**Digital Table S-1: Maternal Antepartum Component Baseline Characteristics**

|  | | **AP Randomization Arm\*** | | |  |
| --- | --- | --- | --- | --- | --- |
|  | | **A (N=1507)** | **B (N=1497)** | **C (N=419)** | **Total (N=3423)** |
| Age (years) | N | 1,507 | 1,497 | 419 | 3,423 |
|  | # missing | 0 | 0 | 0 | 0 |
|  | Min-Max | 18-49 | 18-44 | 18-39 | 18-49 |
|  | Median (Q1-Q3) | 26 (22-30) | 26 (23-30) | 26 (22-30) | 26 (22-30) |
|  | | | | | |
| Race | Asian (from Indian subcontinent) | 1 (<0.5%) | 0 (0%) | 1 (<0.5%) | 2 (<0.5%) |
|  | Black African | 1,459 (97%) | 1,450 (97%) | 418 (100%) | 3,327 (97%) |
|  | Indian (Native of India) | 46 (3%) | 46 (3%) | 0 (0%) | 92 (3%) |
|  | Coloured | 1 (<0.5%) | 1 (<0.5%) | 0 (0%) | 2 (<0.5%) |
|  | | | | | |
| Weight (kg) | N | 1,507 | 1,497 | 419 | 3,423 |
|  | # missing | 0 | 0 | 0 | 0 |
|  | Min-Max | 23-128 | 23-140 | 35-136 | 23-140 |
|  | Median (Q1-Q3) | 64 (58-74) | 65 (58-74) | 64 (58-76) | 64 (58-74) |
|  | | | | | |
| BMI (kg/m2) | N | 1,506 | 1,487 | 415 | 3,408 |
|  | # missing | 1 | 10 | 4 | 15 |
|  | Min-Max | 9.1-88.2 | 10.8-68.3 | 13.7-52.2 | 9.1-88.2 |
|  | Median (Q1-Q3) | 26.0 (23.5-29.6) | 26.3 (23.4-29.8) | 26.2 (23.5-30.1) | 26.1 (23.5-29.7) |
|  | | | | | |
| Screening CD4+ Cell Count (cells/mm3) | N | 1,507 | 1,497 | 419 | 3,423 |
|  | # missing | 0 | 0 | 0 | 0 |
|  | Min-Max | 350-2,033 | 351-1,842 | 350-1,277 | 350-2,033 |
|  | Median (Q1-Q3) | 531 (433-676) | 526 (439-650) | 532 (432-680) | 529 (435-666) |
|  | | | | | |
|  | 350 - <500 | 629 (42%) | 637 (43%) | 174 (42%) | 1,440 (42%) |
|  | 500 - <750 | 630 (42%) | 631 (42%) | 175 (42%) | 1,436 (42%) |
|  | ≥ 750 | 248 (16%) | 229 (15%) | 70 (17%) | 547 (16%) |
|  | | | | | |
| Baseline HIV-RNA (copies/mL) | N | 1,503 | 1,494 | 419 | 3,416 |
|  | # missing | 4 | 3 | 0 | 7 |
|  | Min-Max | 20-1,433,155 | 20-750,000 | 20-2,361,568 | 20-2,361,568 |
|  | Median (Q1-Q3) | 6,415 (1,450-22,699) | 7,790 (1,841-28,767) | 8,830 (2,011-30,027) | 7,184 (1,662-25,675) |
|  | | | | | |
|  | < 1000 | 322 (21%) | 274 (18%) | 68 (16%) | 664 (19%) |
|  | 1000 - < 10000 | 567 (38%) | 558 (37%) | 154 (37%) | 1,279 (37%) |
|  | 10000- < 20000 | 204 (14%) | 209 (14%) | 54 (13%) | 467 (14%) |
|  | ≥ 20000 | 410 (27%) | 453 (30%) | 143 (34%) | 1,006 (29%) |
|  | | | | | |
| WHO Stage | Clinical stage I | 1,454 (97%) | 1,459 (98%) | 409 (98%) | 3,322 (97%) |
|  | Clinical stage II | 50 (3%) | 32 (2%) | 10 (2%) | 92 (3%) |
|  | Clinical stage III | 1 (<0.5%) | 2 (<0.5%) | 0 (0%) | 3 (<0.5%) |
|  | # missing | 2 | 4 | 0 | 6 |
|  | | | | | |
| Gestational Age at Enrollment | N | 1,507 | 1,496 | 419 | 3,422 |
|  | # missing | 0 | 1 | 0 | 1 |
|  | Min-Max | 14-42 | 13-43 | 14-39 | 13-43 |
|  | Median (Q1-Q3) | 26 (21-30) | 25 (21-30) | 26 (22-32) | 26 (21-30) |
|  | | | | | |
|  | < 14 | 10 (1%) | 8 (1%) | 2 (<0.5%) | 20 (1%) |
|  | 14 - < 28 | 926 (61%) | 970 (65%) | 244 (58%) | 2,140 (63%) |
|  | 28 - < 34 | 411 (27%) | 361 (24%) | 110 (26%) | 882 (26%) |
|  | 34 - <37 | 115 (8%) | 110 (7%) | 45 (11%) | 270 (8%) |
|  | ≥ 37 | 45 (3%) | 47 (3%) | 18 (4%) | 110 (3%) |
|  | | | | | |
| HBsAg+ at Screening | No | 1,469 (97%) | 1,450 (97%) | 374 (89%) | 3,293 (96%) |
|  | Yes | 38 (3%) | 47 (3%) | 45 (11%) | 130 (4%) |
|  | | | | | |
| Premature births prior to PROMISE pregnancy | Nulliparous | 308 (20%) | 281 (19%) | 92 (22%) | 681 (20%) |
|  | Parous, no prior preterm | 1,146 (76%) | 1,159 (77%) | 317 (76%) | 2,622 (77%) |
|  | Parous, at least one preterm | 49 (3%) | 57 (4%) | 9 (2%) | 115 (3%) |
|  | | | | | |
| The Most Complex ARV Regimen for Prior PMTCT | HAART including NNRTI | 6 (<0.5%) | 4 (<0.5%) | 2 (<0.5%) | 12 (<0.5%) |
|  | sdNVP+ZDV | 32 (2%) | 45 (3%) | 5 (1%) | 82 (2%) |
|  | sdNVP | 40 (3%) | 41 (3%) | 14 (3%) | 95 (3%) |
|  | One PI | 0 (0%) | 1 (<0.5%) | 0 (0%) | 1 (<0.5%) |
|  | One NRTI | 3 (<0.5%) | 4 (<0.5%) | 0 (0%) | 7 (<0.5%) |
|  | No ARVs for prior PMTCT/no prior pregnancy | 1,426 (95%) | 1,402 (94%) | 398 (95%) | 3,226 (94%) |
|  | | | | | |
| The Last ARV Regimen before Entry during the Current Pregnancy | HAART including NNRTI | 0 (0%) | 1 (<0.5%) | 0 (0%) | 1 (<0.5%) |
|  | Two NRTIs | 2 (<0.5%) | 5 (<0.5%) | 3 (1%) | 10 (<0.5%) |
|  | sdNVP+ZDV | 2 (<0.5%) | 0 (0%) | 0 (0%) | 2 (<0.5%) |
|  | sdNVP | 5 (<0.5%) | 3 (<0.5%) | 0 (0%) | 8 (<0.5%) |
|  | One NRTI | 318 (21%) | 334 (22%) | 117 (28%) | 769 (22%) |
|  | No ARVs during the current pregnancy | 1,180 (78%) | 1,154 (77%) | 299 (71%) | 2,633 (77%) |
|  | | | | | |
| Country | South Africa | 500 (33%) | 485 (32%) | 69 (16%) | 1,054 (31%) |
|  | Malawi | 471 (31%) | 479 (32%) | 146 (35%) | 1,096 (32%) |
|  | Zambia | 32 (2%) | 31 (2%) | 18 (4%) | 81 (2%) |
|  | Uganda | 204 (14%) | 198 (13%) | 83 (20%) | 485 (14%) |
|  | Zimbabwe | 231 (15%) | 234 (16%) | 93 (22%) | 558 (16%) |
|  | Tanzania | 23 (2%) | 24 (2%) | 10 (2%) | 57 (2%) |
|  | India | 46 (3%) | 46 (3%) | 0 (0%) | 92 (3%) |
|  | | | | | |

\* *Randomization Arm ARV Regimen: (A) = ZDV+sdNVP+TRV tail, (B) = 3TC-ZDV/LPV-RTV, (C) = FTC-TDF/LPV-RTV.*

**Digital Table S-2: Analysis results for M-I pairs with preterm delivery (PTD: <37 weeks) and very preterm delivery (VPTD: <34 weeks) outcomes**

|  | | | **Counts** | | **Univariate Analysis** | | **Multivariate Analysis** | | **Multivariate Analysis Backward Selection** | | **Ver3.0 Counts** | | **Ver3.0 Multivariate Analysis\*** | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Risk Factor** |  | **Pregnancy Outcome** | **Y** | **N** | **Odds Ratio** | **95% CI** | **Adjusted Odds Ratio** | **95% CI** | **Adjusted Odds Ratio** | **95% CI** | **Y** | **N** | **Adjusted Odds Ratio** | **95% CI** |
| Treatment | ZDV+sdVNP+TRV tail | PTD | 190 | 1277 | . | . | . | . | . | . | 52 | 345 | . | . |
|  | Triple ARV (3TC-ZDV/LPV-RTV) | PTD | 289 | 1165 | 1.667 | 1.37-2.04 | 1.800 | 1.45-2.23 | 1.822 | 1.47-2.26 | 70 | 324 | 1.809 | 1.17-2.80 |
|  | Triple ARV (FTC-TDF/LPV-RTV) | PTD | 78 | 334 | 1.570 | 1.18-2.10 | 1.754 | 1.28-2.41 | 1.769 | 1.29-2.43 | 69 | 312 | 1.614 | 1.04-2.51 |
|  | ZDV+sdVNP+TRV tail | VPTD | 37 | 1430 | . | . | . | . | . | . | 11 | 386 | . | . |
|  | Triple ARV (3TC-ZDV/LPV-RTV) | VPTD | 43 | 1411 | 1.178 | 0.75-1.84 | 1.169 | 0.72-1.91 | 1.191 | 0.73-1.94 | 9 | 385 | 1.241 | 0.45-3.44 |
|  | Triple ARV (FTC-TDF/LPV-RTV) | VPTD | 25 | 387 | 2.498 | 1.49-4.20 | 3.126 | 1.76-5.54 | 3.138 | 1.77-5.55 | 23 | 358 | 3.055 | 1.30-7.16 |
| Maternal age at delivery | 18 - <21 years of age | PTD | 80 | 307 | 1.386 | 1.06-1.81 | 1.254 | 0.91-1.73 | 1.249 | 0.91-1.72 | 27 | 115 | 1.149 | 0.66-2.01 |
|  | 21 - <35 years of age | PTD | 420 | 2233 | . | . | . | . | . | . | 146 | 787 | . | . |
|  | ≥ 35 years of age | PTD | 57 | 236 | 1.284 | 0.94-1.75 | 1.368 | 0.97-1.93 | 1.369 | 0.97-1.93 | 18 | 79 | 1.406 | 0.75-2.62 |
|  | 18 - <21 years of age | VPTD | 14 | 373 | 1.192 | 0.67-2.12 | 1.162 | 0.57-2.38 | . | . | 8 | 134 | . | . |
|  | 21 - <35 years of age | VPTD | 81 | 2572 | . | . | . | . | . | . | 33 | 900 | . | . |
|  | ≥ 35 years of age | VPTD | 10 | 283 | 1.122 | 0.58-2.19 | 1.028 | 0.48-2.19 | . | . | 2 | 95 | . | . |
| Maternal BMI at entry | < 18.5 | PTD | 9 | 15 | 2.816 | 1.23-6.48 | 1.933 | 0.75-5.01 | 2.015 | 0.78-5.19 | 4 | 2 | 9.100 | 1.42-58.52 |
|  | 18.5 - <30 | PTD | 444 | 2084 | . | . | . | . | . | . | 159 | 752 | . | . |
|  | ≥ 30 | PTD | 99 | 670 | 0.694 | 0.55-0.88 | 0.672 | 0.51-0.88 | 0.677 | 0.52-0.89 | 25 | 220 | 0.482 | 0.28-0.82 |
|  | < 18.5 | VPTD | 0 | 24 | † | † | † | † | † | † | 0 | 6 | † | † |
|  | 18.5 - <30 | VPTD | 84 | 2444 | . | . | . | . | . | . | 38 | 873 | . | . |
|  | ≥ 30 | VPTD | 19 | 750 | 0.737 | 0.45-1.22 | 0.445 | 0.24-0.84 | 0.467 | 0.25-0.87 | 4 | 241 | 0.122 | 0.03-0.61 |
| CD4 count at screening | <500 | PTD | 247 | 1150 | 1.266 | 0.96-1.67 | 1.082 | 0.79-1.48 | . | . | 75 | 400 | . | . |
|  | 500 - <750 | PTD | 233 | 1172 | 1.172 | 0.89-1.55 | 1.069 | 0.79-1.45 | . | . | 88 | 419 | . | . |
|  | ≥ 750 | PTD | 77 | 454 | . | . | . | . | . | . | 28 | 162 | . | . |
|  | <500 | VPTD | 50 | 1347 | 1.755 | 0.91-3.40 | 1.400 | 0.66-2.98 | . | . | 21 | 454 | . | . |
|  | 500 - <750 | VPTD | 44 | 1361 | 1.528 | 0.78-2.98 | 1.425 | 0.68-3.00 | . | . | 18 | 489 | . | . |
|  | ≥ 750 | VPTD | 11 | 520 | . | . | . | . | . | . | 4 | 186 | . | . |
| HIV-RNA at baseline | < 1000 | PTD | 94 | 553 | . | . | . | . | . | . | 35 | 188 | . | . |
|  | 1000 - < 10000 | PTD | 186 | 1060 | 1.032 | 0.79-1.35 | 1.014 | 0.75-1.37 | 1.036 | 0.77-1.39 | 67 | 371 | 0.988 | 0.59-1.65 |
|  | 10000- < 20000 | PTD | 82 | 369 | 1.307 | 0.95-1.81 | 1.251 | 0.87-1.80 | 1.280 | 0.90-1.83 | 26 | 132 | 1.066 | 0.56-2.04 |
|  | ≥ 20000 | PTD | 194 | 788 | 1.448 | 1.11-1.90 | 1.308 | 0.95-1.79 | 1.345 | 1.00-1.82 | 63 | 288 | 1.362 | 0.80-2.31 |
|  | < 1000 | VPTD | 16 | 631 | . | . | . | . | . | . | 7 | 216 | . | . |
|  | 1000 - < 10000 | VPTD | 30 | 1216 | 0.973 | 0.53-1.80 | 0.790 | 0.40-1.58 | 0.841 | 0.43-1.65 | 15 | 423 | 0.789 | 0.27-2.29 |
|  | 10000- < 20000 | VPTD | 16 | 435 | 1.451 | 0.72-2.93 | 1.316 | 0.59-2.92 | 1.404 | 0.65-3.02 | 7 | 151 | 1.486 | 0.43-5.17 |
|  | ≥ 20000 | VPTD | 43 | 939 | 1.806 | 1.01-3.23 | 1.513 | 0.75-3.04 | 1.649 | 0.86-3.17 | 14 | 337 | 1.525 | 0.52-4.48 |
| Gestational age at entry |  | PTD | . | . | 0.972 | 0.96-0.99 | 0.991 | 0.97-1.01 | . | . | . | . | . | . |
|  |  | VPTD | . | . | 0.938 | 0.91-0.97 | 0.949 | 0.91-0.99 | 0.951 | 0.92-0.99 | . | . | 0.950 | 0.89-1.01 |
| Multiple gestation | Singleton | PTD | 522 | 2751 | . | . | . | . | . | . | 175 | 971 | . | . |
|  | Twins/triplets | PTD | 35 | 25 | 7.378 | 4.38-12.43 | 6.409 | 3.63-11.33 | 6.280 | 3.56-11.09 | 16 | 10 | 10.417 | 4.30-25.23 |
|  | Singleton | VPTD | 90 | 3183 | . | . | . | . | . | . | 36 | 1110 | . | . |
|  | Twins/triplets | VPTD | 15 | 45 | 11.791 | 6.34-21.93 | 9.255 | 4.52-18.95 | 9.464 | 4.67-19.17 | 7 | 19 | 16.912 | 5.47-52.27 |
| Prior preterm births | Nulliparous | PTD | 125 | 536 | 1.243 | 1.00-1.55 | 1.129 | 0.86-1.49 | 1.150 | 0.88-1.51 | 43 | 191 | 1.363 | 0.85-2.19 |
|  | Parous, no prior preterm | PTD | 404 | 2153 | . | . | . | . | . | . | 144 | 764 | . | . |
|  | Parous, at least one preterm | PTD | 28 | 82 | 1.820 | 1.17-2.83 | 1.677 | 1.02-2.75 | 1.704 | 1.04-2.79 | 4 | 25 | 1.176 | 0.36-3.82 |
|  | Nulliparous | VPTD | 20 | 641 | 0.979 | 0.60-1.61 | 0.709 | 0.38-1.32 | . | . | 10 | 224 | . | . |
|  | Parous, no prior preterm | VPTD | 79 | 2478 | . | . | . | . | . | . | 32 | 876 | . | . |
|  | Parous, at least one preterm | VPTD | 6 | 104 | 1.810 | 0.77-4.25 | 1.392 | 0.53-3.68 | . | . | 1 | 28 | . | . |
| History of alcohol use | Yes | PTD | 51 | 341 | . | . | . | . | . | . | 20 | 134 | . | . |
|  | No | PTD | 506 | 2432 | 1.391 | 1.02-1.90 | 1.149 | 0.79-1.68 | . | . | 171 | 844 | . | . |
|  | Yes | VPTD | 5 | 387 | . | . | . | . | . | . | 0 | 154 | . | . |
|  | No | VPTD | 100 | 2838 | 2.725 | 1.10-6.73 | 2.769 | 0.93-8.24 | 2.734 | 0.94-8.00 | 43 | 972 | † | † |
| Country | South Africa | PTD | 172 | 844 | . | . | . | . | . | . | 34 | 154 | . | . |
|  | Malawi | PTD | 230 | 836 | 1.350 | 1.08-1.68 | 1.476 | 1.14-1.92 | 1.475 | 1.14-1.91 | 81 | 313 | 1.160 | 0.69-1.96 |
|  | Zambia | PTD | 29 | 52 | 2.737 | 1.69-4.44 | 3.474 | 2.04-5.91 | 3.403 | 2.02-5.74 | 24 | 31 | 3.908 | 1.87-8.19 |
|  | Uganda | PTD | 52 | 422 | 0.605 | 0.43-0.84 | 0.575 | 0.38-0.87 | 0.514 | 0.36-0.74 | 28 | 205 | 0.543 | 0.29-1.01 |
|  | Zimbabwe | PTD | 33 | 518 | 0.313 | 0.21-0.46 | 0.318 | 0.21-0.49 | 0.307 | 0.20-0.46 | 15 | 252 | 0.250 | 0.12-0.51 |
|  | Tanzania | PTD | 14 | 43 | 1.598 | 0.86-2.99 | 1.818 | 0.94-3.51 | 1.809 | 0.94-3.48 | 8 | 25 | 1.478 | 0.57-3.83 |
|  | India | PTD | 27 | 61 | 2.172 | 1.34-3.52 | 1.379 | 0.76-2.49 | 1.334 | 0.75-2.38 | 1 | 1 | 1.098 | 0.02-74.77 |
|  | South Africa | VPTD | 39 | 977 | . | . | . | . | . | . | 9 | 179 | . | . |
|  | Malawi | VPTD | 44 | 1022 | 1.079 | 0.70-1.67 | 1.417 | 0.79-2.53 | 1.391 | 0.79-2.45 | 19 | 375 | 1.008 | 0.34-2.98 |
|  | Zambia | VPTD | 4 | 77 | 1.301 | 0.45-3.74 | 2.093 | 0.57-7.65 | 2.077 | 0.58-7.50 | 4 | 51 | 2.371 | 0.49-11.46 |
|  | Uganda | VPTD | 7 | 467 | 0.376 | 0.17-0.85 | 0.424 | 0.16-1.14 | 0.420 | 0.16-1.10 | 2 | 231 | 0.227 | 0.04-1.40 |
|  | Zimbabwe | VPTD | 7 | 544 | 0.322 | 0.14-0.73 | 0.459 | 0.19-1.14 | 0.451 | 0.18-1.12 | 6 | 261 | 0.559 | 0.15-2.07 |
|  | Tanzania | VPTD | 3 | 54 | 1.392 | 0.42-4.65 | 2.208 | 0.61-7.96 | 2.028 | 0.57-7.24 | 3 | 30 | 2.530 | 0.53-12.09 |
|  | India | VPTD | 1 | 87 | 0.288 | 0.04-2.12 | 0.180 | 0.02-1.64 | 0.156 | 0.02-1.41 | 0 | 2 | † | † |
| Abruptio Placenta | Yes | PTD | 5 | 3 | 8.372 | 2.00-35.14 | 14.899 | 3.24-68.50 | 15.473 | 3.36-71.33 | 2 | 1 | 33.347 | 2.80-396.70 |
|  | No | PTD | 552 | 2773 | . | . | . | . | . | . | 189 | 980 | . | . |
|  | Yes | VPTD | 3 | 5 | 18.959 | 4.47-80.41 | 32.546 | 6.23-170.08 | 32.463 | 6.26-168.31 | 1 | 2 | 36.238 | 2.18-602.63 |
|  | No | VPTD | 102 | 3223 | . | . | . | . | . | . | 42 | 1127 | . | . |
| Chronic Hypertension | Yes | PTD | 6 | 21 | 1.429 | 0.57-3.56 | 1.252 | 0.43-3.69 | . | . | 1 | 2 | . | . |
|  | No | PTD | 551 | 2755 | . | . | . | . | . | . | 190 | 979 | . | . |
|  | Yes | VPTD | 4 | 23 | 5.519 | 1.87-16.25 | 5.114 | 1.32-19.79 | 4.944 | 1.32-18.59 | 1 | 2 | 9.623 | 0.25-370.10 |
|  | No | VPTD | 101 | 3205 | . | . | . | . | . | . | 42 | 1127 | . | . |
| Pregnancy Induced Hypertension | Yes | PTD | 42 | 80 | 2.748 | 1.87-4.04 | 3.830 | 2.45-6.00 | 3.836 | 2.46-5.99 | 7 | 25 | 2.753 | 1.00-7.54 |
|  | No | PTD | 515 | 2696 | . | . | . | . | . | . | 184 | 956 | . | . |
|  | Yes | VPTD | 15 | 107 | 4.861 | 2.72-8.68 | 6.244 | 3.03-12.89 | 5.832 | 2.87-11.86 | 3 | 29 | 4.228 | 0.93-19.23 |
|  | No | VPTD | 90 | 3121 | . | . | . | . | . | . | 40 | 1100 | . | . |
| Oligohydramnios | Yes | PTD | 12 | 17 | 3.575 | 1.70-7.53 | 3.070 | 1.28-7.38 | 3.046 | 1.27-7.30 | 2 | 4 | 2.150 | 0.18-25.17 |
|  | No | PTD | 545 | 2759 | . | . | . | . | . | . | 189 | 977 | . | . |
|  | Yes | VPTD | 5 | 24 | 6.675 | 2.50-17.85 | 14.855 | 4.17-52.86 | 17.509 | 5.19-59.03 | 0 | 6 | † | † |
|  | No | VPTD | 100 | 3204 | . | . | . | . | . | . | 43 | 1123 | . | . |
| Intrauterine Growth Restriction | Yes | PTD | 7 | 4 | 8.820 | 2.57-30.23 | 7.828 | 1.96-31.22 | 7.898 | 2.00-31.13 | 3 | 2 | 3.814 | 0.45-32.36 |
|  | No | PTD | 550 | 2772 | . | . | . | . | . | . | 188 | 979 | . | . |
|  | Yes | VPTD | 2 | 9 | 6.951 | 1.48-32.56 | 2.204 | 0.31-15.60 | . | . | 0 | 5 | . | . |
|  | No | VPTD | 103 | 3219 | . | . | . | . | . | . | 43 | 1124 | . | . |
| Premature Labor | Yes | PTD | 27 | 21 | 6.683 | 3.75-11.91 | 6.172 | 3.25-11.71 | 6.122 | 3.23-11.61 | 11 | 4 | 21.248 | 6.01-75.09 |
|  | No | PTD | 530 | 2755 | . | . | . | . | . | . | 180 | 977 | . | . |
|  | Yes | VPTD | 8 | 40 | 6.573 | 3.00-14.42 | 6.116 | 2.36-15.86 | 6.108 | 2.35-15.86 | 6 | 9 | 22.74 | 5.87-88.11 |
|  | No | VPTD | 97 | 3188 | . | . | . | . | . | . | 37 | 1120 | . | . |
| Premature Rupture of Membranes | Yes | PTD | 23 | 17 | 6.990 | 3.71-13.17 | 10.199 | 5.16-20.15 | 10.113 | 5.13-19.95 | 5 | 2 | 26.120 | 4.73-144.13 |
|  | No | PTD | 534 | 2759 | . | . | . | . | . | . | 186 | 979 | . | . |
|  | Yes | VPTD | 9 | 31 | 9.669 | 4.48-20.87 | 19.030 | 7.42-48.84 | 18.201 | 7.23-45.80 | 2 | 5 | 46.84 | 3.58-612.20 |
|  | No | VPTD | 96 | 3197 | . | . | . | . | . | . | 41 | 1124 | . | . |
| Vaginal Bleeding | Yes | PTD | 2 | 16 | 0.623 | 0.14-2.71 | 0.355 | 0.06-2.06 | . | . | 0 | 0 | . | . |
|  | No | PTD | 555 | 2760 | . | . | . | . | . | . | 191 | 981 | . | . |
|  | Yes | VPTD | 1 | 17 | 1.816 | 0.24-13.78 | 0.629 | 0.06-7.14 | . | . | 0 | 0 | . | . |
|  | No | VPTD | 104 | 3211 | . | . | . | . | . | . | 43 | 1129 | . | . |
| UTI | Yes | PTD | 35 | 226 | 0.757 | 0.52-1.09 | 0.921 | 0.60-1.42 | . | . | 15 | 97 | . | . |
|  | No | PTD | 522 | 2550 | . | . | . | . | . | . | 176 | 884 | . | . |
|  | Yes | VPTD | 9 | 252 | 1.107 | 0.55-2.22 | 1.049 | 0.44-2.49 | . | . | 2 | 110 | . | . |
|  | No | VPTD | 96 | 2976 | . | . | . | . | . | . | 41 | 1019 | . | . |

\* *Only the covariates that remained in the All Data multivariate model after backward selection were included in the multivariate model for Version 3.0 Data.*

† *In the models for the VPTD pregnancy outcome, we encountered instances where valid coefficients for categorical variables having no events in specific categories could not be estimated. For example, the <18.5 category of maternal BMI had no events for VPTD. However, inclusion of these variables provided a valid means of controlling for their effects in estimating the associations between the other variables in the models and the outcomes.*

**Digital Table S-3: Analysis results for M-I pairs with low birth weight (LBW: <2500 g) and very low birth weight (VLBW: <1500 g) outcomes**

|  | | | **Counts** | | **Univariate Analysis** | | **Multivariate Analysis** | | **Multivariate Analysis Backward Selection** | | **Ver3.0 Counts** | | **Ver3.0 Multivariate Analysis\*** | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Risk Factor** |  | **Pregnancy Outcome** | **Y** | **N** | **Odds Ratio** | **95% CI** | **Adjusted Odds Ratio** | **95% CI** | **Adjusted Odds Ratio** | **95% CI** | **Y** | **N** | **Adjusted Odds Ratio** | **95% CI** |
| Treatment | ZDV+sdVNP+TRV tail | LBW | 170 | 1250 | . | . | . | . | . | . | 33 | 340 | . | . |
|  | Triple ARV (3TC-ZDV/LPV-RTV) | LBW | 320 | 1081 | 2.177 | 1.78-2.67 | 2.681 | 2.13-3.37 | 2.669 | 2.12-3.36 | 73 | 299 | 3.699 | 2.21-6.18 |
|  | Triple ARV (FTC-TDF/LPV-RTV) | LBW | 68 | 319 | 1.567 | 1.15-2.13 | 2.192 | 1.56-3.09 | 2.183 | 1.55-3.07 | 62 | 294 | 2.800 | 1.66-4.72 |
|  | ZDV+sdVNP+TRV tail | VLBW | 12 | 1408 | . | . | . | . | . | . | 1 | 372 | . | . |
|  | Triple ARV (3TC-ZDV/LPV-RTV) | VLBW | 18 | 1383 | 1.527 | 0.73-3.18 | 1.991 | 0.81-4.91 | 2.118 | 0.90-5.00 | 2 | 370 | 7.410 | 0.43-128.55 |
|  | Triple ARV (FTC-TDF/LPV-RTV) | VLBW | 10 | 377 | 3.112 | 1.33-7.26 | 6.786 | 2.40-19.19 | 6.390 | 2.35-17.39 | 9 | 347 | 28.236 | 2.34-340.30 |
| Maternal age at delivery | 18 - <21 years of age | LBW | 68 | 295 | 1.127 | 0.85-1.50 | 0.957 | 0.68-1.36 | . | . | 14 | 113 | . | . |
|  | 21 - <35 years of age | LBW | 435 | 2126 | . | . | . | . | . | . | 136 | 746 | . | . |
|  | ≥ 35 years of age | LBW | 55 | 229 | 1.174 | 0.86-1.60 | 1.308 | 0.92-1.85 | . | . | 18 | 74 | . | . |
|  | 18 - <21 years of age | VLBW | 2 | 361 | 0.389 | 0.09-1.62 | 0.460 | 0.10-2.21 | . | . | 0 | 127 | . | . |
|  | 21 - <35 years of age | VLBW | 36 | 2525 | . | . | . | . | . | . | 11 | 871 | . | . |
|  | ≥ 35 years of age | VLBW | 2 | 282 | 0.497 | 0.12-2.08 | 0.458 | 0.09-2.39 | . | . | 1 | 91 | . | . |
| Maternal BMI at entry | < 18.5 | LBW | 12 | 11 | 5.060 | 2.22-11.54 | 1.916 | 0.69-5.31 | 1.871 | 0.68-5.16 | 1 | 4 | 0.344 | 0.01-13.41 |
|  | 18.5 - <30 | LBW | 432 | 2004 | . | . | . | . | . | . | 133 | 723 | . | . |
|  | ≥ 30 | LBW | 110 | 630 | 0.810 | 0.65-1.02 | 0.712 | 0.54-0.93 | 0.731 | 0.56-0.95 | 30 | 202 | 0.739 | 0.45-1.22 |
|  | < 18.5 | VLBW | 0 | 23 | † | † | † | † | † | † | 0 | 5 | † | † |
|  | 18.5 - <30 | VLBW | 32 | 2404 | . | . | . | . | . | . | 11 | 845 | . | . |
|  | ≥ 30 | VLBW | 8 | 732 | 0.821 | 0.38-1.79 | 0.335 | 0.11-0.99 | 0.328 | 0.12-0.89 | 1 | 231 | 0.055 | 0.00-0.97 |
| CD4 count at screening | <500 | LBW | 247 | 1105 | 1.099 | 0.84-1.44 | 0.981 | 0.72-1.34 | . | . | 71 | 382 | . | . |
|  | 500 - <750 | LBW | 225 | 1122 | 0.986 | 0.75-1.30 | 0.878 | 0.64-1.20 | . | . | 70 | 402 | . | . |
|  | ≥ 750 | LBW | 86 | 423 | . | . | . | . | . | . | 27 | 149 | . | . |
|  | <500 | VLBW | 16 | 1336 | 1.207 | 0.44-3.31 | 0.962 | 0.26-3.55 | . | . | 8 | 445 | . | . |
|  | 500 - <750 | VLBW | 19 | 1328 | 1.442 | 0.54-3.88 | 1.670 | 0.48-5.77 | . | . | 4 | 468 | . | . |
|  | ≥ 750 | VLBW | 5 | 504 | . | . | . | . | . | . | 0 | 176 | . | . |
| HIV-RNA at baseline | < 1000 | LBW | 105 | 521 | . | . | . | . | . | . | 39 | 172 | . | . |
|  | 1000 - < 10000 | LBW | 204 | 997 | 1.015 | 0.78-1.31 | 0.954 | 0.71-1.28 | . | . | 65 | 345 | . | . |
|  | 10000- < 20000 | LBW | 74 | 351 | 1.046 | 0.75-1.45 | 1.029 | 0.71-1.49 | . | . | 12 | 132 | . | . |
|  | ≥ 20000 | LBW | 173 | 776 | 1.106 | 0.85-1.44 | 0.948 | 0.69-1.31 | . | . | 51 | 283 | . | . |
|  | < 1000 | VLBW | 9 | 617 | . | . | . | . | . | . | 3 | 208 | . | . |
|  | 1000 - < 10000 | VLBW | 11 | 1190 | 0.634 | 0.26-1.54 | 0.480 | 0.15-1.54 | . | . | 4 | 406 | . | . |
|  | 10000- < 20000 | VLBW | 4 | 421 | 0.651 | 0.20-2.13 | 0.563 | 0.13-2.44 | . | . | 1 | 143 | . | . |
|  | ≥ 20000 | VLBW | 16 | 933 | 1.176 | 0.52-2.68 | 1.088 | 0.35-3.40 | . | . | 4 | 330 | . | . |
| Gestational age at entry |  | LBW | . | . | 0.964 | 0.95-0.98 | 0.971 | 0.95-0.99 | 0.971 | 0.95-0.99 | . | . | 0.986 | 0.95-1.02 |
|  |  | VLBW | . | . | 0.886 | 0.84-0.94 | 0.905 | 0.84-0.97 | 0.881 | 0.82-0.94 | . | . | 0.828 | 0.72-0.95 |
| Multiple gestation | Singleton | LBW | 516 | 2638 | . | . | . | . | . | . | 149 | 929 | . | . |
|  | Twins/triplets | LBW | 42 | 12 | 17.893 | 9.36-34.22 | 22.569 | 11.22-45.39 | 22.492 | 11.26-44.94 | 19 | 4 | 51.460 | 16.00-165.46 |
|  | Singleton | VLBW | 29 | 3125 | . | . | . | . | . | . | 8 | 1070 | . | . |
|  | Twins/triplets | VLBW | 11 | 43 | 27.566 | 12.94-58.74 | 26.422 | 9.62-72.56 | 30.777 | 12.19-77.74 | 4 | 19 | 129.074 | 19.47-855.89 |
| Prior preterm births | Nulliparous | LBW | 137 | 495 | 1.484 | 1.19-1.85 | 1.306 | 0.99-1.72 | 1.246 | 0.97-1.61 | 38 | 177 | 1.387 | 0.87-2.20 |
|  | Parous, no prior preterm | LBW | 388 | 2080 | . | . | . | . | . | . | 126 | 734 | . | . |
|  | Parous, at least one preterm | LBW | 33 | 70 | 2.527 | 1.65-3.88 | 2.248 | 1.38-3.66 | 2.272 | 1.40-3.69 | 4 | 21 | 1.454 | 0.44-4.81 |
|  | Nulliparous | VLBW | 8 | 624 | 1.042 | 0.48-2.28 | 0.996 | 0.38-2.65 | . | . | 2 | 213 | . | . |
|  | Parous, no prior preterm | VLBW | 30 | 2438 | . | . | . | . | . | . | 9 | 851 | . | . |
|  | Parous, at least one preterm | VLBW | 2 | 101 | 1.609 | 0.38-6.83 | 1.044 | 0.15-7.16 | . | . | 1 | 24 | . | . |
| History of alcohol use | Yes | LBW | 44 | 340 | . | . | . | . | . | . | 16 | 132 | . | . |
|  | No | LBW | 514 | 2307 | 1.722 | 1.24-2.39 | 1.425 | 0.95-2.15 | 1.414 | 0.94-2.13 | 152 | 798 | 1.494 | 0.74-3.04 |
|  | Yes | VLBW | 2 | 382 | . | . | . | . | . | . | 0 | 148 | . | . |
|  | No | VLBW | 38 | 2783 | 2.606 | 0.63-10.84 | 4.450 | 0.71-27.88 | . | . | 12 | 938 | . | . |
| Country | South Africa | LBW | 198 | 786 | . | . | . | . | . | . | 37 | 140 | . | . |
|  | Malawi | LBW | 163 | 848 | 0.763 | 0.61-0.96 | 0.895 | 0.68-1.18 | 0.882 | 0.67-1.16 | 58 | 308 | 0.791 | 0.45-1.39 |
|  | Zambia | LBW | 18 | 56 | 1.276 | 0.73-2.22 | 1.846 | 1.00-3.40 | 1.836 | 1.01-3.35 | 15 | 34 | 2.366 | 1.06-5.30 |
|  | Uganda | LBW | 42 | 420 | 0.397 | 0.28-0.57 | 0.441 | 0.28-0.69 | 0.448 | 0.29-0.69 | 25 | 199 | 0.605 | 0.30-1.21 |
|  | Zimbabwe | LBW | 76 | 459 | 0.657 | 0.49-0.88 | 0.914 | 0.65-1.29 | 0.914 | 0.65-1.28 | 27 | 226 | 0.558 | 0.29-1.07 |
|  | Tanzania | LBW | 9 | 45 | 0.794 | 0.38-1.65 | 0.910 | 0.42-1.98 | 0.927 | 0.43-2.01 | 5 | 25 | 0.844 | 0.27-2.62 |
|  | India | LBW | 52 | 36 | 5.734 | 3.65-9.02 | 5.564 | 3.20-9.69 | 5.418 | 3.13-9.38 | 1 | 1 | 3.004 | 0.06-148.39 |
|  | South Africa | VLBW | 22 | 962 | . | . | . | . | . | . | 3 | 174 | . | . |
|  | Malawi | VLBW | 13 | 998 | 0.570 | 0.29-1.14 | 1.168 | 0.42-3.28 | . | . | 6 | 360 | . | . |
|  | Zambia | VLBW | 0 | 74 | † | † | † | † | . | . | 0 | 49 | . | . |
|  | Uganda | VLBW | 4 | 458 | 0.382 | 0.13-1.12 | 0.911 | 0.22-3.73 | . | . | 2 | 222 | . | . |
|  | Zimbabwe | VLBW | 1 | 534 | 0.082 | 0.01-0.61 | 0.161 | 0.02-1.44 | . | . | 1 | 252 | . | . |
|  | Tanzania | VLBW | 0 | 54 | † | † | † | † | . | . | 0 | 30 | . | . |
|  | India | VLBW | 0 | 88 | † | † | † | † | . | . | 0 | 2 | . | . |
| Abruptio Placenta | Yes | LBW | 4 | 4 | 4.776 | 1.19-19.16 | 7.800 | 1.59-38.38 | 7.586 | 1.54-37.29 | 1 | 2 | 5.537 | 0.48-63.58 |
|  | No | LBW | 554 | 2646 | . | . | . | . | . | . | 167 | 931 | . | . |
|  | Yes | VLBW | 2 | 6 | 27.737 | 5.42-141.84 | 58.145 | 7.39-457.27 | 49.560 | 7.30-336.63 | 0 | 3 | † | † |
|  | No | VLBW | 38 | 3162 | . | . | . | . | . | . | 12 | 1086 | . | . |
| Chronic Hypertension | Yes | LBW | 7 | 19 | 1.759 | 0.74-4.21 | 1.117 | 0.40-3.11 | . | . | 1 | 2 | . | . |
|  | No | LBW | 551 | 2631 | . | . | . | . | . | . | 167 | 931 | . | . |
|  | Yes | VLBW | 3 | 23 | 11.088 | 3.19-38.54 | 8.518 | 1.41-51.48 | 7.728 | 1.48-40.31 | 0 | 3 | † | † |
|  | No | VLBW | 37 | 3145 | . | . | . | . | . | . | 12 | 1086 | . | . |
| Pregnancy Induced Hypertension | Yes | LBW | 47 | 69 | 3.440 | 2.35-5.04 | 3.376 | 2.14-5.33 | 3.434 | 2.18-5.41 | 8 | 19 | 4.289 | 1.65-11.18 |
|  | No | LBW | 511 | 2581 | . | . | . | . | . | . | 160 | 914 | . | . |
|  | Yes | VLBW | 11 | 105 | 11.065 | 5.38-22.75 | 16.388 | 5.67-47.38 | 12.983 | 5.24-32.17 | 1 | 26 | 10.456 | 0.47-234.41 |
|  | No | VLBW | 29 | 3063 | . | . | . | . | . | . | 11 | 1063 | . | . |
| Oligohydramnios | Yes | LBW | 19 | 9 | 10.342 | 4.65-22.98 | 8.600 | 2.98-24.84 | 8.639 | 3.02-24.76 | 3 | 3 | 7.628 | 0.96-60.66 |
|  | No | LBW | 539 | 2641 | . | . | . | . | . | . | 165 | 930 | . | . |
|  | Yes | VLBW | 3 | 25 | 10.194 | 2.95-35.25 | 16.933 | 2.66-107.89 | 13.200 | 2.87-60.75 | 0 | 6 | † | † |
|  | No | VLBW | 37 | 3143 | . | . | . | . | . | . | 12 | 1083 | . | . |
| Intrauterine Growth Restriction | Yes | LBW | 10 | 1 | 48.333 | 6.18-378.30 | 60.135 | 6.93-521.86 | 55.296 | 6.42-476.58 | 4 | 1 | 15.612 | 1.15-212.46 |
|  | No | LBW | 548 | 2649 | . | . | . | . | . | . | 164 | 932 | . | . |
|  | Yes | VLBW | 3 | 8 | 32.027 | 8.17-125.52 | 13.132 | 1.21-142.08 | 11.379 | 1.45-89.28 | 1 | 4 | 1.979 | 0.04-89.57 |
|  | No | VLBW | 37 | 3160 | . | . | . | . | . | . | 11 | 1085 | . | . |
| Premature Labor | Yes | LBW | 27 | 18 | 7.435 | 4.07-13.60 | 5.761 | 2.86-11.59 | 5.735 | 2.86-11.51 | 8 | 4 | 17.127 | 4.63-63.41 |
|  | No | LBW | 531 | 2632 | . | . | . | . | . | . | 160 | 929 | . | . |
|  | Yes | VLBW | 4 | 41 | 8.478 | 2.89-24.91 | 5.561 | 1.25-24.74 | 5.067 | 1.31-19.64 | 2 | 10 | 27.353 | 3.58-209.13 |
|  | No | VLBW | 36 | 3127 | . | . | . | . | . | . | 10 | 1079 | . | . |
| Premature Rupture of Membranes | Yes | LBW | 22 | 18 | 5.998 | 3.20-11.26 | 10.064 | 5.00-20.28 | 10.209 | 5.08-20.54 | 4 | 3 | 12.839 | 2.58-63.88 |
|  | No | LBW | 536 | 2632 | . | . | . | . | . | . | 164 | 930 | . | . |
|  | Yes | VLBW | 4 | 36 | 9.667 | 3.27-28.58 | 22.347 | 5.57-89.70 | 16.296 | 4.62-57.43 | 1 | 6 | 84.725 | 3.61->999.99 |
|  | No | VLBW | 36 | 3132 | . | . | . | . | . | . | 11 | 1083 | . | . |
| Vaginal Bleeding | Yes | LBW | 7 | 11 | 3.048 | 1.18-7.90 | 2.891 | 0.97-8.65 | 2.972 | 1.00-8.87 | 0 | 0 | . | . |
|  | No | LBW | 551 | 2639 | . | . | . | . | . | . | 168 | 933 | . | . |
|  | Yes | VLBW | 1 | 17 | 4.755 | 0.62-36.60 | 0.839 | 0.05-13.26 | . | . | 0 | 0 | . | . |
|  | No | VLBW | 39 | 3151 | . | . | . | . | . | . | 12 | 1089 | . | . |
| UTI | Yes | LBW | 40 | 216 | 0.870 | 0.61-1.24 | 1.092 | 0.71-1.69 | . | . | 15 | 94 | . | . |
|  | No | LBW | 518 | 2434 | . | . | . | . | . | . | 153 | 839 | . | . |
|  | Yes | VLBW | 5 | 251 | 1.660 | 0.65-4.28 | 0.966 | 0.28-3.32 | . | . | 0 | 109 | . | . |
|  | No | VLBW | 35 | 2917 | . | . | . | . | . | . | 12 | 980 | . | . |

\* *Only the covariates that remained in the All Data multivariate model after backward selection were included in the multivariate model for Version 3.0 Data.*

† *In the models for the VLBW pregnancy outcome, we encountered instances where valid coefficients for categorical variables having no events in specific categories could not be estimated. For example, the <18.5 category of maternal BMI and three out of the seven countries had no events for VLBW. However, inclusion of these variables provided a valid means of controlling for their effects in estimating the associations between the other variables in the models and the outcomes.*

**Digital Table S-4: Analysis results for M-I pairs with the composite outcome (stillbirth or spontaneous abortion or PTD or LBW) and severe composite outcome (stillbirth or spontaneous abortion or VPTD or VLBW)**

|  | | | **Counts** | | **Univariate Analysis** | | **Multivariate Analysis** | | **Multivariate Analysis Backward Selection** | | **Ver3.0 Counts** | | **Ver3.0 Multivariate Analysis\*** | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Risk Factor** |  | **Pregnancy Outcome** | **Y** | **N** | **Odds Ratio** | **95% CI** | **Adjusted Odds Ratio** | **95% CI** | **Adjusted Odds Ratio** | **95% CI** | **Y** | **N** | **Adjusted Odds Ratio** | **95% CI** |
| Treatment | ZDV+sdVNP+TRV tail | Composite | 308 | 1168 | . | . | . | . | . | . | 73 | 317 | . | . |
|  | Triple ARV (3TC-ZDV/LPV-RTV) | Composite | 500 | 969 | 1.956 | 1.66-2.31 | 2.239 | 1.87-2.69 | 2.244 | 1.87-2.69 | 114 | 269 | 2.324 | 1.60-3.38 |
|  | Triple ARV (FTC-TDF/LPV-RTV) | Composite | 109 | 295 | 1.401 | 1.09-1.80 | 1.668 | 1.26-2.20 | 1.669 | 1.27-2.20 | 98 | 275 | 1.730 | 1.18-2.54 |
|  | ZDV+sdVNP+TRV tail | S-Composite | 78 | 1388 | . | . | . | . | . | . | 19 | 366 | . | . |
|  | Triple ARV (3TC-ZDV/LPV-RTV) | S-Composite | 95 | 1357 | 1.246 | 0.92-1.70 | 1.369 | 0.97-1.93 | 1.382 | 0.99-1.94 | 14 | 363 | 1.028 | 0.49-2.18 |
|  | Triple ARV (FTC-TDF/LPV-RTV) | S-Composite | 33 | 365 | 1.609 | 1.05-2.46 | 1.945 | 1.22-3.10 | 1.940 | 1.22-3.08 | 31 | 336 | 2.025 | 1.07-3.85 |
| Maternal age at delivery | 18 - <21 years of age | Composite | 120 | 264 | 1.247 | 0.99-1.57 | 1.082 | 0.82-1.43 | . | . | 36 | 99 | . | . |
|  | 21 - <35 years of age | Composite | 714 | 1959 | . | . | . | . | . | . | 224 | 693 | . | . |
|  | ≥ 35 years of age | Composite | 83 | 209 | 1.090 | 0.83-1.43 | 1.181 | 0.88-1.59 | . | . | 25 | 69 | . | . |
|  | 18 - <21 years of age | S-Composite | 26 | 352 | 1.126 | 0.73-1.73 | 1.163 | 0.70-1.94 | . | . | 9 | 122 | . | . |
|  | 21 - <35 years of age | S-Composite | 163 | 2485 | . | . | . | . | . | . | 52 | 853 | . | . |
|  | ≥ 35 years of age | S-Composite | 17 | 273 | 0.949 | 0.57-1.59 | 0.857 | 0.48-1.54 | . | . | 3 | 90 | . | . |
| Maternal BMI at entry | < 18.5 | Composite | 17 | 8 | 5.469 | 2.35-12.73 | 2.739 | 1.07-7.00 | 2.684 | 1.05-6.85 | 4 | 2 | 4.331 | 0.70-26.91 |
|  | 18.5 - <30 | Composite | 709 | 1825 | . | . | . | . | . | . | 228 | 661 | . | . |
|  | ≥ 30 | Composite | 181 | 595 | 0.783 | 0.65-0.95 | 0.762 | 0.61-0.95 | 0.767 | 0.62-0.95 | 46 | 194 | 0.664 | 0.44-1.00 |
|  | < 18.5 | S-Composite | 1 | 23 | 0.676 | 0.09-5.03 | 0.609 | 0.07-5.04 | . | . | 0 | 5 | . | . |
|  | 18.5 - <30 | S-Composite | 152 | 2358 | . | . | . | . | . | . | 53 | 824 | . | . |
|  | ≥ 30 | S-Composite | 49 | 721 | 1.054 | 0.76-1.47 | 0.844 | 0.56-1.27 | . | . | 9 | 229 | . | . |
| CD4 count at screening | <500 | Composite | 404 | 1010 | 1.128 | 0.90-1.41 | 0.955 | 0.74-1.24 | . | . | 112 | 357 | . | . |
|  | 500 - <750 | Composite | 374 | 1030 | 1.024 | 0.82-1.29 | 0.901 | 0.70-1.16 | . | . | 125 | 366 | . | . |
|  | ≥ 750 | Composite | 139 | 392 | . | . | . | . | . | . | 48 | 138 | . | . |
|  | <500 | S-Composite | 100 | 1305 | 1.413 | 0.91-2.19 | 1.197 | 0.72-1.98 | . | . | 33 | 435 | . | . |
|  | 500 - <750 | S-Composite | 79 | 1307 | 1.115 | 0.71-1.75 | 1.094 | 0.66-1.80 | . | . | 23 | 457 | . | . |
|  | ≥ 750 | S-Composite | 27 | 498 | . | . | . | . | . | . | 8 | 173 | . | . |
| HIV-RNA at baseline | < 1000 | Composite | 164 | 483 | . | . | . | . | . | . | 59 | 156 | . | . |
|  | 1000 - < 10000 | Composite | 321 | 930 | 1.017 | 0.82-1.26 | 0.980 | 0.77-1.25 | . | . | 103 | 326 | . | . |
|  | 10000- < 20000 | Composite | 134 | 319 | 1.237 | 0.95-1.62 | 1.229 | 0.91-1.66 | . | . | 30 | 121 | . | . |
|  | ≥ 20000 | Composite | 295 | 696 | 1.248 | 1.00-1.56 | 1.138 | 0.87-1.48 | . | . | 92 | 257 | . | . |
|  | < 1000 | S-Composite | 35 | 609 | . | . | . | . | . | . | 10 | 204 | . | . |
|  | 1000 - < 10000 | S-Composite | 67 | 1172 | 0.995 | 0.65-1.51 | 0.876 | 0.55-1.41 | . | . | 25 | 397 | . | . |
|  | 10000- < 20000 | S-Composite | 34 | 412 | 1.436 | 0.88-2.34 | 1.316 | 0.76-2.29 | . | . | 9 | 139 | . | . |
|  | ≥ 20000 | S-Composite | 70 | 910 | 1.338 | 0.88-2.03 | 1.170 | 0.71-1.92 | . | . | 20 | 323 | . | . |
| Gestational age at entry |  | Composite | . | . | 0.964 | 0.95-0.98 | 0.974 | 0.96-0.99 | 0.975 | 0.96-0.99 | . | . | 0.987 | 0.96-1.01 |
|  |  | S-Composite | . | . | 0.921 | 0.90-0.94 | 0.928 | 0.90-0.96 | 0.928 | 0.90-0.96 | . | . | 0.928 | 0.88-0.98 |
| Multiple gestation | Singleton | Composite | 866 | 2424 | . | . | . | . | . | . | 263 | 858 | . | . |
|  | Twins/triplets | Composite | 51 | 8 | 17.844 | 8.43-37.75 | 18.918 | 8.68-41.26 | 18.479 | 8.52-40.06 | 22 | 3 | 30.634 | 8.78-106.89 |
|  | Singleton | S-Composite | 182 | 3077 | . | . | . | . | . | . | 56 | 1049 | . | . |
|  | Twins/triplets | S-Composite | 24 | 33 | 12.296 | 7.12-21.24 | 10.296 | 5.49-19.31 | 10.090 | 5.43-18.76 | 8 | 16 | 10.772 | 3.83-30.34 |
| Prior preterm births | Nulliparous | Composite | 217 | 448 | 1.421 | 1.18-1.71 | 1.288 | 1.02-1.62 | 1.307 | 1.06-1.61 | 68 | 160 | 1.553 | 1.08-2.24 |
|  | Parous, no prior preterm | Composite | 653 | 1915 | . | . | . | . | . | . | 210 | 680 | . | . |
|  | Parous, at least one preterm | Composite | 47 | 64 | 2.155 | 1.46-3.17 | 2.021 | 1.32-3.11 | 2.020 | 1.32-3.09 | 7 | 20 | 1.411 | 0.53-3.74 |
|  | Nulliparous | S-Composite | 42 | 614 | 1.093 | 0.77-1.56 | 0.864 | 0.56-1.33 | 0.931 | 0.63-1.38 | 15 | 208 | 1.352 | 0.70-2.62 |
|  | Parous, no prior preterm | S-Composite | 150 | 2396 | . | . | . | . | . | . | 47 | 832 | . | . |
|  | Parous, at least one preterm | S-Composite | 14 | 95 | 2.355 | 1.31-4.23 | 2.013 | 1.04-3.89 | 1.993 | 1.04-3.83 | 2 | 24 | 1.808 | 0.36-9.03 |
| History of alcohol use | Yes | Composite | 88 | 314 | . | . | . | . | . | . | 34 | 123 | . | . |
|  | No | Composite | 829 | 2115 | 1.398 | 1.09-1.80 | 1.056 | 0.78-1.44 | . | . | 251 | 735 | . | . |
|  | Yes | S-Composite | 20 | 379 | . | . | . | . | . | . | 7 | 148 | . | . |
|  | No | S-Composite | 186 | 2728 | 1.292 | 0.81-2.07 | 1.005 | 0.57-1.79 | . | . | 57 | 914 | . | . |
| Country | South Africa | Composite | 298 | 737 | . | . | . | . | . | . | 57 | 129 | . | . |
|  | Malawi | Composite | 325 | 738 | 1.089 | 0.90-1.31 | 1.275 | 1.02-1.60 | 1.314 | 1.06-1.64 | 107 | 272 | 1.040 | 0.66-1.63 |
|  | Zambia | Composite | 36 | 42 | 2.120 | 1.33-3.38 | 3.057 | 1.84-5.07 | 2.952 | 1.79-4.87 | 29 | 24 | 3.621 | 1.81-7.23 |
|  | Uganda | Composite | 82 | 394 | 0.515 | 0.39-0.68 | 0.565 | 0.40-0.80 | 0.549 | 0.40-0.750 | 45 | 188 | 0.631 | 0.38-1.06 |
|  | Zimbabwe | Composite | 100 | 449 | 0.551 | 0.43-0.71 | 0.695 | 0.52-0.94 | 0.700 | 0.52-0.94 | 38 | 223 | 0.439 | 0.25-0.76 |
|  | Tanzania | Composite | 16 | 40 | 0.989 | 0.55-1.79 | 1.125 | 0.60-2.11 | 1.128 | 0.60-2.11 | 8 | 24 | 0.812 | 0.32-2.08 |
|  | India | Composite | 60 | 32 | 4.637 | 2.96-7.27 | 3.710 | 2.20-6.26 | 3.882 | 2.31-6.53 | 1 | 1 | 0.588 | 0.01-40.75 |
|  | South Africa | S-Composite | 81 | 947 | . | . | . | . | . | . | 14 | 170 | . | . |
|  | Malawi | S-Composite | 81 | 969 | 0.977 | 0.71-1.35 | 1.536 | 1.02-2.33 | 1.729 | 1.17-2.55 | 25 | 349 | 1.567 | 0.69-3.54 |
|  | Zambia | S-Composite | 4 | 70 | 0.668 | 0.24-1.88 | 1.139 | 0.33-3.90 | 1.173 | 0.35-3.94 | 4 | 45 | 2.660 | 0.75-945 |
|  | Uganda | S-Composite | 18 | 455 | 0.463 | 0.27-0.78 | 0.720 | 0.38-1.37 | 0.715 | 0.40-1.28 | 9 | 222 | 0.873 | 0.33-2.35 |
|  | Zimbabwe | S-Composite | 14 | 531 | 0.308 | 0.17-0.55 | 0.549 | 0.29-1.06 | 0.572 | 0.30-1.09 | 9 | 250 | 0.928 | 0.34-2.51 |
|  | Tanzania | S-Composite | 3 | 51 | 0.688 | 0.21-2.25 | 1.086 | 0.32-3.70 | 1.070 | 0.32-3.62 | 3 | 27 | 2.333 | 0.58-9.44 |
|  | India | S-Composite | 5 | 87 | 0.672 | 0.27-1.70 | 0.627 | 0.21-1.87 | 0.656 | 0.23-1.87 | 0 | 2 | † | † |
| Abruptio Placenta | Yes | Composite | 10 | 3 | 8.925 | 2.45-32.50 | 13.429 | 3.45-52.24 | 13.850 | 3.54-54.15 | 2 | 1 | 13.43 | 1.19-152.04 |
|  | No | Composite | 907 | 2429 | . | . | . | . | . | . | 283 | 860 | . | . |
|  | Yes | S-Composite | 8 | 5 | 25.091 | 8.13-77.41 | 34.512 | 10.15-117.35 | 39.417 | 11.48-135.29 | 1 | 2 | 15.300 | 1.26-185.20 |
|  | No | S-Composite | 198 | 3105 | . | . | . | . | . | . | 63 | 1063 | . | . |
| Chronic Hypertension | Yes | Composite | 11 | 18 | 1.629 | 0.77-3.46 | 1.555 | 0.66-3.66 | . | . | 1 | 2 | . | . |
|  | No | Composite | 906 | 2414 | . | . | . | . | . | . | 284 | 859 | . | . |
|  | Yes | S-Composite | 7 | 22 | 4.937 | 2.08-11.70 | 4.665 | 1.65-13.21 | 3.632 | 1.32-9.96 | 1 | 2 | 2.808 | 0.17-46.95 |
|  | No | S-Composite | 199 | 3088 | . | . | . | . | . | . | 63 | 1063 | . | . |
| Pregnancy Induced Hypertension | Yes | Composite | 66 | 65 | 2.824 | 1.99-4.01 | 3.187 | 2.13-4.76 | 3.292 | 2.21-4.91 | 14 | 19 | 3.839 | 1.75-8.42 |
|  | No | Composite | 851 | 2367 | . | . | . | . | . | . | 271 | 842 | . | . |
|  | Yes | S-Composite | 30 | 100 | 5.131 | 3.32-7.93 | 5.704 | 3.35-9.72 | 5.555 | 3.29-9.38 | 6 | 26 | 4.701 | 1.59-13.93 |
|  | No | S-Composite | 176 | 3010 | . | . | . | . | . | . | 58 | 1039 | . | . |
| Oligohydramnios | Yes | Composite | 21 | 9 | 6.309 | 2.88-13.83 | 5.384 | 2.05-14.11 | 5.180 | 1.98-13.55 | 3 | 3 | 3.132 | 0.42-23.41 |
|  | No | Composite | 896 | 2423 | . | . | . | . | . | . | 282 | 858 | . | . |
|  | Yes | S-Composite | 6 | 23 | 4.027 | 1.62-10.00 | 5.831 | 1.95-17.48 | 6.632 | 2.34-18.80 | 0 | 6 | † | † |
|  | No | S-Composite | 200 | 3087 | . | . | . | . | . | . | 64 | 1059 | . | . |
| Intrauterine Growth Restriction | Yes | Composite | 10 | 1 | 26.730 | 3.43-208.62 | 27.262 | 3.22-230.60 | 25.730 | 3.06-216.61 | 4 | 1 | 6.409 | 0.55-74.67 |
|  | No | Composite | 907 | 2431 | . | . | . | . | . | . | 281 | 860 | . | . |
|  | Yes | S-Composite | 3 | 8 | 5.736 | 1.51-21.78 | 2.250 | 0.41-12.36 | . | . | 1 | 4 | . | . |
|  | No | S-Composite | 203 | 3102 | . | . | . | . | . | . | 63 | 1061 | . | . |
| Premature Labor | Yes | Composite | 38 | 15 | 6.965 | 3.81-12.72 | 6.139 | 3.17-11.88 | 6.273 | 3.25-12.11 | 11 | 4 | 12.308 | 3.63-41.69 |
|  | No | Composite | 879 | 2417 | . | . | . | . | . | . | 274 | 857 | . | . |
|  | Yes | S-Composite | 13 | 39 | 5.304 | 2.79-10.10 | 4.867 | 2.25-10.55 | 5.155 | 2.41-11.02 | 6 | 8 | 13.692 | 3.80-49.31 |
|  | No | S-Composite | 193 | 3071 | . | . | . | . | . | . | 58 | 1057 | . | . |
| Premature Rupture of Membranes | Yes | Composite | 26 | 14 | 5.040 | 2.62-9.70 | 7.319 | 3.63-14.74 | 7.319 | 3.65-14.67 | 5 | 2 | 11.902 | 2.21-63.99 |
|  | No | Composite | 891 | 2418 | . | . | . | . | . | . | 280 | 859 | . | . |
|  | Yes | S-Composite | 9 | 31 | 4.538 | 2.13-9.66 | 5.555 | 2.39-12.93 | 5.169 | 2.24-11.93 | 2 | 5 | 7.494 | 1.14-49.14 |
|  | No | S-Composite | 197 | 3079 | . | . | . | . | . | . | 62 | 1060 | . | . |
| Vaginal Bleeding | Yes | Composite | 8 | 11 | 1.938 | 0.78-4.83 | 1.702 | 0.62-4.70 | . | . | 0 | 0 | . | . |
|  | No | Composite | 909 | 2421 | . | . | . | . | . | . | 285 | 861 | . | . |
|  | Yes | S-Composite | 2 | 17 | 1.784 | 0.41-7.77 | 0.798 | 0.14-4.53 | . | . | 0 | 0 | . | . |
|  | No | S-Composite | 204 | 3093 | . | . | . | . | . | . | 64 | 1065 | . | . |
| UTI | Yes | Composite | 55 | 206 | 0.690 | 0.51-0.94 | 0.837 | 0.58-1.21 | . | . | 22 | 89 | . | . |
|  | No | Composite | 862 | 2226 | . | . | . | . | . | . | 263 | 772 | . | . |
|  | Yes | S-Composite | 13 | 247 | 0.781 | 0.44-1.39 | 0.671 | 0.34-1.34 | . | . | 3 | 107 | . | . |
|  | No | S-Composite | 193 | 2863 | . | . | . | . | . | . | 61 | 958 | . | . |

\* *Only the covariates that remained in the All Data multivariate model after backward selection were included in the multivariate model for Version 3.0 Data.*

*† In the models for the S-Composite pregnancy outcome, we encountered instances where valid coefficients for categorical variables having no events in specific categories could not be estimated. For example, country of India had no events for S-Composite for the Version 3.0 Data. However, inclusion of these variables provided a valid means of controlling for their effects in estimating the associations between the other variables in the models and the outcomes.*