Pharmacy Site File Index
Guidance Notes for Site Staff

Pharmacy Site File (PSF)

- Where possible, there should be one 'central' physical Pharmacy Site File (PSF) at site. Where it is necessary for there to be multiple files (for example, where there is involvement of separate dispensary and aseptic pharmacy teams) it must be clear using File Notes what documents are present in each file.
- The PSF 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 PSF.
- Documents should be marked as 'superseded' (and signed/dated) across the front if they have been updated.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 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 PSF prior to archiving.
- Sites may use their own PSF 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. local pharmacy trial specific procedures) in the applicable section(s) of the PSF (or a reference to their location).
- Local policies and procedures (e.g. temperature monitoring) can be covered by a file note referencing their location.

2.0 Pharmacy Staff Information

- The Site Staff Delegation Log(s) 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. At a minimum the lead pharmacist (or main pharmacy contact taking responsibility for pharmacy aspects of the trial) must sign the main delegation log. In this case a separate signature log for pharmacy staff undertaking trial-related activities, such as dispensing, will evidence that they have read and understood relevant procedures before undertaking applicable tasks.

- At a minimum the CV & evidence of GCP training for the lead pharmacist (or main pharmacy contact taking responsibility for pharmacy aspects of the trial) must be filed in the PSF. A file note should be present to indicate the location of CVs/GCP certificates and these documents must be made available when required e.g. during audits and inspections. 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.

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Drug Accountability/Destruction – Nivolumab Drug accountability logs must be completed and maintained for all trial patients. Sites may use their own accountability logs with prior approval from CTC.

Monitoring, Audit and Inspection – The PSF 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
Completed incident reports should be filed in the relevant section according to the nature of the incident (e.g. an incident relating to drug accountability should be filed alongside the relevant drug accountability records).

End of Trial – If desired, the PSF may be merged with the Investigator Site File (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.

1.0 REFERENCE DOCUMENTS
1.1 Trial Contacts
Contact List of CTC Staff
Site Delegation Log
1.2 Protocol
Current Protocol
Superseded Protocols
Protocol Receipts
Protocol Version History Log
1.3 IMP Reference Documents
Current Version of IB: Nivolumab - or file note if held electronically
Superseded IBs - or file note if held electronically
IB Receipts
1.4 IMP Handling & Dispensing Procedures
Summary of Drug Arrangements (SoDA)
Pharmacy Procedures *(e.g. pharmacy dispensing / trial specific guidelines)*
Registration Procedure (see Protocol)
Pharmacy Procedure for Temperature Monitoring & Reporting Temperature Excursions
Local Destruction Procedure
1.6 Trial Authorisations
MHRA Approval
HRA Approval
Relevant Approvals for Amendments
Site Activation Letter
2.0 PHARMACY STAFF
2.1 CV& GCP Certificates
Current CV and evidence of GCP training for main pharmacy staff with oversight of trial activities
2.2 Pharmacy Training
Site Initiation Training Slides
Site Initiation Report & Attendee Log
Internal pharmacy Signature Log

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3.0 TEMPLATES
Prescription(s)
Approved IMP Label(s)
Required Dispensing Label Information
Patient Accountability Logs for Nivolumab
Stock Balance Logs for Nivolumab
Drug Order Form
CTC Incident Report Template
Temperature Excursion Template
4.0 STORAGE
Temperature Logs (or file note indicating location)
Completed Notification of Temperature Excursion Forms (those reported to CTC)
Details of Temperature Monitoring System including location of maintenance and calibration certificates
5.0 NIVOLUMAB
Completed Drug Order Forms
Shipment/receipt documentation (including QP certificate)
Nivolumab Balance Log
Destruction Certificates
Recall Notices
6.0 PATIENTS / SUBJECTS
Master Subject List
Completed Prescriptions for Nivolumab
Patient Accountability Logs for Nivolumab
Aseptic/Preparation Worksheets for Nivolumab
Emails/faxes confirming registration and eligibility for treatment
7.0 SPONSOR MONITORING ACTIVITIES
On-site Monitoring Visit Correspondence
On-Site Monitoring Visit - Site Visit Log
On-site Monitoring Visit – Pharmacy actions
Responses to On-Site Monitoring Visit Actions (signed and dated)
Central Monitoring Requests/Correspondence/Completed PSF Checklists
8.0 CORRESPONDENCE
General Correspondence faxes / emails / newsletters
9.0 END OF TRIAL
Trial and Site Closure Documents and Correspondence

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