

UK Dermatology Clinical Trials Network

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ANNUAL REPORT 2018



Letter from the Chair

Writing these opening sentences for our Annual Report always makes me step back to think again about what the UK DCTN is for and whether there is still a need for us. The UK DCTN was formally set up in 2002 with the aim of “conducting high quality, independent, multi-centre clinical trials for the treatment or prevention of skin disease”. These words can sound a bit boring. Put another way, we are all about discovering how best to treat and prevent skin diseases for patient and public benefit in a way that will influence practice across the world. I like to mention patients and public a lot because it is so easy to lose sight of what we are about - especially when we end up getting into deep methodological discussions or if we get excited about getting our work published in a prestigious journal such as *The Lancet*. Publishing is important, but the value of medical research is nothing unless it is put into practice.



That word “independent” is also an important aspect of our work. There are some fantastic discoveries and new treatments coming from our industry colleagues, but industry will never invest in testing existing inexpensive treatments like we did in the BLISTER study. As you know, the BLISTER study found that starting treatment with doxycycline produced reasonable blister control in the short term when compared with oral steroids, whilst reducing severe and life threatening complications at one year. Were it not for you – our dermatology community, the UK DCTN and our NIHR funders, such an important study would never have been done.

Although our main aim is to develop trials that have been prioritised by patients and health care professionals, the UK DCTN has also played an increasing role in developing new leaders in clinical dermatology research through our Fellowship schemes and Trainee Network. Our trials have provided some methodological spin-offs and influenced better reporting in journals through those we have influenced along the way.

Randomised controlled trials are not going to go away – the methods may change slightly, but the basic principles of fair tests remain the same. The need for developing high quality trials in dermatology has never been greater. I hope you enjoy this annual report of our activities. We are unique, independent, democratic, devolved, inclusive and productive. Long live the UK DCTN – and remember it is your Network.

A handwritten signature in black ink, appearing to read 'Hywel Williams', written over a dotted line.

Hywel Williams
Professor of Dermato-Epidemiology

What is the UK DCTN?

Established by Professor Hywel Williams in 2002, the UK Dermatology Clinical Trials Network (UK DCTN) has driven a step change in applied dermatology research over the past decade. Securing over £15 million pounds in independent funding, the Network has expanded research capacity in the UK for large, multi-centre, national clinical trials that have resulted in a better evidence base for patient care in the NHS. The focus is on developing trials for which collaborative working is needed, such as rare/orphan diseases and trials of low-cost, existing treatments that are highly unlikely to be evaluated by the pharmaceutical industry.

With of over 950 multi-disciplinary members, the UK DCTN is co-ordinated from the Centre of Evidence Based Dermatology at the University of Nottingham. The Network has successfully delivered four multi-centre trials to date, with two currently in follow up and a further six on-going, in addition to a number of pilot and feasibility studies. Unique research capacity building and training initiatives outlined later in this report have expanded the capacity for dermatology research to be embedded routinely within clinical services, and have helped to develop research leaders of the future.



“The UK DCTN has helped my department in Hull and myself to participate in clinical trials which are pivotal in informing clinicians of evidence based practice which can then be incorporated in treatment protocols.”

Dr Shernaz Walton, Consultant Dermatologist, Hull and investigator on STOPGAP and BLISTER trials

“British Dermatology is very proud of the UK DCTN. It has brought hundreds of dermatologists and dozens of dermatology departments into active clinical research through its large multi-centre studies.”

Dr Nick Levell, Consultant Dermatologist and President of the British Association of Dermatologists, 2016-2018

Did you know?

It's FREE to join the UK DCTN! If you are interested in applied dermatology research as a health professional, patient or researcher you can join our Network free of charge and contribute to the development of important clinical trials to improve treatments for skin disease.

Trial Development

The following studies were presented to the Steering Group during the academic year 2017/2018. For further information about our trials in development please email us: ukdctn@nottingham.ac.uk

Study proposal	Lead Investigator	Status August '18
Hidradenitis Suppurativa (HS) - Outline proposal for a HTA Commissioned call on HS - What are the best management options for HS when first line treatments fail? (THESEUS)	Dr John Ingram, Cardiff	Awaiting outcome of funding application
Eczema - Does the addition of antiseptic baths to standard care improve control of atopic eczema compared with standard care alone?	Dr Jane Ravenscroft, Nottingham	In development
Impetigo - Does treatment with oral antibiotics result in faster time to resolution of impetigo, compared to treatment with topical antibiotics? / Does treatment with topical antibiotics result in faster time to resolution of mild localised impetigo, compared to treatment with topical antiseptics, in primary care?	Dr Nick Francis, Cardiff	On hold
Keratoacanthoma (KA) - Can we manage KA better? Can we defer surgery to improve outcomes?	Dr Saleem Taibjee, Dorset	In development
Eczema - Is the effectiveness of methotrexate as good as dupilumab in the treatment of moderate to severe atopic eczema?	Dr Catherine Smith, London	In development

Did you know?

Anyone can submit a research idea to the UK DCTN! All members can suggest an idea for a clinical trial but it is recommended to have a local research team to support you. Guidance is available on our website (www.ukdctn.org) or call the team for advice and information: Tel. 0115 8468625

Research Awards

Annual themed research call 2017 – Skin health in older people

Our themed research call is an open competition with an award of up to £10k. In order to recognise the implications of an increasingly aging population, our 2017 theme focused on skin health for older people.

SCART (Skin cancer) - The research award for 2017 went to a feasibility project to develop a randomised controlled trial to look at high risk primary squamous cell carcinoma (SCC) treated by surgical excision with or without adjuvant radiation therapy. The incidence of SCC in older people has increased considerably in the last ten years. This work will ensure the trial design for SCART is effective and relevant – the first RCT to address treatment of high-risk SCC. The team includes Dr C Harwood, Dr R Martin and Dr A Rembielak.

Pump priming awards

A limited amount of funds is available for members who are developing studies through the UK DCTN. Two awards were made in 2017/2018.

OASIS (wound infection/skin cancer) – An observational study to investigate surgical site infection in ulcerated skin cancers. In 2017 we were very pleased to award £10k to a study looking at the feasibility of running a larger study to see if prophylactic antibiotics reduce the risk of wound infection following excision of ulcerated skin cancers. The team aim to recruit 311 patients from three sites – Cardiff, Oxford and Birmingham. This is being led by former UK DCTN SpR Fellow Dr Rachel Abbott, along with Dr Aaron Wernham.

Hyperhidrosis Priority Setting Partnership - Hyperhidrosis is a common skin condition characterised by abnormal levels of sweating, and is known to affect 1-3% of the population. It can cause both physical problems and psychological distress, and significantly affect quality of life. Despite its prevalence hyperhidrosis is relatively under-researched compared with other skin conditions. Colleagues from Leicester approached us to fund a Priority Setting Partnership on this topic. We agreed that a James Lind Alliance research priority setting exercise would benefit all those involved in hyperhidrosis management. We awarded the project team £10k to undertake this project, to be completed by the end of 2018.

Did you know?

If you do not have a full trial design worked out, you can still submit your research idea via our early outline proposal form. Once confirmed as eligible by the UK DCTN team, it can go straight to our Steering Group for discussion.

Trial Generation & Prioritisation Panel

New Panel Chair – Dr Rubeta Matin

A new Chair was appointed earlier this year to lead the UK DCTN Trial Generation & Prioritisation Panel (TGPP). Rubeta (pictured right) is a Consultant Dermatologist based in Oxford, with an academic interest in cutaneous oncology and skin disease in the immunosuppressed.

The panel is a group of UK DCTN members who review the research submissions/proposals put to the Network before they go forward to the UK DCTN Steering Group. They provide valued feedback to research teams in order to help refine their research ideas into workable study proposals. Rubeta has been involved in the UK DCTN since she was a successful recipient of the SpR Fellowship award in 2010.



Since then Rubeta has been:

- Principal Investigator in Oxford for the SPOT study in 2012 - prevention of squamous cell carcinoma [SCC] in organ transplant recipients.
- Chief Investigator and Trainee Group mentor in 2013 for a 10-year retrospective review of outcomes for dermatofibrosarcoma protuberans (DFSP)
- Mentor for a UK DCTN Trainee Group in 2015 and co-investigator for the subsequent OASIS study (Observational study to investigate surgical site infection in ulcerated skin cancers)
- Co-applicant on the UK DCTN-funded feasibility project to develop the SCART RCT (High risk primary SCC treated by surgical excision with or without adjuvant radiation therapy).

PANEL MEMBERS

- Rubeta Matin
- Claudia de Giovanni
- Antonia Lloyd-Lavery
- Jonathan Batchelor
- Abby Macbeth
- Esther Burden-Teh
- Fiona Collier
- Rakesh Patalay
- Alana Durack
- Kathy Radley
- Vishnu Madhok
- Lucy Bradshaw
- Rachel Abbott

Did you know?

If you are unlikely to submit a research proposal yourself, you can still contribute to the work of the UK DCTN. Members can assist with clinical trials in several ways: completing feasibility surveys about study proposals, joining a trial development group, becoming an investigator to recruit patients to a study... it's up to you!

Priority Setting Partnerships

A Priority Setting Partnership (PSP) is a collaboration between healthcare professionals, patients and their carers/relatives to prioritise research questions for a specific condition. The central aim is to encourage research that answers questions that are important to ALL groups. The James Lind Alliance provide the framework and guidance to conduct a PSP. The end-point of the priority setting exercise is to produce a final list (often a top 10) of agreed research questions that are then publicised widely and sent to potential funders. The results of PSPs are used by funders such as the National Institute for Health (NIHR), to prioritise research questions for funding calls and by other groups such as Cochrane Skin to prioritise and conduct systematic reviews.

There have been eight skin-related PSPs completed in the UK since 2010 (eczema treatments, vitiligo, hidradenitis suppurativa (HS), acne, alopecia, cellulitis, lichen sclerosus and psoriasis), which is more than in any other clinical specialty. The UK DCTN have been involved in most of these, funding three of them and actively taking part in project steering committees and workshops. These PSPs have significantly influenced the research agenda within the dermatology community, with a number of funded studies instigated by a PSP Top Ten question.

PSP topic	What happened next...
Hidradenitis Suppurativa (HS)	The HS PSP resulted in a NIHR research call on HS. A joint Nottingham/Cardiff team have applied with their study THESEUS, to develop a series of interlinked studies, including - What are the best management options for hidradenitis suppurativa when first line treatments fail?
Vitiligo	Hi-Light vitiligo study was developed in response to an NIHR commissioned call following the vitiligo PSP
Acne	SAFA study (Spironolactone for Adult Female Acne) resulted from a similar NIHR initiative after the acne PSP.
Cellulitis	The cellulitis PSP has led to a mixed methods study looking at attitudes towards the prevention of recurrence in people with leg cellulitis and systematic reviews on outcome measures used for clinical trials of cellulitis, and barriers and facilitators to diagnosis of cellulitis

Did you know?

The UK DCTN continues to be significantly involved in dermatology PSPs. We have been involved in three during 2017/2018 - lichen sclerosus (Nottingham University), psoriasis (Manchester University) and hyperhidrosis (De Montfort University, Leicester).

Ongoing Clinical Trials

The following studies have all been developed with input from the UK DCTN. They are each at different stages of progress (recruiting/follow up). Please refer to their individual websites for more detailed information.



HI- Light - Home interventions and light therapy for vitiligo

This RCT is assessing hand-held narrowband UV devices, both alone and in combination with topical steroids, for early focal vitiligo. It has recruited to target, with 517 patients in follow up.

Lead investigator: Dr Jonathan Batchelor **Website:** vitiligostudy.org.uk

Partner: Nottingham Clinical Trials Unit

Funded by NIHR Health Technology Assessment



SAFA - Spironolactone for Adult Female Acne

An RCT investigating the effectiveness of spironolactone for moderate to severe acne in adult women. This placebo-controlled study will initially recruit from five secondary care centres, with recruitment due to start in 2019.

Lead investigators: Dr Miriam Santer & Dr Alison Layton

Contact: f.chinnery@soton.ac.uk (*Miriam and Trial Manager, Fay pictured left*)

Partner: Southampton Clinical Trials Unit

Funded by NIHR Health Technology Assessment



HEALS - Wound healing after skin cancer surgery

Heals is a cohort study, originating from a Trainee Group project. It is looking at healing after excisional surgery for skin cancer on the lower leg. The study recruited to target by end of 2017, with 57 participants in 6 month follow up.

Lead investigator: Professor Jane Nixon **Contact:** ctru-heals@leeds.ac.uk

Partner: Leeds Institute of Clinical Trials Research

Funded by UK DCTN and Leeds CTRU



Apricot - Anakinra for Pustular psoriasis

Comparing the IL-1 receptor antagonist anakinra with placebo for the treatment of pustular psoriasis (specifically palmo-plantar pustulosis). The team aim to recruit 64 patients with this rare form of psoriasis from 15 sites in the UK.

Lead investigator: Dr Catherine Smith, London.

Website: apricot-trial.com

Partner: St Johns Institute of Dermatology

Funded by NIHR Efficacy & Mechanism Evaluation



Funded by NIHR Health Technology Assessment

ALPHA - Hand Eczema

Comparing the effectiveness of alitretinoin and psoralen and UVA treatment (PUVA) for severe chronic hand eczema. The study aims to recruit 500 adult participants. A one year extension to the recruitment period has been granted.

Lead investigator: Dr M Wittmann, Leeds **Website:** medhealth.leeds.ac.uk/info/423/skin/
Partner: Leeds Institute of Clinical Trials Research



Funded by NIHR Health Technology & Assessment

BEEP - Eczema Prevention

An RCT to determine whether application of emollient from birth can prevent eczema in high risk children. The study recruited to target - 1,300 babies in follow up for two years.

Lead investigator: Prof. Hywel Williams, Nottingham. **Website:** beepstudy.org
Partner: Nottingham Clinical Trials Unit



Funded by NIHR Health Technology Assessment

BEE - Eczema in children - Which of the four most commonly prescribed emollients is the best for the treatment of children with eczema? This trial aims to recruit 520 children aged from 6 months to 12 years from GP surgeries at three sites across the UK.

Lead investigator: Dr Matthew Ridd, Bristol. **Website:** bristol.ac.uk/bee-study
Partner: Centre for Academic Primary Care Bristol



Funded by NIHR Efficacy & Mechanism Evaluation

Treat - Eczema in children - Assessing the efficacy and safety of methotrexate vs ciclosporin for severe atopic eczema in children. This study aims to recruit 102 participants aged 2 to 16 years. The team has been granted a recruitment extension until end Nov 2018.

Lead investigator: Prof. Carsten Flohr, London. **Website:** treat-trial.org.uk
Partner: Medicines for Children CTU Liverpool



Funded by NIHR School for Primary Care Research

TEST - Eczema in children - What is the value of food allergy testing in primary care in infants with early onset eczema? Large feasibility study to evaluate the usefulness of food allergy testing and advice in treating eczema in children. 80 children aged between 3 months and 5 years with eczema to be recruited from GP surgeries.

Lead investigator: Dr M Ridd, Bristol. **Website:** www.bris.ac.uk/eczema-allergy-study
Partner: Centre for Academic Primary Care, Bristol

Fellowships and Trainee Groups

The Network has invested in developing the research leaders of the future in dermatology via innovative schemes including our annual Fellowship awards and Research Trainee Groups.

Research Fellowships

The UK DCTN Fellowships are open to applications from Dermatology Specialist Registrars (SpRs), Staff and Associate Specialists (SAs), General Practitioners (GPs) and Nurses. These awards are made on annual basis and Fellows can obtain training and experience in trial development, ongoing clinical trials and critical appraisal skills over a 2 or 3 year period. The 2017 Award winners were:

- David Veitch, Leicester (SpR)
- Sharleen Hill, London (SpR)
- Douglas Maslin, Cambridge (SpR)
- Mitesh Patel, Nottingham (GP)
- Tessa Garland, Liverpool (Nurse)

Fellowship profile - Emma Le Roux, GP Fellow 2016-2019

Emma is a practising mid-career GP with an interest in Dermatology. The Fellowship award in 2016, provided her with new skills in critical appraisal of research studies and knowledge of the processes and collaborations that are needed in national dermatological trials. The fellowship inspired her to pursue a research career alongside her clinical work. Emma has since secured an NIHR In-Practice Fellowship at the Centre for Academic Primary Care, Bristol University and has been recruited by the Royal College of General Practitioners (RCGP) to be 'Clinical Champion for Dermatology'. The aim of this role is to raise the profile of Dermatology in Primary Care, and to develop a programme of practical support and educational resources to frontline healthcare professionals in managing patients with skin problems. This is a brilliant initiative by the RCGP to raise the profile of Dermatology in primary care. Emma is certain that her participation in the UK DCTN fellowship has helped her achieve this new role.



What they said...

"I just wanted to say a huge thank you for including me on the UK DCTN fellowship scheme. I have really enjoyed it and have learned so much, over and above what I could have without the fellowship. It is hard to summarise without being verbose, but I feel that I have had such encouragement and am far more likely to pursue a clinical academic career having taken this path."

Dr Alison Sears, UK DCTN SpR Fellow 2015-2017

Trainee Groups – Research training for Dermatology Trainees

UK DCTN Trainee Groups are an exciting opportunity for Dermatologists at the early stages of their career to become actively engaged in research. The programme aims to help Dermatology Trainees reach their research competencies and develop skills in critical appraisal and clinical research methodology. The scheme requires participants to work in small groups under the guidance of experienced mentors, for a minimum of four months, to develop clinical research ideas. This is complemented by a training day on critical appraisal and clinical research skills. Here the trainee groups present their ideas and are encouraged to pursue their project further, and if possible, publish their work. This training scheme is held every 2-3 years.

UK DCTN Trainee Groups 2018	
Does cleansing with 4% chlorhexidine wash for three consecutive days prior to, or following an excision with primary closure, reduce the incidence of post-operative surgical site infection (SSI) compared to placebo, with a follow up period of 6 weeks post-procedure?	Mentors: Dr Claudia DeGiovanni, Dr Abby Macbeth, Dr Susannah George Group: Dr Angela Alani, Dr Ronan Brennan, Dr Louise Macdonald, Dr Laura Burfield, Dr Inge Kreuser-Genis, Dr Victoria Wray, Dr Lorne Mitchell
In patients who have had skin surgery, are superficial absorbable sutures equivalent to superficial non-absorbable sutures with regards to patient and physician reported outcomes of the surgical scar, frequency of post operative complications and health economics?	Mentors: Dr Jonathan Batchelor, Dr Rachel Abbott, Dr Agustin Martin-Clavijo Group: Dr Padma Mohandas, Dr David Veitch, Dr Heather Whitehouse, Dr Connor Broderick
Does the use of oral nicotinamide result in a reduction in the incidence of squamous cell carcinoma (SCC) in immunosuppressed solid-organ transplant recipients, compared with oral acitretin or placebo?	Mentors: Dr Rakesh Patalay, Dr Rubeta Matin, Dr Alana Durack Group: Dr Charlotte Gollins, Dr Sabrina Khan, Dr Navreet Paul, Dr Beebee Meeajun, Dr Aardash Shah, Dr Khushboo Sinha
Petroleum jelly vs. none applied to excision wounds after dressing removal post-op.	Mentors: Dr John Ingram, Dr Emma Pynn, Dr Prativa Jayaskera Group: Dr Alistair Brown, Dr Livia Soriano, Dr Lloyd Steele, Dr Lucy Webber, Dr Fangyi Xie, Dr Stela Ziaj

Did you know?

The HEALs study (page 8) and OASIS trial (page 5) have both arisen from the work of a UK DCTN Trainee Group. Remember, all research ideas originate from the membership (you!)

Patient Involvement

We are always keen to have a strong patient presence on the Steering Group and throughout the membership as a whole. We were delighted to have two new patient representatives join the UK DCTN Steering Group this year, Tim Burton and Patricia Fairbrother. We talked to Patricia about her experiences in research.

“My working background has always been in healthcare, mostly managing surgical practices. I have a history of skin cancer, primarily basal cell carcinomas (BCCs), all having required surgery, over several years. I also have a history of breast cancer, and it was following that particular diagnosis that I originally became an enthusiast in the developing role of patients in advocacy.



I joined a national cancer charity as a member of their newly formed advocacy steering group. Subsequently, after having two more BCCs I looked for areas I could use my advocacy skills in skin. I felt I had a lot to bring to dermatology because breast cancer support has a very strong patient representative focus. I have been a patient representative for the past four years on the regional clinical advisory group for skin cancer, managed through the East Midlands Clinical Network, plus a consumer representative for the clinical studies group for skin at the National Cancer Research Institute. This role has given me a chance to become involved in the management of a number of skin cancer clinical trials.

I am a trustee of the patient led cancer charity, Independent Cancer Patients Voice, specialising in patients partnering with researchers, providing comment and opinion on study applications. This charity has a unique focus in that it provides patient experience in an unfiltered way and offers regular training opportunities. Most members are involved with the designing and running of at least one clinical trial. I am also involved in skin cancer guidelines for the British Association of Dermatologists.

I joined the Centre of Evidence Based Dermatology Patient Panel approximately two years ago, and found the people I met quite inspirational and hugely knowledgeable. This led to my invitation to be a patient representative on the Steering Group of the UK Dermatology Clinical Trials Network. I look forward to a long association with the Network.”

Did you know?

We really value the contribution that patients/ service users can make to our research. We need their experience and knowledge to get the study designs right. Also, by getting involved they can learn new skills and gain new experiences within the research community.

Evidence Based Update Meeting – Acne & Hidradenitis Suppurativa

In 2018 our Annual Evidence Based Update Meeting focused on acne and hidradenitis suppurativa (HS). We had a magnificent panel of experts from the UK and Europe, who spoke passionately about their experiences of treating these distressing conditions, and provided information on the latest research and treatment guidelines. The meeting included exhibitors from the HS Trust and the British Association of Skin Camouflage.

This event has CPD accreditation and has a loyal following, with dermatologists attending each and every year. The next evidence based update event will be on hair disorders on 15 May 2019.

The 2018 programme included the following:

- Core outcome measures for HS
- What do patients with HS want?
- HS Guidelines from the BAD
- Surgery for HS
- Surgery in HS: What role should it have?
- Maintenance of acne treatment
- Laser therapies for acne/ acne scarring
- Spironolactone for acne in adult women



British Association of Skin Camouflage

Professor Gregor Jemec, Denmark
 Ceri Harris, UK
 Dr John Ingram, UK
 Professor Falk Bechara, Germany
 Dr Tim Goodacre, UK
 Dr Corinna Dressler, Germany
 Dr Daron Seukeran, UK
 Dr Alison Layton, UK

What they said...

“Excellent meeting - excellent presentations, plus time to discuss difficult cases and where evidence is lacking.”

“Very interesting and comprehensive discussion on management of acne and HS, including from patient's perspective.”

“An enjoyable, practical day of learning.”

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The UK DCTN Co-ordinating Centre is based at the Centre of Evidence Based Dermatology, University of Nottingham. The Network is a registered charity (Charity No: 1115745) and an affiliate group of the British Association of Dermatologists.

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