DNDi's practices for innovation and access

DNDi intellectual property workshop

New Delhi, India

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DNDi
Drugs for Neglected Diseases initiative

DND*i* Vision & Objectives

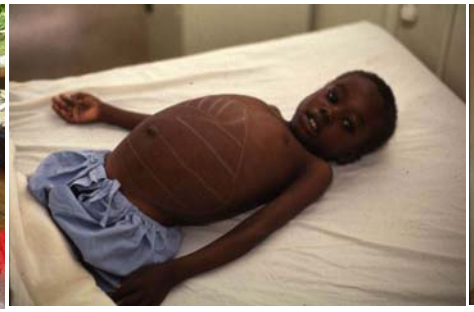
Vision:

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

Primary Objectives:

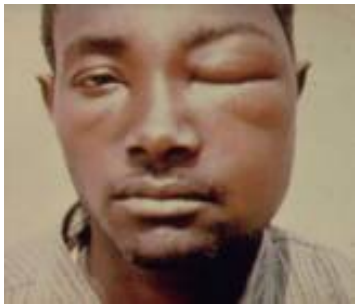
- Deliver 6 - 8 new treatments by 2014
- Establish a robust portfolio for new generation of treatments

Malaria



Visceral Leishmaniasis (VL)

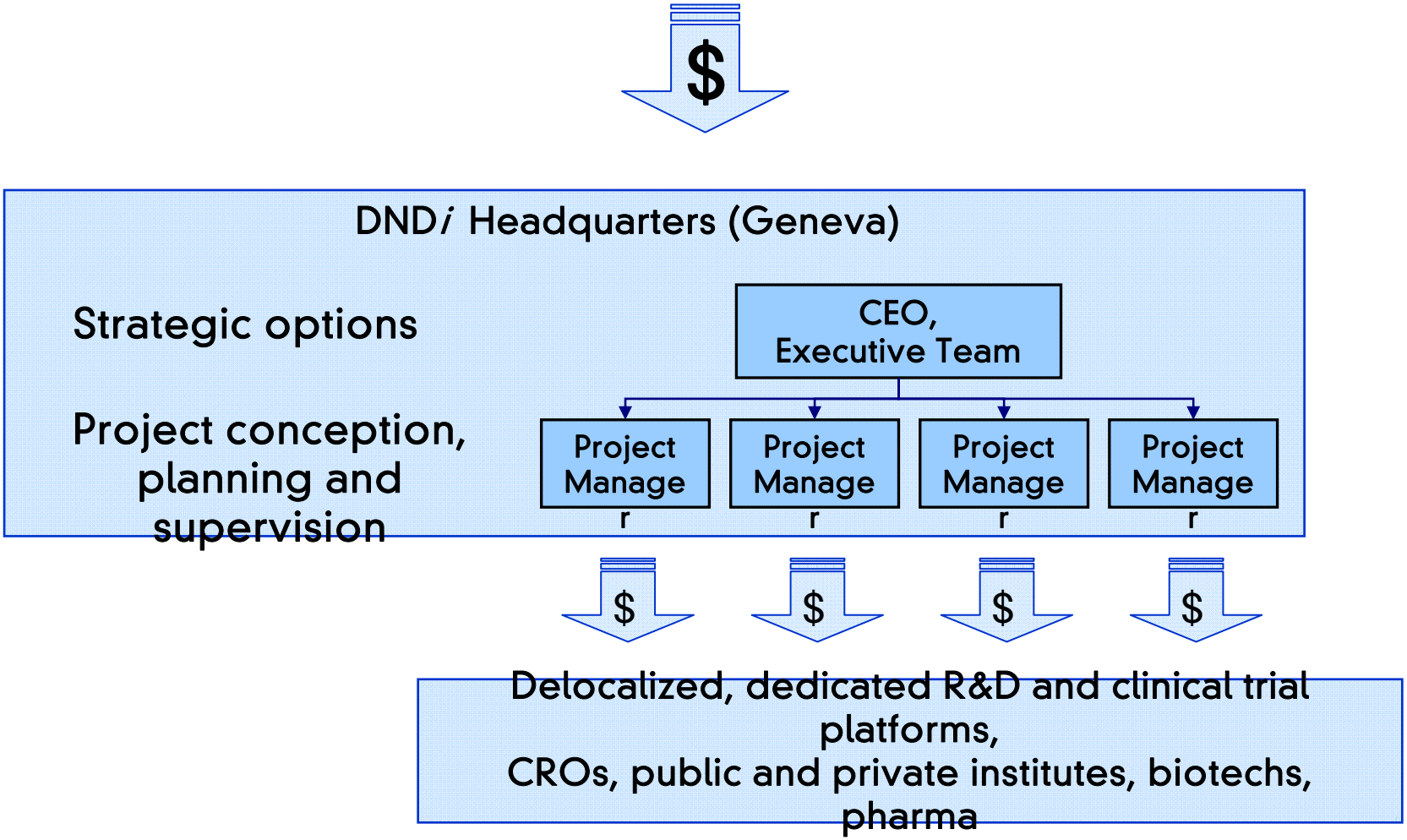
Sleeping Sickness (HAT)



Chagas Disease

DND*i*'s: A Virtual R&D Organization

Public and Philanthropic Money



DND*i*'s Model for Drug Development

DND*i*'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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Innovative R&D model

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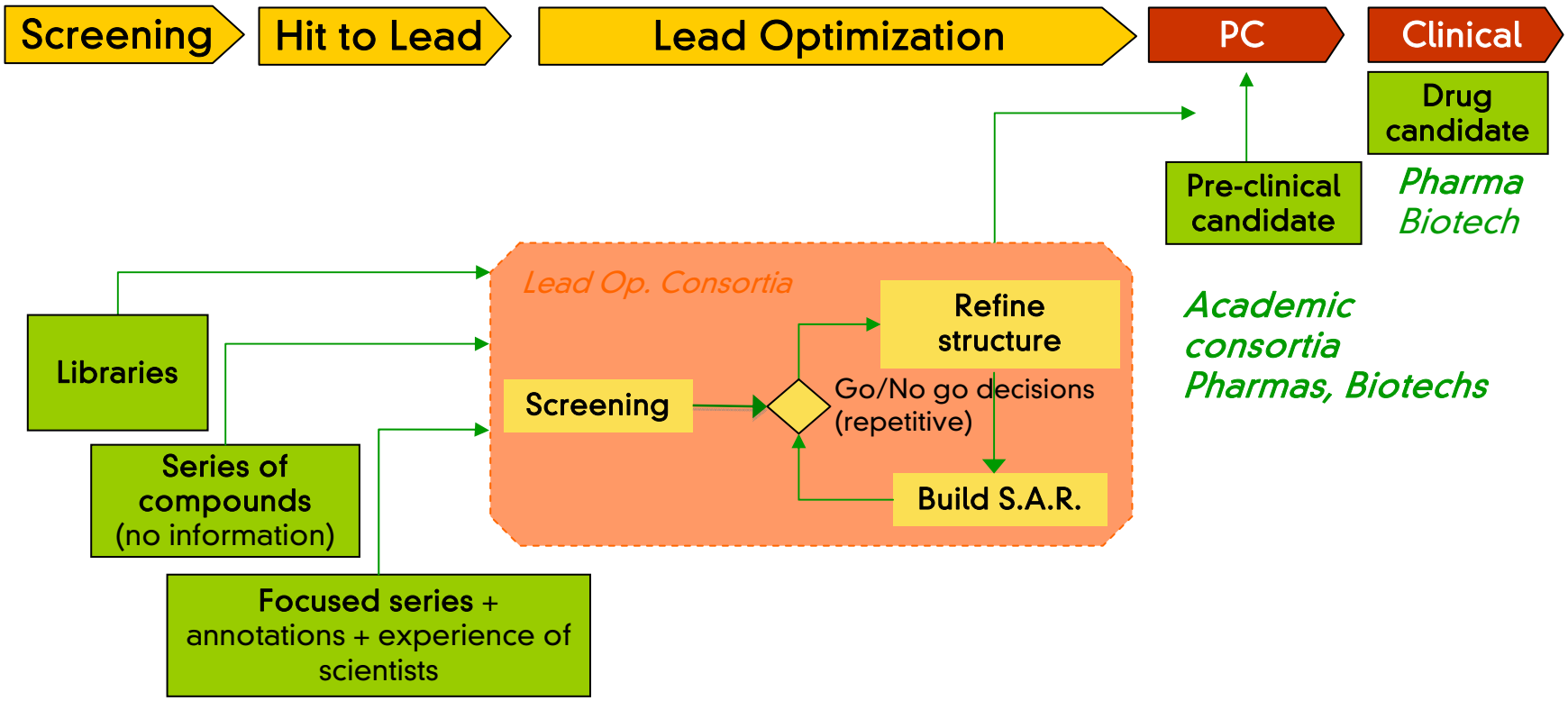
IP framework

Sourcing of innovation



Drug Development Process – Increasing annotations and probability of success

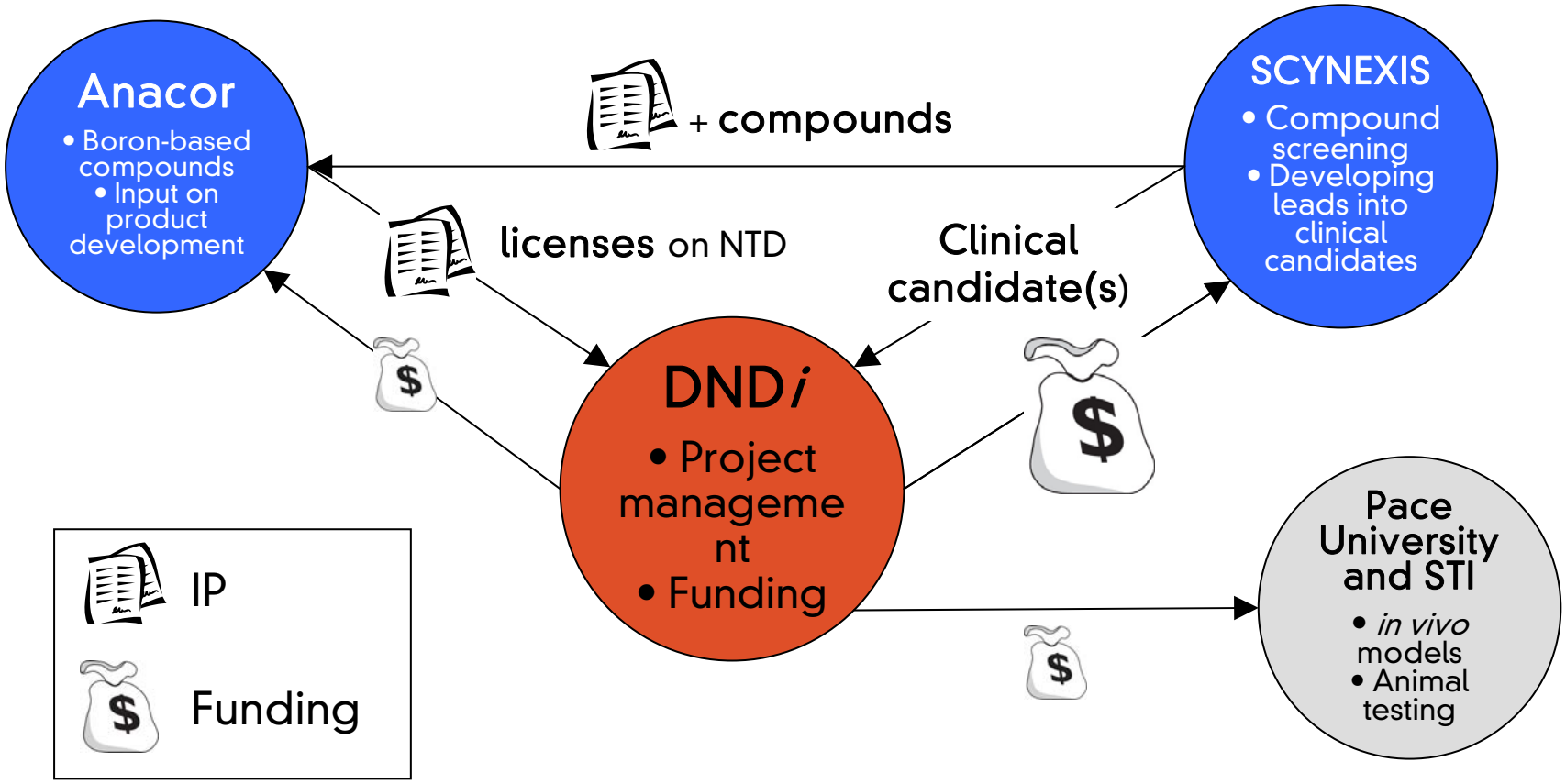
Compound Mining

Category of Source | *Sourcing partner* | Processes

An Example of Partnership

DNDi, Academia, Biotech, CRO

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



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.)

Conclusions

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)