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Global Expert Mission
Advanced Therapies in Canada 2020

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Contents

Welcome

The UK is rethinking its place in the world. The Government's Global Britain agenda is beginning to take shape through its approach to trade, foreign policy, defence and security[1]. We face pressing global challenges, and we are on the brink of technological transformations that will impact us all. The importance of global cooperation to find solutions and to drive our long-term prosperity has never been greater. The UK is ready to play its part—we are a global, outward-looking nation. We have a world-leading research and enterprise environment that attracts collaboration from across the globe[2].

UK Research and Innovation (UKRI) has set out an ambitious international offer for our partners and stakeholders in the UK and overseas, providing a clear direction for our international activities and opportunities for collaboration; and maintaining and growing key bilateral and multilateral relationships with the world's leading and emerging funding agencies for research and innovation[3].

To help UK businesses become truly global enterprises through strategic international innovation collaboration, Innovate UK[4] launched its Global Expert Missions in October 2017. Delivered by the Knowledge Transfer Network (KTN)[5] in partnership with the UK Science and Innovation Network (SIN), a Global Expert Mission provides an expert-led evidence base to strengthen Innovate UK's global investment strategy: how and where it should invest to create UK business opportunities in partnerships with key economies.

Each Global Expert Mission has selected representation from the UK's business, policy, and research community, with the following objectives:

1. **Informing UK businesses and government**
   The findings and opinions of experts on the topic of the mission are made available to UK businesses and government after the overseas visit. These inform UK businesses of opportunities for innovation in the country, and the UK Government on how it can help businesses make the most of those opportunities.
2. **Building international collaborations**
   The expert insights will help inform how Innovate UK can best help UK businesses find and exploit the opportunities for innovation partnerships. The mission creates connections with key organisations and people that will deepen and widen the collaboration with the partner country to the benefit of UK business.
3. **Sharing UK capabilities**
   During the overseas visit, the delegation of experts will use the opportunity to promote and showcase the UK's innovation strengths.

The Canada Advanced Therapies mission travelled to Toronto and Vancouver in March 2020 to:

1. Develop a clear understanding of the challenges in the healthcare system and how they differ between the UK and Canada.
2. Explore the development and manufacturing capabilities in Canada to identify synergies with the growing UK industry landscape.
3. Obtain insight into the advanced therapies landscape in Canada, identifying focus areas for co-development and the market potential.
4. Learn about the advanced therapies business environment, including the make up of the sector (for example, vibrant start-up scene, corporate dominance, mixed model) and the appetite for the development of new therapies and technologies.
5. Look for opportunities for collaboration and areas where there might be clear overlap. Identify potential development or funding partners.
6. Share information about UK capabilities such as viral vector production, contract development and manufacturing organisation (CDMO) in non-viral vector areas, process development, research excellence, skills base, and clinical trials for advanced therapies.

[1] Wellcome (2020). The UK's role in global research available at https://wellcome.org/what-we-do/reports
[2] https://www.gov.uk/government/publications/uk-international-research-and-innovation-strategy
[3] https://www.ukri.org/news/ukri-publishes-its-corporate-plan-2020-21/
[4] www.gov.uk/government/organisations/innovate-uk
[5] www.ktn-uk.org

UK delegation meeting with Precision Nanosystems in Vancouver, Canada

7. Identify and introduce UK contacts to key Canadian points of contact for the topics of mutual interest.

This report summarises the information and insights gathered during the delegation's time in Canada.

A full list of the UK and Canadian participating organisations is included in Annex 1.

All monetary values quoted in this report are in Canadian Dollars unless otherwise specified.

Executive Summary

The Advanced Therapies Global mission travelled to Canada in March 2020 to better understand the innovation landscape in Canada and seek out synergies and opportunities for collaboration between the UK and Canada. Due to time constraints and the size of the country, the delegation was not able to visit all areas in five days and focused specifically on Toronto and Vancouver.

Canada is a priority country for Innovate UK; bilateral funding programmes exist between Innovate UK and NRC Canada in key sectors, and previous missions have successfully covered Advanced Manufacturing, Agri-tech, Artificial Intelligence and Quantum Technology. However, this was the first mission to visit Canada in the Health and Life Sciences sector.

There was a warm welcome and appetite for collaboration and further connectivity across the breadth of the public sector organisations with whom the delegation met (see Annex 1 for full list), in addition to the companies and academics.

It was widely recognised that the UK, being one of the leading global clusters for the development of advanced therapies medicinal products (ATMPs),[6,7,8] is more mature than Canada from an academic and industry perspective. Nevertheless, Canada has put in place strategies and policies to support the growth of life sciences overall. In regenerative medicine there are several world-leading organisations where joint UK-Canada collaboration, if not happening already, would add value and benefit to both counterparts.

There are clear cultural and environmental similarities between Canada and the UK that are striking, and personal links and networks are already strong. Many of the people who met with the delegation had experience of working in the UK, either at a high level or early in their careers. The UK and Canada face similar challenges, such as an ageing society; innovation in ATMPs may provide one avenue to tackle this burgeoning health bill through the development of curative treatments. The federal agencies such as the National Research Council of Canada (NRC)[9] presented extremely ambitious and disruptive plans in this regard for enabling the health security of the nation.

Canadians are rightly proud of their scientific heritage, notably, as an example, stem cells were identified in 1963 by Dr James Till and Dr Ernest McCulloch at the Ontario Cancer Institute, Toronto[10].

The political and governmental landscapes differ significantly, given the scale of the country, and the make up of the government structures, while having echoes of the UK's devolved administrations, are far more marked in terms of the federal versus provincial approach to support funding. The delegation came away with the recognition that, with the Memoranda of Understanding already in place, the UK could set foundations for federally-based collaboration with some organisations in Canada; opportunities to work directly with the provincial institutions in both Ontario and British Columbia were highlighted.

Many collaborations between academic and commercial organisations in both countries exist and building on these arrangements would facilitate stronger ties. A range of facilities exists in both countries which can provide a "soft landing" for businesses taking their first step on a global journey. There are similar ambitions between the two governments to help small companies grow and scale-up, and Canada will be one of four pilot countries for the forthcoming Innovate UK Global Incubator Programme.

There was a markedly positive approach from the academic parties, demonstrating how individuals, departments and teaching hospitals were supported and nurtured to be open to commercialisation, industrial collaborations, networks and deals by their institutions. From a skills and talent perspective the delegation found extremely innovative approaches to building the entrepreneurial mindset in early careers, and an understanding that Canada foresees the same bottlenecks as the UK for skills that need to be addressed to drive industry growth.

[6] http://alliancerm.org/wp-content/uploads/2019/07/ARM-Market-Access-Report-FINAL.pdf
[7] https://alliancerm.org/wp-content/uploads/2019/07/ARM-BIA-Collab-UK-Data-Report-FINAL.pdf
[8] https://www.bioindustry.org/uploads/assets/uploaded/c2ac4647-a10d-41bd-8dc69c51d10cd9f6.pdf
[9] https://nrc.canada.ca/en
[10] https://www.cell.com/fulltext/S0092-8674(05)00919-0

The delegation considered, in numerous meetings, the benefits of having a presence on opposite sides of the world (the UK and Canada) with respect to the advanced therapies regulatory environment. Indeed, in a post-EU exit context, given Canada models its regulatory system on the EU system as a country outside the EU, the UK can probably learn from the Canadian experience when exporting into the EU. Canada is also a member of the International Council for Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) region, which the UK is not a member of yet. Therefore, the guidance for good manufacturing practice (GMP) compliance and inspection (ICH Q7a[11]) is, presumably, satisfied with some nuances in approaches that would be pertinent for the UK to understand better.

Similar to the UK Government, it is a national priority for Canada to focus on ATMPs, and in the locations we visited it is also a provincial priority. Our Canadian colleagues look on the concept of the Life Sciences Industrial Strategy[12] and the Life Sciences Council[13] as a model to explore further to drive a high-level strategy at the federal level, utilising sector champions such as we have in the UK.

[11] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-q7a-good-manufacturing-practice-guidance-active-pharmaceutical-ingredients
[12] https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/650447/LifeSciencesIndustrialStrategy_acc2.pdf
[13] https://www.gov.uk/government/news/uk-life-sciences-sector-brings-record-growth-as-new-life-sciences-council-meets-for-first-time

1. Canada Advanced Therapies Sector Overview

1.1 Landscape Map of Key Stakeholders

The delegation met with a variety of organisations and individual stakeholders from the Canadian ATMP sector in Toronto and Vancouver. Some are presented in the summaries provided in Section 1.4.

Similar to the UK, it is a difficult exercise to map and maintain the detail of this ecosystem. The Canadian Stem Cell Network (SCN) has produced a useful and detailed infographic as shown in Figure 1 (below).

VIEW HERE

Source:
https://stemcellnetwork.ca/about-us/rmac/

Key highlights

In 2017:

- 43 Private sector companies, employ 2,000 in the wider regenerative medicines space.
- 10 Universities with regenerative medicine programmes.
- 18 Regenerative medicine clinical trials active in Canada in 2017, with 11 to follow for the 2018 period.

Healthcare access:

- Canada has a publicly-funded healthcare system, covering medically-necessary hospital care and medicines through provincially-administered formularies. This bears some similarities to the UK's National Health Service, and therefore collaborative work to address common challenges would be of mutual benefit.
- Canada's provincial healthcare systems and associated disease registries and databases could facilitate multicentre clinical trials with diverse patient populations. This is especially relevant for research relating to orphan diseases, where it can be challenging (or impossible) to recruit enough patients for a clinical trial in a single location. In short, Canada's publicly-funded healthcare system allows for the recruitment of patients across the country.

Pricing and reimbursement processes:

- A report from 2017 cites that it can take over 400 days to decide whether to reimburse a drug that has been authorised for sale by the regulator in Canada[14].
- Canadian Agency for Drugs and Technologies in Health[15] (CADTH) conducts national health technology assessments and provides new product reimbursement recommendations through its Common Drug Review process.
- Canada has a Patented Medicine Prices Review Board[16] to restrict the price of emerging products in Canada. This group has the authority to consider the following when making its decisions:
  - The prices at which the medicine has been sold in the relevant market.
  - The prices at which other medicines in the same therapeutic class have been sold in the relevant market.
  - The prices at which the medicine and other medicines in the same therapeutic class have been sold in countries other than Canada.
  - Changes in the Consumer Price Index.
  - Any other factors that may be set out in regulations.

Regulatory bodies - Health Canada[17]:

- Canadian regulators, public funding bodies and health technology assessment bodies appear to be open to considering more collaborative, comprehensive, and earlier engagement. There is an atmosphere of change in Canada. Novel and exciting initiatives are being considered, and some can be accessed by regenerative medicine developers. For example, an innovative approach to planning clinical trials has been used by the MaRS[18] Excellence in Clinical Innovation Technology Evaluation (EXCITE) programme[19] to de-risk clinical trial investments by facilitating pre-commercialisation negotiations with the Ontario provincial government that, once criteria are agreed and met, guarantee reimbursement. Pricing and reimbursement are issues that affect the global regenerative medicine industry and must be addressed early to be effective.

[14] https://www.phacilitate.co.uk/sites/default/files/clarion_phacilitate/pdfs/advanced_therapies_investment_report_phacilitate.pdf
[15] https://www.cadth.ca
[16] http://pmprb-cepmb.gc.ca/home
[17] https://www.canada.ca/en/health-canada.html
[18] https://www.marsdd.com/what-we-do/
[19] https://www.marsdd.com/media-centre/breakthrough-health-technologies-to-reach-patients-faster-through-mars-excite/

- Since recognition that regenerative medicines (within which ATMPs sit) are a key growth area for Canada, there has been a shift towards targeted investments in this area, such as the Centre for Commercialization of Regenerative Medicine (CCRM)[20].

Investment in the sector:

- Public sector federal government investment in regenerative medicine has been significant; a brief overview is provided later, with further information on the organisations in subsequent sections of this report. One such investment included a $114 million grant[21] for a regenerative medicine research initiative, Medicine by Design, at the University of Toronto[22], awarded in the first round of funding of the Canada First Research Excellence Fund[23] in 2015. The federal government and GE Healthcare later announced additional funding in early 2016, each pledging $20 million to Medicine by Design's commercial arm, CCRM, to establish and operate a new Centre for Advanced Therapeutic Cell Technologies[24]. Prime Minister Justin Trudeau noted that this new centre would "use a collaborative approach between research institutions and industry to solve cell therapy manufacturing challenges"[25]. In November 2016, Stem Cell Network (SCN), with the support of the Minister of Science, announced funding of $9 million for regenerative medicine research, which was made available as a 2016 federal budget commitment of $12 million over two years to further the work of SCN[26]. Whilst on the mission, the delegation learned of a new $6.9 million federal investment to SCN to support four clinical trials across the country aimed at bringing new therapies to the clinic and growing Canada's regenerative medicine sector[27]. Provincial governments are also supporting regenerative medicine initiatives; the Government of Ontario established the Ontario Institute for Regenerative Medicine (OIRM)[28] in 2014 with $3 million in provincial funds[29] and ThéCell[30] is financed by Fonds de recherche du Québec – Santé[31].
- One highlight of the private sector is the $225 million investment by Bayer AG and venture capitalists Versant Ventures US to develop a stem cell research company in Toronto; BlueRock Therapeutics[32].
- According to a workshop report produced by the Council of Canadian Academies[33] "Canada lacks accessible funding for home-grown entrepreneurs and regenerative medicine start-ups". The report notes that this reduces Canadian-based researchers' ability to commercialise their research and provides an example of how Canada attracts less venture capital when compared to other leading regenerative medicine groups globally, e.g. Australia and the UK. The report goes on to compare Canada's pharma venture arms presence (currently there are two - Johnson & Johnson and Valeant) with other leading regenerative medicine clusters (e.g. eight in California, six in the United Kingdom). The report references that CCRM drew similar conclusions on the challenges for Canadian regenerative medicine start-ups, as it concluded: "Canadian start-ups raised less than 1% of total overall venture capital funding" compared to much higher percentages raised in other clusters, e.g. UK and Japan[34].

Scientific capability:

- 400 stem cell scientists are working on a range of conditions at 68 centres housed within or affiliated with 25 Canadian universities[35].
- Numerous teaching hospitals, with nine hospitals co-located in the Greater Toronto Area[36].
- Canada has dedicated structures and organisations in place to support the advanced therapy sector with the likes of a national Stem Cell Network (SCN), and Centre for Commercialization of Regenerative Medicine (CCRM), Regenerative Medicine and Cell Therapy Network (CellCAN) as well as provincial networks e.g. Ontario Institute for Regenerative Medicine (OIRM) and ThéCell Network. Please see the reference in footnote number 41 for a more comprehensive list of the structures (pp 9, Table 2.1)[37].
- Stem cell governance and policy is also an area where Canadian-based researchers are active both nationally and internationally, collaborating with agencies such as the International Stem Cell Forum (ISCF)[38] and the International Society for Stem Cell Research (ISSCR)[39].

[20] https://www.ccrm.ca
[21] https://web.cs.toronto.edu/news-events/news/medicine-by-design-to-accelerate-regenerative-medicine-discovery-and-translation-with-new-20-million-investment
[22] https://mbd.utoronto.ca
[23] https://www.cfref-apogee.gc.ca/home-accueil-eng.aspx
[24] https://www.labmanager.com/labs-less-ordinary/toronto-s-centre-for-advanced-therapeutic-cell-technologies-makes-its-mark-on-regenerative-medicine-2339
[25] https://pm.gc.ca/en/news/news-releases/2016/01/13/prime-minister-announces-support-canadian-centre-advanced-therapeutic
[26] https://www.660citynews.com/2016/11/24/ottawa-contributes-another-9-million-stem-cell-research/
[27] https://montreal.ctvnews.ca/canada-is-investing-6-9-million-in-stem-cell-research-1.4834862?cache=
[28] https://oirm.ca
[29] https://www.ccrm.ca/sites/default/files/R%24%20-%20Vol28%2319%20-%20Dr.%20May%20%28CCRM%29%20interview.pdf
[30] http://www.reseauthecell.qc.ca/index.php/about-thecell
[31] http://www.frqsc.gouv.qc.ca/en/
[32] https://bluerocktx.com/news/bayer-and-versant-ventures-join-forces-to-launch-stem-cell-therapy-company-bluerock-therapeutics-with-usd-225-million-series-a-financing/
[33] https://cca-reports.ca/wp-content/uploads/2018/10/2017-03-08-Regen-Med-Book-ENG-WEB.pdf
[34] https://cca-reports.ca/wp-content/uploads/2018/10/2017-03-08-Regen-Med-Book-ENG-WEB.pdf
[35] https://www.nce-rce.gc.ca/NetworksCentres-CentresReseaux/CECR-CECR/MI_eng.asp
[36] https://medicine.utoronto.ca/about-faculty-medicine/fully-affiliated-hospitalsresearch-institutes
[37] https://cca-reports.ca/wp-content/uploads/2018/10/2017-03-08-Regen-Med-Book-ENG-WEB.pdf
[38] https://stemcellforum.org
[39] https://www.isscr.org

Infrastructure:

- In addition to its successful networks, Canada has developed a range of infrastructure to support regenerative medicine research and development (R&D). This includes successful commercial companies that produce inputs needed for research (e.g. STEMCELL Technologies Inc.[40], Tissue Regeneration Therapeutics Inc.[41]), cord blood, stem cell line and tissue banks, and seven large cell therapy manufacturing centres spread across the country. Please see the reference in footnote 47 for a more comprehensive list (pp 18, Table 2.2)[42].

1.2 Toronto and Vancouver as Hubs for ATMPs

The delegation visited Toronto (Ontario) and Vancouver (British Columbia), but did not have time to visit another two key centres for the cell and gene therapy sector, Montreal and Ottawa.

1.2.1 Toronto

Toronto's ATMP ecosystem was particularly impressive in terms of the proximity of all its key components:

- The nine teaching hospitals and the 23 affiliated hospitals are all under one medical faculty.
- The university system (perhaps because they are all co-located in the MaRS Discovery District - Toronto's urban innovation hub[43]) is closely-aligned to the medical centres.
- There is an evolving ecosystem and the interaction with the clinical network is critical in this. For example, BlueRock Therapeutics, a cell therapy company, formally announced its plans to strengthen its ongoing strategic collaboration with the McEwen Stem Cell Institute[44] at the University Health Network (UHN)[45] in Toronto[46].
- There is a focus on innovation leading to company formation (driven by the Toronto-hosted national organisation CCRM).
- The Ontario province health system provision is similar to that in the UK.
- Wrapped around the urban innovation hub are key stakeholders, some of which the delegation met, e.g. J Labs[47] and MaRs, that bring the ecosystem (a word often used in Toronto) together.

From an innovation and business perspective, the delegation was impressed by how comfortable the academics and medical leaders were with concepts of innovation, entrepreneurship, and economic benefit. With the latter, the economic benefit was not from a shareholder's perspective, but for finance to fuel the research and innovation system.

The delegation was impressed by the physical impact of the Toronto urban innovation hub, and similarities with the Cambridge area of Boston, or in particular the Euston Road nexus in London in the UK; The Wellcome, Francis Crick Institute, Syncona Investors, and one of the key universities and teaching hospitals of UCL, all practically co-located, with other major teaching hospitals and world-leading medical research centres and the Cell and Gene Therapy Catapult (CGTC) not far away.

1.2.2 Vancouver

In comparison to the urban nature of Toronto as a hub, Vancouver's key institutions are more dispersed across the city and tend towards leading academic institutions hosting spin-outs and incubators rather than some of the dedicated structures we saw in Toronto:

- The University of British Columbia (UBC) campus hosts several key research departments, including incubator buildings for spin-out companies; Principal Investigator Peter Zandstra is a co-founder of CCRM, as well as specific departments within UBC[48].
- adMare Bioinnovations[49] is an incubator/catalyst for Canada-based life scientists, not just in British Columbia, but across Canada.
- BC Cancer Research Centre[50] supports cancer research across British Columbia; its major research units include the Terry Fox Laboratory[51] and the Michael Smith Laboratories[52].
- Anchor companies of scale such as Stem Cell Technologies, a spin-out from the Terry Fox Laboratory.
- Genome BC[53], a non-profit organisation, leading on genomics innovation in British Columbia.

Meetings that the delegation held reinforced the fact that stakeholders are widely provincially-based and federally-funded,

[40] https://www.stemcell.com
[41] http://www.verypowerfulbiology.com
[42] https://cca-reports.ca/wp-content/uploads/2018/10/2017-03-08-Regen-Med-Book-ENG-WEB.pdf
[43] https://www.marsdd.com
[44] https://www.uhn.ca/Research/Research_Institutes/McEwen_Stem_Cell_Institute
[45] https://www.uhn.ca
[46] https://www.uhn.ca/Research/Research_Institutes/McEwen_Stem_Cell_Institute/Documents/BlueRock_UHN_Collaboration.pdf
[47] https://jlabs.jnjinnovation.com/locations/jlabs-toronto
[48] https://www.med.ubc.ca/person/peter-zandstra/
[49] https://www.admarebio.com
[50] https://www.bccrc.ca
[51] https://www.bccrc.ca/dept/tfl/
[52] https://www.msl.ubc.ca/research-clusters/
[53] https://www.genomebc.ca

which adds to the complexity of the Canadian landscape; this very much fosters a collaboration versus cooperation model – for example Genome BC with a dedicated budget and strategy distinct, but complementary to Genome Canada, which acts nationally[54].

1.3 National Research Council Canada and the Potential for Disruptive Innovation

The UK delegation held a roundtable with a senior group from the National Research of Council Canada[55] (NRC) who led in cell and gene therapy, hosted by the UK Consul in Toronto. NRC is Canada's largest federal research and development organisation.

In addition to the range of research programmes being funded through NRC in this field, the Disruptive Technology Solutions for Cell and Gene Therapy Program[56] was outlined. This programme set up in 2019, will design and develop disruptive technology solutions for precision-engineered cell and gene therapies for the treatment and potential cure of chronic diseases and rare genetic disorders affecting Canadians. In doing so, the NRC will coordinate a national effort to increase the affordability and accessibility of these ground-breaking technologies in collaboration with academic facilities, research centres and networks, clinicians, hospital centres and others, to enable a national ecosystem for health innovation in the area of cell and gene therapies.

As an exemplar, NRC colleagues outlined their drive to produce CAR-T treatments for Canadian patients from government-funded facilities and "bypass" the pharma model. This ambitious concept is potentially disruptive to the UK's global model. And the goal to use microfluidics as a means for delivering a whole autologous cell manufacturing process for personalised treatments could be game-changing.

1.4 Commercialisation, Research and Innovation Structures

The delegation met with a number of support structures and actors in ATMP commercialisation, research and innovation. Some organisations have a tight remit, for example as incubator or research funding support, or skills and training, whereas others have a wider scope. The organisations and the key points arising from the discussions the delegation had in relation to their strategy and appetite for UK interactions are as follows:

- AdMare Bioinnovations[57] is exploring how Canada can redesign its landscape to enable and exploit national centres working together towards innovation/commercialisation. However, it has a wider remit than ATMPs, focusing more on the discovery area in life sciences, particularly oncology and neuroscience. It is described as Canada's Global Life Sciences Venture[58] and acts as an incubator/catalyst for Canadian life sciences, $565 million has been invested in eight spin-outs over the past 12 years; they have provided access to 50+ scientific and 20+ commercial staff. Their strategy is to identify promising research from leading academic and biotech partners to create companies of scale, providing specialist expertise and infrastructure to help existing companies scale-up. They also intend to drive the growth of those companies in Canada by training the next generation of highly-qualified personnel. Great examples of their success are spin-outs such as Notch Therapeutics[59] and Precision Nanosystems[60]. They also play a major role in skills development for the sector with their postdoctoral training programme of over 250 registrants.

  AdMare Bioinnovations collaborates with Life Ark in the UK and discussions highlighted the potential for further engagement with the Medicines Discovery Catapult[61] and awareness of schemes such as the BioMedical Catalyst[62] and Knowledge Transfer Partnership (KTP)[63] model.

- British Columbia Regenerative Medicine's (BCRegMed[64]) role is to work across academic, industry and government entities to foster collaborative activities within the BC regenerative medicine community. The network aims to engage and mobilise the scientific and entrepreneurial community in BC and the wider Cascadia region to translate and commercialise fundamental discoveries. It is funded by UBC's Research Excellence Cluster programme[65] and several partners[66].

- CellCAN[67] is Canada's main network of cell therapy centres, and it operates as a pan-Canadian non-profit organisation

[54] https://www.genomecanada.ca
[55] https://nrc.canada.ca/en
[56] https://nrc.canada.ca/en/research-development/research-collaboration/programs/disruptive-technology-solutions-cell-gene-therapy-challenge-program
[57] https://www.admarebio.com
[58] https://www.admarebio.com/about/
[59] https://notchtx.com
[60] https://www.precisionnanosystems.com
[61] https://md.catapult.org.uk
[62] https://mrc.ukri.org/funding/science-areas/translation/biomedical-catalyst/
[63] https://ktn-uk.org/programmes/knowledge-transfer-partnerships/
[64] https://bcregmed.ca
[65] https://research.ubc.ca/about-vpri/research-excellence-clusters
[66] https://bcregmed.ca/about/support-partners/
[67] https://cellcan.com/en/

The UK delegation with colleagues from AdMare Bioinnovations and Health Canada

as part of the Government of Canada's Networks of Centres of Excellence[68]. CellCAN's mission is to improve the quality, safety and feasibility of cell and gene therapy in Canada through optimal manufacturing practices. The emphasis is on building a network, advancing regulatory standards, effective outreach, and positioning Canada as a world leader. There are parallels with some UK networks, in particular the ATMP Manufacturing Community (amc)[69].

The meeting with the UK delegation focused on the skills needed across the sector and the alignment with the training aspects of the Cell and Gene Therapy Catapult (CGTC) co-ordinated Advanced Therapy Treatment Centre (ATTC)[70] network. There is potential for collaboration in this area, one concept is through virtual training. Given the establishment of the Centre for Advanced Therapies Training and Skills (CATTS) programme[71] by the CGTC in the UK, which aims to boost cell and gene therapy as well as vaccine skills more specifically, this was highlighted as an area to revisit and potential for collaboration.

- The Centre for Commercialization of Regenerative Medicine (CCRM[72]) is a not-for-profit government-funded commercial facility, supported by both the Government of Canada and the Province of Ontario. CCRM has the same goals as the CGTC in the UK, but operates on a different model. CCRM has been involved in successful company spin-outs (e.g. AvroBio[73]), company development (e.g. BlueRock) and promotion of entrepreneurial programmes (such as Creative Destructive Labs[74] and Medicine by Design[75]). There is an existing collaborative relationship between CGTC and CCRM that can be built upon while engaging businesses both in the UK and Canada. Based in Toronto, it has also established a 40,000 square foot space dedicated to advanced cell manufacturing that includes a Good Manufacturing Practices facility for producing cells and viral vectors. CCRM also spoke about the potential for a larger-scale facility to accommodate late Phase 3 or commercial-stage production that is under development at a separate site. There is a strong relationship between CCRM and the CGTC, with opportunities for further collaboration.

  During the meeting with the UK delegation, lots of synergies and potential for collaboration were discussed, in particular building on the existing relationship of CCRM and the CGTC, including the model of the ATTCs and potential commercial interest in the larger facility under development.

[68] https://www.nce-rce.gc.ca/index_eng.asp
[69] https://atmpmanufacture.org
[70] https://www.theattcnetwork.co.uk
[71] https://advancedtherapiesapprenticeships.co.uk/latest-news/catts-2/
[72] https://www.ccrm.ca
[73] https://www.avrobio.com
[74] https://www.creativedestructionlab.com/locations/toronto/
[75] https://mbd.utoronto.ca

The UK delegation with colleagues from CCRM, Health Canada, SCN, Medicine by Design, iVexSol and Sernova

CCRM already has a franchise in Australia and an ambition to build a global network of similar hubs to reach c.1000 companies. A mutual "soft landing zone" for UK and Canadian companies looking to internationalise was also discussed.

- The Centre for Commercialisation of Cancer Immunotherapies (C3i[76]), based in Montreal, is a government-supported development and manufacturing capability. C3i provides an integrated structure to accelerate the discovery, development, commercialisation and access to innovative cancer immunotherapies and regenerative medicine. One of its units, the Centre of Excellence for Cellular Therapy (CETC) is a cGMP manufacturing facility for cellular therapies, including cancer immunotherapies. Located within the Hospital Maisonneuve-Rosemont in Montreal, CETC houses 14 GMP cleanrooms in 37,000 square feet. The CETC has been validated by the Canadian European Medicines Agency (EMA) and US Food and Drug Administration (FDA) regulatory agencies.

  Discussion with the UK delegation highlighted an appetite and potential for international collaboration, including in areas such as analytics, mechanisation, and the automation of ATMP manufacture. Access to Canadian and US markets could be an attractive prospect for UK manufacturers and distributors.

- Genome BC[77] is a non-profit research organisation funded by the Province of British Columbia and the Government of Canada through Genome Canada and Western Economic Diversification Canada[78]. Genome BC funds research and facilitates innovation across a range of sectors, and an example of touchpoints with ATMP therapeutic approaches is their focus on the application of genomics in cancer and rare diseases.

- J-Labs[79] in Toronto is a Johnson & Johnson global innovation hub. It supports a wide range of resident companies across the life sciences sector providing access to lab space, equipment and commercialisation support. It is located within the MaRS Discovery District enabling access to the wider ecosystem in the area. CCRM are partners and host a space within J-Labs. The Ontario government has invested $20 million in the facility.

  The delegation met with some relevant start-ups that are described in Section 1.6.

[76] https://centrec3i.com
[77] https://www.genomebc.ca
[78] https://www.wd-deo.gc.ca/eng/home.asp
[79] https://jlabs.jnjinnovation.com/locations/jlabs-toronto

The UK delegation alongside Health Canada at J-Labs

- MaRS Discovery District[80] supports start-ups, researchers and innovators across four key sectors, one of which is health. MaRS received significant provincial government investment to set up. The linkages and co-location with CCRM and its proximity to several teaching hospitals, makes it an ideal location within Toronto for innovative companies in the ATMP arena. MaRS Ventures has worked with 1,300 companies, 80 of which were in-house.

- The National Research Council of Canada Industrial Research Assistance Program (NRC IRAP[81]) is funded to support Canadian SMEs, by providing advice, connections, and funding to help increase their innovation capacity and take ideas to market. Their function is similar to the combination of roles undertaken by Innovate UK, the Knowledge Transfer Network and Enterprise Europe Network. They manage the EUREKA network within Canada, a mechanism that the UK also uses to drive international collaboration, and where there is already good engagement between Canada and the UK. Several bilateral R&D funding programmes are already in place covering Advanced Manufacturing, Agri-tech and Quantum. As such NRC-IRAP offers a platform to explore collaboration for ATMPs.

- Ontario Institute for Regenerative Medicine (OIRM[82]) is a non-profit stem cell institute funded by the Ontario government to transform discoveries into clinical trials and cures. OIRM has enabled significant commercialisation through its research investments, such as the setup of Satellos[83] and BlueRock, both with OIRM-funded founders.

  It has invested $25 million in research, education, and community development, covering a broad range of disease areas.

  There were opportunities to collaborate on a proposal to fund a cross-centre clinical trial to explore the feasibility of distributed manufacturing, led by CGTC and CCRM and working also with C3i and OIRM. The value of adopting a distributed manufacturing model lies in its ability to cope with small-volume high-value therapies, particularly where cryopreservation is to be avoided[84].

- The Stem Cell Network (SCN[85]) is a key national non-profit organisation that has directed over $100 million of strategic funding since 2001 with the goal of translating science from the lab to clinical application and commercial products in the field of stem cells and regenerative medicine. Funded by the Government of Canada, SCN works in partnership with a range of stakeholders including industry, health charities, government and non-government organisations. Since 2001, SCN-directed investment has supported 170 leading research groups, 3,000 trainees and has underpinned over 19 clinical trials.

[80] https://www.marsdd.com
[81] https://nrc.canada.ca/en/support-technology-innovation/nrc-irap-innovation-assistance-program-iap
[82] https://oirm.ca
[83] https://satellos.com
[84] https://www.researchgate.net/deref/http%3A%2F%2Fdx.doi.org%2F10.1016%2Fj.jcyt.2018.05.003
[85] https://stemcellnetwork.ca

The UK delegation meeting with colleagues from MaRS in Toronto

SCN has generated a detailed landscape map of the Canadian regenerative medicine ecosystem (see Figure 1, page 8), for use to advocate for the sector and signpost for interactions. This could be used to help identify where it makes sense for the UK and Canada to collaborate. Additional networks and infrastructure that the delegation did not meet with, but which play an essential role in supporting ATMP research and innovation in Canada include the Canadian Institutes of Health Research (CIHR)[86], the Centre for Drug Research and Development (CDRD)[87], the National Public Cord Blood Bank[88], the Canadian National Transplant Research Program[89], and the Institute for Research in Immunology and Cancer – Commercialization of Research (IRICoR)[90]. The Council of Canadian Academies report provides more in-depth information on this summary[91].

1.5 Academic and Clinical Expertise in Advanced Therapies

Many of the groups and organisations that we met have relationships with the research community in the UK; there are strong foundations to grow collaborations. The week before the mission, a small UK academic delegation, plus Innovate UK, had visited Toronto for a research showcase, reflecting the strong relationships with the UK academic community, and the UK's Medical Research Council, in particular, built up over a number of years.

In Toronto and Vancouver, the delegation met with leading academic principal investigators (PIs), clinicians and researchers in departments built on the early scientific foundations of seminal researchers such as Till and McCulloch, that in 1963 demonstrated the existence of stem cells; alongside some very strong and forward-thinking networks whose remit is to maximise commercialisation efforts of individual institutions/hospitals. The groups the delegation met with were very open to collaboration with industry.

- The University Health Network (UHN[92]) comprises Toronto General and Toronto Western hospitals, the Princess Margaret Cancer Centre, Toronto Rehabilitation Institute, and The Michener Institute of Education at UHN. UHN has the largest hospital-based research programme in Canada, with major research in cardiology, transplantation, neurosciences, oncology, surgical innovation, infectious diseases, genomic medicine, and rehabilitation medicine. There were many established relationships with UK PIs and research groups, and the delegation took actions to connect into wider areas such as the UK genomics strategy.

- Medicine by Design[93] is an academic research organisation working across the areas of physical and life sciences, engineering, mathematics and medicine in the University of Toronto and its affiliated hospitals to drive transformative research in regenerative medicine and cell therapy. It was

[86] https://cihr-irsc.gc.ca/e/193.html
[87] https://www.nce-rce.gc.ca/NetworksCentres-CentresReseaux/CECR-CECR/CDRD-CRDM_eng.asp#about
[88] https://www.blood.ca/en/article-tags/cord-blood-bank
[89] https://cdtrp.ca/en/
[90] https://www.iricor.ca
[91] https://cca-reports.ca/wp-content/uploads/2018/10/2017-03-08-Regen-Med-Book-ENG-WEB.pdf
[92] https://www.uhn.ca
[93] https://mbd.utoronto.ca

Discussions taking place between the UK delegation and colleagues at the University Health Network in Toronto

funded through the government's Canada First Research Excellence Fund[94]. Alongside research funding, it works to support clinical translation and commercialisation. With an international mandate, the delegation learned that 50% of their international collaborations are with UK groups. This highlighted the strong appetite for UK-Canada academic partnerships in the advanced therapies area, which will underpin long-term innovation collaboration.

- The Health to Innovation Hub (H2i[95]) provides a wrap-around approach to developing and supporting entrepreneurship and stimulating innovation. Working through the Faculty of Medicine at the University of Toronto, UHN works with early-stage companies, providing access to structured programmes and mentorship. Not ATMP-specific, the H2i supports all medicine faculty departments and incubators, from medical devices to diagnostics to therapeutic interventions. One of the mechanisms that they draw on is led by Mitacs[96] which has similarities to Innovate UK's Knowledge Transfer Partnerships[97]. There is already a joint programme in place between Mitacs and UKRI with potential to explore further collaboration beyond the initial programme.
- BC Cancer Research Centre (BCCRC[98]) supports more than 60 laboratories in British Columbia, e.g. the Terry Fox Laboratory[99]. The laboratories host several groups with a focus on cell and gene therapy and a number of core facilities, including the Clinical Cell Therapy Laboratory (CCT)[100]. Separately, the delegation met with Francois Bernard[101] and discussed the area of radiopharmaceuticals for diagnosis and targeted radionuclide therapy of various cancer types, as well as cyclotron production of isotopes. He has established connections in the UK, and the delegation took on the task to facilitate wider introductions.

The delegation attended an advanced therapies roundtable hosted by UBC PI, CCRM Director and Notch Therapeutics founder, Prof Peter Zandstra. The organisations and departments that presented are summarised below.

- University of British Columbia (UBC[102]) departments:
  - The Michael Smith Laboratories[103] including the Zandstra group[104] whose research focus is the generation of functional tissue from somatic and pluripotent stem cells.
  - The Faculty of Medicine[105], in particular, the Cullis group -

[94] https://www.cfref-apogee.gc.ca/home-accueil-eng.aspx
[95] https://h2i.utoronto.ca
[96] https://www.mitacs.ca/en
[97] https://ktn-uk.org/programmes/knowledge-transfer-partnerships/
[98] https://www.bccrc.ca
[99] https://www.bccrc.ca/dept/tfl/
[100] https://www.bccrc.ca/dept/tfl/services/clinical-cell-therapy
[101] https://www.bccrc.ca/dept/ccr/projects/national-program-radioligand-therapy-prostate-cancer
[102] https://www.ubc.ca
[103] https://www.msl.ubc.ca
[104] https://www.msl.ubc.ca/people/dr-peter-zandstra/

Liposomal nanosystems[106] for drug and targeted delivery.
  - Department of Medical Genetics[107] and research of Prof Kelly McNagny[108] whose research interests include stem cells, immunology, inflammatory disease, cancer and kidney disease.

- British Columbia Children's Hospital Research Institute (BCCHR)[109] - the delegation heard about work in CAR-T and Tregs (chimeric antigen receptor T-cell-therapies) from UBC's Prof Megan Levings[110].

- University of Victoria[111], in particular Prof Stephanie Willerth's[112] research in the Biochemical Engineering Department on stem cells, tissue engineering, drug delivery, cellular reprogramming and 3D bioprinting.

- Centre for Brain Health[113] – Prof Cheryl Wellingtons'[114] group on traumatic brain injury models.

- The Simon Fraser University (SFU[115]) and the work of Prof Robert Young[116] in chemical biology, medicinal chemistry and drug discovery.

1.6 Canada's Advanced Therapies Industry

The 2017 Stem Cell Network Ecosystem (Figure 2) indicates that in the wider regenerative medicine field there are 43 companies. Since publication, there have been notable therapeutics company deals such as BlueRock[117], Notch Therapeutics[118] and AvroBIO[119], all with links to key figures in the landscape and across the border with Boston, USA. It seems that the sector is dominated by enabling technology companies with a smaller number of therapeutics developers. In this regard, the UK sector is more mature and invested, with 56 ATMP companies headquartered in the UK[120].

From a manufacturing perspective, given the early nature of the sector in terms of the therapeutics clinical development pipeline, the CDMO space in Canada is currently served by C3i and a CCRM facility. CCRM has further plans and sees the opportunity for a separate larger-scale site, potentially attracting an international CDMO to invest. This would greatly expand Canada's capability in this area.

A number of the companies the delegation met have existing bases or relationships with the UK and are actively looking at building future relationships, in particular StemCell Technologies, Precision Nanosystems and iVexSol.

The delegation also met with several companies with enabling technologies of interest in the ATMP sector as outlined below. A few actions were taken away to engage further and connect these companies through Innovate UK, KTN, UK Department for International Trade (DIT) and the CGTC. There are clear synergies between the challenges tackled and therapies developed by these companies and UK-based ones, and a clear desire for collaboration with the UK has been expressed in the conversations the delegation had with each company. Through recent interviews by Wellcome, voices from the pharma industry with a strong research focus have also stressed the importance of international collaboration in underpinning UK competitiveness[121]. Now more than ever, in the context of COVID, research collaboration is essential for producing world-leading science. UKRI has committed to set a clear direction for its engagement in global collaboration by developing an international strategy that will set a bold ambition to be the international partner of choice for world-leading research and innovation, driving and benefiting from partnership with the world's most innovative nations, such as Canada, and working across borders to tackle global challenges[122].

[105] https://biochem.ubc.ca/person/pieter-cullis/
[106] http://www.liposomes.ca
[107] https://medgen.med.ubc.ca
[108] https://medgen.med.ubc.ca/person/kelly-mcnagny/
[109] https://bcchr.ca
[110] https://bcchr.ca/mlevings
[111] https://www.uvic.ca
[112] https://www.uvic.ca/engineering/mechanical/faculty-and-staff/faculty/willerth.php
[113] https://www.centreforbrainhealth.ca
[114] https://www.centreforbrainhealth.ca/wellington-cheryl
[115] https://www.sfu.ca
[116] https://www.sfu.ca/chemistry/people/profiles/roberty.html
[117] https://financialpost.com/entrepreneur/0410-biz-jl-lorinc
[118] https://www.fiercebiotech.com/biotech/allogene-taps-notch-therapeutics-for-cell-therapy-s-next-chapter-stem-cell-based-cancer
[119] https://investors.avrobio.com/news-releases/news-release-details/avrobio-and-magenta-therapeutics-announce-collaboration-evaluate
[120] https://sciencebusiness.net/news/uk-leading-europe-development-advanced-therapies
[121] Wellcome (2020). The UK's role in global research available at https://wellcome.org/what-we-do/reports
[122] https://www.ukri.org/news/ukri-publishes-its-corporate-plan-2020-21/

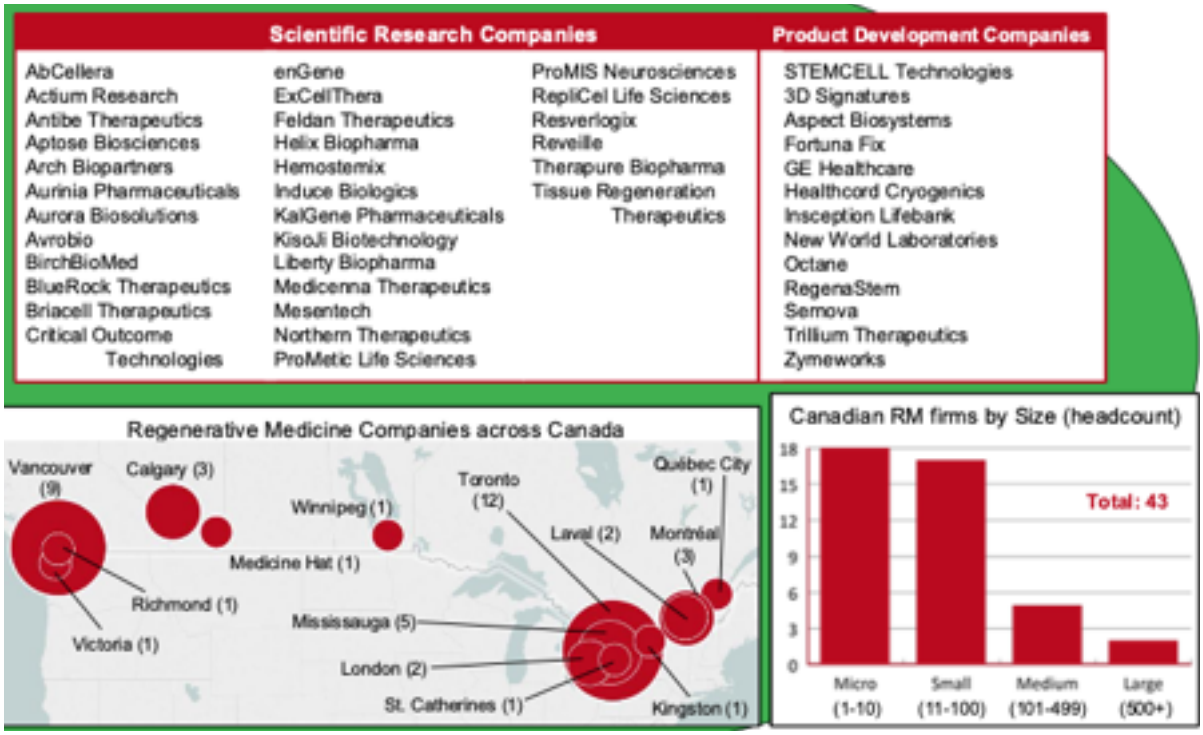

Figure 2 Stem cell network ecosystem highlighting company landscape

- ACORN Biolabs[123] is a service and technology company offering collection, cryopreservation and analysis and storage of individual's hair follicle stem cells for potential future use in personalised healthcare.

- Aspect Bio[124] focuses on proprietary microfluidics and 3D bioprinting technology to drive the development of bio-printed therapeutics.

- Innovakine[125] is a company developing novel molecular tools to improve cell-based therapies for various diseases including cancer and infectious diseases. The technology they are developing is very promising in the CAR-T space and the delegation learned that they had received funding from Genome BC and NRC IRAP.

- iVexSol[126] focuses on inducible genetic systems for next-generation manufacturing technology to revolutionise the production of lentiviral vectors. They are based in Boston, USA, and there is interest in setting up a UK base.

- panCELLA[127] is a platform technology company hosted at J-Labs. panCELLA seeks to provide absolute control of deregulated cell proliferation with its proprietary FailSafe cell technology.

- Precision Nanosystems[128] – Scale-up and manufacturing technology for RNA-LNPs therapeutics, proprietary RNA delivery technology and formulation expertise. With existing collaborations with leading formulation scientists at Strathclyde University and the Centre for Process Innovation, there is immediate potential to follow up about the COVID-19 vaccine pipeline and their capabilities.

- Replicell[129] is a regenerative medicine company focused on aesthetics and orthopaedics, developing several products from two unique cell therapy populations both taken from hair follicles.

- Satellos[130] is developing small molecule drugs that restore faulty muscle regeneration observed in degenerative disease and muscle wasting disorders. Their lead programme is targeting Duchenne Muscular Dystrophy.

[123] https://acorn.me
[124] https://www.aspectbiosystems.com
[125] https://innovakine.com
[126] https://ivexsol.com
[127] https://pancella.com
[128] https://www.precisionnanosystems.com
[129] https://www.replicel.com
[130] https://satellos.com

- Sernova[131] focuses on the development of regenerative medicine technologies for the treatment of patients with insulin-dependent (T1) diabetes, haemophilia A and thyroid disease.

- StemCell Technologies[132] develops speciality cell culture media, cell isolation systems and accessory products for life science research. Founded as a spin-out from the Terry Fox Laboratory in Vancouver, this Canadian anchor company is privately owned and has grown organically to over 1,000 employees and includes an R&D base in Cambridge UK. The core business is the research, development and manufacture of reagents and products to the life sciences market.

Diary commitments meant the delegation, unfortunately, did not get to meet with BlueRock or Notch Therapeutics; however, contact was made for follow up.

1.7 Skills and Training Initiatives

The meeting with CellCAN[133] and the SCN illustrated that the UK and Canada have similar challenges with skills and training development and forecasting for future need to underpin the sector growth. CellCAN's particular focus is to improve the quality, safety and feasibility of cell and gene therapy in Canada through optimal manufacturing practices and the adoption of a "common seal of quality". In our discussion regarding future skills and training strategies, the potential for a virtual skills and training exchange was mentioned. This is a topic that the post-mission follow up should re-visit, as it was clear that skills development strategies and identification of enabling funding to support this were in development in parallel. The delegation also identified synergies with the UK's ATMP manufacturing community (amc)[134] and CGTC's activities. The H2i model described previously also stood out to the delegation for embedding the entrepreneurial skillset early on in careers, and there were several discussions about the parallels between Mitacs and KTPs as potential avenues to stimulate bilateral collaborations. The UK-Canada Globalink Doctoral Exchange Programme managed by UKRI (NERC) and Mitacs, now open for its third round, will support a further 200 doctoral students to participate in a UK-Canada research exchange scheme[135].

1.8 Regulatory Bodies

The delegation met with Health Canada[136] representatives in both Toronto and Vancouver. Health Canada has a long history of cooperation with international counterparts and organisations. They are very engaged in the ATMP sector in Canada and proactively examine how they can support innovation. Their engagement takes many forms, ranging from informal information exchanges to multilateral harmonisation initiatives, and it is the latter that should be the main focus for collaboration between the two countries.

Historically the UK has been a regulatory leader in emerging science and technology. For example, the UK's robust approach to the regulation of human embryos has contributed to the UK becoming a world leader in the study of human development. However, it is no longer enough to simply have a great approach to regulation nationally. The UK must also look outward, sharing these technical advances and regulatory approaches through global engagement and diplomacy, while also learning from others. This was recognised in the Prime Minister's 2019 address to the United Nations General Assembly that called on countries "to agree a common set of global principles to shape the norms and standards that will guide the development of emerging technology".

Regulatory diplomacy is likely to be particularly important and beneficial for emerging science and technologies, such as cell and gene therapies, and there is an opportunity for the UK to take the lead. Cooperation is most likely to be successful in "new" sectors, such as ATMPs, where a significant body of regulation is still evolving and developing. Regulatory diplomacy can therefore be used to support progress towards a common rule book or consistent approaches that reduce friction in trade. Emerging areas are often complex and fast-moving, making it difficult for individual countries to meet these regulatory challenges efficiently and effectively alone. Working together allows for expertise and resources to be shared, ultimately leading to better regulation, and reducing costs[137].

[131] https://www.sernova.com
[132] https://www.stemcell.com
[133] https://cellcan.com/en/
[134] https://atmpmanufacture.org
[135] https://www.ukri.org/research/international/international-funding-opportunities/uk-canada-globalink-doctoral-exchange-scheme/
[136] https://www.canada.ca/en/health-canada.html
[137] Wellcome (2020). The UK's role in global research available at https://wellcome.org/what-we-do/reports

2. Opportunities for UK-Canada Collaborations in Advanced Therapies

Many of the groups and organisations that the delegation met have relationships with the ATMP community in the UK, therefore, there are strong foundations to grow and strengthen collaborations. For example, the week prior to the mission, a small UK academic delegation, plus Innovate UK, had visited Toronto for a research showcase, reflecting the already strong relationships with the UK research community, that have been built over several years. Furthermore, the CGTC have established dialogue with many of the key Canadian organisations, most notably CCRM.

Following many of the UK delegations' engagements in Canada they concluded that further relationships could be built across the business-to-business community. Promoting knowledge exchange with UK business, who may be able to support Canadian commercialisation efforts through services (e.g. CDMO) in the longer term, was a desired outcome for both sides.

During some of the meetings, it was noted that federal funders and agencies, e.g. NRC and Mitacs, could help bridge and strengthen links between research and industry/innovation. This, in part, had been done through sharing knowledge and delivering training programmes. The delegation saw many similarities with the UK in terms of research focus and approach to therapeutic areas (also reflecting global focus areas for the sector); there were further parallels across some of the support structures the delegation met, and several thematic areas which cover the broader UKRI remit in terms of basic research relevant to the Biotechnology and Biological Sciences Research Council (BBSRC), Medical Research Council (MRC) and Engineering and Physical Sciences Research Council (EPSRC).

ATMPs carry a particular onus with regard to early design for manufacture. Failure to ensure comparability (in the regulatory sense) between the early trials that showed proof of concept and the commercial launch might result in costly and time-consuming bridging studies. There will remain a risk that the new process delivers a product that is less than expected. This can be largely avoided if the research work considers the manufacturing needs and the commercial model. Therefore, a degree of integration in academic and business work is required[138].

The delegation concluded that a number of areas merit further discussion:

- Sharing of funding mechanisms between the UK and Canadian research and innovation funding agencies.
- The similarity between the Ontario healthcare system and the NHS could be discussed further as an opportunity for collaboration for both Canadian and UK businesses.
- Maintain company discussions to drive any potential for UK presence, investment or collaboration.
- Regulatory work being undertaken by Health Canada can increase opportunities for the UK through the reduction of barriers. The ecosystem is similar to what we are developing in the UK, and this lends itself to the examination of exemplar projects which test the regulatory system and the adoption pathway. The initiative of Health Canada brings a competitive advantage to Canada. The UK Medicines and Healthcare products Regulatory Agency (MHRA) is also looking to make the UK regulatory landscape attractive. There is a clear opportunity for these regulators to work together and converge requirements for mutual benefit and ease of working in future.
- Opportunities for collaboration in the the viral vector/AAV and stem cell area.
- Skills development and training are areas that both countries have an interest in growing, as the current pool of skilled people in the sector is insufficient and the situation is set to exacerbate in the future.
- The UK should build on the relationship and existing collaborative projects between CCRM and CGTC to drive pan-Atlantic co-operation and best practice. There was a clear opportunity to investigate a distributed manufacturing model and associated clinical trial, working through the key agencies in both countries, CCRM and the CGTC.

[138] https://www.researchgate.net/publication/333862662_The_management_of_risk_and_investment_in_cell_therapy_process_development_a_case_study_for_neurodegenerative_disease

3. Conclusion

The complementary UK-Canada leading technology strengths along with cultural synergies, pre-existing relationships, and enthusiasm to collaborate, make it sensible to pursue opportunities highlighted throughout this report. The delegation noted that throughout the visit there were not only collaborative opportunities in ATMP but more broadly across the life sciences sector which align well with the UK R&D Roadmap[139]. The relationships built from this mission should provide the foundation for the strengthening of UK-Canada ties, to the benefit of both nations.

[139] https://www.gov.uk/government/publications/uk-research-and-development-roadmap

Annex 1

List of UK Participants

Cobra Biologics
Independent pharmaceutical professional
Innovate UK
Knowledge Transfer Network
UK Gene and Cell Therapy Catapult Centre
UK Science & Innovation Network

List of Canada Participants

ACORN Biolabs
adMare Bioinnovations
Aspect Bio
BC Cancer Research Centre
British Columbia Children's Hospital Research Institute
British Columbia Regenerative Medicine
CellCAN
Center for Brain Health
Centre for Commercialisation of Cancer Immunotherapies
Centre for Commercialization of Regenerative Medicine
Genome BC
H2i
Health Canada

Innovakine
iVexSol
J-Labs
MaRS
Medicine by Design, University of Toronto
National Research Council of Canada
National Research Council of Canada Industrial Research Assistance Program
Ontario Institute for Regenerative Medicine
panCELLA
Precision Nanosystems
Replicell
Satellos
Sernova
Simon Fraser University
Stem Cell Network
Stemcell Technologies
University Health Network
University of British Columbia
University of Victoria


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