York and Scarborough Teaching Hospitals NHS Foundation Trust
R&D Unit
Standard Operating Procedure
R&D/S08

Monitoring of Trust sponsored Research Studies

IT IS THE RESPONSIBILITY OF ALL USERS OF THIS SOP TO ENSURE THAT THE CORRECT VERSION IS BEING USED

All staff should regularly check the R&D Unit's website and/or Q-Pulse for information relating to the implementation of new or revised versions. Staff must ensure that they are adequately trained in the new procedure and must make sure that all copies of superseded versions are promptly withdrawn from use unless notified otherwise by the SOP Controller.

The definitive versions of all R&D Unit SOPs appear online. If you are reading this in printed form check that the version number and date below is the most recent one as shown on the R&D Unit website: www.research.yorkhospitals.nhs.uk/sops-and-guidance-/ and/or Q-Pulse

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	Signature:	
	Date:	11th November 2019
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	Signature:	
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This SOP will normally be reviewed every 3 years unless changes to the legislation require otherwise

Version History Log

This area should detail the version history for this document. It should detail the key elements of the changes to the versions.

Version	Date Implemented	Details of significant changes
1.0	2nd March 2006	
2.0	18th October 2007	Inserted 'version history log'. Inserted 'last reviewed' row on front page.
3.0	11th January 2008	Slightly altered the paragraph in the section 'How to inspect at the study site' on page 2. This relates to changes made to Forms 3–3c regarding percentage of records to check. The references to checking a specific percentage of each type of records have been removed. This is not deemed necessary. The Monitor will decide on the percentage of each type of records to check for each individual study.
4.0	21st October 2009	Update to front page box. Change to review dates. Change to SOP reference number. General update to reflect changes to monitoring of Alliance Trust Sponsored or co-sponsored CTIMPs.
5.0	1st June 2010	Information added to Section 4 – Details Monitoring Prioritisation Tool, clarification of requirements re Initiation Report, linked to S14 NHS Permission Procedure. Amendment to Section 5.14 to provide timelines for Sponsor representative response. Minor clarifications added throughout. Change to responsibility for organising site initiation
6.0	21st February 2011	Streamlining of forms to be used; changes to procedure for signing off of reports on behalf of sponsor and issuing / checking of Action Lists; removal of section on monitoring by external sponsors, detail on R&D Unit monitoring of hosted studies, now described as auditing and covered by another SOP. Site initiation requirements more clearly specified.
7.0	19th March 2012	Made applicable to non-CTIMP studies. Change of Author and SOP Controller
8.0	15th April 2013	Removal of references to the North and East Yorkshire R&D Alliance
9.0	23rd June 2014	
10.0	12th August 2014	Change of author; General updates
11.0	17th August 2017	Made applicable to all studies (CTIMP & non-CTIMP) Section 4.2 updated and procedure for heightened and/or reduced monitoring added. Monitoring methods clarified (remote vs on-site monitoring).
12.0	9th December 2019	Change of author. Change of link to R&D

		website. Changes to formatting. Updated Introduction, Background and Purpose. General updates

Contents

1 Introduction, Background and Purpose

Monitoring is the act of overseeing the progress of a study and of ensuring that it is conducted, recorded and reported in accordance with the protocol and any amendments, written procedures, Good Clinical Practice (GCP), and the applicable regulatory requirements.

Monitoring is one of the key mechanisms whereby the Sponsor can be assured that:

- the safety, right and well-being of trial subjects are protected
- investigators are appropriately selected, trained and supported to complete the proposed clinical trial
- processes are consistently followed and activities are consistently documented to ensure high-quality trial conduct and protocol compliance
- the reported trial data are accurate, complete and verifiable against the source documents
- the conduct of the trial is in compliance with the currently approved protocol/ amendment(s), with GCP and with the applicable regulatory requirement(s).

A risk assessment should be completed to ensure that monitoring is proportionate to the identified risks and to determine the type and extent of monitoring which is required. Generally monitoring is required before, during and after active recruitment however this will be informed by the risk assessment and will be documented in a monitoring plan. The Sponsor will maintain responsibility for ensuring that a risk assessment and monitoring plan are completed and make appropriate arrangements to have this carried out.

This is particularly important in clinical trials of investigational medicinal products (CTIMPs) which are required by law (Clinical trials Regulations) to be run to Good Clinical Practice (GCP) standards; however a similar approach should apply to non-CTIMPs in order to ensure consistent practice and scientific quality.

The only exception where risk assessment & monitoring plan will not be required, is for research studies that are considered to be 'low risk' (meet the criteria defined in R&D/G09; for example, studies that involve NHS staff or anonymised, pre-collected data) and are eligible for sponsorship approval via proportionate review process (see R&D/S82). Such studies are required to meet the same quality standards as all other studies; however they may be exempt from a systematic quality control as they are deemed to be low risk with regards to patients' safety and scientific validity of study data.

The purpose of this SOP is to describe the procedures for monitoring research studies sponsored by the Trust: CTIMP & non-CTIMP studies (excluding 'low risk' studies approved via the Trust's proportionate review process).

2 Who should use this SOP

- R&D Unit staff engaged in setting up sponsored or co-sponsored research studies.
- Prospective Chief Investigators (CIs) preparing applications for Trust sponsorship or co-sponsorship of research studies.
- CIs and Trial Co-ordinators for Trust sponsored or co-sponsored research studies.
- Principal Investigators at participating Sites involved in multi-centre Trust sponsored or co-sponsored research studies.
- Monitors employed by or contracted to a sponsoring or co-sponsoring Trust.
- Clinical Trial Managers employed by or contracted to a sponsoring or co-sponsoring Trust.

3 When this SOP should be used

During preparation of, and throughout the conduct of a Trust sponsored research study.

4 Procedure

4.1 The Monitoring Plan and Appointment of a Monitor

A study sponsored by the Trust (excluding 'low risk' studies approved via proportionate review process) will have a trial-specific Monitoring Plan based on the Monitoring Plan Template (see Section 5), that will detail how the procedure set out in this SOP apply to the particular study. In case of any conflict the Monitoring Plan for the trial will prevail over this SOP.

Any co-sponsorship contract including a party that is not the Trust will explicitly define monitoring responsibility and whose SOP will apply.

The R&D Unit will write a draft Monitoring Plan on behalf of the proposed sponsor organisation, in collaboration with the CI. The monitoring methods ('on-site' or 'remote'/ or a combination of both), number and frequency of monitoring visits will be determined following a Risk Assessment completed as a part of the sponsorship application. The draft Monitoring Plan will be submitted for approval by the R&D Group alongside all other sponsorship application documents.

Where the Trust is responsible for monitoring it will appoint a Monitor for the trial. The monitor should be part of the trial team, who is familiar with and has been trained in the study and can perform a quality control check of the study activities. This will usually be the R&D Research QA manager, a Trial Manager or Study Co-ordinator. Alternatively a clinical research organisation or a suitably qualified freelance consultant may be sub-contacted to carry out monitoring functions.

In a multi-centre trial for which the Trust has monitoring responsibility, the Monitoring Plan may provide for monitoring tasks to be shared between the Trial Co-ordinator/ Manager and the Monitor. In such cases, the responsibilities will be specified in the Monitoring Plan. For CTIMPs, as a minimum the Monitor must accompany the Trial Co-ordinator/Manager to the CI's Site Initiation Visit

and the Site Initiation Visit o at least one other Site. If the Site Initiation at other sites is carried out by the Trial Co-ordinator/Manager, the Monitor will make available for the Trial Co-ordinator's use any Powerpoint or other presentation materials prepared for the CI Site or first participating Site Visits.

In the remainder of this document, and in associated forms, where the context permits, the term 'Monitor' is used to include 'Trial Co-ordinator/Manager' who may be authorised to carry out monitoring tasks as specified in a Monitoring Plan. .

To ensure that the Monitor is familiar with the protocol, Case Report Form (CRF) and SOPs to be followed, s/he will be given opportunity to read the relevant materials prior to the CI Site Initiation Visit and to meet with the CI and/or staff of the R&D Unit as required.

If there is a change of Monitor during the trial, full handover will be carried out, involving provision of documentary information and, if possible, briefing of the new Monitor by the previous one. In case of illness or other unavailability, the new Monitor will be briefed by R&D Unit staff.

4.2 Monitoring Visit Pattern

A Site Initiation Visit should always take place before recruitment begins at a Site, including the CI Site, where in addition to work at that particular Site, arrangements for co-ordination of the whole trial will be checked. This may be achieved by organising a face to face meeting, via teleconference or videoconference. For some studies, an SIV may not be conducted at all if such visit is considered unnecessary, for example due to simplicity of the study or where the site has previously received training in a similar study.

Interim Monitoring Visits will be carried out as specified in the study Monitoring Plan. The intensity and focus of the monitoring activities will be based on the vulnerabilities identified by the risk assessment, thus these will vary across different studies and may vary across sites. The following aspects of a clinical study will be taken into consideration when assigning levels of monitoring intensity or focus (as dictated by the risk assessment):

- procedure for obtaining patients' informed consent
- IMP/study intervention
- sample processing/handling
- equipment
- data and source data verification
- investigator site experience/training

Study close out visits should always take place after the end of study date (as defined in the study protocol) and after all outstanding data queries have been resolved and closed, unless a site was closed prematurely. This may be achieved via on-site visit, or remotely via checklists.

Changes to the timing and frequency of monitoring visits, or changes to the methods of monitoring (as prescribed in the Monitoring Plan) may be required during the course of a research study. A Monitoring Plan may require adjusting due to:

- Protocol amendments/Changes to the Risk Assessment;

- Participant recruitment rate variation;
- Quality concerns/ GCP and/or Protocol compliance issues;
- Significant staff changes;

The following escalation procedure should be followed to trigger additional heightened monitoring.

If the monitoring findings identify serious and/or persistent non- compliance with the protocol, written procedure, GCP and/or applicable regulatory requirements on the investigator site, then the following actions will be considered:

- Further investigation and assessment as to whether a serious breach occurred and should be reported in line with R&D/S04;
- Further investigation and corrective and preventative action plan (CAPA);
- Trigger a 'for cause' monitoring visit;
- terminate the investigator site's participation in the trial and notify the competent authority and/or REC as required.

If a 'for-cause' monitoring visit is deemed to be required, it will be arranged and conducted in the same way as routine interim monitoring visit, but it will focus on the issue(s) that triggered it. The Research Monitor MUST meet with Chief Investigator and Principal Investigator (if applicable) during a for-cause monitoring visit. Evidence of the subsequent visits or actions based on the trigger must be documented in the study TMF.

An increase in the frequency of interim visits and/or changes to monitoring methods ('on site' or 'remote') must be agreed with the Head of R&D (or delegated individual) on behalf of the Sponsor. In such cases an amended Monitoring Plan will be notified at the Quarterly QA meetings and reported as a potential risk issue.

The following escalation procedure should be followed to trigger reduced monitoring.

A reduction in the frequency of interim monitoring visits and/or changes to monitoring methods ('on site' or 'remote') could be proposed if the monitor is satisfied that the site is performing well. Reduced monitoring must be agreed by Head of R&D (or delegated individual) on behalf of the Sponsor. In such cases an amended Monitoring Plan will be notified at the Quarterly QA meetings.

4.3 Report Forms and Visit Content

The appropriate Checklist, Action List and Monitoring Report should be used for Site Initiation, Interim Monitoring and Trial Close-Out as required (see Section 5).

On Interim Visits the whole Checklist or selected parts may be used, in accordance with the Monitoring Plan. Source Data Verification requirements will also be specified in the Monitoring Plan. The Monitor may, if s/he judges it necessary in order to follow up issues identified in the planned coverage, cover additional elements of the Report on any Interim Visit where this has not previously been scheduled.

Original Monitoring reports and completed Action Lists will be filed in the Sponsor file situated within the R&D Unit. If required, Summary Reports may be provided to Sites following final sign-off by the Head of R&D (or delegated

individual) on behalf of the Sponsor. Monitoring Visit Log & copy of completed Action List will be filed in the TMF/ISF. Completed Monitoring checklists will be filed electronically and stored on 'X drive' (Applied Learning and Research).

4.4 Site Initiation Visit

4.4.1 Prior to the CI Site Initiation Visit

When all necessary approvals for the study as a whole (though not necessarily for all Sites) have been obtained the CI will set up the TMF in accordance with R&D/S09 and R&D/F95. While responsibility for performing this and subsequent CI tasks documented in this SOP lies with the CI, (s)he may delegate onwards in line with SOP R&D/S03.

The CI (or delegated member of the research team) will contact the Monitor to arrange a Site Initiation Visit to the CI Site, to take place as soon as possible after the TMF is ready, and to agree an agenda for the day in accordance with 4.6 below and any additional provisions in the Monitoring Plan.

The CI will ensure that personnel in the Investigator Team and representatives from supporting departments are able to attend as detailed below and are able to read in advance the Protocol, this and any other relevant SOPs, the Monitoring Plan and the agenda.

Generally two hours to half a day will be needed for the Training Session however this may vary between studies. Attendance of the CI and other members of the Investigator Team is mandatory. Support department representatives are encouraged to attend the whole Training Session but if necessary may attend only for directly relevant elements.

The CI or Trial Co-ordinator/Manager should be available for a further half day to assist the Monitor with checking the TMF and trial preparations in the Investigator Team and support departments.

4.4.2 Prior to the Site Initiation Visit at Participating Sites

The Investigator Site File (ISF) will need to be set up in accordance with R&D/S09 and R&D/F11 prior to the Site Initiation Visit.

The CI or Trial Co-ordinator/Manager will contact the Monitor to arrange Site Initiation Visits to participating Sites that are required, under the Monitoring Plan, to be made by the Monitor. The Trial Co-ordinator/Manager will make similar arrangements for Site Initiation Visits the Monitoring Plan provides for him/her to make. All Site Initiation Visits will take place as soon as possible after the ISF is ready. The agenda for Initiation Visits to participating Sites should follow that for the CI Site as closely as possible, although minor modifications may be appropriate. The CI should agree the agenda with the Monitor and Trial Co-ordinator/Manager prior to the first participating Site Initiation Visit.

The CI will ensure that personnel in the Site Investigator Team and support department representatives are able to attend as detailed below.

The CI will provide and ask the PI to arrange for all relevant Site personnel to review in advance the following documents:

- the Protocol;
- the Investigator's Brochure or Summary of Product Characteristics, as applicable;

- this and any other relevant SOPs;
- the Monitoring Plan;
- the Initiation Visit agenda.

Generally two hours to half a day should normally be allocated to the Training Session however this may vary between studies. Attendance of the PI and other members of the Investigator Team is mandatory. Support department representatives are encouraged to attend the whole Training Session but if necessary may attend only for directly relevant elements.

The PI or another member of the Site Investigator Team should be available for a further half day to assist the Monitor with checking the ISF and trial preparations in the Investigator Team and support departments.

4.4.3 During the Site Initiation Visit (CI and Participating Sites)

As part of Site Initiation a 'Training Session' will be conducted by the Monitor (as prescribed by the Monitoring Plan), with the support of the CI/PI on clinical issues and will include coverage of:

- Overview of the Protocol;
- Primary and secondary endpoints;
- Investigator's Brochure/Summary of Product Characteristics;
- Investigational Medicinal Product (IMP) procedures.
- Participant recruitment, establishment of eligibility, consent and randomisation;
- Discontinuation and withdrawal;
- Definition of source data/maintenance of source data records;
- Applicable SOPs;
- Adverse Event (AE) documentation and safety reporting;
- Data protection;
- Data collection: CRF, File Notes,
- Sample processing/handling;
- TMF/ISF maintenance including Delegation Log, Minuted Meetings;
- Equipment
- Staff training & experience

The Monitor will check the arrangements for handling the IMP (if applicable). At the CI Site this will include checking the Qualified Person Release documentation where relevant. At CI and participating Sites this will cover all documentation that should be held in Pharmacy, including shipment and receipt documentation, handling and storage, dispensing procedures.

The Monitor will check preparatory arrangements for the trial in other support departments at Site, such as laboratories, as specified in the Monitoring Plan.

An attendance log will be signed by all Site personnel present at various elements of the Initiation Visit.

4.4.4 Following the Site Initiation Visit

The Monitor will send the Initiation Report to the Head of R&D as the Sponsor representative (or a delegated individual) within two weeks of the Visit. If, for any reason, it is impossible for this to be done within two weeks the Monitor will agree another due date with the Sponsor representative.

If the Monitor issued any Action Lists in the course of the Initiation Visit the Sponsor representative will co-ordinate actions required and may arrange R&D Unit support if this is cost-effective for the Sponsor. The Monitor must see evidence of completion of any actions before signing confirmation that the study can begin at Site.

The Sponsor representative will sign off the report and notify the Site R&D Office that recruitment may commence at that Site, providing all local approvals are in place.

Once a contract or statement of activity has been signed, arrangements can be made for supply of IMP to the Site.

No participant recruitment should begin at any Site until the CI/PI has received written confirmation of this from the Site R&D Office in the form of a confirmation of capacity and capability.

The signed Initiation Report and Site Initiation Attendance Log will be filed in the Sponsor file in the R&D Unit, together with any completed Action Lists. A copy of the Report, completed Action Lists and Attendance Log will be provided to the Investigator for inclusion in the ISF.

4.5 Interim Monitoring Visit

4.5.1 Prior to an Interim Monitoring Visit

The CI/PI and Monitor will initiate arrangements in line with the timing of visits set out in the Monitoring Plan.

The Monitor will check the elements of the Interim Monitoring Report to be covered, in line with this SOP and the Monitoring Plan.

4.5.2 During an Interim Monitoring Visit

Specific requirements for CI/PI availability may be specified in the Monitoring Plan, based on the risk assessment for the trial. It is not essential to meet with the CI/PI at every monitoring visit; however key communications should be made available to the CI/PI. If findings raise quality or safety concerns, these should be addressed with the CI/PI in person wherever possible. If not possible during the monitoring visit effort should be made to contact the CI/PI following the visit.

Site personnel are expected to provide the Monitor with working space and general assistance. A Monitoring Visit log will be signed by the Monitor and one member of staff at site to confirm each Monitoring Visit and it will be retained in the TMF/ISF.

During the Visit the Monitor will use Checklist and Forms (See Section 5) as required. The investigator site must maintain an up to date log of all SAEs using R&D/F46. This log will be reconciled with the Sponsor's log during trial monitoring at each interim monitoring visit, unless the monitoring plan specifies differently.

Also, a log and documentation of any identified Protocol/GPC breaches should be reviewed at every interim monitoring visit. The Monitor will report to the Sponsor, within 24 hours of becoming aware of any individual events, or series of events that s/he considers may be a Serious Breach of the Protocol, GCP or other urgent issues the Sponsor should review carefully.

4.5.3 Following the Interim Monitoring Visit

As soon as possible after the Visit the Monitor will complete the Draft Interim Monitoring Report, and any Draft Action Lists required to be given to the Site

and the Sponsor, using the appropriate forms (see Section 5). This will be done within two weeks of the Visit unless this is impossible for some reason, in which case the Monitor will agree another due date with the Sponsor representative.

Following review of the Draft Report the Sponsor representative may ask the Monitor to add items to the Action Lists before issuing them to the Site. The CI/PI/other person specified to carry out actions will ensure these are done within the stated time and return all signed Action List(s) to the Monitor in confirmation.

The Monitor will inform the Sponsor representative if there are problems in relation to completion of Action Lists so the Sponsor representative can manage use of time taken to resolve issues and arrange for R&D Unit support where this will be cost-effective for the Sponsor.

When any required actions have been completed the Monitor will present the final version of the Report to the Sponsor representative for signing off on behalf of the Sponsor. The signed Report will be filed in the Sponsor file in the R&D Unit, together with completed Action Lists. If required, a summary Report may be provided to the CI (and PI if a participating Site). Interim Monitoring Visit Log & Copy of completed Action Lists will be filed in the TMF/ISF. Completed Monitoring checklists will be filed electronically and stored on the 'X drive' (Applied Learning and Research).

If required a copy of the signed report and action lists, or summary report, for all participating Sites can be provided to the Chief Investigator for Multicentre Trust Sponsored Studies.

4.6 Close-Out Visit

4.6.1 Prior to the Close-Out Visit

When it is known when the final participant contact at any Site will occur the CI will make arrangements for the Monitor to conduct a Close-Out Visit to that Site. When all participants' contacts has ceased across all Sites, the CI will arrange for the Monitor to conduct a Close-Out Visit at the CI Site, in relation to the TMF and the whole trial.

The CI will inform PIs in advance that a Close-Out Visit is due and will arrange a suitable date. The Close-Out Visit will include full scrutiny of the TMF/ISF, ensuring that any separate elements at Site are brought together for archiving, in addition to final IMP reconciliation, collection of randomisation codes (if specified in the Monitoring Plan) and checking of archiving arrangements.

4.6.2 During the Close-Out Visit

Site personnel are expected to provide the Monitor with working space and general assistance. A Site Pharmacy representative (for CTIMPs only) must be available when the Monitor visits pharmacy as part of the close down visit. .

The Monitoring Visit Log will be signed by the monitor and a Site representative present at the Close-Out Visit and should be retained in the TMF/ISF.

During the Visit the Monitor will use the Trial Close-Out Report and other checklists as required (See Section 5).

The Monitor will report to the Sponsor, within 24 hours of becoming aware of them, any individual events, or series of events that s/he considers may be a Serious Breach of the Protocol, GCP or other urgent issues the Sponsor should review carefully.

4.6.3 Following the Close-Out Visit

As soon as possible after the visit the Monitor will complete the Draft Close-Out Visit Report and any Draft Action Lists required to be given to the Site or the Sponsor, using the appropriate forms (see Section 5). This will be done within two weeks of the visit unless this is impossible for some reason, in which case the Monitor will agree another due date with the Sponsor representative.

Following review of the Draft Report the Sponsor representative may ask the Monitor to add items to the Action Lists before issuing them to the Site.

The CI/PI/other person specified to carry out actions will ensure these are done within the stated time and return all signed Action List(s) to the Monitor in confirmation.

The Monitor will inform the Sponsor representative if there are problems in relation to completion of Action Lists so the Sponsor representative can manage use of time taken to resolve issues and arrange for R&D Unit support where this will be cost-effective for the Sponsor.

When any required actions have been completed the Monitor will present the final version of the Report to the Sponsor representative for signing off on behalf of the Sponsor. The signed Report will be filed in the Sponsor file in the R&D Unit, together with any completed Action Lists. If required, a summary Close-Out Report may be provided to the CI (and PI if a participating Site). Close- out Visit Log & copy of completed Action Lists will be filed in the TMF /ISF. Completed Monitoring checklists will be filed electronically and stored on 'X drive' (Applied Learning and Research).

4.7 Remote/Central Monitoring

Where appropriate remote/central monitoring will be used for Trust Sponsored Multicentre Studies, using the appropriate checklist (see Section 5) the use of remote/central monitoring will be determined by the risk assessment. In some instances this type of monitoring will supplement on-site visits and not be used as a replacement, however there may be instances where this is the sole method of monitoring, in either case the decision will be fully documented in the monitoring plan and supported by the risk assessment. The nature and breadth of remote monitoring will be study specific but as a minimum will include:

- Version control checks on all documents
- Provision of updated CVs & GCP certificates where required
- Provision of pseudo anonymised screening & enrolment logs
- Provision of file note logs
- Investigator Site File maintenance checks

4.8 Communications

The Monitor will:

- Report to the Sponsor representative according to the timelines indicated above.
- Provide Action Lists to the Site and/or Sponsor as required.
- If there are difficulties resolving Action List issues, inform the Sponsor representative and proceed only on the basis of specific agreement.

The Sponsor representative will:

- Sign reports within 2 weeks of receipt.
- Where there are difficulties resolving Action List issues, discuss specific arrangements with the Monitor.
- Report any unresolved problems to the R&D Group.

The CI/PI or others responsible for carrying out actions identified in monitoring will attend to these in the timescales specified and provide signed confirmation of completion to the Monitor.

5 Related SOPs and Documents

R&D/S02	Application to Trust for sponsorship of a CTIMP
R&D/S04	Breaches of GCP or the Study Protocol
R&D/S03	Delegation of Tasks for Trust Sponsored Research Studies
R&D/S09	Set Up and Management of Research Studies
R&D/S21	Trial Close-Out
R&D/T03	Monitoring Plan Template
R&D/F14	Initiation Report
R&D/F95	Trial Master File Contents
R&D/F11	Investigator Site File Contents (Hosted studies)
R&D/F70	Site Initiation Attendance Log
R&D/F17	Monitoring/Audit Visit Log
R&D/F65	Monitoring Checklist
R&D/F64	Source Data Verification (SDV) Form
R&D/F99	Informed Consent Checklist
R&D/F98	Medical Records Checklist
R&D/F10	Interim Monitoring Report
R&D/F69	Monitoring/Audit Summary Report
R&D/F66	Monitoring/Audit Action List
R&D/F19	Trial Close-Out Report
Pharm/F97	Pharmacy Monitoring Form
R&D/F13	Laboratory Audit Checklist
R&D/F78	Investigator Site File Remote Monitoring Checklist
R&D/F88	Pharmacy Site File Remote Monitoring Checklist