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

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

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
• Framework for AU Clinical Quality Registries
  https://www.ncbi.nlm.nih.gov/books/NBK208631/

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