Imperial College London

Research Governance and Integrity Team

Imperial College Healthcare NHS Trust

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Quality Control and Quality Assurance

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Version 8.0	19 Oct 2020	Scheduled review Templates removed and administrative changes to SOP. JRCO name change to RGIT.
Version 9.0	09 Jan 2024	3 year SOP review

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1. PURPOSE

The purpose of this SOP is to describe the Quality Control (QC) and Quality Assurance (QA) procedures for clinical trials and healthcare research of Imperial College Academic Health Science Centre (AHSC). This SOP is intended as an overview of QC and QA, with more specific guidance on Auditing and Monitoring provided in Research Governance and Integrity Team SOPs; RGIT_SOP_018 and RGIT_SOP_015 respectively, these SOP's can be found on the SOP, Associated Documents & Templates page.

2. INTRODUCTION

Under International Conference on Harmonisation (ICH) Good Clinical Practice E6 R2 guidelines, the Sponsor organisation is responsible for implementing and maintaining quality assurance and quality control systems with written SOPs to ensure that trials are conducted, and data are generated, documented (recorded), and reported in compliance with the protocol, GCP, and the applicable regulatory requirement (5.1.1). "Quality control (QC) should be applied to each stage of data handling" (5.1.3). Regular monitoring enables effective QC management. ICH GCP E6 R2 Guideline, section 4.1.4 states "the Investigator/Institution should permit monitoring and auditing by the sponsor, and inspection by the appropriate regulatory authority(ies)".

2.1. Monitoring

Monitoring is an integral role in the QC of a clinical trial and is designed to verify the quality of the study. It is defined as:

> "The act of overseeing the progress of a clinical trial, and of ensuring that it is conducted, recorded, and reported in accordance with the protocol, SOPs, GCP, and the applicable regulatory requirement(s)", ICH GCP E6, section 1.38.

Section 5.18 of ICH GCP E6 R2 states in detail the minimum requirements for monitoring of clinical trials.

The purpose of monitoring is to verify that:

- Rights and well-being of the human subjects are protected
- The reported trial data are accurate, complete, and verifiable from source documents
- The conduct of the trial is in compliance with the currently approved protocol/amendment(s), with GCP, and with the applicable regulatory requirements

2.2. Auditing

Auditing is a tool used to fulfil the QA requirements of GCP; it is designed to assess and assure the reliability and integrity of a trial's quality control systems and is a way of measuring performance against recognised standards.

"The purpose of a sponsor's audit, which is independent of and separate from routine monitoring or quality control functions, should be to evaluate trial conduct and compliance with the protocol, SOPs, GCP, and the applicable regulatory requirements", ICH GCP E6, section 5.19.1.

As a legal Sponsor organisation (an institution that takes responsibility for initiation, management and/or financing of a clinical trial), the Research Governance and Integrity Team (RGIT) is responsible for auditing research practice and assuring adherence to current legislation and guidelines. As such, it is necessary to audit research for which Imperial College AHSC is the lead

Sponsor, against the standards of the UK Policy Framework for Health and Social Care Research 2017, the Medicines for Human Use (Clinical Trials) Regulations 2004 and its subsequent amendments, where applicable, and against the quality systems of Good Clinical Practice intrinsic to those Regulations.

The purpose of a research audit is to:

- Ensure participant and staff safety
- Assist researchers with compliance to regulatory requirements and Sponsor's policy
- Improve research systems and data quality
- Prepare researchers for external audit processes
- Demonstrate robust research processes to external funders and industry

3. PROCEDURE

3.1. Qualification of Monitors and Auditors

Monitors and Auditors should be appropriately trained and should have the scientific and/or clinical knowledge needed to monitor or audit the trial adequately. A monitor's qualifications should be documented. RGIT internal monitors that monitor ICHT sites should attend relevant monitoring courses (e.g. Siobhan Lim course or equivalent). The qualification of external monitors that monitor non-ICHT sites should be reviewed by the RGIT CTIMPs team. The monitor should be familiar with the Investigational Medicinal Product (IMP), the protocol, information sheet and consent form (ICH GCP 5.18.2), as well as the RGIT SOPs, GCP and applicable regulatory requirements.

The auditor should be independent to the research team/research systems to conduct audits appropriately. An auditor should be qualified by training and experience to conduct audits properly. "An auditor's qualifications should be documented" (ICH GCP 5.19.2). Auditors at RGIT should attend the Research Quality Association (RQA) auditing course (or equivalent) and/or perform an audit as the side auditor.

3.2. Extent of Monitoring and Audits

Monitors in accordance with the requirements decided by the CI and Sponsor should ensure that the trial is conducted and documented properly. For full details on how monitoring is carried out please refer to RGIT_SOP_015.

The RGIT audit programme, acting on behalf of Imperial College AHSC as Sponsor organisation, is carried out using a risk-based approach. Auditors are appointed from RGIT to conduct the scheduled audits as per the audit programme along with any other audits as deemed necessary by the senior management team (SMT), such as triggered audits. All observations and findings are documented. Please see the Audit SOP for further information (RGIT_SOP_018).

4. REFERENCES

RGIT_SOP_015 – Monitoring

RGIT_SOP_018 – Trial Audit

CT-Toolkit Trial Management and Monitoring (cited on 14/Mar/2023)

ICH: E 6 (R2): Guideline for good clinical practice - Step 5 (europa.eu) (Cited on 04/May/2023)

SOP, Associated Documents & Templates page (cited on 14/Mar/2023)

UK Policy Framework for Health and Social Care Research - Health Research Authority (hra.nhs.uk) (Cited on 04/May/2023)

The Medicines for Human Use (Clinical Trials) Regulations 2004 (legislation.gov.uk) (Cited on 04/May/2023)