UKTMN Trial Managers' Network

December 2015

The INSIDER

WELCOME TO THE UKTMN CHRISTMAS 2015 NEWSLETTER

Welcome statement from the Chair, Professor Elaine McColl, Director, Newcastle CTU

These are exciting times for the UKTMN. The Network provides members with a passport to a powerful knowledge base and the opportunity to develop expertise, solve problems, share experiences and exchange ideas with trial managers, around the UK.

Membership is burgeoning – and now stands at 864 members. Please do remind your trial manager colleagues to join, if they have not already done so. Membership is still free, for the time-being! (This is likely to change in 2016 and we'll be sending you further details in due course). There are lots of exciting things in the pipeline – read on to find out what we have planned.

The working group has had a busy year, aiming to be responsive to the needs and desires of our membership as highlighted in the 2014 survey and at annual meetings. We've been in negotiations over hosting and enhancement of the website. Plans have been made for delivery of training – both face-to-face and via the web - in a range of topics highlighted by UKTMN members. We've devoted considerable time and thought to the development of a competency-based professional accreditation scheme for trial management staff. The ever popular and useful Guide to Efficient Trial Management is currently been updated. Discussions have been held about developing special interest groups for trial managers working in particular disease areas and in different regions of the country. You can read more about this initiatives below.

We continue to welcome suggestions and ideas from the UKTMN membership, and opportunities to contribute to some of these initiatives will be flagged up in due course.

In the meantime, on behalf of the Working Group, I'd like to wish all members a very Merry Christmas and all the best for 2016.

The Working Group:

Elaine McColl (Chair)	Newcastle CTU
Sarah Meredith	MRC@UCL, London
Alison McDonald	CHaRT, Aberdeen
Suzanne Hartley	CTRU, Leeds
Chris Bray	DTU, Oxford
Louise Bowman	NDPH, Oxford
Barbara Farrell	NPEU, Oxford
Helen Hickey	Liverpool CTU
Kath Foster	Nottingham University
Helen Meadows	ICTM, UCL, London
Ruth Davis	NDPH, Oxford

Annual Meeting

It was wonderful to see so many of you at the 2015 Annual Meeting held in London in September. It was a glorious day and the set up of the venue meant that we could step outside and network in the sunshine during the breaks.

There were a wide range of talks and the slides and videos of these are available at http://www.tmn.ac.uk/?page=2015AnnualMeeting

Jennie Parker, Trial Manager from the Newcastle Clinical Trials Unit sent us this feedback:

"I asked and was given permission to attend this meeting, my first since becoming a member in 2013 (formerly NIHR TMN). I became a TM for the registered Newcastle CTU in 2011 and have over 10 years trial and data management experience.

As expected the agenda was well thought out, with each presentation extremely relevant. The most contentious item was about membership, in that where it is currently free, for it to remain viable a fee will be introduced. Although this is never popular, if we are to be regarded as professionals, with that comes the need have a professional membership, as do nurses and accountants! To keep up with your professional registration you would be offered discounted training through partnerships such as Pharmaschool and Global Health Network (GHN) and free attendance to future meetings. I have completed two online courses with GHN, which have contributed to my ongoing personal development and would recommend.

Shaun Treweek gave an enthusiastic presentation on Trial Forge which I had not previously heard of. I found this extremely interesting, plus it gave me food for thought about what to focus my MSC dissertation on – missing data, oh the joy!

I was allocated to the yellow workshop 'Making Trials Work Harder' facilitated by Jo Rick. This looked at embedded methodology trials, namely SWANS. Unfortunately the breakout room was located so far away from the main hall that by the time we sat down for the discussion it was time to head back! As we were unable to provide feedback at

the meeting, Jo agreed to conduct a webinar to explain embedded methodology trials from a trial manager perspective and answer questions. I was unable to attend the webinar, however I have agreed to participate in a 30 minute structured discussion on how trial managers view this type of methodology with Jo on 16 December 2015. Overall it was a good day, excellent networking opportunities and knowing we are not alone is a great comfort! The venue was good and the food excellent. It was a shame that many who had booked a place did not turn up, as places were limited and this meant that others were unable to attend".

Webinar – Making Trials Work Harder

Earlier this month UKTMN hosted a webinar on embedded methodology trials based on the workshops run by Jo Rick at the UKTMN annual meeting in September. Due to time restrictions on the day it was suggested that the discussion could be continued online and a webinar seemed to be the best option, enabling the team to:

- Open the discussion to a wider group than those attending the original workshop
- Explain the approach, give examples of how it has worked and resulting publications
- Take any questions about the methodology itself, and
- Discuss the barriers and facilitators to embedded methodology trials from a trial manager perspective.

The webinar lasted about an hour, interactive in format, with brief presentations by Professor Peter Bower and Dr Jo Rick (both North West Hub for Trials Methodology Research) with the opportunity for questions about the methodology, followed by a structured discussion session on how trial managers view this type of methodology, what they see as the pitfalls and challenges and what types of support or interventions could be put in place to encourage implementation.

There was a lively Q&A and discussion session and the related documents and link to the recording are available on the UKTMN website.

SWANS - Jo Rick – Institute of Population Health, Manchester

Independent of UKTMN and the webinar, as part of the SWANS study we would like to invite up to 10 volunteers to participate in a short (20 – 30 minute) interview about embedded trial methodology - NO PREVIOUS KNOWLEDGE OR EXPERIENCE NECESSARY!

Whether this is the first time you've come across embedded trial methodology, or whether you've run one (or more!) we're interested in your views. This is an exercise in:

- talking through what would be involved in running an embedded study with each interviewee
- gathering your thoughts and views on what the challenges would be, and
- whether, in your view, there are any forms of support that could be put in place to overcome these obstacles

If you would like to find out more, or would be willing to participate in a 20 – 30 minute telephone interview, please email me direct and I will send through the participant information - jo.rick@manchester.ac.uk

Making trials more efficient: what can trial managers do?

Shaun Treweek, Health Services Research Unit, University of Aberdeen

TRIAL FORGE

Randomised trials are at the heart of evidence-based healthcare, both here in the UK and elsewhere. They are the feedstock of systematic reviews, which in turn are the foundation of most clinical guidelines.

They are also inefficient. Consider an issue that keeps everyone working on a trial awake at night: recruitment. Systematic reviews show that little more than half of trials recruit the number of participants that the trial statisticians said were essential. One study of over 1000 trials (two-thirds sponsored by industry) found that 25% were abandoned, chiefly because of recruitment problems, administrative issues and running out of money[1]. Slow recruitment of trial participants delays delivery of the trial's results and inflates costs because extra staff and clinical sites are needed to find extra participants. Conversely, systematic review of the methodology literature finds high quality evidence for only one thing that could be widely used to support recruitment: telephone people who don't respond to the initial postal invitation to take part. An evidence-based smörgåsbord it is not.

We discussed how to make trials more efficient at the UKTMN meeting held in London on 10th September this year, particularly in one of the workshops, linked to an initiative called Trial Forge (www.trialforge.org & http://www.trialsjournal.com/content/16/1/261). The workshop asked participants to think about trial efficiency from a trial manager's perspective and come up with a short-list of research questions that trial managers, together with Trial Forge, could start work on. To cut to the chase, the Top 3 research questions (not ordered) were:

1. Electronic methods vs paper:
   a) Are electronic TMFs a more efficient way of handling trial information than paper TMFs?
   b) Do electronic methods of collecting patient reported outcomes increase outcome completion rates and reduce missing data?
2. Why do we collect the data we do: what is the purpose of the data we collect on the CRF and do we actually use it?
3. What makes a trial team a good, well functioning team?

There were two bonus questions:

4. Do email or SMS messages to trial participants increase retention?
5. What proportion of outcome measures are directly related to the trial research question?

Shaun giving his talk at the Annual Meeting

UKTMN Trial Managers' Network

All of these are good questions but the one we are prioritising is question 2. Data collection occupies a lot of trial staff time and having a better idea of where effort is currently focused (especially if also linked to question 5) would help us to judge whether effort was being targeted in the right place. If anyone is interested in collaborating on this question (or the others for that matter), get in touch at the email address below.

Email: streweek@mac.com

Reference

1. Kasenda B, Elm von E, You J, Blümle A, Tomonaga Y, Saccilotto R, et al. Prevalence, characteristics, and publication of discontinued randomized trials. JAMA 2014; 311: 1045–51.

Enhancing recruitment and retention in surgical trials: could patient and public involvement be the key?

Nicola Farrar, Nufffield Department of Surgery, Oxford

As many Trial Managers will know, slow recruitment and poor retention are common challenges to the successful delivery of clinical trials. Efforts to improve recruitment and retention vary from trial to trial. Patient and Public Involvement (PPI) in the design and conduct of clinical trials is one method that is often tried, but there is currently limited evidence that it works.

The PIRRIST study (Patient and public Involvement, Recruitment and Retention In Surgical Trials) has been designed to develop a robust and pragmatic PPI intervention aimed at improving recruitment and/or retention in surgical trials. The intervention will then be evaluated in a range of different surgical trials using mixed methods.

The development of the PPI intervention is underway, with stage one of four completed in November 2015. The first stage involved mapping current PPI practice in UK surgical trials through an online survey.

Active, UK-led trials of surgical interventions or other interventions in adult surgical patients were eligible to be included in the survey; 129 trials were identified, 72 (59%) took part and 66 (92%) of these reported some sort of PPI in the trial. Developing participant information materials was the single most common PPI activity, reported in 71% of included trials.

In the second stage of the project, we hope to tease out exactly what PPI in surgical trials entails. What determines whether or not patients' comments are taken on board, or simply received and ignored? With time pressures often resting on the shoulders of Trial Managers to get study documentation approved, is it really possible to get extensive and meaningful PPI input? What support do trial staff and patients need to help make PPI better? Hopefully these intricacies and more will become clear during the focus groups which make up the second stage of the project, due to begin in January 2016.

For more information on the subsequent stages of the project, or to express an interest in taking part, please email pirrist@phc.ox.ac.uk, or visit the study website: http://www.situ.ox.ac.uk/develop/patient-and-public-involvement/pirrist

The PIRRIST study is funded by the MRC Hubs for Trials Methodology Research Network and the NIHR Oxford Biomedical Research Centre, and is part of the Trial Forge initiative to improve trial efficiency.

Nicola Farrar, Surgical Intervention Trials Unit, University of Oxford and PIRRIST team member; Joanna Crocker, NIHR Oxford Biomedical Research Centre Fellow and PIRRIST Lead Researcher; and Richard Bulbulia, Consultant Vascular Surgeon and PIRRIST Surgical Lead.

Raising Awareness of the WOMAN Trial

Danielle Beaumont – LSHTM

The WOMAN trial randomised its first patient on 22nd March 2010; the aim to provide information to reduce maternal mortality due to post-partum haemorrhage (PPH). Five years and 18,500 patients later, we are in the final months of recruitment and preparing for the results. On October 6th this year, Professor Rizwana Chaudhri, Director of the Royal Medical Council of Pakistan, launched the WOMAN trial dissemination campaign to the audience at the International Federation of Gynecology and Obstetrics (FIGO) World Congress 2015. This saw the release of the WOMAN trial film highlighting the effects of PPH on both women and sadly, in some cases, the families left behind.

The common phrase "*success is 1% inspiration and 99% perspiration"* has never been more true than in the WOMAN trial. Designing the WOMAN trial was the 1% inspiration, but it is the 99% perspiration and hard work of the WOMAN trial collaborators from across 20 countries that has enabled the trial to reach such great success.

Traditionally, dissemination of clinical trials has been limited to publication of results in a high impact medical journal, presentation of the findings at medical conferences with perhaps an accompanying press release and/or press conference. While these are all valuable ways to disseminate clinical trial results, they are not enough on their own to ensure rapid and lasting dissemination and implementation of research.

Our aim in advance of the results, due summer 2016, is to raise awareness of the problem and the trial, and engaging with health professionals, health ministers, civil society charitable organisations and public audiences of this global effort. We are actively preparing materials to aid dissemination efforts, and it would be fantastic if UKTMN members could help and support our efforts to raise the awareness of the WOMAN trial and disseminate these results by sharing the trial promotional film available on the WOMAN trial website (http://womantrial.lshtm.ac.uk/trial-film/) and subscribe to the trial results (http://womantrial.lshtm.ac.uk/subscribe-to-results/).

For more information please visit the trial website at: http://womantrial.lshtm.ac.uk/

Were you at the 3rd International Clinical Trials' Methodology Conference – Glasgow - 16th -17th November 2015?

Ruth Davis

For me one of the highlights was Professor Peter Sandercock's closing plenary "Are we developing the next generation of clinical trialists". He talked about the importance of careers for trial management members and the difficulties with career progression. He discussed the knowledge and expertise of trial managers, the wide range of tasks they undertake, which is in their heads as "folk wisdom", and how their career path does not allow them the time to write it down and to be shared. He called for greater career stability.

He endorsed and gave recognition to the progress that has been made with UKTMN to date. In particular, he praised the huge contribution made by Barbara Farrell in working for the continuity and success of the Network.

http://tinyurl.com/jerqjtv

It's exciting that following on from the success of ICTMC 2015 there will be a joint conference to showcase trials methodology research hosted by the MRC Network of Hubs for Trials Methodology Research together with the Society for Clinical Trials in Liverpool in May 2017.

Regional/Specialist Group Meetings

We are planning a UKTMN regional meeting in Oxford early in 2016 so that members can network locally and will be sending details of this to members in the Oxford area. If you have held/ or are planning to hold a local or specialist meeting for trial managers, please let us have details and we'll spread the word!

Update from the Working Group

The bad news and the good news !

Barbara Farrell – Founding member of the UKTMN, originally set up by the MRC in 1998, is retiring from her position as Trial Director at the National Perinatal Epidemiology Unit (NPEU) in Oxford. However, the good news for the UKTMN is that she has agreed to continue as a member of the Working Group.

Barbara has been running trials since 1980 when she began work as a Trial Manager on two international stroke trials. Over the past 34 years Barbara has worked on a number of very large trials in a variety of diseases including CLASP, the International Stroke Trial and the Magpie Trial. She was the UKTMN Co-ordinator from 2000 to 2010 and she also Co-chaired the Advisory Group until 2010 when the network moved to the the NIHR. She remains a member of the Editorial Board of the Guide to Efficient Trial

Management. Barbara was a member of the MRC/DH group that developed the Clinical Trial Toolkit. She also sits on various trial steering committees. Barbara joined the NPEU in May 2005 as the INIS Trial Director. In 2006 she was appointed as the CORONIS Trial Director, a 16,000 women trial evaluating caesaraen section surgical techniques.

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 continues to meet monthly. In addition, the four subgroups; Training, Website, Compentencies & Professional Accrediation Scheme and the Guide to Efficient Trial Management editorial board also meet at least once a month.

The Working Group will be seeking feedbackfrom members in developing these areas of the Network activities over the coming months and years so it can continue to support trial managers to deliver high quality trials on time and within budget.

Training

The Training Sub-group is working in collaboration with the Institute of Clinical Trial and Methodology at UCL and other providers, including PharmaSchool, to make a range of training courses available to Network members at reduced rates. There are plans for workshops on Project Management to be held in Manchester and London in Spring 2016 in addition to developing the provision of online training on a variety of areas of interest to trial managers.

Website

The Oxford based members of the Working Group are leading on this initiative. The UKTMN website will be given an overhaul and a fresh look over the coming months. **Watch this space as we will need testers at the beginning of 2016.**

Competencies and Professional Accreditation Scheme

We are working in collaboration with our website provider to develop the funcionality required within the website to provide a bespoke Trial Managers' professional accreditation scheme which will map an individual's training, skills and experience against recognised competency frameworks provided by a variety of providers. The sub-group, led by Elaine McColl, has been formed to look at these competency frameworks and, in particular, the NIHR Task, knowledge and competency framework for trial managers. Members of the sub-group are also working on mapping these compenticies to required behaviours.

The Guide

The fourth edition of the Guide to Efficient Trial Management was published and uploaded to the website in May 2014. The Editorial Board responsible for ensuring an up-to-date version of the Guide is always available is working hard to finalise the new version in the first quarter of 2016. It has been suggested that it might be valuable to include specialist group appendices to the guide. Following the Editorial Board's January meeting information about proposed appendices will be posted on the website.

Thank you to all of you who have responded to our request for your feedback on the Guide.

Some changes to the the UKTMN administrative team

Ryonfa Lee took maternity leave when her son, Guy, arrived in November last year, a bit earlier than planned. Ryonfa is now back from maternity leave and is taking over the reins from **Ginny Burch** as one of the UKTMN administrators. Ryonfa works part time and her main role is as a trial manager on the ASCEND study.

It is very soon the turn of Ginny to take maternity leave and become the UKTMN team's latest new mum. We would like to wish her good luck from the Working Group and the UKTMN members.

Ryonfa and Guy

On 30th September, **Chris Bray** moved to a new position as Head of Clinical Research at the Diabetes Trials Unit in Oxford. Many congratulations to Chris on this new post. He continues as a member of the UKTMN Working Group and two sub-groups.

Ruth Davis, an experienced Trial Manager from CTSU, Oxford and longstanding member of UKTMN, has recently been appointed to succeed Dr Chris Bray as UKTMN Coordinator. Ruth worked at the National Perinatal Epidemiology Unit on the CAESAR study until her move to CTSU to work on the HPS2-THRIVE Study. She is currently working on the 3C Study and UK HARP-III in addition to her part-time UKTMN role. Ruth has also joined the Working Group and provides support for the sub-groups.

Designing and Running Streamlined Randomised Trials

Mr Richard Bulbulia

How to conduct trials which produce reliable answers

Whether planning a large multicentre trial, or seeking to maximize the effectiveness of a smaller project, delegates on this course will learn how to design and run successful trials to produce reliable answers. CTSU has extensive experience in conducting large clinical trials, which typically randomize thousands of participants, producing reliable results which change practice worldwide.

This intensive course will comprise lectures, workshops and interactive sessions, delivered by a faculty of highly experienced clinical trialists, senior trial administrators and statisticians from CTSU. The main areas covered will include:

1. Key aspects of study design with a focus on streamlined methods
2. Study execution; the practicalities of running trials effectively and efficiently
3. Efficient event reporting and fulfilment of regulatory requirements
4. Appropriate data analysis and reporting

Who should attend?
This course is designed primarily for senior investigators from any discipline and experienced trial administrators who want to conduct successful randomised trials.

We anticipate obtaining CPD points for this course. Places are limited to 25 delegates, so early booking is recommended. For More information see the next page.

Upcoming courses and events

Public and Patient Involvement (PPI) - London
Thursday 25th February 2016, 10.00am-4.00pm
ICTM, Aviation House, 125 Kingsway, London WC2B 6NH
Further information is also available on our website at
http://www.ucl.ac.uk/ictm/education/short-courses/ppi

Designing and Running Streamlined Randomised Trials – Oxford
Monday 11th – Wednesday13th April 2016
Further information and booking: www.ndph.ox.ac.uk/trials-course

The Introduction to Design, Conduct and Analysis of Pragmatic Clinical trials course is now open for registration.
Tuesday19th – Thursday 21st April 2016
If you would like to register please follow the link:
http://eshop.qmul.ac.uk/browse/extra_info.asp?compid=1&modid=2&deptid=34&catid=1&prodid=579

Running Randomised Trials Short Course - Keele University
Tuesday 14th – Friday 16th June 2016 Further details can also be found on the website http://tinyurl.com/h3kknvj

ICTMC 2017 - Liverpool
4th International Clinical Trials Methodology Conference to be jointly hosted with the Society for Clinical Trials . 7th – 10th May 2017
http://www.methodologyhubs.mrc.ac.uk/workshops/methodology-conference/

Please let us know if you would like to write a piece for the next edition of
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Contact Ruth Davis **tmn@ndph.ox.ac.uk**