

CLINICAL DATA REGISTRY/ BIOBANK SET UP GUIDE

This high-level document outlines items to consider before establishment of a clinical data registry and biobank. Once each point is addressed, the next step is to develop a detailed scope and plan.

PURPOSE

- Clearly define the purpose of the registry – it must be developed with clear purpose aimed at improving healthcare, lead to knowledge-sharing activities and research training programmes
- Outline which organisations will utilize the registry (e.g. MQ only or multiple sites)

STAKEHOLDERS

Identify key stakeholders such as:

- Registry owner
- Data owner
- Clinicians
- Participants
- Funding body
- Human Research Ethics Committee (HREC)
- Researchers

PARTICIPANTS

- Define the target population including inclusion and exclusion criteria
- Target number of participants per year and/or total over expected registry lifetime
- How & where participants will be identified
- Which clinician(s) and clinic(s) will support the registry?
- Use of retrospective and/or newly recruited participants

DATA COLLECTION

- Identify suitable data source(s)
- If data will be collected directly from participants, what physical location will this occur at
- Ensure appropriate balance between burden of data collection and value of data
- Longitudinal or a single timepoint?

DATA ELEMENTS

- Outcomes should be assessed using objective measures, where feasible
- Define the data dictionary
- Define the types of data to be collected e.g. data fields, surveys, images etc.
- Identify linkage to other systems/datasets
- Database location (cross border issues), storage and transfer costs
- Links to other data – electronic medical records, MBS/PBS

REGISTRY CONTENT MANAGEMENT SYSTEM (CMS)

- Outline requirements of CMS (details of both laboratory information management system and clinical data requirements)
- Consider hardware and software requirements to support subsequent use of algorithms, machine learning, data mining and AI-based tools
- Consider security and privacy
- Weigh up bespoke versus off-the-shelf (SF created a summary of this & can be provided)
- Does it have built-in quality management e.g. validity checks?
- Are there any licence fees?
- Does the registry require personnel with specific skills (e.g. developer, IT skills) to set up and/or run?
- Does it allow interoperability with other systems?
- Create a list of users that will require access to the CMS including their roles, level of access to the data
- Outline data exports, reports, and stats requirements for research, quality control and participant management
- Can user access to identifiable data be restricted

SAMPLES

- Define what samples are to be collected e.g. blood, biopsies, urine, plasma etc.
- Define level of processing required e.g. PBMCs, RNA, DNA, etc.
- Where will samples be collected
- What experience required to perform collections
- Transport required to MQ
- Long-term storage requirements – including a future review date (e.g. after 10 years)
- Contact people (long term) – see also under Organisation
- Method for identification e.g. barcoding
- How will sample movements be tracked

LABORATORY INFRASTRUCTURE

- Space
- Equipment
- Access
- Expertise
- Consumables

ORGANISATION

- Create organisational structure of the registry
- Define roles and responsibilities of key people in the registry
- Custodian: separate owner of the registry (MQ) and owner of the registry data
- Manager: manage day-to-day operations of the registry
- Coordinator: recruitment, consent, data collection, data entry
- Technician: Sample collection, processing, storage
- Database Support: implement and support the registry
- These roles could have some overlap and be < 1.0 FTE, depending on size and complexity of the registry

GOVERNANCE

- Expert Advisory committee
- Governance committee to oversee access and operations
- Template of committee structure can be provided

APPROVALS REQUIRED

- MQ Health Clinical Research Governance
- Human Research Ethics Committee (HREC)
- Institutional Biosafety Committee
- Consent from participants
- Signed funding contract
- Agreements with other parties (for multicentre registries)

ACCESS

- Will access be restricted to MQ or open to external organisations? (research on *the project*, research outside *the project*, *commercial use*).
- Approval Process for internal requests e.g. project request form reviewed by registry committee or something else.
- Approval Process for external requests (additional requirements to internal)
- Will use of the data be restricted (e.g. licenced data)
- What fees are charged to access the data
- Audits trails

COSTS

- Outline Initial set up costs
- Outline ongoing costs to run the biobank
- Staff
- Licences
- Infrastructure
- Consumables etc.

FUNDING

- Funding contract – external funding organisation/industry – and terms which may restrict or limit the ability to share data.
- Sufficient funding for data collection reporting & application of procedures – using a biobank costing template (to be developed).
- Facilities & infrastructure available.

CMS REPORTING REQUIREMENTS

- Define data exports, reports, and stats requirements for research, quality control and participant management

TIMELINE

- Outline the anticipated timeline for establishment of the registry

FEASIBILITY

- Participant population availability
- Clinician and other important stakeholder buy-in.
- Access to required data to fit purpose
- Resources available to run registry (e.g. staffing, data, software, data storage etc)

RELEVANT MQ POLICIES AND PROCEDURES

- Directory <https://policies.mq.edu.au/browse.php>
- [Privacy Policy](#)
- [Records and Information Management Policy](#)
- [Retention and Disposal Procedure](#)
- [Computer and Network Security Procedure](#)
- [Cyber Security Policy](#)

USEFUL EXTERNAL RESOURCES

- NSW Biobank certification program https://nsw.biobanking.org/webs/certification_program
- ISBER <https://www.isber.org/>
- AU Commission on safety and quality in health care
<https://www.safetyandquality.gov.au/our-work/indicators-measurement-and-reporting/national-arrangements-clinical-quality-registries>
- Framework for AU Clinical Quality Registries
<https://www.safetyandquality.gov.au/sites/default/files/migrated/Framework-for-Australian-Clinical-Quality-Registries.pdf>
- Registries for Evaluating Patient Outcomes: A User's Guide [Internet]. 3rd edition.
<https://www.ncbi.nlm.nih.gov/books/NBK208631/>
- <https://www.ands.org.au/working-with-data/publishing-and-reusing-data/licensing-for-reuse>

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