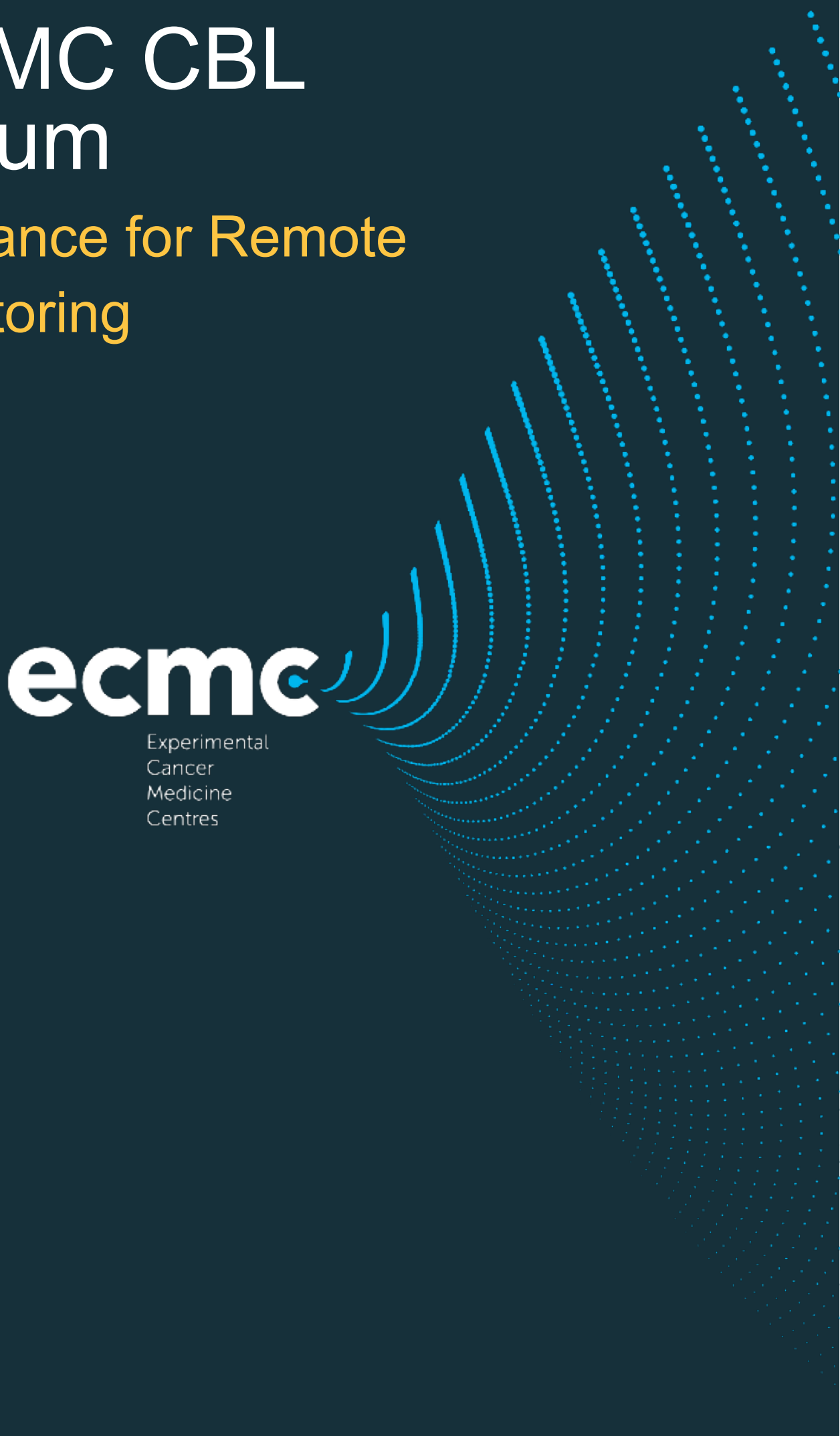
ECMC CBL Forum

Guidance for Remote Monitoring



Contents

Introduction

Purpose and Scope

The purpose of this document is to collate solutions and best practice when approaching remote monitoring of clinical trial data. The contents of this document are not intended as definitive Network guidance on how remote monitoring should be conducted but as suggested guidance based on experiences and approaches across the Experimental Cancer Medicine Centre (ECMC) Network and in line with guidance from the MHRA and HRA. This guidance should be used in conjunction with relevant Trust policies and regulatory guidance.

The document will be updated with further knowledge and guidance from the Network as it becomes available. Please contact the ECMC Programme Office if you have any examples or information which may be included in this document for the benefit of the Network.

The ECMC Network is made up of 18 adult centres and 11 paediatric centres across the UK. Operational teams from these centres worked collaboratively to produce this document, collating knowledge from across the network and can be used by members of the network to help implement or improve remote monitoring practices, resolve common issues or help their Trust or Sponsors to adopt remote monitoring.

This document has been separated into sections of the most common topics of consideration for remote monitoring as determined by the ECMC Centre Business Leads (CBL) forum.

This document has been created by the ECMC CBL Forum Remote Monitoring Sub-Group with support from the ECMC Programme Office.

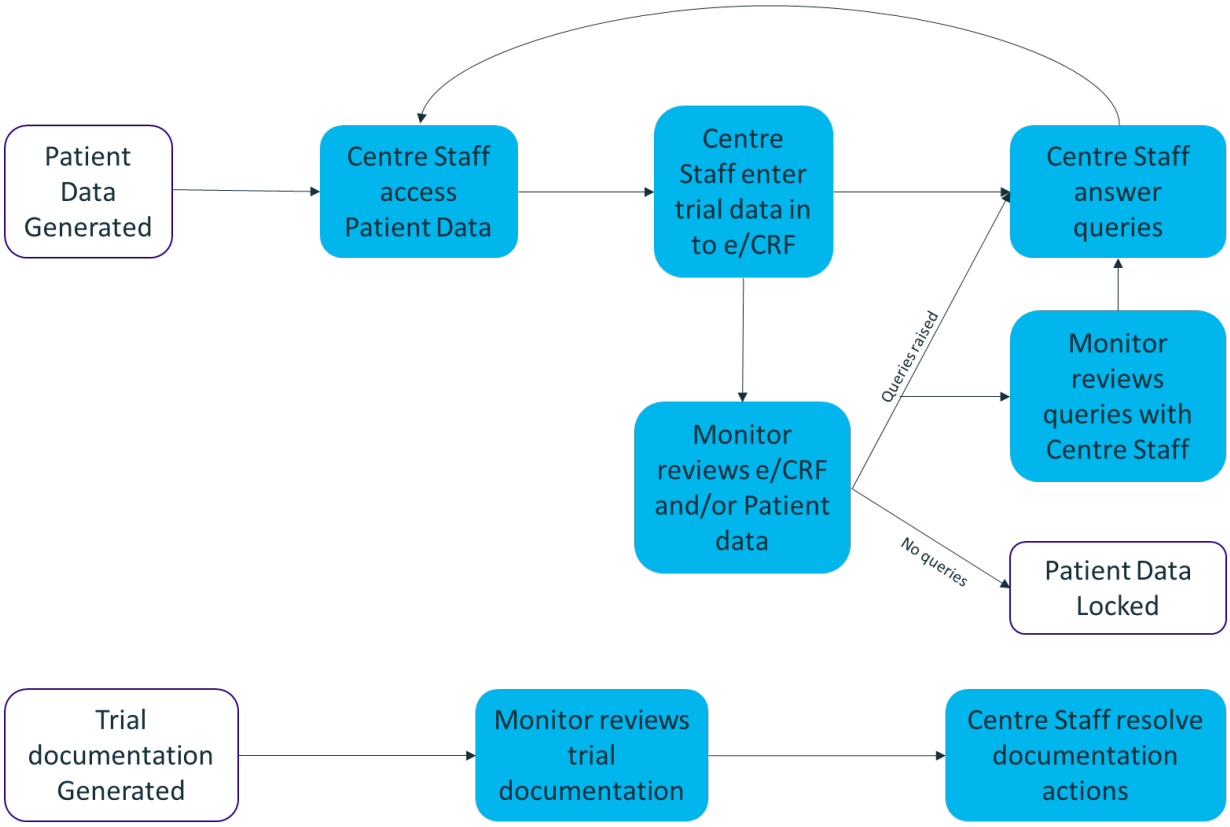
The ECMC Programme Office would like to thank all of the Centres and Network Members who have contributed to the contents and creation of this document.

Background

At the beginning of 2020, the COVID-19 Pandemic resulted in restrictions which made on-site monitoring of clinical trial data and documents more challenging due to safety and social distancing restrictions. These restrictions meant alternative ways of monitoring clinical trials needed to be explored and implemented to ensure data integrity and patient safety on clinical trials. Due to this, the use of Remote Monitoring has been taken up by Sponsors and Trial sites, where possible. Where Remote Monitoring has been managed purely by site staff redacting, scanning and sending documents for Sponsor review, this has proved to be burdensome for site staff, especially during the COVID-19 restrictions. However, with the increased availability of new technologies and experience, Risk Based monitoring can be used to monitor specific aspects or all trial data to the benefit of both site staff and Sponsor, without the burden of increased workload. Where on-site monitoring is not possible at all, Remote Monitoring can help ensure that the scientific integrity, patient safety and regulatory and protocol compliance can be maintained as key data is reviewed contemporaneously, data entry and lock targets can be met ensuring sites are able to receive their data-related payments. Where on-site monitoring is limited, Remote Monitoring activities can also be utilised to decrease the number of required visits. As experience in Remote Monitoring activities and facilitating Remote Monitoring increases, the shared, collective knowledge of the ECMC Network can be used to improve practices

and make use of the benefits of Remote Monitoring during the pandemic and in the future as complementary to traditional, on-site monitoring.

When remote monitoring is explored or implemented at a centre, either in its entirety or alongside on-site monitoring, it is important that relevant SOPs are updated or created and relevant communications and training for site staff or monitors are provided before embarking on new processes.



This guidance document aims to support the monitoring activities shown in blue by sharing practice on the access to trial data and documents either remotely or on site.

Abbreviations

ALCOA+	Attributable, Legible, Contemporaneous, Original, Accurate, Complete, Consistent, Enduring and Available
CBL	Centre Business Leads
ECMC	Experimental Cancer Medicine Centres
HRA	Health Research Authority
ICD	Informed Consent Document
ISF	Investigator Site File
MHRA	Medicines and Healthcare products Regulatory Agency
PPE	Personal Protective Equipment
QA	Quality Assurance

Definitions

The below definitions have been applied by the CBL Monitoring Working Group for the purpose of this guidance document.

Remote monitoring is defined as the overseeing of a clinical trial to ensure it is conducted, recorded and reported in line with ICH GCP, Clinical Trials Regulations, the Trial Protocol and relevant SOPs, by viewing of site trial documents and patient notes at a location separate to the site.

Remote access is defined as viewing or reviewing of site trial documents and patient notes at a location separate to the site using internet enabled devices.

Direct access is defined as the access to Electronic Health Records, and therefore un-redacted patient data, by a monitor away from the site.

Redacted data is defined as clinical trial data in which the personal data has been pseudonymized and can no longer be attributed to a specific patient without the use of additional information, provided that such additional information is kept separately. E.g. patient initials and date of birth but not patient name.

MHRA and HRA guidance summary

The MHRA and HRA support the use of Remote Monitoring and have provided initial guidance related to the change in monitoring practices during the COVID-19 pandemic.

Considerations from the links below have been included in this document.

https://www.gov.uk/guidance/managing-clinical-trials-during-coronavirus-covid-19#remote-monitoring-for-trials

http://mhrainspectorate.blog.gov.uk/2020/03/12/advice-for-management-of-clinical-trials-in-relation-to-coronavirus/

https://www.hra.nhs.uk/covid-19-research/covid-19-guidance-sponsors-sites-and-researchers/

https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/687246/MHRA_GxP_data_integrity_guide_March_edited_Final.pdf

Guidance

1. Onsite access measures for monitors

- When on-site visit capacity is limited, provide priority to early phase monitors and to patient safety or business critical monitoring visits.
- Create a summary of any logistical and safety requirements and contact monitors ahead of the visit so they are aware of expectations. Consider whether this should be signed by the monitor to show agreement.
- Create a checklist for site staff of all requirements for onsite visits (e.g. for monitors or for facilities).
- Points to consider for onsite visits requirements:
    - Monitor use of PPE (e.g. masks) and hand sanitiser. Consider availability of these items at site if monitor does not have these.
    - Confirmation of no COVID-19 symptoms or contact with persons who have symptoms prior to visit
    - Prior approval of appropriate monitoring visits (e.g. safety critical)
    - Whether COVID-19 testing is required
    - Reporting of COVID-19 symptoms after the visit
    - Cleaning of workstations
    - Appropriately distanced workstations
    - Chaperone requirements whilst onsite
    - Time restrictions on days of visits to allow for cleaning
    - If possible, the use of the space away from the hospital for monitors.
    - Additional cost implications for the above.
    - Trust policy requirements for onsite visitors.

2. Remote access to source notes and trial documents

2.1. Sharing of redacted data

- Always refer to Trust Information Governance/Sharing policies.
- Discuss with Sponsors an agreement to only provide essential, priority data for remote monitoring to reduce burden on site staff and reduce backlog of data once onsite monitoring is available.
    - Discuss what is considered critical data for a monitor to review to allow site staff to prepare and ensure any monitoring prioritises relevant data to reduce burden for site staff and time required for any remote monitoring.
- Use of a proforma to capture visit data in one place can ease the burden of sharing data for remote monitoring.
- As trial documents must be ALCOA+ (Attributable, Legible, Contemporaneous, Original, Accurate, Complete, Consistent, Enduring and Available), review documents being shared to ensure the act of redacting has not erased any of these characteristics (e.g. no longer legible, complete or attributable by covering parts of notes or not adding in anonymised patient identifiers).

- When sending to NHS staff, send to and from NHS emails rather than university emails for security.
- Consider whether use of a password protected, encrypted email should be used.

2.1.1. Sharing of Redacted Paper Data

- Upload redacted files and notes to a secure electronic system to share safely with monitors.
- Save pertinent Investigator Site File (ISF) documents to secure electronic system (e.g. EDGE, Teams) enables working from home when/if required.
    - This may also allow for remote review of ISF documents by monitors
    - E.g. private Teams channel for remote review of training logs etc.

2.1.2. Sharing of Redacted Electronic Data

- If redacting data electronically (e.g. black out text electronically i.e. using Word or Adobe etc.) ensure that the redaction cannot be moved or removed by the receiving party to reveal the confidential data.

2.2. Screensharing data

- Always refer to Trust Information Governance/Sharing policies.
- Consider scanning paper data to allow sharing via screenshare.
    - Ensure that where and how to store this scanned data is agreed with the relevant Trust departments (e.g. Information Governance, I.T.). For example storing scanned data in an approved secure file or system and not on staff's personal laptops and how long is appropriate to store this data.
- Collate a list of Trust/Quality Assurance (QA) approved platforms to approve requests by Sponsors or suggest alternatives (e.g. Attend Anywhere, Teams etc.) and prevent the need to consult QA for each request.
- When staff are screensharing, ensure that other application windows or other data is not viewable by the monitor to maintain confidentiality.
- Consider creating a proforma or email template to be sent to monitors which detail the requirements and expected etiquette for the calls and consider whether this should be signed by the monitor. (e.g. screenshots and recording prohibited).
    - Requirements to consider
        - Screenshots, screen sharing with another party and recording calls is prohibited. (HRA Guidance)
        - Device used by monitor is secure, password protected and has relevant firewalls.
        - Monitors should be in a location where their screen cannot be seen by others.

2.3. Remote direct access to electronic patient records

- Always refer to Trust Information Governance/Sharing policies.
- Allow monitors to log in to electronic notes system directly with restricted access.
- Points to consider when implementing direct access:
    - Create and manage Password access to monitors
    - Monitors only allowed access to relevant trial patients' records
    - How can site staff oversee the access

- Audit trails (what data can be collected [e.g. time stamps, data/documents viewed etc.] and what will be reviewed to ensure monitor adherence to guidelines.) (MHRA Data Integrity Guidance)
- Training requirements for staff and monitors and additional time and resource needed to provide and/or undertake this.
- Need of access to additional EPR applications if used for different types of data (e.g. one for notes, one for investigations etc.).
    - Is this possible?
    - Consider burden for site staff for each application vs sharing data another way.
- Would any cost to implement direct access (e.g. to cover licenses etc.) and/or provide training for each study may need to be considered and discussed with Sponsors?

- Provide instructions as to what can be accessed where and request agreement from the CRAs that this will be complied with. (MHRA Guidance)
- Consider creating a proforma to be sent to and signed by monitors which detail the requirements and expected etiquette for the sessions
    - Requirements to consider (MHRA Guidance)
        - Screenshots, printing, downloading, emailing or screen sharing with another party and recording sessions is prohibited. (HRA Guidance)
        - Device used by monitor is secure, password protected and has relevant firewalls and must not be left unattended.
        - Monitors should be in a location where their screen cannot be seen by others.
        - The use of alternative means of oversight such as teleconferences / videoconferences during sessions is encouraged by the MHRA.

2.4. Other regulatory and legal considerations or guidance

- Trial participants will need to consent to any identifiers leaving the site and be assured that their confidentiality will be protected. (MHRA Guidance)
    - Ensure that the wording in ICDs allows for remote monitoring and does not specifically state monitoring of patient data will occur at site. This may require and amendment and some patients may need reconsenting to allow remote monitoring. (HRA Guidance)
- If necessary, review contracts with Sponsors to ensure remote monitoring is permitted.

3. Remote SIVs or training meetings

- Meetings held over video conferencing (e.g. Teams) which allows screen sharing for presentations.
- Consider producing a video tour of appropriate facilities instead of on-site feasibility visits.

4. Remote Monitoring of Pharmacy

- Remote visits may be held over video calls (e.g. Teams) which allows screen sharing of scanned pharmacy documents (e.g. accountability).
- Pharmacy documents may be scanned and emailed for review (and redacted if necessary).
- Where appropriate, reviews of patient returns for oral IMP may be done via video calls.