ECMCs: Overcoming A Crisis Through Collaboration

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ECMC network vision

The Experimental Cancer Medicine Centres (ECMC) network's vision is to build a truly collaborative, internationally competitive national network of early phase experimental cancer medicine centres, translating the most promising innovations from the academic and industry sectors into the cancer medicines of tomorrow. The network brings together world-leading laboratory and patient-based clinical research to build a UK-wide network of clinicians and scientists.

Problem

In 2020 the COVID-19 Pandemic impacted early phase experimental cancer trials. Sites throughout the ECMC network were facing similar issues and trying to ensure that vital research could still continue in the ECMC network.

Proposed Solution

The ECMC Programme Office created the ECMC Centre Business Leads Forum to discuss challenges on the management and delivery of research portfolios, share solutions to get early phase cancer trials back up and recruiting as soon as possible and delivering vital treatments to patients.

ecmc

Jointly funded by:

CANCER RESEARCH UK

NIHR | National Institute for Health Research

Ymchwil Iechyd a Gofal Cymru Health and Care Research Wales

CHIEF SCIENTIST OFFICE

HSC Public Health Agency Research and Development

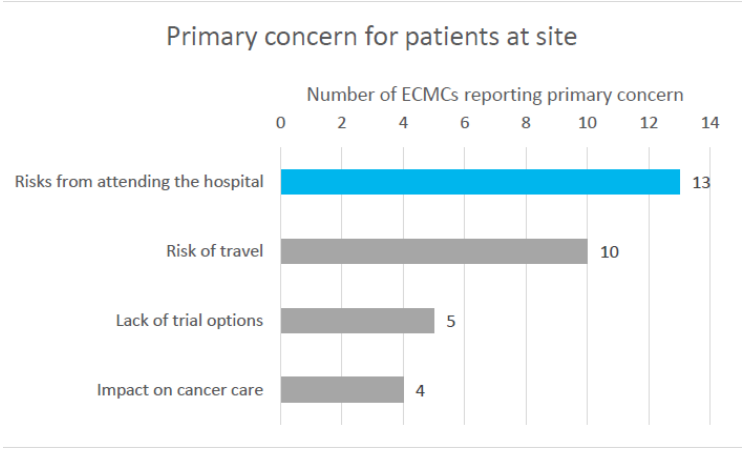
What we did

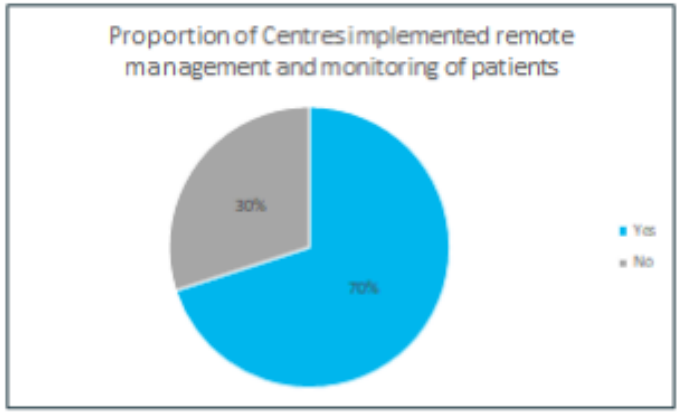
Collaboration has an even greater significance in a crisis and it was important to establish a forum that had a breadth of representation across trials for all patient populations, trial delivery roles, geographical location and tumour type expertise. Delivery colleagues from across both the adult and paediatric ECMC network were united to create the ECMC Centre Business Leads Forum. The Forum discussed challenges on the management and delivery of research portfolios and shared solutions to get early phase cancer trials back up and recruiting as soon as possible.
A steering committee of delivery experts was formed to lead discussions and determine, prioritise and develop operational efficiencies.

Brought together 45 representatives from the 18 adult and 11 paediatric locations.

A survey was conducted in July 2020 to obtain a network picture and determine the main areas of concern:

- Restart of research
- Monitoring
- Operational practicalities



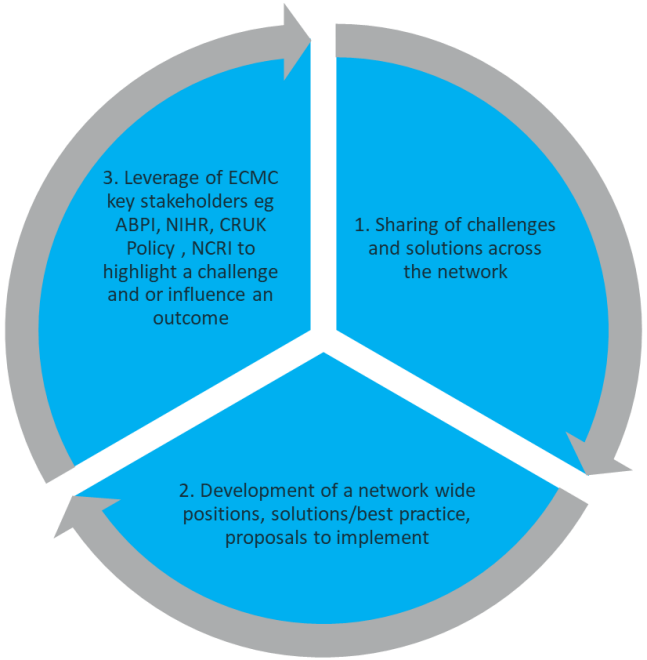


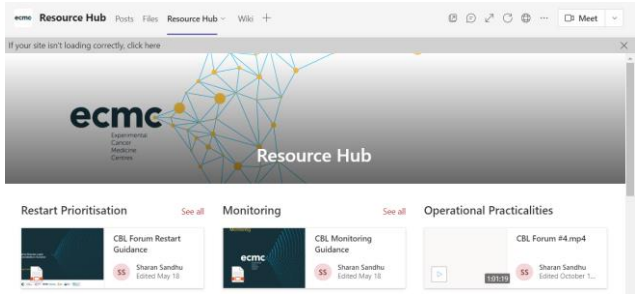
Facilitated the Forum remotely:

- Held monthly meetings via MS Teams
- Created a Teams Channel to support the sharing of solutions and collaboration
- Started a fortnightly drop in mornings for ad-hoc topics of interest

What was achieved

The Forum has proved to be an invaluable source of intelligence. Members feel supported and can speak openly of concerns and above all do not feel isolated in tackling challenges and finding solutions from across NIHR funded infrastructure.





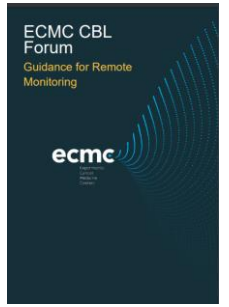
Resource Hub on Teams Channel to share guidance documents, SOPs and templates

The Forum holds **fortnightly coffee catch ups**; an informal drop in and chance to 'ask a colleague' anything. Previous topics have included:

- Costing and contracting processes
- PPI strategy and PPIE activities
- Supporting study set up

Mitigation plans based on an **action framework** of knowledge sharing/resource exchange, network developed solutions and leveraging key stakeholders through a one-network voice was defined to address these areas. Relevant representatives from UKCRFs were invited to be part of the groups.

The Restart of Research and Monitoring subgroups produced **guidance documents** to share experiences and approaches on remote monitoring and restart prioritisation



More to do

The Forum continues to work together as a community sharing best practice and will be very instrumental in delivering the ambitious vision for the future of clinical research delivery in the UK.

ECMC Future Network Strategy

The CBL Forum has been providing valuable insight and is helping shape the ECMC Future Network Strategy. Streamlined and digital operational trial delivery has been identified as a key priority area for development.

Trial Costing Work

The CBL Forum is feeding into some work being led by the UK Clinical Research Facilities (UKCRF) Network and the Advanced Therapy Treatment Centres (ATTC) on costing trials and the NIHR Interactive Costing Tool with a particular focus on Phase I/IIa/ATIMP studies. This is being delivered via the ATIMP Costing Working Group

UK Vision for Clinical Research Delivery

The ECMC network will be involved in the DHSC-led Rapid Delivery Pilot scheme, part of the UK Clinical Research Recovery, Resilience and Growth (RRG) programme to develop an accelerated pathway for early phase trials.

ECMC maintaining early phase oncology trial activity during COVID-19 pandemic and beyond

Badman P; Barker D; Barron C; Barnes A; Bell B; Boast A; Bradley R; Brown H; Calvert J; Chennells F; Ellis L; Frank O; Gray J; Gready K; Guermech R; Hollis L; Hood B; Hoole L; Howarth E; Johnson K; Joseph-Pietras D; Lamb P; Morris M; Mousa K; Orbell E; Patel N; Rao Baikady B; Rees A; Room K; Sandhu SK; Williams A

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Problem

The ECMC Centre Business Leads (CBL) Forum identified areas of concern for the running of early phase oncology trials caused by the COVID-19 pandemic.

Solution

Collation of solutions and best practice when approaching remote monitoring of clinical trial data and the restart of early phase oncology trials in response to the COVID-19 pandemic.

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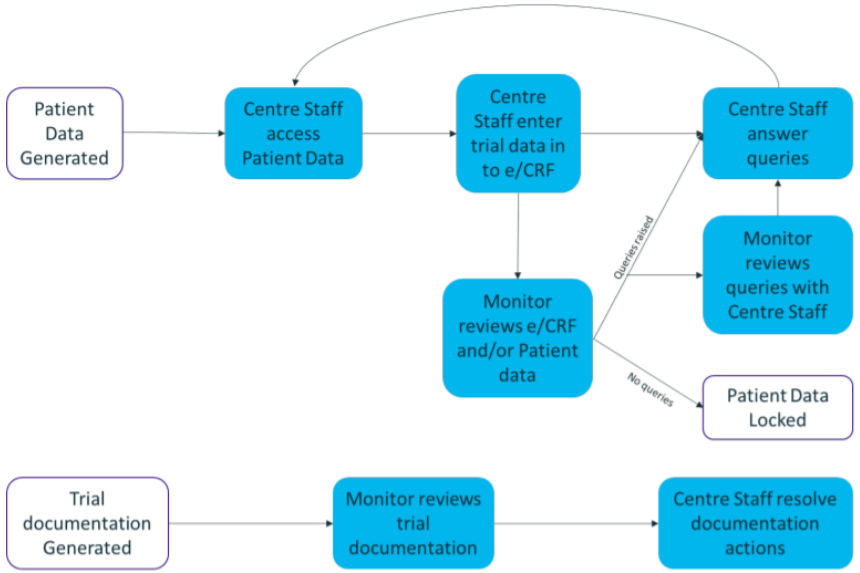
Guidance for Remote Monitoring

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.

The shared collective knowledge of the ECMC Centre Business Leads Forum resulted in the operational teams from centres working collaboratively to produce guidance on remote monitoring activities based on experiences and approaches across the network.



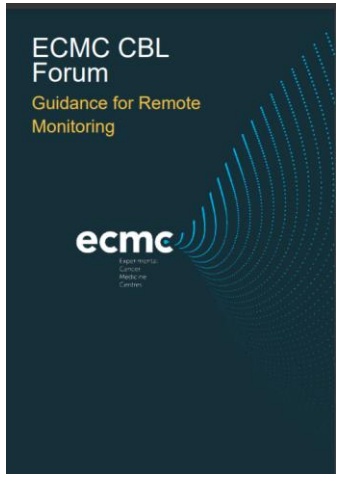
This guidance document aims to support the monitoring activities shown in blue by sharing practice on the access to trial data and documents either remotely or on site.

This document can be used to help:

- Implement or improve remote monitoring practices,
- Resolve common issues
- Help discussions with Trusts or Sponsors to adopt remote monitoring.

The guidance covers topics including:

- Remote access to notes and trial documents
- Remote monitoring of pharmacies
- Remote SIVs and Meetings



Restart Considerations Guidance

Topic
Latest Update – NIHR managed recovery
Purpose
Background
Network trial data analysis
General Restart Considerations
Prioritisation Considerations
- General
- Trial Management
- Patient Management
- Workforce
- Capacity
- Capacity support services
Examples of prioritisation
Risk assessment of trials: RAG rating criteria
Useful links
Contact

Considerations covered in the guidance

The COVID-19 pandemic resulted in Trusts' research teams being redeployed to support the Covid-19 research and front-line clinical services. This impacted vital research and centres needed to plan a phased restart of experimental cancer studies, prioritising the safety of patients and staff and aligning with the NIHR Restart Framework.

Based on experiences and approaches from across the ECMC network, the Centre Business Leads worked collaboratively to produce guidance on what to consider when reviewing and making improvements to local restart frameworks to set up, open and recruit to trials during national emergencies.

This document can be used to help implement or improve restart prioritisation categorisation of trials.

Using data from the ECMC network's digital tool: Experimental Cancer Trial Finder (ECTF)

Data which had been collected as part of ECTF was reviewed and analysed to support understanding of early phase trial status in the ECMC network to help to influence national policy regarding restart.

Examples of data that was collected include:

- Site recruitment status over 3 months
- Patient recruitment numbers
- % of trials opened or paused

The top 5 common cancer types included in the trials impacted by COVID were:

- All-Solid
- Breast
- Small Cell Lung Cancer
- Non-Small Cell Lung Cancer
- Hepatocellular Carcinoma

Continued Engagement

Guidance Documents

These two pieces of guidance [For Remote Monitoring and Restart Considerations] are available on the ECMC website to anyone who would find them of use. They will be reviewed and updated as required by members of the CBL Forum to ensure any new learnings are added and the guidance is current.

Sharing expertise

Authors of the Guidance for Remote Monitoring contributed to the development of another guidance document: Access to Electronic Health Records by Sponsor representatives in clinical trials. This resource was jointly developed by the Health Research Authority and Medicines and Healthcare products Regulatory Agency in consultation with the Information Commissioners Office on behalf of the UK.

Continuation of CBL Forum

The CBL Forum continues to meet and identify areas for future development. Through MS Teams members are able to access and share documents via the Resource Hub and there are also fortnightly coffee catch-ups which are an informal drop in and chance to ‘ask a colleague’ anything