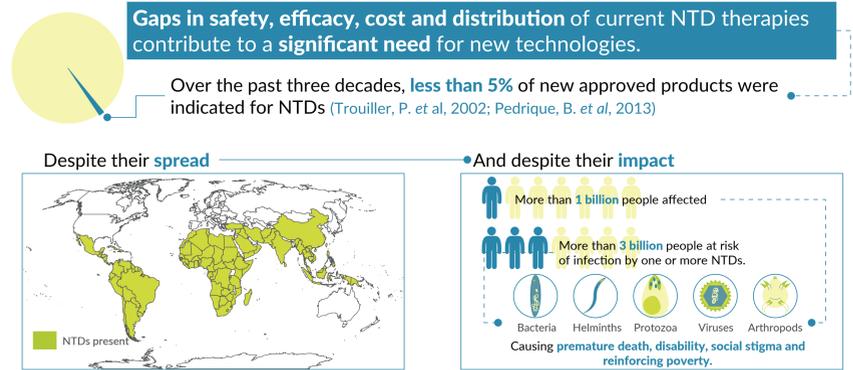


Mark Sullivan¹, Curt LaBelle², Errol Malta¹, Patty Fegan¹, Victoria Ryg-Cornejo¹, David Ridley³

¹Medicines Development for Global Health, Melbourne, Australia; ²Global Health Investment Fund, New York, NY, United States; ³Fuqua School of Business, Duke University, Durham, NC, United States

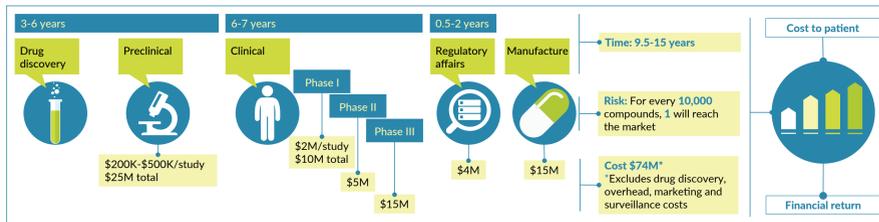
Global impact of neglected tropical diseases (NTDs)



Overcoming underinvestment in drugs for NTDs

Cost and lack of financial return are barriers to investment in the development of new NTD products.

Drug development is **time consuming, costly and risky**. Investment into research and development (R&D) is predicated on potential **financial return**.



Investment into NTD R&D has been **incentivized**.

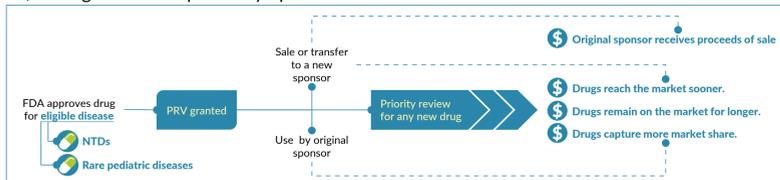
- Push incentives:** decrease R&D costs through upfront financial support.
- Pull incentives:** reward development through increased returns.



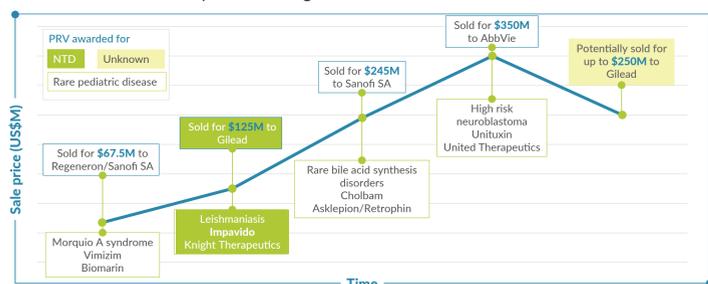
Rewarding drug development with a Priority Review Voucher

The priority review voucher (PRV) program aims to increase the number of NTD technologies by **rewarding sponsors** who successfully register a drug that targets an **eligible disease** (Ridley, D. et al, 2006).

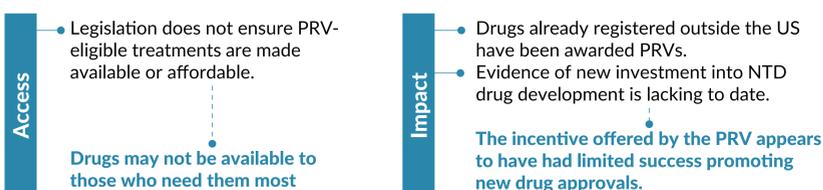
The PRV, which can be sold, entitles the bearer to expedited US Food and Drug Administration (FDA) review, cutting the review period by up to **6 months**.



The **potential reward** of the PRV provides a significant **incentive** to invest in NTD R&D.

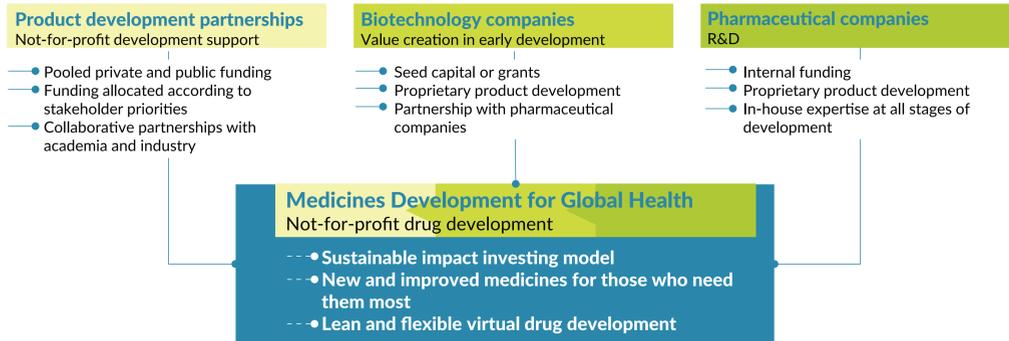


However, as PRVs have been awarded and redeemed, some **concerns** have been raised by the NTD R&D community.



Medicines Development for Global Health – a new model for NTD drug development

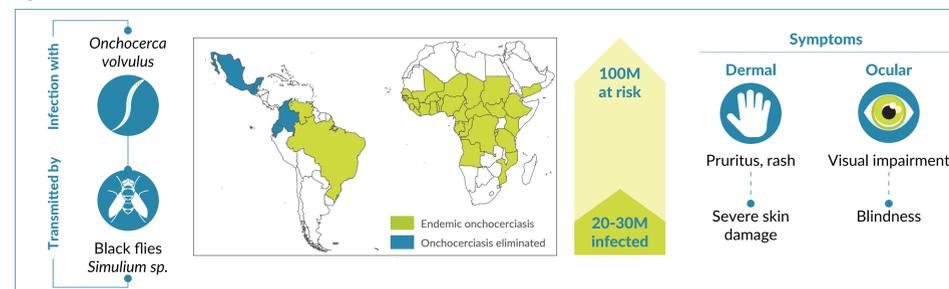
Multiple drug development models are contributing to the increased development of treatments and interventions required for the **control, elimination and eradication of NTDs**.



The PRV as an agent of change – The development of moxidectin for onchocerciasis

Moving towards **elimination of onchocerciasis** requires new treatments.

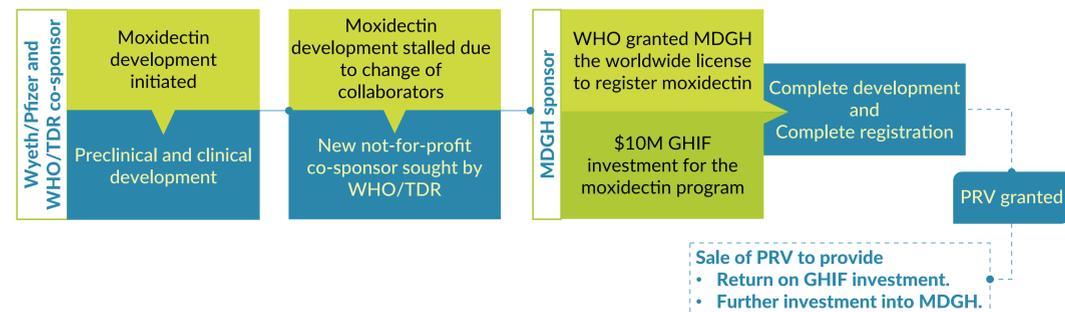
Significant progress has been made in reducing the prevalence of onchocerciasis, but it remains a serious cause of **morbidity and mortality**.



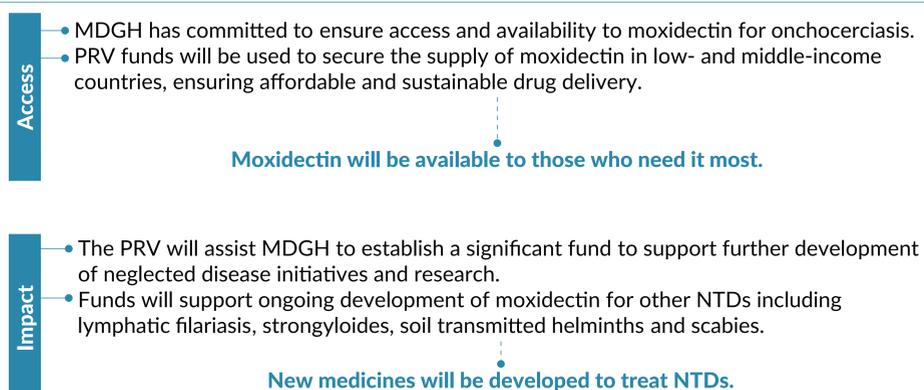
Moxidectin
A PRV candidate and promising new therapeutic option for onchocerciasis

- Macrocyclic lactone.
- Selectively binds to parasite glutamate-gated chloride channels.
- High lipophilicity and long in vivo half-life.
- Used to treat common parasite infections in animals.
- Well-tolerated and highly efficacious at reducing *O. volvulus* in patients. (Awadzi, K. et al, 2014)

The PRV and global health potential attracted **development-enabling investment** for moxidectin from the Global Health Investment Fund (GHIF).



The proceeds from the sale of the PRV will support **global access to moxidectin** and establish a **drug development fund**.



The proceeds from the PRV sale will make MDGH one of the world's largest independent philanthropic organisations dedicated to developing affordable medicines to address global health priorities.

About

Medicines Development for Global Health
<http://www.medicinesdevelopment.com>

- Formed in 2005 in Melbourne, Australia.
- Follows a new model for drug development combining the methods and rigor of the pharmaceutical industry with a philanthropic and impact investment funding model.
- An independent not-for-profit global health company with the mission to put new and improved medicines into the hands of people who need them most.
- Is financially self-sustaining by using funds in excess of running costs for the development of medicines and vaccines that may have limited commercial opportunity.

Global Health Investment Fund
<http://www.ghif.com/>

- Private social impact investment fund backed by a diverse group of sponsors, guarantors and donors.
- Mission to finance late-stage drugs, vaccines and diagnostics for diseases that disproportionately burden low-income populations.
- Public health challenges targeted by the GHIF include malaria, tuberculosis, HIV/AIDS, cholera, maternal and infant mortality and other neglected infectious diseases

World Health Organization and Special Programme for Research and Training in Tropical Diseases (WHO/TDR)
<http://www.who.int/tdr/en/>

- TDR is hosted at the World Health Organization (WHO), and is sponsored by the United Nations Children's Fund (UNICEF), the United Nations Development Programme (UNDP), the World Bank and WHO.
- Global programme of scientific collaboration that helps facilitate, support and influence efforts to combat diseases of poverty
- Research on moxidectin was initiated by TDR in the late 1990s with support of the Onchocerciasis Control Programme (OCP) and the African Programme for Onchocerciasis Control (APOC)

References

- Awadzi, K., N. O. Opoku, S. K. Attah, J. Lazdins-Helds and A. C. Kuesel (2014). A randomized, single-ascending-dose, ivermectin-controlled, double-blind study of moxidectin in *Onchocerca volvulus* infection. *PLoS Negl Trop Dis* 8(6): e2953.
- Pedrique, B., N. Strub-Wourgaft, C. Some, P. Olliaro, P. Trouiller, N. Ford, B. Pécoul and J.-H. Bradol (2013). The drug and vaccine landscape for neglected diseases (2000–11): a systematic assessment. *The Lancet Global Health* 1(6): e371–e379.
- Ridley, D. B., H. G. Grabowski and J. L. Moe (2006). Developing drugs for developing countries. *Health Aff (Millwood)* 25(2): 313–324.
- Trouiller, P., P. Olliaro, E. Torreele, J. Orbinski, R. Laing and N. Ford (2002). Drug development for neglected diseases: a deficient market and a public-health policy failure. *The Lancet* 359(9324): 2188–2194.