

GCP and Governance compliance sample questions

Please note for MHRA regulated studies the question set should be agreed with the GCP and Governance Manager prior to sending to the vendor.

1. Laboratories
2. Database suppliers
3. Any supplier conducting randomisation
4. Investigational Medicinal Product suppliers/distributors
5. Sponsor/Contract research Organisation /Clinical Trials Unit
6. Other

1. Laboratories

To be used for Medicines and Healthcare products Regulatory Agency (MHRA) regulated sponsored studies. Please note that Good Clinical Practice (GCP) applies to all laboratory work but the adherence to the European Medicines Agency (EMA) guidance can be proportionate for work other than primary endpoints.

- a. For this study, what work is your laboratory agreeing to do, and is this towards the primary end point of the study? Is this a novel technique?
- b. Does your lab have any accreditations? (e.g., ISO 15189, Good Laboratory Practice (GLP) etc.) Does the planned work fall under this accreditation?
- c. Has your laboratory conducted this sort of work previously (please provide details)?
- d. Is your laboratory compliant with GCP and the EMA document (28 February 2012 EMA/INS/GCP/532137/2010 Reflection paper for laboratories that perform the analysis or evaluation of clinical trial samples)?
- e. What is your Quality Assurance (QA) Policy? (Please include Audits, external QA and Internal QA, inter-lab testing etc.)
- f. Please describe the quality management system (QMS) in place in your lab (including Computer system validation) and provide a Standard Operating Procedure (SOP) index.
- g. Training specific: please confirm technical training and competency assessments procedures and confirm that evidence of this will be available during the study/work period.
- h. Please provide proof or GCP training for relevant staff within your laboratory.
- i. Method Validation:
 - Please provide details on how the technical methodologies were validated and verified.
 - Who suitably authorised the methods and the results?
 - If method validation is part of the proposed work, please describe Validation and verification plan, including key Milestones and reports to Sponsor for stop go decisions prior to analysis.

2. Database suppliers

- a. Has your company been previously undertaken to provide a database for a clinical trial?
- b. Has any such clinical trial been inspected by the MHRA? If yes, was there a favourable outcome?
- c. Will the work undertaken by your company be in compliance with GCP and the MHRA 2004 (Statutory Instrument 2004/1031), and all subsequent amendments?
- d. Please describe the QMS in place in your company and provide a SOP index.
- e. Please provide a short summary of how databases are designed and validated.
- f. Please provide proof or GCP training for relevant staff.

3. Any supplier conducting randomisation

- a. Has your company been previously provided a randomisation service for a clinical trial?
- b. Has any such clinical trial been inspected by the MHRA? If yes, was there a favourable outcome?
- c. Will the work undertaken by your company be in compliance with GCP and the MHRA 2004 (Statutory Instrument 2004/1031), and all subsequent amendments?
- d. Please describe the QMS in place in your company and provide a SOP index.
- e. Please provide a short summary of how the randomisation systems are designed and validated.
- f. Please provide proof of GCP training for relevant staff.

4. Investigational Medicinal produce (IMP) suppliers/distributors

(Please note where possible the questions should be discussed with the allocated sponsor Pharmacist prior to contacting vendor and the response should always be reviewed and commented on by the Sponsor Pharmacist)

- a. Please list the manufacturing activities that vendor will be undertaking for the study
For example: IMP labelling, IMP packaging, IMP import, QP release, Sourcing of bulk IMP supplies, IMP Blinding
- b. Does vendor hold a valid manufacturing licence for these specific activities?
- c. Has vendor provided these services to other clinical trials of investigational medicinal products taking place in the UK?
- d. Please confirm that vendor have an appropriate QMS in place to cover all contracted activities.
 - i. Please provide an SOP index.
 - ii. Please summaries your staff training programme?
- e. When were vendor last inspected by the MHRA or by the national regulatory agency? Were there any critical findings? If yes, please confirm these are all now closed.
- f. Will the work undertaken by vendor be in compliance with GCP, GMP, GDP and the Medicines for Human Use (Clinical Trials) Regulations 2004 [Statutory Instrument 2004/1031], and all subsequent amendments?
- g. Please advise who will be undertaking QP release activities?
- h. Is vendor able to provide IMP batch manufacturing documentation to the Sponsor in the event that these are required?
- i. Please confirm that vendor is willing to be audited if they are selected to provide services to the sponsor.
- j. Please provide evidence of GCP training for relevant staff.

5. Sponsor/Contract Research Organisation (CRO)/Clinical Trials Unit (CTU)

- a. Has your company previously acted as sponsor/CRO/CTU for a clinical trial conducted within the UK?
- b. Has any such clinical trial been inspected by the MHRA? If yes, are you able to provide a summary?
- c. How many previous Phase I, II, and III (as appropriate) has your company sponsored/coordinated?
- d. Please summarise the monitoring arrangements for these studies.
- e. Please describe the QMS in place in your company and provide a SOP index.
- f. Is your organisation/unit willing to comply with the JRMO overarching SOPs?

6. Other: for questions about these vendors please refer to the GCP Managers.

- a. Statistician
- b. Data managers
- c. Consultant
- d. Freelancer/Contractor