We are keen to build upon the success of the 2011 Annual Meeting and to organise an even more interesting, informative and educational event in 2012 that will bring real value to our members.

We are in the process of setting up a Programme Development Committee (PDC) to advise on this year’s Annual Meeting Programme and therefore we would like to invite our members to have the opportunity to contribute to this. Please feel free to submit to us any new ideas and suggestions regarding the desired format and content of the 2012 NIHRTMN Annual Meeting either via the forthcoming NIHR TMN Annual Evaluation Survey or by emailing at nihrtmn@leeds.ac.uk.

There is one vacant place on the PDC and we invite self nominations from our membership to take on an active role in the development of an exciting programme for the 2012 Annual Meeting. Please do get in touch if you are interested by no later than 5th March.

Haven't registered yet? We have now almost 400 members but just over half of you have registered on the NIHR TMN website. If you haven't registered yet, please do take ten minutes from your busy schedule to complete your website registration. This will enable you not only to access the members only area of our website but to continue to be notified in the future of new training and job opportunities as well as benefiting from the comprehensive links section, the resource/useful documents library and the newly launched discussion forum (see page 2 for more details) Please register now.
Just in case you are not a reader of the Guardian we wanted to let our members know of the new innovative initiative from the Government and The Guardian to promote NHS research through their e-paper clinical research zone. It looks great, has lots of information and we thought you might be interested in taking a look—it is certainly a site to add to your bookmarks!!!

(HSRN) Symposium - 
19-20 June, Manchester Central

The HSRN Symposium, now in its fifth year, is the premier knowledge event for Health Services Research, bringing together presentations and discussions from the leading edge of research. The overarching theme for this year’s symposium is translating knowledge into practice.

This symposium would be of interest to all those working in the field of health services research and healthcare policy and registration is now open.

Find out more about the event and for any further queries please contact:
John de Pury, Research Networks Manager
email: john.depury@nhsconfed.org
tel: 0207 074 3260
To book your place at this event click here.

EUPATI

EUPATI (European Patients' Academy on Therapeutic Innovation) is launched this year. Please follow the link to find out more.

Nottingham Systematic Review Course, 3rd July - 6th July 2012

Hannah Jones, a Trial Manager from Nottingham, has forwarded to us information about the Nottingham Systematic Review Course – it will appeal to anyone interested in completing a Cochrane-style review of randomised trials. After attending the course, participants should be able to understand search strategies, extract data, manage the results of systematic searches, understand the syntheses of the data, apply the methods and conduct reviews independently. More information is available here.
Eleri Owen-Jones is a trial manager in the South East Wales Trials Unit (SEWTU), Cardiff University. She has worked there since August 2007 and has been the trial manager on a randomised controlled trial called Building Blocks since August 2008. The Department of Health Policy Research Programme is funding this £5M trial evaluating the Family Nurse Partnership programme in England.

How did you start in a career in Trial Management?
I was asked by a Uni friend to help out at a CRO (Contract Research Organisation) which carried out first-in-man drug trials. Initially I was dropping blood samples onto a gadget (very technical!) but when the owner of the company realised my background (little did they know!) they offered me a position as a project manager. When that company went bust, after a very brief stint as a medical writer I started this job as a trial manager in SEWTU.

Who has been your greatest Mentor and please explain your reasons why?
Jacqui Nuttall – she just knows everything about trial management (and other things) and always has time for you even when it’s obvious she’s up to her eyeballs with her own work.

What has been your best experience of managing a trial?
A bit unoriginal I’m afraid – getting the first recruit into the Building Blocks trial.

And what about the worst? I sometimes feel like I’m going round and round in circles (usually in relation to R&D permissions…sorry R&D guys) and not getting anywhere!

What piece of advice would you pass on to someone who is just starting out in a career in trial management?
Be good at multi-tasking; keep good records of everything, and I mean everything; use a calendar; write to-do lists; make sure you’ve got thick skin!

Where do you see yourself in Five years time?
I have no idea, I don’t make long-term plans! As far as I know there isn’t really any official career progression, you just hope that you get recognised for your hard/good work.

What is the trickiest problem that you have had to deal with whilst running the trial – and how did you resolve it?
Identifying 42 different Principle Investigators at the beginning of the trial then attempting to identify an additional 58 Local Collaborators. Teenage mum’s don’t always give birth in their planned hospital and move around the country quite a lot, and in order to access their medical records at primary and secondary care level we needed R&D approval and Local Collaborators for all of these new additional sites. Need I say more?! How did I resolve it? With perseverance (still have 15 to go) and a lot of help from Julia Sanders the senior project manager who is also a consultant midwife and called in a lot of favours!

How do you choose to relax?
Relax?! I go to the gym 4 times a week (Tuesdays at 6.30am!); sing in a National Award winning(!) choir called Côrdydd; go to wine club; eat out; eat chocolate; drink wine; buy pretty dresses; watch TV and films; drink wine; eat chocolate; buy pretty handbags….

Which Book could you not live without?
Guideline for Good Clinical Practice – tee-hee!

Which film would you recommend?
Pulp Fiction and/or Moulin Rouge.

Who or what has been the biggest influence in your life?
My Mum and Dad and being Welsh.

Holidays – Home or Abroad?
Abroad – always!

What has been your best holiday experience?
Too many to count: Hong Kong for the rugby sevens Word Cup (with choir – not a lot of official singing but plenty of unofficial singing!); a beautiful trip to the Amalfi Coast; Dubai for the luxury; Cuba for Mojitos; Epernay for …you guessed it – Champagne tasting; Groningen, The Hague and Amsterdam to visit my little (baby) brother.

And what about the worst holiday experience?
It has got to be a school trip to Austria a very long time ago: Our bus turned up with a cracked windscreen; by the time that was fixed and we joined the second bus that one had filled up with black smoke due to an electrical fault; then there was an incident involving a wooden chair and a balcony in the hotel; not to mention the inappropriate actions of the bus driver and I managed to fall over on a glacier and still have a very scarred knee as a memento!! …need I go on!!

Who would you most like to invite to have dinner with you and why?
I’m going to be very soppy here sorry - my boyfriend, as I don’t see him as much as I’d like to as we’re both very busy, and since my relationship history is abysmal (to say the least) – and as you may have guessed – I love eating and drinking good food and wine (esp. NZ Sauvignon Blanc) so it’s actually lovely to have someone to share dinner (and good times) with!!
Strategies for recruitment and retention to clinical trials: TRACE RA trial, an article by Rebecca Storey, Acting Trial Manager, TRACE RA, Research and Development; The Dudley Group of Hospitals NHS Foundation Trust

The Trial of Atorvastatin for the primary prevention of Cardiovascular Events in patients with Rheumatoid Arthritis (TRACE RA) is jointly funded by Arthritis Research UK and The British Heart Foundation and started recruitment in 2007. Since then TRACE RA has recruited 3001 trial participants from 101 recruiting centres from around the UK. Late last year, TRACE RA was closed to recruitment early due to a significantly lower than anticipated annual primary endpoint rate.

Having a wide network of recruiting centres has provided the TRACE RA team with an opportunity to gain a good insight into the working methods of different research teams from across the country. This has been used to further inform and enable the trial team to develop strategies to support the main challenges posed to the TRACE RA trial, and indeed many other large scale clinical research studies: the recruitment and retention of trial participants. This article discusses in detail what strategies were implemented and the rationale behind them.

Trial Promotion
Promotion of a clinical trial not only attracts new colleagues to recruit to it, it keeps the trial at the forefront of the minds of actively recruiting centres as well as creating a brand image to participants which enhances the overall perspective of the trial. TRACE RA was promoted extensively using a variety of methods to suit different audiences; the main methods used are presented as bullet points below:

- United Kingdom Clinical Research Network (UKCRN); Chief Scientist Office (SCO) Scotland and Clinical Research Collaboration (CRC) Cymru adopted TRACE RA onto their clinical research portfolios, enhancing the financial incentive to potential recruitment centres.
- Attendance of the trial team at regional Rheumatology meetings to present the study to Consultants who are members of the consortium in order to generate support for the trial.
- Attendance of the trial team at disease specific national events such as the BSR and hosting a trial specific stand at these study days.
- Contacting Principal Investigators and asking them to recommend colleagues at another centre who would be interested in participating in TRACE RA.
- Speaking at any conference related to the area of investigation i.e. musculoskeletal practitioner study days.

TRACE RA ongoing promotion to centres already recruiting to TRACE RA
- A clear brand image which was revised after 2 years to make the trial appear fresh again.
- High quality printed posters throughout clinic waiting rooms with matching flyers.
- Use of incentivised recruitment drives and presenting the centres with a certificate and a larger prize once the centre had completed their original recruitment target.
- Maintaining a presence at local and national conferences.
- Development of the TRACE RA website where all documents and items of reference are available 24/7 (www.dgoh.nhs.uk/tracre).
- Communicating with sites regularly using a range of media such as newsletters, e-mailed weekly recruitment updates, telephone calls and study days.

TRACE RA promotion to potential and existing trial participants
- Production of glossy, colour printed participant information booklets.
- High quality printed posters throughout clinic waiting rooms with matching flyers.
- TRACE RA website.
- Participant newsletters (see communication for more detail).
- Working extensively with large disease specific charity groups (NRAS) as well as small local patient led initiatives.

Communication
The benefits of open and frequent communication with recruiting centre colleagues are no secret and the trial team utilised many ways of keeping our colleagues informed about the trial progress from e-mailed weekly recruitment updates, recruiting centre quarterly newsletters and a dedicated TRACE RA website. The trial team also hosted trial specific study days to which all research teams were invited to attend. The study days were generally of a more formal nature held at central conference locations.

Our last study day was held at Regents Park College in London, with a stellar faculty of guest speakers and very high attendance rates. All of the aforementioned communication techniques were designed to complement- not

(Continued on page 5)
replace - the important day to day communication conducted within each clinical trial unit, from the coordinator to the research nurse/ research lead at the centre. All communication with our research centre colleagues centred around keeping TRACE RA at the forefront of our colleagues minds- thus increasing recruitment activities on site.

One communication which generally seems to lack attention is communication with the trial participants themselves, this lack of communication from the trial team was felt to be a major contributor to the loss to follow-up rate as the trial progressed. We became acutely aware that beyond consent, the participants had no further updates produced by the trial team to maintain interest and motivation. With this in mind we re-developed the TRACE RA website so that there is a ‘public’ section which anyone can access and read information about TRACE RA, its aims and objectives all presented in lay language. The ‘recruiting centre’ section where all site file, promotional and heath professional directed materials were then in a separate locked section of the website which could only be accessed through individual username and passwords administered by the trial offices. Access to the trial website was promoted on the patient ‘contact cards’.

In addition to website access we produced quarterly participant newsletters updating all involved in TRACE RA of the trial progress as well as including other items of interest in relation to Rheumatoid Arthritis. We also gave much more ownership to the participants with regards to the content of the newsletter and advertised trial unit contacts for the participants to contact us directly regarding anything that they would like to see in the newsletter. With the participants permission we reported in the newsletter ‘milestone participants’ i.e. 1000th patient. All of the newsletters circulated received prior MREC approval and were printed by an external company to give a professional glossy finish.

The TRACE RA trial had successfully gained approval to collect consenting participants’ personal contact details, extending from their home or preferred postal address through to mobile telephone numbers and e-mail addresses. This allowed us to post trial materials directly to the participants at home, reducing the workload burden for the research centre staff.

Future strategies to enhance communication with the participants included sending an MREC approved participant welcome letter from the Chief Investigators which outlined again the aims of the study as well as a quick update on study progress and the possibility of contacting consenting participants by text and e-mail to remind them of forthcoming hospital appointments.

**Trial Evaluation**

We, the TRACE RA team, continually sought ways of evaluating the effectiveness of any communication or promotional initiative that was implemented to assess its efficacy with the intended audience and to develop the technique further for future use. Some examples of how initiatives were evaluated are described as bullet points below:

- Feedback after formal conferences, both as a written evaluation and verbal comments
- Seeking the views of our research teams, including pharmacy colleagues who are often neglected
- Developing an extensive monitoring strategy which utilised our own databases to track trial participant recruitment and retention

Evaluating the trial using our own databases allowed the trial team to target centres that appeared to be having issues in either recruiting or retaining trial participants, we then used this information to provide a tailored advice service in order to help maximise the centres potential in these areas.

The continuing evaluation of the trial also led to protocol and CRF amendments, such amendments included bringing back the trial participants for follow up more frequently in order to improve the compliance and retention rate.

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If you are interested in any of the above strategies or materials, please register to the TRACE RA website: www.dgoh.nhs.uk/tracera or contact Rebecca Storey on 01384 456111 x 3733.

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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 TMN
We are grateful to John Warden, CT Project Manager in the Department of Academic Cardiology at the University of Hull and also an attendee at this Conference, for this report.

The 2012 Annual Conference of the European Forum for Good Clinical Practice was held in Brussels on 24/25 January 2012. The theme of the Conference was “Informed Consent – How Less could be More: Effecting a paradigm shift so we do inform participants.”

Over 200 delegates from some 40 countries attended, including ethics experts, representatives of patient groups, clinical trials managers, clinical researchers and representatives of major pharmaceutical companies.

Exploring the main theme of the conference, several plenary sessions were held discussing various aspects of the Informed Consent process. There was a strong feeling that the present Informed Consent procedures had less to do with really informing the patient but more to do with protecting the researchers. In too many instances, information was presented which could not easily be understood by the patient or in a way which misrepresented the true position. Risks and secondary effects were minimised or skipped over and the long term prognosis ignored. Patients could be distracted by irrelevant information or data presented using statistical formulae which are not fully explained. In many cases, information sheets were far too long to be easily read – patients were overwhelmed by the amount of information they have to absorb. Information sheets and Consent forms use language which is far above the average level of literacy – even in developed countries like the USA.

Various options were proposed as to how information could be better presented:
- Less reliance on written documents
- Use of videos / cartoons
- Verbal presentations
- Use of the internet and social media (Facebook)
- Use of mobile phones / iPads etc

Other solutions to the problem of information overload were proposed:
- Splitting the Information sheet and Consent into smaller sections
- Core Information only, backed up by appendices or online references
- Asking the patient questions to ensure they understand

Finally, the question of consent in less developed regions of the world was discussed.
- This emphasised the need to make information and consent understandable in respect of the local culture.
- In many instances physicians are unwilling to explain fully to the patient what is wrong (eg. Cancer).
- Patients in areas with no public health system are often influenced to participate because they will get free treatment.
- Literacy and education (or lack thereof) is a major barrier to patients’ understanding.

The difference between treatment and research is poorly understood.

All of these issues are ones which should be properly addressed when research is carried out in these countries.
Our member, Gina Cranswick, together with colleagues from the Edinburgh Clinical Trials Unit (ECTU) have recently performed a detailed review of the provision of GCP courses across the UK. As a result of this review, a discussion paper has been produced which the Edinburgh research team would like to share with you

"Variability and provision of good clinical practice courses across the UK"

Gina would very much welcome your comments on this paper via email to gina.cranswick@ed.ac.uk

The team has also published a list of all GCP courses they have identified. This list is accessible via the link below

NHS GCP courses by country

Job Opportunities

We have regular updates of jobs on the NIHR TMN website – if you are on the look out 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:

- Trial Coordinator—London
- Clinical Trials Project Manager, London
- Clinical Trial Coordinator (Cancer ), Warwick
- Head of Trial Management, Leeds
- Trial Coordinators, University of Birmingham
- Trial Manager, Newcastle
- Trial Manager (field based), Newcastle
- Clinical Trial Manager, Sutton, Surrey
- Clinical Trial Manager (Oxford)
- Part Time Senior Trial Manager, Oxford

If your organisation has any Trial Manager positions that they would like to promote through the NIHR TMN—then do please get in touch.

Who would you like us to interview next?

We welcome suggestions of interesting and inspiring researchers and the great and the good in the world of trial management and clinical research that you would like to see interviewed in the future editions of our Newsletter. Please forward your suggestions and any burning questions you wish to ask. 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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