UKCRC Registered Clinical Trials Units

UKCRC CTU Trial Management Operations Group Restart Guidance.

August 2020

UK Clinical Research Collaboration

igniting our potential

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Restart Guidance.

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The following guidance points reflect decisions being made by CTUs, Sponsors and CIs, allowing Trial Management teams to contribute to the Restart process, and references the NIHR Restart Framework This guidance has been designed as a brief framework to aid usability.

STUDY VIABILITY

DESIGN	Is the **study question still pertinent**? What is the impact given the phase of the study i.e. set-up, recruitment, follow-up? What is the impact of Covid-19 on **Primary and Secondary endpoints**? What is the impact due to the **type of study** CTIMP/non-CTIMP and intervention? Are sub-studies/embedded studies still viable?
DELIVERY	Is the Sponsor still able to undertake all their roles and responsibilities? Funder's ability/willingness to continue to support the study? Are the **collaborators essential to the delivery of the study operational** e.g. labs / vendors / oversight committees (DSMC/TSC)? Participating sites are **willing and able** to restart the study? Covid-19 second/regional wave – what will the impact be? Should opening be deferred regionally/nationally?
POPULATION	Can study participant's still complete key activities such as safety events in a vulnerable population who are shielded? Participant pathway is still achievable?

CTU – GENERAL CONSIDERATIONS

STAFFING	**Adequate staff** to support the number of studies to restart? Furloughed Staff – when to bring staff back? Should part-time be considered? **Staff recruitment**, consider early discussions with HR in case of recruitment freeze. Mental health and wellbeing continued support for staff.
OFFICE	Prioritisation of staff to work from the office, **task dependent/access to office equipment**? Use of **shifts/rotas**, layout of office and adherence to social distancing rules. Adequate **oversight** and line management of staff in the office. **PPE requirements**? Are extra cleaning materials required? What about shared areas? **Adequate facilities** to support staff i.e. kitchen facilities, porters, cleaners, security etc. Transport, are staff members able to get to and from work safely.

TRIAL MANAGEMENT

RESTART	What **amendments** are required to restart a study? Is there potential to consider alternative technology such as e-consent and remote data collection? Have any **changes to the protocol** been **approved** by the **funder**? What **approvals** are required from **each site** prior to restarting (*may not be the same*)? **Convene TMG/TSC** to approve the restart and any amendments. Consider **standardise documentation** to record restart in the TMF/ISF across the CTU. Consider **restart site Webinars** to relaunch and provide training on any amendments.
PROJECT MANAGEMENT	What **study deliverables**, if any, have been **affected by the lock down** e.g. follow-up rates? What is the impact of any data entry backlog i.e. interim analysis reports for DSMC/TSC? What is the financial impact? Staff costs, loss of IMP or other supplies (e.g. vacutainers, lab reagents or kits) due to expiration, travel/meetings cancellation costs, extra costs incurred due to remote working or potential cost savings? **What is the impact on study milestones**? Are there any time savings/extensions required? Plan for SIV's, investigator meetings and monitoring visits to be undertaken remotely. Undertake a **reconciliation/audit of the TMF** and any updates to the ISF. Map from the restart date recruitment rates and site restart dates **to continuously monitor the impact on milestones**.
FUTURE BENEFIT	Keep a record of **what has worked well/**new ways of undertaking activities for future benefit. UKCRC CTU to collate and provide feedback to the HRA, RECs and MHRA.