FUND FOR RESEARCH AND DEVELOPMENT IN NEGLECTED DISEASES

Please provide a description of the proposal:

Neglected diseases cause a large health burden (over 139Mn DALYs) on the poorest populations in the developing world. Interventions have been hampered among others by a lack of effective treatments, vaccines and diagnostics.

Neglected diseases affect the poorest in the developing world. Traditional revenue-driven R&D opportunities do not exist, creating a prohibitively high level of R&D risk. To address this market failure, Product Development Partnerships (PDPs) between the research-based pharmaceutical industry and public research entities have been created.

Donors provided funding in excess of 1.8Bn USD in 2008 that, combined with previous funding, has fueled progress in private, public and PDP entities. Over the past decade, these efforts have combined the expertise of hundreds of research institutions, pharmaceutical manufacturers and individual scientists to create the most robust product pipeline for neglected diseases in history. Specifically, PDPs have:

- Brought more than 10 new treatments, vaccines and diagnostics for neglected diseases to the market under a no-profit / no-loss access framework.
- Built up a compound portfolio of over 175 projects (~60% in discovery and ~40% in development stages), and
- Attracted over 300 researchers and managerial staff and over 100 scientific advisors dedicated to these diseases.

Despite these achievements, a funding shortfall is imminent. As the pipeline matures, more compounds move from the discovery to the development stage. Currently there are over 80 compounds in the pre-clinical and early development stages. Large scale funding is needed over the next ten years to continue the development of products currently in the pipeline and to continue to discover new compounds. Failure to find this funding will stall the progress of new compounds, waste the investments made in discovery and jeopardize the health of millions in the developing world.

The urgent need to increase R&D financing for neglected diseases is well recognized within the global health community. Numerous funding mechanisms have been suggested, but little concrete action has materialized.

We have worked over the past years on a Fund for Research into Neglected Diseases (FRIND) that addresses the funding short-fall. Its key elements are:

**Scope and eligibility.** FRIND will focus on the R&D financing of diagnostics, treatments and vaccines in late-stage clinical development (phases II and III). Consultations have shown that the need and feasibility for rigorous portfolio management is the greatest in this phase. All research entities in the neglected diseases space, whether public, private or non-profit, will be eligible.

**Portfolio management.** FRIND will use the scarce resources in the most cost-effective manner. It will use rigorous portfolio management to select the strongest compounds, and finance them in an upfront, ex-ante, basis from milestone to milestone. An independent Scientific Advisory Committee will be tasked to select the best compounds from the different
eligible entities.

**Financing.** FRIND will focus on attracting governmental funds from new, additional, donors, who currently do not have the capacity to perform portfolio management in the neglected diseases space.

**Describe and justify the potential public health impact of the proposal:**

- FRIND will have a public health impact by financing the development of compounds that provide more effective prevention, diagnosis and treatment of infectious neglected diseases, which have a joint health burden of 139Mn DALYs, and claim millions of lives on a yearly basis.

- There are multiple CEWG proposals that target the same financing gap (e.g. different type of prize funds, procurement guarantees, AMCs). FRIND is however the most cost-effective proposal, as it can reach this desired health outcome with the smallest amount of financial resources, due to the upfront financing and the strong portfolio management.

- For a given funding envelope, the public health impact will be greatest with FRIND, and will thus translate into the highest number of lives saved.

- FRIND works within the existing IP framework but aims to prevent IP obstacles from obstructing neglected diseases R&D.

- FRIND will attract new entities to the neglected diseases field through offering new and sustainable financing.

**Describe and justify the technical feasibility of the proposal:**

FRIND has a high technical feasibility, as it combines the two tested-and tried models of ex-ante funding and strict portfolio management.

The ex-ante mechanism means that funding is provided before the research takes place, and is recommended as it:

- **Builds on track-record of success.** Ex-ante financing has a demonstrated track-record of success. It is the current business model of PDPs, public research labs and biotech firms, has supported almost all R&D activity in the past decade and has built the existing compound portfolio.

- **Aligns with existing business models.** PDPs and public entities have no cash reserves to fund R&D activity out of their own pockets with only a financial compensation after the completion of the activities. Ex-ante funding is therefore required.

- **Supports collaboration.** The current ex-ante model supports collaboration between research entities, often on a philanthropic or at-cost basis. An ex-post mechanism that gives out prizes would create tension between collaborators in their struggle to receive adequate compensation in case of success. In an environment where it is not uncommon that over 10 entities work collaboratively on a compound, this would
unnecessarily raise complexity, transaction costs and the overall price-tag of drug development. Ex-ante funding eases collaboration.

- **Avoids complexity and unintended outcomes.** An ex-ante funding mechanism is straightforward, in comparison to the daunting complexity of ex-post funding. The correct setting of “prizes” for 10 diseases would be very difficult. Prizes would need to be high enough to spur innovation, while not over-compensating; prizes would need to account for the estimated risk of failure and the expected number of competitors; prizes would need to provide proper incentive for a balance between “fast-but-inferior” vs. “later-but-better” compounds; and, prizes would need to signal credible donor commitment over 10-15 years, even in the case of unforeseen events. Therefore, although an ex-post mechanism shifts risk from donors to R&D entities, it is thus replaced by a risk that R&D activity will become highly unbalanced or fully absent.

- **Complementarity.** FRIND could be complemented, but not replaced, by experimentation with ex-post mechanisms such as advanced market commitments and prize funds.

The proposed ex-ante financing mechanism is complemented by strong portfolio management, because it brings:

- **Optimal allocation of scarce resources.** Significant additional resources will be required over the next 10 years. Only a portion of this funding might be made available, within the context of a financial crisis and competing health priorities. A clear need exists for strong portfolio management to prioritize among the existing compounds and ensure that the limited resources are spent as effectively as possible, in order to minimize waste.

- **Fragmentation of current portfolios.** The challenge and need for strict portfolio management is underscored by the fragmentation of the existing neglected diseases R&D portfolio. There are currently over 25 entities working on over 200 projects across the 10 neglected diseases, as shown in the annex of this document. Strong portfolio management by a single entity would allow direct comparison of projects with the same indication and selection of the most viable projects to pursue. This system would ensure optimal allocation of resources across this complex and fragmented landscape.

- **Increase of transparency.** Stakeholders have mentioned that comparisons of compounds is technically and scientifically a very complex task. However, selection decisions are

---

1 A clear difference exists with the vaccine market, where ex-post mechanisms like AMCs have been pioneered, as usually only one manufacturer is involved in vaccine development, with no need for collaboration.

2 Collaboration, rather than competition, is essential within R&D for neglected diseases given the limited amount of funding and research in the space of the historic success of partnerships between universities, pharmaceutical manufacturers and PDPs to create compounds.

3 This complexity was illustrated by Andrew Farlow ea in http://www.economics.ox.ac.uk/members/andrew.farlow/CIPIH1May2005.pdf. This problem is magnified in the case of drugs, where the inevitable onset of resistance requires continuous development of new drugs.

4 For example, a drastic change in the incidence of a certain disease (e.g. through a vaccine), social-political developments in donor countries or a drastic shift in global health priorities can be perceived to threaten the credibility of an ex-post commitment. Note: A failure to set the prices and incentives correctly will result in unintended outcomes and wasted money. Mary Moran argues that advanced market commitments (AMCs), a form of an ex-post mechanism, are less cost-effective and may hinder PDP development efforts. Source: Moran M, A breakthrough in R&D for neglected diseases: new ways to get the drugs we need, PLoS Medicine, 2005, 2, 9: e302.

5 For example, focused on a couple of diseases with attractive prices, whereas ignoring other diseases

6 Oxfam acknowledges that already, “scarce funding is often spread among a variety of initiatives and across multiple agencies that finance R&D for poor-country diseases...A lack of co-ordination within and between countries also negatively affects priority setting with respect to different diseases.” Source: Ending the R&D Crisis in Public Health, Oxfam Briefing Paper, November 2008.
already made, often implicitly, by many donors. FRIND would merely bring leading experts together to make the most analytical, professional and transparent decisions.

- **Reduction of complexity for new donors.** FRIND is targeting additional R&D funding from new, currently non-involved, donors. These donors may not have the desire or the capacity to make complicated allocation decisions across diseases, players and compounds. FRIND can reduce significantly the transaction costs for this group of donors. Consultations, among others by R4D7, have shown interest of small donors in this concept.

**Describe and justify the financial feasibility and sustainability of the proposal:**
- FRIND has a high degree of financial feasibility and sustainability. It builds on the tested and tried model of bilateral donor financing, with the addition that it will target new, additional, donors that previously were not engaging due to costs and capacity constraints.

- The required resources of nearly every CEWG proposal will likely outstrip the available resources. The principle of FRIND is scalable, and can be implemented with different levels of resources.

- We propose a pilot phase to build a track-record, at funding levels of $50-100Mn per year, financed by new, smaller, donors that have traditionally not invested in R&D for Neglected Diseases, and for whom the pooling and portfolio management are attractive features.

- The second phase would see an expansion of FRIND, supported by a strong track-record in the first phase, and potentially attracting also the traditional R&D donors, to a funding level of $100-200Mn per year.

- It is important to compare the cost-effectiveness of different CEWG proposals. However, we want to caution for unfair comparisons (e.g. not “apples-to-apples”). Meaningful comparisons are only possible if all proposals are calculated by using the same product portfolio, the same cost estimates, failure rates, discount rates and timelines. We would propose that the CEWG will make available some standard assumptions for all participants to use, in order to allow comparison between the proposals.

**Describe in what way the proposal addresses cross-cutting issues:**

**Intellectual Property and affordable access.**
- FRIND is committed to affordable access through non-for-profit access for all endemic countries. Applicants to FRIND will have to ensure that the compound is ensuring affordable access for the indication funded, and royalties obtained with FRIND funding from developed world applications will flow back in the fund. A possible option for a mechanism would be to ask the recipients of FRIND funds to allocate an exclusive license for the neglected disease indication to FRIND. FRIND would then over time build an IP pool for neglected diseases, which could ensure accessibility.

---

7 Results for Development Institute, *Pooled Funds: Assessing New Models for Financing Global Health R&D*, 2010
• FRIND will however leave recipients (e.g. PDPs) flexibility to determine their own access policies and practices, as long as they meet the minimum agreed criteria of affordable access. We would continue the flexible, results-oriented approaches to dealing with IPR taken by the PDPs and pharmaceutical manufacturers. This approach has created the extensive current R&D portfolio, and has allowed widespread access for affordable products. We believe, and as outlined in the R4D report, that IP needs to be negotiated on a case-by-case basis, depending on markets, technology, partners and magnitude of funding.

Potential to de-link R&D from prices.
• The R&D costs have been fully ex-ante funded by FRIND. The final product will not include any amortized R&D costs, and will be made available at non-for-profit basis in all endemic countries. The R&D is thus de-linked from the prices in endemic countries.

Participatory governance and decision making.
• FRIND is committed to quality, diversity and transparency in all its governance structures, and strives to incorporate best practices.

• FRIND will have a dual governance structure, consisting of an Executive Board and a Scientific Advisory Committee (SAC). The Executive Board would focus on fund-raising and strategy, whereas the SAC would focus on investment decisions and portfolio management.

• The board will be consist of donors, multilateral entities, communities affected by the diseases and civil society. The Global Fund board will be analyzed as a benchmark for its structure and operating policies. The board will be transparent in its deliberations and decisions. It will aim to make all decisions by consensus.

• The Scientific Advisory Committee will include the best functional experts in the respective disease areas. The terms of reference and selection process for these experts will be composed and managed by the board, and will be fully transparent. There will be consultations on the composition with the World Health Organization, independent experts and civil society.

Potential synergies with other mechanisms, including capacity building and technology transfer
• FRIND is a streamlined and lean financing mechanism, and will funnel financing to the best compounds within the best research entities, whether public or private, and whether in developed, emerging or developing countries.

• FRIND will be a crucial building block within a wider set of new interventions and mechanisms that will increase and improve the global response to R&D for neglected diseases. FRIND will not in itself be able to address all challenges, but is complementary to other proposals:
  o FRIND aims to maximize cost-efficiency in R&D for Neglected Diseases. Therefore, it is strongly complementary with initiatives to reduce costs in R&D, such as moving towards shared clinical development trial sites, data sharing in early-stage discovery (e.g. N2D2), precompetitive platforms and regulatory.

8 The FRIND board will however be smaller in size
harmonization.

- FRIND is an ex-ante financing mechanism with strong portfolio management. We believe that this mechanism is more suited to the current challenges than the untested concept of ex-post (“prize”) funds. However, FRIND could be complemented, but not replaced, by experimentation with ex-post mechanisms such as advanced market commitments, procurement agreements and end prizes.

- FRIND focuses on traditional bilateral donors that have historically not been engaged in funding R&D for Neglected Diseases. FRIND is however perfectly compatible with different ways of innovative financing to obtain the required funds (e.g. bonds, airline taxation, voluntary contributions and indirect taxation).

- FRIND would not be able to provide capacity building or technical assistance to research entities itself, to avoid perceived conflicts of interests in its funding allocation. However, FRIND supports any efforts that create stronger research entities in the Global South, and a stronger pipeline of compounds.

**Identify key steps necessary to begin implementation and key issues to be resolved for implementation to begin:**

- There are few remaining operational challenges towards implementation, due to the extensive work on the technical design and the stakeholder consultations in past years.

- FRIND could be implemented within a timeframe of 9-15 months.

- The remaining challenges lie with obtaining stakeholder and donor buy-in. It is critical to obtain support from CEWG in order to create assurance and momentum with new, additional, donors.

**Provide the evidence base for the proposal including literature references and other relevant information:**

- FRIND has been discussed with 40-50 stakeholders in presentations, roundtables and workshops in the last years.

- FRIND was reviewed by R4D in their evaluation on pooled financing mechanisms. The recommendations were analyzed and used to further fine-tune FRIND.

- FRIND is being reviewed for publication in a leading academic journal.
Annex – Key Data

Graph 1: The burden of neglected tropical diseases

Leading Causes of DALYs (disability-adjusted life year) and Premature Death*

- Lower resp. infections
- HIV/AIDS
- Unipolar depression
- Diarrhea
- Ischemic heart disease
- Neglected tropical diseases
- Cerebrovascular diseases
- Malaria
- Road traffic accidents
- TB

Total ~ 139M

*Note: DALYs do not take into consideration the psycho-social impact or the impact due to epidemic outbreaks, which are additional factors of disease burden. Neglected diseases include all helminth infections, including hook- and tapeworms.

Source: “Control of Neglected Tropical Diseases” Hotez, Molyneux, Fenwick, Kumaresan, Sachs, Sacha and Savelli (2007)
Graph 2: Overview of the current combined portfolios

Overview of current combined portfolios

Number of Projects

<table>
<thead>
<tr>
<th>Phase</th>
<th>Projects</th>
</tr>
</thead>
<tbody>
<tr>
<td>Early stage</td>
<td>60</td>
</tr>
<tr>
<td>Lead Generation</td>
<td>15</td>
</tr>
<tr>
<td>Lead Identification</td>
<td>13</td>
</tr>
<tr>
<td>Lead Optimization</td>
<td>21</td>
</tr>
<tr>
<td>Preclinical</td>
<td>27</td>
</tr>
<tr>
<td>Phase I</td>
<td>26</td>
</tr>
<tr>
<td>Phase II</td>
<td>16</td>
</tr>
<tr>
<td>Phase III</td>
<td>24</td>
</tr>
</tbody>
</table>

Graph 3: Overview of the fragmentation in compound ownership

Overview of fragmentation in compound ownership

Number of Projects

<table>
<thead>
<tr>
<th>Company</th>
<th>TB</th>
<th>Malaria</th>
<th>HAT</th>
<th>Dengue</th>
<th>VL</th>
<th>Chagas</th>
<th>Other Schisto</th>
<th>Other</th>
</tr>
</thead>
<tbody>
<tr>
<td>Novartis</td>
<td>13</td>
<td>10</td>
<td>3</td>
<td>11</td>
<td>10</td>
<td>2</td>
<td>2</td>
<td>9</td>
</tr>
<tr>
<td>Sanofi</td>
<td>9</td>
<td>8</td>
<td>4</td>
<td>3</td>
<td>7</td>
<td>3</td>
<td>4</td>
<td>2</td>
</tr>
<tr>
<td>GSK</td>
<td>4</td>
<td>4</td>
<td>4</td>
<td>3</td>
<td>2</td>
<td>2</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>Pfizer</td>
<td>3</td>
<td>3</td>
<td>3</td>
<td>2</td>
<td>2</td>
<td>2</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>Merck</td>
<td>2</td>
<td>2</td>
<td>2</td>
<td>2</td>
<td>2</td>
<td>2</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>AstraZeneca</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>GATB</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Sanofi</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Novartis</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>MMV</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Dundee</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Otsuka</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Sequella</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>DNDI</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>MPhC</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>IOWH</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Abbott</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Eisai</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>SP</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>ICM</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>PATH</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>MSP</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Otsuka</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Sequella</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>DNDI</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>MPhC</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>IOWH</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Abbott</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Eisai</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>SP</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>ICM</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>PATH</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>MSP</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
</tbody>
</table>


Notes: Surface area does not reflect the size of the projects, which vary significantly based on stage of discovery and development. Other industry includes: Biotec, FASgen, J&J, Ranbaxy, Medevir, Bayer, Schering Plough, SciClone, Sequella, and Zenaris. Other public includes: Colorado State, Imperial College, Johns Hopkins, KRICT, Salisbury, Stoney Brook, and Tulane. Other diseases includes diarrheal disease and onchocerciasis.

Graph 2: Overview of the current combined portfolios

Graph 3: Overview of the fragmentation in compound ownership

Excludes diagnostic tools; As of spring 2011
Graph 4: Current collaboration arrangements

PDPs are working with a constellation of biopharmaceutical and academic partners

BCG analysis, as displayed in the DFID analysis “Lessons from PDPDs established to develop new health technologies for neglected diseases.”
## Annex – Detailed overview of the FRIND dimensions

<table>
<thead>
<tr>
<th>Option</th>
<th>Preliminary Recommendation</th>
<th>Rationale</th>
</tr>
</thead>
</table>
| **Disease Scope**       | The 13 disease areas included in G-FINDER report\(^\text{12}\), with exception of HIV/AIDS   | • Scope covers the current R&D pipeline  
• HIV/AIDS is excluded because the R&D dynamics, needs and politics are different from other neglected diseases  
• Ineligible diseases could be considered for inclusion on the list using an expert review procedure (e.g. similar to G-FINDER) |
| **Product Scope**       | Vaccines, therapeutics, diagnostics                                                          | • Facilitates portfolio management and cross-comparability (in contrast to inclusion of e.g. insecticides, vector-control technologies)                                                            |
| **R&D Scope**           | Priority focus on late stage clinical development (Phase II-III)                             | • Facilitates portfolio management (limited number of compounds, specialization; increased data; easier to compare compounds)  
• Most expensive part of R&D process; requires greatest scrutiny |
| **Eligibility**         | No restrictions (open for e.g. PDPs, public research entities, biotech firms, pharmaceutical manufacturers) | • No clear evidence / arguments to focus on subset of R&D entities  
• Not every disease falls within the scope of PDPs  
• Open participation fosters innovation |
| **Funding type**        | Ex-ante funding (funding that is made available before the R&D activity is undertaken)      | • Tested and tried model that builds on track-record of success  
• Aligns with existing business / funding models of PDPs, public research labs and biotech firms |
| **Financing**           | Primarily donor-funded, with eventual royalties on developed world applications flowing back in the fund | • Focus on new, additional, donors, that have traditionally not financed R&D for Neglected Diseases  
• Aligns with the access philosophy (at-cost in developing world, potentially at profit in developed world) |
| **Governance / Portfolio Management** | Independent Scientific Advisory Committee (ISAC) that allocates funding to reach milestones (e.g. successful completion of phase II trials). | • Fragmentation of current portfolios, with over 25 entities working on over 200 projects across the 10 neglected diseases, (see annex).  
• Direct comparison of projects with the same |

\(^{12}\) The Global Funding of Innovation for Neglected Diseases (G-FIND) report, published annually by the George Institute for International Health, tracks resource flows for R&D for 13 disease areas: HIV/AIDS, malaria, tuberculosis, kinetoplastids, diarrheal diseases, dengue, bacterial pneumonia and meningitis, helminth infections, salmonella infections, leprosy, rheumatic fever, trachoma, and buruli ulcer.
At each milestone, performance will be compared against the predefined targets and other competing compounds. Based on this comparison funding might be continued or stopped. The indication and selection of the most viable projects to pursue.

- Optimal allocation of resources across complex and fragmented landscape.
- Reduction of complexity for (new) donors, who may not have the desire or the capacity to make complicated allocation decisions across diseases, players and compounds.
- Aim to incorporate best practices in portfolio management from pharmaceutical manufacturers, PDPs, VC firms and external experts.

| Governance       | Executive Board to be nominated by donors and focusing on e.g. strategy and fundraising, and the ISAC for investment decisions and portfolio management. (see annex for further detail) | Allows using the best available functional experts in the ISAC / portfolio management
|                  | • Allows representation of donors, multilateral actors, civil society and other stakeholders in the Executive Board |

| Access           | Minimum access principles with which recipients must comply to ensure affordable access for all populations in need. FRIND will leave recipients (e.g. PDPs) flexibility to determine their own access policies and practices, as long as they meet the minimum agreed criteria. A possible option for a mechanism could be non-profit licensing, in which the originator patents the molecule and would give exclusive licensing for the neglected diseases indication to a PDP or other entity. | • Aim to support flexible, results-oriented approaches to dealing with IPR
|                  | • PDP’s and pharmaceutical manufacturers have managed access for neglected disease products in the past through non-profit licensing agreements. | • This approach has created the extensive current R&D portfolio, and has allowed widespread access for affordable products. |
|                  | • In addition, this approach has allowed for specific products with potential commercial uses outside of neglected diseases to maintain patent protection. | • FRIND will explore, among other options, whether there are benefits in building a licensing pool.

---

13 This approach to licensing allows the originator to keep ownership for composition of matter, which allows use in any other indications for which a commercial return might be expected.