

Submission of research ideas to the UK Dermatology Clinical Trials Network

Please complete your details:

Name:

Address:

Tel:

E-mail address:

What is the research question?

(Consider 'PICO' i.e. Patients, Intervention, Comparator and Outcomes)

What existing evidence is there to support this question? (It is crucial to provide supporting evidence in the form of references to a systematic review, case studies, database studies, current treatment, or general observation. Please provide references to a maximum of 3 papers)

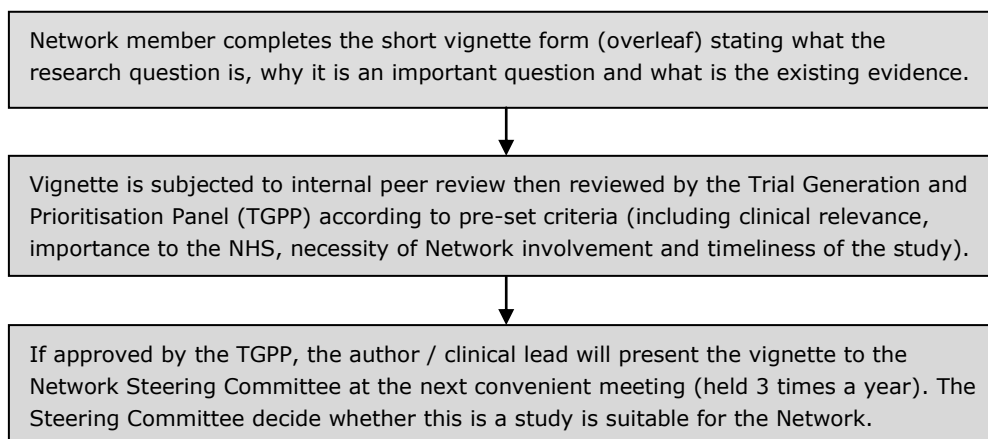
Would you be happy to become the lead for this project if it is developed further through the Network?

(If the answer is no, please don't let this put you off submitting the research question – we just need to know. For further information about what it means to be a trial lead and the support that the co-ordinating centre can offer, please see overleaf.)

What is involved in being a Clinical Lead on a trial?

You may have a good idea for a clinical trial but are concerned that with an already busy clinical workload plus other commitments, you don't have time to lead a clinical trial. To help you make an informed decision, we have outlined below what is typically involved and where staff at the co-ordinating centre can take on the bulk of the work.

Firstly, the **vignette needs to be approved for development** through the Network, according to the following procedures:



If your vignette is approved and you wish to lead the study, you would work closely with your **Trial Development Group (TDG)** over the next **6-12 months** to **develop a grant proposal** for submission to a funding body. The co-ordinating centre can help identify statisticians, health economists etc. to form the TDG. Typically, this involves several meetings (some via teleconference) plus correspondence by email and telephone in between meetings. The UK DCTN senior trial manager will arrange the meetings, draft the grant application and do the trial costings, but your clinical expertise is vital at this stage. If a pilot work or surveys are required, the Network staff can co-ordinate these activities.

If the **funding bid is successful**, the co-ordinating centre will help with the **set up** (preparing protocols, gaining ethics and regulatory approvals etc.). As the Clinical Lead, you would contribute to the development of the protocol and study procedures, again usually through several meetings (some via teleconference) plus correspondence in between meetings with the trial manager and other members of the study team.

Once the study is up and running, you would need to **provide clinical input** throughout the lifetime of the study and attend Trial Oversight Committee meetings. As Chief Investigator, you can delegate the day-to-day management of the study to the trial manager (and the Network co-ordinating centre) but you would retain overall responsibility. You would be central to the final **write up** of the study and any publications.

It takes 2-3 years from submitting a vignette to obtaining funding.

Success to date

The UK DCTN has raised over £2.5 million in external funding. The clinical leads for these studies are: PATCH –Dr Neil Cox (Carlisle), BLISTER- Prof. Fenella Worjanowska (Oxford), STOP-GAP- Prof Tony Ormerod (Aberdeen), LIMIT-1- Dr Jerry Marsden (Birmingham).

And finally, a **comment from Dr Neil Cox**, the PATCH Trial Clinical Lead:

“This is a research avenue that simply isn't available through any other body. It enables research to be performed using either drugs that would not attract pharmaceutical backing, or larger groups of patients than individual centres would be able to recruit. The Network team put a lot of effort into making the process of developing research and getting funding and approval as simple as possible, and give great support to the investigators. It is also a good way to hone research ideas with one's peers, to keep in touch with like-minded colleagues, and for trainees it is a good way to become involved in research that operates at a national level and that answers questions that we, as dermatologists, feel are important.”