

Clinical Trials BC Activities Report

September 2021 - March 2023



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About Clinical Trials BC

Clinical Trials BC's mission is clear: we strengthen efforts to build a robust clinical trials ecosystem to maximize the health, educational and economic benefits of clinical trials to the citizens of British Columbia.

We are an integral part of Michael Smith Health Research BC, and with support from the provincial government, we align with BC's Life Sciences and Biomanufacturing Strategy to lead initiatives that advance clinical trials in the province. By working in tandem with partners, we address pivotal priorities and ensure BC remains at the cutting edge of clinical trials trends, both provincially and globally. We do this by focusing on: **Growing a skilled clinical trials workforce, building and supporting provincial systems and infrastructure, and community engagement.**

We are excited to share our Clinical Trials BC Activity Report with you, which looks back on our key accomplishments together from September 2021 to March 2023. We are even more excited for continued partnerships with our community to expand BC's clinical trial capacity and position our province as a global hub for life sciences in the coming years.

Unleashing the potential of clinical trials in BC:
A vision takes shape

In 2022, Clinical Trials BC engaged 170 stakeholders across Canada to gain a better understanding of the strengths and opportunities for improvement in clinical trials overall.

The outcome of this work is a shared vision that reflects a future in which clinical trials investments are maximized for the benefit of all British Columbians:

A robust, innovative, coordinated, and person-centred clinical trials ecosystem improving health and economic outcomes for British Columbians.

This vision is endorsed by the BC Ministry of Health. [Learn more](#)

September 2021 – March 2023
accomplishments:

E-learning

2173 new learners
5486 courses completed



18 participating groups

Job board

80 opportunities promoted



1100 trials supported



152 events

1559 participants

GCP +
Health Canada

3584 courses completed

AIPP | 10 year anniversary

2000 trained

3291 new volunteers
REACH BC

437 new researchers

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Growing a skilled clinical trials workforce

By the numbers:

- Mandatory training courses completed (GCP, GCP refresher, Division 5): **3584**
- Total education events & attendance: **152** events, **1559** participants

Supporting the growth of a skilled workforce is critical for a strong knowledge economy, a well-functioning healthcare system and resilient communities. Clinical Trials BC has a strong focus on professional development initiatives that bolster the growth of a workforce with the required skills, knowledge and training to conduct world-class clinical trials in BC.

Training and education are made available to all of BC's clinical research community through our in-house developed sessions and workshops and through our partnerships with N2 Canada and ACRP.

Investigator Training Program

On November 2, 2022, Clinical Trials BC partnered with Pfizer Canada to hold the Investigator Training Program (ITP). It was a one-day, hybrid workshop designed for clinical trial investigators and research site team members in BC. In total, more than **300** attendees from over **55** different organizations took part in the training onsite at UBC Alumni Centre and virtually across all parts of BC.

Covering the entire trial process, the ITP offered a great guide to conducting regulated clinical trials in Canada and in improving required skills and practical knowledge. The workshop brought each topic to life with real-world examples, and rich and engaging discussions.



Photo: In-person attendees of the ITP event.



"Our clinical research unit (CRU) utilizes Clinical Trials BC's education and training programs on a regular basis. This has been extremely helpful when onboarding new team members and is part of our team's ongoing professional development."

–Dr. Ted Steiner, medical director, VCHRI CRU

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GROWING A SKILLED CLINICAL TRIALS WORKFORCE

"It was a pleasure collaborating with Clinical Trials BC on the delivery of the ITP." said Claudia De Paola, director, site relationship partner at Pfizer Canada. *"We appreciate this opportunity that allowed us to reach so many individuals in BC who are involved in the clinical trial process".*

More than **260** attendees received training certificates in Good Clinical Practice from TransCelerate which is a great expansion of BC's quality workforce pool to conduct clinical trials in the province.

Clinical Research Professional (CRP) Certification Program

Our CRP Certification Program provides clinical research team members the skills and knowledge to conduct world-class clinical trials that are internationally recognized. We provide clinical research professionals at BC academic-based or health authority-affiliated research sites financial and resource support to become certified by the Society of Clinical Research Associates (SOCRA) or the Association of Clinical Research Professionals (ACRP).

By the numbers:

- **100+** professionals certified to date
- **55** registered for study prep sessions in 2022
- **7** successful applicants received funding

Congratulations to the following individuals:

- **Muhammad Umair Khan (ACRP)**
- **Heather Lockyer from PHSA (SOCRA)**
- **Gayle Carney from Island Health (ACRP)**
- **Sheila Bazett from Island Health (ACRP)**

- **Peyman Goldeh from Island Health (ACRP)**
- **Jenn McKillop from Island Health (ACRP)**
- **Kyrsten Payne from Island Health (ACRP)**

[Learn more](#)

"Clinical Trials BC and the CRP Certification Program provided informative exam preparation support and tools that streamlined the process of becoming a certified professional. My favorite tool was the eLearning Program on the ACRP portal which complemented the ICH documents to prepare for the exam. After passing the exam, getting partially reimbursed was a nice bonus too."

-Peyman Goldeh, clinical research coordinator, Island

"I felt confident going into my CCRC exam thanks to the guidance from the CCRP certification program. Jean Smart broke the ICH documents down into digestible pieces and the eCops had a variety of resources to use for studying."

-Kyrsten Payne, research coordinator, Fraser Health

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GROWING A SKILLED CLINICAL TRIALS WORKFORCE

Quality Leadership Program (QLP)

The QLP ensures regulation compliance and consistency in quality control for clinical trials across the province. We provide mentorship and training courses to quality associates and equivalent persons in BC involved in quality, regulatory initiatives, oversight and the implementation of Quality by Design (QbD) and Quality Management System (QMS) at the study, institution or program/centre levels.

Last year, **16** individuals from **11** organizations were accepted into the program.

“The support we have been getting from Clinical Trials BC over the last several years has made a fundamental difference in our capacity to conduct clinical trials,” said Tess Topor, clinical research leader with Interior Health. “We can now ensure we are complying with regulations and standardizing our processes in a way that was simply not possible before.”

Promoting careers in clinical research

Clinical Trials BC participated in LSBC Career Connect Days in line with our goal to foster awareness of clinical trials as a career option within the life sciences sector. The events brought together post-secondary students, job seekers, business leaders, HR representatives and employers from across the life sciences sector.

As an exhibitor, we collaborated with hiring managers from clinical research programs and organizations to recruit for open positions, help students and candidates explore career pathways in clinical trials and provided resources for their job searches.

LSBC Career Connect Days

The 2022 Career Connect event was one of the most popular events by LSBC. More than **800** virtual attendees, including nearly **600** students from **57** schools worldwide, and **49** employing companies attended the event.

Clinical Trials Provincial Job Board

The Clinical Trials Provincial Job Board features opportunities in clinical trials in BC. Employers are able to attract top talent by reaching an extensive network of professionals and members of the community. Since its establishment in September 2019, the job board has promoted over **240** opportunities from all regions of the province.

By the numbers:

- **80** jobs promoted by
- **24** organizations across
- **5** health regions



Photo: The 2023 event attracted 350 guests and students from 50 companies and 21 universities/colleges in STEM and business programs.

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Building & supporting provincial systems and infrastructure

With the Clinical Trial Management System (CTMS), REACH BC, and the Quality Management System (QMS) Program, Clinical Trials BC ensures that clinical trials are enabled with leading-edge technology, fully compliant with regional regulations, and meet national and international standards.



"Clinical Trials BC provides significant value to the clinical trials community in BC. It is leading and supporting efforts to build capacity and develop provincial infrastructure for a more robust clinical trials ecosystem in the province so as to achieve the best possible health outcomes for everybody."

–Dr. Srinivas Murthy, investigator at BCCH and clinical associate professor at Department of Pediatrics, UBC.

Provincial Clinical Trial Management System

The Provincial Clinical Trial Management System (CTMS) is a critical tool for improving the clinical research process at the site and institutional levels. Since 2020, Clinical Trials BC has supported research sites across British Columbia by providing funding and operational support for the Provincial CTMS Program. Incorporating both provincially harmonized processes and cloud-based software, the program provides clinical trials teams with efficiency gains and improvements, as well as analytics and business intelligence to better achieve their research goals.

Participation in the provincial CTMS program continues to expand, with almost **700** users representing **54** research sites across **6** participating organizations. Since its inception, the Provincial CTMS Program has supported more than **1,100** clinical trials, an addition of over **400** trials from September 2021. Currently, the CTMS houses approximately **40%** of all active clinical trials in British Columbia.

Example of clinical trial used REACH BC for recruiting:

Study: "Drug Trial in Participants with Essential Tremor"

The purpose of this study is to evaluate the effectiveness and tolerability of an oral study drug in individuals who experience upper limb essential tremor.

Principal investigator: Dr. Silke Appel-Cresswell, VCH & UBC.

"Its ability to manage the finances of each study is far superior to what we were using prior to this system being operationalized. That feature alone makes this program useful and saves time and money!"

–Island Health coordinator

"Those running CTMS have been supportive and helpful, and someone should tell them that they're doing a great job [...]. They're great. They should be given praise."

–Interior Health coordinator

REACH BC

REACH BC is a provincial platform that supports recruitment for participants in health research and clinical trials. It provides a gateway for patient partners to participate in trials, and researchers to involve the patient voice in the full life cycle of the trials.

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BUILDING & SUPPORTING PROVINCIAL SYSTEMS AND INFRASTRUCTURE

REACH BC continues to grow in numbers of volunteers, researchers and breadth of health research opportunities shared through the directory. REACH BC volunteers have expressed interest in matched health research opportunities close to **8,000 times**. Of those, over **1,500** volunteers connected with research teams and enrolled in studies/trials or patient partner opportunities. To date, there are over **6,504** volunteers and **1,074** researchers signed up for our platform.

"It is a very effective way to inform people – both patients and volunteers about research opportunities."

–Dr. Thalia Field, UBC Researcher

"I see the value in participating [in health research. If they haven't got people to do this, they are not going to learn things."

–Elizabeth Brennan, REACH BC Volunteer

"REACH BC is really invaluable in helping us connect with the public and... the community at large."

–Dr. Manish Sadarangani, BC Children's Hospital Researcher

Quality Management Programs

Quality has long been a mandatory requirement in the lifecycle of all therapeutic products, including the clinical trial stage. It is incorporated into regulations and law within all regulatory authorities globally.

Our many programs help BC's research sites and institution meet the regulatory requirements and best practices for clinical trials in Canada. These programs raise the level of quality control and regulation compliance at research sites to make BC a more competitive and desirable place to conduct clinical trials.

Quality Management System (QMS) - we offer services, resources and support for the development and implementation of QMS in BC centres, health authorities, academic institutions and agencies. Currently, there are **18** participating groups (7 institutions, 3 units or centres, 8 programs) involved in our QMS program.

Audit & Inspection Preparedness Program (AIPP) - The AIPP celebrated its 10th year anniversary in April 2023. The program improves regulatory compliance through education from the lens of inspection.

We delivered **39** modules of the AIPP over **20** sessions to more than **200** participants. Clinical Trials BC also conducted **9** full-day mock inspections for research sites across BC. As a result, we helped four institutions pass Health Canada inspections.



Photo: REACH BC team at the 2022 BC Patient Safety and Quality Council Quality Forum, Vancouver, BC

Regulatory navigation and guidance - we conducted 176 formal regulatory consultations for sites, qualified investigators and sponsors involved in or planning for trials in BC. 2022 saw an increase in the number of consultations related to biologics, medical devices and clinical trials related to mental health.

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Clinical Trials BC acts as a convener and influencer in BC and nationally. We bring diverse groups together to understand the pressing problems, and to partner on solutions and implementation.

Clinical Trials BC Annual Awards

Every year, we honour individuals and organizations who have made significant contributions to strengthening the BC clinical trials ecosystem. In 2022, there were two awards presented: the Leadership & Advocacy Award and the Service & Support Award. The awards presentation was held in conjunction with the International Clinical Trials Day 2022.

Leadership & Advocacy Award

This award honours outstanding leaders and advocates for clinical trials at the provincial and/or national level. It is awarded to leaders who educate, mentor, advocate or spearhead projects, programs and strategies that benefit the clinical trials community.

Dr. McMaster was recognized for his significant contributions and leadership efforts to advance the conduct of clinical trials in BC. He is also a notable contributor to international guidances that impact the modernization of our regulatory environment in BC and Canada.



Photo: The COVID-19 Clinical Research Coordination Initiative (CRCI) from left to right: Stephania Manusha, Anni Rychtera, and Dr. Michelle Wong.



Photo: Dr. Robert McMaster Vice dean, research Faculty of Medicine, UBC

Service & Support Award

This award recognizes the community-based, volunteer commitment of an individual, organization, company or agency to improve the research and clinical trials community.

In 2022, the Service & Support Award belonged to all the patients, frontline clinicians, scientists, engineers, educators, trainees, as well as health authorities, provincial government, industry, regulatory and funding partners who gave their time and expertise on multiple CRCI's working groups through the pandemic.

- [Learn more about the 2022 recipients](#)
- [Learn more about the Clinical Trials BC Annual Awards](#)

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COMMUNITY ENGAGEMENT

International Clinical Trials Day

Each May, Clinical Trials BC commemorates International Clinical Trials Day (ICTD) to honour everyone involved in clinical trials for their contributions to public health and medical research. In 2022, the event attracted **121** community members from BC and beyond.

ASK US Series

The ASK US Series runs seasonally each year with a summer hiatus. For every episode, we present on a hot topic question that has come from the BC clinical trials research community. We invite experts in senior positions to answer questions raised and encourage further conversation on related topics.

We produced **7** broadcasts in total. The second season (2021-2022) had **5** broadcasts in total. **2** broadcasts of season three were produced so far by the end of March 2023. There were **14** guest speakers and **336** attendees.

[Watch recordings of previous broadcasts](#)

“The format of the ASK US is very nice. It gives a personal touch at the same time, also highlights the speakers’ expertise.”

–Participant

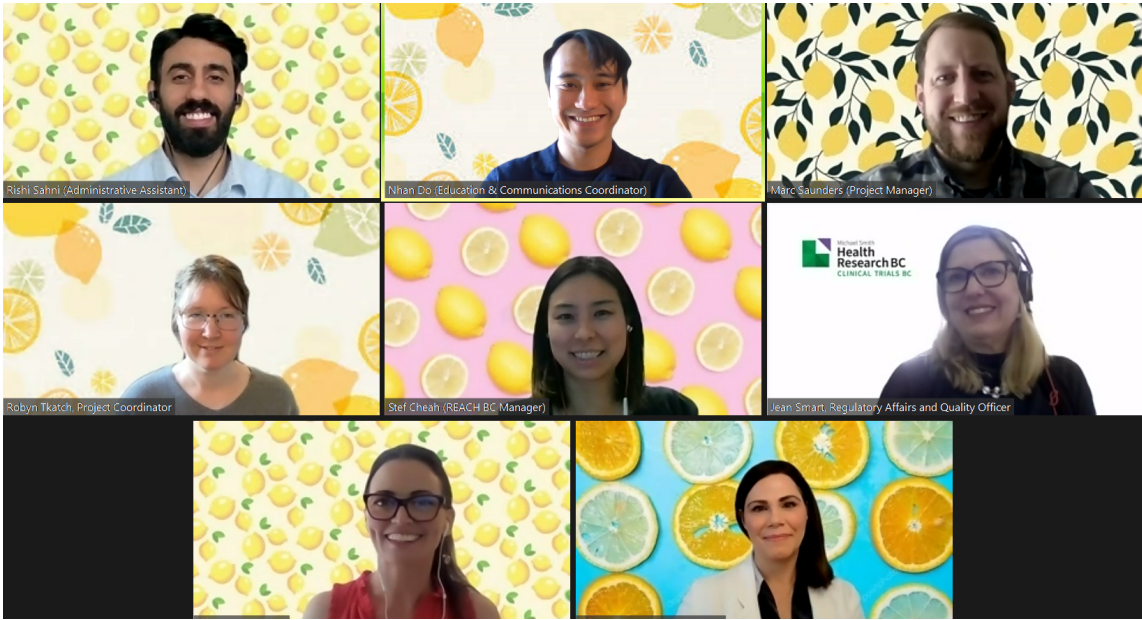


Photo: Clinical Trials BC team members at the International Clinical Trials Day 2022 virtual celebration held on May 19, 2022.

Communities of Practice (CoP)

Since 2020, we have established and coordinated three CoPs for **55** members of the clinical trials community to share experiences, practices and challenges in a variety of topic areas. The three CoPs are:

- Patient Engagement in Clinical Trials CoP
- Health Authority Site Managers CoP
- Quality/Regulatory CoP

Seven issues of the quarterly newsletter were delivered to **1,600** subscribers to update our community on the latest news, announcements and upcoming events from Clinical Trials BC. Check out the past issues of our quarterly newsletter in the [in-case-you-missed-it \(ICYMI\)](#) section.

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Partners in advancing the clinical research workforce

Clinical Trials BC is a partner with ACRP in Professional Workforce Advancement (PWA). We participate in the PWA Initiative to expand, enhance and gain industry alignment on the growth, quality, professionalism, diversity and sustainability of the clinical research workforce. [Learn more](#)

Decentralized Trials & Research Alliance (DTRA)

Decentralized clinical trials (DCTs) utilize technology, processes and services to collect data in a way that reduces the need for patients to physically visit the trial site. DCTs also enable the participation of

rural, remote and other harder to reach populations; facilitate involvement of a broader range of health care providers in clinical trials and reduce costs and burden of clinical trial conduct.

To build capacity for decentralized clinical trials in BC, Clinical Trials BC is a member of the Decentralized Trials & Research Alliance (DTRA), an international membership alliance of more than 100 life sciences and healthcare organizations that seek to accelerate the broad adoption of patient-focused, decentralized clinical trials and research.

The DTRA enables collaboration of community members to accelerate the adoption of patient-focused, decentralized clinical trials and research within life sciences and healthcare through education and research. [Learn more](#)



Photo: Marc Saunders, program manager represented Clinical Trials BC at the DTRA 2022 Annual Meeting in Boston, MA

Life Sciences BC (LSBC)

LSBC is a not-for-profit, non-government industry association that supports and represents the life sciences community of BC through initiatives at the local, national and international level. From 2021 to 2023, Clinical Trials BC partnered with LSBC in multiple activities to engage with diverse community members, leaders and representatives within the sector. [Learn more](#)

N2 (Network of Networks)

N2 is an alliance of networks and organizations working to enhance Canada's capability and capacity for clinical research and trials. Clinical Trials BC funds the provincial membership for **16** institutions across BC to enable BC clinical researchers, institutions and sites to be trained and compliant with clinical trials ethics, best practices and Health Canada regulations. [Learn more](#)

N2 Western Regional Meeting 2022

Clinical Trials BC co-hosted the Western Regional Meeting with N2 in November 2022. This half-day virtual event was an opportunity for leaders, regulators and clinical research professionals in Western Canada to learn about latest regulatory influences and developments in clinical trials across the country.

134 attendees joined the event from across Canada.

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Advisory Council

The Clinical Trials BC Advisory Council advises our strategic priorities. Members of the council represent a range of expertise in clinical trials including academia, the health system, health research-related organizations and patients.

Gavin Stuart (Chair), VGH/BC Cancer/UBC

Julia Bickford, Northern Health

Julia McFarlane, BC Ministry of Health

Kate Keetch, Fraser Health

Kendall Ho, UBC

Lisa Elser, patient partner

Mandeep Manhas, BC Ministry of Health

Martin Dawes, UBC

Melanie Reid, patient partner

Paul Winwood, UNBC

Robert McMaster, UBC/VCHRI

Robert Olson, BC Cancer/UNBC/UBC

Srinivas Murthy, BCCHR/UBC

Stephania Manusha, VCHRI

Tania Bubela, SFU

Wendy Hurlburt, Life Sciences BC

Our sincerest thank you to our advisory council members, colleagues at Michael Smith Health Research BC, partners, funders, participants of the vision consultations, patient partners and the BC clinical trials community. Together, with our dedicated Clinical Trials BC team, we are working to build and strengthen the clinical trials ecosystem in BC.

We look forward to continued partnerships in achieving common goals in the upcoming years. Clinical Trials BC welcomes you to share your ideas on how we can service the clinical trials community together.

ICYMI

Quarterly newsletters:

- Fall 2021
- Winter 2022
- Spring 2022
- Summer 2022
- Fall 2022
- Winter 2023
- Spring 2023

- Spring 2022: Health Canada updates & ICH news
- Summer 2022: Natural health products and homeopathic medicines
- Summer 2022: Natural Health Product Regulations (NHPR) amendment
- Fall 2022: Disaggregated data questionnaire for drug submissions

Regulatory updates:

- Fall 2021: Do I need documented training on Division 5?
- Fall 2021: Adopt & adapt
- Winter 2022: Single-patient studies & CONSERVE Guidelines
- Winter 2022: Health Canada Implementation of ICH E8(R1), Special Access Inspection Strategy, and Quality Risk Management
- Spring 2022: Clinical trials records
- Fall 2022: Health Canada Clinical Trial Risk Classification Guide (version 2) Sep 29, 2022
- Winter 2023: Direct access to source data and documents
- Winter 2023: Amendments and provisions to the Food and Drug Regulations and Medical Device Regulations



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