

# Network News

## Contents:

- Trials update
- Submitting trial ideas to the UK DCTN
- The impact of the EU Clinical Trials Directive
- Dates of upcoming events/meetings

## Trials update:

### Cellulitis pilot study

Boki Savelyich (research associate)



started work on this project in September, thanks to a grant award from the British Skin Foundation. Most of the ethics and R&D approvals are now in place and we are hopeful that recruitment will commence by end of November 2004.



We are currently in discussion with the British Skin Foundation to see how they might help us to fundraise for the definitive trial.

### Pyoderma Gangrenosum trial

Work on the Pyoderma gangrenosum trial is being led by Dr Tony Ormerod. This will involve two parallel studies in which patients are randomised to receive either topical treatment (tacrolimus versus clobetasone propionate) or systemic treatment (cyclosporine versus prednisolone).

We hope to have the proposal finalised by the end of the year.

## Submitting trial ideas to the UK DCTN

Although several trials are currently under development through the Network, it is important that we constantly review trial suggestions and address areas of importance to our membership, to patients and to the NHS. Having a variety of trial proposals ready for submission for funding at any one time will increase our chances of securing relevant funding as and when it arises.

If you would like to submit a trial idea for consideration through the Network, please submit a vignette in the first instance using the following headings as a guide.

1. Condition of interest:  
(Include patient group, type of lesion, location etc)
2. What treatments do you propose to include?  
(Include main intervention and comparators)
3. What outcome measures will you use?
4. What group of patients do you propose to study?  
(Include main inclusion/exclusion criteria)
5. What existing evidence is there?
6. Why is this suggestion particularly suitable for study through the Network?

*(Remember to include your name and contact details)*

If you think that your suggestion is particularly relevant to the NHS and may be suitable for funding through the NHS Health Technology Assessment programme, then please make this clear on your submission. We will then submit your idea to the HTA through our affiliate group portal. For advice on this please refer to the HTA website [www.ncchta.org](http://www.ncchta.org)

*Please return your submissions to:*

Mrs Phillippa Scott  
Centre of Evidence Based Dermatology  
Ward C51, South Block  
Queen's Medical Centre  
Nottingham  
NG7 2UH

## Impact of the EU Clinical Trials Directive

A lot has been said about the Directive and how this will impact on non-commercial trials. The following is intended to be a whistle-stop tour of some of the things that may affect you if you become involved in a Network-run trial.

### Before you start.....

#### Ethics approval

Multi-centre Research Ethics Committees (MREC) approval is needed for all of our trials. This process is not new, but is now centralised and has an on-line application form. Having used this system for the cellulitis pilot study, I think that it is much improved. We no longer have to submit multiple hard copies of all documents and we get a single ethics opinion that covers the whole of the UK.

As a local investigator you will need to submit the site-specific assessment (which is relatively short and simple to complete, once you have mastered the on-line technology). This form is then

submitted to your local ethics committee along with a copy of your C.V.

### R&D approval

All investigators will need to obtain R&D approval for their respective sites. Unfortunately, a standard form for this process is not yet available, and individual R&D departments are still using their own systems. Hopefully this will change in the future, but for the moment, this is likely to be the main hurdle in the approval process. Certainly our experience from the cellulitis pilot study suggests that R&D departments vary widely in the number and type of documents requested.

While I am happy to help as much as possible, the bulk of this process will fall to the individuals running the trial at each site (at least until a standard form becomes available).

### Approval from the MHRA

A Clinical Trials Authorisation certificate (CTA) will be applied for centrally and should not involve the investigators directly.

### Starting the trial.....

#### Training

Once all of the approvals are in place, you will be sent some information containing all of the essential documents and procedures for the trial. It is important that we can prove that investigators have received appropriate training - particularly in relation to the interpretation of the protocol, obtaining informed consent, handling of data and data protection issues. The exact nature of the training will vary from trial to trial, but you will be asked to devote some time to this from the outset. For some studies, this may consist of regional training days, for others it may simply be a telephone conversation or PowerPoint presentation for you to run through.

#### On-going monitoring

Some level of monitoring is now expected for all clinical trials. This does not necessarily mean that you will be visited by a member of the study team, as many of the checks can be conducted centrally. However, if your local R&D department routinely monitors trials involving Trust patients, then we may ask them to check key documents on our behalf.

### End of trial procedures....

#### Archiving

How things are managed at the end of a trial will depend on the trial itself, and the systems that you have in place at your own hospital. We will generally archive all essential documents centrally, so there should not be any need for you to organise archiving at a local level.

### Data management

All data will be managed and analysed centrally, but you may be asked to help with the dissemination of findings within your region, or nationally.

### Further information

Further information on the impact of the EU Directive on non-commercial trials can be found on the HTA website, under their EU Directive pages ([www.hta.nhsweb.nhs.uk](http://www.hta.nhsweb.nhs.uk)). A new website arising from the MRC/HTA joint project has just been launched [www.ct-toolkit.ac.uk](http://www.ct-toolkit.ac.uk)


*Kim Thomas, UK DCTN Co-ordinator*

## Dates for your diary

### Network Meetings:

- **Monday 7 February 2005**  
BAD House, London  
1.00-3.00pm Steering Group only  
3.00-4.00pm Executive Group only
- **July 2005 (date to be advised)**  
BAD Annual Meeting, Glasgow
- **Tuesday 18 October 2005**  
BAD House, London  
1.00-3.00pm Steering Group only  
3.00-4.00pm Executive Group only

### Other Meetings:



**Skin Cancer**  
**An Evidence Based Update**

**Thursday 12 May 2005**  
**Novotel, Nottingham**  
(profits to UK DCTN)

### Contact details:

**Kim Thomas, UK DCTN Co-ordinator**  
E-mail: [Kim.Thomas@nottingham.ac.uk](mailto:Kim.Thomas@nottingham.ac.uk)  
Tel: (0115) 924 9924 ext. 43501

**Phillippa Scott, UK DCTN Administrator**  
E-mail: [Phillippa.scott@nottingham.ac.uk](mailto:Phillippa.scott@nottingham.ac.uk)  
Tel: (0115) 970 9262

**Hywel Williams, UK DCTN Chairman**  
E-mail: [Hywel.Williams@nottingham.ac.uk](mailto:Hywel.Williams@nottingham.ac.uk)  
Tel: (0115) 929 9924 ext. 43000