

The Annual Meeting – Registration is now open

The NIHR TMN Annual Meeting will take place at the Royal Institute of British Architects (RIBA) on Monday 10th October 2011 and is now open for Registration. We are limited to 100 places which are fast being filled – see page 6 for an outline of the conference and information on how to secure your place at the meeting.



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Staying part of the Network

This will be the last newsletter that will be going out to all of those members – both past and present from the original listing that we inherited from the former UK TMN.

From the end of July 11 all those who have not rejoined the new NIHR TMN either as Full or Associate Members will be removed from the JISCMail listing. We do of course want to keep our network as wide as possible and would encourage any of you who haven't already signed up to the network to complete the application form. (attached with this newsletter).

If you have any queries about your membership status – Do please get in touch with us – We want you to stay in the Network.

NIHR Oversight Group – First meeting, 4th May 2011, UCL, London



(From the left – Liz Tremain, Vicky Napp, Professor Jane Nixon, Professor Cindy Cooper, Professor Deborah Ashby, Louise Liddle, Svet Mihaylov.)

The group was established to provide independent oversight of the network as part of the NIHR funding. The group is chaired by Professor Deborah Ashby (Imperial College London) with two other independent members: Professor Cindy Cooper (Director of CTRU, University of Sheffield) and myself as a trial manager (BRTC). I also provide some continuity having been on the UKTMN steering committee. Liz Tremain represents the funders as an observer. The network management group Chair (Professor Jane Nixon, CTRU University of Leeds), Svet and Louise comprising the rest of the group. Vicky Napp (CTRU Leeds) attended the meeting to give a link with the hosting CTU.

At our first meeting we mostly discussed the terms of reference of the group which includes providing advice to the network management group and reviewing progress against the agreed business plan. The categories of network membership were discussed and the recent members evaluation survey.

The first meeting was very positive about the aims and plans for the network presented by Svet including the website and annual meeting. The oversight group will meet twice a year and we anticipated several further developments by the next meeting. The meeting venue also contributed positively with views of canal boats and swans swimming past the windows at regular intervals on the Regent's Canal near Paddington Station!

Written and submitted by Dr Athene Lane, Independent member of the NIHR TMN Oversight Group and Senior Research Fellow, University of Bristol

Making FiCTION fact, a personal experience of working with PCRN

I have to admit that I am not really an expert when it comes to calculating set up, treatment, excess treatment and service support costs. Having got to grips with ARCO (well almost) and constructed a crib sheet and spread sheet I can usually head in vaguely the right direction when it comes to a study that is similar to one that I've already done.

When the opportunity to oversee a pilot rehearsal trial in Primary Care dentistry arose, I must admit I was filled (no pun intended) with trepidation at the thought of working out the various costs for it that were outside of the research budget. Were crowns and fillings treatment or excess treatment costs, where should a radiograph go?*

I have worked very successfully with my PCRN on other trials in the past and so arranged to meet with the local Clinical Trial Coordinator and see whether they could advise on the various costing issues in dentistry.

As Primary Care Dentistry does not have as high a research profile as Medicine we were unable to draw upon existing work to inform our costs. PCRN suggested that we used the British Dental Guild rate as a starting point. We worked through the protocol and mapped out a practice workload spread sheet and patient route through the trial. At every step the trial team was quizzed as to how long each activity would take and how often it would be performed.

Over a series of meetings we developed a framework for an 'average' participant and used this to calculate the per patient accrual data.

PCRN has ensured that all practices were fully reimbursed for all of the time and resources needed during the set up and running of this trial. On completion of the pilot rehearsal trial we will roll out the definitive RCT. PCRN are already working with us to consider new and innovative ways to support participating dental practices. By their own admission they didn't actually know the type of support dentists would need.

We were asked to conduct a pilot rehearsal trial to best design the definitive trial and in much the same way PCRN has joined us to learn how it can best design a package to support dental staff and practices during this trial.

“ *I was filled (no pun intended) with trepidation at the thought of working out the various costs for it that were outside of the research budget* ”



Chris Speed is a Senior Trial Manager at Newcastle University CTU
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Louise Warner is a Clinical Trial Coordinator for PCRN Northern and Yorkshire
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Once again, working with the PCRN has been a rewarding and successful experience. My advice would always be to 'get in early' and discuss your study. You'll not be disappointed.

**OK pedants, I know that for this study it should be in the mouth!*

FiCTION: Filling Children's Teeth Indicted or Not is funded by the NIHR HTA (<http://www.hta.ac.uk/1783>)

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 TMN

Right to Reply

Following on from the publication in the last Newsletter edition of the “Getting Approval – ‘the Grand National for Trial Managers’” article, Dr Ian Holland, Director of R&D, Hull And East Yorkshire Hospitals NHS Trust has requested the right to reply.

Dear Sir,

RE: Trials and Tribulations Newsletter: Getting Approval – ‘the Grand National for Trial Managers’.

I would like the right to reply to the above article on behalf of my department which is referred to in a rather vitriolic manner in the above publication.

The story in itself is rather self-defeating in that it highlights a lack of knowledge/understanding of the processes in place by the author, as well as containing some inaccuracies. These attitudes and the way in which some trials have been handled throughout the research fraternity have indeed led to the current state of legislation and the necessity to “fill forms”.

From the timeline published one would also question why it took three months to recruit a patient when the author felt strongly that the trial should be moving quickly? Having been involved with both ethical and R&D processes over a number of years I have found that the level of risk does not always correlate with the complexity of the study.

As an aside, it should be added that the trial quoted was being sponsored by the Trust which needed to be assured that all procedures/processes in place were correct. This work is carried out by a small department, by dedicated members of staff, the number of whom are insignificant in comparison to the blossoming numbers of research associates.

Kind regards

Dr Ian Holland
Director of R&D
Hull And East Yorkshire Hospitals NHS Trust

We would like the Newsletter to stimulate healthy areas of debate and we actively encourage you to get involved and share your experiences.

JISCMail System



Changes to the NIHRTMN@Jiscmail.ac.uk subscription

The original NIHR TMN JISCMail listing for Trial Managers will be updated at the end of July.

If you are a Full or paid-up Associate Member of the network you will continue to appear on the distribution list.

However, if you haven't completed the online Membership Application Assessment Form or have been notified that you are now eligible for Associate Membership and decide not to register as a member by 31st July 11, your name will be removed from the NIHR TMN membership directory and the nihrtmn@jiscmail.ac.uk distribution list.

If in doubt on how to register as an associate member and continue to have access to the NIHR TMN mailing list and website, please contact:

Louise Liddle or Svet Mihaylov
Email: nihrtmn@leeds.ac.uk
Tel: 0113 3434322

Job Opportunities

Research Fellow for CODIFI Study

University of Leeds - School of Healthcare

Salary: £29,972 to £33,734 (Part Time, 40%)

Closing Date: 6 July 2011

Clinical Studies Co-Ordinator (3 x Posts)

Keele University, Faculty of Health

3 YEAR FIXED TERM

Salary: Grade 7 Starting £29,972

<http://www.keele.ac.uk/vacancies/>

[professionaltechnicalandsupportvacancies/](http://www.keele.ac.uk/vacancies/professionaltechnicalandsupportvacancies/)

Closing Date: 7 July 2011

NIHR TMN Membership - Decisions

The NIHR TMN Oversight Group met in London on the 4th May 2011 and it has recommended the two types of member categories as presented below.

Full members

Full members are entitled to automatic membership of the NIHR TMN subject to filling in a membership registration form and the TMN secretariat is satisfied with the funding source information about the study available in recognised public registers (e.g. UKCRN portfolio, ISRCTN etc).

To become full members, trial managers must meet one or more of the following eligibility criteria.

- Should work on at least one or more **DH/NIHR funded study** (defined as any study where the **research cost is fully or co-funded by DH England/NIHR** for which the research activity may be coordinated either within England or one of the Devolved Nations, or may have a Chief Investigator either within England or one of the Devolved Nations. **Please note that it does not cover NIHR Portfolio adopted studies where only the service support or treatment costs are funded by DH/NIHR. It also does not cover staff on DH England/NIHR Infrastructure funding.**
- Should work on one or more MRC legacy studies (defined as pre 2008 MRC funded, large scale multicentre RCT's for which the research activity may be coordinated either within England or one of the Devolved Nations, or may have a Chief Investigator either within England or one of the Devolved Nations).
- Depending on the funding source, Data Managers carrying out trial management responsibilities for trials included in the UKCRN Portfolio Database could be eligible for either full or associate membership, do contact the secretariat for clarification if you are in this bracket.
- In contrast with the previous membership system, Senior Trial Managers working across a portfolio of studies, where part or all of their time is costed on at least one DH England/NIHR funded grant are also

Associate membership

Trial Managers working on studies included in any of the four UK Nations Portfolios but without any element of NIHR **research funding** (e.g. charity, industry, devolved nations and non-UK funded studies such as FP7, NIH etc.) are eligible to join the NIHR TMN, if they wish to, as 'associate' members. Associate membership is subject to payment of a £75.00 annual fee per member.

Please note

Members of the NIHR TMN Mailing list who have completed the NIHR TMN Membership Application Assessment Exercise have been notified by email either that they are now granted full NIHR TMN membership or advised that they can join the Network if they wish to as associate members.

We are however, aware that some of you did not complete the NIHR TMN Membership Application Assessment Form on Survey Monkey, which was used to determine whether you match or not our membership criteria.

In order to become/remain a member of the NIHR TMN we do need to hear back from you. If you are unsure whether or not you completed the survey – do please get in touch with Louise Liddle at the Secretariat Office. (l.liddle@leeds.ac.uk).

The Membership application form is attached to this newsletter and we urge you to complete it and return it to us to maintain your membership of the NIHR TMN.

NIHR TMN Annual Conference

Registration is now open for the NIHR TMN Annual Conference at RIBA in London on the 10th October 2011, you should all have received an invitation to register for the meeting.

For full and associate members there is a special Early Bird Delegate rate of £55.00 for registering before the 31st August. Thereafter it will be £65.00.

If you are a prospective Associate member of the network, **you must** join the network to be eligible for attendance at the Annual Meeting. We have a Special Rate of £125.00 to register for both the meeting and the network – a saving of £15.

Participants are most welcomed to submit abstracts and share new developments and results from their projects as well as to raise any methodological issues relevant to trial management. Four abstracts will be selected for oral presentation by a decision committee and notified by 29th July. For more details see the attached call for abstracts leaflet.

We are also expecting to here from those of you who have an interesting idea and are prepared to facilitate a workshop at the meeting to email us with your suggestions by 30th June 2011.

NIHR TMN What's On Calendar

4 th /5 th October	MRC HTMR – Clinical Trials Methodology Conference 2011 Bristol
10 th October	NIHR TMN Annual Meeting, RIBA London

Send us your feedback

We would like to thank you for your positive comments and constructive feedback on 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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Svet Mihaylov – s.i.Mihaylov@leeds.ac.uk

NIHR TMN Administrator
Louise Liddle – l.liddle@leeds.ac.uk

NIHR TMN Annual Meeting
Monday 10th October 2011
RIBA, 66 Portland Place,
London, W1B 1AD

Key speakers:

Dr Peter Davidson, director of NETSCC – “Why Trial Managers are Important for NIHR Research”

Professor Deborah Ashby – “A new Pathway for the Regulation and Governance of Health Research”

Bec Hanley, Co-director of TwoCan Associates – “Actively Involving Patients and Carers in Clinical Trials”

Dr. Martin Ward, head of MHRA Clinical Trials Unit and Mrs Paula Walker, GCP inspector – “Feedback from the Risk Based Assessment Pilot”

Four parallel workshops:

1. Tomasz Kurdziel, Lead R&D manager West Yorkshire CLRN – New CSP module
2. Dr. Athene Lane-Site, Monitoring in Clinical Trials
3. TMN-member-led workshop – tbc
4. TMN-member-led workshop – tbc

Four oral presentations given by Trial Managers

Opportunity for poster presentation

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