Thank you to all of you who made the journey to London for the first NIHR TMN Annual meeting.

It was so nice for both myself and Svet to be able to put faces to email addresses and meet people face to face.

There was a buzzing atmosphere throughout the day and we do hope that you enjoyed the meeting, and found it useful. Please see pages 2 and 3 for photos from the meeting and a summary of the day.

We are growing every day!

With the proactive support by our funder NETSCC, the NIHR TMN membership is continuing to steadily grow in numbers.

We have currently exceeded our initial projected expectations with more than 340 registered members.

We are receiving new enquiries on a daily basis from prospective new members wishing to join the NIHR TMN Family and would like to extend our welcome to all new members. Together we are hoping to build a thriving Network. Please do spread the word!
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. We have now had the chance to analyse all evaluation forms including those received by e-mail.

The feedback indicated that overall, participants valued highly the key note presentations along with the networking opportunities, sharing knowledge and experiences and taking part in the workshops. Indeed many expressed a wish to have been able to attend more than one of the workshops. Delegates enjoyed the wide range of topics throughout the day including the peer-led presentations. Particularly those which focused on trial management issues and overcoming obstacles. In addition, through coming together and meeting fellow trial managers facing similar problems, participants felt a valued part of the wider research community. Some expressed satisfaction with the appreciation of the Trial Manager’s role in NIHR research and the value placed in them by the HTA reaffirming their professional identity and skills. For others the meeting provided a boost to their confidence by broadening their knowledge and exposure to new ideas and peer expertise with tips for better trial management and overcoming problems.

Overall, the feedback that we have received from the meeting has been one of enthusiasm and support and where constructive criticism has been given—we will certainly take it on board and hope to deliver informative, relevant and enjoyable annual meetings in the future.

Most of the annual meeting presentations are now uploaded on our website. So if you haven’t already visited—please access here to take a look. Photographs from the day are accessible via the album on the website.

The Poster Prize of an Amazon gift voucher was won by Eleri Owen-Jones from Cardiff University (left with Professor Jane Nixon). Eleri is the Trial Manager for the Building Blocks Trial her poster was entitled—“Building Blocks—Methodological challenges in conducting RCT with Pregnant women. It was voted on by all TMs present at the meeting and it was a close run thing.

Feedback

A full analysis of the annual meeting evaluation forms that will be published on the NIHR TMN website, but below are just some of the comments that we would like to share with you:

“very informative and valuable—learnt from other TM’s”

“A summary of the NIHR TMN Annual Meeting—and some comments from our

“An excellent opportunity to network with research colleagues. A well planned and executed day which really highlights the excellent work of the NIHR TMN”

“excellent meeting—would have been great to have been able to attend all of the workshops”

“really good meeting”
Mat Leighton is a Trial Manager based within the Nottingham Clinical Trials Unit. He is married and has two lively little boys.

He has just successfully completed the recruitment phase of the TOMAS trial (A multi-centre randomised controlled trial of rehabilitation aimed at improving outdoor mobility for people after stroke (TOMAS). He has been an invaluable support to Lelia Duley, the recently appointed Director of Nottingham CTU, over the past few months whilst she has been settling into her new role.

How did you start in a career in Trial Management?

I started my research career in Lab-based research in Glasgow and Manchester following the completion of my PhD. I changed over to Trial Co-ordinator in 2007 when I joined the Wolfson Digestive Diseases Centre in Nottingham working on the HEAT trial. After completion I become a Trial Manager in the Nottingham CTU. I have worked on 3 very different trials – set-up of a paediatric trial (P3MC); primary care occupational therapy trial TOMAS and a secondary care IBS trial called MIBS.

Tell us about the highs and lows of succeeding with the TOMAS trial – meeting your recruitment target? Can you share any vital Trial Manager tips with your fellow trial managers?

Right from the start we had some very difficult timelines to contend with. The timings were based on a very successful pilot, however the availability of suitable participants had decreased dramatically in the meantime. So immediately we started to recruit twice the number of centres envisaged. A key part of the recruitment was to engage with the occupational therapists who were keen to do research but a bit nervous of doing things wrong. So I visited all sites as often as possible to maintain a supportive relationship with the therapists. Once we had the sites up and running we constantly engaged with the site staff with newsletters and regular investigator meetings. I was lucky to also have Pat Morris (Clinical Trial Administrator) in Nottingham to help keep in touch with the sites regularly. Also engaging with the networks was absolutely crucial to support the sites and teaming up with the therapist. That worked really well. A final element that helped in the success of recruitment was instilling some good old fashioned competition—everybody wanted to be the best site in their area and that really increased recruitment.

Who has been your greatest mentor?

I have learnt most of what I know about running clinical trials from my boss of 3 years, Diane Whitham.

What has been your best experience of managing a trial?

Nothing in particular, I just really enjoy the job and have never regretted leaving my lab-based research. There are new challenges every day – always something different to battle with and overcome. Though, if anything, it would be the point when you realise you are going to hit your recruitment target.

And what about the worst?

Whilst I was setting up a paediatric study we were nearing the start of recruitment when the IMP a 3rd party had manufactured was rejected on quality grounds and the whole batch had to be destroyed. Some very difficult conversations ensued, but we managed to arrange the re-manufacture at no extra cost, but it did delay things considerably.

What piece of advice would you pass on to someone who is just starting out in a career in Trial Management?

You have got to be very persistent. Never assume anything. Have self belief - CI’s sometimes view things very differently – so don’t be afraid to challenge or question. It is better to talk about the issues and have a voice – to ensure that all stages in the trial design are relevant to the study and feasible logistically.

What is the trickiest problem that you have had to deal with whilst running a trial – and how did you resolve it?

Securing of excess treatment costs is always tricky. With the TOMAS trial it took some time to get an understanding of the funding routes - I had to do a lot of whittling away to discover who was responsible for paying the treatment costs at most of the 15 sites and then how to make sure the money got to the therapy department.

How do you choose to relax?

At home with my wife and 2 boys – we are lucky to live in the heart of Robin Hood country so Sherwood Forest is on our doorstep. We all enjoy taking the dog for long walks.

What is the best book you have ever read and why?

Frederick Forsyth – Fourth Protocol. I really enjoy spy books. Bit sad but I would have loved to be a spy.

Which film would you recommend?

Either “Something about Mary” or “Me, myself and Irene” – really funny films and not exactly politically correct.

Who would you most like to invite to have dinner with you and why?

Eric Cantona – an absolute Manchester United legend and a real character and I am a massive Man United fan!
Clinical Trial databases - a novel approach, John Warden

John is CT Project Manager in the Department of Academic Cardiology at the University of Hull. He is working on two large multinational 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. John has also been really supportive of the work that we are doing at the NIHR TMN.

Clinical Trials require complex data to be collected and analysed, often outside the normal limits of Hospital or GP clinical databases. There are a number of proprietary packages available from major companies but these come at a high cost and can lack the specific functionality and flexibility required.

The Department of Academic Cardiology at the University of Hull has recently tried a new approach – getting a bespoke systems created by a small software house. The system was tailored to a specific study so that all relevant data could be collected. This is a multi-national, multi-centre observational study into Chronic Heart Failure. Having an IT experienced Clinical Trials Manager enabled the University to produce detailed specifications for the system and database and to manage the chosen IT supplier. This ensured that the system would perform exactly as required and also cut down greatly on the development and testing effort required.

The chosen IT supplier, altcom Ltd (www.altcom.co.uk), were able to turn these detailed specifications into a working system in a matter of months at a cost much lower than any major supplier. The system was delivered on time, within budget and with zero defects and has now been in use for over a year with no problems.

The data entry system is web-based, to allow multi-centre access online. The database is fully relational, with 20 entities and over 1,000 data fields, and is accessed through a simple and straightforward user interface. A multi-lingual interface was considered but not implemented as all users have sufficient command of English. However, some countries do use different units of measurement for certain data, in particular haematology and biochemistry, so an automatic conversion is in place to convert all input data from whatever units are used locally into SI units for analysis. The data input screens also show the local units of measurement so there is no confusion.

The system is being used by a number of Universities and Hospitals across Europe and Russia and there are multiple layers of security in place. Data security far exceeds the requirements of the Data Protection Act, NHS Act, local NHS Trust R&D, MHRA and ICH-GCP. A full audit trail of user logins, data input and amendments is available to the System Administrator, as well as other audit and security information.

The development approach was to use Wireframes to design the user interface and then use Open Source software for the database and associated systems. The database uses Postgre-SQL, the supporting systems are written in Python and the website CMS uses Django.
Courses and Conferences

This two day course considers the perspective of those staff who are new to clinical research and helps to guide them through the challenges of setting up research projects and the processes needed to ensure recruitment and safeguarding of trial subjects together with generation of robust data. Particular reference is made to both the Research Governance Framework and Good Clinical Practice legislation as described in the Medicines for Human Use (Clinical Trials) Regulations. For more information please follow the link below.
http://www.rdforum.nhs.uk/004c.asp?entryid=898

Quality of Life Assessment in Cancer Research (See Flyer)
Date: Thursday 17th November 2011
Time: 10.00-16.15
Venue: Birmingham University Centre for Professional Development
Registration fee £10
Booking form available at http://www.bham.ac.uk/mhtmr
Or Contact: Karen Biddle, 0121 414 6774
K.biddle@bham.ac.uk

Maximising participant recruitment to randomised controlled trials, Monday 28th November 2011, University of York
The York Trials Unit are running a 1-day training course highlighting various issues related to participant recruitment for randomised controlled trials and possible strategies to improve recruitment. The course should be of interest to students, trial researchers, nurses and doctors involved in recruiting participants to take part in clinical trials. For further information and to register on line,
http://www.york.ac.uk/healthsciences/research-information/trials-design/maximising-participation/
or contact Sally Baker (sally.baker@york.ac.uk) or phone 01904 321726

How qualitative methods can contribute to the design and conduct of randomised trials
A MRC ConDuCT Hub Workshop
School of Social & Community Medicine, Canynge Hall, University of Bristol, BS8 2PS
27 March 2012
Previous experience or knowledge of qualitative research is not needed
To book a place please email htmr-conduct@bristol.ac.uk by 20 January 2012. There is no charge for this workshop. MRC HTMR network members are especially welcome, as are those involved in randomised trials.
To view the programme click here

Job Opportunities

Clinical Trial Manager,
MRC Clinical Trials Unit, Oxford
NHS Blood and Transplant(NHSBT)
Salary—£30,460—£40,157
Closing Date 9 November 2011
Click here

Research Associate/ Study Coordinator (Part time)
General Practice and Primary Care Unit, University of Cambridge
Salary £27,428—£35,788 Pro Rata
Closing Date 11 November 2011
Click here

Fixed Term Data Manager/Research Officer.
Centre for Health Information, Research and Evaluation (CHIRAL), Swansea University
Salary: £30,870 per annum (pro rata for part time staff)
Closing Date 17/11/11
Click here

To search for more jobs –please visit our website
New Website has been Launched

We are pleased to announce the release of the public pages of the NIHR TMN website which was launched at the NIHR TMN Annual Meeting. The website can be viewed at: http://www.tmn.ac.uk/

The site currently offers a number of useful areas for Trial Managers. These include: Latest News section with NIHR TMN news, information on governance changes, training courses, conferences etc., a comprehensive links section with links to useful on-line resources, a career section where you can find Current jobs, Resource library with many relevant file libraries.

If your institution has a new Trial Manager position available - then do please ask them to forward details to us - or even better - they can post a new vacancy directly onto the website. It doesn’t appear live on the site until we verify it here at HQ - but once verified it means that it will be seen by a large audience of professional Trial Managers throughout the country, and it is free!!!

The second phase will be the on-line membership area. Very shortly we will be prompting you to submit your membership details on-line which will enable a searchable membership directory, better communication and will enable annual updating of the trials that you are involved with.

The third and final phase will enable groups, forums and blogs to flow through the website, making it a professional networking area - we are confident that it will become an active stimulating Trial Manager hub of excellence

We do hope that you will enjoy surfing the site. Your comments and suggestions are most welcome, either through the site’s "Feedback" facility or directly to the NIHR TMN Secretariat at nihrtmn@leeds.ac.uk. Please do send us suggestions for useful links and file libraries that may be of benefit to your colleagues

Interesting - Take a look!!!!

According to those clever people at the Royal Society of Arts - Our brains take in and retain information more easily when reinforced with visual imagery. They have teamed up with a brilliant animator and have produced quite an innovative way to explain complex issues and theories - take a look - let us know what you think. The Educational Paradigms was very interesting..

In the next Issue

- A report of our first year—Feedback from the NIHR TMN Oversight Group
- Launch of the Membership area of the Website
- A Day in the Life – Interview with a Trial Manager.
- A report on our visit to Nottingham CTU

Send us your feedback

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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