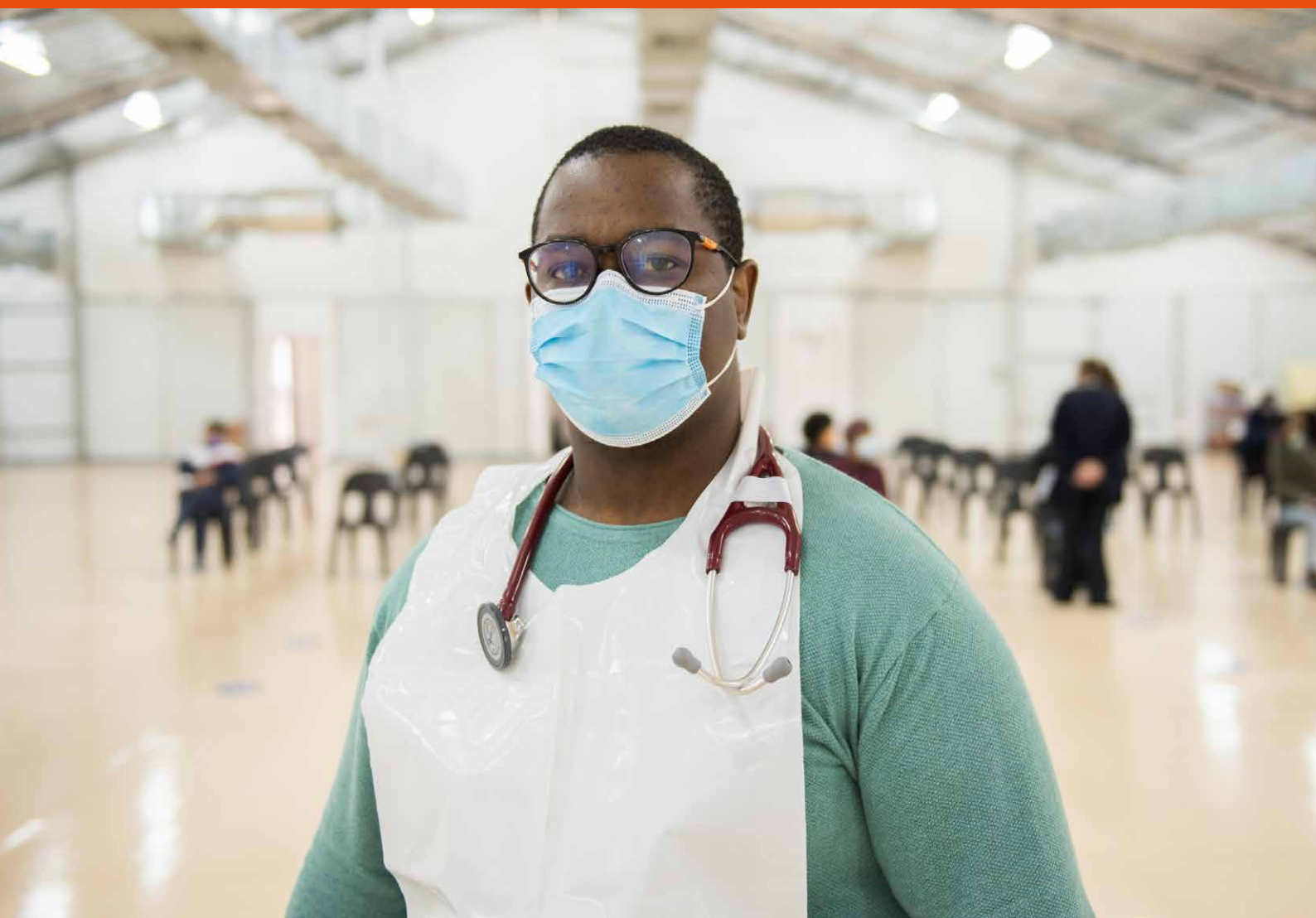


COVID-19 POLICY REPORT
AUGUST 2021

ANOTHER TRIUMPH OF SCIENCE, BUT DEFEAT FOR ACCESS?



Ensuring innovation and equitable access
for COVID-19 treatments, other infectious
diseases, and future pandemics

DNDi
Drugs for Neglected Diseases *initiative*



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Executive summary

The COVID-19 pandemic has brought devastating suffering and loss to families and communities across the globe, and together with it, widespread damage and disruption to economies and livelihoods. Patients and their families, as well as health workers who have put themselves at tremendous risk to treat the sick, have faced the gravest of circumstances – with shortages of everything from gloves, masks, and tests to oxygen therapy and other treatments, intensive care beds, and vaccines.

This points to a truly global lack of preparedness in nearly every region of the world, the fragility of supply chains, and the absence of effective research and development (R&D) coordination and globally agreed rules to ensure equitable access to essential health tools.

COVID-19 has given rise to never-before-seen levels of collaboration and rapid advances in biomedical science that have delivered life-saving technologies to fight COVID-19 – at breakneck speed. But it has also exposed the health consequences of racial and economic disparities within and between countries – and for millions of people in countries and communities still without access, new waves of COVID-19 continue to cause great despair and claim millions of lives.

The Drugs for Neglected Diseases *initiative* (DNDi) was established to address a chronic challenge when it comes to meeting the R&D needs of neglected populations. Many of the challenges that have been identified in relation to the R&D system and access to vaccines, diagnostics, and therapeutics for COVID-19 are acute examples of the chronic failures that DNDi and our partners have faced, and tried to overcome, for neglected populations over the past two decades.

MANY OF THE CHALLENGES THAT HAVE BEEN IDENTIFIED IN RELATION TO THE R&D SYSTEM AND ACCESS TO VACCINES, DIAGNOSTICS, AND THERAPEUTICS FOR COVID-19 ARE ACUTE EXAMPLES OF CHRONIC FAILURES.

From the start of the pandemic, our teams have been working to leverage our experience and partnerships to help ensure the greatest possible sharing of research knowledge, identify effective treatments for COVID-19 – an area that has been neglected and under-resourced in the global response to the pandemic – and advocate for policies that will spur innovation and ensure equitable access to the fruits of scientific progress for all people in need, no matter their income or where they live.

This DNDi Policy Report urges the international community to learn the positive lessons and avoid repeating mistakes that would hinder innovation of and access to COVID-19 therapeutics, offering a series of recommendations for immediate course-correction based on our experience as an R&D organization.

These include the need to:

1. **Increase** political attention to and financing of COVID-19 therapeutics R&D to identify treatment options for all stages of COVID-19, including early treatment interventions – embracing in particular support and coordination for open drug discovery and development of novel antivirals, host-targeted interventions, and repurposed compounds and robust testing of these options in comparable adaptive platform trials.
2. **Transform** governance structures of the Access to COVID-19 Tools Accelerator (ACT-A) to ensure equal representation from low- and middle-income countries (LMICs); make sure ACT-A explicitly addresses intellectual property (IP) barriers and improves transparency of development, production, and supply; and support collaboration between ACT-A pillars to enable a 'test-and-treat' approach to early treatment.
3. **Secure** specific contractual commitments and enabling policies, such as a temporary waiver on IP, to ensure rapid transfer of technology, large-scale manufacturing, and equitable access to new and existing COVID-19 therapeutics in addition to other health tools.

We then outline the specific ways in which the pandemic prevention, preparedness, and response architecture that arises out of COVID-19 will need to be re-oriented in the longer term to:

1. **Guarantee** sustained political attention to and financing of end-to-end R&D for pandemics and all diseases and products of public health importance, with clear priority given to areas most likely to be neglected by the market.
2. **Re-imagine** global health R&D coordination, collaboration, and financing to support a more distributed, decentralized, and democratic approach to the production of knowledge and innovation.
3. **Ensure** there are globally agreed norms and binding rules governing R&D and equitable access to essential health tools to ensure the benefits of scientific progress will be equitably shared and considered global public goods, available to all.

The COVID-19 pandemic is nowhere near over and there are and will be ongoing surges throughout the world due to inequitable access to vaccines and the continued emergence of variants of concern. As we examine where we are and look to the future, responding to the needs of those at highest risk of infection, illness, and death today must remain the top priority.

THIS DNDi POLICY REPORT URGES THE INTERNATIONAL COMMUNITY TO LEARN THE POSITIVE LESSONS AND AVOID REPEATING MISTAKES THAT WOULD HINDER INNOVATION OF AND ACCESS TO THERAPEUTICS AND OTHER HEALTH TOOLS FOR COVID-19 AND OTHER PANDEMICS.



DNDi and COVID-19

The Drugs for Neglected Diseases *initiative* (DNDi) is a not-for-profit R&D organization that discovers, develops, and delivers new treatments for neglected patients. Since our creation in 2003 by Médecins Sans Frontières (MSF) and public research institutions in Brazil, France, India, Kenya, and Malaysia, we have developed nine new and improved treatments for six deadly diseases that have reached millions of people utilizing an alternative, collaborative, not-for-profit R&D model.¹

In response to the COVID-19 pandemic, DNDi has:

1. Co-founded and currently hosts the COVID-19 Clinical Research Coalition,² a coalition of nearly 300 individuals and more than 200 institutions from over 85 countries, primarily from LMICs, to prioritize, facilitate, and accelerate research for COVID-19 in LMICs;
2. Launched ANTICOV,³ a multi-country, adaptive platform trial conducted in 13 African countries with 26 African and global partners to identify treatments for mild-to-moderate COVID-19 outpatients to prevent the need for hospitalization;
3. Joined a spontaneous, global, open drug discovery collaboration called the COVID Moonshot,⁴ participated in Work Stream 1 of the ACT-A Therapeutics Partnership to review the best therapeutic candidates to take forward for clinical testing, and collaborated with various research consortia working to identify novel, early-stage discovery projects to contribute to building the pipeline for new treatments for COVID-19, other coronaviruses, and other pathogens of pandemic potential, including projects originating directly from the Pandemic Response Box, released in 2018 by the Medicines for Malaria Venture (MMV) and DNDi expressly for this purpose; and
4. Advocated for R&D to be driven by the public interest and for COVID-19 health tools to be developed and delivered as global public goods, with equitable access for all.

DNDi was established to address a chronic challenge when it comes to meeting the R&D needs of neglected populations. Many of the challenges that have been identified in relation to the R&D system and access to vaccines, diagnostics, and therapeutics for COVID-19 are acute examples of the chronic failures DNDi and our partners have faced, and worked to overcome, for neglected populations over the past two decades.

Introduction

In just over one year, the novel coronavirus (SARS-CoV-2) has gone from being an almost completely unknown pathogen to a complex global pandemic that has claimed more than 4 million lives,⁵ disrupted economies and livelihoods, undermined critical gains in global health and development, and shone a glaring light on the health consequences of systemic racial and economic inequities within and between countries.

Far from being an acute and temporary crisis that can be eradicated, devastating surges of infection, hospitalization, and death, long-term consequences and complications from the disease, the emergence of new variants of concern, insufficient diagnostic capacity, and painfully slow and inequitable roll-out of first-generation vaccines in LMICs mean that COVID-19 is here to stay.

The scientific response to COVID-19 is enabling major advances and the development of new health technologies, particularly vaccines and diagnostics, at unprecedented speed – shortening clinical development and regulatory timelines and quickly validating platform technologies and modalities in a way that may be transformative for other diseases.⁶

But it has also thrown into sharp relief the limited commitment of global health funders and actors to prioritizing and financing research in LMICs; the serious power imbalances that determine who has a seat at the priority-setting and decision-making table in global health; and the lack of transparency and globally agreed rules to ensure open sharing of knowledge, data, and technology and equitable access to any new health tools developed.

Bringing together a constellation of global health agencies and foundations into a formal partnership to accelerate the development, manufacturing, and distribution of COVID-19 vaccines, therapeutics, and diagnostics, ACT-A was one of several initiatives set up to respond to the pandemic early on. It has made important strides as a response to the initial acute emergency phase but has also highlighted some of the limitations of the approach that was adopted at the global level.

Despite the creation of COVAX,⁷ the vaccine pillar of ACT-A, dedicated specifically to ensuring equitable access to COVID-19 vaccines in every country, only a fraction of the more than 3.6 billion vaccine doses given globally have been in low-income countries.^{8,9,10}

In the early days of the pandemic, many political leaders made lofty promises about ensuring global solidarity and equitable access to COVID-19 vaccines, diagnostics, and treatments as global public goods.¹¹ But faced with limited and highly concentrated and controlled manufacturing capacity, most countries were unable to secure sufficient volumes, especially of vaccines, and nationalism rather than solidarity prevailed.

For example, high-income countries (HICs) have hoarded doses for domestic use – in some cases stockpiling more than three to four times the number needed to cover their populations¹² – and offered jabs to healthy teenagers, incentives to the vaccine-hesitant, and consideration of booster shots before the majority of the world's frontline health workers and those at highest risk of severe disease and death have received even a single dose.

Only after a substantial proportion of their own populations were vaccinated – and after intense international outcry – did G7 countries commit to gradually increase sharing and purchasing of additional vaccine doses for LMICs. There has also been

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significant distribution of vaccines to LMICs from China and Russia, but even then, these various efforts are too slow and fall far short of the estimated 11 billion doses that are needed globally.¹³

In response to 'vaccine nationalism' there have been numerous calls for global solidarity from the World Health Organization (WHO), the UN General Assembly, and other multilateral organizations. There have also been a number of regional initiatives – notably initiatives led by the African Union and Africa Centres for Disease Control and Prevention (Africa CDC)¹⁴ and the COVID-19 messenger RNA (mRNA) technology transfer hub in South Africa¹⁵ – and commitments to greater solidarity, such as those agreed at the Summit for Vaccine Internationalism convened by Argentina, Mexico, Bolivia, Cuba, and Venezuela as well as the regional governments of Kisumu, Kenya and Kerala, India in June 2021.¹⁶

But despite the massive amounts of public funding that went into the discovery and development of vaccines, funders have failed to use their leverage to ensure contractual conditions that would facilitate the sharing of technology, data, and know-how – for example, through the WHO COVID-19 Technology Access Pool (C-TAP)¹⁷ and the Medicines Patent Pool (MPP) – in order to enable greater global production capacity.

Pharmaceutical companies, meanwhile, have largely refused to non-exclusively license and share IP and know-how. Too little has been done to promote the expansion and decentralization of vaccine manufacturing capacity in Africa,¹⁸ Asia, and Latin America to help meet regional and global needs.¹⁹

These shortcomings and failures in the global response to the pandemic have led many commentators – including WHO Director General Dr Tedros Adhanom Ghebreyesus – to describe the situation as of mid-2021 as 'vaccine apartheid'.²⁰

Indeed, if there is one central lesson from the past year, it is that there is urgent 'unfinished business' in global health when it comes to equitable access to health tools and technologies. At almost every step when there was an opportunity to do things differently, political and commercial choices were made that further entrenched the status quo.

In order effectively to address COVID-19, future pandemics, and other emerging threats – as well as long-standing epidemics and pandemics, neglected diseases, and the 'silent pandemic' of antimicrobial resistance (AMR) – decisions about whether and how to discover, develop, produce, allocate, and price essential health technologies cannot be left to narrow national interests or market forces.

Renewed public leadership and international cooperation is required to correct course and move away from a business-as-usual, 'trickle-down'²¹ approach to global health innovation and access.

This DNDi Policy Report urges the international community to learn the early lessons – and avoid repeating the mistakes – of the past year when it comes to innovation of and access to COVID-19 *therapeutics* – a deeply neglected area within the COVID-19 response. Then, zooming out more broadly, it outlines the specific ways in which the pandemic prevention, preparedness, and response architecture that arises out of COVID-19 will need to be re-oriented to enable the emergence of a more effective end-to-end biomedical innovation ecosystem that ensures the benefits of scientific progress will be equitably shared and considered global public goods, available to all.

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Hindering or enabling equitable access to medical innovations: Key 'hand-offs' along the innovation lifecycle

The battle for equitable access to medical innovations has been raging since the mid-1990s, beginning with the struggle for global access to antiretroviral therapy (ART) for HIV, and repeating time and time again for other diseases – from hepatitis C and cancer to diabetes and COVID-19.

HIV made clear to the world the significant capacity that exists in both the public and private sectors in middle-income countries such as Brazil, Thailand, India, and South Africa, to manufacture affordable, quality generic versions of antiretrovirals. In several countries, this production capacity – made possible in part because countries could refuse patenting of essential products such as medicines before the World Trade Organization's Agreement on Trade-related Aspects of Intellectual Property Rights (TRIPS) was fully implemented – enabled large-scale access to affordable ART, even in the poorest countries and communities, through national programmes and major global health initiatives such as the Global Fund to Fight AIDS, Tuberculosis and Malaria, the US President's Emergency Plan for AIDS Relief (PEPFAR), and Unitaid.

COVID-19 has made clear to a broader public that there is a complex chain of funders and actors involved in the earlier stages of the scientific discovery and development process, in many cases with a significant amount of the underlying research being underwritten by the public sector²² and conducted in public research and academic institutions and within small biotech companies.



The development of the first-generation COVID-19 vaccines illustrates this complexity and can only be described as a triumph of science. For example, just two months after the SARS-CoV-2 genome sequence was made publicly available by Chinese researchers through the GISAID platform,²³ Phase I trials of the first-ever mRNA-based vaccine candidate began.²⁴ Nine months after that, two mRNA vaccines received emergency use authorization (EUA) from the US Food and Drug Administration (FDA).^{25,26} A process that normally takes 10-15 years – the previous record was the mumps vaccine, which was developed in 4 years²⁷ – had been compressed to less than a year.

As of early July 2021, there are approximately 20 vaccines that have received full regulatory approval or EUA or listing in at least one country,²⁸ over a dozen of which are approved in multiple countries (see Figure 1), and nearly 200 in pre-clinical or clinical development.^{29,30}

Figure 1: Some of the main COVID-19 vaccines that have been approved or received emergency use authorization or listing in multiple countries worldwide

Developer	How it works	Status
Pfizer-BioNTech	mRNA	Approved in several countries. Emergency use in US, EU, other countries.
Moderna	mRNA	Approved in Switzerland. Emergency use in US, EU, other countries.
Gamaleya	Adenovirus-based (Ad26 and Ad5)	Emergency use in Russia, other countries.
Oxford-AstraZeneca	Adenovirus-based (ChAdOx1)	Approved in Brazil. Emergency use in UK, EU, other countries.
CanSino	Adenovirus-based (Ad5)	Approved in China. Emergency use in other countries.
Johnson & Johnson	Adenovirus-based (Ad5)	Emergency use in US, EU, other countries.
Sinopharm	Inactivated	Approved in China, UAE, Bahrain. Emergency use in other countries.
Sinovac	Inactivated	Approved in China. Emergency use in other countries.
Sinopharm-Wuhan	Inactivated	Approved in China. Limited use in UAE.
Bharat Biotech	Inactivated	Emergency use in India, other countries.

Source: The New York Times and the World Health Organization

This rapid pace of vaccine development, particularly for the mRNA vaccines, is due in part to (i) more than three decades of research into mRNA technology on the part of academic scientists,³¹ (ii) two decades of significant public investment in research following two other coronavirus outbreaks – severe acute respiratory syndrome (SARS) in 2002 and Middle East respiratory syndrome (MERS) in 2012, (iii) substantial public funding of pre-clinical and clinical development (including the financing of multiple clinical trials in parallel), and (iv) important investments at critical moments from the private sector (particularly biotech companies).

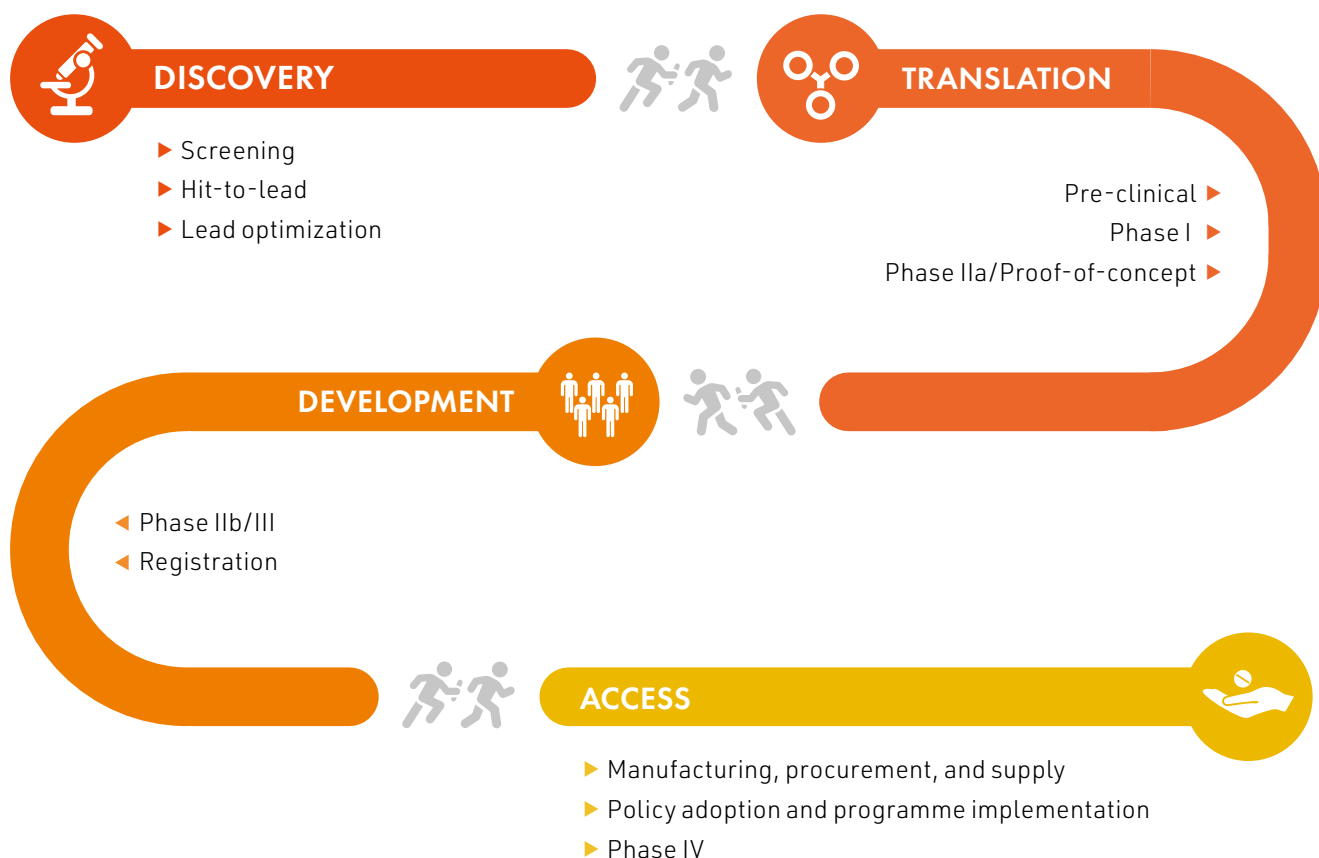
All of this, combined with rapid, rolling regulatory review processes and massive pre-purchase commitments from the public sector to de-risk scale-up of manufacturing – and a bit of luck³² – translated academic discoveries into tangible, life-saving innovations.

Why is such a feat of science – resulting in life-saving technologies so soon after the emergence of a deadly global pandemic – benefiting only a fraction of those who need it?

Bringing a product out of the research pipeline and into the hands of patients requires multiple ‘hand-offs’ across the innovation lifecycle (see Figure 2). At each stage of the R&D process, critical decisions are made that can either facilitate or hinder availability, affordability, and access. What decisions get made at each stage, and who gets to make them, is key.

BRINGING A PRODUCT OUT OF THE RESEARCH PIPELINE AND INTO THE HANDS OF PATIENTS REQUIRES MULTIPLE ‘HAND-OFFS’ ALONG THE INNOVATION LIFECYCLE.

Figure 2: Critical ‘hand-off’ points throughout the R&D process where commercial and policy decisions can determine access



Public and philanthropic R&D funders could have secured terms and conditions with private companies to ensure open collaboration and transparent sharing of the IP, research knowledge, and data that would have been necessary to safeguard affordability, production, supply, and equitable allocation. While public information on contracts for COVID-19 vaccine R&D and pre-purchases is limited, it appears that funders either did not include such conditions,³³ or did not choose to exercise them.³⁴ Instead, a combination of national interests and private commercial interests inevitably led to gross inequities.

Despite the limited information about vaccine manufacturing and distribution agreements that is publicly available, important differences between the approaches taken can already be observed. Generally speaking, these are split between a highly concentrated approach and a more distributed model (although most fall somewhere in between).³⁵

On one extreme is the highly concentrated approach taken, for example, by Pfizer/BioNTech and Moderna, which have used a traditional market-driven model characterized by focusing primarily on HIC markets with high prices and little to no attention to transferring technology or ensuring affordability in LMICs.

On the other side is the more distributed approach, including that taken by Oxford/AstraZeneca as well as Gamaleya Research Institute and Sinovac. For example, Oxford/AstraZeneca took a no-profit/no-loss approach to pricing for LMICs during the course of the pandemic and sub-licensed their technology to the Serum Institute of India and Fiocruz in Brazil³⁶ for production in and for LMICs, including through COVAX.³⁷

Notwithstanding ongoing challenges with the model used by Oxford/AstraZeneca – including a lack of transparency of its contractual terms and conditions with licensees, a reluctance to non-exclusively license relevant IP and know-how to any manufacturer, and an over-reliance on one partner company, the Serum Institute of India – it shows that there is some willingness, though limited, to explore alternatives to a business-as-usual approach.

However, if global equitable access is to be ensured, there must be a more forceful role for the public sector to coordinate and apply globally agreed rules that will ensure sufficient supply, equitable allocation, and affordability of all essential health technologies. In fact, those companies that have made some effort to ensure equitable access, such as AstraZeneca, are due in large part to the willingness of public sector or academic partners (such as Oxford) to introduce at least limited ‘access conditions’ in exchange for use of its technology. Without a more dramatic shift in approach, there will continue to be a struggle for access to new treatments, tests, vaccines, and other health tools – disease by disease, product by product, country by country, company by company.

Global vaccine equity for COVID-19 is clearly the defining challenge of 2021. But we cannot be satisfied with only one set of tools for pandemics and other infectious diseases. There is always a need for diagnostic, therapeutic, and preventive tools.

IF GLOBAL EQUITABLE ACCESS IS TO BE ENSURED, THERE MUST BE A MORE FORCEFUL ROLE FOR THE PUBLIC SECTOR TO COORDINATE AND APPLY GLOBALLY AGREED RULES THAT WILL ENSURE SUFFICIENT SUPPLY, EQUITABLE ALLOCATION, AND AFFORDABILITY OF ALL ESSENTIAL HEALTH TECHNOLOGIES.



The urgent need for COVID-19 therapeutics

The need for treatments at all stages of COVID-19 is more pronounced than ever given the slow pace of global vaccine roll-out and the spiralling COVID-19 crises across Africa, South Asia and Latin America. It is further compounded by the possible waning of immunity over time, uncertainty around the efficacy of vaccines for immune-compromised individuals, and, critically, the continued impact globally of new variants of concern.³⁸

Yet the scientific advances for therapeutics have to date been few and far between.

Current therapeutic landscape

Although some progress has been made in terms of sharing of early information about therapeutic candidates and the identification of dexamethasone, a repurposed and affordable drug, as a life-saving treatment for severe cases requiring oxygen therapy,³⁹ the therapeutic toolbox for COVID-19 remains limited. Most initial research activities that aimed to quickly identify potential therapeutics have been disappointing.

Few of the repurposing candidates that initially held promise and that might have offered immediate and affordable treatment options for people with COVID-19 have panned out⁴⁰ – although the search for already approved drugs that could be re-directed to COVID-19 continues – and the same is true for convalescent plasma.⁴¹

Monoclonal antibodies (mAbs) initially received a great deal of attention and were expected to deliver rapid antiviral options. mAbs remain an interesting potential platform technology, particularly if second-generation mAbs can be delivered as

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single intra-muscular or sub-cutaneous injections – meaning via a single shot in the arm, for example, as opposed to a complex and lengthy intravenous infusion – and delivered at a lower dose so the cost of making them can be brought down.⁴² But to date, the first-generation mAbs that have received FDA EUA or qualified for WHO Emergency Use Listing (EUL) are expensive and only accessible in HICs (and even then, in a limited fashion),⁴³ and their efficacy is profoundly affected by mutations of the SARS-CoV-2 spike protein.

Much more needs to be done to prevent and address all severe complications of the disease and to prevent more patients from progressing to the point that they require hospitalization, intensive care, oxygen therapy, or worse. Efforts are today rightly focused on identifying novel antivirals, additional repurposed therapeutics, and more affordable and adapted new approaches, such as second-generation mAbs and other biologics.

For early treatment of COVID-19, before it progresses to severe disease, there is a clear rationale emerging that a strong antiviral (or combination of antivirals with different mechanisms of action) combined with host-directed therapies (anti-inflammatories and immunomodulators) will be needed to account for the disease evolution and host inflammatory response during the first few days of infection.⁴⁴

These treatments should ideally be easy to take at home after rapid diagnosis – effectively enabling ‘test-and-treat’ approaches at the community level.

Early treatment interventions must be appropriate for diverse racial and ethnic groups, and other vulnerable and at-risk populations, such as pregnant and breastfeeding women, or women who do not have easy access to contraception. In addition, much remains to be learned regarding the pathogenesis and prevention of the chronic consequences of COVID-19, or post-COVID condition, which may disproportionately affect women and people with milder forms of the disease.

Rapid scientific progress in diagnostics – but unequal access in LMICs

As with vaccines, there have been rapid advances in the development of COVID-19 diagnostics. In a field with previously limited research, the first diagnostic test was developed within weeks of the genome sequence being made public and the first antigen rapid diagnostic test (Ag RDT) was granted EUL in September 2020, less than 250 days after COVID-19 was declared a public health emergency of international concern.⁴⁵ However, despite unprecedented speed in the development of some diagnostics, there is growing inequity in access to and use of these tools, potentially resulting in artificially low reporting of COVID-19 cases in many LMICs.⁴⁶

Unequal access to COVID-19 vaccines coupled with the rise of variants of concern mean that there has never been a more important time in this pandemic for the use and rapid scale-up of diagnostics. While in HICs there has been an expansion of the use of Ag RDTs, including self-testing at home, in the workplace, and even in pilots for large-scale events, the availability of such tools in LMICs stands in stark contrast, especially for community-based testing. Although data are limited, testing rates in LMICs range from 0.1–15% of those in HICs,⁴⁷ hitting neglected populations the hardest because they often face the greatest barriers to accessing health services.

There are a variety of reasons for low testing rates, including concerns about the lack of clear and explicit recommendations in WHO guidelines for use of Ag RDTs for community-based testing in LMICs, leading to a lack of prioritization of such testing in national guidelines and donor proposals.⁴⁸ It has also been noted that insufficient urgency has been given to EUL applications of many other brands of Ag RDTs. These, together with efforts to scale up local production, would ensure increased supply and drive down prices. In order to effectively deploy robust ‘test-and-treat’ strategies – particularly for use outside of healthcare facilities to identify and treat early mild-to-moderate cases and reduce the need for hospitalization, community-based testing is key.

Boosting the search for novel antivirals

Despite a series of viral outbreaks over the past two decades – from SARS to MERS to avian influenza and Ebola – and despite warnings from scientists that a ‘stockpile’ of broad-spectrum ‘Phase II-ready’ antivirals would be essential to respond to future outbreaks – the antiviral medicine cabinet has remained stubbornly limited, with the exception of antiretrovirals for HIV and direct-acting antivirals for hepatitis C.⁴⁹

Apart from remdesivir (Gilead), which turned out to be of disappointingly limited use despite much initial hype,⁵⁰ and favipiravir (Fujifilm), with its known limitations due to potential toxic effects on embryos and fetuses,⁵¹ very few promising new antiviral drug candidates were ready to quickly test against SARS-CoV-2.

Even after more than a year, only a handful of direct-acting or host-directed antiviral candidates have advanced through the research pipeline. Even fewer are in a late stage of clinical development. Promising new direct-acting antiviral candidates include molnupiravir (Merck),^{52,53} PF-07321332 (Pfizer),⁵⁴ and AT-527 (Atea, Roche).⁵⁵ The pace of development of these drug candidates has been impressive despite the lack of early prioritization.

Major initiatives are being launched to boost antiviral drug discovery and development, notably a recent USD 3.2 billion investment by the US government, which includes a USD 1.2 billion pre-purchase agreement – for molnupiravir, now in Phase III trials – that is similar to purchase agreements many governments made for vaccines before proof of efficacy was established.⁵⁶

With such massive new public investments in antiviral R&D and manufacturing, what will be the public return? Will treatments be developed to facilitate access even in the most remote and resource-limited settings? Will prices be affordable for all who need access to antiviral treatments? Will companies collaborate to test their drugs in combination with other needed treatments and to share their technology and know-how to ensure large-scale manufacturing and access in LMICs? Will voluntary licences such as those negotiated by Merck with several Indian generics companies⁵⁷ be sufficient to ensure such access in LMICs? What level of post-approval surveillance will be required?

In summary, will new COVID-19 treatments, once developed, represent another triumph of science – but this time also a model for collaboration and knowledge-sharing aimed at global equity and solidarity?

WILL NEW COVID-19 TREATMENTS, ONCE DEVELOPED, REPRESENT ANOTHER TRIUMPH OF SCIENCE – BUT THIS TIME ALSO A MODEL FOR COLLABORATION AND KNOWLEDGE-SHARING AIMED AT GLOBAL EQUITY AND SOLIDARITY?

The COVID Moonshot: A model for open pandemic preparedness drug discovery?

The ‘COVID Moonshot’⁵⁸ demonstrates one clear example of how the antiviral research community might re-align towards a drug discovery model focused and driven by global equitable access from the start. Established by a diverse array of academic scientists early in the pandemic, they embraced a fully public domain approach to open-source early discovery that was initially driven by the necessity of enabling multi-party collaboration without losing time to negotiate contracts. This rapidly evolved into a single and shared vision of no IP protection to ensure any resulting therapeutic was aimed first and foremost at being appropriate for, and accessible to, people in LMICs.

This nimble, open approach has resulted in one of the most promising bespoke therapeutic opportunities emerging for the existing pandemic, attracting major funding interest as well as generous in-kind contributions, ranging from interested individuals through to major pharmaceutical companies. DNDi’s role within this consortium – initially as curious observer, currently as core team member, and soon as consortium lead – provides an opportunity to validate the viability of this model as a blueprint for more open pandemic preparedness and response drug discovery.

ANTICOV: The early treatment imperative

As of July 2021, numerous countries in Africa have been experiencing a devastating surge of COVID-19 cases, with nearly 40 countries reporting dramatic increases in new cases, hospitalizations, and deaths – from South Africa and Uganda to Nigeria and the Democratic Republic of Congo (DRC).⁵⁹

A recent study suggests that COVID-19 mortality among critically ill patients throughout Africa is higher than observed elsewhere – in large part due to the absence of critical care as well as co-morbidities such as HIV, diabetes, and other chronic illnesses.⁶⁰ This makes early intervention to prevent disease progression all the more pressing.

ANTICOV, the multi-country trial in Africa that DNDi is coordinating with 25 African and global partners, was established to try to address this need and is initially testing repurposed drugs, alone or in combination, once they prove promising in pre-clinical or proof-of-concept studies. The most promising therapeutic options are selected in close collaboration with multiple partners, including from the ACT-A Therapeutics Partnership and other experts.

Discussions are progressing to develop a similar trial to ANTICOV in India, where a catastrophic COVID-19 surge in 2021 has claimed hundreds of thousands of lives,⁶¹ and potentially also to expand ANTICOV to Latin America, where infection, hospitalization, and death rates have been devastating, especially in countries like Brazil, Peru, and Argentina.⁶²

ANTICOV is an ‘adaptive platform’ trial, a flexible and innovative trial design that allows for treatments to be added or removed as new evidence emerges. As of July 2021, ANTICOV is testing a new potential treatment that combines the well-known antiparasitic nitazoxanide and the inhaled corticosteroid ciclesonide.

The trial was jointly reviewed with support from the African Vaccine Regulatory Forum (AVAREF),⁶³ a platform established by WHO in 2006, which was recently mandated to expedite clinical trial reviews for COVID-19. Made up of representatives from each study country’s ethical and regulatory review bodies, AVAREF simplifies and helps accelerate country-level approvals.

But it also highlights some of the challenges in undertaking research during this pandemic. Despite incredible mobilization from countries and AVAREF, the consortium has faced multiple obstacles to moving this trial forward, including due to slow, complex, and time-consuming processes to obtain all authorizations, including for importation of treatments to test.

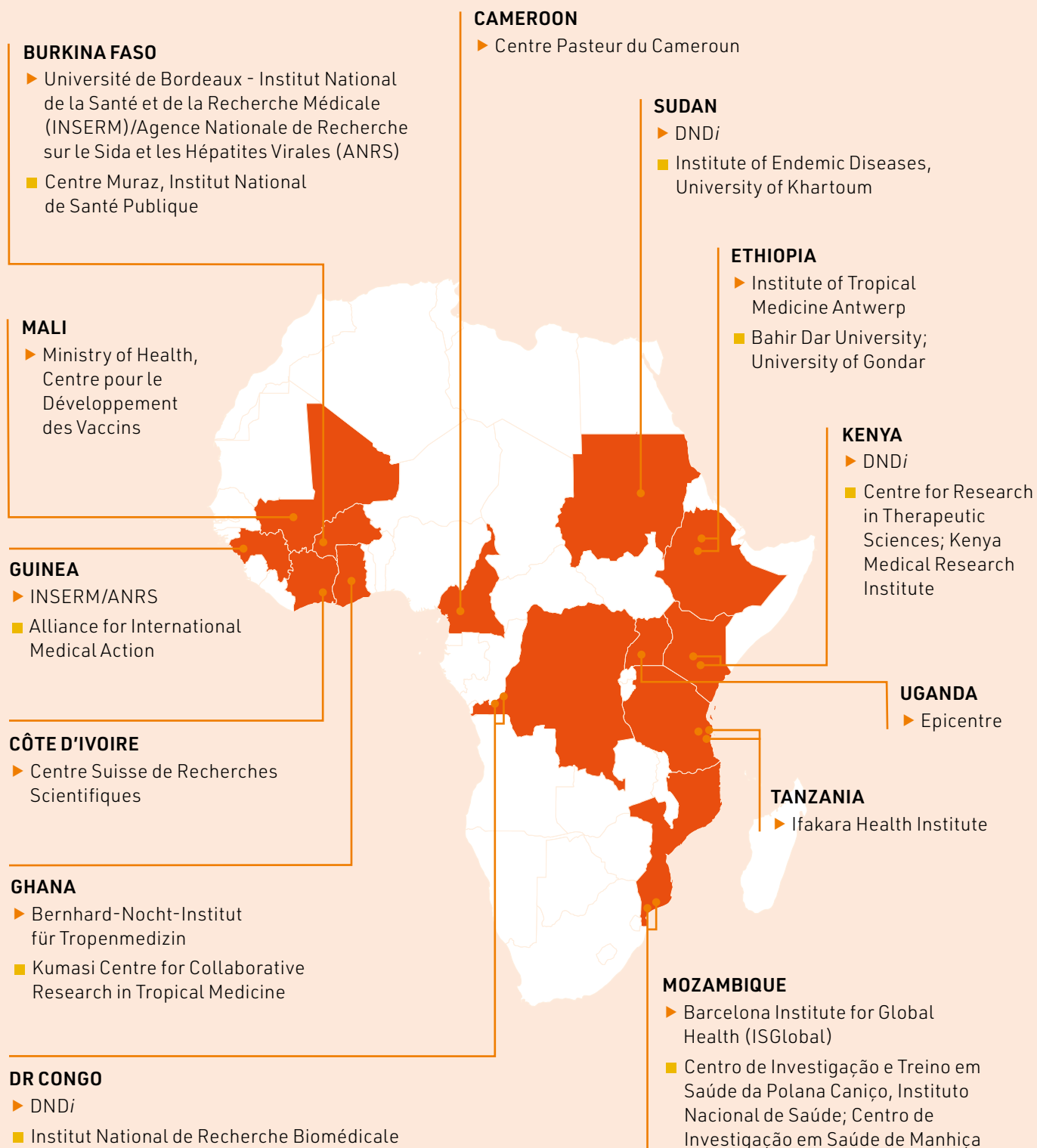
The absence of a simple, effective, and safe treatment for administration early in the course of the disease is more critical than ever. There is an urgent need to ensure collaboration among the few ongoing platform trials for outpatients – both to coordinate the drug candidate selection process and to share ongoing results to ensure that all combined efforts will provide the data needed to inform policy recommendations and clinical practice. DNDi is connecting with other major trials and co-coordinating a working group led by WHO with other major adaptive platform trials.

In the future, this network may also serve as a model for other adaptive platform trial networks and as a valuable platform for future therapeutic candidates and combinations for COVID-19.

* Major funding for ANTICOV is provided by the German Federal Ministry of Education and Research (BMBF) through KfW and by the global health agency Unitaaid as part of ACT-A. Additional support comes from the European & Developing Countries Clinical Trials Partnership (EDCTP), under its second programme supported by the European Union with additional funding from the Swedish government, as well as from the Starr International Foundation and the Stavros Niarchos Foundation (SNF).

Figure 3: ANTICOV participating countries and consortium partners

- ▶ Trial sponsors
- Implementing partners



Transversal partners: DNDi; FIND, the global alliance for diagnostics; Infectious Diseases Data Observatory; INSERM; ISGlobal; Medicines for Malaria Venture; Swiss Tropical and Public Health Institute

Challenges in COVID-19 therapeutics and recommendations for immediate course-correction

There have been several challenges that have hindered progress in COVID-19 therapeutics, which are closely linked to the overarching shortcomings and failures of the global response outlined above.

First, there has been insufficient political and financial attention paid to therapeutics research and regulation as a whole, and the majority of research conducted has been highly fragmented and focused in HICs.

Throughout the pandemic, funding for drug discovery, clinical trials, production, and distribution of therapeutics, including oxygen therapy, has been chronically inadequate, in some cases playing 'second fiddle' to R&D for vaccines.⁶⁴ It does not help that there is a USD 3.2 billion shortfall for the Therapeutics Partnership of the ACT-A.⁶⁵ There is a risk that as HICs achieve high rates of vaccine coverage, their focus may shift almost entirely to investing in surveillance, testing, and follow-up vaccination, even as LMICs with profoundly limited access to vaccines may increasingly need to prioritize treatment access as a means of coping with COVID-19.

Initially, WHO was not sufficiently empowered to play a strong normative role in defining a priority research agenda for therapeutics or coordinating research. As a result, since the beginning of the pandemic, multiple small, often under-powered, heterogeneous trials have been conducted, resulting in fragmented sets of data with often incomparable endpoints.

With the exception of a handful of international studies, such as the RECOVERY,⁶⁶ SOLIDARITY,⁶⁷ and DISCOVERY⁶⁸ trials, this has meant that there has been no simple way of easily and rapidly pooling and analysing data to adjust, adapt, or recommend treatment options. This has led to a situation in which there has been insufficient reliable clinical data – and therefore much confusion and controversy – on the efficacy of potential therapeutic candidates, such as ivermectin, despite a number of studies assessing this drug. This underlines the importance generally of larger, well-coordinated, randomized-controlled and adaptive platform trials, that have comparable endpoints, at different stages of the disease, in order to inform clinical guidelines and practice.

This situation raises many questions, including around the ethics of conducting non-informative clinical trials and the sharing of information. Today, we are at a crossroads. For example, several large groups and consortia are simultaneously planning or conducting large adaptive platform trials in outpatients, evaluating compounds to be tested in this population and conducting regular interim analyses – yet until recently, no mechanisms were in place to ensure rapid, real-time, efficient information- and data-sharing that could inform clinical guideline development and clinical practice.

There are also a number of regulatory delays, challenges, and concerns that have hindered progress on therapeutics (among other tools), especially when it comes to addressing specific needs in LMICs.

There are issues related to the speed and coordination of approval of clinical trials – for example, the WHO Ethical Review Committee, specifically dedicated to rapid review of COVID-19 studies, has operated without the expected sense

of urgency. The ANTICOV team received many non-critical review comments that required lengthy back-and-forth exchanges. These comments ignored those of the review boards of the very countries implementing the study and resulted in delays for study start that were not equally seen in the UK for the RECOVERY trial, for example.

There are also bottlenecks related to the chronic under-resourcing of the WHO prequalification programme and a potential for donors' procurement requirements to have unintended consequences on access to products that have not been either WHO prequalified or approved by a so-called 'stringent regulatory authority'. And there are long-standing unresolved issues around the regulatory pathway for biosimilars, such as for mAbs.⁶⁹

Many of these issues require long-term policy fixes, but there are some immediate steps that can and should be taken.

Immediate course-correction needed

- ACT-A and other global health institutions, including WHO, should fully articulate the resource needs and R&D priorities for COVID-19 therapeutics in order to give funders a clearer picture of the needs and ensure ambitions and actual financing are commensurate with needs. This should include:
 - ▶ Large-scale adaptive platform trials and clinical trial networks, including those based in and driven by LMICs;
 - ▶ Efforts to reduce the dose and simplify routes of administration (ideally intra-muscular or sub-cutaneous) for second-generation mAbs and other newer therapeutic modalities to bring down costs and prices and reduce logistical challenges;
 - ▶ Support for pan-coronavirus open drug discovery – including through novel collaborative approaches, not just closed, industry-led efforts – to identify promising novel antivirals with the broadest possible spectrum of activity and build the pipeline for COVID-19 and future viral pandemics, including in particular pathogens of pandemic potential that are unlikely to attract commercial attention, such as viral haemorrhagic fevers.
- Global health actors should support the Outpatient Clinical Study Group set up by WHO to facilitate sharing of expert methodologies for drug candidate assessment, put in place transparent decision-making about the allocation of compounds to different platform trials, share relevant data, and collaborate on regulatory and safety monitoring.
- Funders and global health actors should address regulatory delays and challenges by, for example:
 - ▶ Strengthening and acknowledging existing regulatory capacity worldwide, supporting collaborative and regional approaches, such as AVAREF and the proposed African Medicines Agency,⁷⁰ and bolstering WHO prequalification;
 - ▶ Adapting donor-funded procurement systems so that countries are not unreasonably constrained by requirements for 'stringent regulatory authority' approval and/or WHO prequalification;
 - ▶ Streamlining requirements and guidelines to accelerate authorization of trials⁷¹ and the regulatory pathways for biosimilars.

Second, the main body set up to accelerate the development and delivery of COVID-19 treatments, the Therapeutics Partnership of ACT-A, has fallen short in critical ways.

Like the vaccines and diagnostics pillars of ACT-A, the Therapeutics Partnership was an important emergency response to the pandemic. But ACT-A's ambitions have been too modest across all three pillars. In the case of COVAX, the original goal was to reach 20% of populations in need of vaccines. It is now clear that this was far too modest a goal – and has been described by Dr Ayoade Olatunbosun-Alakija, Co-Chair of the African Union's Vaccine Delivery Alliance, as the result of a 'colonial mindset'.⁷²

Similarly, the goal for the diagnostics pillar was only set at 500 million tests per year and for therapeutics, only 245 million treatments.⁷³ These limited ambitions have been justified by claims that ACT-A was never meant to provide a long-term solution but rather to support countries during the acute phase of the crisis, with the assumption that after this period, 'normal market activity' would meet the needs in LMICs.

ACT-A is also plagued by funding shortfalls – to the tune of USD 16.8 billion⁷⁴ across all three pillars as of June 2021.⁷⁵ The structure that was set up relied too heavily on an outdated international aid model driven by governments and global health actors in HICs rather than a truly global approach.⁷⁶ The governing bodies of ACT-A lack equal representation for policymakers, experts, and civil society from LMICs – with a resulting lack of prioritization and financing for research driven by and in LMICs.

In addition, it has opaque priority-setting and decision-making processes driven by a handful of largely private actors – processes, for example, that determine which technologies will be developed further.⁷⁷ And to date, ACT-A has been unable or unwilling explicitly to address the underlying structural causes of access inequities that it was ostensibly set up to overcome, such as management of IP, licensing, and technology transfer.

In its final report, the Independent Panel on Pandemic Preparedness and Response recommended to 'Transform the current ACT-A into a truly end-to-end platform for vaccines, diagnostics, therapeutics, and essential supplies, shifting from a model where innovation and access is left to the market to a model aimed at delivering global public goods',⁷⁸ including ensuring its governance bodies include representatives of countries across income levels and regions, civil society, and the private sector.

As one of the organizations that has taken part in deliberations in the ACT-A Therapeutics Partnership, we have seen the benefits of having a process by which the latest scientific evidence from the pipeline is brought together and reviewed – and the potential to link that with strategies to ensure access. However, we have also seen the limitations of the approach and the consequences of the absence of certain voices around the table.

For therapeutics, these limitations have played out in specific ways.

There was an insufficient focus initially on developing therapeutics for mild-to-moderate cases in outpatients, even though such treatments would be particularly useful in places with limited intensive care and hospitalization capacity.

There was also an over-emphasis on mAbs (arguably, to the exclusion of small molecule antivirals or repurposing candidates), despite some feasibility and price concerns and issues related to manufacturing and procurement. Significant energy within the Therapeutics Partnership was consumed, for example, by the 'agnostic capacity reservation' with Fujifilm, which aimed to ensure some mAbs manufacturing capacity was reserved for use in LMICs, even when it became clear that the anticipated supply would only meet 2-4% of the global needs. This limited any creative discussions about expanding supply through local manufacturing.

There were also failures to anticipate and expediently address either the need for oxygen therapy in LMICs – with little priority given to the need for oxygen until late 2020 and early 2021 – or the consequences of treating severe ventilated patients with anti-inflammatory drugs, leading to secondary infections by fungi and bacteria, such as mucormycosis (Black fungus) in India and Nepal and the subsequent need for access to antifungals, such as liposomal amphotericin B, that are unaffordable and in short supply.⁷⁹

Given there is a renewed need to focus on therapeutics – and given that policymakers are considering extending ACT-A – it is critical that these limitations are addressed in the near-term.

THERE WAS AN INSUFFICIENT FOCUS INITIALLY ON DEVELOPING THERAPEUTICS FOR MILD-TO-MODERATE CASES IN OUTPATIENTS.

Immediate course-correction needed

- Across all its pillars, ACT-A and its participating institutions must make immediate changes to governance structures to ensure equal representation from the public sector, scientific and public health experts, and civil society from LMICs in priority-setting and decision-making.
- The ACT-A Therapeutics Partnership and other funders should actively support identification of treatment options for all stages of COVID-19, including the complications and long-term consequences of infection. This implies active support for identifying new antivirals and host-targeted interventions, as well as repurposed compounds, and active support for robust testing of these options in comparable adaptive platform trials.
- The ACT-A Diagnostics Pillar and Therapeutics Partnership should work closely together to develop and support implementation of ‘test-and-treat’ approaches.
- ACT-A should make addressing IP barriers a key transversal workstream across all pillars and explicitly support the TRIPS waiver, non-exclusive licensing via C-TAP and/or MPP non-enforcement declarations, compulsory licensing, etc.
- ACT-A and other global health actors should take explicit steps to improve transparency with respect to development, production, and supply of COVID-19 medicines, diagnostics, and vaccines, including transparency over priority-setting and decision-making, contractual terms and conditions, costs of R&D, costs of manufacturing, and prices paid.

Third, it is unclear if treatments needed for COVID-19 will come with a guarantee of affordable access, sufficient supply, and equitable allocation globally, and related commitments of adequate sharing of knowledge, data, and technology to address the scale of global needs.

Unless specific contractual commitments and an array of rules and enabling policies are proactively established to ensure rapid transfer of technology, large-scale manufacturing, and equitable access, the very same challenges that have stymied equitable access to vaccines (see Section II) will also hinder availability, affordability, and access for future treatments.

Immediate course-correction needed

- Governments, particularly those that fund R&D, should use their leverage to negotiate clear and transparent terms and conditions that ensure sharing of research data, knowledge, and technology on a non-exclusive basis, enabling adequate production scale-up to ensure sufficient supply, equitable allocation, and affordability.
- Governments should support a temporary waiver on IP for COVID-19 technologies (TRIPS waiver), which would support increased access to such technologies globally by removing any risk of IP infringement for all stakeholders. To that end, a waiver must cover all forms of IP (not only patents) and apply not only to vaccines but also to all COVID-19 medical technologies needed to protect health and save lives, including COVID-19 therapeutics and diagnostics.
- In the meantime, companies owning COVID-19 technologies also need to increase their contributions and commit to either not enforcing their existing IP or to sharing relevant know-how, technology, and IP by non-exclusively licensing it to interested entities.
- Where needed, significant domestic and international investments, including from development banks, should be made to expand, build, and sustain manufacturing capacity for treatments.



Conclusion: Getting it right for future pandemics and other global health needs

A shifting global health architecture

A range of new global health institutions and global health security regulations and frameworks have emerged in response to previous disease outbreaks. A handful of these – namely the WHO R&D Blueprint and the Coalition for Epidemic Preparedness Innovations (CEPI) – were specific attempts to address the lack of effective medical countermeasures for pandemics and the challenges of coordinating R&D in such emergencies. They drew on two decades of WHO and UN discussions and reports critiquing chronic shortcomings of the biomedical R&D system.⁸⁰

In the COVID-19 era, a new global health security and pandemic prevention, preparedness, and response architecture is already emerging and continues to evolve. In the future, this may include institutionalizing aspects of ACT-A or changing the remit of existing global health initiatives such as the Global Fund to Fight AIDS, TB, and Malaria, CEPI, or Gavi, the Vaccines Alliance. It could also include the birth of entirely new global, regional, or national initiatives, such as a Global Health Threats Council,⁸¹ financing mechanisms, and legal instruments, such as an international pandemic treaty.⁸²

National and regional approaches may be more likely in the future to ensure more distributed R&D, manufacturing, and regulatory capacity given the global system failures of the past and present and to respond to more regionally concentrated outbreaks.

These initiatives and legal instruments – being debated and discussed among G7/G20 countries, WHO, and between regional blocs and individual countries – must be coordinated to secure an innovation and access ecosystem that drives research to the areas of greatest need and ensures equitable access to health technologies.

But before we look to the future, we cannot forget that this pandemic is nowhere near over and is in fact surging in many regions of the world. Responding to the needs of those at highest risk of infection, illness, and death today must be the top priority.

Recommendations for the future

COVID-19 has highlighted the life-and-death importance of ensuring appropriate preventive, diagnostic, and therapeutic health tools are available to all. This is true for a wide range of infectious diseases – from HIV, tuberculosis, malaria, and hepatitis C to neglected tropical diseases (NTDs) and bacterial and fungal infections – which have long been, or persistently threaten to be, of pandemic or epidemic character.⁸³

Climate change, population growth, and migration are all contributing to increased interconnections between people, animals, and the planet and are changing disease patterns and geographies. Resistance to existing treatments is also increasing, sometimes at an alarming rate. Efforts to support innovation of and access to

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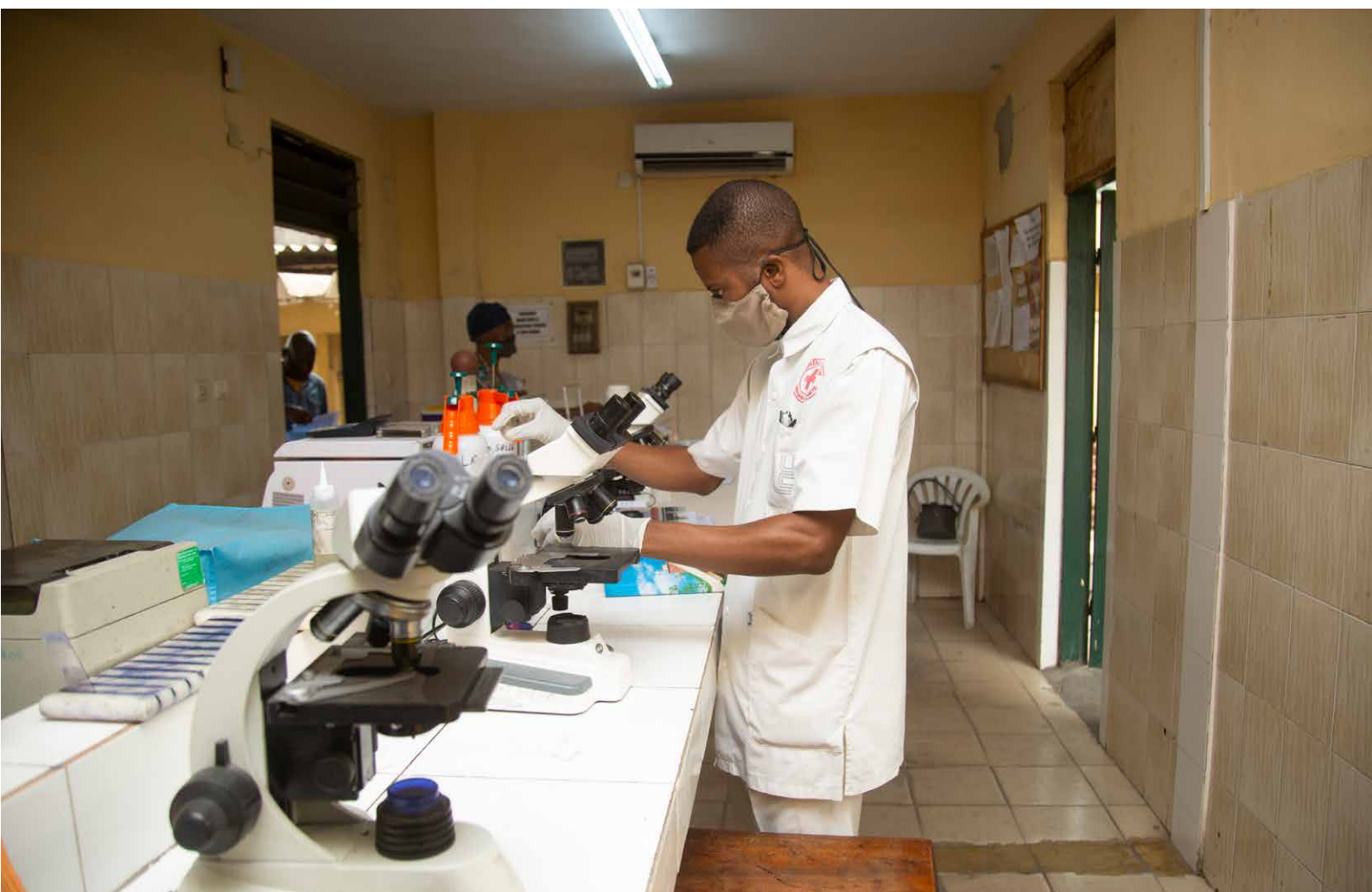
appropriate health tools for pathogens of pandemic potential therefore also warrant a wider lens. Only with a broad 'One Health'⁸⁴ approach can comprehensive global health security – which is resilient to all present and future threats, supports strong health systems, and prioritizes the needs of the most vulnerable – be achieved.

The governments and other actors that will shape these responses at the national, regional, and international level must take as a given two major points:

First, market-based approaches alone will not be sufficient to discover, develop, and ensure access to necessary health tools. Traditional market incentives fail to respond to, prioritize, and ensure R&D investments where the need is uncertain or demand may be low. This is a daily reality for millions of people who are affected by diseases that do not represent a lucrative market for the pharmaceutical industry, whether other pandemic threats, AMR, NTDs, or diseases that predominantly affect children. Even where innovations have been developed, companies engage in a limited 'contract manufacturing model' of technology transfer, in which they retain all control over IP, production, supply, and pricing.

Second, major public and philanthropic funding for research – whether through direct R&D subsidies or pre-purchase commitments – de-risks the R&D enterprise and funders should therefore secure a public return on their public, or public interest-driven, investments. This means requiring clear and transparent terms and conditions that ensure open collaboration, affordability, availability, and equitable allocation of essential health tools and embracing and financing alternative, needs-driven R&D models.

COVID-19 HAS HIGHLIGHTED THE LIFE-AND-DEATH IMPORTANCE OF ENSURING APPROPRIATE PREVENTIVE, DIAGNOSTIC, AND THERAPEUTIC HEALTH TOOLS ARE AVAILABLE TO ALL.



Governments need to ensure a more effective, equitable, and sustainable innovation and access ecosystem that delivers global public goods and guarantees equitable access for all.

They must therefore do the following:

- **Guarantee sustained political attention to and financing of end-to-end 'purpose-driven' innovation^{85,86} for all diseases and products of public health importance**, with clear priority given to those populations and pathogens most likely to be neglected by the market. Such focus and financing must avoid a 'charity-driven'⁸⁷ or narrowly defined 'security threat' approach⁸⁸ and break the 'cycle of panic and neglect'⁸⁹ for pandemics in which there is a surge of attention and investment during a crisis followed by years (or decades) of inaction when a threat is perceived to have subsided in certain regions or globally.
- **Re-imagine global health R&D coordination, collaboration, and financing to support a more distributed, decentralized, and democratic approach** to the production of knowledge and innovation as global public goods in response to pandemics and other public health priorities. Such an approach would support R&D, manufacturing, and regulatory capacity through regional and national networks and hubs, not only through donor-driven global mechanisms, and would ensure greater parity between public and private actors and between the 'global south' and the 'global north', especially when it comes to R&D priority-setting, decision-making, and resource allocation.
- **Ensure there are globally agreed norms and binding rules governing R&D and equitable access to essential health tools⁹⁰** to guarantee such tools are made available as global public goods regardless of where they are discovered, developed, or produced. R&D funders have unique leverage that is rarely exercised to enforce and coordinate the application of these rules by requiring clear and transparent terms and conditions in contractual agreements that will guarantee open sharing of research data, knowledge, and technology; sufficient production, supply, and equitable allocation of health tools; and affordability, including through pro-access management of IP rights.

With renewed public leadership and new models of international cooperation focused on these goals it will be possible to achieve not only continued innovation to meet ever more pressing needs, but also equitable access to the fruits of scientific progress for all people, no matter their income or where they live.

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