0. Proposal name

Psychosis Immune Mechanism Stratified Medicine Trial: The PIMS Trial

1. Description of the data

1.1 Type of study

Proof-of-concept, double-blind, randomised, parallel-group (1:1), single-dose clinical trial

1.2 Types of data

Blood immune-biomarker; genotype; neuroimaging; cognition; psychiatric symptoms from questionnaire and clinical assessments; quality of life and wellbeing.

1.3 Format and scale of the data

De-identified data will be stored using Excel, STATA, SPSS, and other software.

2. Data collection / generation

2.1 Methodologies for data collection / generation

This trial will generate a considerable amount of data. Collection, management, curation, storage, and sharing of this data will be done in accordance with research data management guidelines from the Universities of Bristol, Birmingham, and Cambridge.

2.2 Data quality and standards

Measures will be taken to ensure data quality, for example, data entry validation. Blood biomarker assays will be done following strict quality control processes. Neuroimaging will be performed following a strict procedure following optimisation of data acquisition and imaging parameters, adhering to guidelines at local imaging centres.

3. Data management, documentation, and curation

3.1 Managing, storing and curating data.

Collection, management, curation, storage, and sharing of data will be done in accordance with research data management guidelines from the Universities of Bristol, Birmingham, and Cambridge. Data will be stored on secure computer servers.

3.2 Metadata standards and data documentation

Measures will be taken to ensure research data can be used by others outside of the team. This will include documenting methods used to generate the data, analytical and procedural information, documenting provenance of data and their coding, and generating detailed descriptions for variables. This information will be stored alongside the data itself.

3.3 Data preservation strategy and standards

Raw data, meta-data, and results of analysis will be kept in secure servers for at least ten years after the completion of the trial. Physical data will be archived securely on university premises.

4. Data security and confidentiality of potentially disclosive information

4.1 Formal information/data security standards

Data Protection Act.

4.2 Main risks to data security

Datasets will contain no person identifiable information. All personal data will be de-identified by using participant ID. Data will be stored on secure university computers under password protection. Personal identification key for study participants will be stored separately on secure university computer under password protection to avoid accidental identification of participants in the clinical trial arm.

5. Data sharing and access

5.1 Suitability for sharing

Data amassed and generated will be a resource for the wider scientific community as (a) a reference for scientific information, (b) resource for collaboration and testing of specific hypothesis, subject to approval of participating sites.

5.2 Discovery by potential users of the research data

Potential new users outside of our organisations can find out about the data and identify whether it could be suitable for their research purposes through summary information (metadata) which will be made available on the study website.

Published articles will be submitted to repositories. Results of data analysis will be deposited to a recognised data repository subject to approval of participating sites. Raw and meta-data will be stored in secure servers for at least ten years after the completion of the trial.

5.3 Governance of access

Data arising from participant testing will be shared with other researchers to maximise impact, ensuring participant confidentiality is maintained and the data sharing policy of participating cohorts are followed. We will establish a Data Access Committee, composed of experienced and appropriate persons, to oversee requests for data access and collaboration after project completion.

In accordance with good research practice, it will be ensured that appropriate systems are in place to protect confidentiality and security of data pertaining to participants, and to minimise any risks of identification by data users. We will set up a process including a Data Access and Management Committee to ensure that access to data is maximised.

5.4 The study team's exclusive use of the data

In-line with established best practice in the field, data (with accompanying metadata) will be shared in a timely fashion in three successive stages.

Stage 1: results of analyses will be shared with the participating sites during the trial.

Stage 2: results will be published in scientific journals, and articles will be submitted to repository.

Stage 3: a framework will be established through which other researchers will be able to apply to collaborate subject to approval of the PIMS consortium and participating sites.

5.5 Restrictions or delays to sharing, with planned actions to limit such restrictions

Data sharing policy of participating sites may potentially limit sharing of raw data with other researchers outside the PIMS consortium. It will not be possible to share any potential person identifiable information to ensure compliance with participant consent and

REC approvals.

5.6 Regulation of responsibilities of users

External users of the data will be bound by data sharing agreements.

6. Responsibilities

Apart from the PIs, who is responsible at your organisation/within your consortia for:

- *study-wide data management*
- *metadata creation,*
- *data security*
- *quality assurance of data.*

A Data Access and Management Committee will be set up to assist the PIs.

7. Relevant institutional, departmental or study policies on data sharing and data security

Please complete, where such policies are (i) relevant to your study, and (ii) are in the public domain, e.g. accessible through the internet.

Add any others that are relevant

Policy	**URL or Reference**
Data Management Policy & Procedures	http://www.bristol.ac.uk/research/environment/governance/research-data-policy/ https://intranet.birmingham.ac.uk/as/libraryservices/library/research/rdm/policies/research-data-management-policy.aspx http://www.data.cam.ac.uk/university-policy
Data Security Policy	
Data Sharing Policy	
Institutional Information Policy	
Other:	
Other	

8. Author of this Data Management Plan (Name) and, if different to that of the Principal Investigator, their email contact details

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