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Open science precision medicine in Canada: Points to consider

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Abstract

Open science can significantly influence the development and translational process of precision medicine in Canada. Precision medicine presents a unique opportunity to improve disease prevention and healthcare, as well as to reduce health-related expenditures. However, the development of precision medicine also brings about economic challenges, such as costly development, high failure rates, and reduced market size in comparison with the traditional blockbuster drug development model. Open science, characterized by principles of open data sharing, fast dissemination of knowledge, cumulative research, and cooperation, presents a unique opportunity to address these economic challenges while also promoting the public good.

The Centre of Genomics and Policy at McGill University organized a stakeholders' workshop in Montreal in March 2018. The workshop entitled "Could Open be the Yellow Brick Road to Precision Medicine?" provided a forum for stakeholders to share experiences and identify common objectives, challenges, and needs to be addressed to promote open science initiatives in precision medicine. The rich presentations and exchanges that took place during the meeting resulted in this consensus paper containing key considerations for open science precision medicine in Canada. Stakeholders would benefit from addressing these considerations as to promote a more coherent and dynamic open science ecosystem for precision medicine.

Key words: open science, precision medicine, Canadian health policies, open science in precision medicine, valorisation

Context

Open science can significantly influence the development and translational process of precision medicine for chronic disease management. Precision medicine has been defined as a medical approach wherein patient diagnosis and treatment is individualized based on the patient's unique biological, environmental, and lifestyle factors (National Institutes of Health 2018). In Canada, one in five adults lives with a chronic disease (Public Health Agency of Canada 2017).

Major chronic diseases (cardiovascular diseases, cancer, chronic respiratory diseases, and diabetes) cause 65% of the country's deaths. Healthcare expenditures for these diseases, along with mood and anxiety disorders, account for one third of the country's direct healthcare expenditures (Public Health Agency of Canada 2017). Thus, precision medicine presents an opportunity to improve disease prevention and health care, as well as to reduce health-related expenditures. Genetic testing is at the heart of precision medicine interventions, enabling early diagnosis, prognosis, and treatment optimization (Alyass et al. 2015; Ghosh 2015; Stern et al. 2017; National Institutes of Health 2018). Moreover, greater access to OMICS data (e.g., genomics, transcriptomics, epigenomics, proteomics, and metabolomics) has enhanced the understanding of underlying etiologies of diseases, as well as the pharmacogenomic bases of treatment success (Alyass et al. 2015).

The direct impact(s) of precision medicine on the health of Canadians to date remains modest. Many genetic tests that detect relevant biomarkers have not been adequately validated (Hey and Kesselheim 2016). Many of the measurable advances made in rare diseases (including some rare cancers) and pharmacogenomics by precision medicine have not yet been realized in chronic disease management (Jameson and Longo 2015).

Improving the translation of precision medicine will require multidisciplinary, data-intensive research (Alyass et al. 2015). Intellectual property (IP) rights are expected to promote innovation (and, therefore, advance the translation of precision medicine) in at least three ways. Firstly, IP rights are expected to promote innovation by providing inventors, authors, and investors with economic incentives (i.e., temporary exclusive rights to commercially exploit their inventions) to engage in innovative activities (Vaver 2011; Granados Moreno and Joly 2015). Secondly, by imposing the condition that once those exclusive rights expire, all the knowledge/information associated with the protected inventions and works will form part of the public domain and knowledge commons for anyone to learn, use, build on, and innovate from (Granados Moreno and Joly 2015). Finally, IP is also expected to promote innovation by facilitating collaboration, as it allows the information and knowledge related to protected works and inventions to be "packaged" in IP rights that can be safely and easily exchanged and shared with other innovators (Hope 2009; Granados Moreno and Joly 2015). However, IP holders could exercise their exclusive rights to excessively and negatively restrict who can use their inventions and integrate or build on the information associated with their works and inventions. They could do this by refusing to provide access to their works or inventions or the information or knowledge associated with them or by imposing burdensome licensing fees and conditions. Examples of this include the business models implemented by many corporations with respect to their databases, as in the case of Myriad Genetics (Martin 2008; Gold and Carbone 2010; So and Joly 2013). If IP rights are implemented in this restrictive way, they can discourage members of the research community from undertaking these types of projects, as they may result in complex, lengthy innovation and translation processes. Likewise, the development of precision medicine brings about economic challenges, such as costly development, high rates of failure, and reduced market size in comparison with the traditional blockbuster drug development model. There is a risk that only a few larger firms will be able to overcome the aforementioned challenges. In doing so, such firms may inflate prices to recoup research and development (R&D) expenses, exacerbating inequalities in access to new standards of care (Alyass et al. 2015; Stern et al. 2017).

Open science, a model characterized by principles of open data sharing, fast dissemination of knowledge, cumulative research, and cooperation, presents an alternative to help accelerate innovation processes, streamline translational demands, and reduce some of the associated costs (Hope 2009; Caulfield et al. 2012; Granados Moreno and Joly 2015; Gold 2016; Low et al. 2016; Owens 2016; Rouleau 2017). Open science aims to achieve these goals by circumventing the potential structural barriers and restrictions that IP processes could have hitherto imposed on researchers.

Open science can influence the development and translation processes of precision medicine. Successful precision medicine requires the identification and understanding of predictive biomarkers and molecular mechanisms of diseases (Dalpé and Joly 2014; Alyass et al. 2015; Granados Moreno and Joly 2015; Hey and Kesselheim 2016). Such OMICS data are voluminous and constantly evolving. Most of these data are, however, not fully understood by the scientific community, which contributes to lengthy, complex, and sometimes uncertain translational processes (Hey and Kesselheim 2016). Open science could help to resolve some of these problems by providing researchers and other stakeholders less restrictive access to genetic data, products, and tools, allowing them to collaboratively identify, develop, and validate them (Hey and Kesselheim 2016).

The open science principles of fast dissemination, data sharing, and cooperation can help reduce the redundancy and inefficient resource allocation that so often stall innovative biomedical research (Gold 2016; Hey and Kesselheim 2016; Rouleau 2017). By promoting an expansion of the traditional networks of researchers, centres, and companies, open science avoids unnecessary duplication of work. It also leads to a more efficient allocation of resources to tackle new research areas. Duplication of work can be avoided because transparency allows everyone within the research community to know the focus and extent of other ongoing R&D. Researchers and funders can devote their efforts and support to the activities and stages that need them the most, thus enabling cumulative innovation. Finally, by promoting a more efficient allocation of resources and providing clarity on the focus and extent of ongoing R&D, new areas can be identified and undertaken. Such informational feedback may result in more optimal innovation processes. Furthermore, the expanded open network of researchers, laboratories, and funders may result in the creation and enhancement of partnerships, which can also reduce the economic burden of the innovation process by distributing it across partners (Hope 2009; Caulfield et al. 2012; Gold 2016; Rouleau 2017). Theoretically, this type of collaboration, with minor adjustments, can occur in basic research just as it does in drug discovery and clinical trials.

With this outlook in mind, we identify common objectives, challenges, and needs to be addressed to promote open science initiatives in the field of precision medicine and agree on the following key considerations for open science precision medicine in Canada.[1]

State of the field in Canada

The Canadian open science precision medicine community consists of a small but highly innovative and dynamic group of researchers and projects. This paper elaborates on three projects that illustrate the promise and transformative potential of open science for precision medicine in Canada.

[1]The objectives, challenges, and needs analyzed and presented in this paper as key considerations for open science precision medicine emerged from the discussions that took place in the stakeholders' workshop entitled "Could Open be the Yellow Brick Road to Precision Medicine?" that the Centre of Genomics and Policy at McGill University organized in Montreal, Quebec on 6 March 2018. The workshop gathered 24 precision medicine researchers and open science experts who shared their experiences and perspectives.

Canadian Open Neuroscience Platform

The Canadian Open Neuroscience Platform (CONP) is an emerging, publicly funded data sharing partnership established in early 2018 that includes 33 national and international partner institutions (CONP 2018). It originated as one of the schemes in which the Montreal Neurological Institute (Neuro) promotes open science with respect to its research outcomes, and it follows the framework developed by the Tanenbaum Open Science Institute (TOSI). The CONP intends to break down the barriers to collaboration, facilitating open access to data and samples across the Canadian neuroscience community and beyond. Leading neuroscientists across Canada share data from diverse sources as part of the CONP, maximizing the analytic potential of these data while minimizing costs associated with redundant data collection, poor reproducibility, and other inefficiencies. The CONP consolidates multiple forms of data within a federated national platform, joining several institutional databases to increase ease of access and re-use (The Global Alliance for Genomics and Health 2016). Researchers can store, analyze, and disseminate new data as well as participate in interdisciplinary data management training. Preliminary findings from affiliate studies and institutions will be shared using TOSI's tools and infrastructure. TOSI's goals are to expand the impact of the research generated by the CONP by sharing it with the global community. Partners will also be encouraged to publish their findings openly rather than in subscription-based journals to maximize the impact of their work (CONP 2018; MNI 2018). The CONP aims to enable the sharing of all neuroscience data that are processable, including negative (i.e., unpublished) results, and for these data to be widely used in research and clinical translation.

The CONP has been set up to consider the technical, ethical, and governance issues for open neuroscience as the platform develops. The Ethics and Governance Committee of the CONP is focusing on conditions for consent, including privacy and confidentiality, security, data access tiers, data governance, research oversight, policies regarding research publications, and IP. The CONP will also consider questions related to data quality as well as invest in training efforts in open science.

Structural Genomics Consortium

The Structural Genomics Consortium (SGC) is a charitable open science public–private partnership that carries out research on the 3D structures of proteins and chemical tools, all of which are relevant to drug discovery, with support from pharmaceutical companies, foundations, governments, and philanthropists. Founded in 2003, the SGC adopted an open science position in 2006. Its open science principles prohibit the patenting of its results, stipulate fast dissemination and pre-publication sharing of its structural and chemical biology outputs, and impose these conditions on its collaborators. The SGC places its outputs in the public domain via the RCSB Protein Data Bank.

The SGC has expanded from six organizations at its founding to 20 members, including five laboratories, nine pharmaceutical companies, and more than 250 active research collaborations. It has also established alliances with scientists from associated areas, patient groups, government agencies, funding bodies, and the media to establish an integrated and inclusive innovation process (SGC 2011; SGC 2012). Its funding has been obtained from Canadian research institutions, the Wellcome Trust, and pharmaceutical companies (Morgan Jones et al. 2014; Grabowski et al. 2016).

Now one of the largest and oldest pre-competitive partnerships in the pharmaceutical sector, the SGC is also widely recognized as one of the pioneers of open science. Its open science principles have served as the template for many subsequent projects, such as the G-protein couple receptor (GPCR) Structural Consortium (Los Angeles, California, USA, and Shanghai, China), the Montreal Neurological Institute, and the Usona Institute (Madison, Wisconsin, USA).

Canadian Partnership for Tomorrow Project

Launched in 2008, the Canadian Partnership for Tomorrow Project (CPTP) is Canada's largest health research platform built to better understand and improve the treatment of cancer and chronic diseases. It collects, stores, and shares lifestyle and family history information, biosamples, and physical measurements from multiple provincial research projects and biobanks with the scientific community. It consists of five publicly funded provincial cohorts (BC Generations Project, Alberta's Tomorrow Project, Ontario Health Study, CARTaGENE, and Atlantic PATH) and it has the support of at least 15 partner institutions, the University of Toronto being the most recent addition (Canadian Partnership for Tomorrow Project 2015a).

The project follows principles of collaboration, integration, scientific integrity, transparency, accountability, and stewardship to facilitate studies focusing on disease prevention, health promotion, and health services (Canadian Partnership for Tomorrow Project 2016). To uphold these principles, the CPTP implements an access policy that grants any applicant affiliated with a public or private scientific research institution access to the CPTP's data and biosamples to conduct their approved research project. Applicants must also comply with the approval process and sign the access agreement. Approved users are required to send a copy of any data they derive from the CPTP data back to the CPTP, as per their data sharing agreement. These data become part of the CPTP's database and are made available to other approved users. Furthermore, the CPTP does not seek to obtain patents over its data and biosamples and imposes similar limits to approved users. Nonetheless, it allows users to obtain IP on subsequent inventions and downstream discoveries, including those derived from CPTP's data, expecting them to implement licensing policies that do not impede further research without relieving them from their obligation to provide a copy of their derived data to the CPTP (Canadian Partnership for Tomorrow Project 2015a, 2015b, 2016).

The Canadian innovation context

Canada's innovation ecosystem is composed of institutions in the public sector (e.g., hospitals, research centres, governmental institutions, etc.), private companies, and academic institutions (Watters 2013). Public institutions are under the purview of up to three levels of public policies (federal, provincial, and municipal), and have the possibility of adopting specific institutional policies. Some of them (i.e., hospitals and research centres) devote the majority of their activities to basic research, research infrastructure, and applied R&D; others (i.e., governmental institutions and agencies such as Canada's Innovation Superclusters Initiative), in addition to these activities, provide tax support, direct economic support, and regional support. Private companies (and some universities) provide risk capital to finance start-ups, business management, research infrastructure, and applied R&D (Watters 2013). Academic institutions supply the trained human capital that will be hired in the public and private institutions and are devoted to basic research, research infrastructure, applied R&D and, in some cases, specialized technology and business knowledge (Watters 2013). In this respect, Canada shares some characteristics with the innovation ecosystems of other developed countries, such as the US, with some notable differences.

For instance, despite being in the top half of OECD countries with public expenditures in R&D (OECD 2012), Canada has less public and private funding available than other high-income countries, particularly for scientific R&D. Although public agencies and the private sector in the US devoted $86 billion USD to basic research in 2015 (44% public and 56% private), Canada's public agencies only devoted $2.2 billion USD in the same year (Kondro 2017; Mervis 2017). Furthermore, out of the 1 270 783 active businesses in Canada in December 2017, 0.3% were large (more than 500 employees), 1.7% were medium-sized (100–499 employees), and 98% were small

(<100 employees) (Watters 2013; Statistics Canada 2018). In addition, Canada is a net importer of innovation protected by intellectual property (Canadian Intellectual Property Office 2016). These combined factors make Canada more vulnerable to the demands of foreign firms and weaker when establishing partnerships with private and public institutions from countries like the US, who have many of the largest biotechnology and pharmaceutical companies in the world. Moreover, the culture of commercialization is less prevalent within academia in Canada than in the US, for example, Bramwell et al. (2012). This occurs despite the fact that the Canadian federal government launched formal strategies for university institutions to promote commercialization, create a clear business innovation mandate, and encourage the ownership of inventions resulting from public funding to maximize their return on investment (Joly et al. 2012).

Another relevant difference with the US is that commercialization and innovation support in Canada are often under provincial jurisdiction and are not always well aligned with federal policies. For instance, social, education, science, technology, and innovation policies are generally under the purview of the provincial governments. This has resulted in different and frequently disjointed innovation areas prioritized in accordance with each of the province's political objectives, policies, and financial support. Federal economic policies, including for instance the Superclusters IP Policy (Canada's Digital Technology Supercluster 2018; Government of Canada 2018b), in contrast, encourage collaborative national strategies of commercialization of all the areas and stages of innovation that require coordination and coherence in their frameworks, designs, and policies (Joly et al. 2012). The same is true of technology transfer offices that can also have different levels of expertise and approaches. Incoherence in policies and human resources pose formidable challenges for implementing a new valorization[2] strategy, including an open science approach (Joly et al. 2012).

In the case of health-related R&D, Canada's universal, comprehensive, and accessible publicly funded healthcare system (Government of Canada 1985) directly influences how and where R&D takes place. The federal government contributes to the financial support of the provinces and the territories, who administer, plan, and deliver healthcare services and healthcare insurance plans within their jurisdictions (Government of Canada 2018a). Access to quicker healthcare services via a parallel private system is therefore limited, but growing (Martin et al. 2018). These specific conditions of Canada's healthcare system can conflict, and, in fact, have conflicted, with certain business and commercialization models in the past. For example, Myriad's business model and licensing scheme with respect to its BRCA genetic test required sending samples outside Canada and analyzing them using a methodology determined by a company and not the provincial healthcare authorities. This model did not align well with Canada's healthcare system (Gold and Carbone 2010).

Points to consider

In the following sections, we focus on multiple issues raised by emerging open science models in Canada and the US. The key issues and priorities discussed are synthesized below as points and questions that should be considered by Canadian stakeholders interested in funding or developing open science initiatives in precision medicine.

Terminology

There are multiple emerging models of innovation in Canada that purport to promote open science. Significant differences among these models lie in their strategic, structural, and ideological underpinnings. The reference to IP and the terms and conditions imposed on users could perhaps

[2]Valorization refers to a process that aims to ensure that the outcomes of scientific knowledge add value beyond the scientific domain, including economic, scientific, technological, and societal (Joly et al. 2012).

even call into question the appropriateness of associating them with the open science model with which they bear only limited similarities. For instance, *open innovation* is a model that aims to expand the market and maximize revenues as well as accelerate and make the R&D process more efficient (Chesbrough et al. 2006; West et al. 2014; Chesbrough and Chen 2015). The model pursues collaborations and partnerships and aims to secure competitive dominance and revenue maximization through an emphasized use of IP (Hagedoorn and Zobel 2015; Canada's Digital Technology Supercluster 2018).

Another mechanism sometimes associated with open science is the use of *liability rules*. Liability rules refer to a set of entitlements provided in legal structures that permit third parties to undertake certain actions without prior permission, provided that they compensate the relevant IP holders for any harm the latter suffer as a result of these entitlements. In the context of IP, the regime of liability rules is built on a "take and pay" principle for specified purposes (Reichman and Lewis 2005). Compensatory liability rules could stimulate innovation by allowing access to research outcomes and tools, thereby promoting participation of more parties while ensuring that upstream providers benefit from the commercialization of downstream applications (Reichman and Lewis 2005).

Open data access is a model that enables data to be freely available to the broader research community to use in accordance with the data repositories' terms and conditions (Shaw 2017), which range between no restrictions and fairly stringent contractual and administrative registration processes (Canadian Partnership for Tomorrow Project 2016; Bot et al. 2016; Doerr 2018; Kleiderman et al. 2018; Canadian Partnership for Tomorrow Project n.d.).

The *open source* model uses IP to ensure that access and use of information, data, tools, or inventions by others are safeguarded and maximized (Free Software Foundation 1985; Open Source Initiative 1998; Hope 2009). The *open science* model is characterized by open data sharing, fast dissemination of knowledge, cumulative research, selective and thoughtful eschewal of patent protection, and cooperation with the intention of fostering scientific progress, impact maximization, and the achievement of humanitarian goals (Hope 2009; Caulfield et al. 2012; Donner 2014; Gold 2016; Rouleau 2017; Ali-Khan et al. 2018).

All these "open" models recognize that the R&D and innovation process is more successful and efficient when it incorporates ideas, resources, and strategies from parties that are both internal and external to the institution, organization, or company. However, they differ in the approach, use, and role they give to IP and the extent of the restrictions they impose on the users of the information, works, and inventions they cover. Researchers and scientists may not always understand the conceptual differences among the models and may find it challenging to navigate through their technical concepts. Clarifying the elements of each model and adopting and promoting a common and easily comprehensible nomenclature is necessary to avoid misleading researchers and the public about what such models can do or whether they seek to further private commercial interests, the public good, or both. Identifying these elements can also help to create a platform or set of metrics to assess a model's outcome in specific projects, and the possibility to adjust it in accordance with the project's specific circumstances.

Education/training

There is significant confusion about the meaning, benefits, and costs of open science, giving rise to a need for education and training to support the participation of researchers across both the public and private sectors (Spithoven et al. 2010; Tuomi 2016; Lampert et al. 2017). Academic researchers are major agents of change in achieving the broad implementation of open science, being key

decision-makers about what is shared, with whom, and when (Parthasarathy 2011). However, empirical evidence indicates that many academic researchers are uncertain about the definition and boundaries of open science, its potential risks and benefits, and how they can practically participate (Ferguson 2014; OECD 2015; Ali-Khan et al. 2017; Open Research Data Taskforce 2017). These uncertainties can deter researchers' uptake of open science out of concerns that greater openness may have adverse consequences for their career progression (for example, LERU Research Data Working Group 2013; Levin et al. 2016; Ali-Khan et al. 2017), or their relationships with important research partners (Ali-Khan et al. 2017). Although some industry players are highly engaged in existing open science collaborations (Morgan Jones et al. 2014; Ramsay et al. 2016; Ali-Khan et al. 2017), the full potential of public–private partnering, along with its associated enhanced knowledge flow from academia to industry, has yet to be fully appreciated.

The assessment of the dynamics of how industry internalizes academic knowledge in open science collaborations is poorly understood (Morgan Jones et al. 2014), but some work in the context of open innovation suggests that firms will need new capacities to thrive in an open science environment (Spithoven et al. 2010). Likewise, new data management and promotion roles are needed on the knowledge producer and repository sides to organize and steward knowledge, ensure quality, and support its optimal transfer to users. Stakeholder engagement and awareness-building around the opportunities, risks, and requirements for running open science projects (Rouleau 2017) and providing educational resources, guidance, and best practice standards are key action steps to establishing sustainable and effective open science-based research and innovation in precision medicine and other scientific fields (Ali-Khan et al. 2018). In addition, systematically shifting scientific cultural norms to support and provide incentives for greater openness—for example, by introducing frameworks for recognizing and rewarding the open science practice of academic researchers by funding agencies and university hiring, advancement, "recognized" open access journals[3], and tenure committees—will be critical to broad community adoption of open science (European Commission 2017).

Communication

There is no doubt of a great deal of promise associated with open science approaches to precision medicine, yet the benefits and risks therein should not be hyperbolized. Indeed, inappropriate hype about the promise of both open science and precision medicine may overpromise innovative applications and uses or thwart ideas meant to produce them. Recent studies have found that science hype is on the rise (Vinkers et al. 2015; Chiu et al. 2017), a phenomenon that has also been observed in response to precision medicine. A 2018 study of 774 newspaper articles on precision medicine found an overwhelming emphasis on benefits over risks, limitations, and ethical concerns (Marcon et al. 2018). In addition, a 2014 study found that newspapers also hype the potential benefits of genomic biobanks (Ogbogu et al. 2014).

The media's overpromising portrayal of precision medicine and open science can play a significant role in public perceptions, including the loss of public trust, skewed research priorities, misinformed policy debates, and the premature allocation of technologies, to name a few (Petersen and Krisjansen 2015). The trust issue seems particularly relevant when there is potential for data breaches involving personal information—which is often the case in the context of health research. Unmet high

[3]Although we recognize the benefits of open access journals, we also consider it important to acknowledge two current problems associated with them. There is a proliferation of predatory open access journals willing to publish weak science in exchange for a publication fee. Also, even in recognized peer-reviewed journals, publication fees can prevent students or researchers from lower income countries from contributing valuable science.

expectations coupled with a high-profile mishandling of data (e.g., the Cambridge Analytica case[4]) seems a recipe for an erosion of public support toward open science when such stakeholder buy-in is most pressing (van Staa et al. 2016; Marcon et al. 2018).

Governance

An important theme is the need for Canadian initiatives to adopt common legal and ethical governance standards (e.g., on topics such as the relationship with IP, data protection, access mechanisms, ethics, consent, accreditation, conflict of interests, etc.) and model policies (Canada's Digital Technology Supercluster 2018). Common standards would benefit precision medicine researchers who lack specific skills and expertise in open science models and ensure a level playing field. Moreover, common standards would promote greater transparency and accountability, which, in turn, would increase public trust and participation in open science projects (Vayena and Blasimme 2017; Lin 2018).

Other experts, in contrast, feel that a certain level of freedom and diversity in governance norms should be preserved to encourage some degree of healthy competition among projects. Given that the field is young, researchers may also need the freedom to experiment with different governance models to thoroughly assess whether different open science models are indeed generating anticipated benefits and meeting performance outcomes (Gay 2014). A potential compromise could involve agreeing on key terms and broad governance principles that could apply to open science projects across Canada while affording projects sufficient agency to develop their own specific governance framework.

Legal/ethical challenges

Sharing rich individual-level human samples and data continues to raise legal and ethical concerns about data privacy. The scope of broad consent, where future uses and users are not fully specified, remains contested (Data Protection Working Party 2016). It is also unclear whether Canadian privacy laws will continue to be considered adequate under the new European General Data Protection Regulation (European Commission 2018), which is key for transatlantic research collaboration. Balancing individual and societal interests through data governance is a persistent challenge for the research community and information societies generally (Hockings 2016). This question is even more relevant in open-science-based projects, as the number of projects that could use stored samples and data is likely to increase.

In eschewing restrictive IP, researchers are rethinking the incentive structures, resources, expertise, and practices needed for open science (Parthasarathy 2011). Even where data are willingly shared publicly, the ReusableData.org project has highlighted a persistent failure of the research community to apply clear, traceable, and standard licenses (Reusable Data Project 2017). Sharing software, reagents, and molecules poses important limits on the acquisition of IP, but the example of the SGC shows that non-patentability, competitive advantage, and sustainable funding procure their own benefits and can be maintained throughout translation processes. Public acceptability and sustainability will remain key priorities for open science.

Evaluation

With the goal of optimizing the social and economic value of scientific investments, research is needed to understand how, why, by which mechanisms, and in which contexts open science works

[4]Cambridge Analytica is a British political consulting firm that was at the centre of a controversy in 2018 for using personal data of millions of people (mainly Facebook users) collected without their knowledge and prior permission for purposes of manipulating and influencing voters' opinion to generate political advantage to the highest bidder (Solon 2018).

better than other approaches to organizing research and innovation (Ali-Khan et al. 2018). However, many authors have noted the difficulty of measuring the success of open science, compared with other governance models. For example, traditional metrics such as "patents" and "journal impact factor" often fail to provide meaningful information in an open, networked environment (Parthasarathy 2011; Tracz and Lawrence 2016). Similarly, innovation research, more generally, has been slowed by a lack of diverse and nuanced metrics (Bubela et al. 2012). An international, collaborative Canadian-led group is currently in the process of developing a framework of indicators to measure the progress and impact of open science across a range of health, social, and economic parameters (Ali-Khan et al. 2018). This framework seeks to capture the breadth of successful outcomes of open science using combined quantitative and qualitative variables. Its objective is to allow research units and institutions to assess their open science projects and create a much-needed evidence base to inform decision-makers in Canada and elsewhere. Furthermore, developing mechanisms to assess the effectiveness of open science projects provides investors with useful points of reference that could incentivize them to fund more projects under this model.

Access

Questions of access under open science models, such as "who should have access to data, and for what purposes?" have also attracted a considerable amount of attention (Capps et al. 2014). Given current research ethics standards for more sensitive personal data, should we ever promote unfettered open access? Most open research data are available publicly or through controlled access, where a committee reviews a researcher's qualifications and research proposal, and imposes a data access agreement addressing security, confidentiality, and appropriate use (Dyke et al. 2016; Joly et al. 2016). However, the bounds of this open science "commons" are moving targets. Organizations like Sage Bionetworks, for example, propose to democratize data access to wider communities of data "solvers" (Bot et al. 2016). Alternatively, there are increasing calls for participants' involvement in data governance processes (CIOMS 2016), if not outright "ownership" of research and data (Evans 2016).

Open access suggests that anyone can access that data for whatever reason. Restricting access to specific types of users or collaborators, or only specialists or professionals (either clinical or research based), could therefore be antithetical to the spirit of open science. Traditional approaches to accessing personal data generally limit access to "legitimate" or approved researchers, and require participants' consent if data are not de-identified. Access for research purposes requires approval based on a limited set of criteria mostly elaborated to protect the privacy of research participants, such as the condition not to try to re-identify the participants (Joly et al. 2016), the purpose of and conditions for access, and the scope of qualifications (e.g., "qualified researchers"). Expanding openness could accelerate and democratize research, but it would require reconsidering the concepts of confidentiality and privacy that, to date, have been central to traditional research oversight approaches. Maintaining trust with a contributing public may require keeping some restrictions because of the sensitivity of data and the need to avoid clearly illicit or unethical data use.

The open science community should, therefore, consider when completely unrestricted open access is desirable, and particularly the merits of open science models that assign the responsibility to protect donors' interests to neutral third parties. This need not be an overly restrictive model, but could clearly articulate a public-good approach to access that pre-empts illicit and unethical uses (Capps 2013). At the very least, open access models might require systems that react post facto to unethical uses, such that there is someone who can be clearly responsible for publicly responding to or addressing incidents of data misuse (Global Alliance for Genomics and Health 2016).

Sustainability

Scientific research and product development are generally financed through some combination of government and industry funding. These sustainable investments support the spectrum of research activities, including basic science, translational science, and product development. Projects need to generate and capture value (Chesbrough 2007). Open science projects are expanding their presence in the current innovation ecosystem, and may generate competitive scientific and economic benefits by minimizing transaction costs (licensing and legal fees) and formal requirements (licenses and negotiations) and facilitating knowledge dissemination and training (Allarakhia 2013; Balasegaram et al. 2017; Shaw 2017). Their potentially increasing economic success has been key in justifying continued support from the public sector, as well as growing interest for members of the private sector to invest in the open science model. The involvement of the public sector has been observed to have a "purifying effect" on open science projects. It can validate the trust that the public has in the research and in the decision to release the project's outputs into the public domain. It also limits the risks of working within underdeveloped and new areas of research and can raise the interest of members of the private sector in collaborating and investing in the subsequent stages of the innovation process. The involvement of the private sector is essential to maintain a competitive and innovative edge (Morgan Jones et al. 2014).

Despite the abovementioned facts and reasoning, there is a lack of Canadian public funding opportunities to promote open science projects (both in the health and social sciences domains) outside of a few very specific fields traditionally associated with open science, such as bioinformatics. It is also concerning to see that many public funders promote the values and principles of open science, but do not offer specific means to cover the costs generated by some of the most vital open science activities, such as funds to cover the cost of open publishing (which can be high and prohibitive), data curation or funding schemes to help maintain open data repositories, and secure access processes for more identifying data types (Morgan Jones et al. 2014). This is particularly problematic in the long term (e.g., late translation and clinical trial stages), as the innovation process in precision medicine is lengthy, burdensome, and expensive.

Traditional commercialization strategies, including the use of patents, provide certain competitive and economic advantages that may attract investors and funders. However, as we mentioned above, open science discourages pursuing patents. Instead, the use of data exclusivity and market exclusivity strategies has been suggested as an option to fund open science projects to complement direct public and private funding (U of T News 2017). This alternative, however, could severely limit the open nature of projects. There is also a great fear among investors over losing competitive and economic advantages when foregoing patents (Morgan Jones et al. 2014).

Next steps

Ongoing discussions confirm that interest in, trust of, and support for the open science model is growing in Canada, but they also highlight several issues and challenges that need to be addressed as a matter of priority for open science in precision medicine to progress more effectively, gain broader recognition from funders, and secure public trust. These issues comprise our points to consider. Stakeholders, for instance, should develop and promote the use of terminology and governing principles that are clear, accurate, and in accordance with the objectives and expectations of each project. The open science community should provide a realistic and nuanced portrayal of the benefits, costs, and challenges of the open science model that does not feed into media hype. The performance of these models can only be truly assessed if a sufficiently rich yet rigorous framework of indicators is developed to measure the accomplishments of open science projects. The development and implementation of strategies that ensure the sustainability of open science projects

are also essential. Finally, addressing the legal and ethical challenges associated with open science in terms of access to personal data, privacy, consent, and IP are the cornerstones of a prosperous and responsible open science ecosystem in the field of precision medicine in Canada (Parthasarathy 2011).

The projects we discussed attest to the dynamism and multiple advantages of open science initiatives. Under a more coherent open science framework that takes heed of the points to consider outlined herein, Canada could be well positioned to provide a dynamic context for both innovation and open science in precision medicine.

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Author contributions

PGM and YJ conceived and designed the study. PGM and YJ performed the experiments/collected the data. PGM and YJ analyzed and interpreted the data. DA, GB, RC, PMDGC, JR, JS, DS, and SV contributed resources. PGM, SEA-K, BC, TC, DC, AE, ERG, VR, AT, FB, RC, RC-D, MD, RD, and AMI drafted or revised the manuscript.

Competing interests

YJ is currently serving as a Subject Editor for FACETS, but was not involved in review or editorial decisions regarding this manuscript.

Data availability statement

All relevant data are within the paper.

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