Situational analysis of the clinical trials ecosystem in British Columbia

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EXECUTIVE SUMMARY

This comprehensive situational analysis, commissioned by Michael Smith Health Research BC, evaluates the current state of British Columbia's clinical trials ecosystem, comparing it with other Canadian provinces and global leaders.

Despite its world-class research facilities and expertise, British Columbia underperforms in attracting and retaining clinical trial investments lagging behind Ontario, Quebec, and Alberta in per capita funding and operational efficiency. The report identifies critical barriers, including lengthy study start-up times, bureaucratic complexity, underdeveloped infrastructure, and insufficient public engagement.

Key actionable insights to enhance competitiveness include:

1. **Establish an Ecosystem Convener**: A dedicated coordinating body to streamline collaboration, balance competing priorities, and advocate for the province on the national and international stages.
2. **Mandate Centralized and Harmonized Review Mechanisms**: Simplifying administrative processes to reduce delays and enhance compliance with ethical and regulatory standards.
3. **Integrate Clinical Trials into Clinical Care**: Embedding trials within healthcare systems to ensure sustainability, retain specialized staff, and accelerate trial start-up times.
4. **Leverage Health Data**: Leveraging electronic health records (EHR) to streamline data collection, improve recruitment, and enable a learning healthcare system.

These recommendations are grounded in a comprehensive analysis that incorporates interest-holder interviews, comparative benchmarking, and a review of best practices globally. By implementing these insights, British Columbia can capitalize on its existing strengths, improve its position in the competitive clinical trials landscape, and deliver significant health and economic benefits to its residents.

INTRODUCTION

Background

Over the past three decades, British Columbia has developed a well-established clinical trials ecosystem, driven by substantial investment, strategic partnerships, and a commitment to innovation[1]. These efforts have yielded transformative outcomes across multiple therapeutic areas, establishing British Columbia's strong position in life sciences and clinical research.

Recent milestones demonstrate the province's capacity to translate cutting-edge research into impactful patient outcomes. Between 2020 and 2022, clinical trials at Providence Health Care and the University of British Columbia (UBC) played a pivotal role in the approval of mRNA vaccines, including Pfizer-BioNTech and Moderna, during the COVID-19 pandemic. In oncology, BC Cancer advanced personalized oncolytic virus therapy for late-stage melanoma, transitioning it into real-world treatment by 2021. Stem cell therapy research for type 1 diabetes conducted by UBC has provided patients with an alternative to daily insulin injections, gaining regulatory approval in 2022. More recently, trials at Vancouver General Hospital have contributed to the approval of a new chronic obstructive pulmonary disease (COPD) medication, while UBC-led research on a biologic treatment for multiple sclerosis has significantly improved patient outcomes.

British Columbia's success is underpinned by its emphasis on cross-sector collaboration. Academic institutions like UBC, healthcare authorities, and industry interest-holders[2] form the backbone of these partnerships.

Infrastructure investment is another cornerstone of British Columbia's ecosystem. The province is leveraging integrated data platforms, biobanks, and digital health tools to enhance clinical trial capacity and efficiency. The new Clinical Trials Unit at Mount Saint Joseph Hospital[3] exemplifies BC's focus on early-stage research and precision medicine. By integrating decentralized trial models and expanding facilities, BC enables broader participation while attracting global investment.

For the first time, British Columbia has a shared vision for clinical trials[4] — one that reflects a future in which clinical trials investments maximize benefits for all British Columbians. Led by Michael Smith Health Research BC's Clinical Trials BC team, British Columbia's clinical trials community is using this vision to build on strengths and address gaps and challenges with the common goal of system and organizational change.

With over 100 active clinical trial investigator sites, and an expansive network of over 600 clinical investigators, British Columbia's clinical trials ecosystem supports trials in all phases of clinical

[1] See Appendix B: History of Clinical Trial Infrastructure in British Columbia
[2] "Interest-holders": A new term to replace "stakeholders" in the context of health research and policy. Cochrane Evidence Synthesis and Methods. 29 October 2024. Link
[3] New clinical trials will save lives, support BC innovation. Government of British Columbia, Ministry of Jobs, Economic Development and Innovation. 10 Oct 2023. Link
[4] A Vision for Clinical Trials in British Columbia. Michael Smith Health Research BC's Clinical Trials BC. 2024. Link

development, from public and industry funded sources, with an estimated patient participation volume of up to 40,000 British Columbians annually. Over 7,000 jobs in the province are tied directly to clinical trials delivery, with an annual estimated GDP contribution of $300-500M.

Growth and Position

The global clinical trial industry is experiencing notable trends in research and development (R&D) spending and investment in the life sciences sector, particularly in Canada. Global spending on clinical trials is on the rise, driven by partnerships between pharmaceutical companies and biotech firms, as well as the growing demand for innovative therapies. The global market for clinical trials is projected to reach USD $73.2 billion by 2028, reflecting a compound annual growth rate of approximately 8.7%[5].

Canada has a respectable position in the global clinical trial landscape, ranked fourth in global health and biosciences hubs[6], and leads the G7 in clinical trial productivity, based on the number of trials per capita[7]. By increasing its clinical trial funding and focusing on strategic partnerships and innovation ecosystems, Canada can enhance its standing and influence in the global R&D arena.

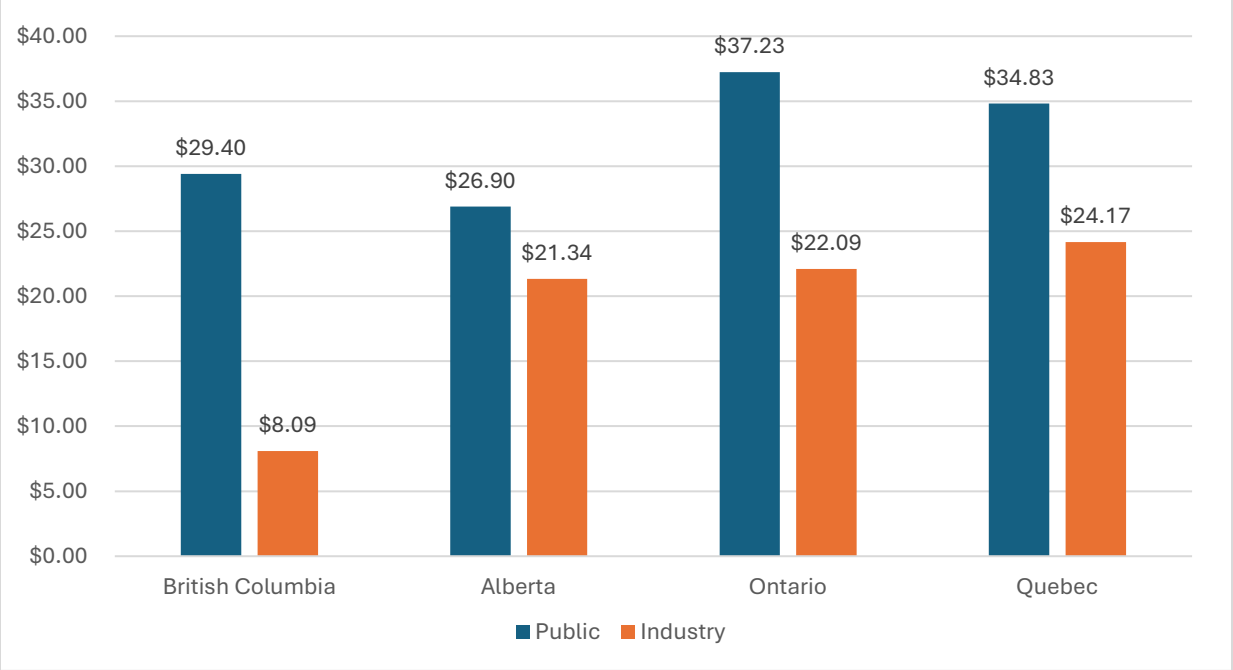
Today, British Columbia is under-indexed in its per capita funding of clinical trials – from both public and private investment, as compared to other leading provinces (see Table 1). From an economic perspective, British Columbia is missing out on opportunities for significant investment, despite being well matched in terms of expertise and capabilities. British Columbia boasts world class research facilities, leading scientists and clinicians, engaged and diverse patient populations, and the support of provincial and national government mandates to "streamline and facilitate research processes with the goal of enhancing clinical trials and other research studies in support of life sciences and health advancement opportunities"[8]. And yet, feedback from ecosystem participants is loud and clear: British Columbia is no longer competitive in a Canadian landscape that has multiple provincial counterparts offering better coordination, speed, and capacity.

As a result, the people of British Columbia are under-served. Clinical trials offer patients access to the latest, innovative treatments[9] that may not be available through standard care, providing new hope and potential for better outcomes—especially when conventional options fall short. Beyond advanced therapies, trials also ensure personalized care with close monitoring, and the opportunity to contribute to the future of medicine. Patients miss out on these life-changing opportunities simply because clinical trials are not part of the conversation. British Columbia must do more to ensure that every patient is informed about these vital options, empowering them to make the best choices for their health.

[5] Clinical Trials Market Report, Research and Markets. September 2023. Link
[6] Canada's Biomanufacturing and Life Science Strategy. Ministry of Innovation, Science and Economic Development and Ministry of Health, Government of Canada. 2021. Link
[7] Clinical trials environment in Canada. Government of Canada. Link
[8] PHSA Mandate Letter. BC Ministry of Health. 15 August 2023 Link
[9] Research is Care Briefing Document. COVID-19 Clinical Research Coordination Initiative. Faculty of Medicine, University of British Columbia. Link

For physicians and healthcare providers, offering clinical trials benefits not only their patients but also their practice and the broader medical community. Participation in clinical trials allows providers to stay at the forefront of medical advancements, giving them access to innovative treatments that could improve patient outcomes. It also provides the opportunity to be directly involved in groundbreaking research, contributing to scientific progress, which is an important differentiator in recruiting and retaining physicians[10]. Engaging in clinical trials can enhance a provider's reputation as a leader in their field, attract patients seeking the latest treatment options, and foster collaboration with researchers and pharmaceutical companies. Additionally, clinical trials can offer financial incentives to healthcare practices, as well as increased resources for patient care. In short, clinical trials enrich the provider-patient relationship, advance the standard of care, and contribute to the growth of medical knowledge.

Figure 1: Clinical Trial Funding, per Capita, by Province
Public[11] and Industry[12] Sources



British Columbia has lost ranking in the Canadian clinical trials landscape to Ontario, Quebec, and Alberta, as a first-choice destination for the conduct of clinical trials, as evidenced by the lower per capita R&D spend[13], and consistent feedback from industry representatives. Interviewees cite lengthy timelines for approvals and negotiations, coupled with nearly unnavigable bureaucracy, leaving clinician scientists frustrated and demotivated, patients in British Columbia excluded, and

[10] Does the engagement of clinicians and organisations in research improve healthcare performance: a three-stage review. Boza A, et al. BMJ Open. 16 October 2015. Link
[11] CIHR Investments in 2022-2023. See Appendix A, Table 1 for detail and source.
[12] Industry R&D Expenditures on Clinical Trials in 2022. See Appendix A, Table 1 for detail and source.
[13] Figure 1 above. For additional detail, see Appendix A: Provincial Comparative Analysis.

drug developers choosing to move significant R&D spend to other regions with collaborative policies, and with clinical trials delivery that significantly out-performs British Columbia.

In parallel, with unstable or inconsistent infrastructure to support clinical trial activities, British Columbia's researchers with investigator-initiated trials are less competitive in the public funding sphere. The lost opportunity for British Columbia is in the range of hundreds of millions of dollars annually, from industry R&D investment and public funds, which are awarded to equivalently experienced researchers in regions with superior infrastructure and efficient processes to support this complex and important work.

Economic Benefits

Participation in clinical trials delivers substantial advantages for British Columbia, not only by advancing medical research but also by driving economic growth and improving healthcare efficiency. These benefits ripple across multiple sectors, strengthening the province's health and economic systems.

- **Reduced Healthcare Costs**: Clinical trials can identify more effective treatments, potentially reducing long-term healthcare costs by improving patient outcomes and reducing the need for expensive, ineffective therapies.
- **Boost to the Economy**: Clinical trials fuel economic growth by attracting investment in medical research, creating jobs, and supporting the biotech and pharmaceutical sectors.
- **Faster Drug Development**: Expedited access to new treatments through clinical trials can reduce the time and cost of bringing new drugs to market, leading to cost savings for healthcare systems.

Patient Outcomes

Clinical trials offer transformative opportunities for patients, advancing medical care and ensuring equitable access to cutting-edge treatments. Increasing participation in trials enhances healthcare outcomes for individuals and communities alike.

- **Improved Patient Outcomes**: Trials provide access to innovative treatments, improving recovery rates and quality of life for patients with conditions that have limited treatment options.
- **Advancing Medical Knowledge**: Increased participation accelerates the development of new therapies, leading to better treatment options for a wider range of diseases.
- **Equity in Healthcare**: By fostering inclusivity in clinical trials, researchers ensure treatments are effective across diverse populations, promoting healthcare equity and extending the benefits of medical advancements to all communities.

CHALLENGES

In British Columbia, operational and systemic barriers are currently limiting the competitiveness and growth of clinical trials. Key challenges, detailed below, include study start-up delays, infrastructure constraints, institutional collaboration, anti-pharma sentiment, and lack of public engagement. These challenges collectively impact the province's ability to attract and retain clinical trial opportunities.

Study Start-Up Challenges

- **Lengthy Approval Processes**: The clinical trial start-up phase often experiences delays due to lengthy regulatory and ethics approval processes. The need to obtain multiple approvals from different bodies slows down the initiation of studies, making British Columbia less competitive compared to regions with more streamlined systems. Approvals in British Columbia can take three to four times longer than in provinces like Ontario and Quebec where six-to-eight-week durations are now the standard.

- **Contract Negotiations**: Prolonged contract negotiation timelines between sponsors, clinical sites, and research organizations further delay study start-up. Variability in contract terms and lack of standardized templates contribute to the time needed to initiate studies. This protracted process takes months to complete, reducing the time available for investigators to enroll participants in a clinical trial, as enrollment periods are fixed and competitive.

Infrastructure Constraints

- **Limited Integration in Clinical Care**: Clinical trials are often isolated from standard healthcare settings. Opportunities to identify eligible participants, streamline patient enrollment, and incorporate trial protocols into everyday care practices are missed. This separation results in duplicative workflows, increased administrative burdens, and reduced efficiency for both researchers and healthcare providers.

- **Technology Gaps**: There is a need for modern digital tools to streamline data collection, patient monitoring, and trial management. While most healthcare settings are now utilizing electronic health records (see Appendix C), the lack of allowable data integration for clinical trials results in paper-based, non-integrated records. Often when technology is available, it is outdated. In aggregate, these conditions result in inefficiency and have a direct impact on staffing. Additionally, this represents risk for patients and clinicians, due to limited ability to engage in data sharing, real-time monitoring, and efficient communication between interest-holders.

- **Workforce Shortages**: The unstable funding for core research positions, driven by the project-based nature of clinical trials, creates retention risks and challenges in recruiting and retaining skilled personnel. Critical roles such as clinical research coordinators, research nurses, research pharmacists, data managers, and regulatory specialists are in high demand yet difficult to fill and retain, as individuals in these roles face job uncertainty tied to the lifecycle of specific trials. Moreover, physicians are typically compensated in a

fee-for-service model, and without protected time for research are less inclined to prioritize opportunities for clinical trial participation which is often administratively burdensome. This instability exacerbates workforce shortages, limits British Columbia's capacity to conduct multiple concurrent trials, and places considerable strain on existing resources, undermining the province's ability to fully leverage its healthcare system to advance research in an integrated and sustainable manner.

- **Inconsistent Funding**: The unpredictable nature of funding cycles makes it difficult for institutions and research teams to plan long-term, invest in essential infrastructure, or retain skilled personnel critical to trial success. Training is time-intensive and requires both virtual and on-the-job training. High rates of staff turnover due to funding instability increases the risk of regulatory non-compliance and can compromise data quality and patient safety when new staff are learning organizational policies, procedures and clinical trial protocols with insufficient support while trials are underway. Without stable financial support, clinical sites may struggle to maintain the necessary resources and workforce, resulting in project delays, reduced trial capacity, and an inability to keep pace with innovations and advancements in clinical research. For independent clinical trial sites this can mean businesses closing and jobs lost. In 2012, two long standing community sites closed their doors[14], one of these had enrolled more than 20,000 participants since the 1980s and employed a staff of 20 including nurses and regulatory specialists. This instability limits British Columbia's attractiveness as a hub for high-quality clinical trials and hampers its ability to compete with regions that offer more reliable, continuous funding for research infrastructure.

These operational and systemic barriers collectively hinder British Columbia's clinical trials landscape. Efforts to standardize processes, improve infrastructure, and reduce administrative burdens are essential to enhance the province's competitive edge in attracting high-quality, impactful clinical trials.

Institutional Collaboration, Anti-Pharma Sentiment, and Bureaucracy

- **Institutional Collaboration Barriers**: Collaboration between academic institutions, healthcare providers, and the pharmaceutical industry in British Columbia often faces challenges due to misaligned objectives, varied organizational cultures, and complex processes. Differences in research priorities and operational structures can create friction, slowing down the development and implementation of collaborative clinical research projects. Without a unified approach, British Columbia struggles to compete with regions that have more cohesive, integrated clinical research networks.
- **Anti-Pharma Sentiment**: Public and institutional skepticism toward the pharmaceutical industry is a significant barrier, particularly in discussions around clinical trials. Concerns over conflicts of interest, data transparency, and profit-driven motives can hinder

[14] From interview with ecosystem participant

recruitment efforts and influence public perception of clinical research initiatives[15,16]. Ongoing cost recovery litigation[17,18,19,20] is headline news and influences public opinion away from the benefits of working with pharmaceutical companies. This sentiment often leads to reluctance among potential investigators, administrators, and service delivery leaders.

- **Bureaucracy and Administrative Complexity**: Clinical trials in British Columbia are affected by extensive bureaucratic requirements that add complexity to the research landscape. Approval processes, documentation requirements, and protocol reviews are frequently delayed by administrative bottlenecks across multiple agencies. The involvement of numerous institutional bodies, each with its own requirements and standards, leads to a protracted and fragmented system that hampers the efficiency of trial start-up, progress, and completion. Additionally, redundant or outdated policies and a lack of alignment across entities make it difficult to streamline processes, adding to administrative costs and delaying research activities.

In addition to operational barriers, these collaborative, societal, and bureaucratic challenges compound the difficulties faced by British Columbia's clinical trials sector. Addressing these barriers will require not only operational improvements but also efforts to build trust, enhance collaboration across institutions, and reduce bureaucratic obstacles. By focusing on these areas, British Columbia can work toward a more cohesive, efficient, and publicly supported clinical research environment that attracts global trials and fosters growth.

Public Engagement Challenges

- **Patient Recruitment and Retention**: Public engagement, particularly in the context of patient recruitment, remains a major challenge for clinical trials in British Columbia. The public often has limited awareness of clinical trials and their benefits, which results in low participation rates. Misinformation or misunderstandings about the purpose and safety of clinical research contribute to this reluctance. Additionally, lack of trust in the clinical research process, fueled by anti-pharma sentiment, can further deter potential participants.
- **Community Involvement and Trust Building**: Effective engagement with communities is essential to ensure diverse representation in clinical trials, yet British Columbia faces challenges in building meaningful partnerships with local organizations and community leaders. This lack of involvement reduces awareness and trust in clinical research,

[15] Commercial concerns may influence whether clinical trials results are reported, says study. Therapeutics Initiative, UBC. 21 Mar 2022. Link
[16] BC addiction centre should not accept drug industry funds. Canadian Affairs. 30 August 2024. Link
[17] BC suing drug companies for opioid crisis healthcare costs. CityNews. 29 August 2018. Link
[18] BC-led lawsuit nets $150M proposed settlement with Purdue Pharma over opioid harms. Life Sciences BC Communications. 29 Jun 2022. Link
[19] BC can pursue class-action suit on opioid providers, top court rules. The Canadian Press. 29 Nov 2024. Link
[20] The Much Broader Future of Cost Recovery Litigation in British Columbia. McCarthy Tetrault. 25 June 2024. Link

especially in communities that are historically underserved or skeptical of medical research institutions. Without strong community engagement efforts, it becomes difficult to foster a supportive environment for clinical trials and address specific local needs and concerns.

- **Democratization and Inclusion of Underrepresented Populations**: The democratization of clinical trials involves breaking down barriers to ensure equitable access and participation for all populations, regardless of geography, socioeconomic status, or cultural background. In British Columbia, rural populations and diverse patient groups, including Indigenous peoples, remain underrepresented in clinical trials, which limits the inclusivity and generalizability of research findings. Geographic barriers, such as distance from research facilities, significantly hinder participation from rural patients. Logistical issues—such as transportation, accessibility of trial sites, and insufficient remote participation options—further exclude these populations. Additionally, a lack of culturally safe and targeted recruitment strategies for diverse communities perpetuates a homogenous participant pool. This not only fails to reflect the broader patient population but also risks neglecting unique health disparities and conditions faced by underrepresented groups. Embedding principles of cultural safety, particularly for Indigenous communities, alongside tailored outreach and inclusive trial designs, is essential to achieving true democratization of clinical research.

The challenge of public engagement, especially in patient recruitment, community involvement, and the democratization of clinical trials, represents a significant barrier to effective and inclusive clinical research in British Columbia. Addressing these issues will require targeted outreach, community partnerships, and flexible, decentralized trial designs that allow for broader and more representative participation. Improving public engagement strategies and making clinical trials more accessible to underrepresented groups will not only enhance the inclusivity of clinical research but also contribute to more comprehensive, equitable health outcomes across British Columbia's diverse population.

OPPORTUNITIES

Evaluating the Strength of British Columbia's Clinical Trials Ecosystem

A strong clinical trials ecosystem is characterized by a set of interdependent components that foster research, ensure high standards of care, streamline research review and approval processes, and promote public trust. British Columbia's current position varies, by component, and in aggregate is under-developed.

British Columbia's clinical trials ecosystem has made notable advancements in recent years[21], with significant contributions to vaccine development, cancer immunotherapy, and treatments for chronic diseases such as diabetes, COPD, and multiple sclerosis. Despite these successes, the province's ecosystem remains unevenly developed across key components. While initiatives by organizations like Michael Smith Health Research BC through its Clinical Trials BC team have improved coordination and provided support mechanisms, and investments in infrastructure and decentralized trial models have expanded accessibility, challenges persist in achieving full integration, partnering more effectively with industry, streamlining review and approval processes, and fostering public engagement. Addressing these gaps is essential to realizing the full potential of British Columbia's clinical trials landscape.

To illustrate this, a scorecard has been prepared to rate each of the interdependent ecosystem components in terms of maturity. The ratings are informed by the research and interviews conducted through the course of this project. The ratings are defined as:

1. **Foundational:** The component is minimally developed, with few structures or processes in place. There is limited evidence of activity, investment, or engagement in this area, and significant development is needed.

2. **Developing:** Basic structures and processes are present, but effectiveness and consistency are limited. There is some activity and investment, though gaps exist, and improvements are needed to meet standards or achieve consistency.

3. **Advancing:** The component shows moderate development, with growing consistency and effectiveness. Structures and processes are functional, though some areas require further enhancement to optimize performance or integration with other components.

4. **Established:** The component is well-developed and consistently meets standards, with strong, effective structures and processes in place. Minor areas may still benefit from optimization, but overall, this component is reliable and robust.

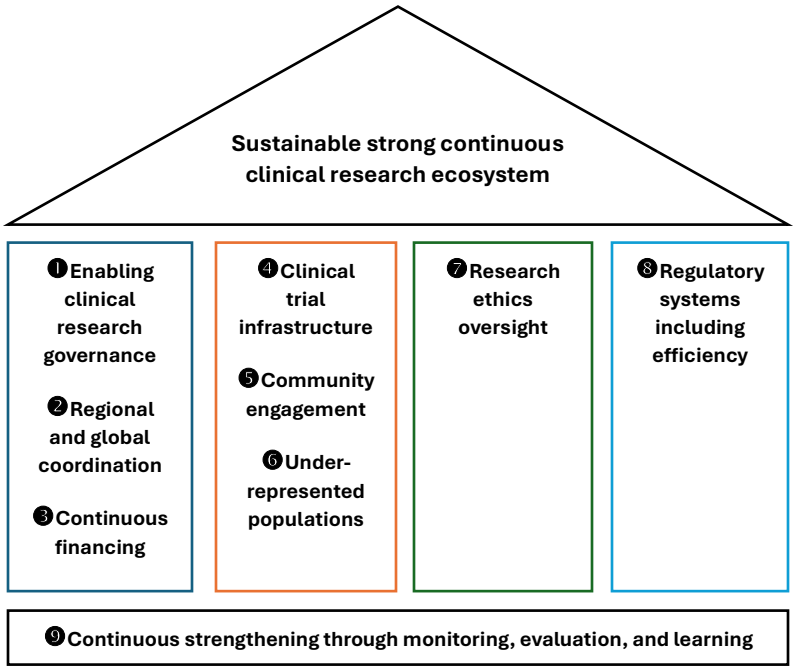
5. **Exemplary:** The component is fully developed and represents best practices within the ecosystem. Processes are highly effective, integrated, and adaptable. This component sets a standard for excellence and operates at a high level of performance and innovation.

[21] See Appendix B: History of Clinical Trial Infrastructure in British Columbia

The Components of a Strong Clinical Trials Ecosystem

The World Health Organization's Global Clinical Trials Forum[22] posits a model for a sustainable, strong, continuous clinical research ecosystem (see Figure 2). This model guided the inquiry and informed the recommendations.

Figure 2: Clinical Trial Ecosystem Pillars[23]



Together, these components create a supportive environment for research, protect patient welfare, and accelerate the development of new therapies.

- **❶ Enabling clinical research governance**
  Effective ecosystems are built on partnerships among academic institutions, healthcare providers, pharmaceutical and biotech companies, and government agencies, with oversight and accountability vested in a centralized governance body. This body must be mandated and empowered to advance clinical trials by coordinating efforts, addressing systemic barriers, and aligning goals across diverse interest-holders. These collaborations facilitate shared resources, expertise, and streamlined pathways for advancing clinical research and delivering therapies to patients. Inclusive governance ensures that the voices of all interest-holders including patients and underserved communities, are represented, fostering trust and transparency. In a collaborative research infrastructure, a resilient ecosystem emerges, that can adapt to new research paradigms, regulatory changes, and technological advancements. For example, flexibility to accommodate decentralized trials, adaptive trial designs, and innovations like

[22] Guidance for best practices for clinical trials. World Health Organization. 25 September 2024. Link
[23] The future of the global clinical trial ecosystem: a vision from the first WHO Global Clinical Trials Forum. The Lancet. 13 January 2024. Link

precision medicine trials ensure that the ecosystem remains relevant and responsive to emerging needs, while governance ensures accountability and sustained progress.

- ❷ **Regional and global coordination**
  Robust collaboration among regions and nations, with harmonized regulatory frameworks, and aligned ethical standards ensures seamless cross-border clinical trials. By promoting the sharing of resources, expertise, and data, the model enhances efficiency, reduces duplication of efforts, and accelerates the development of medical innovations. Regional hubs are envisioned as key facilitators, bridging local research capabilities with global networks to address health priorities equitably and effectively.

- ❸ **Continuous financing**
  Sustainable funding from both public and private sectors is vital. Public funding sources, government grants, and R&D investment from the private sector fuel innovation and support a diversity of trials across therapeutic areas. A thriving ecosystem often has financial incentives or tax credits to encourage ongoing investments from both established companies and emerging startups.

- ❹ **Clinical trial infrastructure**
  Infrastructure in clinical trials is far more than facilities and staffing. Clinical trials require operational efficiency via streamlined, documented processes and adherence to international quality standards (e.g., Good Clinical Practice). Efficient trial management processes, including protocol optimization, standard operating procedures, and risk-based monitoring, improve trial performance and ensure data accuracy and participant safety. Additionally, reliable data infrastructure, including electronic health records, patient registries, and centralized data platforms, enhances trial efficiency, data integrity, and participant safety. The integration of advanced digital tools, such as remote monitoring, wearables, and AI-driven data analysis, supports real-time decision-making and improves trial design, patient selection, and outcome measurement.

- ❺ **Community engagement**
  Successful ecosystems actively involve patients and the public in research design, advocacy, recruitment, and dissemination of results. Public involvement helps ensure that clinical trials address relevant health needs and build trust. Patient advocacy groups and educational initiatives empower participants to understand the benefits and risks of clinical trials, fostering recruitment and engagement.

- ❻ **Under-represented populations**
  Including under-represented populations in clinical trials ensures equity and broader applicability of findings. This aspect of the model calls for intentional outreach, engagement, and recruitment strategies to involve diverse demographic groups, including Indigenous populations, rural communities, and those with limited access to healthcare systems. In British Columbia, this focus aligns with efforts to engage Indigenous communities in health research through culturally sensitive practices and partnerships with organizations like the First Nations Health Authority. BC's diverse population and unique geographical challenges necessitate targeted initiatives to ensure under-represented groups are not only included but actively

involved in shaping research priorities and methodologies, enhancing the relevance and impact of clinical trials for all communities.

- **❼ Research ethics oversight**
  Ethical standards, transparency, and accountability are crucial for maintaining public trust. Independent ethics boards, comprehensive informed consent processes, and transparent reporting of results contribute to participant safety and trust. Publicly accessible trial registries and reporting of all results, including negative findings, ensure transparency.

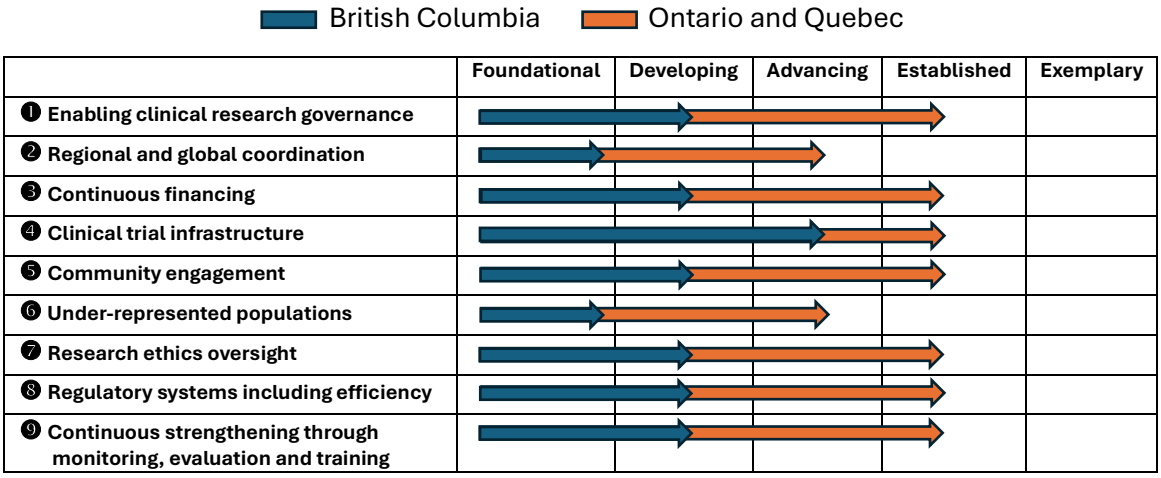
- **❽ Regulatory systems including efficiency**
  Robust regulatory frameworks are essential for ensuring that clinical trials are conducted ethically and in compliance with international standards. Efficient regulatory processes—such as streamlined ethics approvals and adaptive trial designs—can accelerate timelines without compromising quality. Agencies like Health Canada provide oversight, and research ethics review boards ensure patient safety and efficacy while fostering innovation.

- **❾ Continuous strengthening through monitoring, evaluation, and learning**
  A skilled workforce is essential for conducting high-quality clinical trials. Educational programs, certifications, and professional training for clinical researchers, coordinators, data managers, and regulatory specialists improve the expertise within the ecosystem. Ongoing training also ensures adherence to evolving standards and regulations. Additionally, effective ecosystems support pathways for translating research findings into real-world healthcare practices. This includes support for Phase IV and real-world evidence (RWE) studies, which can inform clinical guidelines and policy. Efficient IP management, technology transfer offices, and close collaboration with healthcare providers can facilitate the transition from clinical trials to healthcare solutions.

Ecosystem Scorecard

Based on the research and interviews conducted for this project, the maturity of the British Columbia clinical trials ecosystem, compared to Ontario and Quebec, is rated in Figure 3.

Figure 3: Maturity of British Columbia's Clinical Trial Ecosystem



British Columbia's Strategy for Enhanced Competitiveness and Growth

As British Columbia seeks to increase competitiveness and growth in clinical trials, advancing the maturity of the clinical trials ecosystem will be critical. What it takes to move toward exemplary is collaboration and investment. As evidenced in every interview conducted for this project, the willingness is strong. The desire to make progress is evident in the dedication and commitment of every interest-holder who is today finding it unnecessarily effortful to make a positive impact in the current environment.

The following strategies are recommended as priorities to enhance competitiveness and growth:

Establish a Centralized Ecosystem Convener

Creating a delegated, empowered coordinating body is essential to unite the diverse members of British Columbia's clinical trials ecosystem and advancing the province's competitive positioning. This mandated convener must act as an empowered brand leader, actively promoting British Columbia as an ideal location for clinical research while directly engaging with industry to stimulate economic growth and facilitating robust collaboration within the province and across Canada. By optimizing resources, balancing competing priorities, and representing public and community interests, the convener will foster a more cohesive, resilient, and effective ecosystem that supports sustainable growth. Furthermore, such a body, which does not currently exist, would play a critical role in advocating for and implementing strategies to advance clinical trials by aligning the efforts of ecosystem participants in a coherent and focused manner.

Mandate Centralized and Harmonized Review Mechanisms

Enforcing participation in centralized, standardized, harmonized review processes will streamline administrative workflows, reduce start-up times, and enhance the protection of human subjects, scientific integrity, and regulatory compliance.

Integrate Clinical Trials in Clinical Care

Integrating clinical trials into standard healthcare practices, including health system funding for essential clinical trial staff, will help bridge clinical research with direct patient care, advancing both innovation and quality of care.

Leverage Health Data

Elevating health data integration will enable seamless access to high-quality data, supporting research efficiency and more informed decision-making across clinical trials.

This structured approach will strategically position British Columbia to attract investments, foster innovation, and strengthen its role as a leader in clinical research and life sciences.

These strategies are examined in detail in the next section.

ACTIONABLE INSIGHTS

Increasing competitiveness and fostering growth of clinical trials in British Columbia depends on the ability to collectively act with a sense urgency to address the operational barriers that persist. Evidence of success with this approach can be seen in other provinces, such as Ontario and Quebec, as well as at the national level in Australia, Denmark, Norway, and the United Kingdom.

Addressing the obstacles preventing this growth is paramount. In addition to optimizing research investment and reducing waste, making the conduct of clinical trials more efficient is more attractive to future investment. It is the right way to future-proof this critical aspect of the economy and healthcare delivery, through smarter allocation of resources, focus on harmonization of processes, and overall reduction of administrative burden – while strengthening protection of human subjects, scientific integrity, and regulatory compliance.

Specifically, British Columbia will improve competitiveness and foster growth by:

- **Establishing an ecosystem convener**
- **Mandating participation in centralized / harmonized review mechanisms**
- **Integrating clinical trials in clinical care**
- **Leveraging health data**

These actionable insights are described in detail below.

Establish an ecosystem convener

An ecosystem convener is a coordinating body that connects and aligns diverse interest-holders—such as government, industry, academia, and public interest groups—within a particular ecosystem. Its role is to facilitate collaboration, optimize resource use, and balance competing priorities to drive sustainable growth. By serving as a facilitator, the convener ensures that collective goals are met while also representing community and public interests, creating a more cohesive, resilient, and effective ecosystem.

The clinical trials ecosystem in British Columbia has a rich history of innovation and collaboration, yet it remains fragmented in addressing the growing demands of global industry players, government interest-holders, academic institutions, and the public. As evidenced by the establishment of key infrastructure and initiatives over the decades[24], such as the creation of the British Columbia Clinical Research Infrastructure Network (BCCRIN) and the BC Cancer Agency (now BC Cancer Research Institute), the province has built a strong foundation but lacks a centralized, empowered intermediary to unify and advance its ecosystem. The need for an effective ecosystem convener—a dedicated coordinating body mandated to align diverse interests—has become critical to driving growth, innovation, and competitiveness. Such a convener would optimize resources, bridge institutional silos, and advocate for British Columbia on the national and international stage, while ensuring that community needs, public interests, and patient equity remain central to its mission.

[24] See Appendix B: History of Clinical Trial Infrastructure in British Columbia

Clinical trials work undertaken by Clinical Trails BC as part of Michael Smith Health Research BC and previously through the Academic Health Science Network and BCCRIN, has been and continues to be an important part of British Columbia's research infrastructure. Operating as a branded portfolio within Michael Smith Health Research BC, Clinical Trials BC is not a stand-alone organization however, and lacks the autonomy, scale, and resources necessary to unify the diverse interest-holders across government, industry, academia, and healthcare into a cohesive, coordinated ecosystem. As a portfolio of work, it has funding limitations and a mandate that flows from the larger organization's strategy, governance, and not-for-profit purposes under *The Societies Act (British Columbia)*. As a workstream it cannot be considered an ecosystem convener for the province due to these limitations.

Unlike established ecosystem conveners in other provinces, such as CATALIS in Quebec or Clinical Trials Ontario, Michael Smith Health Research BC's clinical trials team operates with a significantly smaller staff and budget, limiting its capacity to facilitate large-scale collaborations, streamline processes, and advocate for British Columbia's interests on a national and international stage. Its focus is primarily operational and tactical, rather than strategic, leaving gaps in the leadership and integration needed to overcome systemic barriers and foster growth in the clinical trials sector. Every other province reviewed has an entity with a specific and singular focus on driving competitiveness for clinical trials in their jurisdiction (see Appendix A: Provincial Comparative Analysis).

The lack of an empowered, dedicated ecosystem convener leaves British Columbia fragmented and underperforming compared to other provinces, where centralized, well-resourced bodies actively drive competitiveness, streamline operations, and attract significant R&D investments. Addressing this gap is critical to advancing British Columbia's position as a leading destination for clinical trials.

The power of the ecosystem convener is evident in other regions. Clinical Trials Ontario and CATALIS Clinical Trials Quebec are strong exemplars of this model at the provincial level in Canada. On the global scene, national ecosystem conveners in Australia (Australian Clinical Trials Alliance), Denmark (Trial Nation), Norway (NorTrials), and the UK (National Institute for Health and Care Research) are fostering growth by increasing the number of clinical trials in their countries. What they have in common, that is missing in British Columbia, is the role of an empowered brand leader that will promote British Columbia's interests, provide leadership and governance for the provincial clinical trials ecosystem, and create a pathway to growth that is receptive to industry investment.

The Canadian landscape remains fragmented, due to the decentralized, publicly funded system where each province and territory independently manages healthcare services within the framework of *The Canada Health Act*. This decentralized model creates unique challenges for fostering the growth of clinical trials in Canada, as there is no single, unified national mandate for clinical research. Instead, each province has its own processes, ethics boards, and regulatory frameworks, leading to inconsistencies and inefficiencies that can delay study approvals and complicate multi-site trials. In contrast, countries with centralized healthcare systems can streamline clinical trial processes through unified regulations and standardized approaches, making Canada less competitive globally.

Evidence of this as an inhibitor for Canadian participation in research on the world stage was highly evident during the COVID-19 pandemic. Canada faced significant challenges in scaling up clinical trial participation, partly due to its decentralized healthcare system. While countries with centralized healthcare infrastructures were able to quickly mobilize resources and streamline processes for COVID-related trials, Canada struggled with regional inconsistencies and fragmented decision-making across provinces and territories. Each province has its own ethics boards and administrative pathways for clinical trials, creating bottlenecks in approval and coordination. As a result, Canada experienced delays in launching trials, limiting its ability to participate in large-scale, multi-site studies and to respond swiftly to the urgent need for COVID-19 research.

Moreover, the lack of a unified, national approach to clinical trials meant that Canada could not leverage its full research capacity or easily coordinate resources across regions. This fragmented response also made it challenging to recruit patients on the scale seen in other countries, as regional disparities in healthcare delivery and trial access led to uneven opportunities for participation.

While Canada has a robust research community, its decentralized system hindered its ability to rapidly adapt and contribute to global COVID-19 research efforts. This highlighted the need for improved national coordination in clinical trials, which could better position Canada for future large-scale health crises and strengthen its role in global health research.

British Columbia's role in the solution is to prioritize establishing efficient, cross-provincial collaboration and standardization, bolstering British Columbia's clinical trials ecosystem to attract greater research investment. A well-positioned convener would serve as an empowered facilitator, connecting government, industry, academia, and public interest groups to foster a collaborative environment. This role would streamline efforts by coordinating resources, balancing competing priorities, and establishing a foundation for sustainable economic growth that benefits all participants. A key attribute of the convener organization would include cross-provincial collaboration in support of strengthening British Columbia's position on the national stage.

Specifically, the convener would:

- **Establish a governance and mandate** that builds on British Columbia's unique assets and is focused on competitive decision making.
- **Establish a sustainable funding model** that engages all interest-holders within the ecosystem. This model should include mechanisms such as direct funding, membership contributions, or co-investment initiatives to ensure collective accountability and shared commitment.
- **Facilitate strategic partnerships**: By actively engaging with and building connections across sectors, the convener would accelerate the formation of effective partnerships, driving investment and fostering innovation across the British Columbia clinical trials sector.
- **Optimize resource allocation and efficiency**: A dedicated intermediary would identify overlapping initiatives, streamline processes, and help align objectives, maximizing the impact of public and private investments while reducing redundancies.

- **Promote socio-economic balance**: Recognizing the need to balance economic growth with community well-being, this convener would work to ensure that clinical trial activities are conducted responsibly and ethically, fostering a stable and sustainable ecosystem.
- **Enhance community and patient engagement**: As public trust and participation are key to clinical trial success, this role would prioritize transparent communication and patient advocacy, ensuring public interests are represented and effectively integrated into decision-making processes.
- **Represent British Columbia's interests on the national scene**: Collaborating with counterparts in other provinces to advocate for streamlined, harmonized processes, while also promoting British Columbia's unique assets, such as its research expertise, innovative health technology sector, and diverse population. By aligning British Columbia's clinical trials goals with national priorities, the convener would help ensure that British Columbia's specific needs and contributions are recognized in federal policies and funding allocations.

In adding this coordinating body to the ecosystem, British Columbia can position itself as a national leader in clinical research, with an inclusive, efficient, and transparent framework that supports innovation while respecting community values. This addition would bring significant long-term value by creating a structure that supports resilience, adaptability, and inclusive growth across the sector.

Mandate participation in harmonized processes

Mandating participation in centralized, standardized and harmonized review and approval mechanisms for ethics, contracts, and capacity review for operational approval can benefit a provincial government's goal of fostering competitiveness and growth in clinical trials. Here is why such a mandate would be crucial for British Columbia:

- **Reduced administrative burden**: Centralized and harmonized review and approval processes streamline the complex, time-consuming administrative tasks typically spread across multiple institutions and review boards. By unifying ethical and contractual reviews into a single process, redundancies are minimized, and resources can be directed towards more productive, research-focused activities. This can especially benefit smaller or less-resourced organizations that struggle to keep up with the demands of decentralized, duplicative review processes.
- **Accelerated study start times**: Delays in starting clinical trials often stem from sequential and varied reviews, which can differ in requirements, timelines, and criteria. Centralized reviews standardize and synchronize processes, significantly reducing start-up times. When study approvals occur more swiftly, the province can attract a larger volume of trials, helping companies and institutions become more competitive on both a national and international scale.
- **Enhanced protection of human subjects**: Centralized ethical review mechanisms ensure that high standards for human subject protection are consistently applied across all trials. They enable expert oversight committees with deep knowledge of ethical standards and regulatory frameworks to evaluate risks effectively. This harmonized approach reduces variability in ethical assessments, strengthens protections for participants, and improves public confidence in the clinical trials conducted in the province.

- **Improved scientific integrity**: When scientific review and ethics oversight are centralized, they become more rigorous and consistent, which enhances the scientific quality of trials. Centralized reviews also allow for greater transparency and accountability, reducing the potential for conflicts of interest and bias. This contributes to the overall credibility and trustworthiness of the province's clinical research output, further positioning it as a leading and reliable location for clinical trials.
- **Regulatory compliance**: Harmonized review mechanisms can align with provincial and federal regulations more efficiently, reducing the risk of non-compliance. By adhering to consistent standards, organizations can meet or exceed regulatory expectations, ensuring that trials are not only safe but also more readily able to meet approval requirements. This streamlined regulatory alignment can make the province an attractive location for trial sponsors who want to avoid redundant regulatory hurdles.
- **Increased competitiveness and growth**: A centralized, efficient review system creates a favorable environment for clinical trials, making the province a more attractive destination for life sciences companies and research organizations. Reduced administrative burdens, faster trial initiation, and robust standards for participant protection and regulatory compliance make the region more appealing for investment in clinical research, fueling sector growth and leading to economic benefits through job creation and knowledge-based innovation.

By mandating participation in such harmonized review and approval systems, the provincial government can facilitate a competitive, well-regulated, and ethically responsible clinical trial ecosystem that benefits patients, research institutions, and industry interest-holders alike.

Integrate clinical trials in clinical care

Integrating clinical trials into clinical care with dedicated health system funding for clinical trial staff addresses two significant barriers to growing a robust clinical trial ecosystem: the difficulty of retaining specialized staff between trials and the inability to start up new trials quickly when specialized staff are not readily available. Here is how this approach directly resolves these issues:

- **Bridge funding for staff retention**: One of the biggest challenges in clinical trials is the high turnover of specialized staff, such as clinical research coordinators, research nurses, pharmacists, data managers, and regulatory specialists, due to gaps in funding between trials. Without continuous funding, these highly trained professionals are often forced to seek alternative employment, leading to a loss of valuable expertise and a costly, time-intensive process of hiring and retraining when new trials are initiated. By embedding clinical trial staff within the health system and providing bridge funding, the province can retain specialized staff between trials. This stability not only preserves their expertise and institutional knowledge but also reduces the costs and delays associated with recruiting and onboarding new staff for each trial.
- **Rapid trial start-up**: Without specialized staff in place, it can take months to recruit, hire, and train personnel before a trial can begin. Study start-up time is a highly competitive performance metric and is often the deciding factor in the selection of a clinical trial site by a trial sponsor. British Columbia's poor performance in this area deters sponsors from selecting trial sites in the province, and diverts R&D spend to other provinces where performance is reliably better. By

having dedicated, continuously funded clinical trial staff within the health system, the province ensures that skilled professionals are available to start up new trials quickly. This "ready-to-go" model allows trials to launch rapidly, giving the province a significant competitive advantage in attracting trial sponsors who prioritize speed and efficiency. It also enhances the province's reputation as a reliable, efficient location for high-quality clinical research.

- **Sustained expertise and efficiency**: Specialized staff play a critical role in navigating complex regulatory requirements, ensuring patient safety, and maintaining trial data quality. Frequent turnover or a lack of qualified staff can lead to costly errors, compliance issues, and delays. With integrated, stable funding for these positions, the health system can build a workforce of experienced professionals who are adept at managing the intricacies of clinical trials. This sustained expertise allows for higher-quality trial conduct and creates a culture of operational excellence that further strengthens the province's position as a competitive research hub.
- **Elimination of start-stop cycles**: The typical "start-stop" cycle of clinical trials, driven by intermittent staffing and funding gaps, undermines continuity and efficiency. Integrated health system funding removes these disruptions by ensuring a constant level of operational support. This continuity not only enhances trial timelines and quality but also makes it easier to coordinate multiple, overlapping trials without interruptions, maximizing the use of resources and patient access to trials.
- **Increased attractiveness to industry and research sponsors**: Sponsors seek regions with streamlined, efficient clinical trial operations, and they value sites where they can count on stable staffing and rapid study initiation. By funding and integrating clinical trial staff within the health system, the province can signal to sponsors that it has a robust, ready workforce capable of meeting fast-paced clinical research demands. This model attracts more trials to the province, drives further investment, and strengthens the local life sciences sector.
- **Stronger talent pipeline and professional development**: Consistent funding for trial staff positions allows the province to attract, develop, and retain top talent in clinical research. It enables professionals to build long-term careers in the clinical trials sector, knowing they will not face job instability between studies. This attracts skilled professionals and makes the province a destination for top-tier talent, who, in turn, contribute to higher-quality research and improved trial outcomes.

By integrating clinical trials into the healthcare system and securing ongoing funding for critical positions, the province creates a sustainable ecosystem that eliminates costly, time-consuming cycles of staffing turnover and delays in trial start-up. This was repeatedly emphasized in interviews as a major concern with the status quo, and a priority to aid in attracting and retaining healthcare professionals. This model addresses two of the primary barriers to growth in clinical trials, making the province a competitive and reliable location for conducting high-quality research and ensuring consistent access to advanced therapies for patients.

Leverage health data

Integrating electronic health records (EHRs) into clinical trial design and execution offers compelling advantages for a provincially administered health care delivery system, not only improving research efficiency but also delivering substantial benefits to the broader health care delivery framework. By prioritizing health data integration, provincial systems can streamline trial

processes, expedite participant recruitment, and reduce redundancies in data collection. Both Health Canada and the U.S. Food and Drug Administration (FDA) have increasingly advocated for using real-world data (RWD), including EHRs, to inform trial design and regulatory decisions. Health Canada's recent guidance on leveraging RWD to support evidence-based decision-making[25], combined with the FDA's framework for Real-World Evidence (RWE)[26], underscores the value of a data-driven approach. By embracing this integration, provincial health systems align with the latest regulatory expectations, positioning themselves at the forefront of innovative, patient-centered research.

Beyond improving clinical trials, integrating EHR data enhances health system operations and supports a Learning Healthcare System (LHS) model[27]. An LHS is a health care framework where patient care is continuously improved through the systematic integration of clinical data and outcomes, feeding real-time insights back into the system to refine and evolve care practices. By embedding EHR data from clinical trials into the broader health system, provincial systems can create a dynamic feedback loop. This integration allows health providers to leverage trial insights directly within clinical workflows, leading to faster adoption of effective treatments and ensuring that patient care continually evolves based on the latest evidence. Such a model aligns with Health Canada's vision of patient-centered care that adapts to emerging health insights and the FDA's encouragement of adaptive trial designs, both of which enhance the quality and speed of care delivery[28].

Integrating EHR data into clinical trials also offers substantial benefits to investigator-initiated research, that often faces challenges in accessing timely data and sufficient participant pools (see Appendix C). EHR integration enables these researchers to leverage RWD directly from healthcare settings, improving their ability to design studies that reflect real patient populations and healthcare outcomes. With access to large datasets from EHRs, investigator-initiated studies can more efficiently identify potential study participants based on clinical criteria, expediting recruitment and enhancing the representativeness of the study population. This data-driven approach enables investigators to monitor outcomes and adverse events in real time, supporting adaptive study designs that can respond dynamically to emerging data. Additionally, integrated EHRs provide longitudinal health information, which is invaluable for post-market surveillance studies and long-term observational research, allowing investigators to track patient outcomes over extended periods. By aligning with Health Canada and FDA's emphasis on real-world evidence, investigator-initiated researchers can ensure their studies meet high regulatory standards, enhancing their impact and making it easier to translate findings into clinical practice.

Additionally, data integration supports population health initiatives, allowing provincial systems to identify trends, track disease progression, and allocate resources more effectively. Integrated data

[25] Optimizing the Use of Real World Evidence to Inform Regulatory Decision-Making. Health Products and Food Branch Notice. Health Canada. 16 April 2019. Link
[26] Framework for FDA's Real-World Evidence Program. US Food and Drug Administration. December 2018. Link
[27] The Potential of Learning Healthcare Systems. The Learning Healthcare Project. November 2015. Link
[28] Fixing the Clinical Trials System by FDA Commissioner, Robert M. Califf, MD. JAMA Summit Keynote. October 10, 2023. Link

not only improves individual patient outcomes but also enables more comprehensive public health monitoring, reducing the cost and administrative burden of healthcare delivery by identifying preventative care opportunities and optimizing resource allocation. This continuous learning loop, fostered by the LHS model, leads to a more responsive, efficient, and adaptive health system, improving care quality across populations.

By prioritizing health data integration, provincially administered health systems enhance their operational efficiency, establish compliance with international regulatory guidance, and support the development of a more resilient and informed health care model. As health data integration transforms the way clinical trials are conducted, provincial health systems that embrace this innovation can lead the way in creating a model of care that is both evidence-driven and continuously learning, benefiting patients, providers, and the health care system.

Models of health data collaboration between health care systems and drug developers are already underway in several countries, providing strong examples of the benefits of this partnership. The United Kingdom's National Health Service (NHS) has set up partnerships with pharmaceutical companies under the Clinical Practice Research Datalink (CPRD) initiative[29], which provides anonymized patient data to researchers and drug developers for clinical trials and observational studies. This access has significantly improved the speed and efficiency of trials, supporting evidence-based decisions that benefit both drug developers and public health. Similarly, Denmark's national health database allows drug companies to access EHR data to support studies in diverse therapeutic areas. Through this collaboration, the Danish healthcare system supports rapid recruitment and comprehensive safety monitoring, enabling drug developers to generate high-quality, real-world evidence that meets European Medicines Agency (EMA) and FDA standards[30,31].

By establishing similar partnerships with drug developers, the provincial health system can not only drive innovation in clinical research but also create new revenue streams that support reinvestment in healthcare infrastructure. These collaborations foster an ecosystem of data-sharing that benefits all interest-holders, from patients who gain access to innovative therapies to healthcare providers who receive better-informed insights for patient care. As a result, British Columbia can position itself as a global leader in efficient, data-driven drug development, benefiting patients, healthcare providers, and the pharmaceutical industry alike. This vision of integrated health data, regulatory alignment, and industry collaboration creates a win-win ecosystem that accelerates drug development, improves patient outcomes, and supports a continuously learning healthcare system.

[29] Clinical Practice Research Datalink. UK Medicines & Healthcare products Regulatory Agency. Link
[30] National Health Registers. Danish Health Data Authority. Link
[31] National Danish Research Data Gateway Assists Researchers with Accessing Data. Ministry of Foreign Affairs of Denmark. Link

CLOSING

British Columbia stands at a pivotal moment in its journey to strengthen its competitive position in the global clinical trials landscape. With its unparalleled research facilities, top-tier scientific talent, and diverse patient population, the province is well-equipped to lead the charge in advancing medical research and innovation. Yet, to fully realize this potential, a focused and collaborative effort is needed to overcome existing barriers and seize emerging opportunities.

This report outlines a clear and actionable path forward. Establishing an empowered ecosystem convener will unify diverse interest-holders, streamline collaboration, and position British Columbia as a global hub for clinical research. Mandating harmonized review and approval processes will address inefficiencies and accelerate study start-up, enhancing the province's attractiveness to both industry and public sector sponsors. Embedding clinical trials into standard healthcare practices will not only accelerate access to innovative treatments but also create a sustainable and efficient workforce to support continuous growth. Lastly, prioritizing health data integration will unlock the power of real-world evidence, driving smarter decision-making, reducing redundancies, and enabling transformative healthcare advancements.

These strategies promise far-reaching benefits, including improved patient outcomes, enhanced research capacity, economic growth, and a more robust healthcare system. Patients will gain greater access to cutting-edge treatments, healthcare providers will be better equipped to offer innovative care, and researchers will operate in an environment that fosters groundbreaking discoveries. Furthermore, by aligning with best practices from leading jurisdictions globally, British Columbia can build an ecosystem that is not only competitive but also resilient, inclusive, and sustainable.

However, this transformation cannot happen in isolation. Success will depend on the introduction of a mandated convening organization, and the collective will and active engagement of all interest-holders. Government, healthcare providers, academic institutions, industry leaders, research funders, and community groups must come together, leveraging their strengths to build a cohesive ecosystem that benefits all. This report is not just a blueprint but also a call to action—to think boldly, act swiftly, and work collaboratively.

The time to act is now. While the challenges are significant, the opportunities are even greater. With focused effort, British Columbia has the potential to establish itself as a beacon of innovation and excellence in clinical trials, delivering health and economic benefits that will resonate for generations. By fostering a shared vision, the province can position itself as a leader in transforming lives through research, innovation, and collaboration.

APPENDIX A: Provincial Comparative Analysis

Key takeaways from a comparative analysis[32] of British Columbia, benchmarking against Alberta, Ontario, and Quebec.

Provincial Funding

British Columbia is trailing in funding per capita. CIHR investments in British Columbia are 20-30% less than in Ontario and Quebec, respectively. The gap widens significantly with industry investments. Alberta, Ontario and Quebec receive two to three times greater clinical trial R&D spend by industry than British Columbia.

Table 1. Clinical trial funding, per Capita, by Province

	British Columbia	Alberta	Ontario	Quebec
CIHR Investments in 2022-2023[33]				
Total $	$156M	$124M	$566M	$303M
$ per capita	$29.4	$26.9	$37.23	$34.83
Industry R&D Expenditures on Clinical Trials in 2022[34,35]				
Total $	$42.9M	$98.2M	$335.9M	$210.3
$ per capita	$8.09	$21.34	$22.09	$24.17

[32] Comparative framework: British Columbia, Alberta, Ontario, Quebec. Supporting, enhancing and expanding the clinical trials ecosystem. Report commissioned by Michael Smith Health Research BC. 2024.
[33] CIHR in Numbers. Canadian Institutes of Health Research. 2022-2023. Link
[34] Patented Medicine Prices Review Board Annual Report 2022. Link
[35] Patented Medicine Prices Review Board Annual Report 2022. Link. Based on data in Appendix 4, Table 21, with clinical trials (Phase I to III) accounting for 80.0% of R&D expenditures

Provincial Clinical Trial Organizations

While each province has an organization with a focus on enhancing the clinical trial landscape within their respective provinces, there are distinct differences in terms of governance, funding, and strategic priorities tailored to improve processes, build collaborations, and promote their competitive advantages related to clinical trials.

A key distinction lies in British Columbia and Alberta's approach. Clinical trials activities in British Columbia are managed as a portfolio within Michael Smith Health Research BC, operating under the Clinical Trials BC logo (see Appendix B: History of Clinical Trial Infrastructure in British Columbia). In Alberta, Clinical Trials Alberta is coordinated by Alberta Innovates and is structured as a collaborative with multiple interest-holder contributions. These structures contrast with the other two provinces, which have established stand-alone organizations dedicated exclusively to advancing clinical trial competitiveness. As a result, direct comparisons are challenging as are equivalencies for an "apples to apples" comparison.

Mission and Vision

	Michael Smith Health Research BC	Clinical Trials Alberta	Clinical Trials Ontario	CATALIS Clinical Trials Quebec
Mission	To support the people who do and use health research and to strengthen the system in which they work.	To attract and enable high-quality clinical trials that improve the health of people across the globe.	Strengthen, promote, and capitalize on Ontario's competitive advantages to conduct high-quality clinical trials.	Optimize the clinical research environment in Quebec to accelerate the development of innovative patient care and maximize private investment.
Vision	To work towards a future where BC is recognized worldwide for its vibrant, coherent, inclusive and globally competitive health research system that improves the health of British Columbians, the health system and the economy.	To generate lasting health and economic benefits by solidifying Alberta's position as a premier clinical trial destination in North America.	Make Ontario a preferred location for global clinical trials while maintaining the highest ethical standards.	Create an environment that allows easy access to clinical trials in Quebec for all patients who wish to participate.

Strategic Priorities, Governance, Leadership and Staff

	Michael Smith Health Research BC	Clinical Trials Alberta	Clinical Trials Ontario	CATALIS Clinical Trials Quebec
Strategic Priorities	• Build research talent for BC's future • Catalyze change for a stronger health research system • Mobilize communities for research impact	• Promoting Alberta's assets for conducting clinical trials. • Streamlining processes for effective trial management and increasing the province's clinical trial capacity. • Building an advanced digital health research ecosystem and establishing Alberta as a leader in data-driven clinical research. • Encouraging industry partnerships to facilitate commercialization of health solutions developed through clinical trials.	• Streamline: Enhance processes to help make high-quality clinical trials more timely, efficient, and cost-effective. • Engage: Engage with patients and the public to increase awareness, foster collaboration, and improve how clinical trials are conducted. • Promote: Promote Ontario's competitive advantages and clinical trial capacities to attract more trials and industry investment to the province.	• Accelerate the Launch and Facilitate the Conduct of Clinical Research Projects in Quebec • Strengthen Provincial Clinical Research Expertise • Facilitate Patient Recruitment and Referrals • Facilitate the Implementation of an Innovative Environment • Increase Quebec's International Exposure to Attract More Clinical Research Projects • Foster Effective Collaborations
Governance Model	Operates under an independent board of directors including a government-appointed member. Work undertaken through the clinical trials portfolio includes an advisory council comprised of academics, healthcare leaders, and community interest-holders.	Clinical Trials Alberta is a collaborative initiative coordinated by Alberta Innovates, involving government agencies, academic institutions, healthcare providers, and private sector partners to drive strategic planning and governance.	Established with support from the Ontario Government, with oversight from a skills-based Board of Directors comprising professionals from the life sciences sector, including clinicians, researchers, and industry experts	CATALIS operates as a non-profit organization under the support of Quebec's Ministry of Economy, Innovation, and Energy, with advisory boards comprising public health administrators, private sector leaders, and independents
Leadership	The organization is led by President and CEO Bev Holmes. Danielle Lavallee is Vice President of Research Programs and within her responsibilities lies the clinical trials portfolio led by Portfolio Director, Alison Orth.	The organization is a portfolio within Alberta Innovates, under the leadership pf Tammy Mah-Fraser, Executive Director of Health Platforms, Alberta Innovates.	The organization is led by President and CEO, Susan Marlin.	The organization is led by President and CEO, Danika Laberge.
Staff	Dedicated team of 7 staff, with a total of 6.5 FTE allocated to Clinical Trials BC	[information not available]	Dedicated team of 12 professionals with diverse expertise in clinical research, operations, and patient engagement	Dedicated team of 19 professionals with diverse expertise in clinical research, operations, and patient engagement. The organization is structured with a coordination office and 11 advisory committees.

Funding Sources and Operating Model

	Michael Smith Health Research BC	Clinical Trials Alberta	Clinical Trials Ontario	CATALIS Clinical Trials Quebec
Funding Sources	Funded by the Ministry of Health, Government of British Columbia.	Funded by Alberta Innovates and the Ministry of Technology and Innovation, with contributions from Alberta Health Services, universities, and partners	Primarily funded by the Government of Ontario, Ministry of Economic Development, Job Creation and Trade, and Ministry of Colleges and Universities, with additional support from industry partnerships and collaborations.	Funded primarily by the Quebec government, with additional support from private partnerships, including collaborations with major pharmaceutical companies and healthcare institutions.
Operating Model	Clinical Trials BC is a portfolio of work within the Michael Smith Health Research BC. Operating funds for clinical trials work are subject to annual business planning and board approval. Organizational budgets subject to provincial government funding renewal.	Collaborative initiative involving government, academic institutions, and healthcare delivery organizations. Launched with contributions from partners such as Alberta Innovates, Alberta Health Services, Covenant Health, the College of Physicians & Surgeons of Alberta, the University of Alberta, the University of Calgary, and the Government of Alberta. These entities provide funding, expertise, and in-kind resources.	Independent not-for-profit organization. While specific details about its funding model were not provided, such organizations typically receive funding from a combination of government grants, industry partnerships, membership fees, and revenue generating events.	Non-profit partnership dedicated to advancing and optimizing the clinical research environment in Quebec. It was launched in 2017 with financial support from Quebec's Ministry of Economy, Innovation and Energy, and the mobilization of several public and private partners. CATALIS operates under a governmental mandate to increase the number of clinical trials conducted by companies in Quebec.

Service Offerings

	Michael Smith Health Research BC	Clinical Trials Alberta	Clinical Trials Ontario	CATALIS Clinical Trials Quebec
Streamlined Research Ethics Review for industry sponsored clinical trials	Research ethics is a portfolio of work within the organization	Research Ethics Board (REB) Exchange	CTO Stream	FAST TRACK Evaluation Service
Quick Start/Trial Setup Support		Concierge Services Clinical Research Roadmap	QuickSTART	FAST TRACK Evaluation Service
Patient and Public Engagement	Clinical Trials BC activities include: REACH BC provincial patient matching and referral platform ASK US Speaker Series Communities of Practice	Participant Education and Connection	Raising Awareness as a Community CTO Clinical Trials Finder Online education modules Participant Experience Toolkit College of Lived Experience	Personalized support service to aid in matching patients with trials Patient Advisory Committee
Workforce Development and Training	Clinical Trials BC activities include: Investigator Training Program Clinical Research Professional Certification Quality Leadership Program N2 provincial membership ACRP LMS courses Clinical Trials Provincial Job Board		Research Ready training and resources for clinical research professionals and sites	Training programs
Industry and Research Partnerships	Michael Smith Health Research BC supports talent partnerships with national clinical trials platforms Clinical Trials BC activities include: Why BC site Asset map Promotional materials	Alberta Clinical Research Consortium	QuickSTART Ontario Leadership Table Industry Concierge Connecting industry sponsors with resources and research sites	The CATALIS Network Partnerships with major pharmaceutical companies
Other	Clinical Trials BC activities include: Quality Management Systems Program Audit & Inspection Preparedness Program Regulatory consulting and guidance Decentralized trials and research alliance Clinical Trial Management System Program (CTMS)		CTO Conference Promoting Ontario's competitive advantages through targeted marketing activities and events	Provincial Tools: shared services and tools for access to health information, regulatory standards, SOPs, informed consent forms, and standards for evaluating contracts

National Clinical Trial Organizations

Canada's national organizations play a pivotal role in enhancing the infrastructure and growth of clinical trials. Here is an overview of key organizations:

- **Accelerating Clinical Trials (ACT-ACE)**: Part of the Canadian Institutes of Health Research (CIHR) Clinical Trials Fund, ACT-ACE focuses on removing barriers to conducting clinical trials and bolstering Canada's capacity to host trials at a global standard. It supports streamlined processes, collaboration, and infrastructure improvements, driving Canada's competitiveness in clinical research and accelerating access to new therapies. Two of the initiatives that have impact for British Columbia directly are:
    1. **Portfolio Hospitals**: ACT has funded Research Coordinator positions at East Kootenay Regional Hospital, Kelowna General Hospital, Nanaimo Regional General Hospital, and Penticton Regional Hospital.
    2. The **Canadian Trial Units Network** includes the Centre for Cardiovascular Innovation (CCI), Vancouver Coastal Health / Faculty of Medicine, University of British Columbia.
- **Network of Networks (N2):** N2 is a national alliance that unites institutions, health authorities, and clinical researchers to improve the quality and consistency of trials across Canada. By providing standardized training, tools, and advocacy, N2 enhances trial management, patient safety, and accessibility.
- **Canadian Cancer Clinical Trials Network (3CTN)**: 3CTN aims to improve recruitment and the efficiency and quality of academic cancer clinical trials in Canada. It provides coordination and support to cancer research centres, enhancing trial accessibility and participation, thereby accelerating the development of new cancer treatments.
- **Canadian Consortium of Clinical Trial Training (CANTRAIN)**: CANTRAIN is a national initiative aimed at developing clinical trial competency among professionals and trainees. It offers comprehensive training programs that combine theoretical knowledge with hands-on practice, experiential learning opportunities, and expert mentorship.
- **SPOR[36] SUPPORT[37] Units**: An important collaboration between the federal government and the provinces and territories, SUPPORT Units provide specialized services to researchers, patients, clinicians, policy makers and SPOR-funded entities to conduct patient-oriented research. By providing decision-makers and health care providers with the ways and means to connect research to patient-identified priorities, evidence-based solutions can be applied to health care—and then shared throughout the country. Michael Smith Health Research BC participates in this initiative by housing the BC SUPPORT Unit, connecting researchers with patients to help improve health care, moving evidence into practice, and making health data easier to access.

[36] SPOR: Canada's Strategy for Patient-Oriented Research
[37] SUPPORT: Support for People and Patient-Oriented Research and Trials

APPENDIX B: History of Clinical Trial Infrastructure in British Columbia

< 2000

- 1995: The BC Children's Hospital Research Institute (BCCHR) is established, becoming the largest research institute of its kind in Western Canada. BCCHR focuses on discovery, translational, and clinical research to improve the health of children and families. The institute operates in close partnership with The University of British Columbia (UBC) and is supported by the BC Children's Hospital Foundation.
- 1998: UBC launches its Centre for Advancing Health Outcomes, focusing on research to improve patient outcomes and healthcare practices through evidence-based data. The Centre supports clinical trials by generating critical insights into health policy and patient care effectiveness, contributing a unique aspect to British Columbia's research landscape.

2000s

- 2001: British Columbia initiates formal research networks, fostering collaborations among academic institutions, health authorities, and industry. This period marks foundational efforts in building infrastructure for clinical trial support and local research needs.
- 2003: The Vancouver Coastal Health Research Institute (VCHRI) is established as the research arm of Vancouver Coastal Health, in partnership with UBC. VCHRI focuses on translational research, aiming to move discoveries from the laboratory to clinical practice, thereby improving patient care and health outcomes.
- 2005: The Women's Health Research Institute (WHRI) is established by BC Women's Hospital and Health Centre to enhance and galvanize the impact of women's health research conducted at BC Women's Hospital and throughout British Columbia. WHRI is devoted to improving the health and health care of girls and women through knowledge generation, serving as a catalyst for research in women's health and supporting an expanding provincial and national network of women's health researchers, policymakers, and healthcare providers.
- 2005: The BC Cancer Agency (BCCA) Research Centre opens, enhancing its role in clinical trials, positioning itself as a leading center for oncology research in the province with 93 faculty and more than 400 research staff. BCCA provides clinical trial access and specialized cancer treatment services, supporting pivotal trials in cancer therapies that attract global partnerships and funding.

2010s

- 2010: The British Columbia Clinical Research Infrastructure Network (BCCRIN), an association of leading research institutions, health authorities, universities, funding agencies and industry partners that conduct clinical research in British Columbia is established to coordinate clinical trial resources and enhance collaboration. The founding members of BCCRIN included the Vancouver Coastal Health Research Institute, Providence Health Care Research Institute, Provincial Health Services Authority (BC Cancer Agency,

Child and Family Research Institute), Genome BC, Life Sciences BC, Michael Smith Foundation for Health Research, and the UBC Faculty of Medicine.

- 2011: BCCRIN begins major initiatives to standardize clinical trial practices across British Columbia, including the creation of a centralized resource hub. This enhances access to trial resources and increases trial quality, helping researchers navigate operational requirements and promoting consistent trial standards.
- 2013: BCCRIN develops a web-based directory to promote BC's clinical trials capabilities[38]. In the short time since its inception in 2010, BCCRIN has grown to become a province-wide network of 23 member organizations.
- 2016: BCCRIN becomes BC Academic Health Science Network (AHSN) – a non-member society with initiatives and direction provided by the board of directors.
- 2017: Clinical Trials BC is launched under the BC AHSN framework to focus specifically on building a strong clinical trials environment in British Columbia. This organization prioritizes trial quality, regulatory compliance, and training for professionals. Clinical Trials BC develops best practices and support services that facilitate patient-centered and well-coordinated trials, including industry engagement and support for ecosystem navigation and investigator identification, as well as participant experience improvement and public engagement initiatives.
- 2019: Partnerships between Clinical Trials BC, the provincial health authorities, BCCHR, VCHRI, WHRI, and BCCA deepen, attracting increased industry and government funding for oncology, genomics, and other specialized trials. This period sees the expansion of infrastructure and investment in precision medicine, especially in cancer research.

2020s

- 2020: The COVID-19 pandemic accelerates the adoption of remote trial monitoring and digital data collection tools in British Columbia's clinical trials, further enhancing trial flexibility and patient recruitment strategies. Clinical Trials BC supports the implementation of digital solutions to facilitate remote clinical trials. Clinical Trials BC initiated and hosted a clinical trial community network with monthly meetings of participants across the province. This informal network engaged over 120 members during 2020-2021 to enable increased communication, learning, and a coordinated approach.
- 2020: The COVID-19 Clinical Research Coordination Initiative (CRCI) was established to coordinate requests from researchers involved with COVID-19 research projects. Over the next three years, the CRCI played a key role in coordinating experts, resources, and data, from academics, industry partners, and health authorities to support COVID-19 research efforts in British Columbia. The CRCI was a province-wide program developed in partnership with partners across BC[39].

[38] The Canadian Clinical Trials Asset Map. Link
[39] COVID-19 Clinical Research Coordination Initiative. Link

- 2020: BC Cancer Research becomes a formal research institute: the BC Cancer Research Institute (BCCRI). Approved by UBC and the Provincial Health Services Authority, this move enhanced British Columbia's leadership position in cancer research innovation.
- 2020: Clinical Trials BC funded and rolled out a provincial clinical trial management system with participation from all health authorities.
- 2021: Clinical Trials BC becomes part of Michael Smith Health Research BC, following the merger of the Michael Smith Foundation for Health Research and the BC Academic Health Science Network. This integration supports Clinical Trials BC with additional resources and aligns it with broader provincial research goals, including support for R&D and collaboration among institutions. Clinical trials activity now becomes a portfolio of work within Michael Smith Health Research BC.
- 2022: British Columbia's clinical trials infrastructure benefits from increased R&D funding, as the Canadian Institutes of Health Research (CIHR) awards over $76.8 million to British Columbian researchers. BCCA continues to lead in clinical trials, particularly in oncology, advancing new cancer therapies and playing a central role in Canada's cancer research landscape. BC develops a shared vision for clinical trials, demonstrating community / industry collaboration[40].
- 2023: Clinical trials activities strengthen the training and inspection readiness programs, improving regulatory standards across clinical trials. Michael Smith Health Research BC through Clinical Trials BC facilitates collaborations that streamline resources and further enhance British Columbia's reputation in clinical research, including co-funding CANTRAIN[41,42].
- 2023: The Province of British Columbia announces $4.2M investment to create a six-bed unit for Phase I clinical trials at Mount Saint Joseph Hospital in Vancouver, which is operated by Providence Health care, to be operational in late 2024. Michael Smith Health Research BC commits $1.2M to this initiative. It will be the only non-cancer Phase I clinical trial unit in Western Canada.
- 2024: The BC Cancer Research Institute and the Centre for Advancing Health Outcomes sign a memorandum of understanding that will see the two organizations work closely and collaboratively to support clinician–scientists across British Columbia in their clinical trials research. The collaboration between the two organizations will see enhanced shared capacity for database development, statistical support, data management, auditing and regulatory compliance, grant support, finance, and other areas.

[40] Unleashing the potential of clinical trials. Michael Smith Health Research BC. Link
[41] BC among the first to support new national clinical research internships. Michael Smith Health Research BC. 23 July 2024. Link
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APPENDIX C: Electronic Health Records

The terms **Electronic Health Records (EHR)** and **Electronic Medical Records (EMR)** are often used interchangeably but have distinct meanings, especially in the context of clinical trials. Here's how they differ and relate to clinical trials:

Electronic Medical Records (EMR):

- **Definition**: EMRs are digital versions of paper charts in a clinician's office. They primarily contain the medical and treatment history of patients within a single practice or healthcare organization.

- **Scope**: EMRs are more localized and typically include data like diagnoses, treatment plans, and outcomes from a single provider or organization.

- **Clinical Trials Relevance**:
  - **Limited sharing**: Since EMRs are organization-specific, they are less accessible across multiple sites or to external parties such as clinical trial sponsors or Contract Research Organizations.
  - **Primary use**: EMRs are useful for identifying eligible patients within a specific healthcare system during the screening and enrollment phases of a trial.
  - **Challenges**: The lack of standardization and interoperability with other systems can make integrating EMR data into trial workflows cumbersome.

Electronic Health Records (EHR):

- **Definition**: EHRs are more comprehensive and designed for interoperability. They contain patients' medical records from multiple providers, healthcare organizations, and care settings.

- **Scope**: EHRs provide a broader view of a patient's overall health history, often including lab results, imaging, medications, allergies, and care coordination data.

- **Clinical Trials Relevance**:
  - **Data integration**: EHRs can streamline data collection for clinical trials by directly integrating patient data into trial systems, reducing the need for manual data entry.
  - **Patient recruitment**: EHRs enable more efficient identification of eligible participants across multiple sites or geographic regions, making recruitment faster and more inclusive.
  - **Longitudinal data**: EHRs provide long-term patient data, which is valuable for assessing outcomes in long-term or post-market surveillance studies.
  - **Interoperability**: EHRs are better suited for real-world data collection and integration with clinical trial management systems (CTMS), enhancing data standardization and sharing.

Key Differences in Clinical Trial Use:

Feature	EMR	EHR
Data Source	Single provider/organization	Multiple providers and organizations
Interoperability	Limited	High
Recruitment	Localized	Broader, multi-site
Data Scope	Specific clinical visit data	Comprehensive health history
Longitudinal Tracking	Limited	Extensive, across care settings

Summary in Context of Clinical Trials

- EMRs are ideal for single-site trials where data access is restricted to a specific provider's patient population.
- EHRs are invaluable for multi-site, large-scale trials and studies requiring real-world evidence, as they facilitate broader access, interoperability, and longitudinal patient tracking.

The trend in clinical trials is increasingly favoring EHR integration due to its scalability, data-sharing capabilities, and ability to support decentralized trials.

APPENDIX D: Methodology and Research Framework

Project Sponsor

Michael Smith Health Research BC

Objective

This report is a comprehensive situational analysis of the clinical trials ecosystem in British Columbia, including a comparative analysis of other provinces, with the aim of identifying strengths, weaknesses, and opportunities for enhancing British Columbia's clinical trial capabilities.

Method

The project was conducted from September through December 2024. Through a competitive request for proposals, True North Innovation Agency was awarded the project, with the work performed by principal consultant Melissa Bomben, Founder and CEO.

A comprehensive review of existing literature, policy documents, and reports related to the clinical trials ecosystem in British Columbia and comparator locations was performed. Key interest-holders[43] who influence clinical trial activities were interviewed to gain insights in support of implementing actions that will foster growth by increasing British Columbia's competitiveness as a location to conduct clinical trials.

Interviews covered topics of funding and investment, infrastructure, collaboration, the barriers and challenges impeding clinical trial growth, and envisioning the future.

The insights and recommended actions are outlined here with the intent they be enacted. Resulting insights will be shared widely, and implementation will be made more swiftly with the support of mandate-level endorsement from government, and motivated participation from every element of the ecosystem.

All insights and perspectives gathered were anonymized and are reported in aggregate to maximize the candour and openness of the participants. Interview participants included representatives from twenty-eight organizations representing a variety of interests in the clinical trials ecosystem, including:

- Government & Health Authorities
- Academic Institutions
- Hospitals and Research Institutions
- Industry Representatives
- Clinical Trial Networks and Consortia

[43] "Interest-holders": A new term to replace "stakeholders" in the context of health research and policy. Cochrane Evidence Synthesis and Methods. 29 October 2024. Link

Participating Organizations

Government & Health Authorities: BC Ministry of Health, First Nations Health Authority, Island Health Authority, Provincial Health Services Authority

Academic Institutions: University of British Columbia Faculty of Medicine, University of British Columbia Office of Vice President Research & Innovation, University of Northern British Columbia

Healthcare Providers & Research Institutions: BC Cancer Agency, UBC Centre for Advancing Health Outcomes, BC Children's Hospital, East Kootenay Regional Hospital, Vancouver Coastal Health Research Institute

Industry Representatives: Amgen, AbCellera, Bayer, GSK, Life Sciences BC, Medical Arts Research, Moderna, Prime Site Research, Roche

Clinical Trial Networks and Consortia: Alberta Innovates (Clinical Trials Alberta), CATALIS Quebec, Clinical Trials Ontario, Accelerating Clinical Trials Consortium (ACT-ACE), Michael Smith Health Research BC (Clinical Trials BC)

Clinical Trials Advocate: Roy Jackson

Principal Consultant

Melissa Bomben, Founder & CEO, True North Innovation Agency, LLC

Melissa Bomben is a life sciences executive with over 25 years of experience in clinical development, specializing in clinical trials. As the Founder and CEO of True North Innovation Agency, she offers fractional executive advisory services to life science organizations globally.

Her extensive career includes leadership roles in major contract research organizations (CROs) and clinical trial consulting firms. Melissa is known for her strong analytical skills and expertise in facilitation and communication of complex and strategic ideas. She has successfully managed clinical trial operations across various phases and indications for a diverse client base, including small, emerging, and large-scale biopharmaceutical companies.

Analytical Methods

To perform a comprehensive situational analysis of the clinical trials ecosystem in British Columbia, including a comparative analysis with other provinces and global leaders, with the aim of identifying strengths, weaknesses, and opportunities for enhancing British Columbia's clinical trial capabilities, the following analytical methods were utilized.

- **SWOT Analysis**: Identifying British Columbia's strengths, weaknesses, opportunities, and threats in the clinical trials sector compared to other provinces (Alberta, Ontario, Quebec) and global leaders.
- **Benchmarking**: Comparing British Columbia's clinical trial infrastructure, funding sources, and interest-holder engagement with that of other provinces and international leaders.
- **Interest-holder Analysis**: Mapping out key players in British Columbia's clinical trials ecosystem, including healthcare providers, academia, government, and private sector interest-holders, to assess their roles and influence.
- **Gap Analysis**: Identifying specific gaps in resources, expertise, or infrastructure by contrasting British Columbia's capabilities with those of high-performing regions.
- **Market Demand and Capacity Analysis**: Assessing the demand for clinical trials and British Columbia's capacity to meet this demand through resources, facilities, and participant recruitment.
- **Funding and Investment Trend Analysis**: Reviewing trends in public and private funding to evaluate investment flows and compare British Columbia's R&D funding landscape with other regions.
- **Competitive Landscape Analysis**: Evaluating British Columbia's competitive position within Canada and globally by analyzing competing provinces and countries' advancements in clinical trials.
- **Patient and Public Involvement Assessment**: Analyzing efforts in British Columbia to engage patients and the public in clinical trial processes, comparing them with best practices from other regions.

These methods were supported by literature and document review, including a comprehensive review of existing literature, policy documents, and reports related to the clinical trials ecosystem in British Columbia, Alberta, Ontario, Quebec, and leading global regions (e.g., US, UK, Western Europe, Australia). Data sources are included in Appendix E.

The involvement of interest-holders included interviews focusing on qualitative insights to supplement the data analysis, gathering insights on the current state of the clinical trials ecosystem and recommendations for improvement.

Cross-reference of findings from multiple data sources was utilized to validate insights and ensure a comprehensive understanding. The public report will represent a synthesis of the insights from the comparative framework and situational analysis into a cohesive narrative that outlines British Columbia's current position, strengths, areas for improvement, and strategies for enhancing clinical trial capacity. Actionable recommendations tailored to British Columbia to improve its competitive stance in clinical trials will be highlighted.

APPENDIX E: References and Supporting Literature

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Additional materials supporting this project

ANNUAL | IMPACT | ACTIVITY REPORTS

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- Clinical Trials BC Activities Report 2021-2023 Link
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- Government of British Columbia Life Sciences and Biomanufacturing Strategy Report 2023-2024 Link
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STRATEGIC PLANS

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