Investigator Site File Index

Guidance Notes for Site Staff

Investigator Site File (ISF)

- There should be one 'central' physical Investigator Site File (ISF) at site. Please ensure that the listed documents are kept within the ISF.
- The ISF must be stored in a secure location with restricted access.
- All new/amended documents received from the CTC during the course of the trial should be filed in the ISF.
- Documents should be marked as 'superseded' (and signed/dated) across the front if they have been updated.
- Documents can be stored in an alternative location, in which case a File Note or the index should state where they are stored. Large documents (e.g. Investigator's Brochures, previous versions of protocol, etc.) may be stored electronically.
- Documents stored in an alternative location must be made available for review by monitors/auditors/inspectors and placed in the ISF prior to archiving.
- Sites may use their own ISF index, as long as all applicable documents as listed in this document are filed.
- Site staff are responsible for filing all relevant site specific documents (e.g. R&D correspondence master subject log) in the applicable section(s) of the ISF (or a reference to location).
- Local policies and procedures (e.g. staff training, archiving) can be covered by a file note referencing their location.

3.0 Patient Information – Patient Information Sheets/Consent Forms/GP Letters must be put on local headed paper prior to local approval, filing in the ISF and use within the trial.

6.0 Site Information/Site Staff Information

- The Site Staff Delegation Log must be kept up-to-date as and when personnel join or leave the team and all entries must be signed off by the Principal Investigator.
- CVs should be current at the time the trial is opened, be kept up to date and be signed and dated. GCP training is required for all staff responsible for trial activities. The frequency of repeat GCP training may be dictated by the requirements of their employing institution, or every two years where the institution has no policy, and more frequently when there have been updates to the legal or regulatory requirements for the conduct of clinical trials. CVs/GCP certificates stored in an alternative location must be made available when required and archived in the ISF at the end of the trial.

7.0 Patient Screening & Recruitment – The Patient Screening Log and Master Subject List must be kept up-to-date.

11.0 Data Management

At the end of the trial CRFs are to be archived as part of the ISF and not with the medical records / source data.

Monitoring, Audit and Inspection – The ISF will be a key part of any monitoring activity, audit or inspection of the site. Please ensure that it is appropriately maintained and made available to monitors/auditors/inspectors as necessary.

Incident Reports

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Completed incident reports should be filed in the relevant section according to the nature of the incident (e.g. an incident relating to biological samples should be filed alongside the relevant biological sample records).

End of Trial

If desired, the Pharmacy Site File may be merged with the ISF prior to archiving (but only following completion of the active phase of the trial). All pharmacy-specific documents should be integrated into the relevant section(s) of the ISF; however, duplicate copies of documents already held in the ISF may be destroyed.

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1.0 TRIAL MANAGEMENT
Contact List of CTC staff
Trial/CTC Newsletters
Record/Minutes of (internal) trial-related meetings at Site
Completed document receipts
2.0 PROTOCOL/TRIAL INFORMATION
Current Protocol
Superseded Protocols
Version History Log
3.0 PATIENT INFORMATION
Current Approved Version of PIS on Locally Headed Paper
Current Approved Version of Consent Form on Locally Headed Paper
Current Approved Version of GP Letter on Locally Headed Paper
Current Approved Version of Pregnancy Monitoring Information Sheet (Partner) on Locally Headed Paper
Current Approved Version of Pregnancy Monitoring Consent Form (Partner) on Locally Headed Paper
Superseded Versions of Patient/Pregnancy Monitoring Information Documents
Copies of Signed and Dated Patient Consent Forms
Copies of Signed and Dated Pregnancy Monitoring Consent Forms
Patient Contact Card
Version History Log(s)
4.0 ETHICS & REGULATORY
Sponsorship Letter
Letter of Insurance from Sponsor/Insurance Certificate(s)
Clinical Trial Authorisation (CTA) Application to MHRA
Clinical Trial Authorisation from MHRA
Amendments submitted to MHRA & approvals
Ethics Favourable Opinion Letter
Amendments submitted to REC & approvals
HRA Approval for trial
Amendments Log
NHS Permission Letter(s)/Confirmation of capacity & capability
Signed SSI Form (Scottish and Welsh sites only)
ARSAC Documentation (or file note stating nominated PET centre)
5.0 AGREEMENTS AND CONTRACTS
Signed model Non-Commercial Agreement (mNCA)
Completed Site Registration Form
Site Activation Letter
6.0 SITE INFORMATION/SITE STAFF INFORMATION
Site Staff Delegation Log
Site Contacts Form
Site Staff CVs (signed and dated) and details of GCP training (or file note indicating location)
Source Data Form
Electronic Medical Records Questionnaire
Relevant Local Policies/Procedures (or file note indicating location)
7.0 PATIENT SCREENING & RECRUITMENT
Patient Screening Log
Master Subject List
Registration Procedure (see Protocol)
Registration/Eligibility for Treatment Confirmation Faxes or E-mails

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8.0 LABORATORY
Laboratory Normal Ranges
Accreditation Documents
Laboratory Manual
Biological Sample Collection/Shipment Form
Completed Biological Sample Collection/Shipment Form
Biological Sample Inventory Log
Biological Sample Tracking System – file note indicating location and login details as held electronically
Biological Sample Tracking System - manual
9.0 INVESTIGATOR'S BROCHURE (IB)
Current Version of IB: Nivolumab
Superseded IB(s)
IB receipts
Safety Updates/Reports/Alerts/Line Listings
10.0 TRIAL DRUG SUPPLIES/PHARMACY ARRANGEMENTS
Summary of Drug Arrangements
Master Trial Prescription (or file note to state that it is held in pharmacy)
Recall Notices
11.0 DATA MANAGEMENT
Data Management & Collection Guidelines – Please see Blank Case Report Form (CRF)
Blank Case Report Form (CRF)
Completed Case Report Forms (CRFs) (or file note to state location)
Completed Data Clarification Forms (DCFs) (or file note to state location)
12.0 PHARMACOVIGILANCE
Trial Specific Serious Adverse Event (SAE) Reporting Guidelines
Completed SAE reports (with proof of submission and related correspondence with CTC) – or file note location
Completed Pregnancy Reports (with proof of submission and related correspondence with CTC) – or file note location Pregnancy Report Correspondence
Adverse Event Grading System: Common Terminology Criteria for Adverse Events v5
Correspondence regarding Urgent Safety Measures
Correspondence relating to Pharmacovigilance
13.0 SPONSOR MONITORING ACTIVITIES
Site Initiation Report and Slides
Monitoring Plan
On-site Monitoring Visit Letter(s)
On-site Monitoring Visit Correspondence
On-site Monitoring Visit - Site Visit Log
On-site Monitoring Visit Action Items
Responses to on-site Monitoring Visit Actions Items (signed and dated)
Central Monitoring Requests and Correspondence
Completed ISF Checklists
14.0 CORRESPONDENCE
General Emails/Letters/Faxes
15.0 OTHER TRIAL MATERIALS/DOCUMENTS
Imaging Manual
Incident report template

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Other Trial Specific Documents
Audit & Inspection Documents/Correspondence
16.0 TRIAL CLOSURE AND ARCHIVING
End of Trial Notification
Trial and Site Closure Documents and Correspondence
Statement Confirming Archive Location
Archiving Forms

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