**MONITORING PLAN**

STUDY TITLE:

[Insert]

Short title [insert]

**R&D Ref-**

**Chief Investigator- [insert]**

**Sponsor- [insert Barts Health NHS Trust/Queen Mary University of London]**

Revision history:

|  |  |  |  |
| --- | --- | --- | --- |
| Version | Date | Event | Changes if needed |
| 1.0 |  | Study confirmation of sponsorship | N/A |
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**Abbreviations:**

|  |  |
| --- | --- |
| AE | Adverse Event |
| CE | Conformité Européenne |
| CI | Chief Investigator |
| COV | Close Out Visit |
| CRF | Case Report Form |
| CTIMP | Clinical Trial of an Investigational Medicinal Product |
| CTU | Clinical Trial Unit |
| GCP | Good Clinical Practice |
| HRA | Health Research Authority |
| HTA | Human Tissue Authority |
| IB | Investigator’s Brochure |
| IMP | Investigational Medicinal Product |
| ISF | Investigator Site File |
| JRMO | Joint Research Management Office |
| MHRA | Medicines and Healthcare products Regulatory Agency |
| PI | Principal Investigator |
| PSF | Product Specification File |
| PV | Pharmacovigilance |
| RA | Risk Assessment |
| REC | Research Ethics Committee |
| SAE | Serious Adverse Event |
| SDV | Source Data Verification |
| SIV | Site Initiation Visit |
| SmPC | Summary of Product Characteristics |
| SOP | Standard Operating Procedure |
| SUSAR | Suspected Unexpected Serious Adverse Reaction |
| TMF | Trial Master File |

INSERT study specific abbreviations as needed

# 1. Introduction

This Monitoring plan’s objective is to clarify the process of Monitoring that will occur for the above-named study and to ensure that:

* The rights and well-being of study subjects are protected
* The reported data are accurate and complete
* The conduct of the study is in compliance with the protocol, Good Clinical Practice (GCP), and applicable regulatory requirements; and the site continues to be acceptable to conduct the study.

Monitoring procedures have been determined and based on considerations of the risk assessment (RA)which was risked as <Insert Risk here>. Refer to risk the assessment form for details of the studies risk and mitigations.

**All** Monitoring conducted within the trail should be conducted in line with Sponsor Standard Operating Procedure (SOP) 28 Monitoring and all Associated Documents (SOPs *available on the Joint Research Management Office (JRMO) website)*. Any modifications should be agreed in writing and documented below:

Study Information: please complete

|  |  |
| --- | --- |
| **Study Phase** |  |
| **Investigational Medicinal Product (IMP) Risk Adapted Category, based on marketing status and standard medical care** | *Type: A/B/C (delete as appropriate – GCP Manager to complete* |
| **Sponsor’s RA** |  |
| **Study Type** | *Clinical Trial of an Investigational Medicinal Product (CTIMP)/Non-CTIMP/Radiotherapy/CE-marked device/non-* *Conformité Européenne (CE) marked device* |
| **Number of UK sites** | *(Include any caps in place)* |
| **Number of International site (if applicable)** |  |
| **Total No. of Sites** |  |
| **Number of Patients to be recruited** |  |
| **Approx. start date** |  |
| **Planned Recruitment Period** |  |
| **Length of Treatment Period** |  |
| **Length of Follow-up Period** |  |
| **Study Database to be used** |  |
| **IMP Storage** | *In-pharmacy/out-of-pharmacy storage*  *(Delete as appropriate*) |
| **Randomisation process** |  |
| **Central Lab location (if applicable)** |  |

# 2. Risk adapted monitoring strategies:

These may be based upon IMP risk categorisation (Type A, B and C) or the risks associated with study conduct by examining the study design, Chief Investigator (CI) and coordinating team, population and procedures to identify specific areas of vulnerability and to determine how any risks can be mitigated.

*Please insert any risk adapted strategies and mitigations that are in place or will be utilised for this study; these are listed as part of the RA. Please determine where source data will be held (including screening and enrolment data) and consider this when deciding what level of monitoring will be required. The source documentation must have been suitably risk assessed regardless of format; PowerChart has been risked assessed and determined to be suitable to contain source documents for regulated trials. If the trial team intend to use any other systems to hold source data (e.g., Bespoke systems such as local Excel spreadsheet) they must first perform a full risk assessment to determine the suitability of the system.*

# 3. Monitoring type:

Studies monitored directly by the JRMO will consist of on-site visits. Studies monitored by other research groups will consist of on-site monitoring but may utilise a mixture of on-site and central monitoring.

On-site visits will be conducted by <Insert Delegates role > and will allow for the data to be verified against source documents, ensure essential documents are present in the Investigator Site File (IS, that drug or product is delivered, stored, dispensed, and disposed of properly, and that equipment and resources are adequate and used correctly. The onsite Monitoring tool is based on the current Sponsor Monitor tools and changes have been agreed by the relevant GCP manager (delete as needed).

Centralised (remote) Monitoring will be conducted as per this plan by a named delegate of the CI’s team and will allow the CI and Sponsor to maintain oversight of the studies. The central Monitoring delegate will be listed on the study delegation log, GCP trained, and trained in the use of the central Monitoring tool. See appendix B for the centralised Monitoring details (Please insert here if central Monitoring is to be used or delete if appropriate).

The following study oversight committees will be held: <Insert Committees – e.g., Trial Management Group, Data Monitoring Committee , and Trial Steering Committee \*> See SOP 46 – Trial Committee for guidance and templates charters. Trial committees will meet in accordance with their charters.

# 4. Monitoring Scope and schedule:

Based on the RA the study will be monitored as follows (edit as required the text below). The Sponsor (JRMO) reserves the right to request that additional or triggered Monitoring activity be conducted during the duration of the study if required (Please see JRMO SOP 28 - Monitoring).

**Timing and Frequency of Monitoring Visits**

The frequency of monitoring visits is determined by a RA of the study (see SOP - SOP 23 - Risk assessment) and GCP Manager judgement.

The first monitoring visit following initiation of the site and study commencement will take place within approximately ………. weeks after the inclusion of the first patient (First consent of patient). Subsequent Monitoring visits will take place every ………. weeks.

The interval for Monitoring visits may be longer or shorter than stated above, dependant on subject enrolment rate, quality issues, study site compliance or other study site issues.

Any significant deviation from the planned Monitoring timelines will be explained and documented in the monitoring visit report, reported to the JRMO and the Monitoring plan amended if appropriate. Failure to adhere to the monitoring plan is a breach of Sponsor-CI agreements and may result in the Study being halted or closed.

If the site does not enrol any patients or enrolment has stopped, regular monitoring visits may be postponed. If there is an extended gap in study activity the Monitor should ensure that site staff are appropriately trained when study activities recommence.

**Monitoring Schedule for Sites:**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | **Site Initiation Visit (SIV)** | **Monitoring Visit (Monitoring Visit) V1** | **Monitoring Visit 2+** | **Close Out Visit (COV)** |
| **Trial Master File (TMF)** | N/A (TMF checked at confirmation of sponsorship) | On-site (yearly) | On-site (yearly) | N/A (TMF checked prior to archiving) |
| **Site 01** | On-site | On-site1 | On-site/ Central2 | On-site3 |
| **Site 02** | On-site | On-site1 | On-site /Central2 | On-site3 |
| **Site 03** | On-site | On-site1 | On-site/ Central2 | On-site3 |
| **Lab\* (in more than 1 lab insert line for each lab)** | N/A | On-site (yearly) | On-site (yearly) | N/A |
| **Site Management Organisation/ /Contract Research Organisation** | Per contract | Per contract | Per contract | Per contract |
| **IMP Provider**  (Note here if IMP Provider has been delegated Pharmacovigilance (PV)) | Per contract | Per contract | Per contract | Per contract |
| **Clinical Trials Unit (CTU)**  See Conditions of Sponsorship to assess what has been delegated to the CTU | Per conditions of sponsorship | Per conditions of sponsorship | Per conditions of sponsorship | Per conditions of sponsorship |
| 1, Monitoring Visit 1 should be 4 weeks from the date of the first patient consented +/- 1 week  2. Monitoring Visit 2+ should be6 months after the previous Monitoring Visit +/- 1 month  3. COV should be 3 months after the last patient last visit +/- 1 month | | | | |

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If there are any new sites to be added, this plan will need to be amended and agreed to by the GCP Manager.

# 5. Site Initiation Visit or Meeting:

The SIV will be conducted in line with Sponsor SOP 46 - [Site selection, initiation and activation](http://www.bartshealth.nhs.uk/media/295433/SOP%2046%20Site%20activation%20v1%20for%20website.pdf)

Associated document 1: [Site level feasibility assessment guidance](http://www.bartshealth.nhs.uk/media/295441/SOP%2046%20Site%20activation%20AD%201%20Site%20Level%20Feasibility%20Assessment%20Guidance%20v1.pdf)

Associated document 2: [JRMO SIV checklist template](http://www.bartshealth.nhs.uk/media/295445/SOP%2046%20Site%20activation%20AD%202%20SIV%20presentation%20template%20v1.0.ppt)

Associated document 3: [JRMO SIV presentation template](http://www.bartshealth.nhs.uk/media/295449/sop%2046%20Site%20Activation%20AD%204%20%20Site%20Initiation%20Visit%20Report%201.0.doc)

The purpose of the SIV is to ensure the investigator and site staff are familiar with study documentation, investigational medicinal product/s, accountability and verification of the clinical supplies to be supplied to the site (e.g. IMP Management or tissue kits), medical device or equipment (if applicable), administrative procedures and that they are aware of the investigators responsibilities regarding compliance with the clinical protocol and the care of study subjects. The CI/delegate will be conducting the SIV.

Evidence of the SIV and materials used will be filed in the TMF and Investigator Site File (ISF) as evidence of the SIV.

The following people will be present at the SIV: INSERT HERE Principal Investigator (PI), Pharmacy, and Research Nurse etc. (NB The pharmacy SIV can if needed due to other commitments be held separately). The SIV will be in a face-to-face setting.

The following site/investigator training will be conducted: Detail type of initiation to be conducted (e.g., launch meeting with PowerPoint, video conference). List any training tools to be used (e.g., presentations, attendance logs)

Set out site activation procedure See SOP 46, Site selection, initiation and activation associated document 1-3. Alternatively refer to SIV checklist that will be used)

Note that the report is to be signed by the person who performed the SIV and also a reviewer. The reviewer(s) for this study is <insert role and title>. \* This should be a senior role within the team or the GCP manager.

Copies of all SIV reports will be emailed to [research.governance@qmul.ac.uk](mailto:research.governance@qmul.ac.uk) after report sign off, or the SIV report should be logged in the quarterly monitoring summary report to the JRMO.

# 6 Monitoring

## 6a. On-Site Monitoring at site level:

All on site ISF Monitoring visits will include a visit to the Pharmacy, or out of pharmacy storage (delete as necessary see RA and Sponsor’s pharmacy approval).

The PI will be met at each visit, where not possible, the PI should be spoken to via the telephone. The PI must be sent a copy of their site’s monitoring report to ensure PI Oversight.

Monitoring visits are to cover:

(a) Source data chosen for review\*

(b) Review of investigational product procedures

(c) Review of adverse event procedures

(d) Review of subject enrolment responsibilities

(e) Discussion of study personnel, equipment and facilities

(f) Meeting with members of investigator’s team to discuss site-related issues

(g) Review of essential document maintenance (TMF/ISF/Laboratory or Pharmacy file)

(h) Discuss any deviations or protocol violations with investigator and take action as appropriate (e.g., amendments, inform Sponsor, CI)

Copies of all reports should be emailed to research.safety@qmul.ac.uk after report sign-off or logged in the quarterly monitoring summary report to the JRMO.

**As part of Source Data Verification (SDV) and reviewing the data collected the monitor will check:**

* The data required by the protocol is reported accurately in the Case Report Forms (CRF)and that the data is consistent with the source documents.
* The data is entered in a timely fashion and signed off by the PI or delegate in the studies electronic and/or paper CRFs and database if applicable.
* Any dose and/or therapy modifications are within the protocol guidelines and accurately documented for each of the study subjects.
* Concomitant medications and concurrent illnesses are reported in accordance with the protocol and recorded in the CRFs and source data.
* Missing Data: If any subjects have failed to attend any visits, or if tests or examinations have not been conducted according to the protocol, ensure this is clearly reported in the CRFs and deviation log.
* Withdrawn patients are reported in the enrolment log and CRFs and followed up as applicable.
* Any reports of pregnancy for study participants’ or partners’ have been recorded and followed-up in the CRFs and reported to the JRMO in accordance with *SOP 26a - Pharmacovigilance and safety reporting for sponsored ATIMPs/CTIMPs*.
* Any Adverse Events (AE)/Serious Adverse Event (SAE) have been recorded and followed up in the CRFs and reported to the JRMO in the timeframe required.
* Study specific equipment, devices, and software have been validated/calibrated and maintained.
* The CI and PI have signed every version of the protocol.

Correct versions of study documents such as consent forms and GP letters have been used and have been completed correctly.

**The SDV plan for this study is as follows:***Indicate what source data will be reviewed, the %, and list key data to be used. Reference any checklists to be used.* A list of source data is found in the ISF.

|  |  |  |
| --- | --- | --- |
| **Source Data Monitoring** | **Amount** | **Comment/Guidance** |
| **Consent Forms/process** | 100% For all subjects on the  screening log | Request source notes from sites to review the documented consent process. |
| **Eligibility** | 100% of subjects enrolled/randomised  (Not for screen fails) | Request source notes to review the documented consent process.  *Phase 1 Healthy Volunteer studies only: check ID participant (i.e., passport as ID not verified in the medical notes). Also check whether GP has contacted re. healthy volunteers medical history to confirm eligibility (as no medical notes)* |
| **Safety Reporting** | For all / 10% SAE and all Suspected Unexpected Serious Adverse Reaction (SUSAR) perform SDV to ensure presence of full and accurate source data | Ensure SAE/SUSAR forms, Case Report Forms and Source are consistent. |
| **End point or outcome data** | Insert % amount | Insert what the End Point or Outcome data points for this study are |
| **CRF/Visits ( all visits)** | For 10% of the subject sample, for each subject review the complete CRF.  Specify : study specific documents i.e., Quality of life questionnaires and  Patient diaries  This includes all source data for identification of adverse events. Ensure all recorded events have appropriate source data. Ensure all events are recorded and assessed.  Note a minimum of 1 subject-per site. | This can be completed over a number of Monitoring visits.  (Including printed reports with clinical significance assessment.  Are any study specific documents used as per Research Ethics Committee (REC) approval letter / amendments? |
| **Computer Systems** | List computer systems here: | Consider if there are any support department (imaging/pharmacy/pathology)  Computer systems have been verified that are central for primary end points, data integrity or patient safety.  Systems used to transfer images or data across sites. |

**Pharmacy will be visited at each on-site Monitoring visit.**

The IMP for this study is stored in pharmacy/out of pharmacy (delete as appropriate). The Monitor will check compliance by referring to the to the protocol, IMP Management Plan, Investigator Brochure (IB), Summary of Product Characteristics (SmPC/s), Label, IMP Management Plan)

|  |  |  |
| --- | --- | --- |
| **Pharmacy/IMP monitoring** | **Monitoring Required** | **Guidance** |
| **IMP Accountability and Tracking Expiry Dates** | Pharmacy will be visited at each visit to site.  100% of IMP accountability checks will be performed. | The Monitor is responsible for checking the IMP accountability and IMP reconciliation of the IMP both at individual (amount dispensed/used/returned by subject) and site level (total delivered, used, unused, and returned/destroyed by study site).  The Monitor will also check that the IMP is being stored and handled according to the requirements of the protocol information (IB, SmPC, Label, and IMP Management Plan). |
| **Destruction of the IMP**  *.* | The Monitor will verify accountability and reconciliation prior to destruction.  Describe here what will be done with used / unused IMP at the site and what must be verified. If IMP is to be returned to an external partner/provider, insert terms of returns as stated in IMP agreement full instructions for IMP return | Destruction of IMP should not occur until accountability has been completed and approval for destruction given by the Chief Investigator and the Sponsor Representative i.e., JRMO Interim accountability and destruction may be permitted.  See SOP 42a: IMP Management Sponsored MHRA-Regulated studies for pharmacy involvement in IMP destruction |

6b. Remote monitoring [delete if not relevant to the study]

When on-site monitoring cannot be achieved due to country or local level access restrictions, for example, the COVID-19 pandemic or other natural disaster, then remote monitoring may be initiated where applicable.

Details of remote monitoring processes may vary from site to site and will be recorded in the SIV report. A remote monitoring process for each site must be agreed prior to their activation. Remote monitoring should be facilitated and source data made available through secure access in accordance with Sponsor (<http://www.jrmo.org.uk/news-and-training/covid-19>), Health Research Authority (HRA), RA (<https://www.hra.nhs.uk/covid-19-research/covid-19-guidance-sponsors-sites-and-researchers>) and Medicines and Healthcare products Regulatory Agency (MHRA)HRA guidance (<https://www.gov.uk/guidance/managing-clinical-trials-during-coronavirus-covid-19>) including any further guidance which may be published from time to time. For non-UK sites, any local guidance and requirements must be followed.

SDV)will only be carried out remotely if source data can be made available through secure access in accordance with MHRA1 and HRA2 guidance and an agreement is in place with the site to do so. As per this guidance:

* Direct access to patients’ e-Health Records away from the site creates issues around confidentiality. Records must not be accessed in an open plan office, public space or other location where others who are not authorised could view sensitive information. Access from home can be acceptable, provided that there is somewhere private that this can be done, away from family etc. The device through which this is accessed must have adequate security, such as adequate firewalls, secure log-in and passwords etc, and must not be left unattended and accessible.
* There should be explicit instructions from the sponsor and the host organisation (with input from their Caldicott Guardian) as to what can be accessed where and an agreement from the monitor that this will be complied with. The instructions should not allow printing, emailing or downloading of any records, or that this is disabled by the system.
* Trial participants will need to consent to any identifiers leaving the site and be assured that their confidentiality will be protected.
* It is likely that there will be increased pressures on clinical staff during this period, so it is important to make sure that extra burdens are not placed on investigators around scanning and uploading many documents.
* The use of alternative means of oversight such as teleconferences/videoconferences is encouraged.

If SDV cannot be performed remotely it should be prioritised at the next onsite monitoring visit. During such exceptional events it is anticipated that site ability to provide access to remote monitoring will vary, therefore flexibility with regard to nature and scope of remote monitoring should be expected and decided on a per site basis. An example of the scope of remote monitoring activities is detailed below:

Where possible, complete remote source data verification to include the following activities:

* The existence and eligibility of enrolled patients. For example, by receipt of anonymised pathology, radiology or lab reports.
* IMP delivery to site. For example, by review of accountability logs and completed IMP receipt documentation.
* Verification of data directly related to study end points.
* Verification of reported AEs/ SAEs and concomitant medications. For example, by receipt of anonymised AE and concomitant medication logs.
* Tissue sample collected and transfer. For example, by remote review of completed sample transfer forms and sample collection logs.
* Verification of reported protocol deviations/ violations

Verify that the site staff have access to the necessary documentation to conduct the trial via remote ISF/Product Specification Fil e (PSF) documentation reviews:

* Documents from sponsor:Site and pharmacy should be sent a list of all new documents distributed and implemented since the last monitoring visit or SIV and confirm that these have been filed in the ISF/PSF.
* Documents from site and pharmacy: Site and pharmacy will be requested to email copies of documents which would have been requested by the monitor for the TMF as a matter of course at the visit. These may include but are not limited to:

1. Recruitment and enrolment logs [NB: Patient identification logs must not be sent].
2. Deviation Log
3. Sample Inventory
4. Sample storage temperature records
5. Delegation log
6. CVs and GCP certificates (if renewed and for new starters)
7. IMP storage temperature records
8. IMP accountability logs
9. IMP destruction certificates/logs
10. Documents to enable remote SDV (e.g., verification of reported adverse events by receipt of anonymised AE logs)

The above documentation should be reviewed remotely and filed in the site section of the TMF as appropriate.

Suitable delegated staff should be available to be contacted during the visit and to conclude the visit, a telephone or video call should be held with the relevant site staff and PI to provide feedback. A monitoring report should be issued as per usual procedure.

During such exceptional events it is anticipated that site ability to provide access to remote monitoring will vary, therefore flexibility about nature and scope of remote monitoring should be expected and decided on a per site basis. Guidance provided by the MHRA and HRA is also subject to frequent updates, and this shall be reviewed and communicated to participating sites on an ongoing basis by the XXXXXXXXXX study team.

6c. Central Monitoring **[delete if not relevant to the study]**

See appendix B for the centralised monitoring details. The results of central monitoring of the clinical data will be included in the central monitoring report. Copies of all central Monitoring reports will be emailed to [research.governance@qmul.ac.uk](mailto:research.monitoring@bartshealth.nhs.uk) after report sign off, or the central Monitoring report should be logged in quarterly monitoring summary reports to the JRMO (see section). The purpose of centralised monitoring is to maintain oversight of site activity.

The CI must inform the JRMO of any concerns in study management when submitting reports.

**Please use the below table to outline the central monitoring that will be performed or delete if not in use.**

|  |  |  |
| --- | --- | --- |
| **Type of Central Monitoring** | **Monitoring Activity and Frequency** | **Responsibility (insert role)** |
| Checks for missing or inconsistent or invalid data | Specify key data to be  checked and frequency |  |
| Raise discrepancy and  chase resolutions |  |  |
| Track timely completion of CRFs |  |  |
| Periodic review of SAE Reporting | Specify key data to be  check and frequency  Indicate whether cross site checks of SAE data is to be performed |  |
| IMP accountability | Indicate whether IMP accountability records are to be collected sites and frequency at which this is to be done  Detail checks to be  performed |  |
| Study Database | Is the Study Database being updated in a timely manner? | \*See SOP 38B Trial Data Management-Systems for required Study Database approvals |
| CRFs | A data base check for accuracy of data entry will be performed at………. (Insert time points agreed with CI).  The X% of CRFs will be checked and the following data points to be checked:   * End point data * Insert others as applicable   Optional text to be used if the CRFs must be sent to another site or external data management company: INSERT HERE | The monitor will ensure that the appropriate edit practices are being followed.  All CRFs monitored during a visit will be detailed in the Monitoring Visit Report. |

# 7. Monitoring for vendors

## 7a. Laboratory Monitoring

***All non-commercial UK based*** *central laboratories will be monitored.*

*NHS labs that are performing tests that fall within their United Kingdom Accreditation Service (UKAS) accreditation will require minimal Monitoring oversight. However, if they are performing test that are outside of the UKAS these will be monitored.*

Laboratories in use for this study: (insert list)

Samples will be transferred to (insert each lab) from each site / X site.

At the end of the study the participants have consented for their samples to be used in future ethically approved research/transferred to a Human Tissue Authority (HTA) lab/destroyed (delete as appropriate – see protocol and REC approved docs.)

Further details on sample management can be found (insert sample management plan and location i.e., TMF/Laboratory file).

The monitor will meet with the lab manager at each visit and will send a copy of the monitoring report will be sent to them to ensure their oversight of the labs compliance and performance. The Monitor will verify that the protocol requirements have been met regarding timing, storage, shipping and documentation of biological samples.

Detail here what checks of samples records are to be made that are critical to the protocol (i.e., samples that are critical to eligibility, end points or safety). See Lab Monitoring form for guidance.

**Insert other central facilities (e.g., central imaging review)**

# 8. Routine Summary Monitoring Reports to the Sponsor (JRMO)

CTIMPs that are Monitored by other parties i.e., not by the JRMO, must provide the Sponsor with regular summary reports.\* Timelines are to be agreed with the GCP Manager.

For this study summary reports will be submitted at XXXXXX intervals, from first SIV to last COV.

Summary reports will be reported to the research.governace@qmul.ac.uk.

These reports will be submitted reviewed by the GCP team and escalated to the Sponsor Oversight Group as part of Sponsor oversight of the studies performance and compliance.

N.B – this is N/A for CTIMPs where all sites are monitored by the JRMO

# 9. Close Out Visit :

The monitoring of study closure will comply with the following Sponsor SOPs:

SOP 18a - Study closure: guidance for research staff of sponsored studies

SOP 19 - Study closure: guidance for JRMO staff

SOP 20 - Archiving for research studies

COVs will occur when recruitment to the study has been completed at the site and all patient visits are complete (including any follow-up) All COV must be conducted within 3 months of the end of study notification being submitted.

The COV will cover:

* A review/discussion regarding consent forms - to ensure correct completion
* A review of all ISFs, PSF and the TMF to ensure the necessary study closure documentation has been completed/filed
* A review of the end of study notification submissions to the MHRA and the ethics committee
* Safety reporting and documentation relating to any Serious Adverse Events (SAEs) that have occurred in the study to ensure that any SAEs have been reported and followed up appropriately
* All data queries raised from the CRF resolved (clean data)
* Samples transferred to a HTA tissue bank or destroyed
* Equipment – list any supplied equipment and how the Monitor will verify its return
* Finances completed
* Archiving discussed (25 years is the Sponsor policy at all sites – See SOP 20 - Archiving for research studies), including (Technical Support Documents) TSD and ISF
* IMP return and destruction
* Final communications arranged in order to maintain future contacts between the Sponsor and the site (esp. for the destruction of study records)

All signed reports will be processed and sent out as per monitoring visit reports

Reports should be completed and signed within 2 weeks of the visit and sent to the above-named parties within one week of sign off.

|  |  |  |  |
| --- | --- | --- | --- |
| **Role** | **Print Full name** | **Signature** | **Date** |
| **Chief Investigator** |  |  |  |
| **Research Governance and GCP Manager** |  |  |  |