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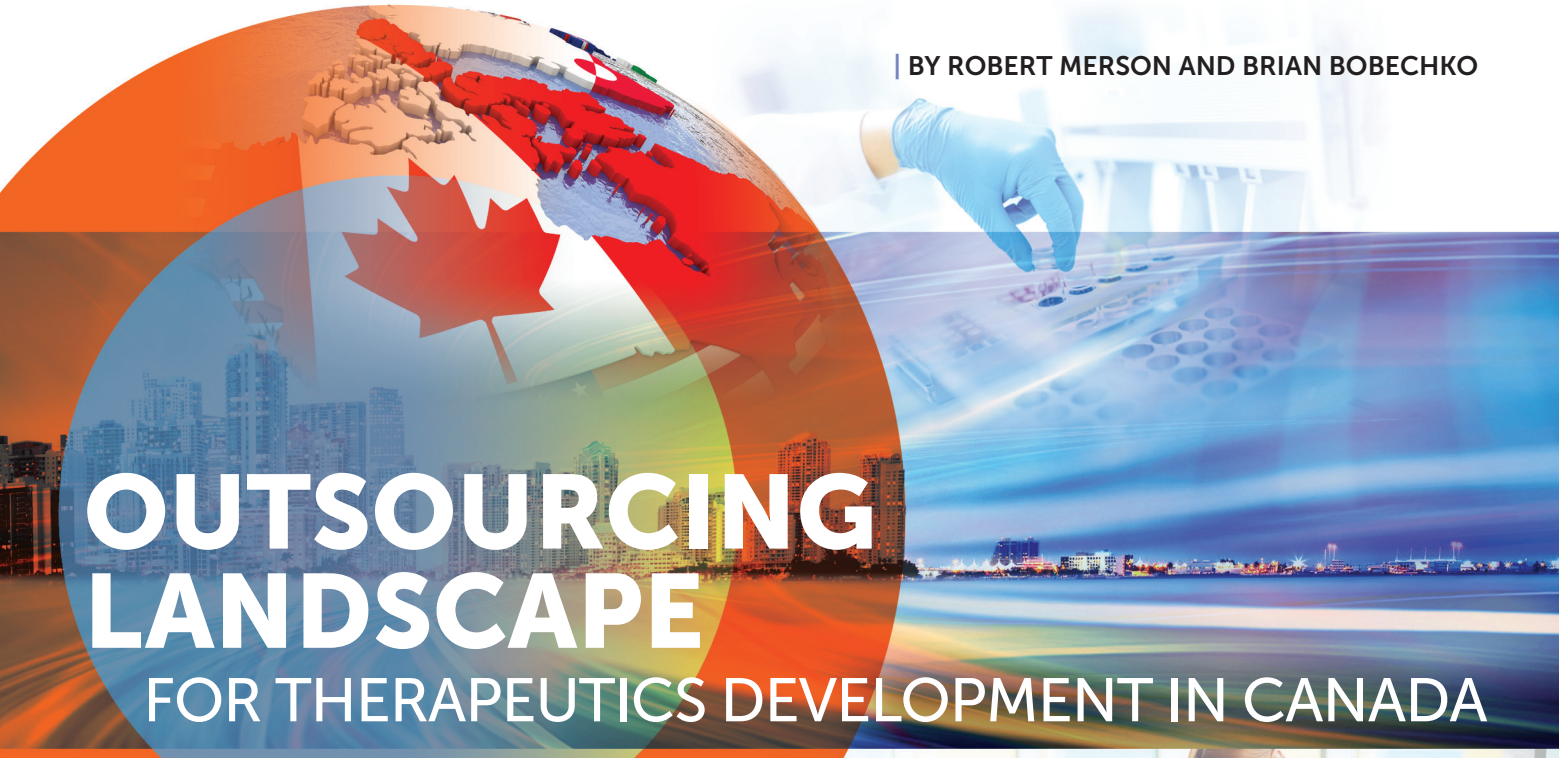


OUTSOURCING LANDSCAPE

FOR THERAPEUTICS DEVELOPMENT IN CANADA

SPECIAL REPORT:

Rare is the therapeutics company that possesses all of the capabilities and expertise needed to bring a technology to market. More typically, particularly for the majority of small early-stage companies that are so prevalent in an innovation economy, the key to a successful therapeutics company (beyond having exceptional underlying technology) has become the ability to engage and manage the best partners to advance the technology through the pre-clinical, clinical, manufacturing and regulatory stages of development. Canadian therapeutics companies have the benefit of world-class options in both the public and private sectors. This report highlights some of those options, as part of an overview of the current landscape for outsourcing therapeutics development in Canada.

A typical therapeutics company – Is there such a thing?

The landscape of Canadian therapeutics companies spans the full spectrum from small start-ups to multi-national biopharmaceuticals. Industry Canada figures from 2016 estimate that there are 163 Canadian biopharmaceutical small and medium-sized enterprises (SMEs) with over 400 promising human health products under development.[1] Within this group, 75% of products are in the early stages of development (i.e. research through phase I/II). According to the Canadian Life Science Database (accessed October 2017), of the 837 catalogued Canadian biotech companies, almost 15% (~125) are focused on therapeutics, with the majority (60%) at the research and early preclinical stages and progressively smaller percentages through the clinical stages of development and post-market surveillance.[2] Not surprisingly, the mosaic of companies involved in developing human therapeutics reflects many disease areas (cancer and CNS being the most prevalent) and a variety of technological specializations (e.g. small molecules, biopharmaceuticals, virus based therapeutics, and cellular therapeutics).

As research activities continue to define novel disease pathways, new chemical entities and libraries of existing compounds are still a primary source for screening prospective therapeutic candidates against newly discovered target sites. Historically, this has required expertise in small molecule and medicinal chemistry, and small molecules remain the dominant category of therapeutics, comprising as much as 90% of the existing pharmaceutical market.[3] Small molecules continue to underpin the therapeutics discovery pipeline, in part due to their long history in the pharmaceutical industry, and well understood manufacturing and routes of administration. Of the 22 new molecular entities approved in 2016, 50% were small molecules.[4] However, medicinal therapeutics represents a range of dramatically different molecular sizes, characteristics and related complexity to discover, manufacture, and test.

Since the biotechnology revolution opened the door to manipulating and harnessing the power of biological components, the number of biologics among approved new molecular entities has been growing steadily and may soon overtake the small molecules among new molecular entities. Representing 50% of the 2016 roster of FDA approved new molecular entities,[5] biologics (which include oligonucleotides, peptides, and antibodies) were recently

estimated to represent 30% of therapeutic candidates now in development in Canada.[6]

The popularity of biologics stems in part from the breadth of opportunity available to modulate biological pathways of interest, and the precision offered by more complex molecules. Depending on the nature of the treatment, these therapeutics can harness the patient's own immune system, or cellular machinery to bring a more curative approach to the target disease. Excitement around the prospect of personalized medicine, where treatments are tailored to the patient, has also boosted interest in biologics. For similar reasons, stem cell and regenerative medicine technologies are also a growing trend for novel therapeutics development with increasing research investment in these areas over the past few years. However, the expertise required to develop these new classes of therapeutics is becoming progressively complex, even branching into different subsectors of therapeutic development. Developing commercial grade tools and processes in these technologies can be prohibitively costly for would be service providers, and represents a barrier to entry for would-be therapeutic and contract research organization (CRO) entrants alike. Yet, access to publicly developed tools and expertise may represent a significant enabling factor underpinning the strength of a life-science economy.

It usually starts with a discovery

In Canada, most therapeutic candidates (or underlying technologies) originate from publicly funded research labs. Canada's 150+ universities, colleges, teaching hospitals, research institutes and government agencies control more than 40% of Canada's $31 billion gross domestic expenditures on research and development, and 74% of federal expenditures on science and technology.[7] While health research investments are only a fraction of this amount, about $3.9 billion in 2015,[8] Canada remains highly reliant on public funding for research that generates the novel discoveries with therapeutic potential. However, compared to the availability of public funding for discovery research, the availability of public funding for protecting and preparing technologies for clinical testing is relatively scarce. While research institutions are increasingly holding onto emerging technologies later into the pre-clinical discovery process in an attempt to increase licensing returns, therapeutics companies are often born out of a need for private capital. This need for capital to transition technologies through the so called "valley-of-death" (referring to stages of technology development where funding is particularly hard to find) explains, in part, the relative abundance of small, resource-poor, early stage therapeutics companies.

Beyond the commonly shared key ingredients of 1) intellectual property (great ideas for new products with market potential) and 2) entrepreneurial talent, there is a true mosaic of therapeutic companies in the Canadian landscape, in terms of size, scale, technology, and therapeutic focus. Given the early stages of development for the majority of these companies, it is not surprising to find many of them clustered around major academic centres, where they are more likely to have access to space that is specially equipped for research. Most early stage therapeutics companies are located either in dedicated incubation facilities in regional research clusters or in seconded academic space that has been made available for companies to lease. Mississauga's life-science cluster, for example, is the 2nd largest in Canada, and hosts some 430+ life-science companies, credited in part to close proximity to 21 universities and colleges and their 300+ life science-related programs.[9] While there are some examples of well financed Canadian companies that have built out larger internal research teams, the majority of Canadian therapeutic companies have less than 10 full-time employees and would cite financing as their number one challenge. Successful management teams are those that are skilled at raising funds and collaborative partnering, since, for these typical small resource starved companies, outsourcing development activities has become a necessity for advancing technologies to the next phase of development, and financing usually requires success in reaching milestones.

Smart money doesn't try to do everything alone

Given the breadth and diversity of therapeutics companies, a prevailing theme might be that no company does everything. Certainly, for SMEs, the business model for therapeutics companies has become one that relies on outsourcing. Even large multinational therapeutics companies choose to outsource capabilities that are either lacking in-house or specialized in nature, or simply to reduce time to market and allow the company to focus on core competencies. According to a survey conducted by www.outsourcing-pharma.com, most pharma companies use CROs for manufacturing, clinical trials, packaging, and to a lesser degree for preclinical research.[10] Particularly in the area of immunobiologics, many developers prefer to outsource for expertise in reducing antibody immunogenicity (humanization) and enhancing its affinity (affinity maturation). A 2016 report suggested that there are close to 60 companies globally offering antibody humanization and/or affinity maturation services or platforms, 56% of these based in North America.[11] The example of immunobiologics is only one, albeit significant, area of biologics CRO expansion. Overall growth in the North American CRO market has been forecast at >10% through 2020, contributing to an estimated $57 billion global market, and underscoring CRO activity as an economic driver in its own right, as well as being an essential ingredient in the life-sciences ecosystem.

Government's role in catalyzing the commercialization of therapeutics

When considering the landscape for outsourcing therapeutics development, government initiatives may not come top of mind, but in its drive to stimulate innovation driven economic growth, government supported initiatives have become a major provider of outsourcing services in the therapeutics industry in Canada. In one sense, publicly funded CRO-like activity could be considered the public-sector response to the "valley of death"; an attempt to help companies advance their technologies in the absence of commercially oriented funding. Many early-stage therapeutics companies in Canada today have credited their success (at least in part) to government-initiated programs. In addition to the critical public funding programs that support early-stage research-based companies, (such as SR&ED credits, IRAP, industry development grants through federal granting councils and provincial agencies), there has also been a considerable public investment in providing technological support for early-stage companies. The two most notable publicly supported "outsourcing" partners for Canadian therapeutics companies have been the National Research Council (NRC) and the Networks of Centres of Excellence (NCE) initiatives; particularly the Centres of Excellence for Commercialization of Research (CECR) program.

The NRC, most often recognized for the IRAP program, has also been strategically focused on supporting the development of Canada's biotherapeutics industry through its Human Health Therapeutics (HHT) portfolio. In addition to their own internal discovery programs, which generate novel technologies for licensing to the private sector, the NRC has also focused on building a partnership model that makes their resources and expertise available to help Canadian therapeutic companies overcome technological challenges related to discovery, validation, and pilot manufacturing. The NRC's HHT portfolio specializes in biologics and biomanufacturing; therapeutics beyond brain barriers; and vaccines and immunotherapeutics.

Their expertise extends from basic research through preclinical development. A full description of NRC's role in Canada's biotech ecosystem has been described in a previous article from Biotechnology Focus.[12]

The CECR program has also been an important partner for early stage therapeutic companies. Often early stage therapeutics companies are launched through these CECR's (in partnership with academic organizations) or they may be incubated at an early stage with access to seed funding, research space, technological expertise, and business mentorship. Given that their role has been to help academic institutions commercialize their research, as well as to support companies in the commercial development of their technologies, CECR's have emerged as a critical outsourcing partner for early-stage therapeutics development, since the creation of the program a decade ago. There are several active CECR's that currently support Canadian therapeutics companies, many of which have been highlighted in Table 1.

The more traditional research Network Centres of Excellence (such as BioCanRx and GlycoNet) are also important to mention, along with the business-led NCE's such as CQDM, as these organizations have also focused on incubating innovative Canadian therapeutics companies, financing of strategic and collaborative research projects, and providing "outsourced" technical service capabilities.

TABLE 1: EXAMPLES OF CECR'S SUPPORTING CANADIAN THERAPEUTICS COMMERCIALIZATION AND DEVELOPMENT

CECR	Brief Description	Public Funding	Partner Funding*
Accel-Rx Health Sciences Accelerator	Leverages expertise and infrastructure of existing health related CECR's and invests in the development of Canadian health companies.	$14.5 M	$2.8 M
Centre for Commercialization of Cancer Immunotherapy - C3i	Accelerate access to innovative cancer immunotherapies for patients.	$15 M	
Centre for Commercialization of Regenerative Medicine - CCRM	Bridging the gap between academia and industry to enable promising regenerative medicine technologies to reach the market.	$15 M	$16 M
Centre for Drug Research and Development - CDRD	Technology incubator for creating spin-off companies and accelerator that supports scale-up companies in moving discoveries through pre-clinical stages.	$23 M	$85.9 M
Centre for Probe Development and Commercialization - CPDC	Provides the expertise and infrastructure needed to develop and manufacture molecular imaging probes, including radiopharmaceuticals.	$28.8 M	$39 M
Centre for the Commercialization of Antibodies and Biologics - CCAB	Commercializing antibodies from the Toronto Recombinant Antibody Centre (TRAC), Canada's leading centre for the production of high-quality antibody and biological assets.	$15 M	$994 K
MaRS Innovation - MI	Commercializing IP from 15 member institutions, including therapeutics IP.	$29.9 M	$56.1 M
NEOMED Institute - NEOMED	Two integrated R&D facilities: one specializing in small molecule therapeutics, and one specializing in biologics and vaccines.	$12 M	$17.6 M
Prostate Centre's Translational Research Initiative for Accelerated Discovery and Development - PC-TRiADD	Leveraging the scientific excellence, platform technologies and specialized facilities of the Vancouver Prostate Centre, it provides discovery, preclinical development and clinical research management for stage cancer progression and therapeutic resistance.	$26.3 M	$11.3 M

**Longer established centres may have more partner investment reported than newer ones.*
Source: www.nce-rce.gc.ca

Outsourcing to the private sector – how is Canada fairing as a commercial outsourcing partner?

The scale of government investment in stimulating economic activity through financial mechanisms and technical service capacity suggests that the government has recognized the critical role of outsourcing to early commercial development in the therapeutics sector. It also begs the questions: what is the health of Canadian private sector CRO's; how are Canadian CRO operations faring alongside international competitors; and how do government programs overlap with private sector activities in relation to outsourced therapeutic R&D?

The Canadian preclinical CRO landscape

The NRC's article on "Outsourcing and Tech Transfer in Canada's Biotech Ecosystem" from the December 2016 / January 2017 edition of Biotechnology Focus,[13] provides an excellent and recent summary of the private sector preclinical CRO landscape in Canada, including the types of services and an analysis of Canada's three main clusters in Ontario, Quebec, and British Columbia. Their findings included identifying: 117 private sector CRO's offering preclinical biologics services; at least 75 supporting discovery activities (hit and/or lead identification); more than 99 offering preclinical services (pharmacology, toxicology, PK/PD); and at least 68 providing chemistry, manufacturing and control (CMC) analytics in preparation for GMP biomanufacturing and clinical trials.

This data suggests a strong preclinical CRO sector in Canada, particularly given the number of pre-clinical stage Canadian therapeutics companies, and suggests a significant international component and strong competitiveness. Based on consultations and secondary research, there are several trends to highlight. First, with numerous competitors in the marketplace, preclinical CRO's compete primarily on cost-competitiveness and specialization. While some of the larger or more established CRO's can demand somewhat higher rates based on an established track record, the majority of CRO's promote their unique areas of specialization. This may include disease area expertise; previous experience with specific models; expertise with specialized equipment or technologies; or novel techniques that provide high quality, reproducible results in a more efficient manner. However, while areas of specialization are becoming an important factor in a CRO's unique selling proposition, the persistent theme is that a track record of previous experience is still critical, with therapeutics companies typically seeking CRO's with a minimum 5-year history to be considered for outsourcing.

The two most notable publicly supported "outsourcing" partners for Canadian therapeutics companies have been the National Research Council (NRC) and the Networks of Centres of Excellence (NCE) initiatives.

Another theme might be that public institutions (universities, research hospitals, publicly funded research centres, etc.) may also be playing a role in bolstering the business models of preclinical CRO's. From one perspective, the public institutions have become clients for preclinical CRO's, with opportunities to provide external validation on research findings or to provide external capacity for priority projects that may have been funded by grants or even private contributions. The Ontario Brain Institute for example has a program that will support Canadian neurotherapeutics companies seeking to engage the services of an Ontario-based CRO. On the other hand, preclinical CRO's also consider public institutions to be competitors in the marketplace. With increased capacity for preclinical research at many public institutions (e.g. institutional infrastructure grants, NRC, CECR programs), therapeutic candidates are undergoing much of their preclinical development activities within the public domain. The challenge remains for preclinical CRO's to define the expertise and cost effectiveness of their services to help shift preclinical development from the public subsidized institutions to the private market.

Lastly, and most importantly, Canada's corporate CRO's recognize that preclinical development is a global business. Our CRO's are in no way limited to servicing the Canadian marketplace, and are actively engaging with global industry. Big pharma are important clients for preclinical CRO's, many of which are seeking out specific areas of expertise or unique models that have been validated. A 2016 survey by Nice Insights showed that big pharma and mid-sized pharma/biotech companies together make up 80% of the pre-clinical CRO's buyers market, and that 61% of the therapeutics companies surveyed choose North American CRO's as their preferred outsourcing partner.[14] Global engagement however, also means global competitors, which reinforces the need for specialization and cost competitiveness for Canadian-based preclinical CRO's. The Canadian therapeutics landscape is even attracting some of the leading CRO's to Canada, such as German-headquartered Evotec (voted one of the top global CRO's in the Nice Insights survey), which recently announced a partnership with MaRS Innovation to establish LAB150 (named in commemoration of Canada's 150th birthday), to accelerate drug discovery and commercialization from Canadian institutions.[15]

Contract manufacturing – an opportunity for Canada to secure a position of global leadership?

Contract Manufacturing Organizations (CMO's) as well as organizations involved with developing the manufacturing process (CDMO's) are important partners at the preclinical stage, and will often remain partners for the therapeutics companies through the clinical and post-market stages. The time and investment required for therapeutics companies to achieve a certified and regulatory approved manufacturing process is significant enough that once successful, it is highly unlikely that the company will seek to switch manufacturers. This is especially true for the newer biologics and cellular therapies, which would require considerable cost to certify and validate a new site for manufacturing. Therefore, even though therapeutics companies may, as a function of their growth, attract foreign investment or ultimately be acquired and moved outside of Canada, it is unlikely that the manufacturing of the therapeutic candidate will be moved if they already have a successful partner in Canada.

This strategy of building manufacturing capacity in Canada is one that has been championed by others in the industry for many years. The NRC-HHT portfolio (previously described) is one partner that has been working with Canadian therapeutics companies to help develop the manufacturing process for their lead candidates. Their cell culture pilot plant in Montreal, with a run capacity up to 500L, is used to support therapeutics companies in the development of their biologics manufacturing process. CECR's have also been playing a role in building manufacturing capacity. CCRM has established a 40,000 sqft cell manufacturing facility in Toronto to help companies develop and scale-up the manufacturing process for novel stem cell therapies. The goal of these public initiatives has not been to operate as a full-time CMO, but rather to help companies develop their manufacturing processes so that they can ultimately be spun-out, or handed off to a Canadian commercial CMO partner. The individual therapeutics company therefore

has become less of a focus for ensuring the sustainability of the sector; but rather the development and retention of the manufacturing of new therapeutics in Canada has become the new strategy for retaining and building high value jobs.

Canadian commercial CMO's have also been developing capacity as a CDMO helping companies to develop the process for manufacturing, before scaling up manufacturing with the company's growth. Examples include: Dalton Pharma Services (small molecules) and Therapure (biologics) who not only provide contract manufacturing services, but are also providing expertise in the development of the manufacturing process. As with the preclinical CRO's, Canadian CMO's recognize that contract manufacturing is a global industry, and are actively engaging global partners, with the majority of their clients coming from outside of Canada. The recent announcement of the $290M spin-off and sale of Therapure's CDMO business is a testament to the company's growing influence and competitiveness in the global market.

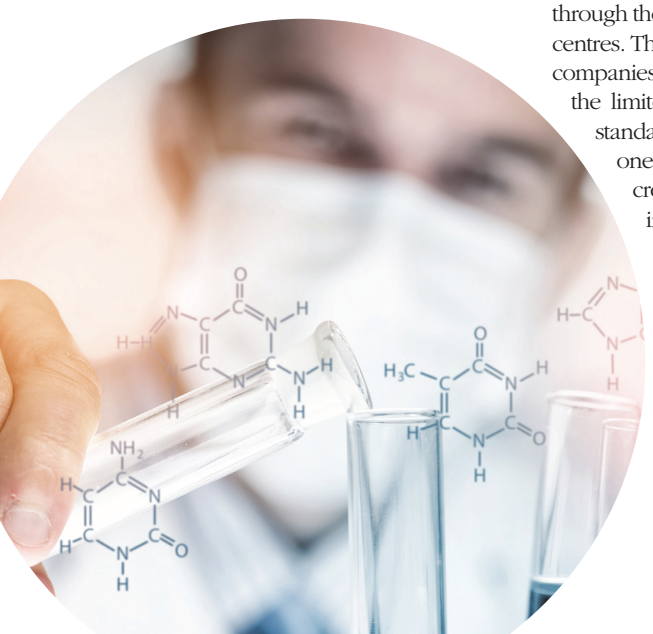
Outsourcing clinical stage development in Canada

Once therapeutic candidates have been approved for clinical development, a whole new set of outsourcing partners are needed. Clinical Trials Organizations (CTO's) or clinical CRO's represent a variety of public and private sector organizations.

Canada's exceptionally robust clinical trial sector is a reflection of significant government investment in clinical research, coupled with the intrinsic benefits of a publicly funded health system and integrated network of academic institutions and research centres. According to public figures, Canada captures as much as 4% of clinical trials globally, and has attracted significant large-pharma clinical research investments and participation in the clinical trial landscape.[16] The Canadian Clinical Trials Coordinating Centre initiative is one example of how government, industry, and health care institutions have recently come together to strengthening clinical trials for Canadians, including through the creation of a clinical trials asset map (accessible at cctam.ca) and by working to improve the speed, cost and efficiency of trials in Canada, for the benefit of all stakeholders.

At the same time, there are many private sector CTO's in Canada that specialize in providing clinical studies, including supporting our own Canadian-based (primarily early phase) therapeutics companies, and the coordination of larger studies (primarily for big pharma) outside of major academic centres. According to the Canadian Association for Independent Clinical Research, more than 60% of all clinical research that is conducted in Canada is conducted at independent research centres.[17] Many of these CTO's offer support for trials ranging from Phase I-IV, often with disease specialization. For start-up therapeutics organizations, the services of these CTOs in recruitment of smaller cohorts of healthy subjects to test for safety and basic pharmacokinetics are critical and help ensure efficient, cost effective testing of their early clinical candidates. These CTO's also provide services such as clinical trials design; data management; statistics, quality assurance; medical writing; and project management. Examples of private Canadian CTO's include: BioPharma Services, Canadian Centre for Clinical Trials, Everest Clinical Research, Inflamax Research, Lambda Therapeutic Research, Scimega Research, JSS Medical Research, and Syreon.

Public institutions also play a leading role in engaging clinical trials, both at the early phases for specialty disease populations (e.g. cancer, neuro, and others requiring specialized clinical expertise) and for larger later stage trials through the coordination of multiple Canadian centres. The challenge that global therapeutics companies have faced in the past has been the limited points of access or established standards for engaging multiple centres at one time. This challenge has lead to the creation of many public supported initiatives to address these issues and ensure that Canadian centres are more actively engaged in clinical testing of novel therapeutics. Examples of publicly funded initiatives are highlighted in Table 2. For a more detailed list of clinical trial resources in Canada, the Canadian Clinical Trials Asset Map is an excellent resource.[18]



Let's not forget about regulatory outsourcing

Many of the CRO's, CMO's, and CTO's already have regulatory expertise as a service offering to help navigate the regulatory requirements and submissions. Therefore, outsourcing of regulatory management is most often already included as an additional service offering with the private sector partners, while the public initiatives also recognize the importance of the regulatory process and help to facilitate workshops and networking events to showcase this expertise. There are also a wide variety of independent regulatory consultants who specialize in the development and management of the required submissions to Canadian (and other jurisdictional) regulatory agencies. Much like the other outsourcing organizations profiled, regulatory consultants are also working in a global market, not only supporting Canadian therapeutics companies, but also foreign companies seeking specific regional expertise to introduce their products to the Canadian market.

Market outlook on Canadian outsourcing – Competing through technology

To compete in the global market, Canadian outsourcing partners (CRO's, CMO's CTO's, etc.) will need to evolve and advance alongside the technological innovations sought by their clients. Specializing in niche areas - for example the administration of orphan drug trials, rare diseases, or providing integrated regulatory submission services, may represent an increasingly important strategy.[19, 20]

We can anticipate that biologics, which has a growing market share of new therapeutics, will continue to grow, particularly as biosimilars find their place in the market, as well as emerging technologies based on stem cells and regenerative medicine research. In 2016 personalized medicines accounted for more than 20 percent of the new molecular entities (NMEs) approved by the U.S. Food and Drug Administration (FDA) for the third year in a row, and some reports suggest that up to 40% of all drugs in development are personalized medicines.[21] The discovery of new personalized biologic therapeutic products and strategies seems likely to accelerate given the blockbuster success of monoclonal antibodies like Humira® ($16 billion dollars in revenue in 2016) and given the onset of the next generation of biologics involving stem cell and regenerative technologies, which are already progressing rapidly through clinical testing. As an example, the Stem Cell Network alone has launched 12 trials to date, and OIRM currently reports 9 active trials, spanning from phase I-III, with 4 trials launching imminently.[22]

TABLE 2: EXAMPLES OF PUBLICLY FUNDED CLINICAL TRIAL ORGANIZATIONS SUPPORTING THE CLINICAL PHASE DEVELOPMENT OF THERAPEUTICS IN CANADA

Clinical Trial Network Organizations*	Key Partners	Brief Description
Population Health Research Institute	McMaster University; Hamilton Health Sciences	Global leader in large clinical trials and population studies. Specialty areas include cardiovascular disease and diabetes. Leverages global network of partners in 92 countries. Has recruited almost 1,000,000 patients into trials to date.
Applied Health Research Centre	St. Michael's Hospital; Li Ka Shing Knowledge Institute; University of Toronto	Not-for-profit academic research organization that provides services to clinical studies (e.g. design; protocol development; data collection, coding, analysis; IT support; quality assurance; health economics). Currently has 70 staff managing 150 studies.
JDRF Canadian Clinical Trials Network	Network of Academic Centres; FedDev Investment; Juvenile Diabetes Research Foundation	Runs multi-site clinical trials aimed at curing, treating and preventing Type 1 Diabetes. In first 7 years, network funded 12 peer-reviewed leading-edge trials.
Network of Networks (N2)	Universities, hospitals, and private sector partners from across Canada	An alliance of Canadian research networks and organizations working to enhance national clinical research capability and capacity. Develops and manages shared resources such as SOP's; training; registries; and references.
Canadian Cancer Clinical Trials Network (3CTN)	N2; Canadian Cancer Trials Group; various cancer funding agencies	Supports cancer trials at networked cancer centres across Canada, improving patient access and efficiency.
CIHR Canadian HIV Trials Network (CTN)	Providence Health Care; University of British Columbia	Established in 1990, has facilitated HIV trials with industry partners and academic sites across Canada. Has implemented over 170 trials with 10,000 participants engaged.
Clinical Trials Ontario (CTO)	Ontario Government; Ontario hospitals; research universities; and industry organizations	Works with the Ontario clinical trials community to improve the environment for trials attract clinical trial investment to the province. Focused on streamlining the ethics review system across multiple clinical sites.
Princess Margaret Cancer Centre – Drug Development Program	PMCC; US-NCI; other Ontario cancer centres in London and Hamilton	Focuses on Phase I and II oncology trials. Through a consortium of Ontario hospitals, it acts as the Canadian site for NCI trials. Since its inception in 2001, it has seen more than 1,200 patients enrolled in 60 trials.
Canadian Cancer Trials Group (CCTG)	Queen's University	Network of 80 member sites across Canada and partners in over 40 countries. Specializes in phase I to III cancer trials.
Q-CROC	Network of Quebec-based cancer centres	Centralized coordinating network for cancer research trials in Quebec, facilitating standards and single point access to the cancer population in Quebec.

**Not a comprehensive list. Examples only of publicly funded clinical trial organizations in Canada.*
Source: Compiled by author from public sources.

To compete in the global market, Canadian outsourcing partners will need to evolve and advance alongside the technological innovations sought by their clients.

The use of technology, including digital hardware and software, may also soon become a disrupting force in the market. Internationally, a number of clinical CRO's have invested in mobile technology to improve clinical trial data collection. Janssen provides a recent example of how companies are investing in mobile technology to track patient engagement on questions like compliance,[23] or even to assist with matching patients to trials.[24] Increasingly, technological competence may even become mandated, as exemplified by recent changes in the ICH e6(R2) amendments, endorsed by Health Canada, and which some experts are calling the biggest change in CRO clinical trial management for years to come.[25, 26] In Canada, Deep Genomics plans to use AI technology for lead compound discovery and development,[27] while internationally, companies like BenevolentAI are already using artificial intelligence to mine and analyze biomedical information, including on clinical trials, to identify opportunities to re-profile failed therapeutics in other disease areas.[28] Datavant is an example of a company that threatens to disrupt the clinical CRO market through the application of AI technology to improving clinical trials.[29]

Concluding thoughts

Outsourcing partnerships have been part of the winning formula for Canada's success in building a vibrant therapeutics sector. Despite a relatively small domestic market for therapeutics, a very Canadian mixture of public-private activity has enabled the technological advancement of Canadian-based outsourcing partners. There is clearly strength in the Canadian therapeutics landscape from both the outsourcing of development activities to advance Canadian therapeutic companies; and the attraction of global investment for outsourcing the development, manufacturing and clinical trials of additional therapeutics candidates in Canada.

The nature of the innovation economy however, demands on-going technological advancement and competitiveness. In the context of technology driving new opportunities, it seems that continued collaboration between publicly funded initiatives and private outsourcing service providers will continue to be important for enabling the rapid technological adoption of commercially available service offerings. For example, as of October 2017, the short-listed candidates for the Innovation Superclusters program did not specifically include an opportunity for therapeutics development (except for precision health and manufacturing as a component of the digital technology cluster). However, there remains an opportunity to expand the short-listed manufacturing and perhaps even the artificial intelligence supercluster proposals to include a component for enhancing the Canadian therapeutics landscape.

It will be important that Canada's public and private sectors continue their tradition of co-development, including cross-fertilization from other high-tech sectors, in order to ensure continued growth in the Canadian life-sciences sector. We must ensure that investments in public initiatives, continue to drive the growth of Canadian companies and attract additional global investment for therapeutics development in Canada.

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