DNDi’s practices for innovation and access

DNDi intellectual property workshop

New Delhi, India

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

Primary Objectives:
- Deliver 6 - 8 new treatments by 2014
- Establish a robust portfolio for new generation of treatments

Malaria  Visceral Leishmaniasis (VL)  Sleeping Sickness (HAT)  Chagas Disease
DND/i's: A Virtual R&D Organization

Public and Philanthropic Money

DND/i Headquarters (Geneva)

Strategic options

Project conception, planning and supervision

CEO, Executive Team

Project Manage

Project Manage

Project Manage

Project Manage

$ $ $ $

Delocalized, dedicated R&D and clinical trial platforms, CROs, public and private institutes, biotechs, pharma
DND’s Model for Drug Development

DND’s Collaboration Model:

• At early discovery stage:
  – Compounds come from academia, pharmas, biotechs
  – Biological characterizations are conducted at major parasitology research centres ("reference centres")
  – Pre-clinical development with dedicated CROs, etc.

• Clinical trials:
  – Collaborating partners include institutions and experts from disease-endemic countries, health authorities, and regulatory experts, and frequently MSF teams

• Registration and manufacturing:
  – Pharmaceutical partners provide essential capabilities to register, and ensure sustainable production and distribution
  – Technological transfer for production in Southern countries
NTD Drug Development Bottlenecks

Scientific Challenges:
1. Compounds sourcing
2. Accessing focused knowledge and data
3. Accessing technical competences
4. Complex clinical trials
5. “Small” scientific community

Economical and Legal Challenges:
1. No financial incentives for the private sector
2. Patent rights and confidential know-how
3. High costs to develop a new drug

Access Challenges:
1. Freedom to operate: -> manufacturing and pricing
2. Regulatory complexity
3. Quality control, distribution and appropriate usage
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Sourcing of innovation

Screening → Hit to Lead → Lead Optimization → PC → Clinical

Category of Source

Processes

Sourcing partner

Drug Development Process – Increasing annotations and probability of success

Go/No go decisions (repetitive)

Build S.A.R.

Refine structure

Pre-clinical candidate

Pharma Biotech

Academic consortia

Pharmas, Biotechs

Public research, Academia, Pharmas, PDP,

Focused series + annotations + experience of scientists

Series of compounds (no information)

Libraries

Lead Op. Consortia
An Example of Partnership
DNDi, Academia, Biotech, CRO

Partnership structure designed to leverage assets and provide upsides from all contributors

Anacor
- Boron-based compounds
- Input on product development

DNDi
- Project management
- Funding

SCYNEXIS
- Compound screening
- Developing leads into clinical candidates

Pace University and STI
- in vivo models
- Animal testing

IP

Funding

+ compounds
licenses on NTD
Clinical candidate(s)
DNDi’s IP policy

• Equitable access and affordable treatment
• Develop drugs as public goods
• Results made available to third parties
• Decisions regarding ownership of patents and of licensing terms are made on a case-by-case basis
• Reflecting characteristics of DNDi’s products:
  – Little commercial value
  – Distributed through the public sector
  – Developed in partnerships
Major IP issues

- *Royalty-free licenses* in the Field: no royalties on sales for targeted patient population and for the Neglected Tropical Diseases

- Territory in which licenses are granted must include *all endemic regions, without exclusion*

- Licenses must be *sub-licensable* to allow for third parties to work on project

- Licenses to allow for R&D and manufacture must be *world-wide*

- Sales on the public sector: *at cost plus*

- Sales on the private sector may include margins, within and outside the Territory (tier pricing) linked to partner’s financial contributions

- To make *freely available all information* generated about the product during its development (publications, databases, etc.)
Factors facilitating R&D in the NTD field:

From the industry:
- Pre-competitive R&D: open access policies
- Access to compounds, know-how and knowledge:
  - a gateway to « meet the experts »
  - automatic licenses on patents if used for NTD drug development
- A legal framework accepted by the industry including the essential provisions insuring patient’s access to the treatment

From the public domain:
- Humanitarian licenses from tech transfer offices regarding NTDs
- Implementing databases focused on NTDs
- Supporting translational research (TRND, NIH)