

DNDi POLICY REPORT
NOVEMBER 2025

OPEN SCIENCE IN A CLOSED WORLD



Lessons and opportunities
securing openness and equitable
access in R&D collaborations

DNDi
Best Science
for the Most Neglected

Executive summary

Advances in the development of new medicines and other health technologies are made possible by having access to existing scientific knowledge. Close collaboration and open sharing of such knowledge are therefore vital.

As an organization that focuses on some of the most neglected unmet medical needs, the Drugs for Neglected Diseases initiative (DNDi) believes in the inherent value of knowledge sharing and collaboration as they can draw new researchers into overlooked areas, generate diverse results, and improve equitable access to health tools – ultimately contributing to better health outcomes. They also help accelerate research and development (R&D) and lower costs by reducing duplication and improving efficiency.

While there is growing recognition that R&D must become more equitable, inclusive, and sustainable, there is also resistance to more open models of innovation. The COVID-19 pandemic, for example, sparked unprecedented scientific collaboration and gave rise to notable examples of open science. However, it also exposed the deadly consequences of an R&D model primarily built on enclosing – rather than sharing – knowledge. Restrictive practices, including in the management of intellectual property (IP), hindered knowledge sharing, technology transfer, and ultimately, equitable access to the very life-saving breakthroughs the world needed most.

Drawing on more than two decades of DNDi experience, this report explores how open and collaborative science, as well as an intentionally pro-access approach to IP and licensing, can lead to affordable, accessible, and effective health technologies that serve the public good. It highlights tensions and trade-offs the organization has faced and emphasizes that for DNDi, openness is not a one-size-fits-all model, but rather a spectrum of practices that can vary depending upon the unique characteristics and goals of a given R&D collaboration.

The report provides a proposed framework for openness and equitable access, as well as concrete policy recommendations for governments, funders, academic institutions, private industry, and global health actors. It argues that small-scale and piecemeal approaches to knowledge sharing are not enough; instead, robust public policies and institutional practices that align scientific progress with more equitable outcomes are needed, especially for the communities most affected by diseases and

least served by traditional market-based approaches to innovation. This is especially critical at a time when the traditional paradigms for financing and conducting global health research are being upended by drastic funding cuts to foreign aid and medical research as well as geopolitical shifts that are leading to new alliances and a determined focus on greater health sovereignty and self-reliance, especially among low- and middle-income countries (LMICs).

At its core, this report calls for a new approach to biomedical innovation that views knowledge not as a commodity to be enclosed but as a shared resource, open by design, to advance public health – a foundation for equity.



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I. Open science in a closed world: tensions and trade-offs

What is open science, and what does intellectual property have to do with it?

When developing a new medicine or other health technology, access to existing scientific knowledge from public and private researchers is essential. As an organization that focuses on some of the most neglected unmet medical needs, the Drugs for Neglected Diseases initiative (DNDi) believes in the intrinsic value of knowledge sharing and open collaborations, as they can attract additional researchers to a neglected field and enable more and different results. Sharing and collaboration can also help to accelerate the research and development (R&D) process by reducing duplication and by making R&D activities more efficient and less expensive. In addition, DNDi views open science as a critical vehicle for ensuring more equitable access to the results of scientific research – in particular health tools and technologies such as treatments, tests, and vaccines – and therefore more equitable health outcomes. Ensuring clear commitments to openness and equitable access is also key to ensuring good stewardship of public and philanthropic donor funds.

The value of open sharing of knowledge applies not only to the most neglected fields. During an outbreak of a new virus, for example, it is critically important to ensure as many experts as possible are quickly working on the challenge. Ideally, there would be thousands of researchers around the world sharing all their new knowledge in real time. This would make it possible for an entire research community to understand, extend, and potentially identify flaws in the underlying research – all of which are critical for advancing the public good. If a scientist finds that something does not work, no one else should need to spend time and resources making the same mistake. Similarly, if someone stumbles upon an important new discovery and validates it, the whole community should be made aware so the idea can move forward as quickly and efficiently as possible. This is the essence of ‘open science.’

Although the notion of open science dates back to the 17th century, the modern concept has evolved over the past three decades as a way to describe scientific research that aims to be more accessible, collaborative, and transparent.¹ One of the best-known recent open science initiatives was the Human Genome Project, which aimed to map the entire human genome and had a policy in place to release all data generated as part of the project into the public domain within 24 hours.² A more recent example is the International Brain Laboratory (IBL)*, a consortium of neuroscience labs across Europe and the United States that standardizes and harmonizes experiments and openly shares data, software, and tools.³

A number of frameworks and approaches have emerged to describe the various dimensions of open science.[†] They have broadly coalesced around the aims of promoting open science throughout the research lifecycle to accelerate scientific progress; strengthening trust in scientific research; ensuring greater transparency in research practices, data, and methods; increasing access to research knowledge (including scientific journals, which often have prohibitively expensive paywalls); and improving scientific collaboration, rigour, and reproducibility.^{1,4}

In the late 1990s and early 2000s, the pharmaceutical industry itself underwent a shift toward what they termed ‘pre-competitive’ collaborations to speed up the

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* <https://www.internationalbrainlab.com>

† See, for example, OSF: <https://osf.io>

drug discovery process and reduce risks and costs. Typically, these collaborations between companies and other stakeholders focused on sharing pre-competitive data, knowledge, and tools related to common challenges in basic science and early-stage drug discovery – while still ‘enclosing’ such knowledge for private use for later-stage clinical development and commercialization.*

A 2017 publication in PLOS Medicine explored the concept of ‘open source pharma,’ describing it as having ‘radically transparent working practices pioneered in software development, such as the prepublication sharing of data and ideas, the possibility of participation in a project by anyone in real time, and a form of shared ownership that ensures that the underlying methods and data are public domain.’⁵

Several open science initiatives from low- and middle-income countries (LMICs) are helping to advance biomedical R&D while promoting equitable access to knowledge and technologies. COVID-19 drove major advances in genomic surveillance and sequencing and bioinformatics capabilities in nearly all regions. Much of the data from these efforts, which now extend well beyond severe acute respiratory syndrome coronavirus (SARS-CoV-2) to other priority pathogens, is openly shared, for example, via the Global Initiative on Sharing All Influenza Data (GISAID)[†].

Brazil’s Oswaldo Cruz Foundation (Fiocruz) has led large-scale collaborations to openly share genomic data on infectious diseases such as Zika and COVID-19.⁶ The African Open Science Platform (AOSP) pilot – launched in 2016-2017 and supported by South Africa’s Department of Science and Innovation, the Academy of Science of South Africa, and the National Research Foundation – has created three regional nodes in East Africa (Kenya), North Africa (Egypt), and southern Africa (Zambia) and inspired similar initiatives in Asia-Pacific and Latin America and the Caribbean.^{7,8} The Science for Africa Foundation has an Open Science Initiative that supports the open publication of research and data across its priority programme areas, which include health,⁹ and India’s Open Source Drug Discovery (OSDD) programme has engaged a global network of scientists to crowdsource research on neglected diseases like tuberculosis, making all data and results freely available.¹⁰

In 2021, the United Nations Educational, Scientific, and Cultural Organization (UNESCO)¹¹ developed the first-ever internationally agreed definition of open science. In the UNESCO Recommendation on Open Science, open science is defined as having four key pillars: access to scientific knowledge; open access to research infrastructure; open engagement between scientists and ‘societal actors’; and open dialogue between different knowledge systems (e.g., between scientific knowledge and Indigenous knowledge).¹²

In the UNESCO definition itself, a tension is highlighted between open science and intellectual property (IP) rights, which are usually claimed on new knowledge generated: ‘Access to scientific knowledge should be as open as possible, but sometimes access may need to be restricted, for example, to protect...intellectual property rights...’¹¹

Scientific knowledge may either be kept confidential as a trade secret or registered as a type of IP, for example in the form of a patent application, which, if granted, benefits from specific protection provided by governments in exchange for disclosure. Patents usually give the owner exclusive rights for at least 20 years, as required by the World Trade Organization Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).¹³

SEVERAL OPEN SCIENCE INITIATIVES FROM LOW- AND MIDDLE-INCOME COUNTRIES ARE HELPING TO ADVANCE BIOMEDICAL R&D WHILE PROMOTING EQUITABLE ACCESS TO KNOWLEDGE AND TECHNOLOGIES.

* See, for example, *The Precompetitive Space for Drug or Vaccine Development: What Does It Look Like Now and What Could It Look Like in the Future?* (<http://bit.ly/3Vqt7ij>) or *A New Pharmaceutical Commons: Transforming Drug Discovery* (<http://bit.ly/3l10ct1>)

† See, for example, *The rise of pathogen genomics in Africa*: <http://bit.ly/42rqzo3>

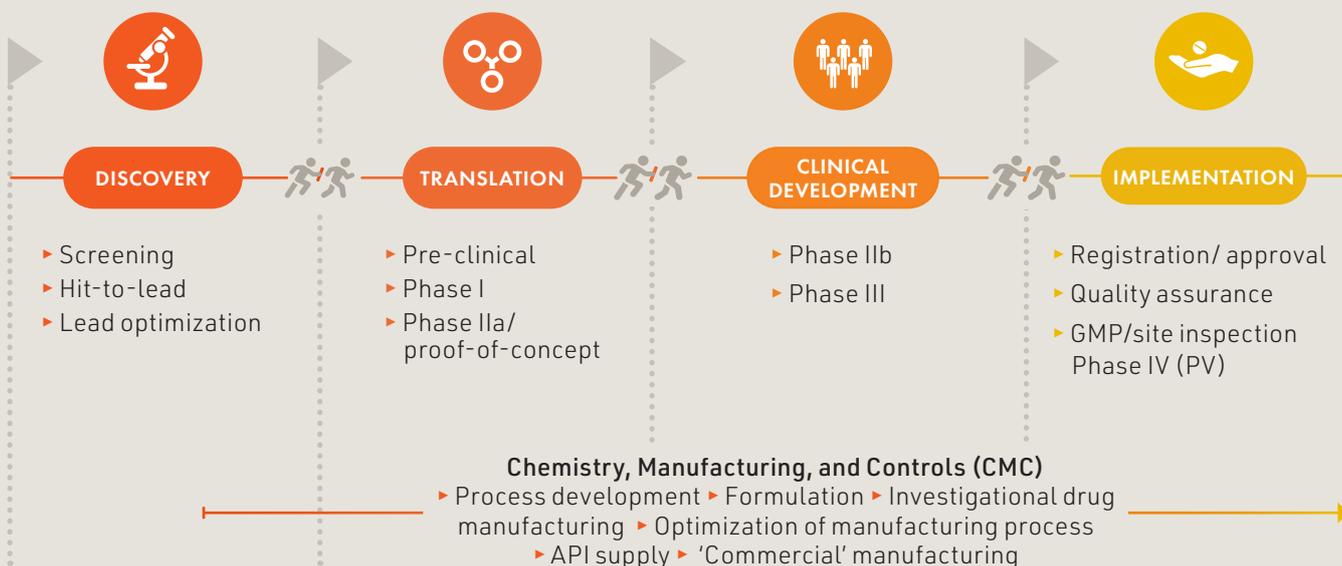
In the field of pharmaceuticals, patents may cover new molecules, knowledge related to their mechanisms of action, safety and/or efficacy in treating or preventing diseases, new formulations, or manufacturing processes, for example. While patents encourage scientists to disclose their inventions in exchange for exclusive rights, as an alternative to trade secrets, patented knowledge cannot be freely used without the consent of the patent holder. Broadly speaking, a patent holder can stop anyone else from commercializing the patented product or process during the period of protection.*

It is widely recognized that secrecy and IP rights can create roadblocks throughout the innovation lifecycle by 'enclosing' knowledge, data, and know-how in a way that can limit or restrain collaborations, follow-on research, production, and/or equitable access to end products.† For this reason, greater openness and increased transparency are essential.

Confidentiality and intellectual property across the innovation lifecycle

Bringing a product from the research pipeline to patients is a long process that involves several types of activities and key transitions among different stakeholders throughout the innovation lifecycle. At every stage of the R&D process, important decisions are made, especially about the sharing (or withholding) of scientific knowledge and IP, that can either support or obstruct openness in research and knowledge-sharing, as well as availability, affordability and access to resulting products. The decisions made at each stage – and who has the right to make them – are crucial, as illustrated in Figure 1 and described in Table 1.

Figure 1: Knowledge sharing is needed at all stages of the product development lifecycle



GMP: Good Manufacturing Practice
 PV : Pharmacovigilance
 API: Active pharmaceutical ingredients

* The rights conferred by patents under TRIPS Article 28 are broader, e.g., 'making, using, offering for sale, selling, or importing.'

† See, for example, *Promoting Access to Medical Technologies and Innovation: Intersections between public health, intellectual property and trade, 2nd edition*: <http://bit.ly/4nFFWB4>

Figure 2: Knowledge & IP management across the product development lifecycle

Innovation planning for health outcomes	<ul style="list-style-type: none"> ▶ Setting IP policies and management strategies ▶ Clarifying ownership, access, and control over research outcomes
Initiating research on unmet public health needs	<ul style="list-style-type: none"> ▶ Surveys of existing technology and patent landscapes ▶ Evaluating ownership patterns and territorial coverage
Initial choices on presence and absence of IP protection	<ul style="list-style-type: none"> ▶ Deciding on open access vs. proprietary approaches ▶ Determining when and where to file for IP protection
Beyond the initial research: proof of concept and scaling up	<ul style="list-style-type: none"> ▶ Securing research tool access through licensing ▶ Addressing background IP and negotiation of collaboration terms
Clinical trials and regulatory approval	<ul style="list-style-type: none"> ▶ Managing IP relevant to product improvements and new indications ▶ Ensuring fulfilment of access commitments ▶ Addressing regulatory issues around data exclusivity
Manufacture and distribution	<ul style="list-style-type: none"> ▶ Monitoring and enforcing access guarantees (e.g., licensing terms) ▶ Managing IP related to improvements and regulatory approval processes
Distribution and marketing phase	<ul style="list-style-type: none"> ▶ Evaluating impact of IP use on market practices (e.g., addressing anti-competitive behaviour) ▶ Ensuring compliance with timely and affordable access commitments

Source: World Health Organization, World Intellectual Property Organization, World Trade Organization. *Promoting access to medical technologies and innovation: intersections between public health, intellectual property and trade*. 2nd ed. Geneva: WHO, WIPO, WTO; 2020.



II. How has DNDi navigated tensions and trade-offs between open science and enclosure of knowledge?

As described in the previous section, there is often a fundamental tension between the public interest goals of biomedical R&D and the tendency toward secrecy and IP protection driven by commercial strategies. The dominant business models for biomedical R&D prioritize profit maximization over transparency and knowledge sharing, and, as a result, scientific knowledge is usually privatized through restrictive IP rights and confidentiality clauses.

This challenge was acknowledged at the inception of DNDi with the crafting of an Intellectual Property Policy, the organization's first internal policy. DNDi's IP Policy¹⁴ reflects its core philosophy, vision, and mission, including its commitment to the idea that scientific knowledge should be shared and that IP rights should not pose a barrier to development of or access to medicines.¹⁵ The Policy has provided the framework for all DNDi partnerships and is grounded in two core goals: ensuring affordable, equitable access to treatments and developing drugs as public goods whenever possible.

In its IP Policy, DNDi treats *research itself* as a public good 'that should primarily lead to the advancement of health' and commits to broad dissemination of research knowledge and data in the public domain whenever possible. Specifically, while being mindful of third parties' IP rights, DNDi aims for public dissemination and transparency of research *inputs* (including specimens, samples, compound libraries, and datasets with appropriate individual data protections), *processes* (including protocols, clinical trial designs, and R&D costs), and *outputs* (including clinical trial results, open access publications, and data sharing).

DNDi's IP Policy is designed to change the default commercial practice of locking knowledge away and sharing it only on a case-by-case basis. Rather, DNDi does the inverse: its starting point is that research will be open, recognizing that there may be some specific and limited circumstances in which knowledge may need to be closed. Changing the default assumption has been important for shifting partners' practices.

This approach has laid the foundation for DNDi's open science initiatives, which prioritize openness and collaboration over secrecy and exclusivity, as well as its commitment to transparency.

DNDi's continuum of open science drug discovery initiatives

Pharmaceutical companies and many research universities have vast, well-curated libraries of novel, proprietary, and often patented, drug-like compounds that have been built up over decades of research in various disease areas. They also have developed or have access to state-of-the-art (and often proprietary) algorithms and computational approaches for assessing chemical 'similarity' between molecules.

In the case of the pharmaceutical industry, these resources are usually closely guarded and kept confidential – certainly not shared with competitors – in the race to commercialize and generate profits. In the case of academia, where an estimated 25-30% of new medicines originate,¹⁶ there are powerful incentives to closely guard research data in order to publish and to patent in the hopes of achieving 'blockbuster' returns. This leads to a reluctance to share – even for use in research for diseases where commercial returns will be negligible. The over-valuation of the potential

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for significant revenue generation has resulted in licensing practices in some academic institutions that restrict sharing of knowledge.¹⁷ To address these challenges, DNDi negotiates access to compound libraries, including patented compounds and proprietary data where relevant, and secures the necessary freedom to operate for one or several diseases to enable researchers to actively collaborate without the constraints of traditional, market-driven approaches to IP.

It is usually easier to negotiate access and downstream sharing of research knowledge in the early stages of research, as fewer or limited IP rights exist, rather than later at the clinical development stage, when IP rights have often been claimed, third-party investments may need to be recovered, and/or commercial returns are expected.

DNDi has initiated, supported, or coordinated numerous open innovation drug discovery collaborations with industry and academia that fall along a continuum of openness as shown in Figure 3.

Figure 3: Spectrum & criteria for openness of DNDi drug discovery collaborations



The following examples illustrate the diverse ways in which DNDi collaborates with its drug discovery partners along the spectrum in Figure 3. In addition to these examples, DNDi has also contributed to several open science initiatives of other not-for-profit product development partnerships (PDPs), such as the Medicines for Malaria Venture (MMV), which has launched a range of such initiatives,¹⁸ including the Pathogen Box to accelerate the discovery of new treatments by providing researchers free access to 400 compounds active against bacteria, viruses, or fungi. In 2019, DNDi and MMV launched a second project, the Pandemic Response Box, along the same lines. Each Box, an open-source collection of unique drug-like compounds, is available free of charge. In return, researchers are expected to share in the public domain any generated data within two years.

Circumventing commercial barriers to accelerate neglected tropical disease (NTD) drug discovery

The **NTD Drug Discovery Booster**¹⁹ was launched in 2015 to circumvent early-stage commercial barriers between pharmaceutical companies, allowing DNDi to screen millions of unique compounds simultaneously – using often proprietary computational approaches to refine the screening iteratively – in the hunt for new treatment leads for Chagas disease and leishmaniasis. Participating companies* committed to not protecting the resulting ‘hit’ compound† if the ‘seed’ compound was in the public domain or belonged to DNDi. If it belonged to one of the participating companies, the commitment was to license any resulting hit series to DNDi for further development on a non-exclusive basis.

Crowdsourcing R&D for neglected diseases

The **Open Synthesis Network (OSN)**‡, launched by DNDi and partner universities in 2016, aims to harness the capacity of chemistry teaching labs to help discover new drugs for patients with neglected diseases. OSN carries out collaborative, early-stage research with master’s and undergraduate students, while furthering their understanding of drug discovery and medicinal chemistry as applied to ‘real world’ R&D challenges. Students at partner institutions – including 30 universities in Australia, Brazil, France, Germany, India, New Zealand, Switzerland, the United States and the United Kingdom – explore data and design new compounds for DNDi to test for anti-parasitic activity. All work generated by OSN is published in the public domain in real time and remains free of IP rights.

Open-source drug discovery for mycetoma

In 2018, DNDi partnered with the University of Sydney in Australia and Erasmus University Medical Center in the Netherlands to launch the **Mycetoma Open Source (MycetOS)**§ project, a virtual drug discovery community, which aims to find new treatments for fungal mycetoma – using a community-driven, fully transparent process. All ideas and results are published immediately in real time to an open-access database**, free of IP constraints, using a Creative Commons licence. Results and the associated data form the starting point for the MycetOS community, which shares data and key project files on the GitHub platform.

DNDi HAS INITIATED, SUPPORTED, OR COORDINATED NUMEROUS OPEN INNOVATION DRUG DISCOVERY COLLABORATIONS WITH INDUSTRY AND ACADEMIA THAT FALL ALONG A CONTINUUM OF OPENNESS

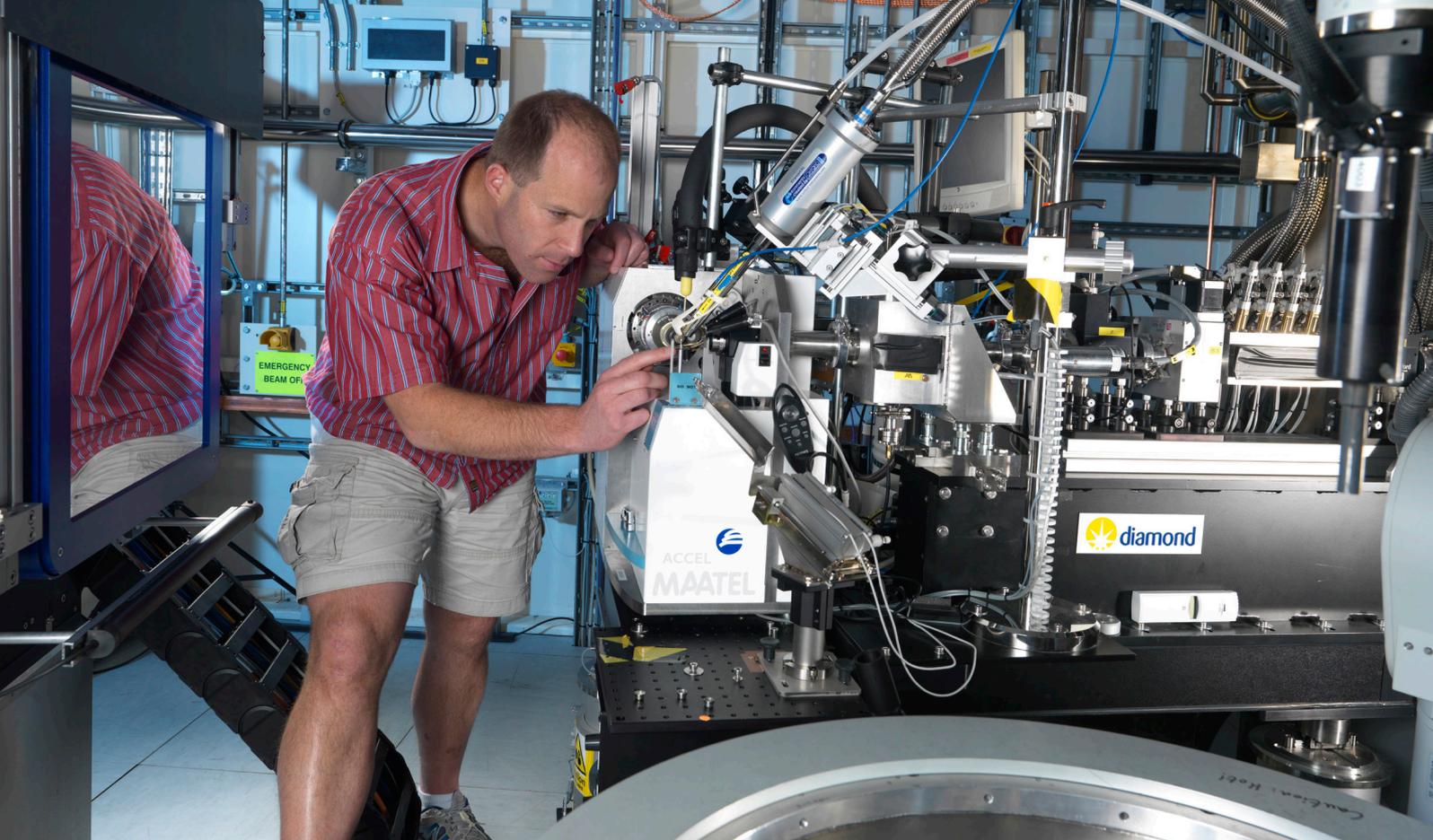
* Booster consortium partners include AbbVie, Astellas, AstraZeneca, Celgene (now part of Bristol-Myers Squibb), Eisai, Merck, Shionogi, and Takeda Pharmaceutical Company Limited.

† A ‘hit’ is a compound that shows a desired biological activity in relation to a specific target that can be reproduced when retested.

‡ <http://dndi.org/project/open-synthesis-network>

§ <https://dndi.org/research-development/portfolio/mycetos>

** <http://github.com/OpenSourceMycetoma/General-Start-Here>



Open innovation for pandemic preparedness

The **COVID-19 Moonshot** consortium, a global grassroots movement of scientists based on ideas, expertise, and goodwill launched at the peak of the COVID-19 crisis in 2020, generated and freely released more than 1,100 crystal structures of the SARS-CoV-2 Main protease (Mpro), including structures disclosing the pre-clinical candidate developed by the consortium.* The approach of this consortium, of which DNDi was a part, was unique in that it was a fully open science, 'IP-free' model, immediately sharing all research results in the public domain with the ambition to ultimately deliver affordable and globally accessible 'straight-to-generic' antiviral therapeutics for COVID-19. As such, all scientific data from the discovery phase, as well as the general learning generated by the project, were immediately made available in the public domain on an open-access website† (see Case Study 1 for further details).

Later, the Moonshot team embarked on a follow-on collaboration, creating the **Artificial Intelligence-driven Structure-enabled Antiviral Platform (ASAP)**‡ for antiviral drug discovery, one of the Antiviral Drug Discovery (AVIDD) Centers for Pathogens of Pandemic Concern funded by the National Institute of Allergy and Infectious Diseases (NIAID) of the US National Institutes of Health (NIH). In line with the open science objectives of the consortium, all data and knowledge generated are released publicly in accordance with an innovative IP strategy anchored in minimally defensive patenting and maximally permissive licensing in order to deliver globally affordable antivirals while preventing any privatization of knowledge fuelled by commercial interests (see Case Study 1 for further details).

* Structure data is available through the Fragalysis and the Protein Data Bank (rcsb.org); structures and data for chemical structures are deposited in ChEMBL (ebi.ac.uk/chembl); assay protocols are available at ASAP

† http://covid.postera.ai/covid/activity_data

‡ <https://dndi.org/research-development/portfolio/asap-0017445>

Case Study 1

Two approaches to open science and collaboration for pandemics*

While there has been much focus on the fact that wealthy countries hoarded COVID-19 vaccines and most companies refused to share their technology with other manufacturers around the world, behind the scenes, scientists were teaming up in remarkable ways.

One such effort was something called the **COVID Moonshot initiative**.^{*} It started during lockdowns, when hundreds of scientists connected online to try and identify a safe, affordable COVID-19 treatment that anyone could ultimately access – no patents, no monopolies. The end goal was simple but ambitious: develop an ‘IP-free’ antiviral pill that could be produced as a generic medicine right away.

The consortium asked medicinal chemists from around the world to help design molecules that could block the virus from replicating. They expected a few hundred ideas. Instead, they got more than 18,000. Social media and artificial intelligence helped speed things up, and funding from Wellcome supported synthesis and lab testing of the most promising candidates.

Normally, drug discovery is a slow process. But one of the team members said it felt like they were on a high-speed train laying down the tracks as they went – and it worked. Moonshot identified several compounds that showed promise against SARS-CoV-2 and similar viruses. One compound, called **DNDI-6510**, even moved into advanced testing.

But here’s where things got tricky. Since all data generated by the consortium was made freely available online and no patents were filed, no manufacturer or donor wanted to invest in downstream development activities in such a competitive environment. Their concern was that, without ownership of the basic patent claiming the compound structure and its effect, anyone could swoop in and file downstream patent applications claiming a change in the structure, a critical manufacturing route, a salt, solid state, or formulation – potentially imposing monopolistic rights, preventing further development, and making the medicine expensive, or restricting availability in all

geographies that may need it. This raised concerns that the consortium’s open approach could make it *harder* to ensure the drug would remain accessible.

In the end, DNDI-6510 did not make it through later testing – something that happens often in drug development. But key interactions observed in Moonshot compounds contributed to the identification of the antiviral drug ensitrelvir, developed by the Japanese pharmaceutical company Shionogi, and the work of the consortium on this compound paved the way for other candidates that could be advanced through a new project: the **ASAP consortium**,[†] led by many researchers from the Moonshot team and supported by NIAID/NIH.

In 2025, ASAP announced a new antiviral candidate from the same chemical series as DNDI-6510 – **ASAP-0017445**[‡] – which has shown promise in pre-clinical testing against SARS-CoV-2, Middle East respiratory syndrome (MERS), and related viruses. In keeping with the open science mission, the ASAP team released the structure of ASAP-0017445 to the public so scientists everywhere can build on their work. In September 2025, the molecule was formally nominated as a pre-clinical drug candidate, moving it closer to being tested in a first-in-human Phase I clinical trial.

To protect the vision of global affordable access while still encouraging development, the ASAP team took a novel approach: they filed a patent²⁰ on the ASAP compound – not to block others, but to make sure no one else could.

This ‘minimally defensive patent’ approach^{**} is coupled with maximally permissive licensing undertaken to ensure that if further development is successful, the medicine can be shared through non-exclusive licenses. That means multiple companies would be able to produce it simultaneously and at a competitive price, with no restriction on supplies.²¹ Furthermore, and in accordance with the agreed-upon IP Policy of the ASAP consortium, this patent was filed and published as quickly as possible, reducing the typical 18-month patent publication timeframe, to ensure full disclosure under the open science approach.

* Adapted from *How patents can serve the public good* (<http://bit.ly/4nixck0>)

† <https://dndi.org/research-development/portfolio/covid-moonshot>; for additional background, see: <https://healthpolicy-watch.news/the-moonshot>

‡ <https://dndi.org/research-development/portfolio/avidd-asap>

§ <https://dndi.org/research-development/portfolio/asap-0017445>

** A similar approach was used in the ‘single nucleotide polymorphisms’ (SNP) Consortium. See, for example, The SNP Consortium: Background and Context (<http://bit.ly/4nHxIsg>)

III. Planning for openness and access throughout the R&D process

Embedding principles of openness and access as early as possible

A key lesson DNDi has learned over the course of the last 20 years is that when open research collaborations and equitable access to health tools are the goals, it is necessary to secure contractual commitments on the sharing of knowledge and access principles, ideally at the conception phase – not just once a product is in late-stage clinical development or has received regulatory approval.

At the initiation of any research project, whether early-stage, pre-clinical, clinical, or implementation research, a fundamental question is whether a promising existing compound or technology is available in the public domain, free of IP rights, or owned by a third party.

In the case of projects that are based on a compound or technology that is publicly available and unencumbered by any pre-existing private rights, DNDi negotiates ‘public domain clauses’ with the partners involved in the further development of the technology, to ensure the release of any new data generated through the partnership in the public domain, free of IP rights, in accordance with the principles of DNDi’s IP Policy.²²

In the case of projects based on a compound or technology that is owned or controlled by a third party and protected by IP rights, DNDi needs to negotiate in-licensing rights to undertake R&D activities on the compound or technology and secure access to any useful existing data or knowledge related to it. In accordance with its IP Policy, DNDi will negotiate such rights in a way that not only provides DNDi *full freedom to operate* (e.g., managing all necessary research activities and collaborations to deliver the final treatment) but also enables DNDi to publish the knowledge it generates.

DNDi has often negotiated in-licensing rights to undertake research on compounds owned by third parties. An example of this was a collaboration initiated in 2008 between DNDi and the US biopharmaceutical company, Anacor Pharmaceuticals (see Case Study 2 for further details).

A KEY LESSON DNDI HAS LEARNED OVER THE COURSE OF THE LAST 20 YEARS IS THAT WHEN OPEN RESEARCH COLLABORATIONS AND EQUITABLE ACCESS TO HEALTH TOOLS ARE THE GOALS, IT IS NECESSARY TO SECURE CONTRACTUAL COMMITMENTS ON THE SHARING OF KNOWLEDGE AND ACCESS PRINCIPLES, IDEALLY AT THE CONCEPTION PHASE.



Case Study 2

Non-exclusive licensing of novel class of compounds for African sleeping sickness ensures multiple partners support development and access

The compound AN5568 was a product of Anacor's novel boron chemistry with promising efficacy against a range of fungal, inflammatory, and bacterial diseases. Realizing this technology could also be used for neglected diseases, Anacor, with the help of the Sandler Center for Drug Discovery of the University of California, San Francisco screened its library of boron-based compounds for activity against the parasites that cause human African trypanosomiasis (HAT), also known as African sleeping sickness, and identified an attractive lead series. To ensure further development of these compounds, Anacor approached DNDi and joined a consortium with DNDi and SCYNEXIS, also including Pace University and the Swiss Tropical and Public Health Institute, to undertake pre-clinical studies.²³

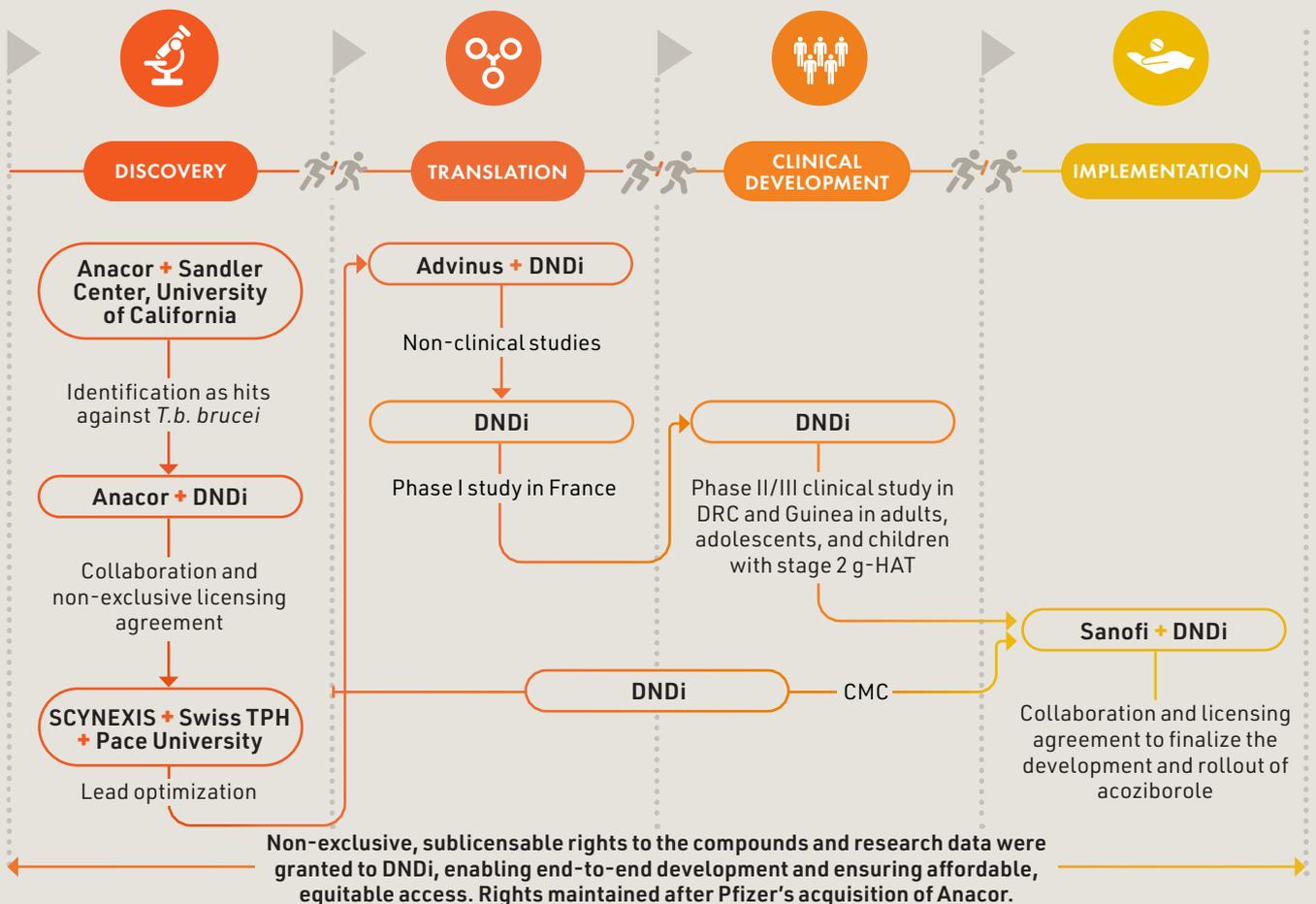
The licensing agreement signed in 2008 with Anacor gave DNDi access to this class of therapeutic compounds owned by Anacor. DNDi was granted non-exclusive rights to the compounds for all applications that may result from its research activities in the field of HAT and other neglected diseases, while Anacor retained its rights for any other indication. This agreement provided the necessary rights and data on the compound, enabling DNDi to coordinate pre-clinical and clinical activities with different partners to demonstrate the safety and efficacy of acoziborole for the

treatment of HAT and ensure production, registration, and distribution by DNDi partners.

After conducting Phase I safety studies in France, DNDi and its partners in the Democratic Republic of the Congo (DRC) and Guinea successfully led a Phase II/III study.²⁴

Because DNDi had the right to share the compound with third parties via a sublicense, in 2020, DNDi and Sanofi were able to sign an agreement to finalize the development and rollout of acoziborole, according to which Sanofi will be responsible for manufacturing, supply, registration, and distribution, in accordance with the terms of the original agreement with Anacor. Once approved, acoziborole will be provided to patients free of charge through affected countries' public health systems, thanks to a 20-year collaboration between Sanofi and the World Health Organization (WHO).²⁵

In this project, the licensing rights and obligations, as well as access objectives, that were agreed upon between DNDi and Anacor have been transferred to all other partners directly or indirectly involved in the collaboration. This has ensured the publication of relevant protocols and study results* and will guarantee the availability and accessibility of the treatment for patients in need, once approved.



*<https://dndi.org/research-development/portfolio/acoizborole>

Another example, this time of a collaboration further downstream and in a more commercial area, is the case of ravidasvir, a partially developed molecule, which DNDi in-licensed to complete development for the treatment of neglected hepatitis C genotypes, in partnership with the Egyptian company, Pharco Pharmaceuticals (see Case Study 3 for further details). DNDi was granted non-exclusive, sub-licensable rights to develop, register, manufacture, and ensure distribution of ravidasvir in select LMICs.

Case Study 3

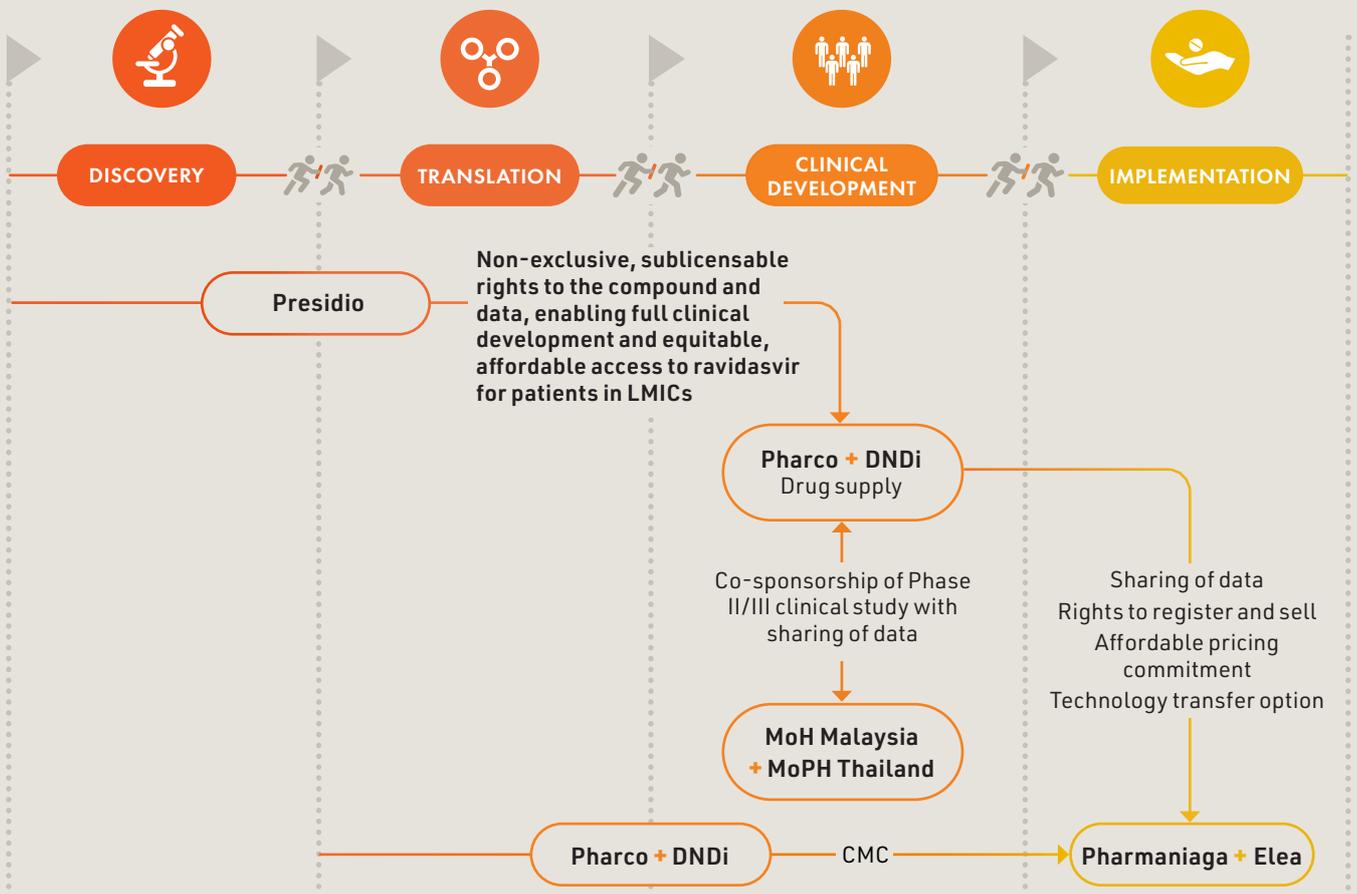
Non-exclusive licensing and technology transfer enable sharing of critical knowledge and affordable hepatitis C treatment

Ravidasvir was discovered and initially developed by the US biopharmaceutical company Presidio Pharmaceuticals, which filed and obtained patents in selected high- and middle-income countries.²⁶ In 2016, DNDi entered into a non-exclusive license agreement with Presidio and its licensed manufacturing partner, Pharco, to enable testing of a new combination treatment using ravidasvir and sofosbuvir. DNDi coordinated a Phase II/III study in Malaysia and Thailand, co-sponsored by the Malaysian Ministry of Health and Thai Ministry of Public Health and co-financed by Médecins Sans Frontières (MSF).

All public and private partners agreed to a common objective from the start: the development of an affordable direct-acting antiviral for the treatment of hepatitis C, which was urgently needed at the time because such treatments were exorbitantly priced at nearly USD 100,000. Presidio granted DNDi non-exclusive licensing rights

providing full freedom to operate in the field of hepatitis C. Pharco committed to affordable pricing and the sharing of its manufacturing process.

In 2021, the Malaysian regulatory authority approved ravidasvir for the treatment of hepatitis C, in combination with sofosbuvir, with a commitment from Pharco to make the combination available at a price between USD 300 and 500 for a 12-week treatment course. The collaboration agreements between DNDi, Presidio, Pharco and regional suppliers include the payment of tiered royalties on sales of ravidasvir of between 0.4% and 7%, depending upon the gross national income (GNI) of the country where it is sold, as well as the possibility of technology transfer from Pharco to local manufacturers. Ravidasvir is currently under review for registration by Elea in Argentina, Farmanguinhos in Brazil, and the Government Pharmaceutical Organization in Thailand.



As these examples illustrate, DNDi's leverage to negotiate favourable conditions in relation to both openness and access often depends upon the type and stage of the research activity undertaken, the funding available, and the partners involved. The more significant the contribution, the easier it is for DNDi to require control of the data and outputs generated. These and other factors influence the details of each specific agreement.

Model agreements and terms and conditions

DNDi embeds open science and access principles at the earliest possible stage in contractual agreements with partners, including commitments to affordability; pro-access management of IP; technology transfer to ensure all necessary knowledge, data, and know-how is 'pulled through' to the next stage of R&D and to third parties whenever necessary; registration, supply, and distribution; and transparency and open access to knowledge, including research inputs, processes, and outputs.

DNDi negotiates two main types of collaboration and licensing agreements:

- ▶ **Research collaboration and license agreements (RCLA)***, which address early research activities ranging from early-stage discovery (hit-to-lead and lead optimization) to pre-clinical studies, including pharmaceutical development and manufacturing activities related to candidate compounds, until one or several candidates are selected for clinical trials in humans.
- ▶ **Development collaboration and license agreements (DCLA)†**, which typically cover clinical development activities from Phase I clinical trials in healthy volunteers to Phase II/proof-of-concept and Phase III studies, as well as pharmaceutical development and manufacturing, registration, and distribution/delivery activities.

DNDi's 'model agreements' (or templates) have been made public‡ to show how equitable access to knowledge, data, and, ultimately, end products is negotiated – from the laboratory bench to the patient's bedside.²² These templates are based on a review of DNDi's 'best practices' and on the most favourable provisions negotiated with different stakeholders, ranging from academic research groups and universities to small and large pharmaceutical companies. DNDi's agreement templates serve as starting points for negotiations but are always adapted based on factors such as disease area, stage of development, level of partner contribution, number of partners, and donor requirements. In addition to ensuring that contract negotiations remain aligned with DNDi's mission, the templates are also important in aligning expectations with partners and setting clear objectives for how collaborators engage and evaluate progress.

Openness and transparency: research as a public good

There is a growing global push for greater transparency across the medical R&D and access to medicines ecosystem. To maximize transparency within DNDi, the organization has adopted several internal policies and made other specific commitments to transparency, which the organization views as a key component of its approach to open science. DNDi endeavours to use these commitments to support the framing of negotiations with partners. These include:

- ▶ **Adoption of a scientific communications policy:** Established in 2015, the DNDi *Scientific Communications Policy*[§] ensures timely and accurate dissemination of research findings to the medical and scientific communities, including by contributing to open-source initiatives such as public databases. DNDi commits to publishing all study results, regardless of their outcome, in open-access, peer-reviewed journals, promoting greater availability and accessibility of research findings.

*RCLA template available at <http://bit.ly/3IsYFkC>

†DCLA template available at <http://bit.ly/4nlvQ94>

‡Model agreements' available at <http://bit.ly/4nlvOxY>

§DNDi Scientific Communications Policy available at <http://bit.ly/4mrAkclU>



- ▶ **Signatory to WHO statement on public disclosure of clinical trial results:** DNDi is a signatory to the 2017 WHO *Joint statement on public disclosure of results from clinical trials*²⁷ and has also pledged to actively engage with initiatives to share individual participant data (IPD). This commitment is reflected in DNDi's Policy on Sharing and Secondary Use of Human Subject Research Data (see below for further details).
- ▶ **Support for WHO transparency resolution:** DNDi was a strong supporter of the 2019 WHO resolution on *Improving the transparency of markets for medicines, vaccines, and other health products (WHA72.8)*²⁸, which urges countries to disclose information on R&D costs, prices of health tools, clinical trial data and results, funding sources, and patent and licensing status. A number of health NGOs were instrumental in its adoption by WHO Member States and have long advocated for improved transparency, carried out strategic litigation, and published reports exposing ways in which secrecy around clinical trial data, R&D costs, procurement contracts, and licencing agreements undermines equitable access.*
- ▶ **Adoption of policy on sharing and secondary use of human subject research data:** Launched in 2022, this DNDi policy[†] focuses on the sharing and secondary use of data from DNDi's research. This aims to enhance transparency, allowing other researchers to validate findings (including negative outcomes) and contribute to broader knowledge generation, while ensuring patient confidentiality. The call for greater transparency and responsible sharing of IPD has been further echoed by regulators and has crystallized in the form of specific provisions in clinical trial legislation.[‡] However, the lack of a standard approach, and sometimes conflicting requirements from personal data protection laws and ethics committees, creates significant challenges that often require case-by-case consideration following guidance from ethics committees to find an appropriate balance between the rights of the individual to confidentiality, the integrity of the research, and the use of IPD for scientific progress.²⁹
- ▶ **Publication of R&D costs:** Since 2014, DNDi has self-published its R&D costs[§] and considers transparency about these costs to be a crucial part of our model (an updated R&D cost analysis is forthcoming). This is important both as an accountability mechanism for public and philanthropic funders and to inform policy debates, as evidence and data about actual R&D costs play a critical role in incentivizing further investment in areas of unmet need, projecting costs for new initiatives, and informing new public funding policies. The organization has taken part in multiple benchmarking exercises and advocacy with partners to improve transparency of R&D costs.^{30,31,32}

*See, for example, MSF (<http://bit.ly/46PdAic>), Health Justice Initiative (<http://bit.ly/3Kwlq6y>), Knowledge Ecology International (<http://bit.ly/48pk8Fx>), Health Action International (<http://bit.ly/3lzuR5l>), Joint NGO Sign-On Letter (<http://bit.ly/48c0lU7>)

[†]Available at <http://bit.ly/4gAmcMV>

[‡]See, for example, *Regulation (EU) No 536/2014* (<http://bit.ly/4gFQnTg>)

[§]See, for example, *An Innovative Approach to R&D for Neglected Patients* (<http://bit.ly/423E4Kg>) and *15 Years of Needs-driven Innovation for Access* (<http://bit.ly/4n8lXKs>)

IV. Translating DNDi's experience into broader policy and practice

A framework for open innovation and equitable access

For each R&D project, DNDi reviews existing and competing IP rights; negotiates with partners over the exact terms of ownership for all IP generated over the course of the project; agrees on what happens if the partnership terminates before the project's completion; specifies responsibilities in relation to affordability, data sharing through publication and other forms of transparency; and ensures that after a technology is developed, IP is managed to support sustainable manufacturing and affordable and equitable access.

What follows is a proposed framework based on DNDi's firsthand experience (see Table 2), which researchers, funders, and other R&D actors can use as a 'checklist' to ensure open innovation and equitable access provisions are in place. This framework reflects key terms and conditions found in DNDi contractual agreements as well as other principles and commitments that DNDi has determined to be fundamental to successful open science collaborations.

Table 2: Framework for openness and equitable access

	Upstream (early discovery, pre-clinical research)	Downstream (Phase I, II, and III clinical trials, registration, distribution)
Affordability	<ul style="list-style-type: none"> Define target price in target product profiles, including an ideal and an acceptable price whenever possible Commit to 'affordability' of the final product (with a clear definition of affordability)* 	<ul style="list-style-type: none"> Better define the 'lowest sustainable price' for a specific product,* including a specific margin over cost of goods (COGs) where appropriate, as a condition of licensing Optimize dose, formulation, and manufacturing processes to reduce COGs Require regular reports on sales (to help assess whether access is achieved or not) Include the right to audit the final price as a contractual commitment
Availability	<ul style="list-style-type: none"> Include necessary provisions on knowledge and data sharing to ensure further development and, ultimately, access to final product, if successful 	<ul style="list-style-type: none"> Define high-level regulatory strategy and responsibilities, including, where appropriate, estimated timelines for preparation and submission of applications for regulatory approval in target priority countries (more detailed regulatory plans can be defined at a later stage) Agree on commercialization ('Access and Implementation') plans at a later stage Include 'technology transfer' provisions to ensure all necessary rights will be made available, if needed, to at least one third party to make/distribute the product and provide such third parties with the full registration dossier and any additional relevant IP, data, material processes, or know-how and training necessary to manufacture the product Commit to engage with international and national clinical guideline development processes, as appropriate, to support registration, adoption, and uptake
Sustainability	<ul style="list-style-type: none"> Include provisions to ensure all necessary rights and data/material will be made available, if needed, to at least one third party to continue clinical development 	<ul style="list-style-type: none"> Define mechanism(s) by which geographically diverse production will be enabled to ensure supply autonomy and stability, where appropriate Define high-level plans to work with relevant programme implementation, financing, procurement, and technology pooling/sharing partners
Openness & transparency	<ul style="list-style-type: none"> Promote, whenever possible, open access to research inputs, processes, and outputs Publish research results (negative and positive) in open-access journals whenever possible 	<ul style="list-style-type: none"> Promote open access to research inputs, processes, and outputs whenever possible Publish research results (negative and positive) in open-access journals whenever possible Document and publish R&D costs whenever possible

*DNDi defines 'affordable pricing at the lowest sustainable level' as including: (1) the full production costs, as optimized without compromising quality; (2) direct distribution costs; and (3) a reasonable margin to ensure manufacturing and distribution on a sustainable basis.

V. Shifting paradigms and opportunities for change

Over the past 20 years, there have been increasing calls and support for making biomedical research more equitable, inclusive, and sustainable. The COVID-19 pandemic was in many ways an inflection point: it sparked unprecedented levels of scientific collaboration and rapid development of life-saving vaccines, tests, and treatments, but it also revealed profound resistance to open sharing of key research knowledge and know-how, as well as stark disparities in access to these crucial technologies.³³

The pushback against this situation was swift during the emergency phase of the pandemic – with LMIC governments, regional bodies, civil society, and opinion leaders rallying around the demand that such secrecy and such dramatic inequities in access to health tools would ‘never again’ be permitted.* This, in turn, has given rise to increased interest in new models for science and innovation† that will:

- ▶ Bolster and increase R&D capacity in LMICs and nurture open, networked approaches to scientific collaboration;
- ▶ Prevent abusive knowledge appropriation; and
- ▶ Ultimately result in more equitable access to health tools.

To this end, there are a range of helpful resources, initiatives, and frameworks for integrating equitable access principles and provisions into the R&D process, for example, the 2024 *Planning Access During Research and Development report* by the United Nations Development Programme’s Access and Delivery Partnership,[‡] the Global Healthcare Innovation Alliance Accelerator’s[§] Master Alliance provisions Guide (MAPGuide) platform,^{**} and the 2025 US NIH Intramural Research Program Access Planning Policy.^{††}

Perhaps most importantly, in April 2025, after three years of negotiations, consensus was reached on a draft convention, agreement, or other international instrument to strengthen pandemic prevention, preparedness, and response under the WHO Constitution (Pandemic Agreement). The Pandemic Agreement^{‡‡} was formally adopted at the 78th World Health Assembly in May 2025 in a rare show of international cooperation and multilateralism.

This first-of-its-kind treaty contains several critically important provisions, including Article 9.5, which commits countries to develop policies about attaching public interest conditions to R&D funding and to publish such terms. This provision marks the first time in history that an international health agreement has explicitly acknowledged the critical

*See, for example, The Independent Panel for Pandemic Preparedness and Response: <http://bit.ly/46u9f2K>

†See, for example, Geneva Graduate Institute Global Health Centre (<http://bit.ly/46UCzjl>) and G20 Health Ministers Launch Coalition to Promote Local Medicine Production (<http://bit.ly/3lzkBdN>)

‡This report underscores the value of integrating access considerations during the product development lifecycle and provides examples of policies and contractual practices from a range of product developers. Available at <http://bit.ly/3Kfrh1h>

§<https://ghiaa.org/>

**This online portal provides a centralized repository of access-oriented contractual and policy strategies used by leading global health actors to foster transparency and enable knowledge sharing. Available at <http://bit.ly/46MS1yN>

††Under this policy, companies or groups that wish to acquire a license to use certain NIH patents must now submit a plan explaining how they will make their products more accessible to patients. These ‘Access Plans’ will be reviewed by NIH and, if approved, will become part of the licensing agreement between NIH and the company. This policy applies to patents that are completely owned by the government and managed by NIH’s Intramural Research Program. Available at <http://bit.ly/424jNUY>. For additional background, see *Integrating Equity Into Licensing Agreements For Taxpayer-Funded Technologies*: <http://bit.ly/4muzg87>

‡‡Available at <http://bit.ly/47Utnxq>

need for governments to leverage the power of public R&D funding to shape health innovation outcomes so that greater openness and equitable access are ensured.

Despite progress in building support for access provisions to be included more intentionally in the medical innovation process, there has been less focus on closed and proprietary approaches to knowledge management, which are still the default. This has been illustrated in multiple health emergencies since COVID-19, for example, in the lack of technology sharing in response to mpox outbreaks in Africa, and in negotiations around a pathogen access and benefit-sharing (PABS) system as part of the Pandemic Agreement.

And there are important questions now arising about how open science principles and practices will be applied as biomedicine moves into the era of platform technologies – such as messenger RNA (mRNA)-based technologies, monoclonal antibodies, gene-editing systems, and viral vectors – and will evolve with new ways of gathering and using data, including through artificial intelligence.

There are also ethical concerns, for example, about striking the right balance between patient privacy and confidentiality and data sharing, as well as addressing the risk of extraction and/or unfair exploitation of local knowledge in LMICs. The history of treating scientists and other knowledge producers in LMICs as suppliers or recipients of scientific knowledge has led to some distrust and scepticism over what proponents of ‘open science’ really aim to achieve – and for whom.³⁴ As such, discussions about open science require candour, not only about commercial versus non-commercial approaches to science but also power dynamics in knowledge management systems between high-income countries and LMICs.

It is important to confront these questions and tensions head-on. Those with power over policy- and decision-making will have to recognize legitimate concerns about who controls data and knowledge and ensure that in every R&D collaboration, ownership of IP and management of knowledge are negotiated and implemented to support the achievement of public health objectives. Public funders, in particular, have immense leverage – and responsibility – to secure more equitable outcomes through the significant investments they make in research. This needs to be done through both funding agreements and through the power of governments more generally to compel more openness, including through compulsory licensing to ensure access to knowledge, technology, and end products, if and when necessary. In the meantime, other public health and R&D actors can and must move quickly too.

THERE ARE IMPORTANT QUESTIONS NOW ARISING ABOUT HOW OPEN SCIENCE PRINCIPLES AND PRACTICES WILL BE APPLIED AS BIOMEDICINE MOVES INTO THE ERA OF PLATFORM TECHNOLOGIES



VI. Conclusion and recommendations

The promise of open science lies in its ability to unlock collective knowledge, accelerate innovation, and ensure that life-saving health technologies reach all who need them. But realizing this promise requires a deliberate and strategic shift away from default systems of knowledge enclosure and restrictive approaches to IP management that dominate biomedical R&D. DNDi's two decades of experience illustrate how pragmatic and principled negotiation, equitable licensing, and early-stage commitments to openness, transparency, and access can drive both scientific progress and more equitable health outcomes.

To embed these lessons more widely, systemic change is needed. That means transforming how governments fund science, how private donors incentivize collaborations, how industry manages knowledge, how academia measures success, and how global health actors structure contractual agreements and other commitments. The following recommendations are not exhaustive but can provide a path forward for different actors across R&D ecosystems to adopt policies and practices that more closely align with the public interest and identify critical issues that may require further discussion and debate.*

Now is the time to move from exceptional case studies to new norms that will promote openness, transparency, and more equitable access to the fruits of scientific progress.

Governments

Align public R&D funding with public interest outcomes:

- ▶ Prioritize funding to address public health needs over commercial prospects
- ▶ Attach openness and access conditions to public R&D funding and licensing agreements as per, for example, the Pandemic Agreement Article 9.5 related to affordability, availability, technology transfer, knowledge and data sharing, transparency, etc.
- ▶ Implement policies requiring publicly funded research outputs (e.g., data, compounds, and clinical findings) to be shared in the public domain and/or licensed non-exclusively (e.g., as per the Pandemic Agreement Article 9.5)

Promote and protect open knowledge ecosystems:

- ▶ Enact legislation and fund infrastructure to support data-sharing, open access publishing, and collaborative platforms
- ▶ Ensure policies and regulations (e.g., on data protection, clinical trial transparency, and procurement) that proactively encourage – and do not obstruct – open science approaches to knowledge management

Ensure public interest safeguards in laws and policies related to IP and licensing:

- ▶ Enact laws and policies consistent with relevant international agreements that contain strong language on public interest safeguards, including but not limited to TRIPS flexibilities, such as compulsory licensing and other non-voluntary measures to promote access and openness

*For additional, and more general, recommendations that may be useful, see the September 2025 Statement of the United Nations Secretary General's Scientific Advisory Board on Open Science. Available at <http://bit.ly/3KujEbo>

Philanthropic R&D funders and investors

Make openness a funding condition:

- ▶ Require grantees to publish research results (positive and negative), share data, and commit to pro-access licensing as a condition of support

Incentivize collaborative and transparent models:

- ▶ Support R&D consortia or initiatives that crowdsource innovation and make IP-free or openly licensed outputs available
- ▶ Support platforms that share data and publish R&D costs and contractual terms

Review internal policies to avoid reinforcing enclosure:

- ▶ Re-examine existing investment practices, IP policies, and publication embargoes that may restrict openness

Academic and research institutions

Adopt institutional open science policies:

- ▶ Encourage open access publication, data-sharing, and provisions to ensure access
- ▶ Develop technology transfer policies that move beyond relying primarily on IP as the main measure of productivity and integrate the culture and principles of open science into research training curricula

Private pharmaceutical and biotech industry

Engage in open innovation beyond early discovery:

- ▶ Expand participation in collaborative platforms that share not only pre-competitive data but also clinical trial results, manufacturing know-how, and regulatory filings

Reform IP practices to serve public health:

- ▶ Avoid practices that enclose knowledge without adding value (e.g., extending patent monopolies via minor modifications, also called 'evergreening')
- ▶ Discontinue advocacy for 'TRIPS-plus' measures that prolong monopolies in free trade agreements and other policies
- ▶ Explore minimally defensive patenting with maximally permissive licensing approaches

Commit to access, technology transfer, and transparency:

- ▶ Implement clear knowledge-sharing, pro-access licensing, and technology transfer arrangements in contractual agreements
- ▶ Ensure transparency, including of prices and R&D costs, as well as contractual agreements

Global health actors and product development partnerships (PDPs)

Embed openness and access in all research and development agreements:

- ▶ Ensure knowledge-sharing, including in relation to IP and data, and other access provisions are negotiated at project initiation, not after product development is completed
- ▶ Publish licensing terms, regulatory strategies, and cost data

Support regional R&D capacity and South-South collaboration:

- ▶ Facilitate initiatives that enable LMIC-led innovation, technology transfer, and end-to-end product development

NOW IS THE TIME TO MOVE FROM EXCEPTIONAL CASE STUDIES TO NEW NORMS THAT WILL PROMOTE OPENNESS, TRANSPARENCY, AND MORE EQUITABLE ACCESS TO THE FRUITS OF SCIENTIFIC PROGRESS.

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For more information,
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Established in 2003, the Drugs for Neglected Diseases initiative, DNDi, is an international not-for-profit organization that discovers, develops, and delivers safe, effective, and affordable treatments for the most neglected patients.

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