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Dear Janet

Sponsor Remote Monitoring Consultation

Thank you for giving the NHS R&D Forum the opportunity to feed into the remote monitoring consultation. Between 4-8th January 2021 the Research Management Working Group provided comments on the challenges that NHS Trusts are experiencing with Sponsors wanting to do remote monitoring (other than issues with SDV and access to medical records). Comments were received on 10 studies with members reporting remote monitoring occurring using a combination of phone calls and TEAMS video calls. The comments received were generally positive.

Uploading Documents

Some Sponsors are requesting R&D department to upload documents into a variety of systems for them to review or send through redacted information. This is being declined on the basis that it places extra burden on the study team to upload and also introduces the potential for data breaches if the study team don't redact all identifiers.

Some Sponsors are using file transfer services but these are not intuitive. Sending via secure email is a better alternative and has worked well were utilised.

Time Constraints

Ensuring that monitors allocate the correct amount of time is challenging with some monitors underestimating and other over estimating the time needed to ensure all tasks are completed. Those not requiring SDV as part of the monitoring visit are significantly less time complex and time consuming. Those who had regular remote monitoring with specific CRA felt they were more efficient.

Resource Challenges

Members reported that it can be difficult to find an appropriate location and equipment to facilitate remote monitoring. Offices can be noisy and phones are not hands free so looking through notes one handed can be awkward. Speaker phones aren't used as they disturb other members of staff and not all desktops/laptops are fitted with cameras. If phones are being used for remote monitoring this means other calls cannot reach R&D.

Remote Monitoring Aspects

Members reported that Sponsors are using remote monitoring for updates on any issues, amendments, site file review, general study discussions, reconciliation reports, recruitment progress, close down visits and archiving.

Positive Feedback Concerning Remote Monitoring

Conversations with monitors have been easy as there is an opportunity to clarify queries in real time rather than waiting until the end of the day for feedback.

SDV

Although outside the remit of this consultation, comments were received on the logistical challenges that can occur with remote SDV ie it is not possible to hold up lots of source data to camera to be verified via remote monitoring. Some Sponsors will not allow redacted source documents to be sent via PDF emails and R&D offices do not have the resources for live SDV in terms of other means of file sharing.

It would be great if these comments could facilitate some positive changes at the start of a new year to make working easier for all throughout the rest of the year.

If we can be of any further assistance, please do not hesitate to contact us.

Many thanks

Sally

Sally Humphreys

NHS R&D Forum Research Management Working Group Chair



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