

HPTN 069 - A Phase II Randomized Study of the Safety and Tolerability of Maraviroc to Prevent HIV Transmission

Live Open Report - October 15, 2014

Visit Cutoff Date: October 15, 2014

**Table 8.1a - Adherence as Measured by Wisepill Electronic Monitoring Device (EDM) by Study Visit and Site
SIM Compatible
MALE**

	Total	Baltimore, MD	Boston, MA	Chapel Hill/ Raleigh, NC	Cleveland, OH	Los Angeles, CA	New York, NY
Distribution of participants' percentage of days with recorded Wisepill opening signals ^{1,2}							
Week 1-8							
100%	13/229 (5.7%)	0/3 (0.0%)	4/32 (12.5%)	2/31 (6.5%)	1/22 (4.5%)	1/12 (8.3%)	2/19 (10.5%)
90-99%	70/229 (30.6%)	0/3 (0.0%)	9/32 (28.1%)	11/31 (35.5%)	10/22 (45.5%)	4/12 (33.3%)	7/19 (36.8%)
51-89%	106/229 (46.3%)	2/3 (66.7%)	13/32 (40.6%)	14/31 (45.2%)	8/22 (36.4%)	5/12 (41.7%)	8/19 (42.1%)
1-50%	39/229 (17.0%)	0/3 (0.0%)	6/32 (18.8%)	4/31 (12.9%)	3/22 (13.6%)	2/12 (16.7%)	2/19 (10.5%)
0% and all heartbeats missing	1/229 (0.4%)	1/3 (33.3%)	0/32 (0.0%)	0/31 (0.0%)	0/22 (0.0%)	0/12 (0.0%)	0/19 (0.0%)
0% and at least one heartbeat	0/229 (0.0%)	0/3 (0.0%)	0/32 (0.0%)	0/31 (0.0%)	0/22 (0.0%)	0/12 (0.0%)	0/19 (0.0%)
Mean ³ (CI)	75.4 (69.8,81)	73.6 (12.6,100)	77.0 (62.4,91.6)	79.9 (65.8,94)	82.1 (66,98.1)	77.1 (53.3,100)	77.1 (58.2,96)
Week 9-16							
100%	6/229 (2.6%)	0/3 (0.0%)	2/32 (6.3%)	0/31 (0.0%)	1/22 (4.5%)	0/12 (0.0%)	1/19 (5.3%)
90-99%	47/229 (20.5%)	0/3 (0.0%)	8/32 (25.0%)	8/31 (25.8%)	9/22 (40.9%)	1/12 (8.3%)	4/19 (21.1%)
51-89%	99/229 (43.2%)	2/3 (66.7%)	12/32 (37.5%)	12/31 (38.7%)	10/22 (45.5%)	6/12 (50.0%)	9/19 (47.4%)
1-50%	58/229 (25.3%)	1/3 (33.3%)	7/32 (21.9%)	9/31 (29.0%)	2/22 (9.1%)	5/12 (41.7%)	2/19 (10.5%)
0% and all heartbeats missing	5/229 (2.2%)	0/3 (0.0%)	0/32 (0.0%)	0/31 (0.0%)	0/22 (0.0%)	0/12 (0.0%)	1/19 (5.3%)
0% and at least one heartbeat	14/229 (6.1%)	0/3 (0.0%)	3/32 (9.4%)	2/31 (6.5%)	0/22 (0.0%)	0/12 (0.0%)	2/19 (10.5%)
Mean ³ (CI)	61.0 (54.6,67.4)	56.0 (0,100)	62.1 (45.2,78.9)	60.4 (43.2,77.6)	78.6 (61.4,95.7)	57.1 (29.1,85.1)	65.9 (44,87.8)
Week 17-24							
100%	4/230 (1.7%)	0/3 (0.0%)	1/32 (3.1%)	1/31 (3.2%)	0/22 (0.0%)	0/12 (0.0%)	1/19 (5.3%)
90-99%	43/230 (18.7%)	0/3 (0.0%)	7/32 (21.9%)	5/31 (16.1%)	7/22 (31.8%)	1/12 (8.3%)	7/19 (36.8%)
51-89%	76/230 (33.0%)	1/3 (33.3%)	9/32 (28.1%)	10/31 (32.3%)	10/22 (45.5%)	6/12 (50.0%)	3/19 (15.8%)
1-50%	68/230 (29.6%)	2/3 (66.7%)	8/32 (25.0%)	13/31 (41.9%)	5/22 (22.7%)	2/12 (16.7%)	2/19 (10.5%)
0% and all heartbeats missing	27/230 (11.7%)	0/3 (0.0%)	5/32 (15.6%)	2/31 (6.5%)	0/22 (0.0%)	2/12 (16.7%)	4/19 (21.1%)
0% and at least one heartbeat	12/230 (5.2%)	0/3 (0.0%)	2/32 (6.3%)	0/31 (0.0%)	0/22 (0.0%)	1/12 (8.3%)	2/19 (10.5%)
Mean ³ (CI)	55.4 (48.6,62.3)	37.5 (0,92.3)	59.2 (40.7,77.7)	51.4 (33.2,69.6)	66.3 (46.6,86.1)	60.9 (30.6,91.1)	69.1 (45.7,92.5)

¹ 11 participants could not be matched with Wisepill data and are excluded.

² Participants are expected to refill the Wisepill device on Monday of each week unless the participant is on a product hold. Wisepill opening signals in this table do not exclude those due to refills.

³ Mean calculated only among participants with at least one heartbeat.

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**Table 8.1a - Adherence as Measured by Wisepill Electronic Monitoring Device (EDM) by Study Visit and Site
SIM Compatible
MALE**

	Total	Baltimore, MD	Boston, MA	Chapel Hill/ Raleigh, NC	Cleveland, OH	Los Angeles, CA	New York, NY
Distribution of participants' percentage of days with recorded Wisepill opening signals ^{1,2}							
Week 25-32							
100%	5/228 (2.2%)	0/3 (0.0%)	1/32 (3.1%)	0/31 (0.0%)	1/22 (4.5%)	0/12 (0.0%)	1/19 (5.3%)
90-99%	37/228 (16.2%)	0/3 (0.0%)	3/32 (9.4%)	5/31 (16.1%)	7/22 (31.8%)	0/12 (0.0%)	5/19 (26.3%)
51-89%	79/228 (34.6%)	1/3 (33.3%)	14/32 (43.8%)	9/31 (29.0%)	5/22 (22.7%)	8/12 (66.7%)	4/19 (21.1%)
1-50%	52/228 (22.8%)	2/3 (66.7%)	2/32 (6.3%)	12/31 (38.7%)	8/22 (36.4%)	1/12 (8.3%)	3/19 (15.8%)
0% and all heartbeats missing	40/228 (17.5%)	0/3 (0.0%)	10/32 (31.3%)	3/31 (9.7%)	1/22 (4.5%)	2/12 (16.7%)	5/19 (26.3%)
0% and at least one heartbeat	15/228 (6.6%)	0/3 (0.0%)	2/32 (6.3%)	2/31 (6.5%)	0/22 (0.0%)	1/12 (8.3%)	1/19 (5.3%)
Mean ³ (CI)	57.9 (50.8,64.9)	37.5 (0,92.3)	69.0 (49.7,88.3)	46.4 (28,64.9)	61.6 (40.8,82.4)	60.7 (30.4,91)	69.6 (45.6,93.7)
Week 33-40							
100%	5/226 (2.2%)	0/3 (0.0%)	0/31 (0.0%)	1/30 (3.3%)	1/22 (4.5%)	0/12 (0.0%)	1/19 (5.3%)
90-99%	34/226 (15.0%)	0/3 (0.0%)	6/31 (19.4%)	4/30 (13.3%)	4/22 (18.2%)	2/12 (16.7%)	2/19 (10.5%)
51-89%	63/226 (27.9%)	0/3 (0.0%)	9/31 (29.0%)	7/30 (23.3%)	6/22 (27.3%)	1/12 (8.3%)	5/19 (26.3%)
1-50%	58/226 (25.7%)	2/3 (66.7%)	4/31 (12.9%)	13/30 (43.3%)	7/22 (31.8%)	6/12 (50.0%)	4/19 (21.1%)
0% and all heartbeats missing	48/226 (21.2%)	0/3 (0.0%)	11/31 (35.5%)	4/30 (13.3%)	1/22 (4.5%)	3/12 (25.0%)	7/19 (36.8%)
0% and at least one heartbeat	18/226 (8.0%)	1/3 (33.3%)	1/31 (3.2%)	1/30 (3.3%)	3/22 (13.6%)	0/12 (0.0%)	0/19 (0.0%)
Mean ³ (CI)	53.1 (45.7,60.4)	22.6 (0,70)	70.4 (50.4,90.4)	45.4 (26.3,64.5)	50.2 (28.8,71.6)	44.4 (12,76.9)	64.8 (37.7,91.8)
Week 41-48							
100%	5/224 (2.2%)	0/3 (0.0%)	1/31 (3.2%)	0/29 (0.0%)	1/22 (4.5%)	0/12 (0.0%)	1/19 (5.3%)
90-99%	27/224 (12.1%)	0/3 (0.0%)	6/31 (19.4%)	3/29 (10.3%)	4/22 (18.2%)	0/12 (0.0%)	2/19 (10.5%)
51-89%	64/224 (28.6%)	0/3 (0.0%)	8/31 (25.8%)	6/29 (20.7%)	8/22 (36.4%)	4/12 (33.3%)	6/19 (31.6%)
1-50%	52/224 (23.2%)	3/3 (100.0%)	4/31 (12.9%)	11/29 (37.9%)	4/22 (18.2%)	4/12 (33.3%)	3/19 (15.8%)
0% and all heartbeats missing	59/224 (26.3%)	0/3 (0.0%)	10/31 (32.3%)	6/29 (20.7%)	3/22 (13.6%)	3/12 (25.0%)	7/19 (36.8%)
0% and at least one heartbeat	17/224 (7.6%)	0/3 (0.0%)	2/31 (6.5%)	3/29 (10.3%)	2/22 (9.1%)	1/12 (8.3%)	0/19 (0.0%)
Mean ³ (CI)	54.3 (46.8,61.9)	31.5 (0,84.1)	65.9 (45.6,86.2)	40.8 (21.1,60.4)	55.5 (33.1,77.8)	48.6 (16,81.3)	74.5 (49.8,99.1)

¹ 11 participants could not be matched with Wisepill data and are excluded.

² Participants are expected to refill the Wisepill device on Monday of each week unless the participant is on a product hold. Wisepill opening signals in this table do not exclude those due to refills.

³ Mean calculated only among participants with at least one heartbeat.

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**Table 8.1a - Adherence as Measured by Wisepill Electronic Monitoring Device (EDM) by Study Visit and Site
SIM Compatible
MALE**

	Total	Philadelphia, PA	Pittsburgh, PA	San Francisco, CA	San Juan, PR	Seattle, WA	Washington DC
Distribution of participants' percentage of days with recorded Wisepill opening signals ^{1,2}							
Week 1-8							
100%	13/229 (5.7%)	0/27 (0.0%)	0/10 (0.0%)	0/23 (0.0%)	1/9 (11.1%)	2/17 (11.8%)	0/24 (0.0%)
90-99%	70/229 (30.6%)	8/27 (29.6%)	4/10 (40.0%)	7/23 (30.4%)	3/9 (33.3%)	7/17 (41.2%)	0/24 (0.0%)
51-89%	106/229 (46.3%)	12/27 (44.4%)	6/10 (60.0%)	12/23 (52.2%)	5/9 (55.6%)	7/17 (41.2%)	14/24 (58.3%)
1-50%	39/229 (17.0%)	7/27 (25.9%)	0/10 (0.0%)	4/23 (17.4%)	0/9 (0.0%)	1/17 (5.9%)	10/24 (41.7%)
0% and all heartbeats missing	1/229 (0.4%)	0/27 (0.0%)	0/10 (0.0%)	0/23 (0.0%)	0/9 (0.0%)	0/17 (0.0%)	0/24 (0.0%)
0% and at least one heartbeat	0/229 (0.0%)	0/27 (0.0%)	0/10 (0.0%)	0/23 (0.0%)	0/9 (0.0%)	0/17 (0.0%)	0/24 (0.0%)
Mean ³ (CI)	75.4 (69.8,81)	71.4 (54.3,88.4)	83.5 (60.4,100)	72.6 (54.4,90.8)	82.9 (58.4,100)	82.7 (64.7,100)	55.1 (35.2,75)
Week 9-16							
100%	6/229 (2.6%)	0/27 (0.0%)	0/10 (0.0%)	0/23 (0.0%)	1/9 (11.1%)	1/17 (5.9%)	0/24 (0.0%)
90-99%	47/229 (20.5%)	3/27 (11.1%)	3/10 (30.0%)	4/23 (17.4%)	2/9 (22.2%)	5/17 (29.4%)	0/24 (0.0%)
51-89%	99/229 (43.2%)	12/27 (44.4%)	4/10 (40.0%)	13/23 (56.5%)	6/9 (66.7%)	8/17 (47.1%)	5/24 (20.8%)
1-50%	58/229 (25.3%)	8/27 (29.6%)	3/10 (30.0%)	5/23 (21.7%)	0/9 (0.0%)	3/17 (17.6%)	13/24 (54.2%)
0% and all heartbeats missing	5/229 (2.2%)	2/27 (7.4%)	0/10 (0.0%)	1/23 (4.3%)	0/9 (0.0%)	0/17 (0.0%)	1/24 (4.2%)
0% and at least one heartbeat	14/229 (6.1%)	2/27 (7.4%)	0/10 (0.0%)	0/23 (0.0%)	0/9 (0.0%)	0/17 (0.0%)	5/24 (20.8%)
Mean ³ (CI)	61.0 (54.6,67.4)	54.9 (35.3,74.4)	68.9 (40.2,97.6)	62.5 (42.3,82.7)	84.1 (60.3,100)	69.5 (47.7,91.4)	29.0 (10.5,47.6)
Week 17-24							
100%	4/230 (1.7%)	0/27 (0.0%)	0/10 (0.0%)	0/24 (0.0%)	1/9 (11.1%)	0/17 (0.0%)	0/24 (0.0%)
90-99%	43/230 (18.7%)	5/27 (18.5%)	2/10 (20.0%)	1/24 (4.2%)	2/9 (22.2%)	5/17 (29.4%)	1/24 (4.2%)
51-89%	76/230 (33.0%)	8/27 (29.6%)	3/10 (30.0%)	7/24 (29.2%)	5/9 (55.6%)	9/17 (52.9%)	5/24 (20.8%)
1-50%	68/230 (29.6%)	9/27 (33.3%)	5/10 (50.0%)	11/24 (45.8%)	1/9 (11.1%)	3/17 (17.6%)	7/24 (29.2%)
0% and all heartbeats missing	27/230 (11.7%)	4/27 (14.8%)	0/10 (0.0%)	4/24 (16.7%)	0/9 (0.0%)	0/17 (0.0%)	6/24 (25.0%)
0% and at least one heartbeat	12/230 (5.2%)	1/27 (3.7%)	0/10 (0.0%)	1/24 (4.2%)	0/9 (0.0%)	0/17 (0.0%)	5/24 (20.8%)
Mean ³ (CI)	55.4 (48.6,62.3)	51.1 (30.7,71.5)	53.4 (22.5,84.4)	42.4 (20.7,64)	78.4 (51.5,100)	68.3 (46.2,90.4)	29.1 (8.1,50)

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³ Mean calculated only among participants with at least one heartbeat.

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MALE**

	Total	Philadelphia, PA	Pittsburgh, PA	San Francisco, CA	San Juan, PR	Seattle, WA	Washington DC
Distribution of participants' percentage of days with recorded Wisepill opening signals ^{1,2}							
Week 25-32							
100%	5/228 (2.2%)	0/27 (0.0%)	0/9 (0.0%)	0/24 (0.0%)	1/8 (12.5%)	1/17 (5.9%)	0/24 (0.0%)
90-99%	37/228 (16.2%)	2/27 (7.4%)	2/9 (22.2%)	4/24 (16.7%)	2/8 (25.0%)	6/17 (35.3%)	1/24 (4.2%)
51-89%	79/228 (34.6%)	10/27 (37.0%)	4/9 (44.4%)	8/24 (33.3%)	4/8 (50.0%)	6/17 (35.3%)	6/24 (25.0%)
1-50%	52/228 (22.8%)	8/27 (29.6%)	3/9 (33.3%)	4/24 (16.7%)	0/8 (0.0%)	4/17 (23.5%)	5/24 (20.8%)
0% and all heartbeats missing	40/228 (17.5%)	5/27 (18.5%)	0/9 (0.0%)	5/24 (20.8%)	1/8 (12.5%)	0/17 (0.0%)	8/24 (33.3%)
0% and at least one heartbeat	15/228 (6.6%)	2/27 (7.4%)	0/9 (0.0%)	3/24 (12.5%)	0/8 (0.0%)	0/17 (0.0%)	4/24 (16.7%)
Mean ³ (CI)	57.9 (50.8,64.9)	51.1 (30.2,71.9)	53.4 (20.8,86)	58.6 (36.4,80.7)	77.2 (48.2,100)	71.7 (50.3,93.1)	35.9 (12.4,59.4)
Week 33-40							
100%	5/226 (2.2%)	0/27 (0.0%)	0/9 (0.0%)	0/24 (0.0%)	1/8 (12.5%)	1/17 (5.9%)	0/24 (0.0%)
90-99%	34/226 (15.0%)	3/27 (11.1%)	2/9 (22.2%)	3/24 (12.5%)	2/8 (25.0%)	6/17 (35.3%)	0/24 (0.0%)
51-89%	63/226 (27.9%)	7/27 (25.9%)	3/9 (33.3%)	9/24 (37.5%)	4/8 (50.0%)	5/17 (29.4%)	7/24 (29.2%)
1-50%	58/226 (25.7%)	7/27 (25.9%)	3/9 (33.3%)	8/24 (33.3%)	0/8 (0.0%)	3/17 (17.6%)	1/24 (4.2%)
0% and all heartbeats missing	48/226 (21.2%)	7/27 (25.9%)	0/9 (0.0%)	3/24 (12.5%)	1/8 (12.5%)	0/17 (0.0%)	11/24 (45.8%)
0% and at least one heartbeat	18/226 (8.0%)	3/27 (11.1%)	1/9 (11.1%)	1/24 (4.2%)	0/8 (0.0%)	2/17 (11.8%)	5/24 (20.8%)
Mean ³ (CI)	53.1 (45.7,60.4)	46.3 (24.5,68.2)	50.8 (18.1,83.5)	50.4 (29,71.8)	82.1 (53.8,100)	63.2 (40.3,86.2)	35.9 (9.8,61.9)
Week 41-48							
100%	5/224 (2.2%)	0/27 (0.0%)	0/8 (0.0%)	1/24 (4.2%)	1/8 (12.5%)	0/17 (0.0%)	0/24 (0.0%)
90-99%	27/224 (12.1%)	4/27 (14.8%)	1/8 (12.5%)	0/24 (0.0%)	2/8 (25.0%)	5/17 (29.4%)	0/24 (0.0%)
51-89%	64/224 (28.6%)	4/27 (14.8%)	4/8 (50.0%)	11/24 (45.8%)	3/8 (37.5%)	6/17 (35.3%)	4/24 (16.7%)
1-50%	52/224 (23.2%)	7/27 (25.9%)	2/8 (25.0%)	6/24 (25.0%)	1/8 (12.5%)	3/17 (17.6%)	4/24 (16.7%)
0% and all heartbeats missing	59/224 (26.3%)	8/27 (29.6%)	0/8 (0.0%)	5/24 (20.8%)	1/8 (12.5%)	0/17 (0.0%)	16/24 (66.7%)
0% and at least one heartbeat	17/224 (7.6%)	4/27 (14.8%)	1/8 (12.5%)	1/24 (4.2%)	0/8 (0.0%)	3/17 (17.6%)	0/24 (0.0%)
Mean ³ (CI)	54.3 (46.8,61.9)	44.8 (22.5,67.2)	53.6 (19,88.1)	52.9 (30.5,75.4)	75.3 (43.3,100)	57.9 (34.4,81.3)	47.8 (13.2,82.4)

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**Table 8.1b - Adherence as Measured by Wisepill Electronic Monitoring Device (EDM) by Study Visit and Site
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FEMALE**

	Total	Baltimore, MD	Boston, MA	Chapel Hill/ Raleigh, NC	Cleveland, OH	Los Angeles, CA	New York, NY
Distribution of participants' percentage of days with recorded Wisepill opening signals ^{1,2}							
Week 1-8							
100%	0/13 (0.0%)	0/0 (-%)	0/0 (-%)	0/4 (0.0%)	0/1 (0.0%)	0/0 (-%)	0/0 (-%)
90-99%	0/13 (0.0%)	0/0 (-%)	0/0 (-%)	0/4 (0.0%)	0/1 (0.0%)	0/0 (-%)	0/0 (-%)
51-89%	6/13 (46.2%)	0/0 (-%)	0/0 (-%)	0/4 (0.0%)	1/1 (100.0%)	0/0 (-%)	0/0 (-%)
1-50%	5/13 (38.5%)	0/0 (-%)	0/0 (-%)	2/4 (50.0%)	0/1 (0.0%)	0/0 (-%)	0/0 (-%)
0% and all heartbeats missing	2/13 (15.4%)	0/0 (-%)	0/0 (-%)	2/4 (50.0%)	0/1 (0.0%)	0/0 (-%)	0/0 (-%)
0% and at least one heartbeat	0/13 (0.0%)	0/0 (-%)	0/0 (-%)	0/4 (0.0%)	0/1 (0.0%)	0/0 (-%)	0/0 (-%)
Mean ³ (CI)	54.9 (25.5,84.3)	-(-,-)	-(-,-)	23.2 (0,81.7)	89.3 (.,.)	-(-,-)	-(-,-)
Week 9-16							
100%	0/11 (0.0%)	0/0 (-%)	0/0 (-%)	0/2 (0.0%)	0/1 (0.0%)	0/0 (-%)	0/0 (-%)
90-99%	1/11 (9.1%)	0/0 (-%)	0/0 (-%)	0/2 (0.0%)	1/1 (100.0%)	0/0 (-%)	0/0 (-%)
51-89%	3/11 (27.3%)	0/0 (-%)	0/0 (-%)	0/2 (0.0%)	0/1 (0.0%)	0/0 (-%)	0/0 (-%)
1-50%	3/11 (27.3%)	0/0 (-%)	0/0 (-%)	0/2 (0.0%)	0/1 (0.0%)	0/0 (-%)	0/0 (-%)
0% and all heartbeats missing	2/11 (18.2%)	0/0 (-%)	0/0 (-%)	1/2 (50.0%)	0/1 (0.0%)	0/0 (-%)	0/0 (-%)
0% and at least one heartbeat	2/11 (18.2%)	0/0 (-%)	0/0 (-%)	1/2 (50.0%)	0/1 (0.0%)	0/0 (-%)	0/0 (-%)
Mean ³ (CI)	41.9 (9.6,74.1)	-(-,-)	-(-,-)	0.0 (.,.)	91.1 (.,.)	-(-,-)	-(-,-)
Week 17-24							
100%	0/11 (0.0%)	0/0 (-%)	0/0 (-%)	0/2 (0.0%)	0/1 (0.0%)	0/0 (-%)	0/0 (-%)
90-99%	0/11 (0.0%)	0/0 (-%)	0/0 (-%)	0/2 (0.0%)	0/1 (0.0%)	0/0 (-%)	0/0 (-%)
51-89%	2/11 (18.2%)	0/0 (-%)	0/0 (-%)	0/2 (0.0%)	1/1 (100.0%)	0/0 (-%)	0/0 (-%)
1-50%	5/11 (45.5%)	0/0 (-%)	0/0 (-%)	1/2 (50.0%)	0/1 (0.0%)	0/0 (-%)	0/0 (-%)
0% and all heartbeats missing	4/11 (36.4%)	0/0 (-%)	0/0 (-%)	1/2 (50.0%)	0/1 (0.0%)	0/0 (-%)	0/0 (-%)
0% and at least one heartbeat	0/11 (0.0%)	0/0 (-%)	0/0 (-%)	0/2 (0.0%)	0/1 (0.0%)	0/0 (-%)	0/0 (-%)
Mean ³ (CI)	41.1 (4.7,77.6)	-(-,-)	-(-,-)	2.1 (.,.)	89.3 (.,.)	-(-,-)	-(-,-)

¹ 9 participants could not be matched with Wisepill data and are excluded.

² Participants are expected to refill the Wisepill device on Monday of each week unless the participant is on a product hold. Wisepill opening signals in this table do not exclude those due to refills.

³ Mean calculated only among participants with at least one heartbeat.

HPTN 069 - A Phase II Randomized Study of the Safety and Tolerability of Maraviroc to Prevent HIV Transmission

Live Open Report - October 15, 2014

Visit Cutoff Date: October 15, 2014

**Table 8.1b - Adherence as Measured by Wisepill Electronic Monitoring Device (EDM) by Study Visit and Site
SIM Compatible
FEMALE**

	Total	Baltimore, MD	Boston, MA	Chapel Hill/ Raleigh, NC	Cleveland, OH	Los Angeles, CA	New York, NY
Distribution of participants' percentage of days with recorded Wisepill opening signals ^{1,2}							
Week 25-32							
100%	0/10 (0.0%)	0/0 (-%)	0/0 (-%)	0/1 (0.0%)	0/1 (0.0%)	0/0 (-%)	0/0 (-%)
90-99%	0/10 (0.0%)	0/0 (-%)	0/0 (-%)	0/1 (0.0%)	0/1 (0.0%)	0/0 (-%)	0/0 (-%)
51-89%	2/10 (20.0%)	0/0 (-%)	0/0 (-%)	0/1 (0.0%)	1/1 (100.0%)	0/0 (-%)	0/0 (-%)
1-50%	3/10 (30.0%)	0/0 (-%)	0/0 (-%)	0/1 (0.0%)	0/1 (0.0%)	0/0 (-%)	0/0 (-%)
0% and all heartbeats missing	4/10 (40.0%)	0/0 (-%)	0/0 (-%)	1/1 (100.0%)	0/1 (0.0%)	0/0 (-%)	0/0 (-%)
0% and at least one heartbeat	1/10 (10.0%)	0/0 (-%)	0/0 (-%)	0/1 (0.0%)	0/1 (0.0%)	0/0 (-%)	0/0 (-%)
Mean ³ (CI)	36.0 (0,74.4)	-(-,-)	-(-,-)	-(-,-)	87.5 (.,.)	-(-,-)	-(-,-)
Week 33-40							
100%	0/10 (0.0%)	0/0 (-%)	0/0 (-%)	0/1 (0.0%)	0/1 (0.0%)	0/0 (-%)	0/0 (-%)
90-99%	0/10 (0.0%)	0/0 (-%)	0/0 (-%)	0/1 (0.0%)	0/1 (0.0%)	0/0 (-%)	0/0 (-%)
51-89%	1/10 (10.0%)	0/0 (-%)	0/0 (-%)	0/1 (0.0%)	1/1 (100.0%)	0/0 (-%)	0/0 (-%)
1-50%	5/10 (50.0%)	0/0 (-%)	0/0 (-%)	0/1 (0.0%)	0/1 (0.0%)	0/0 (-%)	0/0 (-%)
0% and all heartbeats missing	3/10 (30.0%)	0/0 (-%)	0/0 (-%)	1/1 (100.0%)	0/1 (0.0%)	0/0 (-%)	0/0 (-%)
0% and at least one heartbeat	1/10 (10.0%)	0/0 (-%)	0/0 (-%)	0/1 (0.0%)	0/1 (0.0%)	0/0 (-%)	0/0 (-%)
Mean ³ (CI)	29.3 (0,63.1)	-(-,-)	-(-,-)	-(-,-)	76.8 (.,.)	-(-,-)	-(-,-)
Week 41-48							
100%	0/10 (0.0%)	0/0 (-%)	0/0 (-%)	0/1 (0.0%)	0/1 (0.0%)	0/0 (-%)	0/0 (-%)
90-99%	1/10 (10.0%)	0/0 (-%)	0/0 (-%)	0/1 (0.0%)	0/1 (0.0%)	0/0 (-%)	0/0 (-%)
51-89%	1/10 (10.0%)	0/0 (-%)	0/0 (-%)	0/1 (0.0%)	0/1 (0.0%)	0/0 (-%)	0/0 (-%)
1-50%	3/10 (30.0%)	0/0 (-%)	0/0 (-%)	0/1 (0.0%)	1/1 (100.0%)	0/0 (-%)	0/0 (-%)
0% and all heartbeats missing	3/10 (30.0%)	0/0 (-%)	0/0 (-%)	1/1 (100.0%)	0/1 (0.0%)	0/0 (-%)	0/0 (-%)
0% and at least one heartbeat	2/10 (20.0%)	0/0 (-%)	0/0 (-%)	0/1 (0.0%)	0/1 (0.0%)	0/0 (-%)	0/0 (-%)
Mean ³ (CI)	35.2 (0,70.6)	-(-,-)	-(-,-)	-(-,-)	25.0 (.,.)	-(-,-)	-(-,-)

¹ 9 participants could not be matched with Wisepill data and are excluded.

² Participants are expected to refill the Wisepill device on Monday of each week unless the participant is on a product hold. Wisepill opening signals in this table do not exclude those due to refills.

³ Mean calculated only among participants with at least one heartbeat.

HPTN 069 - A Phase II Randomized Study of the Safety and Tolerability of Maraviroc to Prevent HIV Transmission

Live Open Report - October 15, 2014

Visit Cutoff Date: October 15, 2014

**Table 8.1b - Adherence as Measured by Wisepill Electronic Monitoring Device (EDM) by Study Visit and Site
SIM Compatible
FEMALE**

	Total	Newark, NJ	Philadelphia, PA	Pittsburgh, PA	San Juan, PR	Seattle, WA	Washington DC
Distribution of participants' percentage of days with recorded Wisepill opening signals ^{1,2}							
Week 1-8							
100%	0/13 (0.0%)	0/5 (0.0%)	0/3 (0.0%)	0/0 (-%)	0/0 (-%)	0/0 (-%)	0/0 (-%)
90-99%	0/13 (0.0%)	0/5 (0.0%)	0/3 (0.0%)	0/0 (-%)	0/0 (-%)	0/0 (-%)	0/0 (-%)
51-89%	6/13 (46.2%)	2/5 (40.0%)	3/3 (100.0%)	0/0 (-%)	0/0 (-%)	0/0 (-%)	0/0 (-%)
1-50%	5/13 (38.5%)	3/5 (60.0%)	0/3 (0.0%)	0/0 (-%)	0/0 (-%)	0/0 (-%)	0/0 (-%)
0% and all heartbeats missing	2/13 (15.4%)	0/5 (0.0%)	0/3 (0.0%)	0/0 (-%)	0/0 (-%)	0/0 (-%)	0/0 (-%)
0% and at least one heartbeat	0/13 (0.0%)	0/5 (0.0%)	0/3 (0.0%)	0/0 (-%)	0/0 (-%)	0/0 (-%)	0/0 (-%)
Mean ³ (CI)	54.9 (25.5,84.3)	50.4 (6.5,94.2)	72.0 (21.2,100)	-(-,-)	-(-,-)	-(-,-)	-(-,-)
Week 9-16							
100%	0/11 (0.0%)	0/5 (0.0%)	0/3 (0.0%)	0/0 (-%)	0/0 (-%)	0/0 (-%)	0/0 (-%)
90-99%	1/11 (9.1%)	0/5 (0.0%)	0/3 (0.0%)	0/0 (-%)	0/0 (-%)	0/0 (-%)	0/0 (-%)
51-89%	3/11 (27.3%)	1/5 (20.0%)	2/3 (66.7%)	0/0 (-%)	0/0 (-%)	0/0 (-%)	0/0 (-%)
1-50%	3/11 (27.3%)	2/5 (40.0%)	1/3 (33.3%)	0/0 (-%)	0/0 (-%)	0/0 (-%)	0/0 (-%)
0% and all heartbeats missing	2/11 (18.2%)	1/5 (20.0%)	0/3 (0.0%)	0/0 (-%)	0/0 (-%)	0/0 (-%)	0/0 (-%)
0% and at least one heartbeat	2/11 (18.2%)	1/5 (20.0%)	0/3 (0.0%)	0/0 (-%)	0/0 (-%)	0/0 (-%)	0/0 (-%)
Mean ³ (CI)	41.9 (9.6,74.1)	28.1 (0,72.2)	57.7 (1.8,100)	-(-,-)	-(-,-)	-(-,-)	-(-,-)
Week 17-24							
100%	0/11 (0.0%)	0/5 (0.0%)	0/3 (0.0%)	0/0 (-%)	0/0 (-%)	0/0 (-%)	0/0 (-%)
90-99%	0/11 (0.0%)	0/5 (0.0%)	0/3 (0.0%)	0/0 (-%)	0/0 (-%)	0/0 (-%)	0/0 (-%)
51-89%	2/11 (18.2%)	0/5 (0.0%)	1/3 (33.3%)	0/0 (-%)	0/0 (-%)	0/0 (-%)	0/0 (-%)
1-50%	5/11 (45.5%)	3/5 (60.0%)	1/3 (33.3%)	0/0 (-%)	0/0 (-%)	0/0 (-%)	0/0 (-%)
0% and all heartbeats missing	4/11 (36.4%)	2/5 (40.0%)	1/3 (33.3%)	0/0 (-%)	0/0 (-%)	0/0 (-%)	0/0 (-%)
0% and at least one heartbeat	0/11 (0.0%)	0/5 (0.0%)	0/3 (0.0%)	0/0 (-%)	0/0 (-%)	0/0 (-%)	0/0 (-%)
Mean ³ (CI)	41.1 (4.7,77.6)	32.7 (0,85.8)	49.1 (0,100)	-(-,-)	-(-,-)	-(-,-)	-(-,-)

¹ 9 participants could not be matched with Wisepill data and are excluded.

² Participants are expected to refill the Wisepill device on Monday of each week unless the participant is on a product hold. Wisepill opening signals in this table do not exclude those due to refills.

³ Mean calculated only among participants with at least one heartbeat.

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Live Open Report - October 15, 2014

Visit Cutoff Date: October 15, 2014

**Table 8.1b - Adherence as Measured by Wisepill Electronic Monitoring Device (EDM) by Study Visit and Site
SIM Compatible
FEMALE**

	Total	Newark, NJ	Philadelphia, PA	Pittsburgh, PA	San Juan, PR	Seattle, WA	Washington DC
Distribution of participants' percentage of days with recorded Wisepill opening signals ^{1,2}							
Week 25-32							
100%	0/10 (0.0%)	0/5 (0.0%)	0/3 (0.0%)	0/0 (-%)	0/0 (-%)	0/0 (-%)	0/0 (-%)
90-99%	0/10 (0.0%)	0/5 (0.0%)	0/3 (0.0%)	0/0 (-%)	0/0 (-%)	0/0 (-%)	0/0 (-%)
51-89%	2/10 (20.0%)	0/5 (0.0%)	1/3 (33.3%)	0/0 (-%)	0/0 (-%)	0/0 (-%)	0/0 (-%)
1-50%	3/10 (30.0%)	2/5 (40.0%)	1/3 (33.3%)	0/0 (-%)	0/0 (-%)	0/0 (-%)	0/0 (-%)
0% and all heartbeats missing	4/10 (40.0%)	2/5 (40.0%)	1/3 (33.3%)	0/0 (-%)	0/0 (-%)	0/0 (-%)	0/0 (-%)
0% and at least one heartbeat	1/10 (10.0%)	1/5 (20.0%)	0/3 (0.0%)	0/0 (-%)	0/0 (-%)	0/0 (-%)	0/0 (-%)
Mean ³ (CI)	36.0 (0,74.4)	22.0 (0,68.9)	31.3 (0,95.5)	-(-,-)	-(-,-)	-(-,-)	-(-,-)
Week 33-40							
100%	0/10 (0.0%)	0/5 (0.0%)	0/3 (0.0%)	0/0 (-%)	0/0 (-%)	0/0 (-%)	0/0 (-%)
90-99%	0/10 (0.0%)	0/5 (0.0%)	0/3 (0.0%)	0/0 (-%)	0/0 (-%)	0/0 (-%)	0/0 (-%)
51-89%	1/10 (10.0%)	0/5 (0.0%)	0/3 (0.0%)	0/0 (-%)	0/0 (-%)	0/0 (-%)	0/0 (-%)
1-50%	5/10 (50.0%)	3/5 (60.0%)	2/3 (66.7%)	0/0 (-%)	0/0 (-%)	0/0 (-%)	0/0 (-%)
0% and all heartbeats missing	3/10 (30.0%)	2/5 (40.0%)	0/3 (0.0%)	0/0 (-%)	0/0 (-%)	0/0 (-%)	0/0 (-%)
0% and at least one heartbeat	1/10 (10.0%)	0/5 (0.0%)	1/3 (33.3%)	0/0 (-%)	0/0 (-%)	0/0 (-%)	0/0 (-%)
Mean ³ (CI)	29.3 (0,63.1)	22.6 (0,70)	20.2 (0,65.7)	-(-,-)	-(-,-)	-(-,-)	-(-,-)
Week 41-48							
100%	0/10 (0.0%)	0/5 (0.0%)	0/3 (0.0%)	0/0 (-%)	0/0 (-%)	0/0 (-%)	0/0 (-%)
90-99%	1/10 (10.0%)	0/5 (0.0%)	1/3 (33.3%)	0/0 (-%)	0/0 (-%)	0/0 (-%)	0/0 (-%)
51-89%	1/10 (10.0%)	1/5 (20.0%)	0/3 (0.0%)	0/0 (-%)	0/0 (-%)	0/0 (-%)	0/0 (-%)
1-50%	3/10 (30.0%)	1/5 (20.0%)	1/3 (33.3%)	0/0 (-%)	0/0 (-%)	0/0 (-%)	0/0 (-%)
0% and all heartbeats missing	3/10 (30.0%)	2/5 (40.0%)	0/3 (0.0%)	0/0 (-%)	0/0 (-%)	0/0 (-%)	0/0 (-%)
0% and at least one heartbeat	2/10 (20.0%)	1/5 (20.0%)	1/3 (33.3%)	0/0 (-%)	0/0 (-%)	0/0 (-%)	0/0 (-%)
Mean ³ (CI)	35.2 (0,70.6)	31.5 (0,84.1)	42.3 (0,98.2)	-(-,-)	-(-,-)	-(-,-)	-(-,-)

¹ 9 participants could not be matched with Wisepill data and are excluded.

² Participants are expected to refill the Wisepill device on Monday of each week unless the participant is on a product hold. Wisepill opening signals in this table do not exclude those due to refills.

³ Mean calculated only among participants with at least one heartbeat.

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Live Open Report - October 15, 2014

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Table 8.2a - Adherence as Measured by Wisepill Electronic Monitoring Device (EDM) by Study Visit and Site

SIM Non-compatible

MALE

	Total	Baltimore, MD	Boston, MA	Chapel Hill/ Raleigh, NC	Cleveland, OH	Los Angeles, CA	New York, NY
Distribution of participants' percentage of days with recorded Wisepill opening signals ^{1,2}							
Week 1-8							
100%	1/157 (0.6%)	0/18 (0.0%)	0/14 (0.0%)	0/4 (0.0%)	0/11 (0.0%)	0/15 (0.0%)	1/9 (11.1%)
90-99%	28/157 (17.8%)	2/18 (11.1%)	2/14 (14.3%)	1/4 (25.0%)	3/11 (27.3%)	0/15 (0.0%)	3/9 (33.3%)
51-89%	75/157 (47.8%)	11/18 (61.1%)	7/14 (50.0%)	1/4 (25.0%)	4/11 (36.4%)	6/15 (40.0%)	2/9 (22.2%)
1-50%	48/157 (30.6%)	5/18 (27.8%)	5/14 (35.7%)	2/4 (50.0%)	4/11 (36.4%)	7/15 (46.7%)	2/9 (22.2%)
0% and all heartbeats missing	5/157 (3.2%)	0/18 (0.0%)	0/14 (0.0%)	0/4 (0.0%)	0/11 (0.0%)	2/15 (13.3%)	1/9 (11.1%)
Mean ³ (CI)	62.8 (55.1,70.4)	61.6 (39.1,84.1)	60.7 (35.1,86.3)	58.9 (10.7,100)	62.0 (33.3,90.7)	48.1 (20.9,75.2)	72.2 (41.1,100)
Week 9-16							
100%	5/158 (3.2%)	0/17 (0.0%)	1/14 (7.1%)	0/4 (0.0%)	0/11 (0.0%)	0/16 (0.0%)	2/9 (22.2%)
90-99%	17/158 (10.8%)	3/17 (17.6%)	3/14 (21.4%)	1/4 (25.0%)	1/11 (9.1%)	1/16 (6.3%)	1/9 (11.1%)
51-89%	81/158 (51.3%)	8/17 (47.1%)	5/14 (35.7%)	2/4 (50.0%)	7/11 (63.6%)	8/16 (50.0%)	2/9 (22.2%)
1-50%	29/158 (18.4%)	5/17 (29.4%)	3/14 (21.4%)	0/4 (0.0%)	2/11 (18.2%)	0/16 (0.0%)	4/9 (44.4%)
0% and all heartbeats missing	26/158 (16.5%)	1/17 (5.9%)	2/14 (14.3%)	1/4 (25.0%)	1/11 (9.1%)	7/16 (43.8%)	0/9 (0.0%)
Mean ³ (CI)	67.0 (59,75.1)	59.9 (35.9,83.9)	67.1 (40.5,93.7)	83.9 (42.4,100)	74.1 (47,100)	72.8 (43.8,100)	60.5 (28.6,92.5)
Week 17-24							
100%	3/160 (1.9%)	0/18 (0.0%)	0/14 (0.0%)	0/4 (0.0%)	0/11 (0.0%)	0/16 (0.0%)	2/9 (22.2%)
90-99%	21/160 (13.1%)	2/18 (11.1%)	2/14 (14.3%)	2/4 (50.0%)	3/11 (27.3%)	2/16 (12.5%)	0/9 (0.0%)
51-89%	59/160 (36.9%)	8/18 (44.4%)	5/14 (35.7%)	1/4 (25.0%)	3/11 (27.3%)	3/16 (18.8%)	3/9 (33.3%)
1-50%	46/160 (28.8%)	5/18 (27.8%)	3/14 (21.4%)	0/4 (0.0%)	5/11 (45.5%)	5/16 (31.3%)	3/9 (33.3%)
0% and all heartbeats missing	31/160 (19.4%)	3/18 (16.7%)	4/14 (28.6%)	1/4 (25.0%)	0/11 (0.0%)	6/16 (37.5%)	1/9 (11.1%)
Mean ³ (CI)	60.5 (52.1,69)	64.6 (40.3,88.8)	70.7 (42.5,98.9)	91.1 (58.8,100)	54.2 (24.8,83.7)	52.0 (21,82.9)	67.2 (34.7,99.7)

¹ One participant in Seattle was not given study drug and was terminated from the study. 11 participants could not be matched with Wisepill data and are excluded.

² Participants are expected to refill the Wisepill device on Monday of each week unless the participant is on a product hold. Wisepill opening signals in this table do not exclude those due to refills.

³ Mean calculated only among participants with at least one heartbeat.

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Table 8.2a - Adherence as Measured by Wisepill Electronic Monitoring Device (EDM) by Study Visit and Site

SIM Non-compatible

MALE

	Total	Baltimore, MD	Boston, MA	Chapel Hill/ Raleigh, NC	Cleveland, OH	Los Angeles, CA	New York, NY
Distribution of participants' percentage of days with recorded Wisepill opening signals ^{1,2}							
Week 25-32							
100%	4/161 (2.5%)	1/18 (5.6%)	0/14 (0.0%)	0/4 (0.0%)	0/11 (0.0%)	0/16 (0.0%)	2/9 (22.2%)
90-99%	16/161 (9.9%)	2/18 (11.1%)	2/14 (14.3%)	0/4 (0.0%)	0/11 (0.0%)	0/16 (0.0%)	0/9 (0.0%)
51-89%	59/161 (36.6%)	6/18 (33.3%)	6/14 (42.9%)	2/4 (50.0%)	5/11 (45.5%)	4/16 (25.0%)	3/9 (33.3%)
1-50%	42/161 (26.1%)	4/18 (22.2%)	2/14 (14.3%)	1/4 (25.0%)	5/11 (45.5%)	5/16 (31.3%)	3/9 (33.3%)
0% and all heartbeats missing	40/161 (24.8%)	5/18 (27.8%)	4/14 (28.6%)	1/4 (25.0%)	1/11 (9.1%)	7/16 (43.8%)	1/9 (11.1%)
Mean ³ (CI)	59.1 (50.4,67.9)	59.8 (33.2,86.5)	68.4 (39.6,97.2)	56.7 (8.1,100)	46.3 (15.3,77.2)	44.6 (12.1,77)	56.7 (22.4,91)
Week 33-40							
100%	3/156 (1.9%)	0/15 (0.0%)	0/14 (0.0%)	0/5 (0.0%)	0/11 (0.0%)	0/13 (0.0%)	2/9 (22.2%)
90-99%	16/156 (10.3%)	2/15 (13.3%)	2/14 (14.3%)	1/5 (20.0%)	0/11 (0.0%)	0/13 (0.0%)	0/9 (0.0%)
51-89%	54/156 (34.6%)	5/15 (33.3%)	6/14 (42.9%)	1/5 (20.0%)	5/11 (45.5%)	5/13 (38.5%)	3/9 (33.3%)
1-50%	30/156 (19.2%)	4/15 (26.7%)	1/14 (7.1%)	0/5 (0.0%)	2/11 (18.2%)	1/13 (7.7%)	3/9 (33.3%)
0% and all heartbeats missing	53/156 (34.0%)	4/15 (26.7%)	5/14 (35.7%)	3/5 (60.0%)	4/11 (36.4%)	7/13 (53.8%)	1/9 (11.1%)
Mean ³ (CI)	60.1 (50.6,69.5)	51.5 (21.9,81)	70.0 (40.1,100)	84.8 (35.1,100)	55.9 (19.1,92.7)	60.4 (21.3,99.5)	58.5 (24.3,92.6)
Week 41-48							
100%	2/148 (1.4%)	0/14 (0.0%)	0/14 (0.0%)	0/6 (0.0%)	0/11 (0.0%)	0/7 (0.0%)	2/9 (22.2%)
90-99%	8/148 (5.4%)	2/14 (14.3%)	1/14 (7.1%)	0/6 (0.0%)	1/11 (9.1%)	0/7 (0.0%)	0/9 (0.0%)
51-89%	51/148 (34.5%)	5/14 (35.7%)	5/14 (35.7%)	2/6 (33.3%)	2/11 (18.2%)	3/7 (42.9%)	1/9 (11.1%)
1-50%	31/148 (20.9%)	1/14 (7.1%)	3/14 (21.4%)	3/6 (50.0%)	3/11 (27.3%)	1/7 (14.3%)	2/9 (22.2%)
0% and all heartbeats missing	56/148 (37.8%)	6/14 (42.9%)	5/14 (35.7%)	1/6 (16.7%)	5/11 (45.5%)	3/7 (42.9%)	4/9 (44.4%)
Mean ³ (CI)	57.9 (47.9,68)	65.8 (33,98.7)	58.1 (25.9,90.4)	42.2 (0,85.5)	50.6 (10.6,90.6)	60.3 (12.3,100)	63.2 (20.9,100)

¹ One participant in Seattle was not given study drug and was terminated from the study. 11 participants could not be matched with Wisepill data and are excluded.

² Participants are expected to refill the Wisepill device on Monday of each week unless the participant is on a product hold. Wisepill opening signals in this table do not exclude those due to refills.

³ Mean calculated only among participants with at least one heartbeat.

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Visit Cutoff Date: October 15, 2014

Table 8.2a - Adherence as Measured by Wisepill Electronic Monitoring Device (EDM) by Study Visit and Site

SIM Non-compatible

MALE

	Total	Philadelphia, PA	Pittsburgh, PA	San Francisco, CA	San Juan, PR	Seattle, WA	Washington DC
Distribution of participants' percentage of days with recorded Wisepill opening signals ^{1,2}							
Week 1-8							
100%	1/157 (0.6%)	0/5 (0.0%)	0/13 (0.0%)	0/25 (0.0%)	0/13 (0.0%)	0/9 (0.0%)	0/21 (0.0%)
90-99%	28/157 (17.8%)	1/5 (20.0%)	6/13 (46.2%)	4/25 (16.0%)	2/13 (15.4%)	2/9 (22.2%)	2/21 (9.5%)
51-89%	75/157 (47.8%)	4/5 (80.0%)	6/13 (46.2%)	16/25 (64.0%)	9/13 (69.2%)	6/9 (66.7%)	3/21 (14.3%)
1-50%	48/157 (30.6%)	0/5 (0.0%)	1/13 (7.7%)	5/25 (20.0%)	2/13 (15.4%)	1/9 (11.1%)	14/21 (66.7%)
0% and all heartbeats missing	5/157 (3.2%)	0/5 (0.0%)	0/13 (0.0%)	0/25 (0.0%)	0/13 (0.0%)	0/9 (0.0%)	2/21 (9.5%)
Mean ³ (CI)	62.8 (55.1,70.4)	74.6 (36.5,100)	82.8 (62.3,100)	71.5 (53.8,89.2)	73.4 (49.3,97.4)	74.4 (45.9,100)	31.6 (10.7,52.5)
Week 9-16							
100%	5/158 (3.2%)	1/5 (20.0%)	0/14 (0.0%)	0/25 (0.0%)	0/13 (0.0%)	1/9 (11.1%)	0/21 (0.0%)
90-99%	17/158 (10.8%)	0/5 (0.0%)	2/14 (14.3%)	4/25 (16.0%)	1/13 (7.7%)	0/9 (0.0%)	0/21 (0.0%)
51-89%	81/158 (51.3%)	2/5 (40.0%)	11/14 (78.6%)	17/25 (68.0%)	8/13 (61.5%)	6/9 (66.7%)	5/21 (23.8%)
1-50%	29/158 (18.4%)	2/5 (40.0%)	1/14 (7.1%)	3/25 (12.0%)	2/13 (15.4%)	1/9 (11.1%)	6/21 (28.6%)
0% and all heartbeats missing	26/158 (16.5%)	0/5 (0.0%)	0/14 (0.0%)	1/25 (4.0%)	2/13 (15.4%)	1/9 (11.1%)	10/21 (47.6%)
Mean ³ (CI)	67.0 (59,75.1)	55.0 (11.4,98.6)	73.5 (50.4,96.6)	71.3 (53.2,89.4)	72.9 (46.6,99.2)	77.2 (48.2,100)	41.6 (12.4,70.7)
Week 17-24							
100%	3/160 (1.9%)	0/5 (0.0%)	1/15 (6.7%)	0/25 (0.0%)	0/13 (0.0%)	0/9 (0.0%)	0/21 (0.0%)
90-99%	21/160 (13.1%)	0/5 (0.0%)	4/15 (26.7%)	3/25 (12.0%)	0/13 (0.0%)	3/9 (33.3%)	0/21 (0.0%)
51-89%	59/160 (36.9%)	1/5 (20.0%)	7/15 (46.7%)	13/25 (52.0%)	8/13 (61.5%)	4/9 (44.4%)	3/21 (14.3%)
1-50%	46/160 (28.8%)	4/5 (80.0%)	3/15 (20.0%)	7/25 (28.0%)	3/13 (23.1%)	1/9 (11.1%)	7/21 (33.3%)
0% and all heartbeats missing	31/160 (19.4%)	0/5 (0.0%)	0/15 (0.0%)	2/25 (8.0%)	2/13 (15.4%)	1/9 (11.1%)	11/21 (52.4%)
Mean ³ (CI)	60.5 (52.1,69)	40.4 (0,83.4)	72.1 (49.4,94.8)	63.7 (44.1,83.4)	57.1 (27.9,86.4)	71.7 (40.4,100)	25.7 (0,52.8)

¹ One participant in Seattle was not given study drug and was terminated from the study. 11 participants could not be matched with Wisepill data and are excluded.

² Participants are expected to refill the Wisepill device on Monday of each week unless the participant is on a product hold. Wisepill opening signals in this table do not exclude those due to refills.

³ Mean calculated only among participants with at least one heartbeat.

HPTN 069 - A Phase II Randomized Study of the Safety and Tolerability of Maraviroc to Prevent HIV Transmission

Live Open Report - October 15, 2014

Visit Cutoff Date: October 15, 2014

Table 8.2a - Adherence as Measured by Wisepill Electronic Monitoring Device (EDM) by Study Visit and Site

SIM Non-compatible

MALE

	Total	Philadelphia, PA	Pittsburgh, PA	San Francisco, CA	San Juan, PR	Seattle, WA	Washington DC
Distribution of participants' percentage of days with recorded Wisepill opening signals ^{1,2}							
Week 25-32							
100%	4/161 (2.5%)	0/5 (0.0%)	1/15 (6.7%)	0/25 (0.0%)	0/14 (0.0%)	0/9 (0.0%)	0/21 (0.0%)
90-99%	16/161 (9.9%)	0/5 (0.0%)	3/15 (20.0%)	3/25 (12.0%)	2/14 (14.3%)	3/9 (33.3%)	1/21 (4.8%)
51-89%	59/161 (36.6%)	1/5 (20.0%)	8/15 (53.3%)	13/25 (52.0%)	6/14 (42.9%)	5/9 (55.6%)	0/21 (0.0%)
1-50%	42/161 (26.1%)	3/5 (60.0%)	2/15 (13.3%)	7/25 (28.0%)	3/14 (21.4%)	1/9 (11.1%)	6/21 (28.6%)
0% and all heartbeats missing	40/161 (24.8%)	1/5 (20.0%)	1/15 (6.7%)	2/25 (8.0%)	3/14 (21.4%)	0/9 (0.0%)	14/21 (66.7%)
Mean ³ (CI)	59.1 (50.4,67.9)	33.0 (0,79.1)	74.6 (51.8,97.4)	64.1 (44.5,83.7)	61.4 (32.7,90.2)	72.2 (43,100)	32.9 (0,67.7)
Week 33-40							
100%	3/156 (1.9%)	0/5 (0.0%)	0/15 (0.0%)	0/25 (0.0%)	0/14 (0.0%)	1/9 (11.1%)	0/21 (0.0%)
90-99%	16/156 (10.3%)	0/5 (0.0%)	3/15 (20.0%)	5/25 (20.0%)	0/14 (0.0%)	2/9 (22.2%)	1/21 (4.8%)
51-89%	54/156 (34.6%)	1/5 (20.0%)	9/15 (60.0%)	7/25 (28.0%)	8/14 (57.1%)	3/9 (33.3%)	1/21 (4.8%)
1-50%	30/156 (19.2%)	3/5 (60.0%)	2/15 (13.3%)	7/25 (28.0%)	2/14 (14.3%)	2/9 (22.2%)	3/21 (14.3%)
0% and all heartbeats missing	53/156 (34.0%)	1/5 (20.0%)	1/15 (6.7%)	6/25 (24.0%)	4/14 (28.6%)	1/9 (11.1%)	16/21 (76.2%)
Mean ³ (CI)	60.1 (50.6,69.5)	25.4 (0,68.1)	68.4 (44.1,92.8)	61.2 (39.3,83.1)	67.3 (38.3,96.4)	68.3 (36.1,100)	31.8 (0,72.6)
Week 41-48							
100%	2/148 (1.4%)	0/5 (0.0%)	0/13 (0.0%)	0/25 (0.0%)	0/14 (0.0%)	0/9 (0.0%)	0/21 (0.0%)
90-99%	8/148 (5.4%)	0/5 (0.0%)	2/13 (15.4%)	2/25 (8.0%)	0/14 (0.0%)	0/9 (0.0%)	0/21 (0.0%)
51-89%	51/148 (34.5%)	1/5 (20.0%)	7/13 (53.8%)	11/25 (44.0%)	7/14 (50.0%)	6/9 (66.7%)	1/21 (4.8%)
1-50%	31/148 (20.9%)	3/5 (60.0%)	3/13 (23.1%)	6/25 (24.0%)	2/14 (14.3%)	1/9 (11.1%)	3/21 (14.3%)
0% and all heartbeats missing	56/148 (37.8%)	1/5 (20.0%)	1/13 (7.7%)	6/25 (24.0%)	5/14 (35.7%)	2/9 (22.2%)	17/21 (81.0%)
Mean ³ (CI)	57.9 (47.9,68)	24.6 (0,66.7)	63.7 (36.4,90.9)	62.1 (40.3,83.9)	60.7 (28.8,92.6)	69.6 (35.6,100)	33.0 (0,79.1)

¹ One participant in Seattle was not given study drug and was terminated from the study. 11 participants could not be matched with Wisepill data and are excluded.

² Participants are expected to refill the Wisepill device on Monday of each week unless the participant is on a product hold. Wisepill opening signals in this table do not exclude those due to refills.

³ Mean calculated only among participants with at least one heartbeat.

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Visit Cutoff Date: October 15, 2014

Table 8.2b - Adherence as Measured by Wisepill Electronic Monitoring Device (EDM) by Study Visit and Site

SIM Non-compatible

FEMALE

	Total	Baltimore, MD	Boston, MA	Chapel Hill/ Raleigh, NC	Cleveland, OH	Los Angeles, CA	New York, NY
Distribution of participants' percentage of days with recorded Wisepill opening signals ^{1,2}							
Week 1-8							
100%	3/143 (2.1%)	1/5 (20.0%)	0/12 (0.0%)	0/14 (0.0%)	0/15 (0.0%)	0/2 (0.0%)	1/12 (8.3%)
90-99%	11/143 (7.7%)	0/5 (0.0%)	1/12 (8.3%)	1/14 (7.1%)	1/15 (6.7%)	1/2 (50.0%)	2/12 (16.7%)
51-89%	67/143 (46.9%)	4/5 (80.0%)	2/12 (16.7%)	7/14 (50.0%)	4/15 (26.7%)	0/2 (0.0%)	7/12 (58.3%)
1-50%	56/143 (39.2%)	0/5 (0.0%)	8/12 (66.7%)	5/14 (35.7%)	9/15 (60.0%)	1/2 (50.0%)	2/12 (16.7%)
0% and all heartbeats missing	6/143 (4.2%)	0/5 (0.0%)	1/12 (8.3%)	1/14 (7.1%)	1/15 (6.7%)	0/2 (0.0%)	0/12 (0.0%)
Mean ³ (CI)	56.5 (48.1,64.8)	76.9 (39.9,100)	39.9 (11,68.9)	56.5 (29.5,83.4)	46.0 (19.9,72.2)	64.0 (0,100)	73.7 (48.7,98.6)
Week 9-16							
100%	7/125 (5.6%)	1/1 (100.0%)	0/12 (0.0%)	0/13 (0.0%)	0/15 (0.0%)	0/1 (0.0%)	3/11 (27.3%)
90-99%	6/125 (4.8%)	0/1 (0.0%)	1/12 (8.3%)	2/13 (15.4%)	0/15 (0.0%)	0/1 (0.0%)	1/11 (9.1%)
51-89%	41/125 (32.8%)	0/1 (0.0%)	0/12 (0.0%)	3/13 (23.1%)	6/15 (40.0%)	1/1 (100.0%)	4/11 (36.4%)
1-50%	49/125 (39.2%)	0/1 (0.0%)	6/12 (50.0%)	6/13 (46.2%)	8/15 (53.3%)	0/1 (0.0%)	3/11 (27.3%)
0% and all heartbeats missing	22/125 (17.6%)	0/1 (0.0%)	5/12 (41.7%)	2/13 (15.4%)	1/15 (6.7%)	0/1 (0.0%)	0/11 (0.0%)
Mean ³ (CI)	50.6 (41,60.3)	100.0 (..)	23.2 (0,54.4)	54.7 (25.3,84.1)	35.1 (10.1,60.1)	87.5 (..)	77.9 (53.4,100)
Week 17-24							
100%	4/106 (3.8%)	0/0 (-%)	0/10 (0.0%)	1/8 (12.5%)	0/13 (0.0%)	0/1 (0.0%)	3/11 (27.3%)
90-99%	4/106 (3.8%)	0/0 (-%)	0/10 (0.0%)	0/8 (0.0%)	1/13 (7.7%)	0/1 (0.0%)	0/11 (0.0%)
51-89%	26/106 (24.5%)	0/0 (-%)	1/10 (10.0%)	2/8 (25.0%)	2/13 (15.4%)	1/1 (100.0%)	5/11 (45.5%)
1-50%	36/106 (34.0%)	0/0 (-%)	3/10 (30.0%)	3/8 (37.5%)	5/13 (38.5%)	0/1 (0.0%)	3/11 (27.3%)
0% and all heartbeats missing	36/106 (34.0%)	0/0 (-%)	6/10 (60.0%)	2/8 (25.0%)	5/13 (38.5%)	0/1 (0.0%)	0/11 (0.0%)
Mean ³ (CI)	49.7 (38,61.4)	-(-,-)	29.0 (0,73.5)	44.0 (4.3,83.7)	43.3 (9,77.6)	88.4 (..)	73.1 (46.8,99.3)

¹ 9 participants could not be matched with Wisepill data and are excluded.

² Participants are expected to refill the Wisepill device on Monday of each week unless the participant is on a product hold. Wisepill opening signals in this table do not exclude those due to refills.

³ Mean calculated only among participants with at least one heartbeat.

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Table 8.2b - Adherence as Measured by Wisepill Electronic Monitoring Device (EDM) by Study Visit and Site

SIM Non-compatible

FEMALE

	Total	Baltimore, MD	Boston, MA	Chapel Hill/ Raleigh, NC	Cleveland, OH	Los Angeles, CA	New York, NY
Distribution of participants' percentage of days with recorded Wisepill opening signals ^{1,2}							
Week 25-32							
100%	3/87 (3.4%)	0/0 (-%)	0/8 (0.0%)	0/4 (0.0%)	0/13 (0.0%)	0/0 (-%)	3/9 (33.3%)
90-99%	3/87 (3.4%)	0/0 (-%)	0/8 (0.0%)	0/4 (0.0%)	0/13 (0.0%)	0/0 (-%)	0/9 (0.0%)
51-89%	18/87 (20.7%)	0/0 (-%)	0/8 (0.0%)	2/4 (50.0%)	3/13 (23.1%)	0/0 (-%)	4/9 (44.4%)
1-50%	20/87 (23.0%)	0/0 (-%)	1/8 (12.5%)	2/4 (50.0%)	4/13 (30.8%)	0/0 (-%)	1/9 (11.1%)
0% and all heartbeats missing	43/87 (49.4%)	0/0 (-%)	7/8 (87.5%)	0/4 (0.0%)	6/13 (46.2%)	0/0 (-%)	1/9 (11.1%)
Mean ³ (CI)	50.4 (35.6,65.1)	-(-,-)	42.9 (.,.)	39.0 (0,86.8)	35.4 (0,70.8)	-(-,-)	81.9 (55.2,100)
Week 33-40							
100%	3/72 (4.2%)	0/0 (-%)	0/8 (0.0%)	0/2 (0.0%)	0/11 (0.0%)	0/0 (-%)	2/6 (33.3%)
90-99%	3/72 (4.2%)	0/0 (-%)	0/8 (0.0%)	0/2 (0.0%)	0/11 (0.0%)	0/0 (-%)	2/6 (33.3%)
51-89%	12/72 (16.7%)	0/0 (-%)	0/8 (0.0%)	0/2 (0.0%)	2/11 (18.2%)	0/0 (-%)	1/6 (16.7%)
1-50%	9/72 (12.5%)	0/0 (-%)	0/8 (0.0%)	1/2 (50.0%)	1/11 (9.1%)	0/0 (-%)	1/6 (16.7%)
0% and all heartbeats missing	45/72 (62.5%)	0/0 (-%)	8/8 (100.0%)	1/2 (50.0%)	8/11 (72.7%)	0/0 (-%)	0/6 (0.0%)
Mean ³ (CI)	54.8 (36,73.6)	-(-,-)	-(-,-)	1.8 (.,.)	43.5 (0,99.5)	-(-,-)	77.5 (44.1,100)
Week 41-48							
100%	3/59 (5.1%)	0/0 (-%)	0/8 (0.0%)	0/2 (0.0%)	0/7 (0.0%)	0/0 (-%)	3/4 (75.0%)
90-99%	2/59 (3.4%)	0/0 (-%)	0/8 (0.0%)	0/2 (0.0%)	0/7 (0.0%)	0/0 (-%)	0/4 (0.0%)
51-89%	8/59 (13.6%)	0/0 (-%)	1/8 (12.5%)	0/2 (0.0%)	2/7 (28.6%)	0/0 (-%)	0/4 (0.0%)
1-50%	8/59 (13.6%)	0/0 (-%)	1/8 (12.5%)	0/2 (0.0%)	1/7 (14.3%)	0/0 (-%)	0/4 (0.0%)
0% and all heartbeats missing	38/59 (64.4%)	0/0 (-%)	6/8 (75.0%)	2/2 (100.0%)	4/7 (57.1%)	0/0 (-%)	1/4 (25.0%)
Mean ³ (CI)	52.9 (31.6,74.3)	-(-,-)	42.0 (0,100)	-(-,-)	49.4 (0,100)	-(-,-)	100.0 (100,100)

¹ 9 participants could not be matched with Wisepill data and are excluded.

² Participants are expected to refill the Wisepill device on Monday of each week unless the participant is on a product hold. Wisepill opening signals in this table do not exclude those due to refills.

³ Mean calculated only among participants with at least one heartbeat.

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**Table 8.2b - Adherence as Measured by Wisepill Electronic Monitoring Device (EDM) by Study Visit and Site
SIM Non-compatible
FEMALE**

	Total	Newark, NJ	Philadelphia, PA	Pittsburgh, PA	San Juan, PR	Seattle, WA	Washington DC
Distribution of participants' percentage of days with recorded Wisepill opening signals ^{1,2}							
Week 1-8							
100%	3/143 (2.1%)	0/25 (0.0%)	0/11 (0.0%)	1/9 (11.1%)	0/14 (0.0%)	0/8 (0.0%)	0/16 (0.0%)
90-99%	11/143 (7.7%)	3/25 (12.0%)	0/11 (0.0%)	0/9 (0.0%)	1/14 (7.1%)	1/8 (12.5%)	0/16 (0.0%)
51-89%	67/143 (46.9%)	14/25 (56.0%)	4/11 (36.4%)	7/9 (77.8%)	8/14 (57.1%)	5/8 (62.5%)	5/16 (31.3%)
1-50%	56/143 (39.2%)	8/25 (32.0%)	7/11 (63.6%)	1/9 (11.1%)	5/14 (35.7%)	1/8 (12.5%)	9/16 (56.3%)
0% and all heartbeats missing	6/143 (4.2%)	0/25 (0.0%)	0/11 (0.0%)	0/9 (0.0%)	0/14 (0.0%)	1/8 (12.5%)	2/16 (12.5%)
Mean ³ (CI)	56.5 (48.1,64.8)	60.4 (41.3,79.6)	46.8 (17.3,76.3)	78.8 (52.1,100)	53.7 (27.6,79.9)	67.3 (32.6,100)	40.1 (14.4,65.7)
Week 9-16							
100%	7/125 (5.6%)	1/19 (5.3%)	0/10 (0.0%)	1/7 (14.3%)	1/13 (7.7%)	0/7 (0.0%)	0/16 (0.0%)
90-99%	6/125 (4.8%)	1/19 (5.3%)	0/10 (0.0%)	0/7 (0.0%)	1/13 (7.7%)	0/7 (0.0%)	0/16 (0.0%)
51-89%	41/125 (32.8%)	6/19 (31.6%)	3/10 (30.0%)	6/7 (85.7%)	6/13 (46.2%)	4/7 (57.1%)	2/16 (12.5%)
1-50%	49/125 (39.2%)	6/19 (31.6%)	4/10 (40.0%)	0/7 (0.0%)	3/13 (23.1%)	3/7 (42.9%)	10/16 (62.5%)
0% and all heartbeats missing	22/125 (17.6%)	5/19 (26.3%)	3/10 (30.0%)	0/7 (0.0%)	2/13 (15.4%)	0/7 (0.0%)	4/16 (25.0%)
Mean ³ (CI)	50.6 (41,60.3)	51.8 (25.7,78)	40.8 (4.4,77.2)	81.4 (52.5,100)	63.3 (34.8,91.8)	54.6 (17.7,91.5)	21.4 (0,44.6)
Week 17-24							
100%	4/106 (3.8%)	0/15 (0.0%)	0/8 (0.0%)	0/5 (0.0%)	0/12 (0.0%)	0/7 (0.0%)	0/16 (0.0%)
90-99%	4/106 (3.8%)	1/15 (6.7%)	0/8 (0.0%)	0/5 (0.0%)	1/12 (8.3%)	1/7 (14.3%)	0/16 (0.0%)
51-89%	26/106 (24.5%)	3/15 (20.0%)	2/8 (25.0%)	3/5 (60.0%)	3/12 (25.0%)	3/7 (42.9%)	1/16 (6.3%)
1-50%	36/106 (34.0%)	3/15 (20.0%)	3/8 (37.5%)	2/5 (40.0%)	5/12 (41.7%)	2/7 (28.6%)	7/16 (43.8%)
0% and all heartbeats missing	36/106 (34.0%)	8/15 (53.3%)	3/8 (37.5%)	0/5 (0.0%)	3/12 (25.0%)	1/7 (14.3%)	8/16 (50.0%)
Mean ³ (CI)	49.7 (38,61.4)	61.7 (25.7,97.7)	37.5 (0,79.9)	57.2 (13.8,100)	50.4 (17.7,83.1)	62.5 (23.8,100)	15.8 (0,41.2)

¹ 9 participants could not be matched with Wisepill data and are excluded.

² Participants are expected to refill the Wisepill device on Monday of each week unless the participant is on a product hold. Wisepill opening signals in this table do not exclude those due to refills.

³ Mean calculated only among participants with at least one heartbeat.

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SIM Non-compatible

FEMALE

	Total	Newark, NJ	Philadelphia, PA	Pittsburgh, PA	San Juan, PR	Seattle, WA	Washington DC
Distribution of participants' percentage of days with recorded Wisepill opening signals ^{1,2}							
Week 25-32							
100%	3/87 (3.4%)	0/12 (0.0%)	0/8 (0.0%)	0/1 (0.0%)	0/10 (0.0%)	0/6 (0.0%)	0/16 (0.0%)
90-99%	3/87 (3.4%)	1/12 (8.3%)	0/8 (0.0%)	0/1 (0.0%)	1/10 (10.0%)	1/6 (16.7%)	0/16 (0.0%)
51-89%	18/87 (20.7%)	1/12 (8.3%)	3/8 (37.5%)	1/1 (100.0%)	2/10 (20.0%)	2/6 (33.3%)	0/16 (0.0%)
1-50%	20/87 (23.0%)	1/12 (8.3%)	1/8 (12.5%)	0/1 (0.0%)	3/10 (30.0%)	1/6 (16.7%)	6/16 (37.5%)
0% and all heartbeats missing	43/87 (49.4%)	9/12 (75.0%)	4/8 (50.0%)	0/1 (0.0%)	4/10 (40.0%)	2/6 (33.3%)	10/16 (62.5%)
Mean ³ (CI)	50.4 (35.6,65.1)	66.7 (13.3,100)	52.8 (3.9,100)	88.2 (..)	53.3 (13.4,93.2)	64.7 (17.9,100)	6.0 (0,25)
Week 33-40							
100%	3/72 (4.2%)	1/12 (8.3%)	0/7 (0.0%)	0/0 (-%)	0/9 (0.0%)	0/4 (0.0%)	0/13 (0.0%)
90-99%	3/72 (4.2%)	0/12 (0.0%)	0/7 (0.0%)	0/0 (-%)	0/9 (0.0%)	1/4 (25.0%)	0/13 (0.0%)
51-89%	12/72 (16.7%)	2/12 (16.7%)	3/7 (42.9%)	0/0 (-%)	2/9 (22.2%)	2/4 (50.0%)	0/13 (0.0%)
1-50%	9/72 (12.5%)	1/12 (8.3%)	0/7 (0.0%)	0/0 (-%)	1/9 (11.1%)	0/4 (0.0%)	4/13 (30.8%)
0% and all heartbeats missing	45/72 (62.5%)	8/12 (66.7%)	4/7 (57.1%)	0/0 (-%)	6/9 (66.7%)	1/4 (25.0%)	9/13 (69.2%)
Mean ³ (CI)	54.8 (36,73.6)	67.6 (21.8,100)	70.2 (18.5,100)	-(-,-)	56.5 (0.5,100)	74.8 (25.7,100)	1.8 (0,14.8)
Week 41-48							
100%	3/59 (5.1%)	0/10 (0.0%)	0/6 (0.0%)	0/0 (-%)	0/8 (0.0%)	0/2 (0.0%)	0/12 (0.0%)
90-99%	2/59 (3.4%)	1/10 (10.0%)	0/6 (0.0%)	0/0 (-%)	0/8 (0.0%)	1/2 (50.0%)	0/12 (0.0%)
51-89%	8/59 (13.6%)	0/10 (0.0%)	3/6 (50.0%)	0/0 (-%)	2/8 (25.0%)	0/2 (0.0%)	0/12 (0.0%)
1-50%	8/59 (13.6%)	0/10 (0.0%)	1/6 (16.7%)	0/0 (-%)	3/8 (37.5%)	0/2 (0.0%)	2/12 (16.7%)
0% and all heartbeats missing	38/59 (64.4%)	9/10 (90.0%)	2/6 (33.3%)	0/0 (-%)	3/8 (37.5%)	1/2 (50.0%)	10/12 (83.3%)
Mean ³ (CI)	52.9 (31.6,74.3)	96.4 (..)	50.9 (1.9,99.9)	-(-,-)	35.8 (0,77.9)	96.4 (..)	1.8 (0,20.1)

¹ 9 participants could not be matched with Wisepill data and are excluded.

² Participants are expected to refill the Wisepill device on Monday of each week unless the participant is on a product hold. Wisepill opening signals in this table do not exclude those due to refills.

³ Mean calculated only among participants with at least one heartbeat.