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| **SITE INITIATION VISIT CHECKLIST** |

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

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| **Current Trial Reference Documents** | | | | |
|  | **Yes** | **No** | **N/A** | **Comments** |
| Signed protocol and amendments and sample case report form (CRF) |  |  |  |  |
| Participant information leaflet and informed consent form |  |  |  |  |
| Informed consent form for storage and use of your samples and date |  |  |  |  |
| HIV testing informant leaflet and informed consent form |  |  |  |  |
| Informed consent form for the use of blood samples for genetic testing |  |  |  |  |
| Investigator’s brochure |  |  |  |  |
| Financial aspects of the trial |  |  |  |  |
| Insurance statement |  |  |  |  |
| Regulatory approval of:   * Protocol * Participant information leaflet and informed consent form * Informed consent form for storage and use of your samples and date * HIV testing informant leaflet and informed consent form * Informed consent form for the use of blood samples for genetic testing |  |  |  |  |
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| IRB/IEC approval of:   * Protocol * Participant information leaflet and informed consent form * Informed consent form for storage and use of your samples and date * HIV testing informant leaflet and informed consent form * Informed consent form for the use of blood samples for genetic testing |  |  |  |  |
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| IRB/IEC composition |  |  |  |  |
| Curriculum vitae of investigator(s) and sub-investigator(s) |  |  |  |  |
| Normal value(s)/ranges for procedures included in the protocol |  |  |  |  |
| Medical/laboratory/technical procedures/tests |  |  |  |  |
| Instruction for handling of investigational product (IP) and trial-related materials |  |  |  |  |
| Shipping records for IP and trial-related materials |  |  |  |  |
| Certificates of analysis of IP shipped |  |  |  |  |
| Decoding procedures for blinded trials |  |  |  |  |
| Delegation log |  |  |  |  |
| Training log |  |  |  |  |
| Site Contacts |  |  |  |  |
| Specimen processing, storage and tracking SOP |  |  |  |  |
| Facilities appropriate to study execution |  |  |  |  |
| Investigator Site File |  |  |  |  |
| Communication between team members |  |  |  |  |
| Safety reporting (AE/SAE) |  |  |  |  |

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| **Person Completing Form** | |
| **Signature** | **Date** |
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