

Trials and Tribulations

NHS

*National Institute for
Health Research*

The Newsletter for NIHR Trial Managers' Network

Issue 15, June 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 June Issue of the TMN Newsletter

Welcome to the June 2013 edition of our Newsletter – keeping you up to date with what's going on within the Network and beyond!

In this latest edition we bring you update on the NIHR TMN annual meeting, a feature on the UKCRC Registered CTUs Network, relevant news from third party organisations, new job opportunities, forthcoming conferences and training events that may be of interest.

We hope you are all well and managing to catch a few rays of sunshine.

The Editorial Team

Exploring the use of 'away days' in randomised controlled trials Survey — Can you help ?

It is well known that recruitment into randomised trials can be challenging. Some of the consequences of not recruiting to target:

1. Is too wrongly concluded that there is no significant difference
2. It can lead to extending the study which can increase costs
3. Late recruitment can lead to a delay in potentially effective therapy being offered to patients or increase the time that patients are exposed to an ineffective or dangerous treatment.

Managing randomised trials, and meeting recruitment targets, can be complex and requires efficient trial management. In York Trials Unit, we know from experience with other collaborators that 'away days' are sometimes organised by Trial Managers to achieve these aims. This involves inviting the various stakeholders in a trial to a meeting to encourage recruitment or help to maintain recruitment if the study is going well. It can also be used for other purposes such as to facilitate the training of staff, to discuss trial progress, to develop networks and disseminate findings.

These 'Away Days', however, can take considerable time and expense to organise. When choosing a method to ensure recruitment targets in a trial are met on time and on budget, it is important to consider the evidence. We are not aware from the published literature whether 'Away Days' are an effective and/or efficient use of the time of a Trial Manager or indeed of the various stakeholders who take time out to attend these meetings.

We thought it would be very helpful to conduct a survey to find out more about whether and how 'Away Days' are used by Trial Managers and if they are useful. Therefore we are inviting Trial Managers to complete a survey at <https://www.surveymonkey.com/s/RCRWD95> to help us understand the role of 'Away Days' in the conduct of trials. It should only take 15 minutes to complete and you'll be entered into a prize draw to win a Betty's Tea Hamper (www.bettys.co.uk).

Please contact Dr Laura Jefferson if you would like to know more about this survey – email: laura.jefferson@york.ac.uk; telephone: 01904 321511. Please note that responses are needed **by 8th July at the latest**.

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NIHR TMN Update

NIHR TMN Annual Meeting

Don't miss out on the opportunity to partake and network with your peers at the 2013 NIHR TMN Annual Meeting on the 7th October.

We have an exciting programme with interesting speakers. The early bird registration deadline for the 2013 NIHR TMN Annual Meeting is Sunday 30 June 2013.

Places are strictly limited to 130 and filling up quickly, so book early to avoid disappointment.

Member-led presentations session – Voting is open!

This is your chance to shape the content of the member-led session by casting your vote and selecting the presentations you would like to hear.

This year we have received a wide range of very interesting and relevant abstracts. After a review by the Programme Development Committee we have uploaded the abstracts selected by the PDC for you to have your say (see [current results](#)).

The authors of the three highest scoring abstracts will be invited to give a 15- minute talk at the 2013 NIHR TMN Annual Meeting. The authors of all remaining abstracts will be automatically accepted for poster presentation at this year's NIHR TMN Annual Meeting.

Voting closes Monday 1 July 2013. We'll be announcing members' top choices on 3 July 2013.

Every Vote Matters!

Call for Workshop Proposals

The deadline for submitting workshop proposals is fast approaching. All proposals must be submitted by email to nihrtmn@leeds.ac.uk by 30 June 2013.

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

Clinical Trials for Medical Devices: New Forum

Following a request from one of our members and in attempt to boost sharing expertise and knowledge about medical devices trials we have created a new specialist forum for those of you with interest in the delivery of high quality medical device clinical trials.

The forum provides an opportunity for trial managers to come together and collectively discuss issues of interest and problems pertinent to medical device trials.

Do please sign in and register for this forum if this is an area that is of interest to you.

NIHR TMN Guide to Efficient Trial Management

The newly updated edition of the NIHR TMN Guide to Efficient Trial Management is currently under review by NIHR and DH. We would like to thank you all for your patience and hope that the this important tool will be with you very soon.

Contribute to YOUR Newsletter

Thanks to all members who have previously contributed articles and news items to the Trials and Tribulations Newsletter.

We would like to urge all of you to get involved and forward any relevant information you would like published in. We welcome and will consider for inclusion relevant articles in any topic area of importance to trial management.

Share with your peers any success or burning problems you are facing in managing your trial and what strategies you have put in place/ solutions to address these problems to get your trial back on track.

Any questions, please call 0113 343 4322. We'd love to hear your input! Submit an article anytime by using the form in our Contact Details webpage or by emailing the Editorial Team at nihrtmn@leeds.ac.uk.

News from NIHR and other organisations

Professor Dame Sally Davies, CMO, most proud of her work in research and development <http://goo.gl/GjRwH> #NIHR

Please see the new Research Programmes Hub page on the NIHR Website at <http://www.nihr.ac.uk/research/Pages/ResearchProgrammehub.aspx> ...

EME Programme funding opportunities: diseases of the skin, chronic pain and #sarcopaenia <http://goo.gl/8tCaE> Apply before 1 October.

Funding opportunities with the #NIHR #HTA Programme: <http://goo.gl/vBU6o> Deadline for applications 1pm 29 August 2013.

Researcher-led funding opportunities with the #NIHR HS&DR Programme: environmental #sustainability <http://goo.gl/LZChf>

There are five journals in the #NIHRJL. See what's due to publish over the coming months at <http://goo.gl/3O05j> #NIHRJL #Openaccess

Total and complete publication of research findings in the #NIHR Journals Library <http://goo.gl/m2kvh> #NIHRJL #NIHRaddingvalue

Professor Ian Roberts presenting on CRASH-2 #NIHRJL launch <http://www.journalslibrary.nihr.ac.uk/hta/volume-17/issue-10...>

#NIHR media competition winners announced: <http://goo.gl/aa4FK> See the entries here: <http://goo.gl/RIY9K>

#NIHR CLAHRC-NDL feasibility study develops intervention now used for project to get stroke survivors back to work <http://goo.gl/BcfYY>

Follow NIHR at @OfficialNIHR

Health Research Authority News

[The latest HRA's newsletter](#) covers a paper on the HRA proposals to tackle transparent research, interesting findings on who takes part in Phase 1 research, updates on HRA projects as well as information on [two new decision tools](#) aimed at establishing whether a study is *really* research requiring Research Ethics Committee review.

See new tool – [Is my study research?](#)

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

invODIRECT

[invODIRECT](#) is a new online tool from INVOLVE displaying a directory of networks, groups and organisations that support active public involvement in NHS, public health and social care research.

You can:

- Add details of your group or organisation so others can find out more about how you are supporting public involvement in research,
- Search for local and national UK organisations,
- Find out about international organisations and groups supporting public involvement in research.

Visit [invODirect](#)

News from NIHR and other organisations

Update on the proposed new Clinical Trial Regulation from the European Commission

(Contributed by John Warden)

The EC Press Office have released an update on the latest stage of the proposed new Clinical Trial Regulation.

The draft rules were approved by the EC Public Health Committee on 29 May with a number of changes made to earlier drafts, following submissions made by a number of bodies including the European Forum for Good Clinical Practice.

Some key features of the new law will be:

- simplified reporting and regulatory approval procedures
- fixed deadlines for regulatory approval
- increased transparency and a requirement to publish trial results
- provision for compensation from national bodies for low-risk trials rather than the sponsor
- clarification of the role of independent ethics committees
- clarification on the rules for obtaining informed consent especially in emergency situations
- better protection for certain vulnerable groups
- understanding the needs of non-commercial sponsors, such as academic-led trials.

The draft report will now go forward for negotiation with Ministers.

[Read More](#)

European Patients' Academy on Therapeutic Innovations (EUPATI) Rome Conference - Final Report available and much more (Including video streams) on [EUPATI Website!](#)

Hot off the press

The **EFGCP Guidelines on Medical Research for and with Older People in Europe** has just been finalised and published onto the EF GCP website.

This document is the result of 2 years of intensive work based on several workshops organised by the EFGCP's Geriatric Medicine Working Party (GMWP).

The document shows that older patients are underrepresented in clinical trials, especially those over 75 years, with multiple co-morbidities, concomitant treatments and/or frailty. It provides a summary of recommendations on ethical aspects of clinical trials with older people, who may in some cases be considered a vulnerable patient population.

The Guidelines are available for download from [here](#).



PLOS Hub for Clinical Trials

[PLOS Hub for Clinical Trials](#) is a repository of PLOS journal articles that relate to clinical trials.

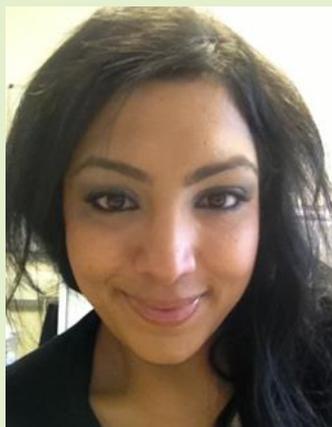
The Hub is a site for researchers to share their views and build a dynamic, interactive community. It features articles originally published in PLOS Clinical Trials, along with articles from all PLOS titles that publish clinical trials.

In the future, it will also feature open-access articles from other journals plus user-generated content.

[Patient Reported Outcomes \(PROs\) in Clinical Trials: Is 'In-Trial' Guidance Lacking? A Systematic Review](#)

More relevant articles in PLOS HCT

[Strategies for Increasing Recruitment to Randomised Controlled Trials: Systematic Review](#)



Saeeda Bashir is the Network Coordinator for the UKCRC Registered CTUs

Update from the UKCRC Registered CTUs Network

About the Network

The UKCRC Registered CTU Network has a mandate to maintain the CTU registration review process. Each member CTU has been successfully reviewed by an International Panel of experts against core competencies that demonstrates a CTU's ability to lead the design, central/national coordination and the overall analysis of multi-centred randomised controlled trials (phase II-IV) or other well-designed studies.

More information about the registration process and eligibility criteria is available on the website www.ukcrc-ctu.org.uk. In addition to this the Working Group has agreed a work programme of activities with the membership, details of which are also on the website.

What has the UKCRC CTUs Network done so far?

The Network has refreshed its membership following the 2012 Call for Registration. Following the results of this review an online Resource Finder has been made available to Researchers, Funders and the public.

The online [Resource Finder](#) provides a comprehensive search facility with direct access to details of the registered CTUs on the basis of location, services, experience in disease research area, study types conducted and methodological expertise just to name a few categories!

We recently established sub groups in the areas of: Core Infrastructure, Costings and Resources, Efficient trials conduct, Industry, Quality Assurance, Information Systems and Statistics. These groups will focus on their individual remit and respond to national issues accordingly whilst providing peer to peer support.

The Network is also lobbying key stakeholders through network responses to consultations on the impact of the new EU CT regulations proposals, changes to the NIHR clinical themes structure and issues on transparency and clinical trials insurance to name just a few. Network responses are available on the website.

We have also improved communication through 'The Exchange' Newsletter, email distribution lists, a new website and delivered several meetings for CTU Directors aimed at providing networking opportunities, discussion on topical issues and facilitating peer to peer support.



The UKCRC Registered CTUs Network Exchange Newsletter. This is distributed to key contacts within CTUs with the view that it would be disseminated internally

Continues on next page ►

What is covered by the UKCRC CTUs Network Sub Groups?

Task and Finish Groups

Industry – To explore frameworks for facilitating and publicising collaborations with industry and small to medium enterprise and medical device companies. To share previous experiences of working with industry to achieve greater transparency and consistency into academic-industry collaborations, addressing key issues such as IP and publications policy.

Core Infrastructure – A UK-wide review of Registered CTU core infrastructure funding with the aim of mapping the availability of resources and expertise to support design and delivery of clinical trials. Interaction with a range of funders and host institutions to publicise the importance and benefits of core infrastructure funding in the delivery of cost effective high quality clinical trials.

Costing Models – Development of a standardised approach to costing studies. The aim of this initiative is to increase transparency, consistency and clarity in funding applications to assist both applicants and funding bodies.

Efficient Trial Conduct – Exploring new approaches and systems to improve efficient trial conduct. This group is currently surveying all staff across registered CTUs to highlight priority areas for inefficiencies. To participate visit: <https://www.surveymonkey.com/s/68JCL9Y>

Each operational group will also be holding an annual meeting to discuss topical issues, provide networking opportunities and workshops to share knowledge and best practice. We are currently designing web pages for each operational group with the intention to host forums; more information will be made available on the website.

Operational themed Groups in the areas of Quality Assurance, Information Systems and Statistics have been established with formal remits in order to share best practice and to help develop standard approaches to common issues. These groups are made up of a single representative from each registered CTU, information is sent directly to these representatives with the onus that pertinent information be distributed internally where appropriate.

Each operational group will also be holding an annual meeting to discuss topical issues, provide networking opportunities and workshops to share knowledge and best practice. We are currently designing web pages for each operational group with the intention to host forums; more information will be made available on the website.

This is a very exciting time for the Network with a flurry of activity, to keep up to date with news and developments please visit the website www.ukcrc-ctu.org.uk.

Training and events

NIHR HTA Conference: What's in it for you?

Learn more about clinical effectiveness research and the impact the HTA Programme is having on 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.

Find out how the HTA Programme can help researchers achieve impact and shape the NHS with presentations by Professor Dame Sally C. Davies, Chief Medical Officer for England, Professor Sir Michael Rawlins, president of the Royal Society of Medicine and Professor Jon Nicholl, Health Services Research in the School of Health and Related Research.

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/

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.

See [MRC NHTMR Workshops and Events](#)

PharmaSchool challenges are a great and fun way to test and extend your knowledge in GCP.

Take the [Recruitment & Consent in Clinical Trials' Challenge](#).

Selected events:

[Comprehensive Systematic Review Training 1st – 5th July 2013, University of Nottingham, UK](#)

[7th DIA / EFGCP / EMA Medicines for Children Conference 24 & 25 September 2013 - Hilton London Docklands Riverside Hotel, London, UK](#)

[Data and Safety Monitoring Board Workshop, Lancaster University, 9 October 2013](#)

[2nd Clinical Trials Methodology Conference 18-19 November 2013 Edinburgh](#)

[EFGCP Annual Conference 2014, Benefits and Risks of Research: How Do We Redress the Current Imbalance?, 28 & 29 January 2014 – Brussels, Belgium](#)

[Society for Clinical Trials 35th Annual Meeting - 18-21 May 2014 Philadelphia, US.](#)

Pear to Pear Learning

Do you have a challenge in the workplace that needs acting on but not sure of the best way forward? It could be a recruitment issue, problems with obtaining R&D approvals, or anything. With support from your TMN peers, Action Learning can help you address these issues and learn from your peer's challenges.

What are Action Learning Sets (ALS)?

Action Learning Sets are groups who meet regularly online in order to explore solutions to real problems and decide on the action we wish to take. When doing this in the set, the stages include:

1. Describing the problem as we see it
2. Receiving contributions from others in the form of open questions
3. Reflecting on our discussion and deciding what action to take
4. Reporting back on what happened when we took action
5. Reflecting on the problem-solving process and how well it is working

If there is sufficient interest NIHR TMN is willing to facilitate running online ALS using the Adobe Connect facility. Please do get in touch or send us any suggestions at nihrtmn@leeds.ac.uk

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, ICR, London](#) (closing date: 3 July 2013)

[Senior Trials Manager, University of Nottingham](#) (closing date: 4 July 2013)

[Clinical Trial Operations Trials Manager](#), UCL Clinical Trials Unit (closing date: July 15th 2013)

[Clinical Trial Manager, ICR-CTSU](#), Sutton, London (closing date 26 July)

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

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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

International Clinical Trials Day 2013

Thanks to all NIHR TMN members who were involved with and helped make the International Clinical Trials Day 2013 such a success.

To mark the day a number of celebratory events took place across the UK under the theme of 'it's OK to ask' campaign, set by the NIHR.

University Hospital of South Manchester (UHSM) NHS foundation Trust is one of the number of organisations that celebrated the International Clinical Trials by opening its doors to the public. UHSM had four information stalls across the Trust managed by dedicated research teams, answering queries and telling visitors, patients and staff all about research

and UHSM research focus; There were interactive learning sessions, along with meet and greet research staff and a tour of Trust research facilities by Research Nurses.

Below are some of the highlights of celebratory activities hosted by our members' employing organisations.

- A mock chocolate trial
- Clinical trials quiz
- Cakes and nibbles and many fun games
- It's OK to Ask