Innovation, Management of Intellectual Property and trade-related determinants of access - *Lessons learned from 10 years of DNDi and its application to new disease areas*

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Regional Meeting on High Cost and Strategic Medicines
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Pan American Health Organization

World Health Organization
REGIONAL OFFICE FOR THE Americas

OUTLINE

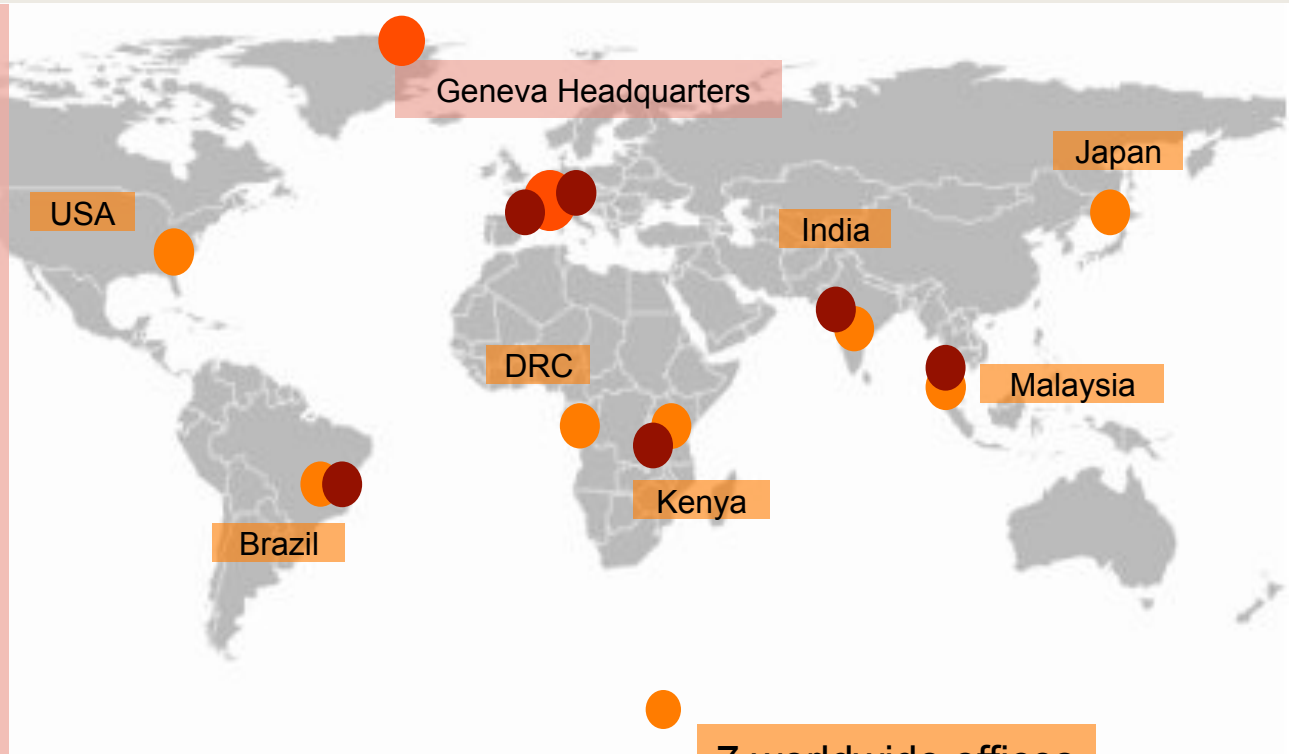
- DND*i*'s Model- lessons learned
- Dndi's new Business Plan
- New Challenges
- Global Challenges

DND*i*:
Patient Needs-Driven & Innovative R&D Model

- Deliver **11 to 13 new treatments by 2018**
- Establish a **robust pipeline**
- **open knowledge innovation: Affordable treatment and equitable access to patients in need ; Develop drugs as public goods, when possible**
- Use and strengthen existing **capacity in disease-endemic countries**
- **Raise awareness** and advocate for increased **public leadership**

Founding Partners

- Indian Council for Medical Research (ICMR)
- Kenya Medical Research Institute (KEMRI)
- Malaysian MOH
- Oswaldo Cruz Foundation, Brazil
- Médecins Sans Frontières (MSF)
- Institut Pasteur France
- TDR (permanent observer)



Presence in Latin America

Argentina

Bolivia

Brasil

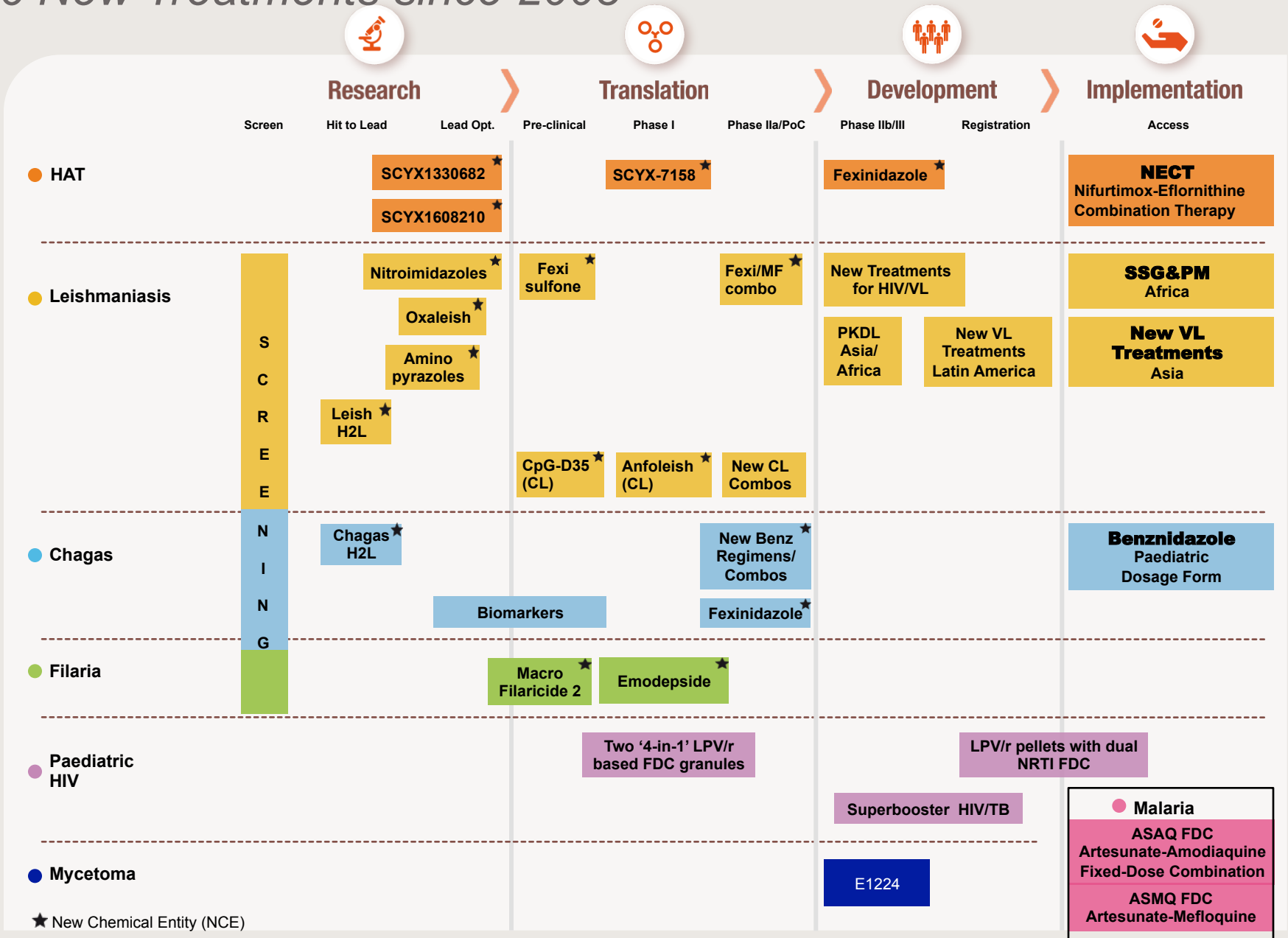
Colombia

Mexico

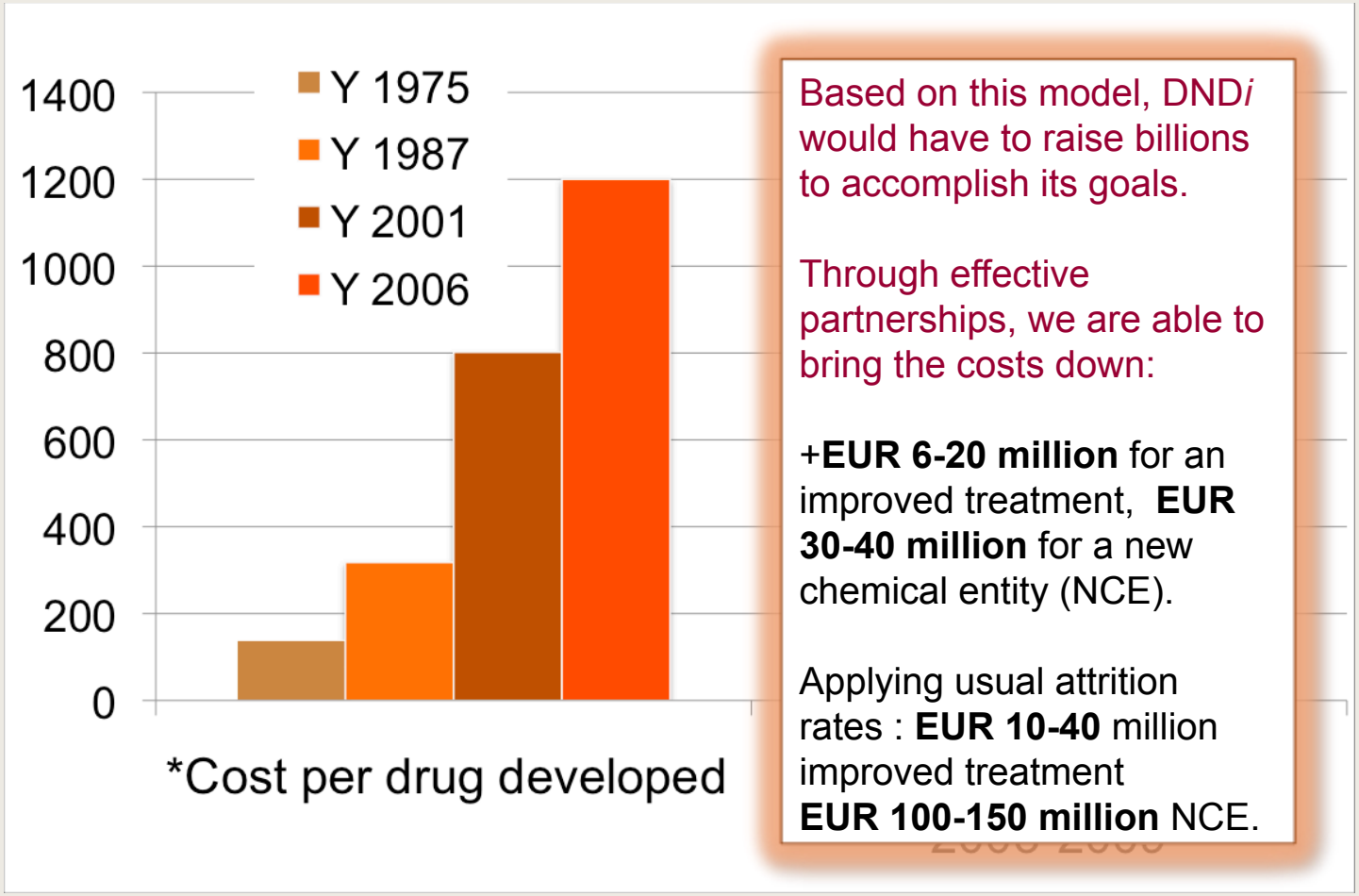
Peru

DND*i* Portfolio June 2015

6 New Treatments since 2003



Average Cost to Develop One Drug – The Pharmaceutical Industry Data



Based on this model, DND*i* would have to raise billions to accomplish its goals.

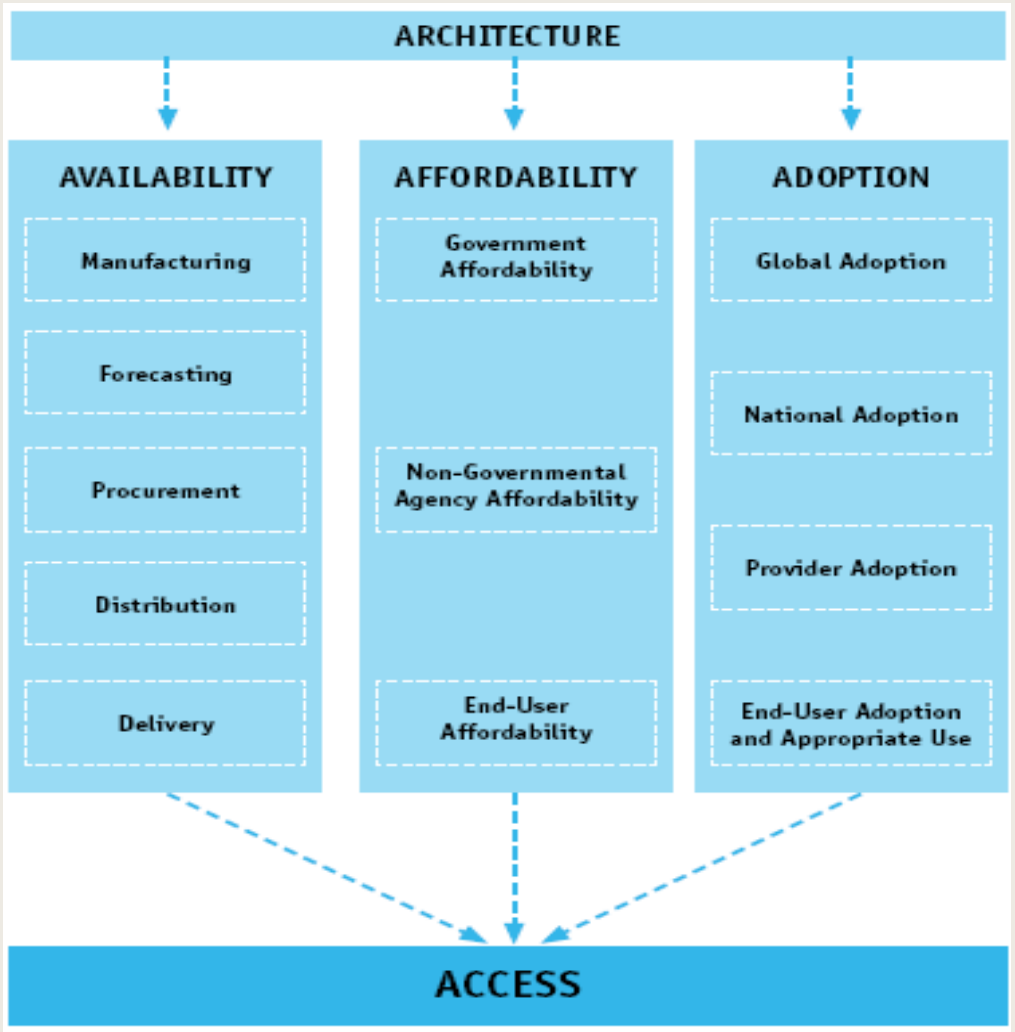
Through effective partnerships, we are able to bring the costs down:

+**EUR 6-20 million** for an improved treatment, **EUR 30-40 million** for a new chemical entity (NCE).

Applying usual attrition rates : **EUR 10-40** million improved treatment
EUR 100-150 million NCE.

*Source: PhRMA Pharmaceutical Industry Profiles 2007
+ Does not take into account in kind donations.

Access not just about the price of a product.



Fuente: Laura J. Frost & Michael R. Reich (2008). ***Access: How do good health technologies get to poor people in poor countries?*** Harvard Center for Population and Development Studies

After 10 years experience key components for success:

- put the specific needs of patients in developing countries upfront, at the start of the innovation process;
- break the link between the cost of R&D and the price of products;
- ensure that the fruits of innovation are accessible and affordable;
- integrate global health R&D monitoring,coordination, and financing;
- strengthen and where relevant harmonize regulatory capacities in endemic regions to facilitate implementation of new health technologies

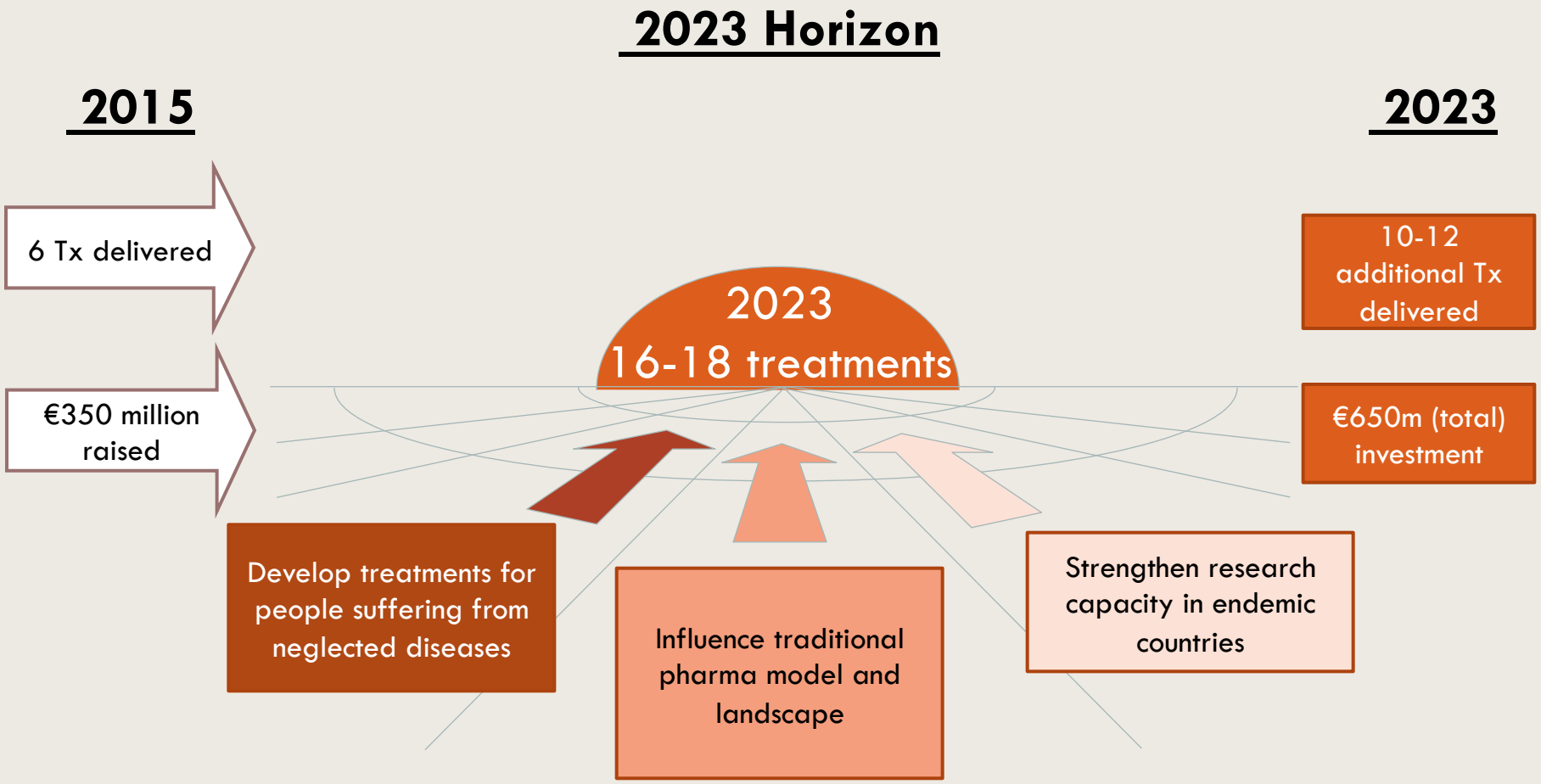
Key Elements of the New “Business Plan”

DNDi NORTH AMERICA
Drugs for Neglected Diseases *initiative*

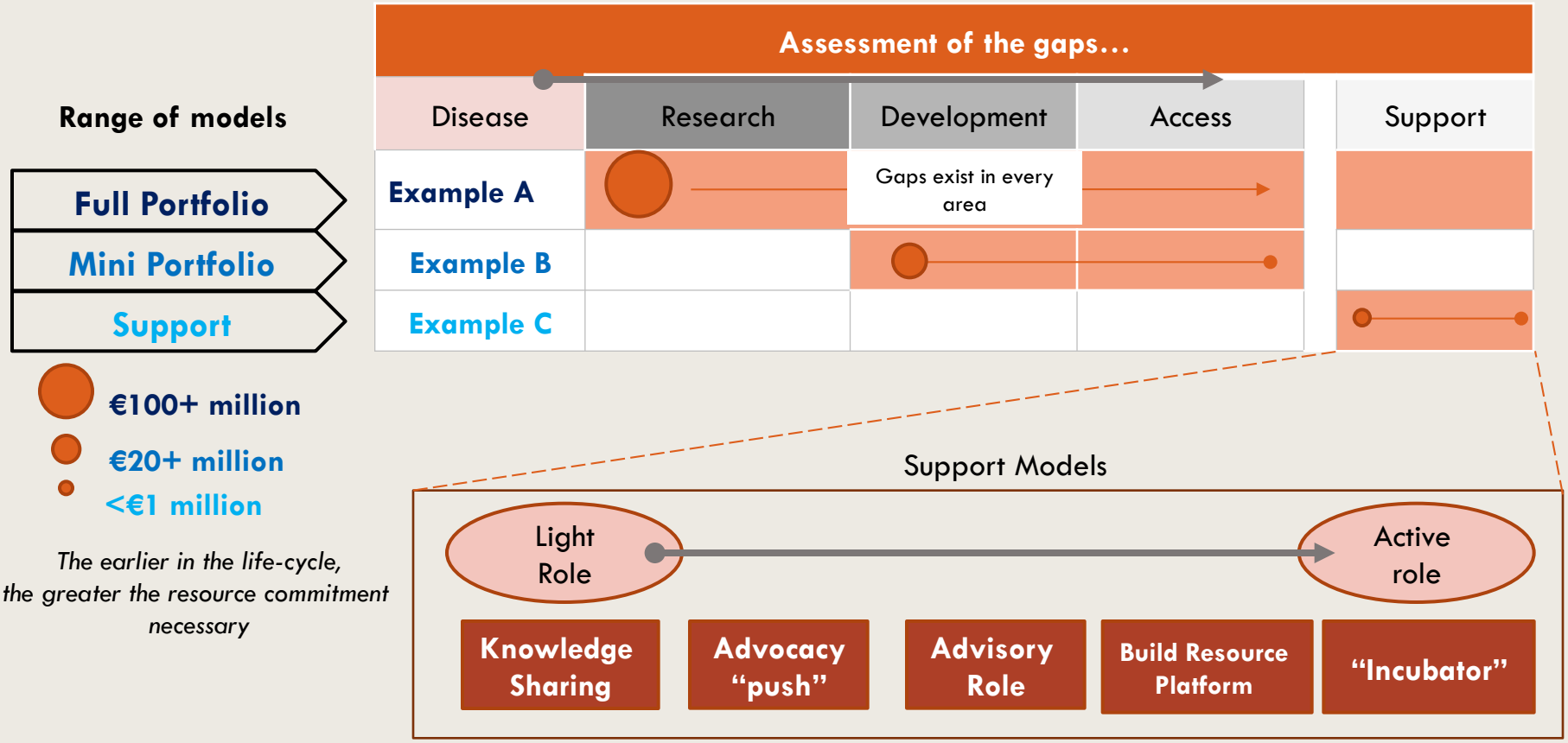
Major Points Of Consideration When Evaluating the Current Landscape In 2015…

- Despite incremental progress, “fatal imbalance” persists
- New R&D initiatives still largely *ad hoc,* fragmented, driven by priorities of few donors (e.g. B&MGF)
- “Pharmaceutical market failure” can no longer only refer to lack of R&D but also lack of access when innovation occurs
- Current biomedical R&D system unsustainable for all countries, regardless of income classification (MICs face specific challenges)
- Changing epidemiological and geopolitical trends mean “old” ways of thinking (“developing countries/infectious diseases” vs “developed countries/NCDs”) no longer appropriate
- New risks (and opportunities) linked to “Ebola effect”, AMR, etc. have surfaced

“2023 Horizon”: 20 Years of DNDi



Range of R&D Models



Hepatitis C

Limited **Public Health** Approaches Using DAAs

DNDi Strategy Addresses Main Drivers of Unmet Need

Drivers of Unmet Need

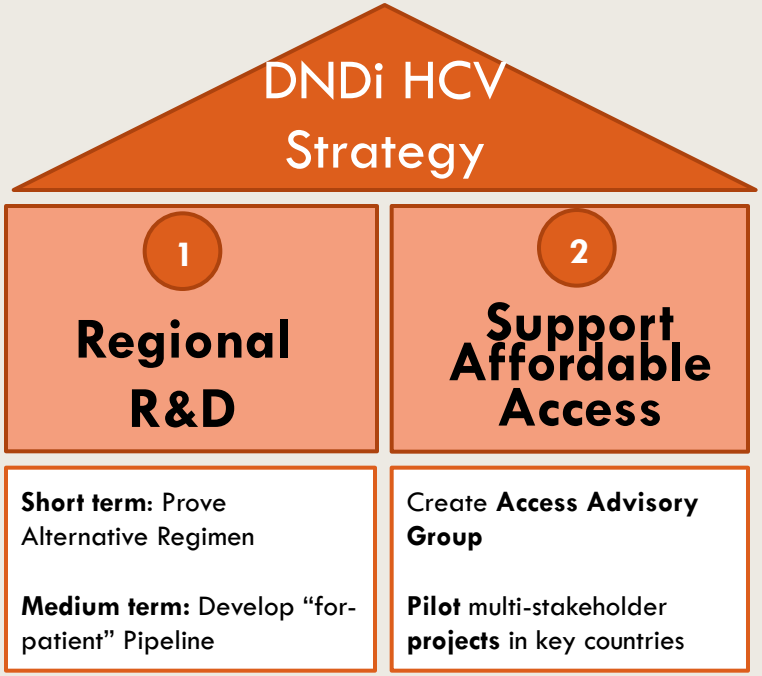
Lack of adequate R&D to support optimal DAA regimen

- Pharmaceutical companies not collaborating, developing regimens in their own pipeline
- Limited information on specific genotypes

Unaffordable treatment

- Prices of HCV drugs are unaffordable (ex. $84,000 per treatment in US)
- Voluntary Licenses exclude several high-burden countries (ex. Thailand, Malaysia, Brazil…)

DNDi HCV Strategy



DNDi
Drugs for Neglected Diseases initiative

5-Year Project (2 Steps)

DNDi Five-Year HCV Project: Enable Development of Public Health Tool

Step 1: Develop Alternative Regimen
Short-term

Step 2: Develop "for-patient" pipeline
Medium-term

Key Outcomes:

1. Conduct Phase 3 Trials with SOF + DCV in Thailand and Malaysia
2. Support access to affordable treatments (via creation of Access Advisory Group) (could include : Developing alternative treatments with favorable licensing /access terms, Patent oppositions, Compulsory licensing, VL's.
3. Projects in key countries with partners

4. Develop for-patient pipeline of regimens
   - Phase 2 Trial "A" (with novel regimen)
   - Phase 2 Trial "B" (with other regimen)
   - Phase 3 PoC adding alternative compound
   - Registration of recommended regimen including "novel" element

Key milestones for next stages

▲Licensing agreements in place/availability of "alternative" compounds
▲Commitment from key governments to implement a Public Health Approach for HCV
▲Secured industrial partner for manufacturing alternative regimens

Policy & Advocacy Objectives

- *Global Challenges- towards sustainable financing and new incentives for R&D*

PLOS | MEDICINE

ESSAY

A Global Biomedical R&D Fund and Mechanism for Innovations of Public Health Importance

Manica Balasegaram[1], Christian Bréchot[2], Jeremy Farrar[3], David Heymann[4], Nirmal Ganguly[5], Martin Khor[6], Yves Lévy[7], Precious Matsoso[8], Ren Minghui[9], Bernard Pécoul[10]*, Liu Peilong[11], Marcel Tanner[12], John-Arne Røttingen[13,14]

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Global Fund & Mechanism

Funding for R&D initiatives

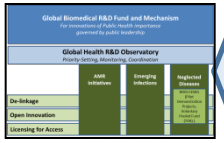
NIH National Institutes of Health

wellcome trust

USAID FROM THE AMERICAN PEOPLE

ruta n MEDELLÍN CENTRO DE INNOVACIÓN Y NEGOCIOS

GHIT Fund
Global Health Innovative Technology Fund



BILL & MELINDA GATES foundation

BNDES The Brazilian development bank

DFID Department for International Development

UNITAID

EUROPEAN COMMISSION

EDCTP

...and others

Global Biomedical R&D Fund and Mechanism

For innovations of public health importance

governed by public leadership

Global Health R&D Observatory

Priority-Setting, Monitoring, Coordination

	AMR Initiatives	Emerging Infections (incl. Ebola)	Poverty Related / Neglected Diseases*
De-linkage			**WHO CEWG** Pilot Demonstration Projects, Voluntary Pooled Fund (TDR)
Open Innovation			
Licensing for Access			

* Type II and III diseases, and the specific R&D needs of developing countries in relation to Type I diseases"

THANK YOU

www.dndi.org

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IP & open innovation: DND*i* vision

- **Affordable treatment and equitable access to patients in need**
  - Delinking the costs of R&D from the price of products
  - DND*i* activities not financed by IP revenues
  - No partnership without overcoming IP barrier
- **Develop drugs as public goods, when possible**
  - Disseminate the results of DND*i* work
  - Encourage open publication of research data and technology transfer
  - Decisions regarding ownership of patents and licensing terms made on a case-by-case basis. Try to obtain ‘Gold standard’ licensing terms.