DEMONSTRATION FINANCING:
CONSIDERATIONS FOR THE NEW INTERNATIONAL FUND FOR R&D

By Suerie Moon, MPA, PhD

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EXECUTIVE SUMMARY

Introduction & Background: This paper outlines the potential contours of the new international fund for the research and development (R&D) of technologies to meet health needs in developing countries. Such a fund was recommended by the World Health Organization (WHO) Consultative Expert Working Group on Research and Development: Financing and Coordination (CEWG) in its 2012 report. At the 2013 World Health Assembly (WHA), Member States recognized in Resolution 66.22 "the importance of securing sustainable financing mechanisms" for R&D to meet health needs in developing countries. Member States selected eight Demonstration Projects, four of which were subsequently prioritized. At the 2014 WHA, Member States decided to move ahead with the creation of such a fund to be hosted by the UNICEF/UNDP/World Bank/WHO Special Programme for Research and Training in Tropical Diseases (TDR). Now that the Demonstration Projects have been selected and the decision to create a fund has been made, the key questions of what any new financing arrangements should "demonstrate" and how it should be governed are now squarely on the table. This paper explores: the Potential Limitations and Opportunities; Functions; Principles and Policies; Governance Arrangements; and Costs of the initial *pilot* phase of the Pooled International Fund (*p*PIF) for R&D.

Potential Limitations and Opportunities: Why Pool?: Countries must agree to contribute funds to the pool if it is to succeed. There are both limitations and opportunities of pooling funds internationally, from the perspective of funders, demonstration project proponents, and coherence with CEWG principles. For example, for funders, pooling entails some loss of control over funds, but also provides the opportunity of sharing risk and increasing efficiency. Taking all factors into consideration, this analysis found adequate benefits to pooling to justify considering in greater depth how such a fund may operate.

Functions, Principles and Policies: The *p*PIF could be expected to carry out primarily five functions: Resource Mobilization; Priority Translation (based on the R&D Observatory); Proposal Selection; Resource Deployment; and Monitoring, Evaluation and Learning (ME&L). In the *pilot* phase, since Demonstration Projects have already been selected, primarily the following three would apply:

- **Resource Mobilization** should reflect shared responsibility among a broad base of Member States contributing new, additional funds. New sources of financing could come from low- and middle-income countries (LMICs), especially but not only the emerging economies that are experiencing rapid economic growth and a simultaneous double burden of communicable and non-communicable diseases; high-income countries (HICs) that have not previously supported R&D; and all actors interested in supporting open knowledge innovation. The ability to mobilize new financing will be an important demonstration objective.
- **Resource deployment** should be guided by CEWG recommendations and principles, summarized as: "needs-driven and evidence-based…guided by the following core principles: affordability, effectiveness, efficiency and equity."[1] For example, the *p*PIF could make the release of funding tranches conditional on the achievement of licenses that demonstrate de-linkage, on the implementation of an open access knowledge-sharing model, on transparent sharing of information on R&D costs, and/or on securing matching financial support from LMIC governments.
- **Monitoring, Evaluation and Learning** will be essential, since a central purpose of establishing a *pilot* fund will be to support groundbreaking approaches to financing, coordinating and carrying out R&D, and to draw broader lessons for the establishment of a more permanent body.

The performance of these functions in the *pilot* phase may be somewhat *ad hoc*. For example, for Resource Mobilization, a small leading group of countries may commit initial funds for the pool, with an eye to broadening the number of contributing countries over time. If the *pilot* demonstrates adequate promise more permanent arrangements would be made for all five functions.

Governance Arrangements: Legitimate and effective governance arrangements for the *p*PIF will be essential for the initiative to reach its potential to demonstrate new approaches to R&D.

- **Governing Board**: An Interim Board will need to adopt basic policies to guide the functioning of the *p*PIF, including policies on the conditions for releasing funds, conflicts of interest, transparency and access to information, arrangements for soliciting multi-stakeholder input, and independent evaluation. A diverse set of countries should be represented, such as those contributing funds, those dedicating significant political commitment to the process, and those directly-affected by neglected diseases and access issues (these three categories need not be mutually exclusive). Given the Member State-driven nature of the CEWG process, most seats should be held by governments, with potential additional seats for patient/end-user representatives or individuals with specified expertise. A small number of individuals well-acquainted with the CEWG goals may be preferable for reasons of efficiency and effectiveness, rather than a large, broadly-representative but also unwieldy decision-making body. TDR already has a governing Joint Coordinating Board (JCB), but it was not designed to oversee R&D funding and with thirty members, it may be unwieldy for the purpose at hand. One possibility is to create a smaller committee of the JCB that would act as the *de facto* Interim Board for the *p*PIF, with the possibility of identifying several additional members to ensure relevant expertise.
- **Independent Scientific/Technical Advisory Committee**: Nearly all PDPs and funding bodies rely on some type of

independent scientific advisory committee that provides input to the Board on specific proposals or projects. Given the network of actors already engaged in the post-CEWG process, it should be relatively straightforward to recruit a small group of qualified individuals to fill core areas of scientific or technical expertise. Such core areas could include the diseases or technologies covered by the Demonstration Projects; policy expertise (e.g. on grantmaking, licensing, patent pooling or creation of novel incentive mechanisms); and governance expertise on managing novel 'start-up' initiatives such as the *p*PIF. TDR has proposed creating a new Scientific Review Group (distinct from its existing Science and Technical Advisory Committee) to advise the fund, and this group could be created to reflect the above areas of competency.

- **Secretariat**: Finally, a small and nimble Secretariat of experienced professionals could provide management and oversight of funds, initiate evaluation processes, and run the daily operations of the *p*PIF.

Costs: Initial budget estimates from the four Demonstration Projects suggest total resource needs of about 60 million USD over five years, or an average of 12 million USD per year (assuming the *p*PIF fully funds all four projects).[2] TDR has estimated administrative costs at about 2 million USD per year, implying total annual resource needs for a *p*PIF of roughly 14 million USD. Resource needs would likely increase if all eight Demonstration Projects are implemented and funded through this source.

Conclusions: Broadly, this analysis finds considerable advantages of a *p*PIF and that Member States should support and contribute to such a fund for the Demonstration Projects. What should the *p*PIF demonstrate? It should provide evidence on at least three key questions:

1. How effective and feasible are open knowledge innovation approaches?

2. How feasible are new forms of coordination among R&D actors? and

3. How will Member States mobilize new funding to support innovative R&D models?

Leading governments should form a **Core Working Group** to demonstrate political support for such a fund, design an interim governance structure, and agree upon minimum starting levels of financing to justify operating costs. While risk and uncertainty are greatest at this early phase, governments willing to take leadership will also benefit from first-mover advantage – the small group of countries who commit today will shape the governance structures, policies and principles on which the fund will operate. More broadly, governments should recognize this unique opportunity to build and test new approaches to R&D intended to deliver needs-driven innovation and access to affordable end products that can ultimately improve the health of populations under-served by the current global R&D system.

INTRODUCTION AND BACKGROUND

This paper outlines the potential contours of the new international fund for the research and development (R&D) of technologies to meet health needs in developing countries. Such a fund was recommended by the World Health Organization (WHO) Consultative Expert Working Group on Research and Development: Financing and Coordination (CEWG) in its 2012 report.[3] At the 2013 World Health Assembly (WHA), Member States recognized in Resolution 66.22 "the importance of securing sustainable financing mechanisms" for R&D to meet health needs in developing countries. The resolution further called on all Member States to "secure resource needs for implementation" of the demonstration projects, and "to contribute to coordinated and sustainable financing mechanisms for health research and development, through voluntary contributions." It also asked the WHO to "develop a proposal for effective mechanisms, including pooling resources and voluntary contributions, as well as a plan to monitor their effectiveness independently."

Member States then engaged in regional consultations to select candidate Demonstration Projects, eight of which were chosen by an expert committee in December 2013. These eight were then narrowed down to the four projects that most closely reflected the CEWG principles at a follow-up meeting in March 2014. At the 2014 WHA, Member States asked that the additional four Demonstration Projects also be "expedited", and decided to move ahead with the creation of a pooled international R&D fund to be hosted by the UNICEF/UNDP/World Bank/WHO Special Programme for Research and Training in Tropical Diseases (TDR).[4]

Now that the Demonstration Projects have been selected and the decision to create a fund has been made, the key questions of what any new financing arrangements should "demonstrate" and how it should be governed are now squarely on the table. This paper explores:

A) Potential Limitations and Opportunities;
B) Functions;
C) Principles and Policies;
D) Governance Arrangements; and
R) Costs

of the initial *pilot* phase of the Pooled International Fund (*p*PIF) for R&D.

The CEWG report launched the most recent chapter of a process that stretches back at least several decades – that is, the search for a sustainable and equitable way to ensure innovation and access to technologies to meet health needs in developing countries. The CEWG outlined a global framework for building such a system, including mandatory financial contributions from all Member States, the establishment of a Global Health R&D Observatory to track pipelines and resource flows in order to identify needs and gaps, a body to coordinate actors and set priorities based on identified gaps, and the use of innovative approaches to accelerate the R&D process and ensure the affordability of end products. (In this paper the general phrase "open knowledge innovation" is used to refer to the set of policies recommended by the CEWG, including grants, prizes, equitable licensing, patent pools, pre-competitive platforms, open source and open access approaches to knowledge-sharing, and other measures to de-link the cost of R&D from the price of products.)

The CEWG recommended a doubling of existing R&D for the health needs of developing countries from about $3 billion to $6 billion per year, a significant part of which should be pooled internationally, and called for increased contributions from Member States, including middle-income countries not currently financing R&D on a large scale. The CEWG report recommended this framework be implemented through an R&D convention, analogous to the 2005 WHO Framework Convention on Tobacco Control. Before considering a convention, Member States decided in 2012 to implement a trial period until 2016, which included a set of demonstration projects and during which certain CEWG principles and approaches would be pilot-tested. Since Member States will convene in late 2015 for a second open-ended meeting to assess progress and begin to draw conclusions from the projects, it seems essential also to use this opportunity to explore what can be demonstrated regarding a potential future pooled international fund for R&D. This paper focuses on these questions.

WHY POOL?: LIMITATIONS AND OPPORTUNITIES OF POOLING FUNDS

While a decision to create a fund has been made, governments must still come forward to commit funds to the pool. Thus it may be useful to begin by considering arguments for and against pooling resources, from the perspective of funders, demonstration project proponents, and coherence with CEWG principles (see summary in Table 1).

1. **For potential funders:**
   - **Limitations**: For funders, the most obvious limitation of pooling, as opposed to bilateral funding arrangements, is the potential of decreased control over how resources are used. Funders may also wish to retain clear attribution for what is achieved with the funds, an important consideration for maintaining political support from constituents for continued funding. (These concerns may be offset by allowing for partial or full earmarking of pooled funds, though earmarking also has costs.) For funders that already support R&D projects through bilateral channels, pooling may also require changing established internal processes, including legal requirements for how certain funds are used. Establishing a new pooling mechanism will also entail overhead costs. Finally, there is inherent risk in establishing any new mechanism, especially at the earliest stages when key policies and governance arrangements are unsettled.
   - **Opportunities**: On the other hand, pooling offers the potential benefit of economies of scale, which is particularly relevant given the scarcity of scientific expertise on many neglected diseases and the considerable costs associated with managing an R&D financing mechanism. Such economies of scale may be particularly beneficial for smaller funders and/or those new to R&D financing. In addition, contrary to the view that pooling reduces control over resources, it may be seen as a means to influence how other funders deploy their resources. Joint decision-making through governing bodies and agreement on certain principles and policies of the fund may offer opportunities for broader leverage. It may also allow individual funders to reduce the risk of any single investment, by sharing and spreading risk over multiple projects. Fostering a sense of shared responsibility for the fund's mission through a multilateral approach may also be appealing to funders who may not want to shoulder the full burden of supporting a particular project or disease area. Furthermore, a pooled fund can provide a focal point for monitoring and evaluation (M&E) of demonstration projects (as compared to multiple streams of bilateral funding), and facilitate learning to improve effectiveness and efficiency. Finally, a clear focal point may make it easier to mobilize additional funds, as mobilizing resources for R&D to meet health needs in developing countries may be more broadly appealing than for one specific project.

2. **For demonstration project proponents:**
   - **Limitations**: For project proponents, total resources going to a project may be lower if such resources are channelled through a pool, since the pool may allocate resources away from one project towards another. (As above, some form of earmarking may be considered to mitigate this risk.) There are also the more general inherent risks in establishing any new mechanism, as stated above, such as delays and unclear processes and requirements for fund recipients.
   - **Opportunities**: On the other hand, establishing a *p*PIF could help share the burden of resource mobilization. It could also provide networks both within the scientific community and a potentially broad set of potential funders. Furthermore, the very fact of having been selected through a broad-based global process and receiving funds from the *p*PIF may provide a valuable reputational "stamp of approval." In addition, as often noted in the development aid literature,[5] pooled funding can reduce administrative burdens on recipients by harmonizing policies and reporting requirements. Finally, if a *pilot* fund later solidifies into a more established fund, it may provide new, streamlined resources for future projects.

3. **Coherence with CEWG principles:**
   - **Limitations**: A key principle of the CEWG was shared responsibility and shared risk, to be operationalized by mobilizing and pooling financial contributions from a broad base of Member States. However, if potential new funders prefer a bilateral approach, a pooled international fund will not lead to the mobilization of new resources. Much depends on the willingness of new funders both to contribute resources, and to do so through a pooled mechanism.
   - **Opportunities**: The CEWG report identified inadequate coordination and priority-setting as an important weakness in the existing global R&D system, and recommended pooling at least 20% of national funds through an international mechanism.[6] Pooling would not only facilitate coordination, but could also help ensure that global public priority-setting processes would be matched with at least some financial resources. Thus there is a strong case that pooling is aligned with CEWG principles. In addition, a pooled mechanism would facilitate testing out the open knowledge innovation approaches recommended by the CEWG, both because such requirements could be built into the fund itself and because having a central focal point would facilitate the monitoring, evaluation and learning that is crucial to assess these novel approaches.
   - **Regional vs Global pooling:** Funds could be pooled on a regional or global basis. The limitations and opportunities of regional vs global approaches largely mirror each other, but for the sake of clarity and at the risk of repetition, they are outlined separately below.

4. **Regional pooling**:
   - **Limitations**: An important limitation of pooling by region is that regional borders do not necessarily correspond to specific R&D needs or scientific networks. For example, some diseases such as malaria or visceral leishmaniasis (kala azar) occur across multiple regions, and the R&D networks to respond often cross regional lines as well. Organizing pooled funds on regional lines may result in sub-optimal allocation of resources to certain diseases or actors if they do not match regional borders. In addition, regional funds may not achieve the economies of scale needed to justify their operational costs, especially at the *pilot* phase. Furthermore,

significant differences in fiscal resources across regions means that some may be relatively underfunded, and potentially result in grossly inadequate financing of some populations' needs. Finally, establishing multiple pooled funds could fragment efforts and create coordination challenges.

- **Opportunities**: Many regions have relatively well-established institutions for intergovernmental cooperation, including the WHO regional offices. For example, the European Union's Horizon 2020 program is a regional fund that has mobilized 80 billion EUR over a 7-year timeframe for research and innovation.[7] Governments may have greater confidence in a pooled financing mechanism that resides closer to home and involves other governments with whom collaborative relationships have already been built. Therefore, pooling on a regional scale may lead to both stronger political ownership and greater resource mobilization than pooling globally. Regional pools may also have greater knowledge of local health conditions and scientific institutions, and therefore lead to better selection and monitoring of projects. Finally, the diversity of approaches that regions may take can provide useful institutional experimentation that yields valuable lessons.

5. **Global pooling**: As noted above, these largely mirror the limitations and opportunities above for regional approaches.

- **Limitations**: Compared to regional pooling, global pooling may result in potentially weaker political ownership from governments, and consequently potentially lower resource mobilization, all else being equal. A global institution may also have less familiarity with local health conditions and scientific institutions than a regional body. Taking a unified global approach may also leave less room for institutional experimentation.
- **Opportunities**: Global pooling may allow for a more comprehensive approach to responding to R&D needs across multiple disease areas, and for taking into account broadly-dispersed scientific networks. There is also greater potential to achieve economies of scale in operating the fund, especially in the *pilot* phase. A global approach could also promote equity through redistribution across regions, by ensuring that the diseases primarily affecting more poorly-resourced regions still receive adequate support. Finally, by nature, it will be more practical to coordinate a single global fund than to coordinate multiple regional funds. Taking a global approach is also likely to facilitate coherence with other global initiatives, such as the R&D Observatory.

Table 1. Summary of Limitations and Opportunities of Pooled International Funding

	Limitations	Opportunities
For Potential funders	Decreased control over resources Changes to established processes Costs of new mechanism Risks of new mechanism	Economies of scale (management costs, scientific expertise) Influence over other joint funders Reduce risk of any one project Shared responsibility, shared burden Centralized M&E for learning Mobilize additional contributions
For Project proponents	Risk of lower resources to projects Risk in new mechanism, including delays	Sharing burden of resource mobilization Access to scientific and funder networks Reputational benefit of "stamp of approval" Streamlined policies and reporting requirements Increased potential for future resources
For CEWG principles	If potential new funders prefer not to pool (i.e. bilateral approaches), adequate new funds will not be raised through a *p*PIF	Strengthen coordination of global R&D efforts Match global priority-setting to resources Vehicle to implement and evaluate open-knowledge innovation approaches
By level:		
Regional	Regional borders do not necessarily correspond to R&D needs or scientific networks No economies of scale Some regions likely to be underfunded Fragmentation and coordination challenges	Potentially stronger political ownership Potentially greater resource mobilization Greater knowledge of local health conditions and scientific institutions Diversity of approaches from institutional experimentation
Global	Potentially weaker political ownership Potentially lower resource mobilization Less familiarity with local health conditions and scientific institutions Less room for institutional experimentation	Comprehensive global approach to R&D needs Potential economies of scale More equitable across regions Fewer coordination & coherence challenges

While there are clearly limitations to establishing pooled R&D financing arrangements in general, a *p*PIF for the Demonstration Projects will have the possibility of realizing many opportunities. In addition, the analysis above is necessarily piecemeal, and does not capture the interrelationships between various factors. For example, the degree of country ownership of a pooled fund may depend as much on its governance structure or priority-setting processes, as on whether it operates at regional or global level. Taking all factors into consideration, there are adequate benefits to pooling to justify considering in greater depth how such a fund may operate.

COST ESTIMATES AND ECONOMIES OF SCALE

This initial analysis also underscores the importance of establishing a minimum level at which certain economies of scale would be achieved and the costs of building a new *pilot* mechanism could be justified. Based on initial budget estimates from the four Demonstration Projects, total resource needs over a five-year period to fully fund the projects would total about 60 million USD, or an average of 12 million USD per year.[8] The WHO and TDR have estimated that a pooled international fund (beyond the *pilot* phase) would need a minimum of 25 million USD per year to justify operating costs of about 2 million USD per year (excluding the Observatory).[9] Primarily for this reason, at this initial *pilot* phase, we also focus primarily on building one global pooled fund rather than multiple regional funds, which is deemed infeasible in the short-term. However, as the analysis above suggests, there are also important potential opportunities to taking a regional approach and this option could be reconsidered after the *pilot* phase. Finally, given the significant risks at this stage in the process, it may be useful for leading governments to agree in advance on some of the key functions, principles, policies and governance arrangements of a *p*PIF to mitigate the uncertainty inherent in establishing any new mechanism. The remainder of this paper addresses these questions.

FUNCTIONS

A pooled international fund for R&D could be expected to carry out primarily five functions (see also Table 2 below):

1. Resource Mobilization: raising funds for the pool;
2. Priority Translation: translating priorities identified through the R&D Observatory into concrete calls for proposals;
3. Proposal Selection: through a technical review process;
4. Resource Deployment: committing and disbursing funds to specific initiatives, and ongoing grant management and oversight; and
5. Monitoring, Evaluation and Learning (ME&L)

As indicated in the second column of Table 2, two of the five functions (Priority Translation and Proposal Selection), are not applicable to the *pilot* Demonstration Project phase (Phase 1) as this process has already been carried out (as described in the Introduction). However, for the other three (Resource Mobilization, Resource Deployment, and Monitoring, Evaluation and Learning), the establishment of a *p*PIF at the Demonstration Project phase should provide important lessons for a more established fund in the future.

The performance of these functions in the *pilot* phase may be somewhat *ad hoc*. Thus, for Resource Mobilization, one could envision a small leading group of countries committing initial funds for the pool, with an eye to broadening the number of contributing countries over time. In terms of Resource Deployment, a small temporary Secretariat of experienced professionals could be formed to manage and provide oversight of the funding, reporting to an interim Board (described further in "Governance Arrangements" below). Finally, ME&L could also be carried out by the Secretariat, or commissioned out to an independent third party. This function will be particularly important during the *pilot* phase, as evaluations should be applied to make adjustments to the model before it is scaled up.

If the *pilot* demonstrates adequate promise, a Phase 2 could be considered in which more permanent arrangements would be made for all five functions. We now turn to examine the three functions relevant to Phase 1 in greater detail.

Table 2. Functions of a Pooled International Fund for R&D[10]

Functions	Phase 1: *Pilot* Fund for Demonstration Projects	Phase 2: Pooled International Fund
Resource mobilization	Small group of leading Member States	Broad-based contributions from many Member States
Priority-translation* ↘ Call for proposals	Not applicable	Governing Board translates high-level priorities into specific priorities*, Secretariat issues Call for Proposals
Proposal selection	Not applicable	Independent Scientific/Technical Advisory Committee
Resource deployment	*Pilot* Secretariat reporting to Interim Board	Secretariat reporting to Board
Monitoring, evaluation and learning	*Pilot* Secretariat or Independent Third Party reporting to Interim Board	Secretariat reporting to Board

* Important questions remain regarding how priorities should be set in any new system. While the R&D Observatory would clearly be a critical source of strategic information to inform priority-setting, it has not yet been decided whether a separate decision-making body (e.g. an expert committee) would be needed to then translate the Observatory's data and gap analysis into concrete priorities. (See endnote ix for a proposal from TDR on this topic.) Nor is it clear how specific such priorities would be (whether priorities would be set at the level of diseases, technologies, target product profiles, or other). In any case, a pooled international fund would need to translate identified priorities into calls for proposals and grants, with the level of specificity to be determined.

PRINCIPLES AND POLICIES

If a *p*PIF were to be created, what principles and policies should govern how it carries out the three functions of Resource Mobilization, Resource Deployment, and ME&L ?

1. **Resource Mobilization:**
Resource-mobilization for the *p*PIF should take place according to CEWG principles. The CEWG report strongly emphasized the principle of shared public responsibility – a principle also endorsed by WHA Resolution 66.22 – and recommended that all Member States should make mandatory contributions to health R&D at a fixed proportion of their ability to pay (embodied in the recommendation of 0.01% of GDP). Though Member States have opted instead to take a voluntary approach, financing a pooled fund could and should still reflect a broad-based Member State-driven sharing of responsibility with many countries contributing.

Establishing sustainable and equitable R&D financing also requires identifying new, additional sources of financing rather than merely shifting pre-existing commitments. One clear source of new financing would be increased contributions from low- and middle-income countries (LMICs), especially but not only the emerging economies that are experiencing rapid economic growth and a simultaneous double burden of communicable and non-communicable diseases. In-kind contributions from such countries should also be welcomed and counted. Another potential source is high-income countries (HICs) that have not previously invested in global health R&D. Finally, for the handful of HICs that have already contributed to neglected disease R&D out of development cooperation budgets, new resources could potentially come from innovative financing mechanisms such as the Financial Transaction Tax under active consideration in 11 European Union member states, or other ministries interested in fostering new approaches to technological innovation, such as ministries of science and technology. The financing of a *p*PIF will be a key test of the political willingness of Member States to contribute to a future fund. The *p*PIF should also mobilize private funders, such as foundations or other non-profit entities, especially those interested in supporting open knowledge innovation and new approaches to tackling the challenge of providing global public goods. The ability to mobilize both new government and private funders will be an important demonstration objective.

2. **Resource deployment:**
Resource deployment of the fund should also be guided by CEWG principles, which were summarized in WHA 66.22 as follows: "health research and development should be needs-driven and evidence-based, and be guided by the following core principles: affordability, effectiveness, efficiency and equity." These principles can be translated into criteria for both proposal selection and funding. While the topic of proposal selection is not directly addressed here (since a *p*PIF would not select any projects), it is worth noting that criteria used for project selection may also be applied as conditions on funding. A rapid review of such criteria may therefore be instructive. Criteria used by the Expert Committee in December 2013 to select the initial set of Demonstration Projects fell into three broad categories:

> "A) Scope of the proposal: meeting a public health need for the poorest and addressing a market failure, in particular addressing Type II and III diseases and special needs of developing countries with regards to Type I diseases;
>
> B) Technical and scientific merit: scientific excellence, feasibility and timescale to achieve a significant milestone; and
>
> C) Use of new and innovative way of supporting R&D: delinkage of R&D costs (risk) from final product price and use of e.g. open innovation approaches, pooled funding, prizes, patent pools."[11]

The eight projects selected according to these criteria then underwent a second round of assessment by the CEWG Chair and Vice-chair based on six criteria that were agreed by Member States in a consultation in December 2013: Delinkage, Open knowledge innovation, Licensing for access, Financing mechanisms, Coordination mechanisms, and Capacity building.[12] Each of these criteria could also be applied as funding conditions.

For example, the *p*PIF could make the release of funding tranches conditional on the achievement of licenses that demonstrate de-linkage, on the implementation of an open access knowledge-sharing model, on transparent sharing of information on R&D costs, or on securing matching financial support from LMIC governments. It could similarly make the release of funds conditional on evidence that inclusive and effective coordination mechanisms had been designed, or of strengthened R&D capacity within disease-endemic countries. Finally, *p*PIF funding could be limited to open knowledge innovation approaches. For example, an R&D project could seek *p*PIF funds to cover the most innovative (and risky) elements of a project, such as a milestone or end-product prize, and leverage that funding to piece together support from other donors for the project's other, more traditional R&D activities.

It is beyond the scope of this brief paper to outline all the specific ways in which such conditions could or should be applied. Furthermore, the crafting of criteria and funding conditions will require careful deliberation to produce the desired results. In particular, thorough consideration should be given to granting project proponents adequate flexibility to run their projects and to avoiding overly restrictive conditions. The objective here is merely to illustrate how CEWG principles could be operationalized through a *p*PIF, rather than to prescribe specific conditionalities. Finally, lessons from the application of these criteria should be used to adapt and refine the way criteria are applied to the proposal selection processes that would ultimately take place if the *p*PIF progresses to Phase 2.

3. **Monitoring, Evaluation and Learning:**
Since a central purpose of establishing a *pilot* fund will be to draw broader lessons for the potential establishment of more permanent institutions, carrying out monitoring, evaluation and learning will be essential. Ideally, the *pilot* fund will be supporting novel and groundbreaking approaches to financing, coordinating and carrying out R&D. Maintaining adequate flexibility to adapt the model based on feedback and evaluation will be essential for transforming the *pilot* into a more established mechanism in Phase 2.

Table 3. Summary of CEWG Principles and *Pilot* Fund Policies

Function	CEWG Principles	Implications for Fund Policy
Resource Mobilization	Public responsibility	Member State-driven
	Shared responsibility	Broad-based financial support from Member States, adjusted by ability to pay (private contributions also welcome)
	Additional (new) financing	Contributions from emerging economies and innovative financing mechanisms
	Sustainable financing	Broad-based support and innovative financing mechanisms
Resource Deployment	Needs-driven	Priority-setting based on health needs
	Evidence-based	Reliance on Scientific Technical Experts and Observatory, among other sources of evidence
	Affordable	De-linkage, licensing for access, other access provisions
	Effectiveness	Independent, scientific technical review
	Efficiency	Open knowledge innovation
	Equity	Capacity building, Legitimate governance arrangements

GOVERNANCE ARRANGEMENTS

Funding bodies frequently include at least three entities involved in governance:

1. Governing Board: for high-level political decision-making, such as establishing policies for funding.
2. Independent Scientific or Technical Advisory Committee: for assessing the technical merit of proposals, and making recommendations to the Board
3. Secretariat: for day-to-day management and oversight of funds, including managing M&E processes

Such structures are relatively well-established, and multiple examples exist as potential models (see a sample of organizations in Table 4 below).

Table 4. Sample of organizations and governance structures*

Organization	Governing Board	Independent Scientific/ Technical Advisory Committee(s)	Secretariat
Global Fund to fight AIDS, TB and Malaria[13]	Board: 20 voting seats based on constituencies, including major donors, regions, civil society, foundations, private sector; 5 ex officio seats	Technical Review Panel, Technical Evaluation Reference Group, Market Dynamics Advisory Group	Secretariat
GAVI Alliance[14]	Board: 28 members of which 9 individuals, 1 CEO, and 18 represent constituencies, including donor countries, developing countries, industry, civil society, research institutes		Secretariat
UNITAID[15]	Executive Board: 12 members, of which 5 founding countries, 1 seat each for Spain, African Union, Asian countries, foundations, WHO, and 2 civil society	Proposal Review Committee	Secretariat
DND*i*[16]	Board of Directors: up to 13 voting members of which 6 founding partners, 1 patient representative, TDR as permanent observer	Scientific Advisory Committee	Executive Team
Medicines Patent Pool[17]	Governance Board: 6 individual voting members, 2 non-voting	Expert Advisory Group	Executive Team

*For a more exhaustive review of potentially relevant organizations and their governance structures, see Chang et al. (2013).

Legitimate and effective governance arrangements for the *p*PIF will be essential. While it is beyond the scope of this paper to prescribe specific governance arrangements, such as exactly how many Board seats are needed or how they should be allocated, some general conclusions can be drawn based on the CEWG report and general principles of good governance[18] (See Figure 1):

1. **Governing Board**:
   for an Interim Board it will be critical to have diverse representation of countries, including those contributing funds, those dedicating significant political commitment to the process, and those directly-affected by neglected diseases and access issues (these three categories need not be mutually exclusive). Given the Member State-driven nature of the CEWG process, it would seem logical that most if not all seats are held by government representatives. Additional seats could be considered, for example, for patient/end-user representatives or individuals with specified expertise, keeping in mind that all governance arrangements should be evaluated and adjusted at the end of the *pilot* phase. Given the interim nature of the Board, a small number of individuals who are well-acquainted with the CEWG goals may be preferable for reasons of efficiency and effectiveness, rather than a large, broadly-representative but also unwieldy decision-making body.
   In addition, the Interim Board will need to adopt basic policies to guide the functioning of the *p*PIF, such as policies on conflicts of interest, transparency and access to information, arrangements for soliciting multi-stakeholder input, and independent evaluations. Finally, the Interim Board will need to create policies on the conditions under which funds will be released in line with CEWG principles (as discussed in Section C above).
   Given the need for light, nimble structures and rapid implementation, a small Interim Board could be constituted as soon as there is a critical mass of governments committing to the *p*PIF. TDR already has a governing Joint Coordinating Board (JCB), but it was not designed to oversee R&D funding and with thirty members, it may be unwieldy for the purpose at hand. One possibility is to create a smaller committee of the JCB that would act as the *de facto* Interim Board for the *p*PIF, with the possibility of identifying several additional members to ensure relevant expertise. Specific governance arrangements should be agreed by governments and

other key stakeholders committed to building the *pilot* fund. These arrangements should also be relatively flexible in the *pilot* phase, and open to adjustment based on experience before Phase 2.

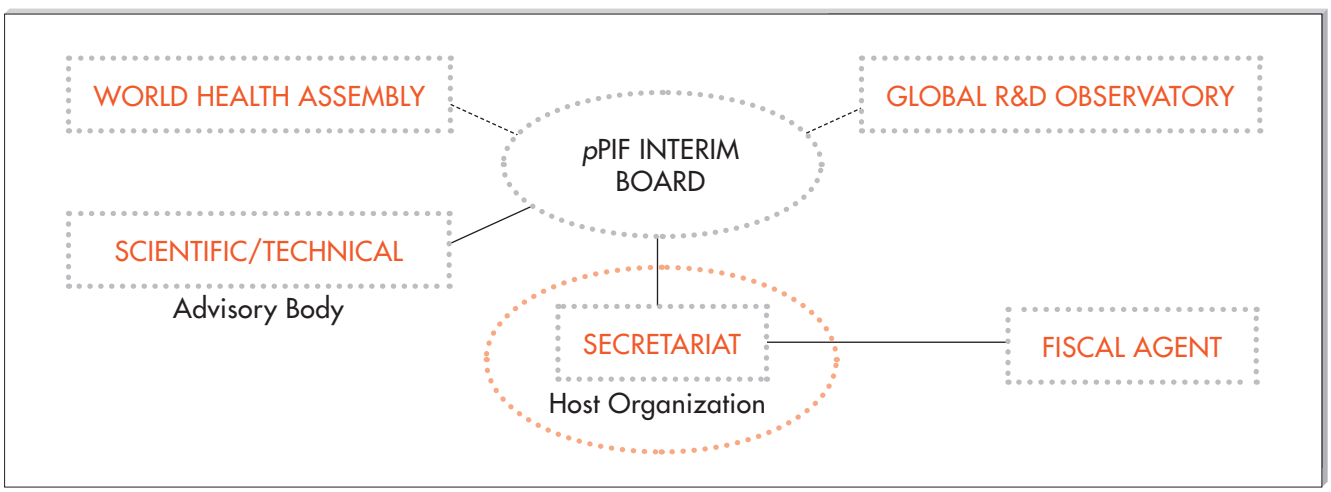
2. **Independent Scientific/Technical Advisory Committee**: Nearly all PDPs and funding bodies rely on some type of independent scientific advisory committee that provides input to the Board on specific proposals or projects. Given the network of actors already engaged in the post-CEWG process, including those involved directly in funding, influencing or performing R&D (including the Observatory and Demonstration Project proponents), it should be relatively straightforward to recruit a small group of qualified individuals to fill core areas of scientific or technical expertise. Such core areas could include the diseases or technologies covered by the Demonstration Projects; policy expertise (e.g. on grantmaking, licensing, patent pooling or creation of novel incentive mechanisms); and governance expertise on managing novel 'start-up' initiatives such as the *p*PIF. The committee could be selected by a small working group, and eventually approved by the Interim Board. TDR has proposed creating a new Scientific Review Group (distinct from its existing Science and Technical Advisory Committee) to advise the fund, and this group could be created to reflect the above areas of competency.

3. **Secretariat**: Finally, a small and nimble Secretariat of experienced professionals could provide management and oversight of funds, initiate evaluation processes, and generally run the operations of the *p*PIF Qualified staff could be seconded to the *p*PIF to accelerate the launch of operations. An outside fiscal agent could be considered to manage the actual funds, analogous to the role the World Bank has played for the Global Fund to Fight AIDS, TB and Malaria.

COSTS

As noted earlier, initial budget estimates from the four Demonstration Projects suggest total resource needs of about 60 million USD over five-years, or an average of 12 million USD per year (assuming the *p*PIF fully funds all four projects).[19] The WHO and TDR have estimated that administrative costs for a pooled international fund should not exceed 20% of the total fund amount, and have also estimated administrative costs at about 2 million USD per year (excluding the Observatory), implying total annual resource needs for a *p*PIF of roughly 14 million USD.[20] Resource needs would likely increase if all eight Demonstration Projects are implemented and funded through this source.

Figure 1. *Pilot* Pooled International Fund



SYNTHESIS & NEXT STEPS

This paper has outlined the contours of a *pilot* Pooled International Fund (*p*PIF) for the four Demonstration Projects, including considerations of a) Potential Limitations and Opportunities of pooling, at regional and global levels, b) Functions of the fund, c) Principles and Policies in accordance with CEWG recommendations, d) basic Governance Arrangements and e) Costs. Broadly, this analysis finds that the potential advantages to pooling at the global level are considerable, that some of the risks can be mitigated, and that therefore Member States should support and contribute to a *pilot* fund for the Demonstration Projects.

What needs to be demonstrated? Such a *pilot* should provide evidence on at least three key questions:

1. How effective and feasible are open knowledge innovation approaches?
2. How feasible are new forms of coordination among R&D actors? and
3. How will Member States mobilize new funding to support innovative R&D models?

Leading governments should form a **Core Working Group** to demonstrate political support for such a fund, design an interim governance structure, and agree upon minimum starting levels of financing to justify operating costs. While risk and uncertainty are greatest at this relatively early-phase, governments willing to take leadership will also benefit from first-mover advantage – the small group of countries who commit today will have the advantage of shaping the governance structures, policies and principles on which the fund will operate. More broadly, governments should recognize this unique opportunity to build and test new approaches to R&D intended to deliver needs-driven innovation and access to affordable end products that can ultimately improve the health of populations under-served by the current global R&D system.

The selection of four Demonstration Projects is not only an opportunity to demonstrate how specific innovative R&D approaches may work, but also to test out new institutional arrangements at the global level that will yield critical insights for the discussions in 2016 and beyond. After decades of debate on how to achieve more equitable innovation and access to health technologies, a *pilot* pooled international fund for R&D is a new form of global cooperation that is long overdue.

Endnotes

1 66th World Health Assembly Resolution 66.22 (2013), available: http://www.who.int/phi/resolution_WHA-66.22.pdf and http://www.ip-watch.org/weblog/wp-content/uploads/2013/05/CEWG-decision-point-May-2013.pdf

2 Author's calculations based on budget estimates provided in initial proposals as of December 2013 (Available: http://www.who.int/phi/implementation/phi_cewg_meeting/en/index2.html). Cost estimates most likely need to be updated and detailed further.

3 WHO Consultative Expert Working Group on Research and Development (CEWG): Financing and Coordination (2012) Research and Development to Meet Health Needs in Developing Countries: Strengthening Global Financing and Coordination. Geneva: World Health Organization. Available: http://www.who.int/phi/CEWG_Report_5_April_2012.pdf

4 67th World Health Assembly, Decisions and List of Resolutions, A67/DIV/3, 24 May 2014. Available: http://apps.who.int/gb/ebwha/pdf_files/WHA67/A67_DIV3-en.pdf.

5 For a recent overview, see for example: Moon S, Omole O. (2013) Development Assistance for Health: Critiques and Proposals for Change. Chatham House Centre on Global Health Security. Working Group on Financing Paper 1: http://www.chathamhouse.org/sites/default/files/public/Research/Global%20Health/0413_devtassistancehealth.pdf

6 CEWG (2012)

7 Horizon 2020: The EU Framework Program for Research and Innovation. Available: http://ec.europa.eu/programmes/horizon2020/en/what-horizon-2020. [Last accessed 12 May 2014]

8 Author's calculations based on budget estimates provided in initial proposals as of December 2013 (Available: http://www.who.int/phi/implementation/phi_cewg_meeting/en/index2.html, last accessed 12 May 2014). Cost estimates most likely need to be update and detailed further.

9 WHO/TDR (2014) Potential mechanism to manage a pooled fund for innovative global health R&D. (May 7). Available: http://www.who.int/phi/implementation/FinancingRD_TDR.pdf [last accessed 12 May 2014]

10 This table and analysis builds on: Angela Y Chang, John-Arne Røttingen, Steven J. Hoffman, Suerie Moon. (2013) Background Paper 2: Governance Arrangements for Health R&D. Background paper prepared for: Expert Workshop on Health R&D as a Global Public Good: Building Institutions for Setting Priorities and Financing. Organized by the Graduate Institute of Geneva Global Health Programme and the Harvard Global Health Institute in Geneva on 24 April 2013. Paper available from the author upon request.

11 WHO (2013) Assessment Criteria for Proposals for Health R&D Demonstration Projects. Available: http://www.who.int/phi/implementation/AsssessmentCriteria.pdf

12 WHO (2014) "7+1 Demonstration Projects Identified by the Global Technical Consultative Meeting on Health R&D Demonstration Projects. Examination of addendum responses to innovation questions." Available: http://www.who.int/phi/implementation/10_March_2014_exam_add_info_results.pdf

13 The Global Fund the Fight AIDS, Tuberculosis and Malaria: http://www.theglobalfund.org/en/board/structures/ [Last accessed 1 May 2014]

14 GAVI Alliance: Governing GAVI. http://www.gavialliance.org/about/governance/ [Last accessed 1 May 2014]

15 UNITAID: Governance. http://www.unitaid.eu/en/how/gov [Last accessed 1 May 2014]

16 Drugs for Neglected Diseases *initiative*: Our People. http://www.dndi.org/about-us/our-people.html [Last accessed 1 May 2014]

17 Medicines Patent Pool: Staffing and Governance. http://www.medicinespatentpool.org/about/staffing-and-governance/ [Last accessed 1 May 2014]

18 John-Arne Røttingen, Suerie Moon, Viroj Tangcharoensathein, Steven J. Hoffman. (2012). Meeting Report: Multistakeholder Technical Meeting on Implementation Options Recommended by the WHO Consultative Expert Working Group on Research & Development (CEWG): Financing and Coordination. Meeting at the Rockefeller Foundation Bellagio Center, 16-19 October 2012. Available: http://globalhealth.harvard.edu/sites/globalhealth.harvard.edu/files/Meeting%20Report%20FINAL.pdf

19 Author's calculations based on budget estimates provided in initial proposals as of December 2013 (Available: http://www.who.int/phi/implementation/phi_cewg_meeting/en/index2.html). Cost estimates most likely need to be updated and detailed further.

20 WHO/TDR (2014) Potential mechanism to manage a pooled fund for innovative global health R&D. (May 7). Available: http://www.who.int/phi/implementation/FinancingRD_TDR.pdf

DNDi

Drugs for Neglected Diseases *initiative*

15 Chemin Louis-Dunant
1202 Geneva Switzerland
Tel: +41 22 906 9230
Fax: +41 22 906 9231
dndi@dndi.org
www.dndi.org

DND*i* AFRICA
c/o Centre for Clinical Research
Kenya Medical Research
Institute
PO Box 20778
KNH 00202 Nairobi
Kenya
Tel: +254 20 273 0076

DND*i* DRC
Avenue Milambo, n°4
Quartier Socimat
Commune de la Gombe
Kinshasa
Democratic Republic
of the Congo
Tel: +243 81 011 81 31

DND*i* INDIA
F - 79 Green Park Main
New Delhi 110-016
India
Tel: +91 11 4550 1795

DND*i* JAPAN
8th Floor,
Nittochi Nishi-Shinjuku Bldg
6-10-1 Nishi-Shinjuku,
Shinjuku-ku
Tokyo 160-0023
Japan
Tel: +81-3-5325-3344

DND*i* LATIN AMERICA
Jardim Botânico
Rio de Janeiro
Rua Santa Heloisa 5
Rio de Janeiro, RJ 22460-080
Brazil
Tel: +55 21 2215 2941
www.dndi.org.br

DND*i* MALAYSIA
Administration Building,
IPharm-MOSTI
Blok 5-A, Halaman Bukit
Gambir
11700 Pulau Pinang
Malaysia
Tel: +60 4 655 2829

DND*i* NORTH AMERICA
40 Wall Street, 24th Floor
New York, NY 10005
USA
Tel: +1 646 616 8680
www.dndina.org