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| **CENTRAL MONITORING REPORT Nº<XX> - SITE <XX>** |

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| **Clinical trial details** | |
| Protocol Title |  |
| Clinical Trials Registry ID/number: |  |
| Site Name |  |
| Site Investigator Name |  |
| Monitor Name |  |
| Date of report |  |

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| **Current Trial Reference Documents** | |
| **Document** | **Version Number and date** |
| Protocol |  |
| Participant information leaflet and informed consent form |  |
| Informed consent form for storage and use of your samples and data |  |
| <Add here if other informed consent forms are needed, e.g. HIV testing information leaflet and informed consent form> |  |
| <Add here if other informed consent forms are needed, e.g. Informed consent form for the use of blood samples for genetic testing> |  |

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| **Patient Recruitment Status** | |
| Total No. Subjects Planned |  |
| Total No. Subjects Completed |  |
| No. Subjects Prematurely Withdrawn |  |
| Date of First Subject Enrolled |  |
| Date of Most Recent Subject Enrolled |  |
| Total No. Subjects enrolled |  |
| Total No. Subjects screened |  |
| No. of subjects active |  |
| No. unanticipated adverse events |  |

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| **Key Risk Indicators Detected** | | | | | | | | | | | | | | | | | |
| **Site performance risk** | | | | | | | | | | | | | | | | | |
| **Risk/presence** | | Low subject recruitment/randomization  (>10% delay of expected) | | | | | | |  | **Yes** | | |  | | | | **No** |
| **Action proposed** | |  | | | | | | | | | | | | | | | |
| **Status** | |  | | | | **Solved** | |  | | **Pending** | | | | | | | |
| **Response/comments** | |  | | | | | | | | | | | | | | | |
| **Risk/presence** | | Disparity on recruitment rates between sites (>20% disparity) | | | | | | |  | **Yes** | |  | | | | | **No** |
| **Action proposed** | |  | | | | | | | | | | | | | | | |
| **Status** | |  | | | | **Solved** | |  | | **Pending** | | | | | | | |
| **Response/comments** | |  | | | | | | | | | | | | | | | |
| **Risk/presence** | % CRF incompletion rate (>10% of all records) | | | | | | | |  | **Yes** | | |  | | | | **No** |
| **Action proposed** |  | | | | | | | | | | | | | | | | |
| **Status** |  | | | | **Solved** | | |  | | **Pending** | | | | | | | |
| **Response/comments** |  | | | | | | | | | | | | | | | | |
| **Risk/presence** | Incorrect randomisations (>5% of all records) | | | | | | | |  | **Yes** | | |  | | | | **No** |
| **Action proposed** |  | | | | | | | | | | | | | | | | |
| **Status** |  | | | | **Solved** | | |  | | **Pending** | | | | | | | |
| **Response/comments** |  | | | | | | | | | | | | | | | | |
| **Risk/presence** | Samples for immunological studies not collected/retrieved at the scheduled timepoints, or incorrect labelling (>10% of all records) | | | | | | | |  | **Yes** | | | |  | | | **No** |
| **Action proposed** |  | | | | | | | | | | | | | | | | |
| **Status** |  | | | | **Solved** | | |  | | **Pending** | | | | | | | |
| **Response/comments** |  | | | | | | | | | | | | | | | | |
| **Risk/presence** | High drop-out of patients during the first 8 weeks (while the investigational drugs are provided) (>5% of all records) | | | | | | | |  | **Yes** | | | |  | | | **No** |
| **Action proposed** |  | | | | | | | | | | | | | | | | |
| **Status** |  | | | | **Solved** | | |  | | **Pending** | | | | | | | |
| **Response/comments** |  | | | | | | | | | | | | | | | | |
| **Risk/presence** | Disparities in lost-of-follow-up between sites (>10% disparity) | | | | | | | |  | **Yes** | | | |  | | | **No** |
| **Action proposed** |  | | | | | | | | | | | | | | | | |
| **Status** |  | | | | **Solved** | | |  | | **Pending** | | | | | | | |
| **Response/comments** |  | | | | | | | | | | | | | | | | |
| **Data acquisition and integrity** | | | | | | | | | | | | | | | | | |
| **Risk/presence** | Missing data in the CRF (data not recorded, delay in entering data on the eCRF) (>10% of all records) | | | | | | | |  | | **Yes** | | | |  | | **No** |
| **Action proposed** |  | | | | | | | | | | | | | | | | |
| **Status** |  | | | **Solved** | | |  | | | **Pending** | | | | | | | |
| **Response/comments** |  | | | | | | | | | | | | | | | | |
| **Risk/presence** | Missing primary and secondary outcome results (key data missing) (>5% of all records) | | | | | | | |  | **Yes** | | | |  | | | **No** |
| **Action proposed** |  | | | | | | | | | | | | | | | | |
| **Status** |  | | **Solved** | | | |  | | | **Pending** | | | | | | | |
| **Response/comments** |  | | | | | | | | | | | | | | | | |
| **Safety vigilance** | | | | | | | | | | | | | | | | | |
| **Risk/presence** | Increased AE/SAE number in one site (>10% disparity) | | | | | | | |  | | **Yes** | | | |  | | **No** |
| **Action proposed** |  | | | | | | | | | | | | | | | | |
| **Status** |  | | **Solved** | | | |  | | | **Pending** | | | | | | | |
| **Response/comments** |  | | | | | | | | | | | | | | | | |
| **Risk/presence** | AE/SAE not captured or properly reported (>5% of all records) | | | | | | | |  | **Yes** | | | | | |  | **No** |
| **Action proposed** |  | | | | | | | | | | | | | | | | |
| **Status** |  | | | | **Solved** | | |  | | **Pending** | | | | | | | |
| **Response/comments** |  | | | | | | | | | | | | | | | | |

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| **Other comments** |
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| **Sponsor** | |
| **Signature** | **Date** |
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