Technology, Infrastructure and Environment Directorate Clinical Research Governance Team

Statement of Policy

Policy for the Management of Laboratory Endpoints in Clinical Trials at the University Of Liverpool

POL003

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1. Regulatory Background

Good Clinical Practice (GCP) is an international ethical and scientific quality standard for designing, conducting, recording and reporting trials that involve the participation of human subjects. Compliance with this standard provides public assurance that the rights, safety and well-being of trial subjects are protected, consistent with the principles that have their origin in the Declaration of Helsinki, and that the clinical trial data are credible.

Any laboratory that intends to collect, store or analyse samples derived from a clinical trial are required to follow GCP. GCP is applicable to all laboratories performing analyses which contribute to the endpoints of a clinical trial.

Good Clinical Laboratory Practice (GCLP) are quality system guidelines for laboratories which undertake the collection and analysis of samples from clinical trials. It was developed by the Research Quality Association (RQA) to provide additional guidance to laboratories. It is similar to GCP for laboratories compliance but is not a standard recognised internationally, or by the Medicines and Healthcare products Regulatory Agency (MHRA).

Laboratories that carry out clinical trials work of this type, may be subject to inspection by the MHRA as part of the agency's laboratory inspection programme, a Sponsor inspection or triggered inspection (Sponsor or MHRA).

2. Policy Scope

This policy covers the laboratory aspects included in Clinical Trials of Investigational Medicinal Products (CTIMPs), Advanced Therapy Investigational Medicinal Products (ATIMPs), and Clinical Investigations of medical devices where clinical trial authorisation (CTA) is required from the MHRA.

This policy is applicable to trials sponsored by the University of Liverpool and external sponsors where the laboratory sample collection or analysis is being carried out in a University of Liverpool laboratory.

3. Primary and Secondary Endpoints

The expectation is that all laboratories performing the collection, storage and analysis of samples contributing to the primary or secondary endpoints of a clinical trial – where those endpoints are not related to safety or tolerability – operate to full GCP for laboratories standards, with validated sample collection methods and analytical workflows, as well as a full and auditable Quality Management System.

4. Exploratory, Tertiary, Translational and Other Endpoints

Laboratory analyses are often included in clinical trial protocols as exploratory, tertiary or translational endpoints or sub studies. These may be hypothesis-generating discovery research and may utilise assays and techniques that are difficult to fully validate. Where such analyses are not intended to support primary or secondary endpoints, do not evaluate safety or efficacy, and are intended solely for future research, the Sponsor strongly recommends that samples be collected and

stored under the clinical trial protocol, with participants consenting to future use of samples, but that analysis is completed under a separate, standalone ethically approved research protocol. If the exploratory analysis is independent of the clinical trial objectives, it may fall outside the scope of the trial protocol and associated MHRA oversight. Ethical review for the analysis of previously collected samples is often evaluated through the relatively quick proportionate review route. Examples of analyses that may not be required to address the trial objectives, influence participant management or generate regulatory conclusions about the IMP and therefore may be removed from the protocol include:

- Future biomarker discovery
- Validation of novel biomarkers
- Unrelated mechanistic research
- Development of new assays
- 'Omics analyses
- AI or machine-learning analyses.

MHRA guidance reflects the expectation that all laboratories performing work in support of clinical trials, regardless of endpoint, should implement appropriate measures to assure the quality and integrity of the data produced and to exercise due diligence to ensure that the trial participants' rights are not compromised. The MHRA generally takes a risk-proportionate approach to analysis of exploratory endpoints, provided an adequate quality system and supporting documentation are in place. Where a reduced level of validation, quality control or audit trail capture is justified or necessitated, the rationale should be documented, alongside an appropriate risk assessment and any necessary risk mitigation measures.

Where exploratory endpoint analysis (documented within the clinical trial protocol) is to be performed within the University of Liverpool, this must be conducted under the **GCP Lite** framework, set up with the agreement from the facility or laboratory and overseen by, and in consultation with, the GCP Laboratories Quality Assurance (QA) Team.

4.1. GCP Lite

GCP Lite is a bespoke, streamlined framework that defines a reduced, risk-proportionate set of GCP requirements for laboratories undertaking the analysis of clinical trial samples **for exploratory endpoints only**. Analyses supporting primary and secondary endpoints must be conducted in full compliance with GCP standards.

The framework encompasses, but is not limited to, the following areas:

- document management
- equipment maintenance and use
- quality assurance
- quality control
- staff training
- contracts and agreements
- experimental assays (including validation, where applicable)
- facilities

- data integrity and data management.

GCP Lite retains the fundamental principles of GCP, such as ensuring data integrity, protecting the rights, safety and wellbeing of trial participants and generating scientifically robust, reliable and regulatory-compliant data. However, these principles are applied in a scaled, risk-based manner that is proportionate to the intended use of the data. It enables exploratory endpoint analyses to be performed using specialist equipment, technologies and expertise that may not be available within the GCP Laboratories, while maintaining appropriate regulatory oversight through the QA Team.

The framework, developed in a trial- and facility-specific manner, is designed for research laboratories that may not have the infrastructure or operational capacity to achieve full GCP compliance across all activities but are required to meet defined regulatory and quality standards for specific exploratory analyses. The QA Team will work with the laboratory to identify the GCP requirements that are applicable to the proposed work and will support the development and implementation of relevant documentation, processes and suitable risk mitigation measures to ensure that the quality and integrity of the data are maintained.

The GCP Laboratories QA Team can be contacted at GCPLaboratoriesQA@liverpool.ac.uk for advice and support.

5. Sponsor Responsibility

The ultimate decision on conduct of laboratory endpoints in clinical trials is the responsibility of the Trial Sponsor.

Where the University of Liverpool is the trial sponsor, laboratories performing the collection, storage and/or analysis of samples contributing to the primary or secondary endpoints must complete FORM013 GCP Laboratory Self-Assessment Questionnaire for assessment by the Sponsor.

FORM013 for each laboratory must be reviewed and signed by the Sponsor before the trial can open to recruitment, as part of the Permission to Proceed process.

For laboratories performing exploratory endpoint analysis for a University of Liverpool-sponsored trial, the Sponsor must sign the trial-specific GCP Lite Scope of Work and Analytical Plan to confer approval of the specified activities.

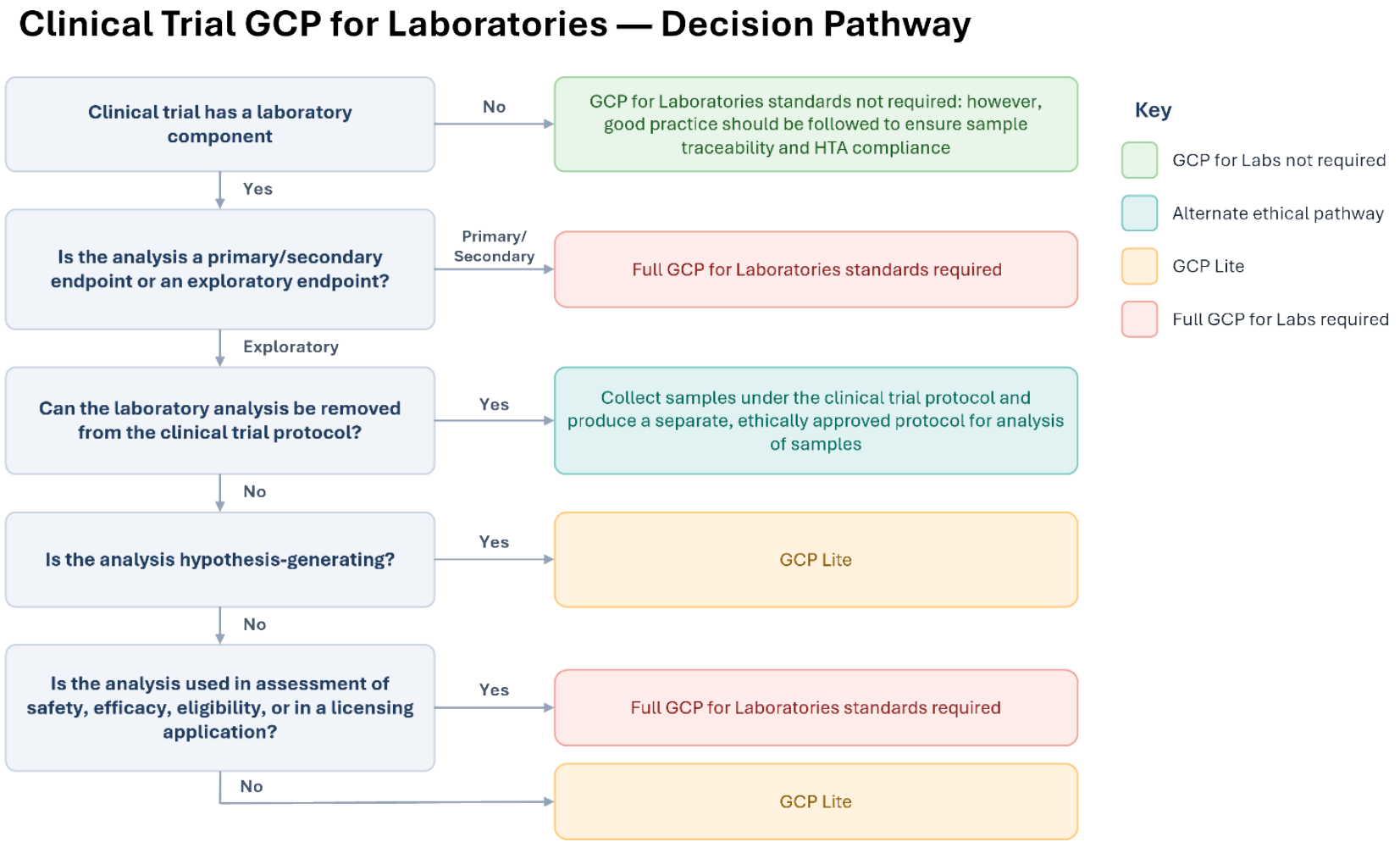
The Sponsor maintains oversight of all laboratory endpoint activities throughout the duration of the trial and reserves the right to audit these activities at any time to verify compliance with GCP, the protocol, applicable regulatory requirements and Sponsor quality management requirements.

6. Associated Documents and References

MHRA Good Clinical Practice Guide, Chapter 13 “Clinical Trial Samples – analysis and evaluation (2012)

EMA Reflection paper for laboratories that perform the analysis or evaluation of clinical trial samples (2012) (EMA/INS/GCP/532137/2010)

International Council for Harmonisation (ICH) E6(R3) Guideline for Good Clinical Practice (GCP)

The Medicines for Human Use (Clinical Trials) Regulations 2004 (SI 2004/1031), as amended by the Medicines for Human Use (Clinical Trials) (Amendment) Regulations 2025

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