

## **Work Package 22 - Clinical recruitment and research facilities**

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**Start date:** Jan 2021

**End date:** Dec 2025

### **Objective of project**

To provide an efficient recruitment and delivery infrastructure for early symptomatic clinical trials

### **Background:**

Recruitment to studies for symptomatic disease is best done close to the clinical research facility. This can be achieved by developing co-located networks for clinical enrolment and recruitment. For enrolment to prodromal and early symptomatic studies a clinical research register will be developed from existing research registers at specialist research facilities and research active memory clinical sites. This will begin by recruiting from 2-3 key 'demonstrator sites'. These sites will be selected to create a trials delivery infrastructure for efficient and targeted recruitment to and conduct of multi-centres trials. The network will then be expanded to other sites around the UK.

Work will then be conducted to achieve a consensus on a potential cognitive screening tool to be utilised at these sites, including digital options. Sites will be linked to developing 'brain health' service models being set up at memory clinic sites across the UK and will aim to collaborate with other similar networks internationally (e.g., Global Alzheimer's Platform (US), Brain Health Scotland), to create a wider network for trial delivery.

### **Objective 1: Build a clinical network for recruitment and trial delivery.**

Deliverable 1: Perform a scoping exercise of activities across research facilities and memory clinics.

Deliverable 2: Obtain agreement with 2-3 facilities to become demonstrator sites.

Deliverable 3: Set up the infrastructure at the demonstrator sites.

Deliverable 4: Expand the clinical network to another 4 UK sites.

Deliverable 5: Data collated and shared on recruited participants.

Deliverable 6: At least one research trial commenced on network participants.

### **Objective 2: Achieve a consensus on a cognitive screening tool.**

Deliverable 7: Review and compare the cognitive screening tools used across sites.

Deliverable 8: Select a cognitive screening tool to use across the clinical network.

Deliverable 9: Establish the use of the selected cognitive screening tool across the clinical network.

Deliverable 10: Cognitive screening tool performance data compared with the clinical outcomes across sites.

**Objective 3: Collaborate with other similar networks internationally (e.g., Global Alzheimer’s Platform (US), Brain Health Scotland), to create a wider network for trial delivery.**

Deliverable 11: Expand the profile of the clinical network.

Deliverable 12: Identify and establish collaborations with other memory clinic sites across the UK.

Deliverable 13: Identify and establish international collaborations.

Deliverable 14: Development of agreed best practice from collaborations.

Deliverable 15: Data from network shared across collaboration sites.

**Objective 4: DPUK/MRC project reporting**

Deliverable 10: Quarterly reporting

Deliverable 11: Annual reporting

Deliverable 12: End report

Deliverable 13: Financial reporting

<b>Objective 1: Build a clinical network for recruitment and trial delivery</b>				
<b>Specifics</b>	<b>Description</b>	<b>How and who</b>	<b>Outcome</b>	<b>Dates</b>
<b>Deliverable 1: Perform a scoping exercise of activities across research facilities and memory clinics</b>				
M1.1.1	Scoping exercise	Send scoping questionnaire to all sites & collate results	Sites scoped ready for selection	Mar 21
<b>Deliverable 2: Obtain agreement with 2-3 facilities to become demonstrator sites</b>				
M1.2.1	Site selection	Select 2-3 demonstrator sites to take part in initial set up, make initial contact and establish framework for working	Sites selected and agree to participation	Jun 21
<b>Deliverable 3: Set up the infrastructure at the demonstrator sites</b>				
M1.3.1	Set up local site infrastructure	Discuss existing registers, recruitment techniques (including JDR), infrastructure (facilities, SOPs, contracts, consent for contact) and agree data sharing (via DPUK Great Minds)	Establish what is needed to set these up, agree data sharing pathways and complete set up	Dec 21
<b>Deliverable 4: Expand the clinical network to another 4 sites</b>				
M1.4.1	Set up infrastructure at another 4 sites	For other sites - discuss existing registers, recruitment techniques (including JDR),	Set up complete at an additional site	Jun 22

M1.4.2		infrastructure (facilities, SOPs, contracts, consent for contact) and agree data sharing (via DPUK Great Minds)	Set up complete at an additional site	Dec 22
M1.4.3			Set up complete at an additional site	Jun 23
M1.4.4			Set up complete at an additional site	Dec 23

#### **Deliverable 5: Data collected and shared on recruited participants**

M1.5.1	Tools for data collation and selection developed	Tool specification, development, testing, data collation, centralised access.	Tools developed for data retention and selection	Jun 22
M1.5.2	Data collated for recruited participants across network sites and available for selection for targeted recruitment		Participant data available for selection	Sep 22

#### **Deliverable 6: At least one research trial commenced on network participants**

M1.6.1	At least one research trial approved to include network participants	Research trial liaison, study development, participant selection and engagement, support for study set up, monitoring of study development, reporting of study results	Research trial approved	Mar 23
M1.6.2	At least one research trial commenced including network participants		Participants selected onto trial from across network sites	Jun 23

### **Objective 2: Achieve a consensus on a cognitive screening tool**

<b>Specifics</b>	<b>Description</b>	<b>How and who</b>	<b>Outcome</b>	<b>Dates</b>
<b>Deliverable 7: Review and compare the cognitive screening tools used across sites</b>				
M2.7.1	Scope cognitive screening tools used across sites	Send scoping questionnaire to all sites & collate results	Sites scoped ready for selection	Mar 22
<b>Deliverable 8: Select a cognitive screening tool to use across the clinical network</b>				
M2.8.1	Finalise which cognitive screening tool to use	Discuss with demonstrator sites and review current literature, NHS practices	Confirmation of selected tool	Sep 22
<b>Deliverable 9: Establish the use of the selected cognitive screening tool across the clinical network</b>				
M2.9.1	Explore and establish use of cognitive screening tool	Explore ways of establishing use in NHS memory clinics, work with existing	Tools able to be used at sites	Sep 23

		infrastructure to set up and agree data sharing		
<b>Deliverable 10: Cognitive screening tool performance data compared with clinical outcomes across sites</b>				
M2.10.1	Cognitive screening tool performance data obtained	Data collection from cognitive screening tool across sites, centralised storage, analysis incorporating clinical outcomes for network participants	Performance data and outcome data obtained and shared	Jun 24
M2.10.2	Cognitive screening tool performance data analysed		Data analysed	Sep 24
M2.10.3	Cognitive screening tool performance data compared with clinical outcomes across sites		Results from data analysis shared	Dec 24

<b>Objective 3: Collaborate with other similar networks in the UK and internationally to create a wider network for trial delivery</b>				
<b>Specifics</b>	<b>Description</b>	<b>How and who</b>	<b>Outcome</b>	<b>Dates</b>
<b>Deliverable 11: Expand the profile of the clinical network</b>				
M3.11.1	Expand profile of clinical network and identify collaborations	Explore potential networks for collaborations, logistical and contractual requirements for cross-working	Data gathered on benefits of collaborations and what is needed to set these up	Dec 23
<b>Deliverable 12: Identify and establish collaborations with other memory clinic sites across the UK</b>				
M3.12.1	Establish collaborations in the UK	Identify and confirm collaborators in the UK	Collaborative partners agreed	Jun 24
M3.12.2			Meeting of UK collaborative partners held	Sep 24
<b>Deliverable 13: Identify and establish international collaborations</b>				
M3.13.1	Establish collaborations internationally	Identify and confirm international collaborators	Collaborative partners agreed	Dec 24
M3.13.2			Meeting of international collaborative partners held	Mar 25
<b>Deliverable 14: Development of agreed best practice from collaborations</b>				
M3.14.1	Best practice agreed with collaborators	Identification of key areas of collaboration, discussion of current practices,	Best practice documentation shared	Jun 25

		development of best practice, development of documentation, distribution		
<b>Deliverable 15: Data from network shared across collaboration sites</b>				
M3.15.1	Data from network shared across collaboration sites	Data collation, secure centralised storage on DPUK data portal	Data accessible to collaborators	Sep 25

<b>Objective 4: DPUK/MRC project reporting</b>				
<b>Specifics</b>	<b>Description</b>	<b>How and who</b>	<b>Outcome</b>	<b>Dates</b>
<b>Deliverable 16: Produce quarterly reports by the required dates</b>				
M4.16.1	Provide Quarterly reports detailing project deliverables and outcomes.	Online quarterly form to be completed for DPUK for MRC meetings	Quarterly report submitted	Mar 21
M4.16.2			Quarterly report submitted	Jun 21
M4.16.3			Quarterly report submitted	Sep 21
M4.16.4			Quarterly report submitted	Mar 22
M4.16.5			Quarterly report submitted	Jun 22
M4.16.6			Quarterly report submitted	Sep 22
M4.16.7			Quarterly report submitted	Mar 23
M4.16.8			Quarterly report submitted	Jun 23
M4.16.9			Quarterly report submitted	Sep 23
M4.16.10			Quarterly report submitted	Mar 24
M4.16.11			Quarterly report submitted	Jun 24
M4.16.12			Quarterly report submitted	Sep 24
M4.16.13			Quarterly report submitted	Mar 25
M4.16.14			Quarterly report submitted	Jun 25
M4.16.15			Quarterly report submitted	Sep 25
<b>Deliverable 17: Produce an annual report by the required dates</b>				
M4.17.1	Annual reports to oversee project status and updates of deliverables and outputs. Information to assess completion criteria as part of payment schedule.	Annual form to be completed for DPUK for MRC meetings. Annual reports submitted to confirm milestone completion for next payment scheduled	Annual report submitted	Dec 21
M4.17.2			Annual report submitted	Dec 22
M4.17.3			Annual report submitted	Dec 23
M4.17.4			Annual report submitted	Dec 24
<b>Deliverable 18: Provide annual financial reporting against the specified budget by the required dates</b>				

M4.18.1	Financial reports submitted at the end of each year. Information to assess completion criteria as part of payment schedule.	Yearly financial statement on spending	Financial report submitted	Dec 21
M4.18.2			Financial report submitted	Dec 22
M4.18.3			Financial report submitted	Dec 23
M4.18.4			Financial report submitted	Dec 24
M4.18.5			Financial report submitted	Dec 25
<b>Deliverable 19: Produce a final work package report by the required date to summarise the work completed and the benefits achieved</b>				
M4.19.1	Final report submitted at end of project.	PI to complete final report and send to DPUK /MRC for final payment to be made.	Final report submitted	Dec 25