CIHR IRSC

Canadian Institutes of Health Research | Instituts de recherche en santé du Canada

Updates - Clinical Trials at the Canadian Institutes of Health Research

Clinical Trials Ontario Conference
November 8, 2023

Building CIHR's clinical trials program

Priority E: *Integrate Evidence in Health Decisions*

- *E.3.3 Enhance Canada's capacity to fund, conduct and use clinical trials by strengthening highly qualified personnel, clinical trials environments and research investments*

Priority A: *Advance Research Excellence in All Its Diversity*

- *A.3.3 Promote monitor and report on CIHR-funded researcher compliance with the WHO statement of Public Disclosure of Results from Clinical Trials*

Implement the Clinical Trials Fund

- Under Canada's Biomanufacturing and Life Sciences Strategy - focus on pandemic preparedness and a strong domestic life sciences sector

Develop and implement a long-term clinical trials strategy

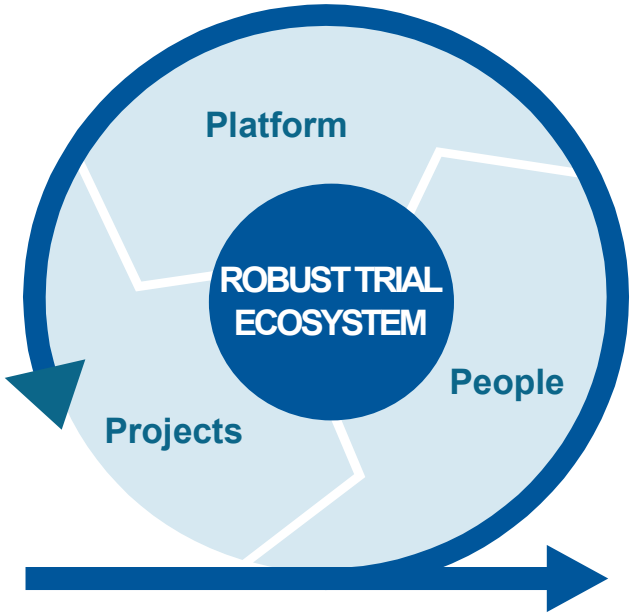
CIHR's Clinical Trials Fund (CTF)

Three inter-related building blocks form the CIHR Clinical Trials Fund

A clinical trial **platform** to coordinate, increase efficiency, and catalyze sustainable infrastructure
(~$39 million awarded to the Accelerating Clinical Trials Consortium, funded until August 2025)

Operating grants to fund CTs in priority areas
(Originally ~$120 million; of which ~$60M has been awarded to 22 projects aligned with BLSS priorities, funded until August 2025)

Second projects funding opportunity launched in July ($41M, funding until March 2027)



Dedicated support for indirect costs of research
Internal CIHR resources

Training grants to develop highly qualified personnel in CT research
($25.5 million awarded to 5 training platforms, plus contributions from the Strategy for Patient Oriented Research to support 2 additional training platforms, funded until August 2025)

Online consultation – who we heard from

- A bilingual **online consultation** was open between September 28 and December 1, 2022 to seek feedback from the research community, partners and stakeholders involved in clinical trials on specific clinical trials themes
- **44** consultation responses were received
- Of these, the majority were not from individuals, but rather represented collated comments from **>100 organizations or groups** of stakeholders, representing researchers, patients, clinical trial organizations, health charities and others
- Feedback received has been reflected in a “what we heard” report published in April 2023
- Online consultation has been supplemented with in depth key informant interviews completed in early 2023
- Additional targeted engagement is ongoing to address identified gaps (Indigenous partners, persons with accessibility needs, provincial clinical trials organizations), as well as ongoing discussions with international funders

Develop a long-term clinical trials strategy: Consultation feedback

Platforms

- Coordinate clinical trial start-up activities, data sharing mechanisms, and research transparency at the national level
- Integrate clinical trials within the health care system through support for enabling platforms and mechanisms

People

- Increase clinical trials capacity by providing training programs in trial design and biostatistics, regulatory compliance, quality assurance and clinical research administration

Projects

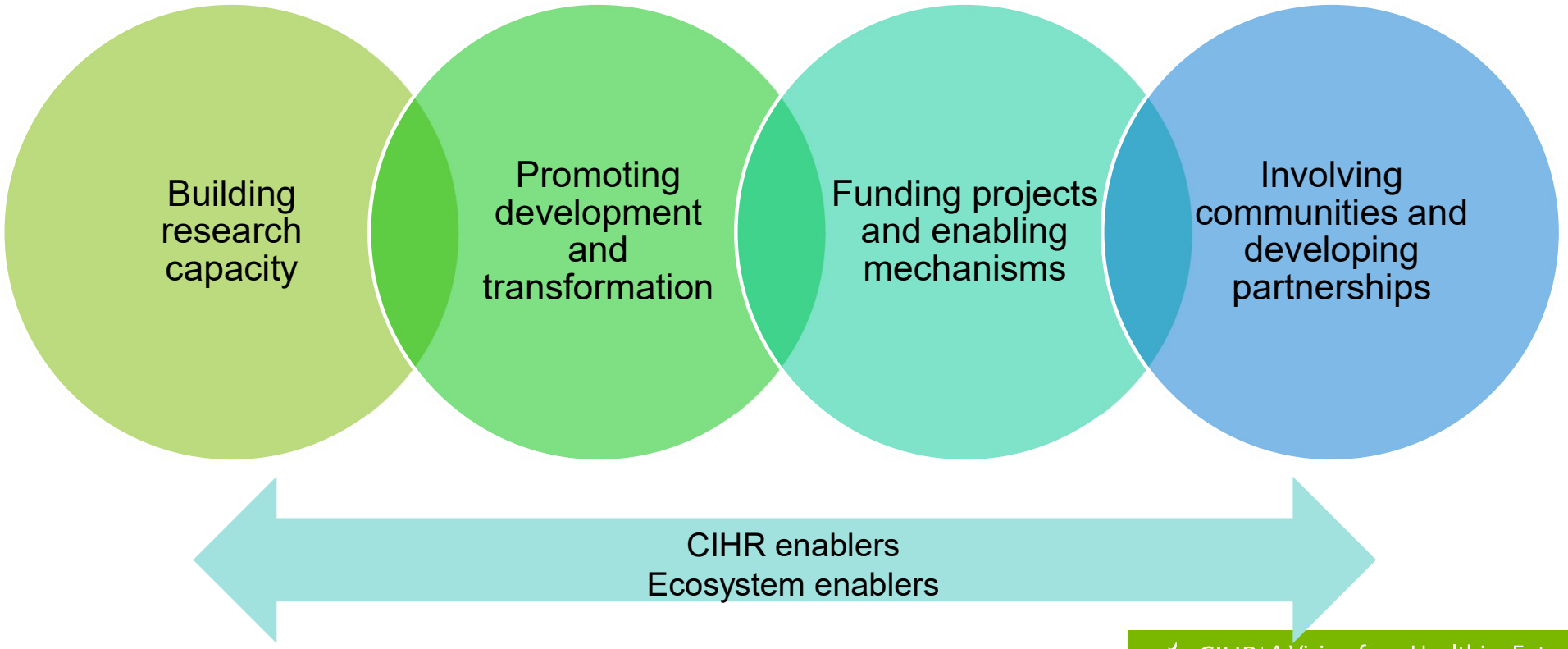
- Build long-term funding streams with predictable cycles of funding opportunities

Policy

- Enable the inclusion of all Canadians in clinical research, and ensure meaningful patient engagement in clinical trial development
- Foster CIHR leadership in clinical trials at a national and international level

Many of these elements have been partially addressed through the recent CTF investments, but they are limited in both time and scope

Proposed elements of a clinical trials strategy



https://cihr-irsc.gc.ca/e/53542.html

Building research capacity

- Objective: To ensure that Canada continues to have sufficient highly-qualified personnel to design, implement, and mobilize the knowledge from trials

Promote development and transformation

- Objective: To invest in projects that will advance efficient and inclusive approaches to clinical trials, provide the foundation for novel health technologies to move into human trials, and bring new treatments to patients

Funding projects and enabling mechanisms

- Objective: To fund mission-driven/strategic clinical trials initiatives

Involving communities and developing partnerships

- Objective: To support research focused on the priorities of patients, with the goal of improving health outcomes and healthcare system efficiency

CIHR enablers

Objective: To create agile structures within CIHR that support research prioritization, decision-making, and long-term strategic evolution of the clinical trials program

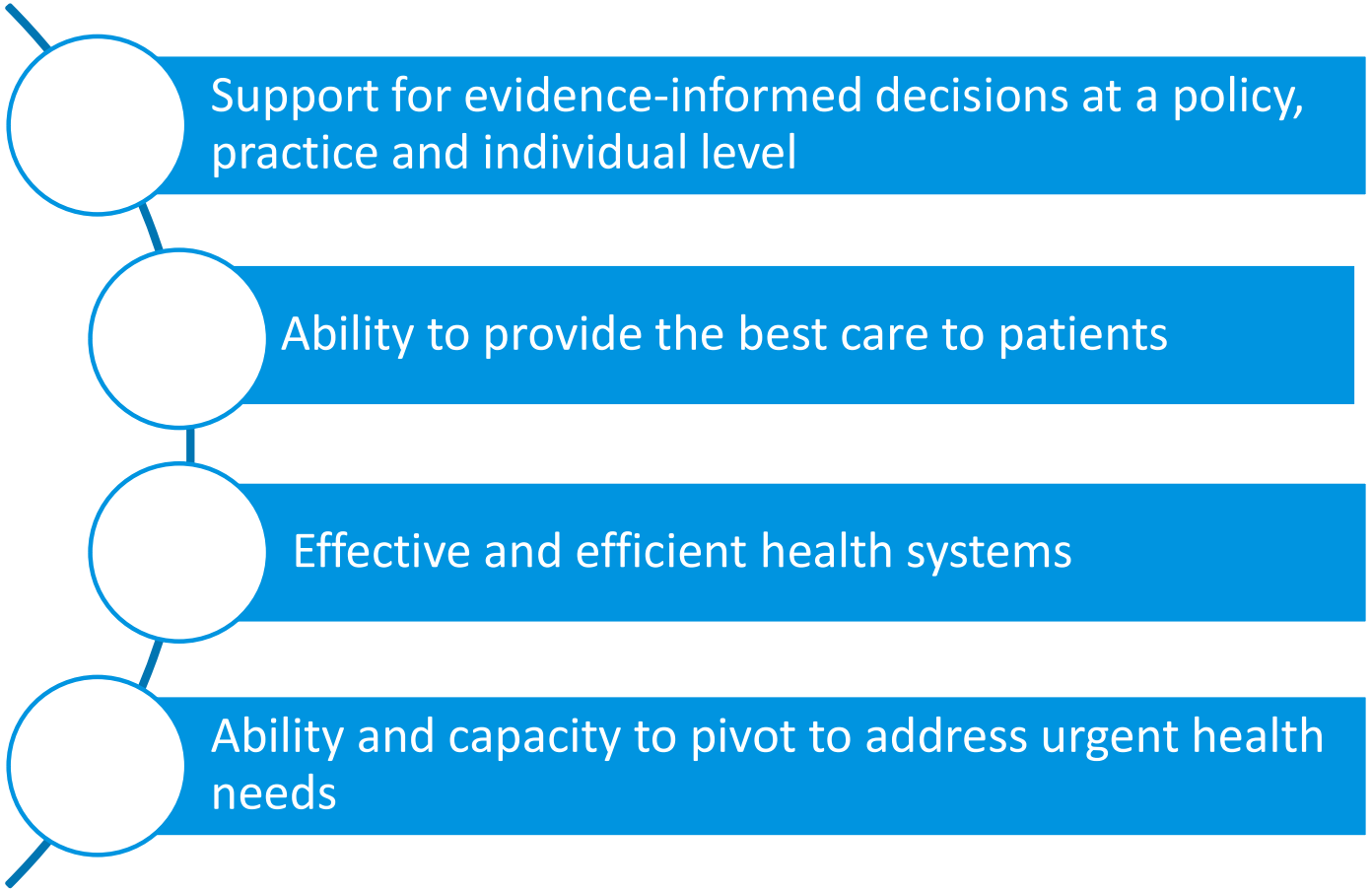
Ecosystem enablers

Objective: To foster an effective integrated clinical trials ecosystem, where CIHR funding contributes to research and capacity that supports the integration of clinical trials within medical care.

Aligning clinical trials funding opportunities with CIHR's strategic plan

Strategic plan priorities	Example requirements from CTF Projects
Priority A: Advance Research Excellence in All Its Diversity	Data management plan Registration of trial before first enrolment and disclosure of results within defined timeframe
Priority B: Strengthen Canadian Health Research Capacity	Plan for the development of highly-qualified personnel
Priority C: Accelerate the Self-Determination of Indigenous Peoples in Health Research	Integrate key principles of equity, diversity and inclusion, and Indigenous rights
Priority D: Pursue Health Equity through Research	Intersectionality – biologic variables, social determinants of health, inclusion throughout the life course (with justification for any exclusions), SGBA+
Priority E: Integrate Evidence in Health Decisions	Knowledge mobilization plan

Ultimate goals of a fully-funded and implemented world class clinical trials strategy



Reminder - clinical trials registration and disclosure policy

Policy requirements

1. **Clinical trials must be registered** in a publicly available, free to access, searchable clinical trial registry complying with WHO's international agreed standards before the first visit of the first participant

The following new requirements apply **to all clinical trial grants funded on or after January 1, 2022**:

2. Publications describing clinical trial **results must be open access** from the date of publication;
3. Public disclosure of results must be done within a mandated time frame: **summary results must be publicly available within 12 months** from the last visit of the last participant (for collection of data on the primary outcome); and
4. All **study publications must include the registration number/Trial ID** (to be specified in the article summary/abstract). N.B. These publications must include an acknowledgement of CIHR contributions and the Funding Reference Number (FRN) or Application ID, as per the Tri-Agency Open Access Policy on Publications

October 2020
CIHR signs the WHO's *Joint Statement on Public Disclosure of Results from Clinical Trials*

February 2022
Policy Guide on *Requirements for Registration and Disclosure of Results from Clinical Trials* published

April 2023
First monitoring report published

Spring - Fall 2023
Lessons learned and preparing for next reporting cycle in 2024

Source: CIHR Policy Guide – Requirements for Registration and Disclosure of Results from Clinical Trials - CIHR (cihr-irsc.gc.ca)

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A Vision for a Healthier Future / Une vision pour un avenir en santé

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