|  |  |  |  |
| --- | --- | --- | --- |
| Form number | **Form 53.010A** | Version  | **7.0** |
| Title | **Monitoring Plan for a Clinical Trial of an Investigational Medicinal Product/Medical Device Investigation** |

|  |  |
| --- | --- |
| R&I Reference |  |
| Study title |  |
| Chief Investigator |  |
| Version and Date |  |

In accordance with the MHRA Guidance on the Risk-adapted Approaches to the Management of Clinical Trials of Investigational Medicinal Products (CTIMPs) – version: 10th October 2011, this trial/medical device Investigation <<delete as appropriate>> is classed as a category <<X>> study as determined by the Sponsor Risk Assessment (Form 51.004A). The Monitoring Risk Assessment (Form 53.010B) will ensure the category is reflected within this assessment.

The Monitoring Risk Assessment deems this trial/medical device investigation to be a <<enter risk level e.g. high, medium or low>> risk and from a monitoring perspective a score of <<enter>> following a monitoring risk assessment (please refer to Form 53.010B)

The monitoring plan was produced using:

|  |  |
| --- | --- |
| Document | Version |
| Protocol |  |
| Sponsor Risk Assessment |  |
| Monitoring Risk Assessment |  |

**(For consideration of any subsequent versions of the above documents see Form 53.010C)**

The plan will encompass risk mitigation to ensure Sponsor oversight and mitigate the risks of the study and is subject to review and updates throughout the course of the trial. To document additions or small changes to the Monitoring Plan, a Monitoring Plan Addendum may be used, as appropriate, and the relevant versions of the above mentioned documents reflected.

The main risks identified from the Sponsor risk assessment (Form 51.004A) and the monitoring risk assessment (Form 53.010B) of this study are outlined below:

|  |  |
| --- | --- |
| **RISK** | **RISK MITIGATION** |
|  |  |
|  |  |
|  |  |
|  |  |

Key Data has been discussed with the Chief Investigator and Statistician and the monitor will focus on the below data points:

|  |  |  |  |
| --- | --- | --- | --- |
| **Data Points** | **Affecting Primary or Secondary Endpoints** | **CI Signature and Date** | **Statistician Signature and Date** |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

**The following objectives will be achieved in throughout this monitoring plan:**

**Monitoring Objectives (to be selected as applicable)**

* X% review of Informed Consent Forms and processes
* X% Eligibility assessment and documentation
* X% review of all Serious Adverse Events reported
* Source Data Verification for X% of all recruited trial subjects (X in total; chosen at random)
* Primary and secondary data endpoints compliance and verification.
* IMP management and accountability
* Collection and Processing of Lab Samples (% check if primary/secondary endpoints)
* Device review/ accountability/ storage facilities
* X% Serious Adverse Device Events and Device Deficiencies
* Imaging – presence check, ensure imaging department are QC’ing during trial (not CTM responsibility)

**Central Monitoring**

(if applicable - state what risks will be mitigated through central monitoring) (also ensure to state that central monitoring is not undertaken by responsible data centre if not done).<instruction to not leave empty and check Sponsor Risk assessment for detail>

Central Monitoring will be reviewed and agreed with the Responsible data Management Centre prior to any review. Monitors will review central monitoring ahead of any planned visit or if the CTM is unable to travel due to restrictions on travel. Review of the data management system including timelines, missed entered data and no data fields. Informed consents will also be reviewed remotely on the data management system, if applicable. AEs and SAEs will be reviewed for outcome. This type of monitoring will highlight any data quality issues, data trending or outliners, the number of protocol deviations and number of SAEs reporting rates. Trial stakeholders should be reminded that data monitoring is the responsibility of all, including the CI, PMs, PV, data centre, TSC and IDMC (as applicable).

Throughout the XXXXX duration of the study the Monitors will aim to complete XXXX visits as follows:

**A Site Compliance Visit (SCV)**

**Justify what the perceived risks of the study are and what will happen to mitigate these risks, refer to both risk assessments. Will all sites receive one or will a selection be done and if no issues then not required? <If trial has large number of sites, pragmatic approach can be utilised i.e. 10% sites>**

**Full Monitoring Visit**

**When will this take place and why, Justify as per the monitoring objectives above the perceived risks of the study are and what will happen to mitigate these risks, focus on trigger point as to when the first visit will take place what should be reviewed at this visit and why, document what will be covered for example the following:**

* Investigator Site File, Pharmacy Site File review
* Protocol Deviations
* Delegation Log review
* Site Training Logs review
* SAEs and Medical device Reporting requirements
* Issues identified prior to the visit
* Archiving, who will be responsible, who is

**<< Concentrate on key data and what visits will affect the primary/secondary endpoints - Refer to risk assessment >>**

**Subsequent Full Monitoring Visits**

**When they will take place (if applicable) Justify what the risks are, e.g. what are the primary and secondary endpoints, SDV of them.**

**Pharmacy Visit**

**External Central Lab** (delete if not applicable)

Will a lab visit be required, who will undertake this.

**Imaging Department** (just note if not applicable)

Will any Imaging be required in the study, does this affect the primary endpoint? Will a visit be required, CTM doing a presence check, not comparing. CTM may want to check Imaging department is performing QC on images uploaded

**Close Out Visit**

This will take place after the last patient has completed their participation at site but sites can be closed during the trial if the Trial stakeholders are in agreement i.e. slow recruiter, PI retires etc. This visit will ensure the ISF and PSF are complete; all regulatory requirements have been met, including resolution of data queries and conclusion of Serious Adverse Events; all actions arising from previous visits have been resolved; and the study documents are archive-ready. This visit will also be used to complete the monitoring objectives stated above if necessary

Additional visits will be performed where necessary if requested by the Lead Clinical Trial Monitor, Research Governance Manager or the Chief Investigator.

**Visit Attendance**

The Monitors will endeavour to arrange visits where possible, to meet the Principal Investigator (or Pharmacist when visiting Pharmacy). When this is not possible, any active member of the study team may attend. This meeting would not be expected to last more than half an hour.

**Visit Reports**

All monitoring visits will be filed in the TMF and logged in Q-Pulse and all relevant visit documentation shall be uploaded to the visit and to the appropriate file in the shared common drive for the trial. All relevant emails received will be captured in the shared mailbox.

Documentation

* Q-Pulse Report
* Report template (excel or similar)
* Full Follow up Letter
* Actions Resolution Document
* ISF, PSF checklist for remote monitoring

**Follow up**

Follow up letters will be emailed to the Chief/Principal Investigator (and Pharmacist if relevant), copying the (NHS/GU Governance Manager(s)/Lead Clinical Trial Monitor/Research Coordinator/Project Manager/Sponsor Pharmacist as applicable). A signed, hard copy should also be sent to the Chief/Principal Investigator by post. Where a hard copy of the follow up letter is not possible, the site will be advised to print and file the follow up documents in the investigator site file.

**Remote Monitoring Visits**

The aim of the remote visit will be the same as that of the full monitoring visit and will be outlined in the plan or an addendum (if implemented) prepared for on-going trials.

The monitor will discuss and agree with site personnel a mutually convenient time to conduct the visit and will request in advance of the visit, a completed ISF (and PSF when monitoring pharmacy) checklist, the site training and delegation logs and any accountability specific to the study. If the site requires it - the Remote Monitoring Form 53.004Pwill be completed with the site prior to the visit going ahead **(not mandatory).** The monitor will also select and review collected data for randomly selected trial participants based on the monitoring objectives as to how many patients, Informed Consent forms for compliance and to verify site source documentation for eligibility and at randomly selected visits for each of the patients as per monitoring plan and in compliance for SOP 53.004. The visit will be conducted over Microsoft Teams, as advised by NHS Greater Glasgow & Clyde IT department, as the safest link. Video link or screen sharing will be utilised for source data verification purposes. Prior to any remote visit, the monitor will set up the teams link and on the day of the visit will only admit the guest if they have confirmed the email matches the one given by the site. The monitor will present their NHS ID badge to the site attendee(s) and confirm there is no one else present within the room to ensure patient confidentiality.

**Compliance of the Monitoring Plan**.

To ensure compliance of this monitoring plan, preventing the risk of inadequate monitoring, the CTM meeting will be held on a monthly basis and CTMs will be asked to confirm compliance to the monitoring plan. If not compliant with the monitoring plan then the reason should be documented. If this fails to happen, the Lead Clinical Trial Monitor or Research Governance Manager will be informed and it will be reported as a non-compliance.

**Review of Stakeholders.**

As per the standard operating procedure on Preparing and Managing monitoring plan SOP 53.010, all stakeholders will review the plan. The monitoring plan will be sent to the key stakeholders of the study including but not limited to, research coordinators, sponsor, project manager, pharmacy, pharmacovigilance and the chief investigator for review. Documentation of the review will be recorded below:

|  |  |
| --- | --- |
| Date sent out to Stakeholders (Include, PV Manager, Sponsor Pharmacy, Data Management and Statistician)  |  |
| Review date |  |
| Confirm Plan updated as per review  |  |
| Confirm Project Manager has documented review in the TMG minutes and a final copy filed in the TMF and a copy send to the Research Co-ordinator |  |

**SIGNATURES**

………………………………………… …………………………….

Monitor Date

………………………………………… …………………………….

Lead Clinical Trial Monitor/

Governance Manager Date

|  |
| --- |
| This Form is a controlled document. The current version can be viewed on the GCTU website. Any copy reproduced from the website may not, at time of reading, be the current version. |