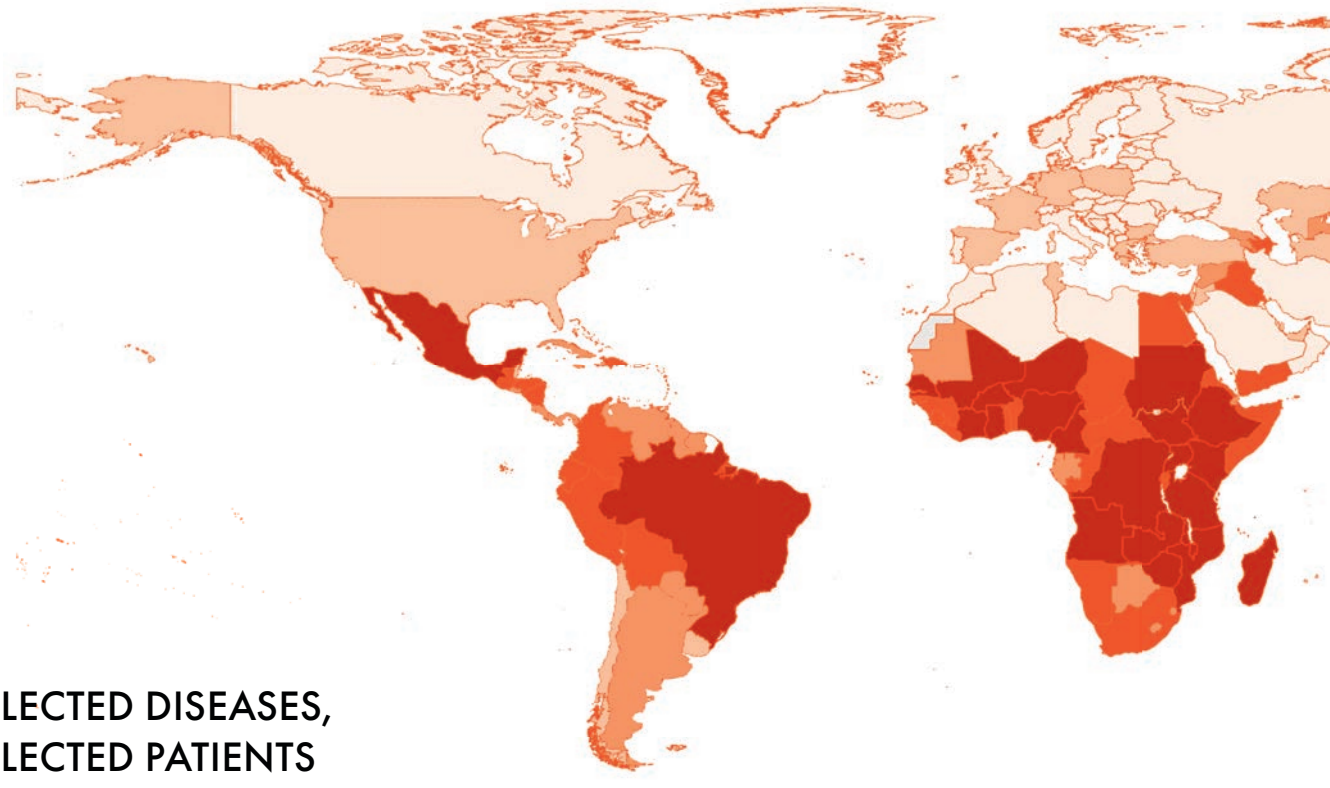
STRENGTHENING PARTNERSHIPS TO RESPOND TO THE NEEDS OF NEGLECTED PATIENTS

DNDi

Drugs for Neglected Diseases *initiative*



NEGLECTED DISEASES, NEGLECTED PATIENTS

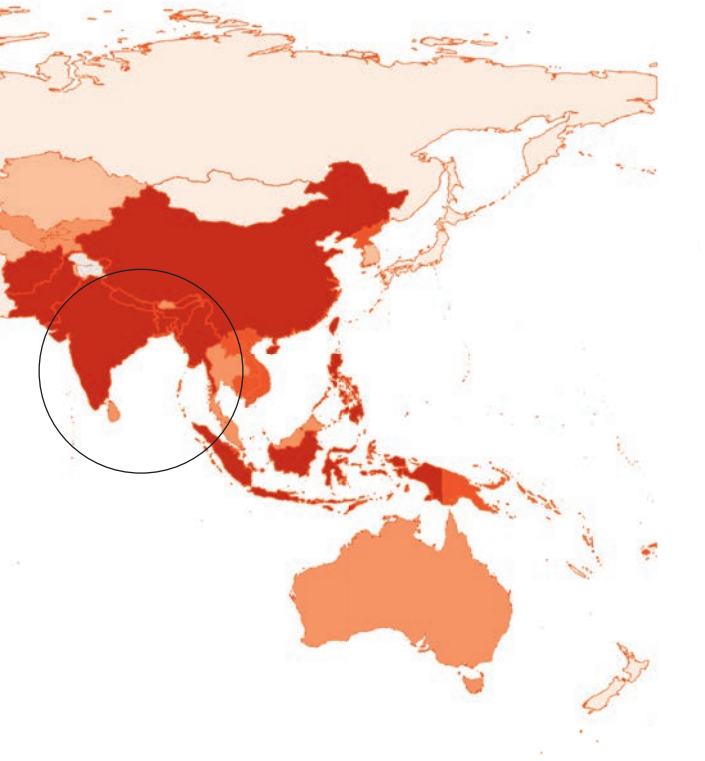
Globally, over one billion people are affected by neglected tropical diseases (NTDs), a group of 21 diseases mainly found in tropical and subtropical regions.* A large proportion of the NTD burden falls in South Asia. Those most affected are the poorest populations, living in remote rural areas, urban slums, or conflict zones. Their needs are not prioritized by policy makers, pharmaceutical companies, or research and development (R&D) institutions, and as a result, there are major unmet treatment needs for many NTDs. Similarly, there are major treatment gaps for neglected patient groups affected by diseases for which medicines are available but unaffordable or not adapted to the patients.

Out of the 850 new drugs and vaccines approved for all diseases from 2000-2011, only 4% (37 drugs) were for neglected diseases,** though these diseases represented 11% of the global burden of disease. Of the 336 brand-new drugs (new chemical entities) approved for all diseases, only four drugs (1%) were for neglected diseases. Of these, none was developed for any of the 17 NTDs listed at that time by the World Health Organization (WHO) as priorities for control or elimination.***

* Neglected tropical diseases: http://www.who.int/neglected_diseases/diseases/en/

** Diseases prevalent in low-income countries, including malaria, tuberculosis, diarrheal diseases, the 17 neglected tropical diseases then defined by the World Health Organization (since increased to 21), and 19 other diseases excluding HIV/AIDS

*** Pedrique B *et al.* (2013). The drug and vaccine landscape for neglected diseases (2000-11): A systematic assessment. *The Lancet Global Health*, 1(6), 371–379. https://doi.org/10.1016/S2214-109X(13)70078-0

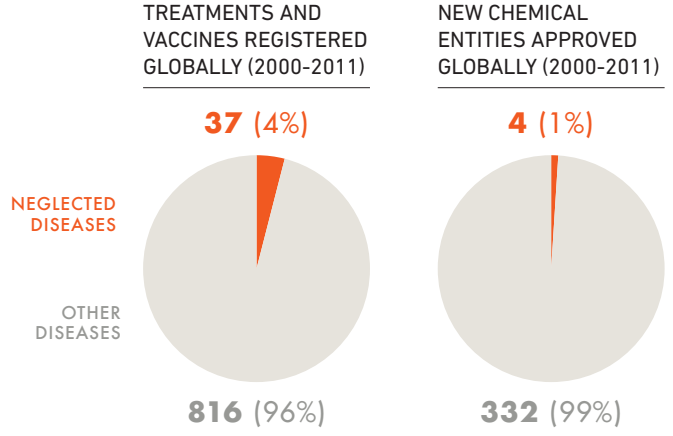


Neglected tropical diseases (NTDs): Reported number of people requiring interventions against NTDs in 2016

- < 30
- 31-15 000
- 15 001-850 000
- 850 001-9 000 000
- > 9 000 000
- not applicable

List of NTDs according to WHO (2017):

Buruli ulcer, Chagas disease, dengue and chikungunya, dracunculiasis (guinea-worm disease), echinococcosis, foodborne trematodiases, human African trypanosomiasis (sleeping sickness), leishmaniasis, leprosy, lymphatic filariasis, mycetoma, chromoblastomycosis and other deep mycoses, onchocerciasis (river blindness), rabies, scabies and other ectoparasites, schistosomiasis, soil-transmitted helminthiases, snakebite envenoming, taeniasis/cysticercosis, trachoma, yaws (endemic treponematoses).



"These illnesses are one of the important reasons that the 1.4 billion people living under the poverty threshold cannot emerge from marginalization. They are the most common infections among the world's poorest, the main cause of chronic disability and poverty."

Dr Bernard Pécoul, DND*i* Executive Director

"All of our work requires committed partners to meet the needs of neglected patients. Drug discovery and development require multidisciplinary partnerships, and we partner with national disease control programmes and research agencies for clinical trials."

Dr Suman Rijal, Head of DND*i* in India

DRUGS FOR NEGLECTED DISEASES *INITIATIVE*

RESPONDING TO THE NEEDS OF NEGLECTED PATIENTS

In October 1999, to address R&D gaps for neglected diseases, Médecins Sans Frontières brought together a group of international experts and created the Drugs for Neglected Diseases Working Group. This group recommended the creation of a new initiative, the Drugs for Neglected Diseases *initiative* (DND*i*), which was created in 2003 by seven founding member organizations. DND*i* is a collaborative, patient-needs driven, not-for-profit R&D organization that works to deliver new treatments for neglected diseases, particularly leishmaniasis, human African trypanosomiasis, Chagas disease, specific filarial infections, and mycetoma, and neglected patient populations, including paediatric HIV and hepatitis C.

SINCE ITS INCEPTION, DND*i* HAS DELIVERED EIGHT TREATMENTS:

- Two fixed-dose **antimalarials** (ASAQ and ASMQ),
- Nifurtimox-eflornithine combination therapy (NECT) for late-stage **sleeping sickness**,
- Sodium stibogluconate and paromomycin (SSG&PM) combination therapy for **visceral leishmaniasis in Africa**,
- A set of combination therapies for **visceral leishmaniasis in Asia**,
- A paediatric dosage form of benznidazole for **Chagas disease**,
- A 'superbooster' therapy for children co-infected with **HIV and TB**.
- The first all-oral treatment for **sleeping sickness**, fexinidazole (for both stages of the disease)

DND*i* AIMS TO DEVELOP 16-18 TREATMENTS BY 2023

To do so, DND*i* uses innovative and collaborative mechanisms to deliver treatments that are safe, effective, affordable, and well adapted for use in areas with limited healthcare systems.

FOUNDING PARTNERS:
Médecins Sans Frontières (MSF)/Doctors Without Borders; Indian Council of Medical Research, India; Kenya Medical Research Institute, Kenya; Ministry of Health, Malaysia; Oswaldo Cruz Foundation, Brazil; Institut Pasteur, France; World Health Organization (WHO) Special Programme for Research and Training in Tropical Diseases (TDR) (*permanent observer*)

NEW THERAPIES FOR VISCERAL LEISHMANIASIS IMPLEMENTED IN SOUTH ASIA (INDIA, BANGLADESH, AND NEPAL) FOLLOWING CLINICAL DEVELOPMENT AND ADVOCACY ACTIVITIES OF DND*i*

- AmBisome single dose and paromomycin+miltefosine recommended in revised Indian Government's elimination roadmap (2014)
- Large-scale implementation with health authorities at state, national, and regional levels
- Highly effective regimens with good safety profiles
- Recommended by WHO Expert Committee on the Control of Leishmaniases (2010)

DND*i* OFFICE IN NEW DELHI

BUILDING R&D PARTNERSHIPS TO MEET THE NEEDS OF NEGLECTED PATIENTS IN SOUTH ASIA

DND*i* started its activities in India in 2004 to build and strengthen regional partnerships to carry out R&D for neglected diseases in South Asia. DND*i* has activities in India and Bangladesh, mainly focused on visceral leishmaniasis and conducting clinical trials and capacity-building initiatives. More recently, DND*i* in India started to be active in the fields of paediatric HIV, antimicrobial resistance, and early drug discovery for leishmaniasis. DND*i* also works to raise awareness of neglected diseases and neglected patient populations, and advocates for increased public responsibility and greater support for neglected disease R&D.

DND*i* IN INDIA – AT A GLANCE

- Seven studies in leishmaniasis completed and two ongoing, plus support for new observational study of neonatal sepsis in India
- More than 85 local partners and collaborators
- Evidence provided through clinical study results to change guidelines for improved treatments for neglected patients in South Asia
- Over 5,000 visceral leishmaniasis patients treated within and outside clinical studies since 2010
- Over 940 people trained in Good Clinical Practice, Good Clinical Laboratory Practice, and parasitology

IMPROVED TREATMENTS TO SUPPORT SUSTAINABLE VL ELIMINATION

LEISHMANIASIS

DND*i* AIMS TO DELIVER:

A safe, effective, low-cost and short-course, oral treatment for VL

A new treatment for PKDL that is shorter and better tolerated than current options

A new treatment regimen for patients co-infected with HIV and VL

LEISHMANIASIS IS A COMPLEX DISEASE, OCCURRING IN MULTIPLE FORMS:

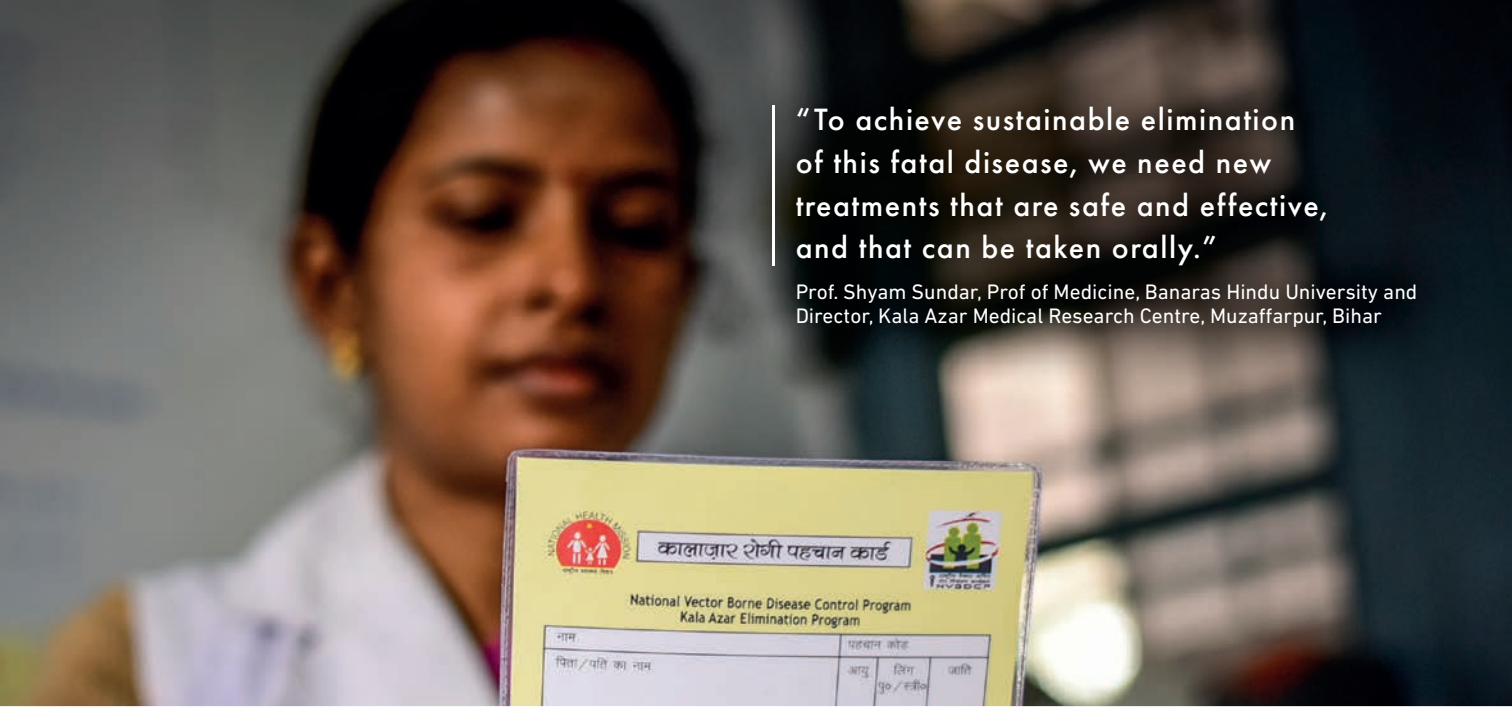
- **Visceral leishmaniasis (VL)**, also known as kala-azar, is fatal without treatment.
- **Post-kala-azar dermal leishmaniasis (PKDL)** develops in some 10% of treated VL patients in South Asia and is characterized by lesions on the body.
- **Cutaneous leishmaniasis (CL**) usually presents as ulcers on exposed body parts (arms, legs, face).

Over one billion people are at risk of leishmaniasis, a parasitic disease transmitted by the sandfly.

Kala-azar is known as a disease of the poor. It primarily affects those of lowest income and brings further financial hardships to those seeking treatment, as well as harsh social stigma. An estimated 6,746 cases were reported in South Asia (Bangladesh, India, and Nepal) in 2016.*

VL is being targeted by the Indian Government for elimination as a public health problem by the end of 2020, meaning less than 1 case per 10,000 population. To reach and sustain VL elimination, new drugs are needed that can be taken orally and are safer, shorter-course, more effective, affordable, and easier to use than existing treatments.

* World Health Organization. Weekly Epidemiological Record. October 2018, No 40, 2018, 93, 521–540. Available at: http://apps.who.int/iris/bitstream/handle/10665/275333/WER9340.pdf?ua=1



> "To achieve sustainable elimination of this fatal disease, we need new treatments that are safe and effective, and that can be taken orally."
>
> Prof. Shyam Sundar, Prof of Medicine, Banaras Hindu University and Director, Kala Azar Medical Research Centre, Muzaffarpur, Bihar

Policy change for control and elimination of VL

BRINGING BETTER TREATMENTS TO PATIENTS IN SOUTH ASIA

In the early 21st century, treatments for VL in South Asia were difficult for patients to take or growing ineffective, including to the oral drug miltefosine (MF). Antimonials such as sodium stibogluconate (SSG) had very poor cure rates due to drug resistance, lengthy treatment courses, difficult treatment administration, and poor tolerability due to frequent side effects.

To address the need for better treatments, DND*i* convened a consortium of partners to identify the best therapies for South Asia. The consortium conducted a four-year implementation study in India (2012–2015) to assess the safety, efficacy, and patient adherence to various new treatment options, including single-dose liposomal amphotericin B (that is single-dose AmBisome or LAB), MF+paromomycin (PM), and LAB+MF. The results showed that these treatments were safe and effective. They also shortened treatment duration, reduced the risk of resistance, and enabled treatment closer to home for most patients, thereby making it easier for patients to take the full treatment course.

This research provided key evidence for policy change by the Indian, Bangladeshi, and Nepali health ministries, which recommended LAB as the first-line treatment for VL, and MF+PM as the second-line treatment.

"I stopped going out, stopped playing with my friends fearing they will tease me. People told me that the scars were permanent and will ruin my life as I will not get married."

Rinki Kumari, first a VL and then a PKDL patient as a teenager, now cured, in Vaishali District, Bihar

Post-kala-azar dermal leishmaniasis

SHORTER, SAFER, AND EASIER TREATMENTS NEEDED

Post-kala-azar dermal leishmaniasis (PKDL), which occurs in an estimated 10% of treated VL patients in South Asia, has been identified as a reservoir for ongoing VL transmission. Untreated PKDL therefore poses a serious threat to the success of kala-azar elimination efforts in South Asia, and requires a focused strategy from the national programmes in India, Nepal, and Bangladesh. Early diagnosis and treatment of PKDL must become a critical element of any kala-azar public health and elimination strategy.

While PKDL is never fatal, it can cause major social stigma due to the lesions and scarring, often occurring on the face and other visible parts of the body. To contribute to the end of kala-azar in India, there is a need to better understand all aspects of the disease. Current treatments are unsatisfactory, as they last as long as 12 weeks, which makes treating PKDL difficult for patients and health programmes alike.

DND*i* AIMS TO DEVELOP

Shorter, safer and highly effective treatments for PKDL. A Phase II study testing both AmBisome monotherapy and a combination of AmBisome and MF has started in India and in Bangladesh to assess safety and efficacy for treating patients with PKDL.

The partners in this project in India are Kala Azar Medical Research Centre, Institute of Medical Sciences, Banaras Hindu University, and Rajendra Memorial Research Institute of Medical Sciences. In Bangladesh, the study is being implemented in collaboration with International Centre for Diarrhoeal Disease Research, Dhaka, Bangladesh (icddr,b) and SK Hospital, Mymensingh.

CONFIRMED:
THE NEED FOR EARLY TREATMENT
OF PKDL TO ELIMINATE VL

- Between 2016 and 2018, DND*i* and icddr,b conducted an infectivity study in Bangladesh to assess whether PKDL lesions of affected individuals could transmit the parasite to uninfected laboratory-reared sandflies. Results confirmed that the lesions of PKDL patients included in the study were capable of infecting sandflies. The study will be extended to assess patients after treatment is completed.
- In another study completed in 2017, DND*i* and partners conducted a cohort observational study in Bihar to better estimate the prevalence of PKDL in patients previously treated for kala-azar. Patients enrolled had been treated at least 24 months before the start of the study, since PKDL often develops in the second year after treatment. Preliminary results showed that PKDL was observed in patients 24 months after treatment of VL.

The results of these two studies confirm the role played by PKDL patients in transmitting the parasite responsible for VL to sand flies, thereby maintaining VL transmission during inter-epidemic periods. **Early treatment of PKDL patients must become a critical element of any public health and VL elimination strategy.**

HIV/VL CO-INFECTION

TREATING A CHALLENGING NEGLECTED CONDITION

HIV/VL co-infection is an emerging global problem, as VL is more difficult to treat in co-infected patients. A growing number of HIV/VL co-infected patients have been observed in Bihar, which has the highest VL burden of any state in India. These patients are at a greater risk of death because the diseases reinforce each other in suppressing the immune system. Conventional VL treatment rarely achieves sustainable control of the parasite in these patients, resulting in frequent relapse.

Studies in Ethiopia have identified more effective treatment regimens for HIV/VL co-infected patients in East Africa. However, the effectiveness of leishmaniasis therapies varies widely by region, and data are needed on more effective therapies for those affected in South Asia.

DND*i* is the technical partner in a study launched in Bihar to evaluate the safety and efficacy of an AmBisome-MF combination therapy and AmBisome monotherapy. The overall objective of this trial is to identify a safe and effective treatment for VL in co-infected patients. The results of the study, which is sponsored by MSF in collaboration with DND*i* and Rajendra Memorial Research Institute, will provide evidence to national and regional decision makers regarding the best treatment for co-infected patients. .

RESEARCH AND DEVELOPMENT

DRUG DISCOVERY FOR LEISHMANIASIS

Although new treatments issuing from DND*i*'s R&D strategy have brought improvements over the toxic pentavalent antimonial monotherapy used in the past, these remain interim solutions. New, safer, shorter-course, and more effective and affordable drugs are needed to support the sustainable elimination of VL.

The underlying objective of DND*i*'s longer-term strategy is to contribute to the sustainable elimination of VL in South Asia.

Following the definition of an optimal treatment, DND*i* is embarking on new partnerships to discover and develop entirely new chemical entities to treat leishmaniasis in its various forms.

Open Innovation

In recent years, DND*i* has been increasingly active in 'open innovation', an approach to new drug discovery in which different actors actively collaborate in finding ways to speed up drug development, reduce costs, harness collective energies, reduce duplication of efforts through sharing of information, and avoid barriers that may be caused by intellectual property.

Open innovation at DND*i* in India is growing through **two active initiatives** to foster innovation and the development of safe and effective new treatments for neglected patients through new collaborations:

OPEN SYNTHESIS NETWORK – INCENTIVISED CROWD SOURCING

Launched in 2016, the Open Synthesis Network (OSN) is a collaborative project that engages master's and undergraduate medical chemistry students in research for neglected diseases as part of their lab training. Out of 18 participating institutions around the world, three are from India: School of Pharmacy & Technology Management, Narsee Monjee Institute of Management Studies (NMIMS, Mumbai), Indian Institute of Technology (Gandhinagar), and the Indian Institute of Chemical Technology (Hyderabad). Students of these universities are working on compounds that kill *Leishmania (L.) donovani* and *L. infantum*, the parasites that cause kala-azar.

Any successful compounds that come from the OSN project will be evaluated further as part of DND*i*'s drug discovery pipeline.

LEAD OPTIMISATION CONSORTIUM IN INDIA

With many world-class research institutions and global pharmaceutical organizations, India is rich in both scientific expertise and drug discovery capabilities. DND*i* is working to identify as many potential partners across India as possible, with capabilities and expertise in the various disciplines required by the Lead Optimisation Consortium in India (LOCI). This consortium of drug discovery partners being built by DND*i* will work together to discover and optimize new pre-clinical drug candidates for leishmaniasis. DND*i* is looking for partners in India with expertise in: medicinal and synthetic chemistry; parasitology screening; microbiology; structural biology; absorption, distribution, metabolism, and excretion (ADME) and pharmacokinetics; and toxicology.

GARDP
Global Antibiotic Research & Development Partnership

The Global Antibiotic Research & Development Partnership (GARDP) was established in May 2016 as a joint initiative of the World Health Organization and DND*i*. Its mission is to develop new and improved antibiotic treatments addressing antimicrobial resistance (AMR), while ensuring their sustainable access.

NEONATAL SEPSIS

AMR is a rapidly growing global health challenge, with estimates of up to 700,000 deaths per year resulting from drug-resistant infections.* Despite significant breakthroughs made in reducing child mortality, neonatal deaths represent 44% of all deaths in children under five. Of particular concern is the estimated 214,000 neonatal deaths in 2015 attributed to drug-resistant infections.** In South Asia, there has been little change in the rates of neonatal sepsis cases (bloodstream and other infections in newborns) in the last decade, while rates of antimicrobial resistance have increased. It is estimated that nearly 40% of sepsis-related newborn deaths occur in South Asia.***

A major knowledge gap is the lack of evidence on how to treat neonatal sepsis. An 11-country observational study was launched in India in mid-2018 with the goal of providing an evidence base as part of GARDP's broader programme to develop and deliver new antibiotic treatments for newborns with drug-resistant bacterial infections. DND*i* is supporting GARDP in the conduct of this study in India.

* O'Neill, J. (2016). Tackling drug-resistance globally: Final report and recommendations. Available at: https://amr-review.org/sites/default/files/160525_Final%20paper_with%20cover.pdf

** Laxminarayan, R. *et al.* (2016). Antimicrobials: access and sustainable effectiveness 1; Access to effective antimicrobials: a worldwide challenge. *Lancet*. 387:168-75

*** Hamer DH, Darmstadt GL, Carlin JB, Zaidi AK, Yeboah-Antwi K, Saha SK, *et al.* Etiology of bacteremia in young infants in six countries. *Pediatr Infect Dis J.* 2015;34(1):e1-8.

INVESTING IN INDIA

STRENGTHENING REGIONAL RESEARCH CAPACITY

SUPPORTING NATIONAL VL ELIMINATION PLANS

Supporting endemic countries' plans to increase national capacity in clinical research is part of DND*i*'s mission. Considerable effort is required to carry out quality clinical research that meets international clinical trial standards. DND*i*'s Regional Office in India integrates sustainable capacity strengthening into its projects to contribute to the cadre of personnel in India trained to work in clinical research and to increase the capacity of affected districts to diagnose leishmaniasis in its different forms.

- **Capacity building for parasitological diagnosis in VL and PKDL**

DND*i* supports the Indian National Kala-azar Elimination Programme by strengthening the capacity of district hospitals in Bihar (Purnia, Saharsa, Saran, Vaishali, and Muzaffarpur) and in Jharkhand (Godda, Dumka, Pakur, and Sahibgunj) to conduct parasitological diagnosis of VL for confirmation of relapse, and diagnosis of PKDL by microscopy.

- **Community mobilisation and awareness**

DND*i*'s information, education, and communications officers regularly visit communities in VL-endemic areas to raise awareness of the disease. 90% of all Indian VL cases occur in Bihar. The disease being frequently misdiagnosed, villagers need to know about VL and PKDL symptoms, the importance of seeking treatment rapidly, and how to help prevent sand flies.

- **Advocacy for sustainable VL elimination**

DND*i* advocates to improve treatment access for patients, and to encourage increased support for drug research and development that meets the needs of neglected patients. Activities include working with health ministries, communities, media, and other stakeholders to create awareness of new and effective treatments. These efforts are augmented by government initiatives, with a growing global awareness of the need to strengthen R&D and evidence-based decision making for public health.

NEXT STEPS IN PARTNERING TO ADVANCE DRUG R&D IN INDIA

In a context of major national and global health needs, India's research and development (R&D) capacity provides opportunities for mutually beneficial partnerships between DND*i* and interested R&D actors in the public and private sectors. Partnership and consortium approaches will help to foster an "end-to-end" approach to the development of new drugs for neglected patients – from drug discovery to patient access.

DND*i* has already begun to formalize new partnerships to generate drug candidates to fight antimicrobial resistance (bacterial and fungal) and neglected parasitic diseases, including through the newly formed Lead Optimization Consortium in India, and to explore new partnerships to take existing leishmaniasis drug candidates through Phase I trials in India.

On behalf of GARDP, DND*i* will also work to build a core group of partners to meet national and global health needs in antibiotic resistance. In addition, DND*i* will identify new clinical trial platforms for neonatal and paediatric studies, and fill evidence gaps to support future R&D, including through studies to enhance disease knowledge and increase understanding of barriers to the uptake of new treatments.

If studies currently underway are successful, DND*i* will support the adoption and implementation of new treatment regimens for PKDL and HIV/VL co-infection in South Asia.

Ultimately, partnerships will allow us to combine the resources, knowledge, trial networks, and regulatory and access strategies of the Government of India and DND*i* with the capacities and technologies of the pharmaceutical and biotech industries, as well as new research emerging from Indian universities. Collectively, we can reinforce Indian R&D capacity, develop and deliver urgently needed drugs, and support evidence-based treatment guidelines for clinicians. Ambitious yet pragmatic partnerships between the public and private sectors will bring important new contributions to solutions for the most neglected patients in India, the region, and globally.

TO REACH ITS OBJECTIVES BY 2023, DND*i*'s OVERALL RESOURCES NEEDED IS EUR 730 M

56%
EUR 303 M
PUBLIC INSTITUTIONAL SUPPORT

44%
EUR 237 M
PRIVATE SUPPORT

a EUR **730 M** budget, of which **540 M** have already been secured

HOW DND*i*'s GLOBAL RESOURCES ARE ALLOCATED

80% **SOCIAL MISSION:** Research & development activities and projects of access to medicines/ treatments

20% **OTHER ACTIVITIES:** activities of support to projects (non-R&D)

Status: Jan. 2019

JOIN US IN THE FIGHT FOR NEGLECTED PATIENTS

Despite encouraging progress, there is still so much to do to ensure that neglected patients get the effective and affordable treatment they so desperately need.

Since its founding, DND*i* seeks diversified funding sources, from governments, public institutions, companies, foundations, NGOs, individuals, and alternative mechanisms that share a commitment to DND*i*'s vision and mission. This diversification is crucial to guarantee independence and avoid dependence on any one donor. Every effort will therefore be made to ensure that no single donor contributes over 25% of all donations.

THANK YOU TO DND*i*'S DONORS*

UK aid; Bill & Melinda Gates Foundation, USA; Federal Ministry of Education and Research (BMBF) through KfW, Germany; Médecins Sans Frontières, International; Dutch Ministry of Foreign Affairs (DGIS), the Netherlands; Swiss Agency for Development and Cooperation (SDC), Switzerland; US Agency For International Development (USAID), USA; French Development Agency (AFD), France; Unitaid; European and Developing Countries Clinical Trials Partnership (EDCTP2 Programme) supported by the European Union; Global Health Innovative Technology Fund (GHIT Fund), Japan; Wellcome Trust, UK; Ministry of Health, Malaysia; International Development Research Centre (IDRC), Canada; Associação Bem-Te-Vi Diversidade, Brazil; Banco Nacional de Desenvolvimento Econômico e Social (BNDES), Brazil; Medicor Foundation, Liechtenstein; Stavros Niarchos Foundation, USA; Republic and Canton of Geneva, International Solidarity Office, Switzerland; Fondation ARPE, Switzerland; Starr International Foundation, Switzerland; World Health Organization - Special Programme for Research and Training in Tropical Diseases (WHO-TDR); FIND supported by Unitaid; Pan American Health Organization (PAHO/ WHO); Fondation Anne Maurer Cecchini, Switzerland ; Ruta-N, City of Medellin, Colombia and private individuals and foundations.

* All active DND*i* grants as of Jan. 2019

DND*i*

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.

The Global Antibiotic Research & Development Partnership (GARDP) is a joint initiative of the World Health Organization and DND*i* launched in 2016. It became an independent entity in 2019.

DND*i* started its activities in India in 2004 to build and strengthen regional partnerships to carry out R&D activities for neglected diseases in South Asia. The office has activities in India and Bangladesh to support drug discovery, clinical trials, and capacity-building initiatives for leishmaniasis, antimicrobial resistance and, soon, paediatric HIV.

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