

Trials and Tribulations

NHS

*National Institute for
Health Research*

The Newsletter for NIHR Trial Managers' Network

Issue 18, December 2013



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Providing a forum for Trial Managers to network, collaborate and share information on best practice for the effective management and delivery of clinical trials

Welcome to the final issue of the TMN newsletter

Dear all

There have been some positive developments aimed at ensuring that trial manager support is sustained in the short and medium term, beyond January 2014, until a longer term solution is found.

Following on from an informal meeting convened by one of the founders of the original TMN, Barbara Farrell at the MRC Clinical Trials Methodology Conference, a working group of trial managers and CTU Directors (all of whom are supportive of TMN) came up with a proposal on how to preserve a TMN function. The proposal is to be considered by the NIHR shortly and members will be informed about the outcome as soon as possible.

Meanwhile it is important to obtain the NIHR TMN membership views and suggestions on the future development of a network which will be used to inform immediate discussions.

The Editorial Team

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Goodbye, and thank you from the NIHR TMN Secretariat in Leeds

As you know the NIHR TMN in its current form is to be suspended from January 2014.

This is not because the work and support for trial managers is not highly valued and seen as crucial for the successful delivery of clinical trials. Quite the opposite!

In these times of austerity it is vitally important to take a moment and consider carefully what is the added value of the TMN for its members and how the Network can best meet their future needs .

The University of Leeds and the Leeds Institute of Clinical Trials Research were extremely privileged to host the TMN through its transition from the former UKTMN into its current format as the NIHR TMN.

On behalf of the NIHR TMN Secretariat in Leeds, we would like to thank all of you for engaging with us via the NIHR TMN website, participation at the annual meetings, reading and contributing to our Newsletter, joining in forum discussions and responding to forum threads.

With publication due of the new edition of the NIHR TMN Guide to Efficient Trial Management we would like to particularly acknowledge the help of all [volunteers](#) who contributed to the initial review of the Guide.

The NIHR TMN will preserve some of its established facilities (such as the website) during the initial suspension period until important decisions about medium and long term future development of any network type support are negotiated and agreed with key stakeholders. However other facilities including the forum and job adverts will be withdrawn until further notice.

Once again, we thank you for your support over the last three years. We sincerely hope that the Trial Managers' Network will continue to grow in the future and deliver much valued support for its members. The University of Leeds will continue to actively support the transition.

Professor Jane Nixon

Dr Svetozar Mihaylov

Mrs Louise Liddle



The bit in the middle

The TMN has been running now for 15 years in one guise or another. Originally founded by the MRC and then co-funded by the HTA programme, and more latterly by the NIHR. The TMN is the only association, society or whatever you want to call it for those people running academic-led clinical trials in the UK. Trial managers conduct, co-ordinate, deliver 'the bit in the middle'. Some of us have more to do with the design and analysis than others but without 'the bit in the middle', there is no trial to analyse or report.

We need to be able to talk to each other without formal meetings or introductions. We need to be able to pass on the knowledge gained by years of apprenticeship and to do this we need a forum. We need a platform to air our views, to pass on the 'good bits' and to promote and publish the methodology of trial management. Of all the disciplines involved in a clinical trial; clinicians, statisticians, IT managers, nurses, health economists; trial managers are the only group involved in making sure a clinical trial comes to fruition that do not have a professional body helping them to develop as a profession and recognising their value. TMN was established to ensure exactly that.

I would urge every one of the 480 trial managers registered with TMN, which is a considerable workforce, to join me in making your views known by completing [the on-line survey](#) circulated recently. Hopefully with this information we can provide more evidence for the need to maintain such a forum as TMN. There is a lot of support across the country at all levels working to ensure that we continue to develop 'the bit in the middle' and to make sure the next generation of trial managers benefit from the last 65 years of trial management.

“We need to be able to talk to each other without formal meetings or introductions. We need to be able to pass on the knowledge gained by years of apprenticeship and to do this we need a forum”

Barbara Farrell
Trial Director
NPEU, CTU

Nuffield Department of Population Health
University of Oxford

As you will be aware, the NIHR TMN in its current incarnation will be suspended from 6th January 2014.

We as a network of trial managers need to decide if we want to move forward with a new network that meets our needs now and in the future. A working group of trial managers and CTU Directors (all of whom are supportive of this initiative) are working on a variety of options. Your feedback via this survey is absolutely crucial to this work.

To help determine what any future network should provide for trial managers, we would like you to tell us what current aspects of the network are most important to you and what you would like in the future.

To have your say and get a trial managers' network that works for you, please access our survey at <https://www.surveymonkey.com/s/Q8TYTC3>

We estimate that this survey should take a maximum of 10 minutes to complete. The survey will close on 10th January 2014, so please respond before then

In anticipation, many thanks
**Barbara Farrell, Elaine McColl, Helen Hickey,
Chris Bray, Jane Armitage, Alison McDonald,
Sarah Meredith and Mike Clarke**



NIHR TMN Suspension: A member perspective

I am very disappointed to see the suspension of the NIHR TMN. I have found the group very helpful and supportive and have learnt a lot through the website, group emails and annual meetings. As we all know, the success of any trial depends crucially upon the skills and knowledge of the trial manager.

I lead a Stroke Trial Managers Group (STMG) that is supported by the NIHR Stroke Research Network. Currently we have 36 members and any trial manager working on a study adopted by the SRN portfolio (through any funding stream) is welcome to join us.

The STMG share knowledge and experience to help support each other, and in particular, less experienced managers in issues specific to stroke. The support has proved invaluable to inexperienced trial managers, and has helped them to manage their trials more efficiently.

Members of the STMG are represented on SRN committees and NIHR working groups, and STMG members have shared an exhibition stand at the UK Stroke Forum (national conference) to help promote stroke trials in an affordable way.

The STMG work closely with the local SRN managers, meeting bi-annually to discuss important topics. Through these meetings we have promoted efficient trial management within the SRN by ensuring a shared understanding of the issues faced by both groups. These meetings have resulted in a set of guidelines to improve the quality of data collection and an escalation process that meant research nurses and trial managers knew any issues they had would be dealt with quickly

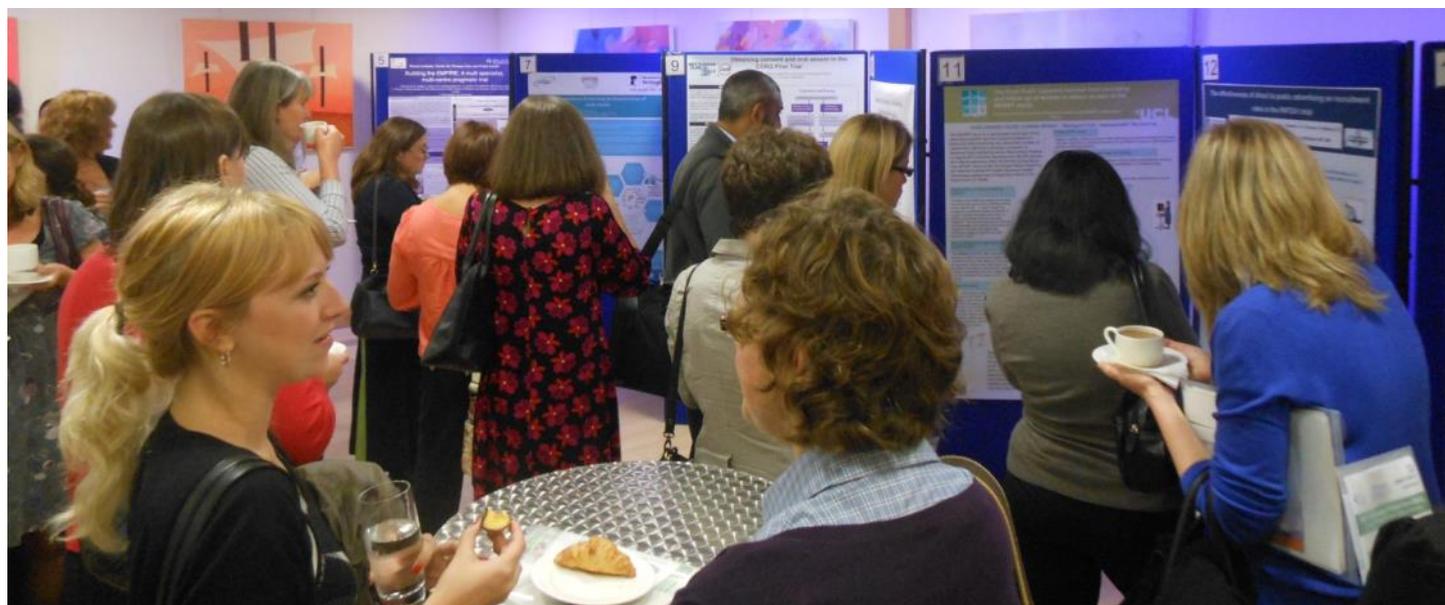
and efficiently. We have also shared experiences and developed top tips on study set-up to achieve the recruitment targets set by the DoH and CLRN.

I would strongly encourage experienced trial managers in other topic areas to consider setting up their own similar groups, and we would be very happy to support you in doing this. Despite the suspension of the UKTMN, we need to continue to work together and to share our experiences to ensure that our trials deliver the highest quality research.

We must also continue to support new and inexperienced trial managers to allow them to learn and be supported in a stressful and sometimes bewildering new role. Importantly, we must also continue to promote the value of the trial managers' role in successful, high quality research in the UK, and ensure that this is understood and appreciated by all key research stakeholders.

Josie Dickerson

Research Programme Manager and STMG Chair



News from NIHR TMN and other organisations

Strategies to improve retention in randomised trials

The Cochrane systematic review on retention in randomised trials has been published.

Many of you will remember Valerie Brueton who presented the preliminary results at this year's annual meeting.

As promised, Valerie provided a [link](#) to the published review and a [pdf version of the slides](#) for the presentation she gave at the TMN meeting in October 2013

Recent NIHR Tweets

- Become a public reviewer of commissioning briefs and research proposals in your area of experience: <http://ow.ly/r3ez1>
- NIHR staff and researchers: The NIHR are holding roadshows to showcase its new collaboration workspace. Sign up at <http://ow.ly/r38QO>
- Help shape NHS research: [#peerreview](#) with [#NIHR](#) <http://ow.ly/rIPTI>
- Register your interest for the [#NIHR](#) workshop on funding for long-term conditions in children & young people, 5 Feb <http://ow.ly/riyii>
- Need help business planning for your funding application? The [#NIHR](#) i4i Accelerator programme is designed to help <http://ow.ly/rIUwY>
- Find out more and book now for the next [#NIHR](#) i4i Accelerator programme workshop in January <http://ow.ly/rUDh>
- View the programme for The Lancet Symposium on Increasing value, reducing waste and book your place: <http://ow.ly/rqK52>
- RT: Our tree lights may be tangled but we've unravelled some evidence! Day 2 of our advent calendar <http://ow.ly/rIMnj> [#CochraneChristmas](#)
- See the current funding opportunities with the [#NIHR](#) Public Health Research (PHR) Programme: <http://ow.ly/rIPQ9>

Journal, of Clinical Research and GCP

Latest articles in the Journal of Clinical Research and GCP. To find out more and sign up for FREE go to <http://www.crgcp.com>

- [Regulatory & GCP Round Up: December 2013](#)
- [Five Golden Rules of Time Management](#)
- [Declaration of Helsinki 2013](#)
- [Five Golden Rules for On-site Monitoring](#)

Click on the [Clinical Trial Management](#) section at the article selector to view more relevant articles.

Sharing Clinical Trial Data in the interest of Patients and Research

FIY please see the [Final Report of the EFGCP Multi-Stakeholder Roundtable Meeting on "Sharing Clinical Trial Data in the Interest of Patients and Research"](#) held in partnership with EFPIA, EORTC, BMJ, SAS, DGHO, FIPRA and IMI on 16 October 2013 at the EORTC Headquarters in Brussels.

The report is also available on the EFGCP website at <http://www.efgcp.eu/>.

Attributing the costs of health and social care research Guidance

The updated AcoRD FAQs are now available from the [GOV.UK website](#).

Evidence Advent Calendar prepared by Cochrane

With evidence in the [Cochrane Library](#) on all manner of festive things from gold, frankincense and myrrh to stockings, the Evidence Advent Calendar will get you in the mood for the festive season. ([Visit the Cochrane evidence advent calendar!](#))



Training and Events

R&D Training

[The Human Tissue Act Workshop](#)

Date: 4th February 2014, London

[IRAS - A Practical Guide Workshop](#)

Are you IRAS trained?

Date: 13th March 2014, Derby

Places are limited to 22 delegates per workshop

For further information regarding any of the above events, please do not hesitate to contact the Events 4 Healthcare Team on 0844 824 6688 or email

enquiries@events4healthcare.com

2014 UK PharmaSchool Open Courses

PharmaSchool Open Courses take place in Oxford, UK unless otherwise stated. The price for each course is £250 + VAT. If you are a freelancer, work for charity, academic institution or in the NHS then you qualify for the non-commercial rate of just £125 + VAT. All of the Courses are one day in duration. Please click on the course below for more information.

[GCP and Guidelines Update](#)

Date: 28th January 2014, Manchester

[GCP and Guidelines Update](#)

Date: 11th February 2014, Oxford

[The Grey Guide](#)

Date: 12th February 2014, Oxford

[Clinical Trial Designs](#)

Date: 18th March 2014, Oxford

[Statistics for Non-Statisticians](#)

Date: 19th March 2014, Oxford

[Clinical Trials Project Management](#)

Date: 27th March 2014, Oxford

[GMP for IMP](#)

Date: 2nd April 2014, Oxford

Qualitative Research in Randomised Trials –

How qualitative methods can contribute to the design and conduct of randomised trials

Thursday 13th March 2014, Bristol. Course fee: £200

More information is available [here](#).

EFGCP Annual Conference 2014 Benefits and Risks of Research: How Do We Redress the Current Imbalance?

28 & 29th January 2014 – Renaissance Brussels Hotel, Brussels, Belgium

Determining a true and fair balance on which to build drug development, regulation, ethical review and research monitoring

The conference will explore the consequences of research, both harm and benefit and look how we might achieve a fair balance that promotes improvements in health care, new medicines without diminishing protection of the research participant. It will also explore the current proposal for an EU Clinical Trial Regulation and its consequences.

It will particularly address

- the approaches of the EU, the EC, competent authorities and drug regulators
- roles of funders and sponsors
- how patients, researchers and ethics committees perceive and assess this balance
- how research risk is monitored
- how insurance and indemnity is and will be approached in the EU
- the representation of research risk and benefit in the media

Registration fee (academia) EFGCP members €453.00 / non members €574.75.

To find out more and register go to [EFGCP Conferences](#)

NIHR R&D Forum Event Listing

Many relevant courses are publicised via the [NIHR R&D External Events Listing webpage](#) and it is always worth browsing their listings.

Job Opportunities

We have regular updates of jobs on the NIHR TMN website – if you are on the lookout for a new position, make sure that you select the 'Subscribe' button within the 'search openings' page of the Careers Section, that way you will receive automatic updates by email whenever any new jobs are posted to the NIHR TMN website.

See below for current vacancies posted on our website:

[Senior Trials Manager](#) , Pragmatic Clinical Trials Unit , London (closing date:6 January 2014)

[COPE Trials Coordinator](#) (Vacancy ID 110631), Nuffield Department of Surgical Sciences, Surgical Interventions Trials Unit., University of Oxford (closing date:3 January 2014)

Please note that the NIHR TMN Jobs Advertising facility will be suspended from 6 January 2014

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Please note that the views expressed in articles within the newsletter are those of the contributors and may not necessarily reflect the views of the NIHR

