# Standard Operating Procedures for Monitoring CTIMPs

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|---|---|---|
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| Version | Effective Date | Reason for Change |
|---|---|---|
| 1.0 | 1 June 2021 | - |
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Out of date documents must not be relied upon

*Acknowledgement, BSUH, BS CTU*

# 1. Purpose & Scope

1.1 The EU Good Clinical Practice (GCP) Directive 2001/20/EC was introduced to establish standardisation of research activity in Clinical Trials throughout the European Union (EU). It was transposed into UK law as the Medicines for Human Use (Clinical Trials) Regulations 2004 (SI 2004/1031) which came into force on 1

management and oversight group(s) or committee(s). This will be managed through the CTU supporting the study.

## 3. Responsibilities

**Sponsor**

3.1 It is the responsibility of the Sponsor to ensure that trials are adequately monitored.

3.13 When applicable, a study specific non-compliance log should also be maintained by the TM.

3.14 The TM is also responsible for filing the report and any relevant correspondence in the TMF.

**US Research Governance Officer (RGO), CTU Operational Manager (OM)**

3.15 In CTIMPs, the TM/tm is responsible for undertaking monitoring risk assessments, creating

- Ensuring the monitoring visit log is signed by both the TM/tmand a member of the research team at the site
- Reviewing emergency 24-

- Copies of local R&D approval letters for amendments

4.11 Any actions [illegible] next monitoring visit, will be discussed with the research team. If the research team still fail to complete the actions then this issue should be escalated to the Sponsor.

4.12 The RGO will present a summary of the findings from monitoring visits to the SSC, who meet at least quarterly.

**Central Monitoring**

4.13 Central monitoring is when monitoring activities are performed remotely from the coordinating centre. With low dda1 v (it)-2O( )10.2 f(is)-1.3 (c)-1.9 RGdiesititOdit6 (e)-3 (n5 (it)-3av)-5.5 (is)ommitnt wf extitm g (it)-

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# ON-SITE MONITORING REPORT

*(To be adapted on a trial by trial basis)*

| | |
|---|---|
| **Study Title**: [Full study title] | |
| **EudraCT Number**: | |
| **IRAS Number:** | |
| **Name and Number of site:** | |
| **PI Name:** | |
| **Reason for visit:** | |
| **Date of visit:** | |
| **Preparation for visit** | |
| **Visit correspondence (date** | |
| **Has version control list been sent ahead of visit and any documents identified as missing now been sent?** | |

| ITEM MONITORED | YES | NO | N/A | |
|---|---|---|---|---|

| 2. | **Informed consent and participant status** |
|---|---|

| | **Item Monitored** | **YES** | **NO** | **N/A** | **COMMENTS (if no is answered, comment)** |
|---|---|---|---|---|---|

| **Outcomes from visit** | |
|---|---|
| Have there been any major or critical findings? | |
| Have there been any protocol deviations? | |
| Are there any other actions required and/or follow ups needed? | |
| Have all actions from previous visits been closed (if applicable)? | |

**Comments**

*Give a brief overview of the meeting and highlight whether there were any particular issues e.g. key member of trio/ team not present, anything raised for discussion that requires further consideration by the CI/NCTU team, or that represents further need to follow up.*

# CENTRAL MONITORING REPORT

*(To be adapted on a trial by trial basis)*

[Short study name]

| | |
|---|---|
| **Study Title**: [Full study title] | |
| **Sponsor reference**: | **EudraCT Number**: |
| **REC reference:** | **IRAS Number:** |
| **Chief Investigator:** | |
| **Sponsor:** | |
| **Trial Manager:** | |
| **Site:** | |
| **Principal Investigator:** | |
| **Research Nurse:**<br><br>**Data Officer:** | |

| **OVERALL STUDY PROGRESS** | |
|---|---|
| **Date Site opened to recruitment/ activated** | |
| **Total number of patients screened:** | |
| **Total number of patients recruited:** | |
| **Number of patients ongoing:** | |
| **Number of patients completed:** | |
| **Study completion due date:** | |
| **Predicted total at study completion based on current recruitment:** | |
| **Total number of withdrawals:** | |
| **Total number of those withdrawals due to safety:** | |
| **Total number of SAEs:** | |
| **Total number of SUSARs:** | |

**Date of previous report:** DD/MMM/YYYY
**Date of current report:** DD/MMM/YYYY

**DATA MANAGER REVIEW (DMR)**

Date DMR completed: DD/MMM/YYYY

DMR reviewed by Trial Manager: δ Date: DD/MMM/YYYY Not reviewed: δ

| **SCREENING/ENROLMENT LOG: Since last monitoring report** | | |
|---|---|---|
| **Date log received** | **Number of people screened / enrolled** | **COMMENTS** |
| | | |
| | | |
| **ACTION:** | | |

| **SCREENING LOG: Since last monitoring report** | | | |
|---|---|---|---|
| **Date screening log received** | **Number of people screened** | **Number of screen failures** | **Reasons for screen failure** |
| | | | |
| | | | |
| **ACTION:** | | | |

**DELEGATION LOG:**

[redacted]

| | | |
|---|---|---|
| **Review of IMP orders** | | |
| **IMP stock check at site** | | |
| **General Drug Accountability log** | | |
| **Patient drug accountability log** | | |
| **IMP Destruction Log** | | |
| | | |
| **ACTION:** | | |
| **LAB MANAGEMENT:** | | |
| **DOCUMENT** | **DATE RECEIVED** | **COMMENTS** |
| **SAMPLE LOG** | | |
| **NORMAL LAB RANGES** | | |
| **TEMPERATURE LOG** | | |
| **SAMPLE TRANSFER LOG** | | |
| | | |

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**<OPTIONAL – REMOVE OR AMEND AS PER STUDY REQUIREMENTS>**

**Appendix 1: Patients overview (as of XXXX)**

## SPONSOR SECTION

**Appendices**

## SPONSOR SECTION

***(NOT TO BE INCLUDED IN MAIN REPORT TO SITE)***

| Issues to be escalated to sponsor | Sponsor review date | Recommended actions / comments |
|---|---|---|