

UKCRC  
Registered  
Clinical  
Trials Units



# High-level principles around the restart of on-site monitoring

## June 2021



igniting our potential

# UKCRC Monitoring task and finish group

## High-level principles around the restart of on-site monitoring

June 2021

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The UKCRC Monitoring task and finish group have collated experience and considerations for re-starting on-site trial monitoring that had previously been suspended due to the COVID-19 pandemic.

When considering the re-start of on-site monitoring activities, the following points may be useful to review. NB: It is suggested that items 1 – 3 are fully explored and resolved before moving on to item 4. This will enable all safety issues to be properly taken into account when discussing a return to onsite monitoring with CTU staff.

- 1) Are the site visits actually needed
  - Review risk assessments and monitoring plans
  - If site visits required, can they be mitigated by other means e.g. remote monitoring, video/conference calls with members of the site team or increased central monitoring
- 2) Organisational issues
  - Does the CTU and/or host institution allow / prohibit staff travel
  - Are there organisational requirements around staff travel / is there a risk assessment
- 3) Pandemic constraints
  - Is travel permitted – when essential travel only is permitted by government guidelines confirm if site visit is considered essential (CTU will need to make an assessment on what travel is essential e.g. site initiation visits can be done remotely)
  - Do the devolved nations have different guidance / stipulations
  - If site visits required, can the site comply – e.g. reduced staff resource if moved to clinical areas / hospitals reducing footfall, limit on number of on-site visits, site stipulating remote monitoring only
  - Is there a site policy for on-site monitoring do they allow it and do they have provision in place for monitors to work safely (i.e. can work 2m apart).
  - Issue of remaining up-to-date with constantly changing site policy
- 4) CTU issues
  - Do you need a Risk Assessment for sending staff out to sites; including travel: Will you allow train/plane/bus/taxis as modes of transport to get to and from site
  - Are CTU staff willing to travel and do site visits – consideration should be given that some staff may not be able to do site visits (high risk, personal anxieties)