Editorial

Personalized Medicine in Developing Countries: A Roadmap to Personalized Innovation

Yann Joly*

Centre of Genomics and Policy, Department of Human Genetics, Faculty of Medicine, McGill University, Montreal, QC, Canada

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1. INTRODUCTION

The 2002 foresight study on biotechnologies for improving health in developing countries by Daar *et al*. highlighted the potential of personalized medicine for developing countries [1]. For example, consulted experts agreed that infectious diseases could be better controlled by introducing molecular diagnostics and recombinant vaccines together with more traditional public health tools. Recombinant therapeutic proteins and technologies for more efficient drug and vaccine delivery were also viewed as highly relevant to developing countries. This biotechnology foresight study [1] and subsequent ones have also recognized the importance of making personalized medicine more affordable to increase its relevance for the developing world [2, 3]. Moreover, to avoid being set aside as passive benefiters, it will be important for developing countries to develop their own local research and development capacities. Cost containment and access to competitive education programs relevant to the reality of developing countries will be important determinants in this respect.

Given the need to limit cost and improve access to information and research tools in order to better integrate personalized medicine in developing countries, many experts have pointed to the advantage that open innovation in the field of biotechnology (sometimes referred to as open biotechnology) could offer in this context [4]. Open innovation can be defined as a model of sharing data, expertise and resources to promote collaboration, transparency and cumulative public knowledge [5]. It is closely linked to the Mertonian scientific ideal [6] (*i.e.,* a scientific ideal, described by the social norms of communalism, universalism, disinterestedness and organized skepticism) and to the more recent information technology *open source revolution* [7] phenomenon. Open biotechnology projects can take many shapes, such as an open journal (*e.g., PLOS Genetics*), a new bioinformatic tool (*e.g.,* the BioMoby messaging standard), a database (*e.g.,* NIH dbGaP), a large-scale scientific consortium (*e.g.,* the International Cancer Genome Consortium or the Human Genome Project), a project to facilitate access to biotech research tools (Cambia BiOS) or a combination of these [8]. It is often contrasted with more proprietary, competitive models based on commercialization and trade secrecy. In practice, the distinction between these different innovation models is not so palpable, with many successful scientific projects resorting to a combination of different models or hybrid version of them in complementary or sequential approaches.

2. THE BENEFITS OF OPEN INNOVATION

The benefit of open biotechnology for fundamental research in the field of personalized medicine has already been demonstrated by the success of large-scale public and private projects such as the Human Genome Project, the SNP Consortium, and the HapMap Project. There are already open biotechnology models specifically targeting neglected diseases that include significant genomic components: Open Source Drug Discovery, Cambia BiOS, TDR targets, the Tropical Disease Initiative and the Structural Genomic Consortium. From a business perspective, research in personalized medicine is both expensive and uncertain. There is, therefore, an obvious interest in using pre-competitive open collaboration schemes rather than applying for intellectual property rights of dubious legal and economic value on the fundamental tools of innovation (*e.g.,* gene sequences, bioinformatics software, databases, *etc*.).

Open innovation is also a convenient way for researchers to acknowledge the contribution of research participants and avoid claims of bio-prospection often associated with more commercial approaches to genomic research, by providing quick open access to research data. However, in order to ensure that open biotechnology models truly benefit developing countries, a limited degree of control/monitoring over who has access to genomic information and for what

*Address correspondence to this author at the Centre of Genomics and Policy, Department of Human Genetics, Faculty of Medicine, McGill University, Montreal, QC, Canada; Tel: 514-398-8041; Fax: 514-398-8954; E-mail: yann.joly@mail.mcgill.ca

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purposes could be justified. This would be particularly relevant in cases where research participants from a developing country have contributed their genetic data and samples, while researchers potentially interested in the data are located in developed countries or belong to pharmaceutical multinationals. Any limitations should be restricted to the strict minimum necessary to ensure the relevance of future projects for participating developing country populations and should not unduly hinder valuable scientific research.

3. LIMITATIONS IN TRANSLATIONAL RESEARCH AND CLINICAL TRIALS

In the context of translational research and clinical trials, it is much less evident how open biotechnology could promote personalized medicine in the developing world [9]. On the one hand, the costs involved in translational research and regulatory approval are particularly high and the private sector will likely need some sort of recognized financial incentive to invest expertise, time and money in the process. This is especially true given that personalized medicine research and development is still in its infancy and the financial prospect of this type of research in the context of developing countries is highly uncertain. On the other hand, pharmaceutical companies have become acutely aware in recent years of the value of maintaining a good public image and the reputational rewards that participation in open innovation initiatives can generate. Thus, open biotechnology models could have a strategic appeal to pharmaceutical companies needing to re-establish/strengthen their public image or increase their ties with universities or research institutions. Lastly, facilitating access to new high cost laboratory equipment (*e.g.,* genomic sequencers) is another area where the potential of open biotechnology remains doubtful. In this context, international research collaborations and public-private partnerships could offer suitable solutions to the access barrier, assuming proper ethical safeguards are in place.

4. OPEN INNOVATION TO IMPROVE KNOWLEDGE TRANSFER

One of the most important contributions of open innovation to the development and integration of pharmacogenomics in developing countries could be improving knowledge transfer to both local scientists and the general population. Open biotechnology is already producing significant results in this domain through open genomic database projects and open publications [10, 11]. Complete personalized medicine textbooks and other educational resources targeting topics of particular relevance to developing countries could be made openly available at little cost via dedicated internet repositories. Open genomic databases and bioinformatics research tools present students in developing countries with unique low-cost training opportunities, as well as the opportunity to learn from and collaborate on common goals with scientists in other developed and developing countries. However, it should be cautioned that the success of open source as a communication tool will be closely linked with the literacy rate and capacity of local populations to access the internet.

CONCLUSIONS AND OUTLOOK

Similar to personalized medicine, open innovation is still at an early development stage. Empirical data on the concrete accomplishments and medium to long-term viability of open projects, as well as on the willingness of private actors to contribute, is lacking. However, given the poor track record of traditional commercial approaches to promote capacity building, research and development in health technologies in developing countries, this should not prevent us from experimenting with new models. Ultimately, the key to promoting capacity building and innovation in developing countries could be to avoid both proprietary and open innovation excesses and to identify the right combination of approaches for a particular project, involving a specific population in a specific research context. In other words: personalized innovation. Indeed, by participating and even taking leadership in creative innovation models tailored to use open biotechnology in ways that best serve their own purposes, developing countries may finally be able to better position themselves in personalized medicine and reap the benefits of this promising field of health research.

ABBREVIATION

NIH dbGaP = National Institutes of Health database of Genotypes and Phenotypes

CONFLICTS OF INTERESTS

None declared/applicable.

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