

## 6 Intellectual Property in Early-Phase Research Public–Private Partnerships in the Biomedical Sector

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### Introduction

To assess the nature of intellectual property (IP) in early-phase research or precompetitive public–private partnerships (PPPs) in the biomedical field, more understanding is required of the ecosystem in which biomedical PPPs function. In essence, biomedical PPPs are knowledge communities. Pooling complementary resources and expertise, as well as sharing the risks and other (often administrative) burdens between the public and the private stakeholders, increases the effectiveness of PPPs.<sup>1</sup> But diverse social, economic, legal, regulatory, and scientific factors make the PPP model a rather complex collaborative one.

Depending on several criteria, (bio)pharmaceutical research and development (R&D) PPPs may be classified into four different types based on the type of projects they conduct. Upstream research projects entail precompetitive (or early-phase) research and the proof-of-concept (POC) phase. This chapter focuses primarily on these upstream PPPs. Downstream development projects include the Product Development (PD) and

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<sup>1</sup> Tanja A. Börzel & Thomas Risse, *Public–Private Partnerships: Effective and Legitimate Tools of International Governance?*, in *COMPLEX SOVEREIGNTY: ON THE RECONSTITUTION OF POLITICAL AUTHORITY IN THE 21ST CENTURY* 195 (Edgar Grande & Louis W. Pauly Eds., 2002); Jennifer M. Brinkerhoff, *Government-nonprofit partnership: A defining framework*, 22 *PUBLIC ADMIN. DEV.* 19, 22 (2002).

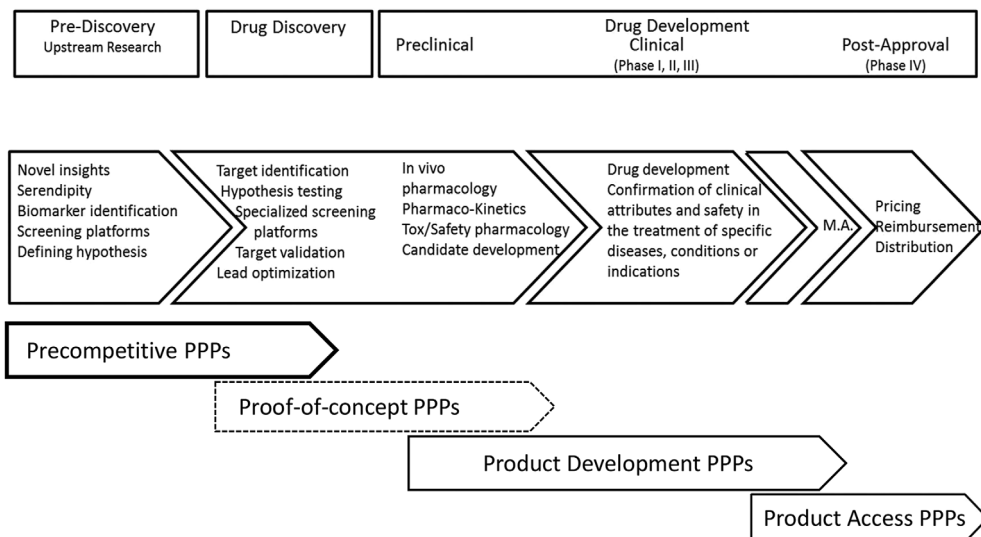


Figure 6.1. Classification of the different types of PPP along the discovery–development–delivery continuum in the biopharmaceutical sector.

Source: Hilde Stevens et al., *Perspectives and Opportunities for Precompetitive Public–Private Partnerships in the Biomedical Sector*, 32 BIOTECHNOLOGY L. REP. 131 (Jun. 2013), 135. Reprinted with permission from BIOTECHNOLOGY LAW REPORT, Volume 32, Issue 3, published by Mary Ann Liebert, Inc., New Rochelle, NY.

the Product Access (PA) phase. These four types are used as the basis for the classification of R&D PPPs in the biomedical sector: precompetitive or early-phase research PPPs, POC PPPs, PDPs, and PA PPPs (Figure 6.1).<sup>2</sup> Other criteria to define PPPs, such as geographic scope, mission and objectives, organizational structure, and/or funding source, can be used to further describe the PPPs within these four classes.

Knowledge development through sharing is enhanced in precompetitive partnerships. Taking into account the multifaceted partnering model of precompetitive PPPs and the heterogeneity of partners – including their often conflicting missions, objectives, and cultures – it is not surprising that IP plays a pivotal role and that intellectual property rights (IPRs) and trust issues are critical parts of the negotiation process.<sup>3</sup> In precompetitive PPPs, highly trained experts are offered a platform to explore the skills, knowledge,

<sup>2</sup> Stevens et al., *Perspectives*, *supra* note \*, at 132–33; Kent Buse & Gill Walt, *Global Public–Private Partnerships: Part I – A New Development in Health?*, 78 BULL. OF THE WORLD HEALTH ORG. 549, 549–50 (2000); Warren Kaplan et al., WORLD HEALTH ORGANIZATION [WHO], *Priority Medicines for Europe and the World 2013 Update*, 186–87 (May 6, 2013), [www.who.int/medicines/areas/priority\\_medicines/MasterDocJune28\\_FINAL\\_Web.pdf](http://www.who.int/medicines/areas/priority_medicines/MasterDocJune28_FINAL_Web.pdf); Pieter Stolk, *Background Paper 8.1 Public Private Partnerships*, 5, 12, 13 (May 1, 2013), [www.who.int/medicines/areas/priority\\_medicines/BP8\\_1PPPs.pdf](http://www.who.int/medicines/areas/priority_medicines/BP8_1PPPs.pdf).

<sup>3</sup> Bernard H. Munos, *Can Open-Source R&D Reinvigorate Drug Research?*, 5 NATURE REV. DRUG DISCOVERY 723, 6–7 (2006); Michel Goldman, *Comment, Reflections on the Innovative Medicines Initiative*, 10 NATURE REV. DRUG DISCOVERY 321, 322 (2011); Gabriel Vargas et al., *Arguments Against Precompetitive Collaboration*, 87 CLINICAL PHARMACOLOGY & THERAPEUTICS 527, 527–29 (2010); Asher Mullard, *Could Pharma Open its Drug Freezers*, 10 NATURE REV. DRUG DISCOVERY 399, 400, (2011); Jagadeesh Napa, *Editorial, Open Source Drug Discovery*, PHARMA FOCUS ASIA, [www.pharmafocusasia.com/strategy/open-source-drug-discovery](http://www.pharmafocusasia.com/strategy/open-source-drug-discovery); Daniel Cressey, *Comment, Animal Research: Battle Scars*, 470 NATURE 452, (Feb. 23, 2011); *Editorial, Expanding Precompetitive Space*, 10 NATURE REV. DRUG DISCOVERY 833 (2011).

and collaborative behavior of researchers operating in the same field. As a result, precompetitive PPPs are perceived as a platform for partner scouting, networking, and selection.<sup>4</sup> Some early-phase research PPPs also perform downstream development of therapies, in which case the importance of IP as well as access to it increases. However, if competitors are working together, potentially conflicting goals and missions need to be put aside in order to increase the chances of the PPP's success.<sup>5</sup>

A complete, publicly available set of policies and procedures allows potential partners to assess their roles and responsibilities as well as gain insight into the rewards and expectations involved in participation.<sup>6</sup> We therefore recommend that biomedical PPPs include basic definitions and information regarding the framework for the management of IP, including IP use, access, and ownership. No single IP framework applies to every PPP in early-phase research. Variation in key IP elements depending on the PPP's focus and the objectives seems appropriate; customization of IP policy can help to incentivize participation in the PPP.<sup>7</sup>

The variation between a more restricted IP framework (what this chapter refers to as a partnership-focused strategy) and an open IP framework (referred to here as an open-collaboration strategy) seems justified given the heterogeneity of the partners and their respective objectives and needs. Tailoring is necessary to serve any particular PPP's mission and to obtain its objectives. PPPs targeting downstream development project results (drugs and diagnostic tests) tend to apply an IP sharing strategy where access to foreground IPRs<sup>8</sup> and freedom to operate are permission-constrained and preferably negotiated with the consortium partners. This is a type of partnership-focused strategy. By contrast, PPPs focused on upstream project results or on specific downstream products for neglected (usually tropical) diseases, HIV/AIDS and malaria (commonly referred to as poverty-related neglected diseases or PRNDs) are more likely to adopt an IP framework that allows more sharing of IPRs. This exemplifies an open-collaboration strategy. Both partnership-focused and open-collaboration models have benefits and drawbacks. Hybrid strategies are deployed when appropriate to advance the project. As such, we argue for a contingency approach, in which different frameworks for sharing knowledge are applied depending on the research focus, business strategy, and feasibility thereof. (See Table 6.1.)

It is estimated that only 10 percent of the resources spent on developing new drugs and therapies is spent on illnesses represented by 90 percent of the burden of disease.<sup>9</sup> Research areas such as PRNDs, which suffer from scarce R&D budgets could benefit

<sup>4</sup> Stevens et al., *Perspectives*, *supra* note \*, at 138–39.

<sup>5</sup> *Id.* at 132.

<sup>6</sup> Elkins, Sean, Maggie A.Z. Hupcey, & Antony J. Williams (eds.), *COLLABORATIVE COMPUTATIONAL TECHNOLOGIES FOR BIOMEDICAL RESEARCH 42* (John Wiley & Sons, Inc. 2011).

<sup>7</sup> Stevens et al., *Intellectual Property Policies*, *supra* note \*, at 509.

<sup>8</sup> “Foreground IP” means the results of the research conducted during the project, including (technological and commercial) knowledge, know-how, and data, as well IPRs pertaining to such knowledge, data, or know-how. The latter category will be referred to as “foreground IPRs” and includes patent rights, copyrights, database rights, and so on. Foreground IP is contrasted in this chapter to “background IP,” which means preexisting (technological and commercial) knowledge, know-how, and data, as well as IPRs pertaining to such knowledge, data, or know-how. The latter category will be referred to as “background IPRs” and includes patent rights, copyrights, database rights, and so on. This background IP can potentially be included in the project at the start or during the project process.

<sup>9</sup> Munos, *supra* note 3, at 2.

Table 6.1. IP frameworks (knowledge sharing strategies) applied in biomedical PPPs.<sup>†</sup>

| IP frameworks (knowledge sharing strategies) applied in biomedical PPPs |  |   |   |
|---|--|---|---|
| Conditions  | Partnership-focused strategy   | Hybrid strategy   | Open-collaboration strategy   |
| Possibility to patent   | Yes  | Yes, but results preferably in public domain  | Yes, but with limitations specified   |
| Access  | Contractual framework based upon IP rights:  | Contracts and IP in case of partnership-focused strategy, licenses in case of open-collaboration strategy   | Contractual framework based upon IP rights: (viral) licenses (e.g., Open Access Protocol, Creative Commons or Copyleft Licenses), to help continue the virtuous cycle of research |
| Access mechanisms / legal basis   | Contracts (e.g., Project Agreement) including different clauses regarding patents and other industrial rights  |   |   |
| Target group  | During project: project participants After project termination: project participants, affiliates and/or defined third parties  | During project: project participants, consortium members or public After project termination: PPP participants, affiliates and/or defined third parties | All   |
| Duration  | Limited/defined  | Limited to undefined  | Undefined   |
| Project focus   | Profit- or nonprofit-driven research, mainly focusing on diseases of affluence   | Nonprofit driven research, focusing on PRNDs  | Profit- or nonprofit-driven research, focusing on NCDs and/or PRNDs   |
| Envisioned project deliverables   | – Biotechnology tools (upstream research results)<br>– Drugs, therapies and diagnostic tests for NCDs (downstream research results)<br>– A mix of tools and drugs for PRNDs and NCDs (downstream research results) | – Biotechnology tools (upstream research results)<br>– Tools and drugs for PRNDs (upstream and downstream research results)                             | – Biotechnology tools (upstream research results)<br>– Diagnostic tests and drugs for PRNDs (downstream research results)   |
| PPPs wherein the strategy prevails                                      | IMI, BioWin, The Biomarkers Consortium, FP7, SC4SM, CTMM, 3 PPPs that expressed for their IP policy to remain confidential   | MMV, DNDi, OMOP, WIPO Re:Search   | SGC, SAGE, TSC (HapMap), OSDD, OAI, TRC, ADNI   |

<sup>†</sup> Stevens et al., *Intellectual Property Policies*, *supra* note \*, at 509.

**Abbreviations:**

NCDs: noncommunicable diseases or diseases of affluence

PRNDs: poverty-related and neglected (tropical) diseases, HIV/AIDS and Malaria

Source: Stevens, Hilde et al., *Intellectual Property Policies in Early-Phase Research in Public-Private Partnerships*, 34 NAT. BIOTECHNOL. 509 (2016).

from the open-collaboration model. Further in-depth research to define success formulas and pitfalls can provide recommendations to leverage this PPP collaborative strategy to a higher level and provide more equitable access to medical care in low- and middle-income countries (LMICs). This benefits not only patients suffering from PRNDs, but also those increasingly affected by the rapidly growing noncommunicable diseases (NCDs) epidemic.

It is important to emphasize the broad definition of IP used in this chapter; IP as described here includes both the IPRs granted and protected by the IP laws, as well as know-how and other intangible assets. The use of the latter forms of IP is controlled by policies, contracts, protocols, and norms.<sup>10</sup> This chapter also considers knowledge sharing mechanisms as a key aspect of IP management for shared goals of any partnership involving multiple stakeholders. The role of IP in the broadest and most inclusive sense of the term is pivotal to deploying IP as a tool for collaboration, rather than as the centerpiece of it.<sup>11</sup> Performance of scientific research and in particular the evaluation of IP in PPPs is quantitatively demonstrated by key performance indicators (KPIs), for instance, the number of patents and patent applications, but increasingly by others measures as well.

This chapter aims to shed a light on the different aspects that come into play when mapping the way IP is generated, protected, and managed (e.g., shared) within and beyond early-phase research PPPs. In Part I, we focus on the relevant concepts and typology of early-phase research PPPs, including precompetitive PPPs.<sup>12</sup> Following this are sections focusing on key issues, including the boundaries of the precompetitive partnership (Part II); the role of trust within those PPPs (Part III); IP ownership and access rights (Part IV), including the importance of transparent IP rules underlying knowledge sharing strategies; and the role of IP in the performance of PPPs (Part V). Most of the content and examples are drawn from previous research on Europe's largest early-phase public-private partnership, the Innovative Medicines Initiative (IMI). We conclude in Part VI with some recommendations for best practices to facilitate efficient and equitable knowledge sharing.

## I Early-Phase Research PPPs: Concepts and Typology

The PPP model in the pharmaceutical industry is not new. Initially, PPPs were set up in the late-stage drug development cycle for the poorest populations, often suffering from PRNDs, such as dengue, leprosy, and leishmaniasis.<sup>13</sup> The first PPP in life sciences dates

<sup>10</sup> Jaakko Paasi et al., *BAZAAR OF OPPORTUNITIES FOR NEW BUSINESS DEVELOPMENT – BRIDGING NETWORKED INNOVATION, INTELLECTUAL PROPERTY AND BUSINESS 4* (Imperial College Press 2013).

<sup>11</sup> Stevens, *THE ROLE OF INTELLECTUAL PROPERTY*, *supra* note \*, at 170–71.

<sup>12</sup> Early-phase research PPPs focus on developing joined projects that are in a preliminary stage of development. Projects are typically based on, e.g. basic research ideas or the need to develop a technology or data platform that could help to accelerate drug development. More specifically, projects in this phase of the drug development cycle are precompetitive. However, as will be explained further in this chapter, early-phase and precompetitive are not complete synonyms; what seems precompetitive for some stakeholders might just be the core business for others.

<sup>13</sup> Roy Widdus, *Public-Private Partnership*, 99 *TRANSACTIONS OF THE ROYAL SOC'Y TROPICAL MED. & HYGIENE* S1, S2, S4 (Suppl.1 2005); Roy Widdus, *Public-Private Partnerships for Health: Their Main Targets, Their Diversity, and Their Future Directions*, 79 *BULL. OF THE WORLD HEALTH ORG.* 713, 716–17 (2001).

from 1987; the Merck Mectizan® Donation Program, a drug donation program set up by Merck, was aimed at improving the conditions for those suffering from onchocerciasis (or river blindness).<sup>14</sup> Later, Merck expanded this program and involved GlaxoSmithKline (GSK) to donate albendazole; co-administration of Mectizan® and albendazole can be used to treat co-endemic lymphatic filariasis and onchocerciasis in Africa and Yemen.<sup>15</sup> In the same decade, PPPs also targeted HIV/AIDS and malaria.

Big pharmaceutical companies came to realize that collaboration is in most instances the only effective way to bring inventions far enough in the value chain to become eligible for industrial take-up or to create interest by venture capitalists. With PPPs set up in the field of PRNDs and successfully performing early R&D projects in other sectors, the pharmaceutical industry began to tackle the innovation crisis in the drug sector through PPPs. These PPPs perform research at the precompetitive stage, and focus on diseases of affluence or NCDs, such as cancer, diabetes, and obesity.<sup>16</sup>

Basic knowledge of underlying disease mechanisms seems required to accelerate the development of the next-generation's drugs. This basic but complex knowledge generation requires interdisciplinary, translational research conducted by different experts from industry and academia. A shared stakeholder objective is to translate basic biological research into therapies serving patients. Industry realizes the potential of combining different ideas, skills, and expertise in technologically demanding areas and is increasingly tapping into early-phase research conducted at universities and small- and medium-sized enterprises specializing in biotechnology (biotech SMEs).<sup>17</sup> Thus, in the biomedical sector, stakeholders generally include pharmaceutical companies, biotech SMEs, academia, and nongovernmental organizations (NGOs). As the concept has evolved over time, PPPs today also involve other stakeholders in healthcare, such as patient organizations, private foundations, and regulatory bodies.<sup>18</sup>

These early-phase or precompetitive PPPs have emerged quite recently and are focused on optimizing the knowledge generation phase or the pre-discovery stage in the drug development lifecycle. PPPs operating in a precompetitive phase start their activities before and at the early discovery of promising drug compounds or diagnostics, although some have led to the identification of potential drug compounds. Such PPPs attempt to answer fundamental research questions and generate technology platforms, research tools, shared databases, and predictive models to progress disease knowledge and enhance the development of safer and more effective drugs.<sup>19</sup> Their primary goal is not to discover or develop products or therapies; therefore it is not necessary for the consortium partners

<sup>14</sup> Widdus, *Public-Private Partnership*, *supra* note 15, at S7; Robert G. Ridley, *Putting the Partnership into Public-Private Partnerships*, 79 BULL. OF THE WORLD HEALTH ORG. 694, 694 (2001).

<sup>15</sup> MECTIZAN DONATION PROGRAM, [www.mectizan.org/](http://www.mectizan.org/) (last visited Sep. 22, 2017).

<sup>16</sup> Teri Melese et al., *Open Innovation Networks Between Academia and Industry: An Imperative for Breakthrough Therapies*, 15 NATURE MED. 502, 502–03 (2009); Janet A. Wagner et al., *The Biomarkers Consortium: Practice and Pitfalls of Open-Source Precompetitive Collaboration*, 87 CLINICAL PHARMACOLOGY & THERAPEUTICS 539, 539 (2010).

<sup>17</sup> Stevens et al., *Perspectives*, *supra* note \*, at 131; Jim Kling, *Biotechs Follow Big Pharma Lead Back into Academia*, 29 NATURE BIOTECHNOLOGY 555, 555–56 (2011).

<sup>18</sup> Stevens, *THE ROLE OF INTELLECTUAL PROPERTY*, *supra* note \*, at 6.

<sup>19</sup> Janet Woodcock, *Precompetitive Research: A New Prescription for Drug Development?*, 87 CLINICAL PHARMACOLOGY & THERAPEUTICS 521, 521 (2010).

to include valuable assets (such as candidate products) as background IP<sup>20</sup> to launch the project.<sup>21</sup> A number of early-phase research PPPs will also perform activities in the POC phase and aim at target identification and validation, assay development, screening hit identification, lead compound optimization, preclinical (in vivo animal) studies, and sometimes early clinical studies to establish first-in-human evidence. Both early-phase research PPPs and PDPs can focus on the POC whereby they increase the value of compounds, making them more attractive to pharmaceutical companies for further investment and entrance into expensive clinical trials.<sup>22</sup> In this way, PPPs focusing on the POC phase have a vital role in filling up the gray zone and bridging the so-called valley of death,<sup>23</sup> that is, the situation where risky projects are abandoned because of lack of funds required during extended time periods, rather than because of negative research outcomes. Other criteria to further specify early-phase research PPPs are the mission and objectives, organizational structure, funding source, and geographic scope.<sup>24</sup>

In contrast to most PDPs, which often focus on PRNDs or diseases affecting commercially unattractive target populations,<sup>25</sup> precompetitive PPPs are directed towards a broad range of topics identified as future priorities for health.<sup>26</sup> And as people in LMICs are increasingly affected by the epidemics of NCDs or so-called diseases of affluence, there is a need to investigate ways to adapt technologies developed for high-income countries for use in LMICs.<sup>27</sup> Having the potential to address broader population needs, such PPPs are therefore more attractive for investment. Governments look favorably on competitors joining forces in a precompetitive phase.<sup>28</sup> Initiatives such as the IMI in Europe and Critical Path Institute in the United States establish PPPs in a precompetitive field.<sup>29</sup>

## II The Boundaries of Precompetitive Partnerships

It is not clear at what time the so-called competitive phase starts and for whom. Depending on the point in time, the organizational structure of the PPP, and the stakeholder perspective, the definition of what is considered precompetitive might differ. For academia, doing fundamental research and publishing in high-impact journals to build out a scientific reputation is a core activity and thus the moment to excel. By contrast, biotech SMEs develop and commercialize technology platforms and research

<sup>20</sup> For a definition of background IP, see, *supra* note 8.

<sup>21</sup> Woodcock, *supra* note 21 at 521.

<sup>22</sup> *What is CD3?*, CENTRE FOR DRUG DESIGN & DISCOVERY, [www.cd3.eu/about-cd3/about-cd3what-is-cd3](http://www.cd3.eu/about-cd3/about-cd3what-is-cd3).

<sup>23</sup> R. Sanders Williams and Susan Desmond-Hellman, *Making Translation Work*, 332 *SCIENCE* 1359 (2011); Arti K. Rai et al., *Pathways Across the Valley of Death: Novel Intellectual Property Strategies for Accelerated Drug Discovery*, in *GENE PATENTS AND COLLABORATIVE LICENSING MODELS. PATENT POOLS, CLEARING-HOUSES, OPEN SOURCE MODELS AND LIABILITY REGIMES*, 247, 248 (Geertrui Van Overwalle Ed., Cambridge University Press 2009).

<sup>24</sup> Stevens et al., *Perspectives*, *supra* note \*, at 133; STEVENS, *THE ROLE OF INTELLECTUAL PROPERTY*, *supra* note \*, at 34.

<sup>25</sup> Widdus, *Public-Private Partnership*, *supra* note 14, at S2-S4.

<sup>26</sup> Goldman, *supra* note 3, at 321; Treaty on European Union [TEU], art. 129, Feb. 7, 1992, 1992 O.J. (C 191), 31 I.L.M. 253.

<sup>27</sup> World Health Organization [WHO], *Health in 2015: from MDGs, Millennium Development Goals to SDGs, Sustainable Development Goals*, 28 (2015), [www.who.int/gho/publications/mdgs-sdgs/en/](http://www.who.int/gho/publications/mdgs-sdgs/en/); see also Stevens et al., *Vaccines*, *supra* note \*.

<sup>28</sup> Wagner, *supra* note 17, at 511.

<sup>29</sup> Vargas, *supra* note 3, at 527–28.

### Box 6.1. The Innovative Medicines Initiative (IMI)

The IMI is a Joint Technology Initiative (JTI) between the European Union, represented by the EC, and the European Federation of Pharmaceutical Industries and Associations.<sup>30</sup> IMI is currently the world's largest PPP in the biomedical sciences. The PPP was launched in 2008 after identification of the key bottlenecks in research that need to be overcome to stimulate innovation in the drug development process. This PPP is situated at a pre-discovery or POC stage and covers early research to improve needed and poorly understood science. The IMI Strategic Research Agenda (targeting key challenges such as safety and efficacy prediction, knowledge management, and education and training) was implemented to enhance the competitiveness of the pharmaceutical sector in Europe for the benefit of patients and scientists.<sup>31</sup> Consortia focusing on projects targeting the development of new methods and tools for safer and more effective drugs are inherently more prone to IP issues than consortia focusing on knowledge management projects. The former type of consortia represent the majority of the IMI consortia.<sup>32</sup>

tools; the related patents are at the core of their business portfolios. And large pharmaceutical companies refer to cooperation at this stage as being “noncompetitive” or “precompetitive.”<sup>33</sup> NGOs often seek to control IPRs at an early stage to secure access to future developments for unmet needs. This might be perceived as ambiguous,<sup>34</sup> as their desire to control IPRs for philanthropic investment goals may exceed the interest in collecting royalties for profit aims.<sup>35</sup> Thus discrepancy in the definition of precompetitive research can exist between the different partners in the partnership, and among the stakeholders in general.

Precompetitive PPPs are relatively new in the biomedical sector. Hence, it remains to be seen if, and when, the precompetitive phase ends and when more product-oriented research objectives come into play. PPPs initially aimed at performing precompetitive research start to extend their successful projects. An example is the IMI, the world's largest precompetitive PPP. (See Box 6.1.) IMI has taken advantage of the most successful project outcomes to be further developed in its second phase IMI 2.<sup>36</sup> Therefore, precompetitive PPPs can be seen as performing open-ended research projects, which

<sup>30</sup> EUROPEAN COMMISSION, *Commission Staff Working Document: Joint Technology Initiatives: Background, State-of-Play and Main Features*, SEC(2007) 692 (2007) 3, 12, [https://ec.europa.eu/research/jti/pdf/background\\_jtis\\_en.pdf](https://ec.europa.eu/research/jti/pdf/background_jtis_en.pdf).

<sup>31</sup> THE INNOVATIVE MEDICINES INITIATIVE [IMI], *The Innovative Medicines Initiative (IMI) Research Agenda: Creating Biomedical R&D Leadership for Europe to Benefit the Patients and Society*, 3, 7 (Feb. 15, 2008), <http://rp7.ffg.at/upload/medialibrary/IMI-GB-research-agenda-006v2-15022008.pdf>; IMI, *The Innovative Medicines Initiative (IMI) Strategic Research Agenda: Revision 2011*, 3, 10, 25 (June, 16, 2011), [www.imi.europa.eu/sites/default/files/uploads/documents/reference-documents/SRArevised2011.pdf](http://www.imi.europa.eu/sites/default/files/uploads/documents/reference-documents/SRArevised2011.pdf) (last visited Nov. 23, 2017).

<sup>32</sup> Stevens et al., *IMI Case Study*, *supra* note \* at 154.

<sup>33</sup> Stevens et al., *Perspectives*, *supra* note \*, at 136–37.

<sup>34</sup> Editorial, *With Strings – Researchers Should Shrug Off Their Fears and Welcome the Concept of Venture Philanthropy*, 475 NATURE 266 (2011).

<sup>35</sup> Stevens et al., *Intellectual Property Policies*, *supra* note \*, at 508.

<sup>36</sup> Michel Goldman et al., *The Innovative Medicines Initiative: An Engine for Regulatory Science*, 14 NATURE REV. DRUG DISCOVERY 1, 2 (2014).



might further be developed in more product-oriented development models after the projects end, whether via an R&D alliance or in private development.<sup>37</sup>

### III The Importance of Trust

Precompetitive PPPs are platforms for scientists and industrial partners sharing thoughts and ideas, gaining more insight into scientific enigmas, as well as discovering breakthroughs and disruptive innovations. Leveraging complementarity and gaining expertise are common motives for all stakeholders participating in precompetitive PPPs.<sup>38</sup> Industry partners are highly interested in the scientific performance of universities as selection criteria for future collaborations.<sup>39</sup> Academic partners may fear they will miss out on visibility and potential collaboration opportunities if they do not participate in PPPs.<sup>40</sup> Thus precompetitive PPPs are perceived as opportunities for partner scouting, networking, and selection.<sup>41</sup>

The collaboration of competitors, sometimes referred to as cooptation, may raise suspicion regarding motives and therefore may contribute to the lack of trust between stakeholders.<sup>42</sup> Trust is based on a mutual understanding of the stakeholders' expectations and a shared perspective on the PPP's mission and objectives. Trust and related relationship issues generally occur during the start-up phase of the PPP, particularly during the first year.<sup>43</sup> The negotiation process preceding the project start, the decisions made, and the behavior of the different participants, will play a determining role in the PPP's success.<sup>44</sup> Trust is translated in the confidence of partners to share information and know-how regardless of the risk that other partners might benefit from such sharing. If these issues are not addressed carefully during the start-up phase of the project, an "us versus them" mindset might cause a potential failure of the PPP.<sup>45</sup> Lessons learned should be communicated to other initiatives via best practices or expert fora.<sup>46</sup> (See Box 6.2.)

Notwithstanding the abundance of precompetitive PPPs, their impact and performance can be at stake when there is a lack of trust among the stakeholders. This lack of trust may find its origin in the IP hurdles, especially with regard to access to background IPRs and information sharing.<sup>47</sup> Through their hybrid structures, PPPs are subject to

<sup>37</sup> Stevens et al., *Perspectives*, *supra* note \*, at 138.

<sup>38</sup> Stevens et al., *Perspectives*, *supra* note \*, at 138.

<sup>39</sup> Bart Van Looy et al., *Entrepreneurial Effectiveness of European Universities: An Empirical Assessment of Antecedents and Trade-Offs*, 40 RES. POL'Y 553, 560 (2011).

<sup>40</sup> Rudolf Strohmeier et al., *IMI Moves Forward*, 29 NATURE BIOTECHNOLOGY 689, 689 (2011).

<sup>41</sup> Stevens et al., *Perspectives*, *supra* note \*, at 138.

<sup>42</sup> Micheal J. Kelly et al., *Managing Alliance Relationships: Key Challenges in the Early Stages of Collaboration*, 32 R&D MGMT. 11, 13 (2002); Maria Bengtsson and Soren Kock, "Coopetition" in *Business Networks – To Cooperate and Compete Simultaneously*, 29 INDUS. MKTG. MGMT. 411, 411–13 (2000).

<sup>43</sup> Kelly et al., *supra* note 43, at 12.

<sup>44</sup> *Id.*, at 12.

<sup>45</sup> *Id.*, at 13.

<sup>46</sup> Stevens and Huys, *Case Study Analysis*, *supra* note \*, at 25–27. In the IMI Case Study, the interview participants clearly expressed the need to communicate, besides the scientific results, also, and equally important, the consortium experiences and best practices, such as how to best create trust between different stakeholder groups or contract templates to share information IP between different parties. These best practices or guidelines developed in expert fora could help other consortia to speed up the development process and save precious time.

<sup>47</sup> Stevens et al., *Perspectives*, *supra* note \*, at 137.

### Box 6.2. Recommendations for sustainable and successful (early-research) PPPs

1. Maximize trust building and communication between the different stakeholders
2. Consider precompetitive PPPs as a scouting platform for future collaborations
3. Foster IP as a tool for collaboration in PPPs, not as the centerpiece of the partnership
4. Provide clear and transparent guidelines for managing IP
5. Consider a stage-gate process
6. Optimize sharing through a flexible IP policy
7. Implement the honest broker model
8. Appoint a neutral IP manager
9. Share (non)confidential data in a data warehouse to increase the stakeholders' level of openness
10. Anticipate a sustainability plan
11. Assure wide dissemination of best practices via, e.g., expert fora
12. Conduct more research in PPP performance evaluation
13. Include sufficient Key Performance Indicators based on qualitative measures
14. Provide an overview of the PPP landscape to avoid duplication
15. Exchange information on the legal framework to ease global research demand
16. Investigate how PPPs with varying objectives (e.g., PPPs focusing on noncommunicable diseases (NDCs) vs. PPPs focusing on poverty-related and neglected (tropical) diseases (PRNDs)) can share best practices and lessons learned

unbalanced power relations between academia, biotech SMEs, and industry.<sup>48</sup> For academia and biotech SMEs, background IPRs are often seen as a barrier to participation in precompetitive PPPs. The reach-through access rights to background IP can cause tensions and suspicion.<sup>49</sup> For example, by participating in PPPs, biotech SMEs, whose business model may be based upon offering drug toxicity testing services on their mouse models to large pharma companies, might fear that they are expected to offer these models to the participating companies for free or unfavorable terms.

The level of trust among stakeholders will determine the capability of precompetitive PPPs to become effective networking platforms. For the PPPs to be information-sharing platforms, flexibility in the IP policy is of key importance.<sup>50</sup> Flexible arrangements, whereby room to renegotiate well-defined issues when predefined milestones have been reached or certain deliverables have been accomplished is provided, can anticipate uncertainties in the negotiation process. This stepwise approach, also sometimes referred to as the stage-gate process,<sup>51</sup> could facilitate trust building. (See Box 6.2.)

Such milestone-driven research also allows for redirecting resources. Contributions could be kept modular in order to reduce the risk if a specific module fails.<sup>52</sup> Precompetitive PPP project results should form the base of an open platform for further drug

<sup>48</sup> Danna Karen Ciccone, *Arguing for a Centralized Coordination Solution to the Public–Private Partnership Explosion in Global Health*, 17 GLOB. HEALTH PROMOTION 48, 49 (2010).

<sup>49</sup> Stevens et al., *Perspectives*, *supra* note \*, at 137; see also Natasha Gilbert, *Universities Shun Europe's Drug Initiative*, 466 NATURE 306, 306–07 (2010).

<sup>50</sup> INTELLECTUAL PROPERTY WATCH, *Partnership To Share Research, Keep IP Rights, On Neglected Diseases*, ¶ 2, IP-WATCH.ORG (Jan. 6, 2011), [www.ip-watch.org/2011/06/01/partnership-to-share-research-keep-ip-rights-on-neglected-diseases/](http://www.ip-watch.org/2011/06/01/partnership-to-share-research-keep-ip-rights-on-neglected-diseases/).

<sup>51</sup> Stevens et al., *Perspectives*, *supra* note \*, at 138.

<sup>52</sup> David Southwood, Comment, *Research Collaboration: When International Partnerships Go Wrong*, 488 NATURE 451, 453 (2012).

development. Whether a partnership-focused, an open-collaboration, or a hybrid strategy is applied, in each of the early-phase research PPPs or PPP projects, the partners engage to share information with each other. Even in partnership-focused PPPs that apply restrictive access rights rules, the partners are convinced that openness toward different stakeholders within the partnership during the project, and beyond the partnership after project termination, as well as sharing of non-confidential information, is pivotal to advancing the projects towards achieving the project objectives. Within the partnership-focus strategy as applied by IMI, for example, partners are able to contractually decide on applying a more open-collaboration strategy. This approach is taken in the U-BIOPRED consortium, where the results from biomarker research are immediately made publicly available in scientific publications. The decision to openly share the results of the U-BIOPRED's biomarker research followed the debate about the Myriad breast cancer gene patent, which was perceived by stakeholders as hindering innovation.

However, the open-ended nature of precompetitive PPPs introduces complexities on the level of IPRs as well as on the sustainability of such platform. More specifically, to accommodate the requisite degree of openness, a maximum amount of information should be shared,<sup>53</sup> while guaranteeing partners IP and other data protection aspects.

IP policies can entail a certain degree of flexibility, incorporating boundaries wherein partners can operate. The IMI IP Policy,<sup>54</sup> for example, allows for a certain degree of flexibility to negotiate IP ownership, the modalities of the access rights to IP, and the management of IP. (See Box 6.3.) However, the IMI IP Policy does not define the roles and responsibilities specific for the different stakeholders. Together with the specific IP clauses with respect to terms and conditions, these roles and responsibilities of the different partners are negotiated prior to the approval of the project agreement and the final description of work.<sup>55</sup>

#### IV IP Ownership and Access Rights

The ownership of the background IP typically remains with the respective party and poses no particular difficulties.<sup>56</sup> By contrast, the access rights to the background IP might pose difficulties.<sup>57</sup> Here, aspects pertinent to background IP are considered briefly.

##### *A General Considerations*

The valuation of background IP before the project start is a very difficult and delicate process, especially with respect to the valuation of patents covering basic research inventions.<sup>58</sup> Due to its unique nature, IP should be valued on a case-by-case

<sup>53</sup> Stevens et al., *Perspectives*, *supra* note \*, at 138.

<sup>54</sup> IMI, *IMI Intellectual Property [IP] Policy* (Jul. 1, 2007), [https://ec.europa.eu/research/participants/portal/doc/call/fp7/imi-ju-03-2010/30831-imi-ipr-policy01august2007\\_en.pdf](https://ec.europa.eu/research/participants/portal/doc/call/fp7/imi-ju-03-2010/30831-imi-ipr-policy01august2007_en.pdf).

<sup>55</sup> Stevens, *THE ROLE OF INTELLECTUAL PROPERTY*, *supra* note \*, at 137.

<sup>56</sup> Stevens et al., *Intellectual Property Policies*, *supra* note \*, at 505.

<sup>57</sup> Stevens et al., *Perspectives*, *supra* note \*, at 138.

<sup>58</sup> Thomas L. Bereuter et al., *IPR-Codes and Guidelines in Europe Facilitating Collaboration of Publicly Funded Research Organizations (PROs) with Businesses*, 46 *LES NOUVELLES* 226, 226, 229, (2011); Jon F. Merz, WHO, *Intellectual Property and Product Development Public/Private Partnerships*, 7 (May 16, 2005), [www.who.int/intellectualproperty/studies/Merz%20WHO%20report.pdf?ua=1](http://www.who.int/intellectualproperty/studies/Merz%20WHO%20report.pdf?ua=1).

### Box 6.3. The IMI IP Policy<sup>59</sup>

The IMI IP Policy was issued at the start of IMI in 2007. Several guidance documents have been published to address the issues of clarity and the lack of clear definitions such as the IMI IP Guidance Note,<sup>60</sup> the IMI Explanatory Note,<sup>61</sup> and the IMI Clarification Note<sup>62</sup> to the IMI IP Policy.

The IMI 2 JU Model Grant Agreement<sup>63</sup> was released on January 12, 2015, and includes the new provisions regarding the IMI IP Policy applied in IMI 2. In addition, the guidance documents have been implemented in the new IMI 2 JU Model Grant Agreement.<sup>64</sup> An overview of the main elements of the IMI IP Policy is provided, and the major changes with the IMI IP Policy as issued in 2007, are highlighted in Table 6.2.

Table 6.2. Summary of the IMI 2 IP Policy, based on previous experiences from IMI 1.<sup>65</sup>

| IMI 2 IP Policy – based on previous experience                            |   |  |
|---|---|--|
|   | BACKGROUND<br>(necessary and identified)  | FOREGROUND   |
| OWNERSHIP   | Remains with owner (1)  | Results belong to the beneficiary who generated it (1,2)   |
| ACCESS RIGHTS GRANTED BY A BENEFICIARY TO/ON (3)                          |   |  |
| Beneficiaries for completion of the project                               | <b>Royalty-free</b>   | <b>Royalty-free</b>  |
| Beneficiaries and affiliates for research use (4)                         | <b>Fair &amp; reasonable terms (5)</b><br>for background needed for using the results | <b>Fair &amp; reasonable terms (5)</b>   |
| Third parties for research use (4) after the project (6)                  | <b>Fair &amp; reasonable terms (5)</b><br>for background needed for using the results | <b>Fair &amp; reasonable terms (5)</b>   |
| Beneficiaries and affiliates or third parties for direct exploitation (7) | To be negotiated  | To be negotiated   |
| IP MANAGEMENT   |   | Mandatory for beneficiaries receiving funding (NEW!)/ Common practice:<br>* lies with the owner(s) in adequate and effective manner → relevant (national) legal provisions, action peculiarities, legitimate interests<br>* if valuable results left unprotected → to be discussed within the consortium |

<sup>59</sup> IMI IP Policy, *supra* note 55.

<sup>60</sup> IMI, *IMI Guidance Note for IMI Applicants and Participants* (Nov. 2010), [www.imi.europa.eu/sites/default/files/uploads/documents/apply-for-funding/intellectual-property/GuidanceNote\\_Draft3-1\\_10Nov2010.pdf](http://www.imi.europa.eu/sites/default/files/uploads/documents/apply-for-funding/intellectual-property/GuidanceNote_Draft3-1_10Nov2010.pdf) (last visited Nov. 23, 2017).

<sup>61</sup> IMI, *IMI Explanatory Note* (Jul. 2008), [www.imi.europa.eu/sites/default/files/uploads/documents/apply-for-funding/intellectual-property/ipr-helpdesk-doc-on-imi-ipr-policy\\_en.pdf](http://www.imi.europa.eu/sites/default/files/uploads/documents/apply-for-funding/intellectual-property/ipr-helpdesk-doc-on-imi-ipr-policy_en.pdf) (last visited Nov. 23, 2017).

<sup>62</sup> IMI, *Clarification Note to the IMI IP Policy* (on file with authors).

<sup>63</sup> IMI, IMI 2 Joint Undertaking [IMI 2 JU] Model Grant Agreement, art. 23(a)-31 (Jan. 12, 2015), [www.imi.europa.eu/sites/default/files/uploads/documents/apply-for-funding/call-documents/imi2/h2020-mga-imi\\_en.pdf](http://www.imi.europa.eu/sites/default/files/uploads/documents/apply-for-funding/call-documents/imi2/h2020-mga-imi_en.pdf) (last visited Nov. 23, 2017).

<sup>64</sup> *Id.*

<sup>65</sup> Stevens, THE ROLE OF INTELLECTUAL PROPERTY, *supra* note \*, at 82–83.

- (1) Possible transfer of ownership: (a) within the consortium to affiliates and purchasers without prior notification, and (b) on a case-by-case basis.
- (2) Joint ownership of results: Individual use of jointly owned results, provided prior notice and fair and reasonable compensation to the other joint owners (based on previous experiences).
- (3) Granting modalities: Access rights are granted on written request unless otherwise agreed. Almost all on-going IMI projects agreed that access rights to background IP are granted without any additional administrative step. Time-limits for requesting access rights: To be agreed in the Project Agreement.
- (4) Research use: Use of results or background necessary to use the results for all purposes other than for completing the project or for direct exploitation (based on previous experiences).
- (5) The terms to grant access rights to beneficiaries and affiliates for research use have changed. In the IMI 1 IP Policy, it was stated to be granted on *royalty-free* OR fair and reasonable terms.
- (6) Access rights to results for third parties: (a) only after the end of the project, (b) possibility to exclude specific elements of background (based on previous experiences), and (c) time-limits to be agreed.
- (7) Direct exploitation: to develop for commercialization or to commercialize the results.  
Disseminating modalities: Each beneficiary has the obligation to disseminate its own results: a) as soon as reasonably possible, and b) for publications open access is mandatory. Additionally, it is mandatory to mention the IMI support & Partners in-kind contribution in patent applications / all communications.

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Source: Stevens, Hilde, *THE ROLE OF INTELLECTUAL PROPERTY IN (PRECOMPETITIVE) PUBLIC-PRIVATE PARTNERSHIPS IN THE BIOMEDICAL SECTOR* 82–83 (2015).

basis.<sup>66</sup> If it concerns an invention, the best approach is to identify the development stage; if it concerns a database, then to identify the completeness and type of data, and the investment needed to translate it to a marketable product or therapy.<sup>67</sup> Highly innovative technologies or products require higher investments and more risks to be taken. Other factors that should be taken into account are the type of product or therapy, the manufacturing process, and the intended market.<sup>68</sup> Furthermore, it is important to include disincentives such as regulatory and liability concerns carried by the pharmaceutical industry once the product goes on the market.<sup>69</sup>

Proper compensation for background IP included in the PPP project is essential to create trust between the different stakeholders. Lack of trust between the parties or competitors might hinder the inclusion of relevant background IP, especially patents, under the preagreed (for free or fair and reasonable) conditions in the PPP's project agreement. Proper compensation for the inclusion of background IP is also essential for the creation of foreground IP.<sup>70</sup>

The stage-gate approach, whereby the general conditions and terms regarding access rights to background IP are discussed during the initial IP negotiations, and more specific

<sup>66</sup> European Commission, *Final Report from the Expert Group on Intellectual Property Valuation*, 5, 13 (Nov. 29, 2013), [https://ec.europa.eu/research/innovation-union/pdf/Expert\\_Group\\_Report\\_on\\_Intellectual\\_Property\\_Valuation\\_IP\\_web\\_2.pdf](https://ec.europa.eu/research/innovation-union/pdf/Expert_Group_Report_on_Intellectual_Property_Valuation_IP_web_2.pdf).

<sup>67</sup> Jennifer Giordano-Coltart and Charles W. Calkins, *Best Practices in Patent License Negotiations*, 25 *NATURE BIOTECHNOLOGY* 1347, 1348 (2007).

<sup>68</sup> Steve Brooke and Janet G. Vail, *Public- and Private-Sector Partnerships in Contraceptive Research and Development: Guiding Principles*, 67 *INT'L J. OF GYNECOLOGY AND OBSTETRICS* S125, S134 (1999).

<sup>69</sup> *Id.*, at S131.

<sup>70</sup> Michael R. Boyd, *The Position of Intellectual Property Rights in Drug Discovery and Development From Natural Products*, 51 *J. ETHNOPHARMACOLOGY* 17, 18 (1996).

conditions are discussed when the opportunity presents itself, could further facilitate the negotiation process.<sup>71</sup> This is discussed in more detail below in the section addressing the importance of clear and transparent IP policies.

Valuation of early-stage research requires the partners to conduct the due diligence exercise for themselves as well as for their future partners.<sup>72</sup> This is a major challenge in precompetitive PPP negotiations.<sup>73</sup> The PPP managing body, responsible for the day-to-day management of the PPP, can help overcome IP hurdles by operating as a neutral mediating party.<sup>74</sup>

An IP policy analysis of thirty precompetitive PPPs revealed that access rights to background IP are granted on royalty-free conditions or on “fair and reasonable” terms.<sup>75</sup> For example, in the IMI IP Policy,<sup>76</sup> it is stated that access to background IP should be granted on a royalty-free basis during the project. After the project ends, access rights to background IP should be granted on royalty-free *or* fair and reasonable conditions, as predefined in the consortium agreement. Fair and reasonable means that the preferential price to compensate a partner for its input is set as low as possible to provide access to the unprotected IP while guaranteeing that partner a reasonable rate of return.<sup>77</sup>

PPPs focusing on PRNDs explicitly state a preference that research results be placed in the public domain (open-collaboration strategy); however, when necessary to meet a project’s objectives, patenting is possible, private ownership will be assigned, and a conditional licensing structure will be negotiated (hybrid strategy).

A clear view on the IP ownership strengthens the collaboration. Pursuing IP ownership *an sich* should not be an end in itself. Ownership structures should be concluded to serve the PPP’s objective.<sup>78</sup>

## B *Foreground IP: Patents and Other Knowledge Assets*

Typically, the ownership of foreground IPRs is assigned to the party who generated the knowledge. The life cycle to develop drugs is relatively long, and IP protection is pivotal to guarantee a return on investment (ROI) to the investor(s). IPRs legally underpin the potential ROI of the innovation process. However, although the value of businesses is greatly defined by the creation of intangible assets, the understanding of the scope of IP differs widely amongst the various stakeholders.<sup>79</sup>

The different stakeholders often specifically address the role of patents in PPPs, but fail to consider other significant forms of IP, such as database rights, as well as other intangible resources prevalent in such collaborations, such as the creation of know-how and

<sup>71</sup> Stevens et al., *Perspectives*, *supra* note \*, at 138.

<sup>72</sup> Melese et al., *supra* note 17, at 504.

<sup>73</sup> Stevens et al., *Perspectives*, *supra* note \*, at 138.

<sup>74</sup> Strohmeier et al., *supra* note 41, at 689.

<sup>75</sup> Stevens, THE ROLE OF INTELLECTUAL PROPERTY, *supra* note \*, at 146.

<sup>76</sup> IMI IP Policy, *supra* note 55.

<sup>77</sup> Clarification Note to the IMI IP Policy, *supra* note 60, at 7.

<sup>78</sup> Antony Taubman, Council on Health Research for Development [COHRED], *Public–Private Management of Intellectual Property for Public Health Outcomes in the Developing World: The Lessons of Access Conditions in Research and Development Agreements*, 17 (2004), [http://announcementsfiles.cohred.org/gfhr\\_pub/assoc/s14831e/s14831e.pdf](http://announcementsfiles.cohred.org/gfhr_pub/assoc/s14831e/s14831e.pdf).

<sup>79</sup> EUROPEAN COMMISSION, *supra* note 67, at 5.

knowledge sharing mechanisms.<sup>80</sup> In the case of IMI, by contrast, reference to background IP was primarily directed towards types of IP such as know-how of the participating research groups and databases. In the eTOX consortium, pharmaceutical companies shared their nonconfidential and, more importantly, confidential data, which was new to the sector, with the consortium partners. The honest broker model, whereby one neutral trusted party supplies a data warehouse, is a model that convinced the companies to increase their level of openness with respect to confidential data sharing. (See Box 6.2.) The inclusion of patents as background IP is thus not always the major driving force behind the scientific excellence of precompetitive PPPs.<sup>81</sup>

One lesson is that partners should carefully consider whether scientific results yielded by precompetitive research need to be protected by patents to advance sciences in general, and to improve the collaborative activities between the stakeholders in particular.<sup>82</sup> (See Box 6.2.) For industry, the main objective is not necessarily IP ownership per se but, rather, the capacity to gain access rights to the IP (both foreground and background IP) in order to be able to further develop or even commercialize the knowledge generated within the consortium.<sup>83</sup> By participating in precompetitive PPPs, industry stakeholders desire to build long-term relationships with highly trained experts present in other stakeholder groups. This could lead them to a preferred position in negotiating access on know-how and IPRs beyond that developed within the precompetitive PPPs. It also offers them the possibility to assess the partners' negotiating strength in accessing third party's technologies. With this additional insight, we argue – again – that precompetitive PPPs are a scouting forum for future partnerships.<sup>84</sup> (See Box 6.2.)

The idea that industry is best placed to bring products and therapies to the market is justifiable in several cases. In general, IP ownership should be assigned to the party that generated the IP. In cases where more than one party generated the IP, joint ownership should be the rule. The fact that industry brings new drugs or therapies to the market is thus not an argument *contra* joint ownership, as license agreements exist to solve this issue. An argument to avoid joint ownership, however, is the lack of clear legal provisions about joint ownership. Joint ownership issues might be raised when different parties are entitled to multiple rights in different national patent laws.<sup>85</sup> Current national, European, and international patent legislation has not yet adapted to the trend of collaborative creation and national laws differ in the scope of the exploitation rights accompanying a jointly owned patent.<sup>86</sup> The same holds true for the protection of trade secrets, although the recently approved European trade secrets directive intends to create more harmonization.<sup>87</sup> Internationally harmonized legal provisions concerning joint ownership or trade secret protection

<sup>80</sup> Stevens et al., *Perspectives*, *supra* note \*, at 131; Stevens, THE ROLE OF INTELLECTUAL PROPERTY, *supra* note \*, at 158, 161.

<sup>81</sup> Stevens, THE ROLE OF INTELLECTUAL PROPERTY, *supra* note \*, at 156–57.

<sup>82</sup> *Id.*, at 156.

<sup>83</sup> Stevens et al., *Perspectives*, *supra* note \*, at 132, 136.

<sup>84</sup> *Id.*, at 138–39.

<sup>85</sup> Arina Gorbatyuk et al., *Intellectual Property Ownership in Coupled Open Innovation Processes*, 47 INT'L REV. OF INTELL. PROP. AND COMPETITION L. 262, 265, 281 (2016).

<sup>86</sup> *Id.*, at 281, 285.

<sup>87</sup> The Council adopted a directive setting our rules for protection of trade secrets and confidential information of European companies. The different member states will have a maximum of two years to incorporate the new provisions into domestic law. European Commission, Trade Secrets, [https://ec.europa.eu/growth/industry/intellectual-property/trade-secrets\\_en](https://ec.europa.eu/growth/industry/intellectual-property/trade-secrets_en) (last visited Nov. 18, 2017).

are currently lacking.<sup>88</sup> (See Box 6.2.) Due to the uncertainty accompanying the lack of clear legal provisions on joint ownership of patents at this point in time, joint ownership should not be considered as a default solution, and especially not as the easy option.<sup>89</sup>

General rules about joint ownership of patents tends to be avoided in most of the IP policies of precompetitive PPPs.<sup>90</sup> Alternatives to joint ownership of patents, such as agreeing on sole ownership for one party, with a license back to the other party who has helped to generate the foreground IP, can circumvent potential issues arising with joint ownership of patents. However, this solution, whereby the owner has the rights to exploit the coinvented technology, while the non-owner licensee is compensated, raises the question whether this agreement reflects the shared efforts of the different parties in the collaboration.<sup>91</sup> This solution resembles more a service contract-relationship between the different parties.

### C Data and Other Knowledge Outputs

There is increased reliance on “big data,” that is, the bits and bytes recording the huge volumes of chemical, metabolic, genomic, phenotypic, and other types of data, generated by multidisciplinary research groups. This supports the recent trend towards more open, and in specific cases, even free sharing of scientific information.<sup>92</sup> Different stakeholders realize that patenting research results might not be a *conditio sine qua non* for protection of scientific achievements anymore.<sup>93</sup> Due to the growing number of collaborative research projects, wherein sharing of techniques and ideas is needed, and the rise of open innovation,<sup>94</sup> the eagerness to seek patent protection for every scientific achievement has changed.<sup>95</sup>

<sup>88</sup> Gorbatyuk et al., *supra* note 86, at 262, 281.

<sup>89</sup> European IPR Helpdesk, Case Study: Allocation of Shares of Jointly Developed Results, 3 (Feb. 2014), [www.iprhelpdesk.eu/sites/default/files/newsdocuments/CS\\_Allocation\\_of\\_shares\\_of\\_jointly\\_developed\\_results.pdf](http://www.iprhelpdesk.eu/sites/default/files/newsdocuments/CS_Allocation_of_shares_of_jointly_developed_results.pdf).

<sup>90</sup> Stevens et al., *Intellectual Property Policies*, *supra* note \*, at 507.

<sup>91</sup> Robert J. Paradiso and Elizabeth Pietrowski, *Dilemmas of Joint Patent Ownership: Provide a Clear Understanding of the Parties' Expectations*, 197 N.J. L. J. 912, 913 (2009).

<sup>92</sup> Maja Larson and Margaret Chon, *The Greatest Generational Impact: The Open Neuroscience Movement as an Emerging Knowledge Commons*, in GOVERNING MEDICAL KNOWLEDGE COMMONS (Katherine Strandburg, Brett M. Frischmann, & Michael J. Madison eds. 2017)

<sup>93</sup> Colin Macilwain, *Sharing Information Is Preferable to Patenting*, 498 NATURE 273 (2013).

<sup>94</sup> The partnership-focused strategy can be considered most in line with Chesbrough's “Open Innovation” principles. Henry Chesbrough, OPEN BUSINESS MODELS: HOW TO THRIVE IN THE NEW INNOVATION LANDSCAPE (2006) (describing firm-centered innovation and the sharing of knowledge with other, specifically selected actors). This system is dominated by the for-profit sector, based on IP, with subsequent license contracts creating restricted openness. See generally GEERTRUI VAN OVERWALLE G, *Inventing Inclusive Patents. From Old to New Open Innovation*, in KRITIKA-ESSAYS ON INTELLECTUAL PROPERTY, VOL. 1, 206 (Peter Drahos et al. eds., Edward Elgar 2015).

We prefer to use the term “partnership-focused” rather than “Open Innovation” to dissociate from the firm-centered perspective, as these PPPs are partnerships wherein all partners are equal, and the “firm-centered” connotation does not reflect the presence of a more balanced network. The open-collaboration strategy, on the other hand, can be compared with the nonprofit motivated user- and community-centered innovation, wherein universal access is aimed for by refraining from focusing too much on (private) ownership of IP, and/or semi-openness (where IP access and use is restricted to a specific group of users) and universal openness (where nobody can be excluded from IP access and use) is targeted. The most extreme form of the open-collaboration strategy is the dedication of foreground IP to the public domain (see Table 6.1), Stevens et al., *Intellectual Property Policies supra* note \*, at 504.

<sup>95</sup> Macilwain, *supra* note 94.



Early-phase research PPPs will not produce ready-to-market drugs or therapies. Instead, tools and technologies that enable the development of downstream products and therapies will be developed. Biomarkers, for example, are research tools aimed at predicting the response of the human body to drugs in terms of toxicity and efficacy. The various case law decisions with respect to the patenting of genes have significantly changed the patent landscape for the biomarker discovery projects focusing on personalized medicine, as a result of which patenting genetic sequences as well as genetic diagnostic methods has become very difficult.<sup>96</sup> In basic science research consortia, some representatives realize that patenting prognostic or diagnostic applications might hinder the steps towards further clinical validation, and therefore they instead focus on the opportunity offered by the PPP to progress such findings towards the step of clinical validation. In the IMI consortia analyzed, whether or not biomarker research is publicly disseminated or kept as trade secrets, patents are considered an option for the biomarker-based companion diagnostics under development and codeveloped therapeutics, or biomarker-based diagnostics developed to guide drug use after drug approval.

The aggregation of and access to datasets of several companies is a major asset of collaborative projects. For example, one of the objectives of precompetitive R&D PPPs could be the setup of toxicology prediction models to screen drug compounds or other types of technology platforms. Open access to parts of the company's database allows for participants to expand the compound libraries used for screening and identification of lead compounds. Access to a company's library might be granted case-by-case; this allows for the company to select nonproprietary restricted structures and structures that are at that moment not subject to the company's internal proprietary research. The confidential data of companies can be masked; sensitive data is firewalled for nonauthorized project participants, for example, whereby the full molecular structure information is kept proprietary. The research potential of the collaborative database is related to the number of participants; with each additional party granting restricted access to its database, the number of screening possibilities increases exponentially. The expanded chemical diversity offers routes for innovative exploration of new entries for medicinal chemistry.<sup>97</sup>

In the case of databases covering clinical trial information, the discussion of collaborative parameters is even more sensitive. On the one hand, there is a need for openness and sharing of clinical trial data among PPP consortia members allowing research to be reanalyzed or to conduct new analysis with existing data. The Clinical Trials Regulation (CTR) (EC) No 536/2014<sup>98</sup> and some other policies at the European Medicines Agency cover principles to disclose results and clinical study reports. On the other hand, confidentiality needs to be guaranteed, for instance, in order to respect and protect the trial participants' privacy, or to prevent the conflict of interest of the sponsor.<sup>99</sup>

<sup>96</sup> Aaron Kesselheim et al., *The Evolving Role of Biomarker Patents in Personalized Medicine*, 95 *CLINICAL PHARMACOLOGY THERAPEUTICS* 127, 127 (2014).

<sup>97</sup> Peter B. Simpson and Melvin Reichman, Comment, *Opening the Lead Generation Toolbox*, 13 *NATURE REV. DRUG DISCOVERY* 3, 3–4 (2014).

<sup>98</sup> Regulation 536/2014 of the European Parliament and of the Council of Apr. 16, 2014, on Clinical Trials on Medical Products for Human Use and Repealing Directive 2001/20/EC, 2014 O.J. (L 158).

<sup>99</sup> With regard to potential conflicts of interest of the sponsor, the US Food and Drug Administration, for example, notes: "We recognize that the potential conflicts of interest faced by government sponsors can be different from those of industry sponsors, so that the implications for the approach to monitoring, particularly with regard to confidentiality and independence issues (*see* Section 4.2 and Section 6), may also differ to some extent." *FOOD AND DRUG ADMIN. [FDA], GUIDANCE FOR CLINICAL TRIAL*

In the IMI Case Study, it was revealed that aggregated databases with enormous potential were created.<sup>100</sup> These databases allowed researchers to explore new routes by grabbing information from combined datasets of an unprecedented size and increasing accompanying research potential. The inclusion of datasets in the Project Agreement clearly specified the difference between nonconfidential and confidential datasets included by the partners.

The IMI IP Policy reflects restricted openness.<sup>101</sup> However, the flexibility incorporated in the IMI IP Policy allows for the PPP projects to decide on the permission constraints (or the level of openness) on a case-by-case base. During the project, only partners within the project are allowed to access the background IP (in case the aggregated database is built upon background IP of one or more consortium partners) or the foreground IP (in case the aggregated database is built upon the efforts performed during the project), and only if needed to complete certain tasks and to develop foreground IP<sup>102</sup>. The preferred access granted to consortium partners is a major incentive for the partners to participate in IMI.<sup>103</sup>

Due to the innovative character and the size of the shared databases, the sustainability thereof requires serious reflection. During the project, the databases created allow researchers to explore combined datasets with different access and security levels. The financial sustainability of such model, and especially the idea of opening up parts of the databases to the wider research community, is still unclear. The EC has stressed the need to explore options to support the datasets' sustainability.<sup>104</sup> Some IMI consortia have reflected on models for sustainability, for instance hosting the databases in a separate foundation.

#### D Knowledge Sharing Mechanisms and Models

A key prerequisite to enhance sharing capabilities is the development of knowledge sharing mechanisms. For example, the creation of an honest broker mediated data warehouse in IMI's eTOX consortium, represents a scientific endeavor of high excellence that allows advancement towards POC-oriented research. It highlights the importance of creating such sharing mechanisms for knowledge exchange, especially of different types of IPRs and knowledge assets, including nonpatented knowledge, in precompetitive PPP settings.<sup>105</sup>

The development of standards and templates for material, data, and information transfer and access such as Material Transfer Agreements (MTAs), Data Transfer Agreements (DTAs), and Confidentiality Disclosure Agreements (CDAs) might be a precompetitive PPP's highest added value for further collaboration. These tools and technologies facilitate the sharing of data, materials, and information. Sharing of nonconfidential data,

SPONSORS: ESTABLISHMENT AND OPERATION OF CLINICAL TRIAL DATA MONITORING COMMITTEES (2006), [www.fda.gov/OHRMS/DOCKETS/98fr/01d-0489-gdl0003.pdf](http://www.fda.gov/OHRMS/DOCKETS/98fr/01d-0489-gdl0003.pdf).

<sup>100</sup> Stevens, THE ROLE OF INTELLECTUAL PROPERTY, *supra* note \*, at 155.

<sup>101</sup> IMI IP Policy, *supra* note 55.

<sup>102</sup> *Id.* at 6.

<sup>103</sup> Stevens et al., *Perspectives*, *supra* note \*, at 136; Stevens et al., *Intellectual Property Policies*, *supra* note \*, at 505–506.

<sup>104</sup> IMI Governing Board Meeting, Chaired by Dr. Rudolf Strohmeier, Deputy-Director General of Directorate General for Research and Innovation (DG RTD) at the European Council, (Oct. 29, 2013).

<sup>105</sup> *Id.*, at 164.

but more importantly, confidential data, enables the development and validation of data standards, research tools, and criteria for new clinical trial design.<sup>106</sup>

A substantial number of the IP policies lack basic clarity and definitions, such as definitions of background and foreground IP, not to mention rules on IP ownership, access, and use. This leaves too much room for ambiguity. Transparency is of utmost importance, not only for the partners in a consortium but also for the general public. Transparency and standardization of definitions could ease the exchange of data and materials between PPPs and avert legal interoperability issues, resulting in reduced coordination costs.<sup>107</sup>

It is essential to establish clear rules regarding IP ownership of potential IP and access rights thereto, in order to provide insight and an understanding of the parties' expectations.<sup>108</sup> Different ideas about protection via IPRs, IP ownership, and access to IP can seriously hinder the negotiations.<sup>109</sup> The IP policy should include rules on IP ownership, the terms and conditions on which parties apportion the ownership shares, as well as definitions of the ownership shares, the conditions to grant access rights to different partners and third parties, the compensation for this access, and the exploitation rights and obligations of the knowledge accessed.<sup>110</sup> Contractual flexibility allows the potential partners to agree upon the rules. This agreement should be established at a very early stage, before the start of the project.<sup>111</sup> A clear, transparent, and unambiguous IP framework, concluded in the PPP's IP policy, provides insight in the objectives of the PPP and the IP framework designed to enable the accomplishment of those objectives. In this way, the different stakeholders are able to align their expectations and their institutions' objectives with the objectives defined in the PPP. The problem, however, is that persons participating in the PPP do not always have the expertise for the development of a solid IP and data management plan. Especially when innovative data results will be created, partners may be confronted with lack of experience in drafting appropriate rules that may govern their future activities.

Different views on stakeholders' objectives, especially the different objectives of the nonprofit and the for-profit partners, might result in lengthy and difficult negotiations, and difficulties in the partnership in general.<sup>112</sup> A lack of a long-term plan for the PPP could impede collaborations. Further, a certain degree of flexibility is deemed to be necessary as not all possible contingencies can be foreseen at the initial phase of the project.<sup>113</sup> The majority of the precompetitive PPPs provide flexibility to negotiate and contractually agree on the terms and conditions with respect to IP within the boundaries of the PPP's IP policy.<sup>114</sup>

<sup>106</sup> *Id.*, at 158; Mark D. Lim, *Consortium Sandbox: Building and Sharing Resources*, 6 SCI. TRANSLATIONAL MED. 242, 1, 5, 6 (2014).

<sup>107</sup> Stevens et al., *Perspectives*, *supra* note \*, at 136; Stevens et al., *Intellectual Property Policies*, *supra* note \*, at 504, 509; Tania Bubela et al., *Recalibrating Intellectual Property Rights to Enhance Translational Research Collaborations*, 4 SCI. TRANSLATIONAL MED 122, at 4 (2012).

<sup>108</sup> IPR Helpdesk, *supra* note 90, at 2; Paradiso, *supra* note 92, at 1, 2.

<sup>109</sup> Taubman, *supra* note 79, at 28.

<sup>110</sup> Stevens et al., *Intellectual Property Policies*, *supra* note \*, at 507.

<sup>111</sup> European IPR Helpdesk, *supra* note 90, at 3.

<sup>112</sup> Brooke et al., *supra* note 69, at S130.

<sup>113</sup> Seungwoo Son, *Legal Analysis on Public-Private Partnerships Regarding Model PPP Rules*, presented at International Colloquium on Public-Private Partnerships (PPPs) in Vienna, 15 (June 2012), [www.unictoral.org/pdf/english/colloquia/public-private-partnerships-2013/20120704\\_Report\\_on\\_PPP\\_legal\\_Issues\\_Son\\_Seungwoover.11.pdf](http://www.unictoral.org/pdf/english/colloquia/public-private-partnerships-2013/20120704_Report_on_PPP_legal_Issues_Son_Seungwoover.11.pdf).

<sup>114</sup> Stevens et al., *Intellectual Property Policies*, *supra* note \*, at 507.

Although trust – important as it is – is usually created at the negotiation stage, too much time is lost during this initial phase of the projects.<sup>115</sup> Clear and transparent IP policies should be made publicly available in order to inform potential partners from the beginning. Precompetitive PPPs should be viewed as a scouting forum to investigate the possibility to collaborate with some of the partners in a more advanced setting. Hence, the IP should be framed accordingly.<sup>116</sup>

As alluded to above, a stage-gate approach could be considered, whereby the flexibility of the partners to negotiate the IP framework applied within the PPP project is discussed and renegotiated at predefined milestones. In this approach, the general rules and contract clauses are negotiated before the project starts, and potentially renegotiated at a later point in time. It offers the partners the opportunity to agree upon a general IP framework at the start. Then when certain opportunities arise or unexpected developments occur (and more trust has been created between the partners), partners may renegotiate the specific terms and conditions needed to optimize the opportunities or tackle the challenges that partners face during the project progress.<sup>117</sup> This stage-gate approach could also be applied for other PPPs such as PDPs, whereby new contracts are negotiated based on milestones reached in the product development phase. For each new phase, new rules and clauses are agreed between the PPP and its respective partners.

The importance of patents in precompetitive PPPs should be balanced with the importance of the creation of scientific databases and the exchange of information based on trade secrets, which is currently underemphasized in importance. Only a few precompetitive PPPs include some information with regard to non-patent IP in their IP policy,<sup>118</sup> while it is clear that the inclusion of such background IP and the development of such foreground IP is highly significant in early-phase research PPPs.<sup>119</sup> Because there is a clear lack of harmonized legislation, especially with regard to the protection of trade secrets, the IP policy issued by the precompetitive PPP could offer an additional basis to create trust. Literature suggests that the success of a PPP depends partly on the implementation and use of an IP framework,<sup>120</sup> which might be related to the trust creation when the partners agree upon clear rules.

## V Knowledge-Sharing Strategies in Early-Phase Research PPPs

Early-phase research PPPs apply a variety of IP frameworks or knowledge-sharing strategies to structure IP ownership, access, and use. By linking elements such as the nature of the research (project focus), the objectives of the PPP (envisioned project deliverables), the PPP business model and its feasibility (funding), three types of IP strategies can

<sup>115</sup> Stevens, *THE ROLE OF INTELLECTUAL PROPERTY*, *supra* note \*, at 157.

<sup>116</sup> Stevens et al., *Perspectives*, *supra* note \*, at 138.

<sup>117</sup> *Id.*

<sup>118</sup> Stevens, *THE ROLE OF INTELLECTUAL PROPERTY*, *supra* note \*, at 157–158.

<sup>119</sup> *Id.*, at 151–152.

<sup>120</sup> Richard T. Mahoney et al., *The Introduction of New Vaccines into Developing Countries: IV: Global Access Strategies*, 25 *VACCINE* 4003, 4007 (2007); Bart Leten et al., *IP Models to Orchestrate Innovation Ecosystems*; IMEC, *a Public Research Institute in Nano-Electronics*, 55 *Cal. Mgmt. Rev.* 51, 51, 52, 61 (2013).

be discerned, as mentioned in an earlier section. These are: (i) partnership-focused, (ii) open-collaboration, and (iii) hybrid strategies (See Table 6.1).<sup>121</sup>

The partnership-focused strategy is dominated by the for-profit sector and builds on the presence of IP, with subsequent license contracts creating restricted openness.<sup>122</sup> The open-collaboration strategy, on the other hand, can be compared with nonprofit user- and community-centered innovation, wherein the main goal is universal access. The most extreme form of the open-collaboration strategy is the dedication of foreground IP to the public domain.<sup>123</sup>

PPPs applying a partnership-focused strategy tend to provide IP policies that facilitate information and knowledge exchange. Owing to information negotiated before the project initiation – such as the establishment of clear definitions, templates and guidelines, as well as information on IP ownership, use, and licensing structure – trust is more easily created. The partners, who might be potential competitors in a later stage of drug development, know exactly what to expect and how to optimally share information according to their respective business strategies and with respect to downstream development. Nevertheless, the IP information is not frequently available to the public. This could be explained by PPPs preferring not to share such details with non-participants.<sup>124</sup>

The partnership-focused PPPs allow for the partners to build a unique IP portfolio at lower cost and in less time than if they were working in isolation.<sup>125</sup> Patenting marketable research results is common, and alternative protection is considered when results are not patentable. Such PPPs generally use a private ownership structure (i.e., background IP remains with the owner, and foreground IP belongs to the idea generator) and a private access structure (i.e., consortium members acquire preferred and conditional access to background and/or foreground IP – see Table 6.1).<sup>126</sup> In exceptional circumstances, the ownership of the foreground IP can be assigned partly to the PPP, whereby the PPP becomes one of the legal owners, together with one or more partners. Ownership or co-ownership of foreground IP allows the PPP to build the strong technological base instrumental for its sustainability.<sup>127</sup>

Partnership-focused PPPs apply IP policies that clearly set out certain constraints, creating a restricted openness. Only project partners are allowed access to background IP and then only to complete certain tasks and to develop foreground IP. The partnership-focused PPP is an investment-friendly model, as preferred access is a major incentive for industrial partners. Contracts – that is, project agreements – are the main legal tools to define the parameters of partners' activities. The PPPs applying this IP framework focus most of their research on drug-development tools, drugs, therapies, or diagnostic tests (or a mix of those deliverables) for NCDs (see Table 6.1). Funding for the majority of these PPPs is provided by both for-profit and nonprofit institutions.<sup>128</sup>

On the other end of the contingency spectrum are open-collaboration PPPs, wherein the main target is to share the foreground IP resulting from the project with a broad

<sup>121</sup> Stevens et al., *Intellectual Property Policies*, *supra* note \*, at 504, 509.

<sup>122</sup> Van Overwalle, *supra* note 95, at 9.

<sup>123</sup> Stevens et al., *Intellectual Property Policies*, *supra* note \*, at 508.

<sup>124</sup> *Id.*, at 504, 509.

<sup>125</sup> Leten et al., *supra* note 121, at 51–52.

<sup>126</sup> Stevens et al., *Intellectual Property Policies*, *supra* note \*, at 504, 509.

<sup>127</sup> Leten et al., *supra* note 121, at 51, 61.

<sup>128</sup> Stevens et al., *Intellectual Property Policies*, *supra* note \*, at 505–507.

research community or the general public (see Table 6.1).<sup>129</sup> Forms of collaboration such as open source, open access, and open transfer were developed as a response to the proprietary approach to DNA sequencing<sup>130</sup> and to mitigate the effect of patent thickets.<sup>131</sup> Several collaborative projects are aimed at resolving patent thickets for key biotechnology tools to ensure that they are available to scientists and for addressing problems in underserved communities.<sup>132</sup>

Sharing with a broader community entails a specific license signed by a user, whereas dedicating research results to the public domain ensures that anyone may gain access to or use the information. This type of IP framework includes different forms of open models, such as open source PPPs (for example, the Open Source Drug Discovery), open access PPPs (for example, the Structural Genomics Consortium), and PPPs applying the commons principles (for example, Sage Bionetworks). The open-collaboration IP framework applies a private ownership–public access logic. Although the PPPs provide users with open access to research results, the use is limited by predefined boundaries. In the majority of PPPs, sharing is organized by means of an open entry license model that specifies the community’s level of access and freedom to operate. Users can easily obtain an open entry license. Often, research results can be improved, modified, and used for commercial or noncommercial purposes, but such results must be provided to the PPP or, if patent applications are filed, blocking of the PPP’s activities is not allowed. “Open” does not necessarily mean that patents (or other forms of legally protected IP) are never involved. Patenting research results is accepted in specific cases.<sup>133</sup>

Commercial entities may be less likely to invest in open-collaboration PPPs, given the requirement to share foreground IP and the limits placed on patents for results arising from PPP information. Nevertheless, this IP framework is applied by PPPs focusing on NCDs, when the project deliverables are research tools, platform technologies, shared databases, and predictive models – all upstream results leading to precompetitive biotechnology tools aimed at speeding up drug development. Common to all these PPPs is that commercialization of drugs is not yet the primary objective. In the field of NCDs, the competition to develop research tools such as models, probes, or assays is high. And the cost implications of patenting can be a hurdle, as it is not always clear which tool might trigger the winning pathway to a solution for the disease.

Research in the field of PRNDs is characterized by unpredictability, uncertainty, and risk. The distribution of probability is unknown, and the time horizon for ROI is considerable. Owing to unpredictability in terms of business strategy, private ownership might not work. The result is a market failure to which PPPs can offer a potential solution. Innovative business models and government incentives will need to convince the pharmaceutical industry and will provide building blocks to develop a model to provide

<sup>129</sup> *Id.*, at 506.

<sup>130</sup> Geertrui Van Overwalle, *Of Thickets, Blocks, and Gaps. Designing Tools to Resolve Obstacles in the Gene Patents Landscape*, in GENE PATENTS AND COLLABORATIVE LICENSING MODELS, 383 (2009); *supra* note 24; *see generally* Geertrui Van Overwalle, *Exclusive Ownership Versus Open Commons: The Case of Gene Patents*, 4 THE WIPO J. 139 (2013).

<sup>131</sup> Bubela et al., *supra* note 108, at 3; Robin Feldman & Kristopher A. Nelson, *Open Source, Open Access, and Open Transfer: Market Approaches to Research Bottlenecks*, 1–2, 7 (May 2, 2008), <http://ssrn.com/abstract=1127571>.

<sup>132</sup> Robin Feldman, *The Open Source Biotechnology Movement: Is It Patent Misuse?*, 6 Minn. J. L., Sci. & Tech. 117, 118, 132 (2004).

<sup>133</sup> Stevens et al., *Intellectual Property Policies*, *supra* note \*, at 508.

more equitable access to medical care to patients in LMICs. IP frameworks applied in PPPs that encourage further investment thus seem not only appropriate but preferable. It remains to be awaited whether early-phase PPPs focusing on NCDs for commercially attractive markets might inspire and provide enough incentive for the pharma industry to invest in diseases affecting people in LMICs.<sup>134</sup>

Between the partnership-focused and open-collaboration strategies is a hybrid strategy, in which the IP framework applied is negotiated on a case-by-case basis. PPPs applying a hybrid strategy provide a limited IP policy with respect to ownership, use, and transfer of knowledge and materials (see Table 6.1). The PPPs explicitly state a preference that research results be placed in the public domain; however, when necessary to meet a project's objectives, patenting is possible, private ownership will be assigned, and a conditional licensing structure will be negotiated (see Table 6.1). Access to research results outside the consortium, however, is strongly preferred, and freedom to operate is restricted through licensing. This hybrid strategy is an interesting IP framework for development of downstream diagnostic tests and drugs for PRNDs, as it allows for negotiation of project agreements, including IP clauses, with industrial partners to create more commercially interesting incentives compared to an open-collaboration strategy. Hybrid PPPs typically are nonprofit funded.<sup>135</sup>

## VI The Evaluation of IP in the Performance of Early-Phase PPPs: Suggested Approaches

Current empirical studies are lacking in which the effectiveness of these partnerships is assessed. Very little research has been performed to identify the key components of successful early-phase research PPPs.<sup>136</sup> However, in the IMI Case Study, the short-term outputs, the long-term outcomes, the added value, and the (so far unexplored) opportunities of the consortia under the umbrella of IMI have been investigated.<sup>137</sup> Some of the conclusions drawn from this case study are discussed here.

The knowledge gathered in the different IMI projects exceeds pure scientific results. An enormous number of templates, harmonized protocols, and standardization endeavors for information exchange has been developed within and between consortia. It took the consortium members considerable efforts and time to come to these harmonized and standardized templates and protocols. Therefore, any assessment of effectiveness should valorize these knowledge assets. One valuable way to leverage these assets could be through the creation of a forum to exchange best practices and disseminate existing knowledge on the legal and regulatory landscape, including topics such as governance, IP, and dissemination of results,<sup>138</sup> to prove the impact and added value of collaboration within PPPs for the society, in addition to scientific excellence.<sup>139</sup>

<sup>134</sup> *Id.*, at 508.

<sup>135</sup> *Id.*, at 508.

<sup>136</sup> Bubela et al., *supra* note 108, at 4; Magdalini Papadaki and Gigi Hirsch, *Curing Consortium Fatigue*. 5 *SCI. TRANSLATIONAL MED.* 200sF35, 1 (2013).

<sup>137</sup> STEVENS, *THE ROLE OF INTELLECTUAL PROPERTY*, *supra* note \*, at 99–100.

<sup>138</sup> *Id.*, at 119.

<sup>139</sup> IMI, *Report of the Independent Expert Panel Accompanying the Commission Report: Assessment of European Innovative Medicines Initiative 2, A Joint Technology Initiative Under Horizon 2020*, at 6–7 (Dec. 23, 2012), [https://ec.europa.eu/research/health/pdf/imi-ppp-expert-panel-report\\_en.pdf](https://ec.europa.eu/research/health/pdf/imi-ppp-expert-panel-report_en.pdf).

Performance of scientific research, and in particular the evaluation of IP in PPPs, is quantitatively demonstrated by key performance indicators (KPIs), often tangible deliverables such as number and impact of publications, number of citations, or number of patents.<sup>140</sup> However, a patent application is far from being the only value-critical step in drug R&D.<sup>141</sup> As such, an over-focus on patent filings as a KPI to evaluate the performance of the precompetitive PPP might distort the evaluation of the project progress and success of the precompetitive PPP. The precompetitive research phase is situated too early in the drug development cycle to rely on solely quantitative metrics such as number of patents filed to evaluate the performance of precompetitive PPPs.<sup>142</sup> In addition, not all PPPs cover patentable research results, which might give a misleading picture of the progress or successes of such often valuable projects. Defining a framework for KPIs is highly intertwined with capturing the different project objectives or strategic interests, as well as the different scientific and nonscientific deliverables and milestones defined by the parties at defined moments (delivery on objectives at different stages). KPIs should also capture the development of, and access to technologies, capability, and talent, as well as the provision of improved rules for decision making or to reduce costs (impact on R&D productivity).<sup>143</sup>

In research-oriented precompetitive PPPs, it should be carefully considered when and if scientific results need to be protected by patents. Expressing a precompetitive PPP's performance solely by means of quantitative KPIs neglects to measure other key missions of PPPs, such as networking or sharing and development of know-how. The balance between quantitatively and qualitatively measuring the tangible and the intangible assets should be considered carefully.<sup>144</sup> Important KPIs to measure the success of IMI are the (1) funding, (2) acquirement of highly performing employees, (3) stimulation of qualitative collaboration between the different parties, (4) development of important changes in R&D, (5) guarantee of quality of reports, and (6) generalization of efficient and continuous sharing of knowledge.<sup>145</sup>

Further, the KPIs measured should reflect both the current value of the PPP and the perceived future value of the PPP, especially in precompetitive PPPs since the time to deliver maximum value is often underestimated in such PPPs. The evaluation of performance also depends on the maturity of the PPP.<sup>146</sup>

<sup>140</sup> David A. Pardoe et al., *Assessing the Value of R&D Partnerships*, 12 DRUG DISCOVERY WORLD 9, ¶ 3 (2010).

<sup>141</sup> J. P. Hughes et al., *Principles of Drug Discovery*, 162 BRITISH J. PHARMACOLOGY 1239, 1240, 1243 (2011).

<sup>142</sup> Stevens, THE ROLE OF INTELLECTUAL PROPERTY, *supra* note \*, at 149; IMI, *Bibliometric Analysis of Ongoing Projects: Innovative Medicines Initiative Joint Undertaking (IMI) Third Report*, 9 (Oct. 2013), [www.imi.europa.eu/sites/default/files/uploads/documents/reference-documents/IMI\\_BibliometricReport\\_3.pdf](http://www.imi.europa.eu/sites/default/files/uploads/documents/reference-documents/IMI_BibliometricReport_3.pdf) (last visited Nov. 23, 2017); IMI, *Bibliometric Analysis of Ongoing Projects: Innovative Medicines Initiative Joint Undertaking (IMI) Fourth Report*, 9–10 (Apr. 2014), [www.imi.europa.eu/sites/default/files/uploads/documents/reference-documents/BibliometricReport4\\_Final.pdf](http://www.imi.europa.eu/sites/default/files/uploads/documents/reference-documents/BibliometricReport4_Final.pdf) (last visited Nov. 23, 2017).

<sup>143</sup> Pardoe et al., *supra* note 141, at ¶ 10.

<sup>144</sup> Stevens, THE ROLE OF INTELLECTUAL PROPERTY, *supra* note \*, at 161.

<sup>145</sup> Michel Goldman, *The Innovative Medicines Initiative: A European Response to the Innovation Challenge*, 91 CLINICAL PHARMACOLOGY 418, 423 (2012).

<sup>146</sup> Stevens, THE ROLE OF INTELLECTUAL PROPERTY, *supra* note \*, at 162; Tom Denee et al., *Measuring the Value of Public–Private Partnerships in the Pharmaceutical Sciences*, 11 NATURE REV. DRUG DISCOVERY 419 (2012).



It is important to value the PPPs' performance to justify the investments of public and private stakeholders in the partnership. By evaluating the PPP, success scenarios as well as pitfalls can be identified and be used to set up guidelines and best practices.<sup>147</sup> As stated earlier, there is a lack of adequate KPIs to measure the performance of (precompetitive) PPPs.<sup>148</sup> Some researchers have identified seven domains to monitor different types of organizations' progress: (a) funding, (b) talent, (c) dissemination, (d) collaboration, (e) output, (f) validation, and (g) external uptake.<sup>149</sup> Dependent on the type of organization, the influence of certain domains, as well as the KPIs that define the progress in these domains, will differ.

The added value of the PPP needs to be measured at different stages: at the start of the project (input), during the project (process), at the time of project termination (outputs), and in the long term (outcomes).<sup>150</sup> For example, the societal impact of PPPs in general, and of IMI in particular, can be measured by the generation of more and better quality research, in addition to the contribution they will make to healthcare via the production of new drugs. The dissemination and sharing of results are critical complements to the R&D itself, and might be the *raison d'être* of IMI. A lack of proper dissemination of research results will diminish the innovative value of carrying out research. On the other hand, dissemination of research results might lead to progressive collaboration and attract new investors. This, in turn, might lead to additional research, job creation, and spin-out companies, whereby the biopharmaceutical industrial level is improved and expanded. Maximizing the social return is one of the key justifications of public expenditure on IMI.<sup>151</sup>

The importance of the creation of knowledge sharing agreements between partners and/or project consortia requires a significant investment and should be valued accordingly. As for the domain of know-how, the sharing of knowledge can be evaluated, by means of measuring the background IP in the broadest sense. This includes knowledge shared by the different stakeholders at the start of the project (input), the amount of foreground IP developed during the project (process), and the IP exploited after the project has ended (short-term output). This also includes both license agreements involving the foreground IP and those involving long-term (outcome) products and/or therapies in development.<sup>152</sup>

The foreground IP developed in PPPs can be used as background IP in other PPPs. Sharing foreground IP with other PPPs might already occur in the process stage. The rules for sharing nonconfidential and confidential know-how within a PPP and also between PPPs can be captured in knowledge sharing models, such as a Memorandum of Understanding (MoU), and knowledge sharing tools, such as MTAs, DTAs, or CDAs to contractually define the exchange of material, data, or information. The practice thereof

<sup>147</sup> *Id.*, at 419.

<sup>148</sup> *Id.*, at 419; Bubela et al., *supra* note 108, at 4; Papadaki, *supra* note 137, at 1.

<sup>149</sup> Robert Pozen & Heather Kline, *Defining Success for Translational Research Organizations*, 3 *SCI. TRANSLATIONAL MED.* 94cm20, 3–4 (2011).

<sup>150</sup> Denee et al., *supra* note 147, at 419.

<sup>151</sup> EUROPEAN COMMISSION, *Commission Staff Working Document: Accompanying Document to the Proposal for the Council Decision on the Setting Up the Innovative Medicines Initiative Joint Undertaking*, SEC (2007) 568 (2007) 28, [https://ec.europa.eu/research/jti/pdf/imi\\_com\\_sec\(2007\)0568\\_en.pdf](https://ec.europa.eu/research/jti/pdf/imi_com_sec(2007)0568_en.pdf).

<sup>152</sup> Stevens, *THE ROLE OF INTELLECTUAL PROPERTY*, *supra* note \*, at 164–65.

should also be taken into account when evaluating PPPs, e.g., through a content analysis of MoUs, with accompanying CDAs, DTAs, or MTAs concluded between projects.<sup>153</sup> IMI fosters collaboration between consortia, and even requests that future projects start from results and knowledge gained from previous IMI PPPs.<sup>154</sup>

It is essential to gain additional expertise in the development of KPIs for PPP valuation,<sup>155</sup> as these indicators could support investors in decision making with respect to future investments to sustain the PPPs' progress, to improve its performance or, in case value is not being realized, to redirect investments to PPPs of higher value.<sup>156</sup> The valuation process needs to be done at regular and up-front well-defined moments in order to proactively steer the PPPs in delivering maximum value. For that reason, we argue that a flexible, stage-gate approach is important.<sup>157</sup>

The generation and dissemination of best practices and guidelines could also be taken into account when evaluating PPPs' performance. The dissemination should occur within the PPP's different consortia, and by extension, between different PPPs globally. Further, the time invested in the creation of such data sharing mechanisms should be acknowledged by the PPP, and by extension by the entire scientific research community by rewarding the publication of these best practices in peer-reviewed scientific literature, especially by academic research community. The reward mechanism for (academic) researchers should indeed not primarily consist of the number of scientific publications in high level journals, or the number of patent applications filed. An alternative KPI could be included, whereby the network built by the researcher is taken into account (e.g., quantitatively measured by the number of co-citations, and qualitatively measured by the degree of participation in national and international collaborations, and the number of follow-on partnerships established in the research field).<sup>158</sup>

## Conclusion

Medical innovations have improved lives of millions of people, and science and technology create the potential for further advances in medicine and healthcare in the near future. At the same time, we witness the painful reality that many people around the world remain in need of effective life-saving treatments and preventive therapies. R&D efforts do not always seem to be directed to the health needs of all people. In September 2016, the United Nations High-Level Panel on Innovation and Access to Health Technologies (UN High Level Panel) issued a report depicting hard figures about urgent worldwide health needs.<sup>159</sup> To address this enormous gap, the 2030 Agenda for Sustainable Development, as adopted by a total of 193 member states of the United Nations (UN) in September 2015, includes Sustainable Development Goal (SDG) 3, which aims

<sup>153</sup> *Id.*, at 165.

<sup>154</sup> Stevens & Huys, *Case Study Analysis*, *supra* note \*, at 26, 30, 37, 40–41.

<sup>155</sup> Lim, *supra* note 107, at 6.

<sup>156</sup> Pardoe et al., *supra* note 141, at ¶ 23.

<sup>157</sup> Stevens et al., *Perspectives*, *supra* note \*, at 138.

<sup>158</sup> Stevens, *THE ROLE OF INTELLECTUAL PROPERTY*, *supra* note \*, at 166.

<sup>159</sup> U.N. Secretary-General, *High-Level Panel on Access to Medicines*, 13–15 (Sep. 2016), <https://static1.squarespace.com/static/562094dee4b0d00c1a3ef761/t/57d9c6ebf5e231b2f02cd3d4/1473890031320/UNSG+HLP+Report+FINAL+12+Sept+2016.pdf>.

“to ensure healthy lives and promote the well-being of all people of all ages.”<sup>160</sup> SDG 3 has as one of its targets to “provide access to affordable essential medicines and vaccines, in accordance with the Doha Declaration on the TRIPS Agreement and Public Health, which affirms the right of developing countries to use to the full the provisions in the TRIPS Agreement regarding flexibilities to protect public health.”

Aside from IPRs as embedded in TRIPS and national frameworks, other incentives prove to be imperative for health care advances to become reality. This pluralistic approach is also recommended by the UN High Level Panel.<sup>161</sup> Different stakeholders in the domain of medical innovation face complex biomedical questions, risks of failure, and high costs of R&D. This is why PPPs aimed at sharing risks and costs are proposed as a model to make medical advancements and bring science closer to those in need. According to the UN SDG 17, a successful sustainable development agenda requires partnerships between governments, the private sector, and civil society,<sup>162</sup> echoing the UN Millennium Development Goal 8, namely, “to provide access to affordable essential drugs in developing countries in cooperation with pharmaceutical companies.”<sup>163</sup>

Other than from PRNDs, new types of PPPs focusing on diseases of affluence have entered the scene in the last decades. Since those research domains are highly competitive, collaborations at the precompetitive level (precompetitive or early-phase research PPPs) have proven to be successful in the developed world, with the IMI as world’s largest PPP operating in the precompetitive and even the POC phase in the health-care sector. Lessons drawn from the IMI experience, albeit in the realm of diseases of affluence, suggest possible mechanisms for IP management, sharing, and negotiations in the context of PPPs directed to PRNDs. The first is the stepwise approach for negotiations,<sup>164</sup> starting from the creation of an open platform as a basis for further drug development, with the necessary flexibilities for sharing ideas about IP ownership and expectations among partners, rather than viewing IP ownership as an aim in itself. Second are transparent, clear, flexible, and unambiguous IP policies covering short but also long-term expectations of partners.<sup>165</sup> Third is the creation of fora or educational workshops for sharing experiences and best practices about conducting PPPs, negotiating IPRs. This can form a first step in creating awareness about the importance of having clear IP arrangements up front of the PPP start. An honest-broker model might support such arrangements and may offer a basis for trust among partners. And finally trust is vitally important. Trust building among stakeholders of the various precompetitive PPPs that developed a virtual business model, especially the open-collaboration PPPs, is less exposed.<sup>166</sup>

<sup>160</sup> *Sustainable Development Goal 3*, U.N. SUSTAINABLE DEVELOPMENT, <https://sustainabledevelopment.un.org/sdg3>.

<sup>161</sup> U.N. Secretary-General, *supra* note 160, at 29–32.

<sup>162</sup> *Sustainable Development Goal 17*, U.N. Sustainable Development, [www.un.org/sustainabledevelopment/globalpartnerships/](http://www.un.org/sustainabledevelopment/globalpartnerships/).

<sup>163</sup> Goal 8: Develop a Global Partnership for Development, Target 8.E, U.N. MILLENNIUM DEVELOPMENT GOALS AND BEYOND 2015, [www.un.org/millenniumgoals/global.shtml](http://www.un.org/millenniumgoals/global.shtml).

<sup>164</sup> Stevens et al., *Perspectives*, *supra* note \*, at 138.

<sup>165</sup> Stevens et al., *Intellectual Property Policies*, *supra* note \*, at 504, 509.

<sup>166</sup> Munos, *supra* note 3, at 6–7.

The many conceptual building blocks for successful partnerships depicted in this chapter need to be further explored and aligned. Only with the knowledge and expertise from civil society, industry, academia, and multilateral organizations such as the UN, can the major sustainable development challenges be addressed to the benefit for all patients, suffering from PRNDs as well as from NCDs, in both developed and developing countries.

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