R&D PORTFOLIO

Patient Needs-Driven
Collaborative R&D Model
for Neglected Patients

DNDi
Drugs for Neglected Diseases *initiative*

DND*i*'s VISION

To improve the quality of life and the health of people suffering from neglected diseases by using an alternative model to develop drugs for these diseases, and by ensuring equitable access to new and field-relevant health tools.

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.

Over 160
R&D partners worldwide

DND*i*'s MISSION

- To develop new drugs or new formulations of existing drugs for **people living with neglected diseases**. Acting in the public interest, DND*i* 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.
- DND*i*'s **primary focus** has been the development of drugs for the **most neglected diseases**, such as human African trypanosomiasis (HAT, or sleeping sickness), leishmaniasis, and Chagas disease, while considering engagement in **R&D projects for other neglected patients** (e.g. malaria, paediatric HIV, filarial infections) and development of diagnostics and/or vaccines to address unmet needs that others are unable or unwilling to address.
- In pursuing these goals, DND*i* enables R&D networks built on global collaborations. While harnessing existing support capacities in countries where the diseases are endemic, DND*i* 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.
- In order to address evolving needs of public health importance and maintain DND*i*'s commitment to delivering on the objectives of the current portfolio of diseases, **a dynamic portfolio approach** has been adopted. This enables DND*i* to take on new disease areas with various operating models, while completing objectives in current diseases.

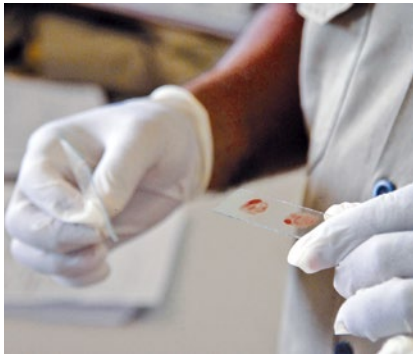
7
new treatments delivered

3
clinical research platforms established

DND*i*
Drugs for Neglected Diseases *initiative*

A DYNAMIC PORTFOLIO APPROACH

Diversified operational models to respond to evolving needs



Created in 2003, DND*i* has always focused on developing adapted treatments for the most in need, endeavouring to fill R&D gaps whilst doing so. In 2015, DND*i* released its Business Plan for the 2015-2023 period. The plan comprises a dynamic portfolio approach, adopted in order to address the evolving needs of public health importance and maintain DND*i*'s commitment to meeting the objectives within the current portfolio of diseases (human African trypanosomiasis (HAT), leishmaniasis, Chagas disease, paediatric HIV, and filariasis), as well as to answer specific needs for new disease or research areas: mycetoma, hepatitis C, and antimicrobial resistance (AMR).

Because not every disease will require the same amount of R&D investment, a range of operating models – full portfolio, mini portfolio, and support model – has been defined to tailor DND*i*'s involvement as appropriate and allow for responding to global health needs as they arise.

The Global Antibiotic Research and Development (GARD) Partnership

A joint initiative by WHO and DND*i*, GARD's vision is to work in cooperation with the public and private sectors, to develop new antibiotic treatments addressing antimicrobial resistance and to promote their responsible use for optimal conservation, while ensuring equitable access for all, with a focus on global health needs.

OPERATING MODELS

Full portfolio

For HAT, Chagas disease, filariasis, and leishmaniasis

Budget of
€100+ million
per portfolio

Mini portfolio

For paediatric HIV, mycetoma, and hepatitis C

Budget of
~€25 million
per mini portfolio

Support

- Knowledge sharing
- Advocacy push
- Advisory role
- Build resource platform
- Incubator (see 'GARD' example above)

Budget of
up to €1 million
per support project

DISEASES and TREATMENTS

Chagas disease*

- About 5.7 million people infected, mostly across 21 Latin American countries, but also Europe, North America, Japan, and Australia
- Less than 1% receive treatment
- *Trypanosoma cruzi* parasite transmitted through the bite of a triatomine vector known as the 'kissing bug', but also congenital transmission, blood transfusion, organ transplantation, or ingestion of contaminated food or beverage
- Approx. 7,000 deaths per year
- Chronic symptomatic disease develops in 10 to 30% of infected patients and most often causes cardiomyopathies and digestive tract pathologies

*American Trypanosomiasis

Current: Only two treatments exist and have specific drawbacks, including tolerability issues

Our work: An adapted paediatric dosage form of benznidazole (delivered 2011); clinical testing of new treatments and regimens

Our aim: Increase access to benznidazole, and develop a new, effective, and safer oral treatment for both the chronic and acute forms of the disease

Human African Trypanosomiasis*

- Number of estimated cases: currently approx. 3,800
- 21 million people at risk
- *Trypanosoma brucei* parasite transmitted through the bite of a tsetse fly
- Affects 36 countries in sub-Saharan Africa, but seven countries report 97% of all cases, with the Democratic Republic of Congo accounting for 87% of them in 2014
- Disease occurs in two stages: stage 1 is often not diagnosed, and the disease passes undetected; stage 2, the neurological stage, is usually deadly without treatment

*HAT; Sleeping sickness

Current: For stage 2, NECT has replaced the older, toxic melarsoprol and the complicated eflornithine monotherapy. For stage 1, two treatments, pentamidine and suramin, exist. All require multiple injections or infusions

Our work: NECT, a combination therapy of nifurtimox and eflornithine, developed and implemented with a large network of partners (delivered 2009) - the first new treatment for HAT in over 25 years; clinical testing of two entirely new drugs

Our aim: An oral, safe, effective, short-course treatment for both disease stages

Visceral Leishmaniasis*

- An estimated 200,000 – 400,000 cases occur per year
- Fatal without treatment (approx. 48,000 deaths in 2012)
- *Leishmania* parasite transmitted through the bite of a sandfly
- Present in over 80 countries across Asia, East Africa, South America, and the Mediterranean region
- Children mostly at risk
- VL in HIV co-infected patients is an increasing concern (35 countries)

*VL; Kala Azar

Current: Several treatments exist, but most have undesirable side effects, are long and complicated to administer in field conditions, or face problems of drug resistance

Our work: For Africa, SSG&PM, a combination therapy of sodium stibogluconate and paromomycin (delivered 2010); for Asia, a set of treatments modalities (2011): both developed and implemented with a large group of partners; early drug discovery and clinical testing of several treatment options

Our aim: An oral, safe, effective, low-cost, and short-course (≤11 days) treatment for VL, ideally for PKDL (Post Kala Azar Dermal Leishmaniasis) as well; a new regimen for VL-HIV co-infected patients

Cutaneous Leishmaniasis*

- An estimated 700,000-1,300,000 cases per year
- Characterized by disfiguring skin lesions; generally not life-threatening but causes disability and leaves permanent scars that can lead to social prejudice
- *Leishmania* parasite transmitted through the bite of a sandfly
- Wider geographic range than VL (on 5 continents); 90% of cases are found in Iran, Syria, Saudi Arabia, Afghanistan, Peru, and Brazil

*CL; *L. tropica* and *L. braziliensis* forms included in DND*i* projects

Current: Few treatments exist specifically for CL. Many are VL treatments used for CL, and their effectiveness or safety have often not been tested in CL patients

Our work: DND*i* and partners are developing a topical (applied to skin) treatment

Our aim: A new topical or oral, safe, effective, and shorter-course treatment for CL

Filarial diseases*

- DND*i*'s focus is on improving treatments for patients with onchocerciasis (river bindness) and lymphatic filariasis (LF, elephantiasis), and those co-infected with Loiasis (*Loa loa* filariasis)
- Over 37 million people infected by onchocerciasis; 169 million at risk
- Over 120 million people infected by LF; 1.4 million people at risk
- About 13 million people infected by *Loa loa* filariasis; 30 million people at risk
- Cause life-long disabilities such as blindness, severe itching and dermatitis (onchocerciasis), and swollen limbs and genitals (LF); have a terrible social and economic impact
- Co-infection of onchocerciasis or LF with *Loa loa* cannot be easily treated with current drugs due to risk of major adverse effects, such as encephalopathy

*Helminth parasitic worm infections

Current: Current treatments are ivermectin, albendazole, and diethylcarbamazine used in mass drug administrations (MDAs), which require repeated annual or biannual treatment for up to 15 years since they only target the juvenile worm (microfilariae)

Our work: DND*i* is developing a macrofilaricide drug (kills adult worms)

Our aim: A new, oral, safe, short-course macrofilaricidal drug for adults and children used in individual patient treatment and to help the elimination effort in MDA programmes, and ideally also in patients with *Loa loa* co-infection

Paediatric HIV

- 2.6 million children (<15 years) living with HIV and 220,000 new infections in children in 2014
- 410 deaths in children every day, mostly in Africa
- 150,000 AIDS-related deaths among children in 2014
- Only 31% of HIV-positive children received antiretroviral therapy (ART) in 2014
- Without treatment, half the children infected during pregnancy, delivery, or breast-feeding die before their second birthday
- Opportunistic infections such as tuberculosis are common

Current: The most effective treatment for babies and young children with HIV currently available is unpalatable (42% alcohol), difficult to administer, and has undesirable interactions with drugs for tuberculosis, the most common co-infection with HIV, in addition to being heavy to transport and requiring refrigeration

Our work: DND*i* and partners are currently developing two child-friendly 4-in-1 antiretroviral formulations, and a booster treatment to add when treating children with HIV and tuberculosis

Our aim: Increase access to recently available solid and existing dispersible formulations, and develop and deliver safe, effective, all-in-one first-line ARTs for young children (≤3 years) with HIV, including HIV/TB co-infected children

Mycetoma

- As a highly neglected disease, no surveillance system exists, so epidemiological data is lacking
- Two forms of mycetoma: bacterial (actinomycetoma), mainly in Central and South America, with a 90% cure rate and fungal (eumycetoma), mainly in Africa, with a 35% cure rate
- Progresses silently (causing little pain) into a chronic infection of the skin tissues which can result in amputation, even after treatment, and is sometimes fatal
- Children and young adults particularly at risk
- Disfigurement and disability cause stigma and social discrimination

Current: Neither safe, effective, nor affordable, with serious side effects, the two existing antifungal treatments for eumycetoma have a duration of 12 months, very often also requiring destructive surgery

Our work: DND*i* and partners are testing an oral anti-fungal drug, currently the only potential new treatment for eumycetoma

Our aim: A more effective, safe, affordable, shorter-term treatment for eumycetoma appropriate for rural settings

Hepatitis C*

- 150 million people suffering from hepatitis C virus (HCV), with six million co-infected with HIV
- 85% of patients living in low- and middle-income countries
- Transmitted through exchange of fluids (mostly contaminated blood)
- 80% of patients develop chronic infection and within the first two decades of infection, 5-20% progress to cirrhosis and 5% to liver cancer

*HCV

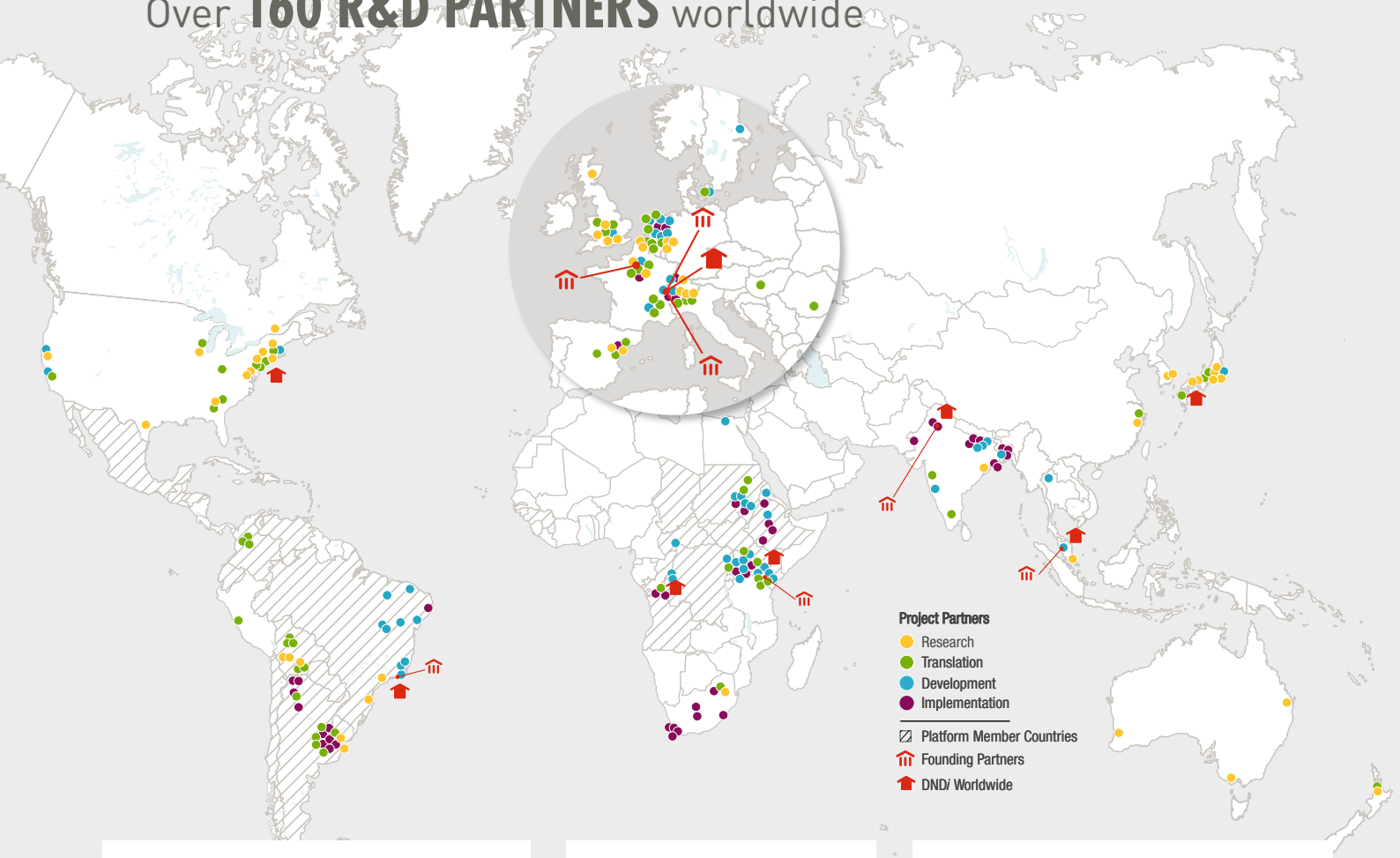
Current: Since 2013, Direct Acting Antivirals (DAAs) have revolutionized the therapeutic landscape. However, their price is exorbitant, making them inaccessible to the vast majority of HCV patients, and prohibiting a public health approach to HCV

Our work: DND*i* is working to develop an alternative DAA regimen to use as a public health tool

Our aim: Continue to support affordable access and develop a novel regimen as a public health tool that is simple, safe, and easy-to-implement

Scientific Network

Over 160 R&D PARTNERS worldwide



Founding Partners

- Médecins Sans Frontières (MSF) (Doctors Without Borders)
- Oswaldo Cruz Foundation, Brazil
- Indian Council for Medical Research, India
- Kenya Medical Research Institute, Kenya
- Ministry of Health, Malaysia
- Institut Pasteur, France
- The Special Programme for Research and Training in Tropical Diseases (WHO-TDR)

DND*i* Worldwide

- DND*i* Headquarters (Geneva)
- DND*i* Latin America (Rio de Janeiro)
- DND*i* North America (New York)
- DND*i* Africa (Nairobi)
- DND*i* India (Delhi)
- DND*i* South East Asia (Kuala Lumpur)
- DND*i* Japan (Tokyo)
- DND*i* in DRC (Kinshasa)

Clinical Research Platforms

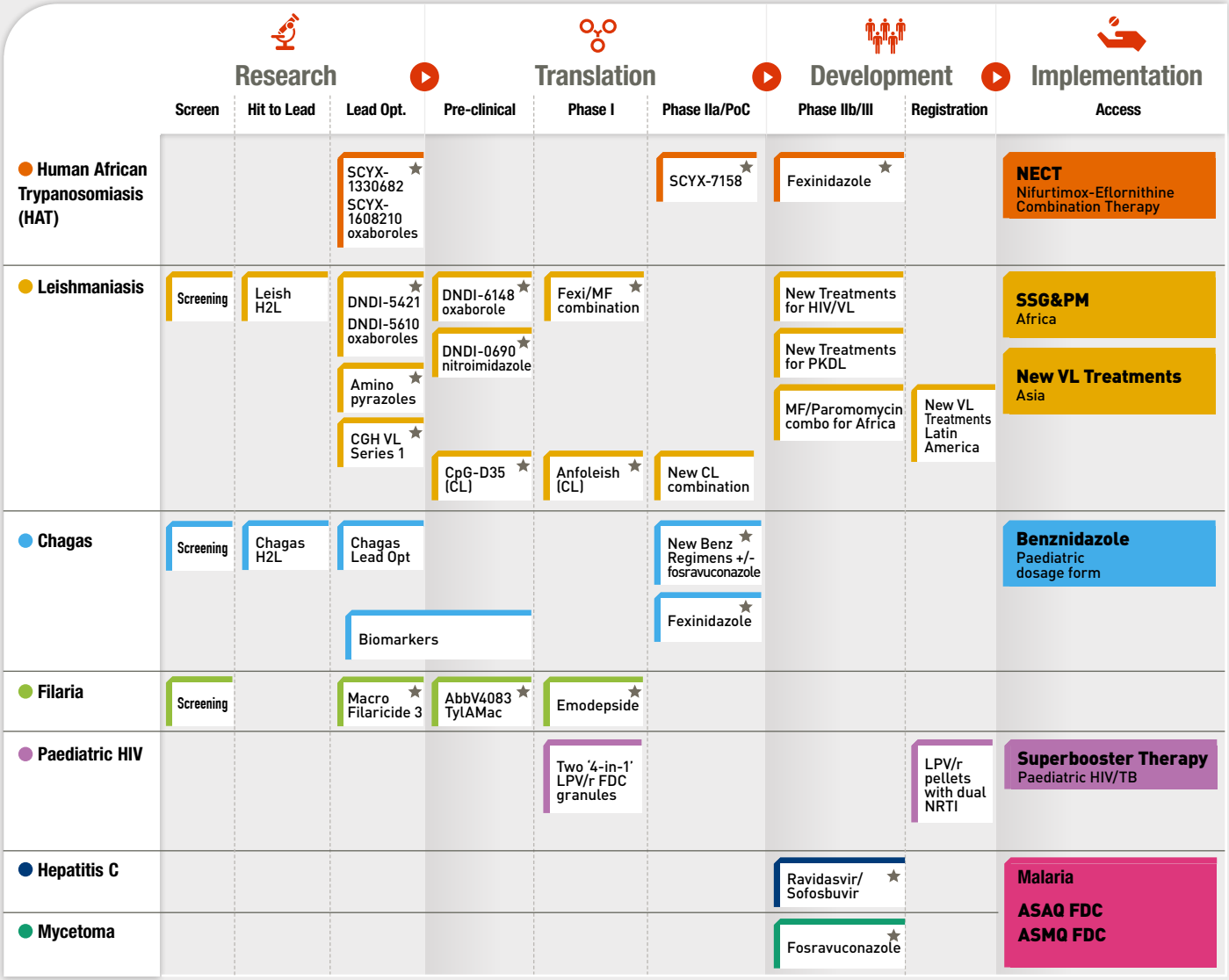
LEAP LEISHMANIASIS EAST AFRICA PLATFORM

LEISHMANIASIS EAST AFRICA PLATFORM (LEAP)

CHAGAS CLINICAL RESEARCH PLATFORM (CCRP)

HUMAN AFRICAN TRYPANOSOMIASIS (HAT) PLATFORM

OVER 30 R&D PROJECTS
and 15 NEW CHEMICAL ENTITIES in the pipeline



★ New Chemical Entity (NCE); Fexinidazole (for HAT, VL, and Chagas) = 1 NCE; Fosravuconazole (for Chagas and mycetoma) = 1 NCE
This portfolio was approved by the Board of DND*i* in June 2016.

RESEARCH

Through compound screening, lead selection, and lead optimization, the objective of DND*i*'s research programme is to identify new drug candidates that meet the criteria described in each disease's target product profile for entry into the pre-clinical development process.

SCREENING

Overall objective: Identification of new active compounds via medium to high throughput screening assays in dedicated centres:

High throughput screening (large-size libraries)

- **for leishmaniasis (*Leishmania*) and Chagas disease (*Trypanosoma cruzi*)**
  The Institut Pasteur Korea, South Korea, and the Drug Discovery Unit, University of Dundee, UK

Medium throughput screening

- **for kinetoplastids (leishmaniasis, Chagas disease, and HAT (*Trypanosoma brucei*)**
  The Swiss Tropical and Public Health Institute, Switzerland; the Laboratory of Microbiology, Parasitology, and Hygiene, University of Antwerp, Belgium; and the Walter Reed Army Institute of Research, USA
- **for filarial diseases**
  The Hospital of Bonn, Institute for Medical Microbiology, Immunology & Parasitology, Germany; the Muséum National d'Histoire Naturelle Paris, France; and the Northwick Park Institute for Medical Research, UK

Screening for kinetoplastids (leishmaniasis, Chagas disease, HAT)

Objective: Establish a robust portfolio of drug discovery quality hits for the three kinetoplastid diseases, with a focus on VL and Chagas disease.

Main compound libraries:
AbbVie, USA; Anacor Pharmaceuticals Inc., USA; Astellas Pharma, Japan; AstraZeneca, UK; Celgene, USA; Daiichi Sankyo, Japan; Eisai Co. Ltd, Japan; GlaxoSmithKline, Tres Cantos, Spain; Institut Pasteur Korea, South Korea; London School of Hygiene and Tropical Medicine (LSHTM), UK; Medicines for Malaria Venture (MMV), Switzerland; Merck, USA; Microbial Chemistry Research Foundation, Japan; Pfizer Ltd, UK; University of Dundee, UK; Sanofi, France; Takeda Pharmaceutical Company Ltd, Japan; TB Alliance, USA

Screening of repurposing libraries for filarial diseases

Objective: Identify new drug candidates using targeted compounds, primarily from repurposing libraries from human and animal health companies.

Main compound libraries:
AbbVie, USA; AstraZeneca, UK; BASF, Germany; Bristol-Myers Squibb, USA; Celgene, USA; GlaxoSmithKline, Tres Cantos, Spain; E.I. DuPont Nemours, USA; Epichem, Australia; Janssen, Belgium; Mercachem, The Netherlands; Merck, USA; Merck Serono, Germany; Medicines for Malaria Venture, Switzerland; National Institutes of Health, USA; Novartis Centre de la Recherche Santé Animale, Switzerland; Sanofi, France; TB Alliance, USA; WuXi AppTech, China

NTD Drug Discovery Booster

LEISHMANIASIS
CHAGAS DISEASE

In parallel to its ongoing bilateral collaborations for screening and lead optimization, in 2015 DND*i* launched the NTD Drug Discovery Booster with several major pharmaceutical companies.

Objective: Identify promising new compounds for treatment of leishmaniasis and Chagas disease by using a multilateral, simultaneous search process across several global pharmaceutical companies. The booster allows DND*i* to access millions of unique compounds, generated over many decades of research, to screen for potential treatments or cures for these diseases.

Main partners: AstraZeneca, UK; Celgene, USA; Eisai, Japan; Shionogi, Japan; Takeda Pharmaceutical Company Ltd, Japan

LEAD OPTIMIZATION

Overall objective: Establish a robust portfolio of optimized leads/pre-clinical candidates for the three kinetoplastid diseases.

Main partners: AbbVie, USA; Anacor Pharmaceuticals Inc., USA; AstraZeneca, UK; Brazilian Biosciences National Laboratory, Brazil; Celgene, USA; Centre for Drug Candidate Optimization, Monash University, Australia; Epichem, Australia; Eskitis Institute for Cell and Molecular Therapies, Griffith University, Australia; Fundaçao de Apoio Universidade Federale de Sao Paolo, USP São Carlos, Brazil; GlaxoSmithKline, Tres Cantos, Spain; iThemba LABS, South Africa; Laboratory of Microbiology, Parasitology and Hygiene, Antwerp University, Belgium; London School of Hygiene and Tropical Medicine, UK; Merck, USA; Novartis Institute for Tropical Diseases, Singapore; Pfizer Ltd, UK; Sanofi, France; SCYNEXIS Inc., USA; TB Alliance, USA; TCG Life Sciences, India; Sandexis, UK; Universidade Estadual de Campinas, Brazil; University of Auckland, New Zealand; WuXi AppTec, China

SCYX-1330682 SCYX-1608210

HAT

Objective: Maintain back-up oxaboroles which could replace the drug candidate SCYX-7158 in case it does not succeed in development.

Main partners: Anacor Pharmaceuticals Inc., USA; Pace University, USA; The Laboratory of Microbioloy, Parasitology, and Hygiene, University of Antwerp, Belgium; SCYNEXIS Inc., USA

Leish H2L

LEISHMANIASIS

Objective: Identify new leads series from current ongoing Hit-to-Lead activities taking advantage of the optimization consortia and screening platforms for VL.

Main partners: Epichem, Australia; Fundaçao de Apoio Universidade Federale de Sao Paolo, Brazil; Centre for Drug Candidate Optimization, Monash University, Australia; TCG Lifesciences, India; Sandexis, UK; WuXi AppTech, China; Laboratory of Microbiology, Parasitology and Hygiene, University of Antwerp, Belgium; London School of Hygiene and Tropical Medicine, UK; Griffith University, Australia; GlaxoSmithKline, Tres Cantos, Spain; Sanofi, France; Anacor Pharmaceuticals Inc., USA; Merck, USA; AstraZeneca, UK; AbbVie, USA

DNDI-5421 DNDI-5610

LEISHMANIASIS

Objective: Maintain back-up oxaboroles which could replace the pre-clinical candidate DNDI-6148 in case it does not succeed in development.

Main partners: Anacor Pharmaceuticals Inc., USA; Laboratory of Microbiology, Parasitology and Hygiene, University of Antwerp, Belgium; London School of Hygiene and Tropical Medicine, UK; WuXi AppTech, China; Sandexis, UK

Aminopyrazoles

LEISHMANIASIS

Objective: Select a pre-clinical candidate from the aminopyrazole series for the treatment of VL.

Main partners: Takeda Pharmaceutical Company Ltd, Japan; WuXi AppTech, China; Laboratory of Microbiology, Parasitology and Hygiene, University of Antwerp, Belgium; London School of Hygiene and Tropical Medicine, UK; Pfizer, UK; Sandexis, UK

CGH VL series 1

LEISHMANIASIS

Objective: Select a pre-clinical candidate from the CGH VL series 1 for the treatment of VL.

Main partners: Celgene Global Health, USA; Laboratory of Microbiology, Parasitology and Hygiene, University of Antwerp, Belgium; London School of Hygiene and Tropical Medicine, UK; WuXi AppTech, China; Sandexis, UK

Chagas H2L

CHAGAS DISEASE

Objective: Identify new leads series from current ongoing Hit-to-Lead activities taking advantage of the optimization consortia and screening platforms for Chagas disease.

Main partners: Centre for Drug Candidate Optimization, Monash University, Australia; Epichem, Australia; Fundaçao de Apoio Universidade Federale de Sao Paolo, Brazil; Griffith University, Australia; London School of Hygiene and Tropical Medicine, UK; WuXi AppTech, China; Brazilian Biosciences National Laboratory, Brazil; University of Campinas, Brazil; AbbVie, USA; Sanofi, France; Sandexis, UK; Laboratory of Microbiology, Parasitology and Hygiene, University of Antwerp, Belgium; TCG Life Sciences, India

Chagas Lead Optimization

CHAGAS DISEASE

Objective: Optimize leads issued from Hit-to-Lead series and identify pre-clinical candidates with the potential to fulfill the target product profile (TPP).

Main partners: Centre for Drug Candidate Optimization, Monash University, Australia; Epichem, Australia; Fundaçao de Apoio Universidade Federale de Sao Paolo (FapUnifesp), Brazil; Griffith University, Australia; London School of Hygiene and Tropical Medicine, UK; WuXi AppTech, China; LNBio/CNPEM, Brazil; University of Campinas, Brazil; AbbVie, USA; Sanofi, France; Sandexis, UK; Laboratory of Microbiology, Parasitology and Hygiene, University of Antwerp, Belgium; TCG Life Sciences, India

Biomarkers

CHAGAS DISEASE

Objective: Identify and evaluate new biological markers of therapeutic efficacy in chronic Chagas disease.

Main partners: Texas Biomedical Research, USA; University of Georgia Research Foundation, USA; McGill University, Canada; London School of Hygiene and Tropical Medicine, UK; CEA/Leti, France; Médecins Sans Frontières; Universidad Mayor de San Simon, Bolivia; Universidad Autónoma Juan Misael Saracho, Bolivia; Barcelona Centre for International Health Research, Spain; Dr Mario Fatala Chaben National Institute of Parasitology, Argentina; University of Texas at El Paso, USA; National Council of Scientific and Technological Research (INGEBI-CONICET), Argentina; University Hospitals of Geneva, Switzerland; NHEPACHA network; Universidad San Martin, Argentina

Macrofilaricide 3

FILARIAL DISEASES

Objective: Develop a third macrofilaricide candidate for filarial diseases

TRANSLATION

Once molecules have been identified in the research stage, the suitability of the molecule to become a drug has to be assessed by testing *in vitro* and *in vivo*. Optimized leads are further evaluated for their properties, safety, and efficacy in pre-clinical studies before progressing to Phase I clinical trials in healthy human volunteers and to Phase IIa/proof-of-concept studies in patients.

SCYX-7158 — HAT

Objective: Develop and register SCYX-7158 as a new drug for the treatment of stage 2 HAT caused by *T. b. gambiense*, ideally also for stage 1 HAT.

Main partners: Anacor Pharmaceuticals Inc., USA; Advinus Therapeutics Ltd, India; SCYNEXIS Inc., USA; Avista Pharma (formerly SCYNEXIS), USA; Swiss Tropical and Public Health Institute, Switzerland; Institute of Tropical Medicine Antwerp, Belgium; Institut de Recherche pour le Développement, France; Institut National de Recherche Biomédicale, DRC

DNDI-6148 — LEISHMANIASIS

Objective: Progress the pre-clinical development of DNDI-6148, a selected oxaborole for the treatment of VL.

Main partners: Anacor Pharmaceuticals Inc., USA; Syngene, India; WuXi AppTech, China; Wil Research/Charles River, France; Sara Pharm, Romania; Sandexis, UK; Laboratory of Microbiology, Parasitology and Hygiene, University of Antwerp, Belgium; London School of Hygiene and Tropical Medicine, UK

DNDI-0690 — LEISHMANIASIS

Objective: Progress the pre-clinical development of DNDi-0690, a selected nitroimidazole for the treatment of VL and possibly CL.

Main partners: London School of Hygiene and Tropical Medicine, UK; TB Alliance, USA; Auckland University, New Zealand; Laboratory of Microbiology, Parasitology and Hygiene, University of Antwerp, Belgium; WuXi AppTech, China; Aptuit, Italy; Accelera, Italy

Fexinidazole-Miltefosine combination — LEISHMANIASIS

Objective: Develop an oral-only therapy for the treatment of VL with a combination of fexinidazole and miltefosine.

Main partners: Institute of Endemic Disease, Khartoum University, Sudan; London School of Hygiene and Tropical Medicine, UK; Kenya Medical Research Institute, Kenya; Koninklijk Instituut voor de Tropen, The Netherlands; Kacheliba District Hospital, Kenya; The Netherlands Cancer Institute, The Netherlands; Makerere University, Uganda; Uppsala University, Sweden; Amudat Hospital, Uganda; Leishmaniasis East Africa Platform; Utrecht University, The Netherlands; BaseCon, Denmark; SGS, Belgium; PhinC, France; Centres d'Investigation Clinique des Centres Hospitaliers Universitaires de Clermont-Ferrand, Lille et Bichat-Claude Bernard, France; Cardiabase, France; Optimed, France; UBC, Switzerland; Sanofi-Chinoin, Hungary; Aptuit, Italy

CpG-D35 — LEISHMANIASIS

Objective: Produce an immunomodulator to stimulate the innate immune system to fight the parasitic infection as an adjunct to drug therapy.

Main partners: US Food and Drug Administration, USA; National Institutes of Health, USA; Ohio State University, USA; Nagasaki University, Japan; University of Osaka, Japan; GeneDesign Inc., Japan

Anfoleish — LEISHMANIASIS

Objective: Develop a topical anti-parasitic treatment containing amphotericin B for the treatment of CL.

Main partners: Humax Pharmaceutical, Colombia; Programa de Estudio y Control de Enfermedades Tropicales, Universidad de Antioquia, Medellin, Colombia

TRANSLATION

New CL combination therapies

LEISHMANIASIS

Objective: Further explore opportunities to better use the existing approved treatment approaches for CL when used in combination.

Main partners: Programa de Estudio y Control de Enfermedades Tropicales, Universidad de Antioquia, Medellin, Colombia; Universidad Peruana Cayetano Heredia, Lima, Peru

New benznidazole regimens +/- fosravuconazole

CHAGAS DISEASE

Objective: Evaluate new therapeutic regimens of benznidazole, in monotherapy and in combination with fosravuconazole, for the treatment of adult patients with chronic indeterminate Chagas disease.

Main partners: ARGENTINA: Fundación Mundo Sano and ELEA; Administración Nacional de Laboratorios e Institutos de Salud; Instituto Nacional de Epidemiología Dr Fatala Cháben; Instituto de Investigaciones en Ingeniería Genética y Biología Molecular "Dr. Héctor N. Torres" - INGEBI-CONICET; Centro de Chagas y Patologia Regional, Hospital Independencia, Santiago del Estero; Fundación Para el Estudio de las Infecciones Parasitarias y Enfermedad de Chagas; BOLIVIA: Collective of Applied Studies and Social Development; Universidad Autónoma Juan Misael Saracho; Universidad Mayor de San Simon; SPAIN: ISGlobal, Centre de Recerca en Salut Internacional de Barcelona; Hospital General de Valencia; SPAIN/BOLIVIA: Platform of Integral Care for Patients with Chagas Disease; JAPAN: Eisai Co. Ltd

Fexinidazole

CHAGAS DISEASE

Objective: Evaluate fexinidazole for treatment of chronic indeterminate Chagas disease.

Main partners: ARGENTINA: Instituto de Investigaciones en Ingeniería Genética y Biología Molecular "Dr. Héctor N. Torres" - INGEBI-CONICET; BOLIVIA: Collective of Applied Studies and Social Development; Platform of Integral Care for Patients with Chagas Disease, Tarija and Cochabamba; Universidad Autónoma Juan Misael Saracho; Universidad Mayor de San Simon; SPAIN: ISGlobal, Centre de Recerca en Salut Internacional de Barcelona

AbbV4083 (TylAMac)

FILARIAL DISEASES

Objective: Develop TylAMac as an anti-Wolbachia therapy and assess its macrofilaricidal efficacy.

Main partners: AbbVie, USA; AWOL, UK

Emodepside

FILARIAL DISEASES

Objective: Develop emodepside as a new macrofilaricidal treatment for patients suffering from onchocerciasis.

Main partners: Bayer HealthCare, Germany

Two '4-in-1' LPV/r FDC granules

PAEDIATRIC HIV

Objective: Develop and register two solid taste-masked first-line LPV/r-based fixed-dose formulations with two NRTIs, 3TC plus ABC or AZT.

Main partners: Cipla, India; Department of Health, South Africa; Medical Research Council, UK; UNITAID; Centre for Disease Control and Prevention (CDC)/President's Emergency Plan for AIDS Relief, USA; Médecins Sans Frontières; Necker Institute, France; various academic partners in South Africa and Kenya; AbbVie, USA; WuXi AppTech, China

DEVELOPMENT

Testing the balance between the safety and efficacy of a drug has to be conducted in large-scale, Phase III trials. This trial phase is necessary to obtain authorization from regulatory authorities and register the drug, in order for countries to produce, import, or distribute the drugs.

Fexinidazole

HAT

Objective: Develop and register fexinidazole as a new drug for the treatment of stage 2 HAT caused by *T. b. gambiense*, ideally also for stage 1 HAT and for children between 6 and 14 years old.

Main partners: Sanofi, France; Swiss Tropical and Public Health Institute, Switzerland; Institute of Tropical Medicine Antwerp, Belgium; Médecins Sans Frontières; Institut de Recherche pour le Développement, France; Institut National de Recherche Biomédicale, DRC; HAT Platform; National Control Programmes of the Democratic Republic of Congo and the Central African Republic

New treatments for HIV/VL co-infection

for Africa

LEISHMANIASIS

Objective: Identify and deliver a safe and highly effective treatment for VL in HIV co-infected patients that will improve long-term survival of these patients.

Main partners: Gondar University Hospital, Ethiopia; Addis Ababa University, Ethiopia; London School of Hygiene and Tropical Medicine, UK; Institute of Tropical Medicine Antwerp, Belgium; Médecins Sans Frontières, the Netherlands; Uppsala University, Sweden; Gilead Sciences, USA; LEAP; The Netherlands Cancer Institute, the Netherlands; Utrecht University, the Netherlands; BaseCon, Denmark; UBC, Switzerland

New treatments for PKDL

for Asia/Africa

LEISHMANIASIS

Objective: Determine the safety and efficacy of two treatment regimens for patients with PKDL, mainly in the Indian Sub-continent and East Africa.

Main partners: International Centre for Diarrhoeal Disease Research, Bangladesh; Rajendra Memorial Research Institute of Medical Sciences, India; Kala Azar Medical Research Centre, India; Institute of Medical Sciences, Banaras Hindu University, India; Uppsala University, Sweden; Institute of Endemic Disease, Khartoum University, Sudan; Ministry of Health, Sudan; LEAP

MF/Paromomycin combination therapy

for Africa

LEISHMANIASIS

Objective: Assess the safety and efficacy of two combination regimens of paromomycin and miltefosine for the treatment of primary VL patients in East Africa.

Main partners: Kenya Medical Research Institute, Kenya; Makerere University, Uganda; Utrecht University, the Netherlands

New VL treatments

for Latin America

LEISHMANIASIS

Objective: Assess the efficacy and safety of amphotericin B deoxycholate, AmBisome®, and AmBisome® combined with Glucantime®, as compared to the first-line treatment, Glucantime®, for the treatment of VL patients in Brazil, supporting the Brazilian Ministry of Health and its partners.

Main partners: BRAZIL: Rene Rachou Research Center–Fiocruz-MG, Belo Horizonte; Paediatric Hospital Joao Paulo II – FHEMIG, Belo Horizonte; Brasilia University; Montes Claros

DEVELOPMENT

State University; Piaui Federal University, Teresina; Sergipe Federal University, Aracaju; Leishmaniasis Control Programme/Ministry of Health; Universidade Estadual do Rio de Janeiro; Hospital Sao José de Doencas Infecciosas, Fortaleza

LPV/r pellets with dual NRTI

PAEDIATRIC HIV

Objective: Evaluate the effectiveness of LPV/r pellets in addition to AZT/3TC (or ABC/3TC) paediatric fixed-dose combination (FDCs) tablet in an implementation study in HIV-infected infants and young children who cannot swallow tablets.

Main partners: Joint Clinical Research Centre, Uganda; Baylor College of Medicine Children's Foundation, Uganda; Epicentre, Uganda; University of Nairobi, Kenya; Gertrude's Children's Hospital, Kenya; Kenya Medical Research Institute, Kenya; Associated Medical Sciences/PHPT International Research Unit, Thailand; Department of Health, South Africa; Cipla Ltd., India; UNITAID; St Lumumba Health Centre, Kisumu, Kenya; Mbagathi District Hospital, Kenya; Moi Teaching and Referral Hospital, Kenya; Ministry of Health, Kenya; Clinton Health Access Initiative, USA

Ravidasvir/ Sofosbuvir

HEPATITIS C

Objective: Conduct a Phase II/III clinical study assessing the efficacy of sofosbuvir + ravidasvir combination as an alternative regimen for the treatment of hepatitis C.

Main partners: Pharco Pharmaceuticals, Inc., Egypt; Presidio Pharmaceuticals, Inc., USA; Clinical Research Malaysia, Ministry of Health, Malaysia

Fosravuconazole

MYCETOMA

Objective: Conduct a randomized controlled clinical study to investigate the efficacy of fosravuconazole for patients with eumycetoma compared to the current treatment, itraconazole.

Main partners: Eisai Co. Ltd, Japan; Erasmus Medical Center, The Netherlands; Radboud University Medical Center, Nijmegen, The Netherlands; Mycetoma Research Centre, Soba University Hospital, Khartoum, Sudan; Institute of Endemic Diseases, Khartoum University, Sudan

DND*i*'s ACHIEVEMENTS

7 NEW TREATMENTS delivered, recommended, and implemented

MALARIA

Two new fixed-dose combinations (2007 and 2008)

With older antimalarials increasingly ineffective due to growing resistance, WHO recommended the use of artemisinin-based combination therapies in 2001. In 2006, WHO urged companies to stop marketing artemisinin monotherapies, and to re-direct their production efforts towards artemisinin-based fixed-dose combinations (FDCs), in order to keep the malaria parasite from becoming resistant to the new drugs.

ASAQ (Artesunate+Amodiaquine Fixed-Dose Combination)

Thanks to an innovative partnership between DND*i* and Sanofi, over 430 million ASAQ treatments have been distributed since 2007. The FDC reduces the pill burden for adults and children alike, and because it dissolves in water, it is easy to administer to infants and young children.

- Prequalified by WHO in 2008, registered in 32 African countries plus India, Ecuador, and Colombia, and included on the WHO Essential Medicines List for adults and children
- Available at low prices: US$1 for adults, $0.5 for children
- No patent: ASAQ was developed as a public good, so provided they met certain quality standards, a generic company interested in producing the drug can do so. Technology transfer to Tanzanian manufacturer Zenufa is ongoing

ASMQ (Artesunate+Mefloquine Fixed-Dose Combination)

Thanks to partnerships across four continents addressing formulation, production, clinical trials, and registration, a second safe and efficacious artemisinin-based FDC treatment was made available to treat patients in resource-poor settings. The project was a first-of-its-kind example of South-South technology transfer, as the manufacturing process was transferred from Brazilian public sector laboratory Farmanguinhos to Indian generic company Cipla.

- Cipla's product was prequalified by WHO in 2012, the Farmanguinhos one is under review
- Registered in 11 countries in Asia, Latin America, and Africa, and included on the WHO Essential Medicines List for adults and children
- Recommended first or second-line treatment in five countries in Latin America and four countries in South East Asia

Implementation activities for ASAQ and ASMQ were handed over to the Medicines for Malaria Venture (MMV) in 2015.

SLEEPING SICKNESS

Better, simpler treatment (2009)

Before 2009, the best available treatment for sleeping sickness, involving over 50 intravenous infusions and 14 days in hospital, was so complex to distribute and administer in resource-poor settings, that all-too-often clinicians chose melarsoprol, a highly toxic, arsenic-based drug that kills 5% of those treated with it.

In 2009, DND*i* clinical trials demonstrated the safety and effectiveness of a simpler and shorter nifurtimox and eflornithine combination therapy (NECT), with considerable benefits for patients, while reducing the logistical and staffing burden on treatment centres in remote locations.

- Partnership between DND*i*, MSF, national control programmes, Bayer, Sanofi, and WHO
- 100% of stage 2 HAT *gambiense* patients treated in all 13 endemic African countries
- NECT included on WHO Essential Medicines List for adults and children

Ongoing activities: DND*i* continues to support access to NECT in endemic countries.
Main partners: National Trypanosomiasis Control Programme, DRC; Epicentre, France; Médecins Sans Frontières, Switzerland; Swiss Tropical and Public Health Institute, Switzerland; Ministry of Health, DRC; HAT Platform

VISCERAL LEISHMANIASIS

Cheaper, more effective treatment in Africa (2010)

Following DND*i* clinical trials in East Africa which showed that sodium stibogluconate & paromomycin (SSG&PM) was as safe and effective as the existing standard treatment, WHO recommended the combination be used in the region. Treatment now lasts almost half as long and costs less. More patients can be treated during outbreaks, and the regimen has the potential to fend off resistance and prolong the life of both drugs.

- Partnership between DND*i*, the Leishmaniasis East Africa Platform (LEAP), national control programmes of Kenya, Sudan, Ethiopia, and Uganda, MSF, and WHO
- Recommended by the WHO Expert Committee on the Control of Leishmaniases for East Africa
- Helped shape the national guidelines in Sudan, South Sudan, Kenya, Ethiopia, and Somalia
- Paromomycin registered in Uganda, Kenya, and underway in other East African countries

Ongoing activities: DND*i* continues to support implementation of and access to SSG&PM in key endemic areas of East Africa by supporting registration of paromomycin and facilitating uptake.
Main partners: Ministries of Health of Uganda, Sudan, Kenya, and Ethiopia; Institute of Endemic Disease, Khartoum University, Sudan; Kenya Medical Research Institute, Kenya; Médecins Sans Frontières, Switzerland and Holland; London School of Hygiene and Tropical Medicine, UK; IDA Foundation, the Netherlands; Gondar University Hospital, Ethiopia; Addis Ababa University, Ethiopia; Arba Minch Hospital, Ethiopia; Makerere University, Uganda; Amudat Hospital, Uganda; LEAP

CHAGAS DISEASE

First paediatric drug (2011)

Despite recommendations to treat children with Chagas disease, benznidazole, the main drug of choice for treating Chagas, was only available in an adult tablet strength. Infants and kids were treated with fractioned or macerated tablets, which complicated administration and made dosing imprecise. DND*i*'s partnership with Brazilian public laboratory Lafepe enabled the development of the first age-adapted, easy-to-use paediatric dosage form of benznidazole for the treatment of children with Chagas disease.

- Age-adapted, easy-to-use, and affordable treatment, with an easily dispersible tablet for children under 2 years of age
- Registered in Brazil
- Included on WHO Essential Medicines List

Ongoing activities: DND*i* continues to support implementation and registration of paediatric benznidazole and aims to secure a second source with the Mundo Sano Foundation.

Main partners: BRAZIL: LAFEPE; ARGENTINA: Fundación Mundo Sano and ELEA; Centro Nacional de Diagnóstico e Investigación de Endemo-epidemias, Administración Nacional de Laboratorios e Institutos de Salud; Centro de Chagas y Patologia Regional, Hospital Independencia, Santiago del Estero; Hospital de Niños de Jujuy; Hospital de Niños Dr. Ricardo Gutiérrez; Hospital Público Materno Infantil – Salta; Instituto Nacional de Parasitología Dr M Fatala Chabén; Ministry of Health; Ministério de Salud, Província de Jujuy

VISCERAL LEISHMANIASIS

Adoption of new treatments in South Asia (2011)

Existing treatment options for VL in South Asia caused severe side effects and were growing ineffective due to resistance. Research was needed to assess the safety and efficacy of and patient compliance to various new treatment options. DND*i* convened a consortium of partners to identify the best combination therapies for South Asia. The results spurred the Indian, Bangladeshi, and Nepali Ministries of Health to select, adopt, and implement the best management strategies to support control and elimination of Kala Azar.

- Large four-arm implementation study with health authorities at national, state, and local levels
- Helped shape the recommendations of the WHO Expert Committee on the Control of Leishmaniases
- Helped shape the Indian National Roadmap for Kala Azar Elimination recommendations

Ongoing activities: DND*i* continues to conduct follow-up studies to accompany the implementation of new treatment options for VL in South Asia.

Main partners: INDIA: Indian Council of Medical Research; Rajendra Memorial Research Institute of Medical Sciences; Bihar State Health Society; National Vector Borne Disease Control Programme; Kala Azar Medical Research Centre; GVK Biosciences; BANGLADESH: Ministry of Health and Family Welfare; International Centre for Diarrhoeal Disease Research; Shaheed Suhrawardy Medical College and Hospital; OTHER: Médecins Sans Frontières, Spain; London School of Hygiene and Tropical Medicine, UK; WHO-TDR, Switzerland; Institute of Tropical Medicine-Antwerp, Belgium

PAEDIATRIC HIV

More effective HIV treatment for children that also have TB (2016)

Among the many challenges of treating children co-infected with both tuberculosis (TB) and HIV is the fact that a key TB drug negates the effectiveness of ritonavir, one of the main antiretrovirals to treat HIV. A DND*i*-sponsored study at five hospitals in South Africa demonstrated the safety and effectiveness of 'super-boosting' or adding extra ritonavir to a child's treatment regimen. WHO has since strengthened recommendations to use super-boosting in TB/HIV co-infected children.

- Supported by interim results from study, 'super-boosting' ritonavir was recommended by WHO in its antiretroviral guidelines in 2016

Ongoing activities: DND*i* continues to support implementation of and access to stand-alone ritonavir, to be added to protease inhibitor regimens for the treatment of children co-infected with TB and HIV.

Main partners: SOUTH AFRICA: Department of Health and Department of Science and Technology; Stellenbosch University and Tygerberg Children's Hospital; Perinatal HIV Research Unit, University of Witswatersrand; Shandukani Research Centre, Wits Reproductive Health and HIV Institute; Empilweni Services and Research Unit, Rahima Moosa Mother and Child Hospital; Enhancing Care Foundation; Division of Clinical Pharmacology, Department of Medicine, University of Cape Town

PLATFORMS & NETWORKS

Clinical Research to Strengthen Capacities in Endemic Countries

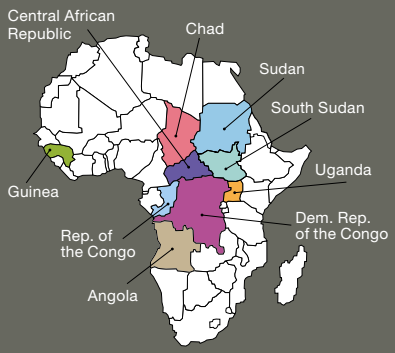
DND*i* works with partners in disease-endemic countries to strengthen clinical research capacity. Research platforms and networks facilitate knowledge sharing and training, as well as infrastructural upgrading of research centres for clinical trials.The expertise of their members help to ensure that target product profiles for treatments address patients' real needs.

Platforms

HUMAN AFRICAN TRYPANOSOMIASIS (HAT) PLATFORM

Founded: 2005 in Kinshasa, Democratic Republic of the Congo

The HAT Platform is a research capacity strengthening network of clinicians, national control programme representatives, and scientists from the African countries most affected by sleeping sickness, as well as international institutions. The HAT Platform strengthens clinical trial capacities and methodologies in HAT-endemic countries so that new and promising treatments for this fatal disease can be rapidly and effectively evaluated, registered, and made available to patients.



CHAGAS CLINICAL RESEARCH PLATFORM (CCRP)

Founded: 2009 in Uberaba, Brazil

The CCRP is a network of health authorities and scientists in the Americas and around the world. The CCRP aims to strengthen capacity, facilitate clinical research, expand community participation, provide a forum for technical discussions, and improve evaluation and delivery of new treatments for Chagas disease across the region.

LEISHMANIASIS EAST AFRICA PLATFORM (LEAP)

Founded: 2003 in Khartoum, Sudan

LEAP is a research capacity strengthening network of health authorities and scientists from the four African countries most affected by visceral leishmaniasis as well as international experts. LEAP aims to study, validate, and facilitate registration of improved treatment options for VL patients in the East African region. It provides capacity strengthening for treatment, evaluation, and clinical studies in the region.

Networks

REDELEISH

The RedeLeish network brings together leishmaniasis experts in Latin America to increase collaboration and maximize existing resources and expertise in clinical trial methodologies as well as in case management of patients with VL and CL.

OTHER NETWORKS

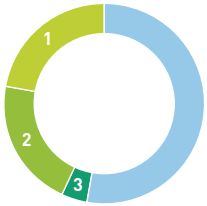
DND*i* is involved in the creation of informal networks of scientists and access advocates across the world, notably for filarial diseases, mycetoma, paediatric HIV, and hepatitis C, and is also part of existing research networks focusing on diseases in DND*i*'s portfolio.

NEGLECTED PATIENTS DESERVE TO BE TREATED

Help us deliver innovative therapeutic options!

Private contributions

1. Médecins Sans Frontières
2. Bill & Melinda Gates Foundation
3. The Wellcome Trust and other private donors



Public contributions

Governments and other public institutional donors:

UK; The Netherlands; France; UNITAID; Spain; Switzerland; Germany; European Union; Japan; Norway; USA (USAID/NIH/NIAID); The Global Fund to Fight AIDS, TB & Malaria; WHO-TDR; EDCTP; Brazil; and others

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- Fondation ARPE, Switzerland
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- Other private foundations and individuals

AWARDS

- BBVA Foundation (through the Frontiers of Knowledge Award in Development Cooperation), Spain
- Carlos Slim Foundation (through the Carlos Slim Award in Health for Outstanding Institution), Mexico
- Rockefeller Foundation (through the Next Century Innovators Award), USA

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- European Union – Framework Programmes 5, 6, and 7
- European and Developing Countries Clinical Trials Partnerships (EDCTP) with co-funding from Member States
- Federal Ministry of Education and Research (BMBF) through KfW, Germany
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- German International Cooperation (GIZ) on behalf of the Government of the Federal Republic of Germany
- Global Health Innovative Technology Fund (GHIT Fund), Japan
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- Swiss Agency for Development and Cooperation (SDC), Switzerland
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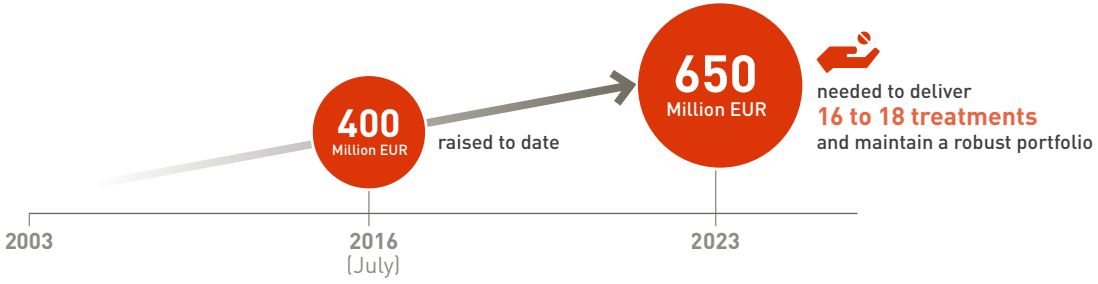

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Carlos Henrique Nery Costa, formerly with the Brazilian Society of Tropical Medicine, Brazil

Piero Olliaro, WHO/TDR, Switzerland and University of Oxford, UK

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DNDi

Drugs for Neglected Diseases *initiative*

The Drugs for Neglected Diseases *initiative* (DND*i*) is a 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, filariasis, paediatric HIV, mycetoma, and hepatitis C.

DND*i*'s primary objective:

→ Deliver 16 to 18 new treatments by 2023 for targeted neglected diseases and establish a robust R&D portfolio that addresses patients' treatment needs

In doing this, DND*i* has two further objectives:

→ Use and strengthen capacities in disease-endemic countries via project implementation

→ Raise awareness about the need to develop new drugs for neglected diseases and advocate for increased public responsibility

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