

**UK Dementias and Neurodegenerative Disease Research Network (DeNDRoN)  
Portfolio Submission form for Non-commercial Studies**

<p><b>Investigator details:</b></p> <p>(i) Chief Investigator:  (ii) Lead organisation:  (iii) Form submitted by:</p>
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*Please complete ALL fields stating not applicable where necessary. Fields in bold comprise the minimum dataset for the UKCRN Portfolio database.*

**Basic Study Data:**

**UKCRN ID:**

<b>1. Basics</b>	
Data Item	Description
<b>Acronym/Short Name</b>	
<b>Full Study Title (as on protocol)</b>	
<b>Study Title for display</b>	
Brief lay summary of study	
ISRCTN	
EudraCT No	
WHO Number	
MREC No	
Date of MREC / LREC approval	
How does this Study qualify to be part of the portfolio?	DeNDRoN CC only
On what date did this study qualify for the portfolio?	DeNDRoN CC only
Record Source	DeNDRoN CC only

<b>2. Topic</b>	
Data Item	Description
<b>Topic(s)</b> – if you also wish the study to be considered for support by an additional network eg PCRN, MHRN, SRN or MCRN, please state here with reason.	DeNDRoN (main)
<b>Subtopic(s) (Disease areas)</b> Dementia, Parkinson's disease, Huntington's disease, motor neurone disease, other (please specify)	
Was the study proposal supported by a DeNDRoN CSG? If yes, please give name of CSG and details of support.	

<b>3. Study Design</b>	
Data Item	Description
<b>Is this a randomised study?</b>	
<b>Primary study design?</b> Please state whether interventional, observational or both	
<b>Intervention Type</b> Eg treatment, screening, diagnosis, prevention, process of care	
<b>Intervention Detail(s)</b> Eg drug, vaccine, cellular, gene therapy, surgery, device, psychological, physical	
<b>Observational Type</b> eg cohort study, cross-sectional, genetic epidemiology, case controlled, validation of outcome measures, validation of process, qualitative, clinical lab study	
Additional Notes	
Length of follow-up (in months)	
<b>Overall Sample Size</b>	
<b>UK Sample Size</b>	
<b>Network sample size</b>	
<b>Geographical scope:</b> UK multi-centre/ international multi-centre/ single centre?	
<b>Phase:</b> I / II/ III / IV or N/App	

<b>Setting (s):</b> primary care, secondary care, tertiary care	
Please describe any consumer involvement in the design of this study	

<b>4. Eligibility</b>	
Data Item	Description
<b>Inclusion Criteria</b>	
<b>Exclusion Criteria</b>	
Sample Gender	
Sample Age Group(s)	

<b>5. Support and Funding</b>	
Data Item	Description
Has the study been fully funded? <b>Please attach full breakdown of study budget including research costs, NHS service support costs and excess treatment costs</b>	
<b>Funder(s)</b> – please provide details of all sources of funding awarded.	
Grant Code	
Grant Start Date	
Value of award	
<b>Name of Sponsor</b>	
Is this the Primary Sponsor?	
Sponsor Code	
<b>Commercial Participation</b> None / Industry supported, non-industry sponsored / Industry supported, industry sponsored (NB use UKCRN Industry form for the latter)	
<b>Please state exactly what support is required from DeNDRoN to ensure</b>	

that the study is completed in a timely and cost-effective manner eg DeNDRoN may be able to support a study by publicising it throughout the network; or by pre-screening patients for recruitment. DeNDRoN is not able to provide any research costs and unless reimbursed from the study funding will not provide dedicated research staff to support individual studies but can use the network infrastructure to facilitate recruitment.	
Please describe resources available for participating sites	
Has the <i>study protocol</i> been peer reviewed?	
Please outline peer review process	

<b>6. Study Recruitment</b>	
Data Item	Description
<b>Planned start of recruitment</b> dd/mm/yyyy	
<b>If recruitment has started, please give date of first patient enrolled</b> dd/mm/yyyy	
Planned length of recruitment	
<b>Planned closure to recruitment</b> dd/mm/yyyy	
Study Entry Mode (ie/Single randomisation, multiple randomisation, registration)	
Planned UK Investigators, site location, NHS Trust, and site recruitment targets (may be provided on a separate sheet if preferred)	
Is the study open to new centres?	
Please describe any anticipated issues with recruitment and outline any plans	

that have been made to address these.	
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<b>7. Management and Contacts</b>	
<b>Data Item</b>	<b>Description</b>
Is the primary Coordinating Centre for this study in the UK?	
<b>Chief Investigator name</b>	
<b>CI address with postcode</b>	
<b>CI email</b>	
CI phone number	
<b>Study Coordinator (SC) name</b>	
<b>SC address with postcode</b>	
<b>SC email</b>	
SC phone number	
<b>Accrual Data Contact (ADC) name</b> to provide monthly accrual figures to the UKCRN once the study is open - may be same as the SC	
ADC address with postcode	
ADC email	
ADC phone number	
Will all members of the research team have completed GCP training prior to initiating the study?	
Would any members of the research team benefit from access to UKCRN training courses eg GCP?	