| **Monitoring Report** |
| --- |
| **Study Title:**  |  |
| **CI Name:** |  |
| **REC reference:** |  | **EudraCT Number** (if applicable)**:** |  |
| **Sponsor:**  |  | **IRAS Reference:** |  |

|  |  |
| --- | --- |
| **Study Title (Short):** |  |
| **Site name:** |  |
| **PI name:**  |  |
| **Scheduled start date:** |  | **Scheduled end date:** |  |
| **Actual start date:** |  | **Actual end date:** |  |
| **Monitor name(s):** |  |
| **Reason for visit:** |[ ]  Initiation |[ ]  Routine |[ ]  Triggered |[ ]  Closure |
| **Monitoring Visit Ref:** |  |

This template is designed to cover both ISFs and TMFs. Please delete throughout as appropriate and amend this checklist as necessary for your research project. NB, Sections 2–5 are only relevant for ISFs and can be deleted from TMF report. ***Delete all red text before finalising checklist.***

# Section 1: ISF/TMF \*\* (delete as applicable) contents

| **Check ID** | **Task** | **Yes** | **No** | **N/A** | **Comments** |
| --- | --- | --- | --- | --- | --- |
| **1** | **Version control log**  |
| 1.1 | Version control log has all current approved documents listed |  |  |  |  |
| **2** | **Protocol and associated documents** |
| 2.1 | Current approved Protocol and amendments, signed by CI  |  |  |  |  |
| 2.2 | Past versions of approved protocols marked as superceded  |  |  |  |  |
| 2.3 | Current Summary of Product Characteristics (SmPC) |  |  |  |  |
| 2.4 | Protocol deviations |  |  |  |  |
| **3** | **Personnel** |
| 3.1 | Contact details of all personnel involved in trial at this Site |  |  |  |  |
| 3.2 | External personnel contacts  |  |  |  |  |
| 3.3 | Training log checks |  |  |  |  |
| 3.4 | Delegation log checks |  |  |  |  |
| 3.5 | Valid CVs and GCP for all people on delegation log |  |  |  |  |
| **4** | **Participant Logs and Consent Forms** |
| \*\*ISF\*\* delete rows as applicable: |
| 4.1 | Participant screening log completed correctly  |  |  |  |  |
| 4.2 | Participant enrolment log  |  |  |  |  |
| 4.3 | Current approved Patient Information Sheets and amendments |  |  |  |  |
| 4.4 | Current approved Patient Consent form and amendments |  |  |  |  |
| 4.5 | Current approved GP letter  |  |  |  |  |
| 4.6 | Sheets of labels for attachment to participants’ medical records noting fact of trial participation |  |  |  |  |
| 4.7 | Original signed consent forms filed in randomisation ID order |  |  |  |  |
| \*\*TMF\*\* delete rows as applicable: |
| 4.1 | Participant screening log template  |  |  |  |  |
| 4.2 | Participant enrolment log template |  |  |  |  |
| 4.3 | Current approved Patient Information Sheets and amendments |  |  |  |  |
| 4.4 | Current approved Patient Consent form and amendments |  |  |  |  |
| 4.5 | Current approved GP letter  |  |  |  |  |
| 4.6 | Sheets of labels for attachment to participants’ medical records noting fact of trial participation |  |  |  |  |
| **5** | **Source data** |  |  |  |  |
| 5.1 | Source data location list completed |  |  |  |  |
| **6** | **Data collection** |  |  |  |  |
| 6.1 | Sample of current approved Case Report Forms |  |  |  |  |
| 6.2 | Signed, dated and completed Case Report Forms |  |  |  |  |
| 6.3 | Data queries |  |  |  |  |
| 6.4 | File notes documenting CRF corrections or data clarifications |  |  |  |  |
| 6.5 | Patient flag on electronic system |  |  |  |  |
| **7** | **Randomisation and unblinding** |  |  |  |  |
| 7.1 | Procedure for randomisation and unblinding / Code Break  |  |  |  |  |
| 7.2 | Code Break envelopes  |  |  |  |  |
| **8** | **Pharmacovigilance** |  |  |  |  |
| 8.1 | Serious Adverse Events (SAE) Reports |  |  |  |  |
| 8.2 | Suspected Unexpected Serious Adverse Reaction (SUSAR) Reports |  |  |  |  |
| 8.3 | Annual Safety Reports (DSUR) to MHRA and Ethics |  |  |  |  |
| 8.4 | Notification by Sponsor to Investigators of safety information |  |  |  |  |
| 8.5 | Blank SAE forms |  |  |  |  |
| 8.6 | Copies of any adverse incident reports made under the normal reporting procedure used by the Trust |  |  |  |  |
| **9** | **Ethical approval** |  |  |  |  |
| 9.1 | Favourable ethical opinion letter and committee composition |  |  |  |  |
| 9.2 | Updates to ethical approval letters |  |  |  |  |
| 9.3 | Correspondence with Ethics Committee about applications; any associated file notes |  |  |  |  |
| **10** | **R&D approval** |  |  |  |  |
| 10.1 | R&D approval letter |  |  |  |  |
| 10.2 | Updates to R&D approval |  |  |  |  |
| 10.3 | Joint Study Review Committee Approval |  |  |  |  |
| 10.4 | Correspondence re R&D approval  |  |  |  |  |
| **11** | **Audit (if applicable)** |  |  |  |  |
| 11.1 | Audit Report |  |  |  |  |
| 11.2 | Audit correspondence |  |  |  |  |
| **12** | **Contracts** |  |  |  |  |
| 12.1 | Letter of acceptance of sponsorship |  |  |  |  |
| 12.2 | Clinical Trial Agreement |  |  |  |  |
| 12.3 | Any other contracts relating to the trial (e.g. IMP supplier) |  |  |  |  |
| 12.4 | Financial records and invoices |  |  |  |  |
| 12.5 | Correspondence and any file notes re agreements, finance etc. |  |  |  |  |
| **13** | **Regulatory (MHRA)** |  |  |  |  |
| 13.1 | Clinical Trial Authorisation letter from MHRA |  |  |  |  |
| 13.2 | Updates to MHRA approval letters |  |  |  |  |
| 13.3 | Correspondence with MHRA about applications; any associated file notes |  |  |  |  |

## 14 Pharmacy Not Applicable [ ]

| **Check ID** | **Task** | **Yes** | **No** | **N/A** | **Comments** |
| --- | --- | --- | --- | --- | --- |
| **14.1 Working Documents** |
| 14.1.1 | Trial Instructions  |  |  |  |  |
| 14.1.2 | Site Study Specific SOP (if applicable, for studies where IMP is stored outside pharmacy |  |  |  |  |
| 14.1.3 | Patient Log |  |  |  |  |
| 14.1.4 | Sample Prescription  |  |  |  |  |
| 14.1.5 | Delegation log (Pharmacy Research Staff)  |  |  |  |  |
| 14.1.6 | Pharmacy Signature Log |  |  |  |  |
| 14.1.7 | Drug Accountability Logs and individual patients prescriptions |  |  |  |  |
| 14.1.8 | Shipping Records (including any IVRS reference material /documents |  |  |  |  |
| 14.1.9 | QP release documentation /Certificate of Analysis (as appropriate) |  |  |  |  |
| 14.1.10 | Drug returns documentation / Drug destructions |  |  |  |  |
| 14.1.11 | Monitoring;* Site Initiation Report
* Monitoring Visit Reports/action lists
* Trial Close out report
 |  |  |  |  |
| 14.1.12 | Correspondence (General)  |  |  |  |  |
| **14.2 Reference Documents** |
| 14.2.1 | Current approved protocol  |  |  |  |  |
| 14.2.2 | Summary of Product Characteristics  |  |  |  |  |
| 14.2.3 | Pharmacy manual or other sponsor provided SOPs |  |  |  |  |
| 14.2.4  | Sample of Labels attached to IMP container. |  |  |  |  |
| 14.2.5 | R&D approval |  |  |  |  |
| 14.2.6  | Ethics approval  |  |  |  |  |
| 14.2.7 | MHRA approval  |  |  |  |  |
| **14.3 Pharmacy File – Review of Pharmacy Site File** |
| 14.3.1 | Procedure for randomisation and code break |  |  |  |  |
| 14.3.2 | Code break envelopes with record of receipt /retrieval/use (if applicable)  |  |  |  |  |
| 14.3.3 | IMP recall documentation |  |  |  |  |
| 14.3.4 | Technical agreement/MA (IMP) licence of the IMP supplier (for ABM UHB Sponsored studies where IMP is sourced by health board  |  |  |  |  |
| 14.3.5  | Clinical trial agreement/financial information and invoices  |  |  |  |  |
| 14.3.6 | File note log and file notes |  |  |  |  |
| 14.3.7  | Pharmacy checklist/pharmacy assessment |  |  |  |  |
| 14.3.8  | Temperature records (and relevant correspondence eg relating to temperature excursion) |  |  |  |  |
| 14.3.9 | Calibration certificates (and relevant correspondence) |  |  |  |  |
| 14.3.10 | Chronological log of amendments with version numbers and dates |  |  |  |  |

## 15 Laboratory Not Applicable [x]

| **Check ID** | **Task** | **Yes** | **No** | **N/A** | **Comments** |
| --- | --- | --- | --- | --- | --- |
| **15.1 Personnel** |
| 15.1.1 | Is there an Organogram? |  |  |  |  |
| 15.1.2 | Is there a designated member of lab staff with overall responsibility for Clinical Trials? |  |  |  |  |
| 15.1.3 | Are there adequate resources available to provide a clinical trial service which avoids inappropriate diversion of resource away from patient care? |  |  |  |  |
| 15.1.4 | Do staff receive research training and is this documented?  |  |  |  |  |
| 15.1.5 | Is Trial Specific training provided? |  |  |  |  |
| 15.1.6 | Is GCP training received? up to date?  |  |  |  |  |
| 15.1.7 | Are training records retained when staff leave?  |  |  |  |  |
| 15.1.8 | Who is authorised to process clinical trial samples? Is this documented in individual job descriptions?  |  |  |  |  |
| 15.1.9 | Is there a QA department and, if so, how do they fit into the overall organisation structure?  |  |  |  |  |
| 15.1.10  | Is there an Internal Audit programme in place?  |  |  |  |  |
| 15.1.11 | Is the facility accredited with any external organisations? Specify.  |  |  |  | For example: ISO 900, ISO 15189, ISO 17025, ISO 45001, GMP, GLP, GCLP, CAP, CLIA |
| **15.2 Facilities** |
| 15.2.1 | Is the access to the laboratories controlled / limited?  |  |  |  |  |
| 15.2.2 | Is there an intruder detection system? (permanently or during out-of-working hours) |  |  |  |  |
| 15.2.3 | In case of power failure, what will happen?  |  |  |  |  |
| 15.2.4 | Overall, are the facilities clean?  |  |  |  |  |
| 15.2.5 | Who is responsible for cleaning (e.g. external company)? |  |  |  |  |
| 15.2.6 | Are the security/cleaning described in written procedures? |  |  |  |  |
| 15.2.7 | Are there documented procedures or contracts in place for facilities maintenance?Are these being followed? |  |  |  |  |
| 15.2.8 | Are records of equipment maintenance /calibration available? |  |  |  |  |
| 15.2.9 | How long is retention period? |  |  |  |  |
| 15.2.10 | Is calibration traceable to recognised standards? |  |  |  |  |
| 15.2.11 | Is user acceptance testing or computer validation carried out for any new equipment? |  |  |  |  |
| 15.2.12 | Does the facility have a disaster recovery plan? |  |  |  |  |
| 15.2.13 | Is the room temperature and / or humidity monitored? How? |  |  |  |  |
| 15.2.14 | How many research fridge, freezers (-20, -80C) or cold rooms are there?  |  |  |  |  |
| 15.2.15 | Is the temperature of fridge/freezer, cold room monitored? If yes how? How are cold chain breaks identified (e.g. alarm, visual)? |  |  |  |  |
| 15.2.16 | Is there a documented process to follow in case of technical problems, if the temperature is out-of-range? |  |  |  |  |
| 15.2.17 | Is there a maintenance contract for refrigerated equipment?  |  |  |  |  |
| 15.2.18 | If there is a back-up fridge/freezer or cold room in case of emergency? |  |  |  |  |
| 15.2.19 | Is the temperature of any backup facility monitored regularly? |  |  |  |  |
| 15.2.20 | Would there be adequate space to relocate clinical trial samples there? |  |  |  |  |
| 15.2.21 | Is there dedicated area for clinical trials sample storage?  |  |  |  |  |
| 15.2.22 | Are all clinical trial samples processed and stored in these laboratories or are samples shipped immediately without requiring processing? |  |  |  |  |
| **15.3 SOPs** |
| 15.3.1 | SOPs - Is there a governing SOP that documents the procedure for creation, revision, approval, distribution, document control and withdrawal of SOPs? |  |  |  |  |
| 15.3.2 | Is there a current SOP index? |  |  |  |  |
| 15.3.3 | How are SOPs made available to staff?Available at locations where required? |  |  |  |  |
| 15.3.4 | What is the review period? Are SOPs within review period? |  |  |  |  |
| 15.3.5 | Is there a system for documenting and handling SOP deviations and CAPAs? |  |  |  |  |
| **15.4 Procedures** |
| 15.4.1 | Do labs have a policy document covering the safe handling / processing of samples? |  |  |  |  |
| 15.4.2 | How is clinical trial sample processing documented? |  |  |  |  |
| 15.4.3 | Are laboratory staff involved in the review of Protocols? If so, at what stage of study planning? |  |  |  |  |
| 15.4.4 | Are laboratory staff involved in Investigator meetings and/or Site Initiation meetings? |  |  |  |  |
| 15.4.5 | Are laboratory staff required to train of other staff e.g. research nurses in sample processing?  |  |  |  |  |
| 15.4.6 | What checks are performed on stored samples? |  |  |  |  |
| 15.4.7 | Do laboratory Clinical Trials staff review lab related forms provided by Sponsors for suitability for use? |  |  |  |  |
| 15.4.8 | What are laboratory archiving arrangements? |  |  |  |  |
| 15.4.9 | Are laboratory clinical trials staff aware of responsibilities in the reporting of suspected fraud, misconduct and other incidents (serious breaches)? |  |  |  |  |
| 15.4.10 | Do laboratory documents provide a full audit trail from receipt to destruction or return? Is Chain of Custody clear/documented? |  |  |  |  |
| 15.4.11 | Do laboratories hold a Clinical Trial Protocol for each study involved in? |  |  |  |  |
| 15.4.12 | How are updates/amendments received and handled? |  |  |  |  |
| 15.4.13 | Is there a documented procedure for timely communication to Sponsor/R&D regarding deviations from work instruction/SOP/Protocol? |  |  |  |  |
| 15.4.14 | Is impact of deviation assessed and documented? |  |  |  |  |
| 15.4.15 | Does subcontracting with other laboratories occur?Is suitability / capability assessed prior to contract? |  |  |  |  |
| 15.4.16 | Is there a documented procedure for the expediting of out-of-range results? |  |  |  |  |
| 15.4.17 | Are there normal ranges? Authorised? |  |  |  |  |
| 15.4.18 | Is there a process to cover withdrawal of informed consent? What happens to samples? |  |  |  |  |
| 15.4.19 | Sample transportation – are transit conditions monitored? Is time in transit recorded? |  |  |  |  |
| 15.4.20 | What happens if there are missing samples, poorly labelled or unexpected samples on receipt? |  |  |  |  |
| 15.4.21 | Are there procedures to maintain patient confidentiality of samples taken for research purpose only? |  |  |  |  |
| 15.4.22 | Is there a validated method available for the analyses being undertaken?Authorised and approved?If not how will this be achieved? |  |  |  |  |
| 15.4.23 | Are appropriate records maintained? |  |  |  |  |
| 15.4.24 | Adequate records retained for preparation of buffers and reagents required by analytical method? Written procedures for preparation? |  |  |  |  |
| 15.4.25 | Quality of reagents traceable to ensure fit for purpose? |  |  |  |  |
| 15.4.26 | How are data recorded?What QC checks are in place to ensure accuracy of any transcribed data? Where are these checks documented? |  |  |  |  |
| 15.4.27 | Are appropriate error correction procedures in place/followed? |  |  |  |  |
| 15.4.28 | Are there any blinding issues? |  |  |  |  |
| 15.4.29 | How are results communicated/reported to PIs? |  |  |  |  |

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| --- |
| Further comments: |
|  |

# *ISF only* Section 2: Participant Recruitment *This section is not applicable to this monitoring visit* [ ]

|  |  |
| --- | --- |
| 1. Number of subjects screened |  |
| 2. Total participants giving consent |  |
| 3. Total number of subjects randomised |  |
| 4. Total participants withdrawn |  |
| Comments: |
|  |

# *ISF only* Section 3: Medical records check *This section is not applicable to this monitoring visit* [ ]

|  |
| --- |
| *Please refer to the medical records checklist for those patients* |
| 1. Number of records checked |  |
| 2. Participant Information Sheets present |  |
| 3. Consent Forms present |  |
| 4. Correct versions used |  |
| Comments: |
|  |
| Were there any discrepancies between the ISF and the medical notes? |
|  |

# *ISF only* Section 4: Source data check *This section is not applicable to this monitoring visit* [ ]

|  |  |
| --- | --- |
| Number of participants for whom Source Data was verified on this visit  |  |
| *Please refer to the source data verification form for those patients and add as an appendix to final report* |
| Comments: |
|  |
| Were there any discrepancies between the ISF and the source data? |
|  |

#  *ISF only* Section 5: Consent Checklist *This section is not applicable to this monitoring visit* [ ]

| **Rand ID** | **Version number used** **\****delete as appropriate* | **Versions correct?**(Y/N) | **Consenting medic *(name)*** | **Issues Noted?** |
| --- | --- | --- | --- | --- |
| Patient info sheet | Patient consent form |  | Securing Patientconsent |
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| **Section 6: Any additional comments** |
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|  | **Research monitor** | **Sponsor representative** |
| **Signature**  |  |  |
| **Date**  |  |  |
| **Name (PRINT)** |  |  |

| **[Research Project name] Monitoring Action List** |
| --- |
| These actions have been identified as necessary following the recent monitoring visit. Please attend to all of them within the prescribed time. When completed, return the form to the Research Monitor. The visit report will be signed off and issued by the Research Monitor and Sponsor representative when all appropriate actions have been taken. |

| **Action Number** | **Finding Detail** | **Correction** | **Correction completed (yes/no)** | **Completed by (initials)** | **Comments** |
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**Chief / PrincipalInvestigator *(delete as appropriate)* please read and sign below:**

**I understand that the information supplied may be submitted to a regulatory authority as evidence of adequate study monitoring according to UK law. I acknowledge that I am liable for the consequences of providing falsified information and confirm that the information provided in this document is accurate and I take full responsibility for it.**

**Signature\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Name \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**