

Dementias & Neurodegenerative Diseases Research Network

Collaborations with industry

This factsheet focuses on how DeNDRoN works with commercial partners. For information about how DeNDRoN supports non-commercial studies, please visit www.dendron.org.uk. For information about getting help to develop or to deliver research, please see the factsheets 'Supporting the development of clinical research' and 'Supporting the delivery of clinical research'

What is DeNDRoN?

The Dementias & Neurodegenerative Diseases Research Network (DeNDRoN) has been established to provide a performance-managed research infrastructure within the NHS. It supports both investigator-initiated and industry-sponsored clinical trials and other well-designed studies. This focuses upon a streamlined system to support site identification, feasibility, site set-up, timely trial recruitment and delivery. The objective is to ensure integration of new best practice into patient care and improve clinical research by harnessing the enormous research potential of the NHS.

Working closely with the UKCRN Coordinating Centre, DeNDRoN brings together a broad range of partners including researchers, funders, academia, the NHS, regulators, industry and patients to develop a world class environment for clinical research in the UK. The key objectives for DeNDRoN are to improve the quality and speed of study delivery, whilst reducing costs wherever possible.

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What services can DeNDRoN provide to industry?

DeNDRoN provides a two-step process to determine the UK feasibility of a study:

Level 1: 'Top level feasibility', 'Country feasibility', 'Study feasibility'

Rapid assessment to determine if the UK has the required subject population for the study and if the treatment plan proposed in the protocol differs fundamentally from the standard UK treatment pathway. This process is undertaken by key UK trialists and can be reported in as little as two weeks from the date of signing the UKCRN confidentiality agreement.

Level 2: 'Detailed feasibility', 'Site feasibility', 'Site capability'

Identification of potential sites that could conduct the study, addressing site specific issues such as research resources – skills, facilities, and equipment. This provides access to established and new investigators, with untapped patient populations, that can be supported by DeNDRoN research nurses (if adopted) to ensure study delivery.

Costings and contracting

The company will be required to complete a full breakdown of per patient costs, using the UKCRN costing template. Procedures and time-based assessments are clearly defined, in order to allocate overheads appropriately at a Trust level. Although this is not a set tariff, it provides a tool to rapidly speed up negotiations, at a Trust level, between the Local Research Network managers and investigators.

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The Local Research Network staff will also support the investigator to complete and submit local research governance requirements and ensure these are in place before study activities commence.

How are collaborations between DeNDRoN and industry established?

The sponsor should make initial approaches to the DeNDRoN Coordinating Centre to discuss the role of DeNDRoN in supporting clinical research and any non-study specific requirements. This will include agreements about timelines, study status and feasibility requirements.

A UKCRN generic confidentiality agreement must be signed before any confidential documents can be circulated to DeNDRoN. Once signed, this generic agreement will cover all future discussions about new studies with any topic specific network. This agreement is necessary for the study to undergo any review prior to adoption.

What will companies need to provide and what are the timelines?

The UKCRN Industry Trials Submission form should be completed. Much of the information requested on this form is routinely provided on the COREC and MHRA application forms.

The UKCRN Industry Trials Submission form is available for download from the UKCRN website: www.ukcrn.org.uk

Following discussions with the DeNDRoN Coordinating Centre, a completed submission form, a populated costing template, an electronic protocol and any site requirements are submitted.

DeNDRoN will then complete level 1 or 2 feasibility, based upon requirements. The study will be reviewed at an industry adoption panel, which are scheduled on a monthly basis, to review any studies requiring level 2 feasibility and adoption.

Adoption is based upon the feasibility of the study to run in the UK, which is assessed by the DeNDRoN Clinical Study Groups (for further information, see www.dendron.org.uk). Local research networks determine the capability and capacity of UK investigators to participate and deliver the trial.

Level 2 feasibility and adoption is ideally performed before, or in parallel with, an MREC application. We would encourage any company to initiate discussions with the coordinating centre as early as possible, so that DeNDRoN can deliver support throughout the protocol development and set-up process.

This process will not add any delays to the study set up process and will always run in parallel with other submissions and approvals.

A UKCRN proposition document, *UKCRN working with industry: How the networks can facilitate trials*, is also available through the UKCRN website: www.ukcrn.org.uk

Further information is available from the DeNDRoN Coordinating Centre, Newcastle, and the DeNDRoN website: www.dendron.org.uk

To discuss running a trial through DeNDRoN, please contact the Study Delivery Manager:

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