

# STRIVING FOR INCREASINGLY OPEN INNOVATION MODELS

Since the year 2000, the R&D landscape for neglected diseases has improved, with a growing number of players now involved in the R&D process through partnerships between not-for-profit organizations and private companies. In addition, this improving landscape is supported by public donors and philanthropists and has led to a replenishing pipeline of health tools.

The year 2011, with new agreements to access compounds and expertise of pharmaceutical companies and new open innovation initiatives, marks a turning point in the landscape for neglected disease R&D.

In order to foster innovation for neglected diseases and deliver major scientific breakthroughs as quickly and efficiently as possible, gaining access to knowledge and compounds and encouraging open innovation models form the cornerstone of DNDi's efforts to advance global health by supporting the research community in the field of neglected diseases.

## Aiming for 'gold standard' research and licensing agreements

The year 2011 and early 2012 were fruitful for DNDi in terms of partnerships with pharmaceutical and biotechnology companies, as well as with other PDPs, with new agreements either signed or underway. Several of these partnerships were highlighted during the 'Uniting to Combat NTDs' event in London in January 2012, where public and private partners pledged to boost efforts to combat ten neglected tropical diseases. DNDi's research and licensing agreements secure access to compound libraries, data, and knowledge in order to boost innovation and jumpstart the expensive and time-consuming discovery phase of R&D to identify promising drug candidates.

Today, DNDi works with over a dozen companies. In 2011, a three-year research collaboration agreement was signed with Sanofi to undertake research on new treatments for nine neglected tropical diseases (NTDs).

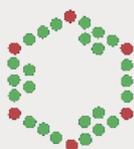
The rights to results produced by this partnership will be co-owned by Sanofi and DNDi and publication of the results will be facilitated to ensure access to the wider community of NTD research. The public sector will benefit from the drugs developed through this agreement under the best possible conditions to facilitate patient access in all endemic countries, irrespective of income level.

In early 2012, a four-year joint research and non-exclusive licensing agreement was signed with Abbott to undertake research on new treatments for Chagas disease, helminth infections, leishmaniasis, and sleeping sickness. Under the agreement, Abbott provides DNDi access to molecule classes and accompanying data. In addition to a non-exclusive licensing structure for relevant IP, the products resulting from the agreement will be provided in all endemic countries, irrespective of income level, at the lowest sustainable price.

Several years of experience have led DNDi to define what can be deemed the 'gold standard' of licensing terms, which includes four key components:

- perpetual royalty-free non-exclusive sub-licensable licenses in the specific disease areas determined in the agreement
- 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.

ChEMBL





## Encouraging innovation through sharing of data and knowledge

Neglected disease R&D requires new and open models for sharing knowledge and research data. As demonstrated by the Open Source Drug Discovery consortium in India, ChEMBL-NTD, WIPO Re:Search, the Medicines for Malaria Venture's open access Malaria Box, GSK's Open Lab, and the Medicines Patent Pool, initiatives for open innovation are flourishing, and while it may be too early to evaluate their impact, they demonstrate increasingly open approaches to boosting innovation. DNDi welcomes this trend and took steps in the year 2011 in this direction.

With eight pharmaceutical companies and nearly a dozen not-for-profit or public research institutions, including Fiocruz, DNDi joined WIPO Re:Search as both a 'user' and a 'provider' of the public database and open innovation platform, launched in October 2011. WIPO Re:Search provides access to intellectual property (IP) for pharmaceutical compounds, technologies, and other data and knowledge for R&D on neglected tropical diseases, tuberculosis, and malaria. In 2011, DNDi posted data on over 5,500 compounds from two of its lead optimization consortia on sleeping sickness and Chagas disease, both on the WIPO Re:Search and on yet another public database: the ChEMBL-NTD medicinal chemistry database. The latter provides open access to primary screening and medicinal chemistry data relevant to neglected diseases.

A special 'Open Innovation Portal' was created to render these datasets easily accessible on the DNDi website. These two public databases represent a move towards more open mechanisms that have the potential to facilitate and foster sharing of IP and knowledge to boost neglected disease innovation, notably by avoiding duplication in research and by reducing costs and development timelines for the benefit of patients.

The data that DNDi makes available is the fruit of collaboration between DNDi and its partners and is part of a constant effort to render accessible to entire scientific community, whenever possible:

- both positive and negative research results, as negative results can offer a wealth of information, allow for new research approaches to the same series with potentially different outcomes, and eliminate duplication of efforts; and
- data that DNDi and its partners have willfully agreed to place in the public domain, free of any and all IP constraints.

