

**Trial Master File (TMF) Index**

Clinical Trials

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| **Document Reference ID:** | Noclor/Spon/T02/01 |
| **Effective Date:** | 21st March 2016 |

**Version History**

|  |  |  |
| --- | --- | --- |
| Template ID | Version, Effective Date | Reason for Change |
| Noclor Template\_02 | Version 1, 01/11/2014 |  |
| Noclor/Spon/T02/01 | 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 Trial Master File Index template should be used for 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.

**TRIAL MASTER FILE (TMF)**

**INDEX**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Trial Title:** | |  | | | | |
| **Chief Investigator (CI):** | |  | | | | |
| **EudraCT number:** | |  | **IRAS Ref:** | | |  |
| **Sponsor Protocol Ref:** | |  | **Sponsorship in Principle Declaration Date:** | | |  |
| **REC Approval Date:** | |  | **CTA Date (if applicable) :** | | |  |
| **All essential documents must be filed in the TMF. If essential documents are located outside of the TMF during the trial please file note their location in the relevant section of the TMF for audit trail purposes. Where sections or sub-sections of the TMF index are not relevant to the a specific trial please check N/A as appropriate. At the end of trial (prior to archive) the TMF must be reconciled and complete.** | | | | | | |
|  | **Trial Contacts** | | | **Yes** | **N/A** | **Notes** |
| 1.1 | Trial Contact Sheet (including all third parties & investigator site details) | | |  |  |  |
| 1.2 | Superseded Versions of Contact Sheet | | |  |  |  |
|  | **Protocol** | | | **Yes** | **N/A** | **Notes** |
| 2.1 | Current Approved Protocol (original signatures) | | |  |  |  |
| 2.2 | Superseded Protocols (original signatures). Refer to amendment log 8.1. | | |  |  |  |
| 2.3 | Peer Review Approval & Correspondence | | |  |  |  |
| 2.4 | Protocol writing group/reviews/meetings | | |  |  |  |
| 2.5 | Draft protocols | | |  |  |  |
| 2.6 | Log of Protocol Deviations | | |  |  |  |
| 2.7 | Related Correspondence | | |  |  |  |
|  | **Approved PIS, Consent & GP Letters** | | | **Yes** | **N/A** | **Notes** |
| 3.1 | Current Approved Patient Information Sheet (PIS) | | |  |  |  |
| 3.2 | Current Approved Informed Consent Form (ICF) | | |  |  |  |
| 3.3 | Current Approved GP Letter (if applicable) | | |  |  |  |
| 3.4 | All Superseded PIS,ICF and GP letters (as they appear on amendment log 8.1) | | |  |  |  |
| 3.5 | Draft PIS, consent , GP Letter | | |  |  |  |
| 3.6 | 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 (as required for the trial)** | | | **Yes** | **N/A** | **Notes** |
| 6.1 | R&D Application & Correspondence (complete with checklist and any additional documents submitted for R&D that are not filed elsewhere in TMF) | | |  |  |  |
| 6.2 | Other Submissions & Approvals (as relevant) | | |  |  |  |
| 6.3 | Related Correspondence | | |  |  |  |
|  | **Registration** | | | **Yes** | **N/A** | **Notes** |
| 7.1 | Portfolio Adoption Form (& related correspondence) | | |  |  |  |
| 7.2 | EudraCT Registration Confirmation | | |  |  |  |
| 7.3 | Other Registrations (as relevant) | | |  |  |  |
| 7.4 | Related Correspondence | | |  |  |  |
|  | **Amendments (section 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)** | | | **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 | Manufacturing Authorization License (MA(IMP)) | | |  |  |  |
| 9.6 | IMP Label Template (Sponsor authorized/MHRA approved)/Label Exemption Details | | |  |  |  |
| 9.7 | Sponsor Authorisation of Regulatory Release of IMP to Sites | | |  |  |  |
| 9.8 | Certified QP release statement | | |  |  |  |
| 9.9 | Certificate of Analysis (CoA) (if applicable) | | |  |  |  |
| 9.10 | TSE Certificate (if applicable) | | |  |  |  |
| 9.11 | IMP Manufacture Specification, PSFs, Quote(s) & Related Correspondence | | |  |  |  |
| 9.12 | IMP Order Forms | | |  |  |  |
| 9.13 | IMP Shipment Records | | |  |  |  |
| 9.14 | IMP Management Procedures (approved by sponsor pharmacy rep) | | |  |  |  |
| 9.15 | Trial Prescription Template | | |  |  |  |
| 9.16 | Template Order/Transfer Form | | |  |  |  |
| 9.17 | Temperature Log Template | | |  |  |  |
| 9.18 | IMP Accountability Log Template | | |  |  |  |
| 9.19 | IMP Destruction Log Template | | |  |  |  |
| 9.20 | Related Correspondence | | |  |  |  |
|  | **Randomisation** | | | **Yes** | **N/A** | **Notes** |
| 10.1 | Master Randomisation List | | |  |  |  |
| 10.2 | Randomisation Schedule Management Plan | | |  |  |  |
| 10.3 | 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 | SAE reports (and related correspondence) | | |  |  |  |
| 11.4 | SUSAR reports (and related correspondence) | | |  |  |  |
| 11.5 | Pregnancy Reports (notification and follow-up) | | |  |  |  |
| 11.6 | Urgent Safety Measures (USMs) | | |  |  |  |
| 11.7 | Notification of Safety Information to Investigators | | |  |  |  |
| 11.8 | Development Safety Update Safety Reports (DSURs) (and notifications to MHRA, REC and investigators) | | |  |  |  |
| 11.9 | Code Break Logs (log not to include details of code but details of whether code broken, when and who informed) | | |  |  |  |
| 11.10 | Related Correspondence | | |  |  |  |
|  | **Data Management and Statistical Analysis/Output** | | | **Yes** | **N/A** | **Notes** |
| 12.1 | Data Management Plan | | |  |  |  |
| 12.2 | Superseded Versions of Data Management Plan | | |  |  |  |
| 12.3 | Final Version of CRF(s) | | |  |  |  |
| 12.4 | Previous Version of CRF(s) (if applicable) | | |  |  |  |
| 12.5 | Instructions for completion of CRF (if applicable) | | |  |  |  |
| 12.6 | Statistical Analysis Plan (if not explicit in protocol) | | |  |  |  |
| 12.7 | Statistical Review (if applicable) | | |  |  |  |
| 12.8 | Interim Data Analysis (if applicable) | | |  |  |  |
| 12.9 | Related Correspondence | | |  |  |  |
|  | **Trial Specific Documentation & SOPs** | | | **Yes** | **N/A** | **Notes** |
| 13.1 | Trial document inventory/version control log | | |  |  |  |
| 13.2 | Trial procedures manual | | |  |  |  |
| 13.3 | Trial specific SOPs (if applicable) | | |  |  |  |
| 13.4 | Sponsor SOPs & Signature logs | | |  |  |  |
| 13.5 | Related Correspondence | | |  |  |  |
|  | **Trial Management & Oversight** | | | **Yes** | **N/A** | **Notes** |
| 14.1 | Delegation of Responsibilities from CI to Trial Team Log (not ‘site’ trial team responsibilities) | | |  |  |  |
| 14.2 | Trial Team CVs as per delegation log (signed and dated) | | |  |  |  |
| 14.3 | Evidence of Competency/Training /Supervision for responsibilities delegated (as relevant) | | |  |  |  |
| 14.4 | Summary of Trial Oversight Groups & Committees and Key Personnel (contacts) | | |  |  |  |
| 14.5 | Trial Management Group (TMG) Minutes | | |  |  |  |
| 14.6 | Trial Management Group (TMG) ToR | | |  |  |  |
| 14.7 | Trial Steering Committee (TSC) Minutes/Correspondence | | |  |  |  |
| 14.8 | Trial Steering Committee (TSC) Charter | | |  |  |  |
| 14.9 | Data Monitoring Committee (DMC) Recommendations/Minutes/Report/Correspondence | | |  |  |  |
| 14.10 | Data Monitoring Committee (DMC) Charter | | |  |  |  |
| 14.11 | Related Correspondence | | |  |  |  |
|  | **Sponsor Declaration and Oversight** | | | **Yes** | **N/A** | **Notes** |
| 15.1 | Sponsor Update Meetings Minutes & Agenda’s | | |  |  |  |
| 15.2 | Final Sponsorship Declaration | | |  |  |  |
| 15.3 | Sponsorship In Principle | | |  |  |  |
| 15.4 | Indemnity Arrangements | | |  |  |  |
| 15.5 | Risk Reviews /Initial Risk Assessment | | |  |  |  |
| 15.6 | Related Correspondence | | |  |  |  |
|  | **Compliance, Monitoring, Audit & Inspection** | | | **Yes** | **N/A** | **Notes** |
| 16.1 | Overview table of site activity/visits and trends | | |  |  |  |
| 16.2 | Monitoring Plan (and superseded versions) | | |  |  |  |
| 16.3 | Audit Reports | | |  |  |  |
| 16.4 | Protocol Violation & Non-Compliance Reports | | |  |  |  |
| 16.5 | Serious breach notification(s) & related correspondence | | |  |  |  |
| 16.6 | Regulatory Inspection Notifications, Reports, CAPA’s (trial specific) | | |  |  |  |
| 16.7 | Related Correspondence | | |  |  |  |
|  | **Contracts & Agreements (variations to any contract should be filed with relevant contract and updated on the summary table of contracts)** | | | **Yes** | **N/A** | **Notes** |
| 17.1 | Summary Table of Contracts & Agreements | | |  |  |  |
| 17.2 | IMP supply Agreement (if applicable) | | |  |  |  |
| 17.3 | Technical Agreement (TA) | | |  |  |  |
| 17.4 | Sponsor Pharmacy Agreement(s) | | |  |  |  |
| 17.5 | Pharmacovigilance Agreement | | |  |  |  |
| 17.6 | Funder Contract (prime contact) | | |  |  |  |
| 17.7 | Delegation of Responsibilities Agreement (Chief Investigator) | | |  |  |  |
| 17.8 | Site Agreements (mNCA) | | |  |  |  |
| 17.9 | Other Agreements (as listed in summary table in 17.1) | | |  |  |  |
| 17.10 | Feasibility & Viability Assessments (for selection of third partied) | | |  |  |  |
| 17.11 | Related Correspondence | | |  |  |  |
|  | **Funding & Finance Related** | | | **Yes** | **N/A** | **Notes** |
| 18.1 | Funder Reports | | |  |  |  |
| 18.2 | Financial Returns - quarterly/six monthly/annual (\*delete as appropriate) | | |  |  |  |
| 18.3 | Invoices | | |  |  |  |
| 18.4 | Grant (Funder) Award Confirmation Letter | | |  |  |  |
| 18.5 | Grant (Funding) Application (submitted/authorized copy) & Financial Costing Schedule | | |  |  |  |
| 18.6 | Related Correspondence | | |  |  |  |
|  | **Milestones & Progress Reports** | | | **Yes** | **N/A** | **Notes** |
| 19.1 | Recruitment Update Reports (monthly during recruitment phase) | | |  |  |  |
| 19.2 | Annual Progress Reports (APRs) (& related correspondence) | | |  |  |  |
| 19.3 | Newsletters | | |  |  |  |
| 19.4 | Trial milestones/gantt charts | | |  |  |  |
| 19.5 | Related Correspondence | | |  |  |  |
|  | **End of Trial** | | | **Yes** | **N/A** | **Notes** |
| 20.1 | Summary Clinical Trial Report Acknowledgments | | |  |  |  |
| 20.2 | Summary Clinical Trial Report | | |  |  |  |
| 20.3 | Summary Clinical Trial Report Correspondence | | |  |  |  |
| 20.4 | MHRA DET Acknowledgement | | |  |  |  |
| 20.5 | REC DET Acknowledgement | | |  |  |  |
| 20.6 | Declaration of the End of Trial (DET) Form | | |  |  |  |
| 20.7 | DET Correspondence | | |  |  |  |
| 20.8 | Presentation(s) | | |  |  |  |
| 20.9 | Abstracts, Papers & Publication(s) | | |  |  |  |
| 20.10 | Related Correspondence | | |  |  |  |
|  | **Central Laboratory Services (if several services sub divide by service)** | | | **Yes** | **N/A** | **Notes** |
| 21.1 | List and contact details of central laboratories | | |  |  |  |
| 21.2 | Sample Handling Instructions | | |  |  |  |
| 21.3 | Central Laboratory Reference Ranges | | |  |  |  |
| 21.4 | Central Laboratory Accreditation (validation) | | |  |  |  |
| 21.5 | Calibration & Maintenance Records (if applicable) | | |  |  |  |
| 21.6 | Viability Assessment (as part of the selection process) | | |  |  |  |
| 21.7 | Shipment Records & Sample Analysis Reports | | |  |  |  |
| 21.8 | Related Correspondence | | |  |  |  |
| **22.** | **Miscellaneous** | | | **Yes** | **N/A** | **Notes** |
|  |  | | |  |  |  |

**TMF - Site File Index**

If the Sponsoring NHS Trust has a ‘lead site’ and the Chief Investigator for the trial (also the Principle Investigator for the site) is delegated responsible for managing the TMF, a separate Investigator Site File (ISF) is not required for this site (the TMF will act as the combined TMF/ISF). A TMF Sponsor Lead Site File Noclor/Spon/T02a/0X should be created and maintained as part of the TMF in these situations. The lead sponsor site should be listed in the table below and a note made that TMF will act as ISF (and provide the TMF file ref).

All other participating sites (not PICs as these should be listed in Part C of R&D form) should have a TMF site file (Noclor/Spon/T02b/0X) established and details of site should be recorded in the table below.

|  |  |  |  |
| --- | --- | --- | --- |
| **TMF File Ref** | **Site Name** | **Site Ref** | **Notes** |
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