

Programme Manager's Update

I always enjoy writing this part of the newsletter, it's great to see all the good work happening across the Network and at our member CTUs.

Since our spring newsletter in April we've had lots going on with more face-to-face meetings for colleagues to hear what's happening and get peer support. These meetings included a great Directors meeting, with talks from NHS Transformation leadership about the data driven future and hearing about exciting plans from Rustam Salman our Clinical Director amongst others.

The Stats Group also had a really great meeting in York discussing everything from accessing NHSE data to the final update on Blinding of Trial Statisticians project, and also thinking about what CTUs need in terms of learning and development for trial statisticians amongst others (see page 8).

Delighted to see the Monitoring Group have released yet more guidance for everyone in the form of a template 'Access and Source Data Information Sheet for use by CTU staff performing remote and on-site monitoring activities (also page 8)

Congratulations to Will Cragg (Leeds CTRU) on his appointment as QA Chair! Will is doing a brilliant job already. A sincere and big thank you to Claire Johnson (Liverpool Clinical Trials Centre) as outgoing QA Chair for all her input, and delighted to confirm Claire will be staying on as Deputy.

Welcome also to our new Policy Group members Lucy Culliford (Senior Research Fellow in Clinical Trials, Bristol Trials Centre), Fiona Hogarth (Co-Director, Tayside CTU) and John Petrie (Director, Glasgow CTU). (see page 4)

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We're pleased to announce we're looking for more members of some of our groups so keep an eye out for the emails!

Helen Evans
Network Programme Manager

Directors' Meeting Update

The spring 2023 Directors' Meeting took place at Mary Ward House in London in May.

As usual it was a packed agenda with sessions focused around increasing efficiency and capacity in UK clinical research.

We were very pleased to welcome Dr Nick McNally, chair of UKRD, to the meeting for the first time. The UKRD brings together research and development leaders from across the NHS to positively impact health research for public and patient benefit

Dr McNally discussed some of the UKRD's ongoing work including their involvement with key national stakeholders such as the Department of Health and

Social Security. He then shared his thoughts on a new programme of work being undertaken with in conjunction with the Network.

This new working group was focusing on three initial pieces of work:

- A review of documentation requested by R&D over and above HRA approval that is having significant impact on trial set up .
- Identifying examples of best practice working between NHS Trusts and CTUs and promulgating that across the community.
- Working with the MHRA to reduce the variability in regulatory inspections that can drive risk-averse behaviour.

Directors' Meeting Update continued...

Rebecca Cosgriff, Data for R&D, NHS Transformation Directorate Head of Strategy, provided Directors with an overview of the Data for R&D programme which seeks to put in place a:

"[...] globally competitive NHS-wide health data research infrastructure that enhances patient care, sustains the NHS and supports innovation."



The programme includes a number of key objectives to support clinical trialists including improving the capabilities of NHS DigiTrials and building an/or expanding existing regional services such as DISCOVER-NOW.

Rustam Salman, the Network's Clinical Director, led a two-part session on the aims and potential impact of this important new role.



He began by discussing his key objectives then outlined some of the ways in which he planned to foster better relationships between CTUs and clinical communities. He also discussed some of the feedback received in response to his recent survey on CTU interactions with clinicians

Tom Pratt, a Senior Programme Manager at the NIHR Academy discussed the opportunities offered by the Efficacy and Mechanism Evaluation (EME) and Advanced Fellowship joint call.

During the meeting time was set aside for networking and productive group discussions. The roundtable session focused discussions on three distinct areas:

- The ongoing relationship between the Network and the UK Research Collaboration and where value could be added..
- The creation of the NIHR Research Support Service (RSS), including how the Network could build relationships with the new centres and the RSS hub to promote success.
- Interaction with clinicians, including ways to initiate productive collaborations with clinicians looking to undertake their first research project.



The outputs from these discussions will be used to inform future Network activities.

Planning is now underway for the November 2023 Meeting. We look forward to seeing you there.

Network involvement in national activities

The Network continues to play an important role in ongoing conversations with national stakeholder on various themes and areas of work.

This includes the DHSC, HRA, MHRA and others on the shape and direction of future national activities. The examples below represent a small fraction of the

work that Network representatives are contributing to:

DHSC's Recovery, Resilience, and Growth (RRG) Programme

We continue to highlight where there may be inefficiencies for units and where CTUs are leading

Network involvement in national activities continued...

the way in decentralised and innovative trials, via both RRG advisory Board meetings and regular informal meetings.

Clinical Trials Legislation Expert Working Group

The MHRA will be re-convening this group which the CTU Network has membership on, and we will continue to ensure the non-commercial perspective and lesson from CTU practise is heard.

We have also had contact our from MHRA colleagues that ensure relevant stakeholders are properly linked in, great to see further recognition of the continuing value of CTUs and our voice.

HRA

The network also continues to have representation on the HRA Partnerships board to add the CTU perspective to discussions there.

We're working with HRA on reducing NHS R&D follow up after HRA approval and ways of creating efficiencies for NHS and CTUs there. (See UKRD.)

Our PPIE group are helping shape HRA guidance for involvement that will support the update to the clinical trials regulations.

NIHR Methodology Incubator

The Network continues to have involvement in to raise awareness of methods research, building capacity via the internships and training workstream and the statistics workstream.

UKRD

A working group has been established with UKRD (a community of NHS leaders responsible for R&D in their respective Trusts) to look at ways we can work together to increase efficiencies and increase risk proportionate approaches in NHS Trusts.

The first meeting was held recently and was very positive, with a lot of excitement about making changes and helping trials in the UK, the HRA are now involved and we're having our second meeting soon!

Operations Group Updates

Data & IS Operations Group

Data Management in DISOG

Since the rebranding of ISOG to DISOG, we have established four Data Management (DM) workstreams focusing on these themes: eCRF Design, Database Lifecycle Development, Data Validation and Working with External Data. In addition to the work streams, DISOG are working on producing data reporting guidance.

The outputs of these workstreams will include producing standalone guidance documentation that will also be collated into an overarching Data Management Handbook. Any previous relevant DM documentation from earlier deliverables will also be considered for inclusion in the handbook.

The data archiving piece is awaiting final review from the MHRA following updates made in response to their initial feedback.

Webinar Series

DISOG continues to deliver is webinar series focusing on current themes and hot topics. Recent webinars included a DM focussed session which included the Sheffield CTRU perspective on reporting (Amanda Loban) and 'Data Management in an Open Room' by John Turgoose (Hull Health Trials Unit) which looked at the possibilities and challenges associated with setting up data management function from scratch. This was followed by a session led by Amanda Bravery, Francesco Lala, and Abinithya Udayakumaran (Imperial CTU) where they discussed



Operations Group Updates continued...

their experiences of migrating from InForm to Openclinica.

The response from delegates to these sessions remains overwhelmingly positive and we are very pleased by the collegiate atmosphere during the Q&A sessions.

If you would like copies of the slides, or to access the recordings, please contact the Secretariat on regctus@leeds.ac.uk. Upcoming topics will focus on experience with EDC systems and platform studies.

Raising the Perception of IT/IS/DM

Following the success of the Rubik's cube poster at the International Clinical Trials Methodology Conference (ICTMC), the DISOG national meeting, and the Association for Clinical Data Management (ACDM) conference, work continues with the 'Perception of IS/IT/DM' group. The current task is focused on collating 'common activities/ job titles undertaken in different CTUs' with the aim of standardising the IT/IS/DM job roles.

National Meeting

The DISOG National meeting is planned for 19 October 2023, as a face-to-face meeting in Leeds. The agenda will cover IT/IS and DM topics including reviewing audit trails, a workshop on reporting guidance, and a session on the RECOVERY Trial, as well as the usual updates and discussions. There will also be another informal poster session over the breaks so please do start thinking of what you might like to bring and share. The final agenda will be circulated shortly.

Based on feedback from previous national meetings, and the results of the recent survey, we will be facilitating a networking session the evening before the meeting. More details on this to follow. We hope to see as many of you as possible there!

Other Activities

DISOG continue to support three EDC (REDCap, OpenClinica and MACRO) User Groups for the purpose of discussing and sharing system specific knowledge. Additionally, a Developer's Forum is run by DISOG to allow CTUs to share ideas and processes. Feedback is positive regarding these user groups. This proved invaluable recently following several REDCap vulnerabilities which led to

arranging an impromptu discussion group to share knowledge and approaches.

Members of DISOG continue to collaborate with other groups e.g. the TMRP and ACDM. Several members are also part of the ACDM CTU Data Management Expert Group. This provides a great opportunity to work with Industry partners in clinical data management to effect positive change

- Amanda Bravery (Imperial CTU) & Tim Chater (Liverpool Trials Centre)

Policy Group

The Policy Group was delighted to welcome three new members earlier this year: Lucy Culliford (Senior Research Fellow in Clinical Trials, Bristol Trials Centre), Fiona Hogarth (Co-Director, Tayside Clinical Trials Unit) and John Petrie (Director, Glasgow Clinical Trials Unit). Each brings considerable relevant experience and expertise.

The group continues to raise the profile of the Network through consultation and liaison with key national stakeholders including the Department of Health & Social Care (DoH), MHRA, HRA, and the UKRI [MRC Regulatory Support Centre](#). Links have also recently been developed with the Association of the British Pharmaceutical Industry ([ABPI](#)) and UK Research & Development ([UKRD](#)).

The group continues to be engaged in the development of the new Clinical Trials Regulations, providing the academic perspective on risk proportionality and risk adaption, and hopes to work with the MHRA on the development of guidance to support the new legislation when it is rolled out.

The group represents the Network on a number of DoH Clinical Research Recovery Resilience and Growth (RRG) groups, ensuring that the importance of the academic trials portfolio is well recognised.

A response to the current consultation on draft ICH E6 (R3) guideline on Good Clinical Practice (GCP) is currently being planned. For more information on this consultation visit www.ema.europa.eu/en/news-events/open-consultations

- Claire Snowden (Institute for Cancer Research - Clinical Trials and Statistics Unit)

Operations Group Updates continued...

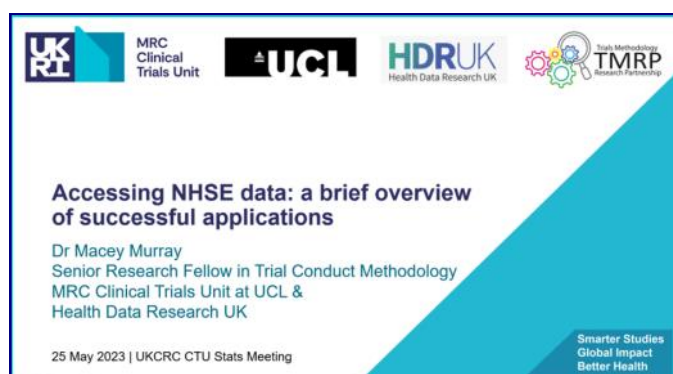
Statistics Operations Group

The Statistics Group held its Spring national meeting in York in May 2023. It was a well-attended event with a range of engaging talks, roundtable discussions, and opportunities for networking.

The day began with updates on activities that had taken place since the meeting in Birmingham in November 2022, including plans to develop materials to help with the recruitment of statisticians. Helen Evans, the Network Programme Manager, also provided an overview of the work taking place around the Network.

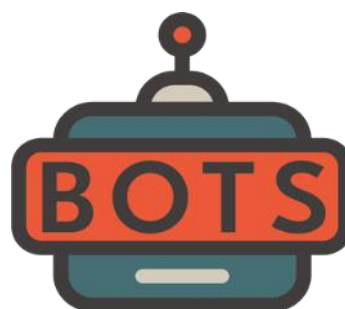
Macey Murray (MRC CTU at UCL) and Ly-Mee Yu (Oxford Primary Care and Vaccines Collaborative Clinical Trials Unit) gave talks on different aspects of working with NHS England data. Macey's presentation (Accessing NHSE data: a brief overview of successful applications) was given remotely and a recording is available. Contact the Secretariat (regctus@leeds.ac.uk) for details.

Fay Cafferty (ICR-CTSU) discussed her unit's project to identify learning and development opportunities for trial statisticians with their aim to put together a document to provide some structure around this, with the typical activities/range of experience a statistician might look to undertake/gain over time. Early work had identified that, whilst there was a wide range of training available for those at the start of their careers, it was more challenging to identify appropriate options for those preparing for more senior roles.



After lunch, there was a chance for a roundtable discussion. Following on from Fay Cafferty's presentation, delegates were invited to feedback on their experiences of learning and development opportunities for trial statisticians within their own

units. For an outline of the key findings, please see page 8. Other topics up for discussion included methods for ensuring the quality of laboratory data and funding for senior statisticians.



Chris Partlett (Nottingham CTU) provided an update on the Blinding of Trial Statisticians (BOTS) project. BOTS aimed to inform and develop guidance documents to advise CTUs on a risk-

proportionate approach to blinding Trial Statisticians within clinical trials. The full guidance document and risk assessment tool are now available from the BOTS webpage www.nctu.ac.uk/other-research/bots-blinding-of-trial-statisticians.aspx.

The final session looked at Adaptive and Bayesian Trial Designs. Pavel Mozgunov of the MRC Biostatistics Unit at the University of Cambridge outlined the use of more efficient trial designs and discussed a number of relevant case studies including the Phase II Multi-Arm Multi-Stage TAILoR Trials and the Phase II Group Sequential REBOA Trial.

The Stats Operations Group is now working on



arrangements for the next meeting which is due to take place in Cambridge in November 2023. More information will follow in due course.

The Group is also in the early stages of scoping two potential deliverables, including one to look at what analysis is appropriate for trials that close early. More information on these will follow.

- Catherine Hewitt (York CTU) & Natalie Rowland (BCTU)

Operations Group Updates continued...

Quality Assurance Operations Group

QA National Meeting

The QA Operations Group has been busy working towards the next annual meeting in September this year. This will be the first in-person session for a few years, and we are looking forward to seeing as many CTUs' QA representatives there as possible!

The agenda will include time for networking and sharing common issues, as well as sessions on current and future QA challenges. For the first time the meeting will also include a poster session.

Recent Group Activities

The updated Network guidance on QA oversight of laboratories is almost ready for publication. A final round of changes has been made and the document is now with the MHRA for confirmation. We hope that they can be released soon.

The iPassport and Q-Pulse User Groups have now met on a number of occasions. Members are keen to hear from anyone who would be willing to demonstrate how they use a particular module or share a process that they follow. If you would like to be added to the mailing list(s) or share some of your work or experiences, please contact the Secretariat on regctus@leeds.ac.uk.

The QA group is feeding into other workstreams, notably via the Chairs' group into work about post-trial data retention, and via the Policy group into a response to MHRA's consultation on the new revision of ICH GCP guidance. We are also planning to feed into the work of the Medical Devices working group which will be moving forward with a revised scope.

Changes to the Group

Finally, the group itself is going through some changes: Will Cragg of the Leeds CTRU has recently taken over as chair. We are pleased to say that the former chair, Claire Johnson (Liverpool Trials Unit) has agreed to stay on as deputy. We are also looking to appoint two new members to the team. Details on how to apply will be circulated to CTU Directors and QA Reps. We hope to be able to announce the new appointments at the national meeting.

- Will Cragg (Leeds CTRU) & Claire Johnson (Centre for Trials Research)

Trial Management Operations Group

2023 National Trial Managers' Meeting

In April 2023, the Trial Management Operations Group held its first national meeting. It was a well attended event and we were exceptionally pleased to finally be able to meet people face-to-face.



Sessions included a very useful update from the HRA, a case study on a complex intervention trial, an overview of the UKTMN's career pathways work, and a very topical presentation on enabling lower carbon clinical trials. There was also lots of time for networking and sharing experiences and expertise.

The roundtable discussions focused on a number of areas, including the collation of site staff CVs, where a lot of time and resource is expended for little clear benefit. Delegates discussed the various ways in which they approached these tasks, considered options for streamlining them, and discussed the results of recent MHRA inspections.

The Trial Management Operations Group has since reviewed and synthesised these discussions and are now planning to review the relevant regulations before drafting high-level guidance to help CTUs understand where changes in practice might be possible. More information on this activity will be shared in due course.

We look forward to this event continuing to grow and become an important date in the trial management calendar.

The group is now hoping to recruit two new members to help build capacity. Details on how to apply will be circulated to CTU Directors and TM Reps.

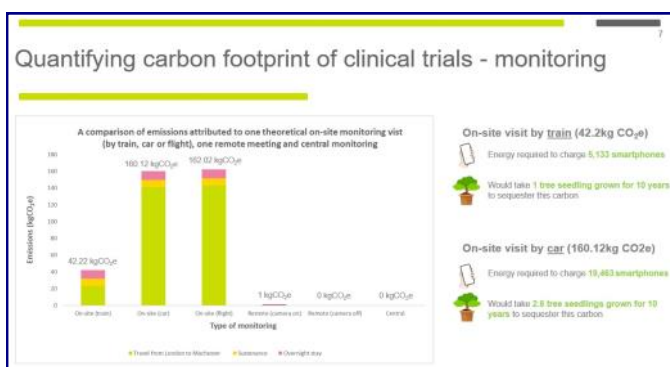
- Lucy Culliford (Bristol Trials Unit) & Jaclyn Brown (Warwick CTU)

Operations Group Updates continued...

Monitoring Operations Group

The 2023 national monitoring meeting took place over two days in June.

On 15th June, we had talks on efficiencies in monitoring. In the first session, Lisa Fox (ICR-CTSU) explained how we could reduce CO₂ emissions in monitoring and Adam Boon (Bristol Trials Centre) described the NIHR-funded MANGO system, which amongst other attributes streamlines the delegation log process.



Aims:

- Develop a generic system to streamline coordination of multiple trial types
- System should include TMF/ISF, delegation log, and interaction with participant databases
- Should be easily accessible on desktop and mobile devices

MANGO TRIAL MANAGEMENT

In the last session before the break, Melanie Boulter (Nottingham CTU) released the T&F Group's template Remote Monitoring Questionnaire. This can be downloaded from <https://ukcrc-ctu.org.uk/guidance-for-ctus/>. For more information on the template please see page 8.

In the second session Suvitha Subramaniam and Matthias Briel (University of Basel) described their work to develop a dashboard to track monitoring activities and Shiva Taheri, a PhD student from the MRC CTU at UCL presented her work on creating a trial monitoring plan template, Carlos Diaz Montana (MRC CTU at UCL) described some monitoring management software that is being developed.

Finally, Carrie Bayliss (Cambridge CTU) and Mel Boulter outlined the progress of the Triggers &

Metrics workstream and shared the latest version of the template that has been designed.

On 22 June our protocol deviation session started with talks on protocol deviation tools. Francesca Schiavone (MRC CTU at UCL) described the protocol deviation framework which is being collaboratively constructed, Jill Wood shared details of the non-compliance management system which is being used in Warwick CTU, and Krista Wills described the protocol deviation management system which CRUK & UCL CTU are using.

NON-COMPLIANCE MANAGEMENT SYSTEM:
OPERATIONAL USE AND STRUCTURE

Jill Wood, Quality Assurance Manager
(Warwick Clinical Trials Unit)

Incident management system at the CRUK & UCL Cancer Trials Centre (CTC)

Krista Wills, Clinical Trials Operations Manager

CANCER RESEARCH UK | UCL CENTRE
Cancer Research UK and UCL Cancer Trials Centre

After the presentation sessions, delegates then had a chance to discuss what they had heard and consider what changes they would like to see with respect to protocol deviations and what work needed to be done to support those changes. All these ideas will now be discussed by the Monitoring Task and Finish Core Group and we hope to start a project in this area later this year.

Thank you to the more than 100 attendees each day from 40 CTUs who joined and took an active part in discussions. And thank you to the UKCRC for exceptional administrative support.

Do contact the UKCRC network at rectus@leeds.ac.uk if you want to become actively involved in any monitoring projects.

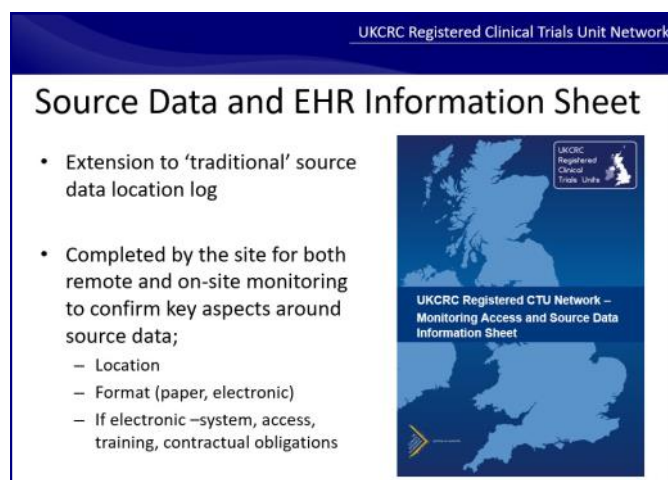
- Sharon Love (MRC CTU at UCL)

New Guidance for CTUs

The Monitoring Task & Finish Group has recently published a template 'Access and Source Data Information Sheet' for use by CTU staff performing remote and on-site monitoring activities.

The resource is designed to be completed by the participating site team to identify upfront where the source data is located and how it can be accessed by those monitoring the trial. Some adjustment may be needed locally in order to meet Sponsor/CTU and/or trial-specific requirements.

The template is not designed to assess the compliance of existing systems. However, some relevant and useful guidance on considerations relating to the use of electronic health records (EHRs) in research has been included.



A copy can be downloaded from the Network website <https://ukcrc-ctu.org.uk/guidance-for-ctus/>

Learning and development for trial statisticians

At the Spring 2023 Statistics National Meeting delegates heard about a project being undertaken by the ICR-CTSU to identify training opportunities for trial statisticians at all stages of their careers.

During the session, Fay Cafferty noted that although learning and development for early career statisticians was generally well provided for, finding options for those looking to move into more senior roles was more challenging.

Delegates at the meeting, who were drawn from units across the UK and who were at varying stages of their career, then had the opportunity to share their personal experiences and discuss the practices at their unit. An outline of the discussions can be found below.

Overview

As expected, there were a range of approaches in the provision of learning and development opportunities. Some units had formal training in place for new starters, either individually or in teams, others provided more informal on-the-job training by experience. Generally, training was better developed for more junior staff.

Shadowing and mentoring

Documented shadowing or working in parallel with more senior colleagues as part of training was discussed, though this depended on there being sufficient time available for both parties.



Given typical hybrid working arrangements, it was recommended that agreeing core or overlapping days could facilitate shadowing more effectively. Some commented that it was more difficult to seek help when working remotely. Others suggested that, in large units, it could be difficult for junior colleagues to know where various types of expertise sat.

Learning and development for trial statisticians continued...

Mentoring from a senior statistician at another CTU could be beneficial, allowing more open discussion and guidance on career development.

Postgraduate study

Various units allowed day-release for junior staff to undertake an MSc (in person or at distance) or support fellowships e.g. at pre-doctoral level, some had a requirement for their staff to hold a PhD in order to progress; others allowed progression based on having accrued several years' experience working in trials. A few units supported candidates working towards a PhD-by-publication.

At least two Units recruited to 'trainee statistician' roles. Progression to a more senior role was often via a postdoctoral research fellowship. Many units liked to grow their own statisticians from postgraduate study all the way through to becoming experienced trial statisticians, noting that it can often be very difficult to recruit more experienced statisticians externally.

Skills development

A good learning opportunity for junior colleagues could be to validate methods used e.g. a more junior statistician tries replicating a sample size calculation that was performed by a more senior colleague.

Aside from learning methods and trial processes, it was regarded as important for staff to develop their soft skills, e.g. by attending generic courses provided by the host institution on writing, leadership, and communication skills.



Teaching was highlighted as an excellent way to develop communication skills. Further, those working in applied research could benefit from reading up on relevant clinical areas to increase understanding and facilitate communication with investigators.

Observing a funding panel meeting was suggested as a good development opportunity. The use of checklists for on-the-job training, or a handbook, was found to be useful by some.

Training resources

Several units had training presentations available or encouraged staff to attend free webinars. Training materials produced during the pandemic were cited as a good resource for staff. Others suggested that, as a Network, we could share such resources between us e.g. recording a training session and then making the recording available to Network colleagues. It was suggested that it would be worth exploring costing training activities into grant applications.

In general, it was thought important that all statisticians in a Unit should have access to the same training opportunities. One person commented on potential inequality of training opportunity between jobbing statisticians and personnel on fellowships. Network resources for training include GCP for Statisticians (in development) and guidance on the validation of statistical programming.

Career progression

In one unit, career progression was contingent on being a co-applicant on at least one successful grant application. In terms of grant applications, a junior statistician might work with a more senior colleague on an application, with both going on as co-applicants. Setting up knowledge sharing or working groups was also suggested. It was agreed that it would be worthwhile to lobby funders for more money for methodological support. Concerns were voiced about the loss of core NIHR funding for CTUs, potentially reducing funds available for training and development.

What next?

The Statistics Operations Group are considering developing a forum for units to share internally created training and development materials and/or signpost to external options. They are particularly keen to identify resources for those looking to move on to a more senior role.

If you would be willing to share resources with colleagues at other Network CTUs please contact the Secretariat (regctus@leeds.ac.uk).

International Clinical Trials Day 2023

The UKCRC Registered CTU Network is pleased to support International Clinical Trials Day 2023

The event marks the day in May 1747 when James Lind, a Royal Navy surgeon, began what many consider to be the first randomised clinical trial ever undertaken. Although his trial into the causes of scurvy consisted of just 12 men and ran for only 6 days he was nevertheless able to establish the link between citrus fruits and scurvy. Worldwide the anniversary of Lind's trial is now used to raise awareness of clinical trials and honour the work of clinical research professionals.

Once again we're pleased to say that many CTUs were able to run some of their usual face to face events. Nevertheless, units continued to find inventive ways to spread the message via social media. It was particularly good to see that units across the Network made full use of social media to spread the word. It was particularly good to see how many units took the opportunity to highlight the input of patients and public contributors. Some of these are featured below.

Brighton and Sussex CTU

Brighton and Sussex Clinical Trials Unit celebrated ICTD with a get-together and homemade chocolate orange cake (which was brought out of 'for Christmas only' retirement!).



Centre for Trials Research

As part of their activities for ICTD 2023, CTR launched their Associate Members Programme.

The Treialon Cymru Associate Members Programme helps staff working in stakeholder organisations across the health and social care sectors to collaborate with the unit.

More information on the programme can be found here: www.cardiff.ac.uk/centre-for-trials-research/collaborate-with-us/associates. Alternatively you

can listen to a recording of the launch event here: www.youtube.com/watch?v=jbcddbYjXJc



MRC CTU at UCL

MRC CTU shared some useful information to help the public understand more about the clinical trials process.



International Clinical Trials Day 2023



International Clinical Trials Day 2023 continued...

You can find the information, including a video of Max Parmar talking about Randomised Controlled Trials, here: www.mrcctu.ucl.ac.uk/patients-public/about-clinical-trials/what-is-a-clinical-trial/

Leicester CTU

Leicester CTU had a stand outside the health sciences building at the University of Leicester on ICTD 2023.



Unit representatives ran a game called Guess the Specialty where students, staff, and passers-by could try to guess what the clinical specialty was based on the study logo.

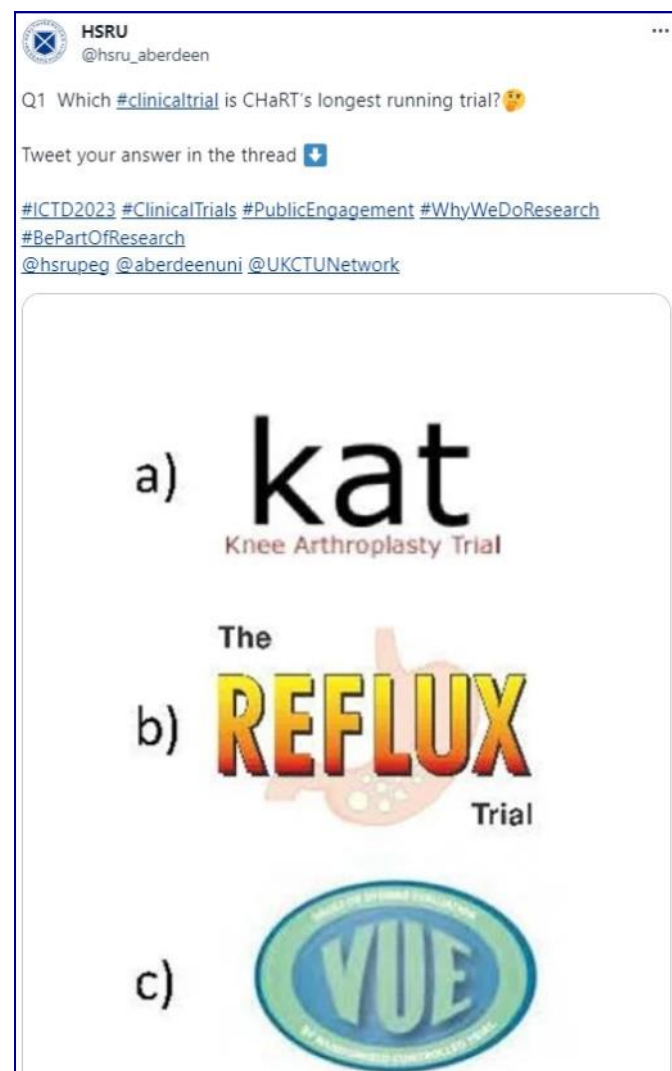
How well would you do?



Centre for Healthcare Randomised Trials (CHaRT)

CHaRT used the Health Services Research Unit (HSRU) Twitter and HSRU Public Engagement Group Instagram accounts to engage with the public by posing some fun questions about CHaRT and some of their studies including:

Which is CHaRT's longest running clinical trial?



[ANSWER: KAT which has been running since 1998]

For the other questions (and answers) visit: www.abdn.ac.uk/hsru/news/22110/

In the run up to the day they also published gifs of

International Clinical Trials Day 2023



International Clinical Trials Day 2023 continued...

colleagues sharing their thoughts on the work they do, including this one from Director Graeme MacLennan/



Exeter Clinical Trials Unit

Exeter took us on another adventure through time and space as they took people through history of clinical trials.



Keele Clinical Trials Unit

Throughout the week leading up to ICTD 2023, Keele used social media to share some interesting facts

about clinical research - as well as talk about some of their own trials.



Oxford Clinical Trials Research Unit (OCTRU)

OCTRU shared a short video thanking everyone including participants, PPI&E contributors, and staff for their input into clinical research. They also shared information on some of their ongoing trials.



Leicester Clinical Trials Unit

To mark the day, Leicester had a stand by the main entrance to the Maurice Shock Medical Sciences Building where they shared information - and cakes - with colleagues and visitors.

International Clinical Trials Day 2023



International Clinical Trials Day 2023 continued...

You couldn't possibly miss them thanks to the large banner displayed outside!



MOTIVE. You can find out more here:

www.birmingham.ac.uk/research/bctu/trials/womens/emotive/e-motive.aspx



Southampton Clinical Trials Unit

As well as celebrating ICTD 2023, Southampton CTU celebrated some great news of their own. You can find out more about their plans here bit.ly/43fwlS9

Liverpool Clinical Trials Centre (LCTC)

Alongside other activities, LCTC took to social media to share what working in clinical trials meant to some of their staff.



Birmingham Clinical Trials Unit

Birmingham marked ICTD 2023 by sharing details of a number of their ongoing clinical trials, including E-

Leeds Clinical Trials Research Unit

Alongside their activities on social media, Leeds CTRU took part in #BeCurious. The event, which includes festivals, talks, and workshops, allows

International Clinical Trials Day 2023



International Clinical Trials Day 2023 continued...

people to learn more about the research that is taking place at the University of Leeds.

This year the CTU asked participants to help answer the question “Which kind of chocolate makes us happier?”

You can see some of the highlights from this years event here: www.youtube.com/watch?v=dxafRzFmIJU&t=5s



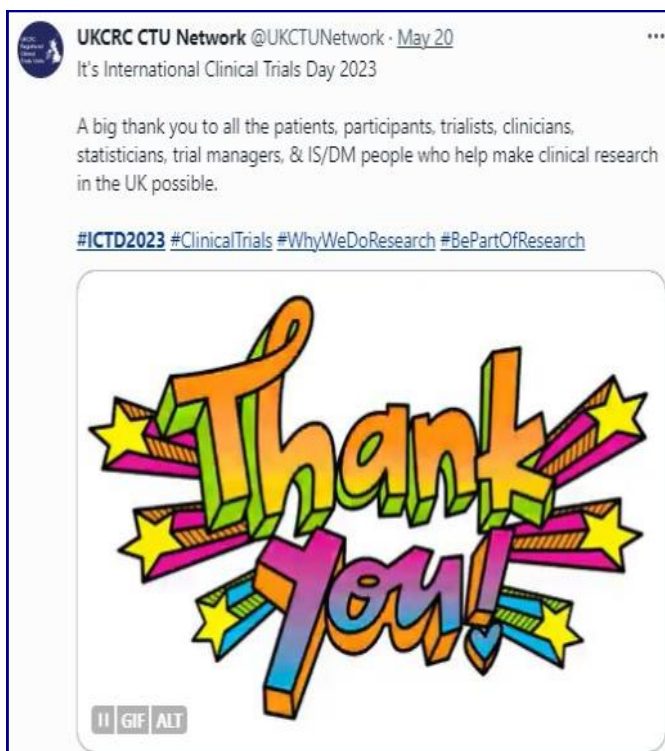
North Wales Organisation for Randomised Trials in Health (NORTH)

NORTH used social media to ask a very important question: Where would we be without clinical research?



AND FINALLY:

A little thank you from the Network:



International Clinical Trials Day 2023



UK Trial Managers' Network Update



The UKTMN has over 1400 members, for whom we continue to be committed to providing a range of support and resources.

The Network has been funded by the Nuffield Department of Population Health (NDPH, University of Oxford) since 2018, and we are delighted to share the news that this support has recently been confirmed up to December 2027. We are hugely appreciative of the NDPH's ongoing commitment to UKTMN and would like to express our thanks to everyone involved.

Training

So far in 2023, we have delivered four online training sessions, covering 'Introduction to statistics for trial management professionals', 'Introduction to grant writing for trial managers' (delivered twice and already has enough interest to run again!), and a brand-new course, 'How to be a good trial manager'. Please see our events page [www.tmn.ac.uk/pages/98-events] for courses that are currently taking bookings.

Publication Statement

In March, the UKTMN released a statement on recognition of trial management staff in academic publications. Disappointingly, despite their critical role in the delivery of clinical trials, trial management staff are sometimes overlooked when it comes to authorship in the academic publication(s) that arise from the trial. Our Publication Statement expresses the UKTMN's view that trial management staff almost always meet the criteria for authorship set by The International Committee of Medical Journal Editors (ICMJE), and so should be included in the list of authors. View the statement here www.tmn.ac.uk/resources/publication-statement.

Annual conference

We thoroughly enjoyed our first in-person UKTMN Annual Conference since the pandemic, in Birmingham in June, and attended by around 150 members.

Headline events included talks on 'Platform and Adaptive Trials' by Francesca Schiavone and 'The INCLUDED Project – Promoting inclusivity through improving the practice and utility of ethnicity data

collection in trials' by Siân Newton and Kirit Mistry. We also ran three breakout discussion groups on 'Platform trials', 'Inclusivity in trials' and 'Regulatory aspects of clinical trials'. From the buzz in the air, it was obvious that our members were happy to back together in person at this annual event!

We enjoyed hearing four UKTMN member presentations, and were able to display 17 posters from UKTMN members. 'Best Poster' was awarded to Stephen Palmer, and 'Best UKTMN Member Presentation' to Nikki Blythe, both from Bristol Trials Centre. It was also great to hear from Prakash Patel, Trial Manager of the Year 2022 (based in Guy's and St Thomas' NHS Foundation Trust).



Competency Framework

In June, we published an updated version of the Competency Framework for Trial Management. This system brings together a compilation of recognised competency, skill and behavioural frameworks, and has been developed specifically for trial management professionals working in clinical trials. This framework should help to identify training and experience necessary for an individual's career development and we recommend trial management teams use it as part of their annual appraisals. Find the Competency Framework here www.tmn.ac.uk/resources/73-competency-framework-for-trial-management.

CONTRIBUTIONS

If you would like to contribute a piece to the next Newsletter, please email regctus@leeds.ac.uk.

UK Trial Managers' Network Update continued ...

Trial Manager of the Year Award 2023

We are delighted to announce that the Trial Manager of the Year Awards 2023 is now open for nominations. This initiative is intended to increase awareness and recognition of the pivotal role trial management professionals play in the clinical trial community.



We're particularly thrilled that, this year, the TMOTY 2023 Award is being sponsored by the NIHR Academy, who are kindly awarding up to £1,000 for the winner(s) to use for a professional development activity of their choice (e.g. training course).

So, what are you waiting for? Nominate a trial management professional who you believe deserves this

award **BEFORE 11pm Sunday 1st October 2023!**

For more information, and to submit a nomination, see here www.tmn.ac.uk/articles/trial-manager-of-the-Year-2023-now-open-for-nominations.

Careers in Clinical Trials

With input from UKTMN members and the UKCRC CTU Network, we developed an e-flyer to highlight the role of Clinical Trials Units and the types of jobs on offer within them. This has been circulated widely but the more shares the better, so please do pass it on! You can download the e-flyer [here](#).

What's upcoming?

Finally, just a brief taster of what's on the horizon. We're hoping to put on training in 'Principles of Costing a Trial' in the near future, and are also developing new training courses on 'Working with NHS Digital' and 'Managing International Trials'. The updated 'Guide to Efficient Trial Management' will also be on our website very soon, as will a new series of Professional Development case studies.

To find out more about the UKTMN:

Email: uktmn@nottingham.ac.uk

Web: www.tmn.ac.uk



Do you use Twitter? Then follow us for our latest news @UKTMN

Careers in clinical trials		TRIAL MANAGEMENT		QUALITY ASSURANCE	
<p><i>Establishing and developing a career in academic clinical trials in the UK to make a difference to patients and public health</i></p> <p>Many universities and NHS Trusts are currently recruiting to non-clinical roles</p> <p>Advantages to working in academic clinical trials:</p> <ul style="list-style-type: none"> ✓ Flexible working ✓ Training ✓ Team work ✓ Transferable skills ✓ Practice changing research ✓ Research ownership ✓ Supportive environment ✓ Development opportunities <p>For more information about the roles available visit: www.jobs.ac.uk</p> <p>UK Trial Managers' Network www.tmn.ac.uk</p> <p>UKCRC Clinical Trials Units Network www.ukcrc-ctu.org.uk</p>		<p>✓ Multi-tasker</p> <p>✓ Forward thinking</p> <p>✓ Team player</p> <p>✓ Good communicator</p> <p>✓ Problem solver</p> <p>✓ Organised</p> <p>• Pivotal role in the day-to-day running of a study</p> <p>• Managing the team and recruiting sites</p> <p>• Writing and maintaining study documents</p> <p>• Obtaining ethical and regulatory approvals</p> <p>• Preparing reports</p> <p>• Liaising with patients and members of the public</p> <p>• Writing publications for scientific journals</p>		<p>If you are interested in science, improving patient choices and treatments, and enjoy working as part of a team, there are many specialist disciplines within clinical trials, some of which have entry level roles.</p> <p>Here are some examples of the different areas within clinical trials, the attributes you might need and the types of activities each role covers</p>	
		<p>INFORMATION SYSTEMS</p> <ul style="list-style-type: none"> ✓ Problem solver ✓ Creative thinking ✓ Analytical ✓ Methodical ✓ Proficient in coding <p>• Writing system specifications, designing, building and maintaining databases such as:</p> <ul style="list-style-type: none"> • study databases • randomisation systems • electronic consent systems • systems for tracking, monitoring and managing research <p>• Ability to turn concepts into reality</p>		<p>STATISTICS</p> <ul style="list-style-type: none"> ✓ Analytical ✓ Attention to detail ✓ Collaborative ✓ Pragmatic ✓ Multi-tasking <p>• Design trials and prepare research grant applications</p> <p>• Design size calculations</p> <p>• Preparing the Statistical Analysis Plan (SAP)</p> <p>• Preparation and data modelling, contributing to design of data collection tools</p> <p>• Preparing reports for oversight committees</p> <p>• Statistical programming</p> <p>• Conducting analyses</p> <p>• Writing publications for scientific journals</p>	
				<p>DATA MANAGEMENT</p> <ul style="list-style-type: none"> ✓ Analytical ✓ Attention to detail ✓ Methodical ✓ Self-motivated ✓ Logical <p>• Designing data collection tools</p> <p>• User-testing of study databases/systems</p> <p>• Managing and tracking of quantitative study data</p> <p>• Data entry</p> <p>• Running data queries and data cleaning</p> <p>• Reviewing ongoing data for reporting</p> <p>• Quality control</p>	

NIHR CRN Coordinating Centre Update

Number of people taking part in life-changing research reaches almost one million

The NIHR Clinical Research Network has published its annual research statistics. It has been another successful year for participation in health and care research, with almost one million participants across England taking part in NIHR research in 2022/23. Read the full story [here](#).

Transforming lives through research: new NIHR video released

Our new video: '[Transforming lives through research](#)' provides a powerful message about the amazing things research has achieved, whilst setting out who we are and what we do. The video was recently shared across all of NIHR's social media channels. Please share it with family, friends and any other contacts who you think might like to learn about the NIHR, using the hashtag #ResearchTransformsLives.

Applications are open for the NIHR-AoMRC Clinician Researcher Credentials Postgraduate Certificate and Postgraduate Diploma clinical research delivery courses commencing in autumn 2023.

These courses are aimed at healthcare professionals looking to develop their research delivery skillset. They focus on the practical elements of clinical research and are aimed at healthcare practitioners from all professional backgrounds who aspire to take on leadership roles in clinical research delivery, such as Co-Investigator or Principal Investigator (PI). This includes those

who have no or limited research experience and those currently working in research delivery.

The courses are designed for learners with busy work schedules who will be studying part time.

For further information, please visit the NIHR-AoMRC Clinician Researcher Credentials Framework website <https://sites.google.com/nihr.ac.uk/crcredentials/home>

To help to promote the courses within your workplace, please print off and display [this poster](#).

Over 200,00 people sign up to new Be Part of Research registry



Over two hundred thousand people have now signed up to a new UK-wide health and care research registry from Be

Part of Research - which is now available through the NHS App.

Delivered by the National Institute for Health and Care Research (NIHR) in partnership with the devolved nations, the new service matches volunteers to suitable studies across the UK.

For researchers, the service greatly speeds up study recruitment. It also makes it easier than ever for people to access health and care research opportunities across every part of the country. Potential participants for studies are identified and 'matched' based on the areas of interest they



NIHR CRN Coordinating Centre Update continued...

selected when signing up - as well as age, ethnic group, sex, location and condition.

While the service is currently in the private beta phase of development, researchers are still able to use the functionality to recruit participants from the registry to their studies. A full public launch of the service is planned for the autumn.

Find out more about this important new service and how it supports study recruitment here:

<https://bepartofresearch.nihr.ac.uk/promote-research/information-for-researchers/recruitment-to-your-study>



May/June Clinical Research Practitioner (CRP) Bulletin

The CRP bulletin for May/June 2023 is now available to download. This edition contains information on how the CRP workforce can develop their skills and knowledge. It includes:

- an article by the winner of the Advancing Healthcare Awards CRP award
- the filmed recordings of the March 2023 CRP conference
- reminder of the upcoming CRP drop in sessions

It can be found here <https://sites.google.com/nihr.ac.uk/crpbulletinnewsitems/mayjune-2023>

NIHR Academy Update

INSIGHT: Inspiring Students into Research Scheme now open for applications

The INSIGHT: Inspiring Students into Research scheme is now open for applications. INSIGHT aims to attract students in registered healthcare, social work and public health professions (not including doctors and dentists) into the full range of research careers.

The INSIGHT scheme will fund institutionally-led programmes across 12 regions in England. Institutions will be able to apply for three years of funding to deliver:

- **Innovative engagement programmes** that showcase and attract people into the full range of research careers, including careers that combine research and practice.
- **Research Masters Studentships** that provide valuable training for individuals who may have had limited exposure to real world research during their training to date.

The INSIGHT scheme is part of the [NIHR Academy's new support for students](#). Further details about the scheme, including guidance notes, can be found on the [Funding Opportunities page](#).

Contact us



Please use these details if you would like to contact the Network Secretariat, provide feedback or contribute to a future edition of The Exchange.

UKCRC Registered CTU Network Secretariat
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LS2 9JT

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Fax: +44 (0) 113 343 1471

Email: regctus@leeds.ac.uk

Website: www.ukcrc-ctu.org.uk

Events, Training & Conferences

2023 NETWORK EVENTS

- QA Away Day - 18 September 2023 (Birmingham)
- Data & Information Systems Meeting - 19 October 2023 (Leeds)

2023 NETWORK EVENTS

- Directors' Meeting - 17 November 2023 (Leeds)
- Stats Autumn Meeting - tbc November 2023 (Cambridge)

OTHER TRAINING OPPORTUNITIES ACROSS THE NETWORK

Improving Research Delivery: Investigator Site Staff

18 - 19 September 2023 (Online)

This 2-day programme will focus on the management of trials from the perspective of the Principal Investigator and the site delivery team.

For more information please contact:
R.meerbaloch@bham.ac.uk

Foundations in Cluster Randomised Trials

18 - 20 September 2023 (3 day) or 18 - 22 September 2023 (5 day) (Online)

This short 3-day or 5-day on-line course will provide training in the design, conduct and analysis of cluster randomized trials (CRTs) and stepped-wedge cluster randomized trials (SW-CRTs).

To find out more or to register your interest please visit: www.birmingham.ac.uk/postgraduate/courses/cpd/med/foundations-in-cluster-randomised-trials.aspx

Conduct of Platform Trials

21 September 2023 (F2F)

This course covers how to conduct a platform trial from set-up to reporting, particularly focussing on the aspects that are different or more difficult compared to a more typical two arm randomised controlled trial.

More details can be found at <https://www.ucl.ac.uk/clinical-trials-and-methodology/conduct-platform-trials>

Clinical Trial Management: Maximising Effectiveness

20 - 21 November 2023 (Online)

This 2-day programme will focus on the fundamentals of the project management of trials.

For further Information and booking please visit:
www.birmingham.ac.uk/postgraduate/courses/cpd/med/clinical-trial-management.aspx

Introduction to Randomised Controlled Trials in Healthcare

27 - 29 November 2023 - Birmingham (F2F)

This 3-day course provides an overview of the research process from idea and design to analysis and publication.

[Visit the website for course details, requirements, and booking](#) or email Razia Meer Baloch R.meerbaloch@bham.ac.uk.

A practical introduction to running randomised clinical trials

21-24 November 2023 (Online)

This 4-day course will improve your knowledge and skills in the design, practical conduct, management and analysis of randomised clinical trials (RCTs).

For more information or to register for this course, please visit: <https://www.keele.ac.uk/primary-care-short-courses/runningrandomisedclinicaltrials/>

CONTRIBUTIONS: If you have a course to advertise, please email regctus@leeds.ac.uk.



Trial Manager of the Year 2023

Recognising the pivotal role trial management professionals play in the design and delivery of clinical trials in the UK

- 1** Think of a trial management professional who you work with whose hard work and dedication should be nationally recognised
- 2** Complete the short online form linked below, telling us why you think the person you are nominating deserves this award
- 3** Sit back and wait for the winner to be announced! Make sure you tell your colleagues to nominate someone too!

For more information, and to access the nomination form, see here - <https://www.tmn.ac.uk/articles/trial-manager-of-the-Year-2023-now-open-for-nominations>

Careers in clinical trials

Establishing and developing a career in academic clinical trials in the UK to make a difference to patients and public health

Many universities and NHS Trusts are currently recruiting to non-clinical roles

Advantages to working in academic clinical trials:

- | | |
|-----------------------|------------------------------|
| ✓ Flexible working | ✓ Practice changing research |
| ✓ Training | ✓ Research ownership |
| ✓ Team work | ✓ Supportive environment |
| ✓ Transferable skills | ✓ Development opportunities |



For more information about the roles available visit: www.jobs.ac.uk



UK Trial Managers' Network
www.tmn.ac.uk



UKCRC Clinical Trials Units Network
www.ukcrc-ctu.org.uk

CONDUCT OF PLATFORM TRIALS

IN-PERSON COURSE



21 Sep 2023, 10am- 4pm



90 High Holborn,
London, WC1V 6LJ



Would several databases or one be more efficient?

One protocol or a modular protocol?



How do I open a new comparison?



How do I close a comparison?



A comparison is closing, should I communicate this to all participants?



For further details, please contact Sharon Love
s.love@ucl.ac.uk



MRC
Clinical
Trials Unit





UNIVERSITY OF
BIRMINGHAM

COLLEGE OF
MEDICAL AND
DENTAL SCIENCES

Improving Clinical Trial Delivery: Investigator Site Staff

2-day online
course £250

2023 Dates:

27th-28th

February

&

18th-19th

September



For sites to achieve their recruitment target on time, in compliance with the trial protocol and with the collection of complete and accurate data, experienced and trained staff are required. This 2-day programme will focus on the management of trials from the perspective of the Principal Investigator and the site delivery team. It will explore clinical trial challenges such as the factors that can affect successful participant recruitment, data quality and the challenges in the assessment and reporting of safety data. It will focus on the impact of protocol deviations on patient safety and data credibility and will improve comprehension of the rationale for specific trial activities. This course is designed to build understanding and efficiency in the ongoing site management and delivery of open trials. It is aimed at site delivery staff who have some previous trial delivery experience, and who would like to build on this skill set.

For more information please contact:

R.meerbaloch@bham.ac.uk



UNIVERSITY OF
BIRMINGHAM

COLLEGE OF
MEDICAL AND
DENTAL SCIENCES

Clinical Trial Management: Maximising Effectiveness 20th-21st November 2023

Bi-modal Delivery:

A mixture of
pre-recorded
lectures & live
online practical
sessions

2-Day Cost
£250



Trials that are successfully delivered on time and to the recruitment target require the employment of good project management. High quality data is driven through data and quality management processes, and these must be combined with an understanding of the trial safety reporting requirements, and the ongoing assessment and evaluation of trial risks.

This 2 day programme will focus on the fundamentals of the project management of trials for sponsor staff. It will explore how to plan for and respond to clinical trial challenges, maximising effectiveness, efficiency and data quality. It is aimed at individuals involved in trial co-ordination and management who have some experience, and who would like to build on this skill set.

For further Information and booking please visit:

<https://www.birmingham.ac.uk/postgraduate/courses/cpd/med/clinical-trial-management.aspx>

Or contact Razia Meer-Baloch: R.Meer-Baloch@bham.ac.uk



A PRACTICAL INTRODUCTION TO **RUNNING RANDOMISED CLINICAL TRIALS**

21 - 24 NOVEMBER 2023

VIRTUAL COURSE @KEELE UNIVERSITY

This 4-day course will improve your knowledge and skills in the design, practical conduct, management and analysis of randomised clinical trials (RCTs).

Through a combination of talks and workshop activities, you will be guided through the principles, methodology and practical implementation of RCTs.

£499

(Student)

£599

(Academic/NHS)

£699

(Commercial)

For further information or to book your place online please visit:
<https://www.keele.ac.uk/primary-care-short-courses/runningrandomisedclinicaltrials/>

All enquires please email Rachael Heath: r.a.heath@keele.ac.uk



UNIVERSITY OF
BIRMINGHAM

COLLEGE OF
MEDICAL AND
DENTAL SCIENCES

Introduction to Randomised Controlled Trials in Healthcare

27th-29th November 2023

3 day cost
£500



This 3-day introductory course is a revised version of 'Research Methods for Clinical Trials' which Birmingham has been delivering for over 20 years. Organised by the Birmingham Centre for Clinical Trials (BCCT) it provides an overview of the research process from idea and design to analysis and publication. This programme combines the theoretical aspects of trial design with opportunities to apply knowledge to practice.

The course is designed for a broad clinical trial audience working in trusts, academia or industry; ranging from those who have little experience in clinical trials to those who wish to expand their knowledge of clinical trial methodology and the clinical trial process.

For further Information please visit:

<https://www.birmingham.ac.uk/postgraduate/courses/cpd/med/randomised-controlled-trials-healthcare.aspx>

For booking contact Michelle Burgess M.Burgess@bham.ac.uk



Edinburgh Clinical Trial Management Course 2023

Thursday 07 and Friday 08 December 2023
08.45 – 16.30

John McIntyre Conference Centre, Edinburgh

The objective of this course is to provide an introduction to the management of clinical trials, by giving an overview of the standard processes and legal requirements necessary to undertake clinical research.

Made up of a range of workshops, practical tasks and lectures, these interactive sessions cover key topics including managing the set up and delivery of clinical research. Sessions aim to facilitate discussion, information exchange and provide networking opportunities.

The course is relevant to individuals currently involved in the management of clinical trials, including trials assistants, trial coordinators, projects assistants and clinical research staff, as well as those who are new to the clinical research field.



#ECTMC23



Course Fees:

- NHS/Academic Rate: £595
- Course Dinner on 07 December: £35 (optional)
- Industry Rate (inc. Dinner): £1600

For more information and to register visit:
<https://edin.ac/459JcLX>



UNIVERSITY OF
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COLLEGE OF
MEDICAL AND
DENTAL SCIENCES

Clinical Trials – MSc/PGDip/PGCert

“My favourite thing about the Birmingham programme is that it draws on the world-class expertise from the researchers at the University's two clinical trials units. It's been the ideal mix of the theory that underpins clinical trials but also the vital day to day aspects needed to deliver a trial in the real world. The knowledge and skills that I've gained are already helping my current job in medical research and I know as I plan my career into clinical trials, this qualification is going to put me at a real advantage.”

Graham McIlroy
MSc Clinical Trials student



A programme designed to produce skilled specialist clinical trial staff and expert chief investigators.

Developed for a broad audience working within NHS trusts, academia and industry; for those already working within Clinical Trials and for those wishing to move into this increasingly important field.

Modules

- Rationale for Clinical Trials, Key Concepts & Features
- Selection, Collection & Reporting of Clinical Trial Outcomes
- Preparation & Set-Up for a Clinical Trial
- Delivery & Management of Clinical Trials
- Analyses of Clinical Trials, Interpretation & Communication of Trial Findings
- Early Phase Clinical Trials
- Design and Delivery of Further Clinical Trials
- Final Research Project

Modes of study:

60, 120, or 180 credit options

Delivered on-campus:

- 1-year full time
- 2-years part time
- Up to 5-years flexible

Entry requirements:

2:1 Hons. degree (or equivalent) in a health or life sciences related subject, medical statistics or health economics.

Equivalent relevant work experience will be considered on a case-by-case basis.

For further information go to: www.birmingham.ac.uk/msc-clinical-trials
or email: clinicaltrialsmsc@contacts.bham.ac.uk