ANNUAL REPORT 2013

A DECADE OF R&D FOR NEGLECTED PATIENTS

DNDi

Drugs for Neglected Diseases *initiative*

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 R&D. They also build public responsibility and leadership in addressing the needs of these patients.

MISSION

To develop new drugs or new formulations of existing drugs for patients suffering from the most neglected communicable diseases. Acting in the public interest, DND*i* will bridge 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 will be the development of drugs for the most neglected diseases, such as sleeping sickness, leishmaniasis, and Chagas disease; and it will also consider engaging R&D projects on other neglected diseases. DND*i* will address unmet needs by taking on projects that others are unable or unwilling to pursue and, as means permit, will consider development of diagnostics and/or vaccines.

In pursuing these goals, DND*i* will manage R&D networks built on South-South and North-South collaborations. While using the existing support capacities in countries where the diseases are endemic, DND*i* will help to build additional capacity in a sustainable manner through technology transfer in the field of drug research and development for neglected diseases.

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 medicines for neglected diseases that afflict millions of the world's poorest people.

DND*i* focuses on developing new treatments for the most neglected patients suffering from diseases such as sleeping sickness (or human African trypanosomiasis), leishmaniasis, Chagas disease, malaria, specific filarial diseases, and paediatric HIV.

The initiative's primary objective is to deliver 11 to 13 new treatments by 2018 and to establish a strong R&D portfolio for these diseases.

CONTENTS

2013 ANNUAL REPORT

THE YEAR 2013 MARKED THE 10-YEAR ANNIVERSARY OF DND*i*...

Dr Bernard Pécoul
Executive Director

Prof. Marcel Tanner
Chair of the Board
of Directors

...and provided us the opportunity to reflect not only on our own work, achievements, and lessons learned, but also on the broader landscape of research and development (R&D) for neglected diseases and how it has evolved since DND*i* was launched. It was also an opportunity to reinforce the voices and perspectives from the disease-endemic regions where DND*i* is rooted, and to open our debates to questioning the future orientations of the organization.

The momentum today is a sign of advancement and engagement

One of the most striking outcomes of the 10-year reflection is that, while DND*i* was established in what was a neglected disease R&D vacuum, we are now in a true landscape, with many initiatives and actors engaging in one way or another, albeit not yet in a coordinated manner. While admittedly this lanscape is fragmented and even fragile in many ways, there is no doubt that the momentum today is a sign of advancement and engagement. But global progress has taken time to bear fruit. A recent analysis of the R&D pipeline for neglected diseases showed that the past ten years have only seen a small increase in the percentage of drugs and vaccines approved for neglected diseases, but that this slight increase was primarily in repurposing or combining existing drugs – so-called incremental improvements.

Truly new drugs have not yet made their way to the end of the development pipeline. While short-term improvements have had a great impact, that of a new, simple oral treatment for a deadly disease such as sleeping sickness for example, would be enormous, and requires greater resources and commitment, especially when such tools are vital to supporting the control and elimination targets established by the WHO.

DND*i* started out as an experiment, and such experiments require innovation, risk taking, knowhow, anticipation, and solid partnerships. While the first decade of DND*i* has rendered important results – six treatments delivered and a robust

drug development pipeline established, with 12 new chemical entities (NCEs) in pre-clinical and clinical development – it has also provided some key lessons that we will endeavor to translate into the DND*i* of the next decade. To do this, we began by analysing the DND*i* model and what we consider the four key pillars of the organization:

- the patient needs' driven approach must remain central to our priority setting and decision making processes;
- a commitment to sharing knowledge and an access-oriented intellectual property policy are vital in a field where R&D incentive is lacking;
- diversifying and balancing funding sources ensures scientific independence; and
- innovative partnerships are crucial.

Sustainability is the fundamental issue

DND*i* conducted this analysis in order to inform all stakeholders, partners, and donors who share DND*i*'s vision and mission of the necessity of establishing a more sustainable framework for neglected disease R&D.

Sustainability is the fundamental issue. For example, sustaining and increasing funding is more important than ever as new chemical entities are reaching clinical trial phases, typically the most costly part of drug development. New incentives, new funding sources and mechanisms, including those that pool funding sources together to specifically target priority R&D, are essential. The financial fragility of many organizations is a constant threat to many crucial projects and is a disincentive to enter into – and stay in – the field. Another example concerns regulatory capacities in developing countries. In addressing developing countries' health needs, many argue that stringent regulatory authorities are the only qualified institutions to evaluate medicines. However, only endemic countries themselves can assess the risks and benefits of health products for the diseases affecting their own populations. It is thus of paramount importance that the regulatory capacities of these countries be strengthened, and regional harmonization – where appropriate – be supported in the long term.

The DND*i* model, while just one example, has experimented with new ways of partnering and conducting R&D for neglected diseases. By expanding on its own lessons learned after ten years, and as part of a global process of WHO member states

> DND*i* STARTED OUT AS AN EXPERIMENT, AND REQUIRES INNOVATION, RISK TAKING, KNOWHOW, ANTICIPATION, AND SOLID PARTNERSHIPS

to move towards a global framework for the financing and coordination of R&D for the priority health needs of developing countries, DND*i* proposed projects aimed at demonstrating the principles laid forth by the WHO Consultative Expert Working Group (CEWG). 'The Visceral Leishmaniasis Global R&D and Access Initiative' was selected. It aims to demonstrate that coordination, transparency, capacity building, and innovative research and financing incentives can truly and effectively boost development and delivery of treatments for patients in need, and will ensure that the cost of treatments is not linked to the investment made in their development.

Learn from all innovative approaches to ensure translation into an effective framework

This process holds the promise of ensuring that needs, and not markets, will drive the development and delivery of essential health tools to those in need of them. But we will have to humbly learn and apply the lessons from DND*i* and other experimental approaches to ensure translation into an effective framework, based on open models of innovation and access. With 70% of the world's poor living in middle-income countries, the challenges of access to essential medicines need to be revisited and addressed in new ways.

DND*i* will continue to work to deliver on its mandate, and to ensure that the future direction of the organization is one that is rooted in the needs of neglected patients and the innovation they deserve, both in terms of science and in how we operate, as we gear up for the next exciting decade.

Dr Bernard Pécoul

Prof. Marcel Tanner

DND*i*'s is an alternative model to develop treatments for neglected diseases and ensure equitable access for all patients.

THE QUEST FOR A SIMPLE PILL IN A PATIENT'S HAND

DND*i* clinical trial expertise has been developed across several diseases and over several continents. Today, clinical activities include more early phase trials to test entirely new drugs.

Since 2003, DND*i* has developed clinical trial expertise across several disease areas and several continents. The regional disease-specific clinical research platforms it has supported and many other partners worldwide have together conducted 25 clinical studies in five disease areas so far, including malaria, visceral leishmaniasis (or kala-azar), cutaneous leishmaniasis, sleeping sickness, Chagas disease, and paediatric HIV. At any given time, some 10 clinical trials are simultaneously ongoing. Testing treatments at all stages of the drug development pipeline, from screening molecules to large-scale implementation studies in developing countries, has been a true experiment in innovative partnership.

A ten-year perspective on clinical trials in neglected disease endemic areas

Over a decade, and as investment made in both short- and long-term drug development approaches begins to bear fruit, DND*i*'s clinical trials have somewhat shifted from being essentially later phase trials using existing drugs, to include more early phase trials testing entirely new drugs as well.

A decade of conducting trials in patients in endemic areas – in what is, in some cases, considered the most challenging of clinical research environments – has reinforced several strategic decisions taken by the organization, notably in terms of the mix of public and private partners, endemic country embedment, capacity building as part and parcel of clinical research, short- and long-term approaches to drug development, and the strong commitment to patient access to treatments delivered.

Regional rooting has been key

DND*i*'s founding partners in endemic countries set the tone for a regionally embedded model for neglected disease R&D, and thus the setting-up of regional offices and regional disease-specific clinical research platforms (see page 45) were quick to follow the foundation of DND*i*. Today, there are fully developed clinical research projects running in Asia, Africa, and Latin America. The latter has also begun to develop early-stage research capacities in the field (see LOLA, page 16) of neglected diseases, a first for DND*i*. But before reaching the clinical research phase, proactive acquisition and investigation of compounds up to testing in healthy volunteers is conducted with a network of pharmaceutical, biotechnology, academic, and other research organizations worldwide, to ensure that the best compounds can reach clinical development.

Only regional investigators and medical field-oriented organizations have the expertise to contribute to clinical development in the field conditions in which DND*i*'s target diseases are most prevalent. For example, in 2013, a Phase II, double-blind, randomized, controlled trial evaluating the safety and efficacy of the oral drug candidate E1224 against Chagas disease was completed, and provided key data that will drive the future research agenda for new treatment regimens. It was the first ever such trial conducted in Bolivia, and proved that it is possible to strengthen research capacity and conduct an international standard clinical trial in a resource-limited, developing-country setting. The capacity built with this trial is now in place, and – as with such DND*i*-sponsored trials around the world – will be brought to bear on future clinical research in these countries.

Clinical trials have direct impact

Clinical research also goes hand in hand with control and elimination strategies in many cases – the studies currently being undertaken for sleeping sickness in the Democratic Republic of the Congo, for example, are contributing to the treatment of patients both inside and outside of the trial, and have built capacity in the detection and treatment of the disease overall. In this way, the reach and impact of clinical research can go beyond just the delivery of a health tool. To date, over 33,000 patients have been enrolled in clinical and pharmacovigilance studies in or directly linked to DND*i* projects.

Because the clinical sites are often in remote areas, DND*i* is committed to supporting improvements in clinical research infrastructure – including solar panels, laboratory equipment, waste management systems, internet connectivity, and other renovations so that patients can access clinical trial facilities as close as possible to where they live. These clinical research capacities in remote settings have resulted in increased numbers of patients who access treatments: a total of 7,700 patients who could not be included in the trials due to strict inclusion criteria, received the best possible treatment for their disease as an indirect result of the trial. Extensive training on the conduct and ethics of clinical trials is given to medical staff through the clinical research platforms.

All DND*i*-sponsored trials comply with international ethical and quality standards and are conducted in neglected disease-endemic regions (except for Phase I studies) in collaboration with local partners, as well as with support from international groups such as MSF.

Increasing patient access to essential medicines

Clinical research also has a very important role to play in helping countries to adapt policies and thus to increasing patient access to essential medicines. Large-scale implementation studies, such as that conducted for ASAQ fixed-dose treatment against malaria and the current study for kala-azar treatments in India, are key to supporting national policy changes necessary to ensuring that the right treat-

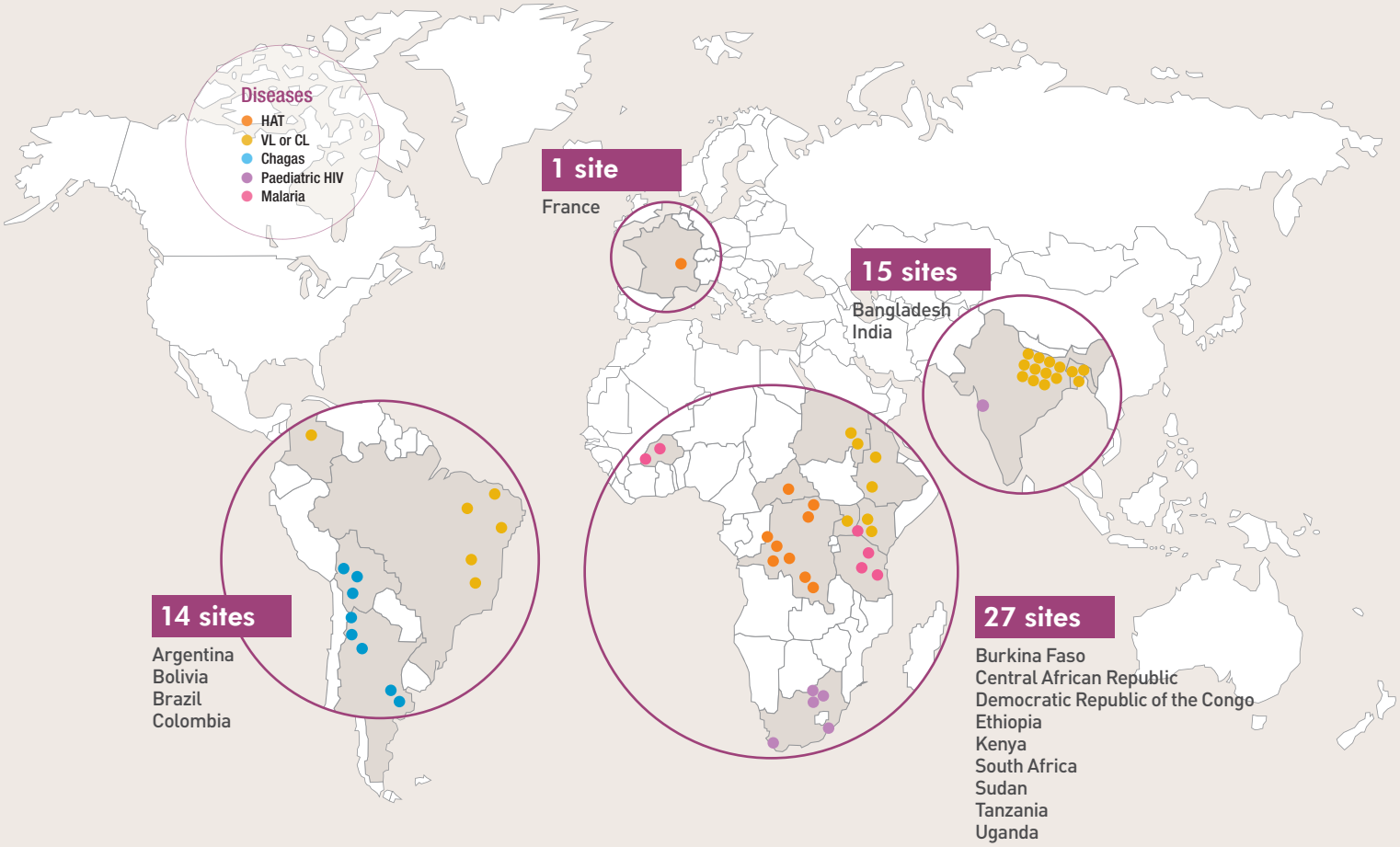
Patients treated in clinical trials to date

- → **Over 3,000 patients** included in kala-azar clinical trials
- → **2,000 included** in a kala-azar pharmacovigilance study for SSG&PM
- → **Over 1,000 patients** were enrolled in sleeping sickness studies
- → **Some 500 patients treated** in Chagas disease studies
- → **Nearly 4,000 patients** included in malaria studies
- → **23,000 patients** in a large pharmacovigilance study for malaria in Brazil
- → **80 patients enrolled** in cutaneous leishmaniasis studies

ments are reaching the patients in need. It should be said, however, that clinical research alone does not constitute a sustainable model of R&D for neglected diseases.

Sustainable financing, enabling international policy frameworks, strengthening of regulatory capacities and priority setting by disease-endemic countries, health system strengthening, technology transfer for sustainable drug production, demand forecasting and procurement processes, to name but a few, are all part of a larger scope of issues that are required to ensure that a treatment is accessible, even when clinical development has delivered a safe, efficacious, and available treatment. DND*i* has learned over the past decade that no one actor alone can ensure patient access to the best possible treatment.

DND*i* clinical activities in 2013: 57 sites on 4 continents, for 5 disease areas



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(Permanent Observer)
Special Programme for Research and Training in Tropical Diseases (WHO-TDR), Switzerland

- Position currently vacant
  Kenya Medical Research Institute (KEMRI)
- Position currently vacant
  Indian Council of Medical Research (ICMR)

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Muriel Vray, Institut Pasteur, France

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Rowan Gillies, former President, MSF International Council, Australia

Lalit Kant, Deputy Director, Immunization, Bill & Melinda Gates Foundation, and former representative, Board, Indian Council of Medical Research (ICMR), India

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Eloan dos Santos, former Executive Director, Farmanguinhos, Brazil

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Vacant, Vice-president

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Marcus Manduca, PricewaterhouseCoopers

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Fumiko Hirabayashi, Drugs for Neglected Diseases *initiative* (DND*i*), Japan

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DND*i* Headquarters, Geneva

Bernard Pécoul, Executive Director
Graeme Bilbe, Research & Development Director
(in alphabetical order)
Jean-François Alesandrini, Fundraising, Communication & Advocacy Director
Ralf de Coulon, Finance, Human Resources & Administration Director (until Sept. 2013)
Robert Don, Discovery & Pre-clinical Director
Jean-Pierre Paccaud, Business Development Director
Thomas Saugnac, Operations Director
Nathalie Strub Wourgaft, Medical Director
Laurence Vielfaure, Finance & Planning Director (as of Jan. 2014)

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Bhawna Sharma, Director, Research and Development Operations, India
Eric Stobbaerts, Director of Regional Office, Brazil
Monique Wasunna, Director of Regional Office, Kenya

DND*i* Team Worldwide

• Headquarters

Jorge Alvar; Fabiana Alves; Byron Arana; Clélia Bardonneau; Hana Bilak (until June 2013); Séverine Blesson; Raphaël Bonacchi; Pascale Boulet (until July 2013); Phouttasone Bouppha; Stéphanie Braillard; Thi Hanh Cao; Gwenaëlle Carn; Pascal Carpentier (as of Feb. 2014); Eric Chatelain; Christine Crettenand; Brigitte Crotty; Violaine Dällenbach; Sophie Delhomme; Graciela Diap; Sally Ellis (until Aug. 2013); Julia Fährmann; Anna FitzGerald; Caroline Gaere Gardaz; Emilie Guttierrez (as of Jan. 2014); Alexandra Heumber; Nina Holzhauer; Jean-Robert Ioset; Michèle Joanisse; Dominique Junod-Moser; Jean-René Kiechel; Marc Lallemant; Gabrielle Landry Chappuis; Delphine Launay; Janice Lee; Sandrine Lo Iacono; Christophine Marty-Moreau; Janine Millier; Béatrice Mouton; Charles Mowbray; Nataliya Omelchuk; Claudia Pena Rossi (as of March 2014); Sophie Raffle; Sylvie Renaudin; Isabela Ribeiro; Stephen Robinson; Ivan Scandale; Rebecca Schmitt; François Simon (as of Feb. 2014); Olena Sushchenko; Antoine Tarral; Donia Tourki; Olaf Valverde; Susan Wells.

• Regional Offices

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DRC
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ASIA

INDIA
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NORTH AMERICA

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Erin Conklin (until April 2013); Jennifer Duran; Richard Feiner; Robert Grembowitz; Jennifer Katz; Oliver Yun.

SUSTAINED GROWTH IN REGIONAL OFFICES AND

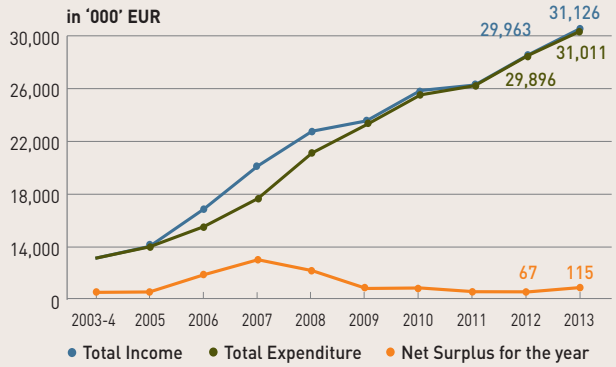
Stable increase in expenditure

DND*i* expenditure totals **EUR 181 million since its inception in 2003. In 2013**, expenditure amounted to **EUR 31 million**, +4% as compared to 2012. This relative stability is mainly due to a contingency plan implemented mid-year 2013 as key funding decisions were delayed between April and August 2013. Full portfolio activity resumed in Q3 2013. The operating gain of EUR 0.231 million is partly cancelled because of exchange rate loss (EUR 0.116).

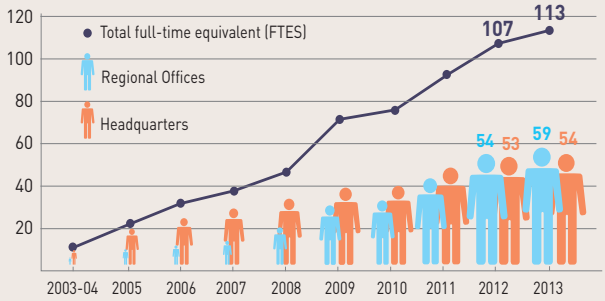
113 FTEs worldwide, the majority in Regional Offices

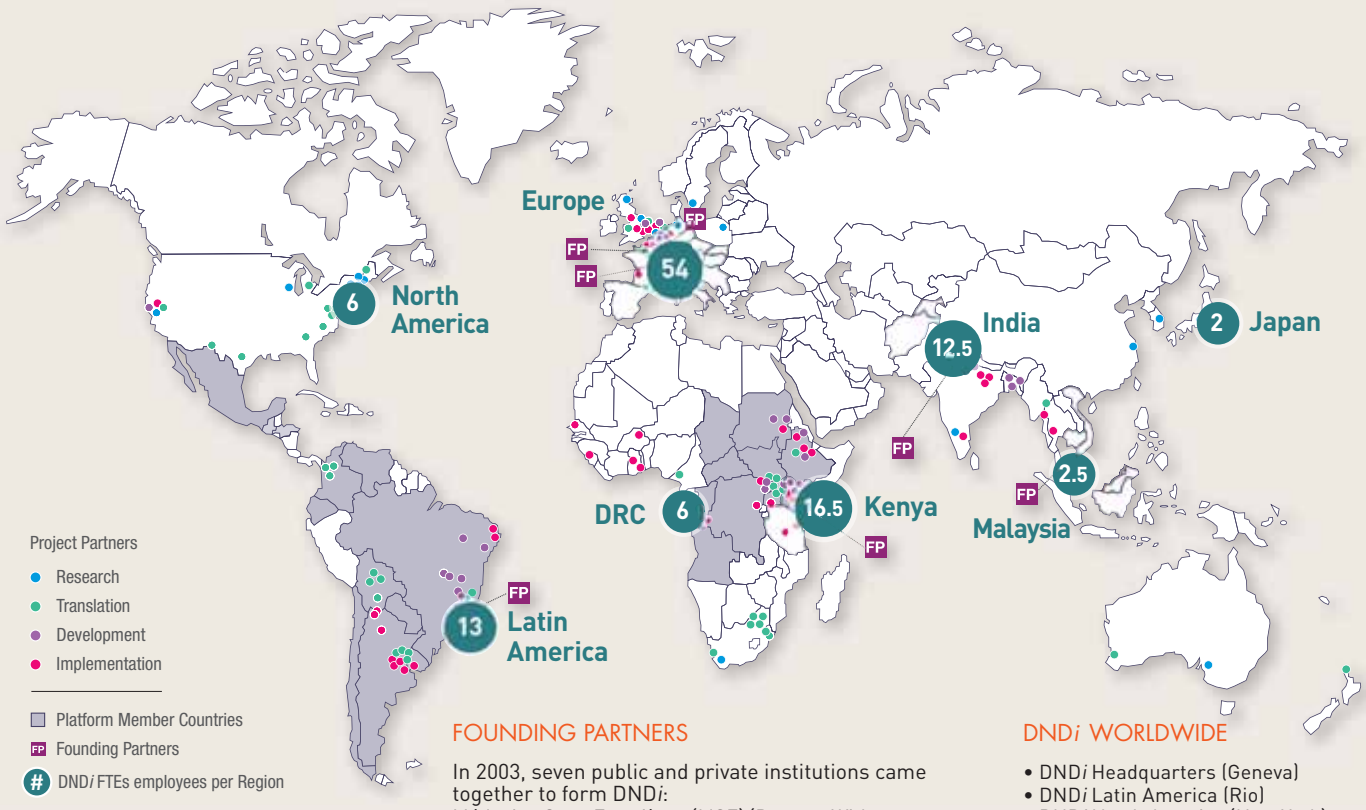
In 2013, DND*i* recruited an additional 6 FTEs (+18 FTEs in 2012), mainly in Regional Offices (ROs): +5 FTEs in Nairobi, New Delhi, Kinshasa, New York, and Rio de Janeiro (+9%) and +1 FTE at Headquarters in Geneva (+2%). This trend towards greater growth in regions, underway since 2012, reached new levels in 2013: Regional Office staff (52%) is higher than Headquarter staff (48%), in accordance with the Business Plan 2011-2018.

STATEMENT OF ACTIVITIES 2003-2013



HUMAN RESOURCES EVOLUTION 2004-2013





FOUNDING PARTNERS

In 2003, seven public and private institutions came together to form DND*i*:
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

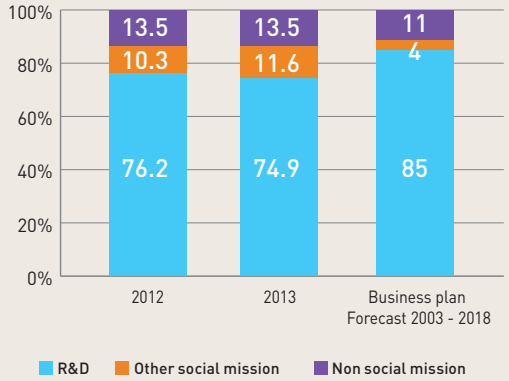
- DND*i* Headquarters (Geneva)
- DND*i* Latin America (Rio)
- DND*i* North America (New York)
- DND*i* Africa (Nairobi)
- DND*i* India (Delhi)
- DND*i* Malaysia (Penang)
- DND*i* Japan (Tokyo)
- DND*i* in DRC (Kinshasa)

2013 KEY FINANCIAL PERFORMANCE INDICATORS

INCREASING DIVERSITY OF PARTNERSHIPS

On track towards Business Plan targets

2013 SOCIAL MISSION BREAKDOWN: 86.5% OF EXPENDITURE



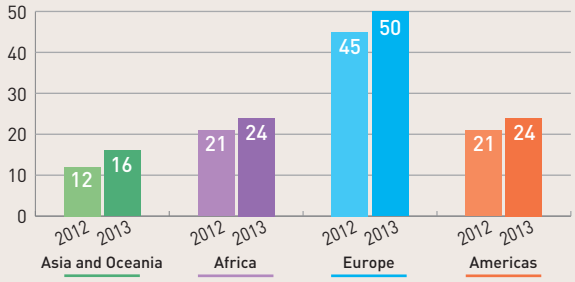
In 2013, DND*i*'s non-social mission ratio remained stable, as the same level of management and fundraising expenditure was maintained from 2012.

Other social mission ratio (including capacity strengthening and advocacy activities) increased significantly in 2013 (from 10.3% in 2012 to 11.6% in 2013) mainly due to DND*i*'s 10-year anniversary activities and events in Nairobi and Paris (events and publication budgets increased by 58% in 2013 compared to 2012). In addition, the involvement of Regional Offices (ROs) in Kenya, Brazil, and North America in advocacy and communication activities increased in 2013 (+48%). Two ROs were strengthened in 2013: the India office moved to a new and bigger office and the Kenya office increased general activities (international conferences, training, travel, meetings).

The increase of other social mission ratio (+1.3%) compensated the decrease of the R&D ratio (-1.3%).

Partnerships in endemic regions increase to support clinical activities

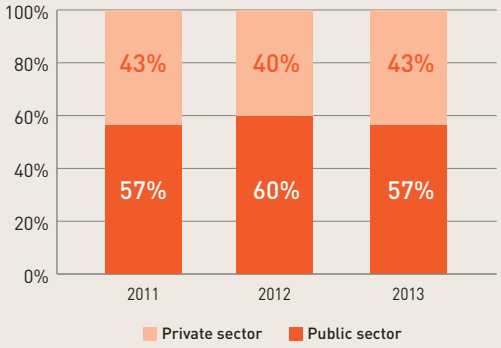
MAIN R&D PARTNERS AND SERVICE PROVIDERS PER CONTINENT with financial compensation over EUR 5,000



In 2013, the number of partners and service providers with which DND*i* had business relations valued at over EUR 5,000 increased by 15% (114 in 2013 as compared to 99 in 2012). The main increase is in Asia (+33%; 16 partners in 2013 compared to 12 partners in 2012), reflecting growth of the India implementation study (Bihar State support, partners for logistical support). In Africa, the increase reflects additional sites for the HAT fexinidazole study in DRC. In the Americas, the increase is due to the new clinical study for CL, and in Europe it is due to project progression such as that for filaria, paediatric HIV, and preparations for new VL combinations.

Stable public-private ratio among DND*i*'s partners and service providers

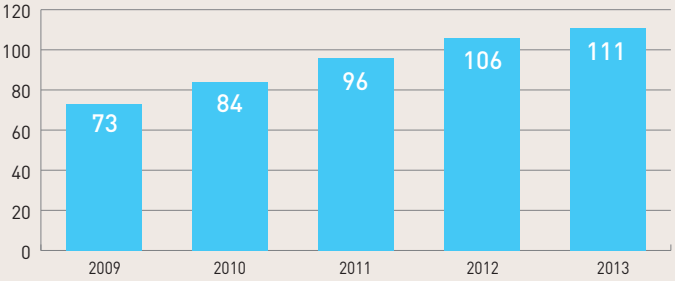
EVOLUTION OF NUMBER OF PARTNERS AND SERVICE PROVIDERS with financial compensation over EUR 5,000



Comparison of the public institutional sector (research institutes, public hospitals, academic groups, universities, PDPs, and other not-for-profit organizations) and the private sector (pharmaceutical and biotechnology companies and contract research organizations (CROs)).

Steady growth in number of partnerships

NUMBER OF CONTRACTS SIGNED ANNUALLY*



** Except confidentiality agreements*

The evolution of contracts finalized annually follows a trend similar to that of R&D Partners & Service Providers with a financial compensation of over EUR 5,000. There is a regular annual increase between 5% and 15%, with 5% in 2013.