HVTN Protocol 105: A phase 1b clinical trial to evaluate the safety and immunogenicity of different combinations of DNA-HIV-PT123 and AIDSVAX B/E in healthy, HIV uninfected adult participants

Safety Analysis Datasets

Dataset	Description	Structure	Keys
SUBJECT_MASTER	Baseline Subject Characteristics	One record per subject	PROTOCOL, PUB_ID
AE_LIST	Adverse Events	One record per adverse event per subject	PUB_ID, AEMDRA, AEONDATE
REACTO_EVAL	Reactogenicity Events	One record per reactogenicity event per time point per subject	PUB_ID, SYSLOC, RGPARAM

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Baseline Subject Charachteristics(SUBJECT_MASTER)

Variable	variable label	Key	Type	Length /Display Format	Control Term or Format	Source	Derivation
PROTOCOL	Protocol Number	1	integer	3		Protocol	
PUB_ID	Publication ID	2	text	7		Derived	Concatenation of PROTOCOL and random number
RX_CODE	Treatment arm		text	2	RX_CODE	Assigned	Assigned based on Randomization
RX_LABEL	Treatment Label		text	11	RX_LABEL	Assigned	Assigned based on Randomization
AGE	Age at Enrollment (Years)		integer	2		Derived	(Enrollment Date - Birth Date)/365.25
SEX	Sex at Birth		text	6	SEX	CRF	
RACE	Race		text	30	RACE	CRF	
HISPANIC	Latino/a or of Hispanic origin?		text	3	YESNOC	CRF	
DISC_FL	Discontinued Vaccination Flag		text	3	YESNOC	CRF	
DISC_RSN	Reason Vaccine Discontinued		text	12	DISCREAS	CRF	
DISC_RSN_O	Reason Vaccine Discontinued for "Other, specify"		text	51		CRF	
EARLY_TERM_FL	Early Termination Flag		text	3	YESNOC	Derived	"No" if TERM_RSN = "Scheduled exit visit/end of study"; "Yes" otherwise
TERM_RSN	Reason for Termination		text	33	TERMREAS	CRF	
TERM_AE	Termination due to AE		text	2	YESNOC	CRF	
NUM_VAC_RECD	Number of Vaccination Received		integer	1		Derived	Sum of the total number of vaccinations the participant received over the duration of the trial

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Adverse Events(AE_LIST)

Variable	variable label	Key	Type	Length /Display Format	Control Term or Format	Source	Derivation
PUB_ID	Publication ID	1	text	7		Derived	Concatenation of PROTOCOL and random number
VISIT	Visit Number		integer	4		CRF	
AEPAGENUM	AE Page Number		integer	2		CRF	
AEDIAG	Adverse Experience (AE)		text	100		CRF	
AESOC	SOC		text	52	MEDDRA	Assigned	
AEMDRA	Preferred Term	2	text	43	MEDDRA	Assigned	
LL_NAME	Low Level Term Name		text	43	MEDDRA	Assigned	
HL_NAME	Higher Level Term, full name		text	70	MEDDRA	Assigned	
HLG_NAME	Higher Level Group Term, full name		text	86	MEDDRA	Assigned	
AEONDT_DSP	AE Onset Date		date	DDMMMYYYY		CRF	
AEONDATE	AE Onset Date (derived)	3	date	DDMMMYYYY		Derived	If Day of Onset is missing, it is imputed as 15th day of the Month, If Monthof Onset is missing, it is imputed as 1st month of the Year
AESEVE	Severity		integer	1	AESEVERE	CRF	
AESEVE_TXT	Severity(Character)		text	8	AESEVEREC	Assigned	
AEREL	Relationship to Study Product		integer	1	AEREL	CRF	
AEREL_TXT	Relationship to Study Product(Character)		text	11	AERELC	Assigned	
AEDRAD	Study Product Administration		integer	1	AEDRVACC	CRF	
AEDRADC	Study Product Administration (Character)		text	9	AEDRVAC	Assigned	
AEOUTC	Status/Outcome		integer	1	AE2OUTCM	CRF	
AEOUTCC	Status/Outcome (Character)		text	40	AE2OUTCMC	Assigned	
AEOCDT_DSP	AE Outcome Date		date	DDMMMYYYY		CRF	
AEOCDATE	AE Outcome Date (derived)		date	DDMMMYYYY		Derived	If Day of Onset is missing, it is imputed as 15th day of the Month, If Monthof Onset is missing, it is imputed as 1st month of the Year
AETREATMENT	AE Treatment		text	41	AETREATC	CRF	
AEICH	SAE according to ICH?		integer	1	YESNO	CRF	
AEICHC	SAE according to ICH?(Character)		text	3	YESNOC	Assigned	
AEDAIDS	AE be reported as an EAE?		integer	1	YESNO	CRF	

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Adverse Events(AE_LIST)

Variable	variable label	Key	Type	Length /Display Format	Control Term or Format	Source	Derivation
AEDAIDSC	AE be reported as an EAE?(Character)		text	3	YESNOC	Assigned	
AEVISIT	At which visit was this AE first reported?		float	4		CRF	
AESAERCT	AE reported on a Reactogenicity form?		integer	1	YESNO	CRF	
AESAERCTC	AE reported on a Reactogenicity form?(Character)		text	2	YESNOC	Assigned	

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Reactogenicity Events(REACTO_EVAL)

Variable	variable label	Key	Type	Length /Display Format	Control Term or Format	Source	Derivation
PUB_ID	Publication ID	1	text	7		Derived	Concatenation of PROTOCOL and random number
VISIT	Visit Number		integer	3		CRF	
SYSLOC	Symptom Type	2	text	3	SYMPTOM	Assigned	
RGPARAM	Parameter or Symptom	3	text	19	PARAM	Assigned	
RGPARAM_TXT	Descriptive Text for Parameter or Symptom		text	72	PARAMCD	Assigned	
EVAL_NUM	Evaluation Period		integer	1	EVALPN	CRF	
EVAL_LABEL	Evaluation Period Name		text	10	EVALPC	Assigned	
ASSESS_DT	Assessment Date		date	DDMMMYYYY		CRF	
RGDGRADE	Severity Grade for Display		integer	3	RGDGRADE	Derived	When SYSLOC="sys" value comes from CRF and GRADEMAP1, When SYSLOC="loc" value derived based on Dimension
RGDGRADE_ TXT	Severity Grade for Display(Character)		text	19	GRADMAP1, GRADMAP2, GRADMAP3	Derived	RGDGRADE: When SYSLOC="sys" value derived based on GRADEMAP1, When SYSLOC="loc" and PARAM not "tempc" value derived based on GRADEMAP2, When SYSLOC="loc" and PARAM="tempc" value derived based on GRADEMAP3

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Controlled Terms

AE2OUTCM	
Permitted Value	Display Value
1	Continuing
2	Resolved
3	Death
4	Severity/frequency increased
5	Continuing at end of study participation

AE2OUTCMC
Permitted Value
Continuing
Resolved
Death
Severity/frequency increased
Continuing at end of study participation

AEDRVAC
Permitted Value
No change
Held
Permanently discontinued
N/A

AEDRVACC	
Permitted Value	Display Value
1	No change
2	Held
3	Permanently discontinued
4	N/A

AEREL	
Permitted Value	Display Value
1	Related
2	Not related

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Controlled Terms

AERELC
Permitted Value
Related
Not related

AESEVERE	
Permitted Value	Display Value
1	Grade 1 (Mild)
2	Grade 2 (Moderate)
3	Grade 3 (Severe)
4	Grade 4 (Potentially life-threatening)
5	Grade 5 (Death)

AESEVEREC
Permitted Value
Mild
Moderate
Severe
Potentially life-threatening
Death

AETREATC
Permitted Value
None
Medication(s)
Procedure/surgery
New/prolonged hospitalization
Other

DISCREAS
Permitted Value
Clinical event other than reactogenicity, HIV infection, or death
Death
HIV infection
Incarceration
Other reason
Participant received medications, experimental agent(s), or therapies that preclude vaccination

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Controlled Terms

DISCREAS
Permitted Value
Participant refused
Participant relocated
Participant unable to schedule vaccination within window
Participant's psychiatric indication
Pregnancy
Reactogenicity symptom
Unable to contact participant

EVALPC
Permitted Value
Baseline
Early
Day 0
Day 1
Day 2
Day 3
Resolution

EVALPN	
Permitted Value	Display Value
0	Baseline
1	Early
2	Day 0
3	Day 1
4	Day 2
5	Day 3
6	Resolution

GRADMAP1	
Permitted Value	Display Value
0	None
1	Mild
2	Moderate
3	Severe
4	Life-Threatening

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Controlled Terms

GRADMAP2	
Permitted Value	Display Value
0	None
1	> 0 to 25 cm2
2	>25 to 81 cm2
3	>9 cm any diameter
4	>81 cm2

GRADMAP3	
Permitted Value	Display Value
0	34.0 - 37.6C (None)
1	37.7 - 38.6C (Gr 1)
2	38.7 - 39.3C (Gr 2)
3	39.4 - 40.5C (Gr 3)
4	> 40.5C (Gr 4)

MEDDRA
Permitted Value
Dictionary Version 19.0

PARAM
Permitted Value
Malaise / Fatigue
Myalgia
Headache
Nausea
Vomiting
Chills
Arthralgia
Maximum Grade of Systemic Symptoms (Any Location)
Temperature (Celsius)
Maximum Grade for Pain (Any Location)
Pain Left Deltoid
Pain Right Deltoid
Maximum Grade for Tenderness (Any Location)
Tenderness Left Deltoid
Tenderness Right Deltoid

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Controlled Terms

PARAM
Permitted Value
Maximum Grade of Pain or Tenderness (Any Location)
Maximum Grade of Erythema Area or Dimension (Any Location)
Maximum Grade of Induration Area or Dimension (Any Location)
Maximum Grade of Erythema or Induration Area or Dimension (Any Location)
Erythema Area Left Deltoid 1st Injection
Erythema Area Right Deltoid 1st Injection
Erythema Largest Dimension Left Deltoid 1st Injection
Erythema Largest Dimension Right Deltoid 1st Injection
Induration Area Left Deltoid 1st Injection
Induration Area Right Deltoid 1st Injection
Induration Largest Dimension Left Deltoid 1st Injection
Induration Largest Dimension Right Deltoid 1st Injection
Erythema Area Left Deltoid 2nd Injection
Erythema Area Right Deltoid 2nd Injection
Erythema Largest Dimension Left Deltoid 2nd Injection
Erythema Largest Dimension Right Deltoid 2nd Injection
Induration Area Left Deltoid 2nd Injection
Induration Area Right Deltoid 2nd Injection
Induration Largest Dimension Left Deltoid 2nd Injection
Induration Largest Dimension Right Deltoid 2nd Injection

PARAMCD	
Permitted Value	Display Value
pain	Maximum Grade for Pain (Any Location)
pain_ldelt	Pain Left Deltoid
pain_rdelt	Pain Right Deltoid
tend	Maximum Grade for Tenderness (Any Location)
tend_ldelt	Tenderness Left Deltoid
tend_rdelt	Tenderness Right Deltoid
paintend	Maximum Grade of Pain or Tenderness (Any Location)
ery	Maximum Grade of Erythema Area or Dimension (Any Location)
ind	Maximum Grade of Induration Area or Dimension (Any Location)
eryind	Maximum Grade of Erythema or Induration Area or Dimension (Any Location)
ery_area_ldelt_inj1	Erythema Area Left Deltoid 1st Injection
ery_area_rdelt_inj1	Erythema Area Right Deltoid 1st Injection

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Controlled Terms

PARAMCD	
Permitted Value	Display Value
ery_dim_ldelt_inj1	Erythema Largest Dimension Left Deltoid 1st Injection
ery_dim_rdelt_inj1	Erythema Largest Dimension Right Deltoid 1st Injection
ind_area_ldelt_inj1	Induration Area Left Deltoid 1st Injection
ind_area_rdelt_inj1	Induration Area Right Deltoid 1st Injection
ind_dim_ldelt_inj1	Induration Largest Dimension Left Deltoid 1st Injection
ind_dim_rdelt_inj1	Induration Largest Dimension Right Deltoid 1st Injection
ery_area_ldelt_inj2	Erythema Area Left Deltoid 2nd Injection
ery_area_rdelt_inj2	Erythema Area Right Deltoid 2nd Injection
ery_dim_ldelt_inj2	Erythema Largest Dimension Left Deltoid 2nd Injection
ery_dim_rdelt_inj2	Erythema Largest Dimension Right Deltoid 2nd Injection
ind_area_ldelt_inj2	Induration Area Left Deltoid 2nd Injection
ind_area_rdelt_inj2	Induration Area Right Deltoid 2nd Injection
ind_dim_ldelt_inj2	Induration Largest Dimension Left Deltoid 2nd Injection
ind_dim_rdelt_inj2	Induration Largest Dimension Right Deltoid 2nd Injection
mf	Malaise / Fatigue
myal	Myalgia
head	Headache
naus	Nausea
vom	Vomiting
chill	Chills
arth	Arthralgia
systemic	Maximum Grade of Systemic Symptoms (Any Location)
tempc	Temperature (Celsius)

RACE
Permitted Value
American Indian or Alaska Native
Asian
Black or African American
Native Hawaiian or other Pacific Islander
Other
White

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Controlled Terms

RGDGRADE
Permitted Value
0
1
2
3
4

RX_CODE
Permitted Value
T1
T2
T3
T4

RX_LABEL	
Permitted Value	Display Value
Placebo for DNA + AIDSVAX B/E mo(0,1) & DNA + Placebo for AIDSVAX B/E mo(3,6)	A/A/D/D
DNA + Placebo for AIDSVAX B/E mo(0,1) & Placebo for DNA + AIDSVAX B/E mo(3,6)	D/D/A/A
DNA + Placebo for AIDSVAX B/E mo(0,1) & DNA + AIDSVAX B/E mo(3,6)	D/D/DA/DA
DNA + AIDSVAX B/E mo(0,1,3,6)	DA/DA/DA/DA

SEX
Permitted Value
Female
Male

SYMPTOM
Permitted Value
sys
loc

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Controlled Terms

TERMREAS
Permitted Value
Death
HIV infection
Inappropriate enrollment
Invalid ID due to duplicate screening/enrollment
Investigator decision
Other
Participant refused further participation
Participant relocated, no follow-up planned
Participant unable to adhere to visit schedule
Scheduled exit visit/end of study
Unable to contact participant
Early study closure

YESNO	
Permitted Value	Display Value
1	Yes
2	No

YESNOC
Permitted Value
Yes
No