DNDi
Drugs for Neglected Diseases *initiative*

BEST SCIENCE FOR THE MOST NEGLECTED

STRATEGIC PLAN 2021–2028

25 TREATMENTS IN 25 YEARS

The Drugs for Neglected Diseases *initiative* (DND*i*) is an international non-profit organization that discovers, develops, and delivers safe, effective, and affordable treatments for the most neglected patients

We use the power of innovation, open science, partnerships, and advocacy to find solutions to a great injustice: the lack of medicines for life-threatening diseases that disproportionately impact poor and marginalized people

DND*i* was created in response to the frustration of clinicians and the desperation of patients faced with medicines that were ineffective, unsafe, unavailable, unaffordable, or that had never been developed at all. The root of the problem? The prevailing profit-oriented model for medical research and development (R&D) leaves little incentive to develop drugs for the poorest and most vulnerable communities.

DND*i* was launched in 2003 when the Indian Council of Medical Research, the Oswaldo Cruz Foundation of Brazil, the Kenyan Medical Research Institute, the Malaysian Ministry of Health, and the Institut Pasteur of France, with the support of the World Health Organization (WHO) Special Programme on Research and Training in Tropical Diseases, teamed up with Médecins Sans Frontières (MSF) after it dedicated a portion of its 1999 Nobel Peace Prize award to exploring a new, alternative, not-for-profit model for developing drugs for neglected populations.

Nearly two decades later, DND*i* has grown into a network of more than 200 partner institutions that spans the globe, united in our pursuit of science driven by collaboration, not competition, and by patients' needs, not profits.

Together, we have delivered eight new treatments for people with sleeping sickness, visceral leishmaniasis, Chagas disease, HIV, and malaria that have saved millions of lives.

HOW DOES DND*i* ADVANCE THE BEST SCIENCE FOR THE MOST NEGLECTED?

We innovate to save lives

From the laboratory bench to the patient's bedside, DND*i* acts as a 'conductor of a virtual orchestra', coordinating and collaborating with public, private, and not-for-profit partners from around the world. Our work spans every stage of the R&D process, from drug discovery and pre-clinical research, to clinical trials and access to new treatments. We ensure access by guaranteeing our treatments are affordable, available, and adapted to the communities who need them. And our steadfast commitment to open science guarantees the broadest possible sharing of knowledge and results.

We foster sustainable solutions

Through our R&D programmes and alliances in low- and middle-income countries (LMICs), DND*i* works hand-in-hand with medical and scientific experts, government leaders, industry and academic partners, non-governmental organizations, and affected communities. Together, we define the most pressing R&D needs, share knowledge and expertise, bolster medical research, development, and production capacity, and accelerate access to new treatments. Our partnerships in LMICs power our progress at every stage of the R&D process, increase national and regional collaboration, and strengthen innovation ecosystems that put people's needs first.

We advocate for change

Anchored in our roots on the frontlines of medical humanitarian action, DND*i* speaks out for the policies and political will needed to re-orient the global biomedical R&D system to ensure that all people benefit from medical innovation and have equitable access to the fruits of scientific progress – no matter their income or where they live. We draw lessons from our own experience to push for open, transparent, and collaborative research and equitable access to medicines and other health technologies.

DNDi'S NEW STRATEGIC PLAN CHARTS AN EIGHT-YEAR JOURNEY TO 2028, BY WHICH TIME WE AIM TO HAVE DELIVERED 25 NEW TREATMENTS IN OUR FIRST 25 YEARS.

We launch this plan against the backdrop of a devastating global pandemic, which has claimed millions of lives, disrupted livelihoods, undermined critical gains in global health and development, and shone a glaring light on the health consequences of systemic racial and economic inequalities within and between countries.

The global response to the coronavirus disease (COVID-19) pandemic is enabling major scientific advances and the development of new vaccines, diagnostics, and treatments at unprecedented speed – while also shortening clinical development and regulatory timelines and utilizing platform technologies in a way that may be instructive for other diseases.

But it has also thrown into sharp relief the limited commitment to prioritizing and financing research needs in resource-limited settings – for COVID-19 and neglected diseases more broadly – and the lack of preparedness and globally agreed rules to ensure both transparency and equitable access to any new health tools developed.

As we face the coming decade, we know we must brace ourselves for ever-increasing needs – as a result of future pandemics, the silent crisis of antimicrobial resistance, climate-sensitive diseases, and long-standing epidemics and neglected diseases, all of which exact a disproportionate toll on already vulnerable and neglected communities and populations.

Our commitment to neglected patients is to deliver safe and effective therapeutic innovations that respond to these needs. Our work will contribute directly to achieving the Sustainable Development Goals, including Universal Health Coverage; multisector 'One Health' approaches for disease control and elimination; and WHO strategies, including the 2030 Roadmap for Neglected Tropical Diseases (NTDs). A key measure of our shared progress in meeting these ambitions will be the extent to which health systems provide healthcare for all, including women, children, the poor, people with neglected or stigmatizing diseases, and those at the margins of society.

Our lifesaving work is more urgent today than ever.

DND*i* maintains a steadfast commitment to deliver therapeutic solutions for diseases where innovation and access to safe, simple, effective, and affordable treatments are lacking. We aim to have delivered 25 new treatments in our first 25 years. We will leverage our rich portfolio of drug candidates and broad clinical networks for the NTDs and viral diseases we work on. We will continuously assess new opportunities to address patients' unmet needs, exploring the feasibility and best pathways to address diseases with persistent R&D and access gaps, including for pandemic-prone and climate-sensitive diseases. We will foster sustainable solutions in close collaborations with LMIC partners, advance a proactive agenda for maternal and child health and gender-responsive R&D, champion open science and transparency, and advocate for change to support a more equitable R&D ecosystem that ensures access to innovation for all.

Please join us.

CONTENTS

ACHIEVEMENTS SINCE 2003

TREATMENTS DELIVERED

8 field-adapted and affordable treatments for 5 deadly diseases, including ASAQ for malaria – with over 500 million treatments distributed since 2007 – and fexinidazole, the first all-oral treatment for sleeping sickness and DND*i*'s first new chemical entity (NCE)

R&D PIPELINE REPLENISHED

20+ NCEs in DND*i*'s portfolio

4 million+ compounds screened

Mature portfolio with 13 projects in Phase III or under regulatory review

POLICIES INFLUENCED

DND*i*'s model, experience, and lessons learned documented and disseminated to influence multiple policy processes – from the WHO, G7/G20, and the United Nations to national and regional policy fora and funders – particularly around core principles and practices that enable needs-driven R&D and equitable access, such as open and transparent sharing of research knowledge, data and R&D costs, and pro-access management of intellectual property and licensing

CLINICAL TRIALS CONDUCTED

An average of 20 active clinical studies from Phase I to Phase IV ongoing – located mostly in LMICs – with more than 2,500+ patients enrolled at any given time

GLOBAL PARTNERSHIPS FORGED

200+ partner institutions in 40+ countries have joined DND*i* to deliver the best science for the most neglected

RESEARCH NETWORKS ESTABLISHED

4 clinical research networks created for target diseases in Africa and Latin America, bringing together 500+ researchers across institutions in dozens of LMICs to support and strengthen R&D capacity, promote scientific exchange, and facilitate access to new treatments

COVID-19 Clinical Research Coalition with 350+ members working to fast-track research for tools adapted to the needs of patients and health systems in resource-limited settings

DIVERSE GLOBAL TEAM MOBILIZED

A diverse global team of 250+ staff driving research, partnerships, and advocacy across 9 organizational hubs in Cape Town, Geneva, Kinshasa, Kuala Lumpur, Nairobi, New Delhi, New York, Rio de Janeiro, and Tokyo

NEW ORGANIZATION TO FIGHT DRUG-RESISTANT INFECTIONS CREATED

DND*i* joined forces with the World Health Organization (WHO) in 2016 to create the Global Antibiotic R&D Partnership (GARDP), now an independent organization developing new treatments for serious drug-resistant infections that pose the greatest threat to health. Both organizations continue to share R&D expertise and capacity, as well as a common approach on global health policy for promoting and contributing to public health needs-driven R&D and access.

COMMITMENTS: 2021–2028

2021 2028

DELIVER 15–18 ADDITIONAL TREATMENTS

10-12 new treatments from current mature portfolio (2021-24)
5-7 new treatments from earlier-stage NCEs and portfolio expansion (2025-28)

FOCUS ON 5 CROSS-CUTTING STRATEGIC IMPERATIVES

1 **Deliver new treatments and expand access for neglected patients by addressing R&D gaps for NTDs and viral diseases, including pandemic-prone and climate-sensitive diseases**

2 Join with public health leaders and R&D actors in low- and middle-income countries to advance sustainable innovation ecosystems that address neglected patients' needs

3 Contribute to building a proactive agenda for maternal and child health and gender-responsive R&D

4 Champion open science and transparency

5 Leverage new technologies to accelerate R&D and access

DRIVE CHANGE ACROSS THE 3 PILLARS OF OUR MISSION

INNOVATE TO SAVE LIVES

- Deliver **15-18 new treatments**
- Identify **8-10 new drug candidates** from discovery efforts
- Conduct at least **6 new studies on indications for paediatric use**
- Develop strategies tailored to target diseases and countries' specific needs to ensure **equitable and affordable access and delivery of new treatments**

FOSTER SUSTAINABLE SOLUTIONS

- Grow partnerships for **'end-to-end' R&D** in LMICs
- **Proactively collaborate** with LMIC pharmaceutical and other partners
- Conduct **half of first-in-human Phase I studies** in LMICs
- Train **600 to 1,000 frontline clinicians and researchers** every year

ADVOCATE FOR CHANGE

- **Secure concrete changes in key policies** to make the innovation system more needs-driven, collaborative, equitable, open and transparent, inclusive, and sustainable
- **Engage with 50+ strategic advocacy partners** to build stronger coalitions and more effective networks of influence
- **Document and disseminate key lessons** from DND*i*'s model

OUR STRATEGIC IMPERATIVES

Deliver new treatments and expand access for neglected patients by addressing R&D gaps for NTDs and viral diseases, including pandemic-prone and climate-sensitive diseases

Joining with our founding partners, public health leaders, researchers, and industry, we are working to address the urgency of innovation for new health tools that meet the needs of vulnerable and marginalized communities.

DNDi'S COMMITMENT

- Discover, develop, and deliver new treatments, including new chemical entities, for DND*i*'s core target diseases, building on our proven track record developing eight new treatments for five diseases affecting neglected populations
- Evaluate the potential to expand our portfolio to other diseases characterized by persistent neglect, such as snakebite, schistosomiasis, or dengue, and to areas of unmet need for diseases already part of our portfolio
- Pilot test-and-treat strategies and advance new alliances to accelerate equitable access to diagnosis and treatment, including for sleeping sickness, Chagas disease, hepatitis C, and HIV
- Leverage our experience and partnerships to develop therapeutic solutions for COVID-19 and other pandemic-prone diseases and help bolster pandemic preparedness and response, with a focus on neglected and marginalized communities
- Address emerging R&D needs resulting from the climate crisis, including new treatments for dengue and other climate-sensitive diseases, which are likely to exacerbate health disparities
- Reduce our carbon footprint by 'greening' the pharmaceutical development process wherever possible and implementing environmentally sustainable work policies and practices

2

Join with public health leaders and R&D actors in low- and middle-income countries to advance sustainable innovation ecosystems that address neglected patients' needs

All people should benefit from medical innovation and have access to the fruits of scientific progress. We are using the power of our partnerships in LMICs to foster engagement in 'end-to-end' health R&D that puts people's needs first.

DND*i*'S COMMITMENT

- Join with our founding partners and other scientific, medical, and public health leaders and institutions in LMICs as equal partners to define R&D priorities, strengthen South-South and cross-regional research collaborations, and develop robust strategies to ensure sustainable access to new health tools
- Support science and policy leadership to strengthen existing and emerging innovation ecosystems that prioritize the needs of neglected populations and ensure innovations originating in LMICs are integrated into international responses
- Strengthen DND*i*-supported clinical research networks and drug discovery consortia in endemic regions, and co-create new collaborative platforms in additional disease areas
- Locate an increasing share of earlier-stage research, such as lead optimization programmes and Phase I clinical research studies, in LMICs
- Prioritize new strategic alliances with industrial partners in LMICs and foster South-South cooperation and technology transfer
- Proactively acknowledge and address, internally and externally, the legacy of colonialism and the underlying racial and economic inequities that have led to an undervaluing of LMIC R&D capacity, and to the historical exclusion of many LMICs from R&D priority-setting, decision-making, and resource allocation

3

Contribute to building a proactive agenda for maternal and child health and gender-responsive R&D

Although women and children are disproportionately affected by infectious diseases, their specific medical needs are widely overlooked in traditional biomedical R&D. We are working to upend this persistent and harmful status quo.

DNDi'S COMMITMENT

Address children's unmet needs by:

- Prioritizing the development of appropriately adapted child-friendly formulations for our target diseases, with at least six new studies on indications for paediatric use
- Joining forces with like-minded groups to close paediatric R&D gaps and advocate for a more systematic approach to the development, registration, and supply of optimal, child-friendly drug formulations

Implement best practices in gender-responsive drug development and access by:

- Identifying gender-specific elements in our target product profiles, and publishing sex-disaggregated results of clinical trials
- Promoting the inclusion of women in clinical trials, including where possible women who could be or become pregnant, as well as breastfeeding women
- Developing pathways for more women to contribute as principal investigators and science leaders
- Applying a broad gender and intersectional lens to access strategies, acknowledging the multiple social, political, and economic determinants of vulnerability to diseases and access to healthcare

4

Champion open science and transparency

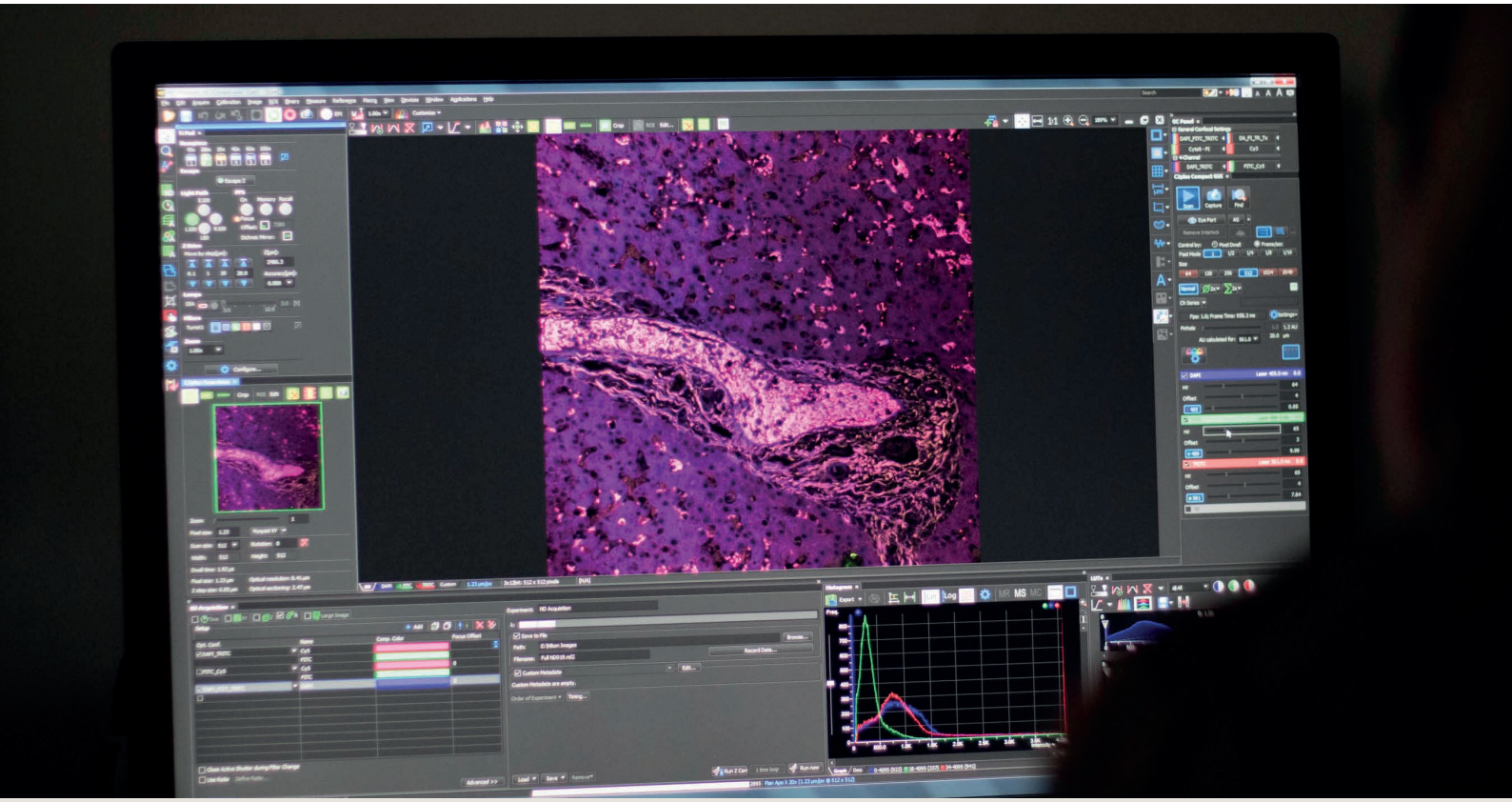
Conducting R&D behind closed doors can reduce efficiency and slow scientific progress. We are promoting open collaboration and knowledge-sharing to ensure value for public investments, accelerate science, and bring solutions for neglected patients.

DNDi'S COMMITMENT

- Promote the broadest possible sharing of research knowledge and data across the innovation lifecycle to accelerate the R&D process and reduce the cost of R&D
- Continue to pilot open and collaborative approaches to drug discovery with partners, building on our experience with the NTD Drug Discovery Booster and Open Synthesis Network and broadening to other disease areas
- Openly share clinical trial protocols, data, and results – both positive and negative – while fully protecting personal data, and support calls from civil society, R&D funders, and normative agencies to require timely sharing of research results
- Continue to document and share our own R&D costs and support calls for innovators to publicly disclose sources and amounts of funding, in particular public and philanthropic funding, to guarantee a public return on public investments in R&D
- Publicly share, at a minimum, summaries of contract terms with partners, including key licensing terms and conditions, management of intellectual property, and strategies for ensuring affordable and equitable access

Leverage new technologies to accelerate R&D and access

Digitalization, machine learning, artificial intelligence (AI), and new technologies and platforms are bringing transformational benefits to the fields of medicine, pharmaceutical research, and public health. We are working to ensure these extend to the most neglected.



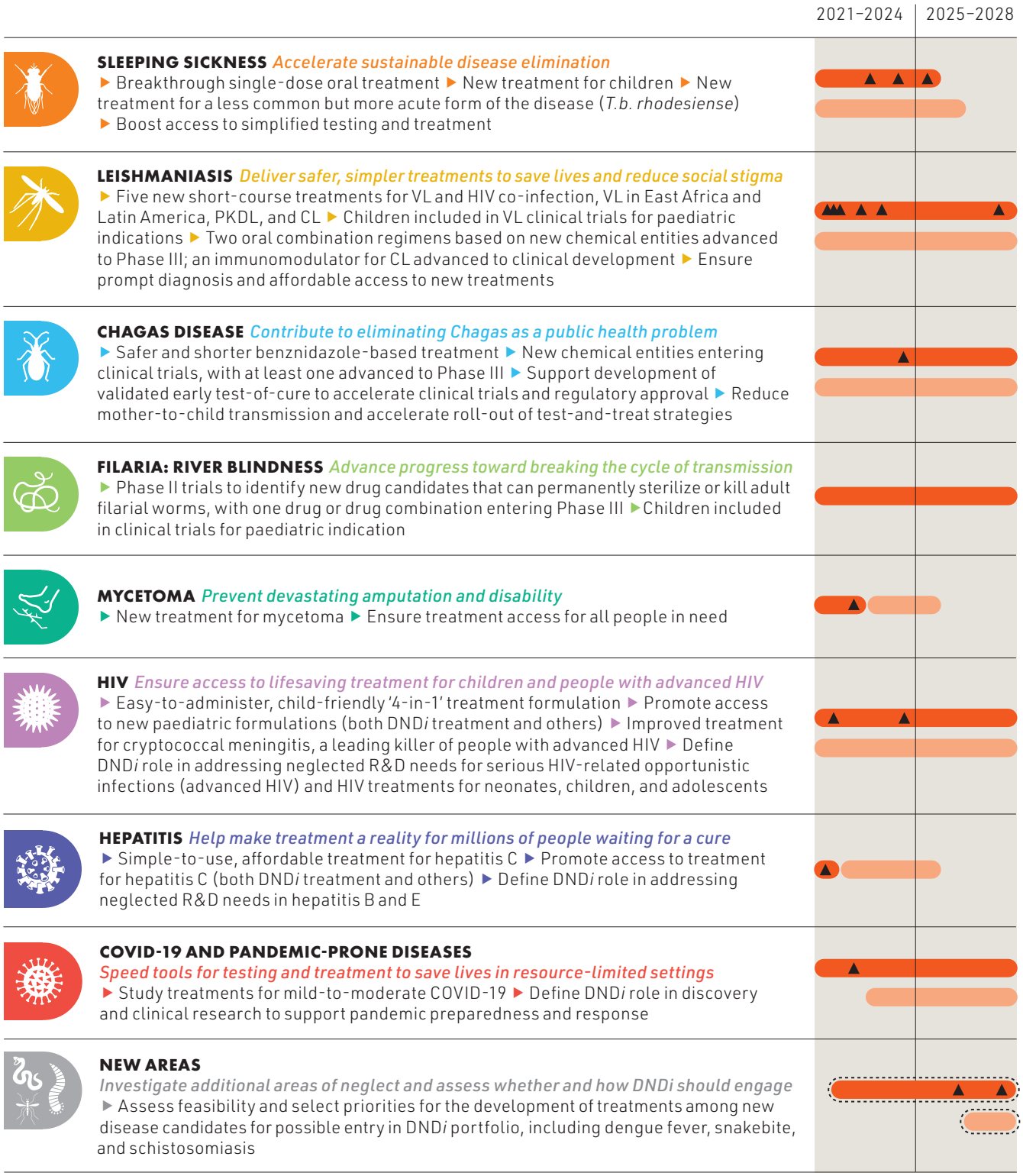
DNDi'S COMMITMENT

- Employ new technologies to improve the efficiency and accelerate the pace of the R&D process, including AI-driven drug discovery tools, novel imaging, diagnostic, and clinical trial design and operations technologies, and AI-driven data analysis
- Consider host targeted therapies as alternative/complementary therapeutic options to single antimicrobial regimens for some DND*i* target diseases
- Explore the potential of fast-evolving therapeutic modalities beyond small molecule drugs – for example, messenger ribonucleic acid (mRNA) therapeutics, monoclonal antibodies, and other biologics – that hold promise for the treatment of DND*i* target diseases
- Expand the use of eHealth solutions at our trial sites to strengthen data collection, processing, analysis, and improve patient safety while managing associated risks, particularly in the areas of privacy and the protection of patients and personal data

WHAT WE WILL DELIVER

INNOVATING TO SAVE LIVES

DND*i* will deliver 15 to 18 new treatments between 2021 and 2028, for a total of 25 new treatments in our first 25 years



SLEEPING SICKNESS *Accelerate sustainable disease elimination*
▶ Breakthrough single-dose oral treatment ▶ New treatment for children ▶ New treatment for a less common but more acute form of the disease (*T.b. rhodesiense*) ▶ Boost access to simplified testing and treatment

LEISHMANIASIS *Deliver safer, simpler treatments to save lives and reduce social stigma*
▶ Five new short-course treatments for VL and HIV co-infection, VL in East Africa and Latin America, PKDL, and CL ▶ Children included in VL clinical trials for paediatric indications ▶ Two oral combination regimens based on new chemical entities advanced to Phase III; an immunomodulator for CL advanced to clinical development ▶ Ensure prompt diagnosis and affordable access to new treatments

CHAGAS DISEASE *Contribute to eliminating Chagas as a public health problem*
▶ Safer and shorter benznidazole-based treatment ▶ New chemical entities entering clinical trials, with at least one advanced to Phase III ▶ Support development of validated early test-of-cure to accelerate clinical trials and regulatory approval ▶ Reduce mother-to-child transmission and accelerate roll-out of test-and-treat strategies

FILARIA: RIVER BLINDNESS *Advance progress toward breaking the cycle of transmission*
▶ Phase II trials to identify new drug candidates that can permanently sterilize or kill adult filarial worms, with one drug or drug combination entering Phase III ▶ Children included in clinical trials for paediatric indication

MYCETOMA *Prevent devastating amputation and disability*
▶ New treatment for mycetoma ▶ Ensure treatment access for all people in need

HIV *Ensure access to lifesaving treatment for children and people with advanced HIV*
▶ Easy-to-administer, child-friendly '4-in-1' treatment formulation ▶ Promote access to new paediatric formulations (both DND*i* treatment and others) ▶ Improved treatment for cryptococcal meningitis, a leading killer of people with advanced HIV ▶ Define DND*i* role in addressing neglected R&D needs for serious HIV-related opportunistic infections (advanced HIV) and HIV treatments for neonates, children, and adolescents

HEPATITIS *Help make treatment a reality for millions of people waiting for a cure*
▶ Simple-to-use, affordable treatment for hepatitis C ▶ Promote access to treatment for hepatitis C (both DND*i* treatment and others) ▶ Define DND*i* role in addressing neglected R&D needs in hepatitis B and E

COVID-19 AND PANDEMIC-PRONE DISEASES
Speed tools for testing and treatment to save lives in resource-limited settings
▶ Study treatments for mild-to-moderate COVID-19 ▶ Define DND*i* role in discovery and clinical research to support pandemic preparedness and response

NEW AREAS
Investigate additional areas of neglect and assess whether and how DNDi should engage
▶ Assess feasibility and select priorities for the development of treatments among new disease candidates for possible entry in DND*i* portfolio, including dengue fever, snakebite, and schistosomiasis

● Research and development ● Access and advocacy ▲ New treatment delivery ◌ Illustrative

New treatments are the result of projects delivering a new registration, a new indication within an existing registration, or a new therapeutic guideline.

SLEEPING SICKNESS

Delivering breakthrough treatments and expediting access to eliminate the disease – for good

Sleeping sickness – or human African trypanosomiasis (HAT) – is a parasitic disease spread by the bite of the tsetse fly. Over time, it causes severe neuropsychiatric symptoms and is almost always fatal if left untreated. Until 2008, the only treatment available for advanced sleeping sickness was melarsoprol, an arsenic derivative so toxic it killed one in 20 patients.

We have been focused on developing better treatments for the disease since our founding in 2003. By 2009, working closely with partners, we finalized the development of nifurtimox and eflornithine (NECT), a simpler, safer treatment for the second stage of the most common form of sleeping sickness. It brought substantial benefits for patients, most importantly eliminating almost entirely the use of melarsoprol, but still required a hospital stay to administer the intravenous component of the treatment.

In 2018, DND*i* and our partners completed the development of fexinidazole, a paradigm-changing simple oral treatment for both stages of the disease that can be taken at home. And we have helped build the HAT Platform, a network of 120 experts from over 20 research institutions in affected countries, closely linked with policy makers, working to increase diagnosis, care, treatment, and research so that new treatments can be rapidly and effectively evaluated, registered, and made available.

Our goal is now to complete development of and then ensure access to acoziborole, a **single-dose oral treatment** that holds tremendous promise for efforts to **sustainably eliminate the disease.** To simplify diagnosis and treatment, we will study the safety and feasibility of administering acoziborole to patients identified following a rapid diagnostic test, and also study its use as a tool to treat populations at risk in order to eliminate the potential human reservoir of remaining cases. Our aim is to make access to treatment easier for people of all ages, particularly in remote communities and settings affected by conflict and instability, and to ensure that more than 80% of people diagnosed with sleeping sickness receive a safe, oral treatment by 2025. We will also continue work to scale up **access to fexinidazole** while studying its use for ***T.b. rhodesiense*** sleeping sickness, a less common but more acute form of the disease, which is still treated with toxic melarsoprol.

CHAGAS DISEASE

Accelerating access to better treatment and identifying new drug candidates

Spread by the bite of the 'kissing bug', Chagas disease is the biggest parasitic killer in the Americas, causing irreversible damage to the heart and other vital organs in many affected patients. Although 70 million people are at risk and up to seven million live with Chagas worldwide, by some estimates, only 1% of those infected have access to diagnosis and treatment.

Together with our partners, DND*i* developed the first formulation of the drug benznidazole for infants and children, and we piloted a simplified model of care for people with Chagas, promoting test-and-treat approaches in Colombia that are now being replicated elsewhere in Latin America. In 2009, we established the Chagas Clinical Research Platform, a network of over 450 members in 25 countries working to conduct clinical trials and advocate for access to diagnosis and treatment for people most at risk.

Our goal is now in the short term to improve current treatments – which were discovered over 50 years ago, last at least eight weeks, and can have serious side effects – by developing a **safer, shorter treatment using benznidazole**. We also aim to limit mother-to-child transmission and will reach people living with Chagas disease with wider roll-out of **test-and-treat strategies**. In the long term, our objective is to identify entirely **new drug candidates** and to initiate the clinical development of at least two compounds, with the aim of launching at least one Phase III trial resulting from this earlier-stage research by 2028.

LEISHMANIASIS

Advancing a portfolio of all-new oral drugs for people of all ages in all affected regions

Visceral leishmaniasis (VL)

Transmitted by the bite of sandflies, VL is a parasitic disease that causes fever, weight loss, spleen and liver enlargement, and, if not treated, death. An estimated 50,000 to 90,000 people are newly infected with VL each year, mostly in Brazil, East Africa, and India. Although current treatments differ from region to region, they all either require hospital stays, or complex infusions, or consist of drugs with serious side effects, all of which complicates care for people who live far from health facilities.

With our partners, DND*i* has developed improved VL treatments that are now part of national treatment guidelines in eastern Africa as well as South Asia, where elimination efforts have contributed to a sharp decline in cases. And we have replenished the R&D pipeline with an unprecedented portfolio of all-new potential drugs. The Leishmaniasis East Africa Platform, founded by DND*i* in 2003, has helped drive progress against the disease in Ethiopia, Kenya, Uganda, and Sudan – with 20 partner institutions strengthening cooperation in clinical research and training across the region.

Cutaneous leishmaniasis (CL)

Also transmitted by sandflies, CL is a disfiguring disease that leaves life-long scars, mostly on the face, causing social stigma, particularly for women and children. People in Asia, East Africa, the Middle East, and South America affected by poverty, malnutrition, forced displacement, and poor housing conditions are most at risk. Current CL treatments are more than 60 years old, costly, and often require weeks of painful injections of toxic, heavy metal-based drugs called antimonials, which have severe side effects.

Our collaborations have identified several promising compounds that are now in different stages of development. In 2014, we established redeLEISH, a network of CL experts working across 90 institutions in 20 countries to share know-how and to design and conduct vital clinical research.

Our goal is now to deliver **new, short-course oral treatments** for both forms of leishmaniasis, including **combinations of new chemical entities**, that are safe and easier to manage at the primary healthcare level, with the goal of bringing prompt diagnosis and treatment closer to patients.

For VL, in the shorter term we aim to deliver four new short-course treatments with existing drugs, including for people with HIV co-infection, people with VL in East Africa and Latin America, and people with post-kala-azar dermal leishmaniasis, a complication of VL that causes stigmatizing skin lesions and that could threaten elimination efforts in South Asia. Longer term, our plan is to bring two or three oral drug regimens close to Phase III completion by 2028, continuing discovery efforts over the next few years to identify suitable additional candidates.

For CL, in the shorter term we will conduct studies to evaluate combinations of miltefosine and thermotherapy, with the objective of removing the use of toxic antimonials whenever possible, and we will provide technical support to Latin American partners working to expand access through test-and-treat strategies. Longer term, we are working to develop new oral treatments, including an innovative approach to stimulate the innate immune response to fight the parasitic infection.

FILARIA: RIVER BLINDNESS

Developing a rapid cure for millions at risk

An estimated 20 million people, primarily in West and Central Africa, are infected with onchocerciasis, or river blindness, a filarial disease caused by a parasitic worm transmitted by the bite of blackflies. Current prevention efforts are based on mass administration of ivermectin. While highly effective in reducing transmission of the disease, the drug must be administered every year for 10 years or more because it only kills juvenile worms, and not the adults. It also cannot be used in people infected with another worm, African eye worm, because of the risk of potentially fatal side effects. New tools that permanently sterilize or kill the adult worms are needed to support elimination of the disease.

We have built a portfolio of four R&D projects for river blindness and are advancing the development of new drug candidates together with our partners. We are also joining forces within the Helminth Elimination Platform (HELP), a consortium of research institutes, universities, NGOs, and pharmaceutical companies committed to developing new treatments for infections caused by parasitic worms.

Our goal is now to identify one or a combination of **new drug candidates** after completing Phase II trials, and to launch a Phase III confirmatory trial that we hope will result soon after in a new treatment option for onchocerciasis. Our research efforts will also support the development of **diagnostic tools** for river blindness, which are urgently needed.

MYCETOMA

Conducting the world's first clinical trial

One of the world's most neglected diseases, mycetoma is a devastating, slow-growing infection most likely transmitted by a thorn prick. Occurring across the so-called 'mycetoma belt,' which stretches from Central and South America to the Sahel, the Middle East, and South Asia, the fungal version of mycetoma leads to horrible deformities and disability. Currently, people suffering from mycetoma are confronted with ineffective, toxic, and overpriced drugs. For many, the only option is amputation.

DND*i* is running the world's first and only randomized comparative clinical trial for mycetoma, working with our partners on a safe, effective, and affordable treatment. Following advocacy from DND*i* and our partners, the WHO added mycetoma to its list of neglected tropical diseases in 2016 – an important step in raising awareness of the disease and encouraging investment in research for diagnostics and treatments that can be easily used in rural areas.

Our goal is now to develop a **new treatment** for mycetoma that can prevent devastating amputation and disability – and to ensure access for all people in need.

HIV

Delivering treatments for the most vulnerable

The antiretroviral treatment revolution has enabled millions of people with HIV to live long and healthy lives, but a lack of appropriate treatments for children and people with advanced HIV continues to leave many behind. Over 300 children die every day of HIV and only half of the nearly 2 million children living with the disease have access to diagnosis and treatment. Until recently, the only options consisted of awful-tasting syrups that are difficult for children to take. In addition, hundreds of thousands of people die each year from HIV-related opportunistic infections for which affordable and easy-to-take medicines are still lacking.

With our partners, DND*i* has developed an easy-to-administer '4-in-1' formulation for infants and young children containing the antiretrovirals lopinavir, ritonavir, abacavir, and lamivudine in one capsule of strawberry-flavoured granules that can be sprinkled on food – which should be approved in 2021. Our research has also helped ensure that kids with HIV and tuberculosis – a leading cause of death among children with HIV – can take their TB treatment at the same time as their HIV medicines without any negative interactions between the many drugs required. We have also initiated work to address access barriers to first-line treatment regimens and to develop improved, simpler formulations of existing treatments for cryptococcal meningitis, a leading killer of people with HIV.

Our goal is now to make sure the **4-in-1 is available to children** who need it, as one of several new child-friendly treatment options, alongside paediatric dolutegravir-based regimens – an effort we will coordinate together with our extensive network of partners in sub-Saharan Africa while exploring the use of the 4-in-1 and lopinavir/ritonavir-based combinations for the estimated 14 million **neonates** exposed to HIV each year. We will also explore whether we can help fill specific gaps in the development of long-acting antiretroviral formulations for **adolescents** or new combinations with improved delivery systems for young children, while assessing opportunities to address urgent gaps in treatment innovation for **serious HIV-related opportunistic infections (advanced HIV).**

HEPATITIS C

Accelerating access to affordable treatment and supporting global elimination efforts

Hepatitis C is a potentially fatal disease that is often called a 'silent killer' because it can go decades without detection while causing serious liver damage and even liver cancer. 71 million people are living with hepatitis C worldwide, despite the existence of safe, simple, and highly effective direct-acting antiviral (DAA) treatments that can cure the disease in weeks. Yet fewer than 10% of people with hepatitis C globally have benefited from these treatments to date.

DND*i* has been developing ravidasvir with sofosbuvir, for use as part of an effective, simple-to-use, affordable treatment for hepatitis C that can increase access and minimize financial burden on patients and health systems. We have also joined with government and civil society groups in Malaysia, industry partners, and the Foundation for Innovative New Diagnostics (FIND) to pioneer test-and-treat strategies that are needed to scale up access to diagnosis and treatment and realize ambitions to eliminate the disease worldwide.

Our goal is now to help **foster an enabling environment for improved availability of HCV diagnostics and treatments in LMICs**, with a focus on making **ravidasvir/sofosbuvir** accessible to people still waiting for a cure. We will continue to support the implementation of new **test-and-treat strategies** for hepatitis C while expanding our collaborations with manufacturers and civil society advocates to bolster **affordable and sustainable supply of DAAs** and foster the political will and financing needed for wide-scale roll-out of lifesaving testing and treatment.

NEW OPPORTUNITIES TO ADDRESS UNMET MEDICAL NEEDS

As needs evolve, so do we.

DND*i* continuously evaluates the unmet treatment needs of vulnerable and marginalized populations. With our founding partners, global and national public health leaders, and pioneering researchers and advocates in LMICs, we explore new opportunities to utilize our experience and capacity to address these gaps – and we join with partners to deliver new innovations where others will not.

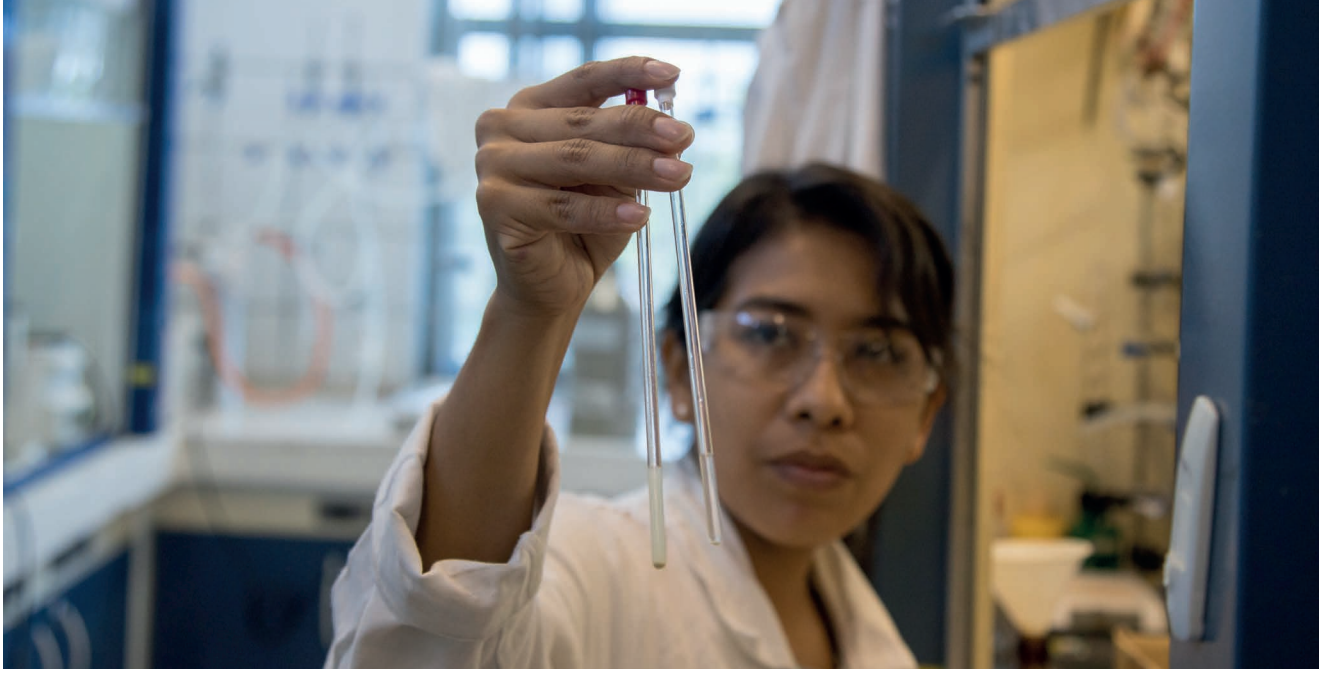
Adopted in our previous strategic plan, our **'dynamic portfolio' approach** has enabled DND*i* to work on better treatments for mycetoma, paediatric HIV, hepatitis C, and cryptococcal meningitis. The approach also allows us to contribute through a variety of support models to help meet neglected patients' needs, from advising on target product profiles and research agendas to coordinating and hosting new partnerships and initiatives. In 2016, we joined with the WHO to create the Global Antibiotic Research and Development Partnership (GARDP) – now an independent organization developing treatments for drug-resistant infections that pose the greatest threat to health, including sexually transmitted infections, sepsis in newborns, and infections in hospitalized adults and children.

Our response to COVID-19

At the start of this Strategic Plan period, we are coordinating ANTICOV – the largest African-led clinical trial testing treatments for mild-to-moderate COVID-19. Carried out by a consortium of 26 prominent African and global R&D organizations in 13 countries, ANTICOV's innovative 'adaptive platform' design allows for several treatments to be simultaneously tested and for rapid adjustments to be made, including adding, continuing, or stopping treatment arms based on an ongoing analysis of results. We are also using our network for open and collaborative drug discovery to identify new treatments for COVID-19 and supporting a coalition of over 350 members working to fast-track COVID-19 research for tools adapted to the needs of patients and health systems in resource-limited settings.

Our goal is now to remain nimble and to continue evolving as we explore new interventions in:

- **Areas of unmet need for diseases already part of DND*i*'s portfolio:** As our established R&D projects in HIV and hepatitis C near completion, we will (1) build from our work on cryptococcal meningitis to assess opportunities to accelerate the development of treatments for serious HIV-related opportunistic infections (advanced HIV) as well as HIV treatment formulations that go further to meet the needs of **neonates, children, and adolescents**, such as long-acting antiretrovirals and (2) evaluate the potential to contribute to the development of safe, effective, and affordable **treatments for hepatitis B and E**.
- **Other diseases with clear R&D gaps:** We will investigate additional areas of neglect continuously over the Strategic Plan period. Robust assessments are ongoing in three disease areas that are new to DND*i* and we may contribute to the development of new treatments for:
  - **Snakebite** – by defining target profiles for next-generation treatments and contributing to their development;
  - **Dengue fever** – by repurposing existing and/or developing new antivirals, or other approaches to treatment for this climate-sensitive disease;
  - **Schistosomiasis** – by addressing the urgent need for new drugs to counter the risk of resistance to praziquantel, provide better efficacy, and treat female genital schistosomiasis.
- **Pandemic-prone diseases:** Building on our experience with COVID-19, we will continue work to make sure **vulnerable communities** are not left behind in future responses to pandemic-prone viral diseases. This will include applying our expertise in drug **discovery**, running **clinical studies** in LMICs, supporting the selection of therapeutic candidates for future trials, and **mobilizing partners to accelerate research** focused on the specific needs of patients and clinicians in resource-constrained settings.



DND*i*'S DRUG DISCOVERY ENGINE

Maintaining a robust R&D pipeline requires long-term investment in early-stage research. We aim to identify eight to ten new drug candidates by 2028 through an agile approach to drug discovery that delivers true innovation for neglected patients.

DND*i*'s team of multidisciplinary drug discovery scientists works with dozens of partners across six continents to identify promising molecules that can be optimized into potential drug candidates for evaluation in clinical trials.

These collaborations are a critical starting point for delivering new treatments that can meet our patient-focused target product profiles, which outline the ideal specifications needed for new treatments to meet the needs of the patients and the health systems that serve them. They also ensure that we can develop multiple drug candidates in parallel, safeguarding R&D progress even when some drug candidates do not succeed in later-stage R&D.

DND*i* has 20 NCEs advancing in our R&D portfolio and through our partnerships we have screened over four million compounds to date. We have proven that collaborative and open approaches to drug discovery can attract new researchers to neglected fields, accelerate the pace of research, reduce duplication and redundancy, and make more efficient use of limited resources.

We will achieve our drug discovery objectives for this Strategic Plan period by strengthening and expanding our vital alliances with industry, public, and academic partners, as well as non-profit product development partners. We will also intensify work to unlock and foster maturing drug discovery capacity in countries most affected by our target diseases, including through our support to consortia established in Latin America and India to advance drug candidates for diseases impacting vulnerable communities.

DND*i* will continue to look to industry and academia to seek the best drug candidates and partners from across the globe. In this Strategic Plan period, we will also:

- **Employ new and emerging technologies** from the fields of parasitology, infectious diseases, AI, and machine learning;
- **Introduce new platforms and technologies** such as monoclonal antibodies and oligonucleotides to target infectious agents and their interaction with the human host;
- Develop drugs to block essential biological targets and pathways using target-based screening, structure-based drug design, targeted protein degradation, and AI approaches to **accelerate, or even short-cut, the drug discovery journey**;
- Develop improved insights into disease progression, the response to treatment, and role of the immune system to **help identify the next generation of drugs, biomarkers and diagnostics**.

By applying the lessons we have learned over more than 15 years of innovative discovery programmes, **our scientists will continue to shape and advance the drug discovery research agenda for neglected patients**, providing the missing ingredients our collaborators sometimes need and linking stakeholders to maximise resources and shared interests.

ENSURING EQUITABLE AND AFFORDABLE ACCESS

From the beginning of every R&D project, DND*i* works to ensure treatments are affordable, available, and adapted to the needs of neglected patients.

While R&D will always be our chief focus, we know that the treatment innovations we deliver will be of little use if they are priced out of reach, in short supply, or poorly suited to the needs of neglected patients and the health systems that serve them. That is why DND*i* works from the earliest stages of the R&D process to identify potential access roadblocks and build the partnerships needed to overcome them.

A broad range of obstacles – some 'upstream' and some 'downstream' – can block people's access to the treatments they need, and no organization can address all these challenges on its own. DND*i* collaborates closely with health ministries, national disease control programmes, industrial partners, NGO allies, community and civil society groups, and others to promote access.

Strategies to address upstream barriers include developing target product profiles that respond to neglected patients' needs with local clinicians, regulators, and affected communities, pursuing 'gold-standard' licensing terms* with partners, and ensuring pro-access management of intellectual property that enables follow-on research, reduces production bottlenecks, and contributes to both access to knowledge and affordability.

Strategies to address downstream barriers include utilizing and testing adapted regulatory approaches that reduce barriers to access, generating the necessary evidence to update international and national treatment guidelines, and identifying appropriate partners to ensure affordable and sustainable production and supply, including through technology transfer when appropriate.

There is no one-size-fits-all approach to accelerating access to new treatments once they are registered, given the widely diverging epidemiological, demographic, geographic, infrastructure, and market dynamics of each specific disease and country. With several new treatments in late-stage development and many more to follow, we are intensifying efforts to lay the groundwork for equitable and affordable access by:

- **Developing comprehensive disease-specific access plans**, tailored to each country's realities, and adapted to the specific needs of the most vulnerable populations;
- **Integrating DND*i* treatments** into specific disease programmes and broader health systems;
- **Building robust collaborations with new access partners** to foster awareness about the disease, create demand for new treatments at the community level, and ensure sustainable supply;
- Working closely with partners to **ensure integrated 'test-and-treat' approaches**, since access to treatment must start with a proper diagnosis;
- Continuously **identifying and removing legal and commercial barriers** to access;
- Identifying financial hurdles and contributing to solutions to ensure **appropriate and sustainable financing mechanisms** are in place for programmes, including for procurement and supply of health technologies;
- **Collecting, analysing, and reporting access-related information** on pricing, procurement trends, product registration, and in-country uptake; and
- More closely **monitoring and evaluating the impact of DND*i* treatments** on reducing suffering, illness, and death, and tracking progress to inform programmes and drive policy change.

*Gold-standard licensing terms include: (1) perpetual royalty-free, non-exclusive, sub-licensable licences to DND*i* in the contractually defined target disease(s); (2) worldwide research and manufacturing rights; (3) commitment to making the final product available at cost plus a minimal margin, in all endemic countries, regardless of income level; and (4) non-exclusivity, enabling technology transfer and local production to multiply sources of production and decrease price of product.

FOSTERING SUSTAINABLE SOLUTIONS

Scientific and public health leaders in low- and middle-income countries (LMICs) are shaping new innovation ecosystems that have the potential to transform how R&D can meet neglected patients' needs. Our partnerships are amplifying and accelerating this progress.

DND*i*'s own roots are in LMICs – four of our six founding partners and six of our nine offices are located in LMICs. And while DND*i*'s strategic alliances span the globe, our partnerships with public health and scientific experts in LMICs contribute in unique and vital ways to meeting neglected patients' needs – from shaping research strategies and advancing drug discovery, to conducting clinical trials and ensuring access to new treatments where they are needed most.

Trusting and equal partnerships with clinicians, scientists, experts, and affected communities in LMICs are also central to achieving our ultimate goal of helping to foster fundamental, lasting shifts in how 'end-to-end' health R&D is prioritized and conducted so that all people benefit from lifesaving medical innovation and have access to the fruits of scientific progress.

Over nearly two decades of collaborating with health ministries, national disease control programmes, regulatory authorities, academia, industry, civil society groups, clinicians, and other key actors in LMICs, DND*i* and our partners have so far:

- **Created four disease-specific clinical research networks** that bring together hundreds of actors across institutions in dozens of LMICs to consolidate and strengthen existing R&D capacity, promote scientific exchange, facilitate access to new treatments, and advocate for an enabling policy and regulatory environment for needs-driven R&D;
- **Trained more than 5,000 people** in clinical trial management and **strengthened health infrastructure** in clinics, hospitals, and laboratories to enable participation in world-class research, even in the most remote and resource-constrained settings;
- **Established drug discovery consortia** in Latin America and India that link scientists advancing new drug candidates for neglected diseases affecting communities in their regions;
- **Facilitated North-South and South-South technology transfer** to boost sustainable production of new treatments.

Our goal is now to more fully **harness our proximity to the needs of neglected patients** and build from our established alliances to **take full advantage of existing and growing LMIC industrial, regulatory, and clinical trial capacity**. Working with partners and expanding our organizational footprint in LMICs, we aim to:

- **Encourage public leadership** for more effective and equitable approaches to R&D and support for policies that accelerate innovation and access;
- **Bolster collaborative research capacity**, including by training clinical staff and facilitating scientific exchange among clinicians, scientists, and global experts in pharmaceutical R&D
- **Sustain and develop our two successful programmes for optimizing new drug candidates**, consolidate existing clinical research networks, and support the development of **new collaborative networks** to drive progress in new disease areas;
- **Grow our partnerships with pharmaceutical companies in LMICs** to ensure the sustainable production and supply of affordable treatments and offset waning engagement from major pharmaceutical companies in infectious disease R&D;
- **Conduct at least 50% of first-in-human Phase I trials in LMICs** and facilitate **trainings and facility upgrades** where needed to sustain robust local management of Phase II-IV trials.

ADVOCATING FOR CHANGE

An essential part of DND*i*'s mission is to promote public responsibility and advocate for public policies that will enable a more effective and equitable global biomedical R&D system that delivers both innovation and access. We will continue to stress the need for political leadership to drive R&D system change, informed by our practical experience implementing an alternative R&D model.

While a more equitable ecosystem for innovation and access remains elusive – made painfully clear by global inequities in the COVID-19 response – the pandemic has also fuelled optimism about how massive public resources and scientific advances have been mobilized at unprecedented speed; demands for increased transparency and sharing of research knowledge, data, and costs have been bolstered; and calls to address racial, economic, and other disparities in global health have been reinvigorated.

DND*i* will contribute to enriching the evidence base for change by further documenting our own experience, particularly on open knowledge innovation, sustainable and equitable financing models, pro-public health intellectual property and equitable licensing terms, transparency of R&D data and costs, R&D approaches that harness new technologies, and use of innovative regulatory pathways to expedite access for patients.

We will work with and expand partnerships at the global, regional, and national levels to advance progressive policy changes that will lead to an R&D system characterized by the following key features:

- **Needs-driven:** Must address priority public health and patient needs, with a focus on low- and middle-income countries, and ensure the development of drugs and other health tools that are adapted for the people and places that need them most. Such a system must be evidence-based, politically legitimate, and able independently to establish a clear priority-setting process while anticipating the challenges of the future.
- **Collaborative and coordinated:** Must have in place coordination mechanisms for both R&D priority-setting and funding so that financial and technical resources are directed towards high-priority gaps and needs, with experts from LMICs equal partners in decision-making. This will enhance efficiency and collaboration and reduce duplication.
- **Equitable:** Must develop innovations of public health importance as public goods to ensure equitable access to the fruits of scientific progress. Essential health tools must be (1) free from intellectual property restrictions that can act as a barrier to follow-on research, large-scale production, and equitable access; (2) priced as close as possible to what it costs to make them; and (3) available, meaning that sufficient production capacity, including through transfer of technology, must be assured.
- **Open and transparent:** Must promote transparency and sharing of research knowledge, data, and costs throughout the R&D process to improve efficiency and accelerate scientific progress. R&D funding should be made conditional upon results and data, promising compounds, clinical trial protocols, licensing terms, and R&D costs being put in the public domain.
- **Inclusive:** Must ensure that R&D, including the use of new technologies, addresses specific populations historically neglected by the dominant pharmaceutical business model. This includes giving special attention to gender, racial/ethnic differences, people living in poverty, children, migrants, people with co-morbidities, and other vulnerable, and marginalized populations.
- **Sustainable:** Will require sustainable R&D financing that does not rely on high prices of end products, from dedicated long-term budgets. Funding and incentive mechanisms must be directed at the right players at the right stage of the R&D process, and with conditions in place to ensure equitable access. Strategies to 'green' the pharmaceutical development process, reduce the carbon footprint of the health technology sector, and ensure the R&D system is responsive to the climate crisis are also essential.

POWERING OUR AMBITIONS

CREATING VALUE THROUGH PARTNERSHIP

DND*i* is a virtual R&D organization – we have no labs or manufacturing facilities of our own. We act as the 'conductor of a virtual orchestra' to coordinate the activities of our more than 200 partners around the world to address the needs of neglected patients.

Our virtual business model harnesses the best of the public, private, non-profit, academic, and philanthropic sectors to bring the best science to the most neglected and drive knowledge creation through open and collaborative approaches to medical innovation.

Our closest partnerships are with the organizations that founded us. Our academic and public health research institute founding partners from Brazil, France, Kenya, India, and Malaysia enable DND*i* to leverage expertise and technical investment across the globe. MSF's field work informs DND*i*'s R&D priorities, and we collaborate on clinical trials and share scientific and policy expertise. As the world's normative agency for global health, our strategic partnership with WHO is central to our mission.

In this Strategic Plan period, we will consolidate these partnerships, and expand them by:

- **Nurturing alliances with major pharmaceutical partners:** Long-term commitment of major pharmaceutical partners and industrial expertise – from discovery and clinical development to registration and access – are essential for DND*i* to achieve our ambitions. A trend of disengagement of some industrial players from collaboration on anti-infectives makes cultivating productive partnerships a vital imperative. DND*i* aims to develop and maintain long-term strategic alliances with at least five major global pharmaceutical partners.
- **Anchoring our network of partnerships in LMICs:** We will proactively support the engagement of expert partners in LMICs. DND*i* will expand private sector partnerships with pharmaceutical and biotechnology companies, mostly located in LMICs. We will also expand our network of academic and public partners in LMICs to develop stronger links with the health ecosystems in the countries where we operate and continue to ensure proximity to patient needs.
- **Engaging with academic and public health research institutes:** Partnerships with academic and public research institutes have proved critical in DND*i*'s past successes. We aim to develop long-term strategic alliances with at least five major public and/or academic partners to support the execution of our discovery and clinical activities.
- **Partnering for access:** We will strengthen and expand our partnerships with governments to ensure appropriate health system policy and financing for diagnostics and treatments, while enhancing collaboration with industry, communities, and civil society groups to overcome challenges to introducing and ensuring access to new health tools. This will include developing robust collaborations with industrial partners to secure sustainable production, supply, and distribution, as well as engaging stakeholders, including affected communities, to ensure public leadership and community support.
- **Working closely with partners focused on diagnostics:** To effectively treat patients, a clear diagnosis is essential, yet appropriate tools to diagnose patients rapidly at the point of care are often lacking. DND*i* aims to work closely with partners such as FIND to ensure integrated approaches to the development and deployment of diagnostics and therapeutics, including concurrent testing of drugs and diagnostics in Phase III studies, with a view to enabling 'test-and-treat' strategies.
- **Enhancing our approach to alliance management:** DND*i* must continue to be seen as 'a partner of choice'. Our efforts will focus on strengthening management of partnerships and developing an alliance management practice to help realize the full potential of what we can achieve together with our strategic partners.

ORGANIZATIONAL EFFECTIVENESS

DND*i* is an engine for innovation built from the diverse skills and competencies of our staff and partners, fuelled by the trust and shared commitment of our donors.

Doing our utmost for neglected patients means we must ensure the optimal utilization of the resources, tools, and talent we have at our disposal. And it demands that DND*i* adapt at pace with the evolving environment in which we operate, by rising to new challenges in the areas of transparency and compliance, and continuing to demonstrate public health impact and value for money.

DND*i* will work across four areas throughout the Strategic Plan period to strengthen and sustain our ability to deliver on our mission and our duty to patients, donors, partners, and staff.

Cultivating skills and managing growth

- Expand scientific and research leadership and ensure proximity to patients by increasing the proportion of our staff, including leadership positions, located in DND*i*'s offices in LMICs (Cape Town, Kinshasa, Kuala Lumpur, Nairobi, New Delhi, and Rio de Janeiro) to 50% by 2028, compared to 40% in 2020
- Ensure efficiency by streamlining project management systems and sustaining DND*i*'s virtual R&D model, which leverages partner capacity and expertise by maintaining a 1:5 ratio of DND*i* staff to partner staff working on DND*i*-led or coordinated projects
- Address – including by looking within – enduring racial, gender, and economic inequities that stifle progress and limit full participation in efforts to meet neglected patients' needs
- Deploy a new Integrated People Strategy to support DND*i*'s work through people development, means of collaboration, and efficiencies needed to accompany growth in a sustainable manner

Investing in sustainability

- Prioritize the selection of partners that demonstrate environmentally responsible manufacturing processes
- Reduce our carbon footprint by 'greening' the pharmaceutical development process wherever possible and implementing environmentally sustainable work policies and practices to achieve a minimum of 30% reduction in our environmental impact by 2028
- Deliver new treatments that contribute to our sustainability agenda – including those that reduce the use of arsenic-based or antimonial treatments, which have a heavy burden on the environment

Leveraging technology to improve operational effectiveness

- Employ new technologies to improve the efficiency of our operations and accelerate the pace of the R&D process, including utilizing AI as a supportive technology
- Expand our use of digital technologies at the clinical site level to improve patient safety through faster data transmission and advanced tools for point-of-care diagnostics
- Deploy eHealth strategies in neglected disease-endemic countries to support data collection, processing, and analysis

Demonstrating and validating our impact

- Devise and employ a robust and transparent monitoring and evaluation (M&E) framework to (1) assess the impact of DND*i* treatments on reducing suffering, illness, and death, (2) guide operational decision-making, and (3) report progress and demonstrate value for money for DND*i* stakeholders
- Disaggregate M&E and clinical trial data according to the intersecting vulnerabilities of the populations we serve to address urgent R&D gaps and galvanize a more systematic response to meeting the needs of the most vulnerable patients

RESOURCES TO SUSTAIN PROGRESS FOR NEGLECTED PATIENTS

Since our creation in 2003, DND*i* has raised EUR 630 million. We estimate our total spending for 2021-28 at just over EUR 600 million.

Close to 60% of our support since 2003 has come from public institutions, with particularly notable funding support from the governments of the UK, Netherlands, Germany, Switzerland, and France. This includes 10% from innovative financing mechanisms like Unitaid, the European and Developing Countries Clinical Trials Partnership (EDCTP), and Japan's Global Health Innovative Technology Fund (GHIT).

Slightly over 40% of our support has come from private sources: 10% from our founding partner Médecins Sans Frontières; 23% from major philanthropic organizations like the Bill & Melinda Gates Foundation and Wellcome; and 10% from other foundations and individual philanthropists.

DND*i* will sustain and expand these strategic partnerships in the decade ahead, while seeking new public donors and enhancing efforts to secure foundation grants and individual major gifts.

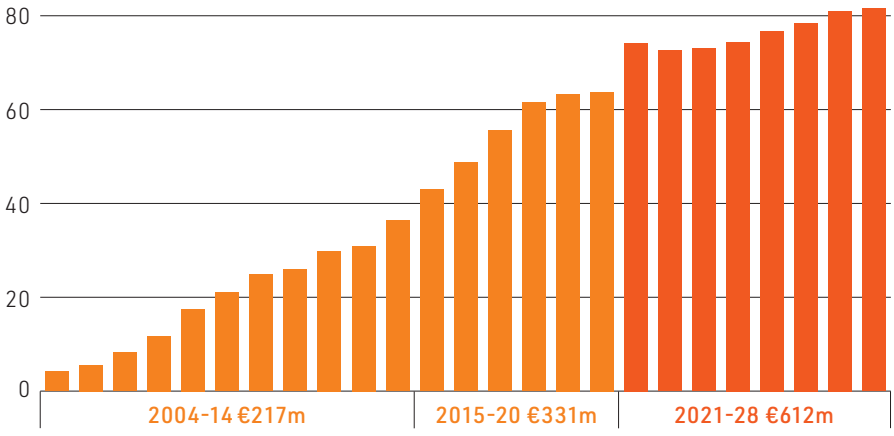
Building from our successful partnerships with public donors in Brazil, Colombia, and Malaysia, we will also prioritize new partnerships with public investors in middle-income countries that contribute to addressing domestic and global R&D priorities, both through direct funding and through collaborative financing that supports a joint R&D agenda.

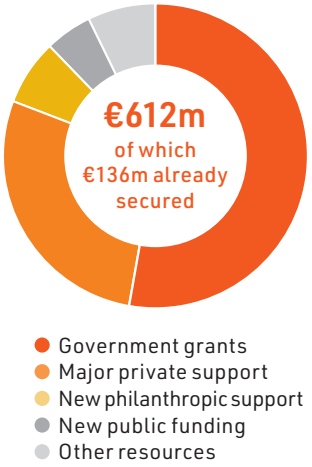
We will also maintain the course set by our funding policy, which plays a vital role in safeguarding DND*i*'s scientific and strategic independence – ensuring continued diversification of funding sources, maintaining a healthy balance of public and private support, and ensuring that no single donor contributes more than 25% of DND*i*'s overall budget. We will also prioritize efforts to secure significant unrestricted (non-earmarked) contributions, which enable DND*i* to respond to urgent needs and unforeseen opportunities, and to focus on extremely neglected or underfunded diseases.

Spending on impact

We keep our overhead low so that we maximize the impact we can have for neglected patients. We aim to keep the ratio of our activities directly related to our social mission (R&D, LMIC partnerships, and advocacy) in line with recent years, where the average was 87%.

A further €612 million investment, to reach 25 treatments in 25 years





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