The Present and Future State of Synthetic Biology in Canada

Discussion Paper of the "Canada Synbio 2018" Conference and Workshop

May 1st, 2018

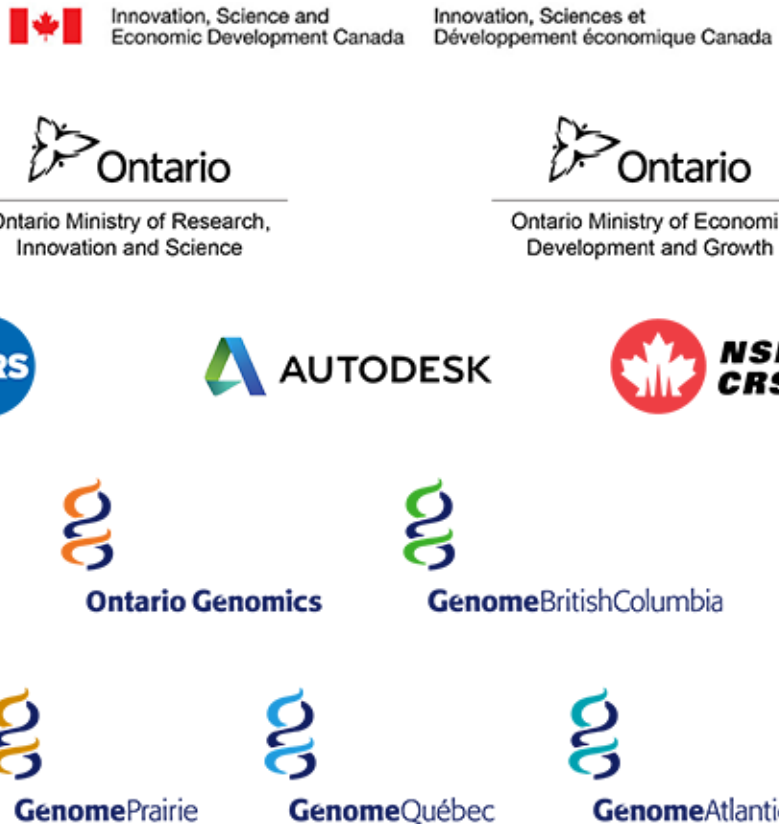
By Jeff Kinder and Mark Robbins

The Institute on Governance

Institute on Governance
LEADING EXPERTISE

Institut sur la gouvernance
EXPERTISE DE POINTE

This research was proudly supported by the following organizations:



To cite this work: Kinder, Jeff and Robbins, Mark. *The Present and Future State of Synthetic Biology in Canada.* Ottawa: The Institute on Governance, 2018.

The Present and Future State of Synthetic Biology in Canada

Discussion Paper of the "Canada Synbio 2018" Conference and Workshop

Executive Summary

The synthetic biology community convened on March 6-7, 2018 at the "Canada Synbio 2018" Conference and Workshop as part of an ongoing effort to raise the profile and capacity of the synthetic biology community in Canada. The conference brought together a wide range of presenters and stakeholders in the interest not only of promoting and cultivating the synthetic biology community of practice, but also to begin establishing the common objectives and parameters for the field. As an emerging discipline at the cutting edge of technological development and scientific progress, synthetic biology is faced with an important set of challenges and opportunities in its process of continued development.

To that end, the Institute on Governance was commissioned to facilitate the Workshop which was designed to help outline the common difficulties, opportunities and prospects for future action across a broad range of subject matter. This exercise aimed to spark discussions among attendees that would touch on a broad range of issues affecting synthetic biology currently and that are expected to affect synthetic biology in the future. In addition to helping promote a common sense of shared mission within the synthetic biology community of practice, this event was an important step towards charting the landscape of issues and path forward to policy development and collective action.

One important finding which should contextualize all others is that there is clear appetite for greater collaboration and collective venture in the Canadian synthetic biology community. One of the most commonly occurring themes was a sense of lost opportunity due to a lack of awareness of synthetic biology, not only among external stakeholders and the public, but also a significant concern that the synthetic biology community itself is not self-aware to the point of having sufficient capacity for meaningful collective action. Some of the basic foundations for moving synthetic biology forward need further development and should constitute the first-tier priority for the sector.

There were many proposals for future action but the extent to which they are all feasible or would interact with one another in a concerted (non-contradictory) fashion, and whether they are broadly representative of the entire synthetic biology field rather than simply those in attendance at Canada Synbio2018, is outside the scope of this work. Indeed, the challenge for synthetic biology going forward will be to reduce an extensive list of prospective future actions to those that are most practicable and will have the highest impact. By our assessment of the issues and in applying a policy process lens, there is a first tier of action items that emerge for the sector to address.

- Establishing a regular forum (or fora) for cooperation within the Canadian synthetic biology community including workshops, an annual conference and training opportunities.
- Curating an easily accessible and interactive registry for common resources available to the synthetic biology community and of those working in the synthetic biology space.
- Developing an evergreen list and mapping of broader stakeholders relevant to the synthetic biology community, such as venture capitalists, social scientists, government decision-makers and the like.
- Producing a policy "white paper" establishing commonly agreed upon priorities for the sector.

This first-tier of next steps should be viewed as pre-requisite to greater action to advance the sector in Canada. It is important to note that in the absence of an established set of broadly agreed-upon priorities for the sector, it becomes impossible to propose an ordering of tasks or balancing of trade-offs. Simply put, despite its rapid advance scientifically and technologically, synthetic biology is at a bottleneck due to policy underdevelopment that prevents the sector from establishing priorities or advancing on them effectively. The fuller development of a policy framework will permit the sector to advance in a way that meaningfully addresses its needs, supports the effective allocation of resources, and pro-actively confronts the broader social implications of synthetic biology.

With that said, participants touched on a wide range of priorities it would like to advance and projects it would like to undertake. These are categorized under four overarching themes for the future development of the sector: Industry and Commercialization, Public Relations and Trust, Training and Education, and the Pursuit of a Future Vision and Governance.

<u>Industry and Commercialization</u>

- Better commercialization training and more supports for synthetic biology researchers, including the development of more biofoundries.
- Research, perhaps case studies more specifically, into successful commercial exits that can inform practice for venture capital financiers and entrepreneurs operating in synthetic biology.
- Clear rules surrounding the use and establishment of intellectual property in the rapidly evolving field of biotechnology, including synthetic biology. This may also help inform and facilitate patent-related policies and practices.

<u>Public Relations and Trust</u>

- A communications strategy which includes mechanisms for thoughtful and continuous public outreach including agreed-upon and market-tested branding.
- A wider and more systemic appreciation for, and exploration of, the ethical and social implications of synthetic biology research and applications, including a concerted effort at improving public perception and understanding of synthetic biology and earning public trust.

Training and Education

- Mentorship opportunities in a cross-jurisdictional and interdisciplinary fashion that is broadly inclusive of all post-secondary institutions, including colleges, polytechnics and CÉGEPs.
- Support for the development of the next generation of synthetic biology researchers to ensure a talent pool of highly qualified personnel.
- Stable, on-going public funding for iGEM, a worldwide synthetic biology competition centred primarily on undergraduate students.

Pursuit of a Future Vision and Governance

- Strategic foresight and planning that situates synthetic biology in the context of Canada's broader innovation agenda as a cross-cutting platform technology for a sector in development with global interconnectivity and great potential for Canada to be a leader.
- Unambiguous signalling from government to industry and the research community about the direction the government seeks to pursue for synthetic biology over the medium to long term.
- Strategic positioning and relationship-building specifically pertaining to synthetic biology's interactions with government, including government departments as well as elected officials.
- A funding environment that is better attuned to the specific needs of synthetic biology, including its multi-disciplinary nature, and that recognizes the capital intensity of synthetic biology research.

A final note is that the proceedings and commentary of attendees were marked by a real sense of opportunity but also urgency and risk regarding the future of synthetic biology in Canada. Synthetic biology is a high-potential and cross-cutting platform technology for research and industry whose principal inputs are highly-mobile researchers and capital. In this sense, the long-term success of synthetic biology in Canada depends greatly on its ability to quickly achieve a coherent and thoughtful policy mix that is well-attuned to the needs of the community.

Introduction

Background of Canada Synbio 2018

What is widely claimed as the first synthetic biology forum to take place in Canada was a one-day symposium in 2009 at MaRS Discovery Centre in Toronto and was comprised of both a conference and a panel session that was open to the public. This was followed by a 2014 workshop held at Concordia University in Montreal that focused on Canada-UK synthetic biology. In 2016, Ontario Genomics released a synthetic biology strategy report for the province and, in 2017, two symposia were held on synthetic biology, one at the University of Western Ontario and one at Genome BC's Genomics Forum.

In November 2016, Federal, Provincial & Territorial (FPT) Ministers responsible for Innovation and Economic Development met and approved five areas of focus for a joint FPT work plan with the broad aims of creating jobs and growing the economy. Among the five areas of focus is "Clusters and Leading-Edge Technologies" (CLET),[1] and the CLET sub-committee further identified "Genomics" as a specific area of interest for collaboration. Under the Genomics work plan, Innovation, Science and Economic Development Canada proposed a pan-Canadian workshop on synthetic biology – an example of a leading-edge technology that is actually based on a strong genomics foundation. The proposed synthetic biology event was endorsed by the FPT Ministers as part of the ongoing and broader FPT work plan at their meeting in October 2017.[2]

This steady increase in activity and interest in synthetic biology directly led to the inaugural "Canada Synbio 2018" conference and workshop, the first broadly national forum of its kind. It was held on March 6-7, 2018, at the MaRS Discovery District in Toronto, Ontario. This event was collaboratively organized by various stakeholders in the synthetic biology community[3] with the goal of advancing a national dialogue about the future of synthetic biology in Canada. In an effort to ensure that the conference would result in tangible and enduring advancement of the interests and capacity of the synthetic biology community, Day 2 of the conference was a workshop facilitated by the Institute on Governance who had been commissioned to generate this discussion paper based on the proceedings.

The purpose of this discussion paper is to highlight some of the common themes and issue areas that arose throughout the event with an eye to identifying key sites of engagement, agreement and contestation. This work will help provide a basis for the synthetic biology community in Canada to engage in future collective action, including the development of a stronger community of practice, and more strategic policy positioning and coordinated public engagement.

---

[1] Source: Canadian Intergovernmental Conference Secretariat. November 18, 2016. *Federal, provincial and territorial innovation ministers work to drive economic growth*. (accessed April 4th, 2018) http://www.scics.ca/en/product-produit/news-release-federal-provincial-and-territorial-innovation-ministers-work-to-drive-economic-growth/

[2] Source: Innovation, Science and Economic Development Canada. October 13 2017. *Federal-Provincial-Territorial Ministers take action to spur economic growth.* (accessed April 4th, 2018) https://www.canada.ca/en/innovation-science-economic-development/news/2017/10/federal-provincial-territorialministerstakeactiontospureconomicg.html

[3] Led by Innovation, Science and Economic Development Canada, Ontario Genomics and the other regional Genome centres, as well as Genome Canada.

Definition of Synthetic Biology

The following definition[4] of synthetic biology was projected on a side panel at the conference:

a) the design and construction of new biological parts, devices and systems;
b) the re-design of existing natural biological systems for useful purposes;
c) the endeavor to make biology and its principles accessible to engineers.

Another simple definition which was presented by Stephen Chambers (CEO of SynbiCITE) during the conference resonated with many of the participants:

"Engineering biology to make useful stuff."

As is often the case with emerging disciplines, there is an ongoing debate about how to define and label synthetic biology. This includes a discussion about what vocabulary is most appropriate for describing the discipline, with some preferring "synthetic biology" and others preferring "engineering biology". For the purposes of this work, the two terms will be used interchangeably.

Day 1 Overview

The first day of Canada Synbio 2018 featured a range of high-profile speakers and panel presentations by experts from the synthetic biology community. In total there were nearly 300 attendees from across the community, including research and academia, private industry and government. Much of the content of these presentations focused on emerging technological developments and new opportunity areas within the sector from a variety of scientific experts.

The afternoon program featured presentations from researcher/entrepreneurs including start-ups as well as a venture capital (VC) investor showcase, where VCs helped to troubleshoot commercialization questions from attendees. The Day 1 proceedings concluded with a networking reception to help further build relationships within this nascent community. Further details of Day 1 proceedings are available online at iog.ca.

Day 2 Overview

The second day of Canada Synbio 2018 was centred on a workshop facilitated by the Institute on Governance. The purpose of the workshop was to draw out and explore high-level insights for the

[4] Source: Syntheticbiology.org (accessed December 1, 2017, as cited by Cumbers, J. and Schmieder, K., in *What's Your Bio Strategy* (2017)).

present discussion paper and, ultimately, for the development of relevant policies for synthetic biology. Attendance at Day 2 was by invitation-only and comprised approximately 70 attendees.

The workshop was bookended by presentations designed to spur thoughtful engagement during two sets of breakout sessions. In the morning this included presentations from Canada's regional Genome centres, and from presenters touching on the development of synthetic biology in the United States and the potential future of synthetic biology in Canada. The afternoon concluded with a funders panel consisting of senior representatives from each of the Tri-Council organizations and Genome Canada.

Further details of Day 2 proceedings are available in online appendices available on the Institute on Governance's website (iog.ca).

Workshop Component

Breakout Sessions

The attendees were organized into five groups covering three different thematic areas during the first break-out session, and a different set of five groups with an additional three thematic areas for the second break-out session. The session themes were as follows:

- HQP, Students, Skills and iGEM (discussed by 1 group)
- Research and Access to Technology and Facilities (discussed by 2 groups)
- Translation and Commercialization (discussed by 2 groups)
- Ethics, Regulation and Public Trust (discussed by 1 group)
- Leveraging Canada's Strengths (discussed by 2 groups)
- Building on International Initiatives (discussed by 2 groups)

By exposing attendees to different thematic areas, and in different combinations of attendees, this helped ensure that a diverse range of opinions were shared during the breakout sessions. Rapporteurs were assigned to each break-out group to guide the discussions and collect notes, and facilitators from the Institute on Governance migrated between sessions taking their own complementary notes on the discussions underway. The results of each break-out session were presented in plenary to give attendees the opportunity to express divergent opinions or simply add detail where necessary.

Notes, observations and presentation materials from all sessions and facilitators were collected, compiled and analyzed to provide a synthesized overview of the core themes that arose as of importance to the synthetic biology community. Note that these represent the opinions shared by attendees, rather than an independent assessment of the state of synthetic biology in Canada. These observations are meant to inform the future direction of the community's policy research and development process rather than to be taken as a conclusive assessment of the state of synthetic biology and its relation to the wider community of interest.

Thematic Highlights from the Workshop

High-Potential Research and Application Areas

Attendees roundly agreed that synthetic biology is a research area with seemingly limitless opportunity. In addition to being a new field of inquiry for discovery research, the applications of synthetic biology are wide-ranging and extensive, and synthetic biology as a discipline finds itself fortuitously well-equipped to specifically respond to some of today's grand challenges. Because of the extensive potential for applying synthetic biology, many felt that the growth potential for synthetic biology is effectively limitless with one participant stating "The only limitation for commercial opportunity is the imagination." With that being said, the applications and prospective research of synthetic biology tended to cluster around several thematic areas during discussions.

Healthcare

Some of the most immediate applications for synthetic biology are in the healthcare system, where the development of precision medicine has heavily featured research from synthetic biology. At a very practical level, future healthcare research in Canada will focus on improving the scalability of synthetic biology-informed treatments such as CAR-T-cell therapy, which is effective but prohibitively expensive for many. Another fruitful avenue for more immediate applications is the development of novel small molecule drugs for new and high-impact pharmaceuticals. The future possibilities for using synthetic biology in the healthcare sector are extensive and potentially revolutionary. Such applications include microbiome management, diagnostics, regenerative medicine and cognitive healthcare and genome editing. Admittedly for genome editing as well as synthetic biology, widespread public acceptance across all applications may still be far off, public acceptance tends to be unevenly distributed with greater acceptance in areas like disease treatment.

Environment and Natural Resources

Use of synthetic biology in natural resources extraction has both a high potential and also a high commercial viability in the immediate term. This includes most immediately the use of synthetic biology in land bioremediation following extractive processes, such as oil-sands extraction and remediation of tailing ponds. Other industry applications under development include synthetic biology alternatives to high impact extractive practices altogether, such as the creation of new chemical entities for industrial petrochemical replacement. With regards to climate change, synthetic biology can play a crucial role in greenhouse gas emissions reduction by playing a role in carbon capture and by using carbon by-product as a fuel. More widely, synthetic biology has the potential to transform industrial value-chains due to its use of biomass, including from agricultural processes, moving from the realm of "waste" to a crucial feedstock.

Agriculture and Food

The agricultural sector has the potential to be radically transformed by synthetic biology and by some interpretations is the first sector to have been directly impacted by this technology with the early use of genetically modified crops. Synthetic biology can take this exponentially further, vastly improving food production processes (including for aquaculture) and improving food security by developing new products that can be grown more sustainably and with better food yields. This may be especially

important in an era when Canada's food exports are increasing and where the global population is expected to continue to grow significantly in the next 20 years. Synthetic biology can also help to improve pest-control practices in the management and reduction of invasive species.

Advanced Materials and Manufacturing

With the increasing permeability of the boundaries between biology and technology represented by synthetic biology, one of the areas of interest for researchers is the application of synthetic biology to industrial supply chains and manufacturing. This includes making certain products from biomass rather than standard raw materials and developing novel small molecules for use in material sciences. There is significant potential for synthetic biology in product replacement for production inputs which are rare, expensive or whose supply is erratic, like vanilla.

Discovery Research

As a new and emerging field, there is still a great deal of discovery research to be undertaken. It is believed that much of the potential of synthetic biology has yet to be discovered since there remain ample opportunities to improve tools, research capacity, and scalability. This will include the development of more molecular biological science and tools and the leveraging of complementary technologies including artificial intelligence. Canada may be especially well-placed for the next generation of synthetic biology research due to legislative and economic conditions, given that, for example, the research applications from stem cells and cannabinoids are permitted in Canada but not necessarily elsewhere or in the same capacity, and the highly developed resource sector in Canada which provides an important input for synthetic biology.

Challenges and Opportunities with Public Funding

Many expressed the desire for greater public funding for their research, suggesting that existing funding levels were insufficient and that there were little to no procurement incentives available from government. On one hand, it is important to recognize that many of the inputs for synthetic biology research are especially expensive given their relative novelty. Yet aside from this, there was little benchmarking or indication of what funding level would be necessary. Indeed, neither was there any noted mention in the breakout sessions about the increases in public funding for scientific research that had been announced the week prior in the 2018 federal budget, which was widely hailed as a pro-research budget that held unprecedented increases in scientific funding in Canada.

This suggests a less literal but perhaps more accurate interpretation of the sentiments that synthetic biology is being underfunded, an explanation also hinted at throughout the conference and workshop. It may ultimately reflect a lack of coordination between the synthetic biology community and granting agencies in addition to a limited awareness of the field that combine to result in synthetic biology initiatives often being bypassed for public funding. Many participants noted that there was limited available funding for pan-disciplinary research and many others felt that there were large funding gaps that affected synthetic biology, the sentiment being that synthetic biology too often "fell between the cracks". This leads to difficult situations for the community, such as the lack of stable funding for student participation in iGEM (an international synthetic biology competition) which has been recognized as a crucial part of higher-calibre synthetic biology research and training.

Some suggested that better coordination of existing resources could be a valuable way forward for the synthetic biology community. For instance, it was noted that there is rather poor connectivity between research nodes and low awareness of what common resources do exist – a challenge that could perhaps be resolved by some sort of resource registry. A similar approach could be applied to funding gaps, which could be mitigated by the regular identification of gaps and the collective allocation of resources to address them. More generally, participants felt that there could be a wider sharing of risks and rewards across the synthetic biology community that would come from supporting one another's initiatives. The possibility was also raised that the federal Innovation Superclusters Initiative might hold some promise for synthetic biology as it marks a convergence of institutions and a blurring of the institutional boundaries and disciplinary silos which continue to present an obstacle to the advancement of synthetic biology.

Private Funding and Commercialization

Due to the high potential applications of synthetic biology, many participants were directly involved in the commercialization of synthetic biology products or at least had given this type of career trajectory some degree of consideration. In many cases this was related to the healthcare sector, which in Canada entails commercialization without fully migrating the technology to the private sector. Still others were interested in how some degree of collaboration with the private sector might improve their funding situation and thereby increase their capacity for discovery research. There were many challenges identified, not the least of which was a low level of business literacy among synthetic biology researchers as well as a generally poor understanding of the commercialization process. Few participants had an intimate understanding of how connecting with the private sector might work in practice, and fewer still voiced views about how to make synthetic biology relevant to established supply-chains or business cases. This exacerbates the already difficult challenge of matching academic researchers with industry partners that have a niche need that could be met by synthetic biology.[5]

For those who had advanced through the commercialization process at some point, they conveyed the existence of challenges related to a low availability of seed funding and funding sources for pre-revenue companies. Synthetic biology also lacks many of the traditional supports available for companies traversing the innovation "valley of death" due to its relative novelty as a discipline. This includes a lack of relevant commercialization supports such as incubators and accelerators that are exclusively dedicated to synthetic biology (e.g., biofoundries). Because of the near total lack of successful exits for synthetic biology companies (again, because of the relative novelty of the subject matter), synthetic biology is only recently starting to attract reliable venture capital. From the perspective of VCs, the best comparable for investments in synthetic biology might be the pharmaceutical sector and adding to the uncertainty is that there has been a long history of pharmaceutical investments not reaching their commercialization expectations.

To complicate the commercialization process for synthetic biology even further, the subject of intellectual property (IP) rights for synthetic biology is highly contested. Some argued that the current structure of academic hierarchy and its approach to IP rights severely disadvantages students in favour of their professorial collaborators. Furthermore, synthetic biology (and biotechnology more

[5] This point will be further explored in the section on Universities and Training.

broadly) faces several particular challenges to turning research into commercializable IP; for example, due to the outright prohibition on patenting naturally occurring DNA. While synthetic DNA may well be patentable there is less certainty about where the distinction between the two types occurs, assuming that there is really a clear distinction at all. The principal issue for investors and researchers alike is the lack of clarity on these details, especially when it comes to things like foods. Where securing IP rights for synthetic DNA is uncontroversial, the overall commercialization process can be prohibitively long for making a valid business case.

In one case, the question was raised as to whether IP protection is meaningful at all for synthetic biology because the rate of discovery is increasing so rapidly and since it is easily within the capacity of researchers to alter DNA in a legally significant way that is functionally distinct or irrelevant to its original purpose. In the same way that designer drugs are able to reach a similar effect through different chemical combinations, with each chemical combination being distinct intellectual property, so too, at least in theory, can a nearly limitless number of legally distinct combinations of DNA perform the same purpose.

Public Relations and Ethics

Perhaps the most significant challenge area that was identified by many attendees is the ongoing issue of how synthetic biology's research and downstream applications relate to the public at large. Much of this stems from concerns about public opinion of synthetic biology which is often viewed unfavourably. Many were concerned about the degree to which synthetic biology can be said to have social licence since low awareness of the discipline is what tends to insulate it from criticism, rather than public trust, understanding or confidence in its activities. While a minority argued in favour of the status quo and continuing to keep a low profile, the majority supported the idea that the synthetic biology community should change its practices and engage more with the public. This seemed to stem from a recognition that both public funding and commercial viability both ultimately depend on social licence and acceptance of synthetic biology, so the future of the discipline would be severely constrained if it avoided addressing public opinion head-on.[6]

While a minority argued in favour of the status quo and continuing to keep a low profile, the majority supported the idea that the Synbio community should change its practices and engage more with the public.

At the earliest stages, this involves a revision to synthetic biology's research ethics protocols, so that they are more widely representative of the public's concerns and the potential impacts of synthetic biology's inventions. This is especially important with regard to developments in food and medicine, both on moral grounds but also due to already unfavourable public opinion in these areas. Many participants mentioned the anti-GMO movement as a case-in-point of how public relations can go

[6] Note, at least one participant argued against use of the term "social license" as too academic, favouring instead the term "public trust".

wrong. Very few considered the science behind the safety of genetically modified foods to be at all in doubt, and yet this technical approval has not always translated into public acceptance. This can pose a significant problem for the investor community as well which may not be aware of the science due to the lack of outreach or may simply be scared away by a potentially unpopular product regardless of whether or not that unpopularity is "rational". Both the scientific community and industry continue to pay for this misstep as a not-insignificant portion of the public continues to set themselves in opposition to GM foods.

To avoid situations like with the anti-GMO movement in the agri-food sector, researchers need to communicate with their relevant stakeholders from early in the research process and regularly throughout the research. In many cases, this will have to start with the broad identification of stakeholders since this is not yet a universally adopted practice. Adopting this practice will help to ensure that relevant groups are not taken by surprise by advances in synthetic biology and will likewise help ensure that any potential ethical missteps are caught early. Connecting with regulators and policy-decision makers in this manner is especially important given their role. Participants felt it would be valuable to connect with the policy community regularly and systematically, perhaps even offering opportunities for regulatory science education, like the science "boot camps" offered for parliamentarians in the UK. All of this will help to improve public understanding and to develop a more durable social licence for the field.

In addition to these long-term efforts at public relations and improving the social licence of synthetic biology, participants felt that the field was in need of an active public communications strategy, or perhaps a marketing blitz of some kind. Part of this need stems from a desire within some of the community to continue with business as usual, in the sense that there was a hesitancy among researchers to involve themselves in communications and public relations. Part of this stems from a sense of urgency about alleviating public reservations with synthetic biology and a sense that coordinated and professional outreach will be necessary to address the issue of public trust. Still others viewed synthetic biology in comparison with artificial intelligence, another disruptive technology but one which benefits from a largely positive public opinion, very generous public sector supports and a strong appetite from private sector investors. Although there was little concrete agreement on the nature of the public communications strategy that should be undertaken, there was nonetheless a widely-held understanding that some kind of systematic outreach would be necessary.

A Synbio Community of Practice

Participants acknowledged that synthetic biology in Canada operates without much of an established community of practice. The community of researchers is disparate and relatively unconnected, with infrequent events held within the community, low awareness of common resources and a lack of fora where community members can find and engage with one another. Indeed, conference proceedings were marked by efforts at being inclusive and a general desire to ensure the widest possible participation, especially given that it was hard to be certain what proportion of the community was represented at the event. Specifically mentioned was inviting more students and entrepreneurs to participate in these kinds of events, as well as researchers from other disciplines including the social sciences. To that end, participants regularly signaled an interest in cultivating a wider and more inclusive community of practice for synthetic biology in Canada.

There was a range of suggestions for how to build up the synthetic biology community in Canada. A more regular and systematic communications strategy was suggested as a way to share information of common interest and encourage collaboration between members of the community, which of course includes universities, governments and the private sector. Many thought this should be anchored by regular events such as an annual synthetic biology conference but also perhaps small group engagement, including networking events, workshops and one-on-one meetings where possible. Other suggestions included developing a mentorship program and a more systematic buy-in to initiatives like the recently launched SynbioCanada.org, which seeks to provide an online forum for community interaction.

Due to the availability of finite resources it would not be possible for every research node in the Synbio community to have exclusive, comprehensive access to all the facilities and tools they might require. This makes coordination and some degree of shared access critical.

Participants noted that in addition to developing an integrated and interconnected community, synthetic biology faces some common challenges that may be best addressed through a range of collective endeavors. Most evidentially these collective ventures would need to include an organizing committee for the above-mentioned community-building events but could also include some policy development and research of shared relevance to the community. For instance, participants felt that synthetic biology would greatly benefit from a common definition and mission statement. The community could also benefit from making some information about itself available to the public at large, not just through a communications strategy but also, for instance, by cataloguing the details of successful business exits for synthetic biology companies as they occur, a venture which may reduce some of the risk and hesitancy from the VC community in investing in synthetic biology. More generally, a well-developed community of practice could help those in synthetic biology to develop strengths and be more proactive about addressing weaknesses, such as tunnel vision or a lack of common standards.

Access to Facilities

There was a widely accepted understanding that there was room for improvement with regards to facilities management and coordination for synthetic biology. Certainly, due to the availability of finite funding and resources it would not be possible for every research node in the synthetic biology community to have exclusive, comprehensive access to all the facilities and tools they might require. This makes coordination and some degree of shared access critical. Several participants noted that Canadian geography and the sheer distances between researchers would present an obstacle to any community of practice and any common pooling of facility capacity.

Certainly, geography and logistics present one challenging barrier; however, it is important to also note that there is not even currently an inventory of the facilities that do exist for synthetic biology in Canada. Furthermore, a thoughtful distinction between core facilities and specialized facilities would present many opportunities for optimizing access and informing future infrastructure investments. Participants generally agreed that there needs to be a collective definition from the synthetic biology community of what facilities are needed. A further step would be to catalogue these facilities as a clear step towards coordinating their shared access.

Participants also argued that there is room for qualitative improvement in existing capacity as well. This includes improving the technical quality of the facilities to ensure that equipment is cutting-edge. There is also room to improve the cost-effectiveness of these facilities as researchers themselves face tight budgets. Some suggested that making facilities funding allotments which are specific to synthetic biology would be key since shared budgets can see to it that compromises are made on crucial equipment that may hold immediate (or disproportionate) relevance to synthetic biology but perhaps not to other research areas.

Universities and Training

Many participants had active affiliations with universities, either through their own training background, professorship positions or through the use of research developed at a university. As a result of this close connection between the university and synthetic biology through research and training, participants had many thoughts to share on how the university system could be better attuned to the needs of synthetic biology. These critiques ranged from policy changes that could be affected by a university department, to those which depended on the attitude of a particular university, all the way to how the discipline could represent itself through university curricula nationally. With regards to a synthetic biology curriculum, a common concern pertained to standardization, including the degree to which it would be possible. There are very few synthetic biology programs at present, but some participants felt that the creation of such programs and departments could be valuable.

Others felt that existing *ad hoc* arrangements for synthetic biology training sufficed, or that existing arrangements could be improved by crossing more disciplinary boundaries rather than creating a new discipline (with new disciplinary silos). There was some suggestion that social sciences be incorporated into existing curriculum to provide graduates with a better sense for policy and ethics, while others suggested that business and entrepreneurship would be a valuable addition to the curriculum. Others felt that there should not be any additions made to curriculum but rather more opportunities made available to easily participate in things like iGEM or alternative entrepreneurial operations training. There were suggestions that the curriculum should be taken outside or at least extended beyond the exclusive boundaries of the university, permitting more co-op placements for undergraduates, integrating across colleges, polytechnics, CEGEPs and high schools, and emphasising undergraduate-level capstone projects. Taken as a whole, the only clear message is that the synthetic biology community remains far from consensus or shared values for what the academic discipline should look like.

The existing training regime was marked by greater consistency in terms of its perceived failings, with many participants expressing concern about the curriculum's ability to impart job readiness.

There was a general concern about how prepared graduates would be for the non-academic career paths which are increasingly the norm for those with graduate education. Important training that would help bridge that gap, such as iGEM, was recognized for being difficult to obtain and only tenuously funded. Supports for commercializing synthetic biology research, which would provide an alternative pathway to non-academic employment, tend to be weak and undeveloped leading several to question the merit of commercialization supports being affiliated with universities at all. There was a general perception that the structure and processes of universities, which can be prohibitively rigid and insulated from market considerations, could present a threat to the potential of synthetic biology if left unaddressed.

Regulatory Uncertainty

It was common for presenters and workshop participants alike to issue a sweeping challenge to government for improvement in its supports for synthetic biology but on closer inspection many of the specific challenge areas for synthetic biology are a matter of shared decision-making and responsibility, where the public administration may find itself with marginal authority. However, government does indisputably have a great amount of power to enact regulations that have the potential to affect synthetic biology. While there were several specific areas which would benefit from some government action, it is important to note that the call to action was seldom for government to enact one specific policy change or another but rather stemmed from a desire for some sort of conclusive action or decision to be taken. Clear action and signalling to the synthetic biology community would then reduce the significant amount of uncertainty pervading the various research and commercialization paths available, the uncertainty itself being the principal cause of concern.

Several noteworthy examples of areas where greater regulatory certainty could be beneficial included: the demand for improved clarity surrounding regulatory approval pathways and reasonable timelines for approval, a reduction in the ambiguities surrounding IP policies relevant to synthetic biology and greater consistency and stability in government funding for research. Uncertainty about the long-term legality of certain potential synthetic biology applications in particular proved very challenging for researchers and VCs alike and this uncertainty was deemed to inhibit the synthetic biology community's ability to press forward with both research and commercial applications. Participants also noted that synthetic biology lacks a champion within government that can bring these kinds of issues forward and would benefit from having someone within government who intimately understands and is charged with promoting the bio economy more broadly.

It is important to note that this will be a continuing challenge for government as the pace of technological change in synthetic biology, and related areas that provide inputs to synthetic biology, continues to accelerate. Participants noted that technological change continues to present new and unforeseen issues for regulators at a rate which far outpaces the current rate of regulatory output.

Conclusions

The only limitation for commercial opportunity is the imagination.
– Canada Synbio 2018 conference participant

Throughout the proceedings, participants roundly recognized the importance of developing a common platform and a better sense of shared values and priorities within the synthetic biology community. A greater sense of shared mission was generally understood to be an important pre-requisite to other next steps under consideration, an assumption borne out by the reality of the policy development process.

In addition to a greater sense of common goals and understanding in the synthetic biology community, many expressed a desire for further coordination and collective action. This included several commonly voiced proposals for the development of a Canada-wide policy (white) paper, a strategic communications plan for public engagement, coordination and pooling of common resources, regular forums for industrial-government relations, adoption of industry standards and a resolution of IP issues facing Synbio.

Based on the discussions that took place at Canada Synbio 2018, it is clear that there is momentum and a strong appetite for action in many of these areas. The development of some shared sense of values and understandings within the community of practice through this discussion paper will be an important foundation for any of these deeper elements of policy development and coordination.

This conference and workshop represented a decisive step forward in the direction of a vibrant, well-coordinated and effective synthetic biology ecosystem. Continuing discussions and assemblies are necessary and should take place at regular intervals, as these are necessary for the sustained development of a meaningful community of practice for synthetic biology. These fora should include a wide range of relevant stakeholders including regulators, industry and research, to be sure, but also ethicists, social scientists, public interest groups and other stakeholders (such as students, post-doctoral students and early career researchers) that may not have been fully included in earlier events. An inclusive approach will contribute to the vibrancy of the discussion while building the foundations for wider public support and understanding.

Beyond the establishment of an improved community of practice and regular fora for its development, synthetic biology in Canada requires coherent and strategically-minded policy. This will require policy development in a wide range of fields that will apply both to the self-government and proactive improvement within the community of practice itself, and also for obtaining the greater regulatory certainty from government that will be key for continued growth. At present, these basic fundamentals are lacking but are within reach with diligent effort.

The development of a coherent policy framework that is forward-looking, proactive and realistically balances the interests of all stakeholders will be a multi-year endeavor. Early steps will require

research into legal precedence, comparative study of synthetic biology in other jurisdictions, public and community focus groups, and interactive consultations with the synthetic biology community as a whole. With greater progress in collaboratively created synthetic biology policy comes the potential for other complementary endeavors raised during the conference proceedings, such as the implementation of a communications strategy for public relations and interest representation to other public institutions.

Appendix A: Program Agenda (Days 1 and 2)

Conference Program

Tuesday, March 6, 2018 MaRS Discovery District, Toronto, ON, Canada	
7:30	Continental Breakfast and Registration
8:30	Opening Remarks Mona Nemer, Chief Science Advisor of Canada
8:40	Introduction Marc LePage, President and CEO, Genome Canada
8:45	Keynote: **Engineering Biology in the Era of Genomics** Hear from industry leader Bill Peck on how Engineering Biology is revolutionizing everything from data storage to our health. Bill Peck, CTO and Co-Founder, Twist Bioscience
9:05	Panel: **AI and Computation Meet Synthetic Biology** Learn how AI and digital technologies are converging with biology to discover new drugs, model disease, and bring design to biology. *Panelists include:* Alison Paprica, VP Health Strategy and Partnerships, Vector Institute (Moderator) Brenda Andrews, Donnelly Centre Director, University of Toronto Nathan Magarvey, Founder and CSO, Adapsyn Ratmir Derda, University of Alberta/CEO, 48 Hour Discovery
9:45	Coffee Break
10:15	Keynote: **Building a Successful Synthetic Biology Ecosystem** Gain insights based on the UK's experience in building a leading synthetic biology ecosystem and how Canada can apply lessons. Stephen Chambers, CEO, SynbiCITE (UK)
10:35	Panel: **Reducing our Carbon Footprint with Synthetic Biology** See how synthetic biology is being applied to reduce emissions and create affordable biofuels and renewable materials today.

	Panelists include: Catalina Lopez-Correa, CSO & VP Sectors, Genome BC (Moderator) Rasmus Jensen, Sr. Scientist, LanzaTech Cathy Hass, Sr. Scientist, BioAmber Murray McLaughlin, Advisor, Bioindustrial Innovation Canada David Bressler, Professor/BCN Director, University of Alberta/Forge Hydrocarbons Steven Hallam, University of British Columbia, ECOSCOPE Director
11:25	Panel: **Human Health – From Gene Editing to Stem Cells** Learn how synthetic biology is tackling human health challenges, from CRISPR and treating cancer, to better stem cell treatments and new diagnostics. *Panelists include:* Molly Shoichet, Ontario's Chief Scientist (Moderator) Peter Zandstra, University of British Columbia/CSO, Centre for Commercialization of Regenerative Medicine Krishna Mahadevan, University of Toronto Rob Holt, University of British Columbia
12:05	**Writing DNA. Advances in synthetic biology construction from genes to genomes** Adam Clore, Technical Director of Synthetic Biology, Integrated DNA Technologies
12:15 – 1:30	Lunch (sponsored by Integrated DNA Technologies)
1:30	Panel: **Writing Genomes** Learn about the global initiative to design and print whole genomes and how Canada could be involved. *Panelists include:* BF Francis Ouellette, CSO/VP of Scientific Affairs, Genome Quebec (Moderator) Vincent Martin, Concordia University Leslie Mitchell, NYU Bogumil Karas, Western University Vardit Ravitsky, Université de Montréal
2:10	Panel: **VC Investor Showcase** Hear from world-leading investors on why synthetic biology is a part of their investment strategies. *Panelists include:* Joško Bobanović, Sofinnova Partners (Moderator) Ken Nickerson, OMERS Ventures Jean-François Pariseau, BDC Venture Capital Sean O'Sullivan, SOSV Andreas Jurgeit, M Ventures Jenny Rooke, Genoa Ventures
2:50	Coffee Break

3:20	Panel: **Food Biotech 2.0 and Learning from GMOs** Learn from the commercialization of the AquAdvantage Salmon and the non-browning Arctic Apple, and the importance of consumer engagement and trust. *Panelists include:* Jun Axup, Scientific Director and Partner, Indie Bio (Moderator) Ian Affleck, VP of Plant Biotechnology, CropLife Canada Neal Carter, President and Founder, Okanagan Specialty Fruits David Conley, Director of Communications, AquaBounty Technologies Jennifer Kuzma, Fulbright Visiting Research Chair in Science and Society, ISSP, University of Ottawa
4:00	Lightning Talks: **SynBio Start-Ups** Enjoy a flash pitch from some of Canada's upcoming biotech success stories. *Panelists include:* Anita Ludwar, Business Analyst, Genome Alberta (Moderator) Hans-Joachim Wieden, SynBridge David Lloyd, CEO, FREDsense Pratish Gawand, CEO, Ardra Bio Justin Pahara, CSO, Amino Labs Bogumil Karas, CEO, Designer Microbes Kevin Chen, CEO, Hyasynth Bio Leo Wan, CEO, Ranomics
4:50	Wrap-Up and Closing Remarks Bettina Hamelin, President and CEO, Ontario Genomics
5:00	Networking Reception- Autodesk Community Space, MaRS Discovery District

Day 2 Workshop Agenda

Wednesday, March 7, 2018
Autodesk Community Space, MaRS Discovery District, Toronto, ON, Canada

8:00	Introduction Jeff Kinder, Facilitator
8:10	Opening Remarks: **How Does Synthetic Biology Fit Into and Strengthen Canada's Research and Innovation Ecosystem?** This panel will set the stage for the day by framing synthetic biology in the broader science and innovation agenda, defining expectations for short and long term goals, and underscoring the need for partnerships. Jeff Kinder, Facilitator Catalina Lopez-Correa, VP Sectors and CSO, Genome BC Francis Ouellette, VP of Scientific Affairs and CSO, Genome Quebec Robin Harkness, VP Research, Ontario Genomics Anita Ludwar, Business Analyst, Genome Alberta
8:35	**A Brief History of Synthetic Biology in the US** Richard Johnson, CEO, Global Helix; Member NAS Board on Life Sciences; Director iGem Foundation and Director, Engineering Biology Research Consortium
8:55	**A Practical Vision for Canadian Synthetic Biology** Vincent Martin, Concordia University
9:15	**Q&A with Speakers** Vincent Martin, Concordia University Richard Johnson, CEO, Global Helix,; Member NAS Board on Life Sciences; Director iGem Foundation and Director, Engineering Biology Research Consortium

<table>
<tr><td>9:25</td><td colspan="3">Setting the Stage for Breakout Sessions
Jeff Kinder, Facilitator</td></tr>
<tr><td rowspan="2">9:35</td><td colspan="3">Breakout #1: Opportunities and Challenges for Synthetic Biology Leadership in Canada
Breakout sessions will explore the opportunities and challenges synthetic biology presents to Canada in a select number of focus areas.</td></tr>
<tr><td>Topic #1- Students, skills and iGem</td><td>Topic #2- Research and access to technology and facilities</td><td>Topic #3- Translation and commercialization</td></tr>
<tr><td>10:45</td><td colspan="3">Coffee Break</td></tr>
<tr><td>11:15</td><td colspan="3">Panel: Discussion with Group ‘Rapporteurs
Moderators from the breakout sessions will share their key findings of opportunities and challenges with the broader group.</td></tr>
<tr><td>12:00</td><td colspan="3">Lunch and Networking</td></tr>
<tr><td rowspan="2">1:15</td><td colspan="3">Breakout #2: Priorities for Canada and a Path Forward
Small group sessions will build on the opportunities and challenges identified in the morning session to discuss what Canada’s priorities should be in advancing synthetic biology and ideas and plans to advance stakeholder goals.</td></tr>
<tr><td>Topic #1- Ethics, Regulation and Public Trust</td><td>Topic #2- Leveraging Canada’s Strengths</td><td>Topic #3- Building on International Initiatives</td></tr>
<tr><td>2:30</td><td colspan="3">Coffee Break</td></tr>
<tr><td>3:00</td><td colspan="3">Panel: Discussion with Group ‘Rapporteurs
Moderators from the breakout sessions will share their key findings of what Canada’s priorities should be and a path forward with the broader group.</td></tr>
<tr><td>4:00</td><td colspan="3">Panel: Funding for Synthetic Biology Innovations as a Driver of Canada’s Bioeconomy
Representatives from some of Canada’s leading funding agencies will react to the day’s discussions and discuss opportunities to work together to advance synthetic biology tools and products enabled through synthetic biology.
Panelists include:
Bettina Hamelin, President and CEO, Ontario Genomics (Moderator)
Marc LePage, President and CEO, Genome Canada
Mario Pinto, President, NSERC
Paul Lasko, Director Institute of Genetics, CIHR
Ted Hewitt, President, SSHRC</td></tr>
<tr><td>4:40</td><td colspan="3">Closing Remarks
Bettina Hamelin, President and CEO, Ontario Genomics
Marc LePage, President and CEO, Genome Canada</td></tr>
<tr><td>4:55</td><td colspan="3">Wrap-Up
Jeff Kinder, Facilitator</td></tr>
</table>

Appendix B: Day 2 Workshop Attendee List

First Name	Last Name	Organization
Alejandra	de Almeida	NSERC
Alison	Symington	Independent consultant
Anita	Ludwar	Genome Alberta
Ben	Scott	synbiocanada.org
Benoit	Leduc	ISED
Bettina	Hamelin	Ontario Genomics
BF Francis	Ouellette	Genome Quebec
Brigitte	Cadieux	PHAC
Catalina	Lopez-Correa	Genome BC
Cathy	Hass	BioAmber Inc.
Daryl	Waggot	Genome Canada
David	Bressler	University of Alberta
David	Edgell	University of Western Ontario
David	Lloyd	FREDsense Technologies
David	McMillen	University of Toronto
David	Stuart	University of Ottawa
David	Woodhall	Mara Renewables Corporation
Dennis	McCormac	Ontario Genomics
Dominic	Sauvageau	University of Alberta
Donna	Viger	Life Sciences Division, NRC
Duncan	Stewart	OIRM
Dylan	Levac	CFIA
Greg	Vilk	University of Lethbridge
Hans-Joachim	Wieden	SynBridge, University of Lethbridge
Ian	Affleck	CropLife Canada
Ihor	Boszko	Ontario Genomics
Jeff	Kinder	Institute on Governance
Jennifer	Kuzma	University of Ottawa
Jim	Louter	ECCC
Jo	Van Betsbrugge	NRC-IRAP
John	Rohde	Dalhousie University
Jordan	Thomson	Ontario Genomics
Julien	Leblanc	ISED
Justin	Pahara	Amino Labs
Kevin	Chen	Hyasynth Bio
Krishna	Mahadevan	BioZone, University of Toronto
Kristen	Baetz	University of Ottawa
Kristin	Tweel	Genome Atlantic

Kyle	Kierstead	AAFC
Laura	Prochazka	University of Toronto - Medicine by Design
Leslie	Mitchell	NYU
Lucy	Su	MRIS
Marc	LePage	Genome Canada
Mario	Pinto	NSERC
Mark	Robbins	Institute on Governance
Miroslava	Cuperlovic-Culf	Digital Technologies Research Centre, NRC
Murray	McLaughlin	Bioindustrial Innovation Canada (BIC)
Nathan	Magarvey	McMaster University and Adapsyn
Paul	Lasko	CIHR
Peter	Goodhand	OICR
Phil	Macdonald	CFIA
Pratish	Gawand	Ardra Bio Inc.
Rahul	Singh	Genome BC
Rasmus	Jensen	LanzaTech
Ratmir	Derda	University of Alberta
Richard	Johnson	Global Helix
Rob	Holt	BC Cancer Agency
Robin	Harkness	Ontario Genomics
Sabrina	Kim	ISED
Sateesh	Kagale	Aquatic & Crop Resource Research Centre, NRC
Sean	Caffrey	BioZone - Centre for Applied Bioscience and Bioengineering
Stephen	Chambers	Synbicite
Steven	Hallam	University of British Columbia
Ted	Hewitt	SSHRC
Teodor	Veres	Medical Devices Research Centre, NRC
Tom	Mikkelsen	OBI
Trevor	Charles	University of Waterloo/Metagenom Bio
Vardit	Ravitsky	University of Montreal
Vik	Yadav	University of British Columbia
Vincent	Martin	Concordia University