



# Redefining responsible research and innovation for the advancement of biobanking and biomedical research

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## ABSTRACT

One of the core objectives of responsible research and innovation (RRI) is to maximize the value of publicly funded research so that it may be returned to benefit society. However, while RRI encourages innovation through societal engagement, it can give rise to complex and previously untested issues that challenge the existing legal frameworks on intellectual property (IP) and public entitlement to benefits of research. In the case of biobanking, the personal nature of human biological materials and often altruistic intention of participants to donate samples intensifies the need to adhere to RRI principles with respect to the research, development, and commercialization of innovations derived from biobanks. However, stakeholders participate and collaborate with others in the innovation process to fulfill their own agenda. Without IP to safeguard investments in R&D, stakeholders may hesitate to contribute to the translation of discoveries into innovations. To realize the public benefit objective, RRI principles must protect the interests of stakeholders involved in the translation and commercialization of knowledge. This article explores the seemingly contradictory and competing objectives of open science and commercialization and proposes a holistic innovation

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framework directed at improving RRI practice for positive impact on obtaining the optimal social and economic values from research.

**KEYWORDS:** biobanking and biomedical research, holistic innovation framework, intellectual property, responsible research and innovation, stakeholder interests, translation and commercialization

## INTRODUCTION

One of the core objectives of responsible research and innovation (RRI) is to maximize the value of publicly funded research so that it may be returned to benefit society. RRI encourages production of new innovations through societal engagement and collaborative research.<sup>1</sup> It implies close cooperation between all stakeholders involved in the innovation process and requires a setting that supports and fosters collaboration to conduct research with and for society. However, RRI as currently described by the European Commission (the ‘Commission’) can give rise to complex and previously untested issues that challenge the existing legal frameworks on intellectual property and public entitlement to benefits of research.<sup>2</sup> Specifically, the Commission identified open access as one of the key pillars of RRI practice,<sup>3</sup> extending the concept to encompass ‘open science’ and therefore adopting the following definition of open access/open science: ‘a practice in which the scientific process is shared completely and in real time’.<sup>4</sup> This definition is particularly problematic from a patent law perspective given that, among other factors, a valid patent grant depends on the lack of any prior enabling disclosure in the art.<sup>5</sup> By encouraging the sharing of scientific knowledge ‘completely and in real time’, the Commission’s approach to open access/open science, in addition to its endorsement of open innovation, has the potential of essentially foreclosing the ability to preserve knowledge for the purposes of obtaining patent protection. Without intellectual property to safeguard investments in R&D, potential stakeholders may be discouraged from contributing to the translation and commercialization of discoveries into innovations if there is no incentive to participate and collaborate. In other words, there is no basis in the law that will incentivize societal engagement and support the *type* of open access/open science described in RRI policy documents to realize the public benefit objective unless RRI principles also consider protecting the interests of stakeholders involved in the translation and commercialization of knowledge. The EU has identified research and innovation as key pillars of its strategy to create sustainable growth and prosperity in Europe.<sup>6</sup> If research is to function as an efficient driver of growth, it is imperative that EU policies support the efficient development of academic discoveries into products and technologies that can address societal challenges or achieve socially

<sup>1</sup> Communication from the Commission, *Europe 2020 A Strategy for Smart, Sustainable and Inclusive Growth* (COM (2010) 2020 final); European Commission, *Horizon 2020 EU Framework Programme for Research and Innovation—Responsible Research and Innovation*, <https://ec.europa.eu/programmes/horizon2020/en/h2020-section/responsible-research-innovation> (accessed Mar. 5, 2016).

<sup>2</sup> European Commission Directorate-General for Research and Innovation, *Indicators for Promoting and Monitoring Responsible Research and Innovation* (EUR 26866 EN, June 2015).

<sup>3</sup> Commission Recommendation, *On Access to and Preservation of Scientific Information* (C(2012) 4890 final).

<sup>4</sup> European Commission, *Supra* note 2 at 32.

<sup>5</sup> Article 54(1) of the Convention on the Grant of European Patents, Oct. 5, 1973 1065 U.N.T.S. 199.

<sup>6</sup> European Commission, *Responsible Research and Innovation—Europe’s Ability to Respond to Societal Challenges* (2012).

desirable outcomes. Translation and commercialization are therefore essential mechanisms to ensure that research can be transformed into innovations so that they can be introduced into the market for the benefit of society.

### RESPONSIBLE RESEARCH AND INNOVATION

Responsible innovation is an idea that is both old and new.<sup>7</sup> At the EU level, RRI was first incorporated toward the end of the 7th European Framework as an approach to govern research and innovation in a manner that is interactive, transparent, and responsive to public concerns.<sup>8</sup> The definition of RRI, as adopted by the Commission, is a ‘comprehensive approach of proceeding in research and innovation in ways that allow all stakeholders that are involved in the processes of research and innovation at an early stage to obtain relevant knowledge on the consequences of the outcomes of their actions and on the range of options open to them and to effectively evaluate both outcomes and options in terms of societal needs and moral values and to use these considerations as functional requirements for design and development of new research, products and services’.<sup>9</sup> The objective is therefore to reduce the risk of societal opposition to new innovations if all stakeholders are involved and consulted throughout the innovation process.<sup>10</sup> The Commission initially identified six key pillars of RRI (societal engagement, gender equality, ethics, open access, science education, and governance)<sup>11</sup> and subsequently added two more pillars (sustainability and social justice/inclusion).<sup>12</sup> Of particular interest and concern to this article is the Commission’s approach to the concept of open access/open science. The growing volume of literature advocating agendas of open access and open science is remarkable and provides a strong argument that commercialization efforts conflict with the free exchange of scientific knowledge and can potentially jeopardize collaborative research.<sup>13</sup> Numerous organizations have expressly adopted policies that embrace open access and free exchange of scientific information, including by way of example, OECD’s *Principles and Guidelines for Access to Research Data from Public Funding*,<sup>14</sup> UNESCO’s *International Declaration on*

<sup>7</sup> Jack Stilgoe, Richard Owen & Phil Macnaghten, *Developing a Framework for Responsible Innovation*, 42 RES. POL’Y 1568, 1580 (2013).

<sup>8</sup> Rene Von Schomberg, *Towards Responsible Research and Innovation in the Information and Communication Technologies and Security Technologies Fields*, EUROPEAN COMMISSION DIRECTORATE GENERAL FOR RESEARCH AND INNOVATION (2011).

<sup>9</sup> European Commission, *Options for Strengthening Responsible Research and Innovation—Report of the Expert Group on the State of Art in Europe on Responsible Research and Innovation* (EUR25766 EN 2013).

<sup>10</sup> Schomberg, *supra* note 8, at 90.

<sup>11</sup> European Commission, *supra* note 6.

<sup>12</sup> European Commission, *Supra* note 2, at 5.

<sup>13</sup> See, for example, Miriam Bentwich, *Changing the Rules of the Game: Addressing the Conflict Between Free Access to Scientific Discovery and Intellectual Property Rights*, 28 NAT. BIOTECH. 137, 140 (2010); Matthew Herder, *Choice Patents*, 52 IDEA: J. L. & TECH. 309, 378 (2011); Wei Hong & John P. Walsh, *For Money or Glory? Commercialization, Competition, and Secrecy in the Entrepreneurial University*, 50 SOC. Q. 145, 171 (2009); Michael A. Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 SCIENCE 698, 701 (1998).

<sup>14</sup> Full and open access to scientific data should be adopted as the international norm for the exchange of scientific data derived from publicly funded research. <https://www.oecd.org/sti/sci-tech/38500813.pdf> (accessed Sept. 28, 2016).

*Human Genetic Data*,<sup>15</sup> the UK's Medical Research Council's *Data Sharing Policy*,<sup>16</sup> and the Global Alliance for Genomics and Health's *Framework for Responsible Sharing of Genomic and Health-Related Data*.<sup>17</sup>

Under open access policy, researchers are encouraged to freely share knowledge and data quickly to foster scientific progress and meet humanitarian goals.<sup>18</sup> Open access is a means of disseminating research in a timely fashion with the intention of accelerating scientific discovery and encouraging innovation by reducing barriers and permitting reuse of available materials with few restrictions.<sup>19</sup> The underlying assumption of the concept is that broader participation in the discovery of new knowledge and unrestricted access to knowledge will accelerate the understanding, advancement, and use of science. The Commission decisively extended the concept of open access to embrace open science by encouraging EU member States to make publicly funded research findings and results freely available to the public as a means to support information exchange, collaboration, and communication among stakeholders.<sup>20</sup> Openness must therefore be 'useful' in order for it to be 'used' to achieve these intended outcomes. As such, examples of proposed outcome indicators for actors in the innovation process that embrace open science include 'data repositories that include explanation and commentary to facilitate use; research projects with daily laboratory notebooks online; [and] research projects that report real added value by an open science mechanism'.<sup>21</sup> At the same time, university imperatives and European Research Area guidelines on intellectual property management in international research collaborations urge researchers to protect the commercial potential of their research by patenting and forming close partnerships with industry to facilitate the translation of knowledge into products.<sup>22</sup> The World Intellectual Property Organization also provides guidelines to universities and

<sup>15</sup> Article 18(c) states that '[r]esearchers should endeavour to establish cooperative relationships, based on mutual respect with regard to scientific and ethical matters and...should encourage the free circulation of human genetic data and human proteomic data in order to foster the sharing of scientific knowledge...'. [http://portal.unesco.org/en/ev.php-URL\\_ID=17720&URL\\_DO=DO\\_TOPIC&URL\\_SECTION=201.html](http://portal.unesco.org/en/ev.php-URL_ID=17720&URL_DO=DO_TOPIC&URL_SECTION=201.html) (accessed Sept. 28, 2016).

<sup>16</sup> The MRC expects valuable data arising from MRC-funded research to be made available to the scientific community with as few restrictions as possible so as to maximize the value of the data for research and for eventual patient and public benefit. Such data must be shared in a timely and responsible manner. <http://www.mrc.ac.uk/documents/pdf/mrc-data-sharing-policy/> (accessed Sept. 28, 2016).

<sup>17</sup> Seek to make data and research results widely available, including through publication and digital dissemination, whether positive, negative, or inconclusive, depending on the nature and use of the data. Dissemination of data and research results should be conducted in a way that both promotes scientific collaboration, reproducibility and broad access to data, and yet minimizes obstacles to data sharing while minimizing harms and maximizing benefits to individuals, families, and communities. <https://genomicsandhealth.org/files/public/Framework%20for%20Responsible%20Sharing%20of%20Genomic%20and%20Health-Related%20Data%20-%20Version%2010%20September%202014.pdf> (accessed Sept. 28, 2016).

<sup>18</sup> European Commission, *Supra* note 2, at 31–33.

<sup>19</sup> <http://www.rri-tools.eu/open-access> (accessed Sept. 28, 2016).

<sup>20</sup> European Commission, *Commission Recommendation of 17.7.2012 On Access to and Preservation of Scientific Information*, SWD (2012) 221 final, SWD (2012) 222 final; see also <http://ec.europa.eu/programmes/horizon2020/en/h2020-section/open-science-open-access> (accessed Sept. 28, 2016).

<sup>21</sup> European Commission, *Supra* note 2, at 32.

<sup>22</sup> Knowledge Transfer Working Group of the European Research Area Committee, *European Research Area Guidelines on Intellectual Property (IP) Management in International Research Collaboration Agreements between European and Non-European Partners* (2012); see also Timothy Caulfield,

research organizations on developing policies related to managing intellectual property rights in research findings and academic discoveries.<sup>23</sup> The intention of the guidelines is to facilitate greater collaboration between the research community and industry and 'lay the foundation for knowledge-based economic development'.<sup>24</sup>

On the one hand, Europe 2020 strategy calls for 'smart growth' by developing the economy based on knowledge and innovation and 'inclusive growth' by fostering a high employment economy.<sup>25</sup> This requires an intellectual property policy that incentivizes and supports translation and commercialization in order to develop a knowledge-based economy and facilitate economic success of industry in order to create jobs and build a sustainable and competitive economy. On the other hand, RRI policy mandates open access and open science to improve knowledge circulation at the expense of intellectual property rights. As a result, an unwanted but likely outcome resulting from this policy tension is 'irresponsibility' arising from the difference between the stakeholders in motivation, interests, and interpretation of RRI to achieve their respective objectives.<sup>26</sup> Generally, RRI has been met with positivity and constructive discourse on how science and innovation can be undertaken to achieve socially desirable outcomes through a dynamic and inclusive process. However, beyond the affirming sentiments associated with the 'concept' of RRI in and of itself, the emerging literature from an academic and policy perspective seems to indicate much confusion and skepticism regarding the practicability of implementing EU-wide RRI practices.<sup>27</sup> The concept of RRI is rapidly evolving and the reality of innovation is that it is a complex collaborative process involving multiple stakeholders with potentially conflicting interests and agendas and different ideas on the conceptualization and application of RRI principles to achieve socially responsible objectives. However, despite the lack of consensus on how to operationalize RRI in practice to facilitate innovation, there are at least 12 active international research projects funded in part by the Commission to develop a robust RRI governance framework.<sup>28</sup> In 2013, the Commission stated that because

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*Commercialization Creep*, 34 POLY OPTION 20, 23 (2012); Tania M. Bubela & Timothy Caulfield, *Role and Reality: Technology Transfer at Canadian Universities*, 28 TRENDS BIOTECH. 447, 451 (2010); C.J. Murdoch & Timothy Caulfield, *Commercialization, Patenting and Genomics: Researcher Perspectives* 1 GENOME MED. 22 (2009); Manuel Crespo & Houssine Dridi, *Intensification of University—Industry Relationships and Its Impact on Academic Research* 54 HIGHER EDUC. 61, 84 (2007); Francis S. Collins, *Reengineering Translational Science: the Time is Right*, 3 SCI. TRANSL. MED. 1, 6 (2011); Elias A. Zerhouni, Charles A. Sanders & Andrew C. von Eschenbach, *The Biomarkers Consortium: Public and Private Sectors Working in Partnership to Improve the Public Health*, 12 THE ONCOLOGIST 250, 252 (2007); Timothy Caulfield, *Sustainability and the Balancing of the Health Care and Innovation Agendas: the Commercialization of Genetic Research*, 66 SASK. L. R. 629 (2003).

<sup>23</sup> World Intellectual Property Organization, *Guidelines on Developing Intellectual Property Policy for Universities and R&D Organizations*, [http://www.wipo.int/policy/en/university\\_ip\\_policies/](http://www.wipo.int/policy/en/university_ip_policies/) (accessed Sept. 28, 2016).

<sup>24</sup> *Id.*

<sup>25</sup> *Supra* note 1, Communication from the Commission, Europe 2020 A Strategy for Smart, Sustainable and Inclusive Growth (COM (2010) 2020 final) at 5.

<sup>26</sup> Stilgoe et al., *supra* note 7, at 1569.

<sup>27</sup> See, for example, Vincent Blok & Pieter Lemmens, *The Emerging Concept of Responsible Innovation. Three Reasons Why It Is Questionable and Calls for a Radical Transformation of the Concept of Innovation* in RESPONSIBLE INNOVATION 2: CONCEPTS, APPROACHES, AND APPLICATIONS 19, 35 (Koops et al. eds, 2015); Rene Von Schomberg, *A Vision of Responsible Innovation* in RESPONSIBLE INNOVATION: MANAGING THE RESPONSIBLE EMERGENCE OF SCIENCE AND INNOVATION IN SOCIETY (Richard Owen, Maggy Heintz & John Bessant eds, 2013); Lotte Asveld, Jurgen Ganzevles & Patricia Osseweijer, *Trustworthiness and Responsible Research and Innovation: the Case of the Bio-economy*, 28 J. AGRIC. & ENVIRON. ETHICS 571, 588 (2015).

<sup>28</sup> See <http://www.progressproject.eu/more-tri-resources/> (accessed Sept. 28, 2016).

RRI is ‘a cross-cutting action that is implemented throughout Horizon 2020, 0.5 per cent of the budgets for the “Societal Challenges” and ‘Industrial Leadership’ pillars of Horizon 2020 will be earmarked for RRI/Science with and for Society actions’.<sup>29</sup> In other words, €462 million of public funds will be allocated to research, develop, and implement a policy that the Commission admittedly is not entirely clear on its feasibility and uptake on an EU level,<sup>30</sup> a concern that is also shared and expressed in the literature.<sup>31</sup>

### BIOBANKING AND BIOMEDICAL RESEARCH — THE ROLE OF STAKEHOLDERS

Biobanks can be defined as a ‘collection of biological material and the associated data and information stored in an organized system for a population or a large subset of a population’.<sup>32</sup> Biobanks make it possible for researchers to analyse large collections of genetic, genealogical, and health-related data of diverse donors to translate knowledge of the human genome into clinically relevant outcomes for the benefit of public health.<sup>33</sup> Biobanks are therefore an essential resource to a range of clinical and biomedical research purposes such as epidemiological studies, drug discovery and development, genomics, and personalized medicine.<sup>34</sup> As such, biomedical research derived from biobanks has immense potential for producing innovations that can be used to advance healthcare. The question as to whether products or processes identified in the context of biobanking should be or are legally eligible for patent protection is subject of much debate.<sup>35</sup> While human biological materials (HBM) are considered natural products isolated from the human body and therefore not patentable as discoveries of natural phenomenon, ‘biological material isolated from its natural environment or produced by means of a technical process may be the subject of an invention even if it previously occurred in nature’.<sup>36</sup> As such, the application of research and data derived from HBM could result in patentable inventions. Some scholars argue that intellectual property rights serve as a tool to protect the substantial investments made

<sup>29</sup> European Commission, *Fact sheet: Science With and for Society in Horizon 2020* (Dec. 2013).

<sup>30</sup> *Id.*

<sup>31</sup> Sarah R. Davies & Maja Horst, *Responsible Innovation in the US, UK and Denmark: Governance Landscapes in RESPONSIBLE INNOVATION 2: CONCEPTS, APPROACHES, AND APPLICATIONS* 37, 56 (Koops et al. eds, 2015).

<sup>32</sup> OECD 2007. ‘Glossary of Statistical Terms—Biobank.’

<sup>33</sup> Madeleine J. Murtagh et al., *Realizing the Promise of Population Biobanks: A New Model for Translation*, 130 HUM. GENET. 333, 345 (2011).

<sup>34</sup> Janet E. Olson et al., *Biobanks and Personalized Medicine*, 86 CLIN. GENET. 50, 55 (2014); Gert-Jan B. van Ommen et al., *BBMRI-ERIC As a Resource for Pharmaceutical and Life Science Industries: the Development of Biobank-Based Expert Centres*, 23 EUR. J. HUM. GENET. 893, 900 (2015); Thane Kreiner & Stefan Irion, *Whole-Genome Analysis, Stem Cell Research, and the Future of Biobanks*, 12 CELL STEM CELL 513, 516 (2013); Naomi Allen et al., *UK Biobank: Current Status and What it Means for Epidemiology*, 1 HEALTH POL’Y & TECH. 123, 126 (2012).

<sup>35</sup> See, for example, Kathinka Evers, Joanna Forsberg & Mats Hansson, *Commercialization of Biobanks*, 10 BIOPRESERV. & BIOBANK. 45, 47 (2012); Saminda Pathmasiri et al., *Intellectual Property Rights in Publicly Funded Biobanks: Much Ado About Nothing?* 29 NAT. BIOTECH. 319, 324 (2011); Timothy Caulfield, *Reflections on the Gene Patent War*, 57 CLIN. CHEM. 977, 979 (2011).

<sup>36</sup> See Article 3 of Directive 98/44 on the legal protection of biotechnological inventions [1998] OJ L213/13–21.



in research projects using HBM and related biobank data<sup>37</sup> whereas others argue that intellectual property rights should not be granted on research results derived from HBM.<sup>38</sup> Arguably, the ‘bigger picture’ concern is donor concern toward commercialization of innovations arising from research derived from HBM, given that trust has been identified as a key predictor of attitude and intention of participants to donate and participate in biobank research.<sup>39</sup> The ethico-legal tension between the voluntary and often altruistic intentions of donors and the profit motives associated with commercialization often attract much concern and criticism.<sup>40</sup> Biobanks can provide crucial platforms for commercially valuable research but the highly personal nature of HBM intensifies the need to adhere to RRI principles with respect to the research, development, and commercialization of innovations derived from biobank data and donor samples. In keeping with RRI principles and objectives to maximize the value of publicly funded research, the translation and commercialization of innovations arising out of research derived from biobanks should endeavor to balance ethical concerns with the best possible use of HBM for the benefit of the public.<sup>41</sup> The need for balance of interests is also articulated by the Human Genome Organization, which states ‘[k]nowledge useful to human health belongs to humanity. Human genomic databases are a public resource. All humans should share in and have access to the benefits of databases’.<sup>42</sup> At the same time, ‘[r]esearchers, institutions, and commercial entities have a right to a fair return for intellectual and financial contributions to database [but] any fees should not restrict the free flow of scientific information and equitable access’.<sup>43</sup> However, as often stated in the literature, ‘what is in the best interests of the public in the context of publically funded biobanks is far from obvious’.<sup>44</sup>

The translation and commercialization of biobank derived and biomedical research entails particular challenges not encountered in other fields of research. The cost of

<sup>37</sup> See, for example, Julien Pénin & Jean-Pierre Wack, *Research Tool Patents and Free-Libre Biotechnology: A Suggested Unified Framework*, 37 RES. POL’Y 1909, 1921 (2008).

<sup>38</sup> See, for example, Christopher Heaney et al., *The Perils of Taking Property Too Far*, 1 STAN. J. L. SCI. & POL’Y 46, 64 (2009); Caulfield, *supra* note 35.

<sup>39</sup> Christine Critchley, Dianne Nicol & Margaret Otlowski, *The Impact of Commercialisation and Genetic Data Sharing Arrangements on Public Trust and the Intention to Participate in Biobank Research*, 18 PUBLIC HEALTH GENOMICS 160, 172 (2015).

<sup>40</sup> See, for example, Daryl Pullman et al., *Personal Privacy, Public Benefits and Biobanks: A Conjoint Analysis of Policy Priorities and Public Perceptions*, 14 GENET. MED. 229, 235 (2012); Herbert Gottweiss, Geroge Gaskell & Johannes Starkbaum, *Connecting the Public With Biobank Research: Reciprocity Matters*, 12 NAT. REV. GENET. 738, 739 (2011); Tore Nilstun & Goran Hermeren, *Human Tissue Samples and Ethics—Attitudes of the General Public in Sweden to Biobank Research*, 9 MED. HEALTH CARE & PHIL. 81, 86 (2006); Timothy Caulfield, Christen Rachul & Erin Nelson, *Biobanking, Consent, and Control: a Survey of Albertans on Key Research Ethics Issues*, 10 BIOPRESERV. & BIOBANK. 433, 438 (2012); Zubin Master et al., *Cancer Patient Perceptions on the Ethical and Legal Issues Related to Biobanking*, 6 BMC MED. GENOMICS 8 (2013); A.A. Lemke et al., *Public and Biobank Participant Attitudes Toward Genetic Research Participation and Data Sharing*, 13 PUBLIC HEALTH GENOMICS 368, 377 (2010); Susan B. Trinidad et al., *Genomic Research and Wide Data Sharing: Views of Prospective Participants*, 12 GENET. MED. 486, 495 (2010).

<sup>41</sup> Kathinka Evers, Joanna Forsberg & Mats Hansson, *Commercialization of Biobanks*, 10 BIOPRESERV. & BIOBANK. 45, 47 (2011).

<sup>42</sup> HUGO Ethics Committee, *Statement on Human Genomic Database* (2002) Recommendation 1, <http://www.hugo-international.org/Resources/Documents/CELS.Statement-HumanGenomicDatabase.2002.pdf> (accessed Sept. 28, 2016).

<sup>43</sup> *Id.*, Recommendation 6.

<sup>44</sup> Pathmasiri et al, *supra* note 35, at 322.

healthcare and research and development to bring new treatments and therapies to market is ever increasing. The average cost of bringing a new drug to market can cost up to USD \$2.6 billion and take an average of 10–15 years to develop.<sup>45</sup> Meanwhile, the economic burden to society associated with the treatment of chronic diseases continues to exceed USD\$1.3 trillion a year.<sup>46</sup> The nature of biomedical research is such that very few early-stage discoveries actually deliver promising results.<sup>47</sup> Much of the costs associated with biomedical research are related to the high risk of failure, demonstrating how challenging it is to transform discoveries into safe and effective innovations.<sup>48</sup> Despite significant investments of public and private funds in the advancement of biomedical research, there remains a gap in the critical step of translating discoveries for development into products and technologies that can benefit the public. Known as the ‘valley of death’ life-saving innovations may be left undeveloped if there is no incentive to advance discoveries beyond early-stage development in order to bridge the gap between research and commercialization.<sup>49</sup>

Commercialization may also result in tension between the interests of industry and those of researchers involved in biobanking. Collaborations between industry and academia incentivized by commercial interests may have the effect of compromising research integrity.<sup>50</sup> For example, studies have shown that ‘industry-sponsored research’ in the field biomedical research tends to support and promote proindustry conclusions,<sup>51</sup> which may further undermine public perception of stakeholder involvement in biomedical research. If participants view stakeholder involvement as introducing a profit motive into what is otherwise an act of public good, there is a risk that the public may refuse to donate HBM or elect to withdraw their samples.<sup>52</sup> In the eyes of potential donors, public funding of biobanks connote common good, scientific and public health benefits, and values of sharing and trust, whereas notions of

<sup>45</sup> See, for example, Asher Mullard, *New Drugs Cost US\$2.6 Billion to Develop*, 13 NAT. REV. DRUG DISCOV. 877 (2014).

<sup>46</sup> See, for example, The Council for American Medical Innovation (CAMI), *Gone Tomorrow: A Call to Promote Medical Innovation, Create Jobs, and Find Cures in America*, prepared by the Battelle Technology Partnership Practice, June 10, 2010. See also Ross DeVol et al. *An Unhealthy America: The Economic Burden of Chronic Disease*. MILKEN INSTITUTE (2007). This study predicts the cost of common chronic diseases can reach up to \$6 trillion by middle of the century.

<sup>47</sup> See also Micheal Hay et al., *Clinical Development Success Rates Much for Investigational Drugs*, 32 NAT. BIOTECH. 40, 51 (2014); Joseph A. DiMasi et al., *Trends in Risks Associated With New Drug Development: Success Rates for Investigational Drugs*, 87 CLIN. PHARMACOL. & THERAPEUT. 272, 277 (2010).

<sup>48</sup> See Arti K. Rai et al., *Pathways Across the Valley of Death: Novel Intellectual Property Strategies for Accelerated Drug Discovery*, 8 YALE J. HEALTH POL’Y, L. & ETHICS 20, 30 (2008).

<sup>49</sup> Karl E. Friedl, *Overcoming the ‘Valley of Death’: Mouse Models to Accelerate Translational Research*, 8 DIABETES TECH. & THERAPEUT. 413, 414 (2006); Nuala Moran, *Public Sector Seeks to Bridge ‘Valley of Death’*, 25 NAT. BIOTECH. 266 (2007); Barry S. Collier & Robert M. Califf, *Traversing the Valley of Death: A Guide to Assessing Prospects for Translational Success*, 10 SCI. TRANSL. MED. 10 (2009).

<sup>50</sup> Justin E. Bekelman, Yan Li & Cary P. Gross, *Scope and Impact of Financial Conflicts of Interest in Biomedical Research: A Systematic Review*, 289 JAMA 454, 465 (2003); Joel Lexchin et al., *Pharmaceutical Industry Sponsorship and Research Outcome and Quality: Systematic Review*, 326 BMJ 1167, 1170 (2003); Mohit Bhandari et al., *Association Between Industry Funding and Statistically Significant Pro-Industry Findings in Medical and Surgical Randomized Trials*, 170 CAN. MED. ASSOC. J. 477, 480 (2004).

<sup>51</sup> *Id.* Bekelman et al., at 455.

<sup>52</sup> Dianne Nicol & Christine Critchley, *Benefit Sharing and Biobanking in Australia*, 21 PUBLIC UNDERST. SCI. 534, 555 (2012); Timothy Caulfield, Christen Rachul & Erin Nelson, *Biobanking, Consent, and Control: A Survey of Albertans on Key Research Ethics Issues*, 10 BIOPRESERV. & BIOBANK. 433, 438 (2012).



profit, private interest, and economic benefit conjures mistrust around privately funded biobanks.<sup>53</sup> Financial incentives may work contrary to the ambition of using biobank samples and associated data to address public health problems by impeding other research collaborations and by modifying the research agenda to satisfy the commercial interests of industry at the expense of addressing important health problems.<sup>54</sup> The literature is equivocal as to whether the public's objection is principled and directed at commercialization in the biomedical field as such, or if the opposition is pragmatic and directed at the possible unjust or exploitative consequences of commercialization strategies. In any event, new legal challenges related to biobanking and biomedical research have emerged where ethical, legal, social, cultural, and economic considerations must be taken into account when formulating policy regarding the advancement of biobanking and biomedical research.

Stakeholders involved in the research, development, translation, and commercialization of innovations derived from biobank research collaborate with each other for their own reasons: (i) donors want to protect their privacy and benefit from the research that uses their samples; (ii) researchers want free and open access to knowledge and data to foster scientific progress; (iii) industry wants to invest in research that will lead to commercial benefits; (iv) universities seek to discover and disseminate knowledge as well as attract public and private funding for further research; (v) government wants to support research that will drive socioeconomic growth and create greatest impact; and (vi) the public is interested in return of benefit from tax dollars invested in basic research (see Figure 1).

Although the advancement of biomedical research derived from biobank data involves the participation of a number of stakeholders, each with different interests and motivations, the parties share at least one common desired outcome: the discovery of new innovations for the advancement of healthcare. To realize the public benefit objective of biobank-related research, RRI principles must also consider the interests of all stakeholders involved in the translation and commercialization of knowledge. As previously mentioned, the overall goals and principles of RRI as a whole are convincing and understandable but the lack of clear incentives at the individual stakeholder level renders the operability of RRI elusive.

### Donors and the public

There is much debate in the literature on the ethico-legal tension between the economics of translating and commercializing innovations derived from biobank resources and the scientific value of HBM for the advancement of biomedical research.<sup>55</sup> Public trust issues tend to be raised in association with commercialization of innovations derived from biobanks, which must be properly addressed to inspire public support for

<sup>53</sup> Maurizio Onisto, Viviana Ananian & Luciana Caenazzo, *Biobanks Between Common Good and Private Interest: The Example of Umbilical Cord Blood Private Biobanks*, 5 RECENT PAT. DNA & GENE SEQ. 166, 168 (2011).

<sup>54</sup> Klaus Hoeyer, *Trading in Cold Blood?* in TRUST IN BIOBANKING: DEALING WITH ETHICAL, LEGAL AND SOCIAL ISSUES IN AN EMERGING FIELD OF BIOTECHNOLOGY 21, 41 (Peter Dabrock, Jochen Taupitz & Jens Ried eds, 2012).

<sup>55</sup> See, for example, Danijela Budimir et al., *Ethical Aspects of Human Biobanks: A Systematic Review*, 52 CROAT. MED. J. 262, 279 (2011); Klaus Hoeyer, *The Ethics of Research Biobanking: A Critical Review of the Literature*, 25 BIOTECH. & GENET. ENG. REV. 429, 452 (2008); Richard Tutton, *Biobanking: Social, Political and Ethical Aspects*, in ENCYCLOPEDIA OF LIFE 1, 7 (2010).

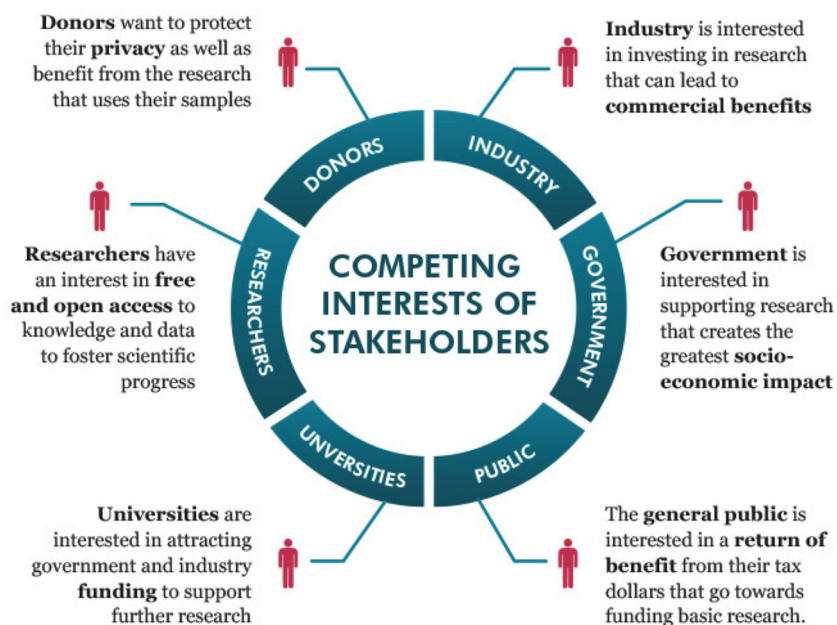


Figure 1. Stakeholder interests.

the advancement of human health.<sup>56</sup> The involvement of industry can create questions about financial motive, thus compromising the integrity of the biobank and associated research in the eyes of the public. Some argue that commercializing biobank resources threatens to undermine the altruistic donation of individual donors<sup>57</sup> and that commercial interests may direct research toward the needs of industry as opposed to the scientific and public good.<sup>58</sup> There is evidence that suggests that donor trust and support in biobanking research significantly decreases if researchers are involved with industry or government as opposed to universities.<sup>59</sup> Numerous guidelines and recommendations specifically recognize the ethical responsibility of researchers to inform donors about

<sup>56</sup> David B. Resnik, *Scientific Research and the Public Trust*, 17 *SCI. & ENG. ETHICS* 399, 409 (2011); Zubin Master & David B. Resnik, *Hype and Public Trust in Science*, 19 *SCI. & ENG. ETHICS* 321, 335 (2013), which stated that '[p]ublic trust' is not a static or easily quantifiable concept. Rather, it is relational, ongoing, and changing....[T]he 'public' is not a homogenous entity that speaks with one voice: there are many different groups that comprise 'the public', and these groups may differ in their trust of scientists. These relationships of trust may be affected by a number of different factors and change at different periods of time.

<sup>57</sup> Catherine Waldby, *Biobanking in Singapore: Post-developmental State, Experimental Population*, 28 *NEW GENET. & SOC.* 253, 265 (2009); Nicol & Critchley, *supra* note 52; Daryl Pullman et al., *Personal Privacy, Public Benefits, and Biobanks: A Conjoint Analysis of Policy Priorities and Public Perceptions*, 14 *GENET. MED.* 229, 235 (2012); Herbert Gottweis, George Gaskell & Johannes Starkbaum, *Connecting the Public with Biobank Research: Reciprocity Matters*, 12 *NAT. REV. GENET.* 738, 739 (2011).

<sup>58</sup> Robert Mitchell & Catherine Waldby, *National Biobanks: Clinical Labor, Risk Production, and the Creation of Biovalue*, 35 *SCI. TECH. & HUMAN VALUES* 330, 355 (2010).

<sup>59</sup> Timothy Caulfield, Christen Rachul & Erin Nelson, *Biobanking, Consent, and Control: A Survey of Albertans on Key Research Ethics Issues*, 10 *BIOPRESERV. & BIOBANK.* 433, 438 (2012); Zubin et al., *supra* note 40; Michael Clemence et al., *Wellcome Trust Monitor Wave 2: Tracking Public Views on Science, Biomedical Research and Science Education* (2013); see also The Swinburne National Technology and Society Monitor (proposed July 30, 2012) <http://www.swinburne.edu.au/lss/spru/spru-monitor.html> (accessed Sept. 28, 2016).

potential commercial applications resulting from research on donor HBM.<sup>60</sup> Donor participation and right to withdraw might be at stake if the public does not associate commercialization with efforts in the interest of the public good.

Furthermore, underlying this commercialization tension is the financial commitment required to ensure the long-term sustainability of biobanks to support ongoing biomedical research for the benefit of public health. Evidence indicates that publicly funded biobanks are concerned with long-term funding in response to financial pressures on public funding,<sup>61</sup> making partnerships with stakeholders a pragmatic means to secure financial security. In order to maintain quality and scientific efficacy, some biobanks have resorted to operating like a business enterprise in order to support continued scientific endeavors.<sup>62</sup> In order to benefit from biomedical research, the sustainability of biobanks as a resource from which such research is based on needs to be secured. However, introducing private funding and partnerships to existing publicly funded biobanks can give rise to various policy and legal concerns. Public trust declines<sup>63</sup> and there is fear that the involvement of stakeholders may limit or prevent the sharing and return of biobank resources and the results derived therefrom.<sup>64</sup> Public expectation that society is entitled to results derived from publicly funded research, regardless of stakeholder participation, can lead to the creation of biobanking policies that may be ethically or legally contentious.<sup>65</sup>

The negative attitude toward the involvement of commercial entities in biobanks and biobanking research is in part associated with questions regarding the degree to which research is being done ethically and primarily for the public good as opposed to commercial interests.<sup>66</sup> However, this attitude may be based in part on misconceptions. There is evidence indicating that the public generally has limited understanding of the

<sup>60</sup> Organization for Economic Co-Operation and Development, *OECD Guidelines on Human Biobanks and Genetic Research Databases* (2009); World Health Organization, *Guideline for Obtaining Informed Consent for the Procurement and Use of Human Tissues, Cells, and Fluids in Research* (2003); Council for International Organizations of Medical Sciences, *International Ethical Guidelines for Biomedical Research Involving Human Subjects* (2002); Council of Europe, *Treaty Series - No. 195 Additional Protocol to the Convention on Human Rights and Biomedicine, concerning Biomedical Research* (2005).

<sup>61</sup> Gail E. Henderson et al., *Characterizing Biobank Organizations in the US: results from a National Survey*, 5 *GENOME MED.* 3 (2013); R. Jean Cadigan et al., *Neglected Ethical Issues in Biobank Management: Results From a US Study*, 9 *LIFE SCI. SOC. & POL'Y* 1, 13 (2013); Aaro Tupasela & Neil Stephens, *The Boom and Bust Cycle of Biobanking—Thinking Through the Life Cycle of Biobanks*, 54 *CROAT. MED. J.* 501, 503 (2013); Saminda Pathmasiri et al., *Intellectual Property Rights in Publicly Funded Biobanks: Much Ado about Nothing?* 29 *NAT. BIOTECH.* 319, 323 (2011); Ingeborg Meijer et al., *Networked Research Infrastructures and their Governance: the Case of Biobanking*, 39 *SCI. & PUBLIC POL'Y* 491, 499 (2012).

<sup>62</sup> Sandra A. McDonald et al., *Fee-For-Service as a Business Model of Growing Importance: The Academic Biobank Experience*, 10 *BIOPRESERV. & BIOBANK.* 421, 425 (2012).

<sup>63</sup> Thirty-two per cent of respondents trusted scientists working with industry, 34% trusted scientists working with government and 66% trusted university scientists. See Clemence et al., *supra* note 59; Caulfield et al., *supra* note 40; Christine Critchley & Lyn Turney, *Understanding Australians' Perceptions of Controversial Scientific Research*, 2 *AUST. J. EMERG. TECH. & SOC.* 82, 107 (2004); Christine R. Critchley & Dianne Nicol, *Understanding the Impact of Commercialization on Public Support for Scientific Research: Is It About the Funding Source or the Organization Conducting the Research?*, 20 *PUBLIC UNDERST. SCI.* 347 (2011).

<sup>64</sup> Christine R. Critchley, *Public Opinion and Trust in Scientists: The Role of the Research Context and the Perceived Motivation of Stem Cell Researchers*, 17 *PUBLIC UNDERST. SCI.* 309, 327 (2008).

<sup>65</sup> Timothy Caulfield, *Biobanks and Blanket Consent: The Proper Place of the Public Good and Public Perception Rationales*, 18 *KING L. J.* 209, 226 (2007).

<sup>66</sup> Nilstun & Hermeren, *supra* note 40; Lemke et al., *supra* note 40, at 374; Trinidad et al., *supra* note 40, at 493.

translational process and the contributions required from stakeholders to translate and commercialize basic research into innovations.<sup>67</sup> In a recent UK report on public attitudes to commercial access to health data, it was concluded that the public knows very little about some key areas, including how the commercial sector contributes to health-care, the role of universities and industry in the development of health and medical research, and the process of how medical and scientific research is carried out to produce drugs and therapies.<sup>68</sup> The public also wanted safeguards put in place to regulate profit motives by creating independent scrutiny and control.<sup>69</sup> To benefit from the publicly funded research derived from donated HBM, industry needs to translate and commercialize early-stage discoveries into socially beneficial innovations *but* industry will only participate if there is a financial incentive to do so. Others have argued that the problems associated with commercialization should be reframed as realizing the benefits of knowledge derived from biobanks as being aligned with public health interests rather than undermining the trust and altruistic intent of donors.<sup>70</sup> To promote effective uptake of publicly funded research, the public needs to be informed of the realities of the translation process. The public needs to critically assess their own preconceptions and know that their participation in collaboration with other stakeholders, including industry, is required in order to facilitate the creation and introduction of socially beneficial innovations into the market. A number of research groups have attempted to develop best practices in biobank governance and engage the public in a wider debate and understanding about biobanking and biomedical research.<sup>71</sup> There is evidence indicating that the more informed people are, the more likely they are to approve of use of their HBM for the advancement of public health, including the involvement of industry.<sup>72</sup>

### Industry

Due to the increasing cost of R&D and budgetary and funding challenges in the public research sector, collaborative partnerships between industry and public research organizations, such as universities, may be a pragmatic means to pool resources, share information, and reduce duplication efforts in order to optimize the impact of research and derisk the development of basic research.<sup>73</sup> If collaborative partnerships are to be

<sup>67</sup> Andy Haines, Shyama Kuruvilla & Matthias Borchert, *Bridging the Implementation Gap Between Knowledge and Action for Health*, 82 BULL. WORLD HEALTH ORG. 724, 731 (2004); Kathinka Evers, Joanna Forsberg & Mats Hansson, *Commercialization of Biobanks*, 10 BIOPRESERV. & BIOBANK. 45, 47 (2012); Jennifer L. Baumbusch et al., *Pursuing Common Agendas: A Collaborative Model for Knowledge Translation Between Research and Practice in Clinical Settings*, 31 RES. NURS. & HEALTH 130, 140 (2008).

<sup>68</sup> Ipsos MORI Social Research Institute, *The One-Way Mirror: Public Attitudes to Commercial Access to Health Data*, prepared for the Wellcome Trust (Mar. 2016) (<https://www.ipsos-mori.com/Assets/Docs/Publications/sri-wellcome-trust-commercial-access-to-health-data.pdf>, accessed Sept. 28, 2016).

<sup>69</sup> *Id.* at 17.

<sup>70</sup> Andrew Turner, Clara Dallaire-Fortier & Madaleine Murtagh, *Biobank Economics and the 'Commercialization Problem'* 7 SPONTANEOUS GENERATIONS 69, 80 (2013).

<sup>71</sup> See for example Karolinska Institute and BBMRI, Education and lectures on biobanking (<http://ki.se/en/research/education-and-lectures-on-biobanking>); UKCRC Tissue Directory and Coordination Centre stakeholder engagement ([www.biobankinguk.org](http://www.biobankinguk.org)).

<sup>72</sup> Ipsos MORI Social Research Institute, *Supra* note 68, at 107.

<sup>73</sup> See, for example, Nuala Moran, *Public Sector Seeks to Bridge 'Valley of Death'*, 25 NAT. BIOTECH. 266 (2007); Paul K. Owens et al., *A Decade of Innovation in Pharmaceutical R&D: the Chorus Model*, 14 NAT. REV. DRUG DISCOV. 17, 28 (2015).

supported as a means to facilitate the translation process, public research organizations and industry must find ways to forge closer ties. Alliances naturally involve risk and concerns, such as preserving the core values of academia while providing industry with the incentive required to justify investment in basic research.<sup>74</sup> Industry, particularly the pharmaceutical industry, has long maintained that patents are crucial to the financial viability of continued R&D.<sup>75</sup> Given the costly and risky nature of translating discoveries into innovations,<sup>76</sup> it is understandable that industry advocates for intellectual property protection as an incentive to derisk the development of early-stage research and be rewarded for their investment should efforts lead to commercialization. Aside from financial incentives, industry also views patent rights as a means to facilitate collaboration and induce R&D investment by allowing the parties with the best knowledge of a particular market or technology to make decisions on how to manage the risks and protect their innovation.<sup>77</sup> In other words, the transactional function of patents (as opposed to the proprietary rights) can itself be seen as an incentive to facilitate collaboration by providing a system by which the parties can organize collaborative R&D in a manner that is most efficient based on their unique knowledge of market dynamics.<sup>78</sup> As such, industry will likely require RRI policies to play a role in protecting the agreements governing collaborations. By reducing transactional hazards associated with creating the relationship between stakeholders, discoveries have a greater likelihood of being translated into innovations for the benefit of the public. As long as industry involvement in the translation of basic research derived from HBM is necessary to achieve this outcome, financial motives associated with commercialization are an undeniable fact, whether or not there is empirical evidence to support the notion that patents are essential to stimulate innovation.

<sup>74</sup> John P. Walsh, Wesley M. Cohen & Charlene Cho, *Where Excludability Matters: Material Versus Intellectual Property in Academic Biomedical Research*, 36 RES. POL'Y 1184, 1203 (2007).

<sup>75</sup> ROY LEVY, FTC BUREAU OF ECONOMICS STAFF REPORT THE PHARMACEUTICAL INDUSTRY: A DISCUSSION OF COMPETITIVE AND ANTITRUST ISSUES IN AN ENVIRONMENT OF CHANGE (1999), which concluded that an estimated 65% of the drugs on the market would not have been developed at all absent patent protection; see also Edwin Mansfield, *Patents and Innovation: An Empirical Study*, 32 MGMT. SCI. 173, 181 (1986) which found that up to 90% of pharmaceutical inventions would not have been developed without patents.

<sup>76</sup> However, there is much debate and conflicting reports over the actual cost of drug development. See, for example, Donald W. Light & Rebecca Warburton, *Demythologizing the High Costs of Pharmaceutical Research*, 6 J. BIOSOC. 34, 50 (2011).

<sup>77</sup> WILLIAM M. LANDES & RICHARD A. POSNER, THE ECONOMIC STRUCTURE OF INTELLECTUAL PROPERTY LAW (2009); James Langenfeld, *Intellectual Property and Antitrust: Steps Toward Striking a Balance*, 52 CASE W. RES. L. REV. 91 (2001). Because parties never have perfect information when entering into a collaboration, uncertainties and information asymmetries manifest themselves as transaction costs when parties use best efforts to negotiate agreements governing their relationship. See Paul L. Joskow, *Transaction Cost Economics, Antitrust Rules and Remedies*. 18 J. L. ECON. & ORG. 95, 116 (2002) and Herbert Hovenkamp, *Harvard, Chicago, and Transaction Cost Economics in Antitrust Analysis*, 57 ANTITRUST BULL. 613, 662 (2012).

<sup>78</sup> Nancy T. Gallini & Suzanne Scotchmer, *Intellectual Property: When is it the Best Incentive System?* in 2 INNOVATION POLICY AND THE ECONOMY 51, 78 (Adam B. Jaffe, Josh Lerner & Scott Stern eds, 2002); Bronwyn H. Hall & Dietmar Harhoff, *Recent Research on the Economics of Patents*. NATIONAL BUREAU OF ECONOMIC RESEARCH (2012).



### Public research organization and researchers

Over the last few decades, the position of universities and public research organizations in the market has evolved considerably.<sup>79</sup> Gradually, they have become more actively involved in the process of transferring technology to industry, since placing publicly funded research in the public domain is no longer seen as sufficient to generate the full benefits of innovation.<sup>80</sup> The overall evolution of the economy toward a knowledge economy creates an important incentive for constant innovation and exploitation of new technologies, which very naturally brings together academia on the one hand and industry on the other.<sup>81</sup> Policy changes to encourage collaboration between academia and industry to commercialize know-how allow academia to own and license patents for inventions derived from publicly funded research.<sup>82</sup> Industry benefits from having access to cutting edge research and discoveries and academia benefits from receiving royalties to fund further R&D to compensate for budgetary cuts to public funding.<sup>83</sup> Research also indicates that university–industry collaborations positively affect academic research performance in terms of patenting and publication activities.<sup>84</sup>

However, despite a shared commitment (and government support to foster university–industry collaborations), significant ‘cultural’ obstacles<sup>85</sup> stand in the way of successful partnerships between researchers and industry. Academics speak the language of science and industry speaks the language of business. Academics are generally motivated by research and publication<sup>86</sup> and industry is motivated by commercial interests. In other words, conflicting objectives create reluctance among the parties to align too closely. Academia is a rich source of basic research and discovery but lacks the funding and translational expertise of how new therapies reach the market. Industry specializes in translational activities and procedures required to convert early-stage

<sup>79</sup> Bart Van Looy et al., *Entrepreneurial Effectiveness of European Universities: An Empirical Assessment of Antecedents and Trade-off*, 40 RESEARCH 553, 564 (2011) which stated that since the late 1970s, many countries have changed their legislation and created support mechanisms to encourage interaction between universities and firms, including through technology transfer.

<sup>80</sup> Mike Wright et al., eds. *Introduction* in ACADEMIC ENTREPRENEURSHIP IN EUROPE 1, 30 (2007).

<sup>81</sup> Petra Andries & Koenraad Debackere, *Adaptation and Performance in New Businesses*, 29 SMALL BUS. ECON. 81, 99 (2007).

<sup>82</sup> Henry W. Chesbrough, *Business Models and Managing Intellectual Property* in OPEN INNOVATION: THE NEW IMPERATIVE FOR CREATING AND PROFITING FROM TECHNOLOGY (Harvard Business Publishing 2003); David Roessner et al., *The Economic Impact of Licensed Commercialized Inventions Originating in University Research*, 42 RES. POL'Y 23, 34 (2013).

<sup>83</sup> Joseph Friedman & Jonathan Silberman, *University Technology Transfer: Do Incentives, Management, and Location Matter?* 28 J. TECH. TRANSFER 17, 30 (2003).

<sup>84</sup> Bart Van Looy et al., *Combining Entrepreneurial and Scientific Performance in Academia: Towards a Compounded and Bi-directional Matthew-Effect*, 33 RES. POL'Y 425, 441 (2004); Bart Van Looy, Julie Callaert & Koenraad Debackere, *Publication and Patent Behavior of Academic Researchers: Conflicting, Reinforcing or Merely Co-existing?* 35 RES. POL'Y 596, 608 (2006).

<sup>85</sup> Kenneth I. Kaitin, *Translational Research and the Evolving Landscape for Biomedical Innovation*, 60 J. INVEST. MED. 995, 998 (2012).

<sup>86</sup> There is literature on a phenomenon known as ‘academic entrepreneurs’ where scientists are interested in creating a spin-off company around their research to develop the commercial potential and utility of publicly funded research or ‘entrepreneurial academics’ where scientists pursue research interests in an entrepreneurial setting. See, for example, Martin Meyer, *Academic Entrepreneurs or Entrepreneurial Academics? Research—Based Ventures and Public Support Mechanisms*, 33 R&D MGMT. 107, 115 (2003); John Egan, Ceri Williams & Josephine Dixon-Hardy, *When Science Meets Innovation: A New Model of Research Translation*, THE INTERNATIONAL SOCIETY FOR PROFESSIONAL INNOVATION MANAGEMENT (2013).

research into new therapies but lack the competency and resources to conduct basic research. It is the mutual desire to develop and deliver new treatments, therapies, and medicines that drive the collaboration and development of partnerships to bridge the translational gap. Furthermore, the relationship is mutually beneficial: Academia requires funding to conduct research. Industry can provide funding. Industry requires innovative research to commercialize. Academia can provide cutting edge early-stage research and discoveries.

### Government

The European Strategy Forum on Research Infrastructure has identified biobanks as one of the main priority research areas.<sup>87</sup> The creation of the pan-European Biobanking and Biomolecular Resources Research Infrastructure (BBMRI) is intended to enable the identification of new targets for therapy and reduce the attrition in drug discovery and development by facilitating the translation of basic research discoveries into the development of innovative strategies for the prevention, diagnosis, and treatment of diseases of particular relevance to the EU and alleviate the associated medical and economic burden.<sup>88</sup> The Commission also recognizes that sound governance of biobanks is one of the most important challenges to ensure that biobanking is conducted ethically and responsibly.<sup>89</sup>

In addition to interests in addressing societal concerns and challenges, the Commission has interests in maintaining the economic health and prosperity of the EU. According to the Commission, research and development could create 3.7 million jobs and increase annual GDP by close to €800 billion by 2025.<sup>90</sup> At the heart of the Europe 2020 strategy is the adoption of a more strategic approach to innovation without reference to any particular fields of research that will contribute to Europe's competitiveness and associated increase of jobs.<sup>91</sup> From the Commission's perspective, the expected positive impact of research and innovation depends largely on the availability and ability to fund research to regain Europe's economic foundation and achieve prosperity.<sup>92</sup> The underlying assumption is that research and innovation will lead to socioeconomic growth (ie more and faster innovation means prosperity, job creation, and overall betterment of society). Economic prosperity and sustainable growth that innovation is expected to yield is therefore dependent upon the ability of stakeholders to collaborate effectively on the translation and commercialization of publicly funded research. Socioeconomic growth sought by government will only be realized if industry can successfully commercialize innovations, which will lead to company creation, job creation, increased tax revenues, and societal uptake of innovations to address societal

<sup>87</sup> European Commission. *A Vision for Strengthening World Class Research Infrastructures on the ERA: Report of the Expert Group on Research Infrastructures*. Brussels (2010).

<sup>88</sup> *Id.*

<sup>89</sup> European Commission. Biobanks for Europe—a challenge for governance. [http://www.coe.int/t/dg3/healthbioethic/Activities/10\\_Biobanks/biobanks\\_for\\_Europe.pdf](http://www.coe.int/t/dg3/healthbioethic/Activities/10_Biobanks/biobanks_for_Europe.pdf) (accessed Sept. 28, 2016).

<sup>90</sup> Communication from the European Commission, *Europe 2020 Flagship Initiative Innovation Union*, SEC (2010) 1161.

<sup>91</sup> *Supra* note 1, Communication from the Commission, Europe 2020 A Strategy for Smart, Sustainable and Inclusive Growth (COM (2010) 2020 final) at 6.

<sup>92</sup> René Von Schomberg, *Prospects for Technology Assessment in a Framework of Responsible Research and Innovation* in *TECHNIKFOLGEN ABSCHÄTZEN LEHREN: BILDUNGSPOTENZIALE TRANSDISZIPLINÄRER METHODEN* 39, 61 (Marc Dusseldorp & Richard Beecroft eds, 2012).

challenges. Successful commercialization of innovations derived from publicly funded research also motivates and demonstrates why government should continue to fund basic research. Government will provide public funding to universities and research institutions if there is evidence (ie successful commercialization) that the funds will be applied toward research that have potential to address societal challenges and drive economic growth.<sup>93</sup>

#### OPEN INNOVATION AND INTELLECTUAL PROPERTY RIGHTS

The literature largely supports the contention that competition on the market is fostered by openness and access to knowledge.<sup>94</sup> It is widely recognized that making research results more accessible contributes to better and more efficient science and innovation in the public and private sectors.<sup>95</sup> Although there is a clear link between open science and open innovation, contrary to popular understanding, they are not the same thing.<sup>96</sup> Science has the purpose of developing knowledge by adding theoretical or empirical insights. ‘Open science’ essentially advocates for freely sharing scientific knowledge as early as practical in the discovery process to accelerate the advancement of science.<sup>97</sup> On the other hand, innovation has the purpose of transforming knowledge for the purpose of bringing new products or technologies to market. ‘Open innovation’ therefore advocates for the purposive use of available knowledge to accelerate the introduction of new innovations into the market. Both open science and open innovation encourage acceleration of knowledge through a process of sharing, but that is where the similarities end. Because scientific findings have the potential of being translated into innovations, it is necessary to understand the link between open science and open innovation to determine whether open science will necessarily lead to open innovation.

Despite advances in biomedical research in the recent past and the push for open science/open access, the potential of early-stage discoveries and its best application is often unknown or unclear at the outset.<sup>98</sup> Significant time can elapse between discovering knowledge and putting that knowledge into practical use for the benefit of society.<sup>99</sup> For example, it took over a decade from the discovery of light activated compounds in the sap of cow parsley to translate research in photodynamic therapy into the drug VISUDYNE for the treatment of blood vessel disorders in the eye.<sup>100</sup> The journey from foundational research of photosensitizer chemicals at the department of botany to the potential of photoactivated chemicals for therapeutic purposes in a biomedical setting was not immediately apparent to the researchers that eventually enabled

<sup>93</sup> Timothy Caulfield, Shawn H.E. Harmon & Yann Joly, *Open Science Versus Commercialization: A Modern Research Conflict?* 4 *GENOME MED.* 17, 28 (2012).

<sup>94</sup> See, for example, Carl Shapiro, *Competition and Innovation: Did Arrow Hit the Bull's Eye?* in *THE RATE AND DIRECTION OF INVENTIVE ACTIVITY REVISITED* 361, 404 (Josh Lerner & Scott Stern eds, 2011) and Henry Chesbrough, *From Open Science to Open Innovation*, INSTITUTE FOR INNOVATION AND KNOWLEDGE MANAGEMENT, ESADE (2015).

<sup>95</sup> See, for example, Sascha Friesike et al., *Opening Science: Towards an Agenda of Open Science in Academia and Industry*, 40 *J. TECH. TRANSFER* 581, 601 (2015).

<sup>96</sup> David Roessner, *supra* note 82, at 38.

<sup>97</sup> Friedman & Silberman, *supra* note 83, at 18.

<sup>98</sup> Chesbrough, *supra* note 94, at 7.

<sup>99</sup> *Supra* notes 45, at 877; 47, at 40; 48, at 3.

<sup>100</sup> *Mass. Eye & Ear Infirmary v. QLT Phototherapeutics, Inc.*, 412 F.3d 215, 221–22 (1st Cir. 2005), cert. denied, 126 S. Ct. 2292 (2006).

the development of VISUDYNE. Translating scientific knowledge into useful applications involves incentives and mechanisms different from those at the discovery and research phase. Academic researchers and scientists are motivated by the pursuit of knowledge and recognition from making discoveries during the scientific process.<sup>101</sup> Open access/open science serves to facilitate the pursuit and dissemination of knowledge for the advancement of science. Translating scientific knowledge into useful applications to the benefit of the public usually involves the participation of other participants in the innovation process, such as industry and translational scientists involved in the application and integration of available knowledge into new innovations, which typically introduces a financial motive into the innovation process.<sup>102</sup> Translating early-stage biomedical research where the clinical and commercial potential of the discovery is unknown involves substantial risks and large investments.<sup>103</sup> Before investing in developing early-stage discoveries, industry needs to evaluate whether there are any third party rights preventing the development and subsequent commercialization of the new innovation. If the discovery is already protected by existing intellectual property rights, an assessment of the scope of those rights must be made to determine if the patent claims adequately protect the new innovation, and if not, whether there are any disclosure problems preventing subsequent patent filings. An infringement and validity assessment will also need to be conducted. Common business sense dictates that any investor will demand that there be some protection for its investment and an assurance that there are no legal consequences preventing the development and commercialization of the innovation. In other words, open science at the discovery phase does not necessarily lead to translation of knowledge into innovations. Intellectual property rights are therefore critical in incentivizing and inducing industry to undertake the risk of development and invest in the commercialization of knowledge to introduce new innovations from the laboratory to the market.

Because of the inventive step and novelty requirement to patentability, open access and open science during the scientific discovery process without the assertion of intellectual property may preclude subsequent patent protection of new innovations. The rise of open science and the proliferation of online resources combined with the accessibility of the internet means the public and patent offices now have easy access to a wealth of knowledge. Freely, completely, and immediately sharing discoveries and research findings arising from the scientific process through typical dissemination channels such as publications and conferences may inadvertently destroy the novelty and/or inventiveness of future innovations.<sup>104</sup> Novelty and inventiveness searches from patent

<sup>101</sup> Paula E. Stephan, *The Economics of Science*, 34 J. ECON. LITERATURE 1199, 1235 (1996); Katherine W. McCain, *Communication, Competition, and Secrecy: The Production and Dissemination of Research-Related Information in Genetics*, 16 SCI. TECH. & HUMAN VALUES 491, 516 (1991).

<sup>102</sup> Helen W. H. Yu, *Bridging the Translational Gap: Collaborative Drug Development and Dispelling the Stigma of Commercialization*, 21 DRUG DISCOV. TODAY 299, 305 (2016).

<sup>103</sup> It has been reported that on average, only 3 in 10 new pharmaceutical products generate revenues equal to or greater than average R&D costs. See Henry G. Grabowski, John M. Vernon & Joseph A. DiMasi, *Returns on Research and Development for 1990s New Drug Introductions*, 20 PHARMACOECONOMICS 11, 29 (2002) and Joseph A. DiMasi & Henry G. Grabowski, *R&D Costs and Returns to New Drug Development: A Review of the Evidence*, in THE OXFORD HANDBOOK OF THE ECONOMICS OF THE BIOPHARMACEUTICAL INDUSTRY 21, 46 (Patricia M. Danzon & Sean Nicholson eds, 2012).

<sup>104</sup> Zachary Quinlan, *Hindsight Bias in Patent Law: Comparing the USPTO and the EPO*, 37 FORDHAM INT'L L. J. 1787, 1820 (2013); see also The Royal Society, *Keeping Science Open: the Effects*

offices include journals and trade literature as well as patents and patent applications. With the bias of perfect hindsight, open science may contribute an abundance of thorough knowledge to the state of the art that independently or cumulatively prevents the grant of a patent. Theoretically, knowledge arising from the development and translation phase of the innovation process relating to the practical application of scientific discoveries should be protected by intellectual property while background knowledge that supports the application remains open to the scientific community. However, the line between basic research and applied research is not always crystal clear from a patentability perspective (and with perfect hindsight). Referring back to the VISU-DYNE example, does research into the potential of photoactivated chemicals for therapeutic purposes constitute background knowledge, therefore rendering the discovery that the light activated compound could be used to activate drugs accumulated in a particular area obvious? Widely distributed knowledge through open science/open access means there is a serious risk that the prior art will prevent patents from being granted on the application of scientific discoveries. The delineation between early-stage research (where open science is encouraged to foster the advancement of science) and applied research (where the preservation of intellectual property rights become relevant to preserve translation and commercialization potential) is particularly difficult for scientists to determine, not that they are trained to do so, nor should they even be burdened with such a role.

While the literature on the relationship between intellectual property rights and innovation is vast, the literature on how open innovation relates to intellectual property and intellectual property policy is very limited. Intellectual property is generally accepted as a powerful asset that can be proactively managed, developed, and maintained to enhance business value.<sup>105</sup> However, there is also significant literature on how intellectual property rights conflict directly with the idea of open science and the free exchange of scientific knowledge.<sup>106</sup> Open innovation is perceived to promote unrestricted sharing of knowledge for the purposes of facilitating new discoveries. However, the literature has a tendency to confuse ‘open science’ with ‘open innovation’. Open innovation recognizes the value of knowledge exchange but does not promote the free sharing of knowledge at the expense of economic gain. In order to accelerate the introduction of new innovations into the market, open innovation must leverage the intellectual property system to facilitate access to and exchange of knowledge to foster innovation in exchange for a degree of protection that will induce industry participation in the innovation process. For RRI and open innovation to achieve its

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*of Intellectual Property Policy on the Conduct of Science* (2003) <https://royalsociety.org/topics-policy/publications/2003/keeping-science-open/> (accessed Sept. 28, 2016).

<sup>105</sup> Raymond Millien & Ron Laurie, *Meet the Middlemen*, 28 *INTELL. ASSET MGMT* 53, 58 (2008) and Henry Chesbrough & Roya Ghafele *Open Innovation and Intellectual Property: A Two-Sided Market Perspective* in *NEW FRONTIERS IN OPEN INNOVATION* 191, 214 (Henry Chesbrough, Wim Vanhaverbeke & Joel West eds, 2014).

<sup>106</sup> See, for example, Miriam Bentwich, *Changing the Rules of the Game: Addressing the Conflict Between Free Access to Scientific Discovery and Intellectual Property Rights*, 28 *NAT. BIOTECH.* 137, 140 (2010); Subhashini Chandrasekharan & Robert Cook-Deegan, *Gene Patents and Personalized Medicine—What Lies Ahead?* 1 *GENOME MED.* 1, 4 (2009); Pierre Azoulay, Waverly Ding & Toby Stuart, *The Impact of Academic Patenting on the Rate, Quality and Direction of (Public) Research Output*, 57 *J. INDUS. ECON.* 637, 676 (2009); Wei Hong & John P. Walsh, *For Money or Glory? Commercialization, Competition, and Secrecy in the Entrepreneurial University*, 50 *SOC. Q.* 145, 171 (2009).



objectives, patents can no longer be seen solely as an exclusionary and negative right. Previous studies have highlighted the potential negative impacts and risks of intellectual property rights in the context of biobanking.<sup>107</sup> However, the assertion of intellectual property rights does not necessarily mean that such rights will be exercised in an exclusionary manner. There is evidence that intellectual property rights are often not exercised in a manner that negatively impacts the research environment.<sup>108</sup> Intellectual property rights are required to stimulate and jump start the innovation process and to sustain businesses via the development of secondary markets for intellectual property.<sup>109</sup> It is therefore the role of RRI to arbitrate the degree of protection required in a given field of research to balance between no intellectual property protection whatsoever (which would discourage risk taking and investment) and strong intellectual property protection (which would inhibit innovation). A balanced intellectual property policy that advocates for the interests of open innovation as well as the interests of all stakeholders involved will likely support follow-on innovations.

Open innovation therefore seeks to cobble together the efforts of various stakeholders involved in the innovation process and leverage existing resources to discover how best to apply and translate new knowledge into socially beneficial innovations. Because the research, development, translation, and commercialization of biobank-derived research are distributed across multiple stakeholders, the innovation process must recognize and ensure each stakeholder receives the *quid pro quo* required to induce participation. Intellectual property therefore plays a role in supporting open innovation by enabling and promoting the exchange of knowledge to introduce innovations into the market for the benefit of the public. In the context of biomedical innovations, the assertion of patent rights is arguably necessary to incentivize and safeguard the interests of stakeholders that are motivated by commercial interests (ie industry, universities, and academic entrepreneurs) and to realize the objectives of stakeholders that are motivated by socioeconomic growth (ie government, public, and donors). However, the commercialization strategies used to introduce new innovations into the market does not necessarily need to rely upon the traditional exclusionary right associated with the patent system. Specifically, commercialization strategies often employed by the biomedical industry such as but not limited to patent pools, broad licensing, and reach-through rights have its foundation in asserting patent rights, but an innovation strategy that embraces patenting does not necessarily need to exercise in an exclusionary manner that negatively impacts the advancement of scientific research. Open innovation should not be adverse to the assertion of intellectual property but it should object to the irresponsible use of intellectual property rights. At its core, commercialization is not only about generating revenue. It is about translating basic research into a form that the public can use and making publicly funded research available for the benefit of the public. 'Openness' requires a willingness to question the process of knowledge production, translation, and commercialization to determine what systems are required

<sup>107</sup> Edward S. Dove & Yann Joly, *The Contested Futures of Biobanks and Intellectual Property*, 11 *TEORIA DRECHO: REV. PENSAMIENTO JUR.* 132, 146 (2012).

<sup>108</sup> Timothy Caulfield et al., *Evidence and Anecdotes: An Analysis of Human Gene Patenting Controversies*, 24 *NAT. BIOTECH.* 1091, 1094 (2006).

<sup>109</sup> *Id.* Chesbrough, *supra* note 94, at 8.

and appropriate to society's current need for access to advancements in science and innovation.

### HOLISTIC INNOVATION FRAMEWORK

EU policies on open access and open science make it very difficult for research institutions to adopt practices that respect the seemingly contradictory and competing objectives of innovation. On the one hand, there is literature that supports the assertion that intellectual property rights are a significant constraint on the advancement of scientific research because they create barriers to free exchange of scientific knowledge. At the same time, universities urge researchers to protect the commercial potential of their research by patenting and forming close partnerships with industry to facilitate the translation of knowledge into products. Although the free exchange of knowledge seems inconsistent with intellectual property protection, in reality, patent rights and open science are not necessarily irreconcilable. Both aim to maximize the impact of research and utility of scientific knowledge through full and enabling disclosure to foster follow-on innovations. After all, the foundation of the patent system rests on the exchange of full enabling disclosure for a period of exclusivity. In fact, the legal requirement of enabling disclosure may even make patents more open than academic publications where researchers may withhold crucial information for personal reasons, such as preserving prospects of obtaining further research funding.<sup>110</sup> How patent rights are used may affect open access but patents and the patent system are not inconsistent with the principles of open access, open science, and/or open innovation. For example, the recent trend of patent donations from industry to research institutions allow researchers to leverage existing (protected) knowledge and extend beyond it to facilitate research in other fields to enable cross industry innovations.<sup>111</sup> As such, commercialization and open access/open science could be seen as complementary strategies within a holistic innovation framework aimed at getting the optimal social and economic values from publicly funded research. The various policy approaches to innovation can be integrated into a coherent framework that embraces both open scientific collaboration and commercialization.

At the root of the problem is the negative stigma associated with the word 'commercialization'.<sup>112</sup> The concept of money and profit, especially in relation to using HBM as a capital resource, is typically seen to be contrary to public policy.<sup>113</sup> However, in the context of advancing biomedical research, commercialization is a much more complicated word that incorporates the concept of making basic research available for the

<sup>110</sup> Patrick Andreoli-Versbach & Frank Mueller-Langer, *Open Access to Data: An Ideal Professed But Not Practiced*, 43 RES. POL'Y 1621, 1633 (2014); Marie Thursby et al., *Do Academic Scientists Share Information With Their Colleagues? Not Necessarily* (2009) <http://www.voxeu.org/article/why-don-t-academic-scientists-share-information-their-colleagues?> (accessed Sept. 28, 2016).

<sup>111</sup> Nicole Ziegler, Oliver Gassmann & Sascha Friesike, *Why Do Firms Give Away Their Patents for Free?* 37 WORLD PATENT INFORM. 19, 25 (2014).

<sup>112</sup> *Supra* note 102, at 300; see also *supra* note 68, at 36–38 where the report found that the public expressed concern over profit motives and mistrust of commercial entities accessing biobank data despite not having very little knowledge of the innovation process and role of industry in biomedical research.

<sup>113</sup> Council of Europe, *The European Convention on Human Rights and Biomedicine* (1997), Article 21 states '[t]he human body and its parts shall not, as such, give rise to financial gain'. See also UNESCO, *Universal Declaration on the Human Genome and Human Rights* (1997), Article 4 which states '[t]he human genome in its natural state shall not give rise to financial gains'.

benefit of the public. Pragmatically viewing and recognizing that translation and commercialization is the only process by which new innovations for the betterment of human health can be introduced may temper some of the concerns and criticisms. The focus should therefore be on making the best possible use of HBM for the benefit of patient interests instead of pure financial motive.<sup>114</sup> The reality is advancing biomedical research requires the involvement of multiple stakeholders, including industry, because none of the individual players in the innovation process have all the necessary skills and resources to research, develop, translate, and commercialize discoveries into innovations independently.<sup>115</sup> Furthermore, the public's desire for biobanks to share results and advance healthcare suggests that benefit sharing and/or return of benefit may help the public accept the notion of commercialization.<sup>116</sup> With a broader view of improving human health, the whole can be more than the sum of its parts if stakeholders can work together to effectively and efficiently translate publicly funded research into innovations that can benefit public health, as well as generate funds for further academic research and drive socioeconomic growth.

Current scientific contributions are still fragmented and far from presenting a holistic picture of open science and policy implications to address the issue of stakeholder incentives to advance the RRI agenda. There is some literature advocating for 'reconceptualizing' the commercialization conflict away from private versus public interests and focusing instead on knowledge production.<sup>117</sup> This approach calls for recognizing the ethical and personal nature of commercializing research derived from biobank samples and data but adopting a social scientific view to the economic aspects of biobanking that acknowledges the value in applying knowledge derived from biobanks instead of 'fetishizing' biological materials.<sup>118</sup> However, 'reconceptualizing' a conflict is a theoretical exercise that does not directly acknowledge the interests or address the concerns of the public and donors. Asking the public and donors to simply 'think differently' about open science and commercialization does not appease or change public perception of profit motives and commercial agendas at the expense of public good. Current literature on open innovation and commercialization predominantly adopts a business-centric view, which continues to feed public perception that the assertion of intellectual property rights is mainly motivated by profits.<sup>119</sup> Mentally navigating the perceived

<sup>114</sup> Kathinka Evers, Joanna Forsberg & Mats Hansson, *Commercialization of Biobanks*, 10 *BIOPRESERV. & BIOBANK.* 45, 47 (2012).

<sup>115</sup> *Supra* note 102, at 300–301

<sup>116</sup> Alexander M. Capron et al., *Ethical Norms and the International Governance of Genetic Databases and Biobanks: Findings from an International Study*, 19 *KENNEDY INST. ETHICS J.* 101, 124 (2009); Gillian Haddow et al., *Tackling Community Concerns About Commercialisation And Genetic Research: A Modest Interdisciplinary Proposal*, 64 *SOC. SCI. & MED.* 272, 282 (2007).

<sup>117</sup> Kean Birch, *Knowledge, Place, and Power: Geographies of Value in the Bioeconomy*, 31 *NEW GENET. & SOC.* 183, 201 (2012); Kean Birch & David Tyfield, *Theorizing the Bioeconomy: Biovalue, Biocapital, Bioeconomics or ... What?* 38 *SCI. TECH. & HUMAN VALUES* 299, 327 (2013); Andrew Turner, Clara Dallaire-Fortier & Madeleine J. Murtagh, *Biobank Economics and the 'Commercialization Problem'*, 7 *SPONTANEOUS GENERATIONS* 69, 80 (2013).

<sup>118</sup> *Id.*, Birch.

<sup>119</sup> Edna Einsiedel & Lorraine Sheremeta, *Biobanks and the Challenges of Commercialization* in *HANDBOOK OF GENOME RESEARCH: GENOMICS, PROTEOMICS, METABOLOMICS, BIOINFORMATICS, ETHICAL AND LEGAL ISSUES* 537, 559 (Christoph W. Sensen ed, 2005); Christine Critchley, Dianne Nicol & Margaret Otlowski, *The Impact of Commercialisation and Genetic Data Sharing Arrangements on Public Trust and the Intention to Participate in Biobank Research*, 18 *PUBLIC HEALTH GENOMICS* 160, 172 (2015).

contradictions between private versus public interests and/or open versus closed innovation still requires the public to accept that a conflict exists. Instead, practical efforts should be made to engage society with the objective of helping them understand that without their participation, the advancement of biomedical research and the discovery of life-saving therapies and treatment will not happen at all or stall if they choose not to play their role in the innovation process.

As such, incorporating the principles of RRI, a holistic innovation framework should focus on societal engagement to ensure that all contributors to the innovation process understand that translation is a complex multistakeholder process whereby each stakeholder plays an essential role in contributing to the successful development of basic research into socially beneficial outcomes. It's not enough for the stakeholders to merely accept their role in the innovation process. There must be a mechanism within a holistic innovation framework that (a) recognizes what motivates each of the relevant stakeholders *and* (b) enables the stakeholders to receive the specific benefit they expect in exchange for their contribution to the innovation process. To incentivize participation, every stakeholder must extract some reward or 'quid pro quo' for doing so. The form of reward may differ given each stakeholder has their own agenda and the payoff may occur at different times during the innovation process or be delayed until the innovation reaches the market. By understanding that the translation process is a part of the innovation value chain, stakeholders can appreciate that they are each an essential part of a larger framework whereby their respective input is required to maximize the prospects of introducing a potentially life-saving innovation to the benefit of the public. A value chain can only work if all stakeholders play their respective role to achieve the common goal. To ensure participation, all the stakeholders must be able to extract their desired reward. In context, biobank donors want to benefit from the research that uses their samples. The general public expects a return of benefit from their tax dollars the government uses to publicly fund basic research. To obtain those benefits, industry needs to translate and commercialize early-stage research and discoveries derived from biobank samples or data. However, industry will only participate if there is a financial incentive to do so. In order for industry to have anything to translate, researchers need to have the means to conduct research, preferably in an environment conducive to knowledge creation and diffusion. Researchers want to have free and open access to knowledge and data to advance scientific discoveries and disseminate results. The emergence of 'academic entrepreneurs',<sup>120</sup> who are motivated by economic interests in their research and 'entrepreneurial academics',<sup>121</sup> who operate as knowledge brokers in the space between academia and industry with track records of leveraging external grants for market-oriented research adds a layer of complexity to the innovation landscape, making it more challenging to incentivize all the stakeholders. In order for researchers to conduct research, universities and public research organizations need to attract funding. Technology transfer and public-private R&D collaborations fostered by universities close the gap between science and practice by merging competences to find applications that address societal challenges. When successful, the resulting research excellence and innovation brings prestige to academia

<sup>120</sup> *Supra* note 86.

<sup>121</sup> Cris Shore & Laura McLauchlan, 'Third Mission' Activities, *Commercialization and Academic Entrepreneurs*, 20 *SOC. ANTHROPOLOG.* 267, 286 (2012).



Figure 2. Interconnectedness of stakeholder interests.

and increases prospects of attracting funding.<sup>122</sup> Government will provide public funding for basic research so long as the funds go toward supporting research that have the potential to drive economic growth and address societal challenges.<sup>123</sup> Socioeconomic growth sought by government will only be realized if industry can successfully commercialize basic research (ie create jobs, generate tax revenue, and introduce innovations to the market to improve social welfare). Industry will also provide funds to support basic research if there is an incentive to invest, such as through intellectual property and commercialization policies that contemplates revenue sharing. The interconnectedness of stakeholder interests is almost like a chain reaction—one needs to happen in order for the next to follow (see Figure 2).

The logistics of bringing a value chain together to develop an innovation is no small challenge but the key to optimizing the social and economic value of publicly funded biobanks and related biomedical research hinges on effective and efficient collaboration between the public and private sector. If all the stakeholders involved in the innovation process understand the interconnectedness of their respective roles in the chain of events from discovery to translation and commercialization and what is at stake if there is a disruption in the chain, at the very least, there is a greater likelihood that basic research will be more efficiently translated into socially beneficial innovations. Any break or weakness along this value chain decreases the likelihood of returning benefits to society or creates costly inefficiencies in the innovation process.

The role of RRI principles is therefore to govern the ‘responsible’ participation of stakeholders in the translation and commercialization process and not to shape the innovation process itself. RRI itself should not be the objective but a way of organizing the interaction between stakeholders with the goal of facilitating the translation and commercialization of innovations and maintaining trust between the stakeholders to be mutually responsive to each other and respectful of public values. Evidence indicates that the public has greater trust in public research institutions, even if the institution receives some private funding,<sup>124</sup> suggesting that publicly funded, not-for-profit independent institutions involved in the translation of research, such as the Centre for Drug Research and Development representing the Canadian Centre of Excellence in Commercialization and Research,<sup>125</sup> the Lead Discovery Centre, representing

<sup>122</sup> See, for example, Bart Clarysse et al., *Creating Value in Ecosystems: Crossing the Chasm Between Knowledge and Business Ecosystems*, 43 RES. POL’Y 1164, 1176 (2014).

<sup>123</sup> See, for example, European Commission, *Innovation: How to convert Research into Commercial Success Story? Part 3: Innovation Management for Practitioners* (2013).

<sup>124</sup> Critchely and Nicol, *supra* note 63, at 84.

<sup>125</sup> [www.cdrd.ca](http://www.cdrd.ca).



the Max Planck Institutes in Germany;<sup>126</sup> the Centre for Drug Design and Discovery representing Katholieke Universiteit Leuven in Belgium;<sup>127</sup> and MRC Technology representing the Medical Research Council in the UK<sup>128</sup> may be in the types of organizations that are in the best position to maintain public trust and manage the translation and commercialization of research and discoveries derived from biobanks. Specialized institutions that attempt to bridge the gap between open science and open innovation in particular fields, such as the above-described independent translation organizations, work directly with specific industry sectors to explore new ways to integrate and apply university research to develop new innovations.<sup>129</sup> With their unique knowledge of the particular dynamics associated with the field and with representation from each of the stakeholder groups, these independent research translation organizations would essentially act as ‘guardians’ and decide on how best to use patent rights to achieve the most desirable socioeconomic outcome. For example, a concrete way to manage the interaction between open science and intellectual property is to entrust the translation organizations with the right to define an access zone around the state of the art and grant licenses to enable follow-on innovations when appropriate and allocate royalties derived from the patents to support the financial sustainability of biobanks. Different drivers and regulatory structures impact each industry sector and because translation organizations operate in the broad scientific community engaged in research and development activities of a particular sector, such organizations are arguably in the most neutral and informed position to determine the best combination of open science and intellectual property rights to derisk the translation and commercialization of research while ensuring that the most desirable socioeconomic outcome can be achieved. Patents do not necessarily create barriers or close the door to open science as there exists an acceptable balance between ‘the spectrum between free use of knowledge by anyone for any purpose, to exclusive use by one entity for its own use’.<sup>130</sup> If the governance and regulation of such publicly funded research organizations are transparent and clearly communicate intentions and goals on how translation and commercialization achieves public health benefit, then the public may be more accepting of commercialization efforts.<sup>131</sup> This may be achieved through adopting guidelines regarding the management of intellectual property that incorporate RRI principles on governing the collaborative relationships and respective quid pro quo of the stakeholders.

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<sup>126</sup> [www.lead-discovery.de](http://www.lead-discovery.de).

<sup>127</sup> [www.cd3.eu](http://www.cd3.eu).

<sup>128</sup> [www.mrctechology.org](http://www.mrctechology.org).

<sup>129</sup> Other examples of specialized institutions representing the interest of different fields include IMEC in Belgium, which specializes in combining basic research in microelectronics and nanoelectronics into semiconductor technologies ([www.imec.org](http://www.imec.org)); ATTRACT, a pan-EU initiative that specializes in accelerating the development of high-performance detector and imaging technologies through a process of co-innovation among European research institutes, small and medium enterprises (SMEs), companies and universities ([www.attract-eu.org](http://www.attract-eu.org)).

<sup>130</sup> Dianne Nicol & Richard Gold, *Standards for Biobank Access and Intellectual Property in Intellectual Property and Emerging Technologies: the New Biology* 133, 157 (Matthew Rimmer & Alison McLennan eds, 2012).

<sup>131</sup> Kristin S. Steinsbekk et al., *We’re Not in It for the Money-Lay People’s Moral Intuitions on Commercial Use of ‘Their’ Biobank*, 16 *MED. HEALTH CARE & PHIL.* 151, 162 (2013); Haddow et al., *supra* note 116, at 278.

## CONCLUSION

The general public is often opposed to the idea of commercialization in the field of biomedical research without truly understanding the process involved in translating discoveries into new innovations and making them safe and available for the benefit of the public. This lack of understanding is precisely what makes it so difficult for public policy and strategies to be implemented with respect to the commercialization of biomedical innovations derived from biobank samples and data. Resources need to be devoted to informing all the stakeholders of the collective effort required to translate research into innovations. The public needs to understand that the process of bringing research and discoveries to market for the benefit of society requires the collaborative effort of multiple stakeholders. Potential profit is what incentivizes the participation of industry. Economic growth sought by government will only be realized if industry can successfully commercialize innovations. Proprietary rights in innovations are the foundation of building successful businesses, which leads to job creation, tax revenue, and socioeconomic growth. From the government's perspective, industry's success in translating and commercializing publicly funded research means the social and economic value derived from academic research has been realized, which in turn justifies further university and public research funding. Researchers and universities therefore benefit from the flow of private and public funding to conduct further basic research to advance science and meet humanitarian goals. Most importantly, the public and individual donors benefit from the availability of therapies, medicines, and technologies derived from the generous donation of HBM in biobanks. Informing stakeholders of the realities of the translation process in the value chain of innovation may make them more willing to collaborate and accepting of compromises in order to achieve a common goal of social responsibility and public good. Re-conceptualizing issues is not going to make people change their opinion but making them see the interconnectedness of their respective roles in the translation value chain in order to achieve the ultimate objective of public benefit may help them recognize that the respective 'quid pro quo' required to ensure the continued responsible participation of the other stakeholders seem more valid. An overemphasis on individual interests without sufficient attention to the greater social, economic, and structural challenges to translation may undermine rather than protect societal interest.<sup>132</sup> As stated by von Schomberg, 'RRI should be understood as a strategy of stakeholders to become mutually responsive to each other and anticipate research and innovation outcomes underpinning the "grand challenges" of our time for which they share responsibility'.<sup>133</sup>

<sup>132</sup> Lori Luther & Trudo Lemmens, *Human Genetic Data Banks: From Consent to Commercialization—An Overview of Current Concerns and Conundrums*, 12 *BIOTECHNOLOGY* 183, 217 (2012).

<sup>133</sup> Von Schomberg, *supra* note 27, at 51.