Intellectual property policies in early-phase research in public–private partnerships

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Knowledge-sharing strategies differ depending on the nature of the research objectives of public–private partnerships, but information about such strategies is often vague.

For more than a decade, big pharma has evolved from the traditional model of intellectual property (IP) in which formally protected knowledge such as know-how, data and materials is used to appropriate returns internally toward a more collaborative model wherein IP becomes shared and pooled. In this article we show how the sharing of IP is organized through specific IP frameworks or knowledge-sharing strategies in early-phase public–private partnerships (PPPs). In such PPPs, several partners combine expertise, materials and sometimes IP, called 'background IP', in a consortium to answer fundamental research questions and create technology platforms, research tools, shared databases and/or predictive models. These activities might result in new or 'foreground' IP instrumental to the development of safer and more effective drugs[1,2]. A number of such PPPs also perform downstream development of therapies, in which case the importance of (access to) IP increases. Given the nature of IP rights (IPRs), which provide the owner the right to exclude others from using protected inventions, establishing agreements on sharing of IP within early-phase research PPPs becomes complex[3].

As PPPs focus on the sharing and pooling of complementary skills, IP ownership and access are key factors and provide an incentive for the pharma industry to engage and invest in PPPs. IP policies and IP-related issues in PPPs have been debated extensively. Several strategies and models to contractually agree on pooling and transferring knowledge have been suggested[4]. Some articles elaborate on the different innovation models applicable in collaborations, whereas others discuss a specific model applied in a well-defined PPP[5,6]. However, what the discussion currently lacks is empirical evidence and detailed information on the different IP frameworks and policies applied within early-phase PPPs, particularly the characteristics of the knowledge-sharing models and the extent to which partners negotiate the sharing conditions[7,8]. Here we aim to unravel the IP policies developed by (bio) pharmaceutical R&D PPPs operating in the precompetitive phase. Our survey methodology is presented in **Box 1**.

DISCUSSION

Patents help to structure, build and define innovation partnerships[9]. Literature suggests that the success of a PPP depends partly on the implementation and use of an IP framework[10,11]. In precompetitive research projects, technical outcomes and resulting economic values are, to some extent, uncertain and unclear. Therefore, negotiations about IP ownership, access to and use of IP in such settings is not evident. However, successful partnering in the early research phase depends on clear agreements about IP at the onset of the project, as they introduce trust and coherence[3,12].

The results from this study (**Tables 1** and **2** and **Supplementary Results**) highlight the need for transparency and explicitness in IP policies. The levels of information offered by the PPPs in their IP policy differ, and a substantial number of the IP policies under investigation lack basic clarity and definitions, leaving room for ambiguity. Transparency is of utmost importance, not only for the partners in a consortium but also for the general public. Transparency reduces coordination costs within and outside consortia and might enable information sharing that would lead to more effective partnerships[6].

Our study further reveals that 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 (PPP funding), we distinguished three types of IP strategies: (i) partnership focused, (ii) open collaboration and (iii) hybrid strategies (**Table 3**).

The partnership-focused strategy can be considered most in line with Henry Chesbrough's 'open-innovation' principles[13,14], which describe firm-centered innovation and the sharing of knowledge with specifically selected actors. This system is dominated by the for-profit sector and builds on the presence of IP, with subsequent license contracts creating restricted openness[15]. We prefer the term 'partnership-focused strategy' over 'open innovation' to distinguish from the firm-centered perspective, as it describes PPPs wherein all partners are equal. 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.

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Box 1 Analysis of the IP frameworks applied by early-phase biomedical research PPPs

In this study, we aimed to provide empirical evidence regarding precompetitive PPPs' use of IP policies and insights into the relationship between the IP elements used and the nature of the PPP. To do this, we explored (i) the transparency and clarity of the IP policies enacted and (ii) the IP policies' approaches to ownership rights, access and use and the potential to negotiate or customize rules and clauses according to partners' needs and desires. In addition, we assess the relationship between the research results and the project focus and deliverables and the PPP's funding sources. Our study focuses on five IP elements used in life-sciences PPPs: (i) ownership of background IP, (ii) ownership of foreground IP, (iii) access rights to background IP, (iv) access rights to foreground IP and (v) IP management.

We compiled a nonexhaustive list of 30 PPPs on the basis of the literature (including searches of PubMed, SSRN, ScienceDirect and Google) and experts' consultations. We included 20 PPPs in the analysis (availability sampling). We characterized the PPPs geographically: five are EU national, two are EU regional, six are US-based and seven are international partnerships covering worldwide collaborations. We then categorized the PPPs according to the research stages covered on the discovery–development–delivery continuum (i.e., early-phase research (precompetitive) and, if applicable, also proof-of-concept research, product development and product access)[3]. We included only PPPs starting projects in the early stage of drug discovery, meaning that we omitted PPPs that focus on product development or access (purposive sampling). We categorized the PPPs according to project focus as follows: (i) poverty-related and neglected diseases (PRNDs; for example, neglected tropical diseases, malaria, tuberculosis and HIV/AIDS), (ii) diseases of affluence or (iii) combinations of PRNDs and diseases of affluence (mixed). We mapped project deliverables: (i) drug development tools, such as technology platforms, (software) models, databases, research tools or materials; (ii) drugs, diagnostic and therapeutic materials or therapies; or (iii) a combination of research tools, tests and drugs. We also identified funding sources and partners (nonprofit, for-profit or mixed). Categorization of the IP strategies (partnership focused, open collaboration or hybrid) was based on the dominant framework described in the IP policy and applied in the majority of the projects.

Our results suggest that a partnership-focused strategy is applied in almost half of the PPPs operating in early-phase research (9/20 or 45%). PPPs applying a partnership-focused strategy tend to provide a moderate to substantial amount of IP information (**Figs. 1** and **2**). This facilitates information and knowledge exchange, as the IP ownership, use and licensing structure are negotiated before the project initiation[4]. Nevertheless, IP information from partnership-focused PPPs is not frequently available to the public. This could be explained by PPPs preferring not to share such details with nonparticipants. Owing to the substantial amount of IP information and the establishment of clear definitions, templates and guidelines, the partners (who might be potential competitors in a later stage of drug development) are supported and protected with respect to downstream development.

Patenting marketable research results is common, and alternative protection is considered when results are not patentable. Partnership-focused 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) (**Fig. 1**). In this way, partners can build a unique IP portfolio at lower cost and in less time than if they were working in isolation[11].

In our study, three PPPs applying a partnership-focused licensing strategy (Stem Cells for Safer Medicines (SC4SM) and two that wish to keep their IP policy confidential) deviated from this in that ownership of the foreground IP is assigned(partly) to the PPP. Co-ownership of foreground IP allows the PPP to build the strong technological base instrumental for its sustainability[11].

Partnership-focused PPPs apply IP policies that clearly set out certain constraints, creating a restricted openness. Only partners within the project are allowed access to

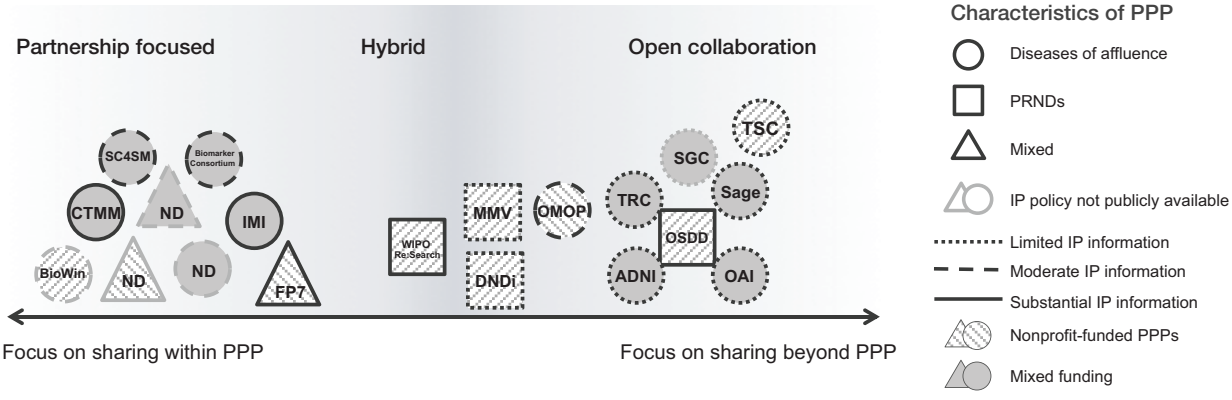

Figure 1 IP frameworks as defined in the policies of the selected PPPs. PPPs are categorized by research focus (diseases of affluence (circles), PRNDs (squares) or a mix (triangles)), availability of IP information (unavailable (gray outlines) and limited, partial or substantial availability (black outlines)) and funding sources (nonprofit (striped shading) or mixed funding (solid shading)). ADNI, Alzheimer's Disease Neuroimaging Initiative; BioWin, Biotechnologies Wallonie Innovation; CTMM, Center for Translational Molecular Medicine; DNDi, Drugs for Neglected Diseases Initiative; FP7, European Framework Programmes; IMI, Innovative Medicines Initiative; MMV, Medicines for Malaria Venture; ND, not disclosed by PPP request; OAI, Osteoarthritis Initiative; OMOP, Observational Medical Outcomes Partnership; OSDD, Open Source Drug Discovery; SC4SM, Stem Cells for Safer Medicines; TSC, the SNP Consortium; TRC, the RNAi Consortium; SGC, Structural Genomics Consortium.

Table 1 Nonexhaustive list of PPPs performing activities in the early research phase in the life-science R&D sector.

PPP	Start date	Geographic scope	Research phase				IP policy availability	IP framework strategy	Project focus	Project deliverables	PPP funding
			Precomp.	POC	PD	PA					
Alzheimer's Disease Neuroimaging Initiative (ADNI)	2004	US	x				On request	Open collaboration	DA	Tools	Mixed
Biotechnologies Wallonie Innovation (BioWin)	2006	National	x				On request	Partnership focused	DA	Mix	Nonprofit
Center for Translational Molecular Medicine (CTMM)	2007	National	x	x	x		Public	Partnership focused	DA	Mix	Mixed
Drugs for Neglected Diseases Initiative (DNDi)	2003	International	x	x	x	x	Public	Hybrid	PRNDs	Drugs	Nonprofit
European Framework Programmes (FP7)	2007	EU	x				Public	Partnership focused	Mixed	Mix	Nonprofit
Innovative Medicines Initiative (IMI)	2008	EU	x	x			Public	Partnership focused	DA	Mix	Mixed
Medicines for Malaria Venture (MMV)	1999	International	x	x	x	x	Public	Hybrid	PRNDs	Drugs	Nonprofit
Osteoarthritis Initiative (OAI)	2001	US	x				Public	Open collaboration	DA	Tools	Mixed
Observational Medical Outcomes Partnership (OMOP)	2007	US	x				Public	Hybrid	DA	Tools	Nonprofit
Open Source Drug Discovery (OSDD)	2008	International	x	x	x		Public	Open collaboration	PRNDs	Mix	Nonprofit
Stem Cells for Safer Medicines (SC4SM)	2007	National	x				Public	Partnership focused	DA	Tools	Mixed
Sage Bionetworks Commons	2009	International	x				Public	Open collaboration	DA	Tools	Mixed
The SNP Consortium (TSC)	1999	International	x				Public	Open collaboration	DA	Tools	Nonprofit
The Biomarkers Consortium	2006	US	x				Public	Partnership focused	DA	Tools	Mixed
The RNAi Consortium (TRC)	2003	US	x	x			Public	Open collaboration	Mixed	Tools	Mixed
Structural Genomics Consortium (SGC)	2004	International	x				On request	Open collaboration	Mixed	Mix	Mixed
WIPO Re:Search	2001	International	x	x	x	x	Public	Hybrid	PRNDs	Mix	Nonprofit
ND	2006	National	x	x	x		On request	Partnership focused	Mixed	Mix	Mixed
ND	2007	National	x				On request	Partnership focused	DA	Drugs	Mixed
ND	2005	US	x				On request	Partnership focused	Mixed	Tools	Nonprofit

ND, not disclosed by PPP request; national, EU national; EU, EU regional; precomp., precompetitive; POC, proof of concept; PD, product development; PA, product access; x, indication of the projects performed in the respective research phase; DA, diseases of affluence; PRNDs, poverty-related and neglected diseases.

background IP and only if they need it to complete certain tasks and develop foreground IP. A restricted-access policy on foreground knowledge developed in the PPP gives partners an advantage over third parties in terms of research use and exploitation of results. Contracts—i.e., 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 'diseases of affluence' (**Figs. 1** and **2**). The majority of these PPPs (6/9) are funded by both for-profit and non-profit institutions (mixed funded) (**Fig. 1**).

The partnership-focused PPP is an investment-friendly model, as preferred access is a major incentive for industrial partners[3]. Although precompetitive PPPs aim to conduct early-phase research and build platform technologies rather than develop drugs or therapies, for the industrial partner it is appealing to gain access to IP in the earlier stage as this might be useful for drug development in a later stage[3].

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 research community or the general public (**Fig. 1**). The foundations for open sharing of research results were laid as a response to the proprietary approach to DNA sequencing[16,17]. Forms of collaboration such as open source, open access and open transfer were developed to mitigate the effect of patent thickets[6,18,19]. 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[20].

We found that 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, Open Source Drug Discovery (OSDD)), open-access PPPs (for example, the Structural Genomics Consortium (SGC)) and PPPs applying

Table 2 Information regarding terms and conditions for IP as specified in IP documents of 20 PPPs operating in the early research phase.

Funding source	Nonprofit									Mix									
Research focus	PRNDs				DA			Mix					DA						
PPP	OSDD	MMV	DNDi	WIPO Re:Search	BioWin	OMOP	TSC	FP7	ND	ND	SGC	TRC	IMI	CTMM	ND	Sage	OAI	SC4SM	Biomarker	ADNI
IP framework	Open collaboration	Hybrid	Hybrid	Hybrid	Partnership focused	Hybrid	Open collaboration	Partnership focused	Partnership focused strategy	Partnership focused	Open collaboration	Open collaboration	Partnership focused	Partnership focused	Partnership focused strategy	Open collaboration	Open collaboration	Partnership focused	Partnership focused	Open collaboration
No information related to ownership/ access rights																	x			
Background ownership info	x			x	x	x		x	x	x			x	x	x	x		x	x	
Remains with owner				x	x	x		x	x	x			x	x	x	x		x	x	
Sideground ownership info									x				x		x					
Foreground ownership info	x	x	x	x	x		x	x	x	x	x	x	x	x	x	x		x	x	x
For PPP	x								x									x		
Idea generator				x	x		x	x					x	x	x	x			x	x
Joint					(x)*			x	x	x			x	x	x				x	
No researcher or institution ownership allowed											x									
Background access rights info	x			x	x	x		x		x			x	x				x	x	
For completion project				x	x			x		x			x	x					x	
For research use	x			x		x		x					x						x	
To practice foreground IP				x				x										x		
For direct exploitation				x						x			x	x						
Foreground access rights info	x	x		x	x			x	x	x		x	x	x	x			x	x	
For completion project	x			x				x					x	x	x			x		
For research use	x			x	x			x	x	x			x	x	x			x		
To practice foreground IP	x			x				x	x					x	x					
For direct exploitation	x			x					x	x			x	x	x			x		
IP management in PPP project	x	x	x	x		x		x	x	x				x	x					
Room for negotiation	No	Case by case	Case by case	Case by case	x			x		Little			x	No	No			Little		
Expert support			x	x						x				x						
IP management	CSIR		Executive director assignee	Database hosted by WIPO		FNIH			Coordinating committee	Patent coordinator				Project IP manager	Project IP manager					

DA, diseases of affluence; PRNDs, poverty-related and neglected diseases; ADNI, Alzheimer's Disease Neuroimaging Initiative; BioWin, Biotechnologies Wallonie Innovation; CTMM, Center for Translational Molecular Medicine; DNDi, Drugs for Neglected Diseases Initiative; FP7, European Framework Programmes; IMI, Innovative Medicines Initiative; MMV, Medicines for Malaria Venture; OAI, Osteoarthritis Initiative; OMOP, Observational Medical Outcomes Partnership; OSDD, Open Source Drug Discovery; SC4SM, Stem Cells for Safer Medicines; TSC, the SNP Consortium; TRC, the RNAi Consortium; SGG, Structural Genomics Consortium; CSIR, Council of Scientific and Industrial Research (India); FNIH, Foundation for the National Institutes of Health. WIPO, World Intellectual Property Organization; x, yes;(x)*, joint ownership is only possible in exceptional circumstances, ownership by the industrial partner is favored.

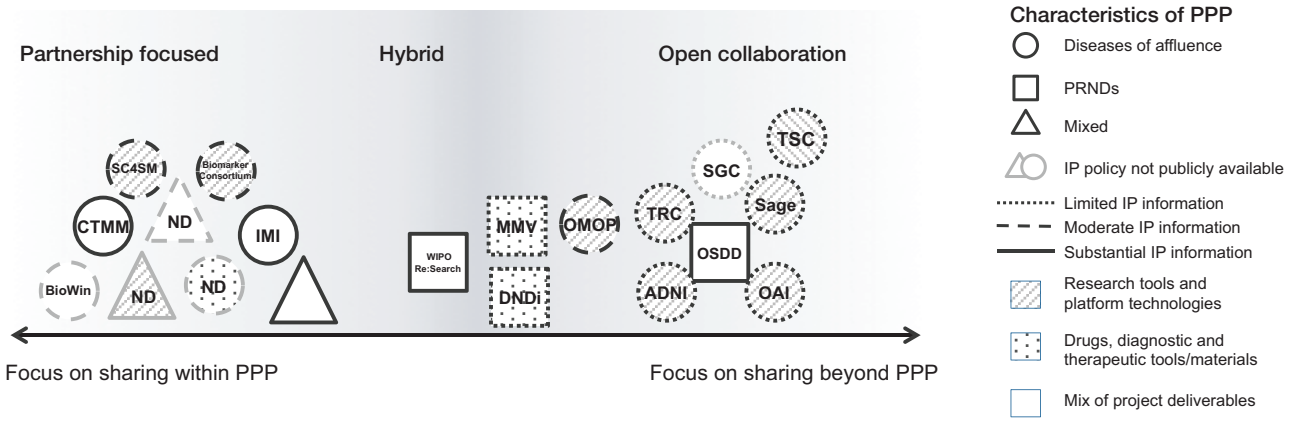

Figure 2 Link between IP frameworks as defined in the IP policies of the PPPs analyzed, the information provided in the IP policies, project focus and project deliverables. PPPs are categorized by research focus (diseases of affluence (circles), PRNDs (squares) or a mix (triangles)), availability of IP information (unavailable (gray outlines) and limited, partial or substantial availability (black outlines)) and deliverables (research tools and platform technologies (striped shading), drugs, diagnostic and therapeutic tools or materials (dotted shading) or a mix (no shading)). ADNI, Alzheimer's Disease Neuroimaging Initiative; BioWin, Biotechnologies Wallonie Innovation; CTMM, Center for Translational Molecular Medicine; DNDi, Drugs for Neglected Diseases Initiative; FP7, European Framework Programmes; IMI, Innovative Medicines Initiative; MMV, Medicines for Malaria Venture; ND, not disclosed by PPP request; OAI, Osteoarthritis Initiative; OMOP, Observational Medical Outcomes Partnership; OSDD, Open Source Drug Discovery; SC4SM, Stem Cells for Safer Medicines; TSC, the SNP Consortium; TRC, the RNAi Consortium; SGC, Structural Genomics Consortium.

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 (FTO). Users can obtain an open-entry license by, for example, ticking a box to verify that they agree to the PPP license before accessing results or creating an account in which they identify themselves as researchers. 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 no patents (or other forms of legally protected IP) are involved. Patenting research results is accepted in specific cases.

None of the PPPs we analyzed apply the most extreme form of open collaboration, the public-domain strategy, wherein research results are systematically put in the public domain and no formal agreements are required to gain access to them. The open-collaboration framework most similar to a public-domain strategy is that of the International HapMap Project coordinated by the SNP Consortium (TSC), which stipulates that HapMap data may not be blocked and that only patent applications on SNPs or haplotypes outside the project core may be filed. Another example of this openness in sharing research data and materials is the Structural Genomics Consortium (SGC), an open-access PPP that claims it "will not perform projects where patent applications are a deliverable"[21].

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. We found that the majority (6/7) of the PPPs applying an open-collaboration model focus on diseases of affluence (**Table 1** and **Figs. 1** and **2**). However, this IP framework is applied when the project deliverables are research tools, platform technologies, shared databases and predictive models—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 diseases of affluence, 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 poverty-related and neglected diseases (PRNDs) is characterized by unpredictability, uncertainty and risk. The distribution of probability is unknown, and the time horizon for return on investment 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. However, PPPs need to provide enough incentive for the pharma industry to invest in PRNDs. IP frameworks that encourage further investment thus seem not only appropriate but preferable.

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 (**Figs. 1** and **2**). 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 (**Table 2**). Access to research results outside the consortium, however, is strongly preferred, and FTO 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. All hybrid PPPs in this study are nonprofit funded.

The variation between a more restricted IP framework (partnership-focused strategy) and an open IP framework (open-collaboration strategy) seems justified given the heterogeneity of the partners and their respective objectives and needs, and is

Table 3 Different IP frameworks in PPPs

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	Access mechanisms and legal basis	Contractual framework based on IP rights: contracts (for example, project agreement) including different clauses regarding patents and other industrial rights	Contracts and IP in case of partnership-focused strategy, licenses in case of open-collaboration strategy	Contractual framework based on IP rights: (viral) licenses (for example, Open Access Protocol, Creative Commons or Copyleft Licenses), to help continue cycle of research
	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 or defined	Limited or undefined	Undefined
Project focus		Profit- or non-profit-driven research, focusing mainly on diseases of affluence	Non-profit-driven research, focusing on PRNDs	Profit- or non-profit-driven research, focusing on diseases of affluence and/or PRNDs
Project deliverables		Biotechnology tools (upstream research results); drugs, therapies and diagnostic tests for diseases of affluence (downstream research results); a mix of tools and drugs for PRNDs and diseases of affluence (downstream research results)	Biotechnology tools (upstream research results); tools and drugs for PRNDs (upstream and downstream research results)	Biotechnology tools (upstream research results); diagnostic tests and drugs for PRNDs (downstream research results)
PPPs in which the strategy prevails		IMI, BioWin, The Biomarkers Consortium, FP7, SC4SM, CTMM, and three anonymous PPPs	MMV, DNDi, OMOP, WIPO Re:Search	SGC, Sage, TSC (HapMap), OSDD, OAI, TRC, ADNI

necessary to serve the PPP's mission and to obtain its objectives. PPPs targeting downstream development results (drugs and diagnostic tests) tend to apply an IP sharing strategy where access to foreground IPRs and FTO are permission-constrained and preferably negotiated with the consortium partners (partnership-focused strategy). PPPs focused on upstream results or PRND-specific downstream products are more likely to adopt an IP framework that allows more sharing of IPRs (open-collaboration strategy). Both 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.

We also observed variation in the degree of transparency and explicitness of IP policies. Transparency is often missing in the IP policies of early research-phase PPPs. Further, the majority of the IP policies lack basic information, such as definitions of background and foreground IP and rules on IP ownership, access and use. Even when a PPP intends to share knowledge in the broadest possible way, IP ownership rules, access and user rights need to be addressed explicitly for the project to proceed effectively. Moreover, standardization of definitions could ease the exchange of data and materials between PPPs and avert legal interoperability issues, resulting in reduced coordination costs. Although the different stakeholders in the partnership agree that transparent and broadly defined IP frameworks are indispensable for successful project negotiations and building trust[3,7,22,23], few PPPs apply a clear and defined framework. A complete, publicly available set of policies and procedures allows potential partners to assess their roles and responsibilities and gain insight into the rewards and expectations involved in participation[21].

We therefore recommend that biomedical PPPs include basic definitions and information regarding 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.

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AUTHOR CONTRIBUTIONS

H.S. wrote the manuscript, designed research, performed research and analyzed data. G.V.O. contributed to the manuscript and interpreted data. B.V.L. contributed to the manuscript and interpreted data. I.H. designed and performed research and contributed to the manuscript.

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The authors declare no competing financial interests.

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