

**Investigator Site File (ISF) Index**

Clinical Trials

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| **Document Reference ID:** | Noclor/Spon/T03/01 |
| **Effective Date:** | 21st March 2016 |

**Version History**

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| --- | --- | --- |
| Template ID | Version, Effective Date | Reason for Change |
| Noclor Template\_03 | Version 1, 01/11/2014 |  |
| Noclor/Spon/T03/01 | Version 1, 21/03/2016 | New numbering system adopted for Noclor SOPs and associated documents (applicable to all Noclor partner NHS Trusts). This template has been assigned first version. |

**Scope of Use**

This Investigator Site File (ISF) Index template should be used to set up ISFs for all participating sites (except lead sponsor site -refer to Noclor/Spon/T02a/0X). The template index is for use in clinical trials sponsored by a Noclor partner NHS Trust in accordance with SOPs Study Set-up and Approval Noclor/Spon/S04/0X and Research Management and Monitoring Noclor/Spon/S06/0X

**Specific Instructions for use**

The trial specific short title and EudraCT reference (for CTIMPs) or IRAS reference (for non-CTIMPs) should be inserted in the header of all pages of this index. Page numbers (page x of y format) and date last printed should be inserted in the footer of every page.

**INVESTIGATOR SITE FILE (ISF)**

**INDEX**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Trial Title** | |  | | | | |
| **EudraCT number:** | |  | **IRAS Ref:** | | |  |
| **Principal Investigator (PI):** | |  | **Site:** | | |  |
| **Sponsor Protocol Ref:** | |  | **Host Site Approval Date:** | | |  |
| **Site Initiation Date :** | |  | **Site Activation Date :** | | |  |
| **All essential documents must be filed in the ISF. If essential documents are located outside of the ISF during the trial please file note their location in the relevant section of the ISF for audit trail purposes. At the end of trial (prior to archive) the ISF must be reconciled and complete.** | | | | | | |
|  | **Trial & Site Contacts** | | | **Yes** | **N/A** | **Notes** |
| 1.1 | Site Contact Details | | |  |  |  |
| 1.2 | Trial Contact Sheet | | |  |  |  |
| 1.3 | Superseded Versions | | |  |  |  |
|  | **Protocol** | | | **Yes** | **N/A** | **Notes** |
| 2.1 | Current Approved Protocol | | |  |  |  |
| 2.2 | Protocol Signature Approval Page-signed and dated for all implemented versions of the protocol | | |  |  |  |
| 2.3 | Superseded Protocols (Refer to amendment log 8.1). | | |  |  |  |
| 2.4 | Log of Protocol Deviations (at site) | | |  |  |  |
| 2.5 | Related Correspondence | | |  |  |  |
|  | **Approved PIS, Consent & GP Letters** | | | **Yes** | **N/A** | **Notes** |
| 3.1 | Current Approved Patient Information Sheet (PIS) on Headed Paper | | |  |  |  |
| 3.2 | Current Approved Informed Consent Form (ICF) on Headed Paper | | |  |  |  |
| 3.3 | Current Approved GP Letter (if applicable) | | |  |  |  |
| 3.4 | All (local) Superseded PIS,ICF and GP letters (as they appear on amendment log 8.1) | | |  |  |  |
| 3.5 | Related Correspondence | | |  |  |  |
|  | **Initial REC Application & Approval** | | | **Yes** | **N/A** | **Notes** |
| 4.1 | REC Favorable Opinion Letter (including REC composition) | | |  |  |  |
| 4.2 | Response to conditions of approval (if applicable) | | |  |  |  |
| 4.3 | Provisional REC approval (if applicable) | | |  |  |  |
| 4.4 | Validation letter | | |  |  |  |
| 4.5 | REC Application (complete with cover letter, checklist and documents) | | |  |  |  |
| 4.6 | Related Correspondence | | |  |  |  |
|  | **Initial CTA Application & Approval (MHRA)** | | | **Yes** | **N/A** | **Notes** |
| 5.1 | Notice of Acceptance Letter | | |  |  |  |
| 5.2 | Response to MHRA remarks (if applicable) | | |  |  |  |
| 5.3 | Notice of Non-acceptance Letter and response (s) | | |  |  |  |
| 5.4 | MHRA Acknowledgement Letter | | |  |  |  |
| 5.5 | CTA application (complete with cover letter and all submitted documents and original signatures) | | |  |  |  |
| 5.6 | Related Correspondence | | |  |  |  |
|  | **Other Initial Submissions & Approvals** | | | **Yes** | **N/A** | **Notes** |
| 6.1 | Other Submissions & Approvals (as relevant) | | |  |  |  |
| 6.2 | Related Correspondence | | |  |  |  |
|  | **Site Selection, Set-Up & Activation** | | |  |  |  |
| 7.1 | Site Activation Notice | | |  |  |  |
| 7.2 | Host Site Approval | | |  |  |  |
| 7.3 | List of referring PIC sites (if applicable) | | |  |  |  |
| 7.4 | SSI Form (signed and dated) | | |  |  |  |
| 7.5 | R&D Application & Correspondence | | |  |  |  |
| 7.6 | Site Feasibility/Viability Forms – (as assessed prior to selection of site) | | |  |  |  |
| 7.7 | Related Correspondence | | |  |  |  |
|  | **Amendments (section this per amendment using amendment code as relates to amendment log)** | | | **Yes** | **N/A** | **Notes** |
| 8.1 | Amendment Log (reference all amendments substantial and non-substantial) | | |  |  |  |
| 8.2 | Ethics approval letter | | |  |  |  |
| 8.3 | MHRA approval letter | | |  |  |  |
| 8.4 | CLRN/R&D (host site) approval letter | | |  |  |  |
| 8.5 | Amendment submission pack (all supporting documents and cover letter for the amendment) | | |  |  |  |
| 8.6 | Related Correspondence (per amendment) | | |  |  |  |
|  | **Investigational Medicinal Product (IMP).**  **File note as relevant for documents located in the Pharmacy Site File (PSF)** | | | **Yes** | **N/A** | **Notes** |
| 9.1 | Investigational Medicinal Product Dossier (IMPD) or simplified IMPD | | |  |  |  |
| 9.2 | Investigator Brochure (IB) | | |  |  |  |
| 9.3 | Summary of Product Characteristics (SmPC/SPC) | | |  |  |  |
| 9.4 | Previous Versions of above IMPD,IB, SmPC | | |  |  |  |
| 9.5 | IMP Label Template (Sponsor authorized/MHRA approved)/Label Exemption Details | | |  |  |  |
| 9.6 | Certified QP release statement | | |  |  |  |
| 9.7 | Certificate of Analysis (CoA) (if applicable) | | |  |  |  |
| 9.8 | TSE Certificate (if applicable) | | |  |  |  |
| 9.9 | IMP Shipment Records | | |  |  |  |
| 9.10 | Confirmation of IMP Delivery (Receipt Forms) | | |  |  |  |
| 9.11 | IMP Management Procedures (approved by sponsor pharmacy rep) | | |  |  |  |
| 9.12 | Pharmacy Checklists/Agreements (where relevant) | | |  |  |  |
| 9.13 | Template IMP Order/Transfer Forms | | |  |  |  |
| 9.14 | Completed IMP Order/Transfer Forms | | |  |  |  |
| 9.15 | Trial Prescription Template | | |  |  |  |
| 9.16 | Completed Trial Prescriptions | | |  |  |  |
| 9.17 | Temperature Log Template | | |  |  |  |
| 9.18 | Temperature Logs | | |  |  |  |
| 9.19 | Temperature Deviations & Correspondence | | |  |  |  |
| 9.20 | IMP Accountability Log Template | | |  |  |  |
| 9.21 | IMP Accountability Logs | | |  |  |  |
| 9.22 | IMP Destruction Log Template | | |  |  |  |
| 9.23 | IMP Destruction Authorisation (from sponsor) | | |  |  |  |
| 9.24 | IMP Destruction SOP (site pharmacy SOP) | | |  |  |  |
| 9.25 | IMP Destruction Log | | |  |  |  |
| 9.26 | Related Correspondence | | |  |  |  |
|  | **Subject Information** | | | **Yes** | **N/A** | **Notes** |
| 10.1 | Screening Log | | |  |  |  |
| 10.2 | Subject Randomisation/ ID Log | | |  |  |  |
| 10.3 | Subject Enrolment Log (to include subject status) | | |  |  |  |
| 10.4 | Signed Informed Consent Forms (attach relevant version of PIS) | | |  |  |  |
| 10.5 | GP Letter Log | | |  |  |  |
| 10.6 | Related Correspondence | | |  |  |  |
|  | **Pharmacovigilance & Code Break** | | | **Yes** | **N/A** | **Notes** |
| 11.1 | Procedures & template forms for adverse event management, monitoring and reporting (responsibilities of third parties detailed where relevant) | | |  |  |  |
| 11.2 | Procedures & template forms for 24 hours medical cover & unblinding/code break (responsibilities of third parties detailed where relevant) | | |  |  |  |
| 11.3 | AE Log | | |  |  |  |
| 11.4 | SAE reports (and related correspondence) | | |  |  |  |
| 11.5 | AE reports (and related correspondence) | | |  |  |  |
| 11.6 | Record of 24 hour Medical Enquiries & Outcome | | |  |  |  |
| 11.7 | Trust Incident Reports | | |  |  |  |
| 11.8 | SUSAR reports (and related correspondence) | | |  |  |  |
| 11.9 | Pregnancy Reports (notification and follow-up) | | |  |  |  |
| 11.10 | Urgent Safety Measures (USMs) | | |  |  |  |
| 11.11 | Notification of Safety Information to Investigators | | |  |  |  |
| 11.12 | Development Safety Update Safety Reports (DSURs) (and notifications to MHRA, REC and investigators) | | |  |  |  |
| 11.13 | Completed Code Break Forms | | |  |  |  |
| 11.14 | Related Correspondence | | |  |  |  |
|  | **Data Management** | | | **Yes** | **N/A** | **Notes** |
| 12.1 | Final Version of CRF(s) | | |  |  |  |
| 12.2 | Previous Version of CRF(s) (if applicable) | | |  |  |  |
| 12.3 | Instructions for completion of CRF (if applicable) | | |  |  |  |
| 12.4 | Source Document Location Agreement | | |  |  |  |
| 12.5 | File Note- Location of Subject CRFs | | |  |  |  |
| 12.6 | Data Queries | | |  |  |  |
| 12.7 | Related Correspondence | | |  |  |  |
|  | **Trial Specific Documentation & Procedures** | | | **Yes** | **N/A** | **Notes** |
| 13.1 | Trial document inventory/version control log | | |  |  |  |
| 13.2 | Trial procedures manual | | |  |  |  |
| 13.3 | Trial specific SOPs and Signature Sheets (if applicable) | | |  |  |  |
| 13.4 | Related Correspondence | | |  |  |  |
|  | **Trial Management & Oversight** | | | **Yes** | **N/A** | **Notes** |
| 14.1 | Summary of Trial Oversight Groups & Committees | | |  |  |  |
| 14.2 | Trial Management Group (TMG) Minutes | | |  |  |  |
| 14.3 | Trial Steering Committee (TSC) Minutes | | |  |  |  |
| 14.4 | Data Monitoring Committee (DMC) Recommendations/Minutes/Report/Correspondence | | |  |  |  |
| 14.5 | Related Correspondence | | |  |  |  |
| **15.** | **Site Trial Team** | | | **Yes** | **N/A** | **Notes** |
| 15.1 | Delegation of Responsibilities Signature Log | | |  |  |  |
| 15.2 | Trial Personnel CVs (signed and dated) | | |  |  |  |
| 15.3 | Trial Personnel GCP /training /supervision evidence | | |  |  |  |
| 15.4 | Honorary Contracts/LoA | | |  |  |  |
| 15.5 | Related Correspondence | | |  |  |  |
| **16.** | **Sponsorship** | | | **Yes** | **N/A** | **Notes** |
| 16.1 | Final Sponsorship Declaration | | |  |  |  |
| 16.2 | Sponsorship In Principle | | |  |  |  |
| **17.** | **Compliance, Monitoring, Audit & Inspection** | | | **Yes** | **N/A** | **Notes** |
| 17.1 | Monitoring Plan (and superseded versions) | | |  |  |  |
| 17.2 | Monitor Visit Log (signature sheet) | | |  |  |  |
| 17.3 | Close-Out Report | | |  |  |  |
| 17.4 | Close-Out Correspondence | | |  |  |  |
| 17.5 | Monitor Visit Reports | | |  |  |  |
| 17.6 | Monitoring Correspondence | | |  |  |  |
| 17.7 | Site Initiation Report | | |  |  |  |
| 17.8 | Site Initiation Signature Sheet | | |  |  |  |
| 17.9 | Site Initiation Agenda, Correspondence & Presentations (copy of slides etc) | | |  |  |  |
| 17.10 | Audit Reports | | |  |  |  |
| 17.11 | Protocol Violation & Non-Compliance Reports | | |  |  |  |
| 17.12 | Serious breach notification(s) & related correspondence | | |  |  |  |
| 17.13 | Regulatory Inspection Notifications, Reports, CAPA’s (trial specific) | | |  |  |  |
| 17.14 | Related Correspondence | | |  |  |  |
| **18.** | **Contracts & Agreements (variations to any contract should be filed with relevant contract)** | | | **Yes** | **N/A** | **Notes** |
| 18.1 | Site Agreements (mNCA) | | |  |  |  |
| 18.2 | Other Agreements (as relevant to site) | | |  |  |  |
| 18.3 | Related Correspondence | | |  |  |  |
| **19.** | **Funding & Finance Related** | | | **Yes** | **N/A** | **Notes** |
| 19.1 | Invoices | | |  |  |  |
| 19.2 | Grant (Funder) Award Confirmation Letter | | |  |  |  |
| 19.3 | Related Correspondence | | |  |  |  |
| **20.** | **Milestones & Progress Reports** | | | **Yes** | **N/A** | **Notes** |
| 20.1 | Recruitment Update Reports (monthly during recruitment phase) | | |  |  |  |
| 20.2 | Annual Progress Reports (APRs) (& related correspondence) | | |  |  |  |
| 20.3 | Newsletters | | |  |  |  |
| 20.4 | Trial milestones/gantt charts | | |  |  |  |
| 20.5 | Related Correspondence | | |  |  |  |
| **21.** | **End of Trial** | | | **Yes** | **N/A** | **Notes** |
| 21.1 | Summary Clinical Trial Report | | |  |  |  |
| 21.2 | Summary Clinical Trial Report Correspondence | | |  |  |  |
| 21.3 | MHRA DET Acknowledgement | | |  |  |  |
| 21.4 | REC DET Acknowledgement | | |  |  |  |
| 21.5 | Declaration of the End of Trial (DET) Form | | |  |  |  |
| 21.6 | DET Correspondence | | |  |  |  |
| 21.7 | Presentation(s) | | |  |  |  |
| 21.8 | Abstracts, Papers & Publication(s) | | |  |  |  |
| 21.9 | Archiving Procedure (site SOP) | | |  |  |  |
| 21.10 | Related Correspondence | | |  |  |  |
| **22.** | **Trial Samples & Equipment** | | | **Yes** | **N/A** | **Notes** |
| 22.1 | List of local/ central laboratory services and equipment used for trial (with locations) | | |  |  |  |
| 22.2 | Sample Handling & Storage Instructions | | |  |  |  |
| 22.3 | (Local) Laboratory Reference Ranges | | |  |  |  |
| 22.4 | (Local) Laboratory Accreditation (validation) | | |  |  |  |
| 22.5 | Equipment Calibration & Maintenance Documents | | |  |  |  |
| 22.6 | Sample Shipment Records | | |  |  |  |
| 22.7 | Log of retained samples | | |  |  |  |
| 22.8 | Temperature Logs | | |  |  |  |
| 22.9 | Related Correspondence | | |  |  |  |
| **23.** | **File Notes** | | | **Yes** | **N/A** | **Notes** |
|  |  | | |  |  |  |
| **24.** | **Miscellaneous** | | | **Yes** | **N/A** | **Notes** |
|  |  | | |  |  |  |