UKCRC Registered Clinical Trials Units

How to move to remote monitoring with least burden to site staff – hints and tips

May 2021

UK Clinical Research Collaboration

igniting our potential

UKCRC Monitoring task and finish group

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Before approaching the site

Risk assessment	Update risk assessment so that you are only monitoring risks relevant at this time. Different phases and cohorts of the same trial can have different monitoring requirements. If remote monitoring is a temporary measure, monitor data that is critical at this point in time.
Risk-based monitoring	Use risk-based monitoring, assessing data centrally by site (central monitoring) for risks by defining triggers (metrics and thresholds) to mitigate or assess these risks. This will reduce the amount of remote monitoring required.

Remote monitoring approaches: For each site, from what is possible, choose the best value to the sponsor with the least burden to site

Increasing burden on site

Direct access	Ask if direct access to electronic records limited to trial patients is possible at sites. This would help with SDV of data without a site burden (e.g. for early phase trials). For sites that have many electronic record systems, check that you will have access to enough data if only given access to one or two systems. Usually no documents can be copied, downloaded, screenshot, emailed or printed from the EMR.
Share via secure document repository	For source data shared via a secure document repository (e.g. EDGE), if the system does not allow copying or has instructions prohibiting saving, downloading, emailing or printing source documents then pseudonymisation is not necessary. Sites have to confirm the copies are good representations of the originals.
Share via video conference	For source data shared via a secure video conferencing platform, the site needs to approve the software (MS Teams suggested) and consider if direct view of the electronic records or scanned paper documents will be used. Again no recording of the video conference, copying of documents, screenshots or printing are permitted
Share via email	For source data sent via email or secure platforms from where the documents will be downloaded, the data must be pseudonymised by the site. Sites have to confirm the copies are good representations of the originals. Once reviewed the data must be deleted from the email box and any download or temporary folders.
Share verbally	If only telephone or a video conference are possible, patient status, patient recruitment and site trial processes can be discussed and documented in a monitoring report. Such calls should not be recorded.
Site self-completed checklist	Sites can be asked to fill in a checklist to show the situation at site.

Increasing value to sponsor