Clinical Trials Pandemic Contingency Plan

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Relevant regulations/legislation/guidelines	Statutory Instrument 2004 no 1031 Statutory Instrument 2006 no 1928 Statutory Instrument 2009 no 1164

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

GLOSSARY

Chief Investigator (CI) - A Registered Physician, Dentist, Pharmacist or Registered Nurse who has overall responsibility for the conduct of the study.

Clinical Trial - 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 of more such products with the object of ascertaining the safety or efficacy.

Global Health Emergency - The World Health Organisation defines a global health emergency, also known as a Public Health Emergency of International Concern, as an event where disease has the risk to spread internationally.

King's Health Partners (KHP) - King's Health Partners Academic Health Science Center is a pioneering collaboration between one of the King's College London (University) and three of London's most successful NHS Foundation Trusts – Guy's & St Thomas', King's College Hospital and the South London & Maudsley.

King's Health Partners Clinical Trials Office (KHP-CTO) - Established in 2006 by King's College London, Guy's & St Thomas' NHS Foundation Trust, South London and Maudsley NHS Foundation Trust and King's College Hospital Foundation Trust to provide a streamlined approach for all aspects of trial administration.

Medicines & Healthcare products Regulatory Agency (MHRA) - UK competent authority responsible for regulation of clinical trials.

Pandemic - is 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.

Principal Investigator (PI) - A Registered Physician, Dentist, Pharmacist or Registered Nurse who has responsibility for the conduct of the trial at a host site.

Public Health England (PHE) – Public Health England (PHE) is an executive agency of the Department of Health and Social Care (DHSC) which is the expert national public health agency which fulfils the Secretary of State for Health and Social Care's statutory duty to protect health and address inequalities, and executes his power to promote the health and wellbeing of the nation

Sponsor - The organisation who takes responsibility for the initiation, management and financing (or arranging the financing) in relation to a clinical trial. The Sponsor organisation has responsibility for carrying out the Sponsor functions of that trial (as defined in the Regulations).

R&D Depts. - NHS department responsible for confirmation of capacity and capability for all clinical research.

The Regulations - The Medicines for Human Use (Clinical Trials) Regulations 2004, transposed the EU Clinical Trials Directive into UK legislation, as Statutory Instrument 2004 1031. This became effective on the 1st May 2004. An amendment to implement Directive 2005/28/EC was made to the Regulations as Statutory Instrument 2006 no 1928. As amended from time to time.

Background and Purpose

The Regulations define both the Sponsor's and the Chief Investigator's responsibilities during the conduct of clinical trials to ensure patient safety and integrity of trial data at all times. The KHP-CTO has developed quality systems and processes to manage and deliver the Sponsors responsibilities for trials sponsored or co-sponsored by King's Health Partner Organisations.

The purpose of this policy is to outline a plan of action to ensure that the Sponsor's and Chief Investigator's responsibilities for ongoing trials are met throughout a period during which a disease is pandemic and a serious risk to human health or potentially a serious risk to human health leading to a shortage of staff resources, or during a time when travel or other measures are implemented to reduce transmission of such a contagion prior to pandemic status.

This policy covers all public health endemic or pandemic occurrences within the UK or areas where KHP Sponsored clinical trials are conducted.

UK Pandemic Planning Assumptions

Contingency planning will be implemented as per advice from Public Health England or the UK Government.

Scope

All clinical trials involving Investigational Medicinal Products (IMP); as defined in the Medicines for Human Use (Clinical Trials) Regulations 2004 (as amended from time to time), sponsored or co-sponsored by the King's Health Partners Organisations.

Procedure

It is very difficult to predict the impact on clinical trial activity during a full pandemic situation as it will be complicated by trial staff being re-deployed to assist with core healthcare activities, as well as potential illness amongst the trial teams and the trial subjects. Where trial activity continues Sponsors are expected to continue to meet their obligations with respect to clinical trials legislation, guided where necessary by advice from the MHRA, Department of Health & Social Care (DHSC), Public Health England and any other relevant local government body as the situation develops.

Pandemic Working Party

Once a pandemic or global health emergency has been announced and national guidelines or actions declared or implemented; a working party will be convened from available KHP-CTO and KHP Staff. The quorum for this group will ideally include: -

- KHP-CTO Director, Quality Manager or delegate.
- R&D Director (or delegate) from at least one of the Partner Trusts.

However, due to the very nature of a pandemic this may not be possible to achieve, in which case members should be drawn from the medical community within the Partner Trusts and/or University.

The working party will be tasked with the following: -

1. The working party will review the portfolio of clinical trials, in the first instance all trials in the set up or planning phase will be put onto hold and available KHP-CTO Quality Team resource directed to ongoing trials.
2. Each ongoing trial will be reviewed to ensure that sufficient clinical resource is available to ensure patient safety and data integrity is maintained. Appropriately trained deputy CI/PI's will be identified and briefed at this stage in case of existing CI/PI absence.
3. If clinical resource is available this should be allocated to trials with patients enrolled into intervention phases of trials according to the risk or the trial. It may be necessary for trials that have single dosing episodes to be temporarily suspended to allow for those trials with subjects in longer term active phases or high risk interventions to be resourced adequately.
4. Each trial will be reviewed with the CI/PI or delegate to discuss temporary suspension of recruitment to ensure adequate safety and monitoring of existing patients on trials.
5. Pooling of organizational research nurse resources should be considered to ensure the rights, safety and well-being of enrolled subjects and data integrity is maintained.

Substantial Amendments to REC & MHRA

Non-substantial amendments do not need to be reported to the MHRA before being made. Substantial amendments should be notified to the concerned Ethics Committee and the MHRA in the normal way.

Urgent Safety Measures

The MHRA have confirmed that all Sponsor and CI responsibilities must be met during a pandemic situation. However, the Sponsor and Investigator may take appropriate urgent safety measures in order to protect the subjects of a clinical trial against any immediate hazard to their health or safety. Any such action taken will be reported to the MHRA as soon as possible.

SUSARS, SAE's & Adverse Events

The MHRA expect Sponsors to continue to meet their obligations with respect to clinical trials legislation, including Pharmacovigilance reporting, guided where necessary by advice from their website and helpline, as the situation develops.

Pandemic/declared global health emergency disease related AEs/SAEs must be recorded in the CRFs as they are reported unless the Sponsor can justify a substantial amendment to the protocol which excludes reporting this type of event. The amendment would require approval by the MHRA in the normal way and the appropriate REC.

Protocol Deviations & Serious Breach Reports

All protocol deviations should be recorded in the CRF, and serious breaches recorded for reporting when the situation allows this to be done.

Emergency Safety Measures

The Sponsor and Investigator will consider and implement any additional emergency safety measures which may be necessary as information emerges.

Associated Documents

MHRA Pandemic Situation Questions & Answers

GSTFT Local Pandemic Influenza Preparedness Plan

APPROVAL and SIGNATURE

18 May 2023

Jackie Pullen
Director, King's Health Partners Clinical Trials Office
King's Health Partners

Date