



Intellectual property licensing, technology transfer, and sharing of know-how and clinical trial information

DNDi experience

WHO, WIPO, WTO Workshop on Innovation in, and Access to, COVID-19 Technologies
27 September 2021

Pascale BOULET, IP & Access Leader

BEST SCIENCE
FOR THE MOST NEGLECTED

DNDi
Drugs for Neglected Diseases *initiative*

DNDi was created by public & private health & research institutions and WHO

- Kenya Medical Research Institute
- Indian Council of Medical Research
- Malaysian Ministry of Health
- Oswaldo Cruz Foundation, Brazil
- Institut Pasteur
- Médecins Sans Frontières
- World Health Organization's Special Program for Research and Training in Tropical Diseases

DNDi develops life-saving medicines for neglected patients around the world



A virtual non-profit R&D organization



15 YEARS, 9 TREATMENTS, MILLIONS OF LIVES SAVED

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

Treatments delivered



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

Clinical trials conducted



An average of 20 active clinical studies per year

Research networks established

- 4 clinical research networks
- COVID-19 Clinical Research Coalition with 350+ members

Global partnerships forged



200+ partner institutions in 40+ countries

Diverse global team mobilized



A diverse global team of 250+ staff

Policies influenced

DNDi's model, experience, and lessons learned documented and disseminated

New organization to fight drug-resistant infections

DNDi joined forces with the World Health Organization (WHO) to create the **Global Antibiotic R&D Partnership (GARDP)**

DNDi Collaboration and Licensing agreements guided by its IP Policy

Key objectives of DNDi IP policy:

- Ensure equitable access and affordability of DNDi end-products
- Make the results of DNDi research available to the global research community
- Develop drugs as public goods when possible

Terms & conditions ensure DNDi Partners cannot use IP to impede access to DNDi products, or follow-on research.

IP ownership and licensing terms decided on a case-by-case basis, with the main objective to disseminate results of DNDi work as widely as possible.

Sharing knowledge and data

- DNDi *Scientific and Clinical External Communications Policy* supports timely communication of all research sponsored by DNDi (discovery, pre-clinical, clinical)
- DNDi is a co-signatory of the May 2017 *WHO Joint statement on public disclosure of results from clinical trials*
- DNDi [policy on the Sharing of Clinical Trial Data](#) aims to share research data generated through DNDi partnerships
 - registering all trials in a publicly available register, such as the US National Institutes of Health (NIH) [clinicaltrials.gov](#) or the [Pan-African Clinical Trials Registry](#)
 - reporting results within 12 months after completion of trials
 - publishing DNDi studies, whether results are positive or negative, in open-access peer-reviewed journals.

DNDi 'Gold standard' licensing terms enable knowledge sharing




- 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;
- **Non-exclusivity, enabling technology transfer and local production** to multiply sources of production and decrease price of product.



Sharing of Know-how and Technology transfer upon Expiry / Early termination of the collaboration

- Upon expiration of DNDi collaboration agreements
 - Survival of licensing rights to DNDi, enabling continuation of project and possible tech. transfer to a third party
- If DNDi partner withdraws or underperforms (eg. product unaffordable or unavailable)
 - Rights secured to ensure full freedom to operate to DNDi (if not already done through licenses), and
 - Partner's commitment to transfer technology, documentation and approvals, free of charge, to the new partner (+ any stock of API or Product)



Thank you!

 facebook.com/dndi.org
 youtube.com/dndiconnect
 twitter.com/dndi

 instagram.com/drugsforneglecteddiseasesinitiative
 linkedin.com/company/dndi