

Network support helps new relationships blossom

The Clinical Research Network is expanding, with the number of research sites in the NHS continuing to grow. This is positive news for society, with more patients getting the opportunity to access leading-edge techniques and treatments, and it's also of huge benefit to the Life-science Industry. With a broader range of locations to recruit from, Industry can reduce its reliance on established partners and use the Network's match-making skills to couple them with new sites that can set-up on time and recruit the patients they need.

A fantastic example of the work being done by the Clinical Research Network to support research can be found in Blackburn. In summer 2009 a project called the North West Exemplar Programme was initiated to demonstrate that the NHS could compete with the best countries in Europe in the performance of commercial clinical research.

One of the studies that took part in the Exemplar Programme was a Phase II trial for patients with mild-to-moderate Alzheimer's disease, with a site based at the Hillview Clinical Trials Unit (Lancashire Care NHS Foundation Trust) in Blackburn. Only two years previously Hillview had no track record for clinical research yet, remarkably, the site succeeded in delivering the study's first patient globally and met its recruitment target ahead of schedule.

Angela Parker, Assistant Manager for North West Dementias and Neurodegenerative Diseases Research Network (DeNDRoN) believes a number of factors put Hillview in a position to compete with the rest of the world in study set-up:

"Firstly, Hillview had an enthusiastic and driven research lead. Dr Iracema Leroi is the Consultant Psychiatrist in Old Age at Lancashire Care NHS Foundation Trust and has dedicated research time within her job plan to work on clinical trials and research. Additionally, the clinic teams at Hillview have been very supportive of our endeavours to embed research within their service and we have had excellent provision of support services, including imaging, pharmacy and cardiology, from East Lancashire Hospitals NHS Trust."

The study was the fifth commercial trial to be placed at Hillview and Dr Leroi is in no doubt that DeNDRoN has been key to the development of the unit:

Front-loading. A full Network research team supported Hillview Clinical Trials Unit during study start-up.

Front row: Kerry Ward, Marianne Hare, Jenny Smith. Back row: Janice Birt, Nichola Verstraelen and Sarah Anderson



"I have a single research assistant, but other than that all admin work is carried out by DeNDRoN Clinical Studies Officers (CSOs) who are based in our offices and have a full-time presence in our work. Because the Network have a mobile team of researchers and CSOs, we also benefit from the fact that if someone is ill, they can ask another member of their team to step in and provide support.

"Another benefit is that Network nurses operate throughout Lancashire and as a result we can cast our net wide and recruit from across the region. If we were independent of the Network we would simply not be able to do this and I would not be in a position to recruit patients as I would not have the staff to carry out study set-up."

As with any commercial trial on the Clinical Research Network Portfolio, the study was supported by a lead Comprehensive Local Research Network, in this case Cumbria and Lancashire. Jill Martin, Research Management and Governance Manager for Cumbria and Lancashire, led the successful completion of global governance checks:

"It's my role to provide a central point of contact for everyone involved in the set-up of the study" explains Jill. "I maintain an overview of the process, synchronise activity and help study partners overcome problems should they arise."

Identifying problems early and solving them quickly is much easier if the Network, site and sponsor maintain open lines of communication. Jill feels a set of strong

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Nurturing new sites. Research community benefits from Network match-making

relationships between the study partners supported this dynamic:

"No set-up is seamless, but the study was a prime example of partners addressing issues as they arose, which led to speedy resolutions. This made set-up simpler and paved the way for the study's recruitment successes."

With Dr Leroi providing leadership for research at Hillview, combined with the support of clinic teams, the Clinical Research Network and a collaborative sponsor, the study had every chance to succeed. But a crucial factor in its performance, explains Network Manager Lynne Owen, was the decision of North West DeNDRoN to change the way they supported set-up and delivery:

"Although our Network was stronger, we found the way we supported studies was staying the same. For this study we made a decision to take advantage of our increased capacity and top-load our resources. Essentially this meant supplementing our team at Hillview to create momentum during set-up, screening and recruitment. Hillview already had a lead research nurse, a research nurse and a CSO from the Network, but we provided two more research nurses to support their work and Angie Parker to oversee the project."

As we know, this change in approach was a resounding success, with study performance outstripping expectations. Not only did Hillview secure its target of 12 patients ahead of schedule, but when recruitment closed before the rest of the UK on 12 July 2010, the site had recruited 17 patients.

The study demonstrated that the growth of the Clinical Research Network is helping to improve the performance of clinical research

within the NHS. By placing a full Network research team at Hillview at study start-up, North West DeNDRoN established early momentum and put the site in a position to succeed. In the short-term, this was of benefit to the sponsor and the Alzheimer's patients at Hillview, but in the future Lynne Owen believes it offers further development opportunities for the Network:

"The benefit of this technique is that someone like Dr Leroi will be able to start recruiting her own team. She's planning to employ a clinical trials manager soon, which will make her more independent. We will work with the manager to make sure they have access to the same knowledge and understanding as ourselves, but in the long term, Dr Leroi will develop an independent unit and we can move on to another centre and fully engage them in the Network and its processes.

"Ultimately, even though we're talking about this process in terms of a business model, it is all about the patients. We want people who work with patients to care about them. Sometimes in our drive to meet deadlines, we lose sight of this, but patients are the focus of the Dementias and Neurodegenerative Diseases Research Network and remain at the heart of our work."

For more information about the Exemplar Programme go online and visit supportmystudy.nihr.ac.uk

More info about this article:
daniel.spiers@nihr.ac.uk

www.dendron.org.uk