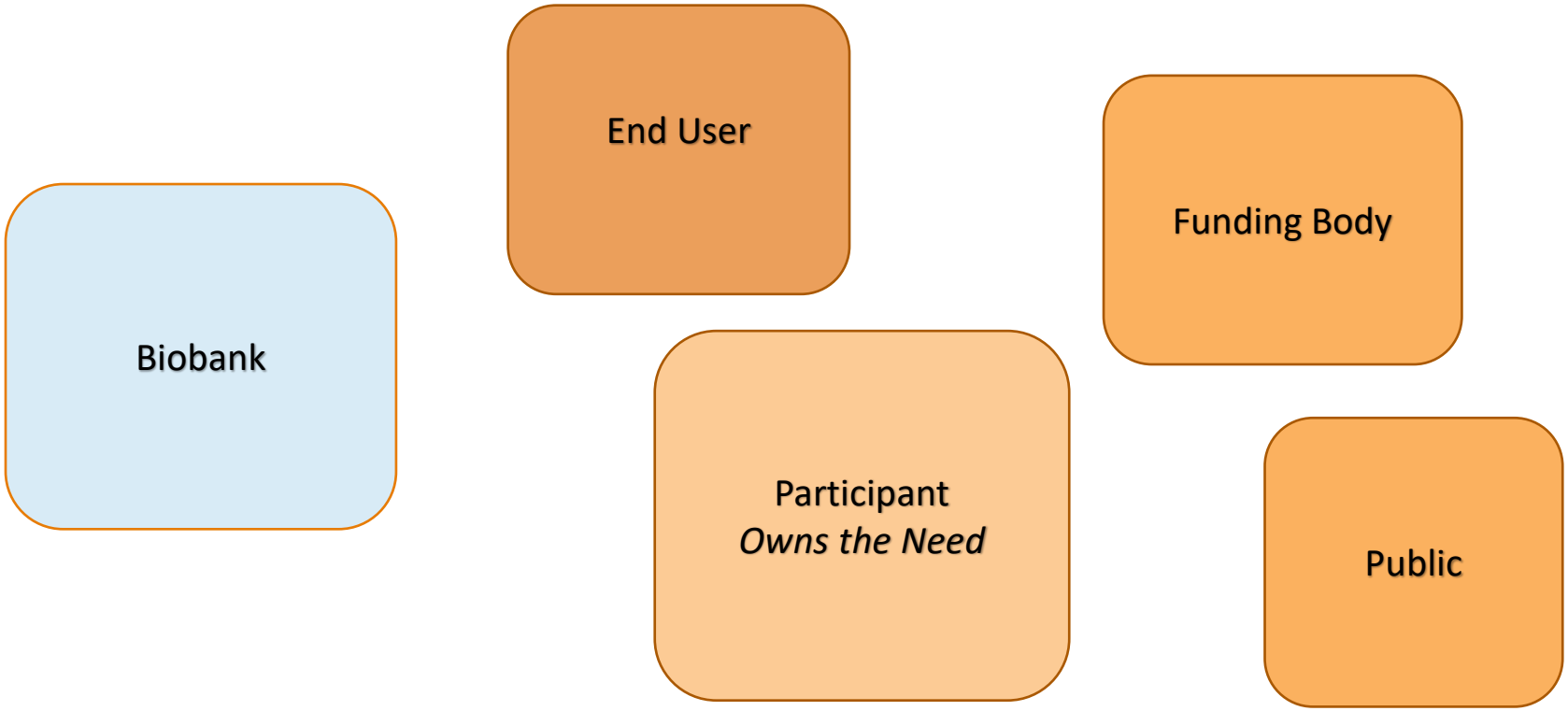
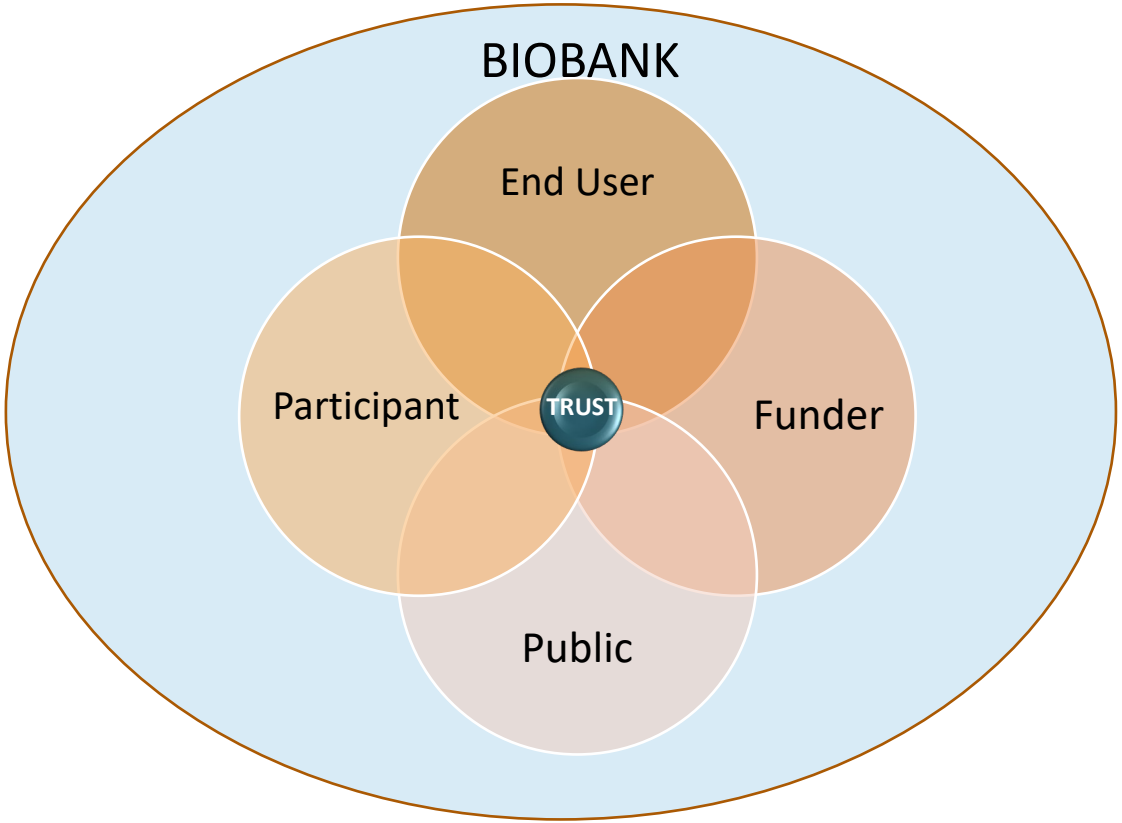
Why Use a Standard?

1. Provide a context for use of standards
2. Different standards
3. Biobanking ISO 20387:2018
4. Questions/suggestions

Without Trust: Exist as Disconnected Silos



With Trust: Interconnectivity

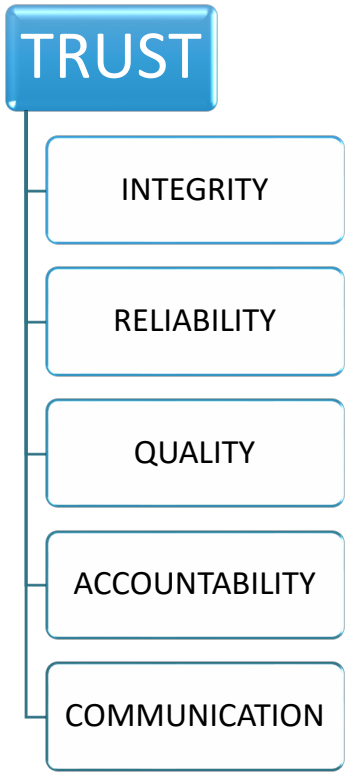


Trust is Like Glass

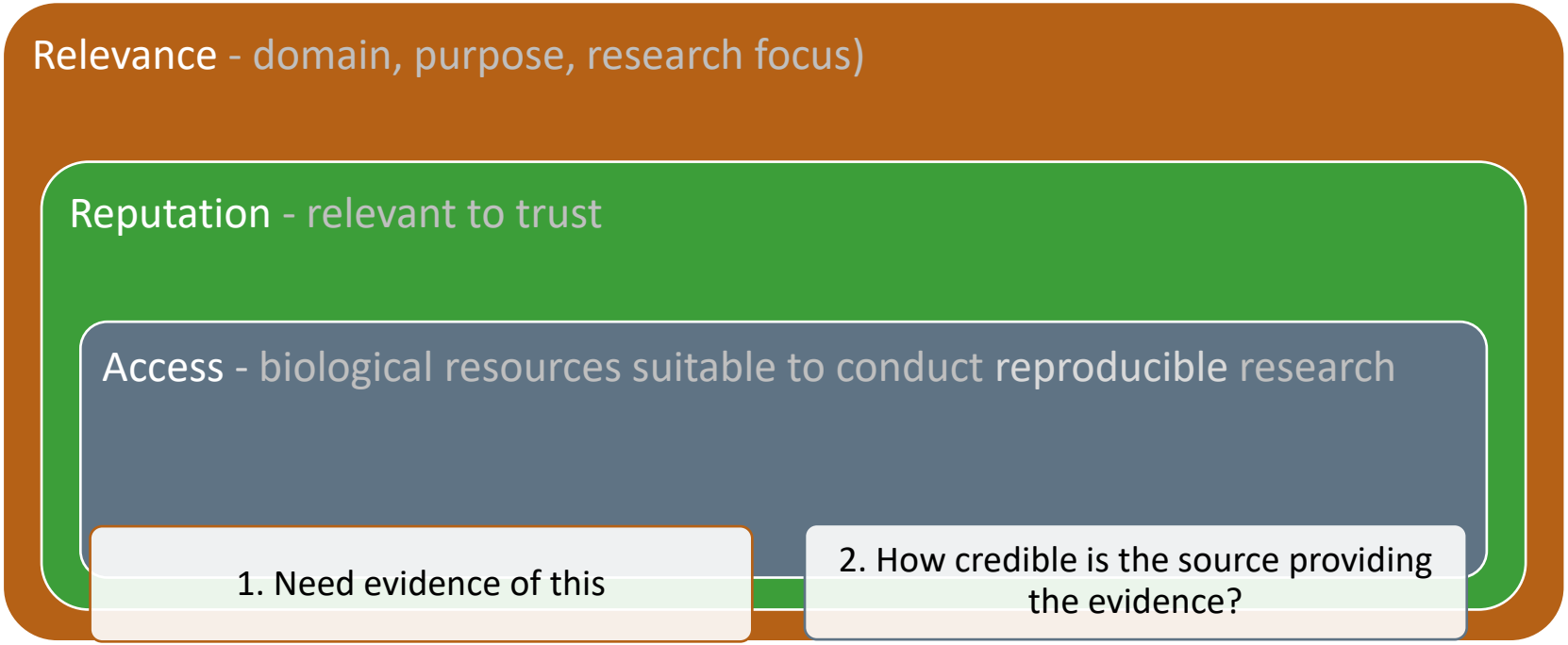
Once broken, cannot be repaired!

Establishing Trust

Fostering a culture of confidence in biobanking core values



Consider How End-Users Assess Collections

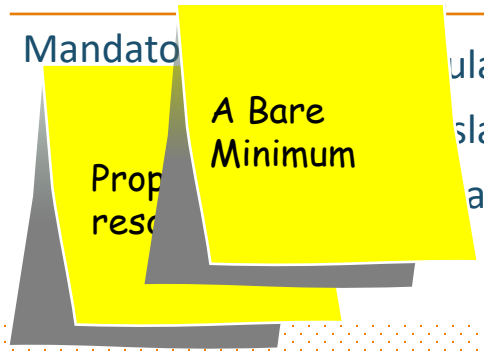


Trust depends on Credibility

Mandato ulations

slation

al Framework



Add Layers of Assurance

Standards – What's in a word

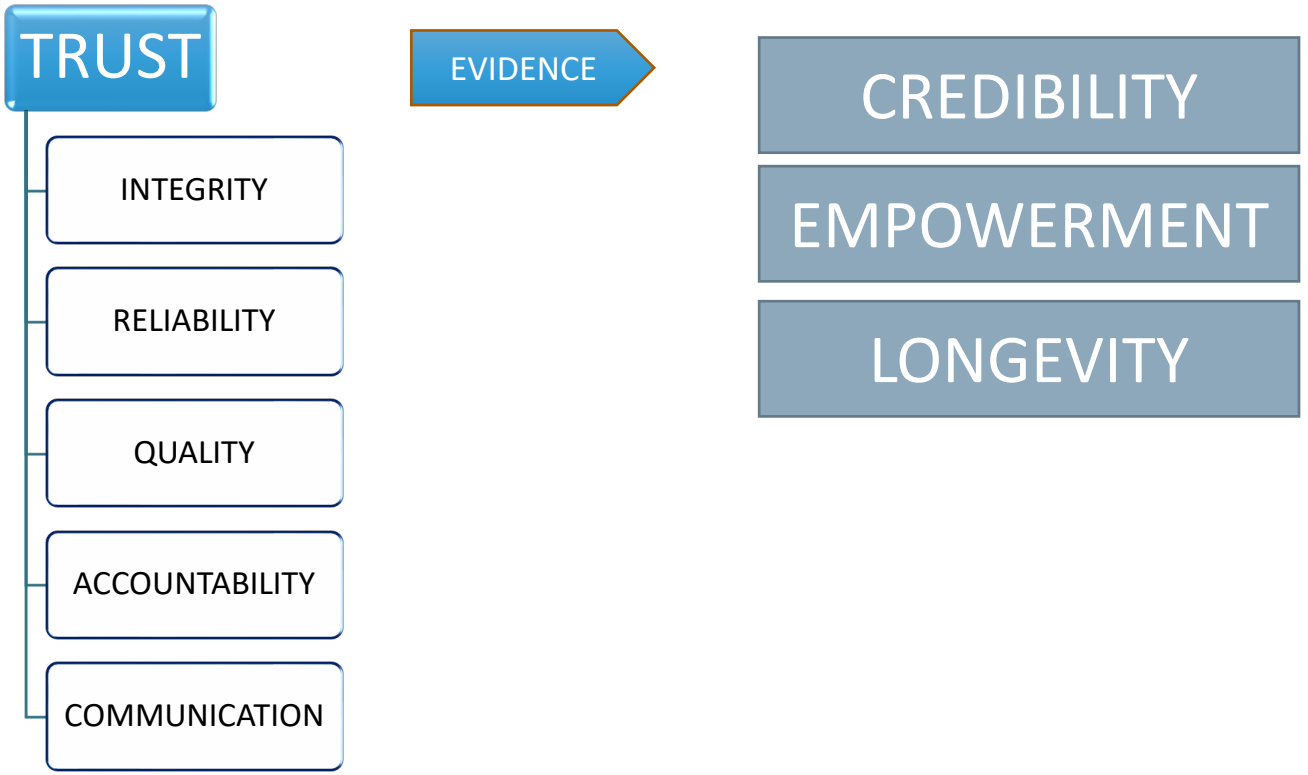
De facto Standards: Result from public acceptance or market forces, widely used e.g. QWERTY keyboard

Consortia Standards: Established by exclusive group or arrangements, common in ICT

Formal Standards Established by standard-setting organizations according to strict procedures (ISO, CEN, …)

Enables an organisation to establish, measure and assure a level of quality & predictability

Trust Creation



Why was ISO 20387 Created?

No single existing resource of requirements available to a biobank to assure quality of their biological resources

Confusing for emerging biobanks & stakeholders

Quality management implemented by some biobanks (ISO 9001)

Accreditation of several biobanks for parts of their activities to

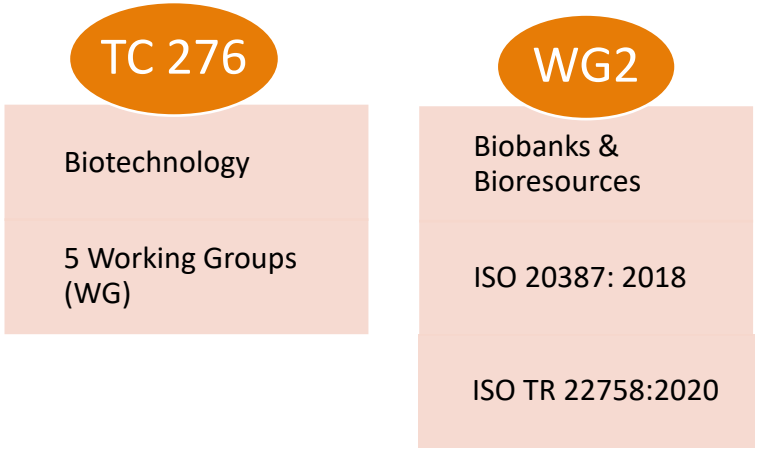
ISO 17025,

ISO 17034,

ISO 15189

and/or other standards

ISO Technical Committee Dedicated to Biotechnology



First int'l standard dedicated to biobanking!

Technical report to assist with implementation

TC 276 WG2 Still Active

- Currently engaged in gathering individual & national feedback on the implementation and use of the standard
- Systematic Review of the Standard
- Potential for revision of the document
- Irish Mirror Committee TC62 - welcome newcomers to the process

Contact Linda.Hendy@nsai.ie if interested

Exploring Value Proposition of ISO 20387

- Pro

  - Offers a common terminology
  - Improves interoperability → Fosters globalization
  - Facilitate trade and technology transfers
  - More efficiency and effectiveness → Satisfaction of interested parties
  - New Opportunities

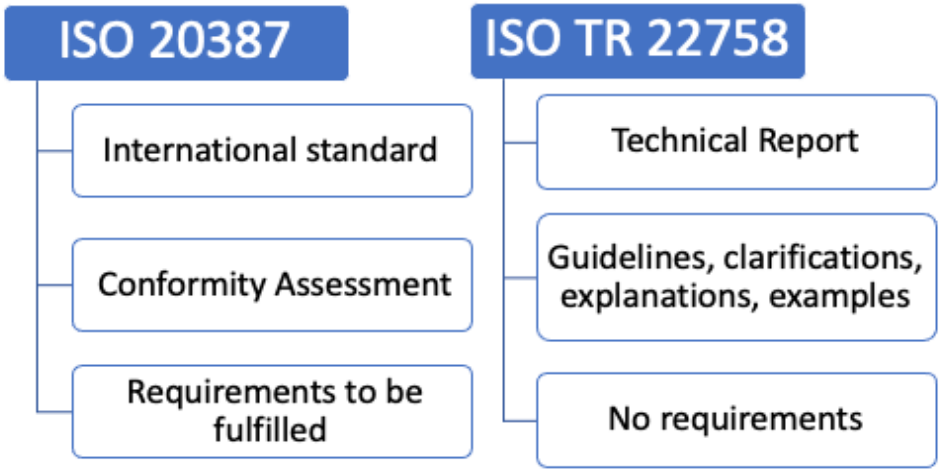
- Con

  - May limit creativity
  - Resources (Costs, time, people)

- Balance

  - Benefits of standards outweighs drawbacks

Clarification of ISO 20387



Central Concepts of ISO 20387

ISO 20387		ISO / TR 22758
📖3.7 **biological material**	any substance derived or part obtained from an organic entity such as a human, animal, plant, microorganism(s) or multicellular organism(s) that is(are) neither animal nor plant (e.g. brown seaweed, fungi)	Biological materials and/or associated data → **BMaD**
📖3.3 **associated data**	any information affiliated with biological material including but not limited to research, phenotypic, clinical, epidemiologic, and procedural data	
📖3.24 **fit for purpose** **fitness for the intended purpose**	**In line with prearranged requirements for an intended use** Note 1 to entry: The definition of such requirements can take place within the biobank itself and/or in collaboration with users and should consider analytical and other relevant criteria.	Denoted by **FIP**

3. ISO 20387

- Providing biological resources **Fit for purpose/Fitness for the intended purpose** (FIP)

  → Defining FIP characteristics

  ✓ **External**: resource requirements, legal and ethical requirements, user requirements

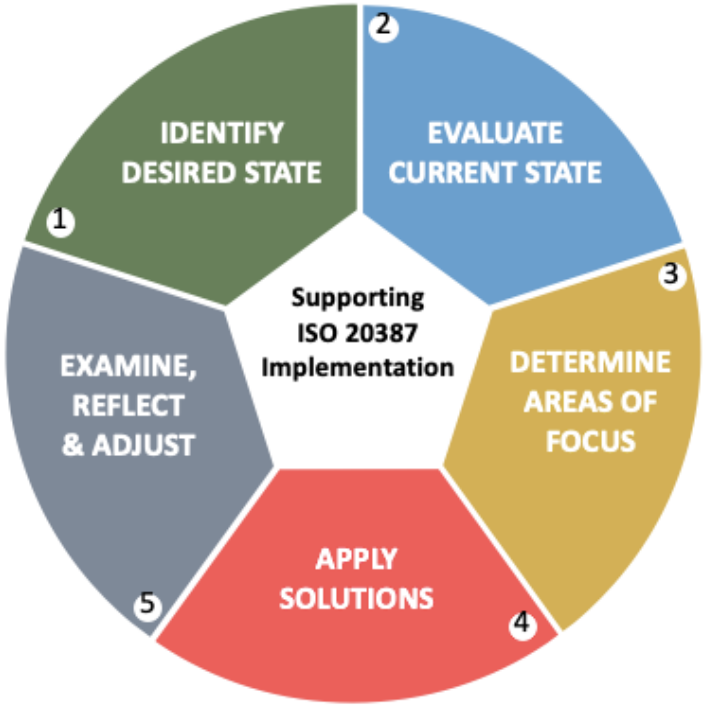
  ✓ **Internal**: processes, quality control

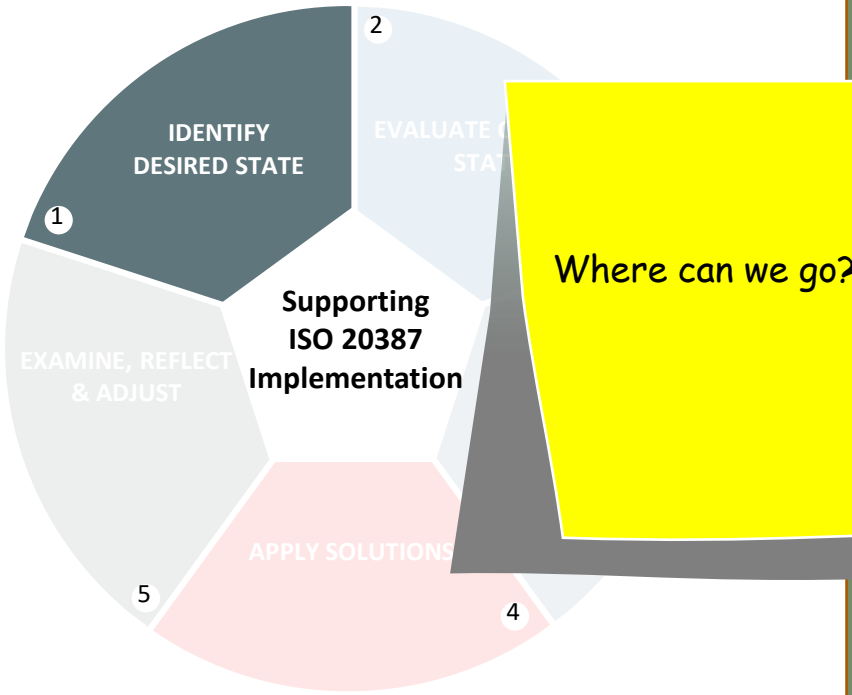
  →Continual assessment of FIP characteristics drives evolving optimization of the biological material and associated data during the lifecycle

- **Risk analysis**
  - **"Shall"** indicates a requirement;
  - **"Should"** indicates a recommendation;
  - **"May"** indicates a permission;
  - **"Can"** indicates a possibility or a capability.

Approaching Implementation

Value proposition





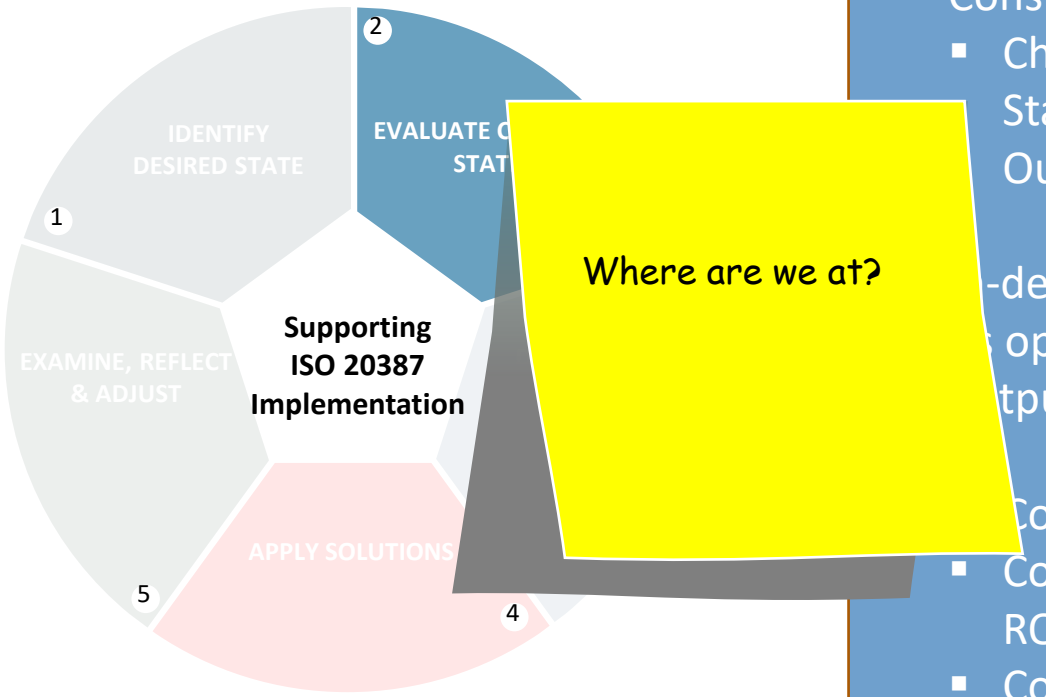
Where can we go?

1. IDENTIFY DESIRED STATE

- ocal, national & international
  gulations & ethical frameworks that
  pply
- 20387 requirements
  - Biobank-specific
  - Technical
  - Management System

Align with biobank's vision and roadmap

2. EVALUATE CURRENT STATE



Where are we at?

Considering environment of operation

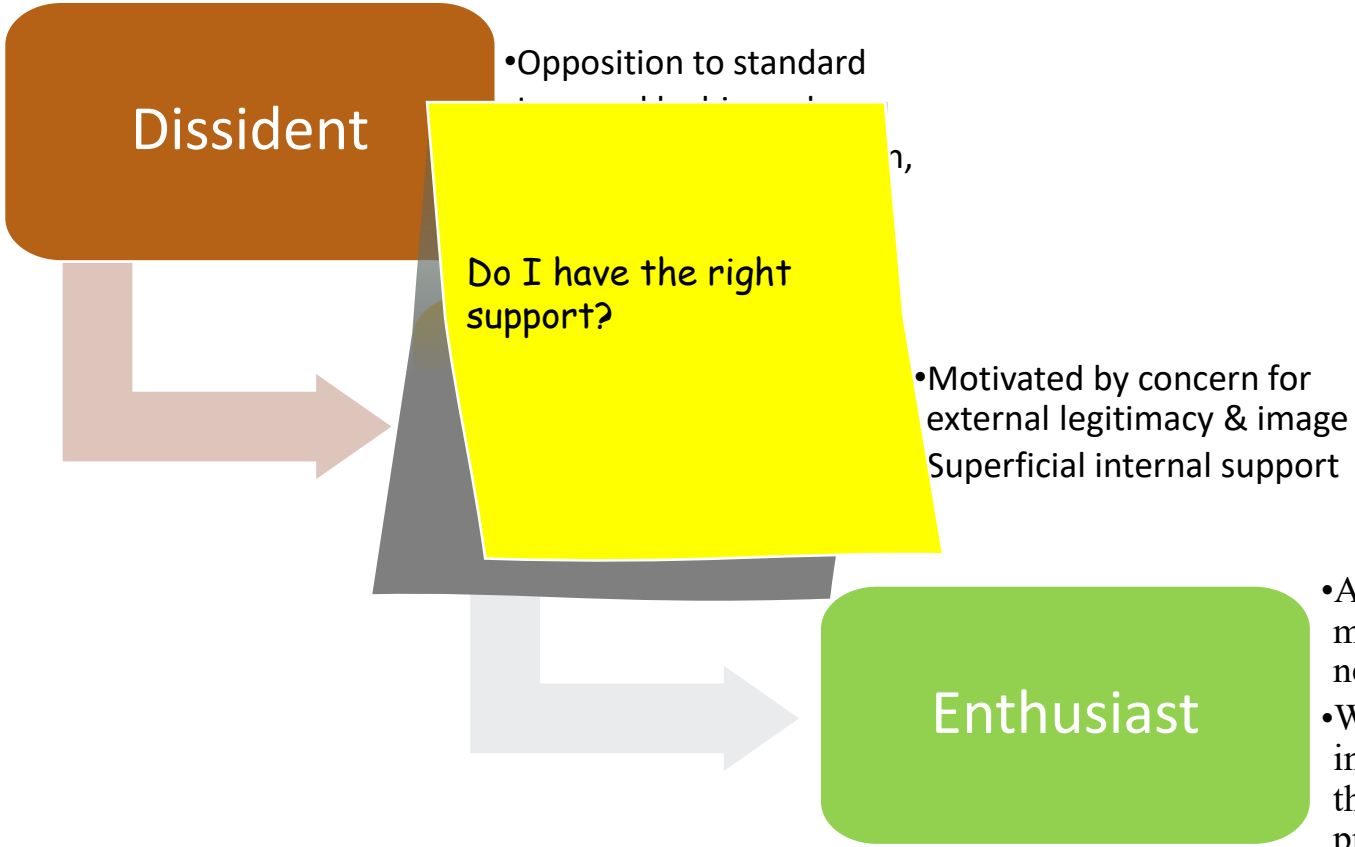
- Changing landscape
  Stakeholders needs
  Output metrics

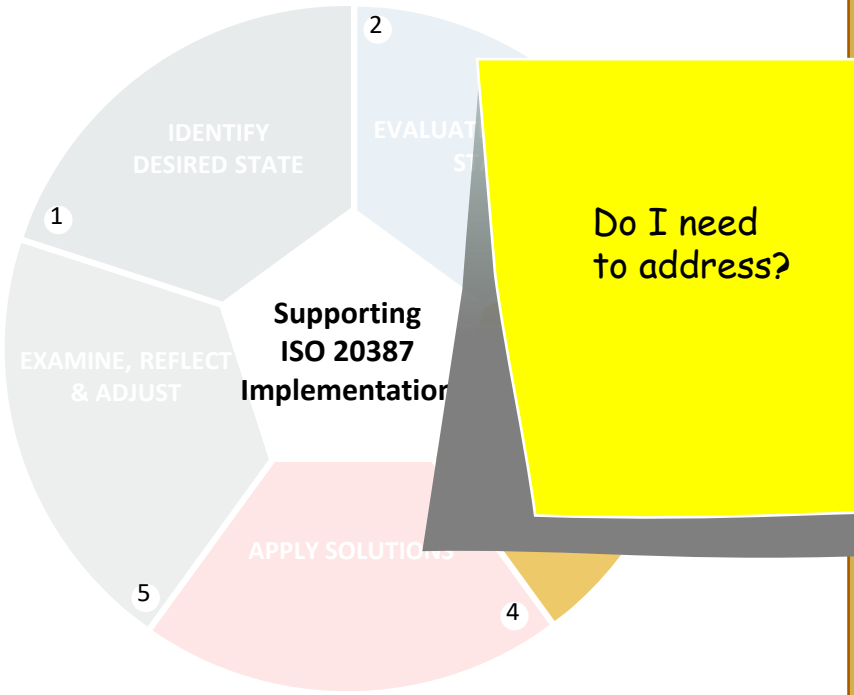
-depth assessment of the biobank &
operations that potentially impact
tput

Consider your organizational support

- Consider resources: financial (e.g. ROI) and other
- Consider implications of both implementation and non-implementation

Evaluate Current Status - 2



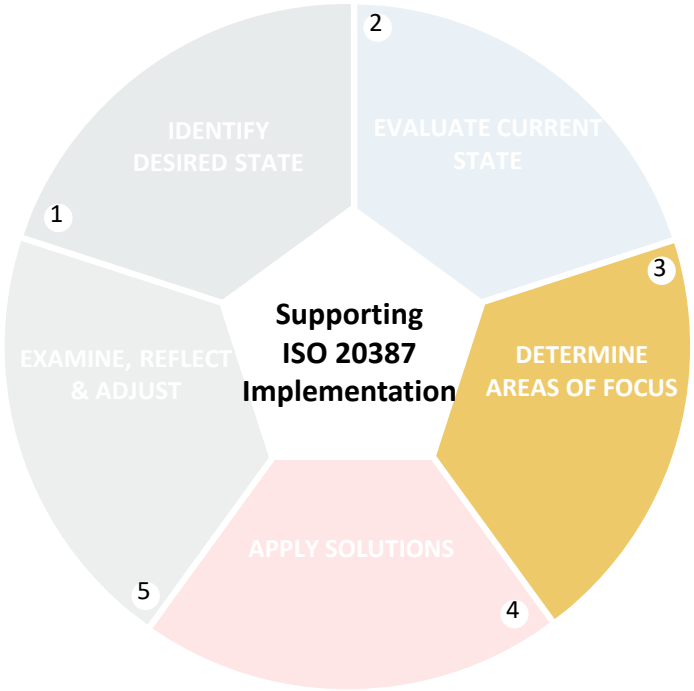


Do I need to address?

3. DETERMINE AREAS OF FOCUS:

- What? Where? Why?
- Gap analysis (e.g., SWOT, RCA)
- Create plan for implementation using parameters:
  - scope of my biobank - selection process
  - ISO 20387 types of requirements & recommendations
  - ISO 20387 underlying concepts

e.g. Impartiality, confidentiality, critical activities, **f**itness for the **i**ntended **p**urpose (FIP)



3. DETERMINE AREAS OF FOCUS:

FIP Criteria

- applicable legislative & ethical framework (predefined)
- biological
- application
- user specified
- combination of biobank & user specified
- feedback from literature, lessons-learned

ISO/TR 22758:2020(E)

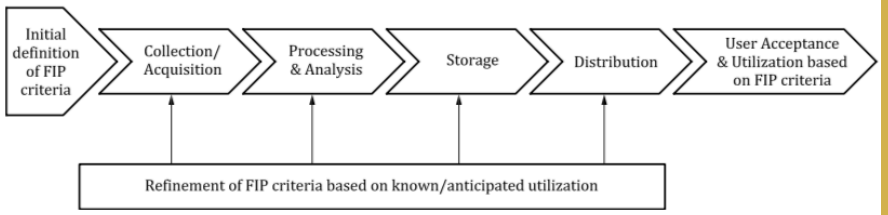
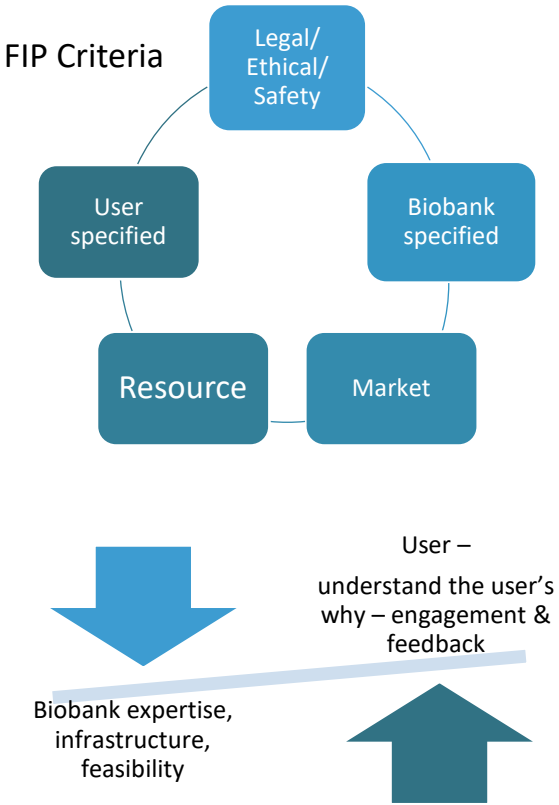


Figure 1 — The progression of BMaD and associated FIP criteria over its life cycle

Fitness for the Intended Purpose

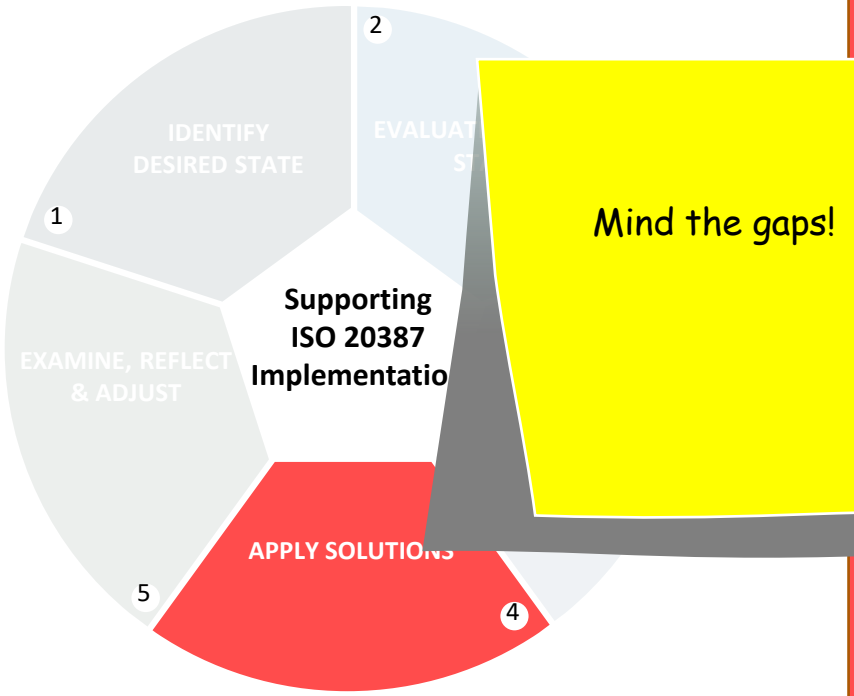
1. Stated Purpose(s)
   Defined by Biobank
   Other - agreements

2. Identify FIP Criteria for the Purpose



3. Design, implement processes to deliver BMaD considered FIP

4. Use of metrics to assess fitness for the identified purpose (QC analyses, test results, etc.)
   - Report to accompany BMaD

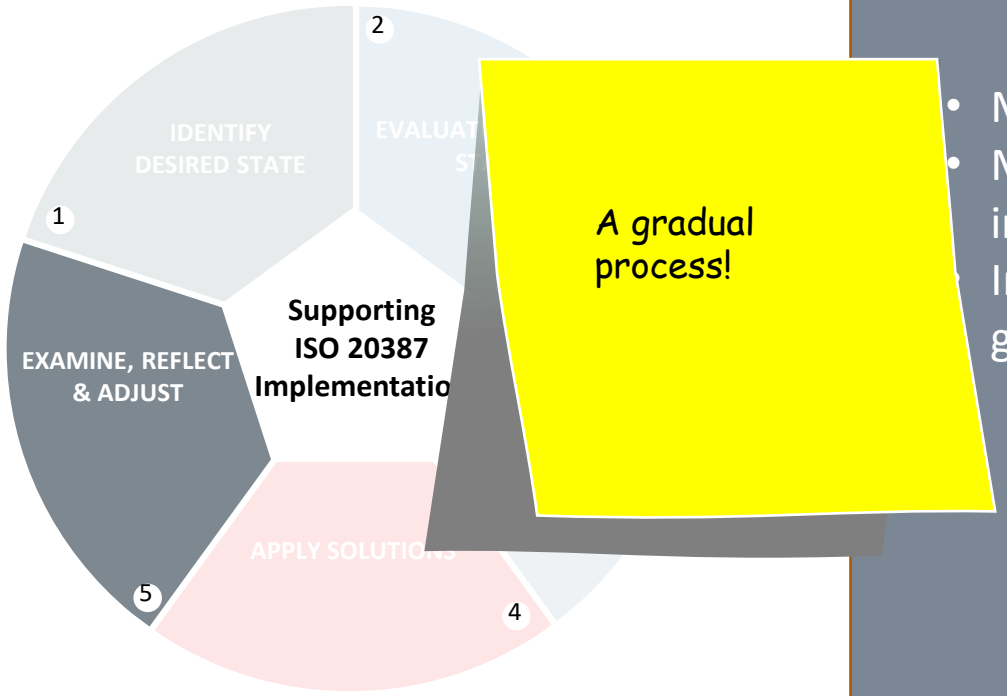


Mind the gaps!

4. APPLY SOLUTIONS

- How? Who? When? How often?
- Further formulate my implement plan
- Address the determined areas of focus in critical processes & activities (defined within scope)
- olutions address gaps & move towards
  - Enabling FIP demonstration (verification and validation)
  - a mindset of ongoing quality and improvement (QMS)
- cross competency of personnel and of biobank

5. EXAMINE, REFLECT & ADJUST



- Monitor for alignment of indicators
- May need to perform further planning in the event of issue discovery
- Implementation is likely to be a gradual process

Implementation Scenarios

In advance of ISO 20387	Action for Implementation	Potential Output	Examples of Evidence
+ QMS elements - No Process workflow - No Internal support	Assess potential to improve: Management support Define processes, roles, resp.s Address risks + ops. Stakeholder needs + expectations Review to improve	A biobank with a commitment to quality	Self attestation of quality motivation
+ QMS risk based + Management clearly onboard - Lacking resources	Put plan in place to implement a QMS to support FIP Work to integrate standard into biobank's practices	Strong QMS fit for purpose to further address ISO 20387 req.	2nd party OR Recognized quality management system certification (i.e. Option A/B of ISO20387)
++ QMS + Resources identified & in place to support ISO 20387 implementation	Specifically address all requirements of ISO 20387 as priority	Proceed to assessment 1st party (by biobank) 2nd party (by user's org) 3rd party (accred. body)	Self declaration Agreement/contract Accreditation
++ QMS certified ++ Process workflow ++ Resources identified & in place	Address requirements & recommendations	Proceed to assessment of conformity	Accred. with enhanced capabilities

Potential Impacts of Accreditation

Operational efficiency

Participation from BMaD providers

Increased researcher interest

Philanthropy

Increased success in grant applications

emmasnapes@gmail.com