**[CTN XXX] SITE INITIATION VISIT/TRAINING REPORT** *(This template may be modified for study specific needs/requirements.)*

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| **SITE NUMBER:** | **VISIT/CONTACT DATE(S):** | |
| **SITE NAME / ADDRESS**      Telephone: | | **METHOD OF CONTACT:**  On-site Visit  Virtual Meeting  Other:       *(specify)* |
| **REPORT PREPARED BY (name/role):** | | |

| **PARTICIPATION IN SIV / TRAINING** | |  | | |
| --- | --- | --- | --- | --- |
| **TITLE/ROLE** | **NAME** | **YES** | **NO** | **N/A** |
| **QI/Site Investigator** |  |  |  |  |
| **Sub-Investigator** |  |  |  |  |
| **Site Coordinator** |  |  |  |  |
| **Pharmacist** |  |  |  |  |
| **Other [specify]** |  |  |  |  |
| **CTN Staff Present (name/role):**  **None** | | | | |
| **Sponsor / SI Staff Present (name/role):**  **None** | | | | |
| **Monitoring Staff Present (name/role):**  **None** | | | | |
| **Comments:** | | | | |

| **SITE PERSONNEL AND FACILITIES** | **YES** | **NO** | **N/A** |
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| 1. **Were any outstanding issues identified with respect to site facilities?**   Issue(s) Identified  Comments: |  |  |  |
| Were the roles and responsibilities of the QI/Site Investigator and designated site study personnel discussed?Issue(s) Identified Comments: |  |  |  |
| Has the Delegation of Authority Log been appropriately completed?Issue(s) IdentifiedCopy ObtainedComments: |  |  |  |
| **Additional Comments/Issues:** | | | |

| **PROTOCOL AND STUDY RELATED PROCEDURES** | **YES** | **NO** | N/A |
| --- | --- | --- | --- |
| 1. **Were the current version of the protocol and related study procedures, including inclusion/exclusion criteria reviewed?**   Protocol Version:        Issue(s) Identified  Comments: |  |  |  |
| 1. **Were the protocol deviation reporting and sign-off procedures reviewed?**   Issue(s) Identified  Comments: |  |  |  |
| 1. **Was participant recruitment (including procedures, timelines, advertising, documentation) discussed?**   Issue(s) Identified  Comments: |  |  |  |
| 1. **Were the informed consent process and documentation requirements reviewed?**   Issue(s) Identified  Comments: |  |  |  |
| 1. **Were adverse event definitions, handling and reporting procedures reviewed?**   Issue(s) Identified  Comments: |  |  |  |
| 1. **Were data collection procedures and Case Report Forms (including CRF completion, transmittal and query/data correction procedures) discussed?**   Issue(s) Identified  Comments: |  |  |  |
| **Additional Comments/Issues:** | | | |

| **INVESTIGATIONAL PRODUCT (IP) AND CLINICAL STUDY SUPPLIES**  **N/A** | **YES** | **NO** | **N/A** |
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| 1. **Were IP related procedures (quantity, receipt, dispensing, accountability, reordering as applicable) discussed?**   Issue(s) Identified  Comments: |  |  |  |
| 1. **Was the storage of IP (security, temperature, other conditions as applicable) discussed?**   Issue(s) Identified  Comments: |  |  |  |
| 1. **Were the IP storage area and conditions found to be satisfactory?**   Issue(s) Identified  Comments: |  |  |  |
| 1. **Was the receipt of other clinical study supplies (quantity, storage and conditions) discussed?**   Issue(s) Identified  Comments: |  |  |  |
| **Additional Comments/Issues:** | | | |

| **LABORATORY/BIOLOGICAL SAMPLES  N/A** | **YES** | **NO** | **N/A** |
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| 1. **Were local laboratory requirements and procedures discussed?**   Issue(s) Identified  Comments: |  |  |  |
| 1. **Were central laboratory requirements and procedures discussed?**   Issue(s) Identified  Comments: |  |  |  |
| 1. **Were local laboratory facilities and storage conditions reviewed?**   Issue(s) Identified  Comments: |  |  |  |
| 1. **Was medical review of Laboratory Results discussed?**   Issue(s) Identified  Comments: |  |  |  |
| 1. **Were labeling and storage of specimens for the central lab(s) discussed?**   Issue(s) Identified  Comments: |  |  |  |
| 1. **Were handling and shipment of biological samples discussed?**   Issue(s) Identified  Comments: |  |  |  |
| **Additional Comments/Issues:** | | | |

| **MONITORING PROCEDURES** | **YES** | **NO** | **N/A** |
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| 1. **Were monitoring procedures (including requirements, frequency, site contacts) discussed?**   Issue(s) Identified  Comments: |  |  |  |
| 1. **Were source documentation requirements (including availability, direct access, location, electronic medical record access) discussed?**   Issue(s) Identified  Comments: |  |  |  |
| **Additional Comments/Issues**: | | | |

| **ETHICS** | **YES** | **NO** | **N/A** |
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| 1. **Were local Ethics Committee procedures discussed?**   Issue(s) Identified  Comments: |  |  |  |
| 1. **Were central Ethics Committee procedures discussed?**   Issue(s) Identified  Comments: |  |  |  |
| 1. **Were regulatory procedures discussed?**   Issue(s) Identified  Comments: |  |  |  |
| 1. **Were essential documents/Investigator Site File (ISF) reviewed**?   Issue(s) Identified  Site Start Up Checklist attached (SOPPM\_13\_T01)  Comments: |  |  |  |

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| **REGULATORY PROCEDURES** | **YES** | **NO** | **N/A** |
| 1. **Were the Health Canada documents on file?**   **Drug/Biologic or Natural Health Product or Medical Device authorization, e.g. No Objection Letter**  **Qualified Investigator Undertaking (QIU)**  **Clinical Trial Site Information Form (CTSIF)**  **Issue(s) Identified**  **Comments:** |  |  |  |
| **Were the US FDA documents on file?**  **Issue(s) Identified**  **Comments:** |  |  |  |

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| **TRAINING** | **YES** | **NO** | **N/A** |
| 1. **Was Good Clinical Practice (GCP) training for all study team members on file?**   **Issue(s) Identified**  **Comments:** |  |  |  |
| 1. **Was Health Canada Division 5 training for all study team members on file?**   **Issue(s) Identified**  **Comments:** |  |  |  |
| 1. **Was Tri-Council Policy (TCPS2) training for all study team members on file?**   **Issue(s) Identified**  **Comments:** |  |  |  |
| 1. **Was Privacy training on file?**   **Issue(s) Identified**  **Comments:** |  |  |  |
| 1. **Was study specific training on file?**   **Protocol**  **Other: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**  **Comments:** |  |  |  |
| 1. **Were site Standard Operating Procedures (SOPs) noted, and was training on file?** |  |  |  |

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| **OTHER STUDY/SITE SPECIFIC ISSUES** | **YES** | **NO** | N/A |
| 1. **Were financial or contractual details/issues (including site reimbursement and other financial implications) discussed?**   Issue(s) Identified  Comments: |  |  |  |
| 1. **[Insert other study/site specific issues as necessary]** |  |  |  |
| **Additional Observations/Comments:** | | | |

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| **STATUS OF ACTION ITEMS:** | | | | |
| **RESPONSIBLE PARTY** | Yes | No | CATEGORY/ISSUE | Resolution |
| QI/ Site Investigator/ Designate |  |  |  |  |
| Monitor/Training personnel |  |  |  |  |
| CTN |  |  |  |  |
| Sponsor/SI |  |  |  |  |
| Comments/Issues: | | | | |
| **Date of Next Visit:**  N/A | | | **Attachments:**   None  Site Start Up Checklist (SOPPM\_13\_T01)  Other (specify): | |

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| Prepared by (Study Project Manager or Study Monitor) |  | Signature |  | Date (dd-mmm-yyyy) |
|  |  |  |  |  |
|  |  |  |  |  |
| Reviewed by (Study Monitor or Study Project Manager) |  | Signature |  | Date (dd-mmm-yyyy) |
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| Approved by (Sponsor or SI) |  | Signature |  | Date (dd-mmm-yyyy) |
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