Clinical Studies Register

WP18

Objective(s):

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 re-contact 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:

1. Gain cohort agreement to enable their participants to be invited to join the CSR
2. Set up registration, cognitive testing, membership management and participant engagement
3. Recruit participants to join the CSR and manage member engagement
4. Facilitate study recruitment from the CSR.

Overview Summary:

The plan to build a new generation of highly targeted clinical studies, establish a register of highly characterised individuals who are consented for re-contact for dementia-focused clinical studies; the DPUK clinical studies register (CSR). Achieved by combining genomic data with detailed phenotyping from cohorts, this register enables risk stratification per hypothesis at a level of detail and convenience that would not be otherwise available.

Executive Summary:

The Clinical Studies Register (CSR) was set up to be a register of highly characterised individuals who are consented for re-contact for dementia-focused clinical studies.

Two separate registers have been developed: Great Minds (GM) is an opt-in register that enables the participants of invited DPUK cohort to consent to targeted re-contact at the GM website and then to provide self- reported demographic and medical history information relevant to recruitment into clinical studies, and the CSR is an opt-out register for cohorts explicitly allowing targeted re-contact.

Both registers are operational with GM holding 4,425 participants from 6 DPUK cohorts and CSR holding 53,528 participants from 2 DPUK cohorts. Feasibility and Participant selection tools have

been developed for both registers and a Customer Relationship Management tool has been developed for GM. One study has been initiated and three further studies have applied to use participants from the registers. It is recommended that the development of the registers continues into DPUK2.
Summary of Outputs: (as per Researchfish categories)
Publications
• Koychev I, et al **Deep and Frequent Phenotyping study protocol: an observational study in prodromal Alzheimer's disease** BMJ Open 2019;9:e024498. doi: 10.1136/bmjopen-2018-024498
Collaborations & Partnerships
Work with Cohorts
Further Funding
DPUK 2
Next Destinations
DPUK 2 to further work
Engagment Activities:
• PPI session through Alzheimer's Society in Nov 2018 focusing on ethical issues surrounding risk disclosure and recruitment into preclinical disease trials. We have recruited a Great Minds panel and have set the terms of reference for this group. • Participant Event 1: June 2020 (On line due to Covid) • Participant Event 2: November 2020 (On line due to Covid)
Influence of policy, practice, patients & the public
• Great Minds and CSR protocol as approved in Oct 2019 amendment
Research Tools & Methods
• Use of Data Portal for data storage and data access
Research Databases & Models
• Use of Data Portal for data storage and data access
Intellectual property & licencing
None
Medical products, interventions & clinical trials
None

Artistic & creative products
None
Software & technical products
• Deep and Frequent Phenotyping study request to recruit through Great Minds • Genetic and Accelerometer pilot study recruited participants through Great Minds • Study on the validity and acceptability of the ICA test requested to recruit through Great Minds • Study on a new digital device application to assess cognitive decline risk in healthy ageing requested to recruit through Great Minds
Spin outs
None
Awards & recognition
Continued funding in DPUK2
Other outputs & knowledge/future steps
Continuation into DPUK2
Medical products, interventions & clinical trials
None
Most successful outcome and what it means for future dementia research:
The Great Minds infrastructure was designed and delivered at a fraction of the cost of comparable projects (e.g. Brain Health Registry) within 18 months. As of end of Q4 2020 membership of GM stands at 4,425 participants and while the CSR allows re-contact with 53,528 individuals.
Lessons learned:
1. There is a willingness of individuals on existing cohort studies to make themselves available for further studies and assessments; 2. Technology can be used to efficiently, yet securely, contact and enrol individuals onto a register, and for them to perform regular cognitive tests, for very modest costs.
Team Members:
Ivan Koychev, Anna Meyers, Heather Holve, Simon Young, Michael Ben Yehuda
Date of Report:
11 January 2021