

# Trials and Tribulations

**NHS**

*National Institute for  
Health Research*

The Newsletter for NIHR Trial Managers' Network

Issue 16, August 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 August issue of the TMN Newsletter

Welcome to the August 2013 edition of the NIHR TMN Newsletter. In this summer edition we bring you update on the forthcoming annual meeting as well as a mix of relevant news, events, training courses and resources that may be of interest to keep you informed and up to date on a range of issues and opportunities pertinent to your line of work.

We hope you enjoy this edition of the Trials and Tribulations.

If you would like to contribute an article for a forthcoming issue of the newsletter, please contact the NIHR TMN team. You could submit an article anytime by using the online form in our Contact Details webpage or by emailing the Editorial Team at [nihrtmn@leeds.ac.uk](mailto:nihrtmn@leeds.ac.uk).

**The Editorial Team**

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## NIHR launches its own peer-reviewed collection of journals

This summer, the National Institute for Health Research (NIHR) launched the [NIHR Journals Library](#), providing open access to an extensive body of health research.

It consists of five programme-specific journal series, published online, which are fully searchable and provide a comprehensive record of work funded by these NIHR programmes.

Building on the success of the existing *Health Technology Assessment* journal, the library will give accessible full publication of findings of the research commissioned by these programmes and will provide an important permanent and comprehensive record of the work which has been funded.

The participating research programmes are:

- [Efficacy and Mechanism Evaluation](#) (first publication expected in early 2014)
- [Health Services and Delivery Research](#)
- [Health Technology Assessment](#)
- [Programme Grants for Applied Research](#)
- [Public Health Research](#)
- MRC-NIHR Methodology Research (MRP)\*

The NIHR is the world's first health research funder to publish comprehensive accounts of its commissioned research within its own peer-reviewed collection of journals. Tom Walley, Editor-in-Chief, recognises how full publication of results will contribute to adding value in NIHR research.

***“The NIHR Journals Library is a really important way to demonstrate the NIHR’s public accountability through the publication of complete results. The journals are a valuable resource for researchers and others who wish to assure themselves of the validity of the work.”***

*\*Selected reports from the Methodology Research Programme (MRP), managed and jointly funded by NIHR and the MRC, will be published within the most relevant journal. The NIHR Journals Library website is available at [www.journalslibrary.nihr.ac.uk](http://www.journalslibrary.nihr.ac.uk)*

## NIHR TMN Update

### NIHR TMN Annual Meeting: Limited Places Still Available but HURRY

It is less than two months until the NIHR TMN Annual Meeting and places are filling up quickly.

With a number of interesting sessions including keynotes, member-led session, workshops and seminars, there's something for everyone at this year's NIHR TMN Annual Meeting.

Moreover, this is a great opportunity to meet and network with fellow trial managers, discuss issues of the day, share your problems, and look for solutions.

The [Programme](#) is now finalised with member – led presentations and workshops have been added in following the voting process.

For those of you new to the Network the NIHR TMN Annual Meeting is organised by the NIHR TMN Secretariat and is the most widely recognised event for Trial Managers working on NIHR Portfolio studies. It provides a platform for our members to keep up to date with developments in their field, interact and collaborate with other Trial Managers from across the United Kingdom. The NIHR TMN Annual Meeting is open to all members of the NIHR TMN.

#### Parallel session:

This year's parallel session will feature a choice of both invited facilitators and member led workshops and seminars. Each workshop/seminar will run only once and we will be writing to you to ask for your workshop/seminar choice early in September.

Places for each are limited and will be allocated on a first come first served basis so keep an eye out for the email asking you for your preferences. We will endeavour to accommodate you into your preferred selection.

The goal of the workshops is to provide an informal forum for members to discuss important trial management issues and challenges.

We encourage our members to join us in London and are looking forward to hosting another successful event. If you haven't registered yet then follow this link to secure your place at the [2013 conference](#).

#### The results are in! – Member-led presentations session

Our thanks go out to all of our members who voted in our online poll and thus selected this year's member-led talks. Following your feedback from the last year's meeting we decided to have three instead of four member led talks to ensure that there is sufficient time for questions and floor discussions. The three most popular abstracts were:

- *The need for a harmonised approach to R&D approvals:*  
**Dr Inaam-ul Haq**, Trial Manager, South East Wales Trials Unit
- *Lessons learned from managing international, academically sponsored studies:*  
**Susana Vitorino**, REACT Clinical Trial Coordinator, **Kelly Mousa**, Clinical Trials Manager, Imperial Clinical Trials Unit – Cancer
- *Implementing a flexible randomised controlled trial design into practice: stopping arms for lack-of-benefit and adding research arms mid-trial in STAMPEDE:*  
**Dr Francesca Schiavone**, STAMPEDE Trial Manager, MRC Clinical Trials Unit

Congratulations to the authors of the three highest scoring abstracts as well as to all of you who submitted your abstracts and will be taking part in the poster session at the conference. We have provided a dedicated time for delegates to view the poster session this year.

## News from NIHR and other organisations

### NIHR Tweets

RT: [@bengoldacre](#) explains why clinical trials are important <http://goo.gl/PoGm0g> [@OfficialNIHR](#) [#nihr](#) [#nhs](#)

Read the latest [#NIHR](#) [#HTA](#) Programme bulletin: <http://ow.ly/npFou>

The EME Programme are holding two webinars for teams interested in applying to the [#NIHRAMR](#) themed call: <http://ow.ly/nqg9k>

See the current funding opportunities with the EME Programme <http://ow.ly/nps0N>

See the current funding opportunities with the [#NIHR](#) [#PHR](#) Programme: <http://ow.ly/nrRH6>

See the latest opportunities for research funding with the [#NIHR](#): <http://ow.ly/nza8l>

Apply for research funding with the [#NIHR](#) [#HTA](#) Programme: <http://ow.ly/nugtb> Deadline 29 August 2013

RT: The online calendar of NIHR funding deadlines produced by RDS South West has been updated and can be found here: [http://www.rds-sw.nihr.ac.uk/documents/Funding\\_Table.pdf...](http://www.rds-sw.nihr.ac.uk/documents/Funding_Table.pdf...)

RT: Latest news from Portfolio team inc eligibility & adoption process, new guidance & the Central Portfolio Management System [http://www.crnc.nihr.ac.uk/news/news\\_archive/update-from-the-crnc-portfolio-team-july2013...](http://www.crnc.nihr.ac.uk/news/news_archive/update-from-the-crnc-portfolio-team-july2013...)

Looking for new people to [#peerreview](#) for [#NIHR](#) <http://ow.ly/nug5n>

RT: Interested in building evidence, knowledge & learning about public involvement in research? Sign up to [#invoNET](#) via: <http://www.invo.org.uk/invoNET/>



### UKCRC Registered CTU Network

The Network has recently established a new task and finish group with a remit to explore insurance issues affecting clinical trials research. The group will also have a focus on how these issues affect international clinical trials. For more information about the Network work programme and its sub groups please visit [www.ukcrc-ctu.org.uk](http://www.ukcrc-ctu.org.uk).

### Health Research Authority News

The HRA newsletter is available as a bimonthly online publication from the [HRA website](#), giving news from across the research community as well as updates on **HRA** activities.

[The latest HRA's newsletter](#) (vol.3, July 2013) contains details of a number of projects to streamline health research, and the outcome of the HRA Assessment feasibility study.

You could [subscribe](#) to receive future issues.

### The second edition of The Journal of Clinical Research & GCP

Members may find interest in this journal which is free to access and includes the following items and more:

- *Declaration of Helsinki*
- *Investigator Site Quality Management: Does Quality Cost?*
- *Quick Guide: Where are we up to with the new EU Regulation on Clinical Trials*
- *The Rise of Russia as a Clinical Trial Hub*
- *SOP Training Clinical Trial*
- *Results & The Media 5 Golden Rules Regulatory Roundup -*

See more at: [http://www.crgcp.com/journal\\_02.asp](http://www.crgcp.com/journal_02.asp)

## News from NIHR and other organisations

### Budgeting for involvement – New resource

INVOLVE and the [Mental Health Research Network](#) have teamed up to produce a new resource to help with budgeting for the costs of public involvement in research. It can be used for everything from putting together an involvement budget for an entire study to working out how much it will cost to run a one-off consultation event.

The first part of the resource is a [guide](#) which:

- provides practical advice on what costs are associated with involvement in research
- includes a step-by-step process for identifying the associated costs and planning the budget
- presents examples of research projects with well-developed budgets for involvement work contains tips, links to useful websites, and references.

The second part of the resource is an [online 'involvement cost calculator'](#) to work out the costs for your research study.

If you have any questions on the new resources, please contact

#### Thomas Kabir

MHRN Service Users in Research Coordinator  
Email: [thomas.kabir@kcl.ac.uk](mailto:thomas.kabir@kcl.ac.uk)  
Tel: 0207 848 0609

#### Lucy Simons

Senior Public Involvement Advisor - Policy and Practice  
Email: [lsimons@invo.org.uk](mailto:lsimons@invo.org.uk)  
T: 023 8065 1088  
M: 07718 657262

To find out about **INVOLVE** visit [www.invo.org.uk](http://www.invo.org.uk)

To find out more about the **Mental Health Research Network** visit [www.mhrn.info](http://www.mhrn.info)

### MRC Celebrate Centenary



The Medical Research Council celebrates its 100th birthday this year. As part of the celebrations, the Medical Research Council (MRC) Clinical Trials Unit (CTU) have produced a series of short films exploring the role of clinical trials and the MRC CTU, and how trials are developed and carried out. To view the seven short films click [here](#)

There are other events organised to celebrate the centenary. For more information visit <http://www.centenary.mrc.ac.uk>

Join the celebrations by taking part in the [MRC Centenary Poll](#) and provide your views on:

**Q1: What medical advance from the past 100 years has had the greatest impact?**

**Q2: What do you think will be the most important medical discovery in the next 100 years?**

### European Forum for GCP

There are a number of interesting articles as well as information on EFGCP outputs and forthcoming events in the Summer 2013 edition of the [EFGCP Newsletter](#).

## Training and Events

### Register now for the NIHR HTA Programme Conference: First in Class

Learn more about clinical effectiveness research and the impact the HTA Programme has had in clinical and public health research at the NIHR HTA Conference.

The two-day event in central London on 9–10 October 2013 will examine the future of clinical effectiveness research and how we can benefit from best practice internationally with presentations from Dr Sean Tunis, Director of the Center for Medical Technology Policy, USA and Dr Richard Horton, Editor-in-Chief, *The Lancet*, among others. Also, find out how the HTA Programme can help researchers achieve impact and shape the NHS with presentations from Rt Hon Jeremy Hunt, Secretary of State for Health and Professor Dame Sally Davies, Chief Medical Officer for England.

Still not convinced that you should attend the conference? Let Professor Tom Walley, Director of the HTA Programme and Isabel Boyer, Patient and Public Bored Member explain to you what delegates can expect to get out of the conference by watching this [online interview](#).

Register now for the HTA Conference 2013 to get the discounted rate of £395 for two days and £250 for one by entering the code **TMN13** in the promotional discount box.

To book your place or to view the programme please visit the conference website: [www.profbriefings.co.uk/nihrhta2013/](http://www.profbriefings.co.uk/nihrhta2013/)

[MSc in Clinical Research](#), University of Liverpool.

Designed for professionals working in health-related disciplines who wish to begin or enrich a career in clinical research. Modules cover the ethical, legal and regulatory considerations that affect clinical trials, from the essentials of Good Clinical Practice (GCP), to the design and conduct of clinical protocol, biostatistics, data management, product development and health economics.

[Clinical Trials](#) (MSc, Postgraduate Diploma, Postgraduate Certificate and Individual Modules).

These courses are suitable for both those wishing to gain an overall understanding of trials before moving into the field, and those who have general or specialist experience in clinical trials and aim to broaden their role in the design, management, analysis and reporting of clinical trials.



### 2nd UK Clinical Trials Methodology Conference: Methodology Matters

18–19 November 2013, Edinburgh International Conference Centre

Registration is now open – prices from £225. Early bird registration end on 8 August 2013. More information at: [www.methodologyconference2013.org.uk/](http://www.methodologyconference2013.org.uk/)



Places are still available for the two-day **Edinburgh Clinical Trials Management Course (ECTMC)** which will be held on 27–28 November.

With a blend of lectures and workshops, and plenty of time to talk to fellow delegates, this course is relevant to people currently involved in managing

RCTs and those new to this field. It's a mixture of education, information exchange, an opportunity for networking, with a pleasant dinner thrown in!

More information and this year's programme can be found on the [ECTMC website](#).

### Randomised Controlled Trials: a guide to design, analysis and reporting

16–20 September 2013, Pembroke College, Oxford

This course provides a thorough grounding in the principles and practice of randomised controlled trials (RCTs) for the evaluation of healthcare interventions. It will include talks and practicals to give examples and guidance on the methodology of trials using a problem-based learning approach.

The course is aimed at persons planning or actively involved in trials, or individuals interested in furthering their knowledge of trial methodology. More information and outline of the course are available from the [course website](#).

### 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.

Current events organised by the **MRC Network of Hubs for Trial Methodology Research** and their partners are listed on their [website](#).

Forthcoming [European Forum for Good Clinical Practice Events](#)

## 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](#), University of Nottingham (closing date: 9 August 2013)

[Clinical Trial Coordinator](#) (3 posts), Oncology Clinical Trials Office, Oxford (closing date 14 August – 12pm)

[Clinical Trials Portfolio Lead](#) (2 posts), Oncology Clinical Trials Office, Oxford (closing date 19 August)

[Senior Trial Manager](#), Sutton (Surrey) (closing date: 21 August 2013)

If your organisation has any Trial Manager positions that they would like to promote through the NIHR TMN – then do please get in touch.

You will be reaching out to over 500 registered experienced Trial Managers to enable you to attract the right applicant to your position.

Remember that as a member of the NIHR TMN you can post new job opportunities directly to the website.

## Contact us

### NIHR TMN General email account

[nihrtmn@leeds.ac.uk](mailto:nihrtmn@leeds.ac.uk)

### NIHR TMN Co-ordinator

Svet Mihaylov – [s.i.mihaylov@leeds.ac.uk](mailto:s.i.mihaylov@leeds.ac.uk)

### NIHR TMN Administrator

Louise Liddle – [l.liddle@leeds.ac.uk](mailto:l.liddle@leeds.ac.uk)

### NIHR Trial Managers' Network

Leeds Institute of Clinical Trials Research  
University of Leeds

Leeds

LS2 9JT

Tel: 0113 343 4322

Fax: 0113 343 1471

### Website

[www.tmn.nihr.ac.uk](http://www.tmn.nihr.ac.uk)

**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**

