DNDi Update: Global Partnership Addressing Needs of Most Neglected From Research to Access

Bernard Pécoul, Executive Director
Shing Chang, R&D Director
Monique Wasunna, Head of DNDi Africa

Outline of the presentation

1. Introduction - Understanding Patients’ Needs
2. DNDi’s Achievements
3. R&D Portfolio
4. Strengthening Capacities
5. Advocacy & Resources
6. Conclusions
Neglected Diseases:
- primarily affect developing countries
- lie outside the world market

*Source: IMS Health, 26.2.2008

Figure 1. The 10 Leading Causes of Life-Years Lost to Disability and Premature Death.
What’s Needed to Combat NTDs?

Large scale interventions
- Lymphatic filariasis
- Leprosy
- Onchocerciasis
- Schistosomiasis
- Helminthiasis
- Trachoma
- Yaws

Rapid Impact Interventions
Improving access

Focused interventions
Improving innovation

Case management and
development of new tools
- Human African trypanosomiasis
- Chagas diseases
- Buruli ulcer
- Leishmaniasis
- Dengue

A Fatal Imbalance

Tropical diseases (including malaria) and tuberculosis account for:
- 12% of the global disease burden
- Only 1.3% of new drugs developed

Tropical diseases: 18 new drugs (incl. 8 for malaria)
Tuberculosis: 3 new drugs
1.3% 21 new drugs for neglected diseases

98.7%
1,535 new drugs for other diseases

Source: Chirac P, Torreele E. Lancet. 2006 May 12; 1560-1561.
Responding to the Needs of Patients Suffering from Neglected Diseases…

- Malaria
- Visceral Leishmaniasis (VL)
- Sleeping Sickness (HAT)
- Chagas Disease

Human African Trypanosomiasis (HAT) or Sleeping Sickness

- 60 million at risk in sub-Saharan Africa
- Transmitted by the tsetse fly
- Difficult to diagnose; many patients go undiagnosed until late stage of disease
- Fatal if untreated
- Needs:
  - A safe, effective, and practical stage 2 treatment
  - A simple stage 1 treatment
**Visceral Leishmaniasis (VL)**

- 200 million at risk worldwide (in 70 countries)
- Transmitted by the sandflies
- **Symptoms**: prolonged fever, enlarged spleen & liver, substantial weight loss, progressive anemia
- Fatal if untreated
- **Current drugs**: antimonials, Amphotericin B, AmBisome®, miltefosine, paromomycin

**Needs**:
- Oral, safe, effective, low-cost and short-course treatment

---

**Chagas Disease: A Silent Killer**

- 100 million at risk in Latin America
- Kills more people in region than malaria
- Patient number growing in non-endemic, developed countries
- Transmitted by 'kissing bug', blood transfusion, organ transplantation, as congenitally or orally
- Majority of patients undiagnosed until late stage

**Needs**:
- An affordable, age-adapted, safe, and efficacious paediatric strength
- A new drug for early chronic stage
Among the most neglected...

- Poorest of the poor
- Living in remote areas
- Socioeconomic burden on family and community
- Marginalised & voiceless patients

Neglected Diseases: Current Treatment Limitations

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

We Need Safe, Effective, Easy-to-Use Drugs
A New Model for Drug Development: DNDi created in 2003

- Non-profit drug research & development (R&D) organization founded in 2003
- Addressing the needs of the most neglected patients
- Harnessing resources from public institutions, private industry and philanthropic entities

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)

DNDi’s Main Objectives

- 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
- Raise awareness and advocate for increased public responsibility
Scope of Activities for DNDi

Major focus on kinetoplastids (HAT / VL / Chagas)

3 Core Diseases
+ malaria: complete the 2 FDC
+ cutaneous leishmaniasis

Success & progress at each stage

HAT: DNDi Achievements so far

- Lead Opt. Consortium (Scynexis/Pace) => Boron-based preclinical candidate (Anacor)

- Fexinidazole (STI, Accelera, Aptuit, Asyntis, Covance, Drugabilis, LPU, SGS; contract: sanofi-aventis)

- NECT (Epicentre/MSF, STI, WHO, Nat. Prog. DRC & Congo)
**VL: DNDi Achievements so far**

Promising discovery & ambitious plan for drug combination

- High-Throughput Screening at IPK

---

**Chagas: DNDi Achievements so far**

Consolidating our portfolio

- Lead Optimisation Consortium establishment
- Paediatric Benznidazole: Lafspo, CeNDiE, Liverpool Uni
**ASAQ: Making a Difference in Fighting Malaria**

Innovative partnership with sanofi-aventis
- A FDC of artesunate-amodiaquine
- Registered in 2007, prequalified by WHO in 2008
- 5.3 million treatments distributed in 2008
- More than 20 millions to be distributed in 2009
- Available in 24 countries
- Ambitious risk management plan (Pharmacovigilance)

- Adapted
- Simple
- Accessible
- Quality

**ASMQ: Available in 2008**

Public partnership with Brazil-funded Farmanguinhos
- A FDC of artesunate-mefloquine
- Registered in 2008
- Incorporated into Brazilian National Programmes
- Extension to other Latin American countries
- Technology transfer to Cipla
- Clinical studies:
  - Latin America (Brazil)
  - Asia (India, Myanmar, Malaysia)
  - Africa (Tanzania)
R&D Portfolio

Shing Chang
R&D Director

DNDi Portfolio-Building Model

- **Long-term projects**
  - Existing chemical libraries
  - New lead compounds

- **Medium-term projects**
  - New formulations (fixed-dose combinations)
  - New indications of existing drugs

- **Short-term projects**
  - Completing registration dossier
  - Geographical extension

Phases:
- Discovery
- Preclinical
- Clinical
- Access to Patients
**Dynamic Portfolio – June 2009**

<table>
<thead>
<tr>
<th>Discovery</th>
<th>Pre-clinical</th>
<th>Clinical</th>
<th>Available</th>
</tr>
</thead>
<tbody>
<tr>
<td>S</td>
<td>LS</td>
<td>LO</td>
<td>Pre-clinical</td>
</tr>
<tr>
<td>• Compound mining</td>
<td>Alternative formulations</td>
<td>Fexinidazole (HAT)</td>
<td>NECT</td>
</tr>
<tr>
<td>E.g.: nitroimidazoles, ...</td>
<td>Amphotericin B – in preparation (VL)</td>
<td>Combination therapy (VL in Asia)</td>
<td>ASMQ (Malaria) Fixed-Dose Artesunate/ Mefloquine</td>
</tr>
<tr>
<td>• Chemical classes</td>
<td>Buparvaquone (VL)</td>
<td>Combination therapy (VL in Africa)</td>
<td>ASAQ (Malaria) Fixed-Dose Artesunate/ Mefloquine</td>
</tr>
<tr>
<td>E.g.: GSK, Merck, ...</td>
<td>Amphotericin B polymer (VL)</td>
<td>• Paromomycin</td>
<td>cokeholder: Nitfurtimox - Eflornithine Co-Administration Stage 2 HAT</td>
</tr>
<tr>
<td>• Target-based</td>
<td>Drug combination (Chagas)</td>
<td>• AmBisome®</td>
<td>Nitfurtimox - Eflornithine Co-Administration Stage 2 HAT</td>
</tr>
<tr>
<td>E.g.: Dundee’s Drug Discovery Unit (DDU), Microtubule inhibitors...</td>
<td>Nitroimidazole backup (HAT)</td>
<td>• Miltefosine – in preparation</td>
<td>Nitfurtimox - Eflornithine Co-Administration Stage 2 HAT</td>
</tr>
<tr>
<td>Screening</td>
<td>Oxaborole (HAT)</td>
<td>Combination therapy (VL in Latin America) – In preparation</td>
<td>Nitfurtimox - Eflornithine Co-Administration Stage 2 HAT</td>
</tr>
<tr>
<td>E.g. natural products (Kiasato, Eskitis), new technology (Institut Pasteur Korea), DDU at Dundee, CDRI screening ...</td>
<td>Exploratory</td>
<td>Paediatric benznidazole</td>
<td>Nitfurtimox - Eflornithine Co-Administration Stage 2 HAT</td>
</tr>
<tr>
<td>Chagas LO Consor</td>
<td>Combination therapy (VL in Latin America) – In preparation</td>
<td>Azoles (Chagas)</td>
<td>Nitfurtimox - Eflornithine Co-Administration Stage 2 HAT</td>
</tr>
<tr>
<td>tium &lt;CDG &gt;Epic</td>
<td>Sitamaquine or Other Aminoquinolines (VL)</td>
<td>Nitfurtimox - Eflornithine Co-Administration Stage 2 HAT</td>
<td></td>
</tr>
<tr>
<td>&gt;Munich</td>
<td>- Sitamaquine</td>
<td>- Tafenoquine</td>
<td>Nitfurtimox - Eflornithine Co-Administration Stage 2 HAT</td>
</tr>
<tr>
<td>University</td>
<td>Exploratory</td>
<td>8-aminoquinolines – in preparation (VL)</td>
<td>Nitfurtimox - Eflornithine Co-Administration Stage 2 HAT</td>
</tr>
</tbody>
</table>

**Reference screening centres:**
LSHTM, Swiss Tropical Institute, University of Antwerp

**a robust pipeline**

**6 to 8 new treatments**

---

**On the Way to Deliver 6 to 8 New Treatments by 2014**

### Timeline

<table>
<thead>
<tr>
<th>2007</th>
<th>2008</th>
<th>2009</th>
<th>2010</th>
<th>2011</th>
<th>2012</th>
<th>2013</th>
<th>2014</th>
</tr>
</thead>
<tbody>
<tr>
<td>Paediatric benznidazole</td>
<td>Combination VL Therapy Africa</td>
<td>Combination VL Therapy India</td>
<td>Combination VL Therapy Latin America</td>
<td>Combination VL Therapy Africa</td>
<td>Combination VL Therapy India</td>
<td>Combination VL Therapy Latin America</td>
<td>Combination VL Therapy Africa</td>
</tr>
<tr>
<td>Fexinidazole</td>
<td>AmBisome Africa</td>
<td>Nitfurtimox - Eflornithine Co-Administration</td>
<td>Sitamaquine or Other Aminoquinolines (VL)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>AS/AQ</td>
<td>AS/MQ</td>
<td>Combination VL Therapy Africa</td>
<td>Combination VL Therapy India</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>DELIVERED</td>
<td>DELIVERED</td>
<td>DELIVERED</td>
<td>DELIVERED</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nitfurtimox - Eflornithine Co-Administration</td>
<td>Nitfurtimox - Eflornithine Co-Administration</td>
<td>Nitfurtimox - Eflornithine Co-Administration</td>
<td>Nitfurtimox - Eflornithine Co-Administration</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Probability of Success in %**

- HAT: 70%
- VL: 33%
- Chagas: 33%
- Malaria: 33%
Discovery - Building the pipeline
2 Breakthroughs in 2009

1) Access of libraries of compounds for chemical diversity

Agreements with pharma
- Merck
- GNF (Genomics Institute of the Novartis Research Foundation)
- Others in negotiation

2) Access to HTS capacity

<table>
<thead>
<tr>
<th>Disease</th>
<th>High Throughput Screening</th>
</tr>
</thead>
<tbody>
<tr>
<td>HAT</td>
<td>HTS available</td>
</tr>
<tr>
<td>VL</td>
<td>HTS developed at Institut Pasteur Korea</td>
</tr>
<tr>
<td>Chagas</td>
<td>HTS in development at Institut Pasteur Korea</td>
</tr>
</tbody>
</table>
Discovery

DNDi’s Capacity to Optimize Leads

- **HAT Lead Optimisation Consortium**
  Scynexis, Pace University

- **VL Lead Optimisation Consortium**
  Advinus Therapeutics, Central Drug Research Institute

- **Chagas Lead Optimisation Consortium**
  CDCO, Epichem, Murdoch University, University of Ouro Preto

Chagas Portfolio – Assembling & Evolving

<table>
<thead>
<tr>
<th>Discovery</th>
<th>Pre-clinical</th>
<th>Clinical</th>
<th>Available</th>
</tr>
</thead>
<tbody>
<tr>
<td>S</td>
<td>LS</td>
<td>LD</td>
<td></td>
</tr>
</tbody>
</table>
| • Compound mining<br> • Chemical classes<br> • Target-based<br> • Phenotypic screening | Drug combination<br> Chagas LO Consortium:<br> • CDCO<br> • Epichem<br> • Murdoch Univ. | Paediatric benznidazole<br> Existing azoles | Sterol biosynthesis inhibitors<br> Cysteine protease inhibitors - UCSF

DNDi's
2nd Stakeholders’ Meeting and 3rd African Meeting
Nairobi, Kenya, June 23, 2009
**Paediatric Benznidazole**
- Unmet need: age-adapted, easy-to-use paediatric formulation
- Anticipated introduction in 2010

**Azoles**
- Therapeutic switching
- Candidates include posaconazole (Schering Plough) and E1224 (Eisai)
- Drug combination with existing drugs

**Key partners include:**
- Pharmaceutical Laboratory of Pernambuco State (LAFEPE)
- Centro Nacional de Diagnostico e Investigacion de Endemio-epidemias (CeNDIE), Argentina
- University of Liverpool

**Key partners include:**
- Federal University of Ouro Preto, Brazil
- Companies which provide compounds of interest
DNDi’s Chagas Strategy

Key partners include:
- Centre for Drug Candidate Optimisation
- Epichem
- Murdoch University
- Federal University of Ouro Preto

Fenarimol series

Lead Optimisation Consortium
Initiated mid-2008

VL Portfolio – Consolidation & Growing

- Compound mining
- Chemical classes
- Target-based
- Phenotypic screening

DNDi’s Chagas Strategy

Long-Term projects

Alternative formulations
Amphotericin B – in preparation

Sitamaquine or Tafenoquine – in preparation

Combination therapy using existing drugs
- Africa
- Asia
- Latin America

DNDi’s VL Consort:
- Advinus
- CDRI

Oral amphotericin B (iCo/CPDD)

Single-dose AmBisome ® (Sundar group)

Amphotomycin – India (OWH)

Amphomul (Bahrat)
**DNDi’s VL Strategy**

**VL Combination Therapy in Asia**

- Identify the optimal 2-drug combination therapy from the following 3 drugs:
  - AmBisome®
  - Miltefosine
  - Paromomycin
- Trial completion India: end of 2009; analysis completion in early 2010
- Recommendation in India, Bangladesh and Nepal by 2011

**Key partners include:**
- Indian Council for Medical Research
- Kala Azar Medical Research Centre
- Rajendra Memorial Research Institute of Medical Sciences
- GVK BIO

**VL Combination Therapy in Africa**

- Geographical extension for broader treatment options; Paromomycin / AmBisome® / Miltefosine
- Recommendation of combination incl. paromomycin + sodium stibogluconate (SSG)
- Development of combination treatment containing short-course AmBisome®

**Key partners include:**
- LEAP partners
DNDi’s VL Strategy

**Medium-term projects**

- **Amphotericin B polymer and oral AmphiB**

  **Key partners include:**
  - BioDelivery Sciences International
  - Imperial College
  - London School of Pharmacy
  - London School of Hygiene and Tropical Medicine

**Long-Term projects**

- **Lead Optimisation Consortium**
  - Promising lead series of 2-quinolines
  - Some compounds show >90% parasite killing *in vitro*
  - One lead compound with >85% efficacy *in vivo*
  - Oxaboroles and licochalcones under evaluation

**Key partners include:**
- Advinus
- Central Drug Research Institute
- Institut de Recherche pour le Développement
- Anacor
**DNDi’s HAT Strategy**

**Nifurtimox-Eflornitine Combination Therapy (NECT)**

- Simplified treatment with less infusions, shorter course, safe & efficacious
- Added to WHO Essential Medicines List in May 2009
- NECT-FIELD study ongoing

**Key partners include:**
- National HAT control programmes
- Epicentre
- MSF
- Swiss Tropical Institute
- WHO
- Drug donors: s-a, Bayer
**Fexinidazole**
- “Rediscovered” by DNDi after extensive review of existing data
- Completed preclinical development
- Entering into Phase I clinical studies in 2009

Key partners include:
- Swiss Tropical Institute, Accelera, Aptuit, Axyntis, Covance, Drugabilis, LPU, SGS
- Agreement signed with sanofi-aventis for joint development

**Oxaboroles**
- Innovative chemistry with potent anti-protozoal activity
- Candidate chosen to enter preclinical development by Q4 2009
Strengthening Research Capacities in Disease-Endemic Countries

Monique Wasunna
Assistant Director, KEMRI & Head of DNDi Africa

Challenges

- Access to patients
- Infrastructure
- Political instability
- Health system barriers
Clinical research capacity

- Research infrastructure in endemic regions has either:
  - Not been sustained
  - Never existed

Idea for Platforms Started in 2003

- 1st DNDi Africa meeting
  - 7-9 May 2003, Nairobi: 18 African Countries, 71 participants
- Neglected, marginalized, forgotten, invisible diseases
- Consensus conclusion: more action, fewer words
- Desire to collaborate to solve many health crises plaguing Africa
  - For diseases urgently needing improvement of treatments: LEAP, HAT Platform
Aims of Clinical Research Platforms

- Strengthen regional capacity in endemic regions
  - training
  - infrastructure
- Identify unmet treatment needs
  - safe
  - efficacious
  - short course
  - affordable
  - registered
  - field adapted
- Testing new treatments
  - LEAP studies focused on combination strategy
    - Paromomycin, AmBisome®, miltefosine

Where Are We Today? Achievements

- DNDi Africa office at KEMRI established
  - Building and coordination of African network
  - Two-way information with the network
  - 2 international conferences held in Nairobi; numerous operational meetings hosted and coordinated
  - Advocacy campaigns: African neglected diseases
  - Coordination of & support to DNDi research projects and platforms in Africa:
    - LEAP, HAT, FACT
Leishmaniasis East Africa Platform (LEAP)

SUDAN: 2 sites (Kassab, Dooka)
Univ. of Khartoum
Federal Ministry of Health

ETHIOPIA: 2 sites (Gondar, Arba Minch)
Addis Ababa Univ.
Gondar Univ.
Ministry of Health

UGANDA: 1 site (Amudat)
• Makerere Univ.
• Ministry of Health

KENYA: 2 sites (Nairobi, Kimalel)
KEMRI
Ministry of Health

A group of scientists and institutions working on developing clinical trial capacity to bring new treatments to patients

MSF
I+ solutions
LSH&TM
AMC/ SU/ KIT (ASK)
IOWH -India
Industry partners

HAT Clinical Trial Platform

Objectives
• To strengthen clinical trial capacity for sleeping sickness
• To overcome health system challenges for clinical research
• To share information on HAT research progress
• To improve HAT clinical trial methodologies

Partners:
• National HAT control programs of most affected endemic countries
• DNDi, STI
• Research institutes like ITMA, INRB, CDC, KARI-TRC
• NGOs like MSF, Epicentre
• FIND, WHO
• Regional networks – e.g. EANETT, PABIN, AMANET
Strengthening Clinical Research Capacity

Platform Accomplishments

• Active in conducting and sharing research – things are happening!
• Both platforms have strengthened clinical trial capacity in member countries
  – Personnel
  – Communications
  – Infrastructure

Accomplishments

Research activities

• Facilitated multi-country, multi-centre studies
  – LEAP: clinical studies in 2009 include paromomycin, AmBisome®, and miltefosine (in preparation)
  – FACT: numerous field studies completed, ongoing or planned to serve as evidence base on value and proper use of ASAQ and ASMQ in Africa
• Regional pools of clinical trial expertise has been created
  – HAT Platform serving as forum for members to share their clinical research experience
    • National sleeping sickness control programme of DR Congo engaged in NECT and NECT-FIELD
Personnel

• A needs-driven approach, adapted per region
  • Training of trial staff (needs, level, methods)
  • Ethics concepts (GCP, informed consent etc)
  • Standard operating procedures (SOPs)
Communications

- Overcoming regional barriers (differences in laws, guidelines, methods, languages, concepts etc.) through regular communications:
  - Platform meetings, newsletters
  - Sharing with regional and international community
  - Various presentations and symposia at key international meetings including RSTMH in 2007, ASTMH in 2008, EAHS in 2009, and WorldLeish2009
Infrastructure

- **LEAP**
  - Building of 2 research and treatment centres in Ethiopia and 1 in Sudan
    - Arba Minch in February 2006; Gondar in May 2008; Dooka planned for late 2009
  - Upgrading of facilities in Kenya and Uganda

- **HAT**
  - NECT study strengthened sites in DRC
**HAT & LEAP Platforms**

**Strengthening Regional Research Capacity**

- A new approach in which platforms serve as bridges for the region
  - Allow effective problem solving at a local level
  - Reference points for DNDi’s global network to show how regional partnership can deliver

---

**Lessons learned**

- Difference in cultural backgrounds appreciated in order to continue working as a team
- Communication and frequent consultations key to success of platform
- Consultative meetings of PIs crucial and play a major role in steering the platforms research activities
- A wide membership of the platform: MoH of member countries, regulatory authorities that provide desired support towards achieving the platforms objectives
- Each member institution appreciated as an equal partner that plays an integral part towards the success of the platform
Chagas Platform to Strengthen Clinical Research

- Inspired by African platforms
- In preparation for endemic countries within Latin America
- Develop a critical mass of expertise
- Strengthen institutional research capacity
- Support an environment conducive to quality research
  - Facilitate registration and recommendation of new therapies

Facilitating Regional Approach From Screening to Production

- Important to engage regions affected by diseases to strengthen capacity in all stages
  - Early-stage discovery research
    - PAN4ND: regional network linking natural products researchers to include neglected diseases in screening
      - 8 countries involved: www.pan4nd.org
  - Technology transfer with FACT products
    - ASAQ: identifying local African manufacturer in process
    - ASMQ: ongoing South-South transfer between public Farmanghuinos and private Cipla
Asante Sana!

Resources & Advocacy

- People
- Partners
- Money
- Advocacy

Bernard Pécoul
Executive Director
DNDi = 287 people worldwide

Governance members provide strategic guidance
Diverse yet complementary expertise
A motivated group committed to the same vision

A harmonised mix of cultures & skills

DNDi’s success hinges on expertise and involvement of partners
Well-balanced partnerships (public/private)

Increased number of partners: 204 in June 09 (128 in June 08)

Partnership distribution (June 2009)

Partners working together from all over the world
Global R&D funding in 2007

Neglected Diseases
$2.5 billion (US)

- Public (governments)
- Not-for-profit
- Big pharma
- Small pharma and biotech
- Other

Kinetoplastids
$125 million (US)

- Public (IDC governments)
- Public (OECD-plus governments)
- Not-for-profit
- Private (multi-pharma companies)
- Other

Source: Moran et al., G-Finder report, 2009

Funding Strategy - Diversity
€110M of €274M Secured (2004-2014)

Private Donors
- Médecins Sans Frontières (€43M)
- Bill & Melinda Gates Foundation (€18M)
- Other Private Foundations (€2.3M)

Public Donors
- UK (€28M)
- France (€7.5M)
- Spain (€5M)
- Netherlands (€3M)
- USA – NIH (€1M)
- Germany (€1M)
- Canton de Genève - Switzerland (€0.7M)
- European Union (€0.6M)
- Tuscany (Italy) (€0.2M)
Best Science for the Most Neglected

€164M Still Needed

2004-2014 Projected:

<table>
<thead>
<tr>
<th>Year</th>
<th>Gap</th>
<th>Pending</th>
<th>Commitments &amp; Pledges</th>
</tr>
</thead>
<tbody>
<tr>
<td>2004</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2005</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2006</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2007</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2008</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2009</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2010</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2011</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2012</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2013</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2014</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Advocacy: Ensure Public Leadership

Waking Up to “Essential Health R&D”

World Health Assembly, towards a new Global R&D Framework:

- R&D priorities
- Sustainable funding
- Intellectual property
- Regulatory environment
- Research capacity and technology transfer
Conclusions:
3 Key Challenges for the Future

• Access
• Sustainability
• Regulatory

Access

1. Access to compounds and knowledge
   • Innovative Agreements
   • Explore Patent Pools, etc.

2. Reaching patients
   • DNDi plays a facilitating role with many partners
Partnership is Key

- Manufacturers: sanofi-aventis, Farmanguinhos, Cipla, Lafepa
- Implementers: NCP, WHO, NGOs (MSF)
- Other PDPs: FIND, iOWH, MMV, Distributors: IDA
- Platforms: LEAP, HAT, FACT, Chagas
- Networks: studies - INESS, WWARN, Epicentre, TDR

Sustainability

- Funding
  - New mechanisms are key (Prize incentives, Global Fund, UNITAID, etc.)
- Strengthening capacities & technology transfer
Regulatory

• Major obstacles: delays in product registration
  – Role of National Regulatory Authorities in Disease Endemic Countries
  – Support of WHO
  – Facilitating role of more experienced agencies (FDA, EMEA and others)

• Innovative IP Management

6-Year Results

• 2 new malaria treatments developed
• 1 new sleeping sickness combination developed
• Largest pipeline ever for the kinetoplastid diseases
• Clinical research platforms in Africa
• €110M of €274M needed raised
• On track to deliver new treatments per business plan
By working together in a creative way, PDPs, large and small pharma, and the public sector can bring innovation to neglected patients!

www.dndi.org