

MTN 042 - DELIVER: A Phase 3b Safety Study of the Dapivirine Ring and PrEP in Pregnant Women
Data as of December 1, 2025

Screen-out Summary by Site - All Cohorts

	Malawi Blantyre	SA Shandukani	Uganda Kampala	Zimbabwe Zengeza	All Sites
Participants Screened ¹	172	161	207	239	779
Participants Enrolled ^{2, 3}	133 (77%)	114 (71%)	154 (74%)	157 (66%)	558 (72%)
Participants not Enrolled	39 (23%)	47 (29%)	53 (26%)	82 (34%)	221 (28%)
Participant did not complete all screening procedures ⁴	2 (5%)	5 (11%)	1 (2%)	6 (7%)	14 (6%)
Participant is eligible but declined enrollment ⁴	13 (33%)	7 (15%)	2 (4%)	0 (-%)	22 (10%)
Reason participant not enrolled is missing(Incomplete screening) ⁴	0 (-%)	0 (-%)	0 (-%)	0 (-%)	0 (-%)
Participant not eligible ^{4,5}	24 (62%)	35 (74%)	50 (94%)	76 (93%)	185 (84%)
Intends to use oral PrEP outside the context of study participation	0 (-%)	0 (-%)	0 (-%)	0 (-%)	0 (-%)
Intends to relocate away from the study site	1 (4%)	1 (3%)	0 (-%)	2 (3%)	4 (2%)
Intends to travel away from the study site that would interfere with study participation	0 (-%)	1 (3%)	0 (-%)	1 (1%)	2 (1%)
Has a positive HIV test at Screening or Enrollment	1 (4%)	1 (3%)	1 (2%)	0 (-%)	3 (2%)
Diagnosed with UTI, cervicitis, STI or RTI requiring treatment	7 (29%)	8 (23%)	6 (12%)	3 (4%)	24 (13%)
At Enrollment, has a clinically apparent Grade 2 or higher pelvic exam finding	0 (-%)	0 (-%)	0 (-%)	4 (5%)	4 (2%)
Report and/or clinical evidence of currently breastfeeding	0 (-%)	0 (-%)	0 (-%)	0 (-%)	0 (-%)
Report and/or clinical evidence of known adverse reaction to any of the study products	0 (-%)	0 (-%)	0 (-%)	0 (-%)	0 (-%)
Report and/or clinical evidence of known adverse reaction to latex and polyurethane	0 (-%)	0 (-%)	0 (-%)	0 (-%)	0 (-%)
Report and/or clinical evidence of symptoms suggestive of acute HIV infection	0 (-%)	0 (-%)	0 (-%)	0 (-%)	0 (-%)
Report and/or clinical evidence of non-therapeutic injection drug use	0 (-%)	0 (-%)	0 (-%)	0 (-%)	0 (-%)
Report and/or clinical evidence of use of HIV post-exposure prophylaxis (PEP) and/or PrEP	0 (-%)	0 (-%)	0 (-%)	0 (-%)	0 (-%)
Participation in any other research study that needs use of vaccines, drugs etc.	0 (-%)	0 (-%)	0 (-%)	0 (-%)	0 (-%)
Multiple gestation, Placenta previa, Cervical cerclage, etc. during current pregnancy	1 (4%)	2 (6%)	3 (6%)	7 (9%)	13 (7%)
Intrauterine growth restriction, Diabetes, Hypertension etc. during previous pregnancy	0 (-%)	3 (9%)	1 (2%)	1 (1%)	5 (3%)
Report clinical evidence of any significant obstetrical complication	0 (-%)	1 (3%)	0 (-%)	3 (4%)	4 (2%)
Positive for hepatitis B surface antigen (HBsAg)	3 (13%)	1 (3%)	4 (8%)	2 (3%)	10 (5%)
Aspartate aminotransferase or alanine transaminase higher or equals to Grade 1	0 (-%)	1 (3%)	0 (-%)	1 (1%)	2 (1%)
Hemoglobin higher or equals Grade 2	1 (4%)	1 (3%)	8 (16%)	17 (22%)	27 (15%)
Platelet count higher or equals Grade 1	1 (4%)	0 (-%)	7 (14%)	0 (-%)	8 (4%)
Creatinine higher or equals Grade 1	0 (-%)	0 (-%)	0 (-%)	0 (-%)	0 (-%)
Estimated creatinine clearance higher or equals Grade 2	1 (4%)	0 (-%)	2 (4%)	0 (-%)	3 (2%)
Glycosuria higher or equals Grade 2	0 (-%)	0 (-%)	9 (18%)	1 (1%)	10 (5%)

¹ Number of participants screened is based on the Inclusion/Exclusion Criteria eCRF, so could differ from the enrollment report total screened which is based on the Screening Date of Visit eCRF.

² Number of participants enrolled is based on the Inclusion/Exclusion Criteria eCRF, so could differ from the enrollment report which is based on the Randomization eCRF.

³ Percentage of participants screened.

⁴ Percentage of participants not enrolled.

⁵ Participants may be ineligible for more than one reason.

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Screen-out Summary by Site - All Cohorts

	Malawi Blantyre	SA Shandukani	Uganda Kampala	Zimbabwe Zengeza	All Sites
Proteinuria higher or equals Grade 2	0 (-%)	0 (-%)	1 (2%)	4 (5%)	5 (3%)
Other condition that could preclude informed consent or interfere with study objectives	1 (4%)	1 (3%)	9 (18%)	0 (-%)	11 (6%)
Not between the age of 18 through 40 years	0 (-%)	0 (-%)	0 (-%)	0 (-%)	0 (-%)
Disagrees about participation in other research studies for the duration of study	0 (-%)	0 (-%)	0 (-%)	0 (-%)	0 (-%)
No evidence of a viable, intrauterine, singleton pregnancy for gestational age assessment	4 (17%)	4 (11%)	3 (6%)	1 (1%)	12 (6%)
No pregnancy within gestational age limits of the currently enrolling cohort at Enrollment	0 (-%)	10 (29%)	0 (-%)	28 (37%)	38 (21%)
Not HIV-uninfected based on testing performed at Screening and Enrollment	0 (-%)	1 (3%)	0 (-%)	1 (1%)	2 (1%)
Not intending to continue her pregnancy until delivery at Screening and Enrollment	0 (-%)	0 (-%)	0 (-%)	0 (-%)	0 (-%)
Not intending to deliver at a health center or hospital	0 (-%)	0 (-%)	0 (-%)	0 (-%)	0 (-%)
Unwilling to be randomized and to continue study product use until delivery	0 (-%)	0 (-%)	0 (-%)	0 (-%)	0 (-%)
Unable and unwilling to comply with all study requirements and procedures	3 (13%)	0 (-%)	0 (-%)	4 (5%)	7 (4%)
Unable and unwilling to provide informed consent for her and her infant	0 (-%)	0 (-%)	0 (-%)	0 (-%)	0 (-%)
Unable and unwilling to provide adequate locator information	0 (-%)	0 (-%)	0 (-%)	0 (-%)	0 (-%)
Unable and unwilling to provide adequate documentation of registration for antenatal care	0 (-%)	0 (-%)	0 (-%)	0 (-%)	0 (-%)
Unable and unwilling to obtain copies of antenatal and postpartum care records	0 (-%)	0 (-%)	0 (-%)	0 (-%)	0 (-%)

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Screen-out Summary by Site - Cohort 1

	Malawi Blantyre	SA Shandukani	Uganda Kampala	Zimbabwe Zengeza	All Sites
Participants Screened ¹	42	59	68	58	227
Participants Enrolled ^{2, 3}	27 (64%)	42 (71%)	44 (65%)	37 (64%)	150 (66%)
Participants not Enrolled	15 (36%)	17 (29%)	24 (35%)	21 (36%)	77 (34%)
Participant did not complete all screening procedures ⁴	2 (13%)	2 (12%)	1 (4%)	6 (29%)	11 (14%)
Participant is eligible but declined enrollment ⁴	0 (-%)	0 (-%)	0 (-%)	0 (-%)	0 (-%)
Reason participant not enrolled is missing(Incomplete screening) ⁴	0 (-%)	0 (-%)	0 (-%)	0 (-%)	0 (-%)
Participant not eligible ^{4,5}	13 (87%)	15 (88%)	23 (96%)	15 (71%)	66 (86%)
Intends to use oral PrEP outside the context of study participation	0 (-%)	0 (-%)	0 (-%)	0 (-%)	0 (-%)
Intends to relocate away from the study site	0 (-%)	0 (-%)	0 (-%)	0 (-%)	0 (-%)
Intends to travel away from the study site that would interfere with study participation	0 (-%)	1 (7%)	0 (-%)	0 (-%)	1 (2%)
Has a positive HIV test at Screening or Enrollment	0 (-%)	0 (-%)	0 (-%)	0 (-%)	0 (-%)
Diagnosed with UTI, cervicitis, STI or RTI requiring treatment	3 (23%)	6 (40%)	0 (-%)	1 (7%)	10 (15%)
At Enrollment, has a clinically apparent Grade 2 or higher pelvic exam finding	0 (-%)	0 (-%)	0 (-%)	1 (7%)	1 (2%)
Report and/or clinical evidence of currently breastfeeding	0 (-%)	0 (-%)	0 (-%)	0 (-%)	0 (-%)
Report and/or clinical evidence of known adverse reaction to any of the study products	0 (-%)	0 (-%)	0 (-%)	0 (-%)	0 (-%)
Report and/or clinical evidence of known adverse reaction to latex and polyurethane	0 (-%)	0 (-%)	0 (-%)	0 (-%)	0 (-%)
Report and/or clinical evidence of symptoms suggestive of acute HIV infection	0 (-%)	0 (-%)	0 (-%)	0 (-%)	0 (-%)
Report and/or clinical evidence of non-therapeutic injection drug use	0 (-%)	0 (-%)	0 (-%)	0 (-%)	0 (-%)
Report and/or clinical evidence of use of HIV post-exposure prophylaxis (PEP) and/or PrEP	0 (-%)	0 (-%)	0 (-%)	0 (-%)	0 (-%)
Participation in any other research study that needs use of vaccines,drugs etc.	0 (-%)	0 (-%)	0 (-%)	0 (-%)	0 (-%)
Multiple gestation, Placenta previa, Cervical cerclage, etc. during current pregnancy	0 (-%)	0 (-%)	2 (9%)	1 (7%)	3 (5%)
Intrauterine growth restriction, Diabetes, Hypertension etc. during previous pregnancy	0 (-%)	1 (7%)	1 (4%)	1 (7%)	3 (5%)
Report clinical evidence of any significant obstetrical complication	0 (-%)	0 (-%)	0 (-%)	1 (7%)	1 (2%)
Positive for hepatitis B surface antigen (HBsAg)	0 (-%)	0 (-%)	2 (9%)	0 (-%)	2 (3%)
Aspartate aminotransferase or alanine transaminase higher or equals to Grade 1	0 (-%)	0 (-%)	0 (-%)	0 (-%)	0 (-%)
Hemoglobin higher or equals Grade 2	0 (-%)	0 (-%)	1 (4%)	6 (40%)	7 (11%)
Platelet count higher or equals Grade 1	1 (8%)	0 (-%)	4 (17%)	0 (-%)	5 (8%)
Creatinine higher or equals Grade 1	0 (-%)	0 (-%)	0 (-%)	0 (-%)	0 (-%)
Estimated creatinine clearance higher or equals Grade 2	1 (8%)	0 (-%)	1 (4%)	0 (-%)	2 (3%)
Glycosuria higher or equals Grade 2	0 (-%)	0 (-%)	3 (13%)	1 (7%)	4 (6%)

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Screen-out Summary by Site - Cohort 1

	Malawi Blantyre	SA Shandukani	Uganda Kampala	Zimbabwe Zengeza	All Sites
Proteinuria higher or equals Grade 2	0 (-%)	0 (-%)	0 (-%)	3 (20%)	3 (5%)
Other condition that could preclude informed consent or interfere with study objectives	1 (8%)	0 (-%)	8 (35%)	0 (-%)	9 (14%)
Not between the age of 18 through 40 years	0 (-%)	0 (-%)	0 (-%)	0 (-%)	0 (-%)
Disagrees about participation in other research studies for the duration of study	0 (-%)	0 (-%)	0 (-%)	0 (-%)	0 (-%)
No evidence of a viable, intrauterine, singleton pregnancy for gestational age assessment	4 (31%)	1 (7%)	3 (13%)	0 (-%)	8 (12%)
No pregnancy within gestational age limits of the currently enrolling cohort at Enrollment	0 (-%)	7 (47%)	0 (-%)	1 (7%)	8 (12%)
Not HIV-uninfected based on testing performed at Screening and Enrollment	0 (-%)	0 (-%)	0 (-%)	0 (-%)	0 (-%)
Not intending to continue her pregnancy until delivery at Screening and Enrollment	0 (-%)	0 (-%)	0 (-%)	0 (-%)	0 (-%)
Not intending to deliver at a health center or hospital	0 (-%)	0 (-%)	0 (-%)	0 (-%)	0 (-%)
Unwilling to be randomized and to continue study product use until delivery	0 (-%)	0 (-%)	0 (-%)	0 (-%)	0 (-%)
Unable and unwilling to comply with all study requirements and procedures	3 (23%)	0 (-%)	0 (-%)	0 (-%)	3 (5%)
Unable and unwilling to provide informed consent for her and her infant	0 (-%)	0 (-%)	0 (-%)	0 (-%)	0 (-%)
Unable and unwilling to provide adequate locator information	0 (-%)	0 (-%)	0 (-%)	0 (-%)	0 (-%)
Unable and unwilling to provide adequate documentation of registration for antenatal care	0 (-%)	0 (-%)	0 (-%)	0 (-%)	0 (-%)
Unable and unwilling to obtain copies of antenatal and postpartum care records	0 (-%)	0 (-%)	0 (-%)	0 (-%)	0 (-%)

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Screen-out Summary by Site - Cohort 2

	Malawi Blantyre	SA Shandukani	Uganda Kampala	Zimbabwe Zengeza	All Sites
Participants Screened ¹	48	37	51	84	220
Participants Enrolled ^{2, 3}	40 (83%)	28 (76%)	42 (82%)	47 (56%)	157 (71%)
Participants not Enrolled	8 (17%)	9 (24%)	9 (18%)	37 (44%)	63 (29%)
Participant did not complete all screening procedures ⁴	0 (-%)	0 (-%)	0 (-%)	0 (-%)	0 (-%)
Participant is eligible but declined enrollment ⁴	5 (63%)	2 (22%)	1 (11%)	0 (-%)	8 (13%)
Reason participant not enrolled is missing(Incomplete screening) ⁴	0 (-%)	0 (-%)	0 (-%)	0 (-%)	0 (-%)
Participant not eligible ^{4,5}	3 (38%)	7 (78%)	8 (89%)	37 (100%)	55 (87%)
Intends to use oral PrEP outside the context of study participation	0 (-%)	0 (-%)	0 (-%)	0 (-%)	0 (-%)
Intends to relocate away from the study site	0 (-%)	0 (-%)	0 (-%)	0 (-%)	0 (-%)
Intends to travel away from the study site that would interfere with study participation	0 (-%)	0 (-%)	0 (-%)	1 (3%)	1 (2%)
Has a positive HIV test at Screening or Enrollment	1 (33%)	0 (-%)	0 (-%)	0 (-%)	1 (2%)
Diagnosed with UTI, cervicitis, STI or RTI requiring treatment	1 (33%)	2 (29%)	2 (25%)	1 (3%)	6 (11%)
At Enrollment, has a clinically apparent Grade 2 or higher pelvic exam finding	0 (-%)	0 (-%)	0 (-%)	3 (8%)	3 (5%)
Report and/or clinical evidence of currently breastfeeding	0 (-%)	0 (-%)	0 (-%)	0 (-%)	0 (-%)
Report and/or clinical evidence of known adverse reaction to any of the study products	0 (-%)	0 (-%)	0 (-%)	0 (-%)	0 (-%)
Report and/or clinical evidence of known adverse reaction to latex and polyurethane	0 (-%)	0 (-%)	0 (-%)	0 (-%)	0 (-%)
Report and/or clinical evidence of symptoms suggestive of acute HIV infection	0 (-%)	0 (-%)	0 (-%)	0 (-%)	0 (-%)
Report and/or clinical evidence of non-therapeutic injection drug use	0 (-%)	0 (-%)	0 (-%)	0 (-%)	0 (-%)
Report and/or clinical evidence of use of HIV post-exposure prophylaxis (PEP) and/or PrEP	0 (-%)	0 (-%)	0 (-%)	0 (-%)	0 (-%)
Participation in any other research study that needs use of vaccines, drugs etc.	0 (-%)	0 (-%)	0 (-%)	0 (-%)	0 (-%)
Multiple gestation, Placenta previa, Cervical cerclage, etc. during current pregnancy	0 (-%)	0 (-%)	0 (-%)	2 (5%)	2 (4%)
Intrauterine growth restriction, Diabetes, Hypertension etc. during previous pregnancy	0 (-%)	0 (-%)	0 (-%)	0 (-%)	0 (-%)
Report clinical evidence of any significant obstetrical complication	0 (-%)	1 (14%)	0 (-%)	0 (-%)	1 (2%)
Positive for hepatitis B surface antigen (HBsAg)	1 (33%)	0 (-%)	0 (-%)	2 (5%)	3 (5%)
Aspartate aminotransferase or alanine transaminase higher or equals to Grade 1	0 (-%)	0 (-%)	0 (-%)	0 (-%)	0 (-%)
Hemoglobin higher or equals Grade 2	0 (-%)	0 (-%)	1 (13%)	9 (24%)	10 (18%)
Platelet count higher or equals Grade 1	0 (-%)	0 (-%)	2 (25%)	0 (-%)	2 (4%)
Creatinine higher or equals Grade 1	0 (-%)	0 (-%)	0 (-%)	0 (-%)	0 (-%)
Estimated creatinine clearance higher or equals Grade 2	0 (-%)	0 (-%)	0 (-%)	0 (-%)	0 (-%)
Glycosuria higher or equals Grade 2	0 (-%)	0 (-%)	2 (25%)	0 (-%)	2 (4%)

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Screen-out Summary by Site - Cohort 2

	Malawi Blantyre	SA Shandukani	Uganda Kampala	Zimbabwe Zengeza	All Sites
Proteinuria higher or equals Grade 2	0 (-%)	0 (-%)	1 (13%)	0 (-%)	1 (2%)
Other condition that could preclude informed consent or interfere with study objectives	0 (-%)	0 (-%)	1 (13%)	0 (-%)	1 (2%)
Not between the age of 18 through 40 years	0 (-%)	0 (-%)	0 (-%)	0 (-%)	0 (-%)
Disagrees about participation in other research studies for the duration of study	0 (-%)	0 (-%)	0 (-%)	0 (-%)	0 (-%)
No evidence of a viable, intrauterine, singleton pregnancy for gestational age assessment	0 (-%)	3 (43%)	0 (-%)	1 (3%)	4 (7%)
No pregnancy within gestational age limits of the currently enrolling cohort at Enrollment	0 (-%)	1 (14%)	0 (-%)	19 (51%)	20 (36%)
Not HIV-uninfected based on testing performed at Screening and Enrollment	0 (-%)	0 (-%)	0 (-%)	1 (3%)	1 (2%)
Not intending to continue her pregnancy until delivery at Screening and Enrollment	0 (-%)	0 (-%)	0 (-%)	0 (-%)	0 (-%)
Not intending to deliver at a health center or hospital	0 (-%)	0 (-%)	0 (-%)	0 (-%)	0 (-%)
Unwilling to be randomized and to continue study product use until delivery	0 (-%)	0 (-%)	0 (-%)	0 (-%)	0 (-%)
Unable and unwilling to comply with all study requirements and procedures	0 (-%)	0 (-%)	0 (-%)	1 (3%)	1 (2%)
Unable and unwilling to provide informed consent for her and her infant	0 (-%)	0 (-%)	0 (-%)	0 (-%)	0 (-%)
Unable and unwilling to provide adequate locator information	0 (-%)	0 (-%)	0 (-%)	0 (-%)	0 (-%)
Unable and unwilling to provide adequate documentation of registration for antenatal care	0 (-%)	0 (-%)	0 (-%)	0 (-%)	0 (-%)
Unable and unwilling to obtain copies of antenatal and postpartum care records	0 (-%)	0 (-%)	0 (-%)	0 (-%)	0 (-%)

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Screen-out Summary by Site - Cohort 3

	Malawi Blantyre	SA Shandukani	Uganda Kampala	Zimbabwe Zengeza	All Sites
Participants Screened ¹	82	65	88	97	332
Participants Enrolled ^{2, 3}	66 (80%)	44 (68%)	68 (77%)	73 (75%)	251 (76%)
Participants not Enrolled	16 (20%)	21 (32%)	20 (23%)	24 (25%)	81 (24%)
Participant did not complete all screening procedures ⁴	0 (-%)	3 (14%)	0 (-%)	0 (-%)	3 (4%)
Participant is eligible but declined enrollment ⁴	8 (50%)	5 (24%)	1 (5%)	0 (-%)	14 (17%)
Reason participant not enrolled is missing(Incomplete screening) ⁴	0 (-%)	0 (-%)	0 (-%)	0 (-%)	0 (-%)
Participant not eligible ^{4,5}	8 (50%)	13 (62%)	19 (95%)	24 (100%)	64 (79%)
Intends to use oral PrEP outside the context of study participation	0 (-%)	0 (-%)	0 (-%)	0 (-%)	0 (-%)
Intends to relocate away from the study site	1 (13%)	1 (8%)	0 (-%)	2 (8%)	4 (6%)
Intends to travel away from the study site that would interfere with study participation	0 (-%)	0 (-%)	0 (-%)	0 (-%)	0 (-%)
Has a positive HIV test at Screening or Enrollment	0 (-%)	1 (8%)	1 (5%)	0 (-%)	2 (3%)
Diagnosed with UTI, cervicitis, STI or RTI requiring treatment	3 (38%)	0 (-%)	4 (21%)	1 (4%)	8 (13%)
At Enrollment, has a clinically apparent Grade 2 or higher pelvic exam finding	0 (-%)	0 (-%)	0 (-%)	0 (-%)	0 (-%)
Report and/or clinical evidence of currently breastfeeding	0 (-%)	0 (-%)	0 (-%)	0 (-%)	0 (-%)
Report and/or clinical evidence of known adverse reaction to any of the study products	0 (-%)	0 (-%)	0 (-%)	0 (-%)	0 (-%)
Report and/or clinical evidence of known adverse reaction to latex and polyurethane	0 (-%)	0 (-%)	0 (-%)	0 (-%)	0 (-%)
Report and/or clinical evidence of symptoms suggestive of acute HIV infection	0 (-%)	0 (-%)	0 (-%)	0 (-%)	0 (-%)
Report and/or clinical evidence of non-therapeutic injection drug use	0 (-%)	0 (-%)	0 (-%)	0 (-%)	0 (-%)
Report and/or clinical evidence of use of HIV post-exposure prophylaxis (PEP) and/or PrEP	0 (-%)	0 (-%)	0 (-%)	0 (-%)	0 (-%)
Participation in any other research study that needs use of vaccines,drugs etc.	0 (-%)	0 (-%)	0 (-%)	0 (-%)	0 (-%)
Multiple gestation, Placenta previa, Cervical cerclage, etc. during current pregnancy	1 (13%)	2 (15%)	1 (5%)	4 (17%)	8 (13%)
Intrauterine growth restriction, Diabetes, Hypertension etc. during previous pregnancy	0 (-%)	2 (15%)	0 (-%)	0 (-%)	2 (3%)
Report clinical evidence of any significant obstetrical complication	0 (-%)	0 (-%)	0 (-%)	2 (8%)	2 (3%)
Positive for hepatitis B surface antigen (HBsAg)	2 (25%)	1 (8%)	2 (11%)	0 (-%)	5 (8%)
Aspartate aminotransferase or alanine transaminase higher or equals to Grade 1	0 (-%)	1 (8%)	0 (-%)	1 (4%)	2 (3%)
Hemoglobin higher or equals Grade 2	1 (13%)	1 (8%)	6 (32%)	2 (8%)	10 (16%)
Platelet count higher or equals Grade 1	0 (-%)	0 (-%)	1 (5%)	0 (-%)	1 (2%)
Creatinine higher or equals Grade 1	0 (-%)	0 (-%)	0 (-%)	0 (-%)	0 (-%)
Estimated creatinine clearance higher or equals Grade 2	0 (-%)	0 (-%)	1 (5%)	0 (-%)	1 (2%)
Glycosuria higher or equals Grade 2	0 (-%)	0 (-%)	4 (21%)	0 (-%)	4 (6%)

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Screen-out Summary by Site - Cohort 3

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Proteinuria higher or equals Grade 2	0 (-%)	0 (-%)	0 (-%)	1 (4%)	1 (2%)
Other condition that could preclude informed consent or interfere with study objectives	0 (-%)	1 (8%)	0 (-%)	0 (-%)	1 (2%)
Not between the age of 18 through 40 years	0 (-%)	0 (-%)	0 (-%)	0 (-%)	0 (-%)
Disagrees about participation in other research studies for the duration of study	0 (-%)	0 (-%)	0 (-%)	0 (-%)	0 (-%)
No evidence of a viable, intrauterine, singleton pregnancy for gestational age assessment	0 (-%)	0 (-%)	0 (-%)	0 (-%)	0 (-%)
No pregnancy within gestational age limits of the currently enrolling cohort at Enrollment	0 (-%)	2 (15%)	0 (-%)	8 (33%)	10 (16%)
Not HIV-uninfected based on testing performed at Screening and Enrollment	0 (-%)	1 (8%)	0 (-%)	0 (-%)	1 (2%)
Not intending to continue her pregnancy until delivery at Screening and Enrollment	0 (-%)	0 (-%)	0 (-%)	0 (-%)	0 (-%)
Not intending to deliver at a health center or hospital	0 (-%)	0 (-%)	0 (-%)	0 (-%)	0 (-%)
Unwilling to be randomized and to continue study product use until delivery	0 (-%)	0 (-%)	0 (-%)	0 (-%)	0 (-%)
Unable and unwilling to comply with all study requirements and procedures	0 (-%)	0 (-%)	0 (-%)	3 (13%)	3 (5%)
Unable and unwilling to provide informed consent for her and her infant	0 (-%)	0 (-%)	0 (-%)	0 (-%)	0 (-%)
Unable and unwilling to provide adequate locator information	0 (-%)	0 (-%)	0 (-%)	0 (-%)	0 (-%)
Unable and unwilling to provide adequate documentation of registration for antenatal care	0 (-%)	0 (-%)	0 (-%)	0 (-%)	0 (-%)
Unable and unwilling to obtain copies of antenatal and postpartum care records	0 (-%)	0 (-%)	0 (-%)	0 (-%)	0 (-%)

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