

WELCOME TO THE UKTMN AUTUMN 2016 NEWSLETTER

Welcome statement from the Chair, Professor Elaine McColl, Newcastle University

I am pleased to welcome all UKTMN members, old and new alike, through our latest newsletter. Over the past year, the Working Group have been very busy, as you can read later in this newsletter. We have been paving the way for the introduction of a self-funded model for UKTMN and we sincerely hope that you will all continue your membership. To adapt the words of Abraham Lincoln, the UKTMN is “by trial managers, for trial managers”. We want it to be responsive to your needs, so please contribute to its future shaping by letting us know what you want and need.

We are delighted that UKTMN now has over 1000 members!

If we can translate this membership into fully paid-up members, we will be on the way to UKTMN achieving self-sustaining mode. At the moment, while UKTMN is in the transitional phase of trying to stand on its own two feet financially, the Nuffield Department Population Health, University of Oxford, is underwriting the cost of running UKTMN (which is not inconsiderable). NIHR has also made a further contribution and we are very grateful to both these institutions.

There are lots of perks for paid-up members of UKTMN: heavily subsidised training courses, opportunities to contribute to the shaping of the Professional Accreditation Scheme, discussion forums for sharing and solving day-to-day problems with your peers, giving your input into the development of future topics for training initiatives being but a few—and don't forget to visit our Career Centre to search for career opportunities and to post vacancies that come up in your CTU!

If you haven't submitted your membership fees as yet, you have until the end of November to do so. After that, the names of any members who have not paid will be removed from the member list. Please remind your colleagues who may not have signed up and paid their £50 yet that they can do this by visiting the following link and click “Securely renew your membership now”:

<http://www.tmn.ac.uk/members/membership.asp>

For further details about the membership renewal and the payment, please follow [this link](#).

We have made enormous strides, now we need your help to keep the Network going!

The Working Group:

Elaine McColl (Chair)	Newcastle University
Louise Bowman	NDPH, Oxford
Chris Bray	OUH NHS Foundation Trust, Oxford
Ruth Davis	NDPH, Oxford
Barbara Farrell	NPEU, Oxford
Suzanne Hartley	CTRU, Leeds
Helen Hickey	CTRC, Liverpool
Alison McDonald	CHaRT, Aberdeen
Helen Meadows	ICTM, UCL, London

Annual Meeting

128 UKTMN members attended the Annual Meeting held at ETC Venues in Marble Arch on 14th September. As well as interesting talks and workshops, the attendees were treated to a delicious lunch, with coffee and tea on tap throughout the day.

We have made the meeting materials, including workshop handouts and the workshop slides, available on [the website](#) (member sign-in required).

Here is feedback from Sarah Tearne, Trial Manager at the Nuffield Department of Primary Health Care in Oxford

I have been working in trial management for almost seven years but this year was my first experience of the UK Trial Managers' Network Annual Meeting. I wasn't quite sure what to expect but I went along hoping to network with some other trial managers from different institutions and possibly get some ideas on how to deal with some of those more difficult areas of managing a trial: recruitment and retention! I have to say I wasn't disappointed.

The meeting was hosted in central London which was very easy to get to. The meeting kicked off with a roundup of the progress that has been made over the year. This included information about courses run by the Network and the other benefits that being a member of the TMN brings. We also had a presentation from the Health Research Authority (HRA) on the new HRA processes that have been introduced this year. It was reassuring to hear that some of their teething problems are starting to be ironed out and to be able to ask questions directly to someone knowledgeable who could answer there and then.

The breakout sessions after the coffee break were very interesting. I went to the one that discussed how best to introduce accreditation for trial management staff. It was easy to see how complicated a

process it is going to be to develop something that accurately reflects the skills of all those working in trial management now. It was also a useful space to discuss



some of the wider issues trial managers face in terms of gaining recognition within their own institutions for the work they do and how to manage their career progress.

After a delightful lunch, the final lecture of the day was about monitoring and whether monitoring should focus specifically on the reporting of events within trials, with the argument being that this information is really the most important information collected in trials. This was interesting and quite controversial with a couple of audience members challenging the presenter about his ideas in a way that I think was helpful for everyone.

Overall the day was a success and I will certainly be returning next year. The TMN seems to be entering a new phase and I'm excited to see what happens next!

Thoughts on attending my first UKTMN meeting **Joanna Cox (Trial Manager, Lancashire CTU)**

I started my job at UCLan in August, so I'm very new to the role of trial manager.

It was interesting to hear about the UKCRC Registered CTU Network in more detail - something I had heard about only briefly in the past, but which is much more relevant to me now, as our unit will be working towards registration.

Update on the new HRA approval process presentation: I was working as a research nurse at the time this was brought in, and had very little information about it. I attended the workshop "A user perspective of the HRA system - A workshop to explore members' positive and negative experiences of the system to date". This and the feedback sessions gave me a much better understanding of the process. I appreciated the opportunity to hear how trial managers had found using the system, and it's great that feedback was gathered in order to improve communication.

The afternoon presentations "Combining qualitative research and RCTs - what should Trial Managers do?" by Alicia O'Cathain and "Coloured blobs and clinical trials" by Ian Roberts were both really interesting and thought provoking. It was clear from the questions asked that there were delegates with very different backgrounds to myself.

I'm looking forward to attending again, when I'll have more experience of working in the role and can contribute more to discussions.

Thoughts on attending my first UKTMN meeting **Denise Forshaw (Principal Trial Manager, Lancashire CTU)**

I have always read with interest any emails about the TMN and sometimes look at the questions on the forum but have never attended a meeting. Although I have been a trial manager for many years, we are only a new CTU and are working towards registration. This year I wanted Joanna to attend as part of her induction training and as I had a gap in my diary decided I would also. The event surpassed my expectations. The presentations were informative and highly entertaining with the speakers fielding (at times quite feisty) questions with both grace and humour. Will I be attending next year? Safe to say that answer is not dichotomous but rather a resounding yes!



Making trials more efficient: what sort of data do we collect?



Shaun Treweek, Health Services Research Unit, University of Aberdeen

At the UKTMN meeting held in September 2015 we asked participants to think about trial efficiency from a trial manager's perspective and come up with a list of research questions that trial managers, together with Trial Forge (see <http://www.trialforge.org>), could work on. We came up with several research questions but the one we've started with is 'What is the purpose of the data we collect and do we actually use them?'

A team of 15 people, most of whom are trial managers, from six institutions has been working on this question since the beginning of the year. The basic approach is to define broad categories of data that appear on data collection forms (e.g. demographics, primary outcomes, process outcomes), test these categories out on a few trial data collection forms, modify the categories if necessary and then repeat the exercise for between 20 and 50 trials. At the end of this we'll be able to say something about the amount of data collected in each category, reflect on whether we use these data and then consider whether it might be worth reducing or increasing the proportion of time spent collecting certain types of data.

We now have our list of data categories and have used them with the data collection forms from three trials: [AMBER](#), [KAT](#) and [SALVO](#). This led to a few minor changes to the categories but the approach worked well. We are now repeating the exercise for AMBER, KAT and SALVO with members of the team who are not connected with those trials. Once that work is complete, we can start working our way through a larger sample of data collection forms from around 20 trials.

There is a clear sense in the team that a lot of time is spent collecting data that are rarely used. We think this piece of work will shine a quantitative light on the problem, which will inform a wider discussion about how we can make sure that data collection resources are targeted on the data that are most important.

If anyone is interested in collaborating on this work (or anything similar for that matter), get in touch at the email address below.

Shaun Treweek
Health Services Research Unit, University of Aberdeen
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Regional/Specialist Group Meetings

We held a highly successful UKTMN regional meeting earlier this month in Oxford with around 90 attendees. A small local working group of Oxford-based trial managers organised the launch meeting. There was a positive buzz at the meeting and we have received enthusiastic feedback.

Professor Jane Armitage gave the keynote talk on the importance of trial managers. Professor Armitage's talk provided a lot of interesting and thought provoking material with perspectives and ideas that appeared to be new to some trial managers but were interesting to all. It was also refreshing to be reminded about the bigger picture of working on trials and not getting side-tracked with minutiae of questionable importance.



There were 10 two-minute presentations about the structure and work of various CTUs / groups in Oxford. Even though Oxford is a small city, you'd be surprised at how many of us knew so little about the work in other trials units / groups within the city and even of their existence! Although there was a half-hour break for networking, Oxford trial managers have asked for this to be longer next time so that they can have longer to mingle and get to know each other! After the interesting presentations from various units the name badges with the trial manager's name and trial unit acted as a good conversation starter/ice-breaker to facilitate chatting to trial managers from other groups.

The Oxford local working group has put together a series of short talks and panel discussions over the coming months. These include:

- MHRA Inspections: what to expect and how to prepare
- HRA: What we have learnt so far, AcoRD cost attribution advice
- Project Management Overview
- Managing International Trials
- Career Progression

If you are a trial manager in the Oxford area, you can register for a place at:

<http://www.tmn.ac.uk/events/>

You could do this in your area, too! Would you like to set up a local hub for trial managers in your area? If so, please let us have details and we'll spread the word!



Update from the Working Group

The Working Group was convened in December 2013 following the withdrawal of the Network's NIHR funding. The remit of the Working Group is to:

- guide and support the organisation and development of network activities during the transition phase (2014-2016)
- guide the future strategic development of the network

The Working Group and the four sub-groups have continued to meet regularly via teleconference over the year. The four sub-groups are Training, Website, Competencies & Professional Accreditation Scheme and the Guide to Efficient Trial Management editorial board. The Working Group members will have a face-to-face meeting at the end of November. Review of the Terms of Reference of the group will be an important agenda item as well as other topics regarding the next steps.

Recently, Kath Foster (formerly of the University of Nottingham, Division of Primary Care) and Sarah Meredith, MRC CTU at UCL have stepped down from the Working Group. On behalf of the members we would like to thank both Sarah and Kath for their contributions to UKTMN over the years.

The Working Group and the Trials Journal

When we read "*Trials is celebrating its 10th anniversary this year and to coincide with publication of its 3000th article we have put together a page to highlight the great milestones of the journal, including a timeline, opinions from those in the field, links to our most popular articles, and more:* <http://trialsjournal.biomedcentral.com/about/10anniversary>" we clicked on the link and found that two of the UKTMN Working Group and founder members were featured.

Alison McDonald's paper "[What influences recruitment to randomised controlled trials? A review of trials funded by two UK funding agencies](#)" was second in the category of the most cited articles with 210 citations.

A paper authored by **Barbara Farrell**, entitled '[Managing clinical trials](#)' is the second most accessed paper in 10 years with over 80000 views in the journal *Trials*.

Congratulations to Barbara and Alison!



UKTMN courses

The Training Sub-group has co-ordinated three fully subscribed courses in Project Management for Trial Managers, one in Manchester and two in London. We have enthusiastic, positive feedback from the course attendees.

“Well organised and good presentation of topics. Have done project management training before but it was great to have it in a trial management context!”

“Using the group activities for networking was an excellent opportunity. Adrian gave an excellent set of presentations.”

“Really liked presenter's method, very informative, illuminating & interesting, loads of material to think about/ implement it.”

We have scheduled further courses from next month to the beginning of next year. There are still a few places left on the UKTMN courses scheduled for November:

[Clear Writing for Trial Managers](#) Tuesday, 1 November 2016 in London

[GMP for IMPs Manufacturing](#) Tuesday, 22 November 2016 in Oxford

[Project Management for Trial Managers](#) Tuesday, 22 November 2016 in Glasgow

[Project Management for Trial Managers](#) Tuesday, 7 February 2017 in Keele

[Clear Writing for Trial Managers](#) Wednesday, 1 March 2017 in Edinburgh

[GMP for IMPs Manufacturing](#) Thursday, 16 March 2017 in Nottingham

Places are available to UKTMN members who have paid their annual membership fee for 2016-17. Please register for the course by following the links above.

Ruth Davis (member of the UKTMN Working Group and administrative team) writes “I attended Martin Rosser’s “Clear Writing for Trial Managers” course a number of years ago and can highly recommend this. I learnt a lot. Martin makes the day fun and informative and he raises many thought-provoking points. You’ll never look at a patient information leaflet or newsletter in the same way again!”

If there are other areas you would like UKTMN to offer courses on, please [email us](#) and let us know.



Website

The new “fresh look” UKTMN website was launched in June.

We are working on further improvements/developments/capacities.

We'd like to draw your attention to the fact that there is now a function to send private messages to other UKTMN members if you want to talk outside of [the forum](#). Please hover your mouse on the name (coloured in green) of the member you wish message, then you will see an option “Message Me”. Click this and you will be taken to a form to send a message. An automated message notification email will be sent to the member you are messaging.

Competencies and Professional Accreditation Scheme

The Competencies & Professional Accreditation Scheme sub-group has done a lot of work and impressive headway has been made in providing a bespoke professional accreditation scheme for trial managers which will map an individual's training, skills and experience against recognised competency frameworks provided by a variety of providers.

The feedback from members in the PAS workshops at the annual meeting was very useful and the sub-group are planning more work on this document. The sub-group will provide an updated version of the document in the next few weeks to be completed by members who attended the workshops.

We'd like to remind respondents that the current versions of the spreadsheet and list of soft skills are drafts / works in progress.

The Guide to Efficient Trial management

The fifth edition of the Guide to Efficient Trial Management was published and uploaded to [the website](#) in June 2016. We think you will agree that it is a fantastic compendium and an invaluable resource, particularly to trial managers in the earlier stages of their career.

You can access this on the website and [post your comments/suggestions](#). As you can imagine, with continuing change in the clinical trials environment it is a challenge to ensure that this is kept up-to-date, therefore the Editorial Board sub-group would welcome your input.



Upcoming courses and events

Please see above for the [full list of UKTMN courses](#)

[Public and Patient Involvement in Clinical Trials](#)

2 November 2016, The Institute of Clinical Trials and Methodology (ICTM) at UCL

[Designing and Running Streamlined Randomized Trials](#)

9 & 10 January 2017, Oxford

[4th International Clinical Trials Methodology Conference \(ICTMC\) and the 38th Annual Meeting of the Society for Clinical Trials](#)

7 – 10 May 2017, ACC Liverpool

[Clinical Trial Management](#)

26 – 30 June 2017, Oxford

Please let us know if you would like to write a piece for the next edition of
The INSIDER

UK Trial Managers' Network

Contact Ruth Davis tmn@ndph.ox.ac.uk

