

HealthSphere Strategy & Implementation

Product Development Partnerships (PDPs): Overview

Product Development Boot Camp

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Product Development Partnerships—A traditional definition

“[PDPs] use public and philanthropic funds to engage the pharmaceutical industry and academic research institutions in undertaking R&D for diseases of the developing world that they would normally be unable or unwilling to pursue independently, without additional incentives.”*

It is advisable to keep an open mind when thinking about partnership arrangements because the landscape has changed dramatically.

There has been a proliferation of innovative partnership models that transcend the traditional definition of PDPs



The spectrum of potential partnership configurations is guided by different underlying priorities and objectives

Global health priorities
Address lack of commercial incentive

Broadly de-risking R&D
Complement commercial incentive



Goal to **reduce burden of malaria in disease-endemic countries** by discovering, developing and delivering new, effective and affordable **antimalarial drugs**.



Goal to improve health—and **economic impact**—by speeding up development of, and access to, **innovative medicines**, particularly where there is an **unmet medical or social need**.



Quebec Consortium for Drug Discovery

Goal to fund a **pre-competitive** research forum that facilitates development of **breakthrough tools** and technologies that **enhance biopharmaceutical R&D productivity**.

Changes in the R&D landscape are driving the continued expansion of PDP models beyond those that fit the traditional definition

Key Drivers

Industry

Rising costs and risks in drug and vaccine development coupled with **thinning pipelines** and **patent expirations**

Governments

Unsustainable healthcare costs, increased **global competition** and uncertain global macroeconomic climate

Academia

Constrained funding and shifting focus of funders toward translational science and **commercialization**

Not-for-profits

Growing demands for **accountability and transparency** by discerning stakeholders/donors

Care providers

Emphasis on the **value** interventions contribute to **future health outcomes** requires population-level, real-world data

PDPs—across the continuum—yield shared benefits that no single partner can achieve on its own

- » Combine expertise and resources from academia and industry
- » Spread funding and risk across multiple players
- » Facilitate dissemination of knowledge across a diverse network
- » Concentrate on missions rather than development costs
- » Allocate resources efficiently through stringent project vetting

PDPs—whether traditional or emerging configurations—can accelerate the translation of R&D from bench to bedside while supporting affordability and data access.

Despite their diversity, successful partnerships exhibit three common elements

- 1 Defined governance mechanisms that enable appropriate participation in decision-making**
- 2 Disciplined approach to communication among partners and with stakeholders**
- 3 IP policies that balance the needs of individual partners with the objectives of the partnership**

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Defined governance mechanisms that enable appropriate participation in decision-making

Transparency

- » Ensure that partners understand issues and their role in decision-making

Accountability

- » Clearly specify roles and responsibilities and establish formal reporting structures

Oversight

- » Ensure that decision-making bodies enjoy recognized authority to act on behalf of the partnership

Focus

- » Establish clear R&D objectives and criteria to guide consistent, predictable, mission-driven decision-making

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Case study: Various governance mechanisms are implemented to overcome challenges intrinsic to these often complex relationships



*Each partner is an **equal voting-member** on an **Executive Committee** that provides strategic leadership and oversees specific **committees/working groups, established on an as-needed basis.***

*A **Scientific Committee** made up of regional thought leaders **advises the Governing Board**, and all stakeholders have an opportunity to provide input at the **Stakeholder Forum.***

***Independent boards** that advise on and guide the Lab's strategy are charged with **proposal review/funding**, limiting industry's involvement.*

Disciplined approach to communication among partners and with stakeholders

Partners

- » Need to be fully abreast of activities, challenges and forthcoming decisions/milestones

Scientific Community

- » Desires publication of data and opportunity to discuss scientific results

Funders

- » Expect financial transparency and accountability

Public

- » Requires evidence that activities are mission-driven and serving the public good

PDPs must pursue consensus-based communication plans to ensure efficient operations, align stakeholder expectations, and maximize potential for sustainability and enduring impact.

Case study: Selected examples of the commitment to communication across a diverse spectrum of PDPs



Structural Genomics Consortium



*Multi-pronged **outreach strategy** targeting patient groups, primary and secondary schools, radio stations, digital media and policymakers.*

***Discloses audited financial results**, including industry partner contributions, through its Annual Work Plan, Annual Activity Report and website.*

***Published >100 peer-reviewed articles** since 2000 and established 'PLoS Neglected Tropical Diseases' journal.**

IP policies that balance the needs of individual partners with the objectives of the partnership

	Target Product	Knowledge/Technology Transfer
Not-for-Profit Partners	<i>Affordable product that will be sold at cost or at a very low margin</i>	<i>Rapid data publication with no restrictions to open access databases</i>
Industry Partners	<i>Marketable product that provides a reasonable return on investment in selected markets</i>	<i>Control access to technology with potential to generate revenue</i>

IP ownership terms are frequently subject to negotiations to address the (often) competing priorities of various partners.

Case study: IP policies are driven by different strategic objectives



- » Will negotiate an **exclusive global license**
- » Licenses must be **royalty-free** in malaria-endemic countries
- » IP will be **transferable** to manufacturing partners

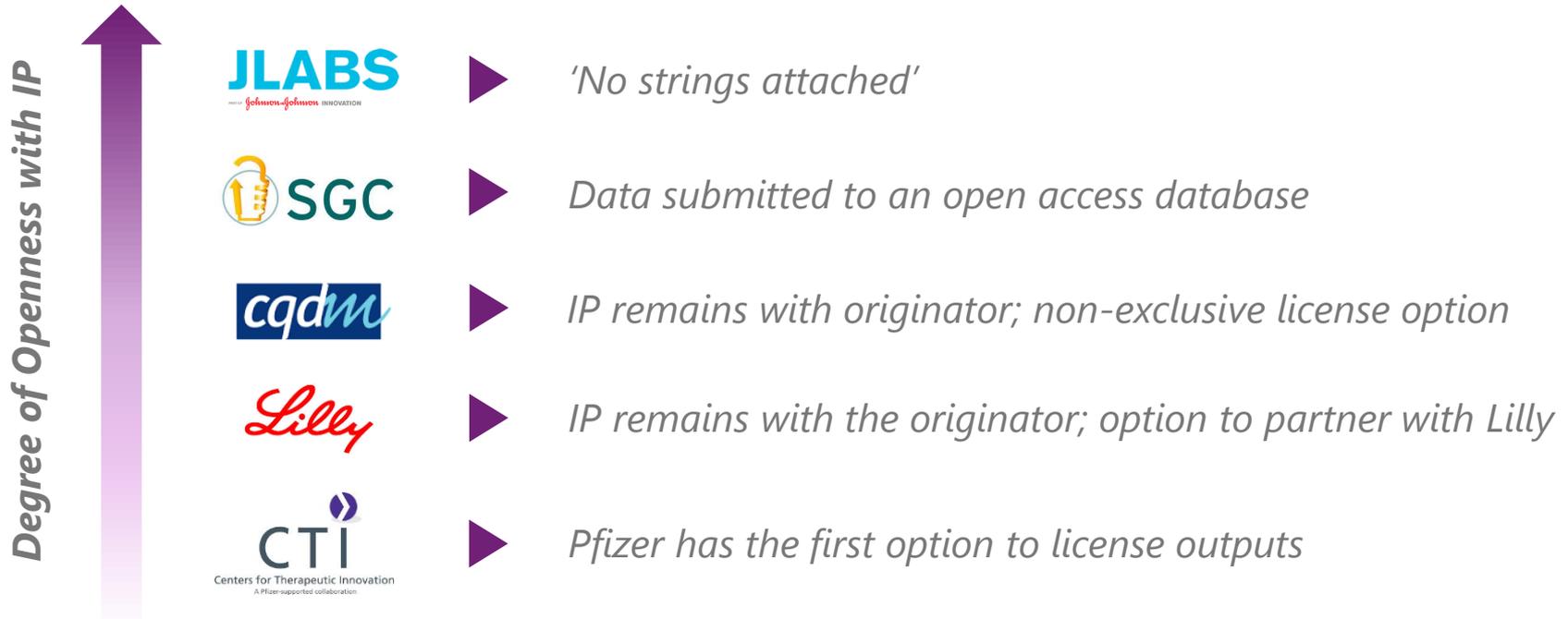
Supports drug access for high-risk populations



- » Provisions are **adaptable** on a 'case-by-case' basis
- » IMI plays a **neutral, advisory role** during IP negotiations
- » Policy was **co-developed** by and **applies equally** to all partners

Promotes collaboration, innovation and economic growth

Case study: 'Open innovation' partnership models exhibit a diverse array of IP and knowledge/technology access policies



There is appetite to experiment with different models that support integration of industry with academic/NFP collaborators.

Conclusions

- » Spectrum of PDPs has widened, ranging from addressing 'market failures' in neglected diseases to broadly de-risking product development
- » Governance, communication and IP/access strategies have diversified—with a common predisposition toward openness and collaboration
- » Experimentation with flexible partnership models to advance healthcare solutions in an environment of constrained resources will continue



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