

R&D Principles and Practices in Use

Needs-driven

The Drugs for Neglected Diseases' Initiative (DNDi) is a non-profit R&D initiative developing health technologies to address neglected diseases, which represent a largely unmet health need. DNDi places the needs of the end-user at the center of their R&D efforts by selecting target product profiles which take into consideration how a given product will reach populations in need. Using this approach DNDi has successfully delivered six treatments for malaria, sleeping sickness, visceral leishmaniasis and Chagas disease since its inception in 2003¹. Despite a slight improvement over the last 12 years, in part due to funds and initiatives like DNDi, neglected diseases continue to represent just 4% of new therapeutic products registered while representing 11% of the global burden of disease².

Evidence-based

Cochrane is a global network of researchers, health professionals and patients striving to produce evidence-based and accessible information on health. For 20 years, contributors from 120 countries have been working together to condense and synthesise evidence through systematic reviews and meta-analyses, combining existing studies to reduce uncertainties³. Their work in finding and collating data from clinical trials has been essential in counterbalancing selective reporting of research results and has shed light on the benefits and harms of new treatments, thereby helping to avoid research duplication⁴.

Openness, transparency and effectiveness

The Indian Open Source Drug Discovery (OSDD) initiative is an online drug discovery platform using crowdsourcing, social networking and open access repositories to solve complex problems associated with discovering novel therapies for neglected tropical diseases. This approach harnesses the contributions of individual researchers to maximise efficiency of early stage basic research⁵. In addition to the OSDD, there are a number of other initiatives aiming to foster faster innovation through open innovation platforms (eg. TB-PACTS for tuberculosis, WWARN for malaria and IDDO for ebola)⁶.

¹ Drugs for Neglected Diseases' Initiative (DNDi). (2015). Retrieved from website: https://www.dndi.org/wp-content/uploads/2016/10/Factsheet_2015_Chagas_disease.pdf

² The drug and vaccine landscape for neglected diseases (2000–11): a systematic assessment. Pedrique, Belen et al. The Lancet Global Health , Volume 1 , Issue 6 , e371 - e379

³ Cochrane. About Cochrane Reviews [Internet]. [cited 2017 Apr 30]. Available from: <http://www.cochranelibrary.com/about/about-cochrane-systematic-reviews.html>

⁴ <http://www.bmj.com/content/342/bmj.d2686>

⁵ Open Source Drug Discovery (OSDD). (n.d.). An Open Collaborative Drug Discovery Model for Tuberculosis. Proposal Submitted before WHO Expert Working Group on R&D Financing. World Health Organization. Retrieved from website: [http://healthresearchpolicy.org/sites/healthresearchpolicy.org/files/Open source drug discovery-TB.pdf](http://healthresearchpolicy.org/sites/healthresearchpolicy.org/files/Open%20source%20drug%20discovery-TB.pdf)

⁶ Balasegaram M, Kolb P, McKew J, Menon J, Olliaro P, Sablinski T, et al. (2017) An open source pharma roadmap. PLoS Med 14(4): e1002276. <https://doi.org/10.1371/journal.pmed.1002276>

Affordability and equity

The Medicines Patent Pool (MPP) brings down prices for HIV drugs and, more recently, treatments for Tuberculosis and Hepatitis C, through voluntary licensing of Intellectual property. To date, the MPP has successfully signed licensing agreement for 12 antiretrovirals and an agreement with the TB Alliance for a novel antibiotic candidate⁷. The MPP demonstrates the acceptability and feasibility of non-exclusive licensing and other flexible approaches to intellectual property to ensure affordability.

Delinkage

Medicines for Malaria Venture (MMV), DNDi and various other non-profit initiatives apply the technical practice of delinkage, mostly due to their non-profit nature. The polemical principle of delinkage is defined by any research initiative which accommodates “universal access to knowledge goods, [induces] openness and sharing of knowledge in general, and [makes] investments in R&D more cost-effective and responsive to the needs of patients and society”⁸. Delinkage is best exemplified by the development of a novel antimalarial, ASAQ, by DNDi. The drug was developed using grants and in-kind contributions, a result of a collaboration between two R&D-focused organisations (Sanofi and DNDi), and targets an unmet health need. The end product is affordable at \$1 for adults and \$0.50 for children⁹.

R&D as a globally shared responsibility

While there is not a specific example of an existing initiative approaching R&D as a globally shared responsibility, it is clear that in order to effectively conduct needs-driven research we need global coordination and cooperation, as proposed in not yet realized initiatives like the WHO Global Biomedical R&D Fund.

⁷ Medicines Patent Pool (MPP). (2015). MPP. UNITAID. Retrieved from website: <http://www.medicinespatentpool.org/?lang=es>

⁸ Love J. An economic perspective on the cost of disease. UNITAID Discussion Paper. 2016;

⁹ DNDi. DNDi Achievements ASAQ [Internet]. Available from: <https://www.dndi.org/achievements/asaq/>