

Developing a network in a neglected area of clinical research: the UK Dermatology Clinical Trials Network

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The UK Dermatology Clinical Trials Network (UK DCTN) was established in 2002 to address our collective ignorance on the treatment of skin disease. Although started with just a good idea and goodwill, the UK DCTN has grown into a UK-wide collaborative group of over 600 members running five fully funded clinical trials. The aim of the UK DCTN is simple: to conduct high quality, independent, multicenter, randomized controlled clinical trials for the prevention or treatment of skin disease. This article describes how the UK DCTN was set up, how such firm foundations have helped it grow and future plans to extend the concept globally. We hope this will be useful to others developing research networks in smaller clinical specialties and other countries.

Keywords: clinical trials • dermatology • independent • network • research

The UK Dermatology Clinical Trials Network (UK DCTN) is a national dermatology clinical trials network open to anyone with an interest in applied dermatological research [101]. It was founded by one of the authors (Hywel Williams) along with a group of academic and clinical colleagues in 2002 in response to the growing need for high-quality evidence to inform dermatology clinical practice, as highlighted in various Cochrane Skin group reviews that were being produced at the time. From that initial meeting of 20 individuals, the UK DCTN has now grown into a UK-wide organization of over 600 members including secondary-care dermatologists, specialist nurses, primary-care clinicians, health-service researchers and patients and carers.

The aim of the UK DCTN is to conduct high-quality, independent, multicenter, randomized controlled clinical trials (RCTs) for the treatment or prevention of skin disease. Priority is given to trials that address questions of importance to clinicians, patients and the NHS and to those that need the involvement of a large collaborative group to recruit sufficient patient numbers.

UK DCTN management committees

When setting up the UK DCTN, initial work concentrated on establishing a democratic management structure consisting of both an Executive and Steering Committee. Getting the right people on board at the start undoubtedly helps, and initial members of these groups included highly respected clinical academics and clinical champions working in the UK NHS. The Executive Committee meets twice yearly, is headed by an independent chair and consists of eight UK DCTN members responsible for the general business of the UK DCTN (including two lay members). The business of the Executive Committee is to make executive decisions on recommendations suggested by the Steering Group and appropriately use funds. The Steering Committee is chaired by our founder member (Hywel Williams) and meets three-times a year, mainly to evaluate trial proposals being developed through the UK DCTN. The Steering Group consists of 30 UK DCTN members from different regions across the UK and includes wide stakeholder

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representation from primary- and secondary-care clinicians, methodologists such as statisticians, as well as patients and carers. Membership from different professional groups and the lay community is essential for such a Steering Committee to work well, as is the development of clear terms of reference, which are available on the UK DCTN website [101]. Members of both groups serve a 3 year term of office, which can be extended with agreement from the relevant Chair. Bringing new people into such groups with time helps to refresh the organization, maintain enthusiasm and stimulate new thoughts and ideas. Setting up the appropriate structures and terms of references was a lot of work initially, but we are of the view that the time and effort invested in the early years of the UK DCTN has been a key factor in contributing to the continued success and development.

The UK DCTN obtained charity status in 2006 (Registered Charity no. 1115745) and operates in accordance with a formal constitution as required by the Charity Commission. This means we are eligible to apply for research funding from charitable trusts in addition to other fund-raising implications. The UK DCTN is an affiliate group of the British Association of Dermatologists (BAD) and an affiliate group for topic prioritization through the National Institute for Health Research (NIHR) Health Technology Assessment Programme, both of which have helped build links with these organizations.

UK DCTN policies & procedures

In addition to the formal constitution, the UK DCTN has a number of other policies and procedures in place that are important when working as a large collaborative group. This includes a publication policy, a policy on working with industry and an agreement document for those investigators developing studies with us. Our publication policy aims to recognize the input of all those who have contributed to a UK DCTN-led study, including the trial-development group, data-monitoring committee and those involved in recruiting into the trial. This is undertaken by nominating a writing team who then draft the paper on behalf of the relevant trial-study group. Each person's contribution is stated in the appropriate section of the paper.

UK DCTN membership

Our members are the backbone of the UK DCTN, as without their time, expertise and research suggestions, our goals would simply not be achievable. All members provide their input into the UK DCTN on a voluntary basis, although it should be pointed out that all clinicians working in the NHS are now expected to participate in clinical research of relevance to the NHS. Membership of the UK DCTN is free and is open to anyone with

an interest in applied dermatology clinical research. Membership continues to grow and currently stands at 635 (May 2011), demonstrating the commitment to independent dermatology research in the UK. Members are free to become as involved in UK DCTN activities as they wish, which can range from simply being kept informed of activities through a quarterly newsletter, suggesting study ideas for further development, helping to inform study design by responding to surveys, through to becoming members of trial-development groups and by getting involved in the management committees described above.

UK DCTN co-ordinating center

Three part-time staff are employed at the UK DCTN co-ordinating center, which is housed within the Centre of Evidence Based Dermatology at the University of Nottingham [102]. Dedicated core staffing is essential to running a network such as the UK DCTN in order to ensure that momentum is maintained and that the business of the network is run in an efficient and professional manner. Funding for this main infrastructure comes from a variety of sources including the BAD. Locating the co-ordinating center within the Centre of Evidence Based Dermatology has worked well as it has an international reputation for conducting high-quality, independent dermatology research and is also the editorial base for the Cochrane Skin Group [103] and a national electronic library of NHS resources for health-care professionals [1,104]. Roles of the co-ordinating-center staff have developed as the UK DCTN has expanded and currently include:

- Network Manager: responsible for funding, publicity and promotional activity, training and awards, infrastructure development and patient/carer involvement;
- Network Administrator: responsible for management of website and membership database, secretariat support to all committees, finance management and general administrative support;
- Network Clinical Trials Development Manager: responsible for trial development, funding and ethics applications and study set up.

Clinical trial development through the UK DCTN

The fundamental aim of the UK DCTN is to develop clinical trials of high quality and relevance to the dermatology community. When the UK DCTN was first set up in 2002, members of the BAD were surveyed for research ideas, which helped to identify and prioritize the main dilemmas facing clinicians dealing with skin diseases.

Such an approach led to the first fully funded trials to be run through the UK DCTN, prophylactic antibiotics for the treatment of cellulitis at home (PATCH) I and PATCH II, which will be discussed in detail later.

The UK DCTN is open to trial suggestions from any of its members within the UK, and co-ordinating center staff will work with those suggesting the idea to move it forward. Suggestions are submitted via a trial vignette form and are then progressed through a predefined trial-development process, outlined in [Figure 1](#). This whole system is a rigorous and robust process, which has been developed over the years to ensure that only high-quality and relevant studies that can be delivered

within the constraints of a busy clinical service are progressed. The successful funding rate of the UK DCTN is a reflection that the system works well. Recent developments in this system include the formation of a Trial Generation and Prioritisation Panel, which was set up in 2008 to identify and prioritize research topics for development through the UK DCTN. The role of this panel is twofold. First, it aims to proactively identify research gaps and source new research questions, rather than simply react to suggestions that come forward. Second, it reviews ideas submitted to the UK DCTN and recommends if they are suitable for further development and presentation to the Steering Committee.

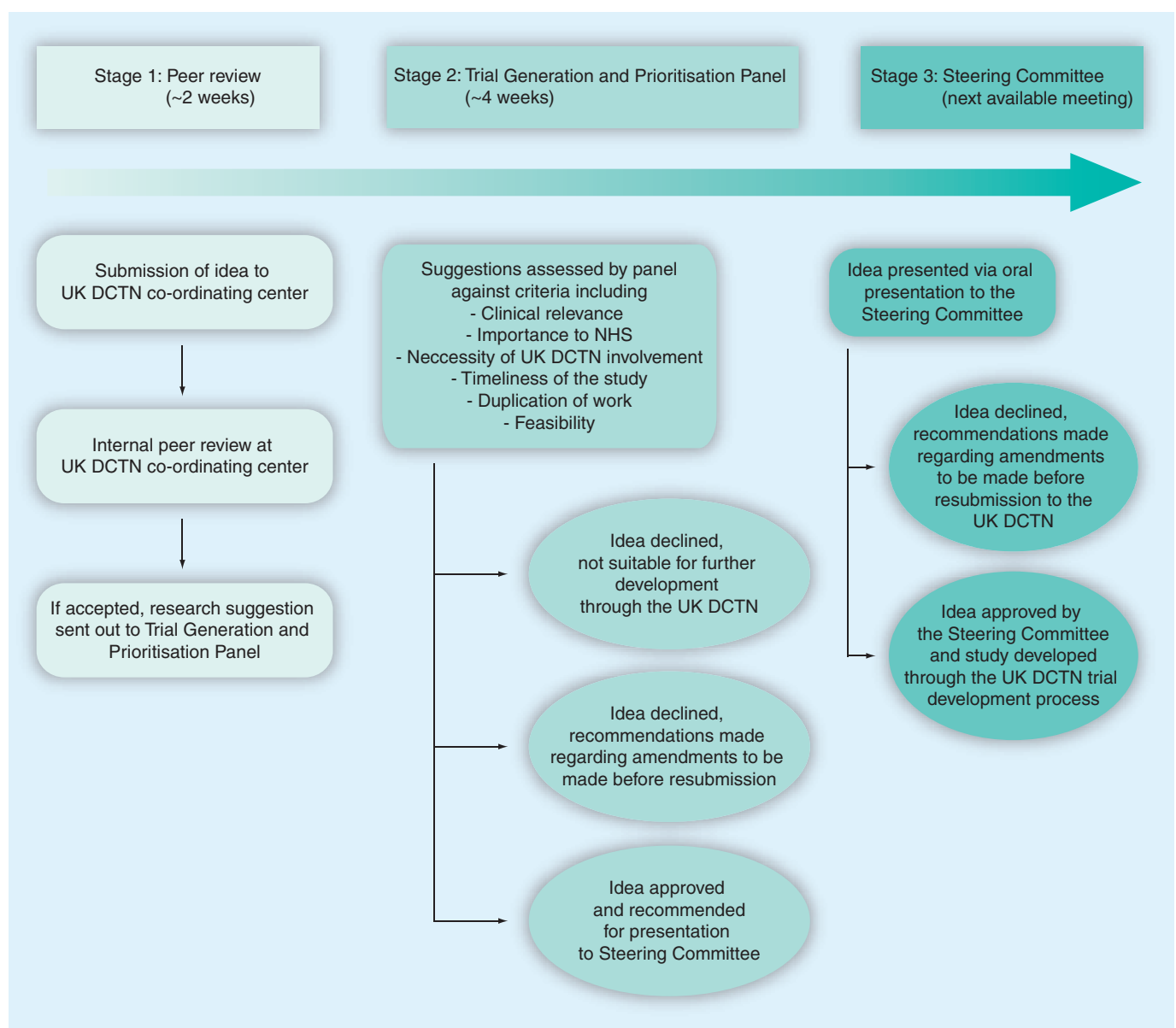


Figure 1. Process for initial prioritization of research ideas submitted to UK Dermatology Clinical Trials Network.
UK DCTN: UK Dermatology Clinical Trials Network.

Following approval by the Trial Generation and Prioritisation Panel, trial suggestions are presented to the Steering Committee by the vignette's author. This is an essential forum to debate and discuss the importance and practical aspects of the proposed trial and to provide advice with regards to the next steps. Once through this stage, the UK DCTN Trial Development Manager will establish a small Trial Development Group to drive the work forward. This usually consists of the vignette author as the clinical lead, along with two or three other interested clinicians, and methodologists such as a statistician and health economist. Input from patients and carers is encouraged at an early stage and often forms part of preliminary feasibility work for the full RCT.

All ideas submitted to the UK DCTN go through a 'traffic light system' and each study in development will be at one of the three stages:

- Red: not currently suitable for development through the UK DCTN or a Chief Investigator has not been identified;
- Amber: approved by the UK DCTN Steering Committee and being actively developed;
- Green – ready for peer review and submission to funding bodies.

This system helps the UK DCTN to keep track of studies in development and identify needs and priorities. Currently, the UK DCTN has 17 studies at various different stages of our trial-development system, covering diverse clinical areas including eczema, acne, vitiligo, erosive lichen planus and epidermolysis bullosa. Such diversity is important in order to avoid saturating the main clinical recruiters and to bring in different specialist-interest groups. It takes on average 3 years for a study idea to progress to a fully funded RCT using the trial-development system outlined above.

UK DCTN funding

One of the main remits of the UK DCTN is that it is independent from the pharmaceutical industry and this is reflected in our funding. This is because the UK DCTN wished to tackle those areas that profit organizations were not interested in and because of the need for a source of clinical evidence that was completely independent. Until 2009, funding for the core infrastructure staff was obtained from the the National Co-ordinating Centre for Research Capacity Development at the UK Department of Health, a source which became unavailable owing to significant changes in the clinical research infrastructure across the UK. Currently, funds for the core staff are identified from a range of sources including the BAD,

contributions from successful funding applications, local NHS Trust funds and additional funds brought in by the center. In 2010, the UK DCTN was awarded a grant from the BAD to cover the costs of employing the Network Trials Development Manager for 3 years – a move that has given stability to the UK DCTN and further strengthen our links with this key stakeholder organization.

Funding for individual trials is sought from independent external bodies such as charities and government funding streams including the NIHR Health Technology Assessment scheme. The UK DCTN has been awarded almost UK£2.5 million over the past 7 years in funding for individual studies in this way.

Ongoing & completed UK DCTN-led studies

It is unlikely that the studies listed below would ever have come about in the absence the UK DCTN, which demonstrates the value of collective working in order to achieve answers to important clinical questions. Even though the UK DCTN was founded in 2002, the time scale for setting up such a network and progressing ideas to fundable proposals and then completing those studies is a long one, approximately ten years or more. The UK DCTN is now at an exciting stage with its first study due to report in 2011. Ongoing UK DCTN-led studies include:

- BLISTER: This on-going study funded by a £829,000 grant from the NIHR Health Technology Assessment scheme is a RCT comparing the safety and effectiveness of doxycycline with prednisolone for the treatment of bullous pemphigoid (a rare blistering skin disease of the elderly) [105];
- STOP GAP: This on-going study funded by a contribution from a £1.9 million NIHR Programme Grant is a RCT to test the hypothesis that ciclosporin is more effective than prednisolone for the systemic therapy of pyoderma gangrenosum (a rare ulcerative condition) [106];
- LIMIT 1: This on-going study funded by a £250,000 grant from the NIHR Research for Patient Benefit Scheme (RfPB) is a smaller Phase II study to help determine whether imiquimod is a sufficiently effective treatment for lentigo maligna (a form of skin cancer). It is hoped that lessons learned from this study will help inform the design of a full-scale RCT in this area;
- PATCH I and II: The PATCH I and II studies, funded by Action Medical Research and the BUPA foundation, respectively, are two closely related RCTs investigating the use of prophylactic penicillin to prevent

further episodes of cellulitis of the leg (a painful and common skin infection). These studies were the first fully funded UK DCTN-led studies and resulted from the initial poll of BAD members for research ideas back in 2002 [107]. They have now closed to recruitment, with study results expected to be published at the end of 2011. The pilot study that helped to inform the design of these studies has been published [2] along with an article outlining issues related to the study [3].

UK DCTN communications

Members are crucial to the success of the UK DCTN and it is critically important that they are kept informed about UK DCTN activities, new studies in development, and funding successes on a regular basis. This is done using a range of approaches that could easily be employed by other networks:

- Production of a hard copy quarterly newsletter
- An informative and regularly updated website [101]
- Short monthly e-mail updates of key developments

The co-ordinating team has worked hard to raise the profile of the UK DCTN over the years. Having exhibition stands at national dermatology meetings has served this aim well through meeting people directly. Branding has been achieved by having a strong, easily recognizable logo, as shown below in [Figure 2](#). Representatives from the UK DCTN including our Chair, Steering Committee members and co-ordinating-center staff have spoken at local, national and international meetings about the UK DCTN and the importance of working collaboratively.

Building research capacity as part of a network

As an organization, we recognize the importance of helping to develop young clinicians early in their careers to become interested in research, which in turn will help to build a critical mass of research capacity. With this in mind, the UK DCTN Specialist Registrar Fellowship Award scheme was instigated in 2007, and it has been a great success with increasing numbers of high-quality applicants applying each year. The aim of this 2-year award is to develop skills in clinical trials and critical appraisal in year 1, and then apply these learned skills in year 2 as the fellows become increasingly involved in the UK DCTN. Such awards only require a modest investment (we make two or three awards of £1500 each on an annual basis) and the award winners work with the central team for an average of 1 day per month through attending steering-group meetings and reviewing scientific papers. We have been greatly encouraged by the response to this scheme and have extended the format to



Figure 2. The UK Dermatology Clinical Trials Network logo.

include awards for the dermatology nursing and specialist and associate specialist clinical communities. This model could be adopted by other specialties and indeed other countries to actively encourage more clinical staff to become fully engaged in clinical research.

How the UK DCTN fits in with new research infrastructures in England

The publication of the 'Best Health for Best Research' by the Department of Health in 2006 [108] set out a 5-year plan for health research in England, which has dramatically changed the clinical-research landscape. A key part of the new national research strategy has been the establishment of a clinical-research infrastructure in the form of the NIHR Clinical Research Network [109]. The Clinical Research Network was initially comprised of topic specific networks such as cancer, mental health and stroke, which reflected government priority areas. In England, the Comprehensive Clinical Research Network was then established to cover areas of clinical research that are not met by these priorities, and dermatology is included as part of this. In order to provide local research infrastructure, 25 Comprehensive Local Research Networks (CLRNs) were set up in 2008–2009, with each area identifying its own research priorities and having support staff such as research governance managers, information specialists and clinical directors, to give help and advice. Most important of all, each CLRN has devolved funds for employing a bank of research nurses, whose main role is to recruit into nationally approved portfolio studies.

To date, 17 out of the 25 CLRNs across England have identified dermatology as a local priority and along with colleagues from Wales and Scotland and representatives from the dermatology nursing, pharmacy, primary-care and wound-care communities, these individuals come together to form the Dermatology Specialty Group. The group meets three-times a year and their main aim is to aid the delivery of NIHR portfolio studies to time and target. This role complements that of the UK DCTN, which is concentrating on the development of studies to add to the NIHR portfolio, and synergy between the two groups is illustrated in [Figure 3](#).

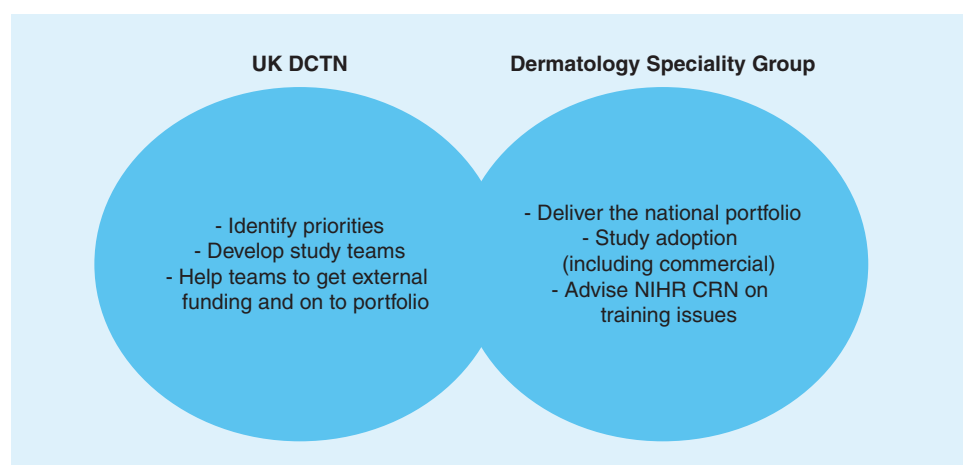


Figure 3. The relationship between the UK Dermatology Clinical Trials Network and the Dermatology Speciality Group.

NIHR CRN: National Institute for Health Research Clinical Research Network;

UK DCTN: UK Dermatology Clinical Trials Network.

one such study at a time, and needs to undertake other smaller scale studies of commoner skin conditions to maintain momentum. The UK DCTN also needs to tap into its various sub-specialty interest groups such as dermatological surgery or vulval disease, and new studies are being worked up in these areas in order to involve colleagues who are not currently recruiting into the main studies.

Other changes in the future will include keeping up to date with advances in clinical-trial design and reporting, plus ensuring that all work emanating from the UK DCTN is published and disseminated fully. Maintaining funding and a critical mass of staff at the co-ordinating

Future perspective

Setting up the UK DCTN has required vision and a long-term perspective, which is now reaping rewards in terms of funded trials and completed trials. Managing the portfolio of the UK DCTN will be a key future challenge. Although trying to tackle rare skin diseases has been one of the aims of the UK DCTN, trying to recruit into studies of bullous pemphigoid or pyoderma gangrenosum across 50 centers can be very difficult. For example, an investigator may only come across two to three such patients per year, and remembering to offer patients the opportunity to take part in a study can be tricky. The UK DCTN is only able to manage around

center will also remain a challenge, and it is hoped that additional funds brought in by externally funded trials will be sufficient to allow the UK DCTN to self-fund. Based on the successful model of the UK DCTN, we also aim to work with international colleagues over the next 5–10 years to develop an International Federation of Dermatology Clinical Trial Networks, in order to share knowledge of ongoing trials, provide advice on developing studies and occasionally collaborate on international trials of very rare conditions.

We are keen to hear from any organizations or individuals who would like to register an interest in joining such a global dermatology federation.

Executive summary

- Setting up effective management committees and processes early on is key to the development of a successful clinical research network.
- Representation from different professional groups, methodologists, patients and carers is essential for a good research network Steering Committee.
- Membership of a research network needs to be free and open for all interested parties to join.
- A long-term view of approximately 5–10 years is needed to develop such a network, given that working up to a trial proposal takes approximately 2 years and delivery of a funded trial takes approximately 5 years.
- A co-ordinating centre in a key location with core funded staff is crucial for the development and smooth running of a clinical research network.
- A well-defined system for trial development will ensure that only high quality and relevant studies are taken forward.
- It is possible to source funding from outside of the pharmaceutical industry if independence is considered to be important. Good links with relevant professional bodies may help in this regard.
- Collaborative research networks work particularly well for studies of rare disorders.
- Communication with network members by means such as newsletters and websites is vital.
- Genuine collaboration achieved through democratic processes and acknowledgement of all contributions in relevant publications is a key ingredient to a successful network.
- Networks can be used to increase research capacity in their specialty by schemes that involve training staff.
- Research networks need to ensure that they continue to develop alongside other relevant groups and that they align themselves with key contemporaneous national and global research strategies.

Disclaimer

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