01. OVERVIEW & GOVERNANCE

An alternative model to develop drugs for neglected diseases and ensure equitable access for all patients.
Fourth new treatment delivered in 2010

In 2010, DNDi delivered its fourth treatment, a combination of sodium stibogluconate and paromomycin (SSG&PM) for visceral leishmaniasis in Africa. This follows the two fixed-dose anti-malarials (ASAQ – 2007 and ASMQ – 2008) and NECT (nifurtimox-eflornithine combination therapy – 2009) for sleeping sickness.

The WHO Expert Committee on the Control of Leishmaniasis recommended SSG&PM as first-line treatment for VL in East Africa and at the close of the year, Sudan recommended SSG&PM as first-line treatment for VL. SSG&PM showed a similar safety and efficacy profile as the standard SSG monotherapy, with shorter treatment duration (17 days versus 30 days) in addition to lower cost.

A BALANCED APPROACH TO ADDRESS UNMET NEEDS

Seven years after DNDi’s inception, this breakthrough for one of the most neglected diseases affecting the poorest people of the world, reinforces DNDi’s strategy of maintaining a balanced R&D pipeline of long-term and short-term projects. The ultimate goal is to develop new treatments that are safe, efficacious, affordable, and field-adapted to support elimination programmes for human African trypanosomiasis and VL, and case management for Chagas disease. Through this balanced approach, DNDi addresses both immediate patient needs, through improvement and/or combination of existing drugs, and the more long-term public health requirements, through the R&D for new chemical entities (NCEs). The latter are developed to correspond to the ideal target drug profiles that are established with a long-term vision of patient needs and with the aim of supporting elimination strategies where possible.

While SSG&PM provides confirmation of the efficiency of DNDi’s model, other outcomes are illustrative of this as well:

- The implementation of ASAQ, launched in March 2007 in partnership with sanofi-aventis, is now registered and available in 30 African countries and India with more than 80 million treatments distributed in Africa by December 2010. Meanwhile, sanofi-aventis, MMV, DNDi, and National Malaria Control Programmes are implementing a vast risk management plan with several studies throughout West and East Africa. This plan is one of the largest ever of its kind for the African continent.

The implementation of NECT, a simplified co-administration of eflornithine and nifurtimox for stage 2 HAT patients, included in the WHO Essential Medicines List in 2009, was running in 10 countries, which cover approximately 97% of all estimated HAT cases. NECT, used to treat over 60% of stage 2 HAT patients by the end 2010, is quickly replacing melaropsin, an arsenic derivative that is painful, toxic, and even fatal for 5% of those who receive it.

- Oxaborole (SCYX-7158 compound), the first novel oral drug candidate developed through DNDi’s lead optimization programme, is prepared to enter Phase I clinical trials in 2011, following promising results obtained from pre-clinical safety studies, in collaboration with Anacor, SCYNEXIS, Pace University (USA), and Advinus (India).

- Following the license agreement signed with the Japanese pharmaceutical company Eisai, DNDi designed the clinical development plans for E-1224, a prodrug of ravuconazole. With CRESIB, DNDi conducted the preliminary activities at the site level for a Phase II proof-of-concept clinical trial in adult patients, to start in 2011 in Bolivia, for chronic indeterminate Chagas disease.

PAVING THE WAY FOR INNOVATIVE PARTNERSHIPS

In order to bring to fruition the new generation of treatments coming from its discovery programmes, DNDi actively seeks access to chemical libraries of pharmaceutical and biotechnology companies, with the aim of identifying the right candidates that will become innovative medicines. Securing this access to compound libraries of private companies is key as it gives a major head start for the otherwise expensive and time-consuming discovery phase. In 2010, DNDi pursued such partnerships resulting in, for instance, research collaboration with Pfizer for the screening of 150,000 compounds against all three kinetoplastid diseases at the Institut Pasteur Korea (IPK). Until recently, …/

OBJECTIVES BY 2014

DNDi’s objective is to
- Develop 6-8 new, field-relevant treatments and a robust pipeline by 2014 for people suffering from neglected diseases

In doing this, DNDi will also
- Use and strengthen existing research capabilities in countries where neglected diseases are endemic
- Raise awareness about the need to develop new drugs for neglected diseases and advocate for increased public responsibility
The lack of high-throughput screening has hampered efforts to screen large-sized libraries for Leishmania (the parasite causing VL) and T. cruzi (the parasite causing Chagas). DNDi has specifically commissioned IPK to develop a new methodology to address this bottleneck and therefore quickly identify hits/leads critical to the discovery programmes (see page 17). The commitment of IPK – supported by the Institut Pasteur, the Korean government, and DNDi’s donors – showed the impact of collaborative models managed by product development partnerships (PDPs) in boosting innovation.

The partnership agreement with the TB Alliance for leishmaniasis treatment announced in 2010 is yet another illustration of the benefits of open innovation practices between PDPs. TB Alliance granted DNDi access to a selected library of chemical entities (see page 26) and shared its scientific expertise and knowledge of the drug classes. The not-for-profit model demonstrates that there are innovative ways to share knowledge, to avoid duplication in research, and thereby save costs and speed up the R&D process for the benefit of patients. This unique PDP-to-PDP agreement maximizes the benefits from the global health community’s investment in research and development, and may serve as a model for future collaborations. With more than 100 clinical research programmes among the 18 major global health PDPs, there may be opportunities to leverage other innovations across diseases, bringing a promise of more rapid progress.

In the past few years, DNDi has formalized strong relationships with several pharmaceutical and biotechnology companies committed to R&D for neglected tropical diseases (NTDs). These business relationships occur at all stages of the R&D pipeline. Sanofi-aventis, GSK, Pfizer, Merck, Eisai, Cipla, Novartis, Anacor, SCYNEXIS, Enzyme, and Advinus are participating in these joint efforts. These novel alliances between not-for-profit organizations and private companies, public institutions, and academia are heralding a new paradigm, with major opportunities to generate new pathways for innovation.
The eight-point ‘Manifesto’, published in PLoS NTDs, co-authored by Peter Hotez and Bernard Pécoul, conveys the message that all NTDs need to implement existing tools and that increased investment in R&D for NTDs is urgent.

DOKA centre

The Leishmaniasis East Africa Platform opened the renovated and expanded Professor El Hassan Centre for Tropical Medicine in Doka, Sudan, the seventh research and treatment centre taking part in LEAP clinical studies.

HAT Platform

The platform and the East African Network for Trypanosomosis (EANETT) held their first joint scientific meeting in Nairobi, Kenya, to discuss further the implementation of NECT treatment.

Alliance

The Global Alliance for TB Drug Development (TB Alliance) and DNDi announce the first-ever royalty-free license agreement between two not-for-profit drug developers, speeding progress toward improved therapies for multiple neglected diseases.

DNDi’s Partners

Over 150 Indian and international health researchers, policy makers, and experts from 22 countries meet in New Delhi, India, for the third international DNDi Partners’ Meeting, organized in collaboration with Indian Council for Medical Research (ICMR).

Art.58

DNDi and sanofi-aventis apply for joint EMA article 58 and US Food Drug and Administration Office (FDA) scientific advice on the clinical development plan for fexinidazole (drug candidate for HAT).

Oxaborole

All safety studies indicate that Oxaborole (SCYX-7158), the first pre-clinical candidate for sleeping sickness developed through DNDi’s lead optimization programme with SCYNEXIS, Anacor, and Advinus, should enter Phase I clinical studies in 2011.

SSG&PM

DNDi’s fourth delivered treatment was recommended and implemented in Sudan end 2010. This combination therapy had been recommended in March 2010 by the WHO Expert Committee on the Control of Leishmaniases as first-line treatment for VL in East Africa.

International status

Special international status organization is granted to DNDi by the Swiss Government.

India

DNDi ‘Project of the year’ is awarded to the Visceral Leishmaniasis Combination Therapies project in India. This clinical research study completed in 2010 showed that three combination therapies of existing drugs for visceral leishmaniasis (VL) are highly efficacious and are shorter, safer, and cheaper than current standard monotherapy available in the region. Results are published in The Lancet in January 2011.
DNDi around the world

DNDi NORTH AMERICA
Established in 2007. The DNDi affiliate in North America supports advocacy, fundraising, and R&D efforts in the region. Based in New York City, DNDi North America operates under the direction of a Board of Directors and collaborates with key partners engaged in a variety of R&D activities.
www.dndina.org

INSTITUT PASTEUR
Established in France in 1887, Institut Pasteur is a non-profit private foundation dedicated to prevention and treatment of diseases such as yellow fever, tuberculosis, poliomyelitis, hepatitis, and HIV/AIDS. With 8 Nobel Prizes awarded to its researchers, Institut Pasteur is at the forefront of medical research with discoveries of antitoxins, BCG, sulfamides, and anti-histamines, as well as key research in molecular biology and genetic engineering.
www.pasteur.fr

MÉDECINS SANS FRONTIÈRES (MSF)
MSF is an independent, private, medical aid organization that has been operational in emergency medical aid missions around the world since 1971. With offices in 19 countries and ongoing activities in over 80, MSF has also run the Campaign for Access to Essential Medicines since 1999. MSF has received numerous international awards for its activities, including the Nobel Peace Prize in 1999, which it dedicated to finding long-term, sustainable solutions to the lack of essential medicines, ultimately leading to the founding of DNDi.
www.msf.org

DNDi LATIN AMERICA
Established in 2004. DNDi Latin America, based in Rio de Janeiro, supports regional R&D activities for Chagas disease, malaria, and leishmaniasis, in addition to advocacy, communication, and fundraising activities to increase awareness of neglected diseases in the region. DNDi Latin America operates under the direction of a Board of Directors.
www.dndi.org.br

OSWALDO CRUZ FOUNDATION (FIOCRUZ)
Founded in 1900, Fiocruz is the largest biomedical research institution in Latin America. Part of the Brazilian Ministry of Health, Fiocruz has facilitated health tool R&D for neglected diseases via the establishment of dedicated centres for vaccine and drug development: Bioman- guinhos and Farmanguinhos.
www.fi ocruz.br

DNDi HEADQUARTERS IN GENEVA

DNDi NORTH AMERICA
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www.dndi.org.br

DNDi IN THE DEMOCRATIC REPUBLIC OF THE CONGO
Established in 2005. The DNDi project support office in Kinshasa, Democratic Republic of the Congo (DRC), provides essential logistical and financial support to the nifurtimox-eflornithine combination therapy (NECT) trials and studies, as well as to the HAT Platform.

DNDi AFRICA
Established in 2003. DNDi Africa, based at the Kenya Medical Research Institute (KEMRI) in Nairobi, provides support to R&D projects in the region, including clinical activities for leishmaniasis, as well as capacity building in the framework of the LEAP and HAT Platforms.

7 FOUNDERING PARTNERS
6 REGIONAL OFFICES
1 AFFILIATE
At the founding of DNDi in 2003, seven key stakeholders joined forces to propel the initiative. Each Founding Partner is a centre of excellence in neglected disease research and/or patient care. In addition, DNDi has secured its regional rooting in countries where neglected diseases are endemic, as well as in other countries where its activities are prominent.


## Governance

### The Board of Directors

DNDi’s Board of Directors is composed of ten to thirteen members, including at least one patient representative, who serve four-year terms. Each of the founding members nominates one Board member.

**DNDi Board Members**

1. **Marcel Tanner**  
   Chair; Swiss Tropical and Public Health Institute (Swiss TPH)
2. **Reto Brun**  
   Secretary; Swiss Tropical and Public Health Institute (Swiss TPH)
3. **Bruce Mahin**  
   Treasurer; formerly with Médecins Sans Frontières (MSF)
4. **Alice Dautry**  
   Institut Pasteur, France
5. **Abul Faiz**  
   Patient representative; Sir Salimullah Medical College, Bangladesh
6. **Lalit Kant**  
   Indian Council of Medical Research (ICMR)
7. **Unni Karunakara**  
   Médecins Sans Frontières (MSF)
8. **Datuk Mohd Ismail Merican**  
   Ministry of Health, Malaysia
9. **Carlos Morel**  
   Oswaldo Cruz Foundation (Fiocruz), Brazil
10. **Gill Samuels**  
    Global Forum for Health Research, Foundation Council, Switzerland, formerly with Pfizer, UK
11. **Bennett Shapiro**  
    Pure Tech Ventures, formerly with Merck & Co, USA
12. **Paulina Tindana**  
    Patient representative; Navrongo Health Research Centre, Ghana
13. **Robert G. Ridley**  
    WHO-TDR (Permanent Observer)

### The Scientific Advisory Committee (SAC)

DNDi’s Scientific Advisory Committee (SAC) is composed of seventeen prominent scientists with expertise in various scientific disciplines related to drug discovery and development, and/or the specific reality of neglected diseases and neglected patients. They operate independently of the Board of Directors and the Executive team. The SAC has the mandate to advise the Board of Directors on matters related to research and development and choice of projects, as well as the quality of the scientific output.

**DNDi Scientific Advisory Committee Members**

- Pierre-Etienne Bost  
  Chair; formerly with Institut Pasteur, France
- Khirana Bhatt  
  University of Nairobi, Kenya
- Marleen Boelaert  
  Institute of Tropical Medicine, Antwerp, Belgium
- Chris Bruegner  
  IDEC, Japan
- J. Carl Craft  
  formerly with Medicines for Malaria Venture, Switzerland
- Simon Croft  
  London School of Hygiene and Tropical Medicine, UK
- Federico Gomez de las Heras  
  formerly with GlaxoSmithKline, Spain
- Chitar Mal Gupta  
  Central Drug Research Institute, India
- Maria das Graças Henriques  
  Oswaldo Cruz Foundation (Fiocruz), Brazil
- Paul Herrling  
  Novartis International AG, Switzerland
- Dale Kempf  
  Abbott, USA
- Nor Shahidah Khairullah  
  Infectious Diseases Research Center, Malaysia
- Shiv Dayal Seth  
  Indian Council of Medical Research (ICMR), India
- Faustino Torrico  
  Universidad Mayor de San Simon, Cochabamba, Bolivia
- Muriel Vray  
  Institut Pasteur, France
- Krisantha Weerasuriya  
  World Health Organization (WHO), Switzerland
- Haruki Yamada  
  Kitasato Institute for Life Sciences, Japan
- Unni Karunakara  
  Médecins Sans Frontières (MSF)

### Affiliate and Regional Office Boards

**DNDi North America Board of Directors**

- Bennett Shapiro, Chair; Pure Tech Ventures, formerly with Merck & Co., USA
- Hellen Gelband, Center for Disease Dynamics, USA
- Joelle Tangy, Global Alliance for Vaccines and Immunization (GAVI), Switzerland
- James Orbinski, University of Toronto, Canada
- Suerie Moon, Harvard School of Public Health, USA
- Bernard Pécou, Drugs for Neglected Diseases initiative (DNDi), Switzerland

**DNDi Latin America Board, Executive Members**

- Michel Lotrowska, Chair, Brazil
- Carlos Morel, Oswaldo Cruz Foundation (Fiocruz), Brazil
- Tyler Fainstat, Médecins Sans Frontières (MSF), Brazil

**DNDi Japan Board of Directors**

- Haruki Yamada, Chair; Kitasato Institute for Life Sciences, Japan
- Koshin Nakahira, Nakahira Certified Tax Accounting Office, Japan
- Bernard Pécou, Drugs for Neglected Diseases initiative (DNDi), Switzerland
- Fumiko Hirabayashi, Drugs for Neglected Diseases initiative (DNDi), Japan
THE EXECUTIVE TEAM

DNDi consists of a team of permanent staff based in Geneva and in seven regional and affiliate offices throughout the world. The Geneva team also coordinates a broad base of consultants and volunteers worldwide.

DNDi HEADQUARTERS / GENEVA

Bernard Pécoul, Executive Director
Shing Chang, Research and Development Director
(On extended leave)
Hyo Jeung Ahn, Site and Travel Assistant
Jean-François Alesandrini, Fundraising and Advocacy Director
Manica Balasegaram, Head of Leishmaniasis Clinical Programme
Sérène Blesson, Project Coordinator
Pascale Boulet, Policy Research Officer
Gwenëuelle Carn, Project Coordinator
Eric Chatelain, Head of Chagas Discovery and Pre-clinical Programme
Brigitte Crotty, Executive & Board Assistant
Violaine Dällenbach, Communications Officer
Julia Fährmann, Fundraising Coordinator (as of January 2011)
Ralf de Coulon, Finance, Human Resources, and Administration Director
Boban Djordjevic, Finance Officer
Robert Don, Head of HAT Discovery and Pre-clinical Programme (until June 2010) and Discovery and Pre-clinical Director (as of July 2010)
Sally Ellis, Clinical Manager
Caroline Gaere Gardaz, Fundraising Officer for Major Donors
Karín Génevaux, Fundraising Coordinator (until September 2010), Head of Fundraising (as of October 2010)
Federica Giovannini, Scientific Communications Officer (until January 2011)
Jean-Robert Ioset, Discovery Manager
Dominique Junod-Moser, Legal Officer

Jennifer Katz, Head of Fundraising (until September 2010)
Jean-René Kiechel, Senior Pharma Advisor and Product Manager
Gabrielle Landry Chappuis, Head of Communication and Advocacy (as of March 2011)
Delphine Launay, Project Coordinator
Sandrine Lo Iacono, Communications and Fundraising Associate
Denis Martin, Head of Visceral Leishmaniasis Discovery and Pre-clinical Programme
Janine Miller, Senior Accountant
Farrokh Modabber, Senior Advisor for Leishmaniasis
Béatrice Mouton, Human Resources and Administration Manager
Jean-Pierre Paccaud, Business Development Director
Sylvie Renaudin, Research and Development Assistant

Ivan Scandale, Project Coordinator
Jérôme Saint-Denis, Fundraising Coordinator
Nathalie Strub Wourgaft, Medical Director
Olina Sushchenko, Administrative Assistant
Antoine Tarra, Head of HAT Clinical Programme
Donia Tourki, Finance Assistant
Olaf Valverde, Medical Manager
Eva Van Beek, Communications Manager (until December 2010)
Laurence Vielfaure, Financial Controller

ASSOCIATE STAFF IN GENEVA

Florence Camus-Bablon, Senior Access Advisor
Graciela Diap, Medical Coordinator, FACT Project
Sandrine Millier, Database Assistant

REGIONAL OFFICES & AFFILIATE

DNDi EAST AFRICA

Monique Wasunna, Head of Regional Office, Kenya
Nicholas Bonyo, Finance Assistant, Kenya
Simon Bolu, Regional Finance and Administration Manager, Kenya
Robert Kimutai, Clinical Trial Manager, Kenya
Joy Malongo, Administrative Assistant, Kenya

Associate staff in Kenya
Josephine Kessusu, Trial Logistician, Kenya
John Kimani, Data Manager, Kenya
Seth Okeyo, Data Management Assistant, Kenya
Raymond Omollo, Head of Data Centre and Statistician, Kenya
Truphosa Omollo, Junior Data Manager, Kenya
Rhoda Owiti, Data Management Assistant, Kenya
Nanfuka Rehma, Clinical Research Associate, Kenya

DNDi INDIA

Bhawna Sharma, Head of Regional Office, India
Sharmila Das, Finance and Administration Officer, India
Babita Papneja, Assistant, India (as of January 2011)
Vikash Sharma, Finance Assistant and Logistician, India

Associate staff in India
Abhijit Sharma, Assistant Project Coordinator, India
Vishal Goyal, Project Coordinator, India (as of January 2011)

DNDi JAPAN

Fumiko Hirabayashi, DNDi Representative in Japan
Emi Khan, Assistant, Japan

DNDi LATIN AMERICA

Eric Stobbearts, Head of Regional Office, Brazil
Fabiana Alves, Clinical Trial Manager, Brazil
Bethania Blum de Oliveira, Project Coordinator, Brazil
Maristela de Oliveira Soares, Accountant and Administrative Assistant, Brazil
Flavio Pontes, Regional Communications Officer
Isabela Ribeiro, Head of Chagas Clinical Programme, Brazil

DNDi MALAYSIA

Visweswaran Navaratnam, Head of Regional Office, Malaysia

AFFILIATE DNDi NORTH AMERICA, INC.

Jana Armstrong, Regional Executive Director, USA (until August 2010)
Rachel Cohen, Regional Executive Director, USA (as of January 2011)
Jennifer Katz, Policy and Development Director, USA (as of October 2010)
Sarah de Tournemire, Administration and Development Manager, USA