When approached by Lilly to explore the feasibility of running an observational study in the UK, DeNDRoN knew they were faced with a challenge. Not only was this a relatively new therapeutic area for Lilly, with whom DeNDRoN had not previously worked, but the recruitment target was also very ambitious.

Judith Headley, Industry Portfolio Manager for DeNDRoN, describes her initial thoughts on the study:

“We knew that the GERAS study, which looked into the resource use and cost of Alzheimer’s disease, would be ideal to run in the Network. However, based on our in-depth knowledge of patient populations, we were concerned that the original projected patient target of 750 was unrealistic.

“So as well as seeking interest from our Local Research Networks we asked the Comprehensive Clinical Research Network if they could help. During this early stage we shared our concerns with Lilly and the target was reduced twice, resulting in a minimum target of 360 and an upper target of 600.”

DeNDRoN received 33 expressions of interest from sites across the UK, 24 of which were selected to run the study by Lilly. This figure included five sites led by principal investigators who’d not previously been involved in commercial research, one of which was Dr Jenny McCleery, Principal Investigator at a site in Thames Valley. Commenting on her experience, she said:

“Prior to my involvement I had presumed clinical studies involved a lot of bureaucracy and form filling. However, this wasn’t the case. DeNDRoN guided me through the process and made many of the necessary arrangements. I was able to delegate trial tasks feeling completely confident that the staff were well trained to carry them out.”

Dr McCleery’s site recruited the highest number of patients in the UK and she even extended her target twice due to the hard

**Networking for success**

By drawing on established, new and cross-Network relationships, DeNDRoN achieved its highest recruitment for a commercial study to date and suitably impressed a commercial sponsor to boot.

**Escalating costs.** Experts warn that the cost of Alzheimer’s and other dementias will soar as life expectancy increases.
work of the research nurse who supported her. Dr McCleery, continues:

“It was a very positive experience, so much so that I’ve since started another study with DeNDRoN.”

The GERAS study involved visiting patients diagnosed with Alzheimer’s disease to undertake assessments with them and their carers four times over an 18-month period.

“It was a very positive experience, so much so that I’ve since started another study with DeNDRoN”

June Warden, Clinical Studies Officer for the Kent and Medway Comprehensive Local Research Network, who supported the study at a site in Ramsgate, explains how she came to be involved:

“My Industry Manager, Anna Plumpton-Sidders, approached me about the GERAS study and I was keen to get involved, especially as I’d not had an opportunity to work with this patient group before. Anna and I met with Dr Lucy Elias, from the Thanet Community Mental Health Team for Older People, who was new to commercial research, to explain how the Network could support the study. We advised her on what the Comprehensive Local Research Network could provide and Dr Elias identified individuals from her team that she wanted to involve, namely a specialist registrar, two mental health nurses and a health care assistant.

“Dr Elias and her team identified potential participants and, after they had introduced the study, I talked them through the process in more detail. Once one of the doctors had obtained consent, two members of the study team visited the patients and carers in their own homes to undertake the assessments.”

Throughout the study June was responsible for organising the patient visits, completing the study documentation, gaining the necessary approvals and managing the recruitment data. To conduct the baseline and follow-up visits June supported members of Dr Elias’ team, guiding them through the process, as they weren’t familiar with research either.

Commenting on her experience June said:

“I hadn’t worked with dementia patients before the trial and found it to be a privilege. Being involved in the study introduced me to the condition and meant I was able to learn about it first hand, from the patients, and from their carers. I thoroughly enjoyed being able to share my knowledge and experience of research with people who were new to this field, helping to build a team that can approach research confidently in the future.”

The study recruited on time, all of the new DeNDRoN principal investigators recruited above target, and, with 541 participants enrolled in total, the study closely approached the upper target of 600.

Understandably, Lilly was pleased with DeNDRoN’s support throughout the planning and execution of the study. Lilly’s Clinical Development Consultant, Annabelle Hickman, had these words of praise for DeNDRoN:

“There was a feeling of positive partnership with DeNDRoN from the start. Network managers were proactive in highlighting potential study challenges as well as suggesting possible solutions which was extremely valuable. We were able to address the feedback and implement some Network ideas which enabled the study start-up and enrolment to run more smoothly.”

“The study team are delighted with the UK performance. I believe this study demonstrates the great things that can be achieved with solid upfront planning, a positive attitude, motivation and effective partnering between sponsor, Network and sites. I’m in no doubt DeNDRoN played a critical role in driving delivery.”

More info about this article:

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