KING'S HEALTH PARTNERS | Clinical Trials Office

Service Provider Selection and Oversight

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1. BACKGROUND AND PURPOSE

The Clinical Trial Regulations part 1 3 Sponsor (12) state: A person who is a sponsor of a clinical trial in accordance with this regulation may delegate any or all of their functions under these Regulations to any person, but any such arrangement shall not affect the responsibility of the sponsor.

The requirements for selection of 'service providers', agreements and oversight by sponsor are detailed in ICH GCP R3. The principles apply to all Clinical Trials of Investigational Medicinal Products in the UK:

ICH GCP R3 principle 10.2: Agreements should clearly define the roles, activities and responsibilities for the clinical trial and be documented appropriately. Where activities have been transferred or delegated to service providers, the responsibility for the conduct of the trial, including quality and integrity of the trial data, resides with the sponsor or investigator, respectively.

ICH GCP R3 annex 1 provides further guidance for effective, risk-based sponsor oversight of service providers involved in clinical trials. Sponsors are required to ensure appropriate quality assurance and quality control, defined processes for the reporting and escalation of potential serious non-compliance, and clear arrangements for the retention and availability of essential records. This SOP describes the processes for the selection, oversight, and management of external service providers to whom sponsor functions are delegated.

This SOP describes the process for selection and oversight of external service providers where one or more of the duties of a sponsor is delegated to an external service provider.

2. SCOPE

All CTIMPs sponsored or co-sponsored by one or more of the Kings Health Partners organisations are within scope of this SOP.

3. PROCEDURE

3.1 Service Provider Selection

Task	Responsibility	Activity

3.1.1	Chief Investigator	Identify the need for external service providers and provide details of all proposed service providers to the Clinical Research Associate set up specialist and Sponsor R&D contract team.
3.1.2	KHP CTO Clinical Research Associate set up specialist or delegate	Ensure that all proposed service providers are discussed during the trial Kick off Meeting. Also refer to **KHP CTO SOP 12: Application and Maintenance of Clinical Trial Authorisation**.
3.1.3	Non-Commercial Trials Manager or delegate	Liaise with the Sponsor R&D Contracts Manager to assess whether new or existing service providers providing new services are suitable, considering trial and activity risk and prior experience with the service provider. Activities may include but are not limited to: • Service provider assessment questionnaire. • Onsite audit(s) carried out by suitably qualified person. • Review service provider SOPs and quality systems. Seek advice from KHP specialists as appropriate (e.g. clinical trials pharmacist for IMP distribution). Service provider systems should meet ICH GCP R3 requirements (robustness, security, retention etc) even if those systems were not designed with clinical trials in mind. Inform Chief Investigator of the outcome of the service provider assessment.
3.1.4	Chief Investigator	File outcome of service provider assessment in the Trial Master File (TMF).
3.1.5	KHP CTO Non-Commercial Trials Manager or delegate	Review division of responsibilities for each party for service provider agreements and ensure provision for: • reporting of incidents, GCP Non-Compliance, Serious Breaches of GCP & Urgent Safety Measures to the Sponsor. • monitoring, auditing and regulatory inspection.
3.1.6	Chief Investigator or delegate	Ensure final fully executed agreements are in place for all service providers before any work is undertaken. File a copy in the TMF.

3.2 Oversight and management during trial delivery

Task	Responsibility	Activity

3.2.1	KHP CTO Non Commercial Trials Manager or delegate	Ensure the trial risk assessment covers risks and risk mitigations in relation to all service providers.
3.2.2	KHP CTO Non Commercial Trials Manager or delegate	Draft the monitoring plan, based on the risk mitigations detailed in the risk assessment for the trial (also refer to **KHP CTO SOP 3: Clinical Trial Monitoring**) determine the requirements for monitoring (on-site or remote) of service providers.
3.2.3	Clinical Research Associate	Ensure appropriate training on any service provider systems is provided and completed by investigators and their delegates. This is typically completed as part of the site initiation visit (**see KHP CTO SOP 13: Initiation)**
3.2.4	Clinical Research Associate	Perform monitoring activities per the monitoring plan.
3.2.5	Clinical Research Associate.	Review and update the risk assessment and monitoring plan as necessary when the clinical trial is modified in relation to the activities of services providers or new service providers are added.
3.2.6	Chief Investigator or delegate	Ensure that service providers are provided with all updates to trial documentation that impact their service.
3.2.7	Clinical Research Associate / Chief Investigator or delegate	Escalate any concerns with services providers or significant non-compliance or breaches of GCP/ protocol/ regulations to the Non-Commercial Trial Manager referring to **KHP CTO SOP 6: Notification of a Serious Breach** where applicable.
3.2.8	KHP CTO Non Commercial Trials Manager	Raise significant issues with service provider performance with the Sponsor.
3.2.9	Clinical Research Associate	At end of trial: Complete close out activities per monitoring plan. Ensure service provider is aware of ongoing duties to make trial essential records available for inspection and other purposes eg audit per contract.

4. RELATED TEMPLATES

None

5. RELATED DOCUMENTS

1) KHP CTO SOP 12: Application and Maintenance of Clinical Trial Authorisation
2) KHP CTO SOP 3: Clinical Trial Monitoring
3) KHP CTO SOP 13: Initiation
4) KHP CTO SOP 6: Notification of a Serious Breach

6. REFERENCES

1. The Medicines for Human Use (Clinical Trials) Regulations 2004

https://www.legislation.gov.uk/uksi/2004/1031/contents/made

2. The Medicines for Human Use (Clinical Trials) (Amendment) Regulations 2025 https://www.legislation.gov.uk/uksi/2025/538/contents/made

2. ICH Topic (E6) guideline for Good Clinical Practice
https://www.ema.europa.eu/en/ich-e6-good-clinical-practice-scientific-guideline

3. UK Policy Framework for Health and Social Care Research UK Policy Framework for Health and Social Care Research - Health Research Authority

7. CHANGE HISTORY

CHANGE HISTORY			
Date	Version Number	Change details	Approved by
05 Jan 2021	1.1	Scheduled review, minor updates to section 4.1.1	Jackie Pullen
19 Apr 2023	1.1	Scheduled review no changes to SOP content.	Jackie Pullen
23 Apr 2026	2	Add specific requirements of service provider selection process per ICH GCP R3 • contract should be in place • service provider systems should meet GCP requirements (robustness, security, retention	Ann-Marie Murtagh

		etc) even if not designed with clinical trials in mind • terminology changed from vendor to service provider per R3 glossary Move SOP to new template	

8. GLOSSARY

GLOSSARY

Chief Investigator (CI) – The overall lead researcher for a Clinical Trial (Outside the UK the term 'Coordinating Investigator', 'Principal Investigator' or 'Investigator' may be used for the overall lead researcher for a Clinical Trial). Chief Investigators are responsible for the overall conduct of a Clinical Trial.

Clinical Research Associate (CRA) – A staff member employed by the KHP-CTO who conducts monitoring activities for a Clinical Trial, including but not limited to the initiation phase, routine phase, and close down phase. Delegate monitors (appointed in exceptional circumstances) are included in this definition.

Clinical Trial of an Investigational Medicinal Product (CTIMP) - Any investigation in human participants (other than a non-interventional trial) intended to discover or verify the clinical, pharmacological and/or other pharmacodynamic effects of one or more medicinal products and/or to identify any adverse reactions to one or more such products and to study absorption, distribution, metabolism and excretion of one or more such products with the object of ascertaining the safety and/or efficacy of those products. Includes clinical trials of ATIMPs.

Good Clinical Practice (GCP) - An international ethical and scientific quality standard for designing, conducting, recording, and reporting Clinical Trials that involve human participants. It ensures the safety, well-being, and rights of participants are protected while maintaining the credibility and accuracy of trial data. GCP is crucial for safeguarding participants and ensuring Clinical Trials produce reliable, scientifically valid results.

ICH GCP E6 (R3) – The International Council for Harmonisation – Good Clinical Practice, Guideline E6 (Revision 3). This is an internationally recognised ethical and scientific quality standard for the design, conduct, oversight, recording, and reporting of Clinical Trials.

KHP-CTO Director – The most senior member of the KHP-CTO.

KHP-CTO Non-Commercial Team - Comprises the Non-Commercial Trials Manager, CRA(s), Clinical Trial Administrator(s), Training Executive(s), Operations Lead and Operations Manager.

King's Health Partners (KHP) - King's College London, Guy's and St Thomas' NHS Foundation Trust, King's College Hospital NHS Foundation Trust, and South London and Maudsley NHS Foundation Trust.

King's Health Partners Clinical Trials Office (KHP-CTO) – The department established by King's College London, Guy's and St Thomas' NHS Foundation Trust, King' College Hospital NHS Foundation Trust, and South London and Maudsley NHS Foundation Trust to 1) undertake the set up and financial Management of commercial research hosted by one or more of the KHP Partners, and 2) undertake the regulatory submissions and oversight, as well as monitoring activity for non-commercial research studies sponsored by one of the KHP Partners.

Monitoring Plan - A Sponsor-approved document that sets out how Clinical Trial monitoring will be conducted, managed, and documented, using a risk-based approach to ensure participant safety, data integrity, and compliance with the approved protocol and applicable regulations.

Regulations – The Medicines for Human Use (Clinical Trials) Regulations 2004 (as amended including the Medicines for Human Use (Clinical Trials) (Amendment) Regulations 2025).

Research & Development Department (R&D Dept.) – The department at a Trial Location that's responsible for research and development at that Trial Location.

Research Ethics Committee (REC) – A national independent body consisting of healthcare professionals and non-medical members, whose responsibility is to protect the rights, safety and well-being of human subjects involved in a Clinical Trial, and to provide public assurance of that protection by, among other things, expressing an opinion on the Clinical Trial protocol, the suitability of the investigators and the adequacy of facilities, and on the methods and documents to be used to inform Clinical Trial participants and obtain their informed consent.

Risk Assessment - A structured, documented evaluation performed by the sCRA to identify and assess risks to participant safety, data integrity, and regulatory compliance in a Clinical Trial, and to define proportionate risk-mitigation and monitoring measures in accordance with the Regulations and ICH GCP E6 (R3) by extension.

Serious Breach - Under Part 4, paragraph 29A of the Medicines for Human Use (Clinical Trials) Regulations 2004 (as amended), a serious breach is defined as a breach of the conditions and principles of good clinical practice, or of the approved clinical trial protocol (as amended in accordance with regulations 22 to 25), which is likely to affect to a significant degree either the safety or the physical or mental integrity of trial participants, or the scientific value of the clinical trial. Where such a breach occurs, the sponsor is required to notify the licensing authority in writing within seven days of becoming aware of the breach.

Setup CRA – The CRA who's responsible for Clinical Trial setup activities on behalf of the KHP-CTO.

Site Initiation Visit (SIV) - A formal visit conducted by the Sponsor or their representative before a Trial Location begins participant recruitment, to confirm that the Trial Location is fully prepared to conduct the Clinical Trial in accordance with the approved protocol, regulatory requirements, and GCP.

Sponsor - The person or body who takes on ultimate responsibility for the initiation, management and financing (or arranging of the financing) of a Clinical Trial. The Regulations allow for two or more persons or bodies to take on responsibility for Sponsor functions.

Standard Operating Procedures (SOPs) - Detailed, written instructions to achieve uniformity of the performance of a specific function. SOPs are the basis upon which Quality Systems and Processes are conducted and monitored against.

Trial Master File (TMF) - A standard filing system which contains all essential documents which individually and collectively permits the evaluation of the conduct of a Clinical Trial and the quality of the data produced. The filing system can be in the form of a single project file or a number of files/filing cabinets, depending on what is deemed most appropriate for a particular Clinical Trial given its size and complexity. The regulatory documents and approvals within the TMF will be maintained alongside Case Report Forms and Source Records.

UK Policy Framework – The UK Policy Framework for Health and Social Care Research.