STI - Zoliflodacin phase III

**PROGRESS REPORT**

By the 5th of every month

*(With data received as of 19-April-2022)*

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# Table 1 Schedule of Events

| PROCEDURES | Enrollment/ Baseline  Visit 1, Day 1 | Up to 30 days post-procedure |
| --- | --- | --- |
| Enrollment | X |  |
| Informed consent | X |  |
| Sociodemographic history | X |  |
| Pregnancy-related/ Sexual history | X |  |
| STI history | X |  |
| STI treatment history | X |  |
| Physical exam | X |  |
| Vaginal/Rectal/Penile swab for NG & CT NAAT | X |  |
| Adverse event review and evaluation |  | X |
| NG NAAT result |  | X |
| CT NAAT result |  | X |

# Table 2: a)Subject Enrollment by Site

|  |  |  |  |
| --- | --- | --- | --- |
| Site | Enrollment Goal | Enrollment Actual | PercentageEnrolled |
| 01-Mbagathi Health Centre | 301 | 292 | 97.0% |
| 02-Special Treatment Centre Casino Health Centre | 224 | 75 | 33.0% |
| 03-Coast Provincial General Hospital | 301 | 13 | 4.0% |
| 04-International Centre for Reproductive Health | 224 | 16 | 7.0% |
| 05-Homa-Bay County Referral Hospital | 302 | 175 | 58.0% |
| Summary | 1352 | 571 | 42.0% |

# b)Weekly Enrollment by Site

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| AsOfDate | 01-Mbagathi Health Centre | 02-Special Treatment Centre Casino Health Centre | 03-Coast Provincial General Hospital | 04-International Centre for Reproductive Health | 05-Homa-Bay County Referral Hospital | AnticipatedEnrollment | TotalEnrollment |
| 12-Feb-2022 | 0 | 0 | 0 | 0 | 8 | 1352 | 8 |
| 19-Feb-2022 | 0 | 0 | 0 | 0 | 29 | 1352 | 29 |
| 26-Feb-2022 | 0 | 0 | 0 | 0 | 45 | 1352 | 45 |
| 05-Mar-2022 | 49 | 14 | 0 | 0 | 61 | 1352 | 124 |
| 12-Mar-2022 | 140 | 48 | 0 | 0 | 81 | 1352 | 269 |
| 19-Mar-2022 | 228 | 64 | 0 | 0 | 101 | 1352 | 393 |
| 26-Mar-2022 | 292 | 74 | 0 | 0 | 126 | 1352 | 492 |
| 02-Apr-2022 | 292 | 74 | 0 | 0 | 151 | 1352 | 517 |
| 09-Apr-2022 | 292 | 74 | 5 | 0 | 175 | 1352 | 546 |
| 13-Apr-2022 | 292 | 75 | 13 | 16 | 175 | 1352 | 571 |

# Table 3: Site Forms Summary Report

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Site Total | FormsExpected | Forms Complete | Forms Not Complete | Forms Not Expected | FormsDone |
| 01-Mbagathi Health Centre TOTAL | 2628 | 1295 | 1333 | 0 | 49.0% |
| 02-Special Treatment Centre Casino Health Centre TOTAL | 675 | 368 | 307 | 0 | 55.0% |
| 03-Coast Provincial General Hospital TOTAL | 117 | 61 | 56 | 0 | 52.0% |
| 04-International Centre for Reproductive Health TOTAL | 144 | 70 | 74 | 0 | 49.0% |
| 05-Homa-Bay County Referral Hospital TOTAL | 1574 | 974 | 600 | 1 | 62.0% |
| TOTAL | 5138 | 2768 | 2370 | 1 | 54.0% |

# Table 4: Query Management Status

|  |  |  |
| --- | --- | --- |
| Site | Open Queries | Total Queries |
| 01-Mbagathi Health Centre | 18 | 65 |
| 02-Special Treatment Centre Casino Health Centre | 7 | 24 |
| 03-Coast Provincial General Hospital | 0 | 2 |
| 04-International Centre for Reproductive Health | 2 | 6 |
| 05-Homa-Bay County Referral Hospital | 5 | 47 |

*\*Open Queries:Queries pending action.*