UKCRC Registered Clinical Trials Units



UKCRC Registered CTU Network – Greener Monitoring: Insights from Real-World Application

UK CLINICAL RESEARCH COLLABORATION

igniting our potential

Greener Monitoring: Insights from Real-World Application

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1. Abbreviations

AE – Adverse Event

CTU – Clinical Trials Unit

CTIMP – Clinical Trial of an Investigational Medicinal Product

DH – Department of Health

EHR – Electronic Health Record

IB – Investigator Brochure

ICR-CTSU - Institute of Cancer Research – Clinical Trials and Statistics Unit

ISF – Investigator Site File

MHRA – Medicines and Healthcare products Regulatory Agency

MRC – Medical Research Council

NHS – National Health Service

PIS – Participant Information Sheet

R&D – Research and Development

SAE – Serious Adverse Event

SDV – Source Data Verification

SOP – Standard Operating Procedure

UKCRC – UK Clinical Research Collaboration

2. Introduction

The UKCRC Monitoring Operations Group established a Greener Monitoring sub-group, who, in August 2024, published a Greener Monitoring guideline (Recommendations for Undertaking Greener Monitoring https://ukcrc-ctu.org.uk/clinical-trial-monitoring/). The guideline was designed to help clinical trials units (CTUs) minimise the carbon footprint of their clinical trial monitoring activities. Travel for on-site monitoring is recognised as a significant contributor to a trial's carbon footprint and can account for an estimated 10 – 15% of the total trial footprint [1]. Monitoring has therefore emerged as an important opportunity for carbon reduction strategies.

Building on our previous work, the Greener Monitoring group felt it would be useful to explore the use of the greener monitoring guidelines and tools in 'real world' scenarios. In this document we provide insights from real teams and real trials, in how they have considered the environmental impact of monitoring and lower carbon monitoring approaches, the opportunities they have identified and challenges that remain.

Direct, remote monitoring of participant electronic health records (EHRs) provides a huge opportunity to reduce the amount of travel required for on-site trial monitoring. However

[1] Griffiths J, Fox L, Williamson PR on behalf of the Low Carbon Clinical Trials Group. Quantifying the carbon footprint of clinical trials: guidance development and case studies BMJ Open 2024;14:e075755. doi: 10.1136/bmjopen-2023-075755

experienced monitors continue to report difficulties and challenges with remote monitoring, and feedback from sites/locations is not always positive. We wanted to explore these challenges and offer some practical suggestions of how these may have been overcome to make remote monitoring work for all staff involved (both monitors and participating site/location staff). We also highlight where challenges remain, so we know where to focus collective efforts on process improvement.

We have included in Appendix 1 information on EPIC as an example of an EHR in use in NHS Trusts.

We hope that by sharing these insights we will encourage others to consider how their monitoring practice could be considered and adapted to lower its impact on the environment.

3. Scope Introducing The Greener Monitoring Checklist

3.1. Purpose

The UKCRC Greener Monitoring guideline (Recommendations for Undertaking Greener Monitoring https://ukcrc-ctu.org.uk/clinical-trial-monitoring/) presents a number of recommendations which are broken down into several areas, from the Institutional level right through to the individual level. We encourage CTUs to read this guidance and use the recommendations as a checklist to consider how the environmental impact of monitoring can be reduced.

3.2. Summary

Here we describe the introduction of the UK CRC Greener Monitoring checklist for use in the ATARI trial. ATARI (NCT04065269) is a CTIMP trial managed by the Institute of Cancer Research – Clinical Trials and Statistics Unit (ICR-CTSU). ATARI investigates the use of ceralasertib as monotherapy or in combination with either a PARP inhibitor (Olaparib), or an anti-PD-L1 immunotherapy (durvalumab) in participants with relapsed gynaecological cancers.

In line with the MRC/DH/MHRA 'Joint Project on the Risk-adapted Approaches to the management of clinical trials of Investigational Medicinal Products', the ATARI trial risk assessment defines ATARI as a Type C trial, requiring prospective, systematic on-site monitoring of a defined proportion of sites/locations and data points. The Monitoring Plan also specifies central monitoring of protocol adherence and data quality, and timeliness of safety and efficacy data with triggered monitoring for poor data return, protocol adherence concerns or unusual patterns of Serious Adverse Events (SAE) reporting, where issues cannot be resolved by other means.

Below, the ATARI trial monitoring team explain how the monitoring undertaken in ATARI aligns with the recommendations in the UK CRC Greener Trials checklist and the steps they have taken to reduce the environmental impact of monitoring activities.

3.3. Findings

Area	UK CRC Greener Monitoring Recommendation	How this was considered and applied for the ATARI trial team
Institutional level	Adhere to institutional level guidance on sustainability initiatives, relating to energy saving measures, commuting and sustainable travel.	Our department has recently written a Sustainable Travel Guidance. There is a prompt to the guidance in forms used to request and approve business travel. That helps remind us to consider more sustainable modes of transport.
CTU level	Use email, video conferencing and telephone as the main means of communication between sites/locations and monitors to avoid the use of paper and postage.	This is absolutely our approach; this isn't just good for the environment but has a co-benefit of making communication faster and more efficient.
	Produce monitoring reports electronically and share via a cloud-based systems to facilitate review and response in a timely manner, removing the need for paper versions.	Monitoring documentation is all electronic now. We've found that it really helps to take key reference documents to on-site visits electronically (protocol, IB, PIS/C etc). Because we can use the search function to search terms, which makes looking up queries much faster. We complete an electronic SDV checklist, and this has made writing up monitoring reports much faster, because the notes and text are already written and can be copied over into the monitoring report.
Trial level	Develop a robust trial risk assessment with clearly defined critical data, maximising the use of central and remote monitoring.	Our risk assessment and monitoring plan clearly defines the critical endpoint and safety data points that require systematic on-site or remote monitoring. The trial-specific SDV checklist is based on this list.
	Conduct robust feasibility assessments to ensure that only sites/locations which can deliver the trial are opened.	We recently amended the trial to introduce two new treatment cohorts. ATARI has international participation, and when the new cohorts were introduced, we limited site/location participation to 6 centres per country enabling more efficient trial delivery.
	Where possible electronic documents should be reviewed remotely.	We complete an electronic Source Data Verification checklist with the data from our database, ahead of the visit. And we cross check this against any other data or information we have from the site/location (delegation logs, SAE reports etc) before any on-site visit. This saves us time on site/location and makes the visits more efficient. We also request an electronic copy of all pharmacy accountability/destruction logs ahead of the visit. We review these before

Area	UK CRC Greener Monitoring Recommendation	How this was considered and applied for the ATARI trial team
		we go, which definitely saves time on site/location.
	Decide whether site/location initiation visits and training activities need to be in-person or if they can be done remotely.	All our site/location initiation visits are performed online. This saves an in person visit and is better for the environment, but it also makes meeting arrangement much easier. Remote meetings are easier for busy clinical staff working across multiple locations to attend. It also allows us to arrange a bespoke call for any member of the team who wasn't able to attend.
	Ensure the trial monitoring plan is developed with a proportionate approach to monitoring. On-site visits should be reserved for essential activities and where review of critical data which cannot be done centrally/remotely.	Central monitoring for ATARI data is defined in the Data Management Plan, and this is conducted to review protocol adherence and data quality, and timeliness of safety and efficacy data. Triggered on-site or remote monitoring will be conducted for poor data return or protocol adherence concerns or unusual patterns of Serious Adverse Events (SAE) reporting, where issues can't be resolved by other means. In the first cohorts, all of our monitoring was performed remotely as a result of the pandemic. But, on addition of the new cohorts with new agents, the risk assessment requires systematic on-site monitoring of critical data. However, this is supported and rationalised with central and remote monitoring.
	Investigate the use of direct access to electronic healthcare records (EHRs) for remote source data verification (SDV).	We use direct access to EHRs as much as we can and as much as our participating sites/locations can facilitate. Although remote monitoring via direct access to EHRs hasn't replaced an in-person monitoring visit for the trial yet, we have used direct access to EHRs to complete some of the simpler data checks, so that our time on-site was shorter and more focused on the tasks that required in person discussion or review. Being flexible to the capabilities of each site/location has been important here.
	Where direct access to EHRs cannot be achieved, other SDV strategies could be considered, (e.g. the remote review of redacted source documents).	We request and review all pharmacy documentation in this way, which makes the in person visit to pharmacy much shorter. This often means we can complete an on-site visit in one day, instead of requiring an overnight stay and second day of monitoring.

Area	UK CRC Greener Monitoring Recommendation	How this was considered and applied for the ATARI trial team
	Where triggers are identified during central monitoring, use remote monitoring as an escalation strategy. Where issues cannot be resolved via remote monitoring, consider if an on-site visit is the appropriate escalation.	This is our approach, we try to resolve issue over the phone, by email, via remote monitoring methods first.
Resourcing & travel for on-site visits	Consider combining site/location visits that are geographically close to each other, to reduce longer distance travel frequency.	The on-site visits we perform are triggered by milestones reached by the participants, so it is difficult to combine visits to different centres. However, the trial team have combined travel for monitoring visits with travel for personal reasons, which has the same benefit of combining journeys and travelling less.
CTU staff training	New monitors should shadow existing staff during remote visits prior to an on-site visit to reduce the number of training visits needed.	Our electronic SDV checklist is really good for this, we can train members of staff on the data points we will review on-site before we go.
Individual level	Travel on foot, bike or use public transport rather than using the car.	Our default is to travel by train and bus. There are instances when we may get a taxi between a station and hospital, if its late at night, or we have heavy bags. But we definitely consider the public transport option first.
	Take a refillable water bottle and re-usable hot drink cup for the day.	This is something we always try to do.

4. Where does this document sit within the study lifecycle?

4.1. Purpose

One way to reduce the environmental impact of monitoring is to reduce the amount of travel to on-site monitoring visits. Where possible and appropriate, and in line with the trial-specific risk assessment, remote monitoring can be used to replace or reduce the need for, or number of, on-site visits. We conducted informal interviews and questionnaires with a total of 8 staff members – 4 clinical trial monitors based in UKCRC registered CTUs and 4 research site/location staff based in Belfast Health & Social Care Trust which is a large NHS Trust. Our aim was to gather knowledge and experience from these staff in an effort to help others looking to conduct remote monitoring as well as provide suggestions on how current practices can be improved.

4.2. Summary

Four Clinical Trial Monitors, from two UKCRC Clinical Trials Units, completed a questionnaire to collect information about their experience with remote monitoring activities. The monitoring activities relate to Phase II-III multi centre trials, including CTIMPs and non-CTIMPs.

Informal interviews were conducted with four research site/location staff from Belfast Health & Social Care Trust (three research nurses and one research optometrist), all of whom had experience of remote monitoring across both commercial and non-commercial research studies—from low-risk observational studies - to higher-risk phase II CTIMPs.

Key themes identified are summarised below, including challenges, benefits and practical recommendations proposed by staff.

4.3. Experience and approach to monitoring

UK CRC CTU Clinical Trial Monitors	NHS Site/location staff
Remote monitoring is widely implemented via Microsoft TEAMS calls, with site/location staff sharing data through screen sharing, verbal readouts, or occasionally showing documents on camera.*	All remote monitoring was conducted via Microsoft TEAMS.
Direct access to Electronic Healthcare Records (EHRs) is possible at some research locations (e.g., EPIC or bespoke systems), but access issues and site-specific Information Governance policies create variability. See Appendix 1 for more information on EPIC as an example of an EHR in use in NHS Trusts.	No staff interviewed were able to offer remote direct access to electronic health records as this is currently unavailable at their Trust; screensharing or reading information aloud was required.
Checklists are useful for Site File reviews, but the length of the checklist is limited, to reduce burden on participating sites/locations.	Staff reported regular use of Site File checklists. They reported checklists were useful but felt more reassured when the review was accompanied by a follow-up call so that they could discuss the contents of the files with the monitor.
Although on-site visits to pharmacy and laboratories are often required to review and verify facilities, physical stock and documentation, sometimes this cannot be supported by teams. In such instances, remote monitoring checklists and questionnaires have been successfully used for pharmacy and lab checks (i.e. asking sites/locations to self-report against a checklist). So there may be some value in considering this, perhaps not to replace on-site visits but to shorten them or reduce their required frequency but this should be conducted in collaboration with the site/location staff.	Staff expressed discomfort with checklist-only approaches to remote monitoring. They didn't feel that completing checklists without monitor review was appropriate and preferred a follow-up call with the monitor to ensure documentation was correct.

* see some challenges with this in section 4.4

4.4. Challenges

UK CRC Clinical Trial Monitors	NHS Site/location Staff
Relationship building with site/location staff can be harder when monitoring activities are conducted remotely.	Site/location staff expressed a preference for a 'hybrid approach'. Stating it was useful to have the monitor on-site for at least one visit. They felt this allowed for more in-depth discussions with the monitors. Some remote "monitoring calls" felt more like brief check-ins. Staff emphasised that if the purpose of

UK CRC Clinical Trial Monitors	NHS Site/location Staff
	the call is a short update or 'check-in', this should be communicated to avoid inefficient use of their time — so the team do not unnecessarily prepare or block out time. Staff would prefer to use the time well to review documentation or resolve issues.
Some processes (e.g. drug accountability, lab checks) cannot be fully replicated remotely. For some trials or some critical to quality factors within trials, there will always be a need to visit the site/location in person.	***UK CRC Monitoring Group comment:*** *Members of the UK CRC Monitoring Group have had separate feedback that there can be issues with capacity and scheduling of the required time for on-site visits, so minimising time on site/location by employing some remote techniques in advance of on-site visits or to support them may be helpful to NHS staff in reducing this capacity issue.*
Risk of missing data since monitors cannot physically verify all source documents for a participant. For example, unreported AEs may be missed if a full review of the source records cannot be completed on-site.	One member of staff highlighted concerns with a method of SDV used during a monitoring visit in which they were asked to read data from the source records. "*How did they know I was reading from the source? I could have been reading straight from the database*". In situations where the source cannot be reviewed by the monitor and the trial specific risk assessment requires that this is completed, it is recommended that an alternative method of remote monitoring is used, such as submission of redacted source data or an on-site visit is arranged. Particularly if this includes critical to quality data.
Locations where participant records are still paper-based pose significant challenges for remote monitoring.	Remote SDV involving paper records was frequently described as *tedious and slow*. Staff often had to hold documents up to the camera—something monitors struggled to see clearly. Long running- trials have become more complex as hospitals transition to electronic systems, requiring staff to navigate multiple platforms while also displaying paper records on camera. Remote monitoring visits for higher risk trials can be *'very time consuming and intense*'. One nurse described a recent SDV session that lasted two full days.
Variability in Trust security policies, leading to inconsistent access to critical documents (e.g. consent forms), and screen sharing is not always viable. Variation in approach across devolved nations (Some sites/locations in Scotland initially resistant to remote monitoring due to perceived policy restrictions). Monitors have encountered data protection issues and Information Governance incidents have been encountered. Examples included Personal Identifiable Data being sent to wrong email inbox and non-redacted source documents shared.	The absence of Trust/R&D SOPs or policies around remote monitoring created anxiety among staff. Two staff members said they felt "afraid of doing something they shouldn't," and noted colleagues who refused screen sharing due to unclear rules.

4.5. Benefits

UK CRC Clinical Trial Monitors	NHS Site/location Staff
Preparation time for remote visits is similar to on-site visits, sometimes longer due to additional steps (e.g. requesting logs and reviewing documents remotely.) However on-site visits require extra time for travel and logistics. Monitors also stated that remote visits often allow same-day report writing and easier scheduling making remote visits more efficient overall.	Staff reported remote monitoring is easier to schedule and allows work to flow more smoothly: "*It is a scheduled part of your day… you get it all done in that time*." Queries are usually resolved during calls, reducing the volume of post-visit action lists and making remote monitoring more efficient. All staff interviewed felt that preparation time was the same for both on-site and remote visits. One staff member reported that since their Trust had moved to a fully digital system, the burden of on-site SDV was the same as remote SDV since they were required to provide guided access to participant records. They stated that at present, it would probably be more efficient overall for the monitors to conduct remote calls.
Monitors reported a quieter work environment, when working remotely meaning they could use their time more efficiently, leading to a quicker turnaround time for reports.	Remote monitoring removes the need to find workspace for visiting monitors and avoids disruptions caused by someone working in the office. All staff reported difficulty in finding a suitable workspace for on-site monitors, particularly for extended visits of more than 1 day. The monitors on-site presence can interrupt the flow of work. "*Sometimes you're trying to do other things, and you keep getting interrupted or you're not sure when they are going to need you for something*".
Remote monitoring allows greater flexibility. Monitors reported they could monitor more research sites/locations and felt scheduling was easier. This leads to time and cost savings.	Staff reported that regular, 1 hour monitoring calls were 'fantastic' and helped them to 'stay on top' of documentation making general trial management more efficient. Staff reported they could see both environmental and cost benefits to remote monitoring.
Remote direct access to EHRs, when available enables thorough SDV while reducing reliance on site/location staff availability.	While remote direct access to EHRs was not currently available in the NHS Trust where the interviewed staff were based, they all expressed that this would make a significant difference to their ability to undertake remote monitoring.
Some trial monitoring plans include randomly selected on-site visits to validate remote monitoring quality. Critical safety checks are also often deferred to on-site visits. This 'hybrid' approach allows some time on-site where perhaps more complex issues can be resolved. This also allows monitors to build relationships with staff – something which many monitors report is more difficult when working remotely.	A hybrid approach to monitoring was viewed as favourable. Remote monitoring meant that on-site visits were reduced in frequency and were often much more focused on a specific area or issue. Staff appreciated time with monitors on-site to resolve general queries or to discuss more complex issues.

4.6. Practical Recommendations

Below is a summary of the key recommendations and tips provided by the staff based on their experience of monitoring.

UK CRC Clinical Trial Monitors	NHS Site/location Staff
• Develop remote monitoring templates for pharmacy and lab departments • Use site/location file checklists and remote monitoring forms, but send them ahead of remote monitoring calls and always follow up with a review call • Conduct video tours for facilities and stock checks • Define pre-agreed tasks for remote visits • Prioritise critical data items for remote SDV • Implement secure environments and show the site/location team the room in which you are monitoring so they can confirm no unauthorised staff are present • Schedule an early remote monitoring call (after 1–2 participants recruited) to identify issues early while data volumes are low. • Resolve queries *during the call* wherever possible, reducing the need for action lists and follow-up calls. • Use visit-specific templates and checklists rather than generic ones. Example: On an ISF checklist, instead of "Ethics amendment letters," specify "Ethics approval letter SA1, 20/12/2025". This clarity helps staff identify missing items quickly	• R&D departments should develop clear SOPs/policies for remote monitoring, particularly regarding SDV and screen sharing. • Staff suggested R&D departments across the UK collaborate and share expertise in developing these SOPs.

5. Conclusions and areas for further consideration

1. Remote access to EHRs has the potential to reduce the number, or duration of on-site visits, but not all Trusts have the systems and procedures to support this. Increasing uptake, use and confidence in systems such as EPIC would be beneficial to trialists seeking to make their monitoring greener. But to facilitate this, there needs to be robust policies and procedures in place to support NHS staff to feel confident in what is permitted and how to reduce the risk of data protection and information governance incidents.
2. There are situations in which on-site visits are required, but there are tools available and activities that can be conducted remotely to reduce time on site/location or the frequency of on-site visits. Increasing consideration of these tools, in line with the trial-specific risk assessment and critical to quality factors provides opportunities to improve the environmental impact of monitoring.
3. There are some instances when remote monitoring methods adds an unnecessary burden to NHS staff and monitors should be aware of these and minimise requests that add burden. E.g. Where a participant's health records are largely held in paper form.
4. Clear communication in terms of the expectations, purpose and conduct of any remote monitoring activities is critical and would help avoid inefficient use of site/location staff time and maximise the benefit of remote monitoring activities.

6. Acknowledgements

The UKCRC Greener Monitoring Group gratefully acknowledges the valuable contributions of the CTU teams and NHS staff who participated in the interviews and completed the questionnaires and checklists. The Group also extends its thanks to the CTU colleagues who reviewed this work and provided thoughtful and constructive feedback.

Appendix 1 – Remote Monitoring via Epic

Health Trusts throughout the UK are now transitioning from paper health records to the use of electronic health records. While there is still a lot of variability in terms of the systems used, there is increased use of one particular system, known as Epic. This system has the advantage of being capable of allowing monitors direct, remote, read-only access to trial participants' health records. While this capability exists within Epic, this functionality may not be being utilised by health trusts for remote monitoring purposes.

If a Trust can facilitate remote monitoring via direct access to an EHR, this could replace some on-site monitoring activities. The carbon footprint of a one-day on-site monitoring visit, with travel between London and Manchester by car is 160kgCO2e. It would take one new tree seedling 10 years to sequester this amount of carbon. Even travelling by train would only reduce this to 32.8kgC02e. Alternatively, a remote monitoring visit conducted via video conferencing and remote access to an EHR is approximately 1kgCO2e.

Below is some information relating to the system functionality of Epic which could be used by R&D departments in order to develop SOPs or policies for the use of Epic by external monitors. This information may also be useful for R&D departments who have Epic within their Trust but who do not currently allow remote direct access for monitoring.

When developing any SOP or policy relating to monitor access to electronic health records, please refer to MHRA blog https://www.gov.uk/guidance/on-site-access-to-electronic-health-records-by-sponsor-representatives-in-clinical-trials

Epic System Functionality for Remote Monitoring

- External research monitors will be able to view a participant's electronic medical record for open studies via their own user account in EpicCare Link. 2 Factor Authentication (2FA) for EpicCare Link is available.
- EpicCare Link is an external, secure digital portal that will connect the research monitor with the Epic system at your health trust.
- Participant information in EpicCare Link can be set to View Only mode for monitors; no edits can be made, and monitor actions are auditable e.g. User logins, into the system as well as activation and deactivation, are logged.
- Monitors will be able to securely view information about research participants, including conditions, tests, procedures, results, treatments, clinical letters, and scanned research documentation, e.g. consent forms
- There is an automatic timeout/logout (typically 15 mins but configurable by the organisation)
- Date and time restrictions are available for the monitors. This allows organisations to agree dates and times of monitoring access prior to releasing participant records into EpicCare Link.
- Printing from EpicCare Link cannot be prevented however print actions are auditable.