



Can a Global Framework on Research & Development (R&D) overcome existing challenges for access to treatment?

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Patient Needs-Driven & Innovative R&D Model

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)





Responding to the Needs of Patients Suffering from Neglected Diseases...



Malaria



Leishmaniasis



Paediatric HIV



Sleeping Sickness (HAT)



Chagas Disease



Helminth infections



Neglected Diseases: Current Treatment Limitations



Melarsoprol



- Ineffective (resistance)
- Toxic
- Expensive
- Painful when delivered
- Difficult to use
- Not registered in endemic regions
- Restricted by patents

Eflornithine

We Need Safe, Effective, Easy-to-Use Drugs



Vision & Objectives

Vision:

A collaborative, patients' needs-driven, virtual, non-profit drug R&D organisation to develop new treatments against the most neglected communicable diseases



- Objectives:
 - Deliver 11 to 13 new treatments by 2018 for sleeping sickness, Chagas disease, leishmaniasis, malaria, paediatric HIV and specific helminth infections
 - Establish a robust pipeline for future needs
 - Use and strengthen existing research capacity in diseaseendemic countries



Dedicated Teams Worldwide Over 630 People Committed to DND*i*'s Vision



A Global Network to Leverage Resources

More Than 100 R&D Partners

Balance of public and private partnerships worldwide



Drugs for Neglected Diseases initiative

Oct. 2012

6 New Treatments Developed Since 2007



☑ Easy to Use ☑ Affordable ☑ Field-Adapted ☑ Non-Patented







DNDi Portfolio: A Mix of Existing Drugs & NCEs



Paediatric HIV: Most Urgent Treatment Needs (TPP)



- Formulations/regimens that are simple, easy to administer, and more tolerable (once daily or less, heatstable, dispersible/sprinkles, tolerable taste)
- Durable (forgiving and minimal requirement for repeated immunological or virological testing; minimal risk for developing resistance)
- Suitable for infants (< 2 mos 3 yrs)
- TB treatment compatible
- ✓ Affordable



Innovative PI Formulation: The Cipla-MRC Collaboration

- LPV/r sprinkles by Cipla*
- CHAPAS-2: Pharmacokinetics and acceptability of sprinkle formulation compared with syrup/tablets**





- Sprinkles preferred: better to swallow, store, transport; important advantage for caregivers
 - 71% (<1 y.o.) chose to continue sprinkles over syrup after study
- Inspired DNDi, leading to the concept of "4-in-1" sachet

* http://www.retroconference.org/2012b/PDFs/982.pdf

** http://www.controlled-trials.com/isrctn/pf/01946535; 4th Pediatric HIV Workshop, 2012 DC



Bring a "4-in-1" Sachet to Patients: DNDi-Cipla **Collaboration on Product Development & Access**

- Address the need for a PI-based first-line ARV FDC
- Adaptable for use in treating TB co-infected children



Caring for life



Negotiating & managing IP to ensure access to patients & access to knowledge

Affordable treatment and equitable access to patients in need:

- Delinking the costs of R&D from the price of products
- DNDi activities not financed by IP revenues
- All patients in need shall have access to the drug at the lowest sustainable price in all endemic countries

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



Delinking R&D costs from product price to ensure access: DNDi practice

Target price in 'target product profile' (TPP)

- e.g. ideally < 50 USD/patient/year (consistent with adult ART), acceptable if lower than current price of products used separately
- Contractual commitment of manufacturer to make final product available at cost, plus a minimal margin, in all endemic countries
- No patent or non-exclusive licenses to enable competition, technology transfer and sharing of knowledge
- No intent to recoup R&D investments



But many challenges remain

- No major scientific breakthrough (NCE)
- Funding gap for development of pipeline candidates
- R&D priorities set by few donors
- Major regulatory and access challenges
- Lack of incentive for private sector (beyond CSR)
- Limited leadership and involvement of endemic countries
- Lack of overall coordination WHO role?





From individual successes to sustainable change

Global framework for R&D

- Define priorities for medical innovation
- New mechanisms for sustainable funding
- New incentives for neglected diseases R&D
- Promote & incentivize open innovation
- Ensure affordable & equitable access
- Coordination mechanisms
- Strengthening capacity & promoting technology transfer

With leadership and spearheading of endemic countries



Thank You to All Our Partners & Donors



www.connect2fightneglect.org

www.dndi.org

DNDi Drugs for Neglected Diseases initiative