

# Trials and Tribulations

**NHS**

*National Institute for  
Health Research*

The Newsletter for NIHR Trial Managers' Network

Issue 17, October 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 October issue of the TMN newsletter

Once again we are bringing you up to date with the latest developments within the Network and beyond. The most significant development has of course been the announcement of the forthcoming changes to the NIHR TMN (see below). Further details on changes will be available on the NIHR TMN website in due course.

Also in this issue you will find a feedback from the 2013 NIHR TMN Annual Meeting which took place on 7th October as well as a feature from one of our workshop facilitators on Managing trials with varying levels of monitoring.

Suggestions regarding content and contributions to our last December 2013 NIHR TMN Newsletter are more than welcome at [nihrtmn@leeds.ac.uk](mailto:nihrtmn@leeds.ac.uk).

### The Editorial Team

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## Forthcoming changes to the NIHR Trial Managers' Network

The Trial Managers Network has been a valuable part of the UK research environment since 1998, and in this period has made a significant contribution to the development of trial management. The network has been run by trial managers for trial managers, and has provided an important professional forum to facilitate the sharing of expertise and knowledge in order to implement best practice in the management of clinical trials.

However the wider research environment is changing and as a result it has been decided that the NIHR TMN will be suspended from 6th January 2014. This has been a difficult decision to take but it is felt that this is an appropriate point to take a pause, and to consider how the needs of Trial Managers could be served in light of changes and developments elsewhere. This decision has been taken following discussion and consultation with various stakeholders over future requirements and funding.

We would like to stress that this is not 'the end' but rather a new phase in the development of support for Trial Managers across the wider NIHR and UK research landscape.

Current NIHR TMN activities will be gradually reduced over the next few months and more information will be posted on the TMN website in due course. Please be assured that until the 6th January, we will continue to support members and will maintain the TMN website (including the online membership database, job advertising facility and TMN forum) as well as publishing the NIHR TMN Newsletter.

We would like to strongly encourage our members to make connections and continue to network .

We would also like to say a huge thank you to all the members, colleagues and stakeholders who have worked tirelessly and supported the activities of NIHR TMN. We look forward to engaging with you in the future.

If you have any questions, please feel free to contact us by phone 0113 343 43 22 or via email:[nihrtmn@leeds.ac.uk](mailto:nihrtmn@leeds.ac.uk).

Best wishes,

**NIHR TMN Secretariat**

## Feedback from the 2013 NIHR TMN Annual Meeting

Another successful annual meeting in London at the beginning of October was enjoyed by over 140 participants from throughout the UK .

### Thank you

A very big thank you to all delegates, invited speakers and workshop facilitators as well as to our members who presented posters and delivered oral presentations at the annual meeting. This year's meeting was themed around current research in trial conduct. All of us present, will remember some excellent speakers and presentations, fabulous food as well as enjoyable reunions with friends and colleagues, old and new.

### Best Poster Award

Fourteen posters were presented at the meeting and were voted on by delegates. This year's best poster prize was awarded to Johanna Perdue from Nottingham CTU for her poster 'The effectiveness of direct to public advertising on recruitment rates in the Patch I trial'. Congratulations to Johanna!

### Access the presentations via the TMN website

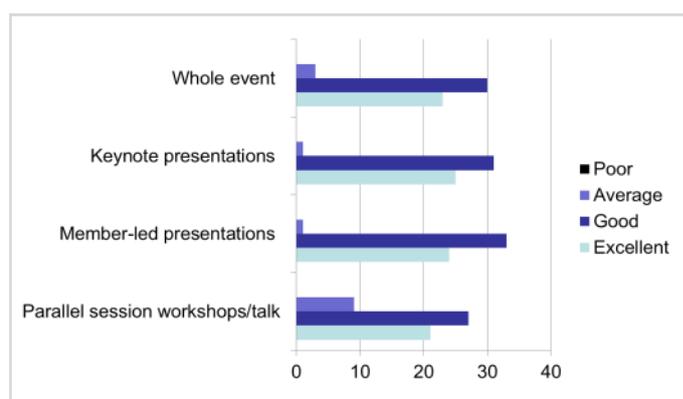
All but one of the 2013 NIHR TMN annual meeting presentations are now uploaded on our website. As for the remaining presentation, it is expected that the results of the systematic review of retention interventions will be published early next year.

To view the annual meeting presentations click [here](#) (note that you must be logged in as a member to be able to see the file library). Photographs from the 2013 NIHR TMN annual meeting are also available to view via the following [link](#).

### Evaluations

We received feedback from 75 delegates (55% response rate).

Overall, the feedback was very positive with the vast majority of participants who completed their evaluation forms rating the annual meeting presentations and the whole event as "excellent" or "good".



We have also received some constructive criticism and suggestions for improvement with regard to specific aspects of the meeting which will be used to inform any future gatherings of the trial managers' community that may be organised in the future.

Overall, the 2013 NIHR TMN Annual Meeting has met the goal of providing attendees with information on current research into trial conduct as well as opportunities to meet, network and discuss issues of interest with fellow trial managers .

[See summary of delegates' feedback.](#)



***“Great meeting, very well organised and a good range of talks”***

# Managing Trials with Varying Levels of Monitoring - Challenges and Lessons

The EU Directive (2001/20/EC) and Commission Directive (2005/28/EC) and the corresponding Medicines for Human Use (Clinical Trials) Regulations 2004 and Medicines for Human Use (Clinical Trials) Amendment (No 2) Regulations 2006 made GCP law for the first time in the UK. Whilst there were no specific guidelines in the regulations regarding monitoring, the implication was that to ensure a trial was running according to GCP the trial should be monitored centrally and at site. Risk-based management was introduced whereby trials were assessed and assigned a risk profile which determined the level of monitoring that should be employed.

For academic trials units, on-site monitoring was a challenge. For the majority of trials funding was not available to employ a monitor. Even where funds were available there was usually a time lag between applying for these funds and receiving them. Existing trial staff were usually already stretched in their day-to-day tasks without incorporating monitoring visits into their role.

In our unit we manage a broad range of cancer trials; from those set up pre-directive with central monitoring only, to the most recently set up trials which follow the on-site monitoring schedule as determined by risk-assessment. Managing and closing out trials that have had little or no on site monitoring is a challenge!

This workshop was an opportunity to discuss the issues which arise when managing trials with no on-site monitoring and to share tips and techniques for managing and closing out such trials. There were interesting discussions and some useful techniques and ideas shared which are summarised here.

## Q1 What issues have you encountered managing trials that have no on-site monitoring?

**1. Relationship** – without on-site monitoring and face-to-face contact there is less of a relationship between the trials unit and site staff. Without meeting site staff periodically it is often difficult to get a realistic picture of how the site is managing the trial day-to-day.

**2. Adherence to protocol** – without on-site visits, it is sometimes difficult to detect whether the protocol is being followed. Examples: 1) patient follow-ups not being carried out, site staff reported they were not aware these follow-ups were to be done 2) sites taking additional assessments not defined by protocol.

The study protocol should in itself be adequate to follow but in reality some older protocols are not as clear as they could be and even with newer & better protocols there are instances where sites interpret wrongly. This can have an impact on how well the study is being carried out at site as well as on safety.

**3. Investigator Site File documents** – without a monitor going to site and checking the ISF, it can mean that the ISF isn't maintained as well as it should with the result that documents are missing. This is a problem in itself as maintenance of ISF is a GCP requirement but additionally it can lead to incorrect versions of documents such as PIS and consent forms being used which will not be picked up unless the site is monitored. Some documents are more difficult than others to obtain retrospectively eg consent forms and screening logs.

If the ISF is not maintained regularly, a lot of work will be required for site and trials unit staff pre inspection or close out.

**4. Staff changes** – without visiting sites, it is easy to miss staff changes. Some sites are better than others about informing the trials unit of staff changes but it has happened that the first time the trials unit know about a new PI is when they are signing off a SAE! It is essential that trials unit know of staff changes – to verify that person is qualified to carry out role and to offer training so the person is adequately trained for the trial. It is difficult to collect CVs and GCP certificates retrospectively especially when staff have moved on.

**5. Data** - without a monitor visiting sites, there may be less well defined targets for sites for data entry & query resolution. There can be a tendency for sites to de-prioritise studies with no on-site visits and therefore backlogs of data entry and queries can form.

With no SDV we can't be sure of data quality. When sites are SDVd after eg. the first 2 patients we can sometimes pick up mistakes in practice which can be rectified for the next patients. Without SDV these errors can continue uncorrected and have implications for eligibility and safety.

**6. Self-monitoring** – some trials operate a self-monitoring process whereby data is entered twice by the site, sometimes by the same member of staff. There are obviously limits to the effectiveness of this as errors may not be identified.

## Q2 What techniques have you used/ideas do you have for managing trials that have no on-site monitoring?

**1. Relationship** – aim to create a good relationship with the site via email and telephone so that the site feels supported. If possible contact the site on a regular basis just to see how everything is going/whether they have any issues. Don't lose contact with the site! If you don't hear from the site for a while, get in contact.

**2. Communication** – Organise frequent meetings for Investigators and Research Nurses to address any issues and to motivate. Create newsletters with trial and accrual news, implementation of new documents, impact of new amendments.

**3. Adherence to protocol** – if you notice a pattern of missing visits or data queries or anything else indicating non-adherence to protocol, contact the site and discuss. Create an 'easy access' protocol summary document that can be used in clinic.

**4. Investigator Site File documents** – provide sites with a detailed list of ISF documents – ask them to go through and check whether these are present in their file. Email missing documents for the site to print and file. There may be some resistance to this at site as it is time consuming but it is the responsibility of the site to maintain the ISF. Site-generated documents such as consent forms and prescriptions should be located by the site.

### 5. Staff changes

**a.** Keep a spreadsheet to log members of staff who are leaving. Create a mailmerge once a month to send an email to these sites requesting name, CV and GCP of new staff member and updated delegation log

**b.** Teleconference training - set up regular training T/Cs (or in person for sites close by) for new staff or for existing staff when significant protocol changes have been made to ensure all staff are adequately trained. Send copies of the presentation and/or protocol before the T/C and encourage people to bring questions. Get site staff to sign a training log to record this session in the ISF. Resources put into training may mean less resources needed for central monitoring.

**c.** Create a Unit contacts database with shared CVs and GCP certificates

**6. Data** – Produce regular outstanding data reports. Give clear deadlines – aim to encourage and support rather than hassle sites. If you notice patterns in missing data or data queries, contact site to see if there is a misunderstanding rather than raise the same queries repeatedly! If there are

backlogs, contact site to see what can be done to resolve, perhaps work out realistic deadlines to get site back on track and to prevent site staff from feeling overwhelmed.

## Q3 What techniques have you used/ideas do you have for the closing out of trials that have no on-site monitoring

**1. Relationship** – if there has been no on-site monitoring, depending on the length of the trial and staff turnover, close out may be the first time the Trial Coordinator meets site staff. If there has been no on-site monitoring the chances are the close out process will be time consuming and you will rely on site staff for cooperation. Aim to create or maintain a supportive and appreciative relationship!

Staff who were involved in the trial may have moved on so it is important to do what you can to support the current staff. It may be low on their list of priorities and so they may require lots of chasing but they must be reminded that it is their responsibility that the ISF is complete before archiving. The MHRA can and do inspect closed trials! If sites haven't been visited for a long time, some sites may require a pre Close out visit.

**2. Investigator Site File documents** – A check list of all documents that should be in the ISF can be sent to site ahead of the close out visit. Request that the site go through and tick whether documents are filed or missing. The trials unit can then email missing documents to the site for printing and filing before the close out visit. A CD containing all the ISF documents can be taken to site at the close out visit so that any documents missed can be printed and filed.

**3. Remote Close out visits** - For sites that didn't recruit, close out visits can be carried out remotely. As above a check list can be sent to site, any missing documents sent by the trials unit. The site then signs off that the ISF is complete.

**4. Staff changes** – If there is a delay in scheduling the close out visits the PI may have left. R&D can act as the contact for close out in this case.

**5. Dedicated Close-Out staff** - If a unit has a number of trials to close out and funding is available, a dedicated member of staff can be appointed solely to close out trials. It is likely that there will be an overlap of sites between trials and therefore this can be a time-efficient way of working. CTA support where available can also be useful.

**Our thanks go to: Marie Miller, Susana Vitorino and Kelly Mousa**

**Imperial Clinical Trials Unit – Division of Cancer, Imperial College London.**



Winner of Best Poster Award Johanna Perdue receives her award from Professor Jane Nixon for her poster 'The effectiveness of direct to public advertising on recruitment rates in the Patch 1 trial'

## News from NIHR TMN and other organisations

### NIHR TMN Guide to Efficient Trial Management Update

The long-awaited new edition of the NIHR TMN Guide to Efficient Trial Management is soon to be released.

The Guide review is now near completion. It is expected that the new fourth version of the Guide will be released before Christmas.

The guide will be produced as a pdf document and will be made freely available for download from the NIHR TMN website (Please note that hard copies of the Guide will not be available).

### Archiving of the NIHR TMN membership database

We would like to inform our membership that prior to the suspension of the NIHR TMN in January 2014, a copy of the online TMN database will be downloaded and transferred to the NIHR Evaluation, Trials and Studies Coordinating Centre (NETSCC) for on-going interim management.

Members who wish their data to be deleted from the TMN Database before it is passed to NETSCC, are requested to opt from this arrangement by emailing the secretariat at nihrtmn@leeds.ac.uk.

To ensure the timely removal of your personal entry, all email requests should be received by 15 December 2013.

### NIHR Tweets

- Presentations from the [#NIHR](#) HTA conference are now available online: <http://ow.ly/q3uwg>
- RT: Good advice from [#HTA](#) conference: be open about potential research problems, show you have considered it [#dayinthelife](#) [@NIHR](#) [RDS](#)
- Help shape NHS research: [#peerreview](#) with [#NIHR](#) <http://ow.ly/q0xDt>
- [#NIHR](#) Clinical Research Network featured on Health Sector TV. Watch at: <http://ow.ly/q0EU3>
- The [#NIHR](#) PHR Programme is celebrating its fifth year of funding research. Read more at <http://ow.ly/q0CSW>
- Part [#NIHR](#) RfPB funded project helps Stroke Research Network win national award for patient involvement in research <http://ow.ly/q0Fbs>
- What's your top health question in [#occhealth?](#) Submit your research suggestion to [#NIHR](#) <http://ow.ly/puj1b>
- [#NIHR](#) HTA articles publish in [@TheLancet](#) following successful 20th anniversary conference: <http://ow.ly/pPLPX>

### EFGCP Report on The Procedure for the Ethical Review of Protocols for Clinical Research Projects in Europe and Beyond

A sub group of the EFGCP Ethics Working Party has tackled the challenge of identifying what over thirty aspects of the ethical review process is for each member state, plus Norway and Switzerland, and has brought this information together in a Report that will be an invaluable reference document for any company, academic department or contract research organisation wishing to conduct clinical research anywhere in Europe.

[Read more](#)

### Health Research Authority News

The [latest HRA's newsletter](#) (vol.4, October 2013) is now available -

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.

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

## Training and Events

### Adaptive Designs for clinical trials workshop

27th-28th January 2014, MRC Biostatistics Unit, Cambridge. No registration fee, but registration is required due to limited places (see below for details on how to register).

Adaptive designs allow changes to be made during a clinical trial for reasons of ethics and efficiency. This workshop will aim to cover a broad range of theoretical and practical developments.

To register, please go to <http://adaptive-designs-workshop2014.eventbrite.co.uk/>.

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

### EFGCP Multi-Stakeholder Workshop on Indemnity Schemes for Clinical Trials: A Societal Obligation?

5 December 2013, EORTC Headquarters, Brussels, Belgium

For details: [European Forum for Good Clinical Practice Events](#)

### EFGCP Annual Conference 2014 Benefits and Risks of Research: How Do We Redress the Current Imbalance? 28 & 29 January 2014 - Renaissance Brussels Hotel, Brussels, Belgium.

Our conference will explore the consequences of research, both harm and benefit and look at 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.

For details : [European Forum for Good Clinical Practice Events](#)



**2nd UK Clinical Trials Methodology Conference: Methodology Matters**  
18–19 November 2013, Edinburgh  
International Conference Centre

Limited delegate places still available. You could access the [full programme online](#).

For more information and to register visit the conference [webpage](#).

### NIHR R&D Forum Event Listing

[Skills for monitoring non-commercial clinical trials](#)

20–21 November 2013, Staff House Conference Centre, Sackville Street Manchester

[Click here](#) to download the programme (fee £490).

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

### University of Liverpool

[MSc in Clinical Research](#), 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.

### London School of Hygiene and Tropical Medicine -

[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.

## 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:

[Clinical Trials Unit Manager](#), N.WORTH, Bangor University (closing date: 19 November 2013)

[Trial Manager](#), The Institute of Cancer Research, Sutton, Surrey (closing date: 12 November 2013)

[Senior Trials Manager](#), The Institute of Cancer Research, Sutton, London (closing date: 17 November 2013)

[Clinical Trial Coordinator](#) (three posts), Department of Oncology, University of Oxford (closing date: 29 November 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.

## 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)

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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**

