STI - Zoliflodacin phase III

**PROGRESS REPORT**

By the 5th of every month

*(With data received as of 09-March-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: Enrollment by Country and Site

|  |  |  |
| --- | --- | --- |
| SiteCode | SiteName | Enrolled |
| 1 | Mbagathi Health Centre | 50 |
| 2 | Special Treatment Centre Casino Health Centre | 70 |
| 3 | Coast Provincial General Hospital | 100 |
| 4 | International Centre for Reproductive Health | 120 |
| 5 | Homa-Bay County Referral Hospital | 175 |

# Table 3: Query Management Status

|  |  |  |  |
| --- | --- | --- | --- |
| Site Name | All Queries | Open Queries | Closed Queries |
| Mbagathi Health Centre | 1050 | 980(96.74%) | 8(0.79%) |
| Special Treatment Centre Casino Health Centre | 1050 | 980(96.74%) | 8(0.79%) |
| Coast Provincial General Hospital | 1050 | 980(96.74%) | 8(0.79%) |
| International Centre for Reproductive Health | 1050 | 980(96.74%) | 8(0.79%) |
| Homa-Bay County Referral Hospital | 1050 | 980(96.74%) | 8(0.79%) |

# Table 4: Serious Adverse Events Listings

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| ID | SAE Description | Start Date | End Date | Intensity | Outcome |
| 1016 | fever of unknown origin | 2018-11-24 | 2018-11-24 | Fatal | None |
| 1021 | multiorgan failure | 2019-02-12 | 2019-02-12 | Fatal | None |
| 1041 | acute kidney injury | 2019-12-08 | 2019-12-08 | Resolved | None |

# Table 5: Adverse Events Listings

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| AE Number | Adverse Event | Start Date | Intensity | Relation to Participant | Outcome | End Date | Was Concomitant Medication Given? |
| 716 | Nausea | 2018-11-24 | 2018-11-24 | Resolved | Yes | None | Yes |
| 700 | Vomiting | 2019-02-12 | 2019-02-12 | Resolved | Yes | None | Yes |
| 724 | Diarrhoea | 2019-12-08 | 2019-12-08 | Resolved | Yes | None | Yes |