


**Best Science for the Most Neglected**

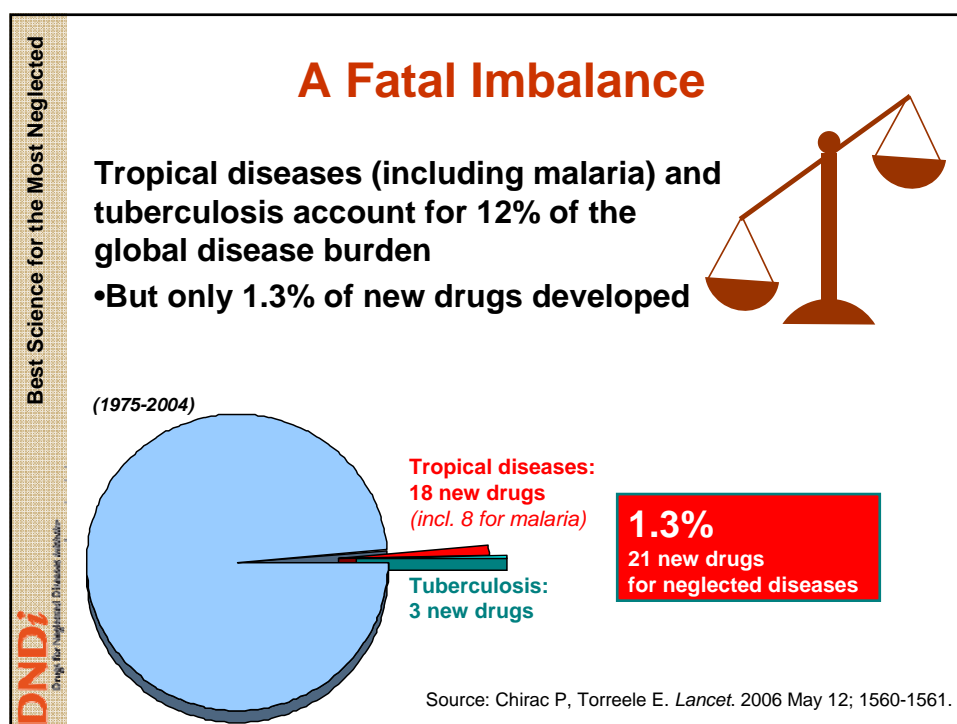

# New tools for neglected diseases in Africa

## *What are the best regulatory pathways?*




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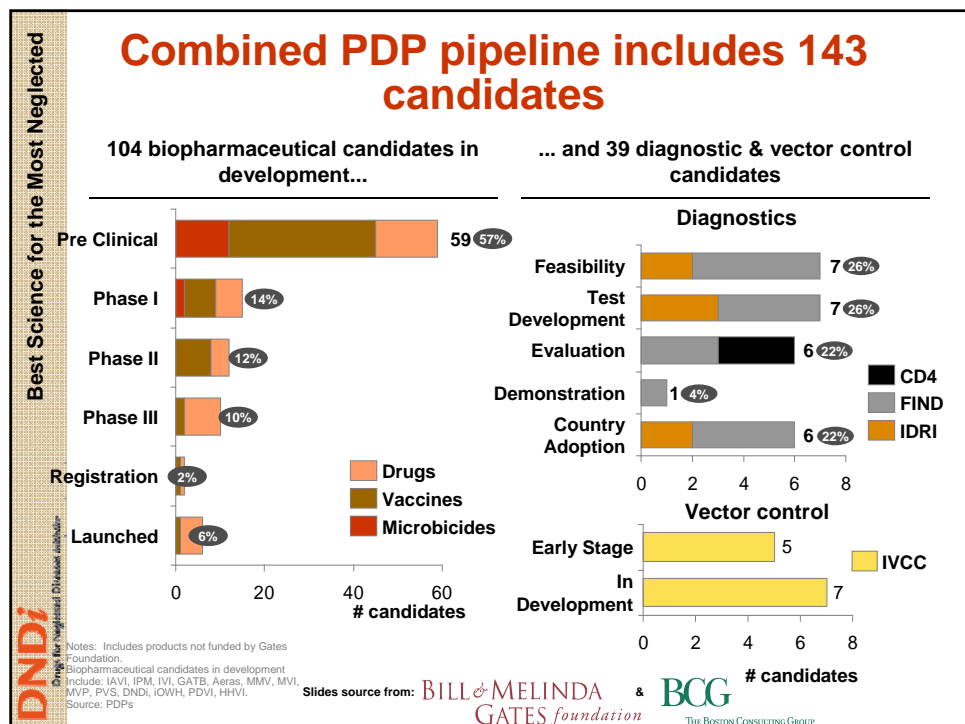
**DNDi**  
Drugs for Neglected Diseases Institute



## Product Development Partnerships (PDPs): Fill the Gaps in R&D for neglected diseases

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DNDi Drugs for Neglected Diseases Initiative





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## Shared objectives

- Develop treatments or vaccines **primarily** dedicated to patients from endemic countries with no or poor access to the best effective and safe treatment, or to prophylaxis options
- For some as DNDi, the mission goes beyond , i.e strengthening existing research capacities and up to ensuring that implementation takes place

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## DNDi

### A patient-needs driven & innovative R&D model

- Deliver **6 - 8 new treatments by 2014** for sleeping sickness, Chagas disease, leishmaniasis and malaria
- Establish a **robust pipeline** for future needs
- Use and strengthen existing **capacity in disease-endemic countries**

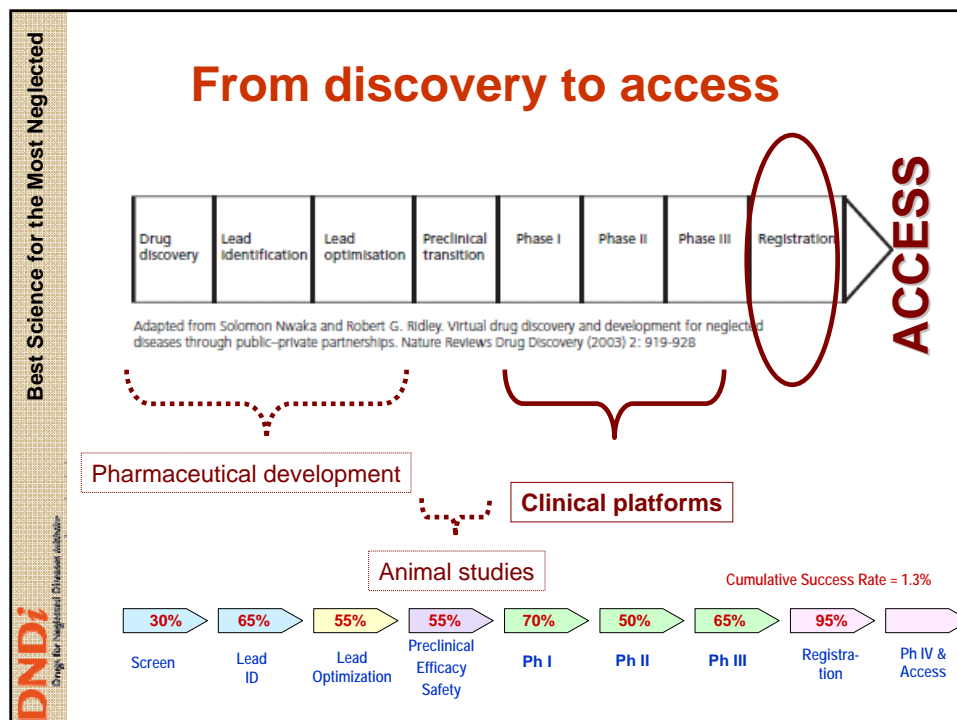
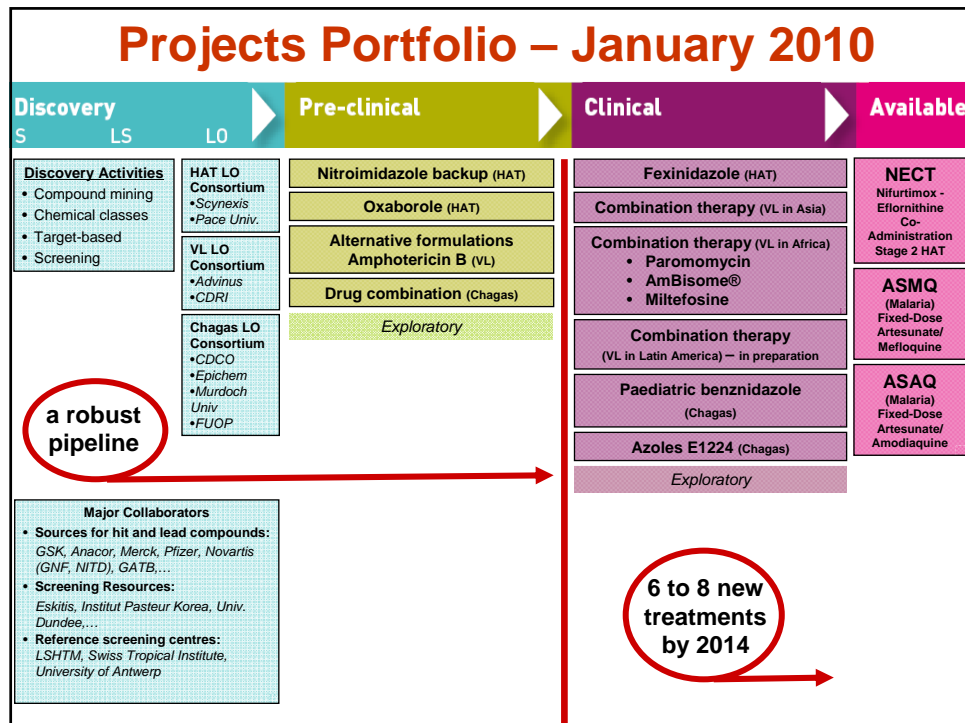
- **7 Founding Partners**
- Indian Council for Medical Research (ICMR)
- Kenya Medical Research Institute (KEMRI)
- Malaysian MOH
- Oswaldo Cruz Foundation Brazil
- Medecins Sans Frontieres (MSF)
- Institut Pasteur France
- WHO/TDR (permanent observer)



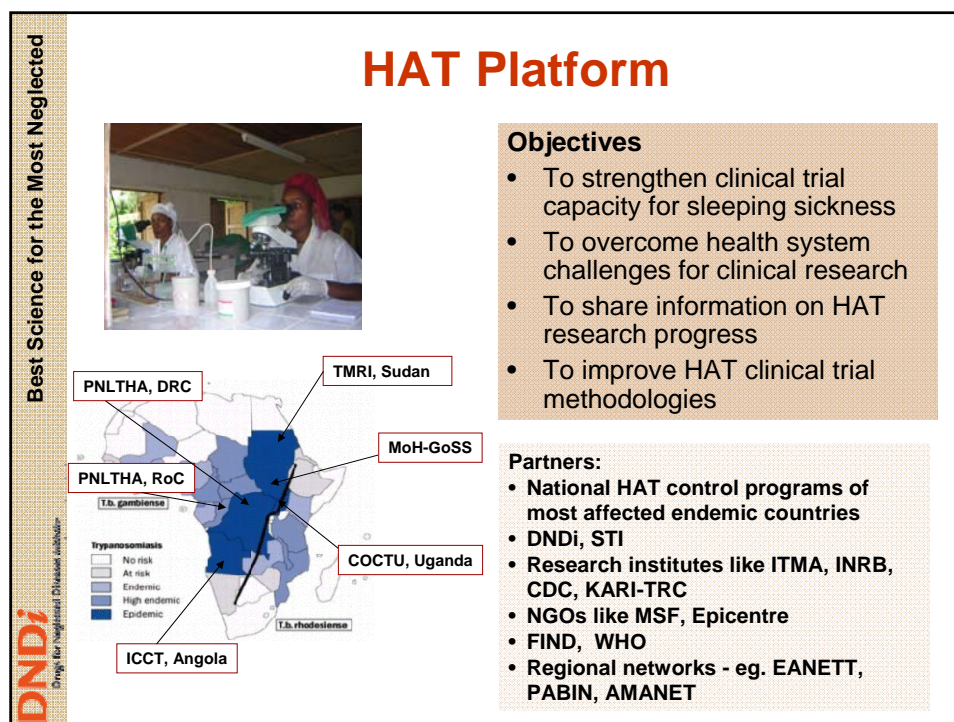
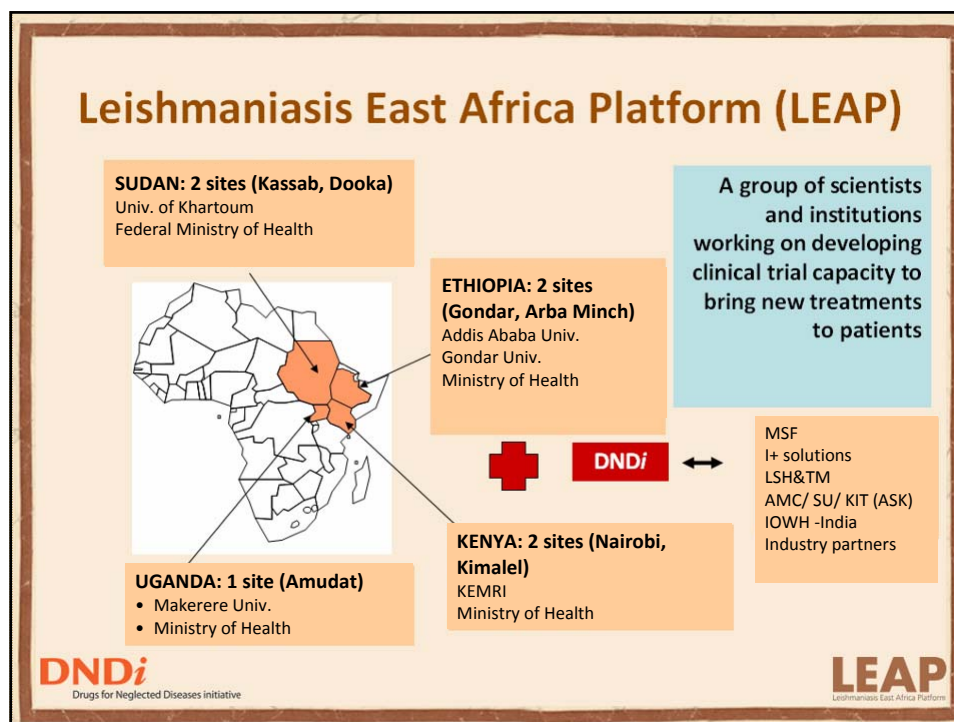
7 worldwide offices

Geneva Coordination Team + consultants

USA, Brazil, DRC, Kenya, India, Malaysia, Japan







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**2 examples of successful registration**



**ASAQ**



**NECT**

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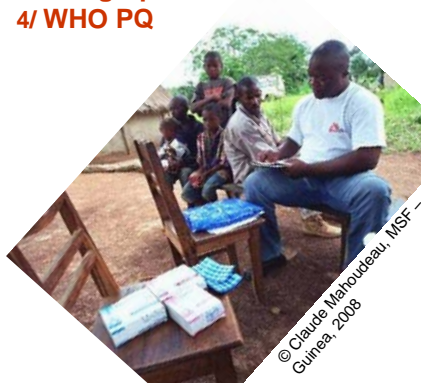
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**ASAQ**  
**Registered & manufactured in Africa**

**Innovative partnership with sanofi-aventis**

- A FDC of artesunate-amodiaquine
- Not patented, at cost in public market
- Manufactured in Morocco
- 2008: Prequalified by WHO
- Registered in 25 African countries
- 25 million distributed in 2009
- Ambitious field monitoring program (Pharmacovigilance)
- Technology transfer on going to an African manufacturer

**Registration Model:**  
1/ Scientific Opinion UK MHRA  
2/ Morocco registration  
3/ Geographical extension  
4/ WHO PQ



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## NECT

### An improved option therapy developed in Africa & implemented in 4 endemic countries

**NECT (nifurtimox-eflornithine combination therapy) :**  
**A simplified, safe & effective treatment for stage 2 HAT**

- Pivotal Phase III trial in DRC NECT included into WHO Essential Medicines List (May 2009)
- NECT-FIELD study initiated in 6 clinical sites in DRC
- Implementation with WHO and national programmes

**Registration Model:**  
**1/ EML for combination**  
**2/ Access via National programs/WHO**



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## But the landscape is evolving ...

- Up to now, the majority of treatments submitted for approval in Africa, were already approved drugs (EU, USA) or generic drugs
- New Chemical Entities (NCEs), vaccines, combination treatments now being developed to respond to the specific needs in developing countries
- African regulatory agencies will have to perform regulatory assessment of new treatments never evaluated before
- **How can this be achieved the most efficiently?**



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## Need for new pathways for registering innovative drugs for Africa

- Increased participation of endemic countries within existing mechanisms
- Regional centres of excellence to support strengthening of African regulatory agencies

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**THE GEORGE INSTITUTE**  
for International Health

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**By working in a creative way, we CAN bring together innovation to neglected patients!**

**[www.dndi.org](http://www.dndi.org)**