



ADVANCING  
THE BEST  
SCIENCE FOR  
THE MOST  
NEGLECTED

# 2019 Annual Report

**DNDi**

Drugs for Neglected Diseases *initiative*



# VISION & MISSION

## ■ BEST SCIENCE FOR THE MOST NEGLECTED

### Vision

**To save lives and improve the health of people living with neglected diseases by using an alternative model to develop drugs for these diseases, and by ensuring equitable access to treatment.**

In this not-for-profit model, driven by the public sector, a variety of players collaborate to **raise awareness of the need to research and develop drugs** for those neglected diseases that fall outside the scope of market-driven research and development (R&D). They also **build public responsibility and leadership** in addressing the needs of these patients.

### Mission

**To develop new treatments for people living with neglected diseases. Acting in the public interest, DNDi bridges existing R&D gaps in essential drugs for these diseases by initiating and coordinating drug R&D projects in collaboration with the international research community, the public sector, the pharmaceutical industry, and other relevant partners.**

In pursuing these goals, DNDi enables R&D networks built on global collaborations. While harnessing existing support capacities in countries where the diseases are endemic, DNDi contributes to **strengthening capacities in a sustainable manner**, including through know-how and technology transfers in the field of drug R&D for neglected diseases.

Above photo: A teenager from a village in Bihar, India with high rates of visceral leishmaniasis (VL) infection. She experienced fever for over one year before being diagnosed with VL and receiving the correct treatment. She is now cured.

Cover photo: A mother helps her young child take her paediatric HIV medication in their home. They are both living with HIV and need to take their medication on a daily basis. Isingiro district, Western Uganda.

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For an in-depth look into our work across 40+ projects spanning drug discovery, clinical research, and treatment access, read our **2019 R&D Programmes in Review**:  
[dndi.org/about/annual-reports](https://dndi.org/about/annual-reports)



You can find more detailed information about DNDi's financial statements and related indicators in the **2019 DNDi Financial and Performance Report**:  
[dndi.org/about/annual-reports](https://dndi.org/about/annual-reports)

# FOREWORD

## ■ FROM THE CHAIR OF THE BOARD AND THE EXECUTIVE DIRECTOR

2019 marked a year of exciting progress for DNDi teams and partners around the world, as we set out from the milestone of our 15<sup>th</sup> anniversary with renewed commitment to advancing medical innovation for neglected patients.

Within weeks of its approval by the European Medicines Agency, our latest drug – fexinidazole for the treatment of sleeping sickness – was registered in the Democratic Republic of Congo (DRC), the country hit hardest by the deadly disease. Our teams and partners worked to pave the way for widespread patient access to the safer, simpler, all-oral treatment, including through trainings for health staff in DRC, Guinea, Central African Republic, Angola, and South Sudan. We were thrilled by the news when doctors administered the first treatments to patients outside clinical trials in January 2020.

Building on the success of 'fexi', we are now developing a new single-dose oral drug that could radically improve prospects for eliminating sleeping sickness, a key target of the WHO roadmap on NTDs. It is one of over 40 research and development projects we are currently advancing to reduce illness, suffering, and death from some of the world's most neglected diseases.

It is our firm belief that the medical innovations we are working to deliver are vital to achieving Universal Health Coverage and the 2030 Sustainable Development Goals. The need to overcome gaps in innovation and access to medical tools developed specifically for the people and places that need them most is in the spotlight now more than ever.

One such innovation impasse that is close to our teams' hearts is the lack of treatments adapted to the needs of children living with HIV. But better treatments for kids and their caregivers are on the horizon – including thanks to Cipla's submission of our new child-friendly formulation of four antiretroviral medicines to the US Food and Drug Administration in October 2019. The easy-to-administer, strawberry-flavoured '4-in-1' requires no refrigeration and is a great improvement over the current bitter tasting syrup with high alcohol content. We hope it will be one of many treatment advances to come as we continue to work to meet the medical needs of infants and young children.

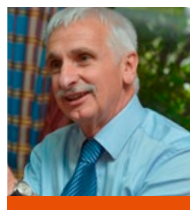
As we look back on the year in the midst of the COVID-19 pandemic and the terrible toll it has brought to bear, we stand firm in our commitment to neglected patients and share our immense gratitude to health workers around the world who are putting themselves at considerable risk to treat the sick and contain the pandemic.

We thank our many friends, funders, and partners who continue to join us in our efforts to help deliver the best science for the most neglected.



A handwritten signature in blue ink, appearing to read 'M. Kiény'.

Dr Marie-Paule Kiény  
Chair of the Board of Directors



A handwritten signature in black ink, appearing to read 'B. Pécoul'.

Dr Bernard Pécoul  
Executive Director

### In memory of Marleen Boelaert

We were profoundly saddened to learn of Marleen's passing in June 2020. She was a true champion in the fight against neglected tropical diseases and was instrumental at DNDi, including as a member of our Scientific Advisory Committee and as an advisor for our sleeping sickness and leishmaniasis projects. Everyone at DNDi who was fortunate enough to know Marleen will remember her for her sharp intelligence, kindness, courage, and humility. We extend our deepest condolences to her family and friends.



# 2019 IN NUMBERS



## R&D portfolio

**46**

R&D projects

**23**

new chemical entities  
in DNDi's drug  
development pipeline

**>350,000**

chemical compounds  
screened for new drug  
potential



## Clinical trials

**18**

clinical trials in 6 disease areas  
at 59 sites in 20 countries

**2,710**

patients enrolled in active  
DNDi clinical studies

**51%**

of patients enrolled  
are children



## Maximizing the virtual model

**4.7:1**

ratio of partner vs DNDi FTEs\*

**15:1**

ratio of partner vs DNDi FTEs\* in Africa



## Support received

**EUR 51.4** MILLION

in multi-year funds secured

**EUR 6.2** MILLION

in-kind contributions and collaborative  
funding from partners



## Sharing knowledge

**45**

peer-reviewed scientific publications  
on DNDi's research

**96%**

published in open-access journals

**50%**

had a female lead or co-lead author

**76%**

had at least one author from a partner  
institution in an endemic country



## Strengthening capacities

**630**

people trained to support  
clinical research in Africa,  
Asia, and Latin America

**64%**

of all R&D partner FTEs\*  
are in Africa

\*Staff in full-time equivalents

# COVID-19



“ On behalf of the German Government I wish to express my gratitude that we could intensify our long-lasting collaboration with DNDi in the fight against the COVID-19 pandemic. This pandemic underlines the necessity of a global approach and shows the advantages of instruments such as product development partnerships. I am confident that DNDi’s work will speed delivery of reliable and accessible drugs and tools to all people, including the most vulnerable. ”

Anja Karliczek,  
Minister, German  
Federal Ministry  
of Education and  
Research (BMBF)

## Accelerating research to protect the most neglected

We cannot look back on the progress of our partnerships in 2019 without acknowledging the unprecedented challenges we are facing as this report goes to print.

Over the first months of 2020, COVID-19 has overwhelmed some of the world’s most advanced health systems. As we write, the capacity of weaker health systems to manage a surge of severe cases is extremely limited, and the low availability of PPE for front-line healthcare workers in some areas means that these key staff are likely to be disproportionately affected by COVID-19.

The overwhelming majority of COVID-19 research studies are taking place in high-income countries. To help protect vulnerable communities in resource-limited settings, DNDi is mobilizing its networks to make sure their specific needs are prioritized in medical R&D for COVID-19 vaccines, diagnostics, and treatments.

## Leveraging the power of collaboration

DNDi co-launched the **COVID-19 Clinical Research Coalition** in early April 2020 to help fast-track desperately needed research for low-resource settings. More than 250 member representatives from 168 institutions in 56 countries have joined so far, working to complement the efforts of the World Health Organization (WHO) and other stakeholders researching new tools for COVID-19 prevention, diagnosis, and treatment in resource-limited settings. With leadership from experts in low- and middle-income countries (LMICs), members are focused on streamlining complex processes and addressing critical concerns such as ethics review, regulation, manufacturing, clinical trials support and logistics, data sharing, and ensuring equitable and affordable access to new tools.

## Conducting research where it’s needed

DNDi and several expert groups from the COVID-19 Clinical Research Coalition have joined forces in preparing to launch the **ANTICOV clinical trial** in about 15 African countries. The goal is to identify one or two treatments that can be used to treat mild and moderate cases of COVID-19 early and prevent mass hospitalizations that could wreak havoc on fragile health systems. Led by the ANTICOV Consortium, the trial will compare the current standard of care with other existing repurposed treatments. Additional drugs could be added as the study advances, as the trial is designed to be able to add new potential treatments as they become available or to drop any treatments that are not working. Up to 3,000 patients with mild COVID-19 across over 20 sites could be included.

## Advocating for accountability

DNDi's expertise in developing and making treatments available in resource-limited settings is relevant to the COVID-19 response in many ways. As the world mobilizes billions of dollars in unprecedented funding to fight the pandemic, we're using this expertise to advocate for six commitments that will help make sure that resulting medical advances will also reach people in LMICs:

1. Target funding and intensify scientific collaboration for research to address the needs of resource-limited settings;
2. Ensure researchers, public health experts, civil society, and political leaders from Africa, Asia, and Latin America are part of decision making and the global search for treatments, diagnostics, and vaccines;
3. 100% open science – publishing results and data in the open, in real time – because it improves efficiency and accelerates scientific progress;
4. Make health tools public goods, free of intellectual property restrictions, to ensure affordability and large-scale production;
5. Up-front agreements to ensure sufficient production, equitable allocation, and affordable pricing;
6. Full transparency on public R&D funding to ensure that both governments and funding recipients are accountable for R&D investments and how they are used.

### THE LANCET

#### **'Global coalition to accelerate COVID-19 clinical research in resource-limited settings'**

*In a comment published in The Lancet in April 2020, a group of scientists, physicians, funders, and policy makers from over 70 institutions in over 30 countries pledged their support for the COVID-19 Clinical Research Coalition.*

2 April 2020

### The Guardian

#### **'Africa's COVID-19 research must be tailored to its realities – by its own scientists'**

*Director of DNDi Africa, Dr Monique Wasunna, highlights the urgent need for an African-led clinical research agenda for COVID-19 that prioritizes the specific needs of African patients and front-line medical staff.*

25 April 2020

**“ It is important that as Africans we do more than just apply the existing scientific knowledge about COVID-19. We should be part of the group that creates this knowledge. ”**

**Dr Evans Amukoye,**  
*Director of Scientific Programmes, Kenya Medical Research Institute (KEMRI)*

**“ Efforts to enhance research capacity, exchange know-how, standardize data collection, and share results rapidly are critical to developing and deploying the tools we need to protect health workers and communities in low- and middle-income countries. ”**

**Professor Sir Nicholas J. White,**  
*Chair of Wellcome's South-East Asian Research Units (Thailand and Vietnam), and Chair of DNDi's Scientific Advisory Committee*

**Learn more about the impact of COVID-19 on DNDi clinical trials on our website: [dndi.org](https://dndi.org)**

# THE URGENCY OF INNOVATION



## Why investing in new tools for NTDs is more important than ever

In our short film 'A Doctor's Dream', we tell the story of Congolese physician Victor Kande's lifetime of dedication to finding a safe and effective cure for sleeping sickness. The disease is one of 20 debilitating and often deadly neglected tropical diseases (NTDs) recognized by WHO that affect 1.5 billion people worldwide – devastating communities and stifling social and economic development.

Control of NTDs is widely considered a litmus test of progress towards achieving the United Nations Sustainable Development Goals (SDGs) – particularly the 'health for all' ambitions of SDG 3, the goal for health. Using NTDs as a barometer, we can ask: Does the progress we are making address the medical needs of the world's most vulnerable and marginalized communities?

### Ambitious targets, remarkable progress

In 2012, WHO launched an ambitious roadmap on NTDs, with plans to control and eliminate 17 diseases by 2020. The 'London Declaration' soon followed, whereby pharmaceutical companies pledged their support to help reduce the burden of 10 NTDs – with billions of treatments delivered through mass drug administration campaigns.

Over 30 countries have since eliminated at least one NTD as a public health problem. This hard-won progress is testimony to the value of bold ambitions, strong national responses, and the resolve of front-line health staff.

Sleeping sickness, now on the brink of global elimination, is arguably one of the biggest success stories. One of the key ingredients of that success is the sustained investment in innovation. Equipped with new tools, steadfast control efforts have brought the number of new cases down from tens of thousands per year to under 1,000. Sustained donor funding for R&D and DNDi's long-standing partnership with Sanofi – initially for nifurtimox-eflornithine combination therapy (NECT), and then fexinidazole – were essential for realizing Dr Kande's dream for safer, simpler, more effective treatments.

### The road ahead

While the NTD community is making significant advances for neglected patients – and that progress should be celebrated – there are worrying risks that could slow or halt our progress.

We are still a very long way from accomplishing what we set out to achieve almost 10 years ago. For most NTDs, we still lack tools for prevention, diagnosis, and treatment that are safe and effective and can be easily integrated into local health systems. Securing and sustaining new gains against NTDs simply cannot happen without new medical innovation.

**“Accelerating work to reach remote and vulnerable communities who experience the greatest barriers to accessing healthcare is central to achieving the Sustainable Development Goals and leaving no one behind. Adequate commitments to research and medical innovation for NTDs will be a critical determinant of progress in the decade to come.”**

**Dr Dirk H. Mueller,**  
Senior Health Adviser,  
Health Research Team,  
Research and Evidence  
Division, UK Department  
for International  
Development



Take Chagas disease: current treatment, while effective, lasts eight weeks and sometimes has serious side effects. For river blindness, mass drug administration campaigns have been successful as a prevention tool, but must be repeated over and over again because the drug that is used does not kill the adult worms, which can live for more than 10 years in the human body. For mycetoma, treatments cure only 35% of patients, leaving many with amputation as their only option.

For these and many other diseases, the fact that R&D funding for NTDs has flatlined over the past decade is of particular concern.

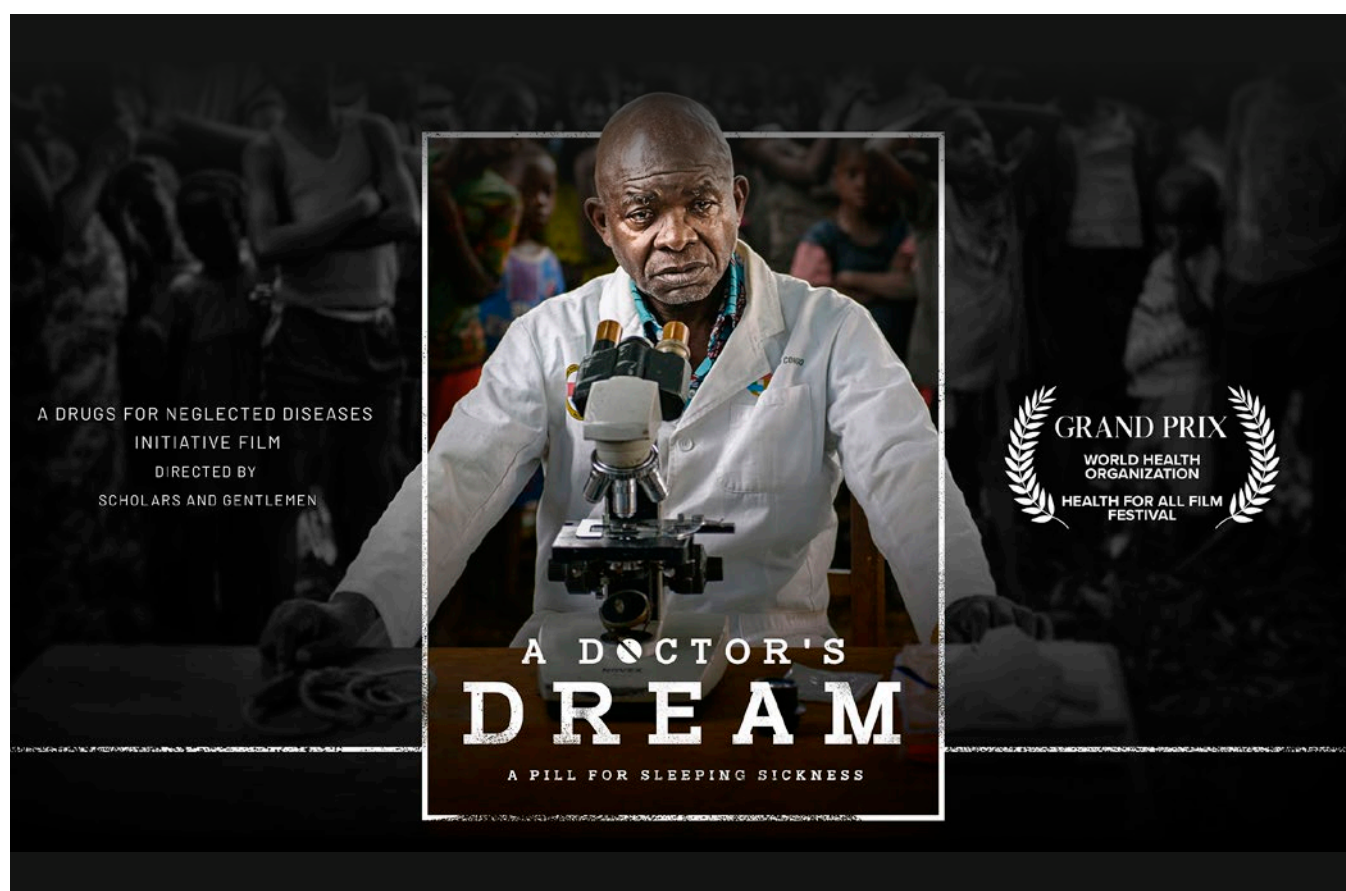
## Investing for the next decade

In 2019, DNDi teams advised on the development of WHO's new 2020-2030 NTD roadmap, which will set new control and elimination targets. At the time of writing, its launch has been postponed due to COVID-19 – as has a high-level donor summit on NTDs that was to be held in Kigali in 2020 to chart the next decade of the response.

Although key events will not go ahead as planned, global momentum against NTDs must nevertheless be accelerated following the publication of the new WHO roadmap. Sustained political will, safe and effective new health tools, and sustainable financing for NTDs are essential to achieving the SDGs and delivering on doctors' dreams and the promise and possibility of health for all.

**“ Drug development is a lengthy, complex, and high-risk process and therefore sustained commitment from funders is needed to develop safer, more effective, affordable treatments for NTDs. Facilitating science that centres directly on the needs of neglected patients is more important than ever. ”**

**Catherine K. Ohura,**  
*CEO and Executive  
Director, Global Health  
Innovative Technology  
Fund (GHIT)*



Our film about Dr Kande and DNDi's search for better treatments for sleeping sickness highlights the power of medical innovation to change the lives of people affected by NTDs. Selected from almost 1,300 entries, the film was honoured with a Grand Prix at the first-ever WHO Health for All Film Festival in 2020. View it here: [dndi.org/fexifilm](https://dndi.org/fexifilm)

# OUR COMMITMENT TO PAEDIATRIC R&D

## More must be done to meet vulnerable children's medical needs



**“ Children with HIV have unique needs that are often overlooked, so the development of innovative, heat-stable, palatable, and easy-to-administer treatments is a powerful achievement for Unitaïd and partners like DNDi and Cipla. ”**

**Philippe Duneton,**  
*Executive Director  
a.i., Unitaïd*

Children are not ‘little adults’ when it comes to medicines; their bodies process medicines differently as they mature. Clinical research that ensures new treatments are safe and effective for kids is crucial – as are efforts to develop medicines in formulations that are easy for them to take.

R&D for treatments adapted to children's needs has lagged far behind R&D for adults. Progress towards closing this gap has been particularly slow for children affected by diseases of poverty that occur in mostly low- and middle-income countries. A 2019 study of clinical trials for NTDs highlights this disparity. Of 369 Phase II-IV trials conducted over an 11-year period, only 17% included patients less than 18 years old; and of the 47 medications WHO recommends for NTDs, just 7 are available in paediatric formulations.<sup>1</sup>

Without the right treatments for kids, cutting and crushing adult medications and mixing them with liquid or food is an everyday practice for caregivers of infants and young children around the world. This is not only burdensome, but can result in incorrect dosing, increased side effects, and poor treatment efficacy. Too often, treatment is stopped altogether.

Since 2003, DNDi has developed four affordable, child-friendly treatments for HIV, Chagas disease, and malaria that have saved millions of lives. And for the first time in 2019, patients under 18 years of age represented more than 50% of participants enrolled in our clinical trials, thanks to our studies of new treatments for HIV, leishmaniasis, and sleeping sickness.

Here are some examples of how we are working to develop the treatments that children need.

### A strawberry-flavoured HIV treatment

Until recently, the only treatments available for babies and young children with HIV were either sub-optimal, bitter-tasting, difficult to dose, or required refrigeration, making them unsuitable for children and their caregivers. With our roots in developing drugs for neglected diseases, Médecins Sans Frontières (MSF) and civil society advocates called on DNDi to apply our R&D experience to help overcome this long-standing innovation impasse – a major barrier to getting more kids on optimal treatment.

<sup>1</sup> Neglected tropical diseases in children: An assessment of gaps in research prioritization by Rees CA et al. *PLoS Negl Trop Dis*, January 2019.



A mother and her child wait for their HIV medicines at the Family Infectious Diseases Clinical Research Unit at Tygerberg Children's Hospital, Stellenbosch University in Cape Town. Studies will be run here soon using the 4-in-1 for neonatal patients.

In October 2019, our partner Cipla Ltd submitted our new child-friendly formulation of four antiretroviral medicines, all combined into one capsule, to the US Food and Drug Administration. The '4-in-1', which comes in the form of easy-to-administer, strawberry-flavoured granules that can be sprinkled on food or milk, will be an important part, along with other anticipated innovations, of the long-overdue treatment revolution for infants and young children who are at the highest risk of dying without treatment. Our teams are now making preparations to work with countries and a wide range of partners to help ensure rapid scale-up of new and improved treatments for children.

## **Saving lives, preventing social stigma**

Fatal if untreated, visceral leishmaniasis (VL), also known as kala-azar, affects the poorest of the poor, and children are most at risk. Our teams are testing a simpler, safer alternative to the current double-injection VL treatment used in eastern Africa, where the disease often strikes children who are charged with tending cattle and who sleep outdoors. In May 2020, we completed patient enrolment in our Phase III study across seven sites in Ethiopia, Kenya, Sudan, and Uganda. More than 70% of patients in the trial are children.

In Sudan, we are also testing simpler, safer treatments for post-kala-azar dermal leishmaniasis (PKDL), a non-lethal

complication of VL that can develop months or years after VL treatment has been completed. PKDL skin rashes, which often develop on the face, can be severely disfiguring and stigmatizing. Almost all patients enrolled in our ongoing Phase II trial are under 18.

## **Championing change**

Greater international commitment is urgently needed to ensure children benefit from the fruits of scientific progress. This means examining all opportunities to include children in research from the earliest stages of clinical trial planning, and dedicating sufficient resources for the development, registration, and supply of optimal paediatric drug formulations.

Today, children are included in five of our ongoing Phase III trials – and we plan to reinforce our commitment to meeting children's needs by launching six more Phase III trials including children by 2028.

Our work on paediatric treatments also provides an entry point for new initiatives to expand testing and treatment for diseases that can be transmitted from mother to child during pregnancy and childbirth, such as Chagas disease and HIV – an approach with tremendous potential to protect the health of women and their babies.

# FROM BENCH TO BEDSIDE

## DNDi Research & Development Portfolio

Acting as a 'conductor of a virtual orchestra', we collaborate with research partners around the world at all stages of the R&D process. Our R&D portfolio includes 46 projects and more than 20 new chemical entities for 7 disease areas (as of December 2019).

	DISCOVERY			TRANSLATION	
	Screen	Hit-to-lead	Lead optimization	Pre-clinical	Phase I
 Sleeping sickness			SCYX-13330682 SCYX-1608210		
 Leishmaniasis	 Screening	Leishmaniasis Hit-to-lead	DNDI-5421 DNDI-5610	DNDI-6174	DNDI-6148
		NTD Drug Discovery Booster Hit-to-lead	Amino pyrazoles	GSK3494245 DDD1305143	DNDI-0690
		Daiichi Sankyo Hit-to-lead	CF series	CpG-D35 for CL	GSK3186899 DDD853651
			Leishmaniasis L205 Series		
 Chagas disease	 Screening	Hit-to-lead	C205 Series	Biomarkers	
		NTD Drug Discovery Booster Hit-to-lead			
		Daiichi Sankyo Hit-to-lead			
 Filaria: River blindness				Macrofilaricide 3 CC6166	Oxfendazole
 Mycetoma					
 HIV					5 FC (cryptococcal meningitis)
 Hepatitis C					
<b>Malaria</b> (Implementation transferred to the Medicines for Malaria Venture in 2015)					

+ New chemical entity



		 DEVELOPMENT		 IMPLEMENTATION
	Phase IIa/Proof-of-concept	Phase IIb/III	Registration	Treatment access
		Acoziborole <sup>+</sup>		<b>Fexinidazole</b> for <i>T.b. gambiense</i> * <sup>+</sup>
		Fexinidazole for <i>T.b. rhodesiense</i> <sup>+</sup>		<b>Nifurtimox-eflornithine combination therapy</b> (NECT)*
<sup>+</sup>		New CL combination	New VL treatments (Latin America)	<b>SSG&amp;PM</b> (East Africa)*
<sup>+</sup>		New treatments for PKDL	New treatments for HIV/VL	<b>New VL treatments</b> (South Asia)*
<sup>+</sup>		Miltefosine + paromomycin combination (Africa)		
	Fexinidazole <sup>+</sup>	New benznidazole regimens <sup>+</sup>		<b>Benznidazole</b> paediatric dosage form*
<sup>+</sup>	Emodepside <sup>+</sup>			
	TylAMac (ABBV-4083) <sup>+</sup>			
		Fosravuconazole <sup>+</sup>		
		4-in-1 (ABC/3TC/LPVr)		<b>Super-booster therapy</b> for children with HIV/TB*
				2-in-1 LPV/r pellets and ABC/3TC or AZT/3TC
		Ravidasvir + sofosbuvir <sup>+</sup>	Ravidasvir <sup>+</sup>	
				<b>Fixed-dose combination ASMQ*</b>
				<b>Fixed-dose combination ASAQ*</b>

\*Treatments delivered by DNDi

# DNDi ACHIEVEMENTS SINCE 2003

**8 new treatments & 1 new R&D initiative**  
creating impact for neglected patients

## Fexinidazole: A paradigm shift for sleeping sickness

2018

First all-oral cure for all stages of sleeping sickness – shorter, easy-to-use medicine that brings treatment closer to patients and boosts elimination efforts.

*In partnership with Sanofi, the Human African Trypanosomiasis Platform, Doctors Without Borders (MSF), national sleeping sickness control programmes, and WHO*



SLEEPING SICKNESS

## NECT: Safer, shorter treatment for sleeping sickness

2009

The first new treatment for sleeping sickness in 25 years finally ends the use of an arsenic-based derivative that kills 1 in 20 patients.

*In partnership with MSF, Epicentre, national sleeping sickness control programmes, WHO, Sanofi, and Bayer*



HIV

## More effective treatment for children with HIV who also have tuberculosis

2016

New hope for children living with both HIV and tuberculosis (TB), after DNDi study shows 'super-boosting' an HIV drug means more effective TB treatment.

*In partnership with the Department of Health, South Africa*

## Easier and safer treatment for children with Chagas disease

2011 & 2018

The first age-adapted paediatric dosage forms to make treatment of infants and children easier and safer.

*In partnership with LAFEPE in 2011, and with Fundación Mundo Sano and Insud/Exeltis/Laboratorio ELEA PHOENIX for a second source in 2018*



CHAGAS DISEASE

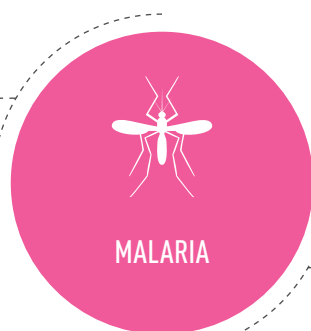
## Two new affordable, patent-free combinations to simplify and ensure effective malaria treatment

### ASAQ

2007

Dispersible, fixed-dose combination of artesunate and amodiaquine requires only one dose per day for three days and is also easier to administer to infants and young children because it dissolves in water. More than 500 million treatments distributed since 2007.

*In partnership with Sanofi*



### ASMQ

2008

Short-course fixed-dose combination of artesunate and mefloquine is suitable for adults, children, and infants from six months of age, has a long shelf life, and decreases risk of resistance emerging.

*In partnership with Farmanguinhos/Fiocruz and Cipla Ltd*

### In East Africa

2010

SSG&PM shown to be as safe and effective as the previous treatment, reducing treatment length by half and allowing more patients to be treated during outbreaks.

*In partnership with the Leishmaniasis East Africa Platform (LEAP), national leishmaniasis control programmes, MSF, and WHO*



### In South Asia

2011

New combination treatments to fend off resistance, improve patient care, and support disease elimination.

*In partnership with South Asian health ministries, research institutes, NGOs, and WHO's Special Programme for Research and Training in Tropical Diseases*



## Global Antibiotic Research & Development Partnership: New entity to fight antimicrobial resistance

2018

Following a three-year incubation by DNDi, the newly independent entity will develop and deliver new or improved antibiotic treatments, and support their sustainable access. 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. In-country implementation of GARDP's programmes is supported by DNDi's international network and a joint DNDi-GARDP office in Southern Africa.

*In partnership with WHO*



# SLEEPING SICKNESS

## MAKING MEDICAL HISTORY WITH REVOLUTIONARY TREATMENTS

Transmitted by the bite of a tsetse fly, sleeping sickness (human African trypanosomiasis) causes neuropsychiatric symptoms, including the debilitating disruption of sleep patterns that have given this neglected disease its name. The illness can evolve into coma and is usually fatal without treatment. While sleeping sickness is now on the cusp of elimination thanks to intensified case detection and innovative new treatments, history shows that it can surge again if control measures are withdrawn, as happened from the 1960s to the 1990s.

### SLEEPING SICKNESS STATISTICS



**8.5 MILLION**  
people live in areas of  
moderate to very high risk



**90%**  
reduction in reported cases  
from 1998 to 2018



**2/3**  
of reported cases in 2018  
were in the DRC

### THE TREATMENT CHALLENGE

Until a decade ago, the only treatment available for sleeping sickness was melarsoprol, an arsenic derivative, killing 1 in 20 patients. In 2009, NECT, a shorter and less toxic combination treatment for the advanced stage of the disease was introduced by DNDi and partners, but it still required hospitalization. Patients also had to endure painful spinal taps to determine the stage of the disease.

In 2018, DNDi and partners delivered fexinidazole, the first all-oral treatment for the *T.b. gambiense* strain of sleeping sickness that affects West and Central Africa. Fexinidazole is a 10-day, once-a-day treatment that eliminates the need for systematic hospitalization for advanced-stage patients.

Nevertheless, the dreaded arsenic derivative is still the main treatment option for severe patients affected by the rarer *T.b. rhodesiense* strain of sleeping sickness found in East Africa.





**“ I was suffering for months, with fever, sleeping problems, becoming aggressive. I took several malaria treatments, but nothing worked. Finally, I went to Bandundu Hospital and received fexinidazole. Shortly after I felt better, and plan to start working again as a teacher. ”**

**Jean Kitala Sedi**, the first patient to receive fexinidazole for sleeping sickness following its approval and registration for use in the Democratic Republic of the Congo (DRC)

## Progress for tools to support sustained disease elimination

Fexinidazole was approved by the European Medicines Agency in November 2018 and was added to the WHO Essential Medicines List in July 2019. For the rest of 2019, DNDi and the National Sleeping Sickness Control Programme (PNLTHA) conducted training sessions of health workers throughout the endemic areas of the DRC on the correct way to administer this new oral drug. The first treatments outside of clinical trials were administered in January 2020.

DNDi continues to develop its second sleeping sickness drug, acoziborole, an oral drug administered as a single dose to treat both stages of sleeping sickness, which could give a radical boost to sleeping sickness elimination plans. A Phase II/III study of the drug in the DRC and Guinea is currently being completed.

Finally, a clinical trial launched in Malawi in 2019 is studying fexinidazole for treatment of *T.b. rhodesiense* sleeping sickness to see if the drug works for this acute version of the disease.

**“ Fexinidazole is a true game-changer for sleeping sickness. If acoziborole, a single-pill treatment, is shown to be safe and effective, we’re hopeful it would provide national programmes an even better tool to help achieve global elimination goals. ”**

**Katey Owen**

Director of Neglected Tropical Diseases,  
Bill & Melinda Gates Foundation

**“ Bringing new, oral, safe and easy-to-administer treatments is a great boost to our efforts to eliminate sleeping sickness in the coming years by finding and treating the last isolated patients in distant rural communities with poor access to healthcare. ”**

**Dr Erick Mwamba Miaka**

Physician Director, DRC National Sleeping Sickness Control Programme (PNLTHA)



# LEISHMANIASIS

## PARTNERING FOR A NEW GENERATION OF TREATMENTS

Caused by parasites transmitted by the bite of a sandfly, leishmaniasis has strong links to poverty, taking its heaviest toll on people affected by malnutrition, poor housing, and displacement. The disease comes in multiple forms. The most severe, visceral leishmaniasis (VL), also known as kala-azar, is deadly if not treated. Post-kala-azar dermal leishmaniasis (PKDL) and cutaneous leishmaniasis (CL) are non-lethal, but cause disfiguring skin lesions that can leave life-long scars and lead to severe social stigma.

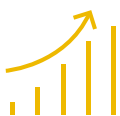
### LEISHMANIASIS STATISTICS



**600 MILLION**  
people at risk of VL  
across the globe



**2,000 x**  
risk of developing active VL  
for people living with HIV



**600,000  
-1.2 MILLION**  
new cases of CL  
each year

### THE TREATMENT CHALLENGE

Better treatments for all forms of leishmaniasis are urgently needed. Existing drugs for VL can be lengthy, toxic, and costly, requiring hospitalization and daily injections, and treatment responses vary in different parts of the world. Current treatment for CL has many of the same serious shortcomings, relying on drugs known as antimonials developed over 70 years ago. Antimonials are not recommended for patients over 50 years of age due to cardiotoxicity, and cannot be given to pregnant women or people with liver or kidney problems.

**DNDi aims to make treatments safer, shorter, and more affordable and effective for all forms of leishmaniasis.** In the short term, better treatment regimens are being developed using existing drugs. In the long term, the goal is to develop an entirely new generation of oral drugs.



“Everyone thought it was malaria ... My health deteriorated and my worst fear become reality: I was a victim of kala-azar. My treatment consisted of 34 painful injections, with many side effects.”

**Poron Lokoler** is a 15-year-old pastoralist and kala-azar survivor from Kalamrekai village, near Kacheliba, Kenya.

## Our long-term goal: All-new, oral treatments for leishmaniasis

With a strong consortium of R&D partners including the University of Dundee, Celgene (now part of Bristol-Myers Squibb), GSK, Pfizer, Takeda Pharmaceutical Company Limited, and TB Alliance, DNDi is working to replace older, toxic, injectable leishmaniasis treatments with all-new, oral drugs that can both dramatically improve patients' lives and support efforts to control and eliminate the disease.

With financial support from the Global Health Innovative Technology Fund, Wellcome, and others, together with partners we have built an unprecedented portfolio of lead series and pre-clinical and clinical drug candidates for leishmaniasis.

In 2019, the consortium made significant progress advancing compounds in Phase I development in preparation for the first Phase II studies in patients. There are currently two new chemical entities in pre-clinical development and three undergoing Phase I safety studies in healthy volunteers. Complementing consortium R&D efforts, DNDi initiated a collaboration and licence agreement with Novartis in early 2020 to jointly develop the first-in-class compound LXE408 as a potential new oral treatment for VL.

## Better VL treatments in Eastern Africa

Patients need alternatives to the current double-injection standard treatment used for VL in East Africa – particularly children, who represent a high proportion of the population at risk. Following positive outcomes using the combination of oral miltefosine and paromomycin (MF+PM) in South Asia, DNDi is now testing MF+PM in a Phase III study across seven sites in Ethiopia, Kenya, Sudan, and Uganda. Study enrolment was completed in May 2020, with 439 patients enrolled – more than 70% of whom were children. Study results are expected in mid-2021.

“Our strategic investment to support DNDi's comprehensive programme for leishmaniasis builds on Wellcome's commitment to driving innovation that can transform the lives of people affected by devastating neglected diseases.”

**Steve Caddick**  
Director of Innovation, Wellcome

## HIV/VL co-infection: Building evidence for better treatment recommendations

People living with HIV have a 2,000 times greater risk of developing active VL. HIV also increases the severity of VL, increasing relapse rates and heightening the risk of death.

In search of a treatment solution, humanitarian organization MSF began using a compassionate regimen in Ethiopia in 2011, combining liposomal amphotericin B (LAmB), an injectable, with the oral drug miltefosine. Results were promising.

To provide the necessary scientific evidence, DNDi and partners ran a Phase III study starting in 2014 to test this combination as well as LAmB alone, the treatment currently recommended by WHO. Results published in 2019 showed that the combination was more effective than standard therapies for treating VL in people living with HIV. Success rates improved to 88% when a second course of VL treatment was given to patients whose first round of treatment hadn't fully cleared the parasite from their bodies.

DNDi and the Rajendra Memorial Research Institute in India acted as technical partners in a second Phase III study sponsored by MSF to evaluate the combination in Bihar, and the last patient follow-up visit was completed in May 2019.

Results of the study in Ethiopia have been presented to national authorities, and guidelines are now under review at the national level to consider adopting the new combination treatment. At the international level, a WHO Guideline Development Group is expected to evaluate HIV/VL treatment recommendations in 2020.

**“ Patients co-infected with HIV/VL are at high risk of treatment failure for VL – with fatal outcomes. The results of our Phase III trial with DNDi strongly support a recommendation of this combination regimen as the first-line strategy for safe and effective treatment of patients with HIV/VL in eastern Africa. ”**

**Dr Rezika Mohammed**

Assistant Professor of Internal Medicine,  
Leishmaniasis Research and Treatment Centre,  
University of Gondar, Ethiopia

**“ Because PKDL is not fatal it has largely been ignored by public health efforts, but our research with DNDi shows that early treatment of PKDL patients will be a critical element of any leishmaniasis public health and elimination strategy. ”**

**Dr Dinesh Mondal**

Senior Scientist, International Centre for Diarrhoeal Disease Research, Bangladesh (icddr,b)

## Post-kala-azar dermal leishmaniasis: The disease that strikes back

Patients can develop PKDL – skin lesions in the form of hypopigmented lesions (macules) and nodules – after successfully completing treatment for VL. Between 50% and 60% of people treated for VL in Sudan and between 5% and 10% of people treated for VL in South Asia develop PKDL.

PKDL lesions contain the same parasite that causes VL, and as a result may play a role in sustaining transmission of the disease from person to person. The results of an innovative ‘infectivity’ study conducted by DNDi and the International Centre for Diarrhoeal Disease Research, Bangladesh (icddr,b) published in 2019 confirm that nodular and macular PKDL can be infectious to sandflies. To confirm the role of PKDL in infectivity in Eastern Africa, DNDi is now preparing to carry out a similar study with our partners at University of Gedaref in Sudan.





“My son had to have injections at the health centre every day for 20 days.”

**Sirane and her son, Daniel,** live in the rural area of Teolandia, Bahia, Brazil. Both were diagnosed and treated for CL.



## CUTANEOUS LEISHMANIASIS IN FOCUS

### Combining existing tools for shorter, safer, more effective treatment

DNDi is working to find safer, more effective CL treatments to replace current options that have been used for nearly 70 years despite their severe side effects. Using a combination of existing therapeutic approaches may improve efficacy and reduce both treatment duration and the rate of adverse events.

Preliminary results of DNDi's Phase II study completed in April 2019 show the combination of thermotherapy (applying heat to a patient's lesion) with a shorter course of oral miltefosine to be significantly better than thermotherapy alone for the treatment of uncomplicated CL in the Americas.

With financial support from Brazil's Ministry of Health and National Council for Scientific and Technological Development (CNPq), planning is now underway for a Phase III study of the combination at sites in Brazil, Peru, Bolivia, and Panama with DNDi's Brazilian research partner, the Oswaldo Cruz Foundation (Fiocruz).

“We hope our research partnership with DNDi can confirm earlier positive results of a new treatment combination that could help improve the lives of people with cutaneous leishmaniasis in Latin America.”

**Marcia Hueb**

Researcher and principal investigator of the Phase III CL study, Mato Grosso Federal University, Brazil

### Stimulating the immune system's response to fight infection

Together with partners GeneDesign and with financial support from Global Health Innovative Technology Fund, DNDi is preparing to conduct the first clinical studies for a novel 'immune modulator' – CpG-D35 – for the treatment of complicated CL.

*Leishmania* parasites are able to persist in human cells by evading or exploiting immune mechanisms. CpG-D35 is being developed as a therapeutic 'booster' to promote the immune system's response to the parasitic infection that causes CL and improve the efficacy of existing drugs.



# CHAGAS DISEASE

## PROGRESS TOWARDS SHORTER, BETTER TREATMENTS TO STOP A SILENT KILLER

Chagas is a parasitic disease that affects over 6 million people in the world. As the disease typically remains asymptomatic for years, new cases often go unnoticed and unreported, and most people with the disease are unaware of their condition. Less than 10% of people affected are diagnosed and the vast majority do not receive the treatment they need. If not treated, Chagas may cause irreversible, life-threatening damage to the heart and other vital organs.

### CHAGAS DISEASE STATISTICS



**6 OVER MILLION**  
people estimated to have Chagas in the world



**21 COUNTRIES**  
The disease is endemic in 21 countries in Latin America



**14,000 DEATHS**  
Chagas causes an estimated 14,000 deaths per year

### TREATMENT CHALLENGE

Currently, there are only two drugs available to treat Chagas disease – nifurtimox and benznidazole – both discovered half a century ago, underlining the persistent lack of investment in R&D.

Treatment is effective during the acute phase of infection, as well as in children and young people. But for about 20% of adults, treatment is not successful in killing the parasites.

Treatment is long and has many potential side effects: 15–20% of those who start the treatment do not complete it. These factors act as barriers discouraging health workers and patients alike, and hampering efforts to scale up diagnosis and treatment.

**DNDi is working with partners to find safer, shorter, and more effective treatments and better tools** to measure the response to treatment. DNDi is also helping scale up diagnosis and treatment and hopes to eventually contribute to eliminating Chagas as a public health problem.



“ I found out I had Chagas during my prenatal tests. Shortly after Gustavo was born, an infection appeared on his arm. I found out he also had Chagas; he got it from me. ”

**Maria Valdirene**, from Goiás Brazil, has chronic Chagas disease. Access to diagnosis and treatment is critical for the prevention of mother-to-child transmission.

## Towards a shorter and safer treatment for Chagas disease

The BENDITA study (Benznidazole New Doses Improved Treatment and Associations) was launched in 2016 in order to identify regimens that were at least as effective as today's standard eight-week treatment, but with fewer side effects, making it easier for patients to complete treatment.

The study was carried out in sites of the Bolivian Chagas Platform coordinated by CEADES and ISGlobal. Six benznidazole treatments of differing lengths and dosages, both in monotherapy and in combination with fosravuconazole, were tested against a placebo.

Study results available in 2019 showed that dramatically shorter treatment could be just as effective, and significantly safer: the trial's two-week treatment arm was particularly promising, as none of the patients interrupted treatment due to side effects.

DNDi is now working with partners to confirm these results, which could help remove one of the barriers to treatment scale-up and bring new hope for people with Chagas disease.

## Breaking down the barriers to diagnosis and treatment

DNDi is also working to support Ministries of Health across Latin America to expand access to diagnosis and

treatment with the existing tools. The pilot approaches include a simplified model of care delivered through clinics close to affected communities. In two municipalities of Colombia, the number of people screened increased from 25 in 2017 to 400 in 2019. The success of the Colombian experience has led to similar access programmes being initiated in the USA, Guatemala, and Brazil. In 2019, a first seminar to identify the barriers to access was also held in Mexico.

## Much-needed visibility

2019 brought some good news for people affected by Chagas disease around the world. Following advocacy efforts led by the International Federation of Associations of People Affected by Chagas disease, the 72nd World Health Assembly declared 14 April official World Chagas Day, an important step to increase visibility of people living with this silent and neglected disease.

“ After two years, we are no longer talking about a pilot. We now have a scalable approach for screening and treatment that has had a positive impact on the health of people affected by Chagas disease. ”

**Dr Fernando Torres**

Head of the Programme for vector-transmitted diseases, Casanare Department, Colombia



# FILARIA: RIVER BLINDNESS

## DEVELOPING A RAPID CURE FOR A DEVASTATING ILLNESS

**New treatments are needed for filarial diseases**, including onchocerciasis (river blindness), an eye and skin disease caused by filarial worms. Millions are at risk of river blindness in sub-Saharan Africa, where people can be infected by blackflies that breed next to fast-flowing rivers. In humans, the worms produce offspring (microfilariae) that migrate through the skin or eyes. This can cause severe itching and disfiguring skin lesions, and infection can lead to visual impairment and blindness.

### FILARIAL DISEASES STATISTICS



**205** ABOUT  
MILLION  
people at risk



**21** MILLION  
people infected with  
river blindness



**>1** MILLION  
people with  
vision loss

### TREATMENT CHALLENGE

The current approach for river blindness is based on the mass distribution of preventive chemotherapy, which has been successful in reducing the prevalence of the disease. But these treatments need to be repeated annually or biannually for many years because they only kill juvenile worms, not adult worms, which can live for more than 10 years in the human body. There are also major gaps in treatment coverage in regions where people are co-infected by both river blindness and *Loa loa*, another filarial disease also known as 'African eye worm'. The current treatment cannot be used in these settings because it can cause a potentially fatal inflammatory reaction in people with the co-infection.

**DNDi aims to deliver a safe, effective, affordable, and field-adapted drug** that can kill adult filarial worms (a 'macrofilaricide') and be used for prevention or individual treatment.



“You’ve got to help people; you can’t leave people like this.”

**Angel Mozenge**, from Uma, Democratic Republic of Congo, volunteers to distribute a drug used to prevent river blindness. She thinks that over half of the population of her village refuses to take the preventive drug.



## Advancing three drug candidates for river blindness

Clinical proof-of-concept studies are being prepared in West and Central Africa for two potentially macrofilaricidal drugs: emodepside with Bayer, and TylAMac with AbbVie. DNDi is planning Phase I trials for a third potential drug, oxfendazole, and has signed an agreement with Celgene (now part of Bristol-Myers Squibb) for another potentially macrofilaricidal compound known as CC6166.

In 2019, DNDi announced the launch of a public-private partnership called the Helminth Elimination Platform (HELP), a new consortium coordinated by the Swiss Tropical and Public Health Institute to identify new treatments against ‘nematode’ worms, including onchocerciasis, lymphatic filariasis, hookworm, and whipworm.



“Bayer is proud to collaborate with DNDi in the development of emodepside as novel treatment for people with river blindness. After completion of Phase I studies, we are excited to conduct a Phase II study with DNDi in Ghana to evaluate emodepside’s potential to alleviate suffering from this debilitating disease.”

**Dr Joerg Moeller**

Head of Global R&D and Member of the Pharmaceuticals Executive Committee, Bayer AG

“We are working closely with DNDi to develop the novel antibiotic ABBV-4083 (TylAMac), which targets the *Wolbachia* bacteria that have an endosymbiotic relationship with the worms that cause river blindness. We are thrilled that DNDi is preparing for a Phase II study in the DRC and is renovating clinical sites in areas hard-hit by river blindness.”

**Dr Dale J. Kempf**

Distinguished Research Fellow, AbbVie



# MYCETOMA

## THE WORLD'S FIRST CLINICAL TRIAL FOR A DEVASTATING DISEASE

**Mycetoma is truly one of the most neglected diseases in the world.** It is not well understood or widely studied. The chronic and slow-growing infection begins most often in the foot, likely after a cut allows the bacteria or fungi that cause the disease to enter, and sometimes spreads to other parts of the body. People are often infected when they step on the thorn of an acacia tree without footwear. Mycetoma causes severe disability, and amputation is often the only option people have.

### MYCETOMA STATISTICS



ONLY **35%**  
cure rate for fungal  
mycetoma with  
current treatments



**Unknown**  
global burden



**Belt**  
occurs most often in the  
so-called 'mycetoma belt'  
between latitudes 15° S  
and 30° N

### TREATMENT CHALLENGE

Mycetoma comes in either a bacterial or fungal form. For the fungal type of mycetoma (eumycetoma), available treatments are frustratingly ineffective – even after 12 long months of treatment cure rates are only around 35%. The medicines are also unaffordable for most of the people affected by the disease and cause considerable side effects. A combination of antifungal drugs and surgery is often used, and amputation is common.

There is currently no effective cure for fungal mycetoma. **DNDi aims to develop an effective, safe, affordable, and simpler curative treatment.**





“ I got mycetoma 19 years ago after I was pricked by a thorn. Even after numerous treatments, eight surgeries, and finally an amputation of my leg, I don’t think I am healed. ”

**Alsadik Mohammed Musa Omer**  
received treatment at the Mycetoma Research Centre in Khartoum, Sudan, one of the world’s leading centres on research and management of the disease.

In 2017, together with the Mycetoma Research Centre in Sudan and the Japanese pharmaceutical company Eisai, DNDi launched a clinical trial for a promising new antifungal treatment, fosravuconazole, in the first-ever double-blind randomized clinical study for mycetoma. This study assesses the efficacy of weekly treatment with fosravuconazole, compared with the standard of care. By January 2020, 101 patients had been enrolled in the study.

To offer additional future options for mycetoma patients, the University of Sydney, Erasmus MC (Erasmus University Medical Center, Rotterdam, the Netherlands), and DNDi launched the Mycetoma Open Source project (MycetOS) to discover new drug candidates for fungal mycetoma. A list of drug targets has been compiled and participating partners of the Open Synthesis Network have received data from MycetOS to begin identifying new compounds for mycetoma.

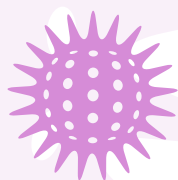
Under WHO’s leadership, a Global Call for Action was launched in 2019 urging the global community to work together with multilateral agencies, partners, research institutions, and pharmaceutical companies to address the devastating consequences of this disease.

“ The Mycetoma Research Centre is the only specialized facility for mycetoma in the world. Our patients are the poorest of the poor, and often travel for days from extremely rural areas to get treatment. These people need more global attention; more research is needed because they have been neglected for too long. ”

**Dr Ahmed Fahal**  
Professor of Surgery, University of Khartoum and Director of the Mycetoma Research Centre, Sudan

“ We are excited fosravuconazole has shown strong anti-fungal activity against mycetoma in the laboratory and has the potential to be an affordable, oral drug. ”

**Dr Katsura Hata**  
Senior Director, Global Health Research Section, hhc Data Creation Center, Eisai Co., Ltd.



# HIV

## A STRAWBERRY-FLAVOURED TREATMENT TO SAVE CHILDREN'S LIVES

While the world has seen tremendous advances in treatment for adults living with HIV, a lack of appropriate treatment options adapted to paediatric needs still contributes to resistance, treatment failure, and low treatment coverage among children living with the disease. Almost half of the estimated 1.7 million children living with HIV today are not accessing treatment. Without treatment, one third of children with HIV die in their first year of life; half die before their second birthday.

### HIV STATISTICS



**50%**

of children with HIV will die before their second birthday without treatment



**1.7 MILLION**

children are living with HIV



**ONLY 54%**

of children are receiving lifesaving treatment

### TREATMENT CHALLENGE

There is currently no cure for HIV, but the disease can be managed with combinations of antiretroviral drugs. Advances for adults and adolescents living with HIV have made today's HIV medicines far simpler and more effective than earlier treatment options. But until recently, the only medicines available for babies and kids were bitter-tasting, difficult to dose, and required refrigeration – making them unsuitable for children and their caregivers. In some places, older paediatric antiretrovirals are still used even though they are no longer recommended because of increasing resistance.

**DNDi aims to help end the neglect of paediatric HIV by developing and rolling out optimal child-friendly antiretroviral formulations** for kids living with HIV, with a special focus on babies and the youngest children who are at the highest risk of dying without treatment.



“ I want my baby to live a normal life but it’s such a struggle to give these medicines every day. But I have to be strong, and do not want to feel sorry for myself. ”

*Junacia struggles to give foul-tasting HIV medications to her child in the Cape Flats neighbourhood in Cape Town, South Africa. Children are still being born with HIV, and local doctors are worried that rates of mother-to-child transmission are not going down enough.*

## A ‘4-in-1’ treatment requiring no refrigeration for less than a dollar a day

Together with our manufacturing partner, Cipla Ltd, DNDi has completed development of a ‘4-in-1’ combination HIV treatment specifically designed for infants and young children. The easy-to-administer, strawberry-flavoured formulation requires no refrigeration and is a great improvement over the current treatment option: a bitter-tasting syrup with high alcohol content that needs to be kept in a cold chain. The regimen comes in the form of granule-filled capsules that parents and caretakers can administer easily by opening the capsules and sprinkling on soft food, water, or milk.

Developed with financial support from Unitaid, Agence Française de Développement (AFD), and others, the 4-in-1 was submitted to the US Food and Drug Administration for tentative approval in October 2019. DNDi began running a study called LOLIPOP in Uganda in 2019 to generate additional data to support worldwide scale-up. To help ensure access, Cipla has committed to price the treatment at under a dollar a day for children weighing up to 14 kg.

## Addressing a deadly HIV co-infection

In keeping with our commitment to respond to evolving research and patient needs, DNDi has initiated work to develop an improved treatment for cryptococcal meningitis, a common, life-threatening opportunistic infection for people with advanced HIV.

The drug flucytosine is a key component of WHO-recommended first-line treatment for HIV-related cryptococcal meningitis, but standard formulations are poorly adapted for use in under-staffed and overburdened hospitals. With pharmaceutical development studies completed in 2019, DNDi is now preparing to start clinical trials that aim to deliver a simpler, sustained-release formulation of the drug adapted for use in resource-limited settings.

“ We are happy to extend our R&D work for children with HIV/AIDS and take an important step forward with the DNDi partnership by developing an entirely new breakthrough paediatric formulation to alleviate suffering and help society. ”

**Dr Y. K. Hamied**  
Chairman, Cipla Limited



# HEPATITIS C

## MILLIONS STILL WAITING FOR A CURE

Hepatitis C (HCV) is a blood-borne virus that can lead to chronic liver disease, cirrhosis, cancer, and, if not treated, death. Symptoms can take decades to develop and most people living with the disease do not know they are infected. As a result, HCV is a silent epidemic. Recent years have seen a revolution in treatment innovation for HCV; however, barely 7% of people living with the disease worldwide have benefited, largely because drugs are priced out of reach.

### HEPATITIS C STATISTICS



**71** MILLION  
people are living  
with HCV globally



ONLY **7%**  
have had access  
to treatment



**>1,000**  
people die from  
HCV every day

### TREATMENT CHALLENGE

With the goal of eliminating HCV globally by 2030, WHO's Global Strategy on Viral Hepatitis aims for 90% of people with HCV to be diagnosed, and 80% of those eligible to be treated by the end of the decade. With cure rates of 90% and above, direct-acting antiviral treatments have opened up the possibility of rolling back the disease; if people are diagnosed and treated early enough to avoid infecting others, elimination is possible. But as of today, treatment remains largely unaffordable, so national HCV programmes to scale up diagnosis and treatment have stalled.

**DNDi aims to develop an affordable, safe, effective, and easy-to-use direct-acting antiviral regimen** that can help pave the way for a public health approach to HCV, and to support the innovative programmes needed to accelerate access to HCV diagnosis and treatment.



**“ Linking patients with hepatitis C to early treatment is essential for Malaysia to achieve the WHO’s elimination target by 2030. ”**

**Dr Rosaida binti Mohd Said**, *Senior Consultant Gastroenterologist and Hepatologist, Serdang Hospital, Malaysia.*



*Two nurses from the hospital prepare members of the public for HCV screening as part of the #MYmissingmillions campaign.*

## **An affordable new regimen**

DNDi is developing ravidasvir (RDV) as part of a simple and affordable HCV treatment combination. Following licencing and manufacturing agreements with pharmaceutical partners Presidio and Pharco in 2016, DNDi conducted the Phase II/III STORM-C1 trial to evaluate RDV in combination with sofosbuvir (SOF) in Malaysia and Thailand. Financed by Médecins Sans Frontières (MSF) and co-sponsored by the Malaysian Ministry of Health and Thai government, the first stage of the trial showed the RDV+SOF combination to be comparable to the very best HCV therapies available today.

Together with our pharmaceutical partner Pharmaniaga, DNDi will pursue registration of RDV in Malaysia in mid-2020, and later in other middle-income countries. The second stage of the trial is now underway to confirm the RDV+SOF combination’s efficacy and safety.

**“ With the necessary will and commitment, we know hepatitis C can be eliminated. Our local and global partnerships, notably with DNDi, are ensuring we have the medical tools and strategies in place to succeed. ”**

**Dr Noor Hisham Abdullah**  
*Director General, Malaysia Ministry of Health*

## **The promise of ‘test and treat’**

Most of the 2.5% of Malaysians living with HCV do not know they have the disease. DNDi and partner FIND are working with the Malaysian Ministry of Health on a new initiative in the country demonstrating the feasibility of ‘test and treat’ strategies using rapid diagnostic tests to screen people for HCV in primary healthcare facilities and link new patients to treatment. With financial support from Unitaïd, the project screened more than 11,000 patients in 2019 and initiated over 400 people on treatment.

**“ Ravidasvir holds tremendous promise for our medical teams, who need a simple, robust, and affordable hepatitis C treatment option to ensure vulnerable patients in developing countries have better access to a cure. ”**

**Pierre Mendiherat**  
*Deputy Operations Director,  
Médecins Sans Frontières*

# NEW TREATMENTS IN CLINICAL DEVELOPMENT

A total of **18** clinical trials in 2019

# 5 CLINICAL TRIALS STARTED

**11** CLINICAL TRIALS  
**ONGOING**

## 2 CLINICAL TRIALS COMPLETED

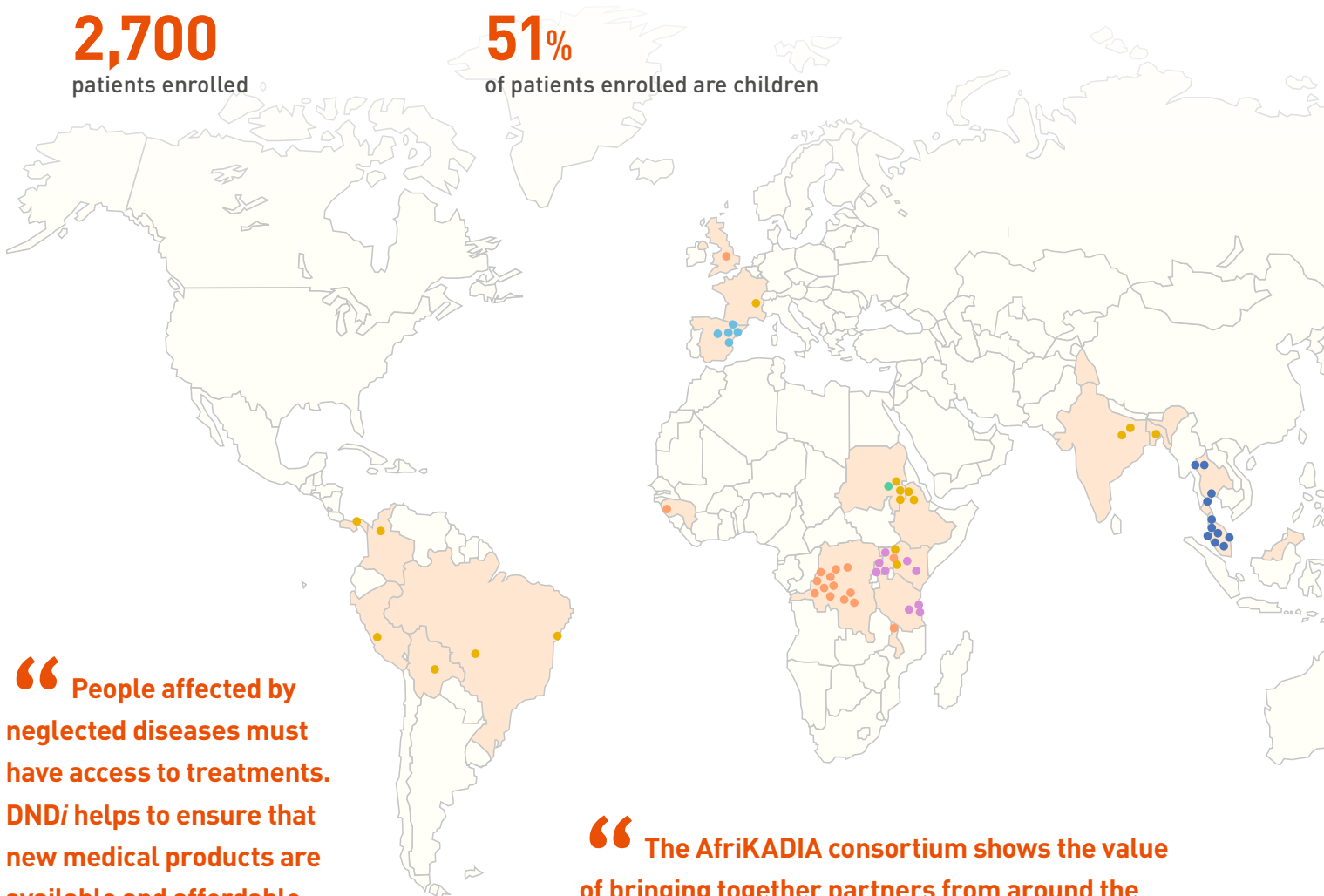
6 diseases

20  
countries

**59**  
clinical trial sites

**2,700**  
patients enrolled

**51%**  
of patients enrolled are children



**“ People affected by neglected diseases must have access to treatments. DNDi helps to ensure that new medical products are available and affordable for all. ”**

**Christian Frutiger,**  
*Ambassador, Assistant Director  
General, Head of Global  
Cooperation, Swiss Agency for  
Development and Cooperation*

**“ The AfriKADIA consortium shows the value of bringing together partners from around the world to generate solid clinical evidence for a safer, more effective treatment for visceral leishmaniasis. ”**

**Dr Michelle Helinski**, Project Officer, The European & Developing Countries Clinical Trials Partnership (EDCTP)



# DNDI's CLINICAL TRIALS IN 2019

## ACTIVE CLINICAL SITES

- Sleeping sickness
- Leishmaniasis
- Chagas disease
- Mycetoma
- HIV
- Hepatitis C



## PHASE I

Research on safe dosage with healthy volunteers

### Sleeping sickness

- Acoziborole mass balance study (UK) **NEW IN 2019**

### Leishmaniasis

- DNDI-6148 (France) **ONGOING**
- DNDI-0690 (UK) **ONGOING**
- GSK3186899/DDD853651 single ascending dose – safety, tolerability, and pharmacokinetics (UK) **COMPLETED IN 2019**

### Hepatitis C

- Ravidasvir bioequivalence study (Malaysia) **NEW IN 2019**

## PHASE IIa

Early safety and proof-of-concept in patients

### Cutaneous leishmaniasis

- Thermotherapy + miltefosine combination proof-of-concept (Colombia, Peru) **COMPLETED IN 2019**

### Post-kala-azar dermal leishmaniasis

- Short-course regimens for treatment of PKDL (India, Bangladesh) **ONGOING**
- Short-course regimens for treatment of PKDL (Sudan) **ONGOING**

### Chagas disease

- Fexinidazole proof-of-concept (Spain) **ONGOING**

### Mycetoma

- Fosravuconazole proof-of-concept for eumycetoma patients (Sudan) **ONGOING**

### HIV

- Abacavir/lamivudine/lopinavir/ritonavir as an easy-to-use paediatric formulation ('LOLIPOP') (Uganda) **NEW IN 2019**

## PHASE IIb/III

Larger-scale safety and efficacy trials

### Sleeping sickness

- Acoziborole pivotal study in adults with stages 1 and 2 *T.b. gambiense* human African trypanosomiasis (HAT) (DRC, Guinea) **ONGOING**
- Fexinidazole for *T.b. rhodesiense* stage 2 HAT (Uganda, Malawi) **NEW IN 2019**

### Visceral leishmaniasis

- Miltefosine + paromomycin for treatment of primary VL patients in Eastern Africa (Ethiopia, Kenya, Sudan, Uganda) **ONGOING**

### Cutaneous leishmaniasis

- Thermotherapy + miltefosine combination proof-of-concept (Brazil, Panama, Peru, Bolivia) **NEW IN 2019**

### Hepatitis C

- Ravidasvir/sofosbuvir combination therapy (Malaysia, Thailand) **ONGOING**

## PHASE IIIb/IV

Post-registration trials for additional data

### Sleeping sickness

- Fexinidazole for *T.b. gambiense* in adults and children, in- and out-patients (DRC, Guinea) **ONGOING**

### HIV

- Lopinavir/ritonavir pellets with dual NRTIs implementation study in infants and young children ('LIVING' study) (Kenya, Uganda, Tanzania) **ONGOING**

# DNDi WORLDWIDE

## ■ 2019 global network highlights

DNDi is headquartered in Geneva, with eight offices around the world leading implementation of R&D projects, as well as building and maintaining partnerships and supporting fundraising and visibility efforts. Close to half of DNDi's employees are based in regional offices.

### Democratic Republic of Congo

- **R&D:** Completed patient recruitment for two clinical studies for sleeping sickness, including one for new chemical entity acoziborole
- **Access:** Started fexinidazole access trainings with the National Sleeping Sickness Control Programme; the first patient to receive fexinidazole outside of a trial was treated in early 2020
- **Capacity strengthening:** Coordinated all HAT Platform activities; prepared clinical trial sites for upcoming study of TylAMac for onchocerciasis

### ■ North America

- **R&D and access:** Prepared access plan for '4-in-1' for kids with HIV; supported Chagas stakeholders (University of Florida, the Center of Excellence for Chagas Disease in Los Angeles, a working expert group on screening and diagnosis for US Chagas patients, and others)
- **Partnerships:** Concluded new agreements with Celgene (now part of Bristol-Myers Squibb) for early filaria development activities, and with Janssen for research into new pre-clinical candidates for Chagas disease
- **Advocacy:** Put paediatric HIV in the spotlight, with front-page New York Times World AIDS Day article; stressed the need for R&D in UN High-Level Meeting on Universal Health Coverage

### ■ Latin America

- **R&D:** Completed BENDITA trial, which opens prospects of shorter and safer treatment for Chagas disease; completed a clinical study in Colombia and Peru to evaluate efficacy and safety of a treatment combination (miltefosine + thermotherapy) for cutaneous leishmaniasis
- **Access:** Alongside Colombia's Ministry of Health, the Chagas Access pilot project completed its third and final year, with positive results leading to similar access programmes being initiated in Guatemala, Brazil, and the USA
- **Partnerships:** Built a robust regional drug discovery platform with two Brazilian universities, USP and UNICAMP, for Chagas and visceral leishmaniasis; collaborated with the Andean Region Health Organization focusing on access to treatments for hepatitis C



## Eastern Africa

- **R&D:** Concluded clinical trials generating evidence for submission of new paediatric '4-in-1' HIV treatment to US FDA; published results of clinical study in Ethiopia opening the possibility for much more effective treatment for people with HIV/VL co-infection; led clinical trials on mycetoma and leishmaniasis
- **Access:** Enrolled first patients in Uganda in study to generate additional data to facilitate uptake and implementation of '4-in-1' treatment for children with HIV
- **Advocacy:** Endorsed and supported visibility around Global Call for Action on mycetoma to galvanize research on this most neglected disease

## South-East Asia

- **R&D:** Launched the STORM C-1 Stage 2 clinical trials in Thailand and Malaysia to confirm the efficacy and safety of ravidasvir/sofosbuvir combination for HCV
- **Access:** Launched new initiative with Malaysian Ministry of Health and FIND to demonstrate feasibility of 'test-and-treat' strategies using rapid diagnostic tests to screen people for HCV
- **Partnerships:** Supported the launch of Malaysia's National Strategic Plan for HBV and HCV; ongoing collaborations and partnerships in Thailand around GARDP STI and Neonatal sepsis study; and with Pharmaniaga towards registration of RDV in Malaysia

## Japan

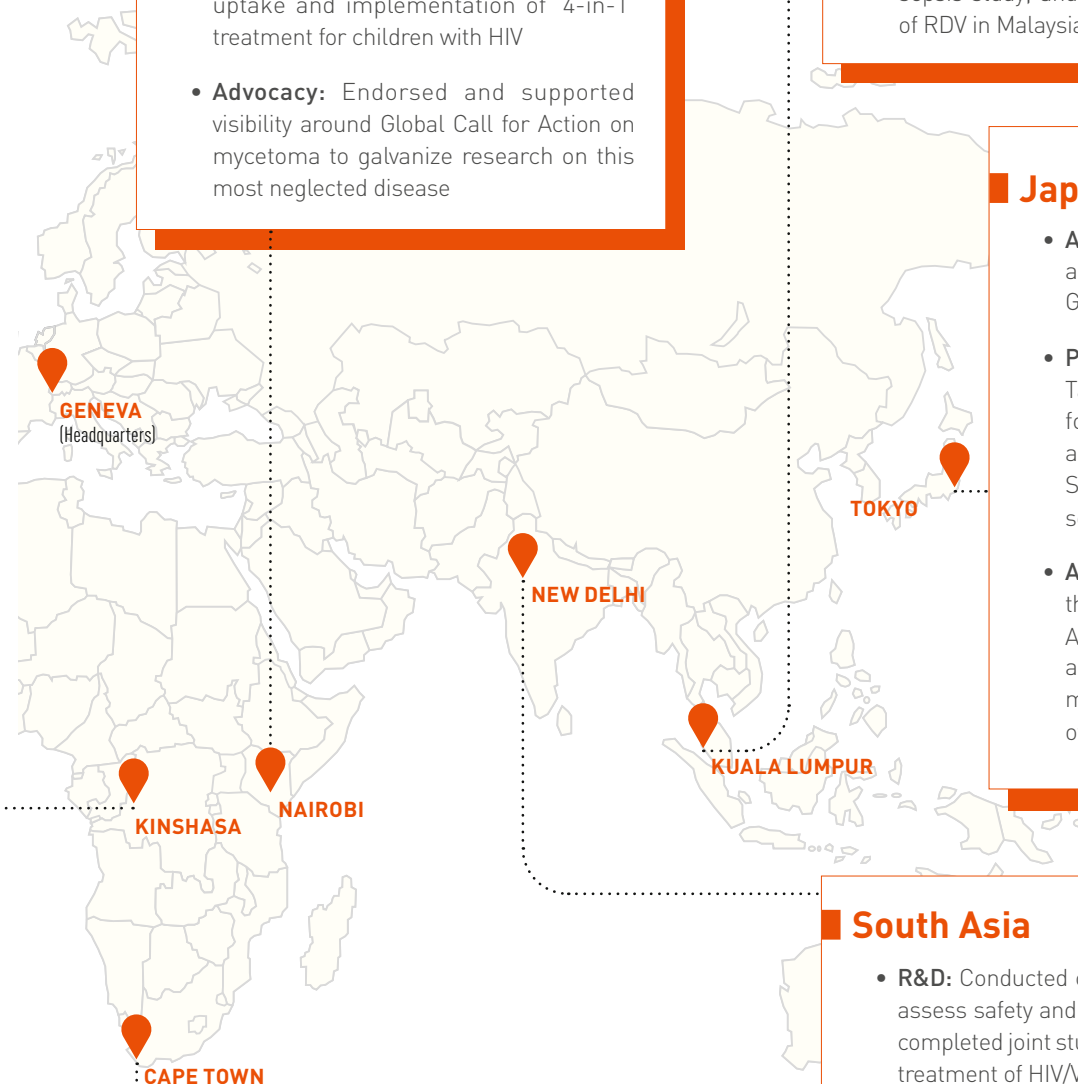
- **Access:** Supported DNDi's global access activities for NTDs thanks to Takeda Global CSR Program
- **Partnerships:** Collaborated with Mitsubishi-Tanabe and GHIT Fund to screen compounds for leishmaniasis and Chagas disease; and with Eisai, Takeda, and Daiichi Sankyo in an antimicrobial resistance screening consortium
- **Advocacy:** Cast the spotlight on NTDs at the 7th Tokyo International Conference on African Development (TICAD7) with JAGntd and GHIT Fund; leveraged the political momentum on AMR, resulting in a pledge of JPY 1 billion to GARDP from Japan

## South Asia

- **R&D:** Conducted clinical trials in India and Bangladesh to assess safety and efficacy for treating patients with PKDL; completed joint study with MSF for better, safer, and shorter treatment of HIV/VL co-infection
- **Partnerships:** Gathered more than 100 leading policy makers and public and private sector representatives on the occasion of our 15th anniversary to expand discussions on new partnerships in R&D and innovation for neglected patients; supported National Kala-azar Elimination Programme in VL and PKDL diagnosis, and in evidence generation to enable sustainable elimination of VL; partnered with two Indian entities as part of Lead Optimization Consortium in drug discovery for leishmaniasis, with Cipla to develop a '4-in-1' treatment for children living with HIV, and with Indian Council of Medical Research on NTDs targeted for elimination to define future priorities for medical research
- **Advocacy:** Published with *British Medical Journal* a special collection on neglected diseases and innovation in South Asia

## Southern Africa (joint DNDi-GARDP office)

- **R&D:** Prepared GARDP Phase III study for gonorrhoea and Phase II for neonatal and paediatric sepsis, both due to start enrolment in 2020
- **Partnerships:** Supported stakeholder efforts to advance treatment access for cryptococcal meningitis with DNDi, and coordinated with research partners for GARDP studies



# BUILDING NETWORKS OF EXCELLENCE

“Mobilizing scientific expertise and public leadership in endemic countries is central to DNDi’s mission and essential to our ability to respond to neglected patients’ needs.”

Dr Bernard Pecoul,  
Executive Director, DNDi

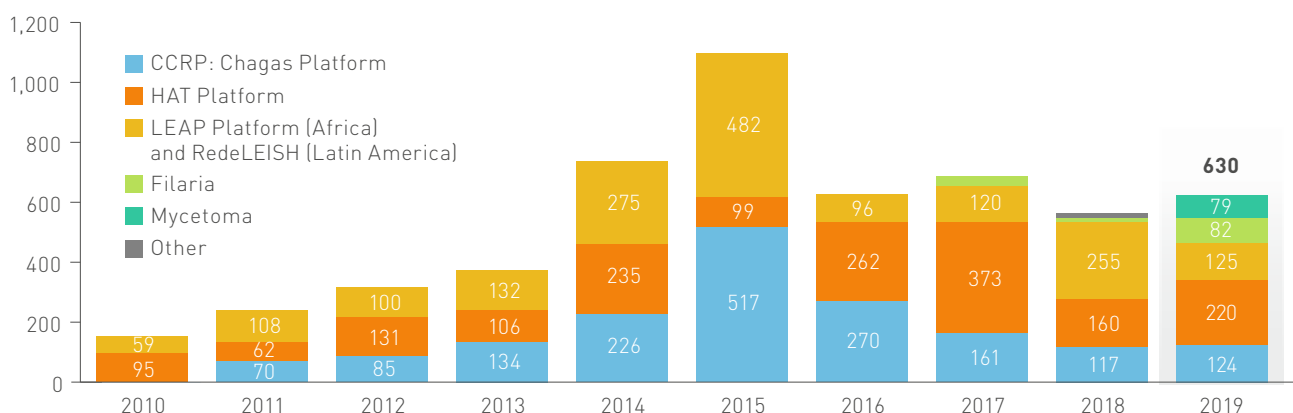
## Towards sustainable R&D in endemic countries

One of DNDi’s ultimate objectives is to contribute to new innovation ecosystems, driven by scientific leaders in LMICs that will fundamentally change how research priorities are defined and where health R&D is conducted in the public interest. Initiatives to use and strengthen research capacities in LMICs and support networks of excellence to sustain R&D are central to the DNDi model.

Since 2003, four disease-specific clinical research platforms and networks have been created. By bringing together key actors, including health ministries, national disease control programmes, regulatory authorities, WHO, academia, civil society groups, as well as clinicians and health professionals, these ‘knowledge hubs’ promote scientific exchange, identify patients’ needs and R&D gaps, strengthen and sustain clinical research capacity, facilitate access to new treatments, and advocate for an enabling policy and regulatory environment for needs-driven R&D.

## Over 5,400 people trained in clinical trial management in 10 years

630 people trained in 2019



## AFRICAN LEADERSHIP AND COMMITMENT AT THE HEART OF SLEEPING SICKNESS SUCCESS STORY

The development of fexinidazole – the first safe, effective, all-oral treatment for sleeping sickness – required tremendous cooperation and determination to enable world-class clinical research and extensive patient screening in some of the most remote African communities. From start to finish, national disease control programmes, medical experts, and healthcare professionals in affected countries contributed their expertise and steady commitment and support – all essential to the long-awaited breakthrough for patients.

Our African partners are now driving the ‘last mile’ efforts to ensure widespread patient access to fexinidazole for all patients in need. In 2019, key health actors – ministries of health, sleeping sickness control programmes, WHO, and NGO representatives – joined forces to organize the roll-out of the game-changing drug, which is now recommended by WHO for first-line treatment.

Training of trainers started in health facilities, first in DRC then in other endemic countries, with 220 health workers trained in 2019. In addition to other actions planned with WHO and control programmes (diagnostic capacity building, pharmacovigilance studies, supply donated by Sanofi through WHO, and with MSF’s logistical support), this set the scene for successful and sustainable access to the treatment.



“ Efforts to improve our capacity to deliver sleeping sickness services through infrastructure improvements and training of health staff will contribute to the sustainability of our response to the disease and its elimination, in line with the SDGs. ”

**Dr Eteni Longondo,**  
*Health Minister,  
Democratic Republic  
of Congo*



## BOOSTING CLINICAL CAPACITY IN SUDAN: NEW LABORATORY FOR MYCETOMA RESEARCH AND TREATMENT

Until very recently, most specialized mycetoma lab procedures in Sudan were carried out in the capital, Khartoum. This meant that patients had to travel long distances – from as far away as Sennar State, about 500 kilometres away – to access diagnosis for this highly neglected disease. Leaving behind family and fields poses an immense economic burden on communities largely dependent on agriculture and pastoralism for their livelihoods.

In 2019, the Mycetoma Research Centre (MRC), DNDi and partners worked on rehabilitating the Wad

Onsa Regional Mycetoma Centre in Sennar. Its new laboratory – officially inaugurated in January 2020 – is now equipped for microbiological testing. A portable ultrasound machine also is now available, both for use in the centre and for outreach activities in the surrounding villages. The imaging and laboratory equipment will improve the quality of medical services for the whole community. Training of staff in good laboratory practices will also benefit the community and the health system.

# RESEARCH NETWORKS



## CHAGAS CLINICAL RESEARCH PLATFORM (CCRP)

**5** active surveillance sites\* **124** people trained

- **Founded: 2009 in Uberaba, Brazil**
- **460 members, from over 150 institutions and 24 countries**

### 2019 Highlights

- Two target product profiles initiated for special populations: children and people with suppressed immune systems
- Development of a data-sharing platform with IDDO to collect and standardize clinical research data. This initiative will avoid duplication and contribute to accelerate development of better treatments
- A workshop was organized in Argentina to streamline decision-making when evaluating therapeutic response in chronic Chagas disease



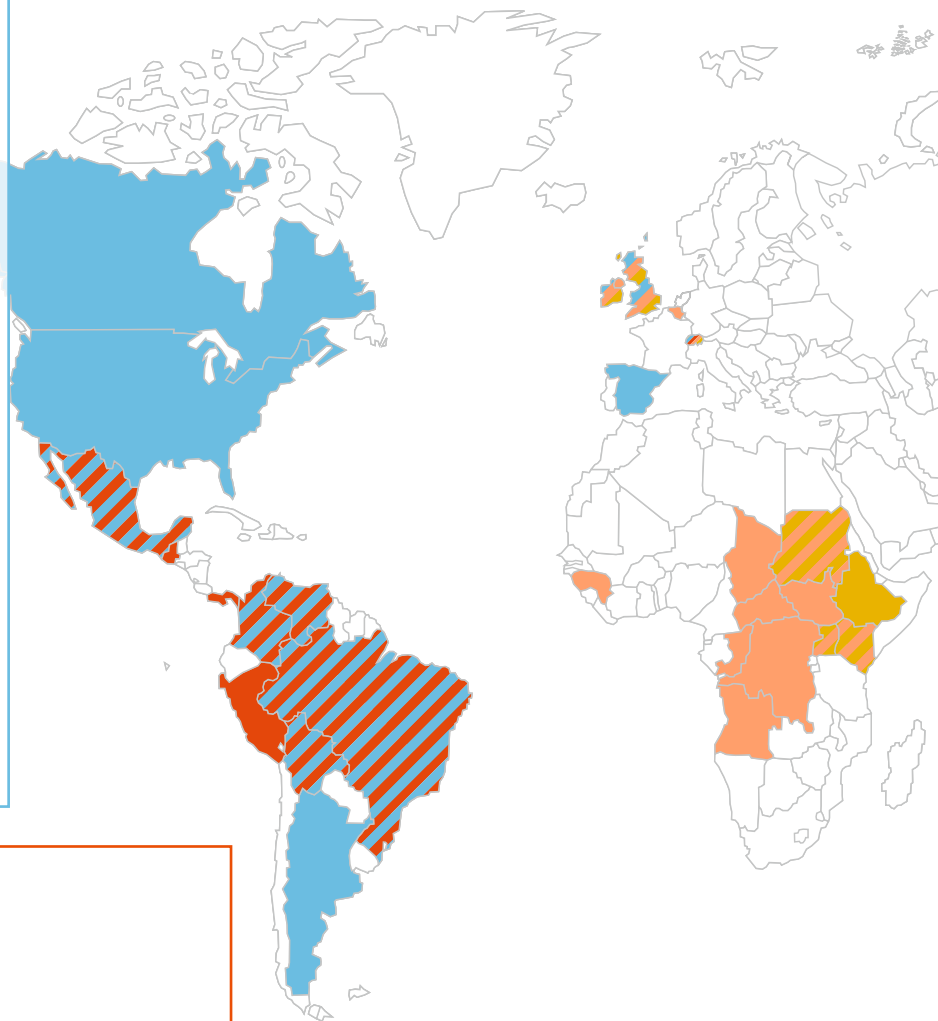
## RedeLEISH

**92** people trained

- **Founded: 2014 in Rio de Janeiro, Brazil**
- **184 members, from 91 institutions and 21 countries**

### 2019 Highlights

- Data-sharing project, with support of WHO-TDR, to collect information on routine CL treatment efficacy in children up to 10 years of age and elderly people in order to provide evidence and make recommendations to the national leishmaniasis programmes of Brazil, Colombia, Bolivia, and Peru for case management
- Facilitated the development of consensus among investigators to reduce the follow-up time to assess treatment efficacy for CL patients included in clinical trials, from 180 days to 90 days
- Preparation of a Phase III CL clinical trial in five sites in Bolivia, Brazil, Panama, and Peru
- Collaborative project of four RedeLEISH sites in Brazil to conduct a clinical trial to assess efficacy and safety of a drug combination for mucosal leishmaniasis



**“ We support clinical research networks in low- and middle-income countries for their power to strengthen and sustain research capacity, expertise, and collaboration. The platforms play a vital role in bringing new knowledge and evidence to national and local disease control programmes and paving the way to treatment access for patients in need. ”**

**Virginie Leroy,**  
Directrice, Département Transition sociale, Agence Française de Développement

\* Sites belonging to platform/network members and used for DNDi studies



## MAIN PARTNERS

### HAT Platform

National sleeping sickness control programmes, research institutions, and national laboratories of public health of the most affected endemic countries: Angola, Central African Republic, Chad, Democratic Republic of the Congo, Republic of Congo, South Sudan, Sudan, Uganda, Guinea; DNDi, Switzerland; Swiss Tropical and Public Health Institute (Swiss TPH), Switzerland; Institute of Tropical Medicine Antwerp, Belgium; Institut National de Recherche Biomédicale (INRB), DRC; University of Makerere, Uganda; Kenya Agricultural Research Institute – Trypanosomiasis Research Centre (KARI-TRC), Kenya; Tropical Medicine Research Institute (TMRI), Sudan; Institut Pasteur Bangui, CAR; Médecins Sans Frontières; Foundation for Innovative New Diagnostics (FIND), Switzerland; Eastern Africa Network for Trypanosomiasis (EANETT), Centre interdisciplinaire de Bioéthique pour l'Afrique Francophone (CIBAF); WHO Department of Neglected Tropical Diseases as observer; INZI project, University of Edinburgh, UK, Juba University, South Sudan.

### LEAP

Center for Clinical Research, Kenya Medical Research Institute, Kenya; Ministry of Health, Kenya; Institute of Endemic Diseases, University of Khartoum, Sudan; Federal Ministry of Health, Sudan; Addis Ababa University, Ethiopia; Gondar University, Ethiopia; Federal Bureau of Health, Ethiopia; Makerere University, Uganda; Ministry of Health, Uganda; MSF; London School of Hygiene & Tropical Medicine, UK; WHO; DNDi, Switzerland; FIND, Switzerland.

### CCRP

Over 150 institutions including: Baylor College of Medicine, Tropical Medicine (USA); Casa de Chagas de Pernambuco (Brazil); Center of Excellence for Chagas Disease at Olive View-UCLA Medical Center (USA); Coalizão Chagas (Spain); Fundação Oswaldo Cruz – Fiocruz (Brazil); Fundación CEADES (Bolivia); Fundación Mundo Sano (Argentina); Grupo de Didáctica de las Ciencias – IFLYSIB, CONICET-UNLP (Argentina); Hospital de Niños Ricardo Gutiérrez (Argentina); Instituto de Investigaciones en Ingeniería Genética y Biología Molecular “Dr Héctor N. Torres” – INGEBI-CONICET (Argentina); Instituto de Salud Global de Barcelona – CRESIB/ISGlobal (Spain); Instituto Nacional de Parasitología “Dr Mario Fatala Chábén” – ANLIS (Argentina); Instituto Nacional de Salud (Colombia); Instituto Nacional de Salud Pública – INSP (Mexico); International Development Research Centre – IDRC (Canada); International Federation of People Affected by Chagas Disease – Findechagas (International); Laboratorio Elea (Argentina); Laboratório Farmacêutico de Pernambuco – LAFEP (Brazil); London School of Hygiene & Tropical Medicine (UK); Medecins Sans Frontières – MSF (International); Pan American Health Organization – PAHO (International); The Foundation for Innovative New Diagnostics – FIND (Switzerland); Universidad Central de Venezuela (Venezuela); Universidad de los Andes (Colombia); Universidad Nacional Autónoma de México – UNAM (Mexico); Universidad Nacional de Córdoba (Argentina); Universidade de São Paulo – USP (Brazil); Universidade Estadual de Campinas – UNICAMP (Brazil); Universidade Federal do Ceará – UFC (Brazil); University of California (USA); WHO (International).

### RedeLEISH

BOLIVIA: Fundación Nacional de Dermatología (FUNDERMA), Universidad Mayor de San Simón. BRAZIL: PAHO; Ministério da Saúde (SVS & SCTIE); Plataforma de Pesquisa Clínica – FIOCRUZ RJ, Centro de Pesquisa Gonçalo Moniz-FIOCRUZ BA; Universidade Federal da Bahia (UFBA); Universidade Federal do Piauí (UFPI); Centro de Pesquisa René Rachou-FIOCRUZ BH; Instituto Nacional de Infectologia – FIOCRUZ RJ; Fundação de Medicina Tropical Heitor Vieira Dourado; Instituto Evandro Chagas; Universidade do Estado do Pará (UEPA); Instituto Nacional de Pesquisa da Amazônia (INPA); Secretaria Municipal de Saúde Unidade Referência em Atenção Primária Drª Claudia Vitorino; Universidade de Brasília – Núcleo de Medicina Tropical (UnB); Universidade Federal de Mato Grosso/Hospital Universitário Júlio Müller; Universidade de São Paulo (USP); Universidade Federal do Pará (UFPA); Universidade do Rio de Janeiro (UFRJ); Universidade Federal do Ceará (UFC); Universidade de Pernambuco (UFPE); Laboratório do Estado de Pernambuco (LAFEP); Universidade Federal de Santa Catarina (UFSC). COLOMBIA: Centro Dermatológico Federico Lleras Acosta; Centro Internacional de Entrenamiento e Investigaciones Médicas (CIDEIM); Instituto Colombiano de Medicina Tropical; Instituto Nacional de Salud (INS); Programa de Estudios y Control de Enfermedades Tropicales (PECET), Ministerio de Salud y Protección Social. GUATEMALA: Universidad del Valle. MEXICO: Universidad Nacional Autónoma de México. PANAMA: Instituto Conmemorativo Gorgas de Estudios de la Salud. PERU: Department of Parasitology, Public Health Training Program – US Naval Medical Research Unit No. 6; Universidad Peruana Cayetano Heredia. VENEZUELA: Instituto Médico la Floresta. SWITZERLAND: DNDi; FIND; WHO-TDR.



## HAT PLATFORM

**13** active clinical sites\* **220** people trained

- **Founded: 2005 in Kinshasa, DRC**
- **120 members, from over 20 institutions**

### 2019 Highlights

- 13 clinical trial sites\* active for acoziborole, fexinidazole for *T.b. gambiense*, and fexinidazole for *T.b. rhodesiense* studies
- 7 sites rehabilitated in DRC and Guinea. The platform identified, assessed needs, and prepared the set-up of all sites

### Preparing for access to fexinidazole:

- 220 people trained, mainly in DRC, including for new *T.b. rhodesiense* study starting in Uganda and Malawi
- Supported policy change, with new HAT treatment guidelines including fexinidazole introduced in DRC
- Advocacy meeting in Kinshasa to facilitate introduction of fexinidazole in national guidelines with representatives from Angola, Central African Republic, DRC, Guinea, and South Sudan



## LEISHMANIASIS EAST AFRICA PLATFORM (LEAP)

**7** active clinical sites\* **125** people trained

- **Founded: 2003 in Khartoum, Sudan**
- **60 members from over 20 institutions**

### 2019 Highlights

- 7 active clinical trial sites\* in Ethiopia, Kenya, Sudan, and Uganda; 1 site constructed and equipped for clinical trials in Sudan
- 125 people trained, mainly on data management, good clinical and laboratory practice, and diagnostics
- 1st AfriKADIA symposium held in Nairobi with key stakeholders on ‘Translating research results into policy for control and elimination of leishmaniasis in eastern Africa’
- Policy change: following revision of the VL guidelines in Uganda in 2018, the Ministry of Health released the 2019 Guidelines for the Diagnosis, Treatment, and Prevention of VL in Uganda

## Network

- CCRP
- RedeLEISH
- HAT Platform
- LEAP



# GOVERNANCE

## DNDi BOARD OF DIRECTORS



**Marie-Paule Kiény**  
Chair; Institut national de la santé et de la recherche médicale, France, formerly with WHO, Switzerland



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**Stewart Cole**  
Institut Pasteur, France



**Joanne Liu**  
Médecins Sans Frontières (until November 2019)



**Alwyn Mwinga**  
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**Bernhards Ogutu**  
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**John Reeder**  
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**Pierre Buffet**  
Paris Descartes University and INTS, France



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**Dale Kempf**  
AbbVie, USA



**Kiyoshi Kita**  
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**Nilima A. Kshirsagar**  
Indian Council of Medical Research, India



**Shahnaz Murad**  
Ministry of Health, Malaysia



**Tomo Nozaki**  
University of Tokyo, Japan (since December 2019)



**Koert Ritmeijer**  
Médecins Sans Frontières



**Nilanthi de Silva**  
University of Kelaniya, Sri Lanka



**Faustino Torrico**  
Universidad Mayor de San Simón, Bolivia



**Muriel Vray**  
Institut Pasteur, France



**John Westwick**  
Imperial College, London University, UK (until December 2019)

Note: Lists include membership from January to December 2019

Photo page 38: Nurse Eunice Abeda works at Lwala hospital in Uganda, a national reference centre for sleeping sickness treatment and a site for DNDi's clinical trial of fexinidazole for the treatment of the *rhodesiense* form of the disease.



## DNDi is deeply grateful to our R&D partners, whose commitment and collaboration have sustained our work since 2003\*



### Sleeping sickness

Accelera, Italy; Advinus Therapeutics Ltd., India; Aesica, UK; Amatsi Aquitaine (formerly Bertin Pharma), France; Analyticon Discovery GmbH, Germany; Anacor Pharmaceuticals (now Pfizer Inc.), USA; Aptuit, Italy; Asinex Corporation, USA; Avista Pharma (formerly SCYNEXIS), USA; Basilea Pharmaceutica AG, Switzerland; Biotrial, France; Bureau d'Etudes d'Ingénierie et d'Architecture (DINA) Sarl, Guinea; Banook Group, France; BIOTEC, Thailand; CBCO, DR Congo; Celgene Corporation, USA (now Bristol-Myers Squibb); Centipharm, France; Chiron Corporation, USA (now Novartis); Creapharm, France; Debiopharm SA, Switzerland; Dow AgroSciences LLC, USA; Drugabilis, France; Eurofins-Optimed, France; Evanston Northwestern Healthcare, USA; Evolva SA, Switzerland; Foundation for the National Institutes of Health, USA; Genzyme, USA; HAT Platform; HES-SO Valais Wallis, Switzerland; Institut de Recherche pour le Développement, France; Institut National de Recherche Biomédicale, DRC; Institute of Tropical Medicine Antwerp, Belgium; Joint Clinical Research Centre, Uganda; Laboratoire La Référence, Guinea; Laboratory of Microbiology, Parasitology, and Hygiene, University of Antwerp, Belgium; Luxembourg Institute of Health, Luxembourg; Médecins Sans Frontières; Ministry of Health, Malawi; Murdoch University, Australia; National Control Programmes of the Democratic Republic of Congo, the Central African Republic, and of Guinea; Novartis, Switzerland and USA; Otsuka Pharmaceutical Co., Ltd., Japan; Pace University, USA; Patheon, UK; Pfizer Inc., USA; Pharmadyn Inc., USA; PhinC, France; Quotient Sciences, UK; RCTs, France; Roche, Switzerland; Sanofi, France; SGS, Belgium; SGS, France; Swiss Tropical and Public Health Institute, Switzerland; Tehran University, Iran; Theradis Pharma, France; TI Pharma, Netherlands; Trade Factors Overseas Ltd., UK; Uganda National Health Research Organisation, Uganda; Venn Life Sciences, Ireland; WHO-NTD (Neglected Tropical Diseases department).



### Leishmaniasis

AbbVie, USA; Accelera, Italy; Academic Medical Center, the Netherlands; Addis Ababa University, Ethiopia; Advinus Therapeutics Ltd., India; Amatsi Aquitaine (formerly Bertin Pharma), France; AMC Medical Research BV, the Netherlands; Amudat Hospital, Uganda; Anacor Pharmaceuticals (now Pfizer Inc.), USA; Analysis Ltd. RAK, Aptuit, Italy; United Arab Emirates; Arba Minch Hospital, Ethiopia; Astellas Pharma Inc., Japan; AstraZeneca, Sweden and UK; Auckland University, New Zealand; Banook Group, France; BaseCon, Denmark; Basilea Pharmaceutica AG, Switzerland; Bayer, Germany; Bioascent, UK; Bioaster, France; Bio Zeq Kenya Ltd., Kenya; BioDelivery Sciences International Inc., USA; BIOTEC, Thailand; Brasilia University, Brazil; Bristol-Myers Squibb, USA; Broad Institute of MIT and Harvard, USA; Celgene Corporation (now Bristol-Myers Squibb), USA; Centre for Drug Candidate Optimisation, Monash University, Australia; Centro de Inovação e Ensaios Pré-Clinicos (CIENP), Brazil; Centro Nacional de Pesquisa em Energia e Materiais (CNPEM), LN Bio, Brazil; Charles River Laboratories (Wil Research), France and the Netherlands; Cornell University, USA; Crystallise!, Switzerland; Daiichi Sankyo Company, Limited, Japan; Daiichi Sankyo RD Novare Co., Ltd., Japan; Dermalaser, Bolivia; Dow AgroSciences LLC, USA; Drug Discovery Unit, University of Dundee, UK; El du Pont de Nemours, USA; Eisai Co., Ltd., Japan; Epichem, Australia; Eurofins Cerep, France; Eurofins Panlabs Thailand, Thailand; Eurofins Panlabs, USA; Eurofins-Optimed, France; Evolva SA, Switzerland; Foundation for Innovative New Diagnostics, Switzerland; Fundação de Amparo a Pesquisa do Estado de São Paulo, Brazil; GeneDesign Inc., Japan; Genomics Institute of The Novartis Research Foundation, USA; Genzyme, USA; Gilead Sciences, USA; GlaxoSmithKline, Spain and UK; Gondar University Hospital, Ethiopia; Griffith Institute for Drug Discovery, Griffith University, Australia; Hospital São José de Doenças Infecciosas, Brazil; Humax Pharmaceutical, Colombia; Hypha Discovery Ltd., UK; IktoS, France; Indian Institute of Technology, Gandhinagar, India; Institut Pasteur Korea, South Korea; Institute of Endemic Disease, Khartoum University, Sudan; Institute of Medical Sciences, Banaras Hindu University, India; Institute of Microbial Chemistry, Japan; Institute of Tropical Medicine Antwerp, Belgium; Instituto de Ciências Biomédicas, Universidade de São Paulo,

Brazil; Instituto de Física, Universidade de São Paulo, Brazil; Instituto de Medicina Tropical Alexander von Humboldt, Universidad Peruana Cayetano Heredia, Peru; Instituto de Química, Universidade Estadual de Campinas, Brazil; Instituto de Salud Carlos III, Spain; International Centre for Diarrhoeal Disease Research, Bangladesh; Johnson & Johnson, USA; Intertek, UK; Kacheliba District Hospital, Kenya; Kala-Azar Medical Research Centre, India; Kenya Medical Research Institute, Kenya; Kimalel Hospital, Kenya; Kitasato Institute for Life Sciences, Japan; Laboratory of Microbiology Parasitology and Hygiene, University of Antwerp, Belgium; Lambda Therapeutic Research Ltd., India; LEAP Platform; London School of Hygiene & Tropical Medicine, UK; Makerere University, Uganda; Médecins Sans Frontières, Spain; Médecins Sans Frontières, the Netherlands; Medicines for Malaria Venture, Switzerland; Merck KGaA, Germany; Merck, USA; Ministry of Health, Neglected Tropical Disease Directorate, Ethiopia; Ministry of Health, Neglected Tropical Diseases Unit, Leishmaniasis Programme, Kenya; Ministry of Health, Neglected Tropical Diseases Unit, Leishmaniasis Programme, Sudan; Ministry of Health, Leishmaniasis Control Programme, Uganda; Mahidol Oxford Tropical Medicine Research Unit, Thailand; Mitsubishi Tanabe Pharma Corporation, Japan; Montes Claros State University, Brazil; Mott McDonald Ltd., UK; Nagasaki University, Japan; National Institute of Pathology, India; National Institutes of Health, USA; Netherlands Cancer Institute, the Netherlands; NKI Stichting Het Nederland Kanker Instituut, the Netherlands; Northeastern University, USA; Northwick Park Institute for Medical Research, UK; Novartis, Switzerland and USA; Novartis Institutes for BioMedical Research, USA; Ohio State University, USA; Osaka University, Japan; Oswaldo Cruz Foundation (Fiocruz), Brazil; Otsuka Pharmaceutical Co., Ltd., Japan; Paediatric Hospital João Paulo II – FHEMIG, Brazil; Pasteur Institute of Iran, Iran; Pentlands Management Systems Ltd., UK; Pkpdesign Sas, France; Pfizer Inc., USA; Pharmadyn Inc., USA; Phi Pharma SA, Switzerland; Piauí Federal University, Brazil; Pierre Fabre Laboratories, France; PolyTherics Ltd., UK; Programa de Estudio y Control de Enfermedades Tropicales, Universidad de Antioquia, Colombia; Programa Nacional de Leishmaniasis, Colombia; Quotient Sciences, UK; Rajendra Memorial Research Institute of Medical Sciences, India; René Rachou Research Center–Fiocruz-MG, Brazil; Research Foundation of the Netherlands Cancer Institute, the Netherlands; Sandexis, UK; Sanofi Meril, USA; Sanofi, France; Sanofi-Aventis, France; Sara Pharm, Romania; Scynexis, USA; Sequella Inc., USA; Sergipe Federal University, Brazil; SGS, Belgium; Shionogi & Co., Ltd., Japan; Shobhaben Pratapbhai Patel School of Pharmacy & Technology Management, India; SK Hospital, Mymensingh, Bangladesh; State Health Society, Bihar, India; Swiss Tropical and Public Health Institute, Switzerland; Syngene, India; Takeda Pharmaceutical Company Limited, Japan; TB Alliance, USA; TCG Lifesciences, India; Thermosurgery Technologies Inc., USA; TI Pharma, the Netherlands; UBC, Switzerland; Universidade Estadual do Rio de Janeiro, Brazil; University of Cape Town, South Africa; University of Gedaref, Sudan; University of Glasgow, UK; University of Gondar, Ethiopia; University of Oxford, UK; Uppsala University, Sweden; US Food and Drug Administration, USA; Walter Reed Army Institute of Research, USA; WHO-NTD (Neglected Tropical Diseases department); WHO-TDR (Special Programme for Research and Training in Tropical Diseases); WuXi AppTech, China; Zoetis (formerly Pfizer Animal Health), USA.



### Chagas disease

AbbVie, USA; Anacor Pharmaceuticals (now Pfizer Inc.), USA; Astellas Pharma Inc., Japan; AstraZeneca, Sweden and UK; Barcelona Centre for International Health Research, Spain; Barcelona Institute for Global Health (ISGlobal), Spain; Basilea Pharmaceutica AG, Switzerland; Bayer, Germany; Bioascent, UK; BioDelivery Sciences International Inc., USA; Bioaster, France; Brazilian Biosciences National Laboratory, Brazil; Bristol-Myers Squibb, USA; Broad Institute of MIT and Harvard, USA; CEADES, Bolivia; Celgene Corporation (now Bristol-Myers Squibb), USA; Centre for Drug Candidate Optimisation, Monash University, Australia; Center of Excellence for Chagas Disease, USA; Centro de Chagas y Patología Regional, Hospital Independencia, Argentina; Centro de Inovação e Ensaios Pré-Clinicos (CIENP), Brazil; Centro National

\*Partners listed here include partners involved since the start of the project

de Pesquisa em Energia e Materiais, LN Bio, Brazil; Chembridge Corporation, USA; Chiron Corporation, USA (now Novartis); Collective of Applied Studies and Social Development, Bolivia; Daiichi Sankyo Company, Limited, Japan; Cornell University, USA; Daiichi Sankyo RD Novare Co., Ltd., Japan; Dow AgroSciences LLC, USA; Drug Discovery Unit, University of Dundee, UK; El du Pont de Nemours, USA; Eisai Co., Ltd., Japan; Exeltis, USA; Epichem, Australia; Eurofins, France; Evanston Northwestern Healthcare, USA; FP Clinical Pharma – Ethel Feleder, Argentina; Fundação de Amparo a Pesquisa do Estado de São Paulo, Brazil; Fundación Cardioinfantil, Instituto de Cardiología, Colombia; Fundacio Investigacio Hospital General Valencia, Spain; Fundación Instituto de Investigaciones Biotecnológicas, Argentina; Hospital Universitario La Paz, Spain; GlaxoSmithKline, Spain and UK; Griffith Institute for Drug Discovery (GRIDD), Griffith University, Australia; Hospital Clínic de Barcelona, Spain; Hospital de Niños Ricardo Gutiérrez, Argentina; Hospital General de l'Hospitalet Consorci Sanitari Integral, Spain; Indian Institute of Technology, Gandhinagar, India; University of Oxford, UK; InfYnity Biomarkers, France; Instituto de Física, Universidade de São Paulo, Brazil; Institut d'Investigacio Biomedica de Bellvitge, Spain; Institute of Microbial Chemistry, Japan; Instituto Nacional de Parasitologia Dr Fatale Châben, Argentina; Institut Pasteur Korea, South Korea; Instituto de Efectividad Clínica Y Sanitaria (IECS), Argentina; Instituto de Química, Universidade Estadual de Campinas, Brazil; Insud Pharma, Argentina; International Development Research Centre, Canada; Janssen Research & Development LLC, USA; Johnson & Johnson, USA; Kitasato Institute for Life Sciences, Japan; International Development Research Center, Uruguay; Laboratório Elea Phoenix, Argentina; Laboratório Farmacêutico do Estado de Pernambuco, Brazil; Laboratory of Microbiology, Parasitology and Hygiene, University of Antwerp, Belgium; LAT Research, Argentina; London School of Hygiene & Tropical Medicine, UK; Luxembourg Institute of Health, Luxembourg; McGill University, Canada; Médecins Sans Frontières; Medicines for Malaria Venture, Switzerland; Merck KGaA, Germany; Merck, USA; Ministry of Health, Colombia; Mitsubishi Tanabe Pharma Corporation, Japan; Mundo Sano Foundation, Argentina; Murdoch University, Australia; National Council of Scientific and Technological Research (INGEBI-CONICET), Argentina; NHEPACHA network; Northeastern University, USA; Northwick Park Institute for Medical Research, UK; Novartis, Switzerland and USA; Nucleus of Pharmaceutical and Cosmetics Development, Brazil; Pfizer Inc., USA; PhinC, France; Pierre Fabre Laboratories, France; Platform of Integral Care for Patients with Chagas Disease, Spain/Bolivia; Sandexis, UK; Sanofi Meria, USA; Sanofi, France; Sequella Inc., USA; Shionogi & Co., Ltd., Japan; Shobhaben Pratapbhai Patel School of Pharmacy & Technology Management, India; Swiss Tropical and Public Health Institute, Switzerland; Syneos Health, LLC, USA; Takeda Pharmaceutical Company Limited, Japan; TB Alliance, USA; TCG Life Sciences, India; Texas Biomedical Research, USA; Unidad de Enfermedades Infecciosas, Sección de Salud Internacional y Consejo al Viajero, Spain; Universidad Autónoma Juan Misael Saracho, Bolivia; Universidad Mayor de San Simón, Bolivia; Universidad San Martín, Argentina; Universidade de São Paulo, Brazil; University Hospitals of Geneva, Switzerland; University of Cape Town, South Africa; University of Georgia Research Foundation, USA; University of Texas at El Paso, USA; Uppsala University, Sweden; Vall d'Hebron University Hospital, Spain; Venn Life Sciences, Ireland; Walter Reed Army Institute of Research, USA; Washington University in St Louis, USA; WHO-TDR (Special Programme for Research and Training in Tropical Diseases); WuXi AppTech, China; Zoetis (formerly Pfizer Animal Health), USA.

## Mycetoma

Eisai Co., Ltd., Japan; Erasmus Medical Center, the Netherlands; Free University Amsterdam, the Netherlands; Institute of Endemic Diseases, Khartoum University, Sudan; Mycetoma Research Centre, Soba University Hospital, Sudan; Radboud University Medical Center, the Netherlands.

## Filarial diseases

AbbVie, USA; A-WOL, UK; Analytical Services International, UK; Bayer, Germany; Bonn University Hospital, Institute of Medical Microbiology, Immunology and Parasitology, Germany; Celgene Corporation (now Bristol-Myers Squibb), USA; Commissariat à l'énergie atomique et aux énergies alternatives, France; Datamatrix AG, Switzerland; Erasmus Medical Center, the Netherlands; Hammersmith Medicines Research, UK; Imperial College, UK; Institut Bouissin Bertrand, France; Institut National de Recherche Biomédicale, DR Congo; Institut de Recherche pour le Développement, France; Liverpool School of Tropical Medicine, UK; Mahidol University, Thailand; Margan Clinical Research Organization, Ghana; MC Toxicology Consulting GmbH, Austria; Merck, USA; National Museum of Natural History, France; Niche Science and Technology, UK; Northwick Park Institute for Medical Research, UK; Programme national de lutte contre les Maladies Tropicales Négligées à Chimiothérapie Préventive, Côte d'Ivoire; Research Foundation for Tropical Diseases and the Environment, Cameroon; Salvensis, UK; University of North Carolina, USA; Swiss Tropical and Public Health Institute, Switzerland; The Task Force for Global Health, USA; University of Health and Allied Sciences, Ghana; University of Liverpool, UK; University of Oxford, UK; Washington University in St Louis, USA.

## HIV

AMPATH, Kenya; AbbVie, USA; Associated Medical Sciences/PHPT International Research Unit, Thailand; Baylor College of Medicine Children's Foundation, Uganda; Centre for Disease Control and Prevention/President's Emergency Plan for AIDS Relief, USA; Cipla Ltd., India; Clinton Health Access Initiative, USA; Department of Health, South Africa; Division of Clinical Pharmacology, Department of Medicine, University of Cape Town, South Africa; Elizabeth Glaser Pediatric AIDS Foundation, USA; Empilweni Services and Research Unit, Rahima Moosa Mother and Child Hospital, South Africa; Enhancing Care Foundation, South Africa; Epicentre, Uganda; Family AIDS Care and Education Services Project, Kenya; Gertrude's Children's Hospital, Kenya; i-Base, UK; ICAP, Columbia University, USA; Ifakara Health Institute, Tanzania; Institute of Tropical Medicine, Antwerp; International Community of Women Living with HIV, Kenya; Joint Clinical Research Centre, Uganda; Kenya Medical Research Institute, Kenya; Kenyatta National Hospital, Kenya; Management and Development for Health, Tanzania; Mbagathi District Hospital, Kenya; Médecins Sans Frontières; Medical Research Council, UK; Ministries of Health of Kenya, Tanzania, Uganda, and Zimbabwe; Moi Teaching and Referral Hospital, Kenya; Moi University, Kenya; Necker Institute, France; NEPHAK, Kenya; Nyumbani Lea Toto Project, Children of God Relief Institute, Kenya; Perinatal HIV Research Unit, University of Witwatersrand, South Africa; Shandukani Research Centre, Wits Reproductive Health and HIV Institute, South Africa; St Lumumba Health Centre, Kenya; Stellenbosch University and Tygerberg Children's Hospital, South Africa; Swiss Tropical and Public Health Institute, Switzerland; UNITE, The Global Parliamentarians Network to End Infectious Diseases; University of Nairobi, Kenya; various academic partners in South Africa, Kenya, Uganda, and Tanzania.

## Hepatitis C

Associated Medical Sciences/PHPT International Research Unit, Thailand; Clinical Research Centre, Malaysia; Clinical Research Malaysia, Malaysia; Crystal Pharmatech, USA; Doppel Farmaceutici, Italy; HIV-NAT AIDS Research Centre, Thailand; Info Kinetics Sdn Bhd, Malaysia; Institute of Medical Research, Malaysia; Insud Pharma/Elea, Argentina; Kinapse Ltd., UK; Maharaj Nakorn Chiang Mai University, Thailand; Médecins Sans Frontières, Ukraine; Ministry of Health, Malaysia; Ministry of Health, Thailand; Ministry of Industry, Science and Technology, Thailand; Mundo Sano Foundation, Argentina; Nakornping Hospital, Thailand; National Science and Technology Development Agency, Thailand; Pharco Pharmaceuticals Inc., Egypt; Pharmaniaga, Malaysia; Pharmetheus AB, Sweden; Presidio Pharmaceuticals, USA; Public Health Promotion Research and Training, Thailand; Toxipharm Laboratoire, France; University Hospitals of Geneva, Switzerland; Zhejiang Ausun Pharmaceutical Co., Ltd.



# CONTRIBUTIONS



## FUNDRAISING PROGRESS AGAINST 2023 TARGET

EUR 615.5 million\* raised,  
2003-2019

2023 target: EUR 730 million

■ funds raised

*\*The total amount raised by year end 2019 includes funds committed to GARDP (EUR 28.8 million)*

## EUR 57.5 million secured in 2019

Thanks to new and existing donors, in 2019 DNDi was able to secure EUR 57.5 million for its R&D projects, including more than EUR 37 million from private donors.

## Flatlining R&D funding for the most neglected diseases

Global investment in 'neglected disease R&D' amounted to USD 4 billion in 2018, the highest level ever recorded and the first time that funding has grown for three consecutive years, according to the G-FINDER, an annual survey of public, private, and philanthropic funding of basic research and product development. However, these funds were concentrated on HIV, malaria, and TB.

Annual funding for kinetoplastid diseases – some of the world's most neglected, including sleeping sickness, Chagas disease, and leishmaniasis – has actually decreased by nearly 10% over the past decade, dropping by USD 34 million in 2018 compared to 2009.

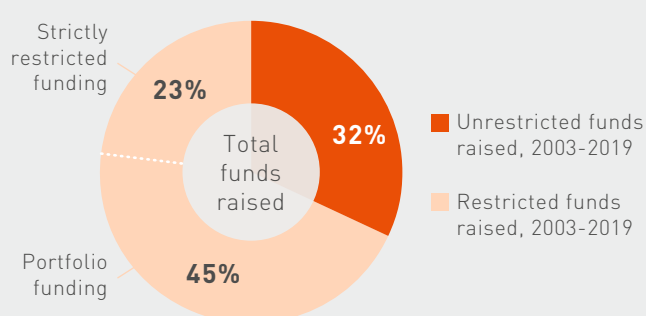
Flatlining funding for the most neglected NTDs means it is crucial that existing donors maintain their support and that new supporters emerge.

## A FINANCING POLICY UNDERPINNING INDEPENDENCE AND EFFECTIVENESS

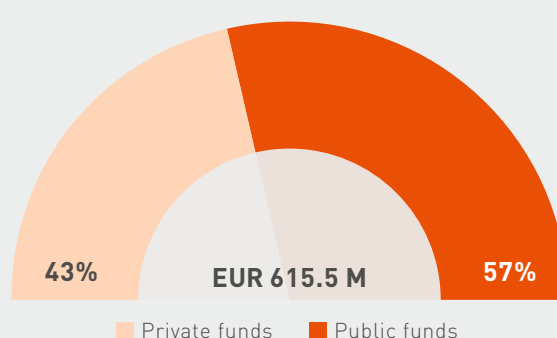
Safeguarding DNDi's scientific and financial independence has been a cornerstone of our development from the beginning. Diversified funding sources allow us to avoid reliance on any single donor. DNDi's fundraising policy is to ensure that no donor contributes more than 25% of all financial resources, and to seek funding from both public

and private sources. To allow for the greatest flexibility and agility in efficiently managing its R&D portfolio, DNDi prioritizes unrestricted funding, as opposed to strictly restricted funding (restricted to a specific R&D project) or portfolio funding (restricted to a specific disease).

### Prioritizing unrestricted funding for stability and flexibility



### Public vs private contributors 2003-2023



While DNDi continues to strive to maintain a balance between restricted and unrestricted funding, unfortunately, in 2019, the proportion of strictly restricted funding (23%) increased (in 2018: 19%), as donors favoured targeted

grants. In addition, several donors are conditioning their support to milestone payments, reducing DNDi's flexibility in managing its scientific portfolio.

## NEW COMMITMENTS

### We thank the following major donors for the new commitments made to DNDi in 2019:

The Bill & Melinda Gates Foundation renewed its support with a donation of USD 29 million to accelerate the development of innovative new drugs for the treatment of sleeping sickness and river blindness.

UK aid and the Swiss Agency for Development and Cooperation (SDC) provided supplemental funding of GBP 10 million and CHF 1.3 million, respectively, in 2019. This was used to implement critical activities that might otherwise have been delayed due to funding restrictions and helped reduce the time between drug development and patient access.

The French Development Agency (AFD) renewed its support through a EUR 8 million donation for development of new treatments for paediatric HIV and sleeping sickness.

DNDi joined the Helminth Elimination Platform (HELP), a new public-private partnership led by the Swiss Tropical and Public Health Institute (Swiss TPH). Funding from the European Union's Horizon 2020 research and innovation programme for HELP will contribute roughly EUR 2.3 million for DNDi research into filarial diseases.

The Canton of Geneva renewed its support to DNDi with CHF 600,000 for the development of a new clinical treatment for mycetoma in Sudan.

Takeda Global CSR Program contributed JPY 1 billion (approximately EUR 8 million) over five years to enable DNDi to help ensure access to quality diagnosis and treatment for people living with five NTDs.

Pharmaniga contributed approximately USD 2.2 million to support the registration of a new treatment combination for people living with hepatitis C virus in Malaysia.

DNDi, together with Fiocruz, secured a collaborative grant of BRL 1.6 million (approximately EUR 290,000) from the Ministry of Health of Brazil for cutaneous leishmaniasis.

The Colombian public joint venture Ruta-N renewed its collaborative support to DNDi for cutaneous leishmaniasis, lead optimization, and various access activities with USD 473,000.

DNDi secured CHF 243,000 from Innosuisse in collaboration with the University of Geneva for early discovery research for Chagas disease.

# A WORD OF THANKS

DNDi has now delivered eight new treatments for neglected patients and aims to deliver another eight to ten, for a total of 16-18 new treatments by 2023. DNDi is deeply grateful for the support of all its donors, and for their commitment and collaboration since 2003. All contributions large and small helped advance DNDi's mission and goals. Listed below are supporters who have given a cumulative contribution of at least USD/EUR 10,000 since 2003.

## PUBLIC INSTITUTIONAL SUPPORT

- Australian Trade and Investment Commission (Austrade), Australia
- Banco Nacional de Desenvolvimento Econômico e Social (BNDES), Brazil
- Department of Health and Social Care (DHSC), UK\*
- Dutch Ministry of Foreign Affairs (DGIS), the Netherlands
- Dutch Ministry of Health, Welfare and Sport (VWS), the Netherlands\*
- European and Developing Countries Clinical Trials Partnership Association (EDCTP1 and 2 Programmes) supported by the European Union
- European Union – Framework Programmes 5, 6, and 7 and Horizon 2020 research and innovation programme
- Federal Ministry of Education and Research (BMBF) through KfW, Germany
- Federal Ministry of Health, Germany\*
- Federal Office of Public Health (FOPH), Switzerland\*
- Foundation for Innovative New Diagnostics (FIND) (supported by Unitaid)
- French Development Agency (AFD), France
- French Ministry for Europe and Foreign Affairs (MEAE), France
- Fundação de Amparo à Pesquisa do Estado de São Paulo (FAPESP), Brazil
- Fundação Oswaldo Cruz (Fiocruz), Brazil
- Fundação para a Ciência e a Tecnologia (FCT), Portugal
- German Corporation for International Cooperation (GIZ) on behalf of the Government of the Federal Republic of Germany, Germany
- Global Health Innovative Technology Fund (GHIT Fund), Japan
- Grand Duchy of Luxembourg, Luxembourg\*
- Innosuisse, Swiss Innovation Agency, Switzerland
- International Development Research Centre (IDRC), Canada
- Ministry of Health, Brazil
- Ministry of Health, Malaysia
- National Institutes of Health (NIH), National Institute of Allergy and Infectious Diseases (NIAID), USA
- National Science and Technology Development Agency (NSTDA), Ministry of Science and Technology, Thailand
- Norwegian Agency for Development Cooperation (Norad), Norwegian Ministry of Foreign Affairs, as part of Norway's in-kind contribution to EDCTP2
- PANAFTOSA – Organização Pan-Americana da Saúde/ Organização Mundial da Saúde (OPAS/OMS)
- Region of Tuscany, Italy
- Republic and Canton of Geneva, International Solidarity Service, Switzerland
- Ruta-N, City of Medellin, Colombia
- Science and Technology Innovation Agency (Finep), Brazil, through the Regional and National Finep Awards for Innovation in Social Technology
- South African Medical Research Council (SAMRC), South Africa\*
- Spanish Agency for International Development Cooperation (AECID), Spain
- Swiss Agency for Development and Cooperation (SDC), Switzerland
- The Global Fund to Fight AIDS, Tuberculosis and Malaria
- UK aid, UK
- Unitaid
- US Agency for International Development (USAID), USA
- US Agency for International Development (USAID), via the 4th Sector Health Project implemented by Abt Associates, Inc., USA
- World Health Organization – Special Programme for Research and Training in Tropical Diseases (WHO-TDR)



## PRIVATE SUPPORT

- Anna-Maria and Stephen Kellen Foundation, USA
- Associação Bem-Te-Vi Diversidade, Brazil
- BBVA Foundation (through the 'Frontiers of Knowledge Award in Development Cooperation'), Spain
- Bennett Shapiro and Fredericka Foster, USA
- Bill & Melinda Gates Foundation, USA
- Broadway Cares/Equity Fights AIDS, USA
- Brian Mercer Charitable Trust, UK
- Carlos Slim Foundation through the Carlos Slim Health Award, Mexico
- Charina Endowment Fund, USA
- Clifford N. Burnstein & Sabra C. Turnbull, USA
- craigslist Charitable Fund, USA
- David and Lisa U'Prichard, USA
- Family of Richard Rockefeller, USA
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- Fondation Pro Victimis, Switzerland
- George H. Stout, USA
- Goldman Sachs & Co., USA
- Guy's, King's, and St Thomas', Giving Week, UK
- Harlan and Sally Weisman, USA
- Jeff Nelson and Betsabe Aristud-Carrillo, USA
- Kristin Ecklund, USA
- Leo Model Foundation, USA\*
- Leopold Bachmann Foundation, Switzerland
- Dr Margaret Golden, USA
- Marsha Fanucci, USA
- Médecins Sans Frontières International and the MSF sections of Australia, Brazil, France, Italy, Japan, Norway, and the USA
- Médecins Sans Frontières International-Transformational Investment Capacity (MSF-TIC)
- Medicor Foundation, Liechtenstein
- Meena and Liaquat Ahamed, USA
- P B and K Family Foundation, USA
- Peter Mensch, USA
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- Rockefeller Brothers Fund, USA
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- Sandoz Family Foundation, Switzerland
- Sasakawa Peace Foundation, Japan
- Starr International Foundation, Switzerland
- Stavros Niarchos Foundation, USA
- Steve Rabin and Jonathan Winslow, USA
- Takeda Pharmaceutical Company Limited, Japan
- The Broder Family Foundation, USA
- The Peter and Carmen Lucia Buck Foundation, USA
- The Robin O'Brien Fund, USA
- The Rockefeller Foundation (through the 'Next Century Innovators Award'), USA
- The Stainman Family Foundation, USA
- Tully Family Foundation, USA
- UBS Optimus Foundation, Switzerland
- Wellcome, UK
- Zegar Family Fund, USA
- Anonymous individuals and organizations

\*Donors who contributed to DNDi specifically for GARDP incubation





Drugs for Neglected Diseases *initiative*

## Best science for the most neglected

The Drugs for Neglected Diseases *initiative* (DNDi) is a collaborative, patient needs-driven, not-for-profit research and development (R&D) organization that develops safe, effective, and affordable treatments for the millions of people across the world affected by neglected diseases, notably human African trypanosomiasis (sleeping sickness), leishmaniasis, Chagas disease, filarial infections, mycetoma, HIV, and hepatitis C.

## We innovate to save lives

We develop urgently needed treatments for neglected patients and work to ensure they're affordable, available, and adapted to the communities who need them.

## We partner for impact

We conduct research where it's needed most, utilizing and strengthening R&D capacity in countries affected by neglected diseases.

## We advocate for change

We speak out for policy change to enable more effective and equitable R&D and access to the fruits of science for all people in need, no matter their income or where they live.

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