

## Supplemental Online Content

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This supplemental material has been provided by the authors to give readers additional information about their work.

**eTable 1. Baseline Participant Characteristics, Post-approval Studies of Emtricitabine/Tenofovir Disoproxil Fumarate for Pre-Exposure Prophylaxis in Cisgender Women, Six Countries, 2012–2020 (N=6296)**

Characteristic	All (N=6,296)		No adherence data (N=3,342)		With adherence data for trajectory (N=2,954)		Any objective adherence data (N=237)		Subjective adherence data only (N=2,717)	
	N	%	N	%	N	%	N	%	N	%
Age at enrollment/PrEP start										
<25 years	3,832	60.9	2,694	80.6	1,138	38.5	111	46.8	1,027	37.8
≥25 years	2,464	39.1	648	19.4	1,816	61.5	126	53.2	1,690	62.2
Country										
Botswana	102	1.6	57	1.7	45	1.5	45	19.0	0	0.0
India	1,325	21.0	1	0.0	1,324	44.8	0	0.0	1,324	48.7
Kenya	2,886	45.8	1,788	53.5	1,098	37.2	66	27.8	1,032	38.0
South Africa	1,751	27.8	1,469	44.0	282	9.5	51	21.5	231	8.5
USA	49	0.8	26	0.8	23	0.8	23	9.7	0	0.0
Uganda	183	2.9	1	0.0	182	6.2	52	21.9	130	4.8
Race										
Asian	1,325	21.1	1	0.0	1,324	44.8	0	0.0	1,324	48.7
Black	4,930	78.3	3,318	99.3	1,612	54.6	219	92.4	1,393	51.3
Unknown	41	0.7	23	0.7	18	0.6	18	7.6	0	0.0
Education										
≤Primary	1,675	26.6	348	10.4	1,327	44.9	36	15.2	1,291	47.5
≥Secondary	1,899	30.2	503	15.1	1,396	47.3	66	27.8	1,330	49.0
Unknown	2,722	43.2	2,491	74.5	231	7.8	135	57.0	96	3.5
Marital Status										
Single	1,791	28.5	1,018	30.5	773	26.2	41	17.3	732	26.9

Characteristic	All (N=6,296)		No adherence data (N=3,342)		With adherence data for trajectory (N=2,954)		Any objective adherence data (N=237)		Subjective adherence data only (N=2,717)	
	N	%	N	%	N	%	N	%	N	%
Married	3,256	51.7	2,133	63.8	1,123	38.0	128	54.0	995	36.6
Separated/Divorced/Widowed	894	14.2	93	2.8	801	27.1	0	0.0	801	29.5
Unknown	355	5.6	98	2.9	257	8.7	68	28.7	189	7.0
Employed										
Employed/Self-employed	1,205	19.1	236	7.1	969	32.8	11	4.6	958	35.3
Unemployed	1,119	17.8	570	17.1	549	18.6	3	1.3	546	20.1
Other/Unknown	3,972	63.1	2,536	75.9	1,436	48.6	223	94.1	1,213	44.6
Number of Children										
Nulliparous	1,816	28.8	1,339	40.1	477	16.1	47	19.8	430	15.8
1 Child	1,506	23.9	838	25.1	668	22.6	61	25.7	607	22.3
2+ children	1,269	20.2	223	6.7	1,046	35.4	61	25.7	985	36.3
Unknown	1,705	27.1	942	28.2	763	25.8	68	28.7	695	25.6
Body Mass Index										
Underweight (<18.5)	226	3.6	147	4.4	79	2.7	13	5.5	66	2.4
Normal (≥18.5 - <25)	2,273	36.1	1,452	43.4	821	27.8	121	51.1	700	25.8
Overweight (≥25 - <30)	1,202	19.1	768	23.0	434	14.7	52	21.9	382	14.1
Obese (>30)	776	12.3	502	15.0	274	9.3	42	17.7	232	8.5
Unknown	1,819	28.9	473	14.2	1,346	45.6	9	3.8	1,337	49.2
Acute viral infection symptoms										
Yes	100	1.6	21	0.6	79	2.7	1	0.4	78	2.9
None reported	6,196	98.4	3,321	99	2,875	97	236	100	2,639	97
Contraception Use										

Characteristic	All (N=6,296)		No adherence data (N=3,342)		With adherence data for trajectory (N=2,954)		Any objective adherence data (N=237)		Subjective adherence data only (N=2,717)	
	N	%	N	%	N	%	N	%	N	%
Yes	3,033	48.2	1,119	33.5	1,914	64.8	93	39.2	1,821	67.0
None reported	3,263	51.8	2,223	67	1,040	35	144	61	896	33
Pregnant										
Yes	175	2.8	148	4.4	27	0.9	6	2.5	21	0.8
None reported	6,121	97.2	3,194	96	2,927	99	231	98	2,696	99
Sexually Transmitted Infections <sup>a,b</sup>										
Any	781	12.4	739	22.1	42	1.4	10	4.2	32	1.2
Chlamydia	666	10.6	631	18.9	35	1.2	8	3.4	27	1.0
Gonorrhea	221	3.5	206	6.2	15	0.5	4	1.7	11	0.4
Hepatitis B	15	0.2	13	0.4	2	0.1	0	0.0	2	0.1
None reported	5,515	87.6	2,603	78	2,912	99	227	96	2,685	99
Sexual Behaviors <sup>b</sup>										
Any	1,420	22.6	30	0.9	1,390	47.1	24	10.1	1,366	50.3
Serodiscordant Partner	120	1.9	29	0.9	91	3.1	24	10.1	67	2.5
Transactional Sex	1,294	20.6	1	0.0	1,293	43.8	0	0.0	1,293	47.6
≥5 Clients/Partners	390	6.2	0	0.0	390	13.2	0	0.0	390	14.4
None reported	4,876	77.4	3,312	99	1,564	53	213	90	1,351	50

<sup>a</sup> Including any diagnosis of bacterial vaginosis, chlamydia, gonorrhea, syphilis, hepatitis B, or hepatitis C at any time (baseline or follow-up)

<sup>b</sup> Categories are not mutually exclusive.

Abbreviations: N, number; CDC, US Centers for Disease Control and Prevention.

**eTable 2. HIV incidence in Subgroups, Post-approval Studies of Emtricitabine/Tenofovir Disoproxil Fumarate for Pre-Exposure Prophylaxis in Cisgender Women, Six Countries, 2012–2020 (N=6296)**

	Number of participants (all)	Number seroconverted	Total person years	Seroconversion rate per 100 person years	95% CI for seroconversion rate
<b>Overall</b>	6,296	32	4,466	0.72	(0.51, 1.01)
<b>Country</b>					
Botswana	102	0	77	.	
India	1,325	0	1,595	.	
Kenya	2,886	15	2,134	0.70	(0.42, 1.17)
South Africa	1,751	12	448	2.68	(1.52, 4.72)
USA	49	0	41	.	
Uganda	183	5	172	2.91	(1.21, 7.00)
<b>Age at Enrollment</b>					
<25 years	3,832	26	1,958	1.33	(0.90, 1.95)
≥25 years	2,464	6	2,508	0.24	(0.11, 0.53)
<b>Baseline Marital Status</b>					
Married	3,256	20	1,739	1.15	(0.74, 1.78)
Single	1,791	10	1,523	0.66	(0.35, 1.22)
Other (Separated/Divorced/Widowed/Unknown/Not collected)	1,249	2	1,204.1	0.17	(0.04, 0.66)
<b>Baseline Education</b>					
≤Primary	1,675	4	1,793	0.22	(0.08, 0.59)
≥Secondary	1,899	11	1,894	0.58	(0.32, 1.05)
Unknown/Not collected	2,722	17	779	2.18	(1.36, 3.51)
<b>Baseline Parity</b>					
Nulliparous	1,816	14	835	1.68	(0.99, 2.83)

	Number of participants (all)	Number seroconverted	Total person years	Seroconversion rate per 100 person years	95% CI for seroconversion rate
1 Child	1,506	7	986	0.71	(0.34, 1.49)
2+ Children	1,269	7	1,288	0.54	(0.26, 1.14)
Unknown/Not collected	1,705	4	1,357	0.30	(0.11, 0.79)
<b>Body Mass Index</b>					
Underweight (<18.5)	226	2	137	1.46	(0.37, 5.85)
Normal (≥18.5 - <25)	2,270	22	1,394	1.58	(1.04, 2.40)
Overweight (≥25 - <30)	1,205	5	767	0.65	(0.27, 1.57)
Obese (>30)	776	2	439	0.46	(0.11, 1.82)
Unknown	1,819	1	1,730	0.06	(0.01, 0.41)
<b>Transmission Risk</b>					
Ever had any transmission risk behaviors <sup>a</sup>	1,669	2	1,830	0.11	(0.03, 0.44)
None reported	4,627	30	2,636	1.14	(0.80, 1.63)
<b>Adherence Trajectory</b>					
With Adherence data	2,954	12	2,958	0.41	(0.23, 0.71)
Consistently daily	498	0	557	.	
Consistently high	658	1	771	0.13	(0.02, 0.92)
High but declining	1,166	6	1,235	0.49	(0.22, 1.08)
Consistently low	632	5	395	1.27	(0.53, 3.04)
No adherence data	3,342	20	1,508	1.33	(0.86, 2.06)

<sup>a</sup> Any of the following at any point (baseline or follow-up): serodiscordant partner, transactional sex, or ≥5 clients/partners. Abbreviations: N, number; CDC, US Centers for Disease Control.

**eTable 3. Adherence Measurements Utilized in Assigning Adherence Trajectory Groups**

	All	Consistently Daily	Consistently High	High but Declining	Consistently Low
N	2,954	498	658	1,166	632
DBS only	130	3	1	19	107
Plasma only	4	0	3	1	0
Physician-reported summary (5-level) only	763	0	588	2	173
Physician-reported summary (2-level) only	186	11	48	123	4
Electronic monitoring only	1,041	59	17	679	286
Self-report only	695	424	1	222	48
Pill count only	1	0	0	0	1x <sup>a</sup>
Multiple types of adherence measures used	134	1	0	120	13
DBS/plasma/electronic monitoring	18	0	0	17	1
DBS/physician-reported summary (5-level)	7	0	0	3	4
DBS/electronic monitoring	54	0	0	48	6
Plasma/electronic monitoring	24	0	0	22	2
Electronic monitoring/self-report	29	1	0	28	0
Electronic monitoring/self-report/pill count	1	0	0	1	0
Self-report/Pill count	1	0	0	1	0

**eTable 4. Association between Baseline Participant Characteristics and Adherence Trajectory Categories in Cisgender Women who had Adherence Trajectories, 2012-2020**

Characteristic	Consistently Daily N (%)	Consistently High N (%)	High, but declining N (%)	Consistently low N (%)	Odds Ratio (95% CI) of having low adherence <sup>a</sup>		
					Consistently daily vs. low	Consistently high vs. low	High but declining vs. low
<b>Characteristic</b>							
Age at enrollment/PrEP start							
<25 years	43 (8.6)	194 (29.5)	539 (46.2)	362 (57.3)	0.42 (0.25-0.71)	0.82 (0.53-1.27)	0.51 (0.37-0.69)
≥25 years	455 (91.4)	464 (70.5)	627 (53.8)	270 (42.7)	1.00 (reference)	1.00 (reference)	1.00 (reference)
Education							
≤Primary	330 (66.3)	466 (70.8)	366 (31.4)	165 (26.1)	1.00 (reference)	1.00 (reference)	1.00 (reference)
≥Secondary	165 (33.1)	180 (27.4)	772 (66.2)	279 (44.1)	0.82 (0.56-1.21)	0.73 (0.50-1.08)	0.93 (0.69-1.24)
Marital Status							
Single	35 (7.0)	56 (8.5)	408 (35.0)	274 (43.4)	0.67 (0.36-1.26)	1.38 (0.67-2.82)	0.90 (0.60-1.34)
Married	241 (48.4)	182 (27.7)	481 (41.3)	219 (34.7)	1.00 (reference)	1.00 (reference)	1.00 (reference)
Separated/Divorced/Widowed	208 (41.8)	369 (56.1)	135 (11.6)	89 (14.1)	1.29 (0.67-2.48)	0.87 (0.55-1.39)	1.24 (0.67-2.30)
Employed							
Employed/Self-employed	25 (5.0)	586 (89.1)	178 (15.3)	180 (28.5)	1.00 (reference)	1.00 (reference)	1.00 (reference)
Unemployed	34 (6.8)	9 (1.4)	315 (27.0)	191 (30.2)	0.62 (0.34-1.11)	0.56 (0.20-1.60)	0.72 (0.52-1.00)
Number of Children							
Nulliparous	28 (5.6)	89 (13.5)	214 (18.4)	146 (23.1)	0.55 (0.24-1.26)	0.79 (0.44-1.40)	0.57 (0.34-0.97)
1 Child	89 (17.9)	236 (35.9)	208 (17.8)	135 (21.4)	0.65 (0.34-1.24)	0.72 (0.46-1.12)	0.72 (0.43-1.19)
2+ children	307 (61.6)	273 (41.5)	369 (31.6)	97 (15.3)	1.00 (reference)	1.00 (reference)	1.00 (reference)



	Consistently Daily N (%)	Consistently High N (%)	High, but declining N (%)	Consistently low N (%)	Odds Ratio (95% CI) of having low adherence <sup>a</sup>		
					Consistently daily vs. low	Consistently high vs. low	High but declining vs. low
Body Mass Index							
Underweight (<18.5)	4 (0.8)	5 (0.8)	45 (3.9)	25 (4.0)	1.90 (0.58-6.24)	2.70 (0.88-8.29)	1.03 (0.57-1.85)
Normal (≥18.5 - <25)	26 (5.2)	30 (4.6)	492 (42.2)	273 (43.2)	1.00 (reference)	1.00 (reference)	1.00 (reference)
Overweight (≥25 - <30)	24 (4.8)	24 (3.6)	244 (20.9)	142 (22.5)	1.37 (0.74-2.54)	1.16 (0.61-2.19)	0.95 (0.70-1.28)
Obese (>30)	18 (3.6)	18 (2.7)	155 (13.3)	83 (13.1)	1.60 (0.81-3.15)	1.63 (0.80-3.31)	1.40 (0.96-2.03)
Unknown	426 (85.5)	581 (88.3)	230 (19.7)	109 (17.2)	4.29 (0.66-28.04)	5.37 (0.72-39.81)	3.49 (0.86-14.21)
Contraception Use							
Yes	414 (83.1)	638 (97.0)	607 (52.1)	255 (40.3)	1.40 (0.63-3.13)	1.76 (0.65-4.75)	1.26 (0.88-1.82)
None reported	84 (16.9)	20 (3.0)	559 (47.9)	377 (59.7)	1.00 (reference)	1.00 (reference)	1.00 (reference)

<sup>a</sup> Multinomial ordinal logistic regression random effect by individual study.