KING'S HEALTH PARTNERS | Clinical Trials Office

Pandemic Contingency Plan

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Table of Contents

1. BACKGROUND AND PURPOSE

The purpose of this policy is to describe the processes at the KHP CTO for proactive management and adjustment of clinical trials and their regulatory oversight when a pandemic occurs during the trial delivery.

The beginning and end of a pandemic is determined by Public Health England or the UK Government.

Any Public Health Emergency of International Concern (PHEIC) declared by the World Health Organisation can also trigger the activities described in this policy, where the emergency has or is anticipated to impact delivery of any trial within the scope of this policy.

2. SCOPE

Any Clinical Trial of an Investigational Medicinal Product which is sponsored or co-sponsored by a Kings Health Partners (KHP) organisation is in scope

3. PROCEDURE

3.1 Pandemic Working Party

Task	Responsibility	Activity
3.1.1	KHP CTO Director or delegate	When a pandemic is confirmed by PHE/ UK government, convene a working party with members as follows: • KHP CTO Director, or KHP CTO Non Commercial Trial Manager, or delegate and • R&D Director or delegate from a KHP Trust or a suitably qualified clinician from a KHP Trust/ KCL. The purpose of the working party is to make decisions on the appropriateness of continuing activity on clinical trials on behalf of the sponsor.
3.1.2	KHP CTO Director or delegate	At working party meeting(s), review the clinical trials in set up. It is expected that any trial in set up phase will be put on hold in order to release resource for ongoing trials. Ensure that the decision on clinical trials in set up is documented in sponsor records.

3.1.3	KHP CTO Director or delegate	At working party meeting(s), review the ongoing clinical trials, including information provided by CIs • Sufficient clinical resource should be available to ensure the safety of trial participants and the integrity of trial data. • Sufficient CTO resource should be available to support regulatory oversight, including but not limited to pharmacovigilance, trial modifications and monitoring of participant data. • Consider changes to trial risk assessments and monitoring plans (**KHP CTO SOP 3 Clinical Trial Monitoring**) such as increasing remote monitoring to mitigate the impact of travel restrictions and disease control measures on CTO staff. • Priority may be given to trials with ongoing long term IMP dosing, or with Advanced Therapy Medicinal Products or other high-risk interventions where participant safety must be upheld. • Modification to trials may be made to reduce infection risk for participants and investigators and delegates, and to account for PHE/ UK Government/ MHRA restrictions and guidance. • Recruitment of participants may be suspended. • Additional Chief Investigator and investigator training may be required. If CIs or investigators are unable to carry out their delegated duties due to reallocation of clinical resource by Trusts, or illness, or other pandemic related restrictions, there should be an appropriately trained delegate to cover their duties. Ensure that the decision on ongoing clinical trials is documented in sponsor records.
3.1.4	KHP CTO Director or delegate	At working party meeting(s), review the completed clinical trials. • Access to records at investigator sites may be reduced due to staff availability and travel restrictions. • Resource to analyse and report clinical trial data may be reduced due to staff re-allocation. Ensure that decision on completed clinical trials is documented in sponsor records.
3.1.5	KHP CTO Director or delegate	Share the outcome of the working party review with each Chief Investigator. • Identify deputy CI if appropriate

		• Confirm suspension or any other restrictions on recruitment of participants • Confirm any necessary modifications to the clinical trial to accommodate PHE/ UK Government restrictions and guidance. • Any other mitigations necessary for the successful delivery of the trial Record the discussion with the CI in sponsor records: this should be in the form of a summary email sent to the CI by the KHP CTO Director or delegate.
3.1.6	KHP CTO Director or delegate	Continue to hold working party meetings at suitable intervals until the pandemic ends.

3.2 Expectations for Chief Investigators

Task	Activity
3.2.1	In addition to the working group review, the Chief Investigator should also consider guidance from funders, feedback from investigators and other relevant sources. Changes to trial management or oversight should be recorded in addition to any changes to trial delivery by investigators and delegates and details provided to the working group for consideration where time permits (see section 3.1.1)
3.2.2	If notification of a modification to the trial is received from MHRA or REC, ensure this is addressed appropriately (per **KHP CTO SOP 12: Application and Maintenance of a Clinical Trial Authorisation**). Email KHP CTO Non Commercial Trials Manager or delegate to ensure CTO resource is assigned to support implementation of such a modification.
3.2.3	Where recruitment to the trial as a whole or at particular sites is suspended by sponsor, inform the relevant investigator(s) promptly.
3.2.4	Where an investigator confirms suspension of some or all trial activity by them and their delegate(s), ensure this update is shared with CTO CRA and study manager if applicable. Email CTO CRA, and study manager if applicable, to confirm investigator has suspended trial activity.
3.2.5	Urgent Safety Measures If appropriate, implement an urgent safety measure per **KHP CTO SOP 12: Application and Maintenance of a Clinical Trial Authorisation**.. NB tan urgent safety measure is an immediate unapproved action taken outside the approved protocol to protect participants for an immediate risk to their health or safety.

	Where a change is required to protect the ongoing integrity of trial data this should be addressed as a modification see section 6 below.
3.2.6	Modifications If appropriate, submit a modification to the clinical trial per **KHP CTO SOP 12 Application and Maintenance of a Clinical Trial Authorisation**.
3.2.7	Pharmacovigilance Serious adverse event reporting and assessment duties are not changed by the announcement of a pandemic. Adverse events related to pandemic/ public health emergency of international concern disease must be recorded in case report forms in the same way as any other adverse event. If sponsor can justify the exclusion of this type of event from trial data, a modification to the trial should be submitted for approval by MHRA/ REC through the usual process in **KHP CTO SOP 12: Application and Maintenance of a Clinical Trial Authorisation**.
3.2.8	Deviations and breaches Deviations from protocol, GCP or regulatory requirements should be recorded in trial records such as deviation logs, case report forms as per usual practice. Follow process in **KHP CTO SOP 6: Notification of a Serious Breach** if a potential serious breach occurs.
3.2.9	End of trial If the end of trial date per protocol occurs, submit the end of trial notification as usual per **KHP CTO SOP 12: Application and Maintenance of a Clinical Trial Authorisation**. Activities including production of clinical study report and preparation of records for archiving may be delayed if resources are not available.
3.2.10	Training For new delegates, or current delegates who are taking on new duties, such as deputy Chief Investigator, ensure that appropriate training is available.
3.2.11	Reopening trial locations and restarting trial activities Discuss and agree appropriateness of reopening trial locations and/ or restarting specific trial activities at trial locations with the KHP CTO. A location should not be reopened or extend the delivery of trial activity unless CRA resource to maintain oversight of the location is available. Where an investigator and delegates recommence trial activities, ensure appropriate training including updates on the delivery of the trial is available.

3.3 Expectations for investigators

Task	Activity
3.3.1	Modifications to trials will be implemented at sites following the **KHP CTO SOP 12: Application and Maintenance of a Clinical Trial Authorisation.** CRA or delegate may send update from CI to investigatorsif required.
3.3.2	Where an investigator or host organisation decides that insufficient resource is available to deliver trial activity, the record of this decision is usually generated by R&D.

	If CTO is informed that there is not capacity and capability for trial delivery by an investigator or host organisation, ensure Chief Investigator is informed promptly.
3.3.3	Investigators remain responsible for ensuring that any new delegates, or delegates who take on additional duties, complete training which is proportionate to the importance of the duties undertaken. This may be trial or duty specific.
3.3.4	Reopening trial locations Where an investigator and delegates recommence trial activities, CRA or delegate will ensure appropriate training including updates on the delivery of the trial is available. If confirmation of capacity and capability is necessary (i.e. if this was withdrawn previously, or if there has been a modification to the trial which requires C&C), ensure that this has been obtained prior to site activity restarting.

4. RELATED TEMPLATES

N/a

5. RELATED SOPs

KHP CTO SOP 3: Clinical Trial Monitoring

KHP CTO SOP 12: Application and Maintenance of a Clinical Trial Authorisation

KHP CTO Pharmacovigilance and Safety Reporting Policy

6. REFERNCES

MHRA guidance Managing clinical trials during Coronavirus (COVID-19) - GOV.UK

International Coalition of Medicines Regulatory Authorities (ICMRA) Covid-19 Working Group remote_inspections_reflection_paper.pdf

7. CHANGE HISTORY

CHANGE HISTORY			
Date	Version Number	Change details	Approved by

22/Oct/2012	2.0	Scheduled review. Change of branding of Dept from JCTO to KHP-CTO	Jackie Powell
22/Oct/2014	3.0	Scheduled review and additional information included to state that this policy covers all pandemics in line with Department of Health recommendations	Jackie Pullen
31/Mar/2015	4.0	Clarify reporting requirements for USM and Emergency Safety Measures	Jackie Pullen
25/Apr/2017	5.0	Scheduled review	Jackie Pullen
05/Mar/2020	6.0	Update due to Covid-19 emergence	Jackie Pullen
18/May/2023	6.0	Scheduled review- no changes made	Jackie Pullen
06/Aug/2026	7.0	New template separating the process for the pandemic working group from the activities to be carried out by Chief Investigators.	

8. GLOSSARY

Advanced Therapy Medicinal Product (ATMP) – A medicine based on genes, cells, or engineered tissues that is intended to treat, prevent, or diagnose disease by modifying biological functions at a cellular or genetic level.

Adverse Event (AE) - Any untoward medical occurrence in a participant who has been administered an IMP, which does not necessarily have a causal relationship with that IMP.

Case Report Form (CRF) - A printed, optical, or electronic document designed to record all of the protocol required information to be reported for each trial participant, to be reported to the Sponsor.**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) (Clinical Trial in this document)- Any investigation in human subjects, other than a non-interventional trial intended to discover or verify the clinical, pharmacological or other pharmacodynamic effects of one or more medicinal product or to identify any adverse reactions to one or more such products and to study absorption, distribution metabolism and excretion in one or more such products with the object of ascertaining the safety or efficacy of those products. Includes clinical trials of ATMPs.

Clinical Trial Authorisation (CTA) – Authorisation from the Medicines and Healthcare products Regulatory Agency (MHRA) to conduct a Clinical Trial. No Clinical Trial can commence in the UK without both a CTA and a favourable ethical opinion. Applications to the MHRA and the Research Ethics Committee (REC) may be made in parallel.

Co-Sponsors – Where two or more organisations take responsibility for the initiation, management and financing (or arranging the financing in relation to) a clinical trial. The Co-Sponsors agree how the Sponsor functions for the Clinical Trial are divided between themselves and document this accordingly.

End of Trial (EoT) – The end of the trial as defined in the protocol. The end of the trial is typically expressed as a condition-based event, not a predetermined date.

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

Investigational Medicinal Products (IMP) - A pharmaceutical form of an active ingredient or placebo being tested or used as a reference in a Clinical Trial. This includes products with marketing authorisation when used in a way different from the approved form, for an unapproved indication, or to gain further information about an approved use.

Investigator - the authorised health professional responsible for the conduct of that trial at a trial site, and if the trial is conducted by a team of authorised health professionals at a trial site, the investigator is the leader responsible for that team.

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's 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.

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

Medicines and Healthcare products Regulatory Agency (MHRA) - The UK government agency responsible for regulating medicines, medical devices, and Clinical Trials. In the context of Clinical Trials, the MHRA i) acts as the licensing authority for Clinical Trials, ii) reviews the scientific, quality, and safety aspects of a Clinical Trial application, iii) issues CTAs, iv) oversees GCP and GMP inspections, v) monitors pharmacovigilance and safety reporting, and vi) enforces compliance with UK medicines legislation.

Modification – Any change to a Clinical Trial after initial approval that affects the information or conditions on which the Clinical Trial was authorised. Includes minor modifications, Modifications of an Important Detail (MOIDs), Route A and Route B substantial modifications.

Monitoring Plan (MP) – 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.

KHP CTO Non-Commercial Trials Manager – The most senior member of the KHP-CTO Non-Commercial Team.

Pandemic - The worldwide spread of a disease, with outbreaks or epidemics occurring in many countries and in most regions of the world. A disease epidemic occurs when there are more cases of that disease than normal.

Participant - An individual who consents to take part in a clinical trial. This individual may previously be known as a patient, volunteer or subject.

Pharmacovigilance (PV) – the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problem.

The 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 Dept (R&D) –** 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.

Serious Adverse Event (SAE) - An Adverse Event that results in death, is life-threatening, requires inpatient hospitalisation or prolongation of existing hospitalisation, results in persistent or significant disability or incapacity, or consists of a congenital anomaly or birth defect.

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.

Source Records - Original documents or data (which includes relevant metadata) or certified copies of the original documents or data, irrespective of the media used. This may include participants' medical/health records/notes/charts; data provided/entered by participants (e.g., electronic patient-reported outcomes (ePROs)); healthcare professionals' records from pharmacies, laboratories and other facilities involved in the Research Study; and data from automated instruments, such as wearables and sensors.

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.

Suspected Unexpected Serious Adverse Reaction (SUSAR) – A Serious Adverse Reaction to an IMP that is unexpected, meaning that the nature or severity of the reaction is not consistent with the applicable product information according to the RSI.

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 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.

Urgent Safety Measure (USM) - An urgent safety measure that must be taken to protect Clinical Trial participants against an immediate hazard to their health or safety.

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