Developing a network for clinical research: The UK Dermatology Clinical Trials Network (UK DCTN) experience

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Abstract

The UK Dermatology Clinical Trials Network (UK DCTN) was established by Professor Hywel Williams and a group of like minded colleagues in 2002 and has since grown to a UK wide collaborative group of over 600 members. The aim of the Network is simple: to conduct high quality, independent, multi-centre, randomised controlled clinical trials for the prevention or treatment of skin disease. This article aims to demonstrate how the UK DCTN was set up, how such firm foundations have helped it continue to grow and develop over the years and our plans to move forward in the future. We hope this will be useful to others planning to develop research networks both in other specialties and other countries.

Keywords

network, clinical trials, dermatology, research, independent

Introduction to the UK DCTN

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 Professor Hywel Williams and a group of academic and clinical colleagues in 2002 in response to the growing need for high quality evidence to inform dermatology clinical practice. From that initial meeting of 20 like-minded individuals the Network has now grown to a UK wide organisation of over 600 members including secondary care dermatologists, specialist nurses, primary care clinicians, health service researchers and patients and carers.

The aim of the Network is to conduct high quality, independent, multi-centre, randomised 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 Network, we concentrated initially on establishing a democratic management structure for the UK DCTN consisting of both an Executive and a Steering Committee. Getting the right people on board at the start undoubtedly helps and initial members of these groups included highly respected clinical academics such as Professor Andrew Findlay and Professor Nick Reynolds. The Executive Committee meets twice a year, is headed by an independent chair and consists of eight Network members responsible for the general business of the UK DCTN. The Steering Committee is chaired by Prof Hywel Williams and, meeting three times a year, one of its key roles is evaluating trial proposals being developed through the Network. It consists of 30 UK DCTN members from different regions across the UK and includes representation from many groups including secondary care dermatologists, primary care, nurses, patients and carers and statisticians. We feel that membership from different professional groups and the lay community is essential for such a Steering Committee to work well. Members of both groups serve a three year term of office which can be extended with agreement from the relevant chair and terms of reference for membership of the groups are in place. Bringing new people into such groups with time helps to refresh the organisation, maintain enthusiasm and stimulate new thoughts and ideas. We strongly believe that the time and effort invested in the early years of the Network in setting up such structures has greatly contributed to the continued success and development of the UK DCTN.

The Network obtained charitable 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 prioritisation through the NIHR (National Institute for Health Research) Health Technology Assessment Programme both of which have helped build links with these organisations.

UK DCTN policies and procedures

In addition to our formal constitution, the UK DCTN has a number of other policies and procedures in place which 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 recognise the input of all those who have contributed to a Network-led study including the trial development group, data monitoring committee and those involved in recruiting into the trial. The Chief Investigator of the relevant study will be the corresponding author for such publications.

Network membership

Our members are the backbone of the UK DCTN as without their time, expertise and research suggestions we would not be able to achieve our goals. All members provide their input into the Network on a voluntary basis. Membership of the Network is free and is open to anyone with an interest in applied dermatology research. Membership continues to grow, demonstrating the commitment to independent dermatology research in the UK and stands at 635 as of May 2011 and members can become as involved in our activities as they wish. This goes from being passive members simply kept informed of our activities by receiving our quarterly newsletter (Network News see Communications section of this article), helping with study design by responding to surveys, through to becoming members of trial development groups, suggesting study ideas for further development and by getting involved in our management committees described above.

UK DCTN co-ordinating centre

Three part-time staff are employed at the UK DCTN co-ordinating centre which is housed within the Centre of Evidence Based Dermatology (CEBD) at the University of Nottingham (102). Such core, dedicated staffing is essential to the running of a network such as this and means that we are able to operate the UK DCTN in an efficient and professional manner. Funding for this main infrastructure comes from a variety of sources including the British Association of Dermatologists (BAD) and further details of UK DCTN funding are outlined later. Locating the co-ordinating centre within CEBD 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). Roles of the co-ordinating centre staff are outlined below and this staffing structure works very well for us.

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, general administrative support.

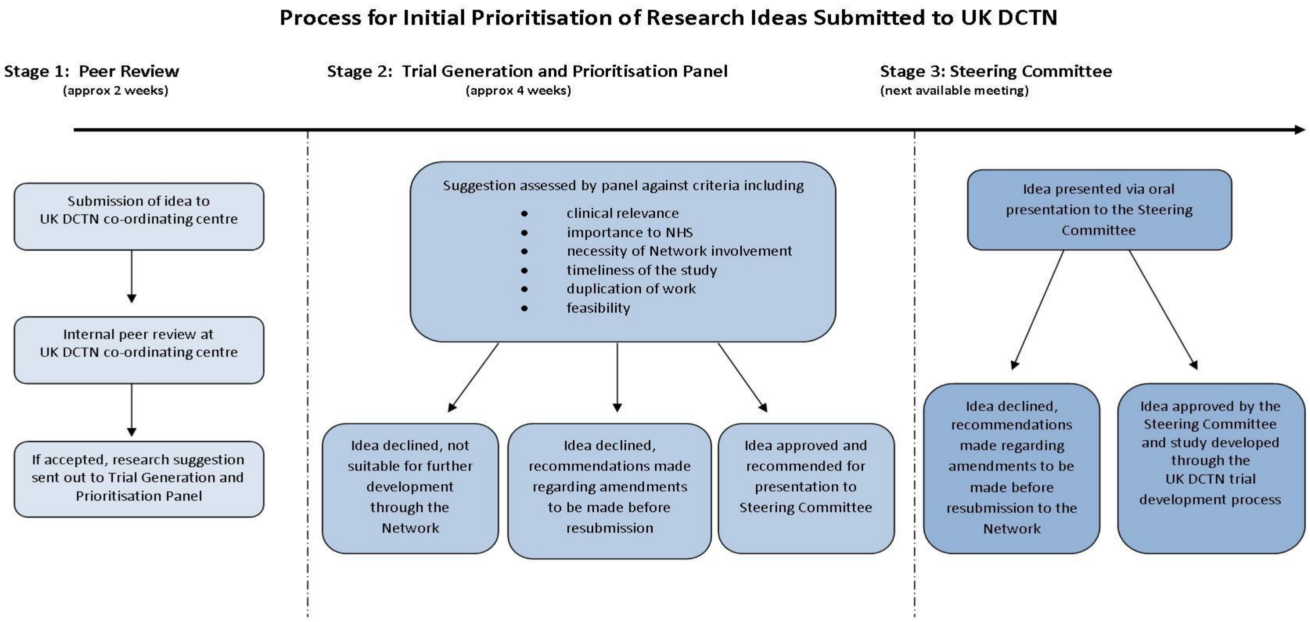
Network Clinical Trials Development Manager: responsible for trial development, funding and ethics applications, study set up.

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 Network was first set up back in 2002, we surveyed BAD members for research ideas and other Networks may find that in their early days links with well established professional groups such as this are essential in getting initial suggestions to take forward. Indeed, this approach led to the first fully funded trials to be run through the UK DCTN, PATCH I and PATCH II (prophylactic antibiotics for the treatment of cellulitis at home) which will be discussed in detail later.

The Network is open to trial suggestions from any of its members within the UK, and co-ordinating centre staff will work with those suggesting the idea to move it forward. Suggestions are submitted via a vignette form and developed by a pre-defined trial development process, the initial steps of this are outlined in Figure 1. This whole system is a rigorous and robust process which been developed over the years to ensure that only high-quality and relevant studies are progressed. Our successful funding rate is a reflection that this system works well. Recent developments in this system include the formation of a Trial Generation and Prioritisation Panel (TGPP) which was set up in 2008 to identify and prioritise research topics for development through the Network. The role of this panel is two-fold. Firstly, it aims to proactively identify research gaps and source new research questions. Secondly, 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 How the UK DCTN Prioritises Research Suggestions



Following approval by the TGPP, trial suggestions are presented to the Steering Committee by the vignette author. This is an essential forum to debate and discuss the importance and practical aspects of the proposed trial and provide advice as to how an idea can be progressed further. 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 clinical lead, along with 2-3 other interested clinicians, methodologists such as a statistician and health economist. Input from patients and carers is encouraged at an early stage and often forms part of a preliminary pilot study 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 below.

Red: Not currently suitable for development through the Network 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 us to keep track of studies in development and identify needs and priorities. We currently have 17 studies at these different stages of our trial development system covering areas including eczema, acne, vitilgo, erosive lichen planus and epidermolysis bullosa. It takes on average three years for a study idea to progress to a fully funded RCT using the trial development system outlined above.

Network 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. Until 2009, funding for the core infrastructure staff was obtained from the Department of Health, the National Co-ordinating Centre for Research Capacity Development (NCC RCD). Due to significant changes in the clinical research infrastructure across the UK, this funding stream is no longer available and we have since had to seek alternative sources including contributions to Network infrastructure from research grants for our funded studies. In 2010 we were awarded a grant from the BAD to cover the costs of employing our Network Trials Development Manager for a further 3 years which has given stability to the UK DCTN and further strengthen our links with this organisation.

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

UK to have such excellent independent funding streams and support for clinical research available and hope that colleagues worldwide will benefit from such support in the future.

On-going and completed UK DCTN-led studies

It is highly unlikely that the studies listed below would ever have been carried out if it were not for the existence of the UK DCTN. This surely demonstrates the value of working together to provide answers to important clinical questions, whatever the clinical specialty.

BLISTER: This on-going study funded by a £829,000 grant from the NIHR HTA scheme is an RCT comparing the safety and effectiveness of doxycycline with prednisolone for the treatment of bullous pemphigoid (a rare blistering skin disease of the elderly). (104)

STOP GAP: This on-going study funded by a contribution from a £1.9 million NIHR Programme Grant is an RCT to test the hypothesis that ciclosporin is more effective than prednisolone for the systemic therapy of pyoderma gangrenosum (a rare ulcerative condition). (105)

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 PATCH II: The PATCH I and PATCH 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 (106). They have now closed to recruitment, with study results expected to be published at the end of 2011. The pilot study which helped informed the design of these studies has been published (1) along with an article outlining issues related to the study (2).

Network communications

As discussed earlier, our members are crucial to the success of the UK DCTN and so we feel it is important that we communicate with them on a regular basis to keep them informed of Network activities, new studies in development, funding successes etc. We do this using a number of methods which could easily be employed by any research network:

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

We have worked hard to raise the profile of the UK DCTN over the years and having exhibition stands at national dermatology meetings has served us well in this purpose. Branding has been achieved by having a strong, easily recognisable log as shown below in Figure 2. Representatives from the UK DCTN including our Chair, Steering Committee members and co-ordinating centre staff have spoken at local, national and international meetings about the Network and the importance of working collaboratively.

Figure 2 The UK DCTN logo

Building research capacity as part of a network

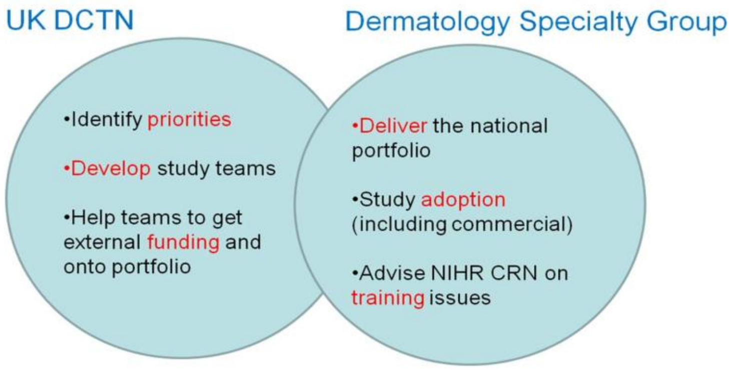
As an organisation we recognise the importance of helping to develop young clinicians early in their careers to become interested in research, which in turn will help to build a critical mass of research capacity. With this in mind, the UK DCTN SpR (Specialist Registrar) Fellowship Award scheme was instigated in 2007 and it has been a great success with increasing numbers of high quality applicants applying each year. The aim of this two year award is to develop skills in clinical trials and critical appraisal in year one, and then apply these learned skills in year two as the fellows become increasingly involved in the Network. You don't need a large amount of funds for projects such as this (we make 2-3 awards of £1500 each on an annual basis) and the award winners work with us for an average of one day per month. We have been greatly encouraged by the response to this scheme and have extended the format to include awards for the dermatology nursing and staff grade 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 'Best Health for Best Research' by the Department of Health in 2006 (ref 3) set out a five year plan for health research in England which has dramatically changed the clinical research landscape in this country. A key part of this has been the emergence of a new clinical research infrastructure in the form of the NIHR Clinical Research Network (CRN, 107). It 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 established to cover areas of clinical need 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 2008/9, 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.

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 (DSG). Also chaired by Prof Hywel Williams, 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 works well with 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 below.

Figure 3 The relationship between the UK DCTN and the Dermatology Speciality Group



Future perspective

There can be little doubt that the UK DCTN has worked well and is now a well established and respected organisation. Based on our success in the UK, the UK DCTN aims to work with international colleagues over the next 2-3 years to develop an International Federation of Dermatology Clinical Trials. Currently, there is no central organisation or place where dermatologists, interested in clinical trials over the world, can visit in order to find out about current activity or to get guidance on developing their own studies.

We are keen to hear from any organisations or individuals who would like to register an interest in such an organisation. Please contact us if you would like to be kept updated about the development of an International Federation of Dermatology Clinical Trials or send us your suggestions about developing this idea.

PLEASE CAN SOMEONE HELP WITH THIS BIT!! IT'S MEANT TO BE A SPECULATIVE VIEWPOINT ON HOW THINGS WILL HAVE CHANGED 5-10 YEARS FROM NOW!

Executive Summary (key bullet points)

- 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 and patients/carers is essential for a good research network steering committee
- Membership of a research network such be free and open for all interested parties to join
- 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
- Funding independent from the pharmaceutical industry is available for research networks and good links with relevant professional bodies may help with this

- Collaborative research networks work particularly well for studies of rare disorders
- Communication with network members by means such as newsletters and websites is vital
- Networks can be used to increase research capacity in their specialty
- Research networks need to ensure that they continue to develop alongside other relevant groups and alongside national and global research strategies

Abbreviations

BAD	British Association of Dermatologists
CEBD	Centre of Evidence Based Dermatology
CLRN	Comprehensive Local Research Network
CRN	Clinical Research Network
DSG	Dermatology Specialty Group
HTA	Health Technology Assessment
NIHR	National Institute for Health Research
RCT	Randomised Controlled Trial
RfPB	Research for Patient Benefit
SpR	Specialist Registrar
TGPP	Trial Generation and Prioritisation Panel
UK DCTN	UK Dermatology Clinical Trials Network

Financial and Competing Interests Disclosure

None to declare.

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2. Thomas, KS and UK Dermatology Clinical Trials Network's Patch Study Team. Studying a disease with no home-lessons in trial recruitment from the PATCH II study. Trials, 11, 22 (2010).

3. Department of Health. Best Research for Best Health Policy. Available at: www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4127127 (2006)

Website references

101 UK Dermatology Clinical Trials Network	www.ukdctn.org
102 Centre of Evidence Based Dermatology	www.nottingham.ac.uk/dermatology
103 Cochrane Skin Group	www.skin.cochrane.org
104 BLISTER trial	www.blistertrial.co.uk
105 STOP GAP trial	www.stopgaptrial.co.uk

106 PATCH trials www.patchtrial.co.uk

107 NIHR Clinical Research Network www.crncc.nihr.ac.uk

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