CIHR IRSC

SPOR:
A Major Strategy in Development

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CIHR strategic plan 2009-2014

1. **Invest in world-class research excellence**

2. **Address health and health system research priorities**

-Enhance patient-oriented care and improve clinical results through scientific and technological innovations;

-Support a high-quality, accessible and sustainable health-care system;

-Reduce health inequities of Aboriginal peoples and other vulnerable populations;

-Prepare for and respond to existing and emerging threats to health;

-Promote health and reduce the burden of chronic disease and mental illness.

3. **Accelerate the capture of health and economic benefits of health research**

4. **Achieve organizational excellence, foster ethics and demonstrate impact**

Structure of Strategic (Institute-related) Funding Opportunities

Level 1 (Priority Announcement) –

- focus on shorter term non-recurring funding opportunities that respond to Institute priorities.
- exploits the open suite of programs; adjudicated within the appropriate peer review committee
- relevance review conducted by the strategic lead.

Level 2 (Institute Led) –

- single or multi-institute/branch initiative
- focus on short to medium term initiatives.
- Investment levels: in the range of $2M/yr (up to 5 years); not to exceed $5M/yr year.
- should be aligned with CIHR's strategic plan and advance one or more Institute's priorities with clear objectives to be achieved.
- run independently from the open programs with a dedicated peer review committee.
- Institutes and Strategic Branches are limited to leading one level 2 initiative per Institute/Initiative per fiscal year.

Structure of Strategic (Institute-Related) Funding Opportunities

Level 3 –

- multi-institute/branch initiative
- intended to focus on medium to longer term activities (typically 5-10 yrs) that may be renewable.
- initiative has either: a) a corporate component to the investment or b) is an Institute led initiative that is large and complex (investment levels of more than $5M a year)- **Roadmap Initiatives**

The 7 Signature initiatives that are being developed into business cases/plans:

CIHR Priorities	Seven CIHR Roadmap Signature Initiatives
Enhance Patient-Oriented Care and Improve Clinical Results through Scientific and Technological Innovations	*Clinical Trials Networks/Support Units* *Personalized Medicine*
Support a High-Quality, Accessible and Sustainable Health-Care System	*Community Based Primary Health Care*
Reduce Health Inequities of Aboriginal Peoples and other Vulnerable Populations	*Pathways to Health Equity for Aboriginal Peoples*
Prepare For and Respond To Existing and Emerging Threats to Health	
Promote Health and Reduce the Burden of Chronic Disease and Mental Illness	*Alzheimer's* *Epigenetics* *Inflammation in Chronic Disease*

Strategy on Patient Oriented Research (SPOR):
Addressing the two Challenging Valleys

Valley 1 refers to the challenges related to translating the results of discoveries generated by basic biomedical research in the laboratory to the bedside as well as to successfully commercialize health discoveries.

Valley 2 refers to the challenges of synthesizing, disseminating and integrating research results more broadly into health care decision-making and clinical practice.

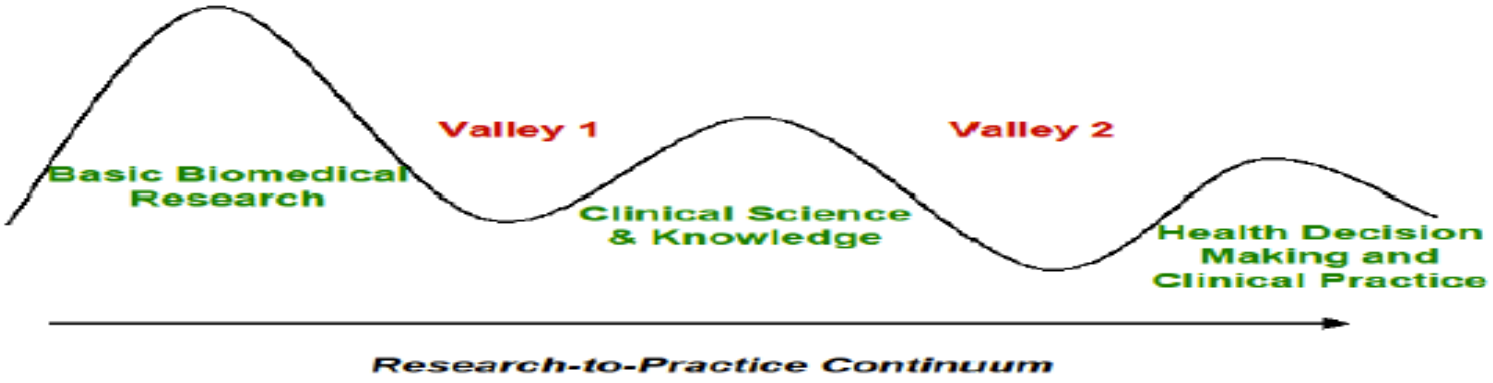

Figure adapted from Steven Reis, University of Pittsburgh and Harold Pincus, Columbia University.

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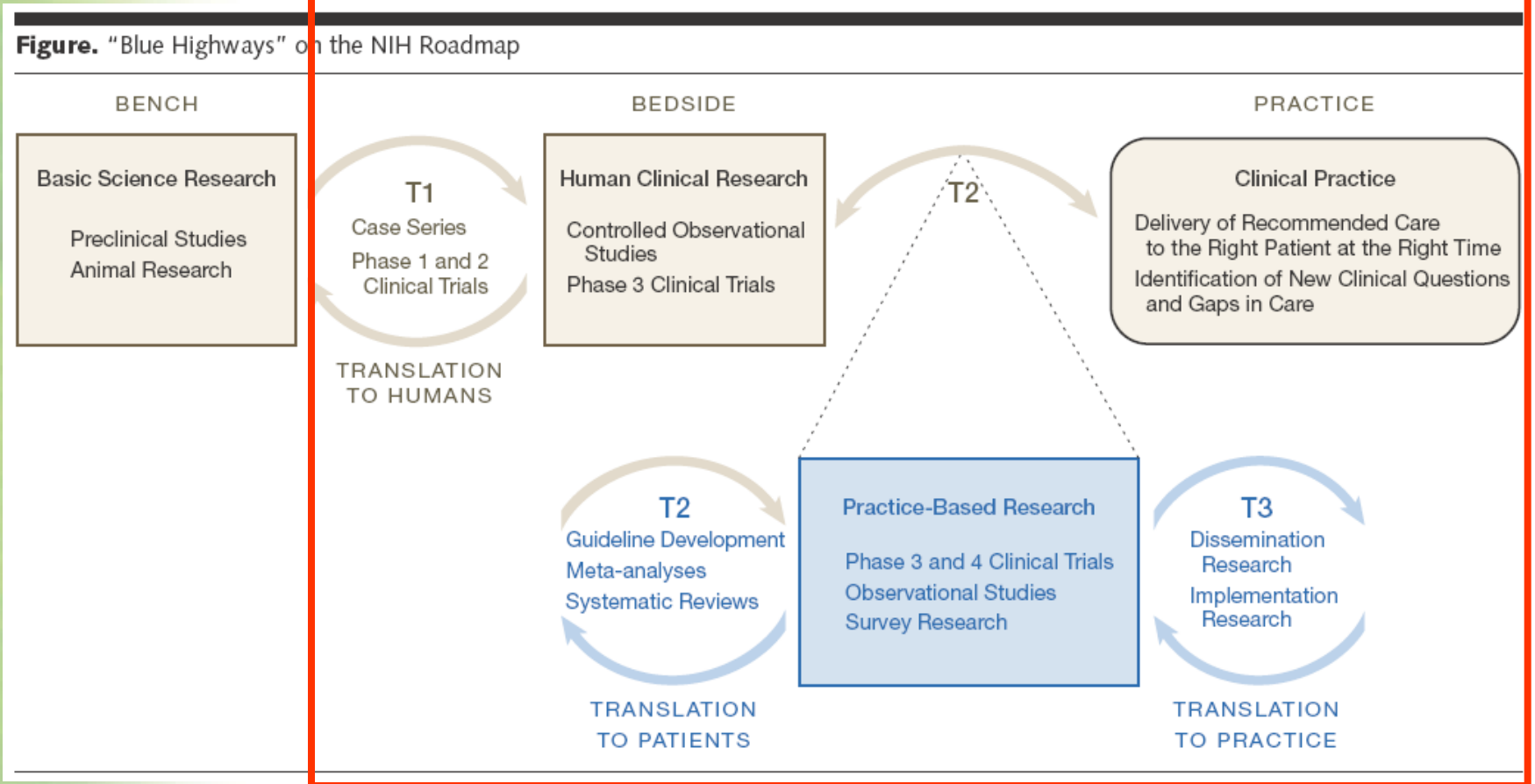
“The significant problems we face cannot be solved at the same level of thinking we were at when we created them”

Albert Einstein

Canada

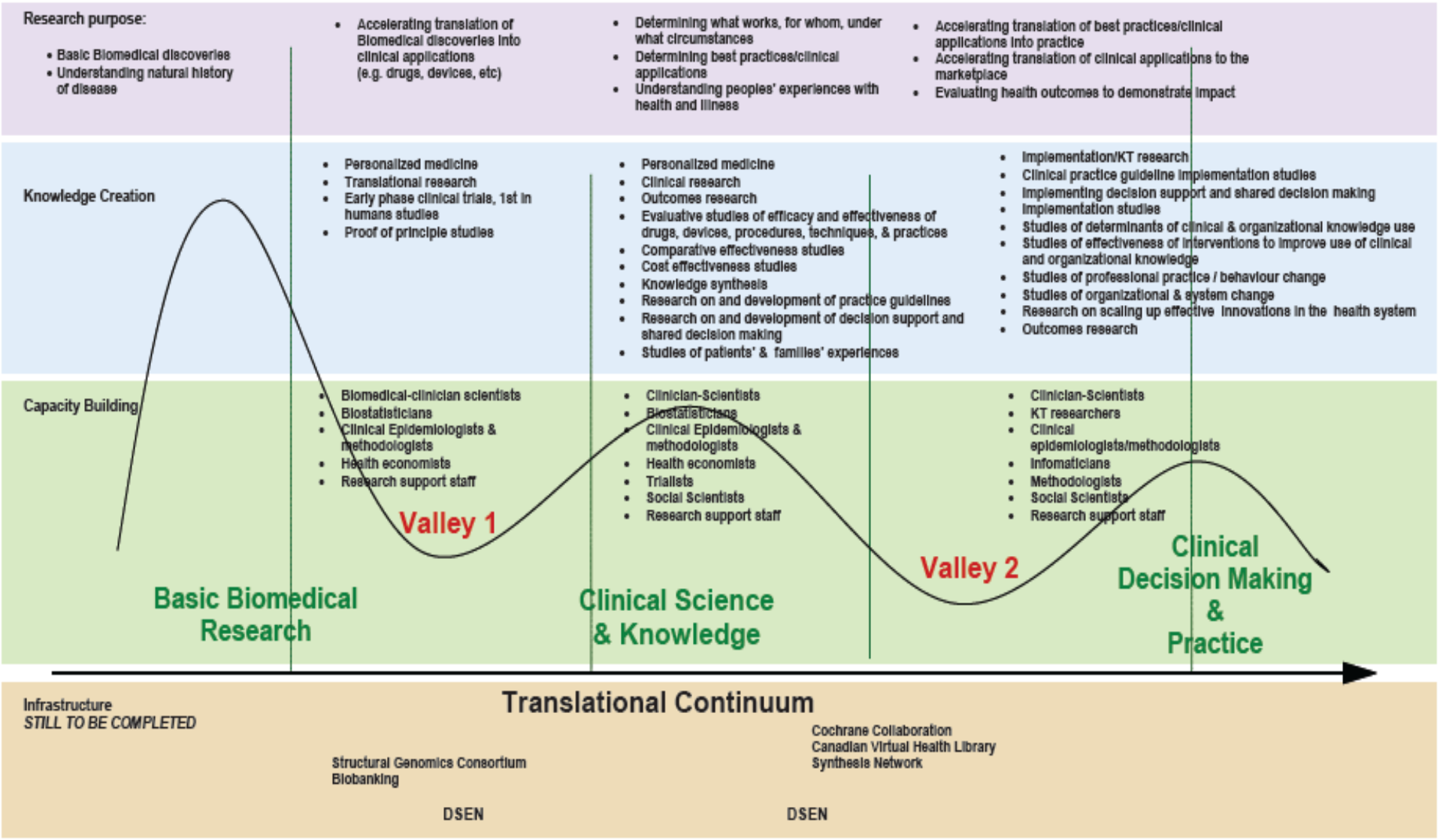
Definition of Patient-Oriented Research

Scope of definition



Westfall, J. M. et al. JAMA 2007;297:403-406

Strategy for Patient-Oriented Research: Bridging "valleys" between research and outcomes



Strategy on Patient-Oriented Research

Goal:

- Improving **health outcomes** through clinical research.

Aims:

- to enhance **clinical applications** and **economic impact** of health innovations.
- to provide health professionals and decision-makers with information on how to deliver **high-quality care** and services in a **cost-effective manner.**

Implies a continuum from:

- “first in patients” studies to
- how new and older drugs, devices and procedures are integrated into health systems and population health as it influences health systems research and the application of best clinical practices in Canada.

Four major components of the Strategy on Patient-Oriented Research

1) **Improve the research environment and infrastructure.**

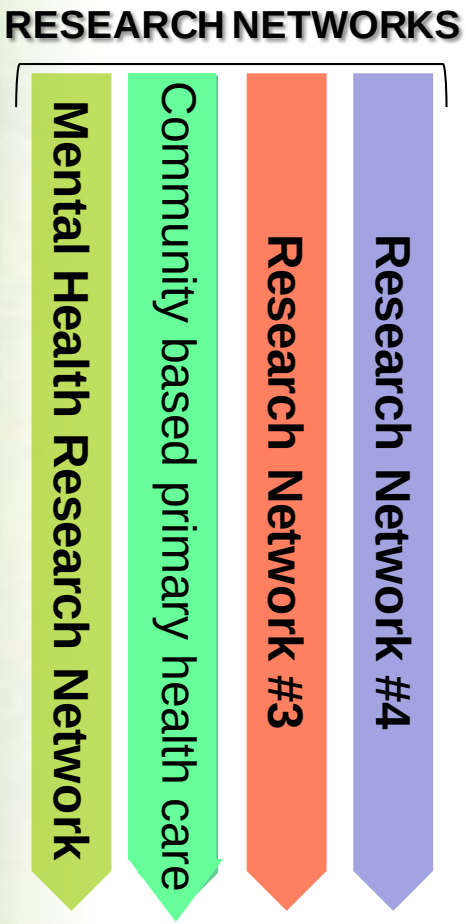
2) **Set up mechanisms to better train and mentor health professionals and non-clinicians in health research.**

3) **Strengthen organizational, regulatory and financial support for multi-site studies.**

4) **Support best practices in health care.**

Establish national infrastructure: Multi-disciplinary research networks

Research Networks bring together a unified group to build a critical mass of technical and scientific expertise on a national scale to provide research leadership and enhance impact.



- Act as one coordinated group to effectively direct resources in specialty areas (e.g. mental health, primary care).
- Ask central questions to direct pan-Canadian studies most relevant to Canadians.
- Generate evidence from previous work and disseminate best practices to the patient-care community.
- Mentor and support the training of emerging talent.

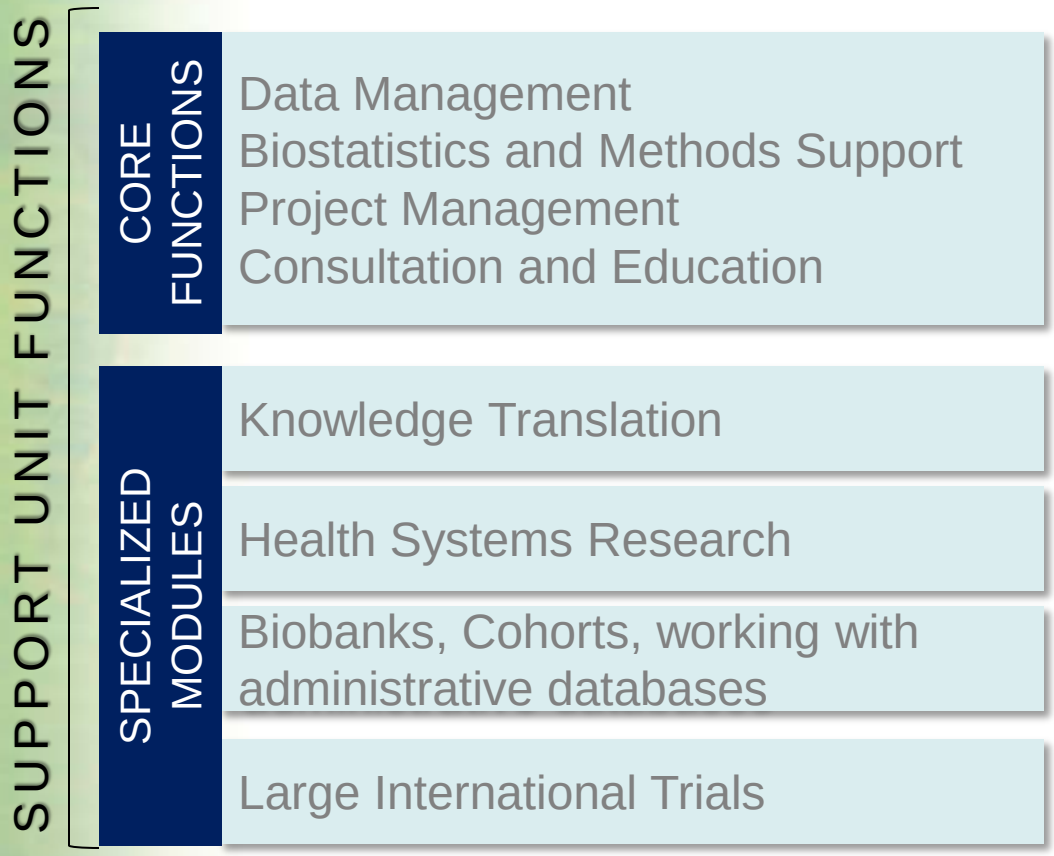
Establish national infrastructure: Multi-disciplinary research networks

Research Networks bring together a unified group to build a critical mass of technical and scientific expertise on a national scale to provide research leadership and enhance impact.

Networks need to be founded and developed on the principles and priorities of its *Partners:* the Charities, Associations, Provinces, CIHR and its Institutes, and Others

Establish local infrastructure: SUPPORT units

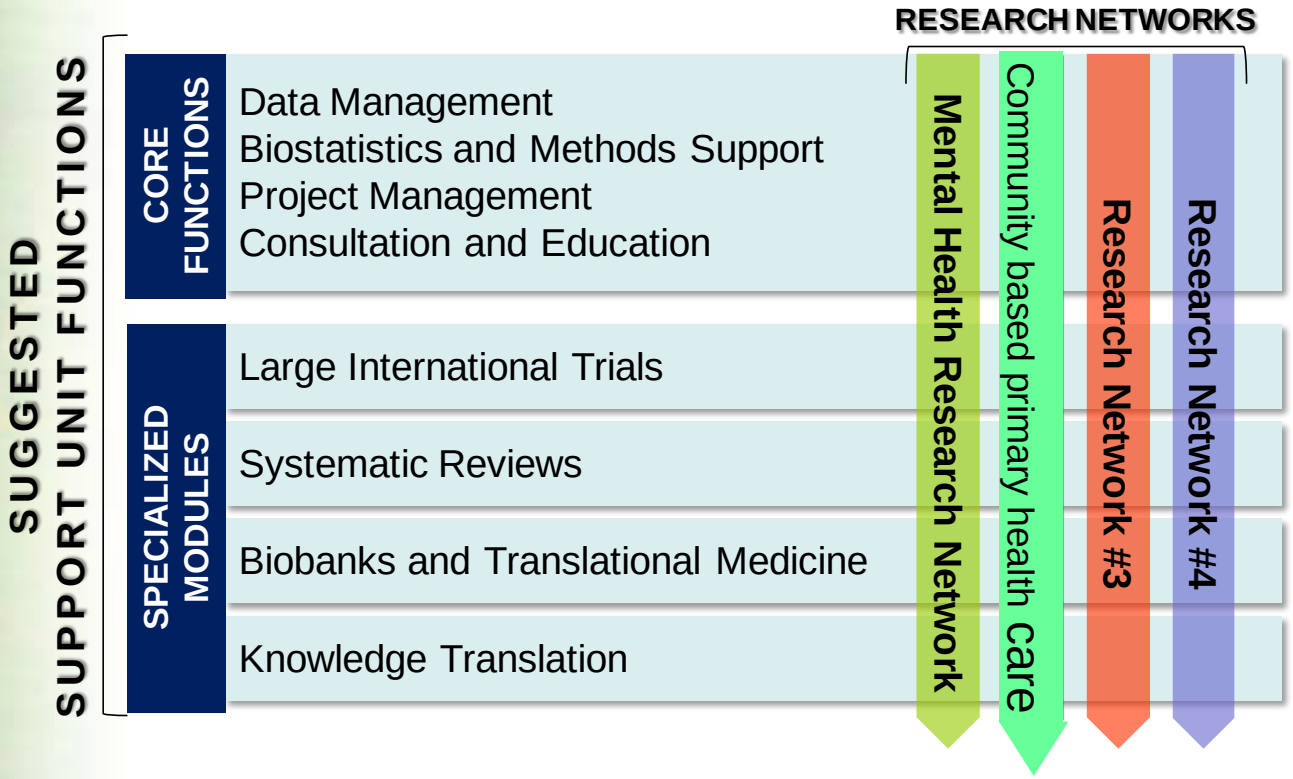
Research networks are underpinned by local SUPPORT units that provide the resources and personnel to conduct research day to day.



- Integrated within a local clinical/care setting.
- Provides communities with access to expertise and resources (i.e. core functions and specialized modules).
- Enhances attraction and retention of talent to communities.
- Creates linkages with health centres (from tertiary hospitals to primary care centres), and national and international health stakeholders.

Relationship between SUPPORT units and networks

When combined, SUPPORT units provide the infrastructure and skills for highly specialized Research Networks to identify and tackle key clinical questions.



SUPPORT Units: Focus and Goals

- Build methodological support where it does not now exist or enhance it where available resources are not sufficient.
- Provide methodological/logistical support to local clinical investigators.
- Use an integrated knowledge translation model.
- Support decision making within the clinical setting and catchment area, and implementation of best practices.
- Are directly involved in local research decision making.

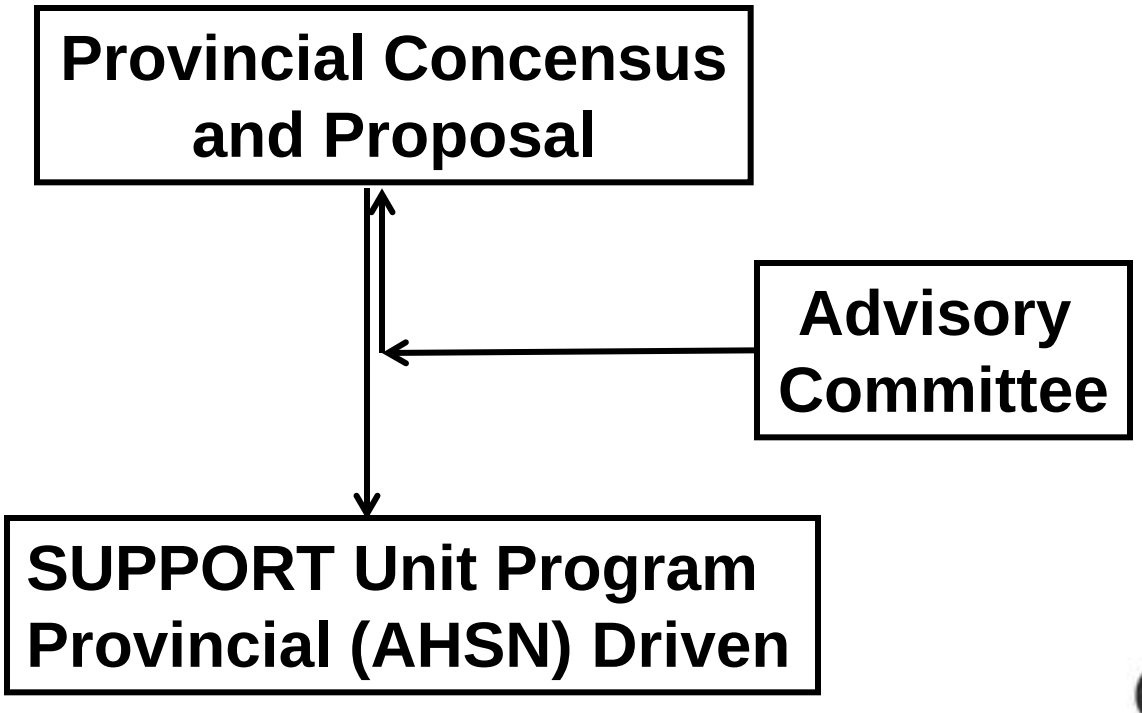
SPOR: Special considerations for the SUPPORT Units Program

- **Macro:** Must engage the provinces to support the funding of SPOR.

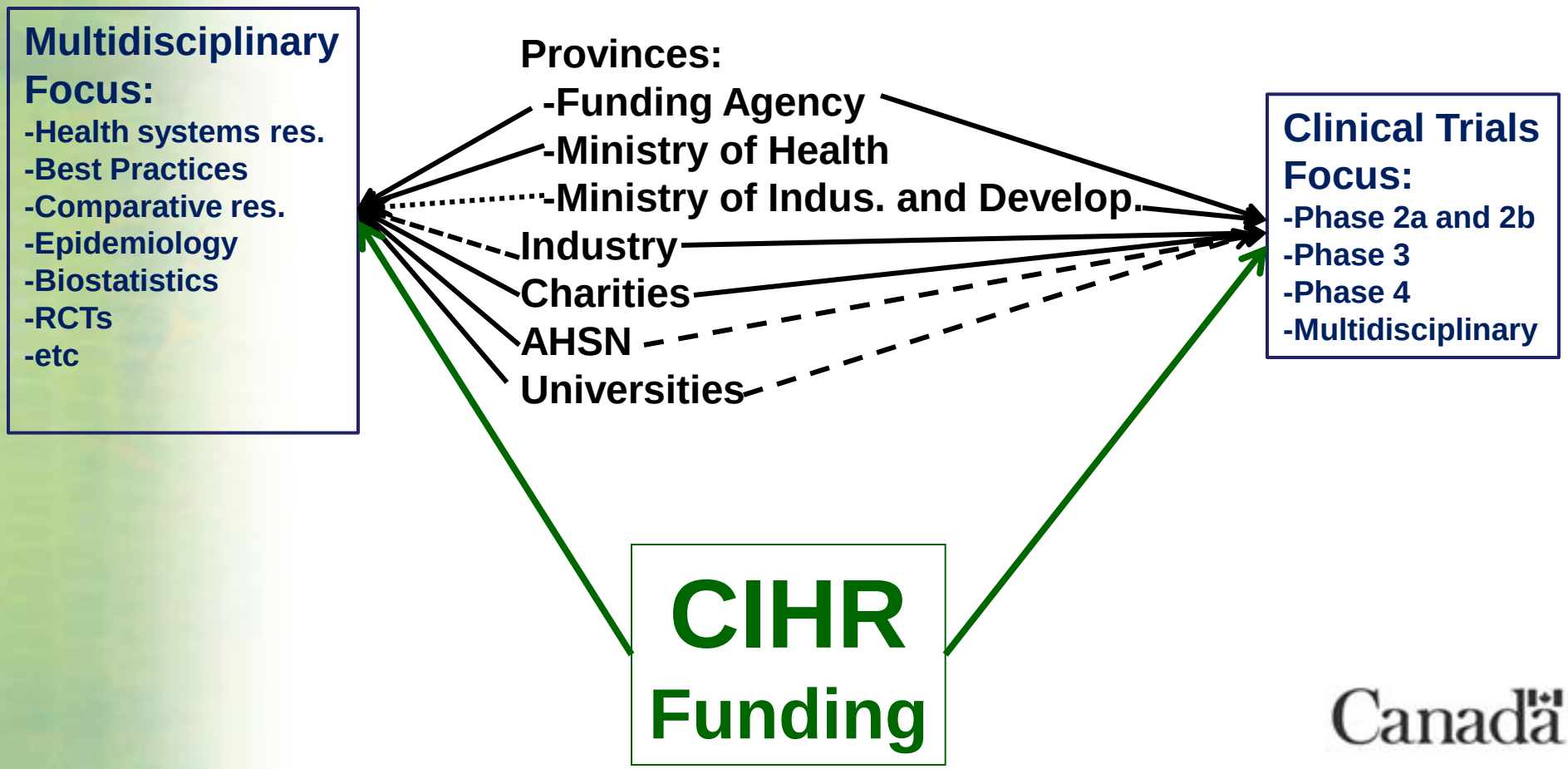
- **Meso: How best to obtain the support of the Provinces**
  - Assure that the program focuses on improving the efficacy as well as the quality of care.
  - Assure that the specifics of the program are largely determined by the provinces in conjunction with their AHSNs.
  - Assure a programatic flexibility of SUPPORT Units that recognizes the diversity of our milieux, is inclusive rather than exclusive, and permits probable funding of most, if not all provincial, SUPPORT Unit proposals.
  - Need to phase-in the funding of SUPPORT Units, and favor the funding of SUPPORT Units rather than Networks.

SUPPORT Unit proposal development

- **Micro: How to best support the development of SUPPORT Unit excellence**
  - -Develop directed RFAs that foster the best possible proposals
  - -Develop an interactive process that includes an advisory committee during which proposal development is interactive and favors the respect of the priorities of the partners, as well as of excellence.



Support Units: Multi-disciplinary focused vs Clinical Trials focused



Composition of SUPPORT Units

Multidisciplinary teams of investigators and methodologists, associated with local and provincial decision makers, including:

- **Patient representatives**
- **Clinical investigators from all related professions and specialties**
- **Clinical epidemiologists**
- **Biostatisticians**
- **Social scientists**
- **Health systems researchers and health economists**
- **Clinical trialists**
- **Research support staff**
  - Nurse research coordinators
  - Research associates and assistants
  - Expert personnel in support and development fields, ex bio-informatics and programming, data analysts, etc…

SUPPORT Units: Multi-disciplinarity

- **Must provide methodological support to specific health disciplines in the clinical setting outside of medicine (nursing, rehabilitation, dentistry, etc.) to help them enhance research skills and conduct more high quality research.**

- **Must provide methodological hubs for allied health disciplines (nursing, rehabilitation, other):**
  - Will improve quality and competitiveness of research in allied health research
  - Will improve and broaden research to include patient reported and patient oriented outcomes research.

SUPPORT Units: Local requirements

- **Commitment to the SUPPORT Unit from:**
  - Hospital CEO's and the University
  - Chairs of regional health authorities and provincial funding agencies or involved ministries
  - Local administrators
- **Commitment comprises:**
  - Physical space
  - Matching funds
  - Developing a plan for sustainability
- **And they need to demonstrate:**
  - How they will engage with Units to promote/conduct of research to address local clinical/health services issues
  - How they will engage to improve uptake of best practices
  - How they will support local investigators, and, as appropriate, NETWORKS.
  - How they will train clinical researchers personnel, including research methodologists

SPOR: SUPPORT Units: Overview

- ***Can take different forms according to the expertise and needs of the milieu.***
- ***A given milieu can combine various expertise and mandates.***
- ***A Province or given milieu can develop a consortium over multiple campuses each with complementary mandates.***

1) **Moderate to large size pluri-disciplinary SUPPORT units with expertise in methodology, practice quality and health technology assessment, health system research, epidemiology/population studies, RCTs, implementation of best clinical practice and systematic reviews.**
2) **Small to moderate SUPPORT units with any combination of expertise in quality and health technology assessment, methodology, health system research, epidemiology/population studies, implementation of best clinical practice, and/or systematic reviews. May have capabilities for small RCTs.**
3) **KT-1 SUPPORT units focused on bench to bedside and back research. Generally focused on Phase 1 and 2 clinical trials, and offering a complete spectrum of supporting plateforms.**

SUPPORT Unit Application Development Process

- Working Group composed of the Provincial authorities and their Academic Health Science Network Partners to set a course for the Development of the SUPPORT Unit/Units with a proposed time table.

- Workshop for the Development of the SUPPORT Unit Partnership, its Structure and its Governance

- Workshop for the Development of the SUPPORT Unit Priorities and Deliverables

Networks: *the Principles*

- **P articipatory**
- **A ffordable**
- **C ollaborative**
- **T ranslatable**
- **E fficient**
- **S ustainable**

SPOR-Networks (overview) #1

- **Must be National and Democratic, and needs to include patients at all levels of the organization of the Network.**
- **Must be well aligned with national associations, interested NGOs (charities) and more clinically oriented partners.**
- **Must have an academic focus: produce new knowledge, and implement (transfer) knowledge**
- **Must have a significant training and mentoring mandate**
- **Must be multi-disciplinary (subgroups/networks), involving at least 3 of the 4 CIHR themes.**

SPOR-Networks (overview) #2

- **Should have a light, effective and academically oriented infrastructure, and use of expertise of SUPPORT groups efficiently for heavier infrastructure.**

- **Must receive funding from multiple sources (CIHR and its institutes, provinces, important organizations (Canadian Blood Services (CBS)), charities, industry, academic institutions, international etc..).**

- **Funding should be available for research projects via a rigorous NETWORK relates evaluation process.**

- **Must have a strong focus on patient reported and patient oriented outcomes.**

Networks in SPOR and Beyond (possible)

- **The development of Networks can be a stepwise process, but eventually funding should be adequate to permit the delivery of their mandates. *Possible Network Funding Levels:***

  - **Level 0: Functionning Network with no dedicated Institute or CIHR NETWORK funding ± Seed Network grant**
  - **Level 1: Dedicated Institute and partner Institute NETWORK funding ±Seed Network grant (not necessarily completely aligned with SPOR characteristics).**
  - **Level 2: Institutes and their partners + *SPOR Focused NETWORK funding (up to 500K$/year)*.**
  - **Level 3: Institutes and their partners + *SPOR Comprehensive NETWORK funding (2.0 to 10M$/yr)*.**
  - **Level 4: NCE program.**

SPOR Networks Mandates

- **Four NETWORK Mandates:**

1. **Improving the delivery of care by developing a structurally altering intervention favoring the delivery of best practices: An intervention that changes a significant aspect of practice**

2. **Internationally competitive characteristics/platforms.**

3. **Training and Mentoring.**

4. **International Partnering and Leadership.**

SPOR Funding Structure (possible)

CIHR Funding	+	Partner Funding	=	SPOR Network Funding
1M$		2M$		3M$

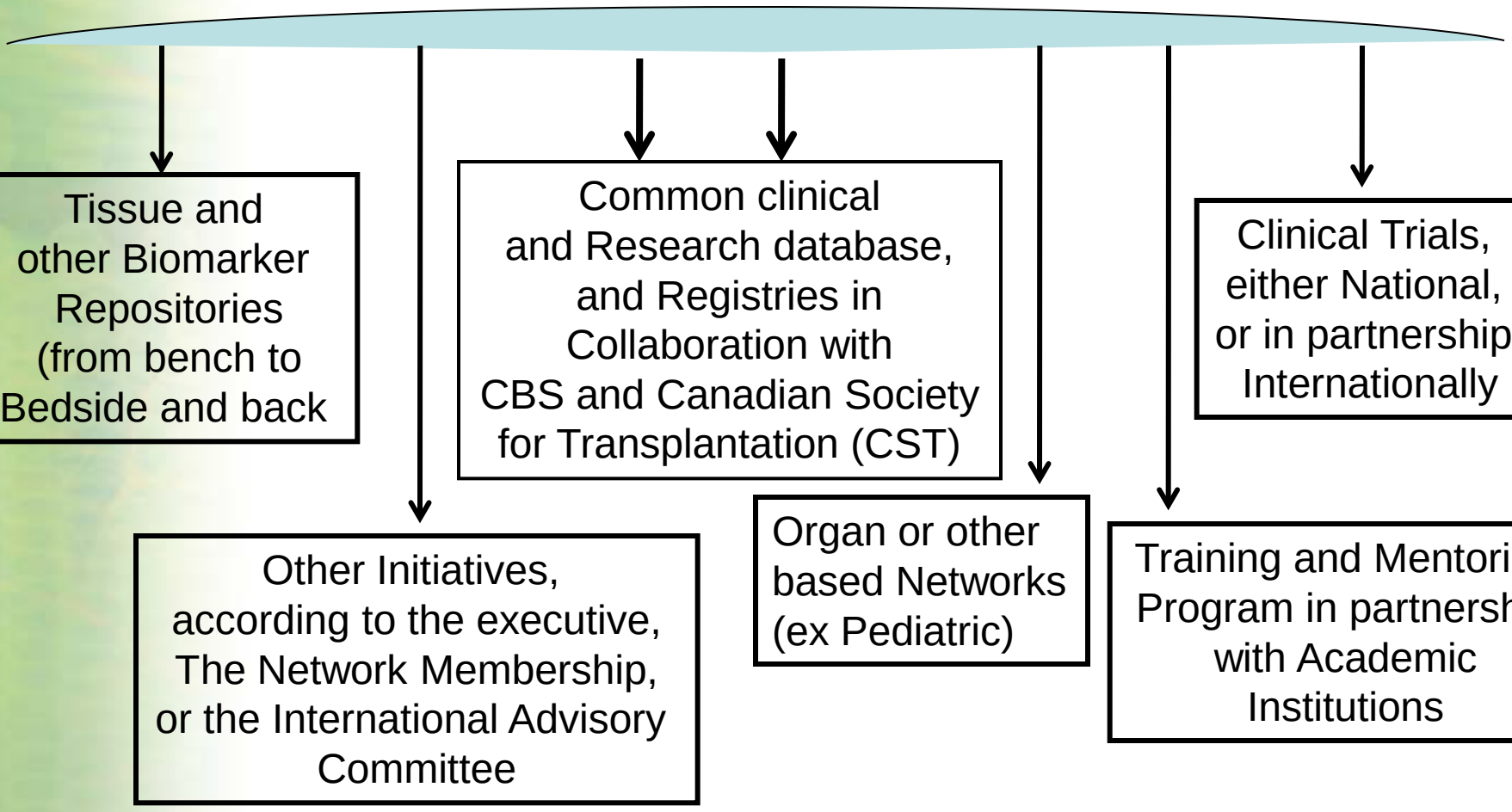
To this add CIHR Institute funding of 0.5M$, and, funding of 400K$ from CIHR signature initiative, such that the total Network funding in this example would be 3.9M$

SPOR Funding Structure (possible)

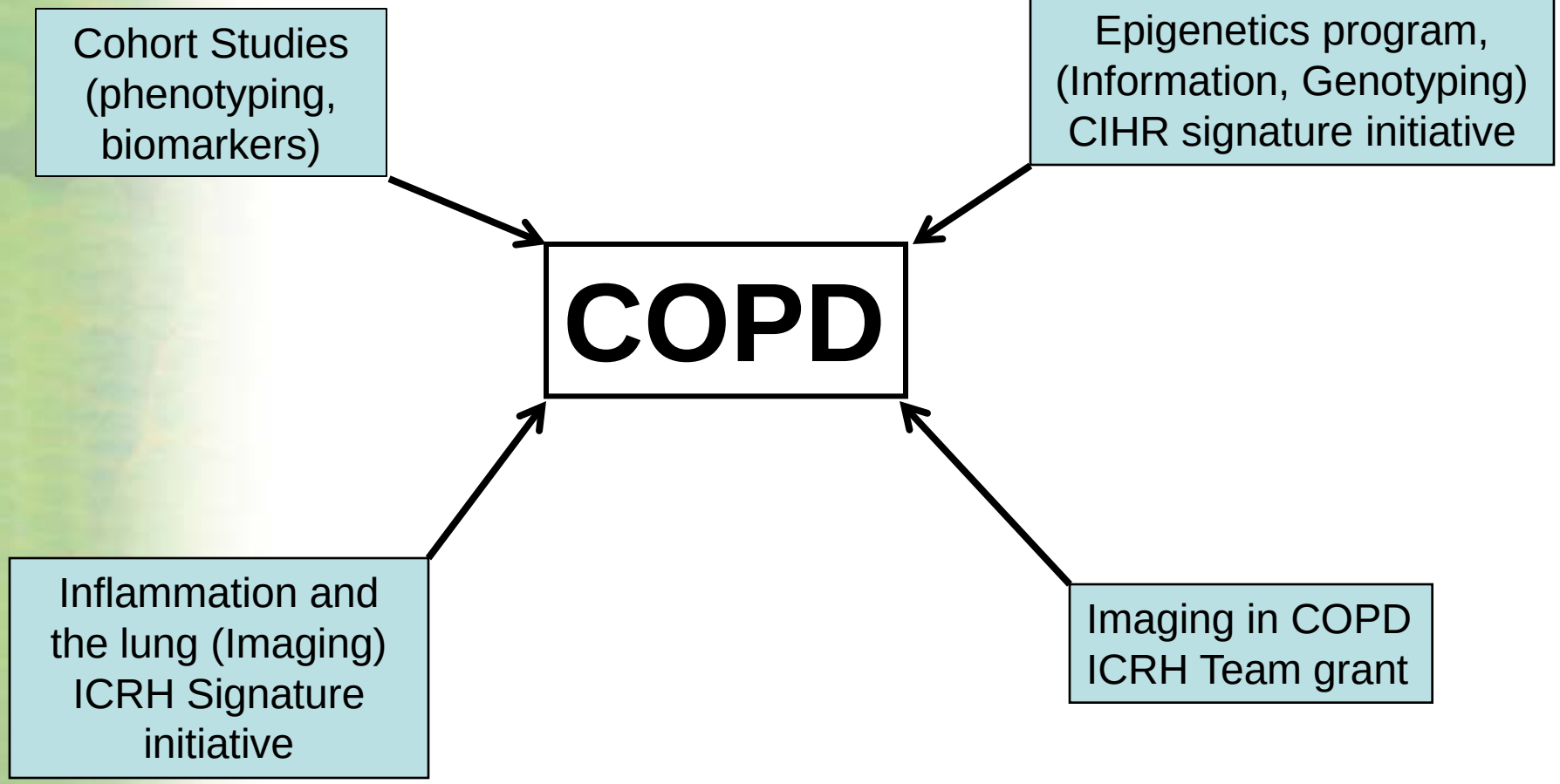
CIHR Funding 2M$	+	Partner Funding 2M$	=	SPOR Network Funding 4M$

To this add CIHR Institute funding of 1.0M$, and, funding of 400K$ from CIHR signature initiative, such that the total Network funding in this example would be 5.4M$

Transplant Network
A Network of Networks



Pulmonary Network
(Leveraging to be even better)



Four major components of the Strategy on Patient-Oriented Research

1) Improve the research environment and infrastructure.

2) Set up mechanisms to better train and mentor health professionals and non-clinicians.

3) Strengthen organizational, regulatory and financial support for multi-site studies.

4) Support best practices in health care.

Develop human capacity for Patient-Oriented Research

- Train **more health professionals** in health-oriented research.
- Mentor, develop and support **careers** of researchers doing patient oriented research.
- Train **more non-clinicians** with advanced degrees in core research methodology.
- **Re-engineer career training and salary awards** to build capacity in patient-oriented research for individuals aligned with patient-oriented research units.
- Not limited to **SUPPORT Units and NETWORKS**, but is central to their mandate and one of their deliverables.

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Strengthen organizational, regulatory and financial support for clinical trials

- **Streamline ethics review** for multicentre trials by developing common (regional or provincial) Ethics Review Boards with reciprocal arrangements: multiple provincial challenges that requires national leadership in order to assure coherence and reciprocity. **Health Canada and CIHR Ethics lead**.
- Develop a **national template for contracts** and inter-institutional agreements, **ACAHA and RxD**.
- Simplify and focus clinical research reporting (adverse events), and develop more flexible and adaptive protocols, **Salim Yusuf**.
- Develop **national standards of operation** for all clinical research activities,N2.
- Common **national administrative data base**, and/or common electronic medical records (**EMR**), **Robyn Tamblyn**.

Four major components of the Strategy on Patient-Oriented Research

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Strengthen the support for multi-site studies.

- **Depending on the structure, the involved partners, and the level of funding of specific SPOR funded Networks, it is anticipated that they would have some funding reserved as seed money for multisite clinical trials, and funding for small to medium clinical trials, and/or as a mechanism for the leveraging of funding for international trials. Other forms of clinical research could also be funded by SPOR Networks through a rigorous peer reviewed process involving an external committee.**

- **The same would be true for SUPPORT Units, but, due to their mandate and the partners involved, their funding for clinical research would likely be much less than that of Networks, would less frequently involve multisite clinical trials, and would more frequently focus on comparative effectiveness or health care delivery research.**

Four major components of the Strategy on Patient-Oriented Research

1) Improve the research environment and infrastructure.

2) Set up mechanisms to better train and mentor health professionals and non-clinicians.

3) Strengthen organizational, regulatory and financial support for multi-site studies.

4) Support best practices in health care.

Support best practices in health care

- This would be one of the major deliverables of SUPPORT Units and thus SUPPORT Units must involve implementation researchers. Research would focus on strategies that would facilitate the delivery of best practices. Projects would be required to test the efficacy of their strategies and programs.

- One of the deliverables of NETWORKS will be the development of a structurally altering intervention (change how health care is delivered) that favors best practices in their health-related field.

- Funding, and the level of funding of SUPPORT Units and NETWORKS will thus depend on firm proposals and deliverables on how to support best practices.

- An independent program for the development and implementation of guidelines will also favor best practices.

SUPPORT Unit Application Development Process

- Working Group composed of the Provincial authorities and their Academic Health Science Network Partners to set a course for the Development of the SUPPORT Unit/Units with a proposed time table.

- Workshop for the Development of the SUPPORT Unit Partnership, its Structure and its Governance (various potential sources of funding, including Meeting Planning and Dissemination (MPD) grants)

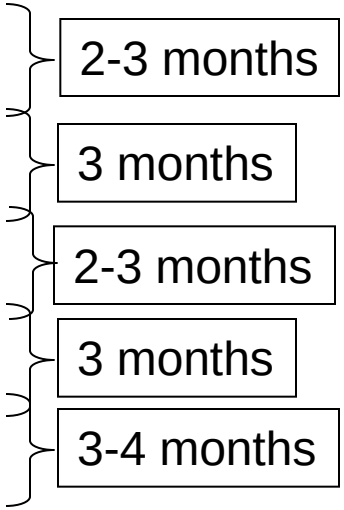
- Workshop for the Development of the SUPPORT Unit Priorities and Deliverables Governance (various potential sources of funding, including MPD grants).

SUPPORT Unit Application Development Process

- Preparation and submission of an LOI
- Review of LOI by the National/international advisory committee and feedback to the proposers of the SUPPORT Unit.
- Preparation and submission of the Support Unit grant.
- Evaluation of the Proposal by National/International advisory committee.
- **Funding** of grant or **recommendations for improvement** for the next round**.**
- Bi-annual external reviews by National/International advisory committee for recommended adjustments of SUPPORT Units.

SUPPORT Unit RFA Development Process

- Discussions with partners and agreement on priorities and proposed directed RFA structure Date -----
- RFA development (with Partners) Date -----
- RFA submission
- Launch of the RFA
- LOI application deadline
- Advisory committee review
- Full application deadline
- Funding start date
- Annual reports and bi-annual advisory committee evaluations



Open Network Application Development Process (Investigators)

Working Group — Leaders' Working group -----

Preliminary Workshop (with Partners) — Date -----

National Workshop (with Partners) — Date -----

Development of: -**FOCUSED** Network Priorities

-Network **Governance** structure

-Clear identification of **Deliverables** and corresponding **Timelines**

- Preparation and submission of **LOI.**

- Preparation and submission of **Grant.**

(Always with Partners)

Open Network RFA Development Process (Institute)

IAB Discussion

Discussions with partners and agreement on priorities and proposed RFA structure — Date -----

RFA development (with Partners) — Date -----

RFA submission

Launch of the RFA — 2-3 months

LOI application deadline — 3-5 months

Full application deadline — 3-5 months

Funding start date — 3-4 months

Annual reports and advisory committee evaluations

Targeted Network RFA Development Process

IAB Discussion — Date ------

Working Group — Leaders' Working group -----

Preliminary Workshop (with Partners) Date -----

National Workshop (with Partners) Date -----

RFA Development (with Partners) Date -----

RFA Submission

Launch of the RFA — 2-3 months

LOI Application Deadline — 3-5 months

Application Deadline — 3-5 months

Funding Start Date — 3-4 months

Annual reports and advisory committee evaluations

Le mot de la fin