THE ROLE OF IP FOR INNOVATION AND ACCESS: CHALLENGES AND OPPORTUNITIES

WHO-WIPO-WTO Trilateral Symposium:

Facing the Future: Human health and climate change

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DNDi
Best Science for the Most Neglected
20 Years

BEST SCIENCE FOR
THE MOST NEGLECTED

We discover, develop, and accelerate access to urgently needed treatments for neglected patients focusing on gaps for infectious diseases that fuel cycles of poverty and disease in resource-constrained settings

DNDi

A TRULY GLOBAL PARTNERSHIP

A patient needs-focused, globally networked R&D organization

Treatments delivered

12

field-adapted and affordable treatments for 6 deadly diseases

R&D pipeline replenished

> 20+ NCEs
> 4 million+ compounds screened
> 13 projects in Phase III and registration

A healthy pipeline of drug candidates for 8 deadly diseases

Clinical trials conducted

An average of 20 active clinical studies per year

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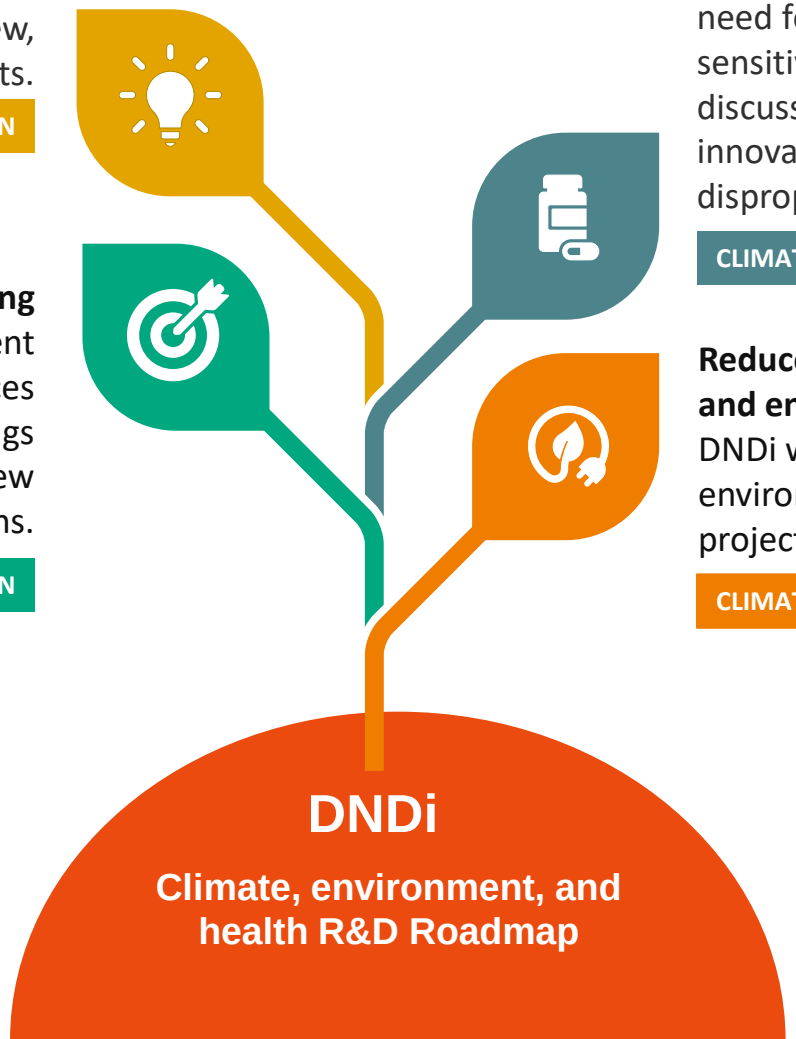
DNDi's four-pronged approach to climate, environment, and health R&D

Develop treatments for climate-sensitive diseases in LMICs
DNDi will innovate for neglected patients with climate-sensitive diseases and deliver new, adapted, and affordable treatments.

CLIMATE CHANGE ADAPTATION

Green biomedical R&D and manufacturing
DNDi will proactively contribute to the movement for greening R&D and manufacturing practices while helping to abandon the use of toxic drugs that harm the environment as we introduce new NTD therapeutic options.

ENVIRONMENTAL PROTECTION



Advocate for medical innovation for climate-sensitive diseases in the climate change response
DNDi will advocate for increased focus on the pressing need for R&D for health tools to combat climate-sensitive diseases in climate adaptation policies and discussions – and for commitments to ensure that innovation caters to the needs of populations disproportionately impacted by climate change.

CLIMATE CHANGE ADAPTATION

Reduce our carbon emissions and environmental footprint (REEF)
DNDi will halve its carbon emissions and reduce its environmental footprint by revisiting its corporate and project approaches.

CLIMATE CHANGE MITIGATION

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Neglected Tropical Diseases: among top climate sensitive diseases

NTDs include several parasitic, viral, and bacterial infectious diseases **that cause substantial illness for 1.65 billion people globally,** mostly in the least developed economies and most impoverished communities.

NTDs are climate sensitive diseases: **Nearly half of the NTDs** (Dengue, Leishmaniasis, Sleeping sickness, Chagas etc.) **are vector-borne or water-borne**, and **are at the forefront of the climate sensitive infectious diseases list**

- **Increased disease transmission:** Favorable conditions for NTD spread. However, incidence of some infectious diseases might be reduced as the environment may become hostile for vector survival
- **Expanded range:** Spread of NTDs to new areas. "tropical diseases" now causing global outbreaks. E.g. dengue in the United States, Europe, and re-emergence in Japan.
- **Treatment resistance rises:** Increased resistance to NTDs treatment.
- **Elevated risk of epidemics:** sustained disease outbreaks due to increased disease incidence
- **Severity of diseases:** Climate change is making it easier for vectors to survive and spread disease
- **Compounding health inequities:** Climate change further exacerbating existing health inequities

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Innovation and access

Innovation gap:

- The prevailing profit-oriented model for medical research and development (R&D) leaves little incentive to develop drugs for the poorest and most vulnerable communities
- As a result, many NTDs still a lack of tools for prevention, diagnosis, and treatment that are simple, safe, and effective – and that can be easily integrated into already overburdened health systems.
- Access gap:
- Despite global spread, countries in the Global South continue to bear the burden due to impact of climate change on infectious diseases
- Spread of climate sensitive infectious diseases to HICs may spur innovation on health tools, however
  - This doesn’t guarantee equitable access to these tools by populations that need them the most, in countries where the burden of disease is already extensive
  - This also doesn’t guarantee R&D for those climate-sensitive diseases which predominantly affect lower-and middle-income countries

LEISHMANIASIS

DELIVERING SAFER, SIMPLER TREATMENTS TO SAVE LIVES AND REDUCE SOCIAL STIGMA

FACTS

Over 600 million
people at risk of VL worldwide

600,000-1 million
new cases of CL each year

About 50%
of people infected with VL and CL are children

CHALLENGES

VISCERAL LEISHMANIASIS (VL): Treatments require either hospital stays or complex infusions.

CUTANEOUS LEISHMANIASIS (CL): Current treatments are more than 60 years old, costly, and often require weeks of painful injections of toxic, heavy metal-based drugs with severe side effects.

OUR WORK

VL: Improved treatments now part of national guidelines in **East Africa (2010)** and **South Asia (2011)**

CL: Several **promising compounds identified,** now in different stages of development

Replenished R&D pipeline with an unprecedented portfolio of all-new potential drugs

OUR GOALS

2021-2028: Deliver safer, simpler treatments to save lives and reduce social stigma

- Deliver **five new short-course treatments** for: VL and HIV co-infection (delivered June 2022), VL in East Africa and Latin America (delivered June 2022), post-kala-azar dermal leishmaniasis, and CL
- Advance **two oral combination regimens** based on new chemical entities to Phase III
- Advance **'immunomodulator' for CL** to clinical development
- Ensure **prompt diagnosis** and **affordable access** to new treatments

MAIN PARTNERS: dndi.org/leish-partners

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The acute challenge for low resource settings

Climate Change

- **Vector-borne (and water borne) infectious diseases**
  e.g., NTDs
- **New Emerging Diseases**
  e.g., Zoonotic diseases
- **Climate-related migration**
  exposes new (& non-immune) populations and ill equipped health systems

+

- **Impacts of climate change disproportionately burden low- & middle-income countries**
- **The global biomedical innovation system is not responsive to the needs of low-resource settings**

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Looming crisis of innovation and access

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IP in neglected diseases:

- IP has **not been** an incentive/ booster/ driver for NTDs/ diseases of poverty

- **BUT** R&D is based on using knowledge which can be subject to preexisting or potential IP rights created as part of the development process.

IP can:

- Limit access to valuable chemical compounds
- Limit use of new technologies, platforms, formulations e.g AI, mRNA
- Restrict distribution (territory limitations)
- Hinder open innovation strategies
- Prevent manufacturing, technology transfer, affordable access and distribution

Pro Access Policies: ensuring IP rights do not hinder innovation and access

To address roadblocks to innovation and access created by intellectual property rights limiting the possibility of collaboration, follow-on R&D, production, or equitable access to end-result products, DNDi's Intellectual Property Policy is based on two guiding principles that inform negotiations:

- **ensure that drugs are affordable and accessible in an equitable manner to patients who need them; and**
- **develop drugs as global public goods whenever possible.**

Examples:

*Building on its experience, DNDi has defined '**gold standard**' licensing terms to ensure equitable and affordable access to treatments, including, whenever possible:*

- *terms such as perpetual royalty-free, non-exclusive, sub-licensable licenses to DNDi in the contractually defined target disease(s);*
- *worldwide research and manufacturing rights;*
- *commitment to make the final product available at cost, plus a minimal margin, in all endemic countries, regardless of income level; and*
- *non-exclusivity, enabling technology transfer and local production to multiply sources of production and decrease price of product.*

DNDi also publishes model contracts or templates of the collaboration and licensing agreements that it signs with public and private partners, including with pharmaceutical companies.

Read DNDi's fuller legal commentary '*Striking fair deals for equitable access to medicines*' published in the Oxford Journal of IP Law and Practice

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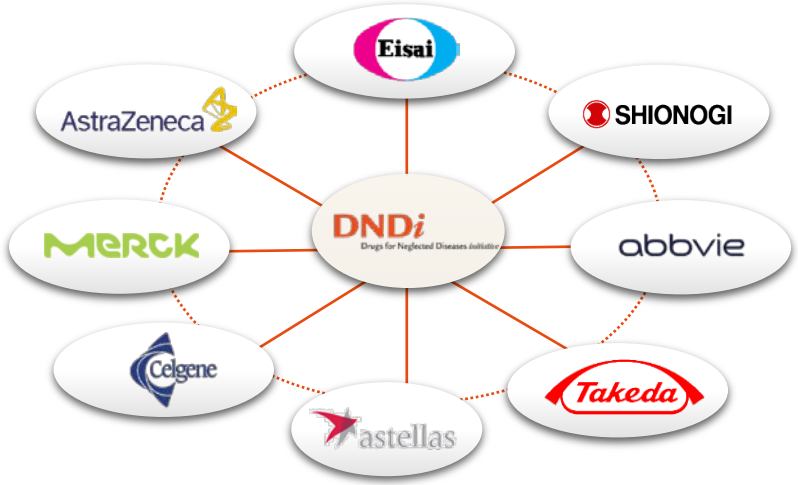
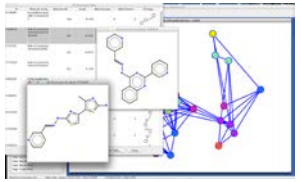
NTD Drug Discovery Booster



Institut Pasteur Korea

Swiss TPH
Swiss Tropical and Public Health Institute
Schweizerisches Tropen- und Public Health-Institut

LMPH
Laboratory for Microbiology, Parasitology and Hygiene
University of Antwerp



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12 NEW TREATMENTS
DEVELOPED FOR **6 DEADLY DISEASES,** SAVING MILLIONS OF LIVES

✓Easy to use
✓Affordable
✓Context-adapted
✓No patent barriers

EMBEDDING EQUITABLE ACCESS
KEY FACTORS:

- Prioritize access from the outset of R&D and embed at all stages, not once a product is in late-stage clinical development or has received regulatory approval (end-to-end approach)
- Underpinned by collaboration agreements with partners based on a shared vision
- Based on: Target Product Profiles that respond to population needs (including target price) with local experts, clinicians, regulators, and affected communities
- Public IP Policy- Key principles:
  - Equitable access and affordability of end-product
  - Make results of DNDi research available to the wider research community
  - Develop drugs as public goods whenever possible

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INNOVATION FOR ACCESS : OPPORTUNITIES

Co-creating solutions: Dengue Alliance

To develop a new treatment, utilizing expertise and capacity of partners from dengue-endemic countries

- Create a joint and collaborative agenda for the development of affordable dengue therapeutics
- Focused on solutions that work best in endemic contexts
- Promote collaborative non-for-profit medical research and development (R&D) environment
- Implement research activities
- Engage in joint fundraising
- Encourage, support and develop research knowledge and skills of personnel
- **Encourage and promote the use and sharing of the research results (including intellectual property) and products, created under this collaboration, for an equitable and affordable access**, policy-making and other public purposes

Dengue Alliance

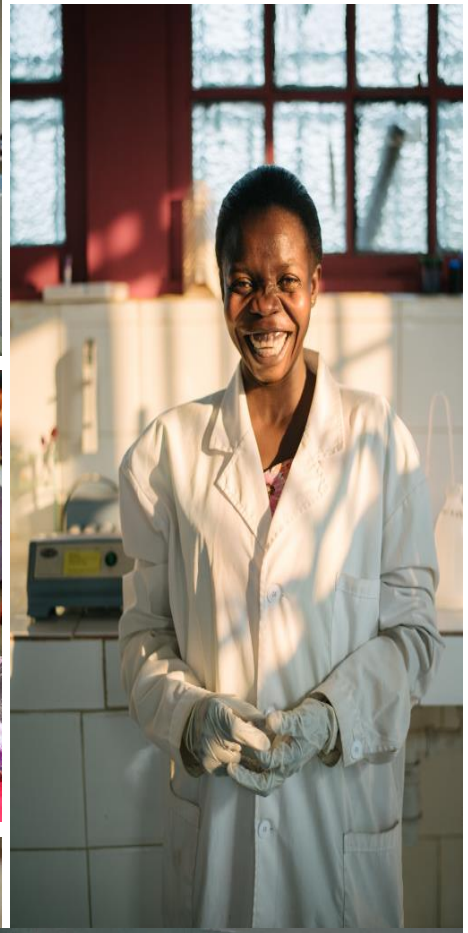
Ministério da Saúde
FIOCRUZ
Fundação Oswaldo Cruz

KEMENTERIAN KESIHATAN MALAYSIA

thsti
TRANSLATIONAL HEALTH SCIENCE AND TECHNOLOGY INSTITUTE
ट्रांसलेशनल स्वास्थ्य विज्ञान और प्रौद्योगिकी संस्थान

DNDi 20 Years
Best Science for the Most Neglected

POLICY ACTION



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Ensure developing new tools (drugs, diagnostics, and vaccines) for primary and community healthcare is a key component of climate adaptation discussions at COP

2

Create an enabling framework :

- Public policies and mechanisms to specifically address IP barriers.
- Conditions on public and philanthropic R&D funding (incl affordability and IP licensing obligations) to ensure development and access to health tools.
- Support alternative ways to fund R&D e.g. not for profit models, prizes.

3

- **Support south-south** and triangular **collaborations** –where countries facing the greatest burden and most affected by climate-sensitive diseases lead innovation

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Thank You

For more information: mchilds@dndi.org

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