MULTI-REGIONAL CLINICAL TRIALS

THE MRCT CENTER of BRIGHAM AND WOMEN'S HOSPITAL and HARVARD

JOINT TASK FORCE FOR CLINICAL TRIAL COMPETENCY

Joint Task Force for Clinical Trial Competency (JTF):
Biannual Global Meeting

Barbara E. Bierer, MD

Co-chair, JTF
Faculty Director, MRCT Center
Professor of Medicine, Harvard Medical School
bbierer@bwh.harvard.edu

Stephen Sonstein, PhD

Co-chair, JTF

Carmen Aldinger, PhD

Director of Administration
MRCT Center

June 6, 2024

https://mrctcenter.org/clinical-trial-competency/

This meeting

- We are recording this meeting and plan to make the presentation (not discussion) available on our website.
- We plan to post slides and an executive summary of the meeting.
- We will follow up regarding permission with the presenters. For persons other than the presenters who speak during the presentations, please note that you will be recorded.

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- We are committed to autonomy in our research and to transparency in our relationships. The MRCT Center leadership retains responsibility and final control of the content of any products, results, and deliverables.
- We have no personal financial conflicts of interest with the content of this presentation.
- Today’s meeting will be recorded as described.

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The Multi-Regional Clinical Trials Center (MRCT Center)

The MRCT Center is a research and policy center focused on addressing the conduct, oversight, ethics and regulatory environment for clinical trials.

Our Vision

Improve the integrity, safety, and rigor of global clinical trials.

Our Mission

Engage diverse stakeholders to define emerging issues in global clinical trials and to create and implement ethical, actionable, and practical solutions.

Brigham and Women's Hospital
Founding Member, Mass General Brigham

HARVARD UNIVERSITY

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Agenda

Time	Topic	Speaker / Facilitator
9:00-9:15	Introduction Overview JTF 10th anniversary	**Barbara Bierer, MD** Co-Chair, JTF Faculty Director, MRCT Center
JTF Updates and discussion		
9:15-10:00	CANTRAIN Canadian Consortium of Clinical Trial Training	**Bruno Battistini, PhD** National Executive Director & Chief Operating Officer, **Lisa Goos, PhD** Chief Operating Officer
10:00-10:10	Data Management update: Results from Delphi	**Meredith Zozus, PhD** Professor, Division Chief, Clinical Research Informatics University of Texas (UT) Health San Antonio, Long School of Medicine, Department of Population Health Sciences
10:10-10:20	CIOMS Update	**Stephen Sonstein, PhD** Co-Chair, JTF
10:20-10:30	Updates: (1) Deploying the JTF Framework around the world: Arabic translation, (2) 3CTN Updates	**Christine Samara, MSc** Coordinator of the Arabic Translation with the Ministry of Health and Prevention, United Arab Emirates Member of the 3CTN Performance Strategy Sub-Committee, Canadian Cancer Trial Network (3CTN)
10:30-10:40	How a competency-based program will contribute to early clinical research professionals' training	**Amy Fox, PhD** Capella University
10:40-11:00	Open discussion and Wrap-up	**Stephen Sonstein, PhD & Barbara Bierer, MD** Co-Chairs, JTF

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JTF 10-Year Anniversary

CANTRAIN

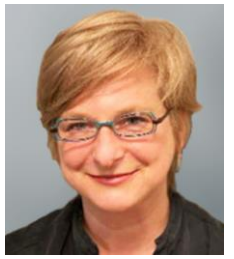
CANADIAN CONSORTIUM OF CLINICAL TRIAL TRAINING

Prof. Jean Bourbeau

Nominated Principal Investigator & National Lead

Dr. Bruno Battistini

National Executive Director & Chief Business Officer



Dr. Lisa Goos

Chief Operating Officer

Ms. Linda Hunter

National Stream Coordinator- Patient and Community Partners

CANTRAIN Overview

Joint Task Force for Clinical Trial Competency (JTF)
Biannual Global Meeting, June 6, 2024

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JOINT TASK FORCE FOR CLINICAL TRIAL COMPETENCY

PRESENTATION OUTLINE

1. Canada’s investment in clinical trials infrastructure

2. What is CANTRAIN?
   - What We Offer
   - Our Strategic Vision
   - Training Programs
   - Mentorship Program
   - Graduate Student and Postdoctoral Salary Awards
   - Internships

3. CANTRAIN’s training programs
   - CANTRAIN Common Core Foundation
   - CANTRAIN Learning Pathways
   - What makes CANTRAIN unique?

4. Patient Centricity and Inclusion in Clinical Trials Training
   - Bringing patient and community partners into the JTF Core Competency Framework for Clinical Research Professionals

5. CANTRAIN and the JTF Core Competency Framework for Clinical Research Professionals

CANTRAIN
CANADIAN CONSORTIUM OF CLINICAL TRIAL TRAINING

Canadian Institutes of Health Research (CIHR) Clinical Trials Fund

2022-Jul-12 — Submission - CIHR

2022-Oct-31 — Approval - CIHR

2023-Jan-19 — Official announcement-gov.ca

$250M investment in clinical trials infrastructure

Français

Government of Canada | Gouvernement du Canada

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Reinforcing Canada's clinical trials infrastructure, training, and research

From: Canadian Institutes of Health Research

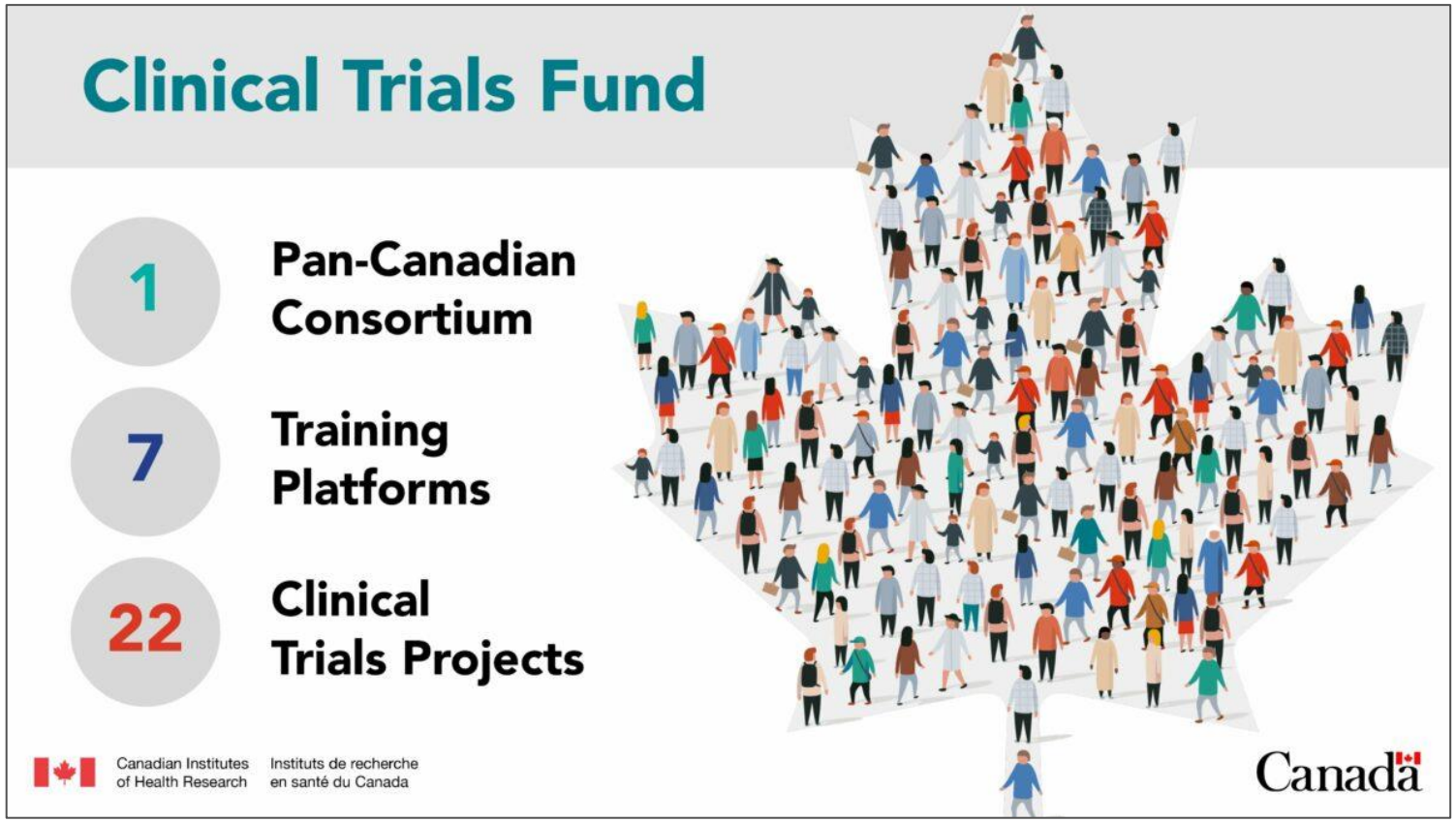
Backgrounder

Clinical trials are an essential part of the healthcare sector and a crucial component of medical research and innovation. Clinical trials allow researchers to assess if new drugs, treatments, and therapies are safe and effective for the population. Announced in Spring 2022, the Clinical Trials Fund earmarked $250M across three funding streams to grow and strengthen Canada's clinical trials infrastructure, training, and research through 2025.

The CTF is an integral component of Canada's $2.2 billion investment under the Biomanufacturing and Life Sciences Strategy, which brings together a suite of federal programming to achieve two main objectives: (1) better preparing Canada to respond to pandemics and other health emergencies; and (2) supporting an innovative, high growth domestic life sciences sector. To advance these objectives holistically, the CTF contributes toward these objectives by helping to create a pipeline for medical innovation and research in complement to other federal investments that have been made to augment domestic biomanufacturing capacity.

The CTF was launched in spring 2022 and successful applications were funded through three CTF funding streams:

- Pan-Canadian Clinical Trials Consortium: The Accelerating Clinical Trials Consortium will bring together a team of 232 researchers across the country to support and expand clinical trials networks to improve collaboration, efficiency, knowledge sharing, and quality of clinical trials in Canada.
- Clinical Trials Training Platforms: Seven different training platforms will train the next generation of clinical scientists and researchers to conduct high quality clinical trials
- Clinical Trials Projects: Twenty-two individual clinical trials projects will create the evidence needed to develop new drugs and treatments

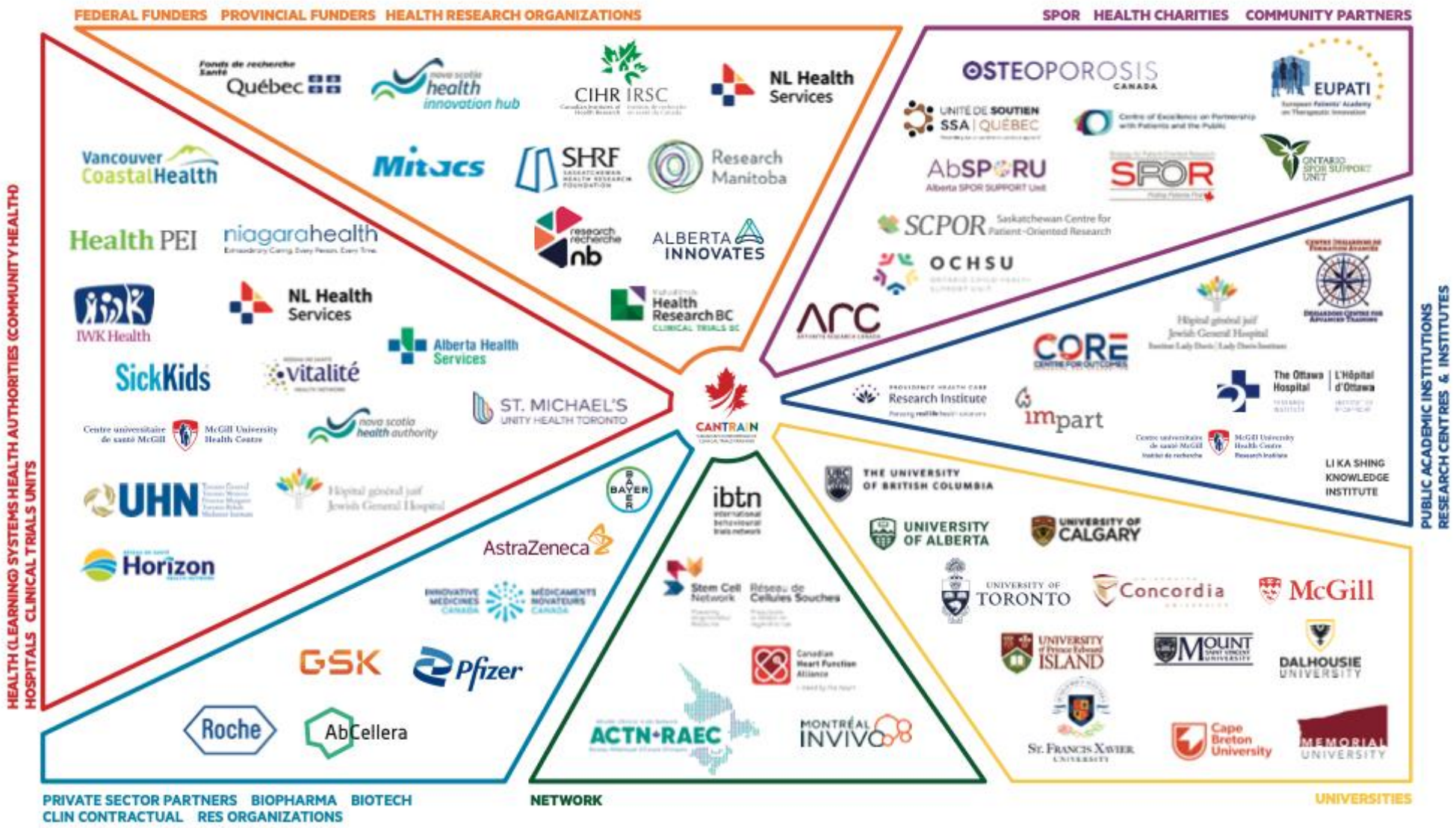


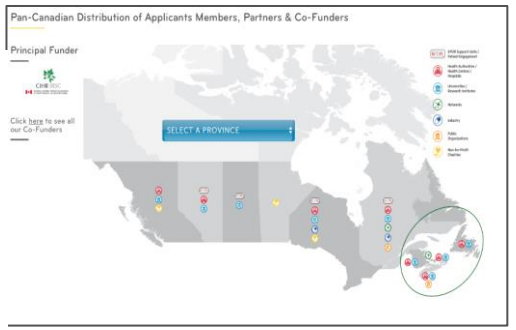
CIHR Investment in Clinical Trials Infrastructure

Project title	Principal Investigator	Project Amount
Clinical Trials Pan-Canadian Consortium		
Accelerating Clinical Trials (ACT) - Canada	Dr. Philip J. Devereaux (McMaster University) with 232 researchers	$38,996,933
Clinical Trials Training Platforms		
The Canadian Behavioural Trials and Interventions Training Platform	Dr. Simon Bacon (Concordia University)	$1,776,068
Canadian Consortium of Clinical Trial Training (CANTRAIN) platform: enhancing career preparedness in RCT research targeting different audiences across the continuum	Dr. Jean Bourbeau (Research Institute of the McGill U Health Centre)	$11,317,324
Canadian Training Platform for Trials Leveraging Existing Networks (CAN-TAP-TALENT)	Dr. Angela Cheung (University Health Network)	$4,314,242
STROKECOG Platform: Innovative Clinical Trials Training Initiatives for STROKE and COGnition	Dr. Jodi D. Edwards (University of Ottawa Heart Institute)	$2,911,416
A Training Platform in Pragmatic Registry-Based Trials: Connecting Canada's Health, Data, and Biomanufacturing Sectors	Dr. Amit Garg (University of Western Ontario)	$3,479,320
Increasing capacity for Maternal and PAediatric Clinical Trials (IMPACT) in Canada	Dr. Lauren Kelly (University of Manitoba)	$4,907,350
Canadian Network for Statistical Training in Trials (CANSTAT)	Dr. Sameer Parpia (McMaster University)	$2,542,144

Members, Partners, and Co-funders

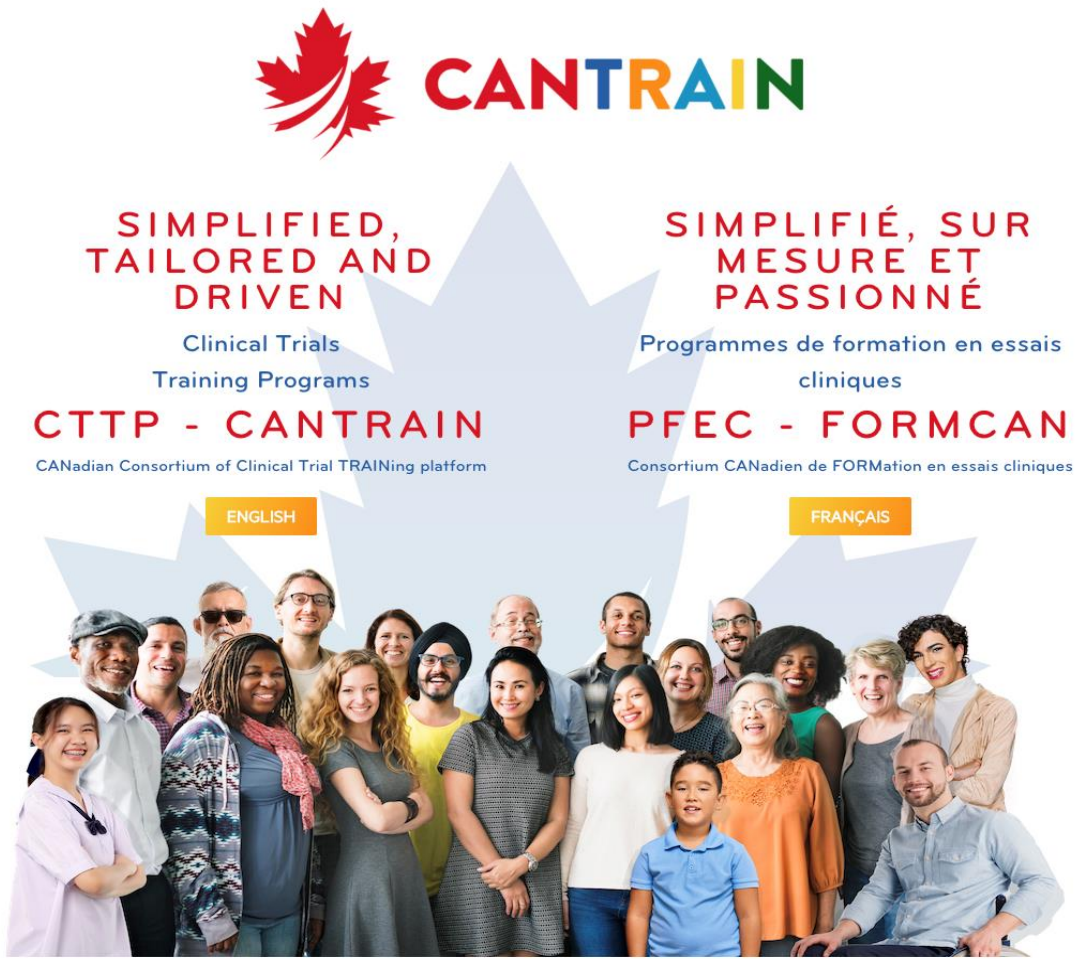
- Pan-Canadian initiative in ten (10) provinces
- More than 200 partner institutions (public & private)





https://wecantrain.ca/members-partners-co-funders/

What is CANTRAIN?



Funded by: | Financé par :

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

A suite of FREE, tailor-made accredited programs for Canadian public academic institutions

- Training tailored to four (4) distinct streams of learners, including patients and community partners
- Customized training programs within each stream: (i) Beginner/Basic/Fundamental, (ii) Intermediate, (iii) Advanced, (iv) Expert
- Competency-based training (*JTF) enriched by experiential learning and expert mentorship
- Three (3) Salary award programs for graduate students and postdoctoral trainees in clinical trials research
- Four (4) Internship awards programs for in-field experience

https://wecantrain.ca/

CANTRAIN's Strategic Vision

OUR HIGHER PURPOSE

Improve health and wellbeing through clinical trial research for the Canadian population and beyond.

"BETTER PREPARED. BETTER CARE."

OUR VISION AND MISSION

VISION

CANTRAIN is transforming how Canadians are prepared to develop, conduct, engage in and benefit from clinical trial research.

MISSION

Develop clinical trial research competency through an efficient training environment delivering cutting-edge, inclusive educational curricula.

Training Programs: Four Streams of Learners

Find the best clinical trial training program for you

STREAM 1-GPT

For Graduate & Postdoctoral Trainees (GPT) in the health sciences

- Postgraduate Master's Students
- Doctoral Students
- Postdoctoral Fellows
- Postdoctoral Researchers in health sciences

STREAM 2-CRP

For Clinical Research Professionals (CRP)

- Registered Nurse
- Nurse Practitioner
- Clinical Research Assistant
- Clinical Research Associate
- Clinical Research Coordinator
- Clinical Research Manager
- Medical/Health Sciences' Graduates

STREAM 3-TRIALISTS

For Clinical Researchers

- Residents/Fellows
- Clinicians
- Family Physicians
- Specialists
- Scientists

STREAM 4-PARTNERS

For Community Partners

- General Public
- Patients
- Public/Private Organizations
- Health Charities
- Families
- Policy-Makers
- Journalists
- Social Media Influencers/Reporters
- Toward Equity, Diversity and Inclusion of Black, Indigenous, and People of Color, Immigrants, Refugees, minoritized, underserved and underrepresented groups

- Levels / Programs within each stream to accommodate increasing experience and areas of specialized expertise

Training Enriched by Expert Mentorship

CANTRAIN CONNECT
College of Clinical Trial Mentors

- **Various types** of mentorship forms available: one-on-one, group presentations, module SME, etc.
- Mentorship integrated within each stream
  - Webinars, mentor-led engagement sessions, etc.
  - Mentors for each module of the Common Core Foundation
  - Mentors critical as SMEs for content development
- Mentorship engagement through LMS that increases accessibility and inclusivity (location, specialization,…)
  - Discussion Board: by domain, by module/course, public/private, office hours, etc.
  - Publication, video, website hosting
  - One-on-one meetings or group presentations
- Training and resources to support mentoring activities (e.g. Mentorship Handbook for Awardees & Supervisors)
- Resources to support local programs and activities
- Mentor incentives include letters for promotion, certification for engagement & training

Domain Expertise:
- Mentors in particular competency domains, SMEs
- Workshops, special presentations, ECHO

Professional Advice:
- Clinical and scientific mentors
- 1:1; supported online through LMS
- ECHO

Talent Development:
- Learning how to do the job well.
- 1:1, Peer mentoring network (CRPs)
- ECHO; workshops on ‘how to…’

Industry Exposure:
- Various roles in clinical trials industry
- Internships w/industry, public sector partners; experiential placements
- Career workshops, events

THREE (3) STUDENTSHIPS AND FELLOWSHIPS AWARDS UNTIL 2025-26

>$2M for 84 studentships & fellowships (42 from CANTRAIN)

- Attributed in 2023-24 FY
  - **24 Master's** studentships
  - **41 Doctoral** studentships
  - **19 Postdoctoral** fellowships

https://wecantrain.ca/home/studentships-fellowships-and-internships/

Studentships and Fellowships

Master's and Doctoral Studentships

NOW OPEN > Closing on May 31st, 2024

Postdoctoral Fellowships

NOW OPEN > Closing on May 31st, 2024

2024-25 PARTNERING CTTPs

CANTRAIN

CAN TAP TALENT

CBITN

StrokeCog

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

Michael Smith Health Research BC
CLINICAL TRIALS BC

ALBERTA INNOVATES

Research Manitoba

SHRF
SASKATCHEWAN HEALTH RESEARCH FOUNDATION

Fonds de recherche du Québec

research recherche nb

nova scotia health authority

Health PEI

NL Health Services

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FOUR (4) INTERNSHIP PROGRAMS UNTIL 2025-26

Clinical Research Internships

Paid industry placements for career development, co-funded by MITACS and private sector biopharma/biotech/CCRO **for Graduate and Postdoctoral Trainees (GPT)**

Mitacs

OPENING EARLY JULY

Paid Inter-institutional exchanges between public academic institutions **for Clinical Research Professionals (CRP) & Early Career Researchers (ECR)**

CANTRAIN

CAN TAP TALENT

StrokeCog

RE-OPENING IN MAY 2024 >

Paid academic and industry placements **for Landed Immigrants** to obtain Canadian experience, critical for job-search success, to bring HQP skilled in medical & health sciences into the Canadian clinical trials sector

COMING SOON

Part of curriculum-based training for patients, family members and patient advocates to observe and experience operations within patient-led or disease-specific organizations or Clinical Trial Units (CTUs) **for Community Partners and Patients**

COMING SOON

https://wecantrain.ca/home/studentships-fellowships-and-internships/

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CANTRAIN's Unique Training Programs

Core Competency Framework for Clinical Research Professionals

Joint Task Force for Clinical Trial Competency (JTF, 2023)

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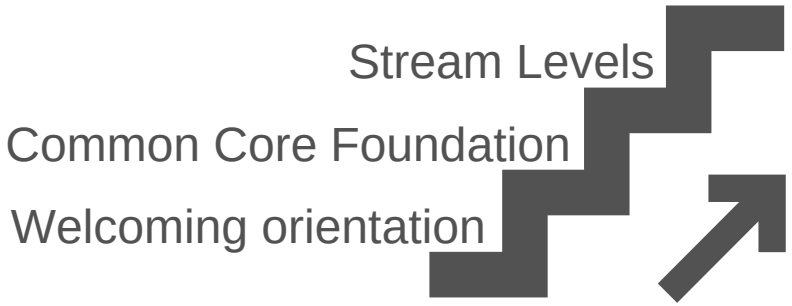
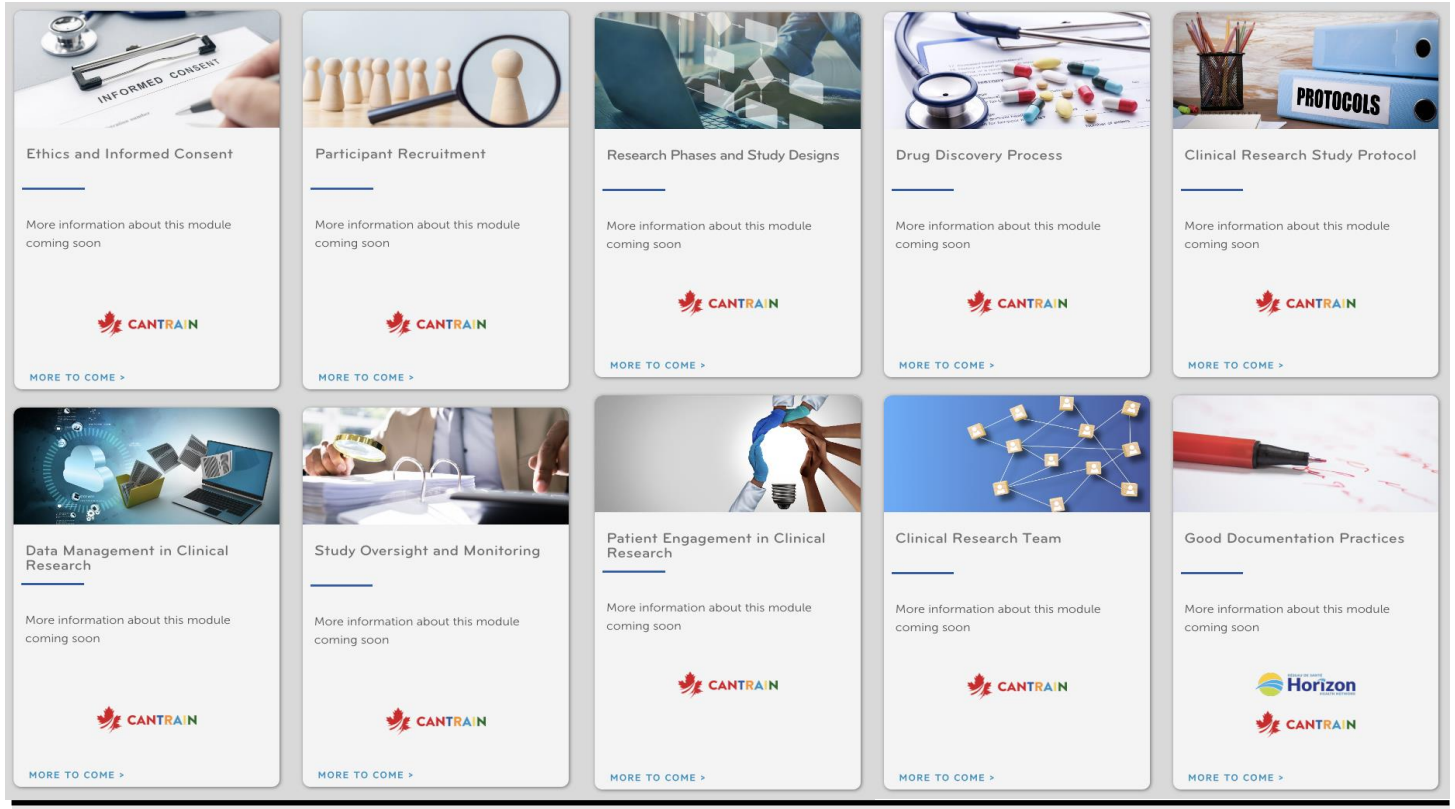


- Four learners' profiles
- Sequenced curriculum
- Training, Mentoring and In-field Experience

CANTRAIN Common Core Foundation



Common Core Foundation (n=11)

Regulatory Compliance Courses (n=3)

Welcome & Orientation

Competency

Knowledge

Awareness

CANTRAIN Learning Pathways

Competency-based learning pathways to serve a variety of career trajectories

Competency

Common Core Foundation (n=11)

Knowledge

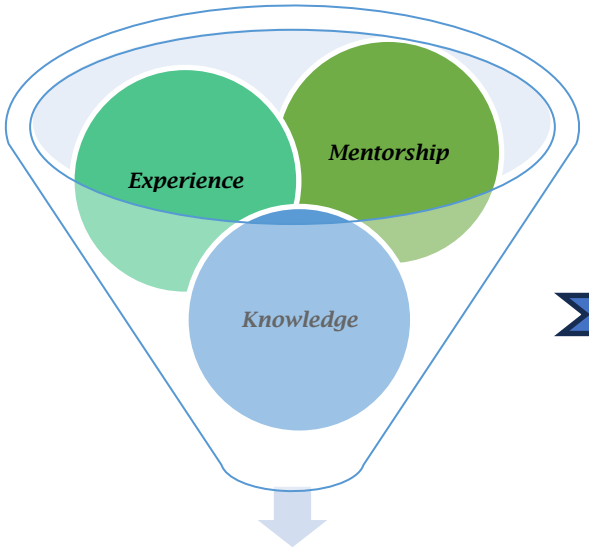
Regulatory Compliance Courses (n=3)

Welcome & Orientation

Awareness

What Makes CANTRAIN Unique

The CANTRAIN Model

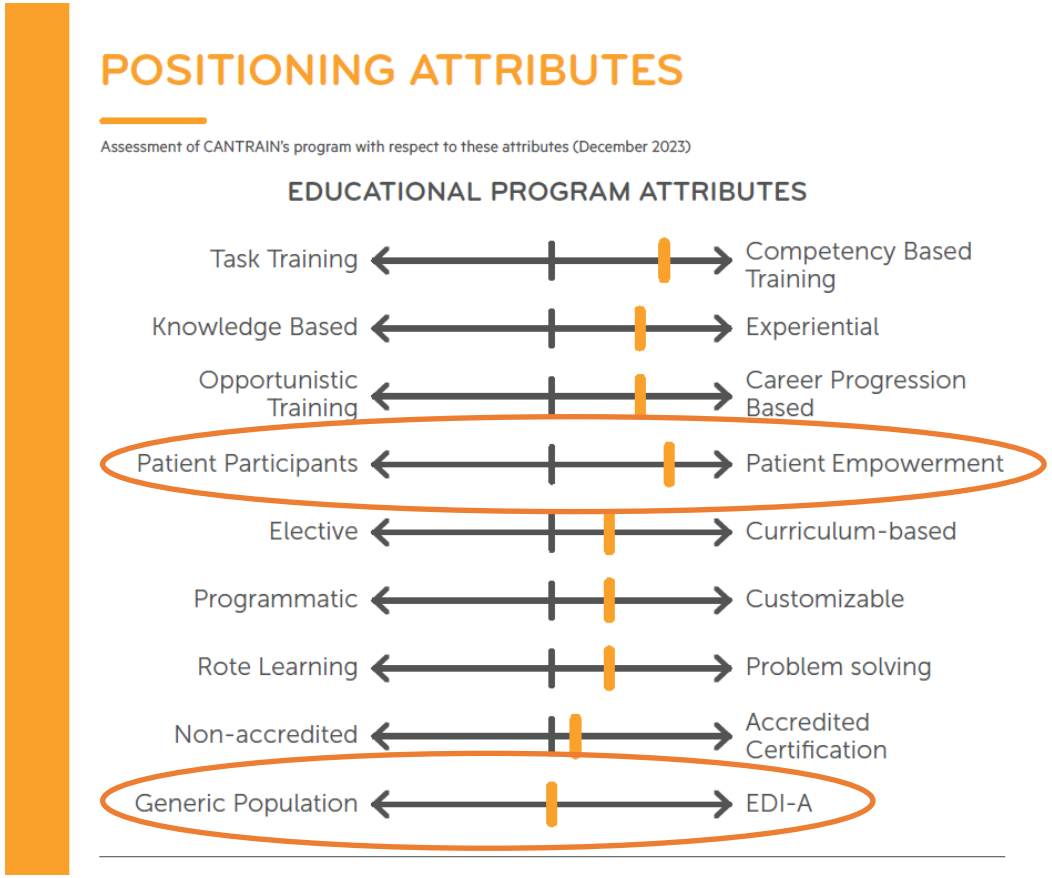


Professional Competence

- ✓ Engagement and experiential learning opportunities facilitate the application of knowledge to develop professional skills and competencies.
- ✓ Expert mentorship supports the refinement of new skills.

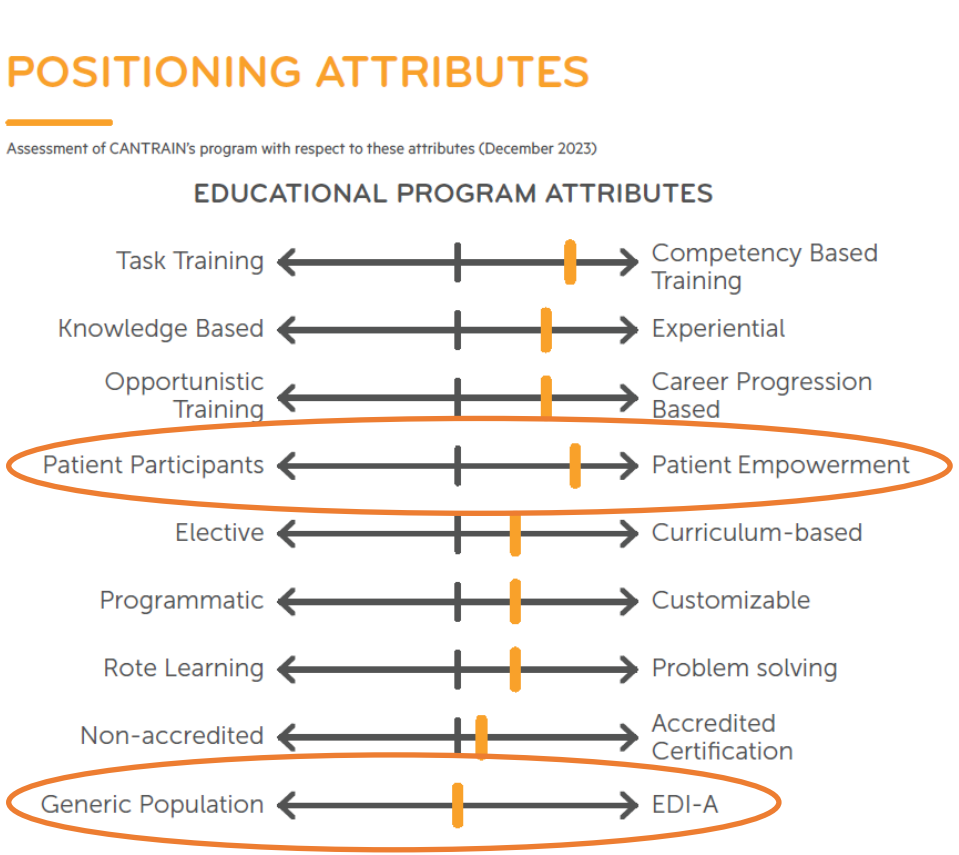
What Makes CANTRAIN Unique

CANTRAIN…not just training people WHAT to do, but HOW to do it well.



- Competency-based
  - Competence encompasses knowledge as well as the skills, abilities and behaviors that contribute to optimal performance.
- Scientifically grounded
  - Curricular approach using cognitive learning strategies to improve comprehension, retention, and the ability to apply knowledge.
- Experiential learning opportunities and expert mentorship
  - Career exploration, real-work relevance, real-world evidence
- Patient-centered and inclusive
  - CANTRAIN is raising the bar on patient engagement by developing evidence-based best practices for training patients and community partners, and advanced training curricula for researchers in patient engagement.

Patient Centricity and Inclusion in Clinical Trials Training



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STREAM 4: PATIENTS & COMMUNITY PARTNERS

Essential partners in Clinical Trials: Patients, family, patient-led and disease-specific organizations

CANTRAIN National Coordinator - Linda Hunter RN, MScN, PhD(c)

- Expert knowledge for patient partners AND research teams
  - Training with a focus on patient empowerment
- Patient partner, patient advocate and patient engagement learning paths
  - Developing patient engagement best practices & competencies for researchers
  - Developing patient engagement curricula and competencies for patients and community partners

Features:

- Interactive, competency-based learning
- Short (<30 min) training capsules

Patient Centricity and Inclusion in Clinical Trials Training

Bringing patient and community partners into the JTF Core Competency Framework for Clinical Research Professionals

Domain 1: Research Design – *What aspects of research design should patient and community partners understand?*

Domain 2: Ethics and Safety – *an ethics framework for research engagement with marginalized populations; cultural competence as an ethical principle.*

Domain 6: Data Management – *What should patient and community partners understand about data management, privacy and classical (normative) statistics?*

Domain 7: Leadership and Professionalism – *for patients and community partners working in the clinical research ecosystem*

Domain 8: Communication and Teamwork – *bidirectional within and across teams; knowledge translation into the patient and community partner space*

Domain 9? *Trauma Informed Care, Compensation, Tokenism, Partnership vs. participation, and so much more…*

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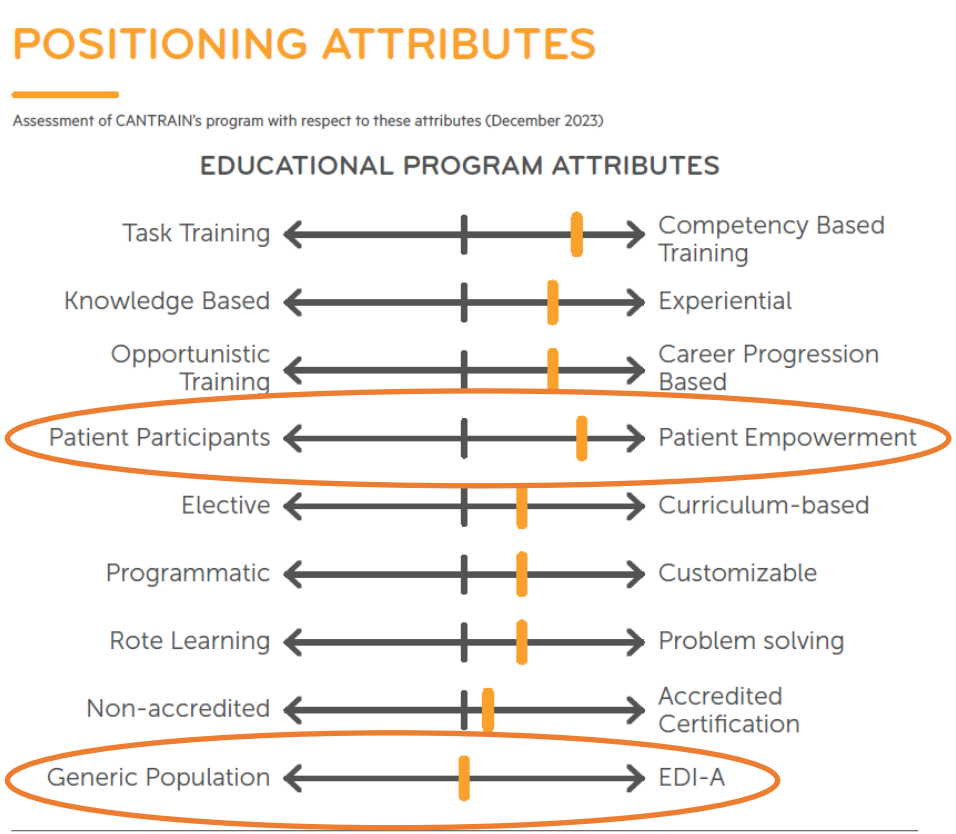
Thinking about the approach…

- Look to other frameworks on patient engagement in healthcare for guidance
  - e.g. Canadian Quality and Patient Framework for Health Services, etc.
- Ensure multidisciplinary, global input with significant diversity in lived experience:
  - Disease, understanding of clinical trials, EDIA, jurisdiction, advocacy, etc. as well as clinical research professionals, clinical scientists, academics, and researchers.
- Consider the approach: separate competency domain(s) or integration across existing domains.

CANTRAIN and the JTF Core Competency Framework for Clinical Research Professionals



We look forward to working with the members of the Joint Task Force for Clinical Trial Competency!

- Adaptation of the JTF Core Competency Framework for Clinical Research Professionals for the Canadian regulatory context
- Co-creating the next iteration of the JTF Clinical Research Competency Framework to include new domains, competencies and levels pertaining to:
  - Equity, diversity, inclusion & accessibility
  - Patient & community partner engagement and empowerment

Thank you !

CANTRAIN

Data Management Update

Meredith Zozus, PhD
Professor, Division Chief, Clinical Research Informatics
University of Texas (UT) Health San Antonio, Long School of Medicine,

CIOMS Update

Stephen Sonstein, PhD
JTF Co-Chair

- an international, non-governmental, non-profit organization established jointly by WHO and UNESCO in 1949
- mission is to advance public health through issuing guidance on health research including ethics, medical product development and safety
- CIOMS convenes international workgroups of experts who work both online and in person to develop guidances
- Many CIOMS guidances have been incorporated into ICH Guidelines

- **2016 -**New CIOMS Ethical Guidelines for Health-related research involving humans.
- **1993 -** Start of CIOMS focus on pharmacovigilance and reporting adverse drug reactions.
- **1982 -** Adoption by UN of CIOMS Medical Ethics for prisoners.
- **1977 -** Launch of Ethics of Research involving humans.

CIOMS rationale for recommending a new guidance

- Despite the universal understanding of the value in the development of new medicines, there is relatively little understanding of the actual development process (the journey from the bench to the bedside), not only among patients and the public, but also among many HCP, especially those who prescribe medicines.
- The rapid pace of scientific advancements, particularly in the last few years, has produced new medicines that have been developed and approved extremely rapidly, thereby rendering appreciation of the benefits and risks, as well as the regulatory assessment of these medicines, challenging for both HCP and the public.
- Understandably, due to this rapid pace of change, many HCP may find it challenging to explain to patients the benefits and risks of the products they prescribe, and especially to explain how such benefits and risks were studied and assessed before granting a marketing authorization . As a consequence, the inability to explain the medicines development process to patients may foster hesitancy in accepting certain treatments and/or prophylactic interventions.
- The COVID-19 pandemic significantly heightened public awareness of the importance and challenges of new medicines development.

Recommended Standards of Education and Training for Health Professionals Participating in Medicines Development

- The main objective of this working group is to discuss and develop a consensus report giving recommendations on the principles of competency-based knowledge needed for healthcare professionals participating in medicines development.
- Group rapidly realized that there were many different populations of health professionals needing varying levels of expertise (sponsors, clinical trialists and staff, regulators, trial participants).
- Agreed to utilize JTF core competency framework to develop education and training standards for health professionals and their staff that are the primary generators of data during the medicines development process (clinical trials).
- One of most significant lackings in understanding principles of medicines development were identified among health professionals (practicing physicians, nurses, allied health professionals) who actually prescribed and cared for individuals who utilized medicines.

Recommended Standards of Education and Training for Health Professionals Participating in Medicines Development

- Several subgroups now working to define competencies and recommendations for the varying populations
  - utilizing currently existing competency frameworks
    - IFAAP/Pharmatrain - sponsors
    - JTF – clinical trials
    - RAPS - regulators
    - EUPATI – trial participants and patient advocates
- Face to face meeting in Geneva in October to hopefully finalize recommendations
- Followed by editing of document, release for public comments and issuance in 2025

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Deploying the JTF framework across the world

Arabic Translation

Christine Samara

June 2024

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UNITED ARAB EMIRATES
MINISTRY OF HEALTH & PREVENTION

الإمارات العربية المتحدة
وزارة الصحة ووقاية المجتمع

Arabic translation of the MRCT JTF Core Competency Framework

- Coordinated by Christine Samara

- Translation has been conducted by the UAE Ministry of Health and Prevention
  - Dr. Khalil Qayed, Director National Center for Health Research
  - Dr. Ahmed Alosi, Research Consultant

June 2024

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الإمارات العربية المتحدة
وزارة الصحة ووقاية المجتمع

Identified the organization for collaboration

Initial contact & agreement with Dr. Khalil Qayed.

November – December 2022

Translation Plan

Discussed the plan for document translation & progress with Dr. Qayed and Dr. Alosi.

Received preliminary draft of 3 domains.

February – April 2023

Translation Phase

Completed the initial draft for all domains.

Initial contacts made validation phase.

May – September 2023

Validation / Proof reading Phase

Ongoing validation / Proof reading Phase

October 2023 – **March 2024**

Published April 8, 2024

June 2024

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وزارة الصحة ووقاية المجتمع

Organizations / Institutions involved in the Validation / Proof reading Phase

Project Coordinator and Lead Reviewer of the Arabic Translation			
Canada	Member, JTF for Clinical Trial Competency Committee, MRCT of Brigham and Women's Hospital and Harvard		**Christine Samara**
Authors of the Arabic Translation			
United Arab Emirates	**National Center for Health Research (NCHR), Ministry of Health and Prevention**	وزارة الصحة ووقاية المجتمع MINISTRY OF HEALTH & PREVENTION	**Dr. Khalil Qayed** Director of the Center **Dr. Ahmed Alosi** Research Consultant
Validation of the Arabic Translation			
Gulf, Levant and North Africa	**Phoenix Clinical Research**	Phoenix Clinical Research	**Georges Labaki** Chief Executive Officer **Racha Aaraj** Head of Medical Writing and Biostatistics
Lebanon	**Lebanese American University**	LAU Lebanese American University	**Dr. Joseph Stephan** Associate Professor, Gilbert and Rose-Marie Chagoury School of Medicine Director, IRB office and Research Ethical Compliance **Karmen Baroudy** IRB Lead Program Manager
Levant and Iraq	**Sanofi**	sanofi	**Dr. Marie-Therese Sawaya** Head of Public Affairs and Market Access
Proof Reading and Final Review of the Arabic Translation			
Belgium	Intercultural Communicator, Translator and Interpreter		**Katia Abi Gerges**
Contribution to the translation process and the editing			
France	F-CRIN	F.CRIN	**Allan Wilsdorf** Head of F-CRIN's Training & Education Unit Coordinator of CRIGH's Project 2 "Global Core Competencies"
	CRIGH	CRIGH	

June 2024

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وزارة الصحة ووقاية المجتمع

Dissemination

First Step - Social Media Platforms

Future Steps:

The National Center For Health Research (NCHR) at the Ministry of Health and Prevention(MOHAP) in the UAE is working to develop an effective dissemination plan for the Arabic Version of the Framework within the UAE and the Region.

June 2024

Canadian
Cancer Clinical
Trials Network

3CTN Updates

Christine Samara, 3CTN PSC member
Performance Strategy Sub-Committee (PSC)

June 2024

Canadian Cancer Clinical Trials Network

Joint Task Force Core Competency Framework

Defines the standardized set of core knowledge domains and associated skills necessary for conducting high quality clinical research

Applications:

- *Supports onboarding, orientation and core training of staff*
- *Informs role descriptions, performance evaluations, career ladders*

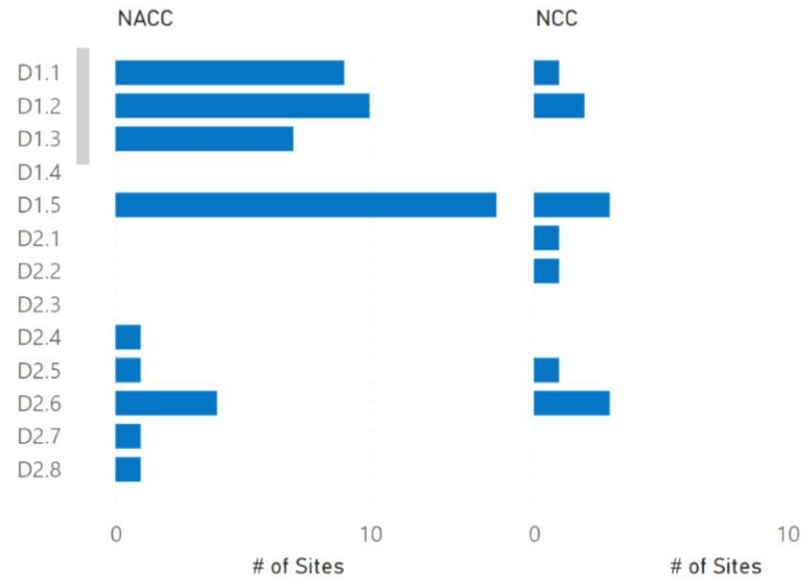
Canadian
Cancer Clinical
Trials Network

3CTN Core Competency Report

Canadian Cancer Clinical Trials Network | Réseau canadien d'essais cliniques sur le cancer

Identified Core Competency Gaps by Domain

Identified Core Competency Gaps



Domain Resources

Domain	Resource Owner	Resource Title	Resource Type	Resource Link
D1	ACRP	ACRP Course Catalog - Scientific Concepts and Research Design	Course	
D1	CCTG	Biennial New Investigator Clinical Trials Course	Course	
D1	CCTG	New Investigator Cancer Trials Practicum	Practicum	
D1	CITI Program	Biomedical (Biomed) Comprehensive	Course	
D1	CITI Program	Biomedical (Biomed) Foundations	Course	
D1	CITI Program	Essentials of Statistical Analysis (EOSA): Complete (Parts 1, 2, and 3)	Course	
D1	CITI Program	Protocol Development and Execution: Beyond a Concept	Course	

Last Updated : September 12, 2023

Canadian Cancer Clinical Trials Network

Network Approach to Core Competency

Global impact

3CTN support for validation of JTF's French translation

- French revisions with 3CTN's feedback published on the JTF website, 21 May 2024

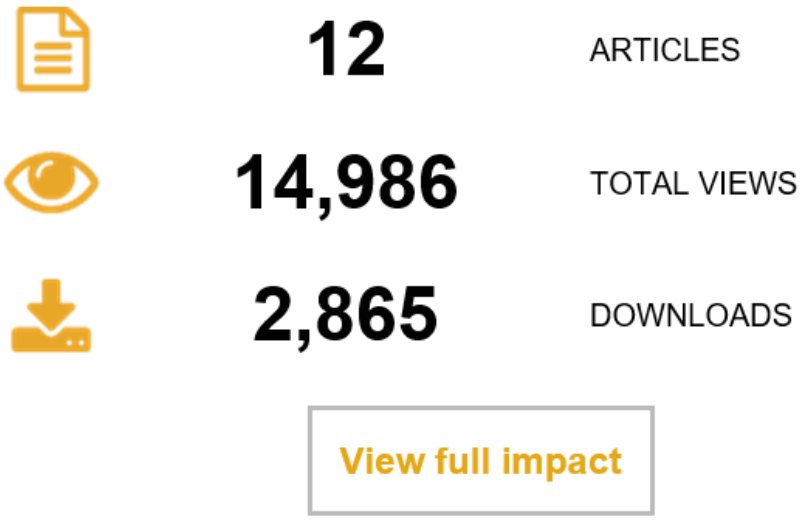
Canadian Cancer Clinical Trials Network

Network Approach to Core Competency

Created a manuscript describing the unique, Network-wide application of the JTF Core Competency Framework

Published in Frontiers, December 2023:

> *Minding the Gaps: assessing and addressing clinical research core competencies across a network of Canadian cancer centres*
> S. Sundquist, D. Kato, R. Chowdhury, C. Samara, J. E. Dancey



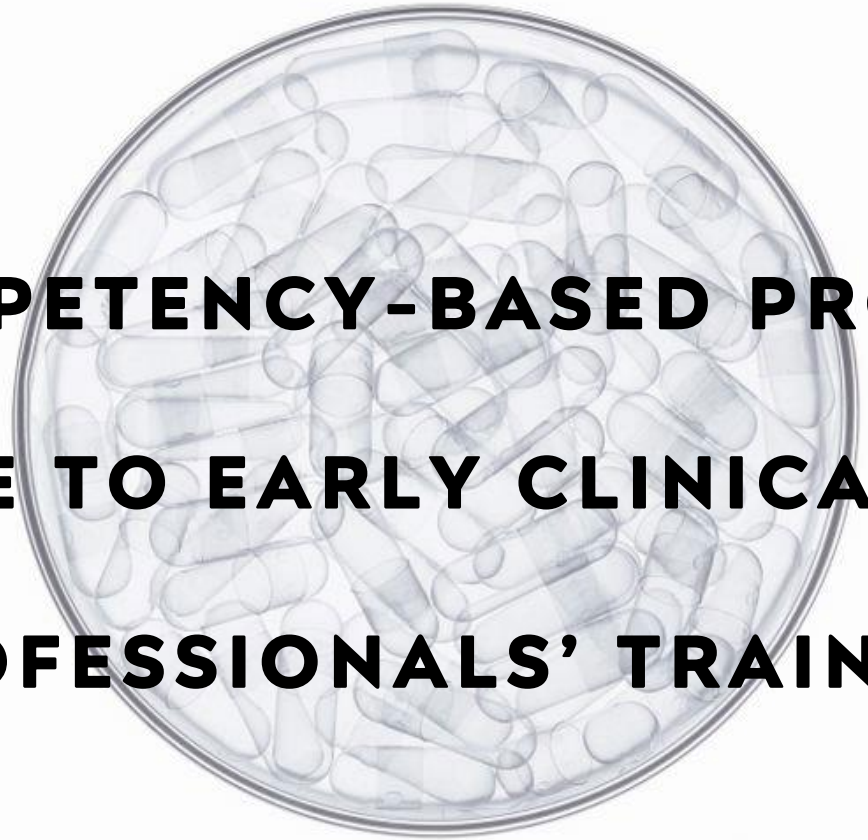
Canadian Cancer Clinical Trials Network

Future Directions

- Support training targeted to address priority core competency domains
- Develop evaluation framework:
  - # of sites that have used framework in staff development plans
  - Track overall changes for competency statement gap areas from 2022 survey and identify emerging gaps
  - Capture a measure of competency levels within each statement
  - Assess effectiveness of initiatives to support Network learning objectives

How a competency-based program will contribute to early clinical research professionals' training

Amy Fox, PhD
Capella University



HOW A COMPETENCY-BASED PROGRAM WILL CONTRIBUTE TO EARLY CLINICAL RESEARCH PROFESSIONALS' TRAINING

AMY R. FOX, DHA, MBA-HCA, MA, CCRC

PRESENTATION 06JUN2024

THE PROBLEM

The specific healthcare administration problem is that CRPs in research positions outside of traditional health-related roles (e.g., physicians, nurses, and pharmacists) do not have professional education mechanisms to adequately prepare them for new demands being put on clinical research services (Calvin-Naylor et al., 2017; Ganatra, 2018; ACRP,2022).

*CRP = Clinical Research Professional staff who support clinical research trial tasks at a designated location (excluded physicians, nurses, and pharmacists).

RESEARCH PURPOSE

This research sought to identify a relationship between the educational programs taken during the CRP's early years and their self-evaluated competencies.

JTFCTC CORE COMPETENCY DOMAINS

The Leveled Core Competency Framework For The Clinical Research Professional Version 3.1 by The Joint Task Force for Clinical Trial Competency (JTF) and the Multi-Regional Clinical Trials Center of Brigham and Women's Hospital and Harvard (MRCT Center) as licensed under CC By-NC-SA 4.0.

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THE QUESTION

Is there a significant relationship between independent variables (formal education and age group) and dependent variables (years working as a CRP, years holding a research certification, and years of on-the-job training) in the educational programs taken during the crps' early years in clinical research compared to their self-evaluated competency?

THE PROCESS

METHOD

- Quantitative Technique using web-based survey
- Linear regression, t-test, ANOVA & descriptive statistics

POPULATION

- Certified CRPs
- Actively working in CR
- Working in the USA

SURVEY TOOLS

- Hornung's CICRP
- Sonstein's CRAI
- 5 levels of proficiency

DURATION

- 20 questions
- Open 50 days

BARRIERS

- Anonymous
- Limited geographic location

THE RESULTS

HA > H0

CRPs found more self-perceived competence after being a CRP for five years and holding a research certification for more than two years, therefore the null hypothesis was rejected in favor of the alternative hypothesis.

EDUCATION

Having on-the-job training was found to be significantly related to self-perceived competence while formal education and age were not.

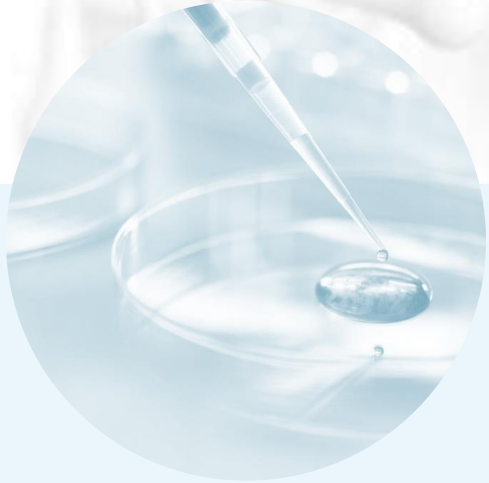
IMPLICATION

While research education and training offerings exist, there is a lack of categorization into research domains necessary to facilitate the CRP's competency to yield a highly competent workforce ready for the medical challenges of the 21st century.

ACKNOWLEDGMENTS

To Stephen Sonstein, Phd, Barbara Bierer, MD, And Carmen Aldinger, Phd, MPH, PMP Of The Multi-regional Clinical Trials Center Of Brigham And Women's Hospital And Harvard... Thank You For Answering My Emails In June Of 2022. I Am Humbled To Use Your Research Tools And Writings To Support And Pursue My Dissertation. Your Continued Work Is Inspiring And Necessary. I Hope I Have Contributed In A Small Way.

DR. AMY R. FOX



THANK YOU

AMY R. FOX
KCFOXES@YAHOO.COM

Open Discussion

Questions, Comments, Suggestions

Questions and discussion

Carmen Aldinger, PhD
caldinger@bwh.Harvard.edu

Barbara E. Bierer, MD
bbierer@bwh.Harvard.edu

Stephen Sonstein, PhD
ssonstein@gmail.com

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