

WP 18

Clinical Studies Register				
Start date: 23 Nov 2017.			Completion date: June 2020	
<p><b>Overall work package objectives:</b></p> <p>In order to build a new generation of highly targeted clinical studies, DPUK will establish a register of highly characterised individuals who are consented for recontact for dementia-focused clinical studies; the DPUK clinical studies register (CSR). By combining genomic data with detailed phenotyping from cohorts, this register will enable risk stratification per hypothesis at a level of detail and convenience that would not be otherwise available. Specific objectives:</p> <ol style="list-style-type: none"> <li>1. Gain cohort agreement to enable their participants to be invited to join the CSR</li> <li>2. Set up registration, cognitive testing, membership management and participant engagement</li> <li>3. Recruit participants to join the CSR and manage member engagement</li> <li>4. Facilitate study recruitment from the CSR.</li> </ol>				
Deliverables	Milestones	Milestone deadline	Work package dependencies	Person(s) responsible
<b>Objective 1:</b>				
D1.1 Gain NHS ethics approval for the register	M1.1.1 Initial application submitted	M1.1.1 Complete	None	Ivan Koychev
	M1.1.2 Final approval given	M1.1.2 Complete	WP16	
D1.2 Gain agreement from UKB and early adopter cohorts for their participants to be invited to join the CSR	M1.2.1 UKB agreement to allow participants to be contacted and for the CSR to have access to a limited number of existing variables relevant to dementia risk	M1.2.1 On Hold		Cohort approval
	M1.2.2 Cygnus, Airwave and BDR agreement to allow participants to be contacted	M1.2.2aBDR: Complete		
		M1.2.2bAirwave: Complete		
	M1.2.2cCygnus: Complete			
D1.3 Extend recruitment to further cohorts	M1.3.1 Two further cohorts	M1.3.1 Jan 2020		
<b>Objective 2:</b>				
D2.1 Create a CSR website that will manage registration, cognitive testing, membership management and participant engagement	M2.1.1 Cambridge Cognition tests ready	M2.1.1 Complete		Ivan Koychev
	M2.1.2 Mobile cognitive application ready	M2.1.2 Complete		
	M2.1.3 Initial website build ready	M2.1.3 Complete		
	M2.1.4 Final website created and ready to use	M2.1.4 Complete		
D2.2 Establish processes for participant contact and support	M2.2.1 Processes for participant contact and support established	M2.2.1 Complete		Ivan Koychev Anna Myers
	M2.2.2 Recruit research assistant	M2.2.2 Complete		

D2.3 Create a communications and events strategy for participant engagement	M2.3.1 Communications and events strategy ready	M2.3.1 Complete		Anna Myers
	M2.2.2 Recruit communications officer	M2.2.2 Complete		
<b>Objective 3:</b>				
D3.1 Pilot recruitment: a joint exercise with the initial CSR parent cohort to ensure all procedures are acceptable, there is a good user experience, and that yield is optimised	M3.1.1 Feedback on CSR experience by participants recruited from the initial CSR parent cohort	M3.1.1 Complete	CSR ethical and cohort approval	Ivan Koychev
	D3.2 Initial recruitment materials are created and circulated to all participating cohort members	M3.2.1 Recruitment materials prepared		
M3.2.2 Recruitment materials circulated		M3.2.2 Complete		Anna Myers Heather Holve
D3.3 Wider communications campaigns are conducted to support recruitment	M3.3.1 Public engagement events organised	M3.3.1 Complete		
	M3.3.2 Annual CSR participant events organised	M3.3.2 Mar 2020 (was Mar 2019)		
D3.4 Conduct web-based enhancement of existing data	M3.5.1 Establish six monthly web-based repeat assessment to assess changes in cognition, mood and everyday functioning	M3.5.1 Mar 2020		Ivan Koychev
	M3.5.2 Make data available to the parent cohort	M3.5.2 Mar 2020 (was Feb 2019)		
<b>Objective 4:</b>				
D4.1 Facilitate recruitment to individual studies through CSR (ie Portfolio Studies)	M4.1.1 Establishment of Data Access Committee	M4.1.1 Complete	CSR ethical and cohort approval	Ivan Koychev
	M4.1.2 Approval of initial Portfolio Study	M4.1.2 Complete		
	M4.1.3 Recruitment to first Portfolio Study	M4.1.3 Complete		
<b>Updates on delivery against milestones since last report</b>				
<ul style="list-style-type: none"> <li><b>M1.2.1 UKB agreement to allow participants to be contacted and for the CSR to have access to a limited number of existing variables relevant to dementia risk (Dec 18).</b></li> </ul> <p>UKB application is still pending the outcome of recruitment of UKB participants through DFP study.</p>				
<ul style="list-style-type: none"> <li><b>M3.3.2 Annual CSR participant events organised (Mar 19)</b></li> </ul> <p>CSR participant events are on hold until a sufficiently large group of people are recruited.</p>				
<ul style="list-style-type: none"> <li><b>M3.5.2 Make data available to the parent cohort (Feb 19)</b></li> </ul> <p>Process to allow HWW access to their participants' cognitive data is being set-up</p>				
<ul style="list-style-type: none"> <li><b>M4.1.1 Establishment of Data Access Committee (Feb 19)</b></li> </ul> <p>The Senior Management Team has taken on the role of Data Access Committee</p>				

<p><b>Summary of plan to deliver on outstanding work (with dates)</b></p> <ul style="list-style-type: none"> <li>• Recruitment of participants to a pilot study (DFP) by the end of Q4 2019</li> <li>• Amendment to allow the division between CSR and Great Minds (end of Q4 2019)</li> <li>• Amendment to allow remote genotyping and actigraphy assessments (end of Q4 2019)</li> <li>• Including the whole of Airwave cohort into CSR and offering Great Minds to a subsection (end of Q4 2019)</li> </ul>	
<p><b>Risks</b></p> <ol style="list-style-type: none"> <li>1) Rate of Great Minds take up</li> <li>2) Engagement with studies offered to participants</li> </ol>	<p><b>Mitigation</b></p> <ol style="list-style-type: none"> <li>1) Co-branding with parent cohort</li> <li>2) Customer management system to monitor engagement</li> </ol>
<p><b>Team members <u>funded</u> (full or part-time) by DPUK</b>  Heather Holve (full-time), Ivan Koychev (10%)</p> <p><b>Team members involved with the project but <u>not</u> funded by DPUK</b>  Michael Ben Yehuda</p>	
<p><b>Outcomes</b>  Protocol, ethics application including amendment have been completed.</p>	
<p><b>Project narrative</b>  Great Minds was launched in Feb 2019 through a pilot in the Airwave cohort (500 individuals, approximately 10% take up rate). It was then offered to the HealthWise Wales cohort and as a result membership currently stands at 1200 individuals. We are in the process of including the Airwave cohort into an opt-out version of the register (CSR) given that they already have a valid consent to recontact. Great Minds will be offered to a subsection of these individuals which would allow prospective cognitive assessment. An amendment is currently in preparation that will draw the distinction between CSR and Great Minds. It would also allow remote genotyping and actigraphy testing. The Deep and Frequent Phenotyping study has been identified as the first pilot study to recruit participants to with recruitment expected to begin by Q4 2019 end.</p>	