



## THE CURRENT DRUG PIPELINE FOR NID<sub>s</sub> IN AFRICA FOCUS ON DNDI'S PORTFOLIO



### **EDCTP Stakeholder Meeting on Neglected Infectious Diseases**

27-28 June 2013  
Ministry of Foreign Affairs (MOFA)  
Bezuidenhoutseweg 67, The Hague, the Netherlands

**DNDi**  
Drugs for Neglected Diseases *initiative*

# THANK YOU EDCTP-2 !



Starting with the end in mind ...

# Criteria for NTDs ...

- A proxy for poverty and disadvantage / Affect populations with low visibility and little political voice / Do not travel widely / Cause stigma and discrimination, especially of girls and women / Have an important impact on morbidity and mortality / Are relatively neglected by research / Can be controlled, prevented and possibly eliminated using effective and feasible tools

The screenshot shows the WHO website's page for 'Neglected tropical diseases'. The browser address bar indicates the URL is 'http://www.who.int/neglected\_diseases/disease'. The page features a navigation menu with links to 'Health topics', 'Data and statistics', 'Media centre', 'Publications', 'Countries', 'Programmes and projects', and 'About WHO'. A search bar is located below the navigation menu. The main content area is titled 'Neglected tropical diseases' and includes a list of 'The 17 neglected tropical diseases' with links to their respective pages. The diseases listed are: Buruli Ulcer (Mycobacterium ulcerans infection), Chagas disease, Dengue/Severe dengue, Dracunculiasis (guinea-worm disease), Echinococcosis, Foodborne trematodiasis, Human African trypanosomiasis (Sleeping sickness), Leishmaniasis, Leprosy, Lymphatic filariasis, Onchocerciasis (River blindness), Rabies, Schistosomiasis, Soil transmitted helminthiasis, Taeniasis/Cysticercosis, Trachoma, and Yaws (Endemic treponematoses). There is also a section for 'Other neglected conditions' including Podocniosis, Snakebite, and Strongyloidiasis. A sidebar on the right contains 'NTD in the news!' with two news items and a 'Contact' section for the Control of NTD. The footer of the page includes links to 'Help and Services', 'WHO Regional Offices', and 'Connect with WHO'.

Other definitions:  
Hotez et al,  
G-Finder, BVGH reports:

**Total 49 ... ?**

# Priority setting: unmet medical needs

- Defined at foundation – FDC for malaria
- Defined at foundation – kinetoplastids
  - ▣ HAT: safer treatment for HAT... later oral treatment for stage 2 and stage 1 that can be used at primary care level
  - ▣ Leishmaniases
    - Safer treatment for VL - oral treatment/combination for all regions and all age groups for VL
    - Later --- need to address HIV/VL, PKDL, asymptomatic patients
    - Later ... CL: topical/oral for L braziliensis and L tropica
  - ▣ Chagas: oral treatment for chronic indeterminate stage and pediatric dosage form
- Defined later and added as mini-portfolio:
  - ▣ Pediatric user-friendly ARV (PI) formulation
  - ▣ macrofilaricide

# DNDi Portfolio-Building Model:

Address Immediate Patient Needs & Deliver Innovative Medicines

- New chemical entities (NCEs)

**Long-term projects**

- New formulations (fixed-dose combinations)
- New indications of existing drugs

**Medium-term projects**

- Completing registration dossier
- Geographical extension

**Short-term projects**

**Discovery**

R

LS

LO

**Pre-clinical**

**Clinical**

**Implementation**

**DNDi**

Drugs for Neglected Diseases *initiative*

# Visceral Leishmaniasis - context

- ▣ 0,15-0,3 million annual incidence (VL).
- ▣ Six countries harbor 95% of 150,000-300,000 VL cases per year: (India, Bangladesh, Sudan, South Sudan, Ethiopia, Brazil)
- ▣ Anthrooponotic in Asia, Africa and zoonotic in America.

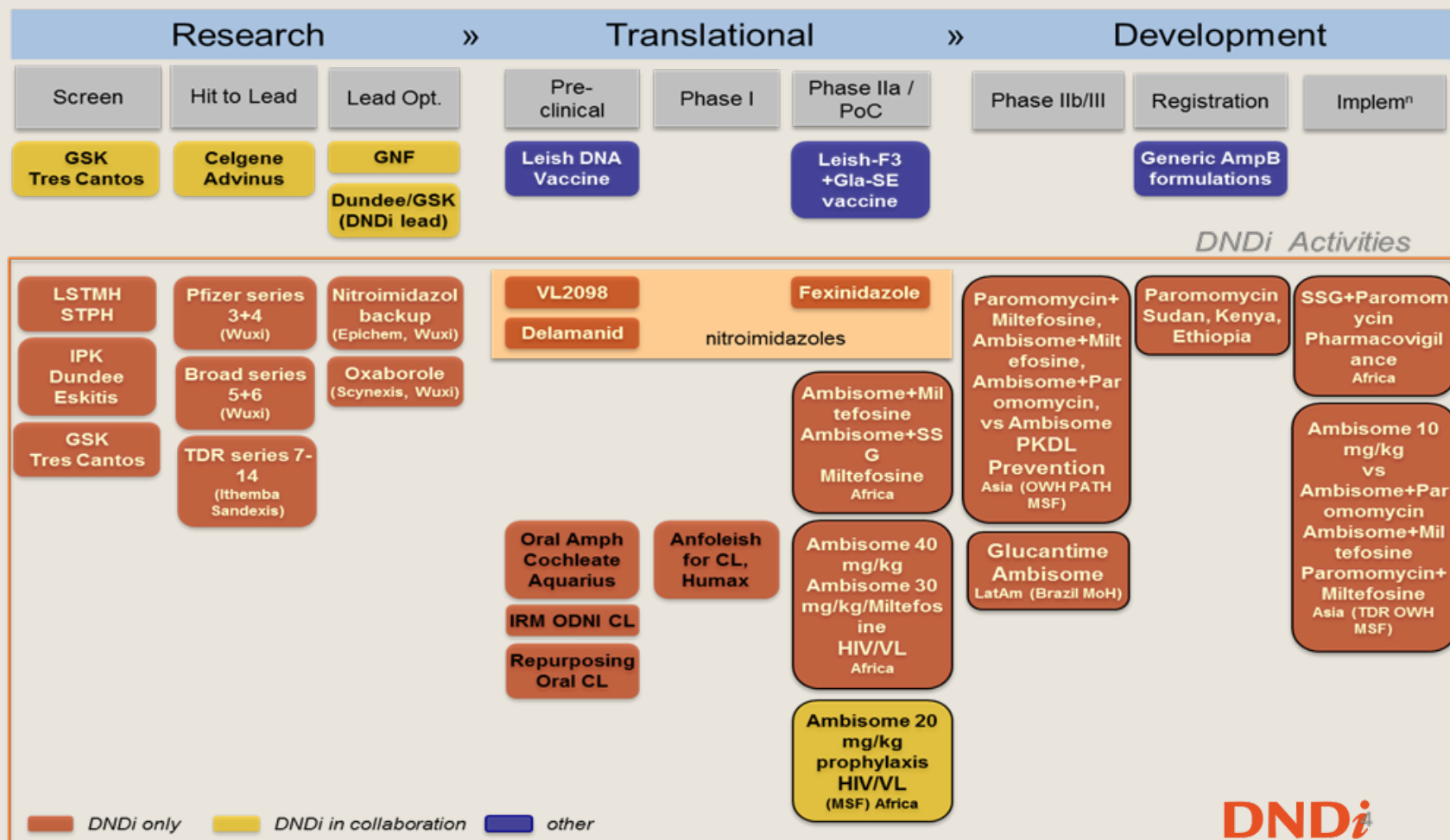
Interlinked contexts with poorly described infection sources driving disease manifestation and outbreaks on top of a complex nutritional and immune picture





# Leishmaniasis – R&D activities

## Leishmaniasis Landscape/DNDi Activities 2013



# Sleeping Sickness: From Unacceptable To Better, Towards Tools for Elimination



**10 years ago:**

Eflornithine

Melarsoprol

**Since 2009:**  
NECT

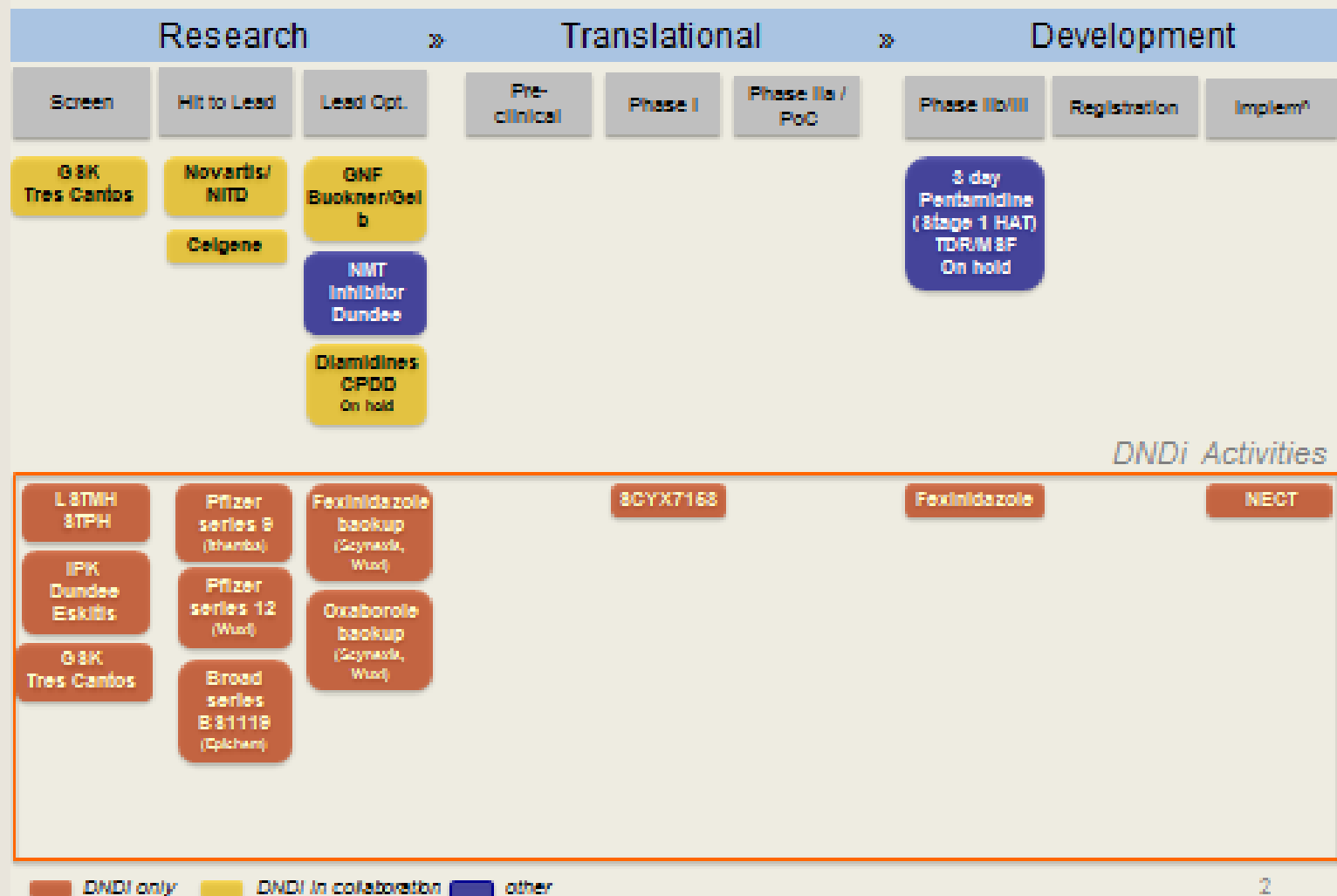
**2016?**

Oral treatment  
& rapid  
diagnostic test



# HAT R&D activities

## HAT Landscape/DNDi Activities 2013



# Filariasis: different needs for macrofilaricide

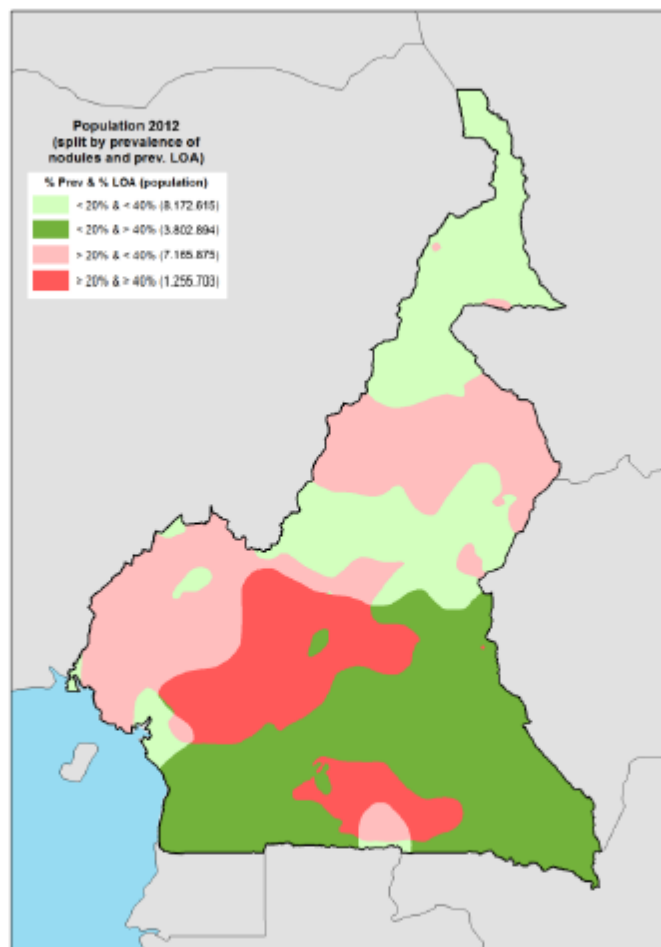


Figure 5. The map represents areas at high risk of suffering SAEs following ivermectin treatment (>40% *Loa loa* prevalence) and areas at low risk of suffering SAEs following ivermectin treatment (<40% *Loa loa* prevalence). The legend contains the total estimated number of people living in each area.

For example in oncho/*Loa* co-infection

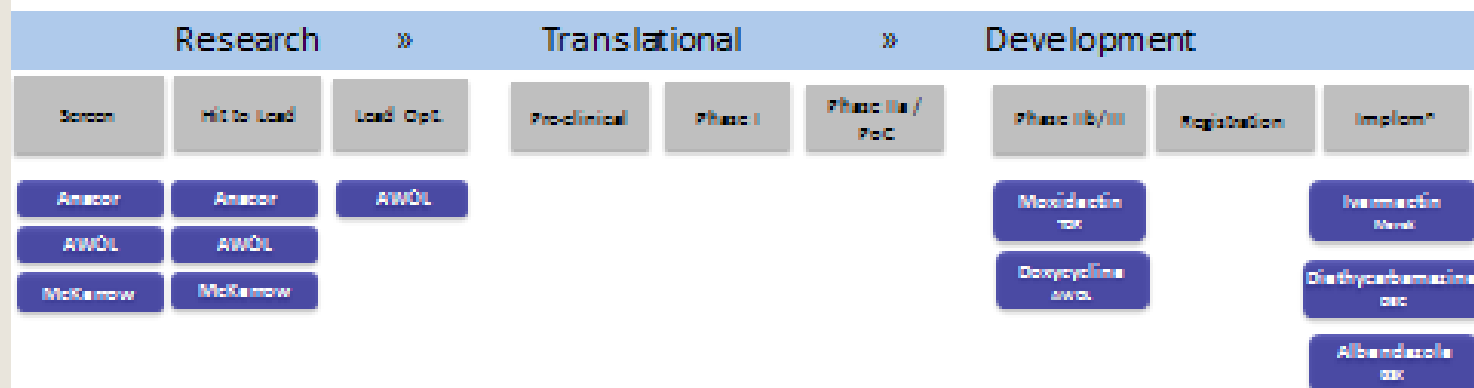


Table 2. Population living in hypo-endemic and the estimated number of people infected in 2012 considering the risk of suffering SAEs after ivermectin treatment.

| Area   | Population 2012 | Estimated number of people with onchocerciasis in 2012 |
|--|-----------------|--|
| Hypo-endemic areas at low risk of SAEs ( <i>Loa loa</i> prevalence < 40%)  | 8 172 615       | 655 945  |
| Hypo-endemic areas at high risk of SAEs ( <i>Loa loa</i> prevalence > 40%) | 3 802 894       | 305 226  |
| Total  | 11 975 509      | 961 171  |

# Filariasis R&D activities

## Filarial Diseases Landscape/DNDi Activities 2013

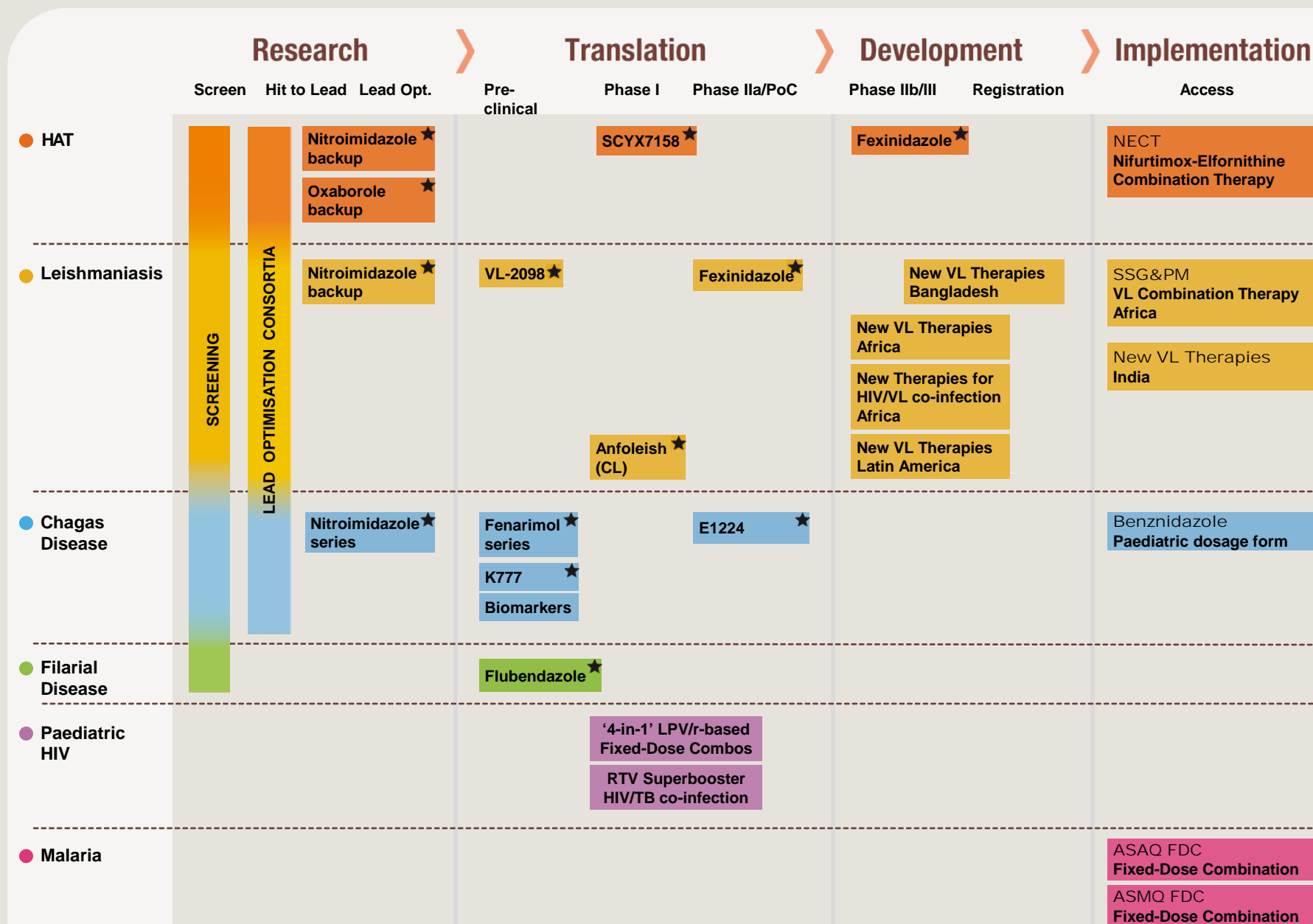


### DNDi Activities



■ DNDi only 
 ■ DNDi in collaboration 
 ■ other

# DNDi Portfolio June 2013



★ New Chemical Entity (NCE), Fexinidazole (for HAT and VL) = 1 NCE

# Transversal needs – points to consider

- ❑ Surrogate markers of efficacy
- ❑ Pediatric clinical development /studies
- ❑ Need for late stage / PV / field trials
- ❑ Utilise and strenghten existing research capacities / platforms
- ❑ Laboratory normal ranges ...

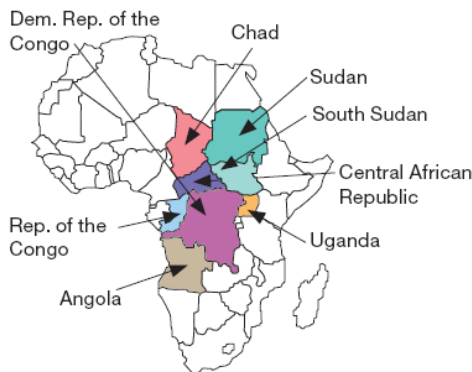
# 3 Clinical Platforms to Strengthen Research Capacities in Endemic Countries



VL



CHAGAS



## Major Role of Regional Disease Platforms

- ❑ Defining patients' needs and target product profile (TPP)
- ❑ Strengthening local capacities
- ❑ Conducting clinical trials in Good Clinical Practice (Phase II/III studies)
- ❑ Facilitating registration
- ❑ Accelerating implementation of new treatments (Phase IV & pharmacovigilance studies)

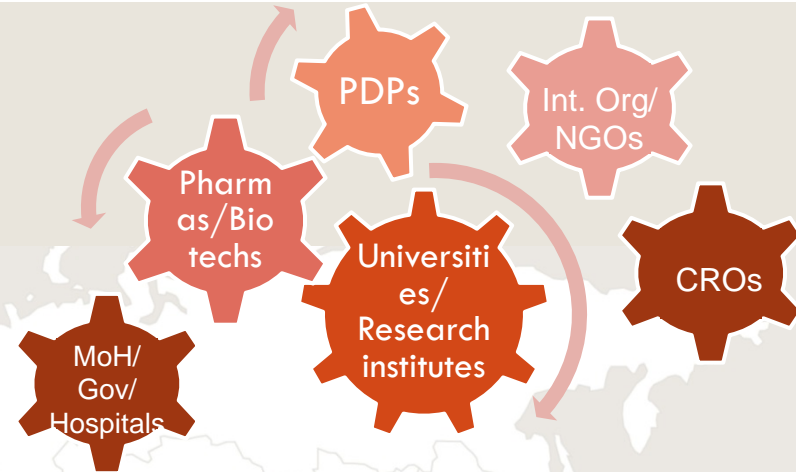


# Partnerships: No One Can Do It Alone

## A Global Network to Leverage Resources

### Criteria for Success:

- Share the same vision
- Mutual understanding
- Involvement throughout the whole process



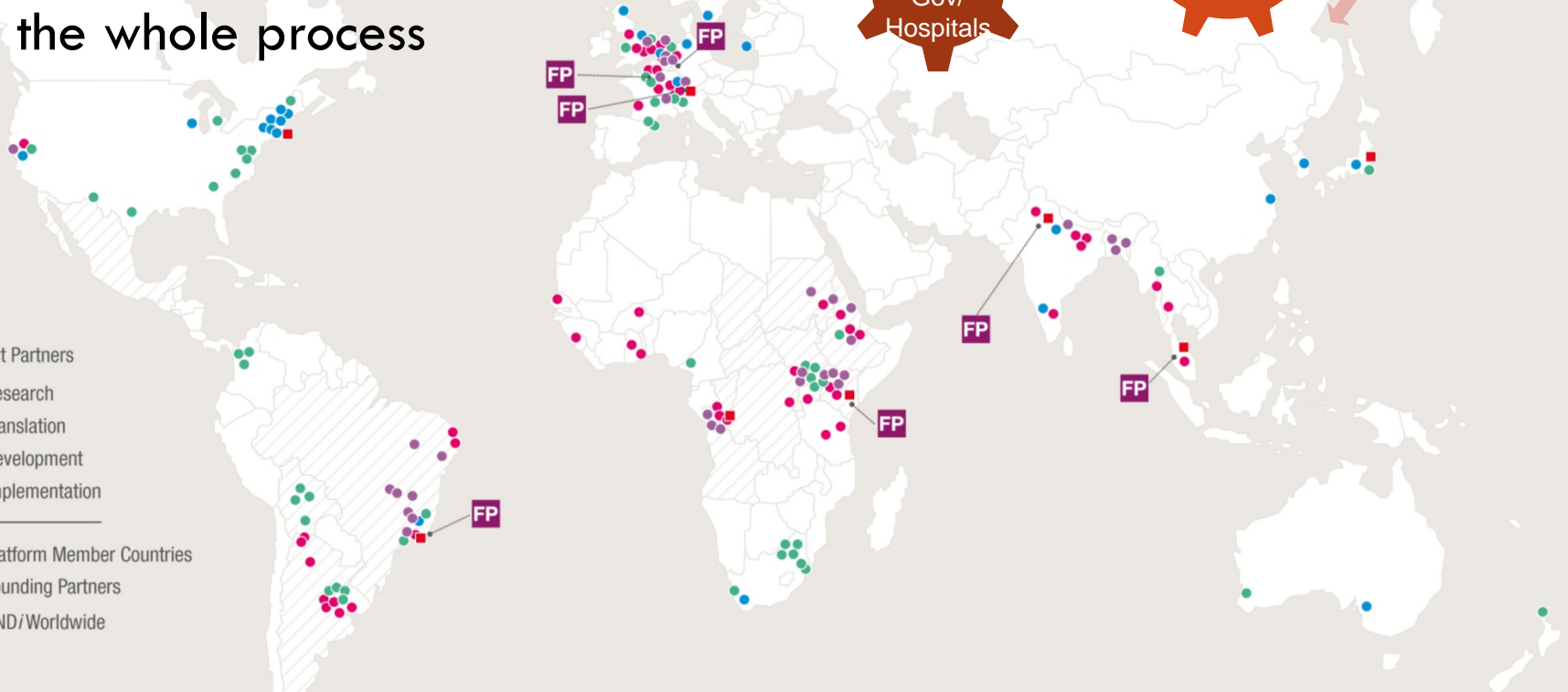
### Project Partners

- Research
- Translation
- Development
- Implementation

▨ Platform Member Countries

FP Founding Partners

■ DND/Worldwide



**Thank you**

