NIHR RDN commercial eligibility & feasibility submission form

NIHR | National Institute for Health and Care Research

Section B: The information in this section has been provided by the commercial company in the non-confidential section of the submission. While catergorised as non-confidential for the purposes of the RDN feasibility and eligibility process, the information is COMMERCIALLY SENSITIVE and should be managed as defined in the RDN business processes. It may be distributed to third parties involved in supporting the delivery of RDN feasibility and eligibility process WITHOUT the need for a formal RDN Confidential Disclosure Agreement, however the confidentiality terms of the Performance and Operating Framework for RDN Host or Partner Organisations remain applicable.

Full study title	Development of an internationally-diverse, linked genomic and longitudinal phenotypic research data asset to accelerate precision treatment pathways for patients with serious mental illness
Study protocol reference number	GlobalMinds

SPONSORSHIP & FUNDING

B4: Name of research sponsor:	Akrivia Health
B5: Is Research Funder different to above?	Yes
B5a: If yes, please specify:	Wellcome Trust; Johnson & Johnson
The name and organisation of the Chief Investigator is required to submit a request for the Study Resource Review service.	
B6: Name of Chief Investigator	Prof. James Walters
B6a: Chief Investigator Organisation	CARDIFF & VALE UNIVERSITY LHB Wales

STUDY TYPE

B8: Category of research	Study administering questionnaires/interviews for quantitative analysis, or using mixed quantitative/qualitative methodology
B8a: Are any of the investigational medicinal products (IMPs) advanced therapy investigational medicinal products (ATIMPs)?	
B11: Phase of development	

N/A	No
I	No
II	No
III	No
IV	No
B12a: If this is a Phase IV study, is this at the request of regulators?	
B12b: Category of medical device study	
B12d: Phase of clinical investigation	
B12e: Is this post-marketing study a regulatory follow up requirement?	

APPROVAL

B6b: Select the type of approval you will be applying for	HRA Approval
B6c: Provide details of the ethical approval you will be applying for	
B6d: Explain why you will not be applying for ethical approval	
B6e: Date of approval submission	17/09/2024

STUDY DESIGN

B13: What is the disease indication / target patient population for the study?	Neuropsychiatric and neurodegenerative (dementia) patients
B13a: Is your trial recruiting UK subjects under 16 years of age?	
B13b: If Yes, has a Paediatric Investigation Plan (PIP) been developed?	
B13c: If a PIP has not been developed, please give details why not:	
B15: Please briefly describe the treatment and (if applicable) the randomisation schedule. Please include details of all study related treatments	NA

including comparator drugs, other protocol specified treatment regimens and the ratio of treatment groups.

B15a: Are the study drugs / comparators being provided or will they be reimbursed?

B16: Primary objective(s)

To use the linked genomic biomarker and phenotypic data to investigate associations between clinical, demographic, developmental, biological, psychological and social variables with transdiagnostic symptoms and outcomes, and apply advanced analyses to this dataset to examine methods of stratification to improve diagnosis and identify treatment targets.

B17: Secondary objective(s)

B18: Full inclusion criteria

All participants must have an electronic health record in a primary or secondary care service.
Mental Health cohort(s)

- Have received a diagnosis and/or treatment/referral for mental illness for MDD, BD, Schizophrenia.
- Having an available electronic health record
- Current age 18+ (no upper age limit)
- Can speak English

Dementia cohort

- Participants aged 18+ (no upper age limit)
- Currently alive and are, or have been, old age psychiatry patients
- Received relevant diagnosis or referral:

EITHER

- Clinical diagnosis of dementia, mild cognitive impairment (MCI) or subjective cognitive impairment (SCI)

OR

- Memory clinic referral
- Must be willing and able to complete a validated cognitive assessment.

All dementia patients will undergo extended biomarker analysis.

B19: Full exclusion criteria	Mental Health cohort(s) • Patients without capacity to provide consent. Dementia cohort • Inability to understand spoken and/or written spoken English • Individuals with intellectual disability. • Patients with dementia in Creutzfeldt-Jakob disease (CJD), Huntington's, HIV dementia, alcohol-related dementia, intellectual disability, traumatic brain injury at any time. • Patients diagnosed with depression (only an exclusion criterion for MCI/SCI patients), psychosis, bipolar disorder prior in the pre-index period – to be checked at screening.

PRODUCT INFORMATION

B7: Name(s) and class(es) of investigational product	NA
B7a: Route of study drug(s)	
Inhalational	No
Intramuscular (IM)	No
Intranasal	No
Intravenous (IV)	No
Oral	No
Rectal	No
Subcutaneous (SC)	No
Sublingual / buccal	No
Transdermal	No
Vaginal	No
Other (please specify)	No

B7b: Other route of study drug(s)	
B7c: Type of investigational product / GMDN classification	1
Active implantable devices	No
Anaesthetic and respiratory devices	No
Dental devices	No
Electro mechanical medical devices	No
Hospital hardware	No
In vitro diagnostic devices	No
Non-active implantable devices	No
Ophthalmic and optical devices	No
Reusable devices	No
Single use devices	No
Assistive products for persons with disability	No
Diagnostic and therapeutic radiation devices	No
Complementary therapy devices	No
Biological-derived devices	No
Healthcare facility products and adaptations	No
Laboratory equipment	No
Other	No
B7d: Other	
B9: Who is responsible for the development of the product(s)?	NA

DELIVERY CONSIDERATIONS

B27: What is the care setting you anticipate for each of the following activities (select Not known if you are unsure which setting applies):	
B27a: Participant identification	

Primary care	Yes
Hospital	Yes
Community based	Yes
Residential care	No
Not known	No
Not applicable	No
B27b: Participant recruitment	
Primary care	Yes
Hospital	Yes
Community based	Yes
Residential care	No
Not known	No
Not applicable	No
B27c: Participant treatment	
Primary care	No
Hospital	No
Community based	No
Residential care	No
Not known	No
Not applicable	Yes
B27d: Participant follow up	
Primary care	No
Hospital	No
Community based	No
Residential care	No
Not known	No

Not applicable	Yes
B22: Does the study involve any investigations using ionising radiation (this includes examinations which would be considered standard care in this patient group)?	No
B22a: Does the study involve any additional investigations using ionising radiation not viewed as part of standard care, (please note there may be variation in practice between trial sites)?	
B23: Are there any other study requirements / practicalities which may have an impact on feasibility?	Training on cognitive assessment for dementia patients. Otherwise, there is no special requirements.

TRIAL MANAGEMENT

B33a: Planned Final Protocol date	01/04/2028
B33e: Duration of study treatment	0 Years 0 Months 0 Days
B33f: Duration of follow up	0 Years 0 Months 0 Days
B33j: Is or will the study be running globally i.e. outside of the UK?	Yes
UK Study Timelines	
B33b: Planned date to have site selection finalised	31/10/2024
B33c: Planned FPFV (First Participant First Visit)	15/12/2024
B33d: Planned LPFV (Last Participant First Visit)	18/07/2028
B33g: Planned LPLV (Last Participant Last Visit)	20/07/2028
Global Study Timelines	
B33h: Planned FPFV (First Participant First Visit) globally	11/03/2025
B33i: Planned LPLV (Last Participant Last Visit) globally	20/07/2028

RECRUITMENT TARGETS

B34: Is the study already open to recruitment in other countries?	No
B35a: If yes, have any issues with recruitment been identified?	
B35b: Please provide the global recruitment to date versus target	
B36: What is the target recruitment:	
B36a: In the UK?	47000
B36b: In the EU (if applicable)?	
B36c: Worldwide (if applicable)?	3000
B36d: What is the minimum recruitment target for individual sites?	Dependent on feasibility and agreed targets per site
B38: If worldwide recruitment applies, is this competitive?	Yes
B39: What is the planned total number of study sites within the UK?	17

SITE INTELLIGENCE

B24: In order for the NIHR RDN to best support your study, we need to understand how far you have progressed in the site selection process. Therefore please provide details of sites which you have already contacted about the study and their current feasibility status. This is important, so that we do not duplicate work or cause misunderstanding when we discuss your study with investigators.

Name of site/practice	Status	Investigator Name	Investigator Email Address	Investigator Specialty	Additional Information
Cornwall - Cornwall Partnership NHS Foundation Trust	Interested and awaiting feasibility questionnaire	Ben Hyams	b.hyams@nhs.net	Mental Illness	

Name of site/practice	Status	Investigator Name	Investigator Email Address	Investigator Specialty	Additional Information
KMPT - Kent and Medway NHS and Social Care Partnership Trust (Recent name change)	Interested and awaiting feasibility questionnaire	Sarah Dickens	sarah.dickens@nhs.net	Mental Illness	
Cardiff & Vale - Cardiff and Vale University Health Board	Interested and awaiting feasibility questionnaire	Norman Young	norman.young@wales.nhs.uk	Mental Illness	
LYPFT - Leeds and York Partnership NHS Foundation Trust	Interested and awaiting feasibility questionnaire	Zoe Jackson	zoe.jackson14@nhs.net	Mental Illness	
CNTW - Cumbria, Northumberland, Tyne and Wear NHS Foundation Trust	Interested and awaiting feasibility questionnaire	Simon douglas	simon.douglas@cntw.nhs.uk	Mental Illness	
Southern - Southern Health NHS Foundation Trust	Interested and awaiting feasibility questionnaire	Peter Phiri	peter.phiri@southernhealth.nhs.uk	Mental Illness	
SWLSTG - South West London and St George's Mental Health NHS Trust	Interested and awaiting feasibility questionnaire	Robert Lawrence	robert.lawrence@swlstg.nhs.uk	Mental Illness	
AWP - Avon and Wiltshire Mental Health Partnership NHS Trust	Interested and awaiting feasibility questionnaire	Hannah Antoniades	hannah.antoniades@nhs.net	Mental Illness	

Name of site/practice	Status	Investigator Name	Investigator Email Address	Investigator Specialty	Additional Information
TEWV - Tyne, Esk and Wear Valleys NHS Foundation Trust	Interested and awaiting feasibility questionnaire	Sarah Daniel	s.daniel@nhs.net	Mental Illness	
BSMHFT - Birmingham and Solihull Mental Health Foundation Trust	Interested and awaiting feasibility questionnaire	Emma Patterson	emma.patterson4@nhs.net	Mental Illness	
Devon - Devon Partnership NHS Trust	Interested and awaiting feasibility questionnaire	Tobit Emmens	tobit.emmens@nhs.net	Mental Illness	
RDASH - Rotherham, Doncaster and South Humber NHS Foundation Trust	Interested and awaiting feasibility questionnaire	Heather Rice	heather.rice3@nhs.net	Mental Illness	
Mersey - Mersey Care NHS Foundation Trust	No response	Nusrat Husain	nusrat.husain@manchester.ac.uk	Mental Illness	
Notts - Nottinghamshire Healthcare NHS Foundation Trust	Interested and awaiting feasibility questionnaire	Mark Howells	mark.howells@nottshc.nhs.uk	Mental Illness	
Oxford - Oxford Health NHS Foundation Trust	Interested and awaiting feasibility questionnaire	Vanessa Raymont	vanessa.raymont@psych.ox.ac.uk	Dementia and Mental Illness	

Name of site/practice	Status	Investigator Name	Investigator Email Address	Investigator Specialty	Additional Information
Sussex - Sussex Partnership NHS Foundation Trust	Interested and awaiting feasibility questionnaire	Mark Hayward	mark.hayward@spft.nhs.uk	Mental Illness	
WLT - West London NHS Trust	Interested and awaiting feasibility questionnaire	Sophie Coronini	sophie.coronini-cronberg@westlondon.nhs.uk	Mental Illness	

SITE IDENTIFICATION

B28: How many sites would you like us to identify as part of this Site Identification service?	10
B31a: In which geographical locations would you like us to identify sites? (for UK wide, tick all four nations)	
England	Yes
Northern Ireland	No
Scotland	No
Wales	No
B32: Are there any specific questions in relation to deliverability for this particular study that you would like interested sites to respond to?	No
As standard, sites will provide information around their research expertise and a suggested target recruitment for your study.	
B32a: Additional question 1	
B32b: Additional question 2	
B32c: Additional question 3	
B32d: Additional question 4	

CONFIRMATION

B42: Please provide any additional information or questions you have below :

We are looking to initiate sites that are in Akrivia's HCO network to contribute to GlobalMinds recruitment (via PIC activity, promotion and/or in-person recruitment). The COO of Akrivia Health is communicating with these sites and therefore the support at this stage that we would require is to disseminate the final iCT to the sites at the appropriate time,. Additionally, we are looking to identify sites and obtain information around recruitment figures for dementia cohort in primary care. Is this something you could support with?

The information provided in the submission will be treated as CONFIDENTIAL however it may be distributed to third parties without the need for a formal confidentiality agreement, to support site feasibility. NIHR RDN site level feasibility is based on the information supplied, the schedule of events and any additional information supplied that can be circulated without the need for a CDA.