Shared Health Research and Innovation

Learning Together Session
February 12, 2024

Why care so much about research?

1. Patients should have access to opportunities for participating in new innovations and treatments.
   - Robust ==evidence to support decision making== in healthcare services.
   - Excellence in research correlates with public perception of excellence in care.
   - ==Patient participation in clinical research is a right== and a health system responsibility.
2. Reputational risk (national and international).
   - Patients rely on Shared Health to conduct research in Manitoba.
   - University of Manitoba – faculty/ clinicians.
   - Cancer Care MB – reliant on SH services.
   - Important for ==Recruitment and Retention== of Researcher/Clinicians.
3. Clinical Research is Cost-effective
   - No research = No $$
   - ==Research creates revenue streams to fund health system innovation and more research.==

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Shared Health Research and Innovation

SH Research — Mission

To lead, conduct, foster, disseminate, implement and develop capacity for excellent interdisciplinary innovation and research in Manitoba.

SH Research — Vision

To be a research and innovation world leader in health systems, in order to improve the health and care of patients and _provide each patient an opportunity to be involved in research._

SH Research — Values
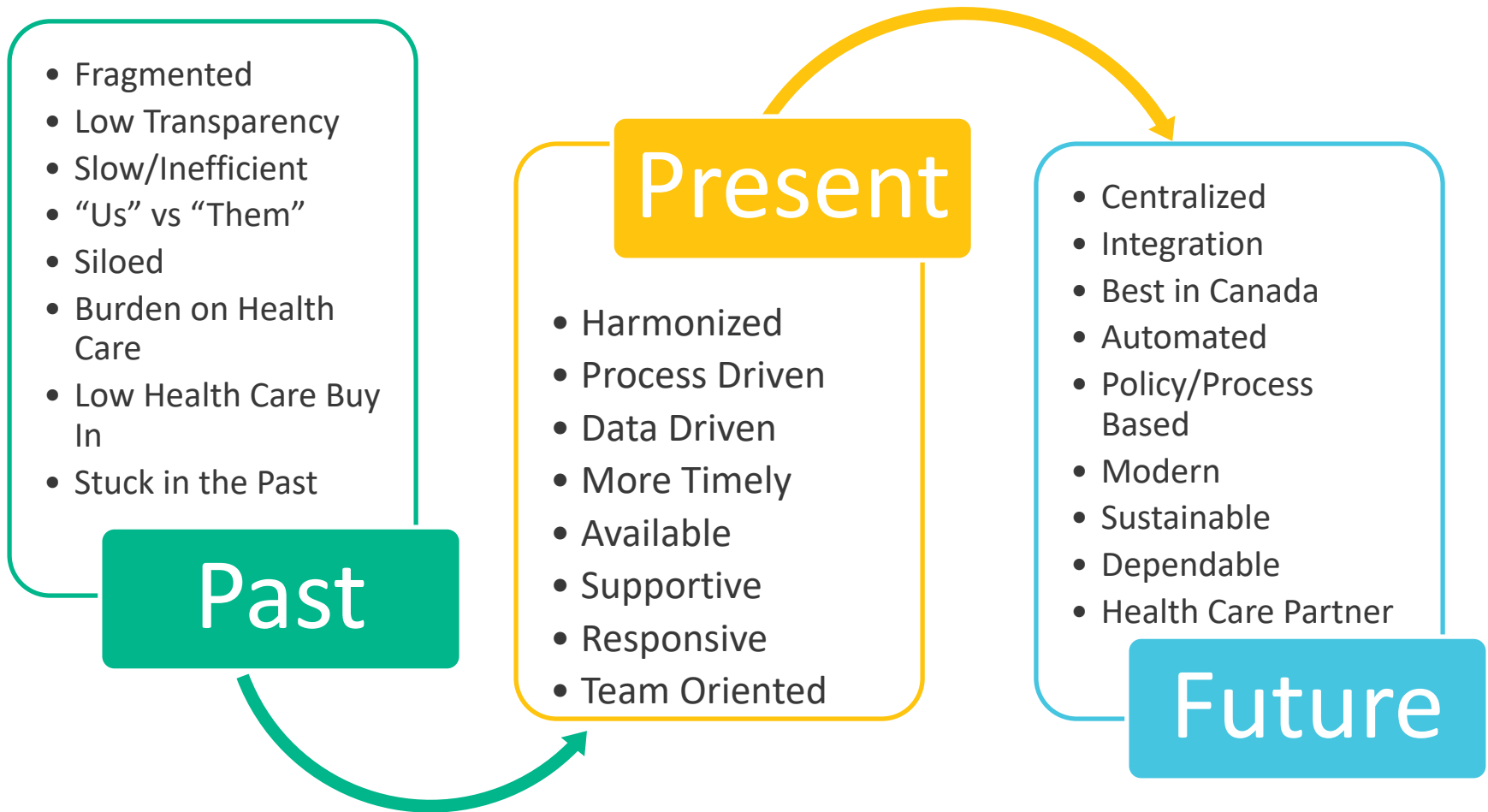
Adhere to ethical standards and scientific integrity; promote evidence informed care; develop new and innovative methods of inquiry.

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SHRI Areas of Focus

- Integration of research services:
  - HSC Research Dept
  - SH/WRHA RAAC
  - Diagnostic Services RSO
- One coordinated office to resolve systemic challenges

Shared Health Research and Innovation

- Institutional Approval and Impact
- Research Access to Trustee PHI
- Innovation Intake
- Research Agreements and Contracts
- Research Facility Management
- Research Policy and SOPs
- Provincial Lead and Coordinate for Research Administration
- Health System Lead for RITHIM
- HSC Foundation Grants

The Past, Present and the Future

Past

- Fragmented
- Low Transparency
- Slow/Inefficient
- "Us" vs "Them"
- Siloed
- Burden on Health Care
- Low Health Care Buy In
- Stuck in the Past

Present

- Harmonized
- Process Driven
- Data Driven
- More Timely
- Available
- Supportive
- Responsive
- Team Oriented

Future

- Centralized
- Integration
- Best in Canada
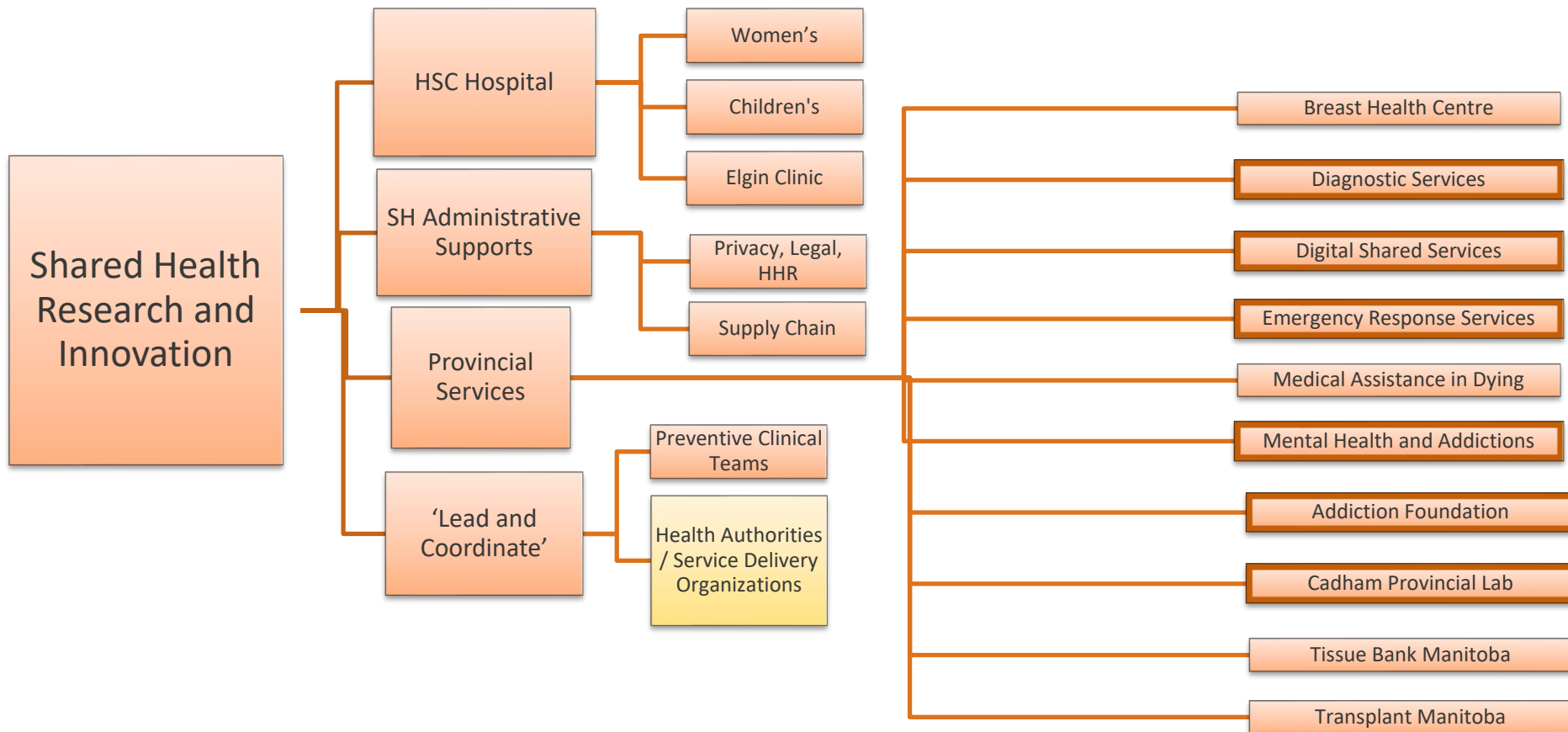- Automated
- Policy/Process Based
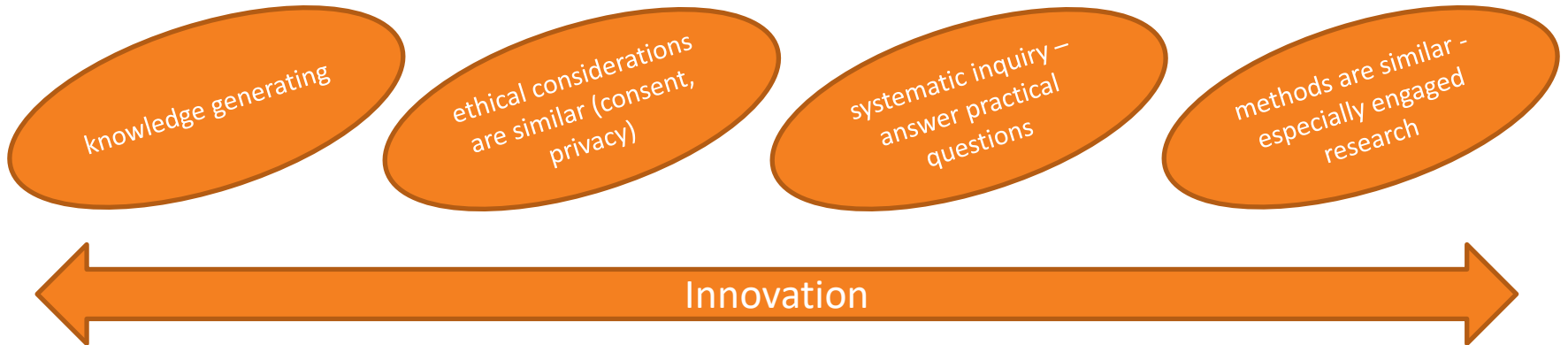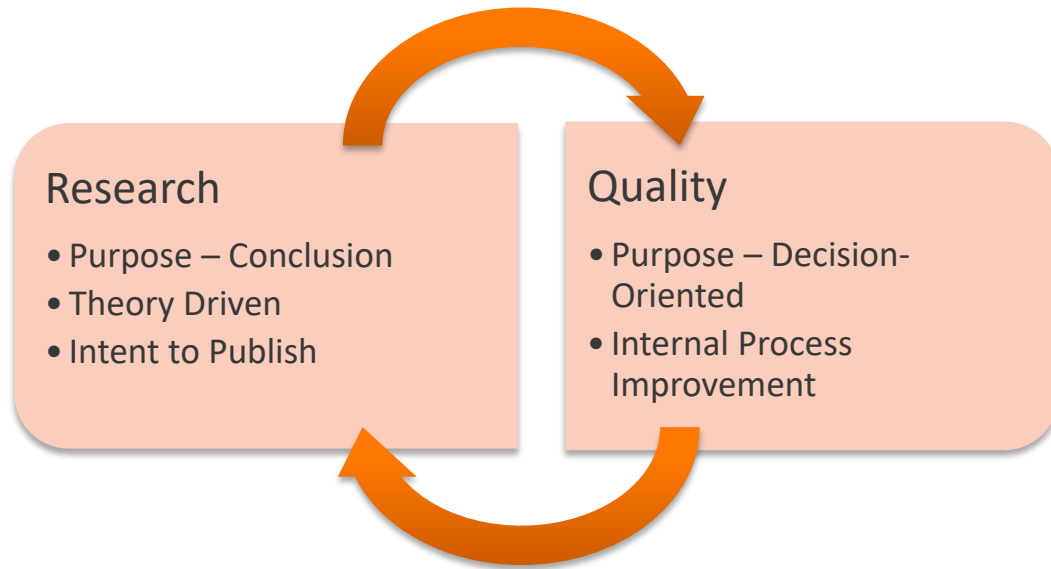- Modern
- Sustainable
- Dependable
- Health Care Partner

Shared Health Research and Innovation

Supports Research and Innovation Directly and Indirectly across Manitoba

Research vs Quality

Research
- Purpose – Conclusion
- Theory Driven
- Intent to Publish

Quality
- Purpose – Decision-Oriented
- Internal Process Improvement

knowledge generating

ethical considerations are similar (consent, privacy)

systematic inquiry – answer practical questions

methods are similar - especially engaged research
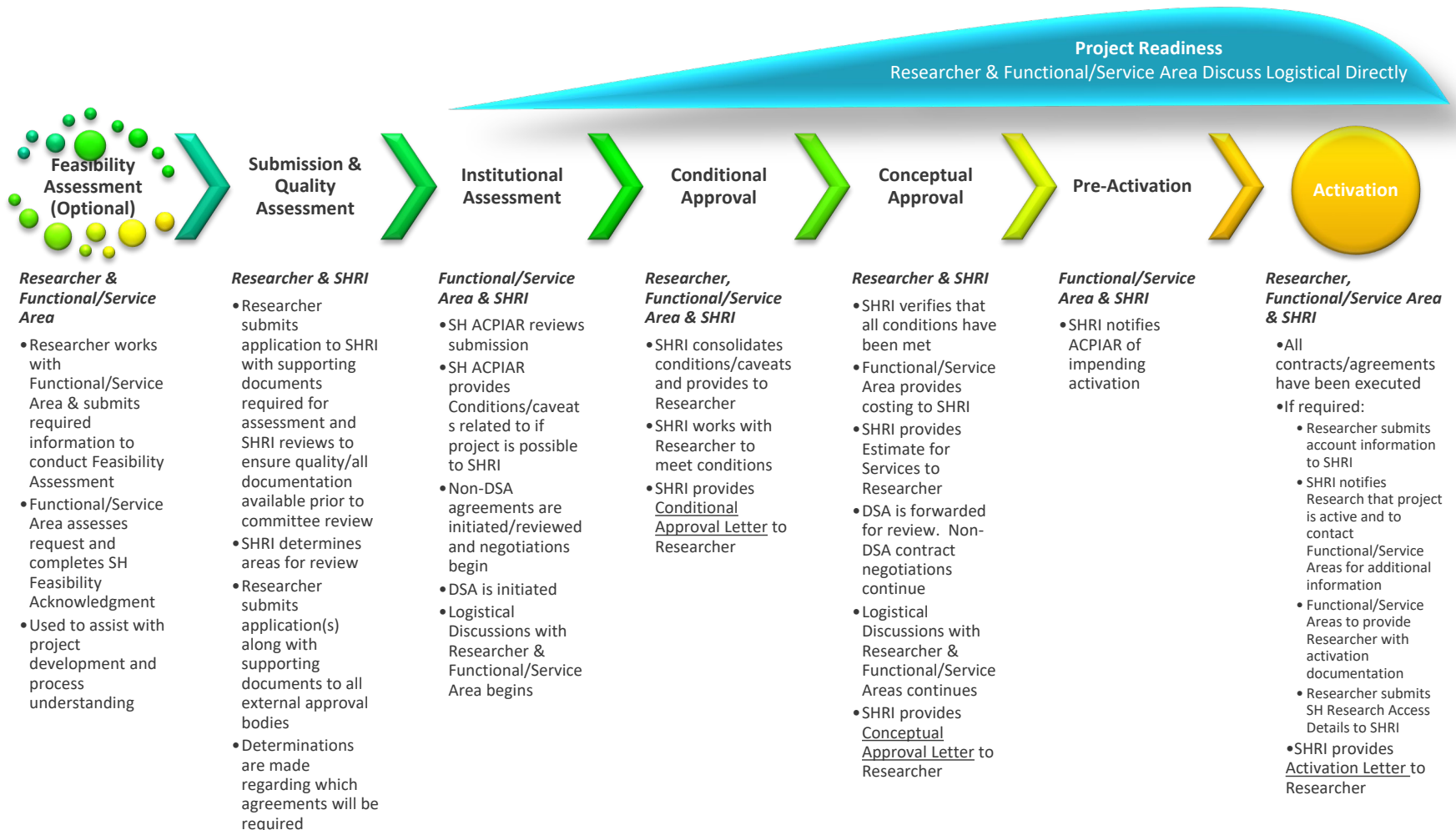
Innovation

Institutional and Trustee Review and Approval

Shared Health Research and Innovation (SHRI) Assessment Process

Project Readiness
Researcher & Functional/Service Area Discuss Logistical Directly

Feasibility Assessment (Optional) → **Submission & Quality Assessment** → **Institutional Assessment** → **Conditional Approval** → **Conceptual Approval** → **Pre-Activation** → **Activation**

Researcher & Functional/Service Area

- Researcher works with Functional/Service Area & submits required information to conduct Feasibility Assessment
- Functional/Service Area assesses request and completes SH Feasibility Acknowledgment
- Used to assist with project development and process understanding

Researcher & SHRI

- Researcher submits application to SHRI with supporting documents required for assessment and SHRI reviews to ensure quality/all documentation available prior to committee review
- SHRI determines areas for review
- Researcher submits application(s) along with supporting documents to all external approval bodies
- Determinations are made regarding which agreements will be required

Functional/Service Area & SHRI

- SH ACPIAR reviews submission
- SH ACPIAR provides Conditions/caveats related to if project is possible to SHRI
- Non-DSA agreements are initiated/reviewed and negotiations begin
- DSA is initiated
- Logistical Discussions with Researcher & Functional/Service Area begins

Researcher, Functional/Service Area & SHRI

- SHRI consolidates conditions/caveats and provides to Researcher
- SHRI works with Researcher to meet conditions
- SHRI provides Conditional Approval Letter to Researcher

Researcher & SHRI

- SHRI verifies that all conditions have been met
- Functional/Service Area provides costing to SHRI
- SHRI provides Estimate for Services to Researcher
- DSA is forwarded for review. Non-DSA contract negotiations continue
- Logistical Discussions with Researcher & Functional/Service Areas continues
- SHRI provides Conceptual Approval Letter to Researcher

Functional/Service Area & SHRI

- SHRI notifies ACPIAR of impending activation

Researcher, Functional/Service Area & SHRI

- All contracts/agreements have been executed
- If required:
  - Researcher submits account information to SHRI
  - SHRI notifies Research that project is active and to contact Functional/Service Areas for additional information
  - Functional/Service Areas to provide Researcher with activation documentation
  - Researcher submits SH Research Access Details to SHRI
- SHRI provides Activation Letter to Researcher

Assessment / Activation Timelines

Our goal within SH is to ensure that our timelines are better than industry standards

Institutional Review / Assessment

5-10 business days

Initial Review / Assessment of Agreement

5 business days

Total Time from Submission to Activation

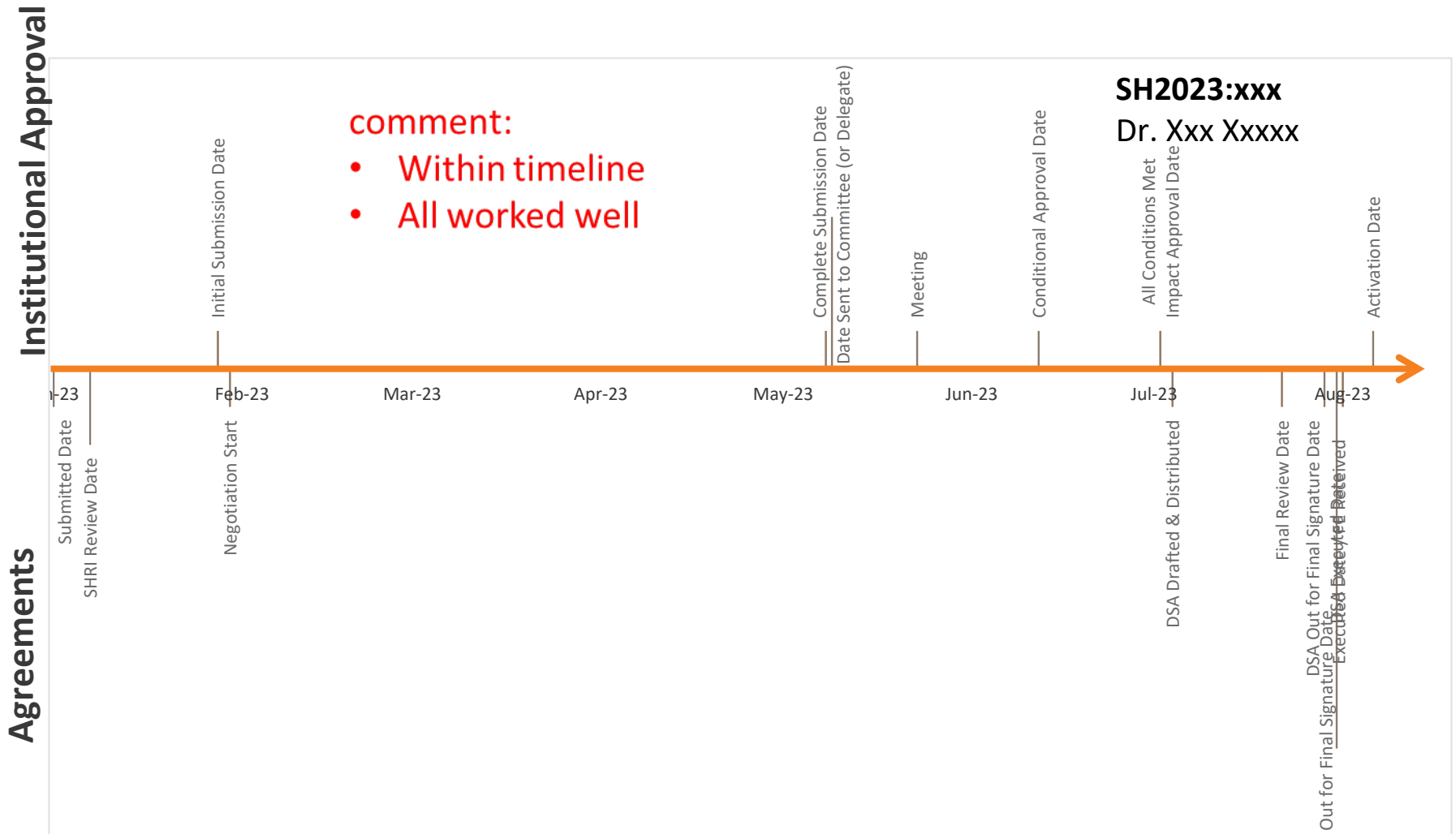| Industry Sponsored/ Clinical Trials	Non-Clinical Trial/ Observational	Student Based
4-6 Months	3-5 Months	1-2 Months

Time to Activation includes institutional reviews/approvals and execution of all necessary agreements

Activation Timeline – Clinical Trial

Institutional Approval

Agreements

SH2023:xxx
Dr. Xxx Xxxxx

comment:
- Within timeline
- All worked well

Initial Submission Date

Complete Submission Date
Date Sent to Committee (or Delegate)

Meeting

Conditional Approval Date

All Conditions Met
Impact Approval Date

Activation Date

Jan-23   Feb-23   Mar-23   Apr-23   May-23   Jun-23   Jul-23   Aug-23

Submitted Date

SHRI Review Date

Negotiation Start

DSA Drafted & Distributed

Final Review Date

Out for Final Signature Date

DSA Out for Final Signature Date

Executed Date
Executed Retrieved

Complete Submission to Activation = 65 Business Days (Target 120 days)

SH Partnership Project Trackers

1. Tool is intended to create transparency between partner organizations such as CCMB/ CHRIM and SH with regard to the status of pending and active initial submissions.
2. Consists of two tabs.
   a. Instructions - has information about the tool
   b. Tracker - has the project information
3. Read Access version of the document can be made accessible to anyone with a Digital Shared Services account.

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Research Improvements Through Harmonization in Manitoba (RITHIM)

1. Consolidation of over 25 separate approval bodies
   a. Harmonized REB, Privacy and Impact review/ approval for ALL health research in Manitoba
2. Produce a singular research application which will be distributed to the various parties as appropriate
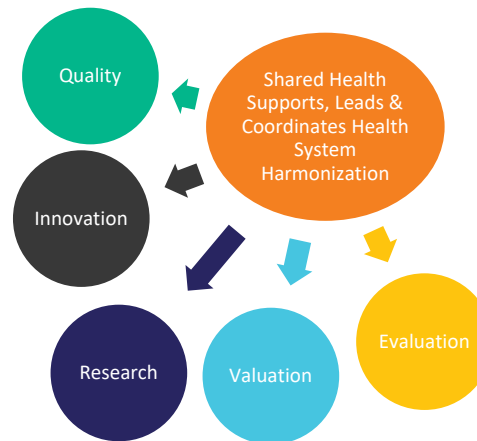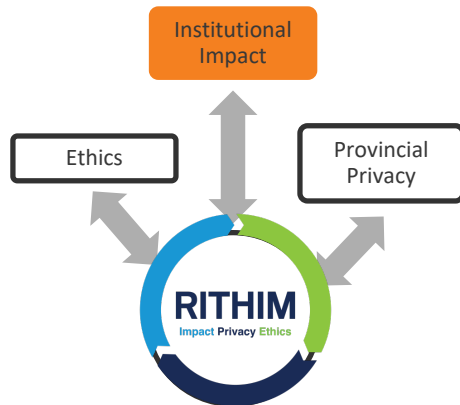
Innovation

What is Innovation in Healthcare?
…and where does it live?

The World Health Organization (WHO)*

'health innovation' improves the efficiency, effectiveness, quality, sustainability, safety, and/or affordability of healthcare. This definition includes:

1. **'new or improved'** health policies, practices, systems, products and technologies, services, and delivery methods that **result in improved healthcare**.

2. The ultimate goal of health innovation is to improve our ability to meet public and personal healthcare needs and demands by optimising the performance of the health system.

*Kimble, L. and Massoud, M. R., (2017) 'What do we mean by Innovation in Healthcare?' EMJ Innov. 2017;1[1]:89-91.
What do we mean by Innovation in Healthcare? - EMJ (emjreviews.com)

Est. Common Intake to Find the Right Path

Research & Innovation

Pre-Commercial

- R&D
- Feedback to inform design
- Supports local industry & economic development
- Opportunity to influence innovation
- Requires evidence for Health Canada Approval

E.g.: Reusable Respirator

Research & Innovation

Disruptive Technology

- Health System Innovation
- Challenges the status quo
- Addresses a problem
- Benefits Health system
- Requires data/evidence to support business case
- May require a re-distribution of resources and supports across multiple services
- Possible Research project

Value Analysis

Change in Std of Care or Practice

Requires validation to confirm:
- Meets a need/fills a gap
- Delivers value
- Improves patient outcomes
- Clinically acceptable
- Requires data/evidence to support business case
- Proof of Concept Evaluation

Value Analysis

Routine-No Change in Std of Care or Practice

- Similar product currently in use but better functionality/new technology available now
- Intended to replace existing products
- Evaluation required to confirm acceptability and value
- Competition usually exists
- Contingent on NO conflicts with an existing contract

- ✓ Supports both Supplier and SDO requests
- ✓ Alignment with PCT efforts
- ✓ Due diligence PRIOR to commitment to procure (Purchasing Policy)
- ✓ Allows for targeted and restricted use
- ✓ Supported by New Product Request Guidelines and Site

- ✓ Sustainability considerations
- ✓ Operational Processes
- ✓ Evidence informed decisions making

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Innovation/ New Product Pathways

Problem Definition — Solution Identified

Product and Innovation Intake

- Exploratory 'Research'
  - Proof of Concept
  - Re-design and refine product
- Pre-Commercial
  - Testing and Validation of Concept
  - Product revisions
- Commercial with or without Clinical Practice Change
  - Pilot implementation
  - Validation, Valuation and Evaluation
  - Scale up
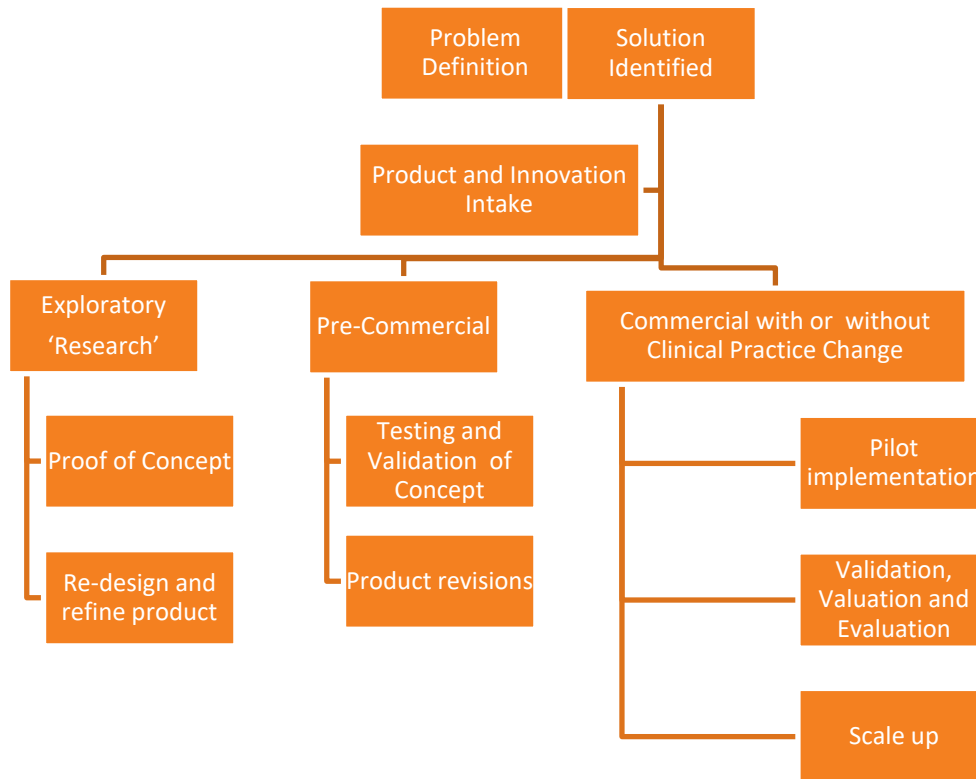
Defining each step:

✓ Priority setting

✓ Budget consideration

✓ Scope (SDO or Provincial)

✓ Services implicated (site specific or shared provincial services)

✓ Approvals and authorizations

✓ Type of information/ evidence required (e.g., value)

✓ Services required for decision support (e.g., Information Services, Project Management, Evaluation, etc.)

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New Products and Device Innovation Review Process
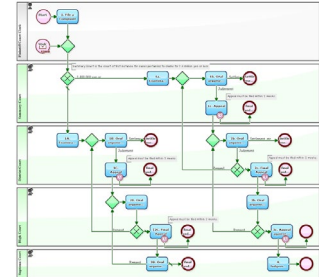
1. Leveraging Existing Processes and Networks

   e.g., Shared Health Research and Innovation (SHRI) - Project submission process.

   a. Online submission form.

   b. Automated responses.

   c. Network of reviewers and authorizers managed with Teams (or other) platform.

      • Reviewers have linked access to all relevant product information .

      • Currently, SHRI manages approximately 58 departmental, site, program and service level reviewers and processes approximately 500+ transactions /yr.

      • Reviewers can accept/ reject/ or request additional information needed to made a decision.

   d. Can create a point of engagement with any necessary group (e.g., PCTs, Shared Services, Operations, Leadership, etc.) at any step as required to move forward.

CAN Health Network

Building Economic growth in Canada by solving health system problems.

1. Health Systems (called EDGES) identify a 'problem' that requires a solution, which the EDGE is prepared to purchase.

2. CAN Health Network links the problem with Canadian companies ready to provide a solution.

3. The problem and solution become a commercialization project.

4. The project can be funded by CAN Health Network to assist in assessing, evaluating, and implementing the project within the EDGE.

5. If the solution is successful, the Health System Edge moves to purchase the solution.

6. Procurement steps are considered along the way.

7. The solution is also offered to other Health System Network members across Canada.

8. Canadian Companies grow as a result of this and this leads to the creation of more Canadian jobs!

Moving Forward - Next Steps:

- Branding and Communication:
  - Website Development – SOPs; processes, timelines, etc.
- Continue research approval and activation timeline improvements
  - Increase delegated reviews/approvals
  - Centralize service estimates, invoicing, and cost recovery process
- Research and Innovation Strategic Planning:
  - Equipment inventory, research facility assessment
  - Stakeholder engagement and assessment
    - Researcher Community, SDOs, PCTs, industry, academic partners, funding partners (Research Manitoba, Government)
- Purchase management software for:
  - institutional approval, research contract/ agreements, innovation intake
- Develop health system innovation pathways for industry solutioning (e.g., CAN Health, BAM)
- HSC Foundation planning:
  - Develop an HSC Research Institute with associated research direct support services
  - Upgrades and renovations of HSC research facilities
  - Develop a research and innovation space (e.g., live lab, design lab)

Discussion / Questions

SH Research and Innovation

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