Discussion paper

IP and access to publicly funded research results in health emergencies

Publicly funded international R&D projects

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WIPO

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Executive summary

During the COVID-19 pandemic, the public sector provided significant funding to accelerate the research and development (R&D) of health products. Globally, however, unequal and inequitable access to such products has prompted questions on how placing strategic conditions on public funding could improve access to the fruits of R&D. An important aspect of this issue is how conditions on intellectual property (IP) can contribute to achieving public policy goals such as affordable pricing and reliable supply. To facilitate the discussion, the present report provides empirical evidence of conditions adopted by publicly funded international R&D projects directed at health emergencies, with a particular focus on IP management.

A review of the literature found that public funding plays a central and critical role in R&D for health emergencies. However, governments have largely taken national rather than international approaches to such investments, prioritizing funding for research entities based in their own territories. Numerous expert bodies have called for conditions on public R&D funding to be strengthened, both for emergencies and for day-to-day R&D, but limited action has been taken to date.

We present five case studies of publicly funded international R&D projects, based on publicly-available information and interviews with key informants. For each project, we review and analyze the operational model, IP management approach and progress to date. To the extent possible, sample contractual provisions are included in Annex II for reference and further analysis.

Research limitations include the confidentiality of many relevant documents. In addition, due to resource constraints, we conducted only one to two interviews per case study, which provide a limited picture of complex projects involving many parties and often lasting many years. Finally, by design this study is limited to R&D funded by more than one government, so the findings omit important lessons that could be drawn from the wide range of national governments that fund R&D for health emergencies (including but not limited to COVID-19). There is a need for more in-depth research and greater transparency of information to improve empirical understanding of practices in this area.

We found that global access conditions have become an established feature of international publicly funded R&D initiatives for health emergencies, particularly those with an objective to ensure access in low and middle-income countries (LMICs). Such conditions are generally developed and negotiated by an intermediary entrusted with public funds (such as the Coalition for Epidemic Preparedness Innovations, Unitaid, FIND, the Global Antibiotic Research and Development Partnership or the World Health Organization), rather than by the government funders themselves. Some public funders are nevertheless involved in the high-level decision-making of the intermediary organizations they funded, including in the development of IP policies and access policies. Findings are summarized in the table below.

Table i: Summary of conditions on funding and IP management in the case studies

Case	Funding conditions of major government donors	Funding conditions of Intermediaries* and IP management
Case 1: Partnership between CEPI and Novavax on a COVID-19 Vaccine (NVX-CoV2373)	No policy requiring global access conditions. Donors are involved in high-level decision-making through the Investor Council.	CEPI: Public Health License; affordable pricing; supply commitment to a global distribution entity; publication of data and study results.

Case 2: Partnership between Unitaid and FIND on hepatitis C diagnostics	No policy requiring global access conditions. Donors are involved in high-level decision-making through donor representatives on the Executive Board.	Unitaid: General conditions to ensure access; FIND: retained rights, affordable pricing and supply commitment in target countries; publication of data and study results.
Case 3: Partnership between GARDP and Entasis on a novel antibiotic for gonorrhea (zoliflodacin)	No policy requiring global access conditions. Donors are involved in high-level decision-making through the Board and the Donor Partnership Advisory Committee.	GARDP: Control of technology in 168 countries; affordable and sustainable pricing; publication of data and study results.
Case 4: International collaboration on an Ebola vaccine (rVSV-ZEBOV)	No policy requiring global access conditions.	WHO: Retained IP rights; real time supply commitment and favorable pricing, designed to maximize access for affected populations, including in particular for affected Gavi eligible countries; mechanism for equitable distribution of the vaccine in the event demand exceeds available supply; publication of data and study results.
Case 5: Partnership between Baylor and Biological E on a COVID-19 vaccine (Corbevax)	No global access conditions attached to the public funding.	No intermediaries; open-science approach, no patents, sharing of know-how with vaccine developers in low and middle-income countries.

* Intermediaries refers to organizations that received public funding from national governments and invested such funding in R&D initiatives. Intermediaries in our sample were intergovernmental organizations or non-profit organizations.

The monopolies that IP rights can provide are not a major incentive for innovation in disease areas with limited commercial markets, including neglected diseases, antimicrobial resistance and pathogens with pandemic potential (prior to any major outbreak). Nevertheless, IP conditions are an important subset of funding conditions, as funders must manage IP in a manner that facilitates access to the fruits of research. The case studies illustrate how the impacts of IP, particularly patents and know-how, vary by the nature of the product – i.e., whether it is a vaccine, a therapeutic product or a diagnostic product – and the technologies used in making the product. Some organizations have guiding policies on IP and/or access policies outlining the principles of the organization's IP management approach, including general support for the open sharing of data and study results, non-exclusivity and technology transfer.

A common feature across the case studies was that funders sought to retain sufficient control over IP to reach a range of project objectives. In some cases, funders retained ownership of IP, whereas in others they secured rights through licenses while grantees retained ownership. In either case, funders leveraged those rights to ensure advances in product development, data-sharing, affordable pricing, sustainable supply, technology transfer and/or follow-on research. The ability to revoke a license or to license a third party to use IP was an important enforcement tool for funders.

There is no global legal framework governing publicly funded international R&D, but there is a collection of practices captured in contracts agreed between collaborating parties. Conditions generally fall into four categories, with practices varying within categories, as summarized in Table ii. The case studies demonstrated that contracts need to be tailored to the specificities of each R&D project, including the type of product, technology and disease area, and that some flexibility is needed to achieve the goal of global equitable access.

Table ii: Summary of types of conditions on funding and IP management

Type of condition	Discussion
Open-access publication of data and study results	Widely implemented by science research funders.
Pricing commitments	Pricing commitments are a common feature of the case studies we examined, but the specific form of such commitments varies. Examples include: cost-plus pricing subject to external audit; pricing constraints in certain countries (such as some or all low and middle- income countries); affordable pricing in the public sector or to certain procurement agencies; competitive market-based pricing through non-exclusive licensing and/or technology transfer; and fair pricing to sustain supply by ensuring a reasonable profit margin.
Supply commitments	Supply commitments are also a common feature of the case studies, with varied approaches. Examples include: a commitment to register in certain countries (such as some or all low and middle- income countries); minimum or priority supply levels, either to certain groups of countries, for an international stockpile, or to certain international procurement agencies; and volume guarantees.
Funder retention of some IP and other rights	Funders retain certain rights, either ownership of any foreground IP or a license to certain IP rights, including background IP. The purpose of retaining such rights can be to ensure product-development advances and/or grantee compliance with pricing, supply or other commitments. If the grantee does not fulfill its obligations, the funder can terminate a license, require the transfer of data and technology to a third party, and/or grant a license to a third party, for example. The funder can also require that foreground and/or background IP be made available for follow-on research.

In addition to the four categories outlined above, there is the cross-cutting issue of transparency, which is of important intrinsic value for the good governance of public funds. Increased transparency of funding agreements and conditions is also critical for at least three instrumental reasons. First, transparency facilitates the *ex-post* monitoring of contract implementation, which is important in an issue area in which the devil is often in the details and full effective implementation cannot be assumed. Second, health emergency R&D can take place over many years and involve a relay race among many different organizations (such as governments, small and large companies, intermediaries and others). Transparency enables each party to see and understand conditions and access commitments that should be carried through, even when a technology changes hands multiple times. Third, transparency helps to build a community of practice, as practitioners can see what others have been able to do.

There appears to be a slowly growing trend toward greater transparency, but it is still far from the norm. Further research is needed to determine which funding conditions are most effective and in which circumstances, and doing so requires transparency in agreements. The World Intellectual Property Organization could play an important role in supporting further efforts to collect data on funding conditions and IP management in publicly financed R&D.

In conclusion, we have found that conditions on public funding of international R&D projects are a regularly used and effective tool to ensure better access to the fruits of publicly funded R&D for health emergencies. The cases demonstrate that conditions can be applied with sufficient flexibility to tailor contracts to specific projects. However, there are no clear international norms or rules for doing so. Rather, the global governance of public funding for R&D in health emergencies remains *ad hoc* and piecemeal, with ample room for improved coherence and effectiveness across organizations.

To ensure better preparedness for future health emergencies and a swift response during an emergency, pre-negotiated common approaches among public funders and similar conditions on funding could deliver more impactful, equitable access to products. Agreeing on international

norms would create a more level playing field. As demonstrated in the CEPI-Novavax case, the leverage of one funder trying to obtain access commitments from a private firm can be undermined when another funder offers financing with fewer strings attached. There is an important opportunity for governments to agree on an international standard in ongoing negotiations at WHO toward a pandemic accord. In parallel, major public and philanthropic research funders could jointly articulate and commit to placing public interest conditions on their funding for emergency R&D. These are proven, practicable steps toward greater equity in access to health technologies in future health emergencies.

List of abbreviations

ACT-A	Access to COVID-19 Tools Accelerator
AMR	Antimicrobial resistance
BPS	BioProtection Systems Corporation
C-TAP	COVID-19 Technology Access Pool
cAg RDT	core antigen rapid diagnostic test
CEPI	Coalition for Epidemic Preparedness Innovations
DNDi	Drugs for Neglected Disease initiative
EIDs	emerging infectious diseases
EMA	European Medicines Agency
FDA	Food and Drug Administration (of the United States of America)
FIND	Foundation for Innovative New Diagnostics
GARDP	The Global Antibiotic Research & Development Partnership
Gavi	Gavi, the Vaccine Alliance
HCV	Hepatitis C virus
HEAD-Start	Hepatitis C Elimination through Access to Diagnostics
IP	Intellectual property
IPRs	Intellectual property rights
LMICs	low and middle-income countries
NIAID	National Institute of Allergy and Infectious Diseases (of the United States of America)
NML	National Microbiology Laboratory (of the Public Health Agency of Canada)
PHAC	Public Health Agency of Canada
R&D	Research and Development
SII	Serum Institute of India
TCH-CVD	Texas Children’s Hospital Center for Vaccine Development
TRIPS Agreement	Agreement on Trade-Related Aspects of Intellectual Property Rights
UNICEF	United Nations Children’s Fund
WHO	World Health Organization
WTO	World Trade Organization

Introduction and methodology

During the COVID-19 pandemic, the public sector provided significant funding to accelerate the research and development (R&D) of health products to meet public health needs. Despite this, globally unequal and inequitable access to such products have prompted questions on how access to the fruits of publicly funded R&D can be ensured. An important aspect of this issue is how intellectual property (IP) can be managed in publicly funded R&D projects to support public policy goals.

To facilitate the discussion, we prepared this paper to present empirical evidence from IP management policies and practices adopted by publicly funded international R&D projects. The projects included in this paper received funding from more than one government and involved collaboration between R&D bodies from more than one country, including but not limited to universities, pharmaceutical companies and product-development partnerships. (R&D projects funded by a single government are covered by other studies in this series.) The study focuses on R&D projects for the development of health products (including vaccines, diagnostic products and therapeutic products) for diseases that have caused or have the potential to cause a national, regional or global health crisis.

To provide background information, we primarily drew on literature syntheses and research reports on relevant topics, including public funding for pharmaceutical R&D, biosecurity R&D, new business models for pharmaceutical R&D, and technology transfer and affordable access in funding agreements for biomedical R&D. We then conducted case studies of five publicly funded international R&D projects based on publicly available data and semi-structured interviews with key informants. For each project, we collected information on the funding sources, operational models, IP policies and practices, and the accessibility of the final results, with particular emphasis on how IP was managed to achieve the project goals. Contracts are generally confidential, but some changes of practice in recent years to increase the transparency of agreements allowed us to obtain some information on relevant provisions. To the extent possible, we included contractual provisions between different parties involved in the projects or sample provisions used by the parties. These are provided either in the main text or in Annex II and can be used for reference purposes and further analysis. We conducted the study during the first half of 2023.

Based on the literature review and case studies, we propose potential approaches to enable globally equitable access to the fruits of publicly funded international R&D collaborations and better preparedness for future health emergencies.

Major limitations to the research include the confidentiality of many relevant documents. In addition, due to resource constraints, we conducted only one to two interviews per case study, allowing us to provide only a limited picture of complex projects involving many parties and often lasting many years. Finally, by design this study is limited to R&D funded by more than one government, so the findings omit important lessons that could be drawn from the wide range of national governments that fund R&D for health emergencies (including but not limited to COVID-19). There is a need for more in-depth research and greater transparency of information to improve empirical understanding of practices in this area.

Background

Public funding for emerging infectious diseases and international R&D on COVID-19

Pharmaceutical innovation is fundamentally a public-private enterprise, with the public and private sectors generally both making important contributions to R&D.[1] Public funding plays a particularly critical and pronounced role in areas with limited market incentives, such as emerging infectious diseases (EIDs), which are usually considered threats to security but have limited commercial markets until a large-scale outbreak occurs.[2]

Evidence suggests that, traditionally, public funding for EIDs focused primarily on stimulating invention for national interests, with little attention to ensuring global availability or access to the technologies that result from R&D.[3] The creation of the Coalition for Epidemic Preparedness Innovations (CEPI) in 2017 was a marked shift, as CEPI aimed not only to accelerate the development of vaccines for EIDs but also to make them globally accessible when an outbreak occurred.[4]

During the COVID-19 pandemic, most public funding for R&D was directed toward national R&D efforts. In other words, governments largely funded research entities based in their own territories.[5] CEPI was one of the few organizations we identified that received multi-government funding to invest directly in R&D projects.[6]

In addition to direct investment, public funding also went into a few pull mechanisms to accelerate and de-risk the R&D of vaccines, particularly advanced purchase agreements concluded before a product was given emergency authorization by a regulator. Some governments also supported R&D projects coming to fruition by facilitating regulatory cooperation or the scaling up of manufacturing capacities.[7]

In April 2020, a multistakeholder group launched the Access to COVID-19 Tools Accelerator (ACT-A), a dedicated platform to fast-track the development of diagnostics, therapeutics and vaccines, and to pool demand for and procurement of such technologies. The co-convening agencies of ACT-A included CEPI; the Foundation for Innovative New Diagnostics (FIND); Gavi, the Vaccine Alliance (Gavi); the Global Fund to Fight AIDS, Tuberculosis and Malaria; and Unitaid.[8] A fair amount of public funding for COVID-19 at the international level went into supporting activities under ACT-A, which operated through pooled procurement, and grants for

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[1] Swaminathan S. *et al.* (2022), Reboot Biomedical R&D in the Global Public Interest, *Nature* 602, 207-210. Available at: https://www.nature.com/articles/d41586-022-00324-y.
[2] Sunyoto T. *et al.* (2020), Biosecurity Research and Development (R&D), Knowledge Network on Innovation and Access to Medicines. Available at: https://www.knowledgeportalia.org/biosecurity-r-d.
[3] Moon S., Ruiz A., and Vieira M. (2021), Averting Future Vaccine Injustice, *New England Journal of Medicine* 385, 193-196. Available at: https://www.nejm.org/doi/full/10.1056/NEJMp2107528.
[4] Ibid.
[5] Global Health Centre (2021), COVID-19 Vaccines R&D Investments, Graduate Institute of International and Development Studies. Available at: https://www.knowledgeportalia.org/covid-19-vaccine-r-d-funding.
[6] Another organization identified was the International Vaccine Institute, a non-profit international organization established in 1997 by the United Nations Development Programme to make vaccines available and accessible for vulnerable populations in developing countries.
[7] Moon S., Ruiz A., and Vieira M. (2021), idem.
[8] ACT-Accelerator, Areas of Work. Available at: https://www.act-a.org/areas-of-work (accessed in April 2023).

low and middle-income countries (LMICs).[9] In general, these mechanisms were not involved in the public funding of R&D or IP management.

As we found relatively few cases of multi-country financed R&D during the COVID-19 pandemic, we expanded our case study selection to incorporate international publicly financed R&D for products for actual or potential health emergencies, as explained further below.

Intellectual property, pharmaceutical innovation and global access to medicines

There is a long-running debate regarding the relationship between intellectual property, innovation and access to medicines.

On the one hand, intellectual property rights (IPRs) and other government-granted monopolies provide the private sector with incentives to develop medical products, as monopolies allow the seller to charge a relatively high price once the product reaches the market.[10] IP and other market-based incentives are a mainstay of the current pharmaceutical innovation system and have been credited with enabling significant technological innovation and medical progress.

This mechanism, however, has failed to stimulate adequate innovation for health conditions with insufficient market potential, including neglected diseases of poverty; antimicrobial resistance; most rare diseases; and EIDs.[11] EIDs can be highly profitable after an outbreak begins to spread, but such situations cannot be predicted with any specificity. Because of the high risks in investments in R&D for EIDs, such R&D has traditionally been funded by governments.[12]

On the other hand, IP monopolies can also create barriers to globally equitable access to medical products. As Sarnoff and Santos Rutschman noted, since at least the early 1990s, when members of the World Trade Organization negotiated the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement), concerns have arisen that IP would increase prices, artificially limit supply and impede follow-on innovation for health technologies.[13] These concerns escalated in the early 2000s, particularly regarding international abilities to assure affordable access to needed medicines in developing countries, including but not limited to drugs for HIV/AIDS.[14]

There have also been long-standing debates regarding the relationship between IP and technology transfer. On the one hand, IP systems can structure and thereby facilitate technology transfer through licensing and other contractual agreements, which may give IP holders greater confidence in sharing technologies.[15] On the other hand, IP rules can limit the dissemination of technology, particularly to developing countries, by strengthening the monopoly rights of IP

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[9] World Health Organization (2022), ACT-Accelerator Outcomes Report, 2020-2022 (incorporating Q3 Update). Available at: https://www.who.int/publications/m/item/act-accelerator-outcomes-report--2020-22.
[10] World Intellectual Property Organization, World Health Organization and World Trade Organization (2020), Promoting Access to Medical Technologies and Innovation - Intersections between Public Health, Intellectual Property and Trade (2nd Edition). Available at: https://tind.wipo.int/record/42806.
[11] *Ibid*.
[12] Sunyoto T. *et al.* (2020), *ibid.*
[13] Sarnoff J. and Santos Rutschman A. (forthcoming), Best Practices for Technology Transfer and Affordable Access Contract Terms of Funding Agreements for R&D, Clinical Trials, and Manufacturing: A Literature Review. (Available from the authors upon request.)
[14] *Ibid.*
[15] Mazzoleni R. and Nelson R. R. (1998), Economic Theories about the Benefits and Costs of Patents. *Journal of Economic Issues* 32, 1031–1052. Available at https://www.tandfonline.com/doi/abs/10.1080/00213624.1998.11506108.

holders who do not wish to transfer the technology they control, and by cutting off the "imitation to innovation" path that many industrialized countries followed when building their pharmaceutical and other industries.[16] Patent monopolies on earlier-stage research can also impede innovation by blocking follow-on research.[17]

During the COVID-19 pandemic, challenges in ensuring globally equitable access to health products have reignited debates on IPRs. Various efforts have been made to promote access to health products by addressing the IP aspects of the issue. For example, in May 2020, WHO and its partners launched the COVID-19 Technology Access Pool (C-TAP) to facilitate faster, equitable and affordable access to COVID-19 health products through voluntary licensing and patent pooling.[18] In June 2022, after two years of negotiation, the World Trade Organization's Ministerial Decision on the TRIPS Agreement provided a partial waiver to the obligation under Article 31(f) in relation to patents for COVID-19 vaccines.[19] The Medicines Patent Pool negotiated voluntary licenses with patent holders on three COVID-19 therapeutics, which authorized competitive generic production, and co-launched with WHO and other partners the mRNA vaccine technology transfer hub in South Africa.[20] The management of IP in publicly financed R&D projects, however, remains a relatively under-studied aspect of the debate.

Conditionality in public funding agreements

Before the COVID-19 pandemic, there had been discussions on how the public sector could use its funding to ensure better access to the results of R&D, in particular, whether there should be conditions attached to the funding agreements and, if so, what kind of conditions could lead to optimal results.

The idea of attaching conditions to public funding was raised in several United Nations reports. The WHO Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property (2011) recommended promoting public access to the results of government-funded research by requiring publication in open-access databases and further dissemination of inventions and know-how.[21] In its final report in 2012, the WHO Consultative Expert Working Group on Research and Development: Financing and Coordination suggested that "funders or research organizations should adopt licensing conditions that permit non-exclusive licensing or prescribe a low target price for a product, especially where the public sector has funded most of the R&D". Four years later, the United Nations Secretary General's High-level Panel on Access to Medicines, in its final report, mentioned explicitly that data-sharing and data access should be conditions for public funding and recommended the adoption of other conditions to promote

[16] *Ibid.*; See also Sell S. K. (1998), *Power and Ideas: North-South Politics of Intellectual Property and Antitrust*, New York: SUNY Press; Chang, H.-J. (2002), *Kicking Away the Ladder: Development Strategy in Historical Perspective*, London: Anthem Press.
[17] Feldman, R. C. *et al.* (2021). Negative innovation: when patents are bad for patients, *Nature Biotechnology* 39, 914-916. Available at https://doi.org/10.1038/s41587-021-00999-0.
[18] WHO COVID-19 Technology Access Pool. Available at: https://www.who.int/initiatives/covid-19-technology-access-pool (accessed in April 2023).
[19] World Trade Organization (2022), Ministerial Decision on the TRIPS Agreement (WT/MIN(22)/30 WT/L/1141). Available at https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/WT/MIN22/30.pdf&Open=True.
[20] Medicines Patent Pool. COVID-19 and pandemic preparedness, prevention and response. Available at https://medicinespatentpool.org/covid-19 (accessed in June 2023).
[21] Vieira M. and Moon S. (2019), Public funding of pharmaceutical R&D, Knowledge Network on Innovation and Access to Medicines. Available at: https://www.knowledgeportalia.org/public-funding-r-d.

availability and affordability.[22] The report of the WHO Fair Pricing Forum in 2017 suggested that "governments should attach conditions to research funding so that public funding is explicitly taken into account in pricing discussions and the results are made publicly available".[23]

In a literature review conducted by Sarnoff and Santos Rutschman on contractual terms and associated policies for contracts for funding the R&D of medical products, particularly those needed to respond to international public health crises, it was found that the literature was largely silent on contractual provisions governing technology transfer and affordable access in funding agreements for medical R&D, clinical trials and manufacturing.[24] In their report on the public funding of pharmaceutical R&D, Vieira and Moon explained that in the few pieces of literature addressing the conditionality of public funding, the main condition identified was related to the dissemination of the findings in open-access publications. They noted that research by Van Hecke and Gils had shown that, in Belgium, few access conditions were placed on products generated from publicly funded research and no conditions existed to ensure that medicines were available and affordable. They also noted that a report by Stopaids and Global Justice Now had concluded that there were no safeguards to ensure that medicines derived from publicly funded R&D in the United Kingdom of Great Britain and Northern Ireland were accessible and affordable. In addition, they drew attention to a report by Tomlinson and Low in which they noted that funding agreements in South Africa typically included provisions on access and affordability, but that such provisions were not always clear and were sometimes hard to enforce.[25]

Although Sarnoff and Santos Rutschman found relatively little literature on the contractual terms of funding agreements, they noted that there was extensive literature on licensing agreements. They summarized the specific contractual provisions of licensing agreements described in the literature into the following categories: (1) geographical scope provisions on background and foreground technology, IP and data; (2) authorizations and restrictions on background and foreground technology, IP and data; (3) progress and control provisions; (4) access, supply, market segmentation and pricing provisions for foreground products; (5) reserved rights provisions; (6) warranties, liabilities and indemnities; (7) transparency of negotiated contracts; and (8) government contract regulation provisions (Bayh-Dole Act, Federal Acquisitions Regulation Defense Federal Acquisitions Regulation Supplement).[26] Most of these categories also arise in the funding agreements in our case studies.

[22] United Nations Secretary-General's High-level Panel on Access to Medicines (2016), Promoting innovation and access to health technologies".
[23] World Health Organization (2017), Fair Pricing Forum: 2017 Meeting Report.
[24] Sarnoff J. and Santos Rutschman A., *ibid.*
[25] Vieira M. and Moon S., *ibid.*
[26] Sarnoff J. and Santos Rutschman A., *ibid.*

Case studies

To supplement these findings from the literature, we conducted case studies of five publicly funded international R&D projects, providing examples of how conditions on such funding and IP management shape access and other outcomes.

The five selected cases had various collaboration models and different approaches to IP management. We included one case for each type of technology: vaccines, diagnostics and therapeutics. To the extent possible, we selected projects that were at relatively advanced stages of development, i.e., the final product was available or in late-stage development at the time of the research, to assess access to benefits.

We examined four internationally funded global health initiatives – CEPI, FIND, Unitaid and GARDP – and their respective approaches to IP through three R&D projects: the partnership between CEPI and Novavax on a COVID-19 vaccine (NVX-CoV2373), the partnership between Unitaid and FIND on hepatitis C diagnostics, and the partnership between GARDP and Entasis on a novel antibiotic for gonorrhea (zoliflodacin). In these cases, public funding from different governments was pooled into the initiatives, which acted as intermediaries to fund, facilitate or implement R&D projects through partnerships with drug developers/manufacturers. We reviewed the IP policies of these initiatives and how the policies were implemented in the respective projects.

Additionally, we selected two international R&D projects under different collaboration models: international collaboration on an Ebola vaccine (rVSV-ZEBOV) and partnership between Baylor and Biological E on a COVID-19 vaccine (Corbevax), which received public funding to various extents. The Ebola vaccine was the result of decades of collective efforts from both the public and private sectors. The public sector funded and led the R&D of the vaccine, which was developed to be used during health emergencies. The R&D of the Corbevax vaccine provided an example of how open science could be adapted to the development of vaccines during health emergencies.

Table 1: Key characteristics of case studies

Case	Intermediary organizations	Government funders of the intermediary organizations or projects*	Developers	Product	Phase of development[27]
1	CEPI	CEPI has more than 30 government funders, including Norway, Japan, Germany, the United Kingdom and Saudi Arabia.	Novavax	COVID-19 vaccine	Approved by regulatory authority
2	Unitaid, FIND	The government funders of Unitaid are Brazil, Chile, France, Japan, Norway, the Republic of Korea, Spain, and the United Kingdom. The government funders of FIND include Australia, Germany, Canada, the United States of America, Saudi Arabia, the Kingdom of the Netherlands, the United Kingdom and Switzerland.	Not available (work for hire)	Hepatitis C diagnostics	Prototype stage
3	GARDP	The government funders of GARDP include Germany, United Kingdom,	Entasis	Antibiotic for drug-	Phase 3 clinical trial finished

[27] As of May 2023.

		Japan, the Kingdom of the Netherlands, Switzerland and South Africa.		resistant gonorrhea	
4	WHO	The main government funders of the Ebola vaccine project of the World Health Organization between 2014 and 2016 included Canada, the United Kingdom, the United States of America and Norway.	Newlink, Merck	Ebola vaccine	Approved by regulatory authority
5	No Intermediary	The main government funders were the United States of America and India.	Baylor, Biological E	COVID-19 vaccine	Approved by regulatory authority

* The countries listed are the government funders of the organization; some funders of an organization may not have supported the specific project examined in the case study.

Each case had its unique features, but approaches to conditionalities on R&D funding generally fell into four broad categories:

1. Open-access publication of data and study results
2. Pricing commitments
3. Supply commitments
4. Funder retention of some IP and other rights

Case study 1: Partnership between CEPI and Novavax on a COVID-19 vaccine (NVX-CoV2373)

Launched at the World Economic Forum 2017 in Davos, CEPI describes itself as an "innovative global partnership between public, private, philanthropic, and civil society organizations" with the mission "to accelerate the development of vaccines and other biologic countermeasures against epidemic and pandemic threats so they can be accessible to all people in need."[28] It acts as a system integrator, funneling resources from public and philanthropic organizations to fund the R&D initiatives of research institutions and companies working on its target pathogens.[29] As of 2023, CEPI has received financial support from more than 30 governments, the private sector and major philanthropic foundations.[30]

CEPI was one of the co-leading organizations of COVAX, the vaccines pillar of the ACT-A. CEPI managed a COVID-19 vaccine portfolio, which covered a diverse range of vaccine candidates. As of May 2023, three CEPI-supported vaccines had been granted the WHO Emergency Use Listing, among which was the NVX-CoV2373 vaccine developed by Novavax, a biotechnology company in the United States of America, with funding primarily from the public sector.[31]

The Novavax vaccine was among the first few vaccine candidates supported by CEPI at the beginning of 2020. CEPI provided up to 388 million US dollars to Novavax to support the preclinical studies, phase 1 and phase 2 clinical trials, and technology transfer to manufacturing partners in Europe and Asia for large-scale production of the vaccine. Among the funding that CEPI received, 142.5 million dollars was in the form of a forgivable loan that was recoverable on product sales.[32] These investments were directly linked to equitable access commitments.

In addition to the investment by CEPI, Novavax also received funding from the US Government through the Operation Warp Speed project and the US Department of Defense.[33]

Operational model and the IP policy of CEPI

In the partnership between CEPI and Novavax, public funding was channeled through CEPI to Novavax, and any conditionalities on access were negotiated between CEPI and Novavax. Although the public funders of CEPI are not engaged directly in any negotiation process, they are involved, through the Investors Council, in high-level decision-making for the strategies and investment plans of CEPI. The Investors Council must approve any single investment proposed

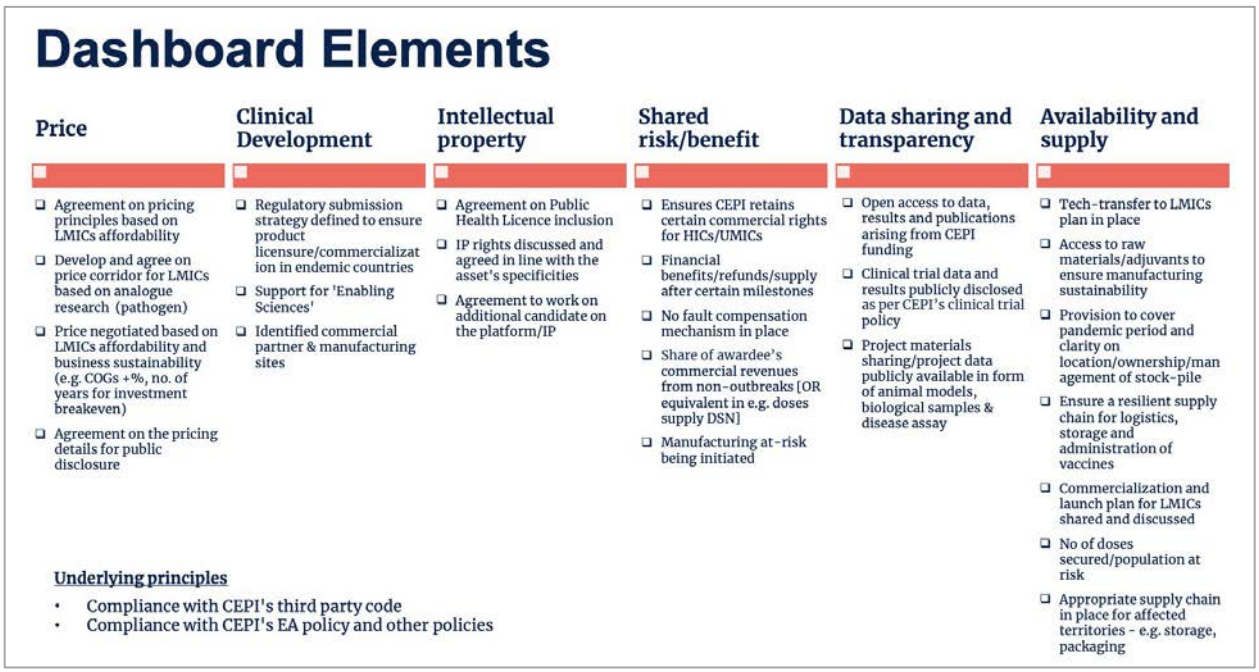
[28] Coalition for Epidemic Preparedness Innovations, Why we exist - about us. Available at: https://cepi.net/about/whyweexist/ (accessed in March 2024).
[29] Moon S. *et al.* (2022), New business models for pharmaceutical research and development as a global public good: considerations for the WHO European Region, World Health Organization. Available at: https://apps.who.int/iris/handle/10665/361752.
[30] Coalition for Epidemic Preparedness Innovations, Support CEPI - Get involved. Available at: https://cepi.net/get_involved/support-cepi/ (accessed in March 2024).
[31] Coalition for Epidemic Preparedness Innovations, COVAX: CEPI's response to COVID-19 – COVAX. Available at: https://cepi.net/covax/ (accessed in March 2024).
[32] Coalition for Epidemic Preparedness Innovations (2021), CEPI statement: CEO welcomes emergency use listing for NVX-CoV2373. Available at: https://cepi.net/news_cepi/cepi-statement-ceo-welcomes-emergency-use-listing-for-nvx-cov2373/ (accessed in March 2024).
[33] Novavax (2023), All in to protect global health: 2022 annual report. Available at: https://novavax.widen.net/s/q2c5wwtmnb/novavax_2022_annual_report_web (accessed in March 2023).

by the CEO for funding that exceeds 100 million US dollars.[34] Four members of the Investors Council also currently serve on the Board, the primary governing body of CEPI.[35]

The mission of CEPI is to advance the R&D of vaccines for pathogens of pandemic potential and enable equitable access for LMICs. Shortly after CEPI was founded, it developed the Equitable Access Policy, which required all contracts to have a baseline of provisions related to pricing, IP management, risk and benefit sharing, and data-sharing and transparency. The policy was revised one year later to be more flexible, with implementation of the policy to be negotiated individually with each grantee.[36]

In addition, CEPI developed the Equitable Access Dashboard based on the Equitable Access Policy and the practical learning of CEPI. The Dashboard was designed to help guide discussions with funding applicants. The Equitable Access Dashboard was integrated into discussions with awardees during the grant contract negotiation process.[37]

Figure 1: CEPI Equitable Access Dashboard[38]



In general, CEPI does not take ownership of any IP generated through a project, except potentially through the options under a "Public Health License". Under CEPI's agreements, the awardee

[34] Coalition for Epidemic Preparedness Innovations (2022), CEPI Investors Council terms of reference. Available at: https://cepi.net/wp-content/uploads/2022/12/CEPI-Investors-Council-Terms-of-Reference_07-December-2022_FINAL.pdf.
[35] Coalition for Epidemic Preparedness Innovations, Who we are. Available at: https://cepi.net/about/whoweare/ (accessed in April 2024).
[36] Coalition for Epidemic Preparedness Innovations (2022), Equitable access review of CEPI's COVID-19 vaccine development agreements. Available at: https://cepi.net/wp-content/uploads/2022/05/EQUITABLE-ACCESS-REVIEW-OF-CEPIS-COVID-19-VACCINE-DEVELOPMENT-AGREEMENTS_Final_April-2022.pdf; Moon S. *et al.*, *op. cit.*
[37] Coalition for Epidemic Preparedness Innovations (2021), Equitable Access Dashboard. Available at: https://cepi.net/wp-content/uploads/2022/05/CEPI-Equitable-Access-Dashboard.pdf.
[38] *Ibid.*

grants CEPI a worldwide and royalty-free Public Health License, on the condition that CEPI may only exercise the rights when certain conditions are triggered, for example, if the awardee fails to advance the development of the product. As of April 2023, at the time of our research, CEPI had not exercised such rights under the Public Health License, although there had been cases in which CEPI had disagreements or experienced challenges in its partnerships with developers.[39] CEPI usually sought other mechanisms before exercising the Public Health License, including reaching an agreement with the awardee on additional work packages or project expansion.[40]

CEPI takes a relatively flexible approach to IPRs, allowing them to be "discussed and agreed in line with the asset's specificities".[41] CEPI also aims to reach an agreement with the awardee regarding additional products that could be developed on a platform technology.[42] In addition, CEPI promotes data-sharing and transparency, including the sharing of clinical data and study results.

Despite flexibilities in the implementation of the Equitable Access Policy, CEPI reports that conditionalities attached to its funding discouraged some companies from collaborating with the organization at the beginning of the COVID-19 pandemic, in early 2020.[43] In an external review commissioned by CEPI on how equitable access had been achieved through its COVID-19 vaccine development agreements, it was also found that "CEPI enjoyed the most favorable equitable access terms with newer and smaller biotechnology companies, including manufacturers, and universities."[44]

IP management in the partnership between CEPI and Novavax

The funding agreement of CEPI with Novavax reflects the Equitable Access Policy of CEPI, and the conditions for exercising the Public Health License were detailed in the contract.

In the agreement, "Intellectual Property" was defined as the "intangible property rights claiming or covering the discoveries, inventions, and materials as well as the works of authorship made by Awardee under the Project, such as copyrights, patents, and trademarks."[45]

The ownership of project results and IP was defined in Clause 5 of the agreement. Regarding background IP, the agreement states that Novavax "shall retain ownership of its intellectual property existing as of the Effective Date or developed or acquired independently of the Project during the term of this Agreement… and licenses to third party intellectual property secured prior to the Effective Date." It also states that the agreement shall not be "deemed to assign any ownership in, or grant a license to, CEPI with respect to such Background IP."

In the partnership, Novavax owns all project results, or "foreground IP". Novavax also has the right, but not the obligation, to seek IP protection at its own cost, and, upon request, should

[39] Interview with Richard Wilder, former CEPI General Counsel.
[40] *Ibid.*
[41] Coalition for Epidemic Preparedness Innovations (2021), *ibid.*
[42] *Ibid.*
[43] Interview with Richard Wilder, former CEPI General Counsel.
[44] Coalition for Epidemic Preparedness Innovations (2022), Equitable Access Review of CEPI's COVID-19 Vaccine Development Agreements. Available at: https://cepi.net/wp-content/uploads/2022/05/EQUITABLE-ACCESS-REVIEW-OF-CEPIS-COVID-19-VACCINE-DEVELOPMENT-AGREEMENTS_Final_April-2022.pdf.
[45] COVID-19 vaccine funding agreement between CEPI and Novavax, available at: https://ghiaa.org/wp-content/uploads/2021/05/Novavax%E2%80%93-CEPI-Outbreak-Response-to-Novel-Coronavirus-COVID-19-Funding-Agreement.pdf.

provide updates to CEPI regarding the status of IPRs sought and obtained.[46] While doing so, Novavax needs to ensure that all other conditions regarding equitable access are met.

In Clause 13.4 of the agreement, the awardee agrees to grant a "worldwide and royalty free Public Health License to CEPI, on the condition that CEPI may only exercise the rights granted under the Public Health License in the event that: (a) CEPI is not in material breach of its obligations under [the] Agreement; (b) the Project Vaccine has achieved licensure with at least one regulatory body (including but not limited to emergency licensure); and (c) one or more of the triggers set out in Clause 13.5 has occurred." The Clause also allows CEPI to sublicense the project results, enabling IP and background IP included in the Public Health License. The license is also non-exclusive. [47]

Clause 13.5 establishes certain triggers that allow CEPI to exercise the public health license, including: (1) if Novavax declines to participate in the additional work package or project expansion requested by CEPI; (2) if CEPI and Novavax agree that Novavax shall not be able to perform the activities under the agreed work package; and (3) if Novavax is in material breach of the agreement and the equitable access plan and has not cured such breach within an agreed notification period.[48]

When the Public Health License is exercised, CEPI may require Novavax to reach an agreement directly with an assigned "Trusted Collaborator" or "Trusted Manufacturer" and to transfer all relevant data and materials to the latter.[49] The Public Health License gives CEPI important leverage with the grantee, but it is not automatic, nor does it seem sufficient to guarantee access. For example, Novavax must agree that it is unable to perform the contracted activities in order for CEPI to activate the license. In addition, making use of the license depends on the availability and willingness of alternative developers or manufacturers, which is not always guaranteed.[50] Other kinds of public interest safeguards most likely need to be developed for health emergencies.

In addition to the Public Health License clauses, there are several clauses aimed at ensuring the accessibility of the project results. For example, Clause 14 is dedicated to Equitable Access, which it defines as the availability of a project vaccine first to the population at risk, at affordable prices, when and where such vaccines are needed" (Clause 14.1). The Clause commits Novavax to supply and sell the vaccine to a global allocation and purchasing entity endorsed by CEPI at least during the Pandemic Period (Clause 14.3). The pricing of the product "shall be reasonable to achieve Equitable Access for populations in need" as well as providing "an appropriate return on investment for vaccine manufacturers that make ongoing supply commercially sustainable" (Clause 14.6). The agreement also requires Novavax to make available and disseminate the project data, materials and results in a timely manner (Clause 9).[51]

Progress of the Project

In December 2021, NVX-CoV2373 was granted an Emergency Use Listing by the WHO, a prerequisite for inclusion in the COVAX portfolio. In Europe, the vaccine was manufactured by Novavax and sold under the trade name Nuvaxovid, and in India, the vaccine was manufactured by the Serum Institute of India (SII) under a no-cost license from Novavax, with the trade name

[46] *Ibid.*
[47] *Ibid.*
[48] *Ibid.*
[49] *Ibid.*
[50] Interview with Richard Wilder, former CEPI General Counsel.
[51] COVID-19 vaccine funding agreement between CEPI and Novavax, *ibid.*

Covovax.[52] As of May 2023, Nuvaxovid had been approved for emergency use in 41 countries or economies, and Covovax (owned by SII) had been approved by 6 countries or economies.[53]

In February 2021, Novavax signed a memorandum of understanding with Gavi to commit a cumulative volume of 1.1 billion doses of NVX-CoV2373 to COVAX, which included 350 million doses manufactured at facilities directly funded by CEPI investments through an advanced purchase agreement with Gavi.[54] The remainder would be provided by the SII under a separate agreement with Gavi. Novavax also agreed to provide additional doses if SII could not materially deliver the expected vaccine doses. In February 2022, CEPI published a summary of the equitable access provisions contained in its COVID-19 vaccine development agreements and stated that "the price has been determined in negotiations between Novavax and Gavi on behalf of the COVAX Facility, consistent with Novavax's commitment to CEPI's equitable access policy".[55] Novavax also signed an advanced purchase agreement with Canada, in which it stated that "all rights, title and interests in, to and under any intellectual property that relate to the Product are and shall remain the sole and exclusive property of Novavax."[56] Novavax also agreed to "work in good faith with the Government and/or the private sector of Canada to establish a mutually beneficial contract manufacturing relationship(s) in Canada for one or more Novavax vaccines."[57]

The agreement between Novavax and Gavi, however, was terminated in November 2022, and there is an ongoing arbitration hearing to determine whether Novavax must refund a payment of approximately 700 million US dollars that it received through the advanced purchase agreement with Gavi.[58] According to Gavi, Novavax was not able to make any dose available to COVAX from the contractually stipulated sites after more than 18 months of signing the agreement.[59] This was reportedly due to difficulties in the roll-out of the vaccine on Novavax's side, including issues related to manufacturing quality issues (NVX-CoV2373 was Novavax's first marketed product).[60]

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[52] World Health Organization (2021), WHO lists 9th COVID-19 vaccine for emergency use with aim to increase access to vaccination in lower-income countries. Available at: https://www.who.int/news/item/17-12-2021-who-lists-9th-covid-19-vaccine-for-emergency-use-with-aim-to-increase-access-to-vaccination-in-lower-income-countries (accessed in March 2023). The supply and license agreement between Novavax and SII is publicly available at: https://www.sec.gov/Archives/edgar/data/1000694/000155837020013462/nvax-20200930xex10d4.htm.

[53] United Nations Children's Fund, COVID-19 market dashboard. Available at: https://www.unicef.org/supply/covid-19-market-dashboard (accessed in April 2023).

[54] The agreement is available at: https://www.sec.gov/Archives/edgar/data/1000694/000155837020013462/nvax-20200930xex10d4.htm.

[55] Coalition for Epidemic Preparedness Innovations (2022), Enabling equitable access to COVID-19 vaccines: summary of equitable access provisions in CEPI's COVID-19 vaccine development agreements. Available at: https://cepi.net/wp-content/uploads/2020/12/Enabling-equitable-access-to-COVID19-vaccines-v8-14-February-2022.pdf.

[56] The agreement is available at: https://www.sec.gov/Archives/edgar/data/1000694/000100069421000004/exhibit1037.htm. See, for example, sections 7 and 15.

[57] See section 15.

[58] Novavax (2022), Termination of COVID-19 vaccine purchase agreement with Gavi. Available at: https://ir.novavax.com/Termination-of-COVID-19-Vaccine-Purchase-Agreement-with-Gavi (accessed in April 2023).

[59] Erman, M. (2023), Novavax raises doubts about ability to remain in business, shares fall, Reuters. Available at: https://www.reuters.com/business/healthcare-pharmaceuticals/novavax-raises-doubts-about-its-ability-remain-business-2023-02-28/ (accessed in April 2023).

[60] Reuters (2022), Gavi rejects Novavax's claim on COVID vaccine deal breach. Available at: https://www.reuters.com/business/healthcare-pharmaceuticals/gavi-says-it-is-not-breach-novavax-vaccine-deal-2022-11-22/ (accessed in April 2023).

Novavax, on the other hand, claimed that it terminated the agreement due to Gavi's "failure to purchase the contracted COVID-19 vaccines before the end of 2022".[61]

In terms of actual deliveries, around 59 million doses of the Novavax vaccines (produced both by Novavax and SII) were sold, almost all to high-income countries via bilateral agreements.[62]

It is worth noting that, in August 2020, Novavax filed a patent application with the US Patent and Trademark Office covering its NVX-CoV2373 spike protein vaccine under the name "Coronavirus vaccine formulations". The patent was filled in August 2020 and granted in March 2021 for a protection period of 20 years, with an anticipated expiration date of August 2040.[63]

Discussion

CEPI was the intermediary that tied access conditions to public funding channeled to Novavax. Any IP generated through the project would be owned and managed by Novavax, unless the "Public Health License" was triggered, which did not actually occur in this case. There were also conditions on pricing, supply commitment, and data sharing, among others, to facilitate equitable access to the final product.

By the time the vaccine became available, many alternatives were already on the market. Relatively few countries purchased the Novavax vaccine, and relatively few doses were purchased. The agreement between CEPI and Novavax contains a number of important access provisions, but a fuller understanding requires seeing it within the broader context of R&D on COVID-19 vaccines. As mentioned earlier, smaller companies and academic institutions that rely more heavily on public funding to advance R&D projects seem more likely to accept public interest conditions, and these are also the very entities that conduct the most EID R&D prior to an outbreak.[64] During a large-scale pandemic, however, larger firms are an important asset with their ability to conduct multi-country clinical trials, rapidly scale-up manufacturing and prepare regulatory dossiers.

Nevertheless, some larger and more experienced firms did not accept CEPI funding (and its conditions). They did, however, benefit from large-scale contracts from other public funders, notably the US R&D grants and European Commission advanced purchase commitments, neither of which had global access conditions tied to them. Even relatively small firms like Moderna, which accepted an initial CEPI grant in January 2020 for COVID-19 vaccine development, subsequently obtained access to large-scale US Government funding that is not tied to global access conditions. If large public funders do not tie access conditions to their funding, entities like CEPI are at a competitive disadvantage, as firms can decline CEPI funding in favor of other funders that have fewer strings attached. The absence of access conditions also weakens the leverage that governments have to persuade their own grantees to work toward public interest goals, such as by transferring technology to accelerate manufacturing scale-up. For example, despite having supported Moderna with over 1 billion US dollars of public R&D funding (excluding tens of billions more in vaccine purchases), the US Government was unable to persuade the firm

[61] Novavax (2022), *ibid.*
[62] Global Health Centre (2022), COVID-19 vaccine access, Knowledge Network on Innovation and Access to Medicines.
[63] Coronavirus vaccine formulations, Patent No. US 10,953,089 B1. Available at: https://patentimages.storage.googleapis.com/4d/45/36/e8872e9b08700a/US10953089.pdf.
[64] Sunyoto T. *et al.*, *op cit.*

to share the messenger ribonucleic acid (mRNA) technology that had been developed in part by US Government researchers and with US Government funds.[65, 66]

Smaller, less-experienced firms such as Novavax may be more willing to accept access conditions, since they rely more heavily on public funding to survive and may have a harder time obtaining other sources of investment. Novavax was one of the later companies to complete the development of a COVID-19 vaccine, obtaining its WHO Emergency Use Listing about one year after Pfizer and Moderna received their first regulatory approvals. By late 2021, a number of other COVID-19 vaccines had already been supplied or committed for supply worldwide, including those developed by AstraZeneca, Johnson & Johnson, Sinopharm and Sinovac, leaving little demand for a newer entrant such as Novavax. Further, as noted above, possible manufacturing difficulties at Novavax led to delays, ultimately resulting in very little supply to developing countries, whether directly or via COVAX.

In addition, if governments retain IP rights to R&D that they have funded or require grantees to transfer technology in the event of a health emergency, they can support global access objectives by making such IP or technology transfer obligations available to entities like CEPI or directly to other manufacturers.

> *"The contract negotiations we had with [companies] would have been significantly facilitated if we could have turned to the public sector investors for IP rights in the basic technology they funded and assigned or licensed exclusively to the companies."*[67] *(Interview with Richard Wilder, former CEPI General Counsel)*

Commitments by all governments to apply access conditions to public R&D funding would create a more level playing field. Similarly, government commitments to retain sufficient control over IP that they have funded and to manage it in a pro-access manner would enable more equitable access to technologies in health emergencies.

[65] Lalani H. S. *et al.* (2023), US public investment in development of mRNA covid-19 vaccines: retrospective cohort study, *British Medical Journal* 380.
[66] Nolen, S and Stolberg S. G. (2021), Pressure grows on US companies to share Covid vaccine technology, Available at: https://www.nytimes.com/2021/09/22/us/politics/covid-vaccine-moderna-global.html.
[67] Interview with Richard Wilder, former CEPI General Counsel.

Case study 2: Partnership between Unitaid and FIND on hepatitis C diagnostics

The Hepatitis C Elimination through Access to Diagnostics (HEAD-Start) project was managed by FIND and funded by Unitaid. The project ran from 2016 to 2020 and was aimed at improving the diagnosis of hepatitis C virus (HCV) by making it more affordable and more widely available to those in need.[68]

Hepatitis C is a liver infection spread through contact with blood from an infected person. For more than half of the people infected, HCV is a long-term, chronic infection that can result in serious health problems, including cirrhosis and liver cancer. People with chronic hepatitis C often have no symptoms. When symptoms appear, they are often a sign of advanced liver disease.[69] According to the WHO, viral hepatitis caused 1.34 million deaths in 2015, a figure comparable to the number of deaths caused by tuberculosis and higher than the number of deaths caused by HIV. Globally, there were an estimated 71 million people with chronic HCV infection in 2015,[70] with 80% living in LMICs.[71]

From 2013 to 2015, the US Food and Drug Administration (FDA) approved a number of direct-acting antiviral drugs for treating hepatitis C, which largely improved the cure rates from the 40 to 65 per cent range to the 90 to 95 per cent range and significantly changed the treatment landscape.[72] With this breakthrough, the elimination of hepatitis C became within reach. In 2015, the global response to viral hepatitis entered a new phase, as the UN placed combating hepatitis on the international agenda as part of efforts to achieve the 2030 Agenda for Sustainable Development.[73]

Significant challenges remained, however, in identifying persons with HCV infection, especially in LMICs. In 2015, when the HEAD-Start project was conceptualized, screening for HCV was costly, and there were no quality-assured rapid diagnostic tests (RDTs) on the market. Confirmatory testing was not only expensive, but also limited to centralized laboratories and available only in a few major cities across LMICs. As a result, people remained undiagnosed and unlikely to benefit from the revolutionary treatments.[74]

In 2016, Unitaid approved a grant to FIND for the HEAD-Start project, which was designed to develop urgently needed new tools for HCV diagnosis and to build the evidence base that would drive a change in global implementation guidelines and national policies that would support the

[68] HEAD-Start, FIND. Available at: https://www.finddx.org/what-we-do/projects/head-start/ (accessed in February 2023).
[69] Centers for Disease Control and Prevention, Hepatitis C information. Available at: https://www.cdc.gov/hepatitis/hcv/index.htm (accessed in June 2023).
[70] World Health Organization (2017), Global Hepatitis Report, 2017. Available at: https://apps.who.int/iris/bitstream/handle/10665/255016/9789241565455-eng.pdf;jsessionid=88D37B524E58E17A8BE07A78C030669E?sequence=1.
[71] Razavi H. (2020), Global epidemiology of viral hepatitis. *Gastroenterology Clinics* 49(2), 179-189.
[72] World Health Organization, *ibid.*
[73] *Ibid.*
[74] Unitaid (2021), Unitaid investments in Hepatitis C – portfolio evaluation and end of grant evaluations of the FIND HEAD-Start and Coalition PLUS grants. Available at: https://unitaid.org/assets/Final_Report_HCVEvaluation_CEPA.pdf.

scale-up of HCV management.[75] As of December 2020, when the project was completed, 26.9 million US dollars had been disbursed by Unitaid to FIND.[76]

Unitaid is a global health initiative hosted by the WHO. It is described as "a global health agency engaged in finding innovative solutions to prevent, diagnose, and treat diseases more quickly, cheaply, and effectively, in low and middle-income countries".[77] Its work includes funding initiatives to address major diseases and cross-cutting areas. Since its establishment in 2006, Unitaid has received about 3 billion US dollars in contributions from donors, which include the Governments of France, the UK, Norway, Brazil, Spain, the Republic of Korea and Chile, as well as the Bill & Melinda Gates Foundation. A key source of income for Unitaid is the solidarity levy on airline tickets implemented by France, which was later adopted by a number of other Unitaid donor countries, including Cameroon, Chile, Congo, Guinea, Madagascar, Mali, Mauritius, the Niger and the Republic of Korea (Unitaid also receives multi-year contributions from its other government and philanthropic donors).[78]

FIND is a global non-profit organization with the mission of ensuring equitable access to reliable diagnoses around the world. It describes itself as "connecting countries and communities, funders, decisionmakers, healthcare providers and developers to spur diagnostic innovation and make testing an integral part of sustainable, resilient health systems."[79] Its major government donors in 2021 included the Governments of Germany, Switzerland, Canada, Norway, the United Kingdom, Saudi Arabia and the Kingdom of the Netherlands. It also received significant funding from the Global Fund to Fight AIDS, Tuberculosis and Malaria; Unitaid; and the Bill & Melinda Gates Foundation.[80]

The HEAD-Start project had multiple components and focused on two core areas: (1) R&D to expand the number of diagnostics to screen and test for HCV, and (2) demonstration studies to show the operational feasibility and effectiveness of implementing decentralized, integrated and simplified HCV testing models, treatment and care in LMICs.[81] In the following discussion, we will focus primarily on the R&D component of the HEAD-Start project, particularly on the development of a core antigen rapid diagnostic test (cAg RDT) for HCV. Such a test was considered a potential game changer, as it could allow the decentralization and simplification of HCV diagnosis, making it accessible to more marginalized populations.[82]

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[75] HEAD-Start, FIND, *ibid.*
[76] New diagnostics for hepatitis C and HIV co-infection, Unitaid. Available at: https://unitaid.org/project/new-diagnostics-hepatitis-c-hiv-co-infection/#en (accessed in February 2023).
[77] Unitaid (2023), About us. Available at: https://unitaid.org/news-blog/unitaid-and-the-global-health-innovative-technology-fund-strengthen-ties-to-improve-access-to-critical-health-tools/#en (accessed in March 2024).
[78] *Ibid.*
[79] FIND (2023), About us. Available at: https://www.finddx.org/about-us/ (accessed in March 2023).
[80] KPMG (2022), Report of the statutory auditor to the Board of the Foundation for Innovative New Diagnostics (FIND), Geneva. Available at: https://www.finddx.org/wp-content/uploads/2022/12/20221208_financial_statement_2021_FV_EN.pdf.
[81] Unitaid (2021), *ibid.*
[82] *Ibid.*

Operational model and guiding frameworks on IP management

The project was governed by a two-level structure: public funding went through Unitaid to FIND, then through FIND to a contract developer (work-for-hire), to whom FIND provided milestone payments.[83]

Donors did not attach access conditions to the funding provided to Unitaid, but they are involved in other mechanisms to oversee the use of their funding.[84] For example, there are donor representatives in the Executive Board, the decision-making body of Unitaid, which consists of 13 members, including seven representatives nominated from each of the five founding countries and two other donor countries.[85]

In general, Unitaid adopts an approach to IP that facilitates access. In its Constitution, the organization expresses its support for using legal instruments to reduce the prices of products when IP poses barriers:

> *"Unitaid will base its price reduction strategy on market competition. Where intellectual property barriers hamper competition and price reductions, it will support the use by countries of compulsory licensing or other flexibilities under the framework of the Doha declaration on the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement and Public Health, when applicable."*[86]

In the Unitaid Strategy 2023-2027, IP was identified as one of the two key areas revealed by the COVID-19 pandemic in which Unitaid could make a difference. The Strategy stated that "intellectual property protections were exposed as an obstacle to equitable access to health products" and that "going forward, intellectual property interventions will remain a Unitaid priority.[87] According to the Strategy, Unitaid will strive to establish an enabling environment for access, including IP management and regulation to accelerate more secure and potentially more affordable and faster access to health products.[88] Unitaid also operates under WHO rules and policies, including the WHO Policy on Open Access, which addresses access to publicly funded research.[89]

The approach adopted by FIND is based on the specific IP situation of diagnostics. According to FIND:

> "In vitro *diagnostics such as blood tests have four components: biomarkers, capture reagents, detection reagents, and sensing technology. Biomarkers are generally considered a 'product of nature' and are therefore not eligible for patent protection and/or deemed to be novel inventions. Capture reagents come in many forms, and some may be novel and patentable, such as monoclonal antibodies. Many detection reagents are already generic and commoditized products, and the most widely used detection reagents*

[83] Interview with Karin Timmermans, Unitaid; Interview with Sergio Carmona, FIND.
[84] Interview with Karin Timmermans, Unitaid.
[85] Unitaid, Governance - About us. Available at: https://unitaid.org/about-us/governance/#en (accessed in April 2023).
[86] Unitaid (2018), Unitaid Constitution. Available at: https://unitaid.org/assets/UNITAID-Constitution-revised-version-15-June-2018.pdf.
[87] Unitaid (2022), Strategy 2023-2027. Available at: https://unitaid.org/assets/Unitaid_Strategy_2023-2027.pdf.
[88] *Ibid.*
[89] Interview with Karin Timmermans, Unitaid. See the Policy at https://www.who.int/about/policies/publishing/open-access.

are not novel and cannot be patented. Sensing technologies may qualify as patentable IP and are often where novelty arises in the diagnostics industry."[90]

The problem of patent thickets can arise where multiple patents cover different components of a diagnostic test. Freedom to operate and the facilitation of follow-on research are therefore important objectives of IP management. The R&D costs and timelines required to develop diagnostic tests are relatively low compared with that of drugs and vaccines, which makes it relatively more feasible for a public or non-profit funder to cover the full costs of development.

The Global Access Policy of FIND recognized IP management as a critical component of Global Access and outlined the approaches that FIND takes to IP management. The Policy is designed to meet four objectives: (1) to make high-quality diagnostic products available in LMICs, (2) to ensure the appropriateness of diagnostic solutions, (3) to seek diagnostic solutions that are affordable to LMICs, and (4) to shape pathways to accelerated adoption.[91] Under the third objective, FIND specifically outlined its IP management objectives, as follows:

- *"Provide required freedom to operate for the development, manufacture and commercialization of diagnostic products and services for its target diseases, pathogens, and populations.*
- *Minimize costs (e.g. from royalty burdens) to maximize affordability.*
- *Maximize freedom for others to use the outputs of FIND projects (including but not limited to: data, algorithms, reagents including cell lines, software, know-how) for follow-on research."*[92]

FIND forges partnerships with for-profit developers of *in vitro* diagnostics. The contracts with the developers require them to ensure that FIND-supported products are globally accessible.[93] IP management is therefore clearly agreed upon and contractually defined. Any pre-existing IPRs (background IP) should be identified, to the extent possible, at the start of the project, and the potential partner should conduct a freedom-to-operate analysis to minimize potential encumbrances. Any IPRs generated in a FIND-supported project (foreground IP) should be managed according to the objectives listed above. Further, FIND "will not enter into projects where it is clear that IP may pose an insurmountable barrier to research, affordability or availability in LMICs."[94]

In terms of IP ownership: "where necessary to achieve its broader mission, FIND might take an ownership position or accept rights that are limited to use only for target diseases, pathogens, or non-profit purposes. Generally, FIND will not take an exclusive position on IP rights."[95]

The Global Access Policy also states that FIND may change its position on IP "in the light of changing business models, for example, the open diagnostic platform concept, to ensure the executability of potentially cutting-edge models."[96]

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[90] FIND (2022), Diagnostics & intellectual property. Available at: https://www.finddx.org/wp-content/uploads/2022/12/20221201_rep_factsheet_dx_ip_FV_EN.pdf.
[91] FIND (2018), Global Access Policy. Available at: https://www.finddx.org/wp-content/uploads/2022/12/20221124_pol_global_access_FV_EN_jul_2021.pdf.
[92] *Ibid.*, paragraph 3.4.a.
[93] *Ibid.*, paragraph 3.4.b.
[94] *Ibid.*
[95] *Ibid.*, paragraph 3.4.b.
[96] *Ibid.*, paragraph 3.4.d.

In addition to IP management, there are many other components in the strategies of Unitaid and FIND to enable access. Such components include but are not limited to commitments on pricing, knowledge-sharing, and sustainable product supply.

IP management and conditionalities

The IP management frameworks of Unitaid and FIND were adapted in the context of the HEAD-Start project. The contractual provisions between Unitaid and FIND and between FIND and the contract developer were not publicly available and were not available to the research team at the time of writing.

In the grant by Unitaid to FIND, there were generic terms regarding access to the final product. According to Unitaid, the uncertainty of R&D projects prevented it from adding detailed conditions to the grant. When the project was initiated, the candidate was still in early-stage development. It was unclear what the new product would be like or what would be the best approach to IP management.[97] However, Unitaid engaged with FIND closely throughout the project to ensure that access conditions were reflected in the collaboration of FIND with the developer. The agreement with FIND granted Unitaid the right to review future contracts that FIND would negotiate with developers before finalization.[98] At later stages of the project, when FIND negotiated access terms with its partners, Unitaid actively participated in the process and had detailed discussions with FIND on what the access commitments should be.[99]

In 2018, FIND went through a process of selecting partners to develop a new rapid lateral flow assay platform for detecting the HCV cAg. FIND owned the IP (largely technical know-how, not patents) on the product with the intention of transferring the technology for manufacture in LMICs.[100] After the feasibility stage was completed in 2019, FIND planned to continue product optimization and development activities with two product-development partners and sought a partner with the commercial capability to bring the HCV cAg test to the market.[101]

In its call for partners for the global commercialization of the cAg RDT, FIND offered to provide support, including an exclusive license (royalty-free in LMICs), for the manufacture and commercialization of the developed cAg test. According to the preliminary key terms set out in the call, IP rights to the HCV cAg RDT would be held by FIND, and the manufacturer would operate under an exclusive license, in exchange for which FIND would require appropriate pricing commitments in LMICs.[102] FIND has the right to file patent applications and to obtain and maintain patents, but at the time of writing, FIND has not prosecuted or secured any patents or other exclusive rights on the cAg RDT product, for which the IP mostly comprises technical know-how.[103]

It was also stipulated in the call for proposals that FIND may select more than one commercialization partner for the product if the access requirements agreed in the contract were not met in LMICs. If the manufacturer was unable to develop the product or commercialize it to

[97] Interview with Karin Timmermans, Unitaid.
[98] *Ibid.*
[99] *Ibid.*
[100] Interview with Sergio Carmona, FIND.
[101] Unitaid (2021), *ibid.*
[102] FIND (2019), Call for partners for the global commercialization of a core antigen rapid diagnostic test (cAg RDT) for hepatitis C virus (HCV) infection with a focus on low- and middle-income countries (LMICs). Available at: https://archive.finddx.org/wp-content/uploads/2019/08/2019-07-19-FIND-RFP-for-HCV-cAg-Commercialization-extension.pdf.
[103] Email from Maica Trabanco, FIND, 29 June 2023.

meet the access conditions, FIND may terminate the agreement and require the transfer of any know-how and IP to an alternative manufacturer.[104] Where relevant and appropriate, certain terms of the funding support from Unitaid would apply to the manufacturer, including access commitments, obligations to provide Unitaid with information on the progress of the commercialization of the product, and acknowledgment of Unitaid's funding support.[105]

The selected commercial partner would also have some obligations to ensure the availability and accessibility of the final product, including ensuring adequate manufacturing capacity to meet demand, promoting the product in the public sector in agreed target markets, and maintaining adequate inventory levels to meet demand.[106]

Progress of the Project

In 2019, FIND identified a suitable commercial partner, and the product was originally expected to be available for manufacturing by mid-2020. The emergence of COVID-19, however, derailed (at least temporarily) the HCV project. At the time of writing, no agreement had yet been signed between FIND and the potential manufacturer. In an independent end-of-grant evaluation of the HEAD-Start project commissioned by Unitaid, it was noted that a number of steps needed to be achieved before market entry. These steps included a commercialization agreement, clinical studies, manufacturing, performance qualification, demonstration projects and country roll-out. As the need for COVID-19 diagnostics has ramped down, the cAg RDT may be picked up again for final stage development.[107]

As mentioned earlier, the HEAD-Start project had many components, and the development of the cAg RDT was a relatively small portion of the project in terms of the funding allocated.[108] Although this specific product has not reached the market, the end-of-grant evaluation report noted that the FIND grant had "accelerated the development of HCV diagnostic products by providing incentives to diagnostic manufacturers to invest in HCV." The report also noted that the investment risk for some of the diagnostics under development was too high, since the returns that would be achieved were unclear due to uncertainty around the size of the market. It added that the funding provided by Unitaid through the FIND grant reduced the investment risk, thus providing an incentive for companies to invest in HCV diagnostics.[109]

Discussion

We are unable to assess empirically how well funding conditions improved access in this case, since development of the HCV cAg RDT has not yet been completed. Nevertheless, the case offers useful insights on how conditions attached to public R&D funding can operate.

Both Unitaid and FIND have general policies on IP to promote accessibility and affordability to the largest extent possible, and these policies guided the negotiation of contracts with the developer. From the perspective of Unitaid, attaching detailed conditions on IP management was not feasible in its grants due to the uncertainty of R&D projects at earlier stages. However, by reserving the right to review contracts between FIND and developers at later stages of the project, Unitaid found a channel to ensure that access conditions meeting its objectives would be included.

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[104] FIND (2019), *ibid.*
[105] *Ibid.*; Interview with Karin Timmermans, Unitaid.
[106] FIND (2019), *ibid.*
[107] Interview with Karin Timmermans, Unitaid.
[108] Idem.
[109] Unitaid, *op. cit*.

For FIND, the organization departed from its usual practice by choosing to retain IP ownership. It believed that doing so was necessary to exert control over the technology and ensure its downstream affordability and accessibility. The relatively small market size for health tools targeting LMICs means that public funding is often necessary to drive R&D. This funding creates an opportunity to ensure equitable access through the use of conditions.

Although HCV is a global disease, a rapid diagnostic test for HCV would have been of particular use in LMICs, where there is relatively limited access to the kind of centralized testing conducted at healthcare facilities in high-income countries. An affordable price, reliable supply and ease of use are all important considerations for such a diagnostic.

However, developing a diagnostic targeting LMIC contexts could raise challenges for finding an interested company, since profitability would likely be lower than for high-income country markets. One way to make the opportunity more attractive to a business is to offer market exclusivity while requiring affordability and supply commitments so that the objectives set by FIND are achieved. FIND was able to identify a commercial partner willing to accept these terms (at least in principle, since COVID-19 prevented finalization of an agreement). Depending on the nature of the product, a certain level of flexibility in the mix of access conditions may be needed.

> *"The ideal situation would be that a product would be available at an affordable price in all low and middle-income countries as quickly as possible. But in practice, it is very hard to achieve that. We try, either directly or indirectly via our grantee, to really push to get the most that we can achieve in terms of access. But what that is, and what we even focus on, very much varies from one product to another and from one situation to another."*[110] *(Interview with Karin Timmermans, Unitaid)*

In this case, paying the full costs of R&D with public funds allowed FIND to retain full control of the IP, and then to leverage that control to offer a manufacturer a monopoly in exchange for global access commitments. This mix of strategies underscores that there is not one single approach to achieving access to health products, but that conditions on public funding can be leveraged in different ways to do so.

[110] Interview with Karin Timmermans, Unitaid.

Case study 3: Partnership between Entasis Therapeutics and the Global Antibiotic Research and Development Partnership on a novel antibiotic for gonorrhea (zoliflodacin)

The Global Antibiotic Research and Development Partnership (GARDP) is a global public-private partnership created in 2016 by the WHO and the Drugs for Neglected Disease initiative (DNDi) to accelerate the development of and access to treatments for drug-resistant infections.[111] GARDP has received significant contributions from public funders, including the Governments of Germany, the United Kingdom, Japan, the Kingdom of the Netherlands, Switzerland, Monaco and Luxembourg, as well as the Republic and Canton of Geneva. It has also received funding from the Bill & Melinda Gates Foundation, the Wellcome Trust, Doctors Without Borders and other private foundations.[112] Antimicrobial resistance has been called "the silent pandemic", and efforts to develop new antibiotics may be particularly relevant for the broader question of health emergencies.

In 2017, GARDP signed an agreement with Entasis Therapeutics (Entasis) – a biopharmaceutical company in the United States of America that focuses on next-generation antibacterial therapeutics – under which they would co-develop zoliflodacin, a first-in-class antibiotic to treat gonorrhea infection in patients with limited treatment options.[113] Gonorrhea is a widespread sexually transmitted infection that is treatable in most cases with antibiotics. However, resistant strains of gonorrhea are on the rise all around the world, and the WHO has thus labeled *Neisseria gonorrhoeae* (the bacteria that causes gonorrhea) a priority pathogen in urgent need of new treatments.[114]

Before the partnership was created, the US National Institute of Allergy and Infectious Diseases (NIAID) sponsored the early clinical studies of zoliflodacin.[115] Zoliflodacin was developed initially in the AstraZeneca lab in Waltham, and a US patent application was filed entitled "compounds and methods for treating bacterial infections."[116] In 2015, Entasis was established as a spin-out from AstraZeneca and it took over the development of zoliflodacin. Before collaborating with GARDP, Entasis had already filed an investigational new drug application with the FDA and completed two phase-1 clinical trials and one phase-2 trial, with funding from NIAID.[117]

Following the positive results of the phase-2 trial, GARDP partnered with Entasis for the late-stage development of zoliflodacin, with GARDP fully funding and sponsoring the global phase-3

[111] Global Antibiotic Research and Development Partnership, About GARDP. Available at: https://gardp.org/about-gardp/ (accessed in February 2023).
[112] Global Antibiotic Research and Development Partnership (2022), Financial report 2021. Available at: https://gardp.org/publications/financial-report-2021/.
[113] Global Antibiotic Research and Development Partnership (2017), Entasis Therapeutics and the Global Antibiotic Research & Development Partnership to develop a new treatment for gonorrhea. Available at: https://gardp.org/entasis-therapeutics-and-the-global-antibiotic-research-development-partnership-to-develop-a-new-treatment-for-gonorrhea/ (accessed in February 2023).
[114] *Ibid.*
[115] National Institute of Allergy and Infectious Diseases (2018), Novel antibiotic shows promise in treatment of uncomplicated gonorrhea. Available at: https://www.nih.gov/news-events/news-releases/novel-antibiotic-shows-promise-treatment-uncomplicated-gonorrhea (accessed in March 2023).
[116] American Chemical Society (2020), Molecule of the week archive: zoliflodacin". Available at: https://www.acs.org/molecule-of-the-week/archive/z/zoliflodacin.html (accessed in April 2023).
[117] U.S Securities and Exchange Commission (2022), Entasis Therapeutics Holdings Inc. Form 10K Annual Report 2021. Available at: https://www.annualreports.com/HostedData/AnnualReportArchive/e/NASDAQ_ETTX_2021.pdf**Error! Hyperlink reference not valid.**.

trial, covering the costs of manufacturing and supplying the product candidate. GARDP also took the lead in phase-3 clinical development activities.[118]

Operational model and the IP Policy of GARDP

As of 2021, most of the funding that GARDP received was from public funders, with varying levels of flexibility.[119] Some funding was unrestricted, while other funding was restricted to one or a few programs. For example, the South African Medical Research Council provided restricted funding for the activities carried out by GARDP under its Sexually Transmitted Infections program in South Africa in 2018 and 2019.[120]

Like CEPI and Unitaid, the donors are not directly involved in the development of the IP policies or access conditions of GARDP.[121] Nevertheless, they are involved in the high-level decision-making of the organization through the Board and the Donor Partnership Advisory Committee, which have representatives of key donor countries.[122]

GARDP was incubated in DNDi until 2018, when GARDP was legally established as an independent entity.[123] Since it shares some of the goals of DNDi, namely of researching and developing new drugs that meet public health needs, GARDP adapted some of the policies of DNDi to its own needs, including the IP policy, which is guided by two principles: affordable drugs that are accessible in an equitable manner to patients who need them, and the development of drugs as public goods whenever possible.[124]

Under these principles, GARDP works to ensure that the results of the R&D it supports are disseminated as widely as possible and made available and affordable in LMICs. It takes a pragmatic approach toward IPRs, under the principle that when IP is generated through research projects sponsored by GARDP, it should be used to achieve the mission of GARDP.

> *"IP is conceived as a tool that potentially and hopefully is to be used to benefit patients, and not for generating profit."[125] (Interview with Jean-Pierre Paccaud, GARDP Director of Corporate Strategy)*

The IP policy of DNDi, which GARDP adopted, notes that patenting is likely to be "the exception rather than the rule", because of the costs involved, but acknowledges that it might seek patents "to strengthen [its] ability to ensure control of the development process and to negotiate with partners." DNDi also aims to ensure full freedom to operate, "including retaining the right to use the inventions on which IP is obtained for DNDi's further research, including with other partners". Last but not least, DNDi states in its IP policy that it "will not accept projects in which IP is obviously going to be an insurmountable barrier to follow-up research on behalf of DNDi and/or equitable

[118] *Ibid.*
[119] Global Antibiotic Research and Development Partnership (2022), *ibid.*
[120] *Ibid.*
[121] Interview with Jean-Pierre Paccaud, GARDP Director of Corporate Strategy.
[122] Global Antibiotic Research and Development Partnership, Governance. Available at: https://gardp.org/governance/ (accessed in March 2023).
[123] Global Antibiotic Research and Development Partnership, *ibid.*
[124] Moser D. *et al.* (2023), Striking fair deals for equitable access to medicines, *Journal of Intellectual Property Law & Practice* 18 (4), April, 323-335. Available at: https://doi.org/10.1093/jiplp/jpad025.
[125] Interview with Jean-Pierre Paccaud, GARDP Director of Corporate Strategy.

and affordable access" and underscores the importance of negotiations with the public and private sector being backed by advocacy support, either at the start of a project or as problems arise.[126]

In addition to IP policies, GARDP is currently developing an access policy that will be critical to allow GARDP to deploy its assets in the regions where it operates, as well as a publication policy and a policy on data-sharing and data access. It is expected that these policies will be publicly available once they have been finalized.[127] Regarding its study results, GARDP is committed to making the results of its research "easily and broadly accessible to the medical and scientific community" by contributing to open-source initiatives such as public databases and by publishing its research in open-access journals whenever possible. Furthermore, publications disclosing chemical structures and data not protected by confidentiality or privacy should be deposited into public databases, and, if applicable, this should be done in line with the GARDP Sharing of Clinical Trial Data Policy.[128]

IP management and conditionalities

The agreement between GARDP and Entasis provides an example of how IP was managed to ensure access in LMICs. At the time of the signing of the contract, GARDP had not yet become an independent legal entity. The start of the contract therefore states that the agreement is between Entasis and DNDi, with the latter described as "acting through [GARDP], which is currently hosted within DNDi".[129]

The agreement defines IP as "Patent Rights, Know How, copyrights, any improvements, enhancements or modifications to any of the foregoing and any rights or property similar to any of the foregoing in any part of the world, whether registered or not".[130]

When GARDP and Entasis negotiated the partnership, Entasis held patents on the active pharmaceutical ingredient for zoliflodacin. Under the agreement, to ensure global access, Entasis has granted GARDP an exclusive and royalty-free license for the use of zoliflodacin in the treatment of gonorrhea, with sublicensing rights for manufacturing worldwide and for the sale and/or distribution in 168 countries or territories, covering all LMICs and a few high-income countries. Entasis retained the rights in most high-income countries. In its announcement of the agreement, GARDP underlined the commitment of both parties to "affordable and equitable pricing in their respective territories.".[131] GARDP has the right to register and commercialize zoliflodacin in its territories upon approval of the drug, while Entasis retains all commercial rights to zoliflodacin in its territories.[132] In the agreement, commercialization was defined as "any

[126] Drugs for Neglected Diseases Initiative (2004), Intellectual property policy. Available at: https://dndi.org/wp-content/uploads/2024/02/Intellectual-Property-Policy.pdf
[127] Interview with Jean-Pierre Paccaud, GARDP Director of Corporate Strategy.
[128] *Ibid.*
[129] Gonorrhoea medication collaboration agreement between the Drugs for Neglected Diseases Initiative/Global Antibiotic Research and Development Partnership and Entasis, available at: https://ghiaa.org/wp-content/uploads/2022/06/DNDi_Entasis-Collaboration-Agreement-and-Novation.pdf.
[130] *Ibid.*
[131] Global Antibiotic Research and Development Partnership (2017), *ibid.*
[132] Global Antibiotic Research and Development Partnership (2019), GARDP and Entasis Therapeutics initiate global phase 3 trial of zoliflodacin, a first-in-class oral antibiotic for the treatment of gonorrhoea. Available at: https://gardp.org/gardp-and-entasis-therapeutics-initiate-global-phase-3-trial-of-zoliflodacin-a-first-in-class-oral-antibiotic-for-the-treatment-of-gonorrhoea/ (accessed in April 2023).

relevant activities directed to marketing, promoting, importing, distributing, offering for sale, having sold and/or selling a pharmaceutical product".[133]

Concerning any new IPRs generated during the development process, Entasis and GARDP have agreed to grant certain royalty-free exclusive licensing rights to each other, with the right to sublicense to enable registration and manufacturing. Both Entasis and GARDP will share the data needed to obtain marketing approval to register the drug. Once the product is developed, GARDP and Entasis will agree on a manufacturing and supply plan that considers access in consultation with the WHO or a similar agency.[134]

In the event that Entasis undertakes and funds additional efforts outside the scope of the current agreed-upon development plan for zoliflodacin in a territory assigned to Entasis, and such efforts lead to the creation of new IP, Entasis will have the right to file and maintain that IP.

Progress of the Project

As of May 2023, GARDP had finished phase-3 trials together with its partners. Once the data analysis is finalized, the study results will be published and the clinical trial data will be made as widely accessible as possible.[135] GARDP has also started initial discussions with potential partners to facilitate the commercialization and distribution of the product once it is developed, especially in countries where GARDP has previously established partnerships or had a presence, including in the countries in which phase 3 clinical trials were conducted. The need for the product in the country and the willingness of the national government to introduce the product are also considered when prioritizing where to launch the product.[136]

In terms of registration, zoliflodacin has been designated a "qualified infectious disease product" by the FDA and was awarded "fast track status".[137] An important factor that can lead to better global access in the partnership is the distribution of territories, with GARDP placed in charge of the distribution of the product in LMICs, which would not otherwise have been considered a priority.

Discussion

The partnership between GARDP and Entasis provides an informative example of an alternative approach to funding conditions and IP management to ensure access, compared with the more common approach of attaching conditions in funding agreements and relying on developers or manufacturers to ensure access in LMICs.

The partnership is mutually beneficial to both GARDP and Entasis. For a small biotech company, it could be challenging to find private investors to fund phase-3 clinical trials of zoliflodacin and to conduct them globally. GARDP sponsored and fully funded the phase-3 trials in exchange for the rights to commercialize and distribute the product in 168 countries once it had been developed. This funding allowed GARDP to obtain rights in all LMICs, which is notable, since commercial

[133] Gonorrhoea medication collaboration agreement between the Drugs for Neglected Diseases Initiative/Global Antibiotic Research and Development Partnership and Entasis, Available at: https://ghiaa.org/wp-content/uploads/2022/06/DNDi_Entasis-Collaboration-Agreement-and-Novation.pdf.
[134] *Ibid.*
[135] Interview with Jean-Pierre Paccaud, GARDP Director of Corporate Strategy.
[136] *Ibid.*
[137] Newman, Lori M et al. "Thorough QT Study To Evaluate the Effect of Zoliflodacin, a Novel Therapeutic for Gonorrhea, on Cardiac Repolarization in Healthy Adults." Antimicrobial agents and chemotherapy vol. 65,12 (2021): e0129221. doi:10.1128/AAC.01292-21

partners are often reluctant to give up rights in potentially profitable upper-middle-income countries. The geographic scope of the license also suggests that Entasis found it commercially sufficient to retain rights in high-income markets.

In addition, even if the product is successfully developed, a small firm such as Entasis is unlikely to have the capacity to distribute, market and conduct pharmacovigilance on the product in LMICs. By holding exclusive licenses for the product in its territories (covering all LMICs), including the right to sublicense to multiple manufacturers, GARDP will retain control over the product once it is developed, ensuring that the funding GARDP provided for the project could lead to better access in LMICs.

Reflecting on the negotiation of the contract, it was mentioned that "the mindset of partners" was one of the most important enabling factors for the establishment of such an innovative partnership. It was critical that the leadership of the company had the aspiration to ensure global access and the understanding of the urgency of addressing antimicrobial resistance issues in LMICs. In addition, there was a level of trust in GARDP to work for the public interest.[138]

The project is still in progress and subject to many potential challenges. For example, markets for novel antibiotics pose unique challenges, since the need to limit their use to mitigate the risk of resistance ("stewardship") implies lower sales volumes and profits, unless alternative payment models are implemented. It will be instructive to continue following the development of this case, in particular to see the role that public funding may need to play to enable both globally equitable access to a novel antibiotic and responsible stewardship to protect its efficacy for as long as possible.

[138] Interview with Jean-Pierre Paccaud, GARDP Director of Corporate Strategy.

Case study 4: International collaboration on an Ebola vaccine (rVSV-ZEBOV)

Ebola virus disease is a deadly disease with occasional outbreaks that occur mostly in Africa.[139] The 2013-2016 outbreak in West Africa was the largest and most complex Ebola outbreak since the virus was first discovered in 1976.[140] Despite the previous occurrence of several outbreaks in sub-Saharan Africa, there were no proven preventive or therapeutic products for the disease at the time of the West Africa outbreak. The development of such products was not considered particularly difficult scientifically, but there was not a big enough market to attract investment.[141] In 2005, almost 10 years before the West African outbreak, a group of Canadian researchers had developed a very promising vaccine candidate, a live attenuated recombinant vesicular stomatitis virus vaccine called rVSV-ZEBOV. However, the candidate was not picked up for further development until the 2013-2016 outbreak, when the international community stepped in to advance the vaccine R&D efforts as part of the emergency response.

In particular, the WHO led the clinical trials of rVSV-ZEBOV with Merck, the Ministry of Health of Guinea, Doctors Without Borders, and the Norwegian Institute of Public Health. This trial provided pivotal clinical data for the late-stage development of the vaccine, which eventually became the first Ebola vaccine approved for medical use to date upon its approval by the FDA and the European Medicines Agency in 2019.

Multiple efforts contributed to the R&D of the Ebola vaccines during the 2013-2016 outbreak, including those led by the US Government in partnership with GSK on a different vaccine candidate, and with Merck for other studies related to the rVSV-ZEBOV vaccine. This case study focuses on the coordinated efforts led by the WHO on the rVSV-ZEBOV vaccine.

R&D of the vaccine before the 2013-2016 outbreak

From 1997 to 2015, public sources contributed more than 73% of the total funding allocated to Ebola and other filovirus research.[142] The development of the rVSV-ZEBOV vaccine also relied heavily on public funding. The vaccine candidate was developed initially by researchers at the National Microbiology Laboratory (NML) at the Public Health Agency of Canada (PHAC), which is one of the health agencies overseen by the country's Minister of Health. The Governments of Canada and the United States of America provided the majority of the funding for the development of the candidate at NML.[143]

In July 2002, the Government of Canada, represented by the Minister of Health, filed a provisional US patent application entitled "Recombinant vesicular stomatitis virus vaccines for viral hemorrhagic fevers". The rVSV-ZEBOV patent was eventually granted by patent offices in

[139] What is Ebola Disease? Centers for Disease Control and Prevention. Available at: https://www.cdc.gov/vhf/ebola/about.html#:~:text=Ebola%20virus%20disease%20(EVD)%20is,%2C%20gorillas%2C%20and%20chimpanzees (accessed in March 2023).
[140] World Health Organization, Ebola virus disease. Available at: https://www.who.int/health-topics/ebola#tab=tab_1 (accessed in March 2023).
[141] Fisher W. and Syed T. (2022), Rethinking global pharmaceutical policy. Available at: https://ipxcourses.org/GPP/GPP_Diseases_6.pdf.
[142] Herder M., Graham J. and Gold R. (2020), From discovery to delivery: public sector development of the rVSV-ZEBOV Ebola vaccine, *Journal of Law and the Bioscience*, 7(1). Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8249092/#fn7.
[143] *Ibid.*

Europe (in 2010), the United States of America (2011) and Canada (2013).[144] An international patent application was also filed in 2003.[145]

Despite the patent application and the initially positive study results, there was no commercial interest in the vaccine. In 2005, PHAC entered into a material transfer agreement with the United States Army Medical Research Institute of Infectious Diseases for non-commercial research. In 2006, NML scientists secured some funding under the Canadian Safety and Security Program to advance the development of the vaccine candidate, including to manufacture 1,000 to 2,000 doses of a vaccine manufactured under current good manufacturing practices (cGMP-grade vaccine) for use in clinical trials. [146] In 2008, NML arranged the production of cGMP-grade rVSV-ZEBOV through a contract with IDT Biologika, a German contract research organization.[147]

In 2010, the Canadian government, acting through PHAC, granted the small US startup BioProtection Systems (BPS) a "sole, worldwide, revocable and royalty-bearing license to make, use, improve, develop and commercialize the technology in the field of prevention and prophylaxis against and treatment of [viral hemorrhagic fever] viruses in humans, whether before or after exposure." [148] In the agreement, there are also specific carve-outs protecting the ability of the Government of Canada to use the patented inventions under certain conditions. The carve-outs state that Canada will retain non-commercial rights in the technology, including rights to use and further develop the technology for educational and research purposes; BPS grants to Canada a non-exclusive and royalty-free license to make, use, manufacture and sell the viral hemorrhagic fever vaccine products developed by the company in the exercise of the licensed rights, in the event of a public health emergency; and BPS will make good faith efforts to collaborate with Canada on its basic R&D activities related to viral hemorrhagic fever virus vaccines.[149]

These rights also extend to any sublicensing deals between BPS and other parties.[150] After the licensing agreement, however, BPS failed to make substantial progress to bring the candidate forward. There were also various delays caused by IDT Biologika. In June 2013, IDT Biologika finally delivered 1,350 doses of the cGMP vaccine to NML. As the Canadian Safety and Security Program funding came to an end in 2014, NML planned to transfer the immunological assays, accompanying treatment protocols and the cGMP-grade vaccines entirely to BPS, which at that time had been acquired by another US biotech company, Newlink Genetics Corporation (Newlink).

R&D of the vaccine during the 2013-2016 outbreak

In 2014, with the Ebola outbreak in West Africa spiraling out of control, the WHO decided to coordinate international consultations and activities to facilitate R&D of countermeasures,

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[144] See the US patent at https://patentimages.storage.googleapis.com/e1/2c/4f/75603411c5fa14/US20060193872A1.pdf; the European patent at https://register.epo.org/application?number=EP03771017; and the Canadian patent at https://brevets-patents.ic.gc.ca/opic-cipo/cpd/eng/patent/2493142/summary.html.
[145] See https://patentscope.wipo.int/search/en/detail.jsf?docId=WO2004011488.
[146] Current good manufacturing practices are usually regulated and enforced by the relevant regulatory authorities, particularly the US Food and Drug Administration, to ensure proper design, monitoring and control of manufacturing processes and facilities.
[147] Herder M., Graham J. and Gold R., *ibid.*
[148] Sole licensing agreement for recombinant vesicular stomatitis virus vaccines for viral hemorrhagic fevers. Available at https://www.sec.gov/Archives/edgar/data/1126234/000104746911009169/a2206169zex-10_67.htm.
[149] *Ibid.*
[150] *Ibid.*

including vaccines.[151] In September 2014, the WHO identified three vaccine candidates that were sufficiently advanced for testing in humans immediately. The rVSV-ZEBOV vaccine was one of the two cGMP-grade vaccine candidates that were ready for use in clinical trials. However, the owner of the vaccine at that time, Newlink, did not have any experience or capacity to conduct clinical trials outside the United States of America. The WHO was therefore actively involved in crafting partnerships with several clinical trial sites to help advance the vaccine to phase 2 and in providing technical consultations for the design of phase-3 trials.[152]

Due to the limited capacities of Newlink to develop the vaccine in a timely manner, the WHO tried to find a vaccine manufacturer with the appropriate capacities to take the candidate forward to commercialization. It was difficult to find a manufacturer, because most companies were not interested in developing the vaccine, but the WHO was eventually able to facilitate a partnership between Merck and Newlink.[153]

In November 2014, Newlink granted Merck exclusive rights to the rVSV-EBOV vaccine, as well as any follow-on products, and received 50 million US dollars from the license.[154] In the agreement, PHAC retained non-commercial rights on the vaccine candidate, as agreed in the licensing agreement between PHAC and BPS (which later became Newlink).[155]

Meanwhile, using the cGMP-grade vaccines produced by IDT Biologika and donated by the Government of Canada, a WHO led consortium arranged and paid for the phase-1 clinical trials in the United States of America, Switzerland, Germany and Kenya in late 2014.[156] The Canadian Center for Vaccinology also began a phase-1 trial with funding from the Government of Canada.[157]

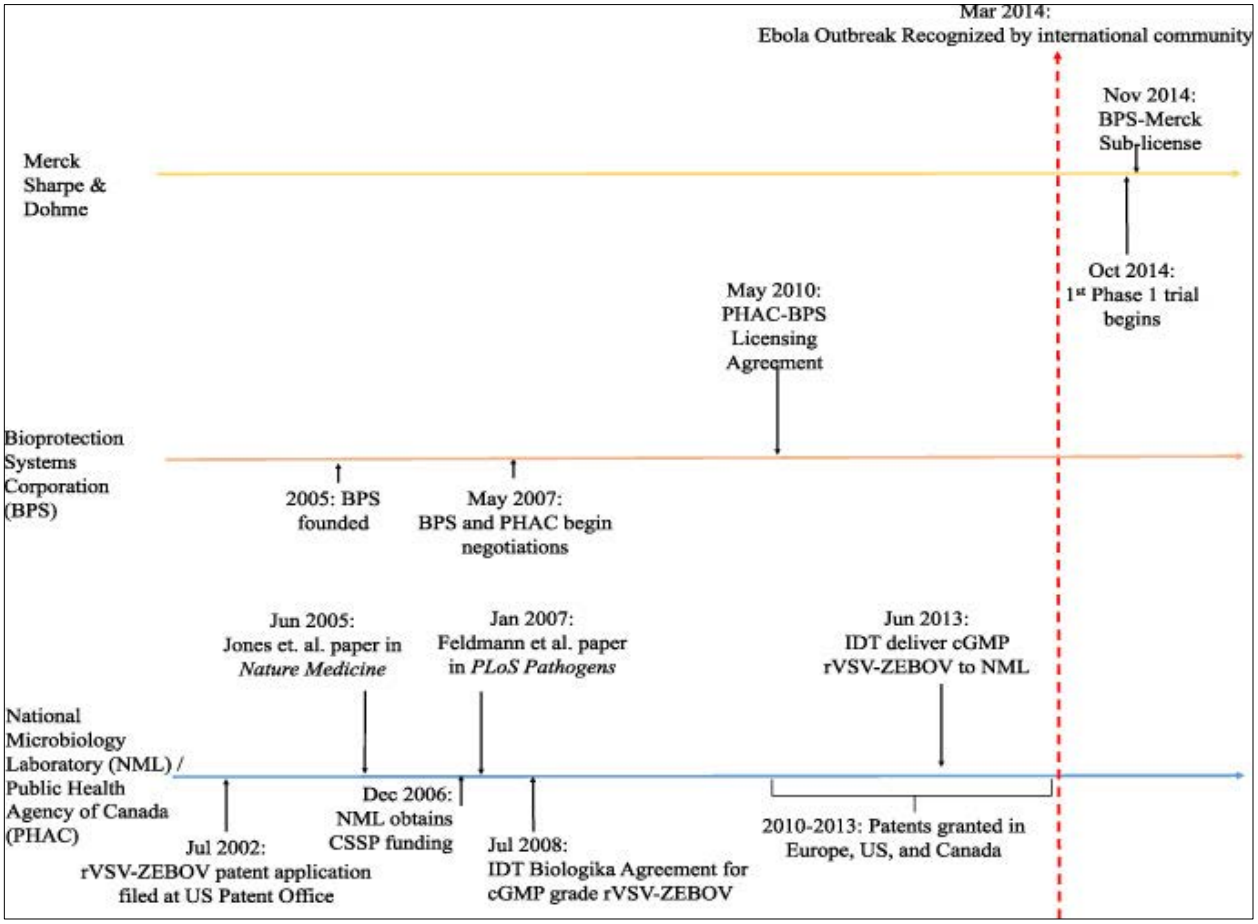
After positive data was obtained from the phase-1 and phase-2 trials, WHO led the phase-3 "Ebola ça suffit !" trial in Guinea with international partners.[158] It also played a central role in managing the funding.[159]

The trial was funded by the WHO, the Wellcome Trust, the UK Department of International Development, Doctors Without Borders, the Norwegian Ministry of Foreign Affairs (through the GLOBVAC program of the country's Research Council), and the Government of Canada (through PHAC, the Canadian Institutes of Health Research, the International Development Research Centre and Global Affairs Canada).[160] There were no access conditions attached to the funding

[151] Kieny M. P. (2018), Lessons learned from Ebola vaccine R&D during a public health emergency, *Human Vaccines & Immunotherapeutics* 14(9), 2114-2115. Available at: https://pubmed.ncbi.nlm.nih.gov/29452047/.
[152] Interview with Marie-Paule Kieny, former WHO Assistant Director-General.
[153] Ibid.
[154] Kieny M. P., *ibid*.
[155] Merck (2014), Merck and NewLink Genetics Enter Into Licensing and Collaboration Agreement for Investigational Ebola Vaccine. Available at: https://www.merck.com/news/merck-and-newlink-genetics-enter-into-licensing-and-collaboration-agreement-for-investigational-ebola-vaccine/ (accessed in March 2023).
[156] Phase 1 Trials of rVSV Ebola Vaccine in Africa and Europe, https://www.nejm.org/doi/full/10.1056/nejmoa1502924
[157] Herder M., Graham J. and Gold R., *ibid.*
[158] World Health Organization (2016), Final trial results confirm Ebola vaccine provides high protection against disease. Available at: https://www.who.int/news/item/23-12-2016-final-trial-results-confirm-ebola-vaccine-provides-high-protection-against-disease (accessed in March 2023).
[159] Interview with Marie-Paule Kieny, former WHO Assistant Director-General.
[160] Henao-Restrepo A. M. *et al.* (2017). Efficacy and effectiveness of an rVSV-vectored vaccine in preventing Ebola virus disease: final results from the Guinea ring vaccination, open-label, cluster-

that WHO received for this project from public funders, which included Norway, Canada and the United Kingdom, but WHO negotiated such conditions into the agreement with Merck.

Figure 2: Key milestones and events during the development of rVSV-ZEBOV in the lead-up to the 2014-2015 Ebola epidemic



Source: Herder M., Graham J., and Gold R. (2020), From discovery to delivery: public sector development of the *r*VSV-ZEBOV Ebola vaccine, Journal of Law and the Bioscience, 2020 Jan-Dec; 7(1): lsz019. Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8249092/figure/f1/. Reproduced under a Creative Commons license.

IP management and access to the product

To facilitate and conduct clinical research, WHO signed an agreement with Newlink and subsequently with Merck.

To ensure the continuity of the project, WHO and Merck agreed that the company would – if and as soon as the vaccine is approved or recommended by a national regulatory authority for broad use outside of a clinical trial setting – use reasonable efforts to expeditiously seek WHO prequalification of the vaccine. They also agreed to enter into good faith discussions with UN agencies and governments of affected developing countries with a view to agreeing on the

randomised trial (Ebola Ça Suffit!). *Lancet* 389(10068), 505-518, Available at: https://doi.org/10.1016/S0140-6736(16)32621-6.

availability of the vaccine in real time for procurement by such agencies and/or governments in reasonably sufficient quantities to meet demand (in so far as production capacity allows) and at a reasonable price, which shall be negotiated in good faith with the UN agencies and governments. In addition, WHO and Merck agreed that for affected GAVI-eligible countries, the company will provide the vaccine at the lowest possible access price to, at most, cover costs directly attributable to the manufacture of the vaccine plus no more than a modest mark-up designed to maximize access to the vaccine by affected populations.

There are additional terms that aimed to ensure access. For example, Merck agreed to work, in collaboration with WHO and other key stakeholders, to determine the most appropriate mechanism for equitable distribution of the vaccine in the event demand from UN agencies and governments of affected developing countries exceeds available supply."[161]

Due to the urgency of the Ebola epidemic, the most important consideration for WHO at that time was to start the trials as soon as possible.[162]

> *"This question of pricing, access, and IP management is always treated in the agreements that we [WHO] have with the industry. In an emergency, what is first and foremost important is to try to push a product down the line as quickly as possible. Nonetheless, the agreement with Merck contains provisions to ensure access." (Interview with Marie-Paule Kieny, former WHO Assistant Director-General)*

Progress on vaccine development and international stockpiling efforts

After phase-3 trials were completed in 2015, Merck continued to work on the late-stage development of the vaccine. In January 2016, it signed an agreement with Gavi to receive 5 million US dollars for the development of the vaccine.[163] The funding from Gavi was aimed toward the future procurement of the vaccine once it had been approved, prequalified and recommended by the WHO. As such, it acted as an advanced purchase commitment, which can de-risk and thereby support R&D on a product before it receives regulatory approval. As part of the agreement, Merck committed to ensure that 300,000 doses of the vaccine would be available for emergency use in the interim and agreed to submit the vaccine for licensure by the end of 2017. Merck also submitted the vaccine to the WHO Emergency Use and Assessment Listing procedure, a mechanism through which experimental vaccines, medicines and diagnostics can be made available for use prior to formal licensure.[164]

Although Merck missed the target of submitting the filing by 2017, the agreement between Gavi and Merck was reportedly not substantively affected by the filing delay.[165] In 2017, the US Government, through the Biomedical Advanced Research and Development Authority, signed an agreement with Merck under which the Government would provide 39.2 million US dollars to validate its manufacturing processes and make final preparations needed to apply for FDA

[161] Interview with Marie-Paule Kieny, former WHO Assistant Director-General.
[162] Ibid.
[163] Herder M., Graham J. and Gold R., *ibid.*
[164] World Health Organization (2016), *ibid.*
[165] Sagonowsky E. (2017), Merck will delay filing Ebola vaccine for approval until 2018, company confirms. Available at: https://www.fiercepharma.com/vaccines/merck-to-miss-2017-filing-target-for-ebola-vaccine-spokesperson (accessed in May 2023).

approval, and the Biomedical Advanced Research and Development Authority would buy the vaccines and keep them in a national stockpile.[166]

Merck submitted the regulatory filing in 2018,[167] and the vaccine was approved by the FDA and European Medicines Agency in December 2019 under the commercial name Ervebo.[168]

In 2021, an international stockpile of effective Ebola vaccines was launched, which was managed by the International Coordinating Group for Vaccine Provision, under the auspices of the WHO.[169] Merck committed to making an emergency international stockpile of 300,000 doses available, funded by Gavi and primarily aimed at vaccinating communities during outbreaks rather than for inter-epidemic times. Gavi committed 178 million US dollars from 2020 to 2025 for the Ebola program.[170] UNICEF served as the procurement agency responsible for establishing emergency stockpiles and for ensuring the rapid supply of vaccines to disease outbreaks upon request from the International Coordinating Group.[171] As of May 2023, Ervebo was the only vaccine procured for the stockpile.[172]

The Strategic Advisory Group of Experts on Immunization of the WHO recommended a global Ebola vaccine stockpile containing 500,000 doses.[173] As of May 2023, the Ebola vaccine global stockpile had reached 449,440 doses, and it was estimated that the stockpile would reach the target by the end of 2023.[174]

The final price of the vaccine was 98.6 dollars per dose, according to the procurement data of UNICEF. This is a relatively high price for a vaccine procured for use in developing countries.[175] According to former Merck official Dr. Mark Feinberg, the high price was a result of the material used for the production of the different components of the vaccine and the costs of running the production facilities, maintaining regulatory approvals and conducting pharmacovigilance. One explanation provided for the high price of the final vaccine was related to the suboptimal manufacturing process. When Merck took over the candidate, there was already a manufacturing process established by IDT Biologika, which produced the cGMP-grade vaccines for clinical trials in Guinea. IDT Biologika produced only a small number of doses using a relatively outdated, labor-intensive process that was not very scalable. Due to the urgency of the situation in 2015,

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[166] Steenhuysen J. (2017), US invests $170 million in late-stage Ebola vaccines, drugs. Available at: https://www.reuters.com/article/us-health-ebola-treatment-idUSKCN1C42G2.
[167] *Ibid.*
[168] Merck (2016), Merck confirms agreement with UNICEF to establish the world's first global Ebola vaccine stockpile with ERVEBO® (Ebola Zaire Vaccine, Live). Available at: https://www.merck.com/news/merck-confirms-agreement-with-unicef-to-establish-the-worlds-first-global-ebola-vaccine-stockpile-with-ervebo-ebola-zaire-vaccine-live/#:~:text=KENILWORTH%2C%20N.J.%20January%2013%2C2021,Ebola%20Zaire%20Vaccine%2C%20Live (accessed in April 2023).
[169] World Health Organization, Ebola vaccine stockpiles. Available at: https://www.who.int/groups/icg/ebola-virus-disease/ebola-stockpiles (accessed in May 2023).
[170] Potet J. (2021), The devil is in the details: a new stockpile for Ebola vaccines, Medium. Available at: https://msf-access.medium.com/the-devil-is-in-the-details-a-new-stockpile-for-ebola-vaccines-a3c003be2a65 (accessed in May 2023).
[171] *Ibid.*
[172] United Nations Children's Fund, Pricing Data. Available at: https://www.unicef.org/supply/pricing-data.
[173] World Health Organization, Ebola vaccine stockpiles. Available at: https://www.who.int/groups/icg/ebola-virus-disease/ebola-stockpiles (accessed in May 2023).
[174] United Nations Children's Fund (2023), Ebola vaccine emergency stockpile (updated on 1 May 2023). Available at: https://www.unicef.org/supply/documents/emergency-stockpile-availability-report-ebola-vaccine (accessed in May 2023).
[175] Potet, *ibid.*

however, there was no time to optimize the manufacturing process to make it more efficient. Since all clinical data was generated using the vaccines produced through this manufacturing process, which formed the basis of regulatory approval, Merck had to continue using this manufacturing process, which resulted in a higher price for the final vaccine. Although technical improvements to the manufacturing process could lower the price of the vaccine, such improvements required significant investment, which was not provided by either the public or the private sector.[176] The relatively low volume of vaccines produced for the stockpile and for use in sporadic outbreaks may also have impeded the economies of scale that could have reduced per-unit prices, a frequent challenge for products for pathogens of pandemic potential. It is unclear from public information whether Merck has earned a profit on the product.

Discussion

Commercial interest in the R&D of the Ebola vaccine was very limited both before and during the 2013-2016 Ebola crisis in West Africa. As was the case with Entasis, it was necessary to have a leadership team within Merck that was willing to take on a project that was not commercially attractive. The vaccine was developed predominantly through support from the public sector, including significant public funding and the contributions of government health agencies. Once the vaccine had been developed, it was procured predominantly by the public sector. Merck played an important role by manufacturing the product, obtaining regulatory approval and made a commitment to supply it for international and national stockpiles and sporadic outbreaks. Although the main patent covering the vaccine generated revenues for Newlink and royalties for PHAC, it did not create enough of an incentive for private sector R&D.

The WHO managed IP to enable further development of the vaccine candidate, with provisions for making the vaccine affordable and available once developed. At the time of writing, the agreement was not publicly available, and we could not assess how the access provisions have been implemented, monitored or enforced in practice.

> *"It was really an emergency project. While at that time, nobody wanted to potentially put [up] any barrier that would have resulted in any delay, the agreement with Merck contains access conditions."*[177] *(Interview with Marie-Paule Kieny, former WHO Assistant Director-General)*

The significant time pressure on negotiating IP terms and conditions in the middle of an emergency suggests that it would be beneficial to agree in advance on the norms and principles that should govern such R&D contracts and to pre-negotiate contractual provisions to serve as a baseline for negotiation in a crisis. While public funders did not have policies requiring global access conditions on their funding to WHO, WHO did put access conditions on the funding used to advance development of the vaccine.

WHO informed us that "it works on the basis of standard approaches in respect of all R&D activities it funds and otherwise supports, including during emergencies, and that this includes future access covenants, including real time supply commitments during emergencies, pricing commitments designed to maximize access for affected populations, including in particular in developing countries, mechanisms for equitable distribution in the event demand exceeds available supply, and publication of data and study results. In addition, WHO habitually retains

[176] Interview with Mark Feinberg, former Merck Vice President.
[177] Interview with Marie-Paule Kieny, former WHO Assistant Director-General.

rights to the IP it develops, and any license to such IP is made subject to compliance with the above-mentioned covenants."[178]

This intermediary role, in which the organization managing public funds for R&D places global access conditions on those funds, is similar to the pattern seen in previous cases in this paper. In addition, as with the other cases, the majority of the R&D was publicly funded, giving the public sector leverage and some degree of control.

[178] Personal communication, 11 April 2024.

Case study 5: Partnership between Baylor and Biological E on a COVID-19 vaccine (Corbevax)

In the four cases discussed so far, there was always a multi-government-funded international agency or organization acting as an intermediary between public funders and developers. Publicly funded international R&D projects, however, can also take different forms and operate without such intermediaries, as was the case in this final case study.

The Texas Children's Hospital Center for Vaccine Development, at Baylor College of Medicine (Baylor) is a product-development partnership based in Texas, United States of America. The Center has more than 20 years of experience developing vaccines to prevent neglected and emerging infections. In 2011, it worked to develop coronavirus vaccines, making it one of the first organizations to recognize the pandemic threats posed by coronaviruses.[179]

From 2011 to 2016, through a grant from the US National Institute of Allergy and Infectious Diseases (NIAID), a recombinant protein-based vaccine was developed at Baylor against two earlier coronaviruses, SARS-CoV and MERS-CoV. A total of 6 million US dollars was granted by NIAID between 2012 and 2016 (NIAID attaches a range of conditions to its funding, but they do not generally include global access conditions).[180] During the COVID-19 pandemic, Baylor built on its previous program to develop a patent-free COVID-19 vaccine with technology suitable for lower-income settings, and it partnered with the Indian biopharmaceutical company Biological E (BioE) to develop the vaccine that later became known as Corbevax. BioE conducted the clinical trials and obtained emergency authorization from the national regulatory authority of India.[181]

Although Baylor received public funding for its earlier-stage research, it relied almost exclusively on private philanthropy for its COVID-19 vaccine development.[182] The total cost was estimated at around 7–8 million US dollars, with Texas Children's Hospital and Baylor providing underlying support for the infrastructure.[183] In the late-stage development of the vaccine, BioE received modest funding for the clinical trials from the Bill & Melinda Gates Foundation and the Government of India under the National Biopharma Mission of the Department of Biotechnology.[184] CEPI also committed up to 5 million US dollars in funding to BioE for scaling up the production of the vaccine once it had been developed.[185] In addition, BioE received US Government funding (through the Development Finance Corporation) for the production of a COVID-19 vaccine developed by Johnson & Johnson. Potentially, some of the improved infrastructure could have had spillover effects benefiting the manufacture of Corbevax.[186]

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[179] Baylor College of Medicine, Coronavirus vaccines. Available at: https://www.bcm.edu/departments/pediatrics/divisions-and-centers/tropical-medicine/research/vaccine-development/coronavirus-vaccines (accessed in March 2023).
[180] NIH RePORT, RBD recombinant protein-based SARS vaccine for biodefense. Available at: https://reporter.nih.gov/search/WNMviEkAEk-ohjdU9a9JTg/publications/project-details/9056977 (accessed on March 2023).
[181] Baylor College of Medicine, *ibid.*
[182] Hotez P. J. and Bottazzi M. E. (2021), A COVID vaccine for all. Available at: https://www.scientificamerican.com/article/a-covid-vaccine-for-all/ (accessed in March 2023).
[183] Interview with Peter J. Hotez and Maria Elena Bottazzi, Baylor College of Medicine.
[184] Coalition for Epidemic Preparedness Innovations (2020), CEPI partners with Biological E Limited to advance development and manufacture of COVID-19 vaccine candidate. Available at: https://cepi.net/news_cepi/cepi-partners-with-biological-e-limited-to-advance-development-and-manufacture-of-covid-19-vaccine-candidate/ (accessed in March 2023).
[185] *Ibid.*
[186] Interview with Peter J. Hotez and Maria Elena Bottazzi, Baylor College of Medicine.

IP management

Since the agreement between Baylor and BioE was not publicly available at the time of writing, the following analysis relies primarily on information from an interview with Peter J. Hotez and Maria Elena Bottazzi, the leading scientists at Baylor in the development of Corbevax. The vaccine was developed based on a recombinant protein technology using yeast, a conventional technology used in the hepatitis B vaccine.[187] The core technology has been well-known and available off-patent for many years. Around 10 years ago, when Baylor started working on coronavirus vaccines using this technology, a provisional patent application was sent to the US Patent and Trademark Office, which then provided feedback indicating that the patent application would be rejected because of prior art. In addition, the initial goal of Baylor was to develop a vaccine for use in an emergency scenario, which would not attract much commercial interest regardless of the existence of a patent. Baylor therefore decided to take patents off the table from the very beginning.[188] Scientists at Baylor placed every step of their vaccine development activities in the open-access scientific literature indexed on the PubMed database of the National Library of Medicine of the United States of America. During the COVID-19 pandemic, Baylor also decided to not go through any IP protection process, in part because of its philosophy of "decolonizing the ecosystem" by enabling manufacturers from LMICs to develop their own vaccines with the technical assistance of Baylor.

In addition to operating without patents, Baylor made its data and study results available in open-source scientific papers that can be searched and downloaded from PubMed. This meant that, technically, a manufacturer with the necessary expertise to develop the vaccine could do so without any help from Baylor.[189] To facilitate the development of the vaccine by manufacturers in LMICs, Baylor also licensed, at no cost, non-exclusive "information packages" to companies that were interested in collaborating with Baylor. The packages consisted of production and research seed banks, technical documents on how to make the vaccines, a link to a Dropbox folder containing all reports and regulatory-enabling records, and a Zoom link through which the manufacturer could reach the team at Baylor if it had any difficulties.[190] The rationale behind this approach was to facilitate the dissemination of know-how, which Baylor considered more important than the transfer of IP in the case of vaccine development:

> *"Intellectual property, in my view, is far less important than the training of the staff and the sharing of technical know-how in the years or decades it takes for people to make these biologics, which are so much more complicated under a quality umbrella."* [191] *(Interview with Peter Hotez, Baylor College of Medicine)*

BioE was among the companies that received the license to data and materials from Baylor and developed the vaccine. Baylor facilitated the development of the vaccine candidate by physically sending the production and research seed and cell banks and by providing technical expertise to BioE, but BioE had the autonomy to decide how to proceed throughout later-stage development. BioE was also responsible for obtaining any funding required for vaccine development and for developing commercialization plans if the vaccine was successfully developed. The only specification regarding IP was that, if any party decided to seek IP protection, it should inform the

[187] Chiu M. (2021), Biological E. Limited to begin phase III clinical trials with Baylor and Texas Children's vaccine. Available at: https://www.bcm.edu/news/biological-e-limited-to-begin-phase-iii-clinical-trials-with-baylor-and-texas-childrens-vaccine (accessed in March 2023).
[188] Interview with Peter J. Hotez and Maria Elena Bottazzi, Baylor College of Medicine.
[189] *Ibid.*
[190] *Ibid.*
[191] *Ibid.*

other party and decide whether there should be co-ownership of the IP.[192] However, it would have been difficult for any party to file a patent application on the technology, as Baylor had published the relevant information in open-access outlets. One of the reasons why Baylor chose the open-science approach was to enable others to develop the technology and reduce the possibility of blocking the technology.[193]

Progress of the Project

In December 2021, BioE received emergency-use authorization for Corbevax in India. As of May 2023, 74 million doses of the vaccine had been administered to children aged 12 to 14 years in India for their primary immunization against COVID-19. Corbevax was the only vaccine approved by the Government of India for use in this age group, partly because it was one of the only technologies that had a track record of being administered to children in the age group.[194] Another 10 million doses were administered in India as a heterologous booster for adults who had previously been immunized with other vaccines.[195]

The COVID-19 vaccine technology from Baylor was also licensed in parallel to BioFarma in Indonesia, Incepta Vaccine in Bangladesh, and ImmunityBio in the United States of America.[196] While Incepta failed to bring the candidate to clinical development, BioFarma successfully developed Indonesia's first Halal-certified, domestically produced COVID-19 vaccine, known as IndoVac.[197] Approximately 10 million doses of the vaccine were administered in Indonesia.[198] ImmunityBio aimed to build manufacturing capacity in Africa, particularly in South Africa and Botswana, and the vaccine candidate was in the preclinical stage as of May 2023.[199]

In addition, Baylor has sent various second-generation versions of the vaccine technology designed for the COVID-19 Omicron variant to BioE and BioFarma, and both companies are in the process of obtaining regulatory approvals for clinical studies of second-generation COVID-19 vaccines at the time of this research in 2023.[200]

Discussion

The R&D of Corbevax provided an example of an alternative model of international R&D collaboration that received public and philanthropic funding and showcased how an open-science approach could be adopted to facilitate globally equitable access, not only to the product but also to the knowledge and data related to it.

Notably, unlike other vaccine candidates, the Baylor project did not receive large-scale public funding during the COVID-19 pandemic. One reason may be that funders did not initially consider the established protein technology to be as promising as other newer technologies, such as mRNA and viral vectors.[201] Although it ultimately turned out that the Baylor technology could be

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[192] *Ibid.*
[193] Interview with Peter J. Hotez and Maria Elena Bottazzi, Baylor College of Medicine.
[194] *Ibid.*
[195] Baylor College of Medicine, *ibid.*
[196] Hotez P. J. and Bottazzi M.E., *ibid.*
[197] Surianta A. (2022), Indonesia's slow path to vaccine self-sufficiency. Available at: https://www.eastasiaforum.org/2022/11/22/indonesias-slow-path-to-vaccine-self-sufficiency/ (accessed in April 2023).
[198] Interview with Peter J. Hotez and Maria Elena Bottazzi, Baylor College of Medicine.
[199] *Ibid.*
[200] *Ibid.*
[201] *Ibid.*

developed and produced at scale in LMICs, it was also one of the later-developed vaccines, having received regulatory approval in India in December 2021 (the same month as Novavax). It did meet a specific public health need in India, however, and was administered at large scale. The project is nevertheless an interesting case of vaccine development for a health emergency conducted without patents, large multinational firms or large-scale public funding, but with vaccine manufacturers in LMICs developing the product in a decentralized manner.

One important factor that enabled this model to succeed is that the vaccine was built on an established underlying technology that was in the public domain, and therefore not likely to be patentable. Older technologies for which there is already a track record and safety data may play a more important role in health emergency R&D than is recognized. It is thanks to pre-existing data that Indian regulators considered Corbevax suitable for 12-14-year-olds, in whom other vaccines had not yet been tested. Nevertheless, replicating this model for newer platform technologies, such as mRNA, would be very difficult, since they have been widely patented.[202]

[202] Gaviria, M. and Kilic, B (2021). A network analysis of COVID-19 mRNA vaccine patents, *Nature Biotechnology* 39, 546-548. Available at: https://doi.org/10.1038/s41587-021-00912-9.

Conclusions

Public funding plays a particularly important role in financing R&D for products for health emergencies, especially for emerging infectious diseases, for which market incentives are insufficient. Public funding is therefore an important tool for leverage, and conditions tied to such funding can help ensure widespread access to the fruits of R&D. This is particularly important given that access to countermeasures during health emergencies is often limited and inequitable, as was the case during the COVID-19 crisis between 2020 and 2022, the H1N1 influenza pandemic in 2009, the West African Ebola crisis between 2014 and 2016 and the mpox emergency in 2022 and 2023.

Global access conditions have become an established feature of international publicly funded R&D initiatives for health emergencies, particularly those with an objective to ensure access in LMICs. Such conditions are usually developed and negotiated by an intermediary (such as CEPI, Unitaid, FIND, GARDP or the WHO) entrusted with public funds, rather than by the government funders themselves. Some public funders were nevertheless involved in high-level decision-making by the intermediary organizations they funded, including the development of IP and access policies.

Table 2: Summary of conditions on funding and IP management in the case studies

Case	Funding conditions of major government donors	Funding conditions of intermediaries* and IP management
Case 1: Partnership between CEPI and Novavax on a COVID-19 Vaccine (NVX-CoV2373)	No policy requiring global access conditions. Donors are involved in high-level decision-making through the Investor Council.	CEPI: Public Health License; affordable pricing; supply commitment to a global distribution entity; publication of data and study results.
Case 2: Partnership between Unitaid and FIND on hepatitis C diagnostics	No policy requiring global access conditions. Donors are involved in high-level decision-making through donor representatives on the Executive Board.	Unitaid: General conditions to ensure access; FIND: retained rights, affordable pricing and supply commitment in target countries; publication of data and study results.
Case 3: Partnership between GARDP and Entasis on a novel antibiotic for gonorrhea (zoliflodacin)	No policy requiring global access conditions. Donors are involved in high-level decision-making through the Board and the Donor Partnership Advisory Committee.	GARDP: Control of technology in 168 countries; affordable and sustainable pricing; publication of data and study results.
Case 4: International collaboration on an Ebola vaccine (rVSV-ZEBOV)	No policy requiring global access conditions.	WHO: Retained IP rights; real time supply commitment and favorable pricing designed to maximize access for affected populations, including in particular for affected Gavi eligible countries; mechanism for equitable distribution of the vaccine in the event demand exceeds available supply; publication of data and study results.
Case 5: Partnership between Baylor and Biological E on a COVID-19 vaccine (Corbevax)	No policy requiring global access conditions for public funding.	No intermediaries; open-science approach, no patents, sharing of know-how with vaccine developers in low and-middle-income countries.

* Intermediaries refers to organizations that received public funding from national governments and invested such funding in R&D initiatives. Intermediaries in our sample were intergovernmental organizations or non-profit organizations.

The monopolies that IPRs can provide are not a major incentive for innovation in disease areas with limited commercial markets, including neglected diseases, antimicrobial resistance and pathogens with pandemic potential (prior to any major outbreak). Nevertheless, IP conditions are an important subset of funding conditions, as funders must manage IP in a manner that facilitates access to the fruits of the research. The cases also illustrate how the impacts of IP, particularly patents and know-how, vary by the nature of the product (vaccines vs. therapeutics vs. diagnostics) and the technologies used to make the product. Some organizations have guiding IP policies or access policies (or both) that outline the principles of their IP management approach, including general support for the open sharing of data and study results, non-exclusivity and technology transfers.

A common feature across the case studies was that funders sought to retain sufficient control over IP to reach a range of project objectives. In some cases, funders retained ownership of IP, and in others they secured rights through licenses while grantees retained ownership. In both cases, funders leveraged those rights to ensure advances in product development, data-sharing, affordable pricing, sustainable supply, technology transfer and/or follow-on research. The ability to revoke a license or to license a third party to use IP was an important enforcement tool for the funder. The cases also illustrated other approaches to IP management, including the retention of rights within a certain geographic scope in the case of GARDP, and the open licensing of the data and know-how needed to advance development of the COVID-19 vaccine in the case of Baylor. Some funders retained IP rights not only in LMICs but also in high-income countries, giving them an effective tool to retain control over the technology. For example, the rights to the Ebola vaccine held by the Government of Canada ensured that, even after the technology had passed through many hands over many years, the Government could still conduct follow-on research or manufacture and sell the technology during a public health emergency (see case study).

Although there is no global legal framework governing publicly funded international R&D, several practices are captured in contracts agreed between collaborating parties. Such conditions generally fall into four categories: (1) open-access publication and sharing of data and study results, (2) pricing commitments, (3) supply commitments, and (4) retention of IP and other rights by funders. Practices vary within these categories, and the cases demonstrated the need for contracts to be tailored to the specificities of each R&D project, including the type of product, technology and disease area, and for some flexibility to exist to ensure that the goal of globally equitable access is achieved. Such conditions are summarized in Table 3.

Table 3: Summary of types of conditions on funding and IP management

Type of condition	Discussion
Open-access publication of data and study results	Widely implemented by science research funders.
Pricing commitments	Pricing commitments are a common feature of the case studies we examined, but the specific form of such commitments varies. Examples include: cost-plus pricing subject to external audit; pricing constraints in certain countries (such as some or all low and middle-income countries); affordable pricing in the public sector or to certain procurement agencies; competitive market-based pricing through non-exclusive licensing and/or technology transfer; and fair pricing to sustain supply while retaining a reasonable profit margin.
Supply commitments	Supply commitments are also a common feature of the case studies, with varied approaches. Examples include: a commitment to register in certain countries (such as some or all low and middle- income countries); minimum or priority supply levels, either to certain groups of countries, for an international stockpile, or to certain international procurement agencies; and volume guarantees.

Funder retention of some IP and other rights	Funders retain certain rights, either ownership of any foreground IP or a license to certain IP rights, including background IP. The purpose of retaining such rights can be to ensure product-development advances and/or grantee compliance with pricing, supply or other commitments. If the grantee does not fulfill its obligations, the funder can terminate a license, require the transfer of data and technology to a third party, and/or grant a license to a third party, for example. The funder can also require that foreground and/or background IP be made available for follow-on research.

In addition to the four categories outlined above, there is the cross-cutting issue of transparency, which is of important intrinsic value for the good governance of public funds. Increased transparency of funding agreements and conditions is critical for at least three instrumental reasons. First, the devil is often in the details of the conditions in funding agreements, and full effective implementation cannot be assumed. *Ex post* monitoring of contract implementation is important to assess how well a particular agreement has worked, but this requires much more transparency than is currently the norm (most contracts remain confidential). In our study, public access was available for the contracts between CEPI and Novavax, GARDP and Entasis (both made available as part of the Master Alliance Provisions Guide database, developed by the non-profit organization the Global Health Innovation Alliance Accelerator) [203] and Canada-BioProtection Systems (in a filing to the US Securities and Exchange Commission). We did not find in the public domain the agreements between Unitaid and FIND or between the WHO and Merck; information on the access provisions in these agreements were provided to us in interviews or other personal communication.

A second reason for transparency is that health emergency R&D can take place over many years and is often akin to a relay race involving many different participants (governments, small and large companies, intermediaries), as was the case for the Ebola vaccine. Transparency enables different parties to see and understand conditions and access commitments that should be carried through, even when a technology changes hands multiple times.

Third, transparency helps to build a community of practice among funders and other stakeholders seeking to ensure that publicly funded R&D generates a public benefit, as practitioners can see what others have been able to do. There appears to be a slowly growing trend towards greater transparency, but it is still by no means the norm. Further research is also needed to understand which conditions are most effective and in which circumstances, and such research is only possible if transparency is part of the agreements. The World Intellectual Property Organization could play an important role in supporting further efforts to collect data on funding conditions and IP management in publicly financed R&D.

In conclusion, we have found that conditions are regularly attached to public funding for international R&D projects and are an effective tool to ensure better access to the fruits of publicly funded R&D for health emergencies. The cases demonstrate that conditions can be applied with sufficient flexibility to tailor contracts to specific projects. However, there are no clear international norms or rules for doing so. Rather, the global governance of public funding for R&D in health emergencies remains *ad hoc* and piecemeal, with ample room for improved coherence and effectiveness across organizations.

To ensure better preparedness for future health emergencies and a swift response during an emergency, pre-negotiated common approaches among public funders and similar conditions on

[203] Available at: https://ghiaa.org/mapguide-home/ (accessed June 2023).

funding could deliver more impactful, equitable access to products.[204] It is challenging to negotiate detailed, comprehensive access conditions during an emergency.

Recognizing the importance of both clear government obligations on funding recipients, and flexibility to adopt strategies tailored to specific products, diseases and crises, a rule with flexibility built in could be considered. In other words, governments and other research funders could commit to require of their grantees the sharing of data, licensing of IPR so that public health objectives are reached, and conditions on pricing and supply; however, if the funder decided it was necessary to depart from this default norm in a particular case, it would have the flexibility to do so on the condition that it publicly explained and justified its decision. A default norm would be established, but without a potentially counter-productive rigidity that could discourage adoption of the norm at all, or even undermine achievement of a shared goal of timely, equitable access to countermeasures.

The focus of the present paper is on international publicly funded R&D initiatives, but most public R&D funding during the COVID-19 crisis was national – that is, governments provided funding to entities based in their own territories – and there are reasons to believe this will remain the trend. In this context, it is worth noting that the kinds of conditions described above need not apply only to international collaborations, as they can also be applied by funders nationally.

Nevertheless, part of the value of agreeing upon norms internationally is that it would create a more level playing field. As we saw in the CEPI-Novavax case, the leverage of one funder trying to obtain access commitments from a private firm can be undermined when another funder offers financing with fewer strings attached. There is an important opportunity for governments to agree on an international standard in ongoing negotiations at WHO towards a Pandemic Accord. In parallel, major public and philanthropic research funders could also jointly articulate and commit to placing public interest conditions on their funding for emergency R&D. These are proven, practicable steps towards greater equity in access to health technologies during future health emergencies.

[204] Torreele E. *et al.* (2023), Stopping epidemics when and where they occur, *The Lancet* 401, 324-328. Available at: https://doi.org/10.1016/S0140-6736(23)00015-6.

Annex I: List of interviewees

Richard Wilder, Former General Counsel and Director of Law and Business Development, CEPI (partnership between CEPI and Novavax on a COVID-19 vaccine (NVX-CoV2373))

Karin Timmermans, Technical Manager, Strategy Team, Unitaid (partnership between Unitaid and FIND on hepatitis C diagnostics)

Sergio Carmona, Chief Medical Officer, FIND (partnership between Unitaid and FIND on hepatitis C diagnostics)

Jean-Pierre Paccaud, Director of Corporate Strategy, GARDP (partnership between GARDP and Entasis on a novel antibiotic for gonorrhea (Zoliflodacin))

Marie-Paule Kieny, former Assistant Director-General for Health Systems and Innovation, WHO (international collaboration on an Ebola vaccine (rVSV-ZEBOV))

Mark Feinberg, former Chief Public Health and Science Officer, Merck Vaccines (international collaboration on Ebola vaccine (rVSV-ZEBOV))

Peter Hotez, Dean, National School of Tropical Medicine, Baylor College of Medicine (partnership between Baylor and Biological E on a COVID-19 vaccine (Corbevax))

Maria Elena Bottazzi, Associate Dean, National School of Tropical Medicine, Baylor College of Medicine (partnership between Baylor and Biological E on a COVID-19 vaccine (Corbevax))

Annex II: Examples of contractual provisions[205]

1. IP management: IP ownership	
COVID-19 vaccine funding agreement between CEPI and Novavax[206]	5. Ownership of Project Results; Intellectual Property: 5.1. Background IP. Awardee shall retain ownership of its intellectual property existing as of the Effective Date, or developed or acquired independently of the Project during the term of this Agreement ("Awardee Background IP") and licenses to third party intellectual property secured prior to the Effective Date [***] ("Third Party Background IP" which, along with Awardee Background IP, shall be referred to as "Background IP"), and nothing in this Agreement shall be deemed to assign any ownership in, or grant a license to, CEPI with respect to such Background IP; except for the limited license rights otherwise expressly provided herein for the Public Health License. 5.2. Ownership of Project Results. Awardee shall own the rights to Project Results. 5.3. Ownership of Intellectual Property. Awardee shall own all Intellectual Property. Upon request [***] Awardee shall update CEPI regarding the status of Intellectual Property rights sought and obtained. Awardee shall have the right, but not the obligation, to seek IP protection at its own cost.
UnitaidExplore funding agreement sample terms and conditions[207]	4 Intellectual Property The Recipient represents, warrants and undertakes (as appropriate) to Unitaid the following as of the Effective Date: (i) the Recipient holds all Intellectual Property Rights existing at the Effective Date which are necessary in order to develop, manufacture, seek regulatory approval [for], commercialise and sell the Health Products in accordance with the terms of this Agreement; (ii) to the best of the Recipient's knowledge, the development and commercialisation of the Health Products in accordance with the terms of this Agreement will not infringe any third party Intellectual Property Rights; (iii) the Recipient has the full right, power and authority to authorize or license the use of the Recipient Foreground IP in the manner set out in this Agreement; (iv) the Recipient has not granted and will not grant, during the period from the Effective Date to the end of the Access Enforceability Period, to any third party any right, license or interest in, to or under the Recipient Background IP or Recipient Foreground IP that would conflict with, limit or adversely affect the Recipient's ability to comply with the terms of this Agreement including, without limitation, the commitments set out [in] Section 3 (Access to Health Products); and (v) the Recipient will manage the Recipient Background IP and Recipient Foreground IP in a manner which furthers and is consistent with the Access Objective, including in accordance with the Commercialisation Plan. The Recipient will make best efforts to ensure that the development and commercialisation of the Health Products will not infringe any third party

[205] The contractual provisions are available in the Master Alliance Provisions Guide (MAPGuide) Provisions Database at https://ghiaa.org/mapguide-home/search-results/?qs=.
[206] Available at: https://ghiaa.org/wp-content/uploads/2021/05/Novavax%E2%80%93-CEPI-Outbreak-Response-to-Novel-Coronavirus-COVID-19-Funding-Agreement.pdf.
[207] Available at: https://ghiaa.org/wp-content/uploads/2022/12/UnitaidExplore_Sample-Legal-Terms_Oct-2020.pdf.

	Intellectual Property Rights in any jurisdiction worldwide. Without prejudice to the generality of this obligation, the Recipient will commission a formal freedom-to-operate search in order to determine whether there are any potentially blocking Intellectual Property Rights in relevant jurisdictions by the date set out in the Milestone Schedule. The Recipient will provide Unitaid with the results of the freedom-to-operate search on request.
Gonorrhoea medication collaboration agreement between DNDi/GARDP and Entasis[208]	7.1 All rights in, title to and interest in the DNDi Background Technology and the DNDi Collaboration Technology shall be owned by DNDi. DNDi shall promptly notify Entasis upon the creation of DNDi Background Technology and DNDi Collaboration Technology. Notwithstanding the foregoing or Clause 7.17, DNDi shall solely own all rights, title, and interest in and to all IP developed or conceived and reduced to practice in DNDi's performance of [*] as DNDi Collaboration Technology; provided, that if DNDi does not file for Patent Rights on DNDi Collaboration Technology that would be reasonably patentable in the DNDi Territory or Entasis Territory within six (6) months of making such invention, or thereafter does not use commercially reasonable endeavors to prosecute and maintain such Patent Rights, then DNDi shall and hereby does assign to Entasis all of DNDi's right, title, and interest in and to such IP. DNDi shall take, and shall cause its employees, agents, sublicensees, and contractors to take, all further acts reasonable required to effectuate the transfer of such IP. Any IP transferred to Entasis pursuant to this Clause 7.1 shall thereafter be considered as Entasis Collaboration Technology. 7.2 All rights in, title to and interest in the Entasis Background Technology and the Entasis Collaboration Technology shall be owned by Entasis. Entasis shall promptly notify DNDi upon the creation of Entasis Background Technology and Entasis Collaboration Technology. 7.3 The Parties agree that each Party shall retain ownership of all rights, title and interest in any part of the Regulatory Dossier which it (or any Party acting on its behalf) has authored provided that each Party shall be entitled to use the Regulatory Dossier for the purposes set out in Clauses 5.7 to 5.9 inclusive without the approval of the other Party. 7.4 Each Party shall procure that under the terms of any appointment of a CSP or Sublicensee that the CSP or Sublicensee does all such acts and things necessary to vest all right, title and interest in its Collaboration Technology in such Party. **Licensing** 7.5 Entasis hereby grants to DNDi, a worldwide, fully paid up, exclusive and royalty-free license with the right to sublicense to any Sublicensee (subject to Clause 7.6) through multiple tiers to use the Entasis Background Technology and the Entasis Collaboration Technology: 7.5.1 in connection with all activities associated with the development of the Drug Product in the Field in accordance with the Development Plan and the Regulatory Plan; 7.5.2 to Manufacture the API and the Drug Product for Commercialisation in the

[208] Available at: https://ghiaa.org/wp-content/uploads/2022/06/DNDi_Entasis-Collaboration-Agreement-and-Novation.pdf.

	Field in the DNDi Territory; and 7.5.3 to register and obtain and maintain Marketing Authorisation in the DNDi Territory and to Commercialise the Drug Product in the Field in the DNDi Territory. For the avoidance of doubt, subject always to Clause 4.14, Entasis retains the right to use and grant licenses to the Entasis Background Technology and the Entasis Collaboration Technology (i) to perform its obligations under this Agreement and (ii) for any purposes not set out above. 7.6 The appointment of distributors and other commercial Sublicensees (for clarity, excluding all CSPs) by DNDi will be subject to Entasis' prior written consent, not to be unreasonably withheld or delayed, provided that the Sublicensee is required to comply with the restrictions set out in sub-clauses Clause 7.5.1 to 7.5.3 inclusive. 7.7 DNDi hereby grants to Entasis, a worldwide, fully paid up, exclusive and royalty-free license with the right to sublicense to any Sublicensee through multiple tiers to use the DNDi Background Technology and the DNDi Collaboration Technology: 7.7.1 in connection with the development of the Drug Product in the Field in accordance with the Development Plan and the Regulatory Plan; 7.7.2 to Manufacture the API and the Drug Product for Commercialisation in the Field in the Entasis Territory; and 7.7.3 to register and obtain and maintain Marketing Authorisation in the Entasis Territory and to Commercialise the Drug Product in the Field in the Entasis Territory. For the avoidance of doubt, subject always to Clause 4.14, DNDi retains the right to use and grant licenses to the DNDi Background Technology and the DNDi Collaboration Technology (i) to perform its obligations under this Agreement and (ii) to enable registration of the Drug Product in the DNDi Territory and for any purposes not set out above (including, without limitation, for academic and research purposes). 7.8 The appointment of a Sublicensee (other than a CSP) by Entasis will not be subject to DNDi's prior written consent. **Future Indications** 7.9 If the Parties agree to develop a Drug Product for Future Indications, each Party shall and hereby does grant to the other a worldwide, fully paid up, non-exclusive and royalty-free license to use its respective Background Technology and Collaboration Technology for development for Future Indications. 7.10 If a Drug Product is developed by a Party for Future Indications in accordance with Clause 4.14, the Party that develops technology for such purpose ("Future Indications Technology") shall: (a) provide to the other on a confidential basis, details of any Future Indications Technology arising from such development activities that is necessary for the performance of the other Party's obligations under the Collaboration Programme; and (b) grant to the other Party

	a right to use such Future Indications Technology in the Field (including for Future Indications in accordance with Clause 4.14) on the same terms set out in Clauses respectively in Clauses 7.5 and 7.7 respectively, provided that such licence shall be non-exclusive. […] 7.15 Entasis shall use its best efforts to file, prosecute, and maintain the Patent Rights claiming the Entasis Background Technology or the Entasis Collaboration Technology in all countries in the DNDi Territory listed on Schedule 3 as of the Effective Date and in any country in Schedule 3 in the DNDi Territory or the Entasis Territory in which Manufacturing is agreed to take place in accordance with the Manufacturing and Supply Plan. […] 7.17 DNDi shall have the right but not the obligation to file, prosecute, and maintain the Patent Rights claiming the DNDi Background Technology and the DNDi Collaboration Technology on a worldwide basis (including for the avoidance of doubt in the Entasis Territory and the DNDi Territory).
2. IP Management: "Public Health License", "Access License" and retained rights	
COVID-19 vaccine funding agreement between CEPI and Novavax	13.4. Public Health License. Subject to the terms of this Agreement, Awardee hereby grants a worldwide and royalty free Public Health License to CEPI, on the condition that CEPI may only exercise the rights granted under the Public Health License in the event that: (a) CEPI is not in material breach of its obligations under this Agreement; (b) the Project Vaccine has achieved licensure with at least one regulatory body (including but not limited to emergency licensure); and (c) one or more of the triggers set out in Clause 13.5 has occurred. CEPI shall be entitled to sublicense Project Results, Enabling IP and Background IP included in the Public Health License in accordance with this Clause 13. Each sublicense shall be in writing and CEPI shall require that each sublicensee complies with the terms of the Public Health License, and if receiving a sublicense to Third Party Background IP, also complies with the terms of the Third Party Background IP license agreement. If a license to Third Party Background IP does not permit further sublicensing by CEPI, Awardee agrees to directly grant CEPI's designee a sublicense consistent with the Public Health License, provided such third party designee agrees to comply with the terms of the Third Party Background IP license agreement, including, without limitation, any payment of sublicense fees attributable to such sublicense grant. CEPI will remain responsible and liable for the performance of sublicenses under such sublicensed rights to the same extent as if such activities were conducted by CEPI. 13.5. Public Health License Triggers. Consistent with Clause 13.4, CEPI's right to exercise the Public Health License shall be satisfied when: (a) Awardee declines to participate in an Additional Work Package or Project Expansion as requested by CEPI, either directly or indirectly through a

	Subawardee; (b) CEPI and Awardee agree, in good faith, that Awardee shall not be able to perform the activities under an agreed Work Package, either directly or indirectly through a Sub awardee; (c) Awardee is in material breach of this Agreement or the Equitable Access Plan and has not cured such breach within [***] days of notification of such breach by CEPI unless otherwise mutually agreed; or (d) the Agreement is terminated by CEPI pursuant to Clause 19.2(a)-(b) (default or insolvency) or 19.3(c) – (e) (unavailability to perform Project activities, failure to satisfy payment criteria or fraud). 13.6. Agreement between CEPI and the Trusted Collaborator or Trusted Manufacturer. In the event that the Public Health License is exercised, CEPI may request assignment of the relevant Trusted Collaborator or Trusted Manufacturer contracts from Awardee or, at CEPI's option, endeavour to reach agreement directly with the Trusted Collaborator and/or Trusted Manufacturer, as the case may be, to perform such activities as CEPI may deem necessary. At CEPI's request, Awardee shall use [***] to facilitate the conclusion of a direct contractual relationship between the Trusted Collaborator or Trusted Manufacturer, as the case may be, and CEPI. If those negotiations do not result in an agreement in [***], then CEPI may grant rights under its Public Health License to a third party unilaterally designated by CEPI as a Trusted Collaborator or Trusted Manufacturer, without approval from Awardee. 13.7. Effects of Exercise of the Public Health License. Upon exercise of the Public Health License and written notice to Awardee, Awardee [***] shall: (a) provide CEPI with an updated list of Enabling Rights and applicable Background IP, along with an invoice for any payments due under any license agreement for Third Party Background IP attributable to the grant of the Public Health License to CEPI or a sublicensee; (b) provide CEPI with a good faith schedule of key technology transfer activities and estimated costs for the technology transfer in Clause 13.6; (c) [***] transfer to the Trusted Collaborator and/or Trusted Manufacturer, as the case may be, and at CEPI's reasonable cost, all Project Results, Project Materials described in Clause 13.2(b), all guidance, information, materials and assistance reasonably required to accomplish the Project activities identified by CEPI; and (d) shall be deemed to have covenanted not to sue CEPI or designee for the exercise of the Public Health License.
UnitaidExplore funding agreement sample terms and conditions	The Recipient hereby grants to Unitaid a conditional, non-exclusive, royalty-free, worldwide, irrevocable and sublicensable license to use the Recipient Foreground IP in order to research, develop, make, have made, offer-for-sale, sell, import, export and distribute the Health Products in for the benefit of the Public sector in LMICs ("Access License"). The Access License is conditional and will be granted in the event that the Recipient: (i) commits a material breach of this Agreement which, if capable of

	being cured, is not cured within ninety (90) days of receipt by the Recipient of written notice from Unitaid; (ii) experiences a Force Majeure event which, if capable of being resolved, is not resolved within one hundred and twenty (120) days of receipt by the Recipient of written notice from Unitaid; (iii) becomes unable to pay its debts as and when they fall due, makes any voluntary arrangement with its creditors, becomes subject to an administration order, goes into liquidation, or is subject to any other bankruptcy, insolvency or similar proceedings, such situation which is not resolved within thirty (30) days; (iv) makes a strategic decision to discontinue development and/or commercialisation of a Health Product; or (v) experiences a Change in Control or Transfer in breach of Section 8 (Change in Control or Transfer) of this Agreement, which, if capable of being cured, is not cured within ninety (90) days of receipt by the Recipient of written notice from Unitaid; or (vi) is unable to secure Commercialisation Agreements complying with the requirements set out in Section 3 (Access to Health Products) of this Agreement; (each of (i) to (vi), an "Access Default"). In the event of notice from Unitaid indicating occurrence of an Access Default leading to the unconditional granting of the Access License, the Recipient will work with Unitaid to take any action and/or execute any documents which may be reasonably required to complete or formalise such license of the Recipient Foreground IP to Unitaid, or an alternative industry partner nominated by Unitaid. Such action will include, without limitation, transferring and/or making available all technology, know-how, documentation and information relating to the Recipient Foreground IP which may be necessary to permit Unitaid, or its nominated alternative industry partner, to utilise the Access License and facilitate the continued development, manufacture and commercialisation of the Health Products for the benefit of the Public Sector in LMICs.
FIND: Call for partners for the global commercialization of a core antigen rapid diagnostic test (cAg RDT) for hepatitis C virus (HCV) infection with a focus on low- and middle-income countries (LMICs) – Appendix IV: Preliminary key term sheet[209]	If [the] manufacturer is unable to develop the Product or commercialise [it] in accordance with [the] access conditions, FIND may terminate the Commercialisation Agreement and require [the] transfer of any know-how and IP to an alternative manufacturer.
3. Access to product: definitions of "access"	
COVID-19 vaccine funding agreement between CEPI and Novavax	14.1. Commitment to Equitable Access. CEPI is committed to achieving equitable access to the results of all CEPI-supported programmes pursuant to the "Equitable Access Policy" referenced in CEPI's Third Party Code. Equitable Access means that a Project Vaccine is available first to populations at risk when and where they are needed at

[209] Available at: https://archive.finddx.org/wp-content/uploads/2019/08/2019-07-19-FIND-RFP-for-HCV-cAg-Commercialization-extension.pdf.

	affordable prices. For clarity, it is CEPI's intention that the price of a Project Vaccine shall be commercially sustainable to the manufacturer.
UnitaidExplore funding agreement sample terms and conditions	3. Access to Health Products The Recipient acknowledges that the objective of the Project is to ensure that the Health Products are made widely available, as quickly as possible and on a continuing basis, at an affordable and sustainable price, to the Public Sector seeking to supply them to LMICs and in sufficient quantities to meet the needs of LMICs (the "Access Objective"). The Recipient will make best efforts to ensure that the Health Products are developed and commercialised in a manner which is consistent with the Access Objective.
4. Access to product: pricing commitment	
COVID-19 vaccine funding agreement between CEPI and Novavax	14.1. Commitment to Equitable Access. CEPI is committed to achieving equitable access to the results of all CEPI-supported programmes pursuant to the "Equitable Access Policy" referenced in CEPI's Third Party Code. Equitable Access means that a Project Vaccine is available first to populations at risk when and where they are needed at affordable prices. For clarity, it is CEPI's intention that the price of a Project Vaccine shall be commercially sustainable to the manufacturer. 14.6. Pricing Objectives. The Parties acknowledge that the price of the Project Vaccine is critical to achieving Equitable Access during the Pandemic Period. Accordingly, Awardee agrees that its pricing shall be reasonable to achieve Equitable Access for populations in need of a Project Vaccine as well as an appropriate return on investment for vaccine manufacturers that make ongoing supply commercially sustainable. The Parties acknowledge that the availability of pandemic insurance as described in Clause 17.7 shall be a relevant cost factor in Equitable Access. For clarity, the purchase of Project Vaccine by the Global Allocation Body or by any other purchasing agent(s) designated by CEPI shall be considered to have satisfied the pricing requirements for Equitable Access.
UnitaidExplore funding agreement sample terms and conditions	3. Access to Health Products […] In furtherance of the Access Objective, the Recipient will ensure that the Health Products are made available in accordance with the following commitments ("Access Commitments"): (i) "Price Commitment" – the Health Products will be offered for sale to the Public Sector seeking to supply them to LMICs at a price which is no more than the lowest sustainable competitive price level ("Affordable Price"). The Affordable Price will cover: (a) the cost of raw materials, labour and other manufacturing costs incurred in manufacturing the Health Product (including assembly); (b) the actual distribution costs incurred in the marketing, promotion, offering for sale, importing for sale, exporting for sale, distribution and sale of the Health Product; and (c) a reasonable mark-up not to exceed the mark-up set out in the Commercialisation Plan attached to this Agreement to help ensure the economic sustainability of the production and distribution;

FIND: Call for partners for the global commercialization of a core antigen rapid diagnostic test (cAg RDT) for hepatitis C virus (HCV) infection with a focus on low- and middle-income countries (LMICs) – Appendix IV: Preliminary key term sheet	Manufacturer commits to making the Product available to Public Sector Purchasers seeking to supply the Products to the Target Countries at an "Affordable Price". "Affordable Price" means the lowest, sustainable, competitive price level for the Products. It will cover the cost of raw materials and full production costs and may also include a reasonable margin to help ensure the economic sustainability of production, product promotion, distribution and support in targeted LMIC's. "Affordable Price" may be determined on the basis of one of the following approaches: • Appropriate benchmark price (if an appropriate benchmark exists); or • COGS plus a reasonable margin. The applicable approach to determining the Affordable Price should be agreed and set out in the Commercialisation Agreement (together with the amount or range of reasonable margin, if applicable). Final product pricing will be negotiated upon completion of development and successful evaluation trials. Pricing may be a function of manufacturing volumes.
Gonorrhoea medication collaboration agreement between DNDi/GARDP and Entasis	The parties are required to use commercially reasonable efforts to make products affordable and sustainable in their respective territories. 6.1 Within six (6) months of the Effective Date or such longer period as may otherwise be agreed in writing (including by email), the Parties shall agree a detailed Manufacturing and Supply Plan for the supply of the Drug Product through the JSC. The Manufacturing and Supply Plan shall be based on the following principles: 6.1.1 the Parties shall develop a detailed forecasting, supply, access and implementation plan for the supply of the Drug Product and define related operational supply chain management processes to ensure availability and access of the Drug Product in the Field with the consultation, as appropriate, of one or more funding agencies or partners, e.g., the World Health Organisation; […] 6.1.7 each Party will use commercially reasonable endeavours to ensure that the Drug Product is made available at price which is affordable and sustainable in its respective Territory and any part thereof; […]
5. Access to product: supply commitment	
COVID-19 vaccine funding agreement between CEPI and Novavax	14.3. Global Allocation. It is the Parties' expectation that a global allocation and purchasing entity (the "Global Allocation Body") shall be constituted within six (6) months after the Effective Date of this Agreement to purchase, allocate, and direct the distribution of COVID-19 vaccines including Project Vaccine. Awardee, will negotiate, in good faith a separate agreement or purchase order to supply Project Vaccine as may be required by the Global Allocation Body in such agreement or purchase order to the Global Allocation Body during the Pandemic Period and after the Pandemic Period for LMICs. For the purposes of this paragraph "Pandemic Period" means the period of time between the date that WHO declared COVID-19 to be a PHEIC [Public Health Emergency of International Concern] (that is, 30 January 2020) and the date that WHO declares the PHEIC to have ended including any period of a COVID-19

	pandemic re-emergence as declared by the WHO. 14.4. Pandemic Period Production and Supply. During the Pandemic Period, Awardee shall: […] (d) supply up to [***] of the quantity of the Project Vaccine produced for purchase by the Global Allocation Body pursuant to Clause 14.3 during the Pandemic Period. For clarity, Awardee may not allocate or obligate Project Vaccine doses to other third parties during the Pandemic Period that conflicts with its obligations under this Clause 14; […] 14.5. Post-Pandemic Period Production and Supply. After the Pandemic Period, Awardee shall continue to produce and supply Project Vaccine for purchase as required by the Global Allocation Body pursuant to Clause 14.3. […] 14.12. Alternative to the Global Allocation Body. In the event that a Global Allocation Body is not constituted as expected by the Parties in Clause 14.3, then CEPI or its designated purchasing agent(s) shall have the rights attributed in this Clause 14 to the Global Allocation Body.
UnitaidExplore funding agreement sample terms and conditions	3 Access to Health Products [...] (ii) “Supply Commitment” – the Health Products will be made available in a timely manner and in sufficient quantities to meet the demands of the Public Sector seeking to supply them to the target countries listed in the Commercialisation Plan (“Target Countries”). The Recipient will supply the Health Products to the Target Countries in accordance with the minimum annual volume target set out in the Commercialisation Plan (“Minimum Supply Target”). In addition to the Minimum Supply Target for the Target Countries, the Recipient will make best efforts to ensure that the Health Products are available in sufficient quantities to meet the demands of the Public Sector in all LMICs which are not Target Countries; (iii) “QA Commitment” – the Health Products will be developed in accordance with appropriate quality standards and, when appropriate, approval will be obtained from the US FDA and/or another Stringent Regulatory Authority or WHO Listed Regulatory Authority; and (iv) “Registration Commitment” – the Health Products will be registered for commercial use, if, as and where required, in the Target Countries in accordance with a timeline to be agreed between Unitaid and the Recipient (“Registration Timeline”).
FIND: Call for partners for the global commercialization	Manufacturer commits to making the Products available in sufficient quantities to meet the needs of the public sector in the Target Countries. This will essentially include a commitment in relation to minimum annual production capacity.

of a core antigen rapid diagnostic test (cAg RDT) for hepatitis C virus (HCV) infection with a focus on low- and middle-income countries (LMICs) – Appendix IV: Preliminary key term sheet	A base minimum annual production capacity commitment may be agreed and set out in the Commercialisation Agreement. The Parties may agree to adjust this commitment closer to product launch. If the Product will also be commercialised in High Income Countries, the Commercialisation Agreement will include an obligation to implement measures to protect volumes destined for Public Sector Purchasers in the Target Countries.
6. Access to data and information	
COVID-19 vaccine funding agreement between CEPI and Novavax	**9. Dissemination of Project Results; Publication** **9.1 Dissemination of Project Data.** Awardee shall disseminate pre–clinical and clinical trial data (including any negative results, animal model deaths and any toxicology study issues) produced under the Project (collectively, ***"Project Data"***), as described in the iPDP [Integrated Product Development Plan] and this Agreement or as otherwise agreed by the JMAG [Joint Monitoring and Advisory Group]. **9.2 Dissemination of Project Materials.** Awardee shall disseminate biological samples, Project Vaccines, and other tangible materials produced under the Project (collectively, ***"Project Materials"***) as described in the iPDP and this Agreement or as otherwise agreed by the JMAG. If Awardee develops animal models under the Project, they shall also be considered Project Materials and disseminated as described in the iPDP and this Agreement or as otherwise agreed by the JMAG. **9.3 Dissemination of Project Results to the Broader Outbreak Community.** As described in the iPDP and elsewhere in this Agreement, or as otherwise agreed by the JMAG, and subject to the payment by CEPI of actual costs and reasonable protection for Awardee's rights under this Agreement, Awardee shall disseminate Project Results (excluding any chemistry, manufacturing and controls ("***CMC***") data, or any information that would violate relevant privacy laws, or any information that Awardee can reasonably demonstrate to CEPI is sensitive and should not be so disseminated) with the broader Outbreak research community, such as disease–specific assays and standards, animal models, correlates of protection or risk, or diagnostics and epidemic preparedness mechanisms. **9.4 Dissemination of Project Data to Countries Hosting Clinical Studies.** Subject to reasonable protection for Awardee's rights under this Agreement, Awardee shall, to the extent it has the legal right to do so, make all Project Data (excluding any chemistry, manufacturing and controls (CMC) data), such as results of disease–specific assays, animal models, correlates of protection or risk, or diagnostics and epidemic preparedness mechanisms arising from such clinical trial available to that country's Ministry of Health or equivalent. **9.5 Publication of Project Data for the Outbreak Research Community.** Project Data shall be shared rapidly with the broader community, consistent with Awardee's requirements as a public company, in accordance with (i) WHO's 2016 Guidance for Managing Ethical Issues in Infectious

	Disease Outbreaks;[210] (ii) WHO's 2016 Guidance on Good Participatory Practices in Trials of Interventions Against Emerging Pathogens;[211] (iii) and Wellcome Trust's Statement on Sharing Research Data and Findings Relevant to the Coronavirus (COVID–19) Outbreak[212] to which CEPI is a signatory. **9.6 Clinical Trial Data.** CEPI's Clinical Trials Policy requires that clinical data and results (including negative results) must be disclosed publicly in as close to real time as possible. Accordingly, such data must be shared through an easily discoverable existing public route (website or system) that includes a metadata description, where patient privacy is upheld, and the system follows a request–for–information approach (where requests are fulfilled subject to an independent review and approval step). Clinical trial data shall be submitted for publication within twelve (12) months after each final study report or report submitted to CEPI. During the same time period, Awardee shall make the results available to the relevant country's Ministry of Health or equivalent. The clinical trial ID or registry identifier code/number shall be included in all publications of clinical trials. **9.7 Open Access.** CEPI requires "Open Access" for Project Data. This means that a copy of the final manuscript of all research publications, journal articles, scholarly monologues and book chapters published under this Clause 9 must be deposited into PubMed Central (or Europe PubMed Central) or otherwise made freely available upon acceptance for publication or immediately after the publisher's official date of final publication. Moreover, all peer–reviewed published research that is funded, in whole or in part, by CEPI shall be published in accordance with the principles of Plan S ("Accelerating the transition to full and immediate Open Access to scientific publications"),[213] a UK and European data-sharing initiative for research funded by public grants.
UnitaidExplore funding agreement sample terms and conditions	5 Dissemination of the Project Results The Intellectual Property Rights in, and ownership of, the Project Results will remain with the party having created or produced such results. Subject to the confidentiality provisions set out in Section 15 (Confidentiality) of this Agreement, the Recipient: (i) hereby provides a non-exclusive, irrevocable, worldwide, royalty-free, sub-licensable license to WHO on behalf of Unitaid to use the Project Results for non-commercial public health, education and research purposes; (ii) will provide Unitaid and/or WHO with the Project Results, or any part thereof, promptly following a request from Unitaid; and (iii) will disseminate the Project Results promptly and broadly in the interests of public health, including, without limitation, in accordance with the Project Description. In order to ensure that the Project Results may be shared and disseminated as broadly as possible in the interests of public health, the Recipient will: (i) obtain all necessary consents and authorisations to sharing of the Project Results generated by such activities with Unitaid and/or WHO including, without

[210] Available at: https://apps.who.int/iris/handle/10665/250580.
[211] Available at: https://cdn.who.int/media/docs/default-source/blue-print/good-participatory-practice-for-trials-of-(re-)emerging-pathogens-(gpp-ep)_guidelines.pdf.
[212] Available at: https://wellcome.org/press-release/sharing-research-data-and-findings-relevant-novel-coronavirus-ncov-outbreak.
[213] Available at: https://www.coalition-s.org/.

	limitation, from relevant national and regulatory authorities, ethical review boards, consultants and sub-contractors; (ii) publish any scientific articles or chapters using or incorporating the Project Results in an appropriate open access mechanism in accordance with WHO's policy on open access (available at: http://www.who.int/publishing/openaccess/en/); and (iii) make the data generated by the Project publicly available on open access terms in an appropriate online data repository: (a) at the same time as publication, in relation to data supporting, or which may be necessary to validate, the main findings of any publication; and (b) no later than six (6) months after the last Milestone Payment, in relation to all other data which may have public health value.
Gonorrhoea medication collaboration agreement between DNDi/GARDP and Entasis	7.11 Within thirty (30) days of the Effective Date, the Parties shall establish an electronic data room in which of all documents that relate to the Collaboration Programme must be filed (the "Data Room"). 7.12 Within thirty (30) days of the Effective Date, Entasis shall provide to DNDi all of the Entasis Background Technology in its possession on the Effective Date. Each Party shall deposit any relevant documents relating to its Background Technology that is not in its possession on the Effective Date in the Data Room within thirty (30) days of such Background Technology being included in the Development Plan. 7.13 During the Term of this Agreement, each Party shall promptly communicate and make available to the other Party in a prompt manner and as it becomes available all of its Collaboration Technology and Regulatory Dossiers shall deposit all relevant documents in the Data Room as soon as reasonably practicable and in any event within thirty (30) days of creation of any relevant document. 7.14 Entasis shall be responsible for maintaining the Data Room for a period of one (1) year following expiry or termination of this Agreement and shall permit nominated representatives of DNDi or any DNDi CSP or Sublicensee to have access to the data room during that period.