

HPTN 076 - Phase II Safety and Acceptability of an Investigational Injectable Product, TMC278 LA, for Pre Exposure Prophylaxis (PrEP)
Report January 17, 2018
Visit Cutoff Date: January 16, 2018
Table C - Screening Summary by Site

	Overall	Bronx Prevention Center CRS Site ID 253	New Jersey Medical School CRS Site ID 254	Emavundleni CRS Site ID 255	Spilhaus CRS Site ID 256
Screened	295	35	23	137	100
Enrolled					
Yes	136/295 (46.1%)	19/35 (54.3%)	17/23 (73.9%)	48/137 (35.0%)	52/100 (52.0%)
No	159/295 (53.9%)	16/35 (45.7%)	6/23 (26.1%)	89/137 (65.0%)	48/100 (48.0%)
Reason Not Enrolled					
Other	57/159 (35.8%)	7/16 (43.8%)	3/6 (50.0%)	23/89 (25.8%)	24/48 (50.0%)
Active STI or had STI in last 6 months	46/159 (28.9%)	0/16 (0.0%)	0/6 (0.0%)	40/89 (44.9%)	6/48 (12.5%)
Abnormal laboratory values	19/159 (11.9%)	4/16 (25.0%)	1/6 (16.7%)	9/89 (10.1%)	5/48 (10.4%)
Unable to attend all study visits	16/159 (10.1%)	3/16 (18.8%)	0/6 (0.0%)	11/89 (12.4%)	2/48 (4.2%)
Abnormal EKG or history of cardiac abnormalities	12/159 (7.5%)	1/16 (6.3%)	1/6 (16.7%)	0/89 (0.0%)	10/48 (20.8%)
Unwilling to use condoms or contraception for duration of study	4/159 (2.5%)	0/16 (0.0%)	0/6 (0.0%)	4/89 (4.5%)	0/48 (0.0%)
High risk for HIV-infection per Investigator	3/159 (1.9%)	0/16 (0.0%)	0/6 (0.0%)	2/89 (2.2%)	1/48 (2.1%)
Pregnant or currently breastfeeding	2/159 (1.3%)	0/16 (0.0%)	0/6 (0.0%)	1/89 (1.1%)	1/48 (2.1%)
HIV-infected	2/159 (1.3%)	0/16 (0.0%)	0/6 (0.0%)	2/89 (2.2%)	0/48 (0.0%)
Younger than 18 or older than 45	1/159 (0.6%)	0/16 (0.0%)	1/6 (16.7%)	0/89 (0.0%)	0/48 (0.0%)
History of severe allergic reactions	1/159 (0.6%)	1/16 (6.3%)	0/6 (0.0%)	0/89 (0.0%)	0/48 (0.0%)
Unable to provide adequate locator information	0/159 (0.0%)	0/16 (0.0%)	0/6 (0.0%)	0/89 (0.0%)	0/48 (0.0%)
Unable to agree to local reporting requirements for STIs	0/159 (0.0%)	0/16 (0.0%)	0/6 (0.0%)	0/89 (0.0%)	0/48 (0.0%)
Injected recreational drugs in past 52 weeks	0/159 (0.0%)	0/16 (0.0%)	0/6 (0.0%)	0/89 (0.0%)	0/48 (0.0%)
Previous Participation in HIV vaccine study	0/159 (0.0%)	0/16 (0.0%)	0/6 (0.0%)	0/89 (0.0%)	0/48 (0.0%)
PrEP or PEP in past 90 days	0/159 (0.0%)	0/16 (0.0%)	0/6 (0.0%)	0/89 (0.0%)	0/48 (0.0%)
Serious acute, chronic, or progressive disease	0/159 (0.0%)	0/16 (0.0%)	0/6 (0.0%)	0/89 (0.0%)	0/48 (0.0%)
Uncontrolled depression or active suicidal ideation	0/159 (0.0%)	0/16 (0.0%)	0/6 (0.0%)	0/89 (0.0%)	0/48 (0.0%)

¹Reasons Not Enrolled are not mutually exclusive.

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Table C - Listing of 'Other' Reasons by Site

Site	Date	Reason Given
Bronx Prevention Center CRS	06MAY2015	due to medical follow-up, exceeded 28 days from sc
Bronx Prevention Center CRS	06MAY2015	exceeded 28 days since scening date, ppt did not
Bronx Prevention Center CRS	16APR2015	currently taking LAMISIL which can cause hepatotox
Bronx Prevention Center CRS	01JUN2015	> 28 days since screening date; did not call back
Bronx Prevention Center CRS	01JUN2015	> 28 days since screening, unable to enroll due to
Bronx Prevention Center CRS	01JUN2015	clinician discretion
Bronx Prevention Center CRS	06MAY2015	Clinician discretion, extremely difficult blood dr
New Jersey Medical School CRS	23FEB2015	poor venous access
New Jersey Medical School CRS	23FEB2015	hysterectomy
New Jersey Medical School CRS	26MAR2015	urine pregnancy test kit issue.
Emavundleni CRS	31MAR2015	hysterectomy --> amenorrhoea > 6 monthes
Emavundleni CRS	22JUN2015	Participant thought Not Suitable but after discuss
Emavundleni CRS	14MAY2015	contradictory information provided and therefore,
Emavundleni CRS	22JUL2015	not contactable
Emavundleni CRS	24JUN2015	sexually abstinent
Emavundleni CRS	22JUN2015	sexually abstinent
Emavundleni CRS	06JUL2015	intending a pregnancy next year 2016
Emavundleni CRS	05AUG2015	had to leave to go to another area - eastern cape
Emavundleni CRS	26AUG2015	Recalled, but she was busy at school >28 days; She
Emavundleni CRS	24JUL2015	only should family planning on 24 Jul 15 > 28 days
Emavundleni CRS	28JUL2015	Not contactable
Emavundleni CRS	10SEP2015	Not Contactable
Emavundleni CRS	10SEP2015	Not Contactable
Emavundleni CRS	10SEP2015	Not Contactable
Emavundleni CRS	21AUG2015	Sexually Abstanent
Emavundleni CRS	22SEP2015	No Family Planning
Emavundleni CRS	22SEP2015	enrollment target reached
Emavundleni CRS	08SEP2015	Relocating to Eastern Cape in a few monthes
Emavundleni CRS	22SEP2015	enrollment target reached
Emavundleni CRS	10SEP2015	Sexually Abstanent Since 2013
Emavundleni CRS	22SEP2015	enrollment target reached
Emavundleni CRS	22SEP2015	enrollment target reached
Emavundleni CRS	22SEP2015	Difficult Blood Draw
Spilhaus CRS	22APR2015	grade 2 HGSIL.
Spilhaus CRS	11MAY2015	No documentation confirming BTL
Spilhaus CRS	01JUN2015	fear for blood draws
Spilhaus CRS	19MAY2015	phobia for injections
Spilhaus CRS	17JUL2015	participant did not turn up for enrolment until sc
Spilhaus CRS	17JUL2015	History of urticaria

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Spilhaus CRS	17JUL2015	had fibroid uterus and wanted to have myomectomy.
Spilhaus CRS	10JUN2015	Unexplained amenorrhoea for more than 6/12
Spilhaus CRS	25JUN2015	Recurrent Urticaria
Spilhaus CRS	28JUL2015	uncontrolled hypertension
Spilhaus CRS	17JUL2015	Hepatitis B surface antigen positive
Spilhaus CRS	14SEP2015	Screening visit window closed
Spilhaus CRS	15JUL2015	unexplained amenorrhoea since 2000.
Spilhaus CRS	14SEP2015	Not willing to be an long term contraception
Spilhaus CRS	14SEP2015	Not willing to be on contraception
Spilhaus CRS	14SEP2015	screening visit window closed.
Spilhaus CRS	14SEP2015	hbsag postiive
Spilhaus CRS	14SEP2015	Indeterminate rapid HIV test
Spilhaus CRS	29SEP2015	Potentially difficult to retain. Across border trad
Spilhaus CRS	21SEP2015	accrual target met
Spilhaus CRS	29SEP2015	Accrual target met.
Spilhaus CRS	29SEP2015	Accrual target met.
Spilhaus CRS	29SEP2015	Accrual target met.
Spilhaus CRS	29SEP2015	Accrual target met.