Linking Innovation and Access for Neglected Patients

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ASTMH Nairobi 9th February 2016

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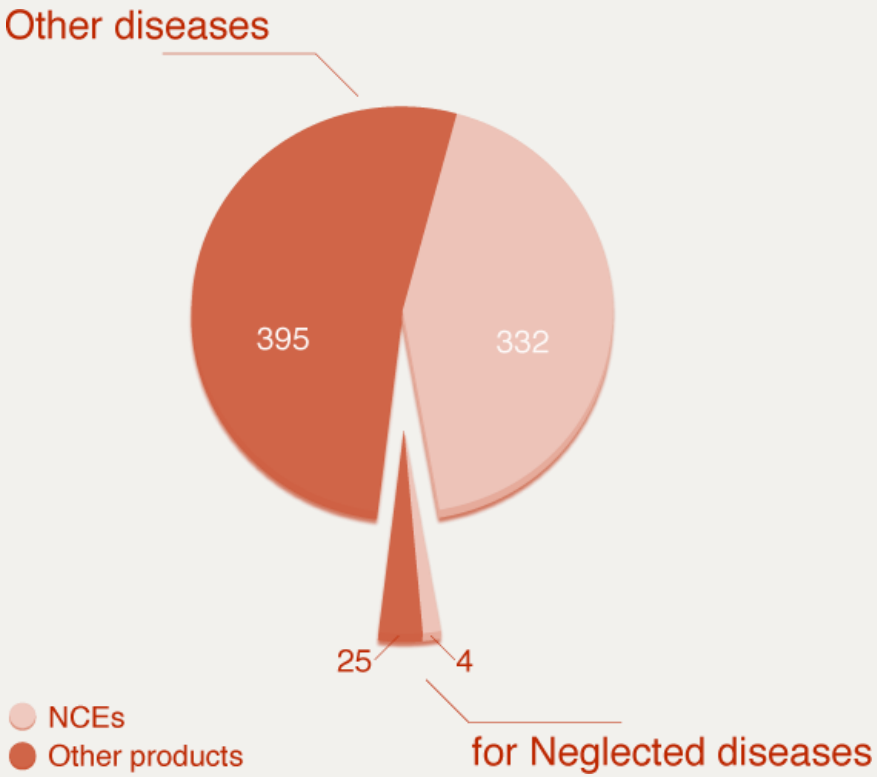
Drugs for Neglected Diseases *initiative*

Fatal imbalance still exists, an adapted R&D response is required

Among 756 products developed, only 4 NCE's for NTD's (excluding vaccines & biologicals) (2000-2011)*



=> Failure of the current biomedical research and development (R&D) system

* Source: Pedrique B et al. The drug and vaccine landscape for neglected diseases (2000-11): a systematic assessment. *Lancet Global Health*, Early Online Publication, 24 Oct 2013.

What has changed?

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Where are the gaps?

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What must we do ?

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The R&D landscape for neglected patients has changed but large gaps still remain

1. R&D priorities do not sufficiently originate from low- and middle-income countries

2. Patients' needs are not prioritized (e.g. Ebola, Zika, Mycetoma, etc.)

3. Innovation is not linked to equitable access even when there is commercial incentive to drive innovation (e.g. HCV)

4. Market incentives aligned with IP/exclusivity do not adequately address health needs in LMICs (e.g. AMR)

These are the fundamental challenges for the future of biomedical innovation.

DNDi's New Business Plan: to deliver 16 to 18 treatments by 2023

Influence the R&D landscape for neglected patients

- Political leadership for **needs-driven R&D**
- Creation of a **global fund and mechanism**
- Evidence on alternative **R&D models**

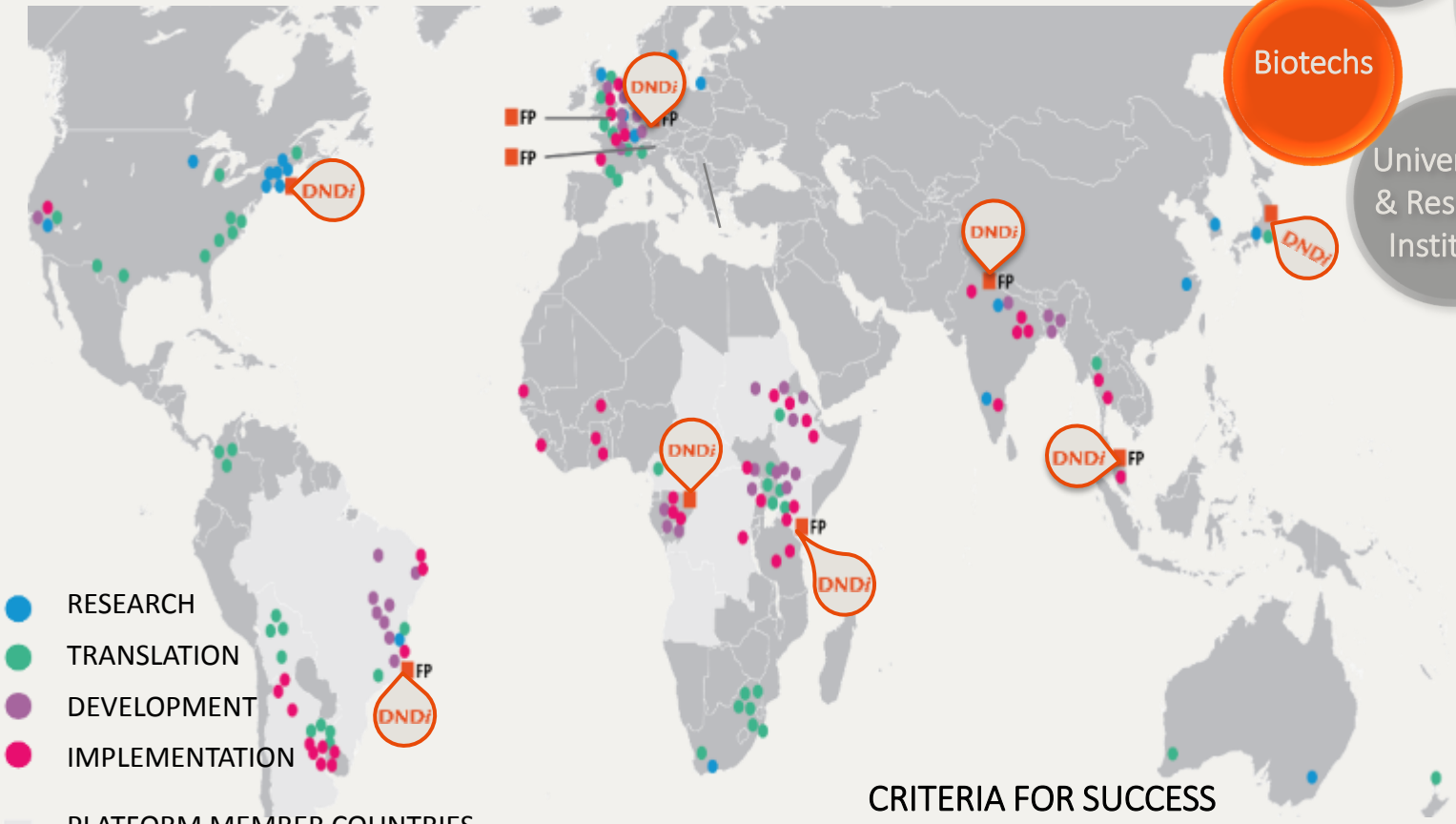
Develop treatments for people suffering from neglected diseases

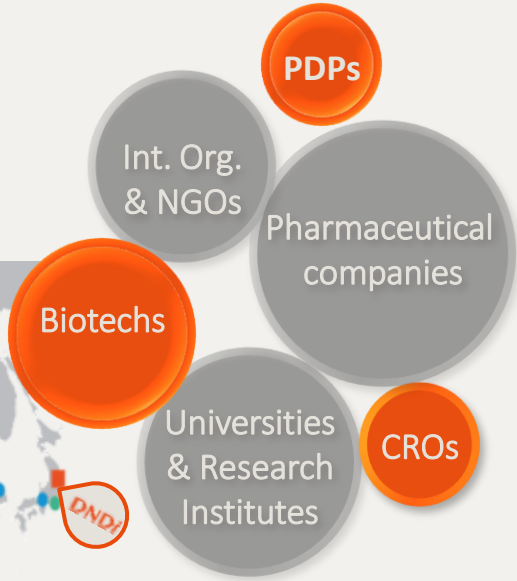
- Deliver 16-18 **treatments**
- **3 new chemical entities (NCEs)**
- ~10 disease areas
- **Focus on access and measure impact**

Strengthen research capacity, led by Regional Offices

- **R&D platforms** in disease-endemic countries
- **Regionally-driven** initiatives
- **Patient access** to treatments
- **Transfer of technology**

DND*i*'s success is only possible through innovative partnerships



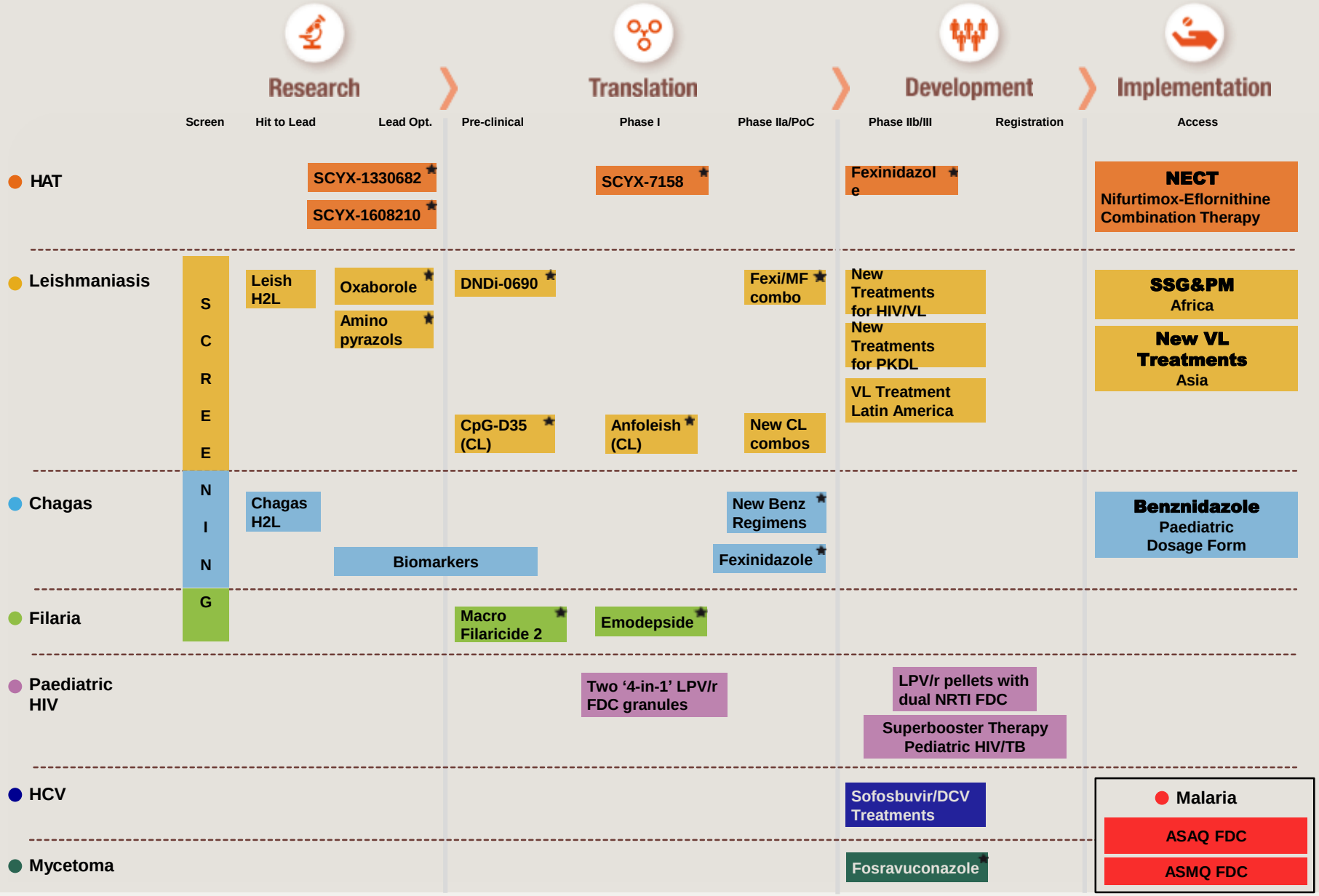


CRITERIA FOR SUCCESS

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

DND*i* Portfolio December 2015

6 new Treatments since 2003



New Chemical Entity (NCE); Fexinidazole (for HAT, VL, and Chagas disease) = 1 NCE

10 Years achievements: 6 New Treatments Developed

Malaria

ASAQ 2007

(Fixed-dose combination of artesunate + amodiaquine)

- Innovative partnership with Sanofi
- Simple regimen: 1 or 2 tablets once a day for 3 days
- Registered in 35 countries, of which 31 in Africa
- WHO prequalified
- WHO Essential Medicines List (adults and children)

320 million
treated in 31 African countries

Malaria

ASMQ 2008

(Fixed-dose combination of artesunate + mefloquine)

- Developed by DNDi and Farmanguinhos/Fiocruz, Brazil
- Simple and adapted regimen for children and adults
- Registered in Brazil (2008), India (2011), Malaysia and Myanmar (2012), Tanzania (2013), Vietnam and Niger (2014)
- South-South technology transfer from Farmanguinhos to Cipla, India
- WHO prequalified (Cipla)
- WHO Essential Medicines List (adults and children)

1.2 million
treated in Latin America and Asia

Sleeping Sickness

NECT 2009

(Nifurtimox-eflornithine combination therapy)

- Partnership between DNDi, MSF, governments, pharmaceutical companies, and WHO
- Approximately 96% of all stage 2 sleeping sickness patients in endemic countries treated with NECT (2013)
- WHO Essential Medicines List (adults and children)
- On essential medicines lists of 12 African countries (covering 98% of reported cases)

13,000
treatments in Africa

Visceral Leishmaniasis

SSG&PM 2010

(Sodium stibogluconate & paromomycin combination therapy)

- Partnership between DNDi, 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 (2010)
- National VL guidelines of Sudan, South Sudan, Kenya, and Ethiopia
- Paromomycin registered in Uganda (2011), in Kenya (2013), and underway in other East African countries

25,000
treated in East Africa

Visceral Leishmaniasis

NEW VL treatments in India 2011

(SD AmBisome® / PM+M / M+A®)

- Large-scale implementation programme with health authorities at state, national, and regional levels
- High efficacy and good safety profiles
- Field-adapted
- Recommended by the WHO Expert Committee on the Control of Leishmaniases (2010)

SD AmBisome® and PM+M
recommended
in revised Indian VL elimination roadmap

Chagas Disease

Benznidazole 12.5 mg 2011

(Paediatric dosage form of benznidazole)

- Partnership with LAFEPE, Brazil
- Age-adapted, easy-to-use, and affordable treatment
- Easily dispersible tablet for children under 2 years of age
- Registered in Brazil in 2011
- WHO Essential Medicines List
- Agreement with Mundo Sano Foundation for second source (2013)

Only child-adapted
dosage form

HAT

A Key Role for Regional Disease Platforms

Defining patient needs and Target Product Profile (TPP)

Strengthening local capacities

Conducting clinical trials (Phase II/III studies)

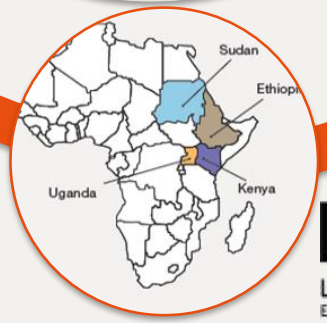
Facilitating Registration of new therapies

Accelerating implementation of new therapies, ensure therapies reach patients

LEISHMANIASIS

redLEISH

CHAGAS

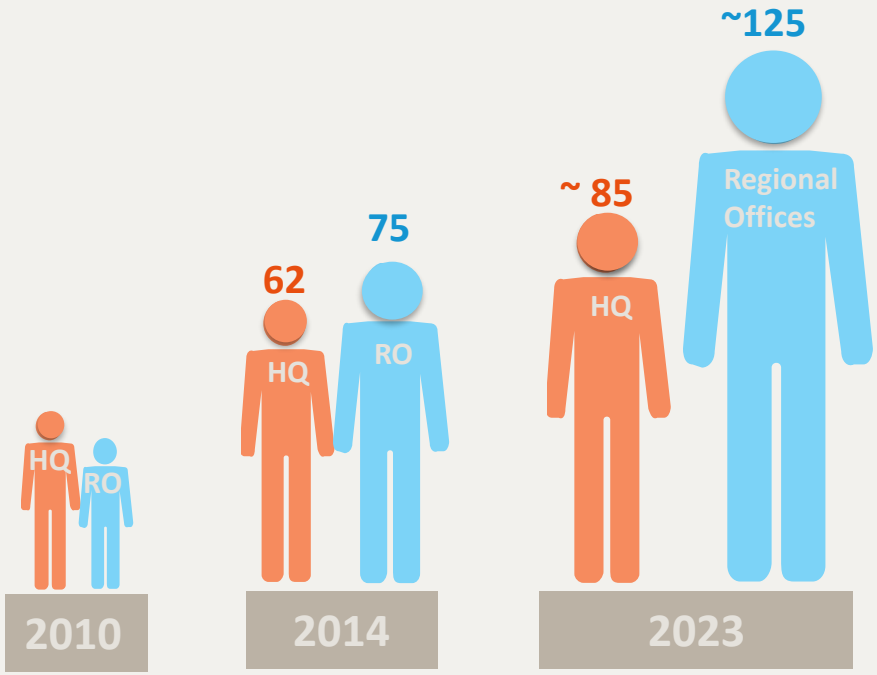


LEAP
LEISHMANIASIS
EAST AFRICA PLATFORM

LEISHMANIASIS

People behind the work… in proximity to patients

Partnerships are critical to access – DNDi continues to play a facilitating role



x 4

DND*i* staff

Partner staff

Teams in Asia

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Teams in Africa

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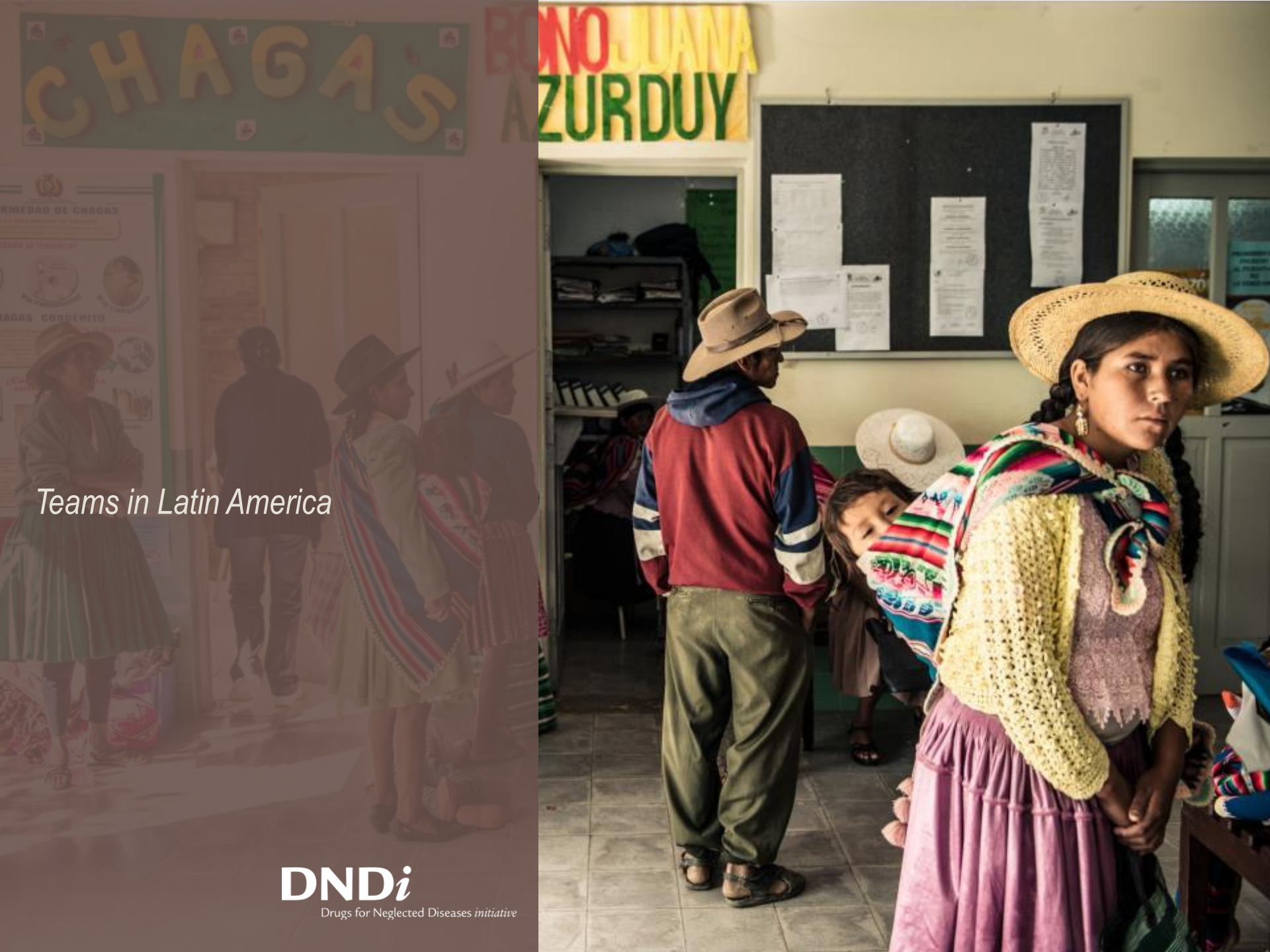

Teams in Latin America

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Our concern for Access:
Keeping Patients at the Core of Innovation

Serafino Moreno

Colombian miner

Access at DNDi has taken many shapes and formats over the years…

BP 2011-2018 objectives

Access Policy ✓

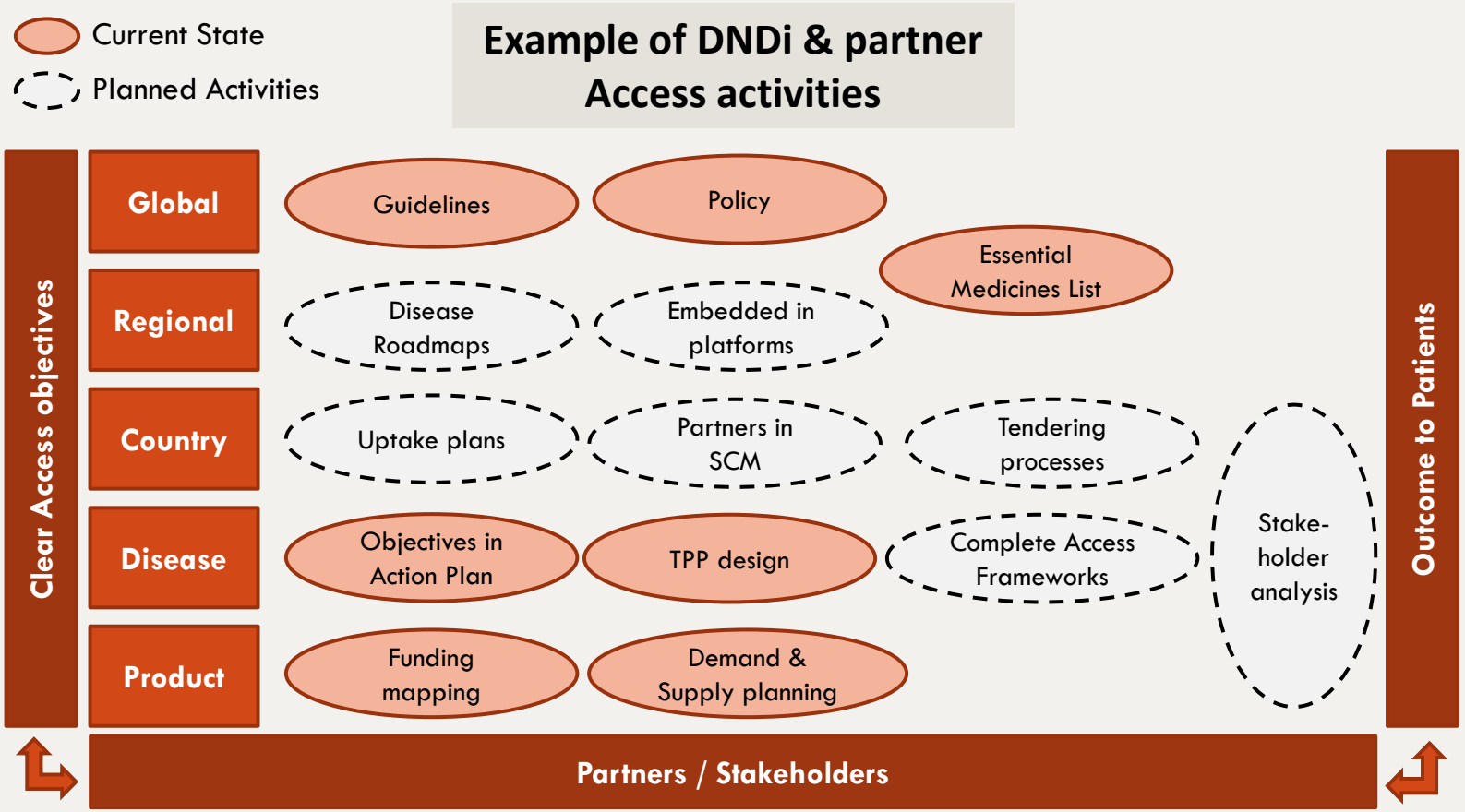
Guiding Principles ✓

BP 2011-2018 objectives ✓

Access Objectives

- Facilitate maximum impact via appropriate use of treatments
- Assure effective transition of treatments to relevant access partners and implementers, including national control programs, WHO and NGOs
- Further demonstrate success to support the DNDi model
- Target disease control strategies

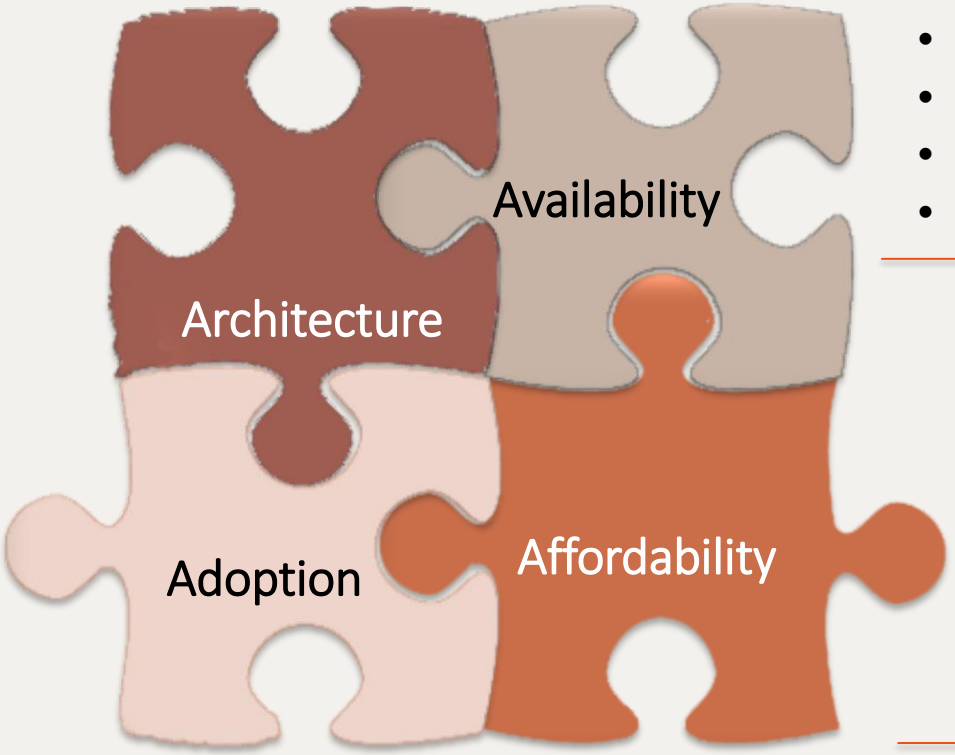
Linking Innovation with Access is difficult and requires many stakeholders working on collective activities



Some activities have been completed for certain disease areas. DNDi will create a more systematic approach to ensure Access at multiple levels across the organization

Access Framework*

Availability
- Regulatory
- Manufacturing
- Forecasting
- Procurement
- Distribution
- Delivery



Adoption
- Global
- National
- Provider
- Patient

Affordability
- Government
- NGO
- Patient

* Source: *Laura J. Frost & Michael R. Reich*. **ACCESS How do good healthtechnologies get to poor people in poor countries?** Published by the Harvard Center for Population and Development Studies. 2008.

The example of Chagas Disease in Latin America

Its impact

Approximately **5.7 million** infected
10,000 deaths per year
528,000 DALYs

In Brazil alone, losses of over US$ **1.3 billion** in wages and industrial productivity were due to workers with Chagas disease

Endemic in 21 countries in Latin America, Chagas kills more people in the region than any other parasite-born disease, including malaria. Patient numbers are growing in, developed countries

Two old treatments available- Few Health Technologies
Only **1% are currently under treatment-** No access

Amazonas, Brazil
João Roberto Ripper, 2010

The example of Chagas Disease in Latin America

Access Barriers: What we have achieved so far…

Connecting the dots: break the cycle of neglect

R&D

Health Market

MoHs

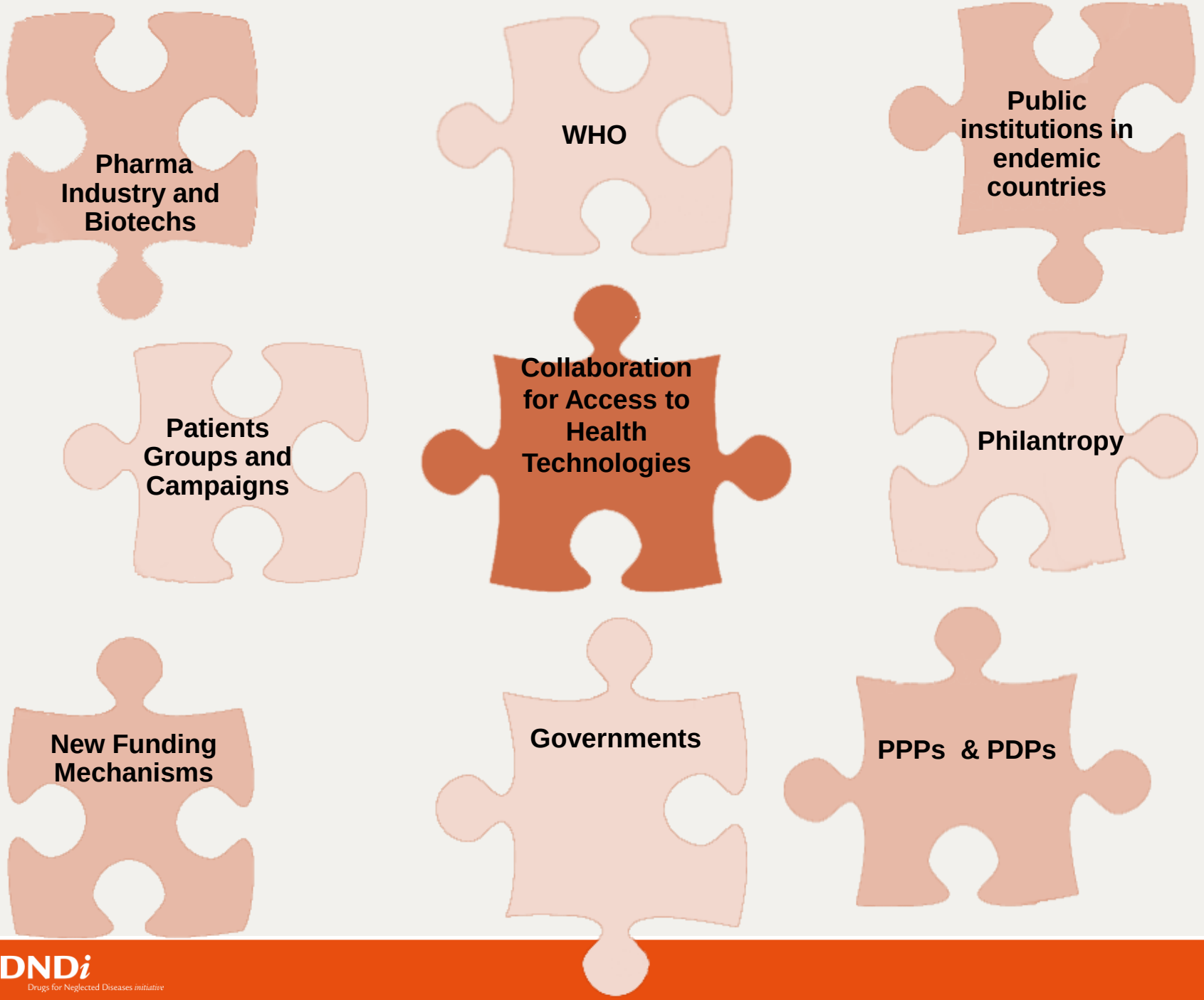
Doctors

Academia

Pharmas

Governments

Neglected cycle faced by Chagas patients


Pharma Industry and Biotechs
WHO
Public institutions in endemic countries
Patients Groups and Campaigns
Collaboration for Access to Health Technologies
Philantropy
New Funding Mechanisms
Governments
PPPs & PDPs

Linking Innovation to Access: Partnering in Access

- Re-Introduce the notion of **emergency response**: patients are dying!
- L**eadership and coordination** from the endemic countries
- Break the silence: Visibility; V**oice of the patients** and Campaigning
- Build C**ollaborative models:** develop road maps (drug access strategies per disease)
- New **Organizational structures** established with the purpose of coordinating the availability, affordability, and adoption activities (define roles and responsibilities+ joint KPI's)
- Moving beyond: **advocating to change the R&D Landscape**

Santiago del Estero, Argentina

João Roberto Ripper, 2009

Without political commitment and strong collaborations, we are bound to fail!

Amazonas, Brasil
João Roberto Ripper, 2010

ASANTE- OBRIGADO - GRACIAS

THANK YOU