Trials and Tribulations

The Newsletter for NIHR Trial Managers' Network
April 2011

NHS
National Institute for Health Research
Trial Managers Network

It has been two months since the first Newsletter. We have been incredibly busy and are pleased to report that from the launch of the newsletter we have had increased interest from new members to join the network. We now have 372 members on our circulation list – and growing. A very big thank you to all who took the time to complete the evaluation survey. There is some interesting feedback attached as an appendix to this Issue – and we are listening to what you have to say.

In this issue...

Save the date

We have set a date for the Annual Meeting of the Trial Managers Network.

Please hold the 10th October 2011 free in your diary – more information on page 4.

New website and database

We are in the final phase of the selection process for purchasing a comprehensive system to support the creation of a truly virtual and dynamic Network of Trial Managers. The new website will not only be the public face of NIHR TMN but also a primary communication tool for our members to communicate, exchange information and ideas via dedicated forums, upload templates, documents and useful links to relevant resources.

Potential members will be able to join the Network online, create and maintain professional profiles, set up different interest groups, book online places at Annual Meetings and other TMN events, search for jobs and advertise their job needs and much more .

We are really exited about the potential to boost collaborative work and virtual networking between our members and look forward to the website release in July 2011.

In collaboration with our German partners from TREAT-NMD regulatory affairs database (RAD), we have recently reviewed and updated the relevant UK information. TREAT-NMD RAD is a valuable source of information on regulations governing trials across Europe and may be useful for Trial Managers involved in the planning of single- or multi-centre clinical trials within different European countries.

The database contains contact details for the relevant national authorities as well as national legislation and documents from 13 European countries. Additionally, European regulations and other important international documents and guidelines are provided (e.g. from ICH and EMEA). You could also use the database as a single entry point to the relevant UK legislation.

TREAT-NMD RAD is open for public use and can be accessed online (login/username is not required) from the link below. Please do let us know if you spot any inaccuracy or have any suggestions for inclusion in the database.

http://tnmd.ukl.uni-freiburg.de/regulatoryaffairs/staticContent.jsf

Clinical Trial Magnifier is a free monthly electronic journal on clinical trials which contains a number of relevant articles that may be of interest. Subscription to this electronic journal is free and will give you access to all previous issues from 2008–2011 issues of the journal. Please note that it takes some time until each PDF file is downloaded onto your computer. To subscribe please follow the link below.

http://ww2.clinicaltrialmagnifier.com/register.aspx

Have your say!

In response to your suggestions, we take great pleasure in introducing the Members' Contribution Section. Whether your endeavours are innovative, empowering, frustrating or life changing, you are invited to share with your colleagues relevant information and experience, examples of good practice as well as lessons learned from overcoming pertinent problems in your day to day work.

For the next edition, we would like to focus on the following topics:

- **Problems and pitfalls in securing excess treatment cost** – Submit your view and tips on how other trials might become more successful in securing them.

- **Exemplar Trial Managers** – Provide us with a glimpse into the management process of your clinical trial. Tell us about the problems and issues you have encountered in your day to day work as a Trial Manager and how using innovative thinking and your problem solving skills you were able to overcome difficulties and keep your study on the right track.

- **A Day in the Life—**We will be interviewing TM's up and down the country to give a snapshot of their lives—Volunteers most welcome!!!

- **News and Events** – Submit a short report on latest news and events (e.g. information on regional meetings, courses) that may prove useful for your TMN colleagues.

- **Let's have a laugh** – In an attempt to introduce some humour into the Network we invite members to send us clinical research related jokes, funny videos/images and light-hearted articles that can brighten our busy working days.

Submissions will be accepted until **10 June 2011**, with selected pieces published in the third edition of the NIHR TMN Newsletter. This is your network – and your newsletter – so we really do need to hear from you.

Getting Approval – the Grand National for Trial Managers by John Warden

***John Wardens** is CT Project Manager in the Department of Academic Cardiology at the University of Hull. He is working on two large multi-national observational studies, SICA-HF and BIOSTAT-CHF, which are both funded by the European Commission.*

As well as project managing these two trials he is responsible for designing and implementing bespoke database and associated systems for SICA-HF and another major Phase IV Trial, CACHE.

He has an extensive background in information systems development, working for major companies in the UK and abroad including 4 years with IBM in the USA.

Coming into Clinical Trials management after many years in the "real" world I never realised just how many fences had to be jumped in order to get a new trial up and running and what a mountain of paperwork would be required to satisfy the endless ranks of box-tickers and form-fillers. It makes the Grand National seem like a Sunday morning hack in Windsor Park.

More to the point, how many of these obstacles actually provide any real benefit to the patient?

Let us take as an example one simple, screening study – not a CTIMP, not even a Phase IV trial – just a simple epidemiological analysis.

SICA-HF *(Studies Investigating Co-morbidities Aggravating Heart Failure)* is a multi-national, observational study funded by a European Commission FP7 grant. One sub-study, which is only being carried out in the UK, is to use GP practices to screen patients with Diabetes Mellitus type 2 (DM2) over the age of 40 to try and establish the prevalence of previously undiagnosed heart failure. The study was designed by a diabetic with a family history of heart failure (here, I should do what I did at the Research Ethics Committee hearing and declare a vested interest) to fit in with GPs normal annual check-ups for diabetics. The initial screening would be a self-completed questionnaire of symptoms plus a simple blood test. The blood would be drawn at the same time as other samples so no additional phlebotomy required and no additional appointments. The results would then be reviewed by a cardiologist to determine whether or not the patient had any cardiac problem.

Having written a 30-page protocol, 10-page patient information sheet, informed consent form, drawn up a simple one-page symptom questionnaire with some basic body measurements and vital signs added and produced draft versions of all the various letters which would be sent between patients, their GPs and the research clinicians who would be screening the results I was then faced with IRAS. Not the most user-friendly system I have come across (and that is from 30 years experience in IT including several years working for IBM). This produced a further 44 pages of output.

The Ethics Committee, while lauding the idea and being very complimentary about the way the study was designed, nevertheless decided to have a nit-picking session and requested various changes, including "ensure that you include the patient's full name, date of birth and NHS number in all communications, just in case the GP has two patients of the same name, same date of birth with the same condition".

Having satisfied the REC, next came the Trust R&D Department – no problem, I thought, they are on the same corridor so communication should be easy. Not so, in order to get to R&D everything had to go through the CLRN for them to check first. Pedantry rules supreme! The one benefit of the CLRN was that by adopting the study we were able to get funding from them to cover the GPs additional costs. Despite the REC ruling that no site-specific approvals were needed it took over a month to get R&D to agree that since this was an observational study we would not need an SSI for every GP practice involved, just blanket approval from the two PCTs. At least I was spared the effort of getting CVs and GCP certificates from 50 or 60 GPs and practice nurses. Finally, R&D gave their approval – some four months after the trial had been approved by Ethics. Off we go, I thought – naively!

Oh no, can't start yet, R&D need to issue a formal agreement to proceed – and then want to review the contract with each GP practice involved before we can start.

Final timeline:

Protocol Completed	**18 Jun 2010**
Ethics Hearing	**16 Jul 2010**
Ethics Approval	**17 Aug 2010**
PCT Approval	**28 Oct 2010**
R&D Approval	**17 Dec 2010**
First patient recruited	**28 Mar 2011**

Why does it have to be such a time-consuming process for a simple epidemiological screening using a one page questionnaire and a well established blood test?

Now, about this Phase IV trial which was awarded funding from the HTA in 2009 and still hasn't started recruiting patients ...

News from the SW Trial Managers Forum – 23rd March 2011

Bristol Clinical Trials and Evaluation Unit recently hosted the second successful meeting of the South West Research Managers' Forum. The meeting was an all-day event held at the Colston Hall in Bristol. The forum is targeted at individuals in the South West of England and in South Wales managing non-commercial clinical trials/research studies and aims to provide opportunities for networking and sharing best practice/ideas for trial management. The Forum was established in October 2010 with the support of the Peninsula Clinical Trials Unit (PenCTU) and the Mood Disorders Centre (University of Exeter).

The main focus of the meeting was the role of a Trial Manager from different perspectives. We thought it would be interesting to compare how the role is viewed in academia/NHS in comparison to industry. Although the forum is for managers of non-commercial studies, we felt it would be interesting to learn about the differences between the way trials are run in both areas. We also wanted to have an insight into what a Sponsor expects from a Trial Manager. We were lucky to have had 3 excellent speakers, who also agreed to stay and run workshops in the afternoon to build on the talks of the morning and encourage sharing of best practice.

A Senior Trial Manager from South Wales Clinical Trials Unit, gave an overview of her experiences of the role of an Academic Trial Manager. One of the things she highlighted was the importance of publishing papers on trial management to share experiences and to improve knowledge sharing in the field. This should help to promote the development of best practices for Trial Management.

This was followed by a presentation from an Education Manager and former Study Manager, at GlaxoSmithKline who gave us an insight into her experiences in industry. It was interesting to compare the scale of projects and the different expectations of industry and academia. She also told us that sometimes recruiting too quickly can cause industry problems, an unfamiliar problem to many of us working in the NHS!

Two senior managers from the Research & Innovation Department at UHBristol NHS Foundation Trust, gave us their insight into the role of a Trial Manager from a Sponsor's perspective. They managed to summarise just how new the role is and how varied it can be. Encouragingly, they also commented how invaluable Trial Managers are in bridging the gap between Sponsor and Researcher. This talk facilitated an interesting and interactive discussion about how Sponsors and Trial Managers interact and what we would like from each other. Networking happened over lunch and coffee.

In the afternoon, delegates had a choice of workshops: Consenting Patients, Recruitment, Managing Sites, or a Research and Development "Question and Answer" session. There were several discussion topics that arose from the workshops, including remembering to incentivise your sites (certificates of achievement, boxes of chocolates and reams of paper were among the suggestions!) and that most people find the centralised R&D systems (CSP) frustrating at some point, even R&D departments themselves!

On the whole feedback from the meeting was good. Several people suggested that a longer session for the workshops would have been beneficial as this session seemed a little short for the amount of discussion we could have had! One of the things identified by several delegates was how useful it is to have an opportunity to meet and network with other Trial Managers and how much can be gained from sharing knowledge, documents, templates and experience. We do not all need to reinvent the wheel with every new study. Another message that came through from the feedback was how useful it was to have input from an R&D/Sponsor perspective. The next meeting is likely to be hosted by South East Wales Clinical Trials Unit in about 6 months time. We hope that the website for forum members will be up and running shortly! If anyone from the South West area would be interested in future meetings, please email Adwoa Hughes-Morley (A.Hughes-Morley@exeter.ac.uk) and you will be added to the mailing list.

For more information about the Bristol CTEU, please see our website at http://cteu.bris.ac.uk/.

NIHR TMN Annual Meeting

The NIHR TMN Annual Meeting is provisionally scheduled to take place on 10 October 2011 at RIBA in London. Sadly it is a self funded event and TMN members and/or their respective employing institutions will be responsible for covering the attendance fee and travel expenses.

The speakers confirmed so far are:

- **Professor Deborah Ashby**, Chair in Medical Statistics and Clinical Trials, School of Public Health, Imperial College London who will be presenting the results from the Academy of Medical Sciences Review - A new pathway for the regulation and governance of health research
- **Bec Hanley**, Co-Director of TwoCan Associates will give a talk on PPI in clinical trials with references to the forthcoming INVOLVE guidelines about involvement in research
- **MHRA (tbc)**, Feedback from the MHRA risk-based approach for authorising clinical trials pilot

The meeting will involve workshops, as per your suggestions as well as a Poster Session and a Trial Managers Oral Presentation Section. We will be sending out a call for abstracts as well as a registration form to register for a place at the Annual meeting towards the end of May. Abstracts selected for Oral Presentation (four in total) will be able to attend the Annual Meeting for free. We are hopeful that the Annual Meeting will stimulate and encourage vibrant debate on many issues and will provide an arena for networking and exchanging best practice and ideas.

Training and Development News

The results from the NIHR TMN Evaluation Survey have unequivocally communicated your need for more training and development events tailored specifically to meet the needs of the Trial Managers. **Please note** that training is outside the remit of the NIHR TMN and the Network will not run training courses/workshops in a similar manner as the former UKTMN.

Despite this, we will endeavour to identify relevant courses for Trial Managers and will popularise this information via different media (i.e. NIHR TMN mailing list , Newsletter and website. To this end we rely on you to highlight to us any relevant development events and courses in your area. Some relevant information follows.

Career structure for TMN initiative

It is often suggested that despite the wide and varied spectrum of existing support for Trial Managers there is no apparent, formalised training structure for this important group.

The NIHR Trainees Coordinating Centre (NIHRTCC) is presently tasked with putting together a formalised training structure for Trial Managers. Please note that this work is in a very early phase. The first task is to identify what training is required (i.e. an appreciation of what relevant training already exists, what is absent and the cost implications). The second task is to determine who will be responsible for delivering the relevant training portfolio. It is likely that there would be a role for numerous partners including the HEIs (as employers with staff development and training responsibilities), the NIHR (as the main provider of trials funding) and perhaps NIHR TMN (in supporting Trial Managers).

Very soon we will be establishing a time-limited project group to facilitate this initiative that will be overseen by the NIHR TMN Oversight Group. More detail will follow.

Development opportunities

Clinical Trials Course

Keele University (non-residential) – After the success of its three-day course over the past five years the Clinical Trials Unit at Primary Care Sciences, Keele University are running the next "Practical Introduction to Running Randomised Clinical Trials" course which will be held from the 6 –8 June 2011, registration for the course is now open. Further details about the aims of the course, the course content and tutors, and how to register can be found at the course website below.
http://www.keele.ac.uk/research/pchs/pcmrc/trials/
To reserve your place, you can download the registration form from the website and email it to the course administrator Sue Weir at s.weir@cphc.keele.ac.uk

PG Diploma and MSc in Clinical Trials

New members of the Network should also be aware of the PG Diploma and MSc in Clinical Trials distance learning course run by London School of Hygiene and Tropical Medicine for Trial Managers (more information available at http://www.lshtm.ac.uk/prospectus/masters/dmsct.html)

Useful links section: PPI

Patient and Public Involvement (PPI)
Some useful documents regarding PPI can be found here:
http://www.invo.org.uk/Documents.asp

It is worth noting that the RDS will facilitate applying for some money for PPI support – however this is limited in nature and is not meant to replace budgeting in PPI in a grant application. The RDS are available to help for free by making an appointment, and have some documents here which may be useful:
http://www.rds-yh.nihr.ac.uk/patient-and-public-involvement.aspx

Useful documents regarding PPI from the TwoCan Associates website
http://www.twocanassociates.co.uk/pubs.php

Yammer on Trial

A number of you have expressed an interest in piloting the use of Yammer as a corporate networking interface. We have already invited those members to take a look and try it out for themselves. It is proving to be quite a success and will be the forerunner to the forums that will be an intrinsic part of the new NIHR TMN Website. We have posted some useful documents such as The UKCRC Registered CTUs Core SOPs Templates. This info has already been circulated via the UKCRC Registered CTUs mailing list, but those of you based outside of the CTUs may find the templates useful. If you wish to be added to the pilot system, please get in touch.

NIHR TMN Calendar

- **First NIHRTMN Oversight Group Meeting** 4th May 2011, London
- **NIHR TMN Annual Meeting** - 10th October 2011, London

And a Joke to finish!!!

Beware—It's a little long!!!! But it is relevant—and quite funny—Follow the link below

http://www.certifiedresearchers.com/joke.htm

Send us your feedback

We would like to thank you for your positive comments and constructive feedback on the first edition of the NIHR TMN Newsletter. Please continue to send us your views and suggestions for improvements. We look forward to hearing from you with any information that you would like to share with your colleagues through this Newsletter.

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