Getting involved in relevant, rewarding and

Our Experience at Brighton

Our department first became involved in National Institute for Health Research (NIHR) research with the PATCH II study (Prophylactic Antibiotics for the Treatment of Cellulitis at Home) in 2007. Recruitment was heavily dependent on the SpRs as we didn't have research nurse time and was therefore disappointing. In 2010/11 we recruited 8 patients to NIHR studies. In March 2011 we secured 1PA consultant time (for comprehensive local research network lead) and 0.2 WTE generic research nurse support for Brighton with R&D support to increase this time as our portfolio grew. Recruitment to studies increased to 44 in 2011-12. We now recruit to 4 dermatology studies (BADBIR (British Association of Dermatologists Biologic Interventions Register), BLISTER (Bullous Pemphigoid Steroids and Tetracyclines Study), STOPGAP (Study of Treatments for Pyoderma Gangrenosum Patients) and Genetics in Acne) and 1 cancer study (Melanoma Lifestyle). We were in the top 5 recruiting sites to the control arm of BADBIR (2011) and we received awards from the STOPGAP study for most enthusiastic Principle Investigator and site (2012). Based on recruitment, we secured funding for 2 years for a dermatology research nurse 0.8WTE who joined our department in April 2012. We intend to recruit to 2 new NIHR portfolio studies and our first commercial study in 2012/13.

The NIHR and CLRN

Research has been targeted by the government as a priority for the NHS. The role of the National Institute for Health Research (NIHR) is to create a research health system through development of expertise, infrastructure systems and funding/commissioning research. NIHR portfolio studies are clinical, national/international, peer reviewed research studies that have been adopted onto the specialty group portfolio.

The comprehensive local research network (CLRN) has been set up to develop research infrastructure based on local need and facilitate the conduct of clinical research. It encompasses a number of specialties, including dermatology. There are 25 CLRNs in England http://www.crncc.nihr.ac.uk/about_us/ccrn. Your CLRN can support you to recruit to NIHR portfolio studies. This can be through access to research nurse time, funding research nurse/doctor time, or admin support etc.

Why get involved in NIHR research?

Being a recruiting site for NIHR research has many advantages. Trusts are signed up to research and are financially rewarded for recruitment to national studies. The dermatology portfolio is diverse with observational and interventional studies covering many dermatological conditions. This diversity allows you to develop a portfolio of studies that matches your department's skills and expertise. If you have a specialist interest you could be an invaluable recruiting site to a study in your clinical field. Recruiting to NIHR studies allows involvement in research without having to complete the ethics process or daunting grant applications and it shows you how to conduct high quality research should you wish to take this step in the future. It allows involvement in research with resources that you may not have easy access to e.g. genetic testing (Genetics in Acne) and some studies challenge our prejudices (STOPGAP/ BLISTER). Ultimately, this research will make a difference to patient care for the future and it is fundamentally important to us all.

Overcoming barriers to getting involved

In the current economic climate, pressure on consultant time has never been greater. Good quality research does require time but this does not necessarily have to be consultant time. Some studies rely more on research nurses (RN) than doctors. For example, BADBIR requires

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clinicians to identify potentially eligible patients, but most of the work can be carried out by a research nurse (RN). Alternatively, if you wish to be more involved, the CLRN can fund doctors' time (junior and senior) to recruit to NIHR research.

Lack of experience in research can be overcome. Good Clinical Practice (GCP) training is the only absolute requirement to be an investigator. R&D departments offer this training locally and there is an on-line NIHR GCP course, which is now available, see http://www.crncc.nihr.ac.uk/training/courses/gcp/gcp_courses/gcp_online.htm for details. Anyone recruiting into any of the NIHR portfolio studies is eligible to attend both the taught and on-line course free of charge. GCP training needs to be refreshed every 2 years. All NIHR research studies have strict protocols and clear case report forms (CRF) to complete making the research process straightforward. All studies have an induction at which point the study and paperwork are explained in detail. The study monitors can always be approached with any queries that arise during the study.

Access to research nurse (RN) time is the key to successful involvement in NIHR research in my opinion. Speak to your R&D manager about accessing generic RN time. An experienced generic RN can be invaluable in

NIHR Research - relatively easy

developing research awareness and skills within your department but they won't have specific dermatology skills e.g. be able to perform PASI score. You may be able to secure funding for a dermatology research nurse through your CLRN though you may wish to consider how many studies you need to be involved in to maintain that role, and how to cover leave.

Identifying patients can be quite straightforward. Some studies allow retrospective recruitment e.g. Genetics in Acne, BADBIR, BSTOP (Pharmacogentic Markers of Systemic Treatment Outcomes in Patients with Severe Psoriasis) so if you keep databases these patients can be easily identified. Clinics may already be set up that could be perfect for recruiting e.g. biologics clinics can be used to recruit patients to BADBIR and BSTOP.

How to get started

Identify individuals in your department who are willing to be investigators. Investigators can be junior or senior but you need more than 1 investigator on each study to cover leave. All investigators need GCP training. Try to gain the support of your whole department to identify potentially eligible patients even if they don't wish to become investigators themselves.

Speak with your R&D manager to secure RN time. You may be able to negotiate an arrangement to increase RN support as your portfolio grows. Try to ensure there is cover for your RN during times of leave. If R&D cannot support you, consider applying to your local CLRN for funding for a RN.

Contact your CLRN local lead (http://www.crncc.nihr.ac.uk/about_us/ccrn/specialty/dermatology/contact_us/) for advice and contact details for suitable studies that are currently open to new sites and advise them of any particular clinical areas of interest that your team could recruit to.

Once a suitable study has been identified, contact R&D as you will need approval before you can start recruiting. You will need to complete a feasibility questionnaire for most studies to confirm the number of patients you expect to recruit. Set realistic targets. Consider how many potentially eligible patients you may see in a month. Be aware that not all eligible patients will wish to enter studies so set your target below this number.

The principle investigating site also needs to complete paperwork to include you as a recruiting site. This process is likely to take a few weeks. Once complete, an induction meeting will be set up with the principle investigating site to go through the study in detail. This may be done by telephone or the monitor may visit your site. You will receive a site file with all relevant information on the study.

Recruiting

It is important to engage all your clinical staff to identify potentially eligible patients for studies. Mention the studies at departmental meetings, GP teaching sessions, grand rounds (especially if conditions may be seen in other departments e.g. STOPGAP). Have posters with inclusion criteria and patient information leaflets in clinics rooms. Motivate your team with frequent updates on recruitment progress. Provide trainees with certificate of patients recruited for their portfolio. Attend your local dermatology research meetings to gain support and tips on how to maximise your recruitment.

If recruiting is not going to plan

In the first instance meet with your RN to discuss barriers to recruitment and to identify potential solutions. Have you exhausted all databases that could identify patients? Are there any other clinics that might be better for recruiting? If you are having problems recruiting it is unlikely that you are alone so discuss the study with your CLRN lead and the trial monitor as they may have come across solutions from other sites. Attending your local dermatology meeting may also identify successful recruiting strategies. If funding is an issue (RN time, doctor time, admin), the local CLRN may be able to help. If your initial target was too optimistic this can be altered.

Local Dermatology Meetings

These regular meetings are organised by your local CLRN lead and are valuable forums to learn about the national Dermatology Specialty Group (DSG) meetings and the CLRN. New studies are discussed and barriers to recruitment and successful strategies can be shared in a supportive environment.

Conclusions

Involvement in NIHR research is an enjoyable and rewarding adjunct to clinical care and it is not as daunting or time consuming as may be feared. It is beneficial for your department, Trust and patients. There is plenty of support available to help you get started and there has never been a better time to get involved.

Studies to make a difference to:

BADBIR (British Association of Dermatologists Biologic Interventions Register) Study ID 8090

Genetics in Acne Study ID 5793

Identification of Susceptibility Genes for Eczema and Food Allergy (children) Study ID 10226

Genetic Analyses of Eczema Subtypes (adults) Study ID 6218

BSTOP Pharmacogentic Markers of Systemic Treatment Outcomes in Patients with Severe Psoriasis Study ID 10646

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