VISIT	9	Visit 9 Visit 10													
VISIT	11	Visit 11/Final Contact Interim Visit													
Yes/No	Y	Yes													\blacksquare
Yes/No Yes/No/NS/UNK	Y	No Yes													
Yes/No/NS/UNK Yes/No/NS/UNK	N NS	No Not assessed													
Yes/No/NS/UNK PODELIVTYP	UNK 1	Unknown C-section													
PODELIVTYP PODELIVTYP	3	Standard vaginal Operative vaginal													
PODELIVTYP IETEST	4	Vaginal 11. Individuals who are 18 years of age or older at Screening													
IETEST	2	12. Able and willing to provide written informed consent to be screened for and enrolled in MTN-039													
IETEST	4	HIV-1/2 uninfected at Screening and Enrollment and willing to receive HIV test results Able and willing to provide adequate locator information													-
IETEST IETEST	5	Able to communicate in spoken and written English Available for all visits and able and willing to comply with all study procedural requirements													
IETEST	7	17. In general good health at Screening and Enrollment, as determined by the site loR or designee													
IETEST IETEST	9	 At Screening, history of consensual RAI at least once in lifetime per participant report Willing not to take part in other research studies involving drugs, medical devices, genital or rectal products, or vi 	accines for t	ne duration of study parti	cipation (including the ti	me between Screening a	nd Enrollment)								
IETEST	10	I10. Willing to comply with abstinence and other protocol requirements													
	11	115 For additional of additional and other protects against the formula and for all and													+-+
IETEST IETEST	11 12	 For participants of childbearing potential: a negative pregnancy test at Screening and Enrollment For participants of childbearing potential: Per participant report at Enrollment, using an effective method of 	contracepti					for the durat	ion of study	participation	n				
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