Michael Smith Health Research BC

Economic Impacts of Clinical Research in British Columbia

Over the past 10 years, advances and investments in BC's life sciences and biomanufacturing sector, and actions to grow clinical research and clinical trials, have increased. BC's interest in advancing this sector is not dissimilar to what is occurring in other provincial jurisdictions and in Canada. In this environment, Health Research BC felt it timely to advance an update of an economic impact report released in 2018 but expand the review to include clinical trials. This work is one step towards our continued focus on strengthening the clinical trials ecosystem and advancing BC's vision for clinical trials where economic investments are maximized for British Columbians.

Health Research BC again contracted MMK Consulting to conduct and produce the appended report. This internal report provides insights not only into economic investments in clinical research, but also into the challenges that exist in accessing complete data to inform such a report. Key takeaways for Health Research BC include:

- When adjusting for inflation, economic spending on clinical research remains flat despite an uptick in spending related to the COVID-19 pandemic
- Despite limited change in spending, BC's clinical research footprint has increased
- Federal funding flowing into provincial health research remains critical and consistent
- A data reporting system for efficiently pulling comprehensive economic data on clinical research and clinical trials activity at the provincial, regional and local levels is needed.

Any report on a sector's economic impact is subject to challenges and limitations like data availability and reliability. This report is no different. Data to inform this study within the definitions of clinical research and clinical trials (detailed in the report) are based on information provided by participating institutions and health authorities. Despite many organizations providing valuable contributions of available data from their research system(s) some constraints remain:

- All figures should be considered conservative as they do not include:
    - Studies undertaken by other public institutions not reported through the UBC-operated RISe database system
    - Health clinical or non-clinical health research conducted in the private sector including independent clinical trial sites and medical clinics
    - Any other clinical or non-clinical health research expenditures undertaken and not reflected in institution-provided information
- GDP impact is likely under-reported for the following reasons:
    - Multipliers for calculating impacts are not well established for clinical research and clinical trials activity. For example, a complete picture of employment is not available from commonly used data sources like National Occupational Classification codes, the North American Industry Classification System, or the Occupational and Skills Information System in Canada.
    - Investment data was provided by the institutions who participated. Depending on their ability to pull data, variations may occur.

Michael Smith Health Research BC

Increased support and recognition – both from the private and public sectors – is advancing clinical research and clinical trials in BC. The experience commissioning this report, and insights gleaned, shed light on the importance of understanding broader factors that impact the clinical trials ecosystem in BC. To place this report in that context, Health Research BC has commissioned a situational analysis of clinical trials in BC. Insights are expected to be shared in December 2024.

Economic Impacts of Clinical Research in British Columbia

Prepared for:

Michael Smith Health Research BC

Alison Orth
Portfolio Director, Research Programs
Michael Smith Health Research BC

Submitted by:

MMK Consulting Inc.

Stuart MacKay
Graeme Johnsen

September 29, 2024

Contents

Terms and Acronyms

BCCA, BC Cancer – BC Cancer Agency, BC Cancer Research Institute

BC Children's – BC Children's Research Institute

BCCDC – BC Centre for Disease Control

BCIT – BC Institute of Technology

BCMHSUS – BC Mental Health and Substance Abuse Services Institute

Clinical Research – (see definition page 7)

Clinical Trials – (see definitions page 7)

CTBC – Clinical Trials BC, a part of Michael Smith Health Research BC

CTMS – Clinical Trials Management System, a system established in late 2020 to provide a central source for tracking the nature, size and status of clinical trials being undertaken in BC by participating entities

Entities, public reporting entities – BC-based public reporting agencies that perform health research. Includes public institutions, public institutes, UBC Faculty of Medicine, and BC Regional Health Authorities

Health Research BC – Michael Smith Health Research BC, sponsor of this economic impact study

Institutes – BC public health research institutes. Includes VCHRI (Vancouver Coastal Health Research Institute), Providence Research, BC Cancer, BC Children's, BC Women's Health Research Institute, BCCDC, and BCMHSUS. Does not include UBC Faculty of Medicine, RHA's, private health research agencies.

Institution*s* – All healthcare organizations/agencies conducting health research in BC. Includes universities, institutes, Regional Health Authorities, Provincial Health Services Authority, and private firms performing health research on a contracted or internally funded basis

Providence Research – Providence Health Care Research Institute

PHSA – Provincial Health Services Authority. PHSA institutes include BC Cancer, BC Children's, Women's, BCCDC and BCMHSUS.

RHA*'s* – The four Regional Health Authorities based outside Vancouver area (Fraser, Island, Interior, North)

RISe – The Research Information System operated by the UBC Office of Research Services (ORS), which tracks annual activity and expenditure levels on UBC-affiliated funded research projects

SFU – Simon Fraser University

UBC *FoM* – University of BC Faculty of Medicine

VCHRI – Vancouver Coastal Health Research Institute

BC Women's – BC Women's Health Research Institute

Executive Summary

The advances in medical knowledge through clinical research (including clinical trials), and the tremendous gains in health care that result, are widely acknowledged throughout the world. However, the economic impacts and benefits of clinical research, for the jurisdictions that perform the research, are less well understood.

This report assesses the economic impacts of clinical research on the British Columbia (BC) economy. It also discusses a number of issues relating to the current state and outlook for clinical research in BC and offers recommendations for achieving further economic growth and development.

This report has been developed by MMK Consulting (MMK) on behalf of Clinical Trials BC (CTBC), part of Michael Smith Health Research BC (Health Research BC). It is an update and expansion of a previous 2013 MMK report. Unless otherwise indicated, all opinions are those of MMK.

For this study, clinical research is defined as "the testing and evaluation of interventions and diagnostics tests involving humans, in clinical, community and academic settings." Clinical research is a type of health research, which includes both clinical and non-clinical research (e.g. lab-based "discovery" research, desk studies). Clinical trials are a type of clinical research and include Phase I-IV and unclassified clinical trials, as registered on the *ClinicalTrials.gov* website.

Key findings

This report's key findings include:

- **Clinical research activity levels in British Columbia** – As detailed in Exhibit ES-1, overleaf, BC's public reporting entities accounted for an estimated $204 million in direct clinical research activity in 2022-23, including $64 million in clinical trials activity. Also including non-clinical health research (lab research, desk studies, etc.), total BC direct health research activity is estimated as $489 million. These estimates are conservative in that they do not capture all of the clinical research activities taking place in BC, because of measurement and reporting challenges.

- **Economic impacts of clinical research –** The $204 million in direct clinical research activity generates:
  - Total GDP (direct, indirect, induced) impacts of $245 million (BC only) to $269 million (Canada)
  - Total household income of $155 million (BC only) to $169 million (Canada)
  - Employment impacts of 1,792 (BC only) to 1,984 (Canada)
  - Average income levels within the sector of $105,000.

- **Long-run and short-run trends** – Since MMK Consulting's previous 2013 report, long-term trends in BC health research activity levels have been relatively flat in "real" terms (net of cost escalation). At the same time, there have been significant recent year increases in expenditures at some health research institutes. These increases are attributable to a number of sources – including:
  - Increased appreciation of the importance of health research, as a result of the COVID pandemic
  - Increased federal and provincial interest in and funding of health research initiatives
  - The expanding role of private and public/private health research funding agencies, including Health Research BC.

Exhibit ES-1 – Health Research Activities by Major BC Public Reporting Entities (2022-23, $million)

	All Health Research (Clinical plus Non-clinical)	Clinical Research (including Clinical Trials)	Clinical Trials Only (Phase I to IV, or not indicated)
Vancouver Coastal Health Research Institute	**$124.4**	**$43.5**	**$19.2**
Providence Research	**$71.7**	**$42.4**	**$11.9**
PHSA Institutes			
BC Cancer Research Institute	$120.4	$42.1	$17.1
BC Children's Research Institute	$77.5	$38.7	$12.0
Women's Health Research Institute	$8.2	$3.6	$2.4
BC Centre for Disease Control	$7.0	$3.5	$0.5
BC Mental Health & Substance Use Services	$1.2	$0.4	$0.0
Sub-total PHSA	**$214.3**	**$88.4**	**$32.0**
UBC Faculty of Medicine	**$68.9**	**$24.0**	**$0.0**
Regional Health Authorities			
Fraser	$2.9		
Interior	$3.1		
Island	$3.1		
North	$0.7		
Sub-total RHA's	**$9.7**	**$5.2**	**$1.1**
Total - VCHRI, Providence, PHSA, UBC FoM, RHA's	**$488.9**	**$203.5**	**$64.2**
Percentage of all health research	100%	42%	13%
Health research at other BC public reporting entities	additional	additional	additional
Privately-performed healthcare research	additional	additional	additional
Unfunded additional health research activity	additional	additional	additional

- **Leverage of federal and provincial funding support –** For six sizable BC health research institutes, Canadian federal and provincial funding accounts for slightly less than half of total health research funding. More than half of health research funding comes from other sources, including private industry, non-government organizations, and US/international sources.

- **Impacts of clinical research on provincial healthcare costs –** There are many anecdotal examples of clinical research studies helping to reduce the provincial cost burden in providing patient care. Estimating the size of these savings to the BC health care system is difficult because of the way in which financial accounts are structured. Addressing this challenge would require a significant research program, likely involving a case study approach. Given that this topic is of interest to many jurisdictions, there may be an opportunity for a cross-jurisdictional study.

- **Impacts of clinical research on patient care and outcomes –** With regard to levels of care, clinical research studies by their nature involve higher levels of care and attention for participating patients than for non-participating patients. For life-threatening illnesses, they may also provide a cause for hope that would not otherwise exist. With regard to patient outcomes, the academic literature clearly indicates that hospitals performing clinical trials have better patient outcomes than ones that do not.

- **Growth strategies in other jurisdictions –** Ontario, Quebec and Alberta all have much greater levels of clinical research and clinical trials activity than BC. Their growth strategies feature:

- Investment in clinical trials infrastructure facilities, plus clinical trials delivery capabilities.
- Pursuit of clinical research and clinical trials sponsors/customers that are based not only in their home jurisdictions, but also in other Canadian provinces, the US, and overseas.
- Establishing industry-wide associations (government, research institutes, hospitals, private industry) to achieve a more a research-friendly jurisdictional environment.
- In particular, streamlining the clinical trials approval and start-up process.

These strategies have helped these three other Canadian jurisdictions to achieve much higher clinical trials research levels than BC. In less-populous Alberta, activity levels are 61% higher than BC for Phase 1 trials; 49% higher for Phase II trials; and 20% higher for Phase III trials.

- **Measurement and reporting completeness –** This report's findings are based on combining information from multiple sources – including the UBC RISe system, the financial records of BC health research entities, and the financial records of BC provincial and regional health authorities. Despite the establishment of a BC Clinical Trials Management System (CTMS) in 2020, there is no current source of information that records all of the clinical research activity taking place in BC. Some BC clinical research is not being fully captured at present, including privately conducted clinical studies, plus other non-UBC-affiliated studies. The issue is expected to become more significant with the increase in SFU-affiliated clinical research upon establishment of the new SFU medical school.

- **Opportunities –** The current outlook for clinical research in BC is brighter in 2024 than at any time in the past 15 years. There is strong policy support for life sciences and biomanufacturing at both federal and provincial levels. A number of major public investments have been announced over the past year to build BC's bio-manufacturing capabilities, supporting the growth of BC-based "anchor companies" in the life sciences sector. These investments will drive an increase in BC-based clinical research.

  The outlook for clinical trials in BC is particularly positive. The BC clinical trials community has developed (through Health Research BC) *A Vision for Clinical Trials in BC*. The Province of BC's *Life Sciences and Biomanufacturing Strategy* has established five pillars, one of which is "Expanding our clinical trials capacity." A new Phase I (first-in-human) clinical trials facility has received provincial funding and is scheduled to commence operations by early 2025. Several other potential new or expanded clinical trials facilities are in various stages of planning.

- **Challenges and issues** – Key clinical research challenges and issues for BC include:
  - Federal (Canadian Institutes for Health Research – CIHR) research awards and grant levels, which are only a fraction (even on a per-capita basis) with those of the comparable US funding agency.
  - Structural and organizational barriers to integrating hospital-based patient health care and clinical research.
  - Achieving positive working relationships among government, academia, and industry. One key issue facing BC is whether and how much to follow other jurisdictions' leads in developing industry partnerships to streamline clinical trials approval and administration processes.

Recommendations

1. Implement a strategy for attracting more clinical trials and research activity to BC

BC significantly lags the leading Canadian provinces in terms of clinical trials and research activity levels, despite BC's strong international reputation for early-stage discovery and pre-clinical research.

Pillar Four of BC's 2023 *Life Sciences and Biomanufacturing Strategy* calls for "Expanding our clinical trials capacity, through initiatives such as supporting the establishment of Phase I (first-in-human) clinical trials

facilities in BC …". In 2024, BC has already committed significant funding to support several capacity-related projects throughout the province, including a Phase I clinical trials facility. Many other capacity-related clinical trials facility and program investments are also in development.

To achieve the benefits of this added capacity, BC will need to also develop and implement a complementary strategy to attract new clinical trials and research activity to the province. This strategy will need to target industry and other sponsors that are based both within and outside the province.

The development and implementation of an effective BC competitive strategy will need to learn from, and in some cases emulate, the strategies of Clinical Trials Ontario, Clinical Trials Quebec, Clinical Trials Alberta, and agencies in other jurisdictions.

Developing an effective clinical trials attraction strategy for BC will also require the active involvement of the entire BC health research and life sciences sector – academic entities, health research institutions, private industry, regional health authorities, and others.

2. Develop a central source of information for reporting BC clinical trials and research activity

The UBC RISe system has traditionally been the best central source of financial information about BC health research activity levels. However, this system is aging, and does not record all of the clinical research activity being undertaken in BC. BC's Clinical Trials Management System (CTMS), introduced in 2020, has the potential to become the primary central source of information regarding BC clinical research and clinical trial activities, with the support of the BC health research community.

3. Other recommendations

In addition to these two key strategic initiatives, other study recommendations include:

- **Undertake an informal survey of private clinical research activity in BC.** Health Research BC, through its Clinical Trials BC's contacts with a number of BC private clinical research firms, could conduct an informal survey of private clinical research activities taking place in the province. This exercise would reduce the current information gap regarding private clinical research in BC.

- **Communicate the importance of clinical research to BC and Canada** – disseminating the findings of this report with regard to: clinical trials and research activity levels; economic impacts of these activities; leverage of federal and provincial funding; BC's position in regard to leading Canadian provinces; and the opportunity to build on clinical trials capacity investments to increase activity levels.

- **Build on federal/provincial investments in life sciences/clinical trials activity levels and capacity** – Including the UBC-led $575 biomanufacturing initiative, announced in 2023; the $300 million federal-provincial support for AbCellera, announced in 2023; the provincial funding of a new Phase I clinical trial facility at Mount St. Joseph Hospital in Vancouver, also announced in 2023; and the proposed new clinical trials facilities at several other BC locations, currently in development in 2024.

- **Advocate for increased federal/provincial support for clinical and other healthcare research** – continuing to provide education about the much lower per-capita federal/provincial support for healthcare research in Canada, relative to the US.

- **Reduce the institutional barriers to integration of clinical research with patient care** – working with BC's academic entities, health research institutions, and provincial health authorities to achieve greater coordination of clinical research and patient treatment.

1. Introduction

Background, Objectives, and Scope

The advances in medical knowledge through clinical research (including clinical trials), and the tremendous gains in health care that result, are widely acknowledged throughout the world. However, the economic impacts and benefits of clinical research, for the jurisdictions that perform the research, are less well understood.

The economic impacts of clinical research to British Columbia were last examined in 2012-13, in a report by MMK Consulting (MMK) to the BC Clinical Trials Research Infrastructure Network (BCCRIN), a predecessor to Clinical Trials BC (a part of Health Research BC [1]). The objectives and scope of the 2013 report included:

- Clinical Research Activity Levels – estimating the levels of clinical research activities in BC being undertaken by BC's public healthcare research entities.
- Economic Impacts of Clinical Research - in terms of employment, GDP, and other economic indicators – considering direct, indirect (supplier), and induced (workforce re-spending) benefits.
- Government Fiscal Impacts and Leverage - assessing the various governmental and non-governmental sources of clinical research funding, and the implications for government in terms of fiscal impacts and leverage of government funding.
- Other Benefits – presenting an overview of the healthcare and societal benefits of clinical research.

The scope of this 2023-24 update study has been expanded, to also include:

- Incorporating the provincial vision for clinical trials into the report.
- Distinguishing between "clinical research" and "clinical trials" activity, reporting on each category.
- Assessing the current quality and availability of clinical trials data sources, relative to needs.
- Assessing the status of centralized reporting of clinical research activities in BC.
- Performing direct research with BC's public and industry-based representatives.
- Gathering information regarding the different approaches to clinical research and clinical trials development being undertaken in comparable jurisdictions, and the implications for BC.
- Identifying studies regarding the implications of clinical research and clinical trials for the cost burden on the public healthcare system, and well as the benefits in terms of patient care levels and outcomes.
- Developing a report for use at both the provincial and national level.

[1] Health Research BC is British Columbia's health research agency. Health Research BC is *"… working towards a future where BC is recognized worldwide for it vibrant, coherent, inclusive, and globally competitive health research system, which improves the health of British Columbians, the health system, and the economy."* As a part of Health Research BC, Clinical Trials BC (CTBC) is responsible for facilitating and furthering the growth of clinical trials activities in BC.

Defining Health Research, Clinical Research, and Clinical Trials

Definitions of clinical research and related terms vary by source. This study is based primarily on the definitions used by the World Health Organization (WHO). [1]

In this study, **clinical research** is defined as "the testing and evaluation of interventions and diagnostics tests involving humans, in clinical, community and academic settings."

Clinical research is a type (subset) of total **health research**, which includes both clinical and non-clinical health research. Non-clinical health research does not directly involve working with humans in a clinical community, or academic setting. Examples of non-clinical research include laboratory research not involving human tissue, animal testing, externally administered surveys, and desk research using published and/or unpublished sources. [2]

Clinical trials are a type (subset) of clinical research. Clinical trials test the safety and effectiveness of medical interventions – including medications, procedures, and tools – in living people. Drug-related clinical trials are typically undertaken in four phases:

- **Phase I (first-in-human)** – Small-scale initial tests that focus on the safety of a drug rather than its potential efficacy. For non-cancer-related drugs, Phase I clinical trials are typically administered to healthy humans in a closely controlled and monitored environment, with close proximity to emergency treatment facilities. For cancer-related drugs, where effective alternative treatments are unavailable, Phase I clinical trials may involve existing cancer patients.

- **Phase II** – Limited-scale clinical trials that gather preliminary data regarding the effectiveness of a drug or treatment on people that have a certain disease or condition. Testing may include the use of placebos and alternate drugs, while also evaluating safety issues including short-term adverse effects.

- **Phase III** – Larger-scale clinical trials that gather more information on a drug's effectiveness and safety in different doses, on different ethnic groups, and in combination with other drugs.

- **Phase IV** – Clinical trials that occur after a drug has received US FDA (Food and Drug Administration) and/or Health Canada approval, to gather additional information about the drug's safety, efficacy, and optimal use.

Clinical trials that do not involve new drugs and medications, such as trials of medical devices or behavioural interventions, may be undertaken without reference to the four-phased approach.

Federal/provincial Biomanufacturing and Life Sciences Strategies

The governments of Canada and BC have closely aligned strategies for developing the Canadian and BC biomanufacturing and life sciences sector.

[1] Other sources include the ClinicalTrials.gov website, *Glossary of Common Site Terms*, and thehopkinsmedecine.org website, *Clinical Research: What is it?*

[2] There are inevitably some gray areas in distinguishing between clinical and non-clinical research – for example in classifying research studies that involve secondary processing of data gathered through clinical trials and other clinical research. This study relies on the assessments of the participating entities in distinguishing clinical from non-clinical research. (Details in Appendix C.)

Canada's *Biomanufacturing and Life Sciences Strategy*

At the federal level, Canada's *Biomanufacturing and Life Sciences Strategy* has two primary objectives – (1) growing a strong, competitive domestic life sciences sector with cutting edge biomanufacturing capabilities, and (2) ensuring preparedness for pandemics or other health emergencies. The federal strategy has five pillars:

- **Collaborate** with stakeholders in building Canada's biomanufacturing and life sciences capacity to produce vaccines, therapeutic, and other life-saving medicines.
- **Lay the foundation** by strengthening research systems and talent pipelines, through investing in post-secondary institutions and affiliated research hospitals.
- **Grow the business** in terms of Canada's domestic readiness and self-reliance in responding to future health emergencies and in contributing to the development of the next generation of medicines.
- **Building public capacity** by supporting biomanufacturing construction projects across Canada.
- **Enable** health innovation, from discovery to application, to make Canada a more attractive destination for biomanufacturing and life sciences ecosystem companies.

BC's *Life Sciences and Biomanufacturing Strategy*

In April 2023, the BC government released its *"Life Sciences and Biomanufacturing Strategy".* It calls for *"… a bigger vision; to invest in the people and infrastructure needed to better capitalize on the industry value chain, from discovery through to clinical trials and manufacturing."* The province's vision has five key pillars:

- **Pillar 1 – Improving access to talent**, through the provision of education and training, to build a "biomanufacturing talent pipeline" for industry.
- **Pillar 2 – Growing innovative local companies**, including increasing the availability of wet lab space and small-scale biomanufacturing facilities.
- **Pillar 3 – Increasing biomanufacturing capacity and attracting anchor companies,** through initiatives such as streamlining access to light industrial zoned land and encouraging investment/co-investment in clean biomanufacturing operations.
- **Pillar 4 – Expanding our clinical trials capacity,** through initiatives such as supporting the establishment of Phase 1 (first-in-human) clinical trials facilities in BC, as well as providing funding for cancer research and clinical trials to be undertaken across all cancer centres in the province.
- **Pillar 5 – Leveraging and commercializing research capacity,** including encouraging collaborations between industry and academia, and supporting BC companies in commercializing their products.

The BC strategy has been developed over a multi-year period, following extensive consultation with the BC Life Sciences and Heath Research communities. Further details of Pillar 4 are contained in Appendix A, and the full 24-page strategy is available on the BC Government website.

Federal and provincial strategic initiatives

The federal and provincial strategies are already being implemented through initiatives such as:

- The establishment of Canada's *Immuno-Engineering and Biomanufacturing Hub* (CIEBH), announced in March 2023. The CIEBH initiative is being led by UBC and will involve more than 50 government, academic & research organizations, health authorities, non-profits, and industry partners. CIEBH will coordinate research and infrastructure project submissions and awards, towards a share of $570 million in federal funding.

- The $300 million ($225 million federal, $75 million provincial) in financial support being provided to BC-based AbCellera. This initiative, announced in May 2023, will be applied toward the establishment and operation of a $701 million research, development and biomanufacturing facility in Vancouver.

- Several other recent and pending federal/provincial initiatives in support of BC clinical research. For example, a new BC Phase I (first-in-human) clinical trials facility was approved for provincial funding in 2023 and is being implemented in 2024. At least four other potential new or expanded BC clinical trials units and facilities are also in various stages of planning and development.

Health Research BC's *A Vision for Clinical Trials in BC*

Health Research BC has led the BC health research community's development of *A Vision for Clinical Trials in British Columbia.* This vision, developed in 2022 and released in February 2023, envisages *"A robust, innovative, coordinated, and person-centred clinical trials ecosystem improving health and economic outcomes for British Columbians."* Features of the vision include:

- *"Build a **universally embraced research-positive environment** that values, supports and actively promotes health research, including clinical trials."*
- *Value clinical trials as an approach to responding to questions in a learning health system context when embedded into **the clinical care continuum** in our healthcare system.*
- *Build **provincial and diverse governance structures** for clinical trials to support the successful implementation of the vision for clinical trials in British Columbia.*
- *Demonstrate and capitalize on our **comparative advantages** for clinical trials, including our population (diversity and location), data assets, research capacity and research facilities, so British Columbia is seen as a prime location for clinical trials.*
- *Maximize the **economic contribution** of clinical trials and their ability to create high-value employment, investment and growth for British Columbia.*
- *Support **collaboration** among academia, healthcare, government, patients, clinical trial organizations, funders and life science companies at the provincial, national and international levels.*
- *Advance **person-centred approaches and designs** to create a clinical trial experience that is culturally safe, trauma-informed, inclusive, accessible, and available to all who want to participate.*
- *Support the **full scope of activities within the clinical trial lifecycle** from discovery to first-in-human trials to regulatory approval. Value and enable BC-based investigator-led, Indigenous-led and institutionally sponsored clinical trials.*
- *Fund and support **sustainable clinical trial infrastructure**. Ensure that clinical trial research has timely access to data, biobanks, technology, clinical services, digital tools and resources and is enabled by leading-edge technology, methodology, dedicated spaces and specialized research facilities.*
- *Develop and support a **skilled and viable clinical trial workforce** across the province, including urban, rural, and remote settings.*
- *Ensure that clinical trials in British Columbia are **quality-focused and fully compliant** with national regulations and ethical guidance.*
- *Enable research **ethics reviews to be meaningful, streamlined, timely, effective**, and supported by transparent performance metrics.*
- *Create and sustain **agile and efficient business services** and operations to support clinical trials (contract negotiation, privacy and security reviews, finance, and legal reviews). Develop accountable and transparent performance metrics focussing on fast, efficient approvals and service.*

The two-page Vision is contained in Appendix B, and further details are provided on the Health Research BC website.

2. Size of BC Clinical Research Activities

BC Clinical Research and Clinical Trials Expenditure Levels

The estimated value of BC health research, clinical research, and clinical trials activities by BC's major public reporting entities is illustrated in Exhibit 2a. In summary:

- **Total Health Research** – BC's major public health research institutes and hospitals accounted for approximately **$489 million** in spending on funded health research in 2022-23.
- **Clinical Research** – Of this total, approximately **$204 million** (42%) is estimated to involve clinical research (directly involving humans), with the balance consisting of non-clinical research (laboratory research, desk research, animal studies, etc.).
- **Clinical Trials** – Clinical trials (Phase I-IV, or not indicated), a subset of clinical research, is estimated to account for approximately **$64 million** in spending during 2022-23.

Further details and sources are provided in Appendix C.

Exhibit 2a – Health Research Expenditures by Major BC Public Reporting Entities (2022-23, $million)

	All Health Research (Clinical plus Non-clinical)	Clinical Research (including Clinical Trials)	Clinical Trials Only (Phase I to IV, or not indicated)
Vancouver Coastal Health Research Institute	**$124.4**	**$43.5**	**$19.2**
Providence Research	**$71.7**	**$42.4**	**$11.9**
PHSA Institutes			
BC Cancer Research Institute	$120.4	$42.1	$17.1
BC Children's Research Institute	$77.5	$38.7	$12.0
Women's Health Research Institute	$8.2	$3.6	$2.4
BC Centre for Disease Control	$7.0	$3.5	$0.5
BC Mental Health & Substance Use Services	$1.2	$0.4	$0.0
Sub-total PHSA	**$214.3**	**$88.4**	**$32.0**
UBC Faculty of Medicine	**$68.9**	**$24.0**	**$0.0**
Regional Health Authorities			
Fraser	$2.9		
Interior	$3.1		
Island	$3.1		
North	$0.7		
Sub-total RHA's	**$9.7**	**$5.2**	**$1.1**
Total - VCHRI, Providence, PHSA, UBC FoM, RHA's	**$488.9**	**$203.5**	**$64.2**
Percentage of all health research	100%	42%	13%
Health research at other BC public reporting entities	additional	additional	additional
Privately-performed healthcare research	additional	additional	additional
Unfunded additional health research activity	additional	additional	additional

Trends in research activity levels

Longer-run BC health research funding trends

At the time of MMK's previous 2013 report, the levels of health research activity in BC had declined during the early 2010's, in the wake of the 2008-09 recession.

Over the past decade, research awards and other revenues at BC health research institutes have increased in nominal dollar terms. As illustrated in Exhibit 2b, for the eight BC research institutes for which comparative data are available, the nominal value of research awards increased by approximately 34% between 2011-12 and 2022-23.

Cost escalation trends for health and other scientific research have also been significant during that time. After allowing for costs escalation trends in BC professional/scientific/technical wage levels, the increase in research awards and activities has been generally flat in real terms (net of cost escalation), even as BC's population has grown.

These long-term trends are reflected in the literature regarding Canadian health research funding trends, which document the increasing competitiveness for scarce research funding awards over the past decade. (See Chapter 4 for further discussion.)

Exhibit 2b – Longer-run Research Funding Trends at Eight BC Public Reporting Entities ($million)

	2011-12	2022-23	11-Year Change	
			Nominal	"Real"*
Vancouver Coastal Health Research Institute (VCHRI)	$98.7	$109.6	11%	-18%
Providence Research	$35.6	$59.1	66%	23%
PHSA Institutes				
BC Cancer	$57.3	$89.4	56%	16%
BC Children's (formerly CFRI)	$55.8	$66.8	20%	-11%
BC Centre for Disease Control	)	$6.0	)	
BC Women's	) $10.5	$9.2	) 56%	16%
BC Mental Health & Substance Use Services	)	$1.2	)	
Subtotal - PHSA	$123.6	$172.6	40%	3%
UBC Faculty of Medicine	$42.9	$61.1	42%	5%
Eight-institution total - VCHRI, Providence, PHSA	$300.8	$402.4	34%	-1%

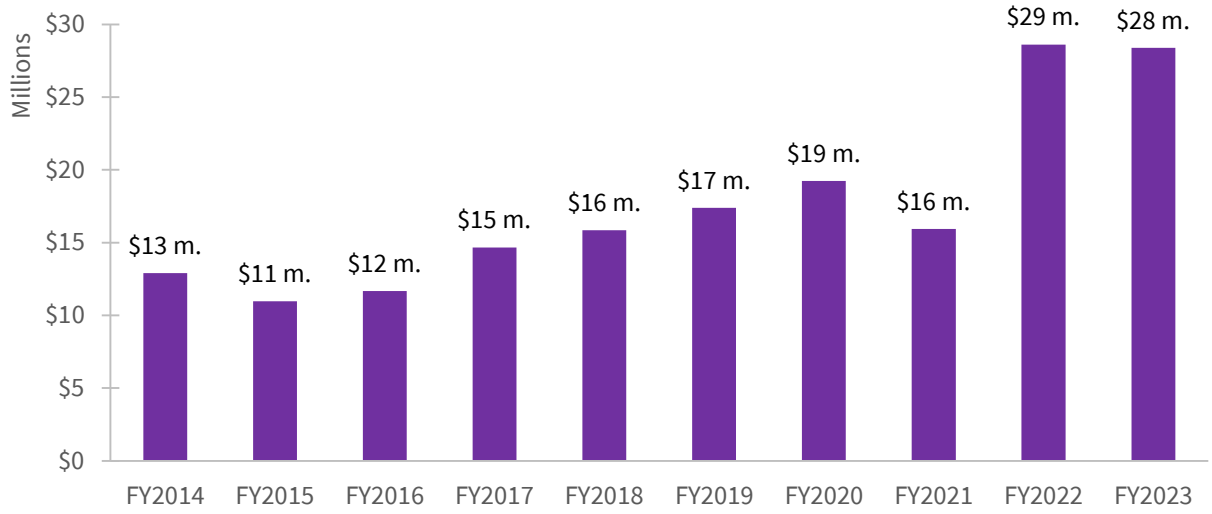
* Allowing for 11-year increase in professional/scentific/technical wage levels (per STATCAN) of approximately 35%

Note: To increase data comparability between 2011-12 and 2023-23, analysis excludes overheads allowances and RHA data.

Recent-year clinical trials activity trends at PHSA institutes

While the longer- term trends in funded BC health research activities have been generally flat in real terms, there have been some recent year increases in grant funding at some health research entities. As illustrated in Exhibit 2c, for five PHSA institutes, the operating grants for clinical trials increased to $28-29 million in 2021-22 and 2022-23, after having ranged between $13 million and $19 million over the previous eight years.

Exhibit 2c – Operating Grants for Clinical Trials at Five PHSA Institutes



CIHR research award funding trends

The Canadian Institutes of Health Research (CIHR) is Canada's largest source of public funding for clinical and non-clinical health research projects. CIHR grants and awards were less than $1.1 billion in 2018-19 but increased with the onset of COVID to more than $1.4 billion in 2020-21. However, they have since decreased to $1.32 billion in 2021-22, and to $1.26 billion in 2022-23 = approximately $32 per capita. Four-year CIHR funding trends, after allowing for cost escalation, have been essentially flat. [1] Competition for CIHR funding has also become more intense, with the success rate on CIHR applications declining from 31% in 2005 to approximately 15% in 2023 [2]

CIHR health research funding levels, relative to other jurisdictions

While inter-country comparisons are complicated by differences in economies, healthcare systems and approaches to funding of healthcare systems, some high-level comparisons can be made.

In the United States, the US National Institutes of Health (NIH) has an annual budget of approximately C$60 billion – approximately $176 per capita, about five to six times those of CIHR.[3] This nearly order-of-magnitude difference between per-capita US NIH and Canadian CIHR funding levels is consistent with the Canada-US funding relationships reported in the previous 2013 MMK report.

In the United Kingdom, the three largest public health research funding agencies provided funding equivalent to C$3.8 billion in 2022 – approximately $56 per capita. [4]

[1] CIHR Annual Report, 2022-23, p. 14-15.

[2] Stephen L. Archer, "Two decades n stagnant funding have rendered Canada uncompetitive in biomedical research".

[3] Ibid.

[4] UK Clinical Research Collaboration, *UK Health Research Analysis 2022*, Table A2-p3, 2022 Funding Organisation. Total of C$3.8 million represents combined results for three major UK public funding organizations – Department of Health and Social Care (including NIHR), Medical Research Council, and Cancer Research UK. Conversion based on 1.00 Canadian dollar equals 0.58 UK pound sterling.

Challenges in Measuring Clinical Research Economic Activities

The findings of this report are based on analyzing available BC health research data, compiled from multiple sources. They are subject to the following qualification with regard to (1) gaps in the completeness of clinical research and clinical trials information that is currently being recorded, and (2) the limitations of current sources of information about BC clinical research and clinical trials activity.

Gaps in the completeness of information recorded

Current gaps in the completeness of information being recorded for BC clinical research and clinical trials activity include:

- **Unbudgeted early-stage clinical research.** Many clinical research projects are not initially funded through a specific research grant or award. One of the common paths to securing clinical research project funding is to first undertake a small unfunded study as a pilot or proof-of-concept and use the initial results as the basis for securing for grant/award funding for the next phase.

  This study is based primarily on the budgeted revenues and expenditures for BC's public research entities s that undertake significant clinical and non-clinical research. To the extent that unfunded initial clinical research projects are undertaken by investigators whose costs are reflected in these entities' budgets, the costs of unbudgeted early-stage research may be captured in the analysis. However, to the extent that these clinical research activities are being funded through other budget areas (for example BC hospitals' operating budgets, university faculty/staff salaries, student bursaries, etc.), the economic value of these clinical research activities will not be captured.

- **Private clinical research.** In addition to the clinical research being performed through public entities, Health Research BC is aware of significant clinical research being performed by private clinical research organizations and firms. Since this information is privately held, information about its size is not available through public sources. Health Research BC, through its Clinical Trials BC team, is well positioned to gather information about the nature and size of private clinical research activity in BC.

- **Clinical research by non-UBC-affiliated public research entities.** As discussed further in the next section, this analysis relies on multiple sources – in particular, the RISe research information system that is operated by the UBC Office of Research Services. With UBC currently operating the only accredited medical school in the province, and with clinical research grants typically requiring projects to be undertaken in association with an accredited medical school, the RISe system is believed to capture the vast majority of clinical and non-clinical research undertaken in the province. However, Health Research of BC is also aware of some clinical research activities being undertaken by other BC reporting entities that are not captured through RISe. The amounts of publicly funded clinical research in BC not recorded by RISe is expected to increase when the new SFU school of medicine is established.

These areas of missing clinical research information for BC are believed to be relatively small in comparison to the activity levels that are gathered and presented in this report. At the same time, the estimates of total levels of clinical research and clinical trials activity in BC, and their resulting economic impacts, should be considered somewhat conservative in view of the missing information.

Limitations of current clinical research information sources

Estimating BC's clinical research and clinical trials activity levels is limited by the differences among sources in terms of definitions, measurement methods, and scope of data recorded and reported.

The main information sources underlying this report include:

- **Clinical Trials.gov** – This major US-based website (details in Appendix D) provides a comprehensive registry of clinical trials being performed in the US and Canada. However, it does not contain the expenditure-related research information (annual expenditures, by jurisdiction, for individual projects) that is required to assess economic impacts.

- **Research Information Systems (RISe)** – The University of BC's RISe system is *"an online research administration tool … to manage and track applications [for research funding] online through to approval, certification and awarding of funds."* Most of the significant clinical research projects being undertaken by BC involve Principal Investigators that are affiliated with UBC, and these activities are captured through the RISe system. BC's public health research institutes all provide information to RISe and have access to the data that is relevant to their institute.

  RISe is the most comprehensive source of BC healthcare research award and expenditure information in the province and is believed to capture most of the clinical research being undertaken. However, it may not capture clinical research in BC that does not involve UBC in some respect (privately conducted research, other academic agencies such as UVic/SFU, and health authorities such as Fraser Health who do not use RISe). It also does not capture the non-recoverable overhead/admin expenditures undertaken by BC's Regional Health Authorities in supporting clinical research projects.

- **Financial accounting systems** – BC's health research institutes and health authorities all operate separate financial accounting systems, with variations in approach to accounting for their clinical-research-related activities and expenditures. These differences create technical challenges in interpreting and combining data from different sources.

- **Clinical Trials Management System (CTMS)** – CTMS has been established in BC, as of December 2020, with funding from Health Research BC and PHSA. CTMS contains detailed information about the progress and status of individual clinical trials (nature, size and duration, current status, etc.) that are being performed by BC health research entities. Most (but not all) BC health research institutions are participating in CTMS – for example, the BC Cancer Agency has fully adopted CTMS at all of its sites.

  With full sector participation, CTMS has the potential to provide a more complete picture of overall BC clinical trials activity, for use in future editions of this report.

There is no central source that tracks overall BC clinical research and clinical trials activity levels, on an ongoing basis. As a result, the findings of this economic impact report are not easily updatable.

3. Economic and Other Impacts

Economic Impacts of BC Clinical Research and Clinical Trials

The economic impacts of BC-based clinical research and clinical trials, as well as the broader category of BC health research (clinical and non-clinical), are illustrated in Exhibit 3a.

Exhibit 3a –Economic Impacts of BC Health Research, Clinical Research, and Clinical Trials (FY23, $m.)

	Within BC				Within Canada			
	Direct	Indirect	Induced	Total	Direct	Indirect	Induced	Total
BC Health Research								
Total clinical/non-clin. output ($m.)	$489				$489			
GDP @ basic prices ($m.)	$385	$61	$143	$589	$385	$82	$179	$646
Labour Income ($m.)	$278	$39	$56	$373	$278	$52	$75	$405
Employment	2,657	595	1,054	4,305	2,657	766	1,344	4,766
Average income ($000)	$105			$87	$105			$85
BC Clinical Research								
Total clinical/non-clin. output ($m.)	$204				$204			
GDP @ basic prices ($m.)	$160	$25	$59	$245	$160	$34	$75	$269
Labour Income ($m.)	$116	$16	$23	$155	$116	$22	$31	$169
Employment	1,106	247	439	1,792	1,106	319	559	1,984
Average income ($000)	$105			$87	$105			$85
BC Clinical Trials								
Total clinical/non-clin. output ($m.)	$64				$64			
GDP @ basic prices ($m.)	$51	$8	$19	$77	$51	$11	$24	$85
Labour Income ($m.)	$37	$5	$7	$49	$37	$7	$10	$53
Employment	349	78	138	565	349	101	176	626
Average income ($000)	$105			$87	$105			$85

Source: Statistics Canada, Multipliers for scentific research and development serivces [BS541700]

Economic Impacts of BC Clinical Research

Based on direct expenditures of $210 million, and also including the indirect (supplier) impacts and the induced (workforce re-spending) impacts, the total economic impacts of BC clinical research are estimated as:

- **Gross Domestic Product [1] (GDP)** impacts of $245 million in BC – including $160 million in direct GDP impacts, $25 million in indirect impacts, and $59 million in induced impacts. Also considering the rest of Canada, the total GDP impacts of BC-based clinical research are estimated as $269 million in Canada.

- **Labour Income** impact of $155 million in BC – including $116 million in direct impacts, $16 million in indirect impacts, and $23 million in induced impacts. Also considering the rest of Canada, the total labour income impacts of BC-based clinical research are estimated as $169 million in Canada.

[1] Gross Domestic Product (GDP) is the measure of the value added to the economy as a result of the economic activity.

- **Employment** impacts of 1,792 jobs in BC – including 1,106 direct jobs, 247 indirect jobs, and 439 indirect jobs. Also considering the rest of Canada, the total employment impacts of BC-based clinical research are estimated as 1,984 jobs in Canada [1]

Exhibit 3a also illustrates the well-paid nature of scientific research employment in Canada, with average income levels of approximately $105,000.

Economic Impacts of BC Clinical Trials

Exhibit 3a also provides economic impact estimates for BC's $64 million in measured clinical trials activity.

Within BC, the economic impacts of BC-based clinical trials are estimated as $77 million in value-added GDP, $49 million in labour income, and employment of 565.

For Canada as a whole, the estimated impacts of BC-based clinical trials are estimated as $85 million in GDP, $53 million in labour income, and employment of 626.

Economic Impacts of BC Health Research (clinical and non-clinical)

Exhibit 3a also provides economic impact estimates for the BC's $489 million in measured total health research (clinical and non-clinical) activity.

[1] Employment generation estimates for 2022-23 are not directly comparable to those from our 20211-12 report because of adjustments to the Statistics Canada economic impact model.

Leverage of Federal/Provincial Health Research Funding

Health research in BC is funded from many sources, and BC public entities that conduct health research classify their research awards in somewhat different ways This section assesses of sources of funding for six BC health research institutes, and the way in which these institutes leverage Canadian and BC government support to attract funding from domestic and international foundations, non-profits, and industry sources.[1]

PHSA

As illustrated in Exhibit 3b, the largest source of research award funding for PHSA's five health research institutes in 2022-23 came from domestic and international foundations and non-profits – accounting for approximately 41% of the value of research awards. Funding from industry sources accounted for 11%, while funding from international government sources (e.g., U.S. National Institutes of Health) accounted for 4%. Overall, approximately 57% of total PHSA research award funding in 2022-23 came from sources other than the Canadian federal and provincial governments.[2]

PHSA's research institutes are also a source of foreign exchange for Canada and BC, with total research awards from foreign sources of approximately $23 million in 2022-23, representing 12% of all research awards.

Most of the approximately 43% of overall funding from Canadian national and provincial sources originates from federal agencies such as CIHR, NSERC, SSHRC, Genome Canada, and others. British Columbia is also a significant funding contributor, both directly and indirectly, through provincial sources such as Health Research BC, Genome BC, and the University of BC's Faculty of Medicine.

Exhibit 3b - Leverage of Canada/BC Government Funding at Five PHSA Institutes (2022-23, $m.)

	Canadian Sources		Foreign Sources		Total		Canada/BC Govt.	
Major Canadian Funding Entity	$43.4	*23%*			$43.4	*23%*	$43.4	*23%*
Foundations & Non-Profits	$71.1	*37%*	$7.2	*4%*	$78.3	*41%*		
Government	$34.2	*18%*	$7.5	*4%*	$41.8	*22%*	$34.2	*18%*
Educational Institution	$4.9	*3%*	$0.3	*0.1%*	$5.2	*3%*	$4.9	*3%*
Industry	$13.5	*7%*	$8.0	*4%*	$21.5	*11%*		
	$167.1	*88%*	$23.0	*12%*	$190.1	*100%*	$82.5	*43%*

Source: PHSA. "Major Canadian Funding Entity" includes CIHR, NSERC, SSHRC, Genome Canada, provincial genome agencies, Health Research BC.

Figures are five-institute totals (Cancer, Children's, Women's, CDC, Mental Health).

Providence Research

Results for Providence Research are generally consistent with those for PHSA. As illustrated in Exhibit 3c, Providence Research's largest source of direct research funding is the Canadian federal government, and Providence Research also receives indirect cost of research funding. Federal sources account for approximately 44% of Providence's annual funding support.

[1] This assessment is with respect to overall institute operation, including both clinical and non-clinical research.

[2] The classification of research awards by sources is complicated by the nature of the funding entities, which themselves may have combinations of funding sources. For example, Health Research BC is classified as a major Canadian Funding entity by PHSA, so that the portion of its funding that comes from foundations is not included in the 56% estimate – tending to understate the amount of research award funding coming from non-government sources.

The Province of BC is also a significant funding source, both through research grants and through direct support for Providence Research from its affiliated health care provider. Provincial support for Providence Research is conservatively estimated as accounting for approximately 9% of Providence's annual budget. [1]

Combined, funding sources other than Canada/BC is conservatively estimated as accounting for more than 47% of Providence Research's annual budget.

Exhibit 3c - Leverage of Canada/BC Government Support at Providence Research, 2022-23 ($m.)

	Total all sources		Canada	BC	Canada/BC
External Research Revenue (direct grants/sponsorships)					
BC Government Agencies	$3.0	5%		$3.0	$3.0
Canadian Government Agencies	$26.5	40%	$26.5		$26.5
Other-Government Agencies	$3.4	5%			
Non-profit NGOs	$8.8	13%			
Industry	$7.7	12%			
Other revenue sources					
Federal Indirect Cost of Research (ICR) funding	$2.4	4%	$2.4		$2.4
Industry ICR funding	$1.4	2%			
Direct support from affiliated health care provider	$2.9	4%		$2.9	$2.9
Affiliated foundations	$8.2	13%			
Other sources	$1.1	2%			
	$65.5	100%	$28.9	$5.9	$34.9
	100%		44%	9%	53%

Assessment of Funding Leverage

For the six institutes combined, Canada/BC government sources accounted for approximately 46% of total funding in 2022/23 – with the remaining 54% of funding coming from Canadian foundations and non-profit organizations, Canadian industry, and US/offshore private and government sources.

Direct government research award funding is provided mainly through federal sources, while the enabling infrastructure, facilities and support services are provided mainly through provincial sources.

[1] The Provincial contributions to Providence Research's activities are likely understated, to the extent that the costs of UBC-paid scientist support and benefits are not recovered through direct grants and sponsorships.

Impacts on BC Healthcare System Costs

Among BC clinical research professionals, there is a strong consensus that clinical studies help to ease the province's healthcare cost burden. Anecdotal examples of healthcare system cost savings include:

- When a hospitalized patient is participating in a clinical trial, the costs of some tests that would be required in any case may be paid through the clinical trials budget, rather than through the hospital.
- Where the annual MRI (Magnetic Resonance Imaging) costs for Parkinson's patients may be paid for through a clinical trial budget, rather than through the BC healthcare system.
- Where the costs of providing a new drug for a clinical trial are paid by the clinical trials budget, in place of the costs of the alternate treatment that would otherwise be incurred by the healthcare system.
- Where nurses and other clinical research professionals are working directly with outpatients in the community, easing the provincial cost burden of providing community health services.

While anecdotal examples of cost impacts are numerous, the cost accounting systems of BC's public hospitals and labs/clinics are not designed to distinguish between expenditures on regular standard-of-care treatment, versus expenditures on clinical research projects. In addition, there is no mechanism for estimating costs not incurred – the avoided drug, testing, and other costs to the healthcare system because of the clinical study.

As a result, most of the evidence with regard to the net impacts of clinical trials on healthcare system costs has been developed on a case study basis:

- With regard to the avoided drug costs associated with clinical trials, a survey of 288 empirical articles on the costs of clinical trials found that 12% of the articles had identified some levels of cost savings for the healthcare system, mainly with respect to avoidance of some drug-related costs.[1] Another study of 101 cancer-related clinical trials at an Alberta clinic (Tom Baker Cancer Centre) found that 42% of studies provided some level of drug cost avoidance, with a median range of $1,377 to $23,751 per patient in avoided drug costs.[2]
- With regard to the net public health system costs of clinical trials, a comparison of 59 prostate cancer patients participating in various clinical trials, relative to 59 patients receiving standard-of-care treatment, found some differences in the types of services provided to and consumed by each group, but did not find statistically significant evidence of a net difference in overall costs in either direction. [3]

[1] See *Conducting clinical trials – costs, impacts, and the value of clinical trials networks: a scoping review*, Colene Bentley et.al., 2019.

[2] *Drug costs avoidance resulting from cancer clinical trials*, Correne Bredin, Misha Eliasziw, Rachel Syme, Journal of Contemporary Clinical Trials, 2010.09.004.

[3] *Incremental costs of prostate cancer trials: Are clinical trials really a burden on a public payer system?* Britney Jones, Rachel Syme, Misha Eliasziw, Bernhard J Eigl, Canadian Urology Association Journal, March-April 2013.

Impacts on Patient Care and Patient Outcomes

There is also a strong consensus within the BC clinical research and treatment community that patients participating in clinical studies receive a significantly higher level of care and attention than those that do not. Clinical trials can also give patients a sense of purpose, and in the case of potentially terminal illnesses can give a cause for hope that otherwise might not exist.

With regard to outcomes, the academic literature indicates that patients who are treated at more research-intensive healthcare facilities tend to have better outcomes than patients who are treated at less research-intensive facilities.[1] (Studies are inconclusive with regard to whether the outcomes are better for individual patients participating in clinical trials at a specific facility, relative to non-participating patients at the same facility.)

The implication for BC healthcare patients is that being treated at research-intensive BC hospitals is a win-win situation – both in terms of the quality of care and attention, and in terms of the likelihood of a positive patient health outcome.

[1] See for example *Better Outcomes for Patients Treated at Hospitals That Participate in Clinical Trials,* Majumdar et. al, 2008; and *The impact of the process of clinical research on health service outcomes*, Selby and Autier, 2011.

4. Expanding BC Clinical Research Activity Levels

This chapter discusses some of the key issues and opportunities in expanding BC clinical research and clinical trials activity levels.

Growth Strategies of Other Jurisdictions

As also noted in our previous 2013 report, health research is considered a highly desirable economic sector by governments throughout the world. Many national, state, and provincial governments provide generous support programs to encourage the growth of healthcare research centres within their jurisdictions, and to attract both academic and industry-sponsored clinical research and clinical trials.

During the early 2010's, clinical research and clinical trials activity levels were declining in BC and in other Canadian Provinces. [1] Recognizing the importance of clinical research and clinical trials activity to their healthcare ecosystems, several Canadian provinces – notably Ontario, Quebec, and Alberta – have developed and implemented significant programs to foster the growth of clinical research and clinical trials within their jurisdictions. [2]

Ontario

Clinical research and clinical trials activity levels are much higher in Ontario than in BC. Clinical Trials Ontario (CTO) estimates that Ontario has a total of 4,800+ active clinical trials, more than any other province. [3] CTO estimates that Ontario's clinical trials participation rate, on a per-capita basis, is more than 2.5 time the US average. Ontario also has much higher levels of industry-sponsored clinical trial sponsorship than BC, reporting more than 2,400 industry sponsored clinical trials in Ontario with an R&D investment of $466 million. [4]

Clinical Trials Ontario

Clinical Trials Ontario (CTO) is a non-profit organization that was established in 2012 in response to the decline in clinical trials activity in Ontario. CTO's formation was led by the Government of Ontario, along with hospitals, industry, research ethics boards, and others.

CTO is heavily focused on the attraction of clinical trials to the province. CTO has *"… a goal of making trials more efficient, effective, and accessible, and also promoting Ontario as a leading location to conduct clinical trials. CTO is an essential pillar in the clinical trial ecosystem, helping to fuel Ontario's thriving life sciences sector. We are dedicated to strengthening, promoting and capitalizing on Ontario's competitive advantages for conducting high-quality clinical trials."*

[1] See for example MMK's 2013 report on the economic impact of clinical research in BC

[2] See for example the Clinical Trials Ontario website ("About Clinical Trials Ontario").

[3] A December 2023 scan of the ClinicalTrials.gov website identified 4,115 clinical research studies (clinical trials plus observational studies) with an Ontario component, compared with 2,526 in Quebec and 1,352 in BC.

[4] Source: Clinical Trials Ontario, 22/23 Annual Report.

CTO's "flagship" program is CTO Stream, which allows a single ethics review for multi-site clinical trials. CTO indicates that the program has grown to include more than 19 research ethics boards, 117 trials sites, and 195 pharmaceutical and medical device companies.

CTO has also established a "QuickSTART" program, to help participating clinical trials sites (seven sites) work with industry sponsors to establish standardized processes to improve efficiency and reduce start-up times for clinical trials – "months faster than the current standard." Companies registering for the QuickSTART program include Bayer, Merck, Medtronic, Novartis, and Roche.

CTO is also actively increasing Ontario's clinical trials profile throughout North America – for example by co-hosting a panel discussion at the BIO 2023 International Convention in Boston; participating in the MedTech 2023 Conference in Anaheim; working with Invest Ontario on a clinical trials blog; and hosting the CTO annual conference in Toronto during the Fall of each year.

Ontario *Leadership Table for Clinical Trials*

In Spring 2023, CTO facilitated the establishment of a collaborative initiative with industry, the *Ontario Leadership Table for Clinical Trials. Leadership Table* membership includes many of Ontario's research-intensive hospitals (Sick Kids, Hamilton Health Sciences, Ottawa Hospital, etc.) and leading pharmaceutical companies (Merck, Pfizer, Lilly, Novartis, etc.).

The top priority of the *Leadership Table,* as announced in Fall 2023, is to reduce the target start-up time for clinical trips to 45 days – a significant shortening of the previous CTO target of 90 days.

Other *Leadership Table* priorities include (1) improve patient recruitment and activation, (2) leverage data platforms to facilitate research, (3) capitalize on Canada's new rare disease strategy, and (4) improve timely access to therapies.

Quebec

Quebec performs the second largest number of clinical trials (after Ontario) among Canadian jurisdictions.

Clinical Trials Quebec (CTQ) is a Quebec government agency whose mission is to provide information about clinical research in Quebec, and to promote access to clinical trials for Quebecers. CTQ is "powered" by CATALIS Quebec, a non-profit "neutral" entity whose *Network of Partners* includes government, health research entities, and industry.

Launched in 2017 with the support of the Quebec government and several public and private partners, CATALIS' mandate is *"to increase the number of* clinical trials *conducted by companies in Quebec, facilitate collaboration between the life sciences sector's various stakeholders, and accelerate the development of innovation treatments."* CATALIS' strategic objectives include:

- Accelerating the launch and optimizing the conduct of clinical trials in Quebec
- Facilitating the recruitment and referral of patients throughout Quebec.
- Increasing Quebec's international visibility to attract more clinical trials.

As in Ontario, CATALIS' promotional messages are heavily oriented towards Quebec's ability to achieve expedited clinical trials authorizations, through its *FAST Track Evaluation Service*. For example, the CATALIS website cites a recent Phase 1a study by Pfizer, where three Quebec health research entities were able to authorize the Phase 1a trial within a median time of 8.2 weeks. The website includes a testimonial from Pfizer Canada.

Examples of CATALIS' *Network of Partners* industry members include AstraZeneca, Bristol Myers, GSK, Merck, Novartis, Pfizer, Roche, Sanofi, Squibb, Takeda and Vertex. CATALIS announced the addition of AbCellera to its *Network of Partners* in October 2023.

Alberta

Like Ontario and Quebec, Alberta has also invested significantly in developing and promoting its clinical research capabilities over the past decade. Unlike BC, where Health Research BC is responsible for both the development and promotion of clinical research, Alberta has established separate agencies.

With regard to development, the Alberta Government's "innovation engine," Alberta Innovates, established the Alberta Clinical Research Consortium (ACRC) in 2011. ACRC is focused on providing resources and support to researchers. ACRC membership includes Alberta Health Services, Alberta Innovates, the College of Physicians & Surgeons of Alberta, Covenant Health, the Universities of Alberta and Calgary, and the Government of Alberta. Alberta Innovates provides ongoing administrative and management support to ACRC.

With regard to promotion, Clinical Trials Alberta (CTA) has been developed as a partnership among academic, government, and research organizations, with support from the Alberta Ministry of Jobs, Economy and Innovations. CTA's mandate is to promote Alberta's ability to conduct clinical trials, to attract industry investment to the province through centralized access to services, and to facilitate collaboration among industry sponsors, Alberta-based investigators, and site/service providers.

In 2021, Alberta introduced a Research Ethics Board Exchange (REBX) system. This system enables the lead site on clinical trials to complete all ethics submission activities, providing a streamlined process for other participating REBX sites to use the submission in securing research ethics board approval. In 2022, Alberta introduced a provincial clinical trials management system that has been implemented in much of the province.

Alberta represents itself as having (through Alberta Health Services), Canada's largest provincial health system, and the fifth largest integrated healthcare system globally. Alberta also promotes its provincial electronic medical record (EMR) platform that "provides access to robust patient data."

Alberta's investments in clinical research have contributed to significantly higher levels of clinical trials activity in Alberta than in BC. An MMK review of active clinical trials on the *ClinicalTrials.gov* website found that Alberta has a significantly higher number of active Phase I, II, and III clinical trials than BC, on both a per-capita and absolute basis, as illustrated in Exhibit 4a.

Atlantic Provinces

In 2022, the Atlantic Provinces formed an Atlantic Clinical Trials Network (ACTN), to coordinate clinical research across Atlantic Canada in pursuit of leading the country in terms of active clinical trials per capita. According to ACTN, Nova Scotia ranks first among Canadian Provinces in terms of the number of active clinical trials per capita, while New Brunswick ranks first in the number of cancer-related clinical trials per capita. The formation of the ACTN results in a potential population base for clinical trials in Atlantic Canada of approximately 2.5 million.

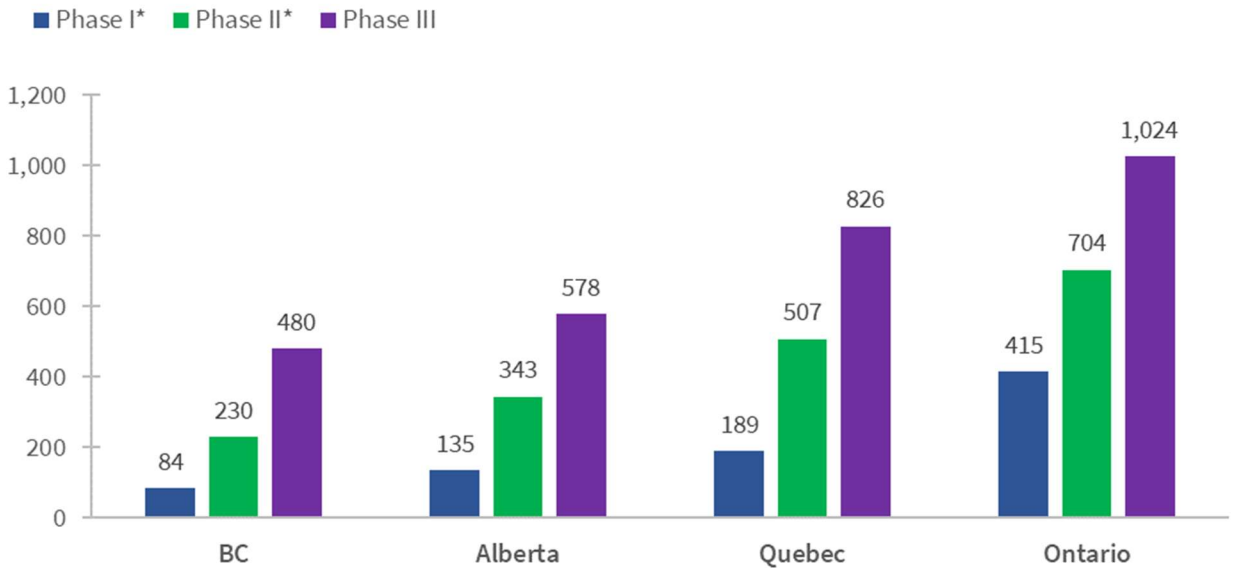
Summary - other jurisdictions' lessons for BC

Over the past decade, other Canadian jurisdictions have invested significantly in initiatives to build their clinical research and clinical trials capabilities, and to actively promote their Phase I, II, and III clinical trials to the life sciences industry.

To promote their jurisdictions, Ontario, Quebec and Alberta have all formed provincial/industry collaborative associations. One of the top priorities of these associations has been the pursuit of streamlined clinical trials approval and start-up processes.

As illustrated in Exhibit 4a, other jurisdictions' investments in capacity and industry attraction have led to much higher participation levels in clinical trials in Ontario, Quebec, and Alberta than in BC. Even in less-populous Alberta, clinical trial participation rates are higher than in BC by 61% for Phase I trials, 49% for Phase II trials, and 20% for Phase III trials.

Exhibit 4a – Active Phase I-III Clinical Trials in Major Canadian Provinces



* Early Phase I and Phase I/II clinical trials are counted as Phase I, and Phase II/III clinical trials are counted as Phase II.
Source: ClinicalTrials.gov. Accessed March 2023.

Over the past decade, BC has been much less proactive than the leading provinces in terms of investing in clinical trials capacity, and also in pursuing and securing industry-sponsored clinical research and clinical trials economic activity.

If BC wishes to catch up with these other Canadian jurisdictions, it will need to emulate some of their sector development strategies – for example in forming collaborative associations with industry and becoming more active at industry conferences and events.

Growth Opportunities

Federal and BC provincial support for clinical research and clinical trials in BC is brighter in 2024 than at any time prior to 2008. As discussed in Chapter 1, Canada's *Biomanufacturing and Life Sciences Strategy* and BC's *Life Sciences and Biomanufacturing Strategy* are very well aligned, and both policies are strongly supportive of building the economic basis of clinical research.

Growth opportunities for cancer-related BC-based clinical research

As detailed in this report, there have been very significant recent year increases in clinical trials activity levels at several BC health research institutes, with research expenditures at the five PHSA institutes more than doubling between 2015-16 and 2022-23 (see Exhibit 2c). PHSA's largest health research institute, BC Cancer Agency (BCCA), has been a major component of this growth.

Approximately two-thirds of clinical research studies in BC and Canada are cancer-related. BCCA reports that nearly 4,000 British Columbians participated in its clinical trials between 2019 and 2023, at one of six BC Cancer centres in the province. The number of BCCA full-time positions has doubled since 2019, and BC Cancer Centres in Prince George and Victoria have more than quadrupled the size of their clinical research units. BC Cancer estimates that it performed 19,600+ clinical trial procedures in 2022-23 (study visits, imaging, lab visits, etc.), with a value of $11.4 million in revenue. (See Appendix E for further details.)

Growth opportunities for non-cancer BC-based clinical research

Approximately one-third of clinical research studies in BC are non-cancer-related. Non-cancer research activities have also been growing in recent years at BC public research entities. The 2023 announcements of $300 million in federal-provincial funding for AbCellera, plus up to $575 million for the UBC-led *Canada's Immuno-Engineering and Biomanufacturing Hub* (*CIEBH*), will also stimulate additional demand for BC-based non-cancer clinical research.

The lack of Phase I (first-in-human) clinical trial facilities for non-cancer treatments has held back the growth of non-cancer BC clinical research over the past decade. However, a new BC Phase I clinical trials facility has received provincial funding and is scheduled to open in late 2024. This new Phase I facility will address the current gap in the BC non-cancer drug development pipeline, between the early-stage pre-clinical research and the later-stage Phases II-IV clinical trials. A number of other potential BC Phase I clinical trials facilities are also in early-stage development.

Challenges and Issues

Research funding availability, relative to demand

While 2023-24 has seen some very significant federal and provincial investments in BC-based clinical and non-clinical research, there is still a significant disparity between the US and Canada in terms of ongoing research grants and awards funding levels. As discussed in Chapter 3, the per-capita level of CIHR funding support for health research projects is only a small fraction of its US National Institutes of Health (NIH) counterpart.

Increasing competition for CIHR funding has resulted a drop in the success rate on grant applications from approximately 31% to 15% over the past 20 years. Many health research professionals in BC and Canada indicate that clinical research projects with significant promise are not proceeding due to underfunding.

Institutional barriers to integrating clinical research with patient care

Hospitals that participate in clinical research projects are proven to have better patient outcomes than those that do not, as discussed in Chapter 3. Having a robust BC clinical research sector not only contributes to advances in medical knowledge, but also contributes to better BC patient healthcare services and outcomes.

The importance of integrating clinical research with patient care is recognized in the BC government's strategy. Pillar 4 (*Expanding our clinical trials capacity*) of the *BC Life Sciences and Biomanufacturing Strategy* envisages "… initiatives from the bench to the bedside", including "…building our capacity to conduct clinical trials …" and "Fostering a research-positive culture across the healthcare system."

At the same time, there are many long-standing institutional barriers to achieving greater integration of hospital/clinical patient services with clinical research activities – in terms of organizational structure, financial budgeting, cost accounting, and delineating patient care roles and responsibilities. Addressing these barriers will continue to be a challenge for the foreseeable future.

Relationships among government, academia and industry

Another significant clinical research issue is the nature of the working relationships and collaboration that the federal and provincial governments wish to pursue with the academic, industry, and other participants in the BC and Canadian healthcare and health research system.

As discussed in Chapter 3, Clinical Trials Ontario and Clinical Trials Quebec have both developed a strategy of facilitating collaboration among the various participants, through a "Leadership Table" (Ontario) and "Network of Partners" (Quebec). Consideration of a similar strategy for BC could require revisiting some existing BC healthcare delivery and research policies in other areas – for example with regard to reference-based drug pricing, and with regard to sharing of provincial healthcare data.

5. Conclusions and Recommendations

Summary of Findings

This report's key findings Include:

- **Clinical research activity levels in British Columbia** – BC's reporting public health research entities accounted for an estimated $204 million in direct clinical research activity in 2022-23, including $64 million in clinical trials activity. Also including non-clinical health research (lab research, desk studies, etc.), total BC direct health research activity is estimated as $489 million. These estimates are conservative in that they do not capture all of the clinical research activities taking place in BC, because of measurement and reporting challenges.

- **Economic impacts of clinical research –** The $204 million in direct clinical research activity generates:
  - Total GDP (direct, indirect, induced) impacts of $245 million (BC only) to $269 million (Canada)
  - Total household income of $155 million (BC only) to $169 million (Canada)
  - Employment impacts of 1,792 (BC only) to 1,984 (Canada)
  - Average income levels within the sector of $105,000.

- **Long-run and short-run trends** – Since MMK Consulting's previous 2013 report, long-term trends in BC health research activity levels have been relatively flat in "real" terms (net of cost escalation). At the same time, there have been significant recent year increases in expenditures at some health research institutes. These increases are attributable to a number of sources – including:
  - Increased appreciation of the importance of health research, as a result of the COVID pandemic
  - Increased federal and provincial interest in and funding of health research initiatives
  - the expanding role of private and public/private health research funding agencies, including Health Research BC.

- **Leverage of federal and provincial funding support –** For six sizable BC health research institutes, Canadian federal and provincial funding accounts for slightly less than half of total health research funding. More than half of health research funding comes from other sources, including private industry, non-government organizations, and US/international sources.

- **Impacts of clinical research on provincial healthcare costs –** There are many anecdotal examples of clinical research studies helping to reduce the provincial cost burden in providing patient care. Estimating the size of these savings to the BC health care system is difficult because of the way in which financial accounts are structured. Addressing this challenge would require a significant research program, likely involving a case study approach. Given that this topic is of interest to many jurisdictions, there may be an opportunity for a cross-jurisdictional study.

- **Impacts of clinical research on patient care and outcomes –** With regard to levels of care, clinical research studies by their nature involve higher levels of care and attention for participating patients than for non-participating patients. For life-threatening illnesses, they may also provide a cause for hope that would not otherwise exist. With regard to patient outcomes, the academic literature clearly indicates that hospitals performing clinical trials have better patient outcomes than ones that do not.

- **Growth strategies in other jurisdictions –** Ontario, Quebec and Alberta all have much greater levels of clinical research and clinical trials activity than BC. Their growth strategies feature:

- Investment in clinical trials infrastructure facilities, plus clinical trials delivery capabilities.
- Pursuit of clinical research and clinical trials sponsors/customers that are based not only in their home jurisdictions, but also in other Canadian provinces, the US, and overseas.
- Establishing industry-wide associations (government, research institutes, hospitals, private industry) to achieve a more a research-friendly jurisdictional environment.
- In particular, streamlining the clinical trials approval and start-up process.

These strategies have helped these three other Canadian jurisdictions to achieve much higher clinical trials research levels than BC. In less-populous Alberta, activity levels are 61% higher than BC for Phase 1 trials; 49% higher for Phase II trials; and 20% higher for Phase III trials.

- **Measurement and reporting completeness –** This report's findings are based on combining information from multiple sources – including the UBC RISe system, the financial records of BC health research entities, and the financial records of BC provincial and regional health authorities. Despite the establishment of a BC Clinical Trials Management System (CTMS) in 2020, there is no current source of information that records all of the clinical research activity taking place in BC. Some BC clinical research is not being fully captured at present, including privately conducted clinical studies, plus other non-UBC-affiliated studies. The issue is expected to become more significant with the increase in SFU-affiliated clinical research upon establishment of the new SFU medical school.

- **Opportunities –** The current outlook for clinical research in BC is brighter in 2024 than at any time in the past 15 years. There is strong policy support for life sciences and biomanufacturing at both federal and provincial levels. A number of major public investments have been announced over the past year to build BC's bio-manufacturing capabilities, supporting the growth of BC-based "anchor companies" in the life sciences sector. These investments will drive an increase in BC-based clinical research.

  The outlook for clinical trials in BC is particularly positive. The BC clinical trials community has developed (through Health Research BC) *A Vision for Clinical Trials in BC*. The Province of BC's *Life Sciences and Biomanufacturing Strategy* has established five pillars, one of which is "Expanding our clinical trials capacity." A new Phase I (first-in-human) clinical trials facility has received provincial funding and is scheduled to commence operations by early 2025. Several other potential new or expanded clinical trials facilities are in various stages of planning.

- **Challenges and issues** – Key clinical research challenges and issues for BC include:
  - Federal (Canadian Institutes for Heath Research – CIHR) research awards and grant levels, which are only a fraction (even on a per-capita basis) with those of the comparable US funding agency.
  - Institutional barriers to integrating hospital-based patient health care and clinical research.
  - Achieving positive working relationships among government, academia, and industry. One key issue facing BC is whether and how much to follow other jurisdictions' leads in developing industry partnerships to streamline clinical trials approval and administration processes.

Recommendations

1. Implement a strategy for attracting more clinical trials and research activity to BC

BC significantly lags the leading Canadian provinces in terms of clinical trials and research activity levels, despite BC's strong international reputation for early-stage discovery and pre-clinical research.

Pillar Four of BC's 2023 *Life Sciences and Biomanufacturing Strategy* calls for "Expanding our clinical trials capacity, through initiatives such as supporting the establishment of Phase I (first-in-human) clinical trials

facilities in BC …". In 2024, BC has already committed significant funding to support several capacity-related projects throughout the province, including a Phase I clinical trials facility. Many other capacity-related clinical trials facility and program investments are also in development.

To achieve the benefits of this added capacity, BC will need to also develop and implement a complementary strategy to attract new clinical trials and research activity to the province. This strategy will need to target industry and other sponsors that are based both within and outside the province.

The development and implementation of an effective BC competitive strategy will need to learn from, and in some cases emulate, the strategies of Clinical Trials Ontario, Clinical Trials Quebec, Clinical Trials Alberta, and agencies in other jurisdictions.

Developing an effective clinical trials attraction strategy for BC will also require the active involvement of the BC health research and life sciences sector – academic organizations, health research institutes, private industry, regional health authorities, and others.

2. Develop a central source of information for reporting BC clinical trials and research activity

The UBC RISe system has traditionally been the best central source of financial information about BC health research activity levels. However, this system is aging, and does not record all of the clinical research activity being undertaken in BC. BC's Clinical Trials Management System (CTMS), introduced in 2020, has the potential to become the primary central source of information regarding BC clinical research and clinical trial activities, with the support of the BC health research community.

3. Other recommendations

In addition to these two key strategic initiatives, other study recommendations include:

- **Undertake an informal survey of private clinical research activity in BC.** Health Research BC, through its Clinical Trials BC's contacts with a number of BC private clinical research firms, could conduct an informal survey of private clinical research activities taking place in the province. This exercise would reduce the current information gap regarding private clinical research in BC.

- **Communicate the importance of clinical research to BC and Canada** – disseminating the findings of this report with regard to: clinical trials and research activity levels; economic impacts of these activities; leverage of federal and provincial funding; BC's position in regard to leading Canadian provinces; and the opportunity to build on clinical trials capacity investments to increase activity levels.

- **Build on federal/provincial investments in life sciences/clinical trials activity levels and capacity** – Including the UBC-led $575 biomanufacturing initiative, announced in 2023; the $300 million federal-provincial support for AbCellera, announced in 2023; the provincial funding of a new Phase I clinical trial facility at Mount St. Joseph Hospital in Vancouver, also announced in 2023; and the proposed new clinical trials facilities at several other BC locations, currently in development in 2024.

- **Advocate for increased federal/provincial support for clinical and other healthcare research** – continuing to provide education about the much lower per-capita federal/provincial support for healthcare research in Canada, relative to the US.

- **Reduce the institutional barriers to integration of clinical research with patient care** – working with BC's academic organizations, health research institutes, and provincial health authorities to achieve greater coordination of clinical research and patient treatment.

Appendix A – BC Life Sciences & Biomfg. Strategy Excerpt

Pillar 4:
Expanding our clinical trials capacity

Companies that have developed a promising treatment must test it in clinical trials to prove it is effective and safe. Only then can the treatment be produced at scale and prescribed to treat disease and improve health. Jurisdictions with a robust clinical trial environment benefit in many ways. Not only do they have greater connections between research and care, their residents also have access to novel treatments.

Over 1,300 clinical trials take place across the province each year; however, we have limited capacity for Phase 1 clinical trials, which must be conducted within hospital settings. B.C. hospitals however do not currently have Phase 1 clinical trials facilities, resulting in local companies having to test their products out of the province at higher costs, often leading to subsequent trials being conducted in the same jurisdiction.

Oncology trials in B.C.

B.C.'s 10-year Cancer Care Action Plan, recently announced, includes a $150M to the BC Cancer Foundation to support cancer research, including clinical trials across all cancer centres in the province. These trials will: allow for greater participation of patients living outside of large cities; increase studies on radiation treatment approaches; and include precision radiation therapy research to enhance effectiveness of radiation treatment while reducing toxicity.

Expanding B.C.'s clinical trials capacity, including Phase 1 trials, will create both health and economic benefits. B.C. life sciences companies will be able to conduct early-stage clinical trials here at home, making it less expensive and more streamlined than if they had to carry them out in other jurisdictions. If the initial stages of the trial are successful, these companies can get more value from their intellectual property, which ultimately empowers them to invest in new research, hire more people and continue to grow here in B.C.

Increasing our clinical trials capacity will also enable us to attract more foreign companies who want to test their therapeutics in a province that boasts an ethnically diverse population, province-wide health authority structure and highly respected clinical researchers.

Maximize the health, educational and economic benefits of clinical trials for British Columbians

In collaboration with stakeholders that include Michael Smith Health Research BC and its Clinical Trials BC Unit, the Province will undertake initiatives to mobilize innovation from the bench to the bedside. We'll achieve this by:

- Building our capacity to conduct clinical trials by enabling infrastructure, accelerating skills training and streamlining the research approvals process
- Fostering a research-positive culture across the health system

What are clinical trials?

Clinical trials test the safety and efficacy of new drugs, medical treatments and health interventions to prevent, treat or manage medical conditions or diseases. Phase 1 is the first phase that involves in-person testing of the treatment for safety. Phase 2 evaluates a treatment's effectiveness on diseases and dosing requirements, Phase 3 tends to focus on larger numbers of patients to further monitor for side effects and compare to other treatments, and Phase 4 looks at post-market risks and benefits. In early 2023, more than 1,300 active clinical trials were under way in B.C., with over 90 per cent being later-stage trials.

Source: Province of BC, StrongerBC Life Sciences and Biomanufacturing Strategy (2023).

Appendix B – A Vision for Clinical Trials in British Columbia

Michael Smith Health Research BC
CLINICAL TRIALS BC

A Vision for Clinical Trials in British Columbia

Realizing a future in which clinical trial benefits are maximized for British Columbians

Clinical trials generate robust and rigorous evidence for the safety, effectiveness, and outcomes of life-saving and health-promoting interventions, such as vaccines, drugs, devices, and clinical practice changes. Significant health benefits result from clinical trials; primarily from evidence-informed care delivery, health policy, and associated population health improvements.

BC's comparative advantages include clinical trial expertise, leading research institutions and networked infrastructure, a diverse population, and a strong and growing life sciences sector. These advantages position the province to build a unique and highly successful clinical trials ecosystem, delivering health and economic benefits.

Clinical Trials BC, part of Michael Smith Health Research BC, consulted with investigators, trial participants, funders, life sciences companies, health system policymakers, and more to create a shared vision for clinical trials in BC. The vision is endorsed by the Ministry of Health.

BC's Vision for Clinical Trials

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

Desired Outcomes

The unique and highly successful clinical trials ecosystem will:

- Build greater connections between research and care.
- Create more high-skilled jobs in the conduct and delivery of clinical trials.
- Increase early adoption of new and promising innovations to further improve health outcomes for British Columbians.
- Attract more economic investment that supports growth and development of the provincial life sciences sector.
- Increase capacity for clinical trials to attract more trials to the province.
- Enhance BC's research profile on the international stage.

How to Realize the Vision

A collaborative and multi-partner approach with engagement across BC's health research system and broader life sciences sector is required to realize this vision. Priorities for our collective attention:

Build a **universally embraced research-positive environment** that values, supports, and actively promotes health research, including clinical trials.

Value clinical trials as an approach to responding to questions in a learning health system context when embedded into the **clinical care continuum** in our health-care system.

Build **provincial and diverse governance structures** for clinical trials to support the successful implementation of the vision for clinical trials in BC.

Demonstrate and capitalize on our **comparative advantages** for clinical trials, including our population (diversity and location), data assets, research capacity, and research facilities, so BC is seen as a prime location for clinical trials.

Maximize the **economic contribution** of clinical trials and their ability to create high-value employment, investment, and growth for BC.

Support **collaboration** among academia, health care, government, patients, communities, clinical trial organizations, funders, and life science companies at the provincial, national, and international levels.

Advance **person-centred approaches and designs** to create a clinical trial experience that is culturally safe, trauma-informed, inclusive, accessible, and available to all who want to participate.

Support the **full scope of activities within the clinical trial lifecycle** from discovery to first-in-human trials to regulatory approval. Value and enable BC-based investigator-led, Indigenous-led, and institutionally sponsored clinical trials.

Fund and support **sustainable clinical trial infrastructure**. Ensure that clinical trial research has timely access to data, biobanks, technology, clinical services, digital tools, and resources, and is enabled by leading-edge technology, methodology, dedicated spaces, and specialized research facilities.

Develop and support a **skilled and viable clinical trial workforce** across the province, including urban, rural, and remote settings.

Ensure that clinical trials in BC are **quality focused and fully compliant** with national and international regulations and ethical guidance.

Enable research ethics review to be **meaningful, streamlined, timely, effective**, and supported by transparent performance metrics.

Create and sustain **agile and efficient business services** and operations to support clinical trials (contract negotiation, privacy and security reviews, finance, and legal reviews). Develop accountable and transparent performance metrics focusing on fast, efficient approvals and service.

Together, we can realize this vision.

Engage with us and share your thoughts to advance the vision into action.
Scan the QR code.
healthresearchbc.ca | info@healthresearchbc.ca | 604.730.8322

Appendix C – Detailed Clinical Research Activity Analysis

The Appendix C table, overleaf, provides details of the key sources and assumptions underlying the estimates of BC clinical research activity levels.

These estimates are based on analysis of information provided by participating institutes and authorities. They include:

- Direct revenues and expenditures on individual research projects, where funding is provided through granting agencies' research awards and other project funding sources. This information has been provided by participating agencies, through reference to (1) the RISe database, as operated by the UBC Office of Research Services, and (2) entity-specific accounting and administrative records.

- Allowances for additional non-recoverable overhead and administrative expenditures incurred by the research institutes and their affiliated healthcare entities in supporting these health research projects. In some cases, these may include allowances for the costs to affiliated hospitals and authorities of providing research space and equipment to the research institute at little or no charge.

These estimates are tabulated and presented primarily on the basis of the administering authority (research institutes, UBC Faculty of Medicine, Regional Health Authorities, etc.), as recorded in UBC's RISe database. The vast majority of publicly funded health research in BC is led by principal investigators and researchers that are affiliated with the UBC Faculty of Medicine.

These figures represent conservative estimates of the total amount of clinical research activity in BC in that they do not include:

- Health research and clinical studies undertaken by other BC public agencies that may not be reported through the UBC-operated RISe database system.

- Privately performed health research projects that may not be recorded in the RISe database.

- Other clinical and non-clinical health research expenditures that may be undertaken by individuals or groups that are not reflected in any of the entity-provided information (including RISe database information), or in the overheads/administrative allowances established for the various entities as indicated in the following table.

Appendix C - Expenditures on Funded Clinical Research by Major BC Public Reporting Entities ($ millions, 2022-23)

Administering Authority	Health Research at BC Public Entities (both clinical *and* non-clinical research)			Assessed as Clinical Research (including Clinical Trials)		Assessed as Clinical Trials (Phases I-IV, or not indicated)	
	Research Awards and Other Sources (Note 1)	Overheads and Administrative Costs (Note 2)	Total Value of Health Research	% of Health Research Assessed as Clinical (Note 3)	Total Value of Clinical Research	Clinical Trials as a % of Health Research (Note 4)	Total Value of Clinical Trials
Vancouver Coastal Health Research Institute	**$112.3**	**$12.1**	**$124.4**	**50%**	**$43.5**	**15.4%**	**$19.2**
Providence Research	**$61.7**	**$10.0**	**$71.7**	**59%**	**$42.4**	**16.7%**	**$11.9**
PHSA Institutes							
BC Cancer Research Institute	$106.8	$13.6	$120.4	35%	$42.1	14.2%	$17.1
BC Children's Research Institute	$68.8	$8.7	$77.5	50%	$38.7	15.4%	$12.0
Women's Health Research Institute	$7.2	$0.9	$8.2	44%	$3.6	29.6%	$2.4
BC Centre for Disease Control	$6.2	$0.8	$7.0	50%	$3.5	7.8%	$0.5
BC Mental Health & Substance Use Services	$1.1	$0.1	$1.2	35%	$0.4	1.8%	$0.0
Sub-total PHSA	**$190.1**	**$24.2**	**$214.3**	**41%**	**$88.4**	**14.9%**	**$32.0**
UBC Faculty of Medicine (Note 5)	**$61.1**	**$7.8**	**$68.9**	**35%**	**$24.0**		
Subtotal - VCHRI, Providence, PHSA, FoM	**$425.1**	**$54.1**	**$479.2**	**41%**	**$198.3**	**13.2%**	**$63.1**
Regional Health Authorities (Note 6)							
Fraser			$2.9				
Interior			$3.1				
Island			$3.1				
North			$0.7				
Sub-total RHA's			**$9.7**	**54%**	**$5.2**	**11.2%**	**$1.1**
Total - VCHRI, Providence, PHSA, UBC FoM, RHA's			**$488.9**		**$203.5**		**$64.2**
			100%		42%		13%
Health research at other BC public institutions (Note 7)			additional		additional		additional
Privately-performed healthcare research (Note 8)			additional		additional		additional
Unfunded additional health research activity			additional		additional		additional

Note 1 - VCHRI/Providence/PHSA/UBC FoM as provided by entity. Includes RISe-recorded research awards, plus direct research funding from other sources where known.

Note 2 - Allowance for overhead/admin costs incurred by the entity, plus unrecovered costs incurred by by affiliated entities (e.g. space occupancy) .
VCHRI and Providence assessments based on information provided by entities. PHSA and FoM overhead allowance based on VCHRI/Providence results.

Note 3 - Providence percentage as estimated by entity. VCHRI percentages based on other entity/previous study estimates.
PHSA percentages estimated by PHSA/Health Research BC. FoM estimates based on percentage of health research expenditures requiring human ethics certificates.

Note 4 - PHSA percentages per PHSA-provided data. Providence assessement per staff inputs. VCHRI/RHA assessment per analysis for Providencece/Cancer/Children's.
FoM-led clinical trials activity assessed as zero, based on FoM-led clinical trials typically being registered & administered through BC research institutes.

Note 5 - These amounts refer to research awards administered through UBC FoM. The vast majority of BC entity-administered awards are also led by UBC-affiliated researchers.

Note 6 - RHA health research estimates based on Research Ops in Enviromental Scan (ESHORI) report. Clinical research/clinical trials estimates based on funding sources.
Most funded clinical research & clinical trial activity at RHA hospitals in not is funded through the RHA budgets.

Note 7 - For example, some SFU/Uvic/UNBC health research may not be included in the RISe database.

Note 8 - Privately-funded BC healthcare research is known to be significant, but this information is closely held by private entities and sponsors.

Appendix D – The *ClinicalTrials.gov* Registry

ClinicalTrials.gov is a US registry of public and private international clinical studies with human volunteers. More than three-quarters of study records are of clinical trials. The others are almost entirely observational studies.

Section 801 of the FDA (Food and Drug Administration) Amendments Act of 2007 requires certain clinical studies of drugs (including biological products) and medical devices to be registered at ClinicalTrials.gov. The International Committee of Medical Journal Editors also requires clinical trials to be registered at ClinicalTrials.gov before publication of results. [1]

While ClinicalTrials.gov contains hundreds of thousands of clinical studies, registration is not required by law for all clinical studies including observational studies and trials that do not examine a drug, biologic, or device.

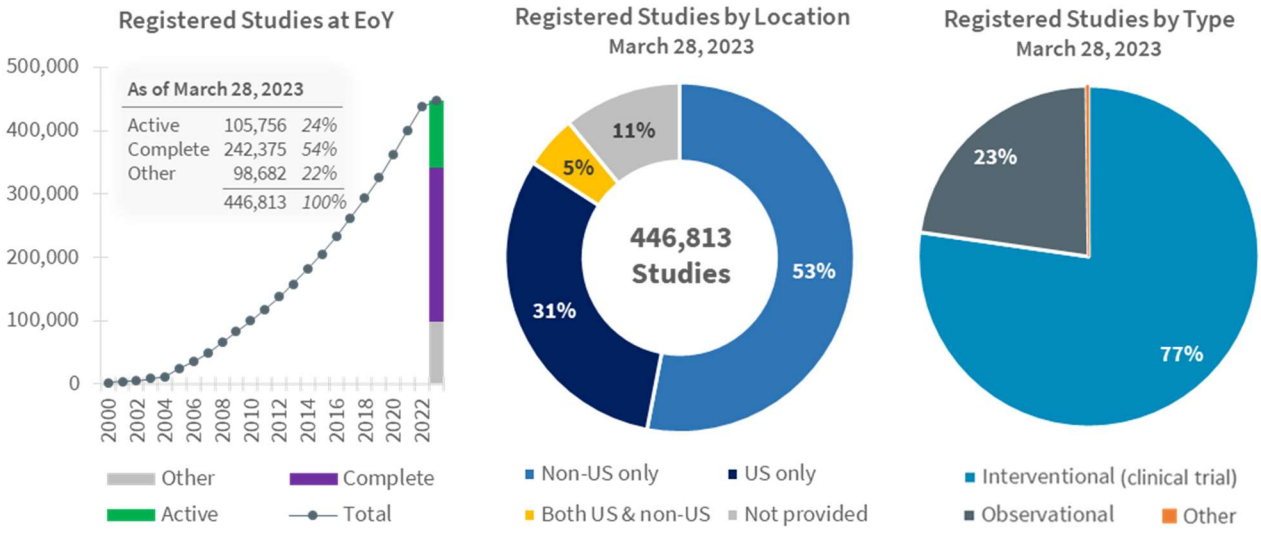
Registry Background

The registry initially started in 2000 as a result of the FDA Modernization Act (1997). Following the expansion of registration requirements in the FDA Amendments Act (2007), the ClinicalTrials.gov database launched in 2008.

The website is maintained by the US National Library of Medicine at the National Institutes of Health (NIH). The information contained in its database is provided and updated by study sponsors and/or principal investigators.

Studies typically register when they begin and are updated in the database on an ongoing basis through to study completion. Once a study has been registered at ClinicalTrials.gov, it is not removed from the database.

ClinicalTrials.gov Database Overview



Source: ClinicalTrials.gov. Accessed March 29, 2023.

[1] Source : https://ors.ubc.ca/compliance-reporting/clinical-trials-registration.

Database Contents

The ClinicalTrials.gov database contains a summary of information about each study record – including:

- **Current Status –** The status of a study at the time of its last update, either as an (1) active study (not yet recruiting, recruiting, enrolling by invitation, or active and not recruiting), (2) completed study, or (3) other status including suspended, terminated, withdrawn, unknown, or others.

- **Study Type –** The classification of the study protocol. ClinicalTrials.gov defines these as:

  - Interventional (clinical trial) – A type of clinical study in which participants are assigned to groups that receive one or more intervention (or no intervention) so that researchers can evaluate the effects of the interventions on biomedical or health-related outcomes. Assignments are determined by the study's protocol. Participants may receive diagnostic, therapeutic, or other interventions.

  - Observational study – A type of clinical study in which participants are identified as belonging to groups and are assessed for biomedical or health outcomes. They may receive diagnostic, therapeutic, or other interventions, but the investigator does not assign them a specific one.

  - Other – A study record, for patients with serious diseases or conditions who cannot participate in a clinical trial, to gain access to a medical product that has not been approved by the FDA.

- **Study Phase –** The clinical trial phase for interventional studies, including:

  - Early Phase I – A phase of exploratory trials (before traditional phase I trials) to investigate how or whether a drug affects the body, typically involving limited human exposure to the drug and without therapeutic or diagnostic goals (for example, screening studies, microdose studies).

  - Phase I – A phase of clinical trials that focus on the safety of a drug, usually with a small number of healthy volunteers, and with the goal to determine the drug's most frequent and serious adverse events and, often, how the drug is broken down and excreted by the body.

  - Phase II – A phase of clinical trials that gather initial data on whether a drug works in people who have a certain condition/disease (i.e., the drug's effectiveness). Participants receiving the drug may be compared to others receiving a different treatment, usually an inactive substance (i.e., placebo) or a different drug. Safety continues to be evaluated, and short-term adverse events are studied.

  - Phase III – A phase of clinical trials that gather more information about a drug's safety and effectiveness by studying different populations and different dosages and by using the drug in combination with other drugs. These studies typically involve more participants.

  - Phase IV – A phase of clinical trials occurring after FDA has approved a drug for marketing. These trials gather additional information about a drug's safety, efficacy, or optimal use.

- **Study Locations –** The locations that the study has been or is going to be conducted, identifying the facility, city, and country of each study location (e.g., hospital/city/country).

In addition, the database also contains other pieces of summary information about each study, as illustrated in the following Exhibit. This includes the study title, description, disease or condition of focus, study funders, enrolment, participant demographics, methodological approach, outcome measures, results, and other data.

ClinicalTrials.gov Database Contents

Categories	Available Information by Study
Name	Tile/description
Status	Active, complete, or other
Type	Interventional, observational, or other
Phase	Early Phase 1, Phase 1, Phase 2, Phase 3, Phase 4, not applicable, or blank
Conditions	List of diseases/conditions (e.g., tumor, respiratory disease, Type 1 diabetes)
Interventions	List of interventions (e.g., drug, procedural, behavioural, radiation, device)
Sponsor/Collaborator	List of organizations (e.g., universities, health authorities, private entities)
Funders	Industry, US Federal, NIH, or other (e.g., universities, individuals)
Enrolment	Number of participants
Sex	All sexes, male, or female
Age	Age ranges and groupings (i.e., child, adult, or older adult)
Design	Methodological description (e.g., randomized allocation)
Outcome Measures	List of measures (e.g., change in diabetes distress)
Dates	Start date, (expected) completion date, first posted date, and last updated date
Locations	List of individual study locations (e.g., hospital/city/country)

Source: ClinicalTrials.gov. Accessed March 2023.

Studies with a Canadian Presence

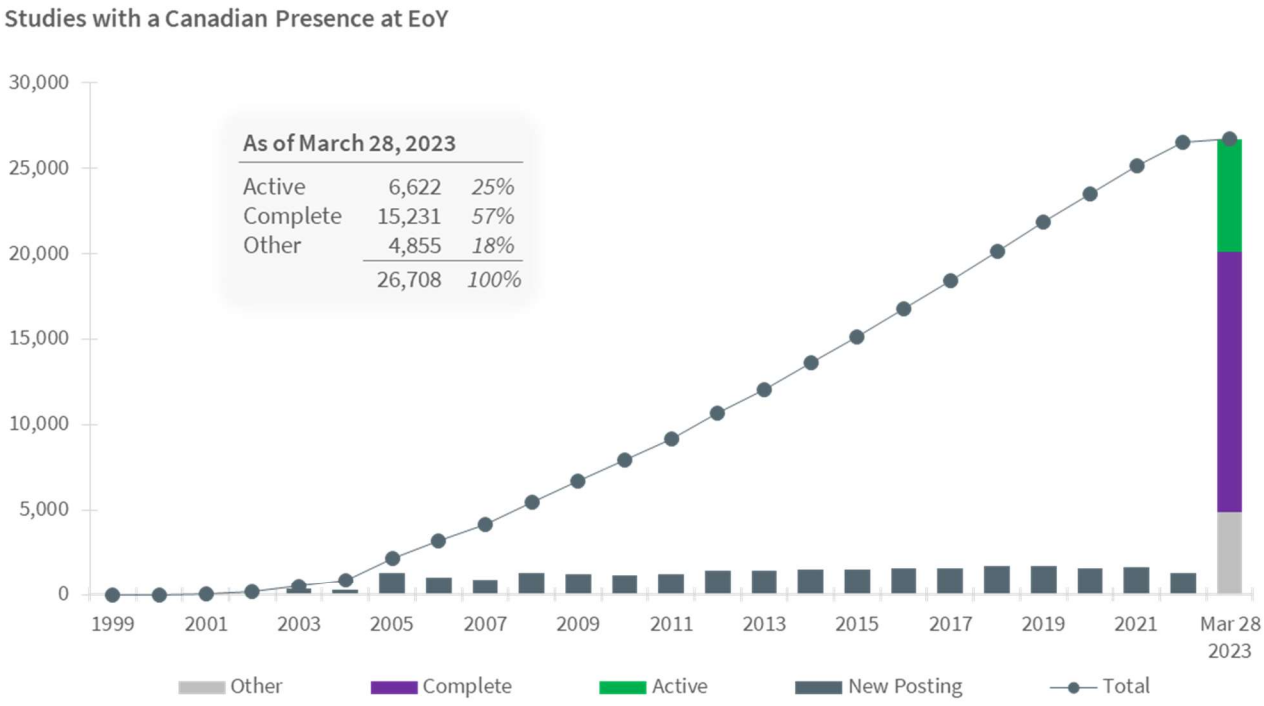
For the purposes of this study, clinical study records from ClinicalTrials.gov have been extracted based on whether they have a presence in a Canadian location. This includes separate records collected:

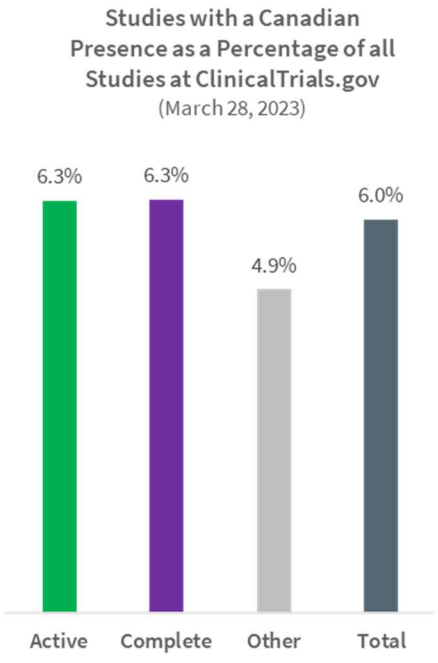
- By Province – including studies with a presence in BC, Alberta, Saskatchewan, Manitoba, Ontario, Quebec, New Brunswick, Nova Scotia, Prince Edward Island, or Newfoundland and Labrador; and
- For Canada as a whole **–** including studies with a presence in any Canadian province or territory.

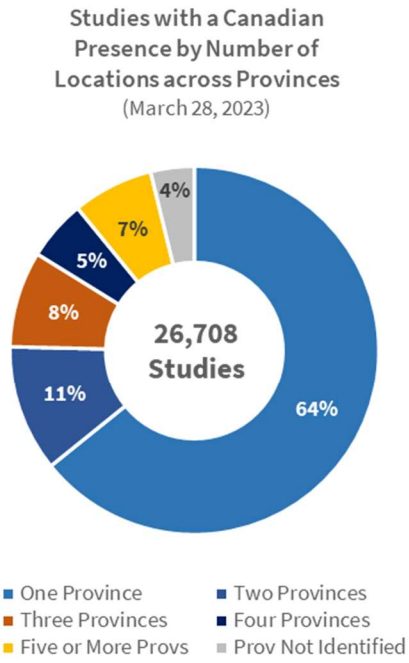
As illustrated in the following Exhibit, registered studies with a Canadian presence as of March 2023:

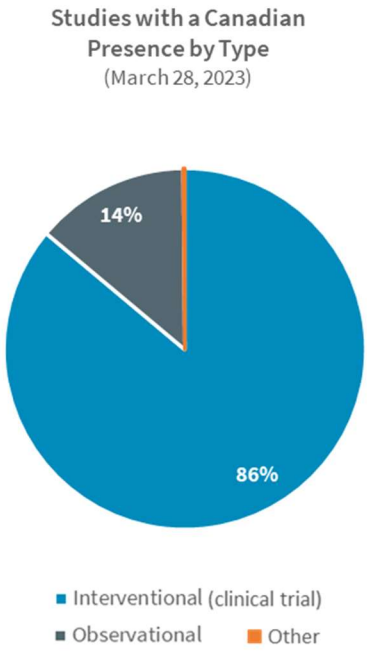
- Total more than 26,700 studies, or 6% of all studies, at ClinicalTrials.gov. These include studies located in one Province as well as others with a locational presence in multiple Provinces.
- Include more than 6,600 active studies.
- Mostly represent interventional clinical trials (86%).
- Have increased by an average of approximately 1,600 studies per year over the past decade.

ClinicalTrials.gov Registered Studies with a Canadian Presence









Source: ClinicalTrials.gov. Accessed March 29, 2023.

Appendix E – Cancer-Related Clinical Trials in BC

BC Cancer has provided the following information with regard to cancer-related trials clinical trials in BC.

"*Between 2019-2023, nearly 4000 British Columbians participated in a clinical trial at one of six BC Cancer centres around the province. Clinical trials are embedded in the delivery of care at BC Cancer. Patients access cutting-edge therapies and achieve better outcomes while cancer centres benefit by attracting leading medical talent. With 165 clinical trials currently recruiting participants (featured on their public-facing website), BC Cancer is a strong contributor to global oncology clinical trials.*

"BC Cancer clinical trials not only improve the lives of patients, but also provide high value employment with the number of full-time positions more than doubling since 2019. Of note, BC Cancer centres in Prince George and Victoria have more than quadrupled the size of their respective clinical research units over 5 years – increasing jobs and providing more clinical trial participation opportunities in remote areas of BC. With the recent creation of a BC Cancer provincial Contract Research Organization (CRO), in-house research management services now support "made in BC" clinical research initiatives, keeping more dollars in our province. And direct employment only tells part of the story; 19,600+ BC Cancer clinical trial procedures performed in FY22-23 – study visits, imaging, lab tests, etc. – contributed $11.4M in revenue with resultant indirect and induced community impact.

"In the absence of annualized core healthcare funding for clinical trials, the BC Cancer Foundation – backed by generous donors – remains a strong funding partner. Industry-sponsor revenue ultimately drives financial sustainability with approximately 50% of BC Cancer's clinical trial offerings supported by industry dollars. Clinical trials at our largest centre, BC Cancer Vancouver, contributed $38M over the past 5 years to the local economy. Leveraging recent investments from the Ministry of Health's 10-year cancer plan, BC Cancer is poised for continued growth and economic benefit. Transparent metrics will ensure accountability for expanded clinical research opportunities, offering more trials to more patients.

Appendix F – BC's Clinical Trial Management System

The following overview of BC's Clinical Trial Management System has been provided by Health Research BC and by BC Cancer.

Background

In December 2020, a new Provincial Clinical Trial Management System (CTMS) Program for the province of British Columbia (BC) was initiated to provide access to a provincially harmonized CTMS. This program aims to improve clinical trial management and has the following key objectives:

***(1) Provincial harmonization** – standardization of a provincial clinical trial management tool and process.*

***(2) Efficiency gains and improvement** – reduction of administration and overhead costs.*

***(3) Analytics and business intelligence** – use of reporting at provincial, organization, and site levels.*

The Provincial CTMS Program is operationalized by a group of Participating Organizations (POs). These POs are currently comprised of health authorities whose clinical trial sites are the end users of the CTMS (including Vancouver Island, Vancouver Coastal Health, Interior Health, Fraser Health, Northern Health, and Provincial Health Services Authority) and Michael Smith Health Research BC (Health Research BC). Health Research BC funds access to the CTMS and provides operational support and governance for the program through their Clinical Trials BC unit (herein referred to as "Clinical Trials BC"). PHSA funds and manages the CTMS platform for their programs and receives partial support from Health Research BC.

*The CTMS program presents an opportunity to **fill gaps in current clinical trial management across the province** at various levels including individual (end-user and site), regional (health authority), and provincial (BC health and research landscape). Examples include the ability to facilitate intra-provincial communication and knowledge-sharing, identification of best practices or areas of opportunities in BC and use of provincial-level metrics to demonstrate the collective impact of clinical trial work across the province.*

BC Cancer's role in establishing CTMS and achieving its benefits

Increasing trial complexity and persistent clinical staffing challenges require innovative solutions to drive efficiencies. In 2019, with the vision of becoming a world-class research organization, insightful BC Cancer leaders mandated the harmonized use of a leading-edge Clinical Trial Management System (CTMS). Realtime CTMS implementation allowed the sites to maintain Health Canada regulatory compliance while reducing time and costs with streamlined processes. Systematic data capture supported comprehensive provincial reporting and superior business analytics. Elegant invoicing and reporting revealed where to focus cost-recovery efforts; one determined finance team member recovered $945k in outstanding industry-sponsor revenue in under 6 months noting the CTMS provided the evidence needed to collect that which would previously have been uncollectable. Taking BC Cancer's lead, Realtime CTMS was soon rolled out across all BC Health Authorities in partnership with and funded by Michael Smith Health Research BC. More than 1300 clinical trials are currently managed by over 800 active CTMS users across the province.