

**Trial Master File (TMF) - Sponsor Lead Site File Index**

Clinical Trials

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| **Document Reference ID:** | Noclor/Spon/T02a/01 |
| **Effective Date:** | 21st March 2016 |

**Version History**

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| Template ID | Version, Effective Date | Reason for Change |
| Noclor Template\_02a | Version 1, 01/11/2014 |  |
| Noclor/Spon/T02a/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 where the sponsor Trust has a lead site and the plan is for the TMF to act as a combined TMF/ISF (to avoid over-duplication of essential documents filed for site). 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.

**TRIAL MASTER FILE (TMF)**

**Sponsor Lead Site File Index**

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| --- | --- | --- | --- |
| **Trial Title** |  | **EudraCT No** |  |
| **IRAS No:** |  |
| **Site Ref :** |  | **Site Name :** |  |
| **Principal Investigator :** |  | **Date of host site approval:** |  |
| **Date of site initiation :** |  | **Date site activated:** |  |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **1.** | **Site Contact Details** | **Yes** | **N/A** | **Notes** |
| 1.1 | Site Contact Sheet |  |  |  |
| 1.2 | Superseded Versions of Site Contact Sheet |  |  |  |
| 1.3 | Related Correspondence |  |  |  |
| **2.** | **Protocol & Procedures Manual** | **Yes** | **N/A** | **Notes** |
| 2.1 | Current Approved Protocol |  |  | For reference |
| 2.2 | Trial Procedures Manuals |  |  | For reference |
| 2.3 | Principal Investigator Protocol approval page(s) – signed and dated for all implemented versions of protocol |  | x | Filed in TMF section 2 (The Chief Investigator is the Principal Investigator) |
| 2.4 | Protocol Deviation Log |  | x | Filed in TMF Section 2.6 |
| 2.5 | Related Correspondence |  |  |  |
| **3.** | **Site Specific PIS, Consent, GP Letters** | **Yes** | **N/A** | **Notes** |
| 3.1 | Final approved version of Participant Information Sheet, Informed Consent forms and GP letter on local Headed Paper |  |  |  |
| 3.2 | Superseded versions of Participant Information Sheet, Informed Consent forms and GP letter on local Headed Paper |  |  |  |
| **4.** | **Subject Information** | **Yes** | **N/A** | **Notes** |
| 4.1 | Screening Log |  |  |  |
| 4.2 | Subject Randomisation/ ID Log |  |  |  |
| 4.3 | Subject Enrolment Log (to include subject status) |  |  |  |
| 4.4 | Signed Informed Consent Forms (attach relevant version of PIS) |  |  |  |
| 4.5 | GP Letter Log |  |  |  |
| 4.6 | Related Correspondence |  |  |  |
| **5.** | **Initiation, Monitoring Compliance and Close-Out** | **Yes** | **N/A** | **Notes** |
| 5.1 | Monitor Visit Log (signature sheet) |  |  |  |
| 5.2 | Close-Out Report |  |  |  |
| 5.3 | Close-Out Correspondence |  |  |  |
| 5.4 | Monitor Visit Reports |  |  |  |
| 5.5 | Monitoring Correspondence |  |  |  |
| 5.6 | Protocol Violation and Non-Compliance Reports |  | x | Filed in TMF Section 16.4 |
| 5.7 | Site Initiation Report |  |  |  |
| 5.8 | Site Initiation Signature Sheet |  |  |  |
| 5.9 | Site Initiation Agenda, Correspondence & Presentations (copy of slides etc) |  |  |  |
| **6.** | **Site Selection, Set-Up & Activation** | **Yes** | **N/A** | **Notes** |
| 6.1 | Site Activation Notice |  |  |  |
| 6.2 | Site Set-up document checklist |  |  |  |
| 6.3 | Host Site Approval |  |  |  |
| 6.4 | List of referring PIC sites (if applicable) |  |  |  |
| 6.5 | SSI Form (signed and dated) |  |  |  |
| 6.6 | Site Feasibility/Viability Forms – (as assessed prior to selection of site) |  |  |  |
| 6.7 | Related Correspondence |  |  |  |
| **7.** | **Investigational Medicinal Product (IMP). File note as required for records retained in Pharmacy Site File (PSF)** | **Yes** | **N/A** | **Notes** |
| 7.1 | Site Pharmacy Agreements/Checklists (as relevant) |  |  |  |
| 7.2 | IMP Management & Handling Procedures |  |  |  |
| 7.3 | Confirmation of IMP Delivery (Receipt Forms) |  |  |  |
| 7.4 | Template Order/Transfer Form |  |  |  |
| 7.5 | Completed Order/Transfer Forms |  |  |  |
| 7.6 | Trial Prescription Template |  |  |  |
| 7.7 | Completed Trial Prescriptions |  |  |  |
| 7.8 | Temperature Log Template |  |  |  |
| 7.9 | Temperature Logs |  |  |  |
| 7.10 | Temperature Deviation Notifications & Correspondence |  |  |  |
| 7.11 | IMP Accountability Log Template |  |  |  |
| 7.12 | IMP Accountability Logs |  |  |  |
| 7.13 | IMP Destruction Log Template |  |  |  |
| 7.14 | IMP Destruction Authorisation (from sponsor) |  |  |  |
| 7.15 | IMP Destruction SOP (site pharmacy SOP) |  |  |  |
| 7.16 | IMP Destruction Log |  |  |  |
| 7.17 | Related Correspondence |  |  |  |
| **8.** | **Adverse Events & Unblinding (group by event/ attach all relevant information to the reported event and file events in chronological order)** | **Yes** | **N/A** | **Notes** |
| 8.1 | Procedures & template forms for adverse event management, monitoring and reporting (responsibilities of third parties detailed where relevant) |  |  |  |
| 8.2 | Procedures & template forms for 24 hours medical cover & unblinding/code break (responsibilities of third parties detailed where relevant) |  |  |  |
| 8.3 | AE Log |  |  |  |
| 8.4 | SAE Reports |  | x | Filed in section 11.3 of TMF |
| 8.5 | AE Reports (attach all relevant documents/correspondence) |  |  |  |
| 8.6 | Record of 24 hour Medical Enquiries & Outcome |  |  |  |
| 8.7 | Trust Incident Report Forms (as relevant) |  |  |  |
| 8.8 | Completed Code Break Forms |  |  |  |
| 8.9 | Related Correspondence |  |  |  |
| **9.** | **Data Management** | **Yes** | **N/A** | **Notes** |
| 9.1 | Source Data Location Agreement |  |  |  |
| 9.2 | File Note - Location of Subject CRFs |  |  |  |
| 9.3 | Data queries |  |  |  |
| 9.4 | Related Correspondence |  |  |  |
| **10.** | **Site Trial Team** | **Yes** | **N/A** | **Notes** |
| 10.1 | Delegation of Responsibilities Signature Log (for site) |  |  |  |
| 10.2 | Trial Personnel CVs (signed and dated) |  |  |  |
| 10.3 | Trial Personnel GCP /training /supervision evidence |  |  |  |
| 10.4 | Honorary Contracts/LoA |  |  |  |
| 10.5 | Related Correspondence |  |  |  |
| **11.** | **Local Laboratory Services & Equipment Maintenance (if applicable)** | **Yes** | **N/A** | **Notes** |
| 11.1 | List of local/central laboratory services and equipment used for trial (with locations) |  |  |  |
| 11.2 | Sample Handling & Storage Instructions |  |  |  |
| 11.3 | (Local) Laboratory Reference Ranges |  |  |  |
| 11.4 | (Local) Laboratory Accreditation (validation) |  |  |  |
| 11.5 | Equipment Calibration & Maintenance Documents |  |  |  |
| 11.6 | Sample Shipment Records |  |  |  |
| 11.7 | Log of retained samples |  |  |  |
| 11.8 | Temperature Logs |  |  |  |
| 11.9 | Related Correspondence |  |  |  |
| **12.** | **File Notes** | **Yes** | **N/A** | **Notes** |
|  |  |  |  |  |
| **13.** | **Miscellaneous** | **Yes** | **N/A** | **Notes** |
|  |  |  |  |  |
| **14.** | **Archive** | **Yes** | **N/A** | **Notes** |
| 14.1 | Archive Notification, Location & Duration |  |  |  |