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# EVENT WORKING PAPER 2 GOVERNANCE ARRANGEMENTS FOR HEALTH R&D

HEALTH R&D AS A GLOBAL PUBLIC GOOD: BUILDING INSTITUTIONS FOR SETTING PRIORITIES AND FINANCING

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# Event Working Paper 2: Governance Arrangements for Health R&D

## Executive Summary

This discussion paper was prepared for participants attending a workshop at the Graduate Institute in Geneva on 24 April 2013 to explore ideas for securing collective action towards a credible platform for monitoring, coordinating, and financing research and development (R&D) for the health needs of people living in low and middle income countries. In this paper, we describe potential governance approaches to design and implement demonstration projects, as requested in Resolution WHA 66.22 approved by the 66th World Health Assembly (WHA) in May 2013 with an additional decision point WHA 66(12) on implementation, and how they can be scaled up into a sustained, long term solution.

Following on from the 2008 Global Strategy and Plan of Action and the Consultative Expert Working Group (CEWG) report, one way to demonstrate the feasibility of a global R&D platform is through a two (or more) phase approach to designing, building, and implementing novel processes for setting and following global priorities. The first phase would address the request in the WHA resolution that asks for the implementation of a few health R&D demonstration projects. This phase would identify, fund, and implement demonstration projects that would provide opportunities to carry out policy experiments to test the feasibility and merit of new systemic approaches. The second phase would involve the scale up of the successes from the demonstration phase into a sustained, long term model for coordination and financing of health R&D. In the paper we provide stylized options to facilitate the discussion on both of these phases, with options along two dimensions: 1) level of cooperation and 2) type of implementation mechanisms for operationalizing agreements.

	<b>Phase 1 Demonstration projects</b>	<b>Phase 2 Global Platform</b>
<b>A. Coordination</b>	Coordination Mechanism for Priority Disease R&D (A1)	Global Coordination Forum for Health R&D (A2)
<b>B. Joint programming<sup>1</sup></b>	Joint Programming on Priority Disease R&D (B1)	Global Board for Health R&D (B2)
<b>C. Pooled funding</b>	Joint Funding for Priority Disease R&D (C1)	Global Fund for Health R&D (C2)

<sup>1</sup> See descriptions of JPIs in Europe [http://ec.europa.eu/research/era/how-does-it-work\\_en.html](http://ec.europa.eu/research/era/how-does-it-work_en.html)

In addition, there has been a significant growth in international cooperation in recent years, much of which has been based on addressing emerging global challenges or issues, such as ensuring the supply of vaccines for children in low-income countries, development of new crops suitable for contexts in developing countries or combating climate change. In addition to the important contributions they delivered in achieving their ultimate goals, their experiences in establishing and operating a global platform is worth exploring. In this paper we highlight relevant experiences and the lessons learned from the health, environmental, and agricultural sectors, and examine what the global system for health R&D sector can learn from them. Experiences such as convening both traditional and non-traditional stakeholders in priority setting and decision-making processes, mobilizing financial resources, and ensuring transparency and accountability show how diverse the options for implementation can be. As the options available for each implementation mechanism is being considered for a global platform for health R&D, it is important to pay attention to lessons learned by predecessors across sectors to establish better governance arrangements and achieve more effective strategies in the long run.

Building on the information provided in the paper, we identified five sets of questions to catalyze workshop discussion towards the development of concrete conclusions and suggestions for follow up after the 66th WHA meeting in May 2013.

- **Question Set 1 – Coordination and financing functions:** Assuming that monitoring functions will be served by the Global Observatory on Health R&D when established, what are the key functions that should be performed by a platform for coordination and financing R&D efforts? What level of cooperation among states should the platform be designed to promote?
- **Question Set 2 – Demonstration Projects:** Given there is broad consensus for initiating demonstration projects, should the demonstration projects focus on providing some 'quick wins' or incorporate more comprehensive functions? What criteria should be used for selection of these projects?
- **Question Set 3 – Role of WHO:** Some have suggested that it would be preferable to rely on existing institutions if possible, especially WHO, given its normative mandate, governance structure, and role as an arena for intergovernmental negotiations on health issues. What should the role of WHO be in the establishment and operations of the Global platform for health R&D?
- **Question Set 4 – Learning from the Past:** As we review existing institutions to assess their suitability to perform the required functions of health R&D, what are the potential success stories/models that are relevant to us? What should the role of existing

organizations other than WHO be? Should we rely on existing structures to build the R&D platform? If so, which ones, and how?

- **Question Set 5 – Learning from the Present:** Evaluation is an important part of planning, as it would provide an understanding of what worked and what did not. How can we identify and measure the impact of establishing the platform? And what are some potential measures of success of the global R&D platform?

The goal of the workshop was to explore ideas for securing collective action towards a credible platform for monitoring, coordinating, and financing R&D for the health needs of low- and middle-income countries. With the passage of the Resolution WHA 66.22 and decision point WHA 66(12), the concepts proposed in this paper and the topics discussed in the workshop could be valuable in facilitating the dialogue towards the technical consultative meeting in late 2013.

A summary report of the workshop is available at:

[http://graduateinstitute.ch/webdav/site/globalhealth/shared/1894/Events/Events%202013/PolicyBrief\\_Health%20R%26D%20as%20a%20Global%20Public%20Good\\_2013.pdf](http://graduateinstitute.ch/webdav/site/globalhealth/shared/1894/Events/Events%202013/PolicyBrief_Health%20R%26D%20as%20a%20Global%20Public%20Good_2013.pdf)

## I. Introduction

This discussion paper was prepared for participants attending a workshop at the Graduate Institute in Geneva on 24 April 2013 to explore ideas for securing collective action towards a credible platform for monitoring, coordinating, and financing research and development (R&D) for the health needs of people living in low- and middle-income countries. In this paper, we describe potential governance approaches to design and implement demonstration projects, as requested in Resolution WHA 66.22 approved by the 66th World Health Assembly (WHA) in May 2013 with an additional decision point WHA 66(12) on implementation, and how they can be scaled up into a sustained, long-term solution. We draw upon experiences from international cooperation across health, environmental, and agricultural sectors, and we examine what the global system for health R&D can learn from them. Lastly, we provide a list of questions to lead the workshop discussions in exploring scenarios for creating a global R&D platform.

## II. Background

Recognition is now widespread that the global system for R&D of new health technologies has largely failed to meet the need for affordable, well-adapted products in low- and middle-income countries, particularly for diseases prominently or exclusively found in poor populations. There has been a long-standing WHO process of negotiation and debate on public health, innovation and intellectual property to address this issue, including the 2008 Global Strategy and Plan of Action (GSPA-PHI-PHI) approved by the WHA, and two consecutive expert working groups which have examined the key remaining issue of how to finance and coordinate R&D. The report of the Consultative Expert Working Group (CEWG) was welcomed by the WHA in 2012 and the CEWG recommendations were discussed in an open-ended member state meeting in November 2012. The meeting concluded with a draft resolution that was then debated at the Executive Board of WHO in January 2013. During the 66th WHA in May 2013 the resolution<sup>2</sup>, along with the decision point proposed by the United States<sup>3</sup>, was passed. Resolution WHA 66.22 includes the following key actions to be implemented by WHO:

1. Establish a Global Health R&D Observatory;
2. Facilitate... “implementation of a few health R&D demonstration projects to address identified gaps which disproportionately affect developing countries, particularly the poor and for which immediate action can be taken”;
3. Review existing mechanisms to assess their suitability to perform the coordination function of the global system for health R&D; and
4. Explore and evaluate existing mechanisms for contributions to health R&D, and... develop a proposal for effective mechanisms, including pooling resources and voluntary contributions

In addition, decision point WHA 66(12) urges the Director-General to convene a technical consultative meeting by the end of 2013 to assist in the identification of demonstration projects that:

1. Address identified R&D gaps related to discovery, development and/or delivery;
2. Utilize collaborative approaches, including open-knowledge approaches, for R&D coordination;
3. Promote the de-linkage of the cost of R&D from product price;
4. Propose and foster financial mechanisms including innovative, sustainable and pooled funding; and
5. Provide evidence for long-term sustainable solutions.

2 [http://apps.who.int/gb/ebwha/pdf\\_files/WHA66/A66\\_R22-en.pdf](http://apps.who.int/gb/ebwha/pdf_files/WHA66/A66_R22-en.pdf)

3 <http://www.ip-watch.org/weblog/wp-content/uploads/2013/05/CEWG-decision-point-May-2013.pdf>

While the purpose, scope and potential areas of activity of a Global Observatory on Health R&D have already begun to be examined, relatively little attention has been given to the questions of how to design and implement mechanisms for coordination and financing of demonstration projects and how that can lay the groundwork for a more sustained system. With the passage of the resolution and the decision point, the information and concepts proposed in this paper could be valuable in facilitating the discussion and preparing for the technical consultative meeting in late 2013.

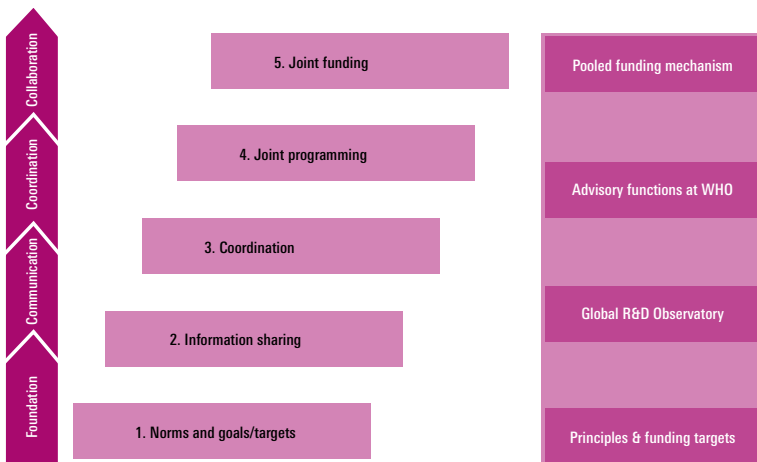


### III. Package Options for Global R&D Platform

Following on from the GSPA-PHI and the CEWG report, one way to demonstrate the feasibility of a global R&D platform is through a two (or more) -phase approach to designing, building, and implementing novel processes for setting and following global priorities. The first phase would address the request in the resolution that asks for the implementation of a few projects which would phase into a sustained, long-term model for coordination and financing of health R&D. For both of these phases there would be options along two dimensions: 1) level of co-operation and 2) type of implementation mechanisms for operationalizing agreements.

In general, we can conceptualize stakeholders' degree of ambition for collective efforts according to four different levels of cooperation<sup>4</sup>:

- Cooperation foundations: Agreement on some principles and norms for interaction
- Communication: Information sharing
- Coordination: Independent decision-making processes but informed by decisions of other actors
- Collaboration: Joint decision-making
  - Strategic level: Joint programming leading to harmonization
  - Operational level: Pooled funding and collective decision-making



4 This idea builds on the concept of three levels of cooperation in: Framework for Action on Inter-professional Education and Collaborative Practice. Geneva:WHO. 2010. Available at [http://whqlibdoc.who.int/hq/2010/WHO\\_HRH\\_HPN\\_10.3\\_eng.pdf](http://whqlibdoc.who.int/hq/2010/WHO_HRH_HPN_10.3_eng.pdf).

Given generally positive reception of the CEWG report and agreement on the need for better monitoring functions, we believe there is an emerging consensus on the need for cooperation at the foundation and communication levels. We will therefore focus on the higher levels of cooperation that are needed to achieve results in this area. We have developed three different stylized options for each of the two phases based on these levels of cooperation and with varying degrees of ambition, and have used the following terms to describe them:

Table 1: Stylized options for the two-phase approach

<b>Phase 1</b>	<b>Phase 2</b>	<b>Global Platform</b>
<i>Cooperation Foundations</i>	<i>Agreement on principles and norms that will inform the platform</i>	
<i>Communication based on National mechanisms</i>	<i>Developing a Global Observatory</i>	<i>Global Observatory on Health R&amp;D</i>
<b>A. Coordination</b>	Coordination Mechanism for Priority Disease R&D (A1)	Global Coordination Forum for Health R&D (A2)
<b>B. Joint programming</b> <sup>5</sup>	Joint Programming on Priority Disease R&D (B1)	Global Board for Health R&D (B2)
<b>C. Pooled funding</b>	Joint Funding for Priority Disease R&D (C1)	Global Fund for Health R&D (C2)

We use the terms “Priority Disease R&D” and “Health R&D” to differentiate more explicitly between the phase 1 and phase 2 options. However, this does not necessarily indicate a different scope for the two phases other than suggesting that since the demonstration phase will be more limited with resources and time, it may benefit from potentially a more narrow and defined scope than in the sustained phase when a global platform is in place. This potentially more narrow scope may be on a set of neglected diseases (type II and III diseases) or any other defined priority area.

We describe the modus operandi of these six stylized options below. For all of them we have decided to concentrate on the implementation mechanisms related to advisory functions and decision-making for both setting priorities and identifying and deciding on projects and programs.

## Phase 1 – Demonstration projects

In the first phase of implementation, we focus on the different levels of coordinated advisory and decision-making mechanisms to identify and decide priorities and potential projects. We also suggest that stakeholders consider how funds should be generated and allocated for a pooled funding option (see C1).

### Coordination Mechanism for Priority Disease R&D (Option A1)

This option uses existing structures within WHO to identify and decide on priorities for investment. If priorities are accepted by Member States, WHO would then identify potential projects that could then be funded by individual funders through their ordinary mechanisms without any joint decision-making or funding processes.

Mechanism	What	Who	How
Advisory	Identifying needs and priorities	WHO Secretariat	<ul style="list-style-type: none"> <li>→ Literature review</li> <li>→ Survey/submissions</li> <li>→ Consultations</li> </ul>
Decision-making	Deciding priorities	WHO Secretariat	<ul style="list-style-type: none"> <li>→ No formal decision, but a collated list of priorities</li> <li>→ Endorsement (governing bodies) or acceptance (consultation) by Member States</li> </ul>
Advisory	Identifying potential projects	WHO Secretariat	<ul style="list-style-type: none"> <li>→ Call for letters of interests or suggestions</li> <li>→ Development of a menu of options linked to the priorities</li> <li>→ Endorsement (governing bodies) or acceptance (consultation) by Member States</li> </ul>
Decision-making	Deciding and funding projects	Governmental R&D funders or others	<ul style="list-style-type: none"> <li>→ Through their ordinary mechanisms</li> <li>→ Notification to WHO Secretariat</li> </ul>

## Joint Programming on Priority Disease R&D (Option B1)

This option introduces a 'Joint Programming Group' that would collectively decide on a list of priorities based on information provided by WHO. It would also be responsible for identifying potential projects based on predetermined priorities that would then be funded by individual funders through their ordinary mechanisms.

Mechanism	What	Who	How
Advisory	Identifying needs and priorities	WHO Secretariat	<ul style="list-style-type: none"> <li>→ Literature review</li> <li>→ Survey/submissions</li> <li>→ Consultations</li> </ul>
Decision-making	Deciding priorities	Joint Programming Group (appointed by EB or WHA)	<ul style="list-style-type: none"> <li>→ Decide on a list of the highest priorities</li> <li>→ Endorsement (governing bodies) or acceptance (consultation) by Member States</li> </ul>
Advisory	Identifying potential projects	Joint Programming Group	<ul style="list-style-type: none"> <li>→ Call for letters of interests or suggestions</li> <li>→ Develop a strategic research agenda linked to the priorities with target product profiles (TPPs)</li> <li>→ Endorsement (governing bodies) or acceptance (consultation) by Member States</li> </ul>
Decision-making	Deciding and funding projects	Governmental R&D funders or others	<ul style="list-style-type: none"> <li>→ Through their ordinary mechanisms</li> <li>→ Notification to WHO Secretariat</li> </ul>

## Joint Funding for Priority Disease R&D (Option C1)

This option appoints a 'Joint Funding Group' that would be responsible for deciding both the priority list and the projects that should be implemented. The funding required for implementation would be generated through member contributions, and would be distributed through different funding mechanisms determined by the Joint Funding Group.

Mechanism	What	Who	How
Advisory	Identifying needs and priorities	WHO Secretariat	<ul style="list-style-type: none"> <li>→ Literature review</li> <li>→ Survey/submissions</li> <li>→ Consultations</li> </ul>
Decision-making	Deciding priorities	Joint Funding Group (appointed by EB or WHA)	<ul style="list-style-type: none"> <li>→ Decide on a list of the highest priorities</li> <li>→ Endorsement (governing bodies) or acceptance (consultation) by Member States</li> </ul>
Advisory	Identifying potential projects	Joint Funding Group	<ul style="list-style-type: none"> <li>→ Call for letters of interests or suggestions</li> <li>→ Develop a research funding plan linked to the priorities</li> <li>→ Endorsement (governing bodies) or acceptance (consultation) by Member States</li> </ul>
Decision-making	Deciding projects	Joint Funding Group	<ul style="list-style-type: none"> <li>→ Call for proposals</li> <li>→ Decide on projects based on available total joint funds or matching projects to funders' potential earmarked priorities</li> <li>→ Notification to WHO Secretariat</li> </ul>
Financing	Generating funds	Members	<ul style="list-style-type: none"> <li>→ Voluntary or mandatory contributions</li> </ul>
Funding	Allocating funds	Joint Funding Group	<ul style="list-style-type: none"> <li>→ Decide on how to allocate funds to projects (e.g., push/pull mechanisms)</li> </ul>

## Phase 2 – Global Platform

Building on the progress of demonstration projects, in phase 2 the platform would expand its scope to a more sustainable system. Here we describe three stylized options on the key operational and fiscal mechanisms.

### Global Coordination Platform for Health R&D (Option A2)

This option relies on the Global Observatory on Health R&D to provide a list of priorities and potential projects. The Observatory would provide advisory services like the Advisory Committee on Health Research (ACHR), and based on this information, the individual funders would determine which projects to implement and fund through their ordinary mechanisms.

Mechanism	What	Who	How
Advisory	Identifying needs and priorities	Global Observatory	<ul style="list-style-type: none"> <li>→ Literature review</li> <li>→ Survey/submissions</li> <li>→ Consultations</li> </ul>
Decision-making	Deciding priorities	Global Observatory	<ul style="list-style-type: none"> <li>→ No formal decision, but a collated list of priorities</li> <li>→ Deliberations in a Global Coordination Forum (of research funders)</li> </ul>
Advisory	Identifying potential projects	Global Observatory	<ul style="list-style-type: none"> <li>→ Call for letters of interest or suggestions</li> <li>→ Development of a menu of options linked to the priorities</li> <li>→ Deliberations in a Global Coordination Forum (of research funders)</li> </ul>
Decision-making	Deciding projects	R&D Funders	<ul style="list-style-type: none"> <li>→ Through their ordinary mechanisms</li> <li>→ Notification to Global Observatory</li> </ul>
Financing	Generating funds	R&D Funders	<ul style="list-style-type: none"> <li>→ Through their ordinary mechanisms</li> </ul>
Funding	Allocating funds	R&D Funders	<ul style="list-style-type: none"> <li>→ Through their ordinary mechanisms (e.g., push/pull mechanisms)</li> </ul>

## Global Board for Health R&D (B2)

This option introduces a 'Global Board' to collectively decide on a list of priorities and identify potential projects based on information provided by the Observatory. The outcomes from the Board would then be used by the individual R&D funder to determine which of the endorsed projects they would fund. Since this option does not involve a pooled fund, individual R&D funders would use their existing financing and funding mechanisms to generate and distribute money.

Mechanism	What	Who	How
Advisory	Identifying needs and priorities	Global Observatory	<ul style="list-style-type: none"> <li>→ Literature review</li> <li>→ Survey/submissions</li> <li>→ Consultations</li> </ul>
Decision-making	Deciding priorities	Global Board (appointed by Member States)	→ Decide on a list of the highest priorities
Advisory	Identifying potential projects	Global Board	<ul style="list-style-type: none"> <li>→ Call for letters of interest or suggestions</li> <li>→ Develop a strategic research agenda linked to the priorities with target product profiles (TPPs)</li> </ul>
Decision-making	Deciding projects	R&D Funders	<ul style="list-style-type: none"> <li>→ Through their ordinary mechanisms</li> <li>→ Notification to Global Observatory</li> </ul>
Financing	Generating funds	R&D Funders	→ Through their ordinary mechanisms
Funding	Allocating funds	R&D Funders	→ Funding of projects through their ordinary mechanisms (e.g., push/pull mechanisms)

## Global Fund for Health R&D (Option C2)

This option appoints a ‘Global Fund’ that collectively decides priorities (based on inputs from the Observatory), identifies and decides which projects to fund. It would also be responsible for generating funds for a pooled fund and allocating money through different funding mechanisms. Here we highlight the fact that choosing one way of applying a mechanism may automatically determine how another would be implemented. Rather than allowing individual funders to decide on how to generate and allocate funds through their ordinary mechanisms, as shown in Option B2, in this scenario the creation of a pooled fund requires collective action by the Global Fund to design and adopt various ways to generate and allocate funding.

Mechanism	What	Who	How
Advisory	Identifying needs and priorities	Global Observatory	<ul style="list-style-type: none"> <li>→ Literature review</li> <li>→ Survey/submissions</li> <li>→ Consultations</li> </ul>
Decision-making	Deciding priorities	Global Fund (established by Member States)	<ul style="list-style-type: none"> <li>→ Decide on a list of the highest priorities</li> <li>→ Endorsement (governing bodies) or acceptance (consultation) by Member States</li> </ul>
Advisory	Identifying potential projects	Global Fund	<ul style="list-style-type: none"> <li>→ Call for letters of interest or suggestions</li> <li>→ Develop a global R&amp;D plan linked to the priorities with target product profiles (TPPs)</li> </ul>
Decision-making	Deciding projects	Global Fund	<ul style="list-style-type: none"> <li>→ Call for proposals (or other mechanisms for investing in or incentivizing R&amp;D)</li> <li>→ Decide on projects based on available total joint funds or matching projects to Fund’s priorities</li> </ul>
Financing	Generating funds	Members	<ul style="list-style-type: none"> <li>→ Voluntary/mandatory contributions</li> </ul>
Funding	Allocating funds	Global Fund	<ul style="list-style-type: none"> <li>→ Collectively decide on how to allocate funds to projects (e.g., push/pull mechanisms)</li> </ul>



## IV. Implementation Mechanisms

In addition to the six options presented above, alternative combinations of options and mechanisms can be explored. We apply the agreement implementation framework developed by Hoffman and Røttingen to assess the full range of mechanisms available for implementing a global system for health R&D<sup>6</sup>, and have extended this conceptual framework with some additional dimensions. This section provides a comprehensive list of the implementation mechanisms under three main categories that are required to establish a functional global platform for health R&D.

**Operational mechanisms:** This set of mechanisms lays out the fundamental guiding principles, including the overarching strategies and processes that govern the platform.

1. *Normative mechanisms* refer to the mission, vision, goals, principles, and core beliefs underpinning any agreement which are intended to guide future directions and choices. These norms include the goals against which the agreement can be evaluated for success or failure. This is a necessary foundation of any agreement on cooperation and is therefore also described as the constitutional level or cooperation foundations above.
2. *Advisory mechanisms* describe who decides what types of information should feed into the decision-making process. This includes who should be consulted to set priorities, what processes should be in place to solicit consultation, what level of agreement is needed to set priorities, whether to develop priority criteria, and if so, what the criteria should be.
3. *Decision-making mechanisms* are the ways in which subsequent agreements are reached and collective decisions on activities, budgets, priorities and disputes are made. Two dimensions of this mechanism should be considered and determined: decision-making bodies and decision-making procedures.
4. *Administration mechanisms* determine how, who, and where the administrative activities for the operation will be delivered.
5. *Dispute resolution mechanisms* include processes and policies that address disputes that arise between two or more parties engaged in the arrangement. This can be effective in establishing communication channels between parties and offer a credible way for parties to voice and resolve concerns related to projects. It should also enable more systematic identification of emerging issues and trends.
6. *Learning mechanisms* describe how the processes of reaching agreements can be improved over time and how the stakeholders learn to be more effective and efficient in achieving their common goals. These could be done through conducting monitoring and evaluations and incorporating feedback systematically.

6 Hoffman, S. J., & Røttingen, J. A. (2012). Assessing implementation mechanisms for an international agreement on research and development for health products. *Bulletin of the World Health Organization*, 90(11), 854-863.

**Fiscal mechanisms:** This category encompasses mechanisms related to the generation, management, allocation, and auditing of funds.

7. *Financing mechanisms* describe the mechanism to generate or mobilize funds. How (eg, mandatory or voluntary; general pool or earmarks) and when (eg, rounds or windows) countries and other stakeholders should contribute need to be determined. An alternative is that money can be managed and generated separately by each donor but spent in a coordinated way, i.e. joint programming. Financing is then left to the responsibility of each partner.
8. *Financial mechanisms* refer to the management of the funds that are required for implementation, including how the mechanism should be organized and governed. A pooled financial mechanism is considered to be the highest level of cooperation
9. *Funding mechanisms* determine how the money should be allocated to fund and stimulate priority R&D efforts. Members may decide to allocate such funds through traditional methods (eg, grant making) or innovative incentive mechanisms (eg, prizes or milestone rewards).
10. *Auditing mechanisms* are performed to maintain financial records and evaluate financial health of the fund.

**Accountability mechanisms:** this set of mechanisms allows members and non-members to voice and seek solutions to problems, monitor progress, and report alleged non-compliance with policies and procedures.

11. *Commitment mechanisms* allow states and potential non-state actors to commit themselves to obligations vis-à-vis other states and potential actors in the pursuit of mutually shared goals. The level of commitment can range from legally binding instruments to mutual agreements.
12. *Compliance mechanisms* can be drawn to promote adherence to commitments among members in order to bring agreements into effect. Legal processes, institutional agreements, economic sanctions, and political pressure are examples that have been applied in international settings.
13. *Transparency mechanisms* are aimed at holding countries and research funders accountable for their level and profile of investments and ensure more transparency and efficient information sharing among all actors.
14. *Oversight mechanisms* determine how partners collectively oversee and monitor their respective implementation of any agreement. The ideal oversight mechanism will balance information accuracy and due process with cost and available financial resources.
15. *Appeal mechanisms* refer to the process in which non-members can request a formal explanation, second opinion or change to an official decision, made either by the decision-making body or the administration mechanisms.

In the current stage of discussions, the key questions that need to be addressed include: 1) whether the demonstration projects should focus exclusively on providing some ‘quick wins’ that will allow a timely demonstration of feasibility, or whether they should incorporate more thorough criteria that would demonstrate the feasibility of a more comprehensive platform; 2) what method(s) should be used to identify potential demonstration projects and select those to be conducted; and 3) what levels of cooperation would most likely attract broad international support. While all mechanisms are crucial in achieving the goals of a global system for health R&D in the long run, the answers to the questions above may determine which of these implementation mechanisms should be considered first. The interactions between mechanisms should also be considered, since choosing one way of applying a mechanism may automatically determine how another would be implemented. For example, choosing to create a joint pooled fund limits the options for deciding how to allocate funds. Likewise, not choosing to create a pooled fund makes the fiscal mechanisms redundant since this will be covered by already established systems.

In line with the options presented in the previous section, here we highlight some key operational and fiscal mechanisms (i.e., advisory, decision-making, financial, financing, and funding mechanisms) and provide additional options based on different levels of cooperation and potential ambition. Under these mechanisms, stakeholders should consider whether the options are realistic and feasible, what the key advantages and disadvantages are, how to refine the options, and what barriers need to be overcome to obtain support for implementation. Potential additional or alternative mechanisms and options may also be identified through further deliberations. They should be assessed according to the appropriateness and feasibility for the first phase of demonstration projects and how suitable they may be for more sustainable solutions in the second phase. Ultimately, these key mechanisms would serve as a foundation on which other implementation mechanisms could be built.

While determining which options are suitable for demonstration projects, it is important to take into consideration the concept of “path dependency.” Once a particular option for implementation mechanisms is locked in, it may limit other options for the next phase, either by definition, interaction between mechanisms, political feasibility, or other unintended consequences. For example, choosing to apply international law as the commitment mechanism in phase 1 will certainly limit participation from NGOs as decision-makers since they lack international legal personality. Stakeholders should therefore fully analyze the potential consequences of selecting one model over another and recognize the potential challenges in modifying the scope once it is determined and implemented. One approach to avoid this scenario would be

to reverse the thinking process by first thinking through what the full model should look like in the long run (i.e., phase 2), and then design pilots according to this long-term vision as a first step to reaching it (i.e., phase 1).

We provide a comprehensive list of options for all mechanisms for the different levels of co-operation in the Appendix (Table 4). We highlight the different options for the main implementation mechanisms in Table 2.

Table 2: Options for key operational and fiscal mechanisms – advisory, decision-making, financial, financing, and funding

		Levels of Cooperation		
		Coordination	Harmonized or joint efforts (e.g. joint programming with common decisions but separate funding)	Collaboration
		Coordinated efforts (e.g. a platform for discussing and coordinating priorities)	Between funders and/or recipients Between governments and civil society/public	Collective efforts (e.g., pooled funding mechanism)
Advisory	Who	→ Between funders and/or recipients → Between governments and civil society/public	→ Between funders and/or recipients → Between governments and civil society/public	→ Advisory group (delegation) → Technical experts → Representative from each stakeholder → All stakeholders: member states and/or non-state actors
	How	→ Ad hoc → Bilateral agreement	→ Ad hoc → Joint group agreement	→ Predetermined priority-setting criteria → Consultation processes
Decision Making	Who	→ Between funders and recipients	→ Between funders and recipients	→ Board members (delegation) → Member state representatives and/or non-state actor representatives → All stakeholders: member states and/or non-state actors
	How	→ Mutual agreement	→ Joint group agreement	→ Delegated → Unanimous or consensus model → Majority or supermajority voting → Modified voting system (e.g. based on financial contribution)
Financing (generation)				→ Voluntary discretionary contributions → Voluntary multi-year contribution → Voluntary contribution based on a soft norm → Voluntary pledges based on achievement of a collective goal (e.g. financing level, matched funding by others) → Mandated assessed minimum contributions and additional voluntary contribution
		→ Separate financing mechanisms	→ Separate financing mechanisms	→ Mandated assessed contributions
Financial (management)				→ All members agree on a pooled mechanism → A smaller group of members create pooled fund in which other countries may later opt to participate
		→ Separate financing mechanisms	→ Separate financing mechanisms	
Funding (allocation)				→ Investment / venture capital model (owner/partner) → Infrastructure (investment in processes, e.g., patent pool) → Pull mechanisms (e.g., incentives, prizes, market or procurement commitments) → Push mechanisms (e.g., grants)
		→ Separate funding mechanisms	→ Separate funding mechanisms	

## V. Experiences from health and other sectors

Over the past several decades, there has been a significant growth in international cooperation, much of which has been based on addressing emerging global challenges or issues, such as ensuring the supply of vaccines for children in low-income countries, development of new crops suitable for contexts in developing countries or combating climate change. Their experiences in establishing and operating global institutions are worth exploring. In this section, we highlight relevant experiences from the health, environmental, and agricultural sectors, and summarize their operational and fiscal mechanisms in Table 3 to understand how they have been implemented. This section is by no means exhaustive, and each organization is described in more detail in Appendix I.

Table 3: Combinations of implementation mechanisms used to support various international cooperation efforts

	Implementation Mechanisms			
	Advisory	Decision Making	Financing	Funding
GAVI	Delegated → Independent Review Committee	Delegated → GAVI Alliance Board (including public & private stakeholders) → GAVI Fund Executive Committee	Different financing methods for different programs → Direct contributions → International Finance Facility for Immunisation → Advance Market Commitment → GAVI Matching Fund	→ Procurement of supplies → Pull mechanism – Advance Market Commitment (AMC) → Investment in infrastructure or projects (eg, health systems strengthening)
The Global Fund	Delegated → Technical Review Panel	Delegated → Global Fund Board	→ Voluntary 3-year replenishment mechanism → Additional ad-hoc contributions	→ Grants → Investment – capacity building (direct payment to service providers)
UNITAID	Delegated → Advisory Group on Funding Priorities → Proposal Review Committee	Delegated → Executive Board	→ Voluntary discretionary contributions → Voluntary multi-year contribution	→ Majority of the funds are earmarked for the purchase and supply of commodities → Works through programmatic partners, which can be NGOs, PDPs, multilaterals, private firms, or foundations
CGIAR	Delegated → Independent Science and Partnership Council	Delegated → Fund: Fund Council → Consortium: Board of Directors	→ Voluntary discretionary contributions → Some donors choose to sign legally binding contribution agreements with the Trustee	Depend on how restricted the fund is based on donors' designation to three "Windows" → Window 1: distributed according to Fund Council's priorities → Window 2: designated by donors to certain projects → Window 3: allocated directly to specific research centers
GEF	Delegated → Scientific and Technical Advisory Panel	Delegated → GEF Council	→ Voluntary multi-year replenishment mechanism <sup>7</sup>	→ Grants to countries and GEF agencies

## **GAVI Alliance – governance arrangements and innovative financing mechanism**

GAVI was launched in 2000 to fund the procurement and delivery of vaccines for low- and lower-middle income countries. GAVI raises funds through traditional and innovative mechanisms, and transfers resources directly to country governments, relying on country-based systems and partners to deliver its programs.<sup>8</sup>

### **Governance arrangements**

GAVI's initial governance body included four separate boards, with one to ensure multi-stakeholder inclusiveness (advisory & decision-making mechanism), another to monitor fiduciary accountability (commitment mechanism), a third to maintain budgetary control and a fourth to enhance financial management integration (financial mechanisms). In 2008 an independent review concluded that roles and responsibilities at various levels of the organization was inadequately defined.<sup>9</sup> GAVI's governance design caused confusion the roles of each board, and that the complexity of the arrangement not only caused significant inefficiencies in both time and money but also blurred accountability lines.<sup>10</sup> GAVI later switched to a single governing body and established a hybrid model for the board, which includes two-thirds constituency-determined board members and one-third independent members. A 2010 evaluation of the organization concluded that the new board structure brought about significant improvements, but that its size of 28 board members and its dominant constituency character made decision-making processes "more bureaucratic and inefficient."<sup>10</sup> Issues around potential conflicts of interest were also raised, as some constituency members were also recipients of GAVI funding.<sup>9,10</sup>

### **Innovative financing mechanism <sup>11</sup>**

GAVI's innovative financing mechanism accounts for roughly 37% of overall funding portfolio. It includes the Matching Fund program, International Finance Facility for Immunisation (IFFIm) and the Advance Market Commitment (AMC). The Matching Fund program is supported by UK's Department for International Development (DFID) and by the Bill & Melinda Gates Foundation. The private sector partner makes a financial pledge to GAVI, which then works with the organization to explore ways to engage its customers, employees, business partners and others to contribute through the Matching Fund. Between now and 2015, every donation to GAVI through the Matching Fund is matched either by DFID or by the Gates Foundation. As of

8 (2012). [http://www.who.int/phi/2-funding\\_mechanism\\_factsheets\\_6nov12.pdf](http://www.who.int/phi/2-funding_mechanism_factsheets_6nov12.pdf)

9 GAVI First Evaluation Report. <http://www.gavialliance.org/results/evaluations/gavi-first-evaluation-report/>

10 Bezanson, K., Isenman, P. (2012) Governance of New Global Partnerships: Challenges, Weaknesses, and Lessons. Center for Global Development.

11 <http://www.gavialliance.org/funding/how-gavi-is-funded/>

January 2013 the total amount raised was US \$78 million.<sup>12</sup> IFFIm relies on long-term pledges from donor governments to sell “vaccine bonds” in their financial markets, thus making funds available for GAVI.<sup>13</sup> AMC for vaccines was designed as a “pull mechanism” to encourage the development and production of affordable vaccines for the poor. In the pilot AMC for pneumococcal vaccine, donors committed funds to guarantee the price of vaccines once they are developed. These strong financial commitments provided vaccine producers with the incentive to invest in R&D and sign a legally binding commitment to provide the vaccine at an affordable price for a defined period.<sup>14</sup>

### **The Global Fund – resource forecasts and funding allocation model**

Created in 2002, the Global Fund to Fight AIDS, Tuberculosis and Malaria is a public-private partnership dedicated to mobilizing and allocating additional resources to the three diseases. Unlike most development agencies, it finances but does not implement programs. The Global Fund emphasizes country ownership, transparency and efficiency, and “strives to pursue a balanced funding approach between regions, diseases, interventions, and treatment and prevention.”<sup>15</sup>

#### **Resource forecasts<sup>15</sup>**

Forecasting is conducted during every Board meeting, including both pledges and the projections of donor contributions to decide whether the Global Fund is in a financial position to approve funding for a new funding opportunity and when to approve funding for successful proposals. The forecast helps the Board to understand the resource picture so that it can make informed decisions about policies that will affect the Global Fund’s financial situation in the future.

#### **Funding allocation model**

The Global Fund recently announced their new funding model that replaced the former rounds-system with one timing window for funding applications. The previous model had been criticized for several reasons, including the fact that the timelines were mainly determined by the Global Fund and not by the recipient countries and low predictability of its funds due to the timing of the rounds, success rates, and the availability of funding.<sup>16</sup> The new funding model addresses these issues by providing countries with more flexibility around when they apply for funds, as well as more predictability on the level of funding available, while still encouraging countries

12 <http://www.gavialliance.org/library/news/press-releases/2013/gavi-alliance-significantly-expands-private-sector-involvement-in-saving-lives/>

13 <http://www.iffim.org/about/overview/>

14 <http://www.gavialliance.org/funding/pneumococcal-amc/how-the-pneumococcal-amc-works/>

15 [http://www.theglobalfund.org/documents/core/guides/Core\\_GovernanceHandbookSection9FinancialResources\\_Handbook\\_en/](http://www.theglobalfund.org/documents/core/guides/Core_GovernanceHandbookSection9FinancialResources_Handbook_en/)

16 [http://www.theglobalfund.org/Documents/core/newfundingmodel/Core\\_NewFundingModel\\_Presentation\\_en/](http://www.theglobalfund.org/Documents/core/newfundingmodel/Core_NewFundingModel_Presentation_en/)



to clearly express how much funding they need to effectively treat and prevent the diseases.<sup>17</sup>

## **UNITAID – innovative financing mechanism, priority setting and resource allocation**

UNITAID is an innovative financing initiative created to provide sustainable and predictable funding to impact market dynamics, including ways to reduce prices and improve access to high quality medicines, diagnostics and related commodities for the treatment of HIV/AIDS, malaria and tuberculosis for the poor.<sup>18</sup>

### **Innovative financing mechanism**

Since UNITAID is mainly funded by a levy on airline tickets (approximately two-thirds of all donor funding between 2006 and 2011), its revenue is inevitably closely tied with the performance of the airline industry. Although this reliance on airline tax was initially aimed to provide a steady and consistent funding source, some have suggested that since air travel is a luxury good, it is highly vulnerable to economic fluctuations. According to a report by the Center for Global Development, UNITAID's revenues fell 21% between 2008 and 2009, while overall development assistance for health globally rose 3% during the same period.<sup>19,20</sup> The most recent UNITAID 5-year evaluation report describes this heavy reliance on airline tax as "a double-edged sword", since there is a risk that this tax will not continue to provide secure and sustained financing. It suggested UNITAID to consolidate its other donor funding and explore more financing beyond the airline tax.<sup>21</sup>

### **Priority setting and resource allocation<sup>22</sup>**

The Executive Board selects projects that meet the needs of UNITAID's chosen markets for health commodities. An advisory group composed of external experts reviews all funding requests, and the Executive Board then takes all decisions related to approval of funding for specific projects.

For priority setting, UNITAID takes two approaches: strategic prioritization (decision-making about which markets to prioritize) and project selection (decision-making about which proposals

17 <http://www.theglobalfund.org/en/activities/fundingmodel/>

18 WHO. (2012). [http://www.who.int/phi/2-funding\\_mechanism\\_factsheets\\_6nov12.pdf](http://www.who.int/phi/2-funding_mechanism_factsheets_6nov12.pdf)

19 Silverman, R. (2012) UNITAID – Background paper prepared for the Working Group on Value for Money: An Agenda for Global Health Funding Agencies. Center for Global Development.

20 UNITAID, however, states that the funding has remained stable in the past five years, and strongly suggesting that innovative financial mechanisms can "weather an economic storm" (UNITAID Annual Report 2011)

21 ITAD. (2012). UNITAID 5 Year Summary. <http://www.unitaid.eu/images/Five-year-evaluation/5YE%20Exec%20Summary-UNITAID%202012-12-03%2016h00.pdf>

22 ...

to fund as well as impact assessment). According to UNITAID, inputs supporting strategic and effective Board decision-making towards maximal impact include:<sup>23</sup>

- Landscape analyses provide background information and market intelligence on current and future trends in disease, technology and market characteristics for medicines, diagnostics, and prevention used in target diseases.
- Primary criteria to guide strategic prioritization and project selection including: (i) potential market impact; (ii) potential public health impact; (iii) value for money; and (iv) innovation; as well as consideration for principles embedded in the UNITAID Constitution, including: (i) leveraging; (ii) equity; and (iii) relative value-add.
- Guiding portfolio principles to monitor the spread of funding within UNITAID's portfolio of projects, including balance of funds across: the three diseases, types of products, number and size of investments; and investments per organization.
- Financial analyses of actual and expected funding against committed expenditure to determine resources available for new projects.

### **Consultative Group on International Agricultural Research (CGIAR) – 'a la carte' model**

CGIAR is a global partnership that connects research organizations working on agricultural development. Its organizational goals are "to reduce rural poverty, increase food security, improve human health and nutrition, and ensure more sustainable management of natural resources."<sup>24</sup> Research is carried out by 15 Centers that are members of the CGIAR Consortium, in close collaboration with various partner organizations, such as national and regional research institutes, civil society organizations, academia, and the private sector. The Centers generate and disseminate knowledge, technologies, and policies through the CGIAR Research Programs (CRPs), while the CGIAR Fund provides reliable and predictable multi-year funding to "enable research planning over the long term, resource allocation based on agreed priorities, and the timely and predictable disbursement of funds."<sup>24</sup>

In terms of its financing mechanism, donors may choose to designate their contribution to one or more of the three funding "Windows":<sup>24</sup>

- Window 1 - the least restricted type of funding. The Fund Council sets overall priorities and makes specific decisions about the use of Window 1 Funds such as allocation to CRPs, payment of system costs and any other use required to achieve the CGIAR mission;
- Window 2 –designated by Fund Donors to one or more specific CRPs. For each approved CRP, a sub-account is created to which donors may allocate funds. Once Window 2 funds are allocated to a given CRP, they flow to the lead center implementing the CRP;

<sup>23</sup> UNITAID 2011 Annual Report. [http://www.unitaid.eu/images/Annual\\_Report\\_2011/UNITAID\\_AR2011\\_EN.pdf](http://www.unitaid.eu/images/Annual_Report_2011/UNITAID_AR2011_EN.pdf)

<sup>24</sup> CGIAR website: <http://www.cgiar.org>

- Window 3 – the most restricted type of funding, consisting of funds that Fund Donors wish to allocate to specific Centers. Neither the Consortium nor the Fund Council makes decisions about the use of Window 3 funds. Within 2 years after the CGIAR Fund's establishment, the Fund Council will review the use of Window 3 in consultation with the Consortium Board.

The CGIAR encourages donors to provide predictable funding to the Research Centers through the CGIAR Fund, rather than directly in the form of bilateral grants. In 2012, roughly 56% of contributions were designated to Window 1, 18% to Window 2, and 26% to Window 3.<sup>25</sup>

## Global Environment Facility – replenishment model and resource allocation

The Global Environment Facility was founded by the World Bank, the United Nations Development Program (UNDP), and the United Nations Environment Program (UNEP) in 1991 as an independent financial mechanism “to unite countries in partnership with international institutions, civil society organizations, and the private sector to address global environmental issues while supporting national sustainable development initiatives.”<sup>26</sup>

### Replenishment model<sup>27</sup>

Resources for the GEF Trust Fund are replenished every four years when countries that wish to contribute to the fund pledge financial resources through a replenishment process. During the negotiating sessions, participants agree on a set of policy reforms to be undertaken, a document to guide the programming of resources, and a level of resources that the GEF will aim to provide to recipient countries during the replenishment period. The negotiation sessions also provide an opportunity for donors to review organizational performance and progress, and decide on future programming and strategic directions. The size of a given replenishment depends on a number of factors, such as the estimated overall funding requirements for approved future programming, donors' priorities, and their ability to fund the replenishment. A unique design of GEF's replenishment model is that donor pledges are then formalized by the deposit of an Instrument of Commitment (IoC), which constitutes a legally binding obligation on the part of the donor to pay the specified amount. Due to national constraints some donors are not able to offer legally binding IoCs for the entire replenishment period, therefore they may deposit a Qualified IoC with the Trustee, agreeing to pay a part of their contribution without qualification while the rest remains subject to enactment by national legislative

25 CGIAR Financial Report 2012. <http://library.cgiar.org/handle/10947/2770>

26 GEF website: [www.thegef.org](http://www.thegef.org)

27 GEF Replenishment: Overview of Financial Structure 2013. <http://www.thegef.org/gef/sites/thegef.org/files/documents/GEF-6%20Replenishment%20Financial%20Structure.pdf>

approval. The donor is then expected to obtain approval for the full amount of its contribution by the same payment dates applicable to unqualified IoCs.

### **Resource allocation<sup>28</sup>**

When the GEF was first established, member countries chose to tap into the strengths of three founding organizations (the World Bank, UNDP, and UNEP) to implement its projects, rather than construct a new organization. The three organizations were appointed as GEF Agencies to create project proposals and supervise or implement approved projects. In 1999, an additional seven executing agencies were added: the Asian Development Bank, the African Development Bank, the European Bank for Reconstruction and Development, the Food and Agriculture Organization, the Inter-American Development Bank, the International Fund for Agricultural Development, and the United National Industrial Development Organization. The GEF provides an administration fee to GEF agencies, equal to about 10 percent of GEF financing, to cover the costs of project preparation and supervision. GEF agencies are expected to leverage their respective comparative advantages in GEF projects. For example, the comparative advantage of UNEP is listed as “catalyzing the development of scientific and technical analysis and advancing environmental management in GEF-financed activities,” that of UNDP as “developing and managing capacity building programs and technical assistance projects”, and that of the World Bank as “developing and managing investment projects.” In integrated projects that include elements of expertise that are lacking in one GEF agency, that agency is expected to partner with another agency so that all aspects of the project will be managed well.

### **Summary of experiences**

As demonstrated by these prominent international organizations, there is no one single approach in achieving implementation of agreements on international cooperation. Their various attempts in activities such as convening both traditional and non-traditional stakeholders in priority-setting and decision-making processes, mobilizing financial resources, and ensuring transparency and accountability show how diverse the options for implementation can be. It also merits mentioning that many of these organizations have undergone reform processes to improve their governance structures and performance over time. In considering options available to build a global platform for health R&D, the experiences of these predecessors offer important cues for workable governance and financing arrangements.

## VI. Conclusion and questions for consideration

Building on the information provided above, here we identify five sets of questions to catalyze debate to guide next steps after the passage of Resolution WHA 66.22 and decision point WHA 66(12) at WHA in May 2013.

### Question Set 1: Coordination and financing functions

While the monitoring function of the global system has already begun to be examined, relatively little attention has been given to designing and implementing mechanisms for coordination and financing. Assuming that monitoring functions will be served by the Global Observatory on Health R&D when established, we would suggest first exploring the functions of an R&D platform regarding coordination and financing:

- What are the key functions that should be performed by a platform for coordination and financing R&D efforts? (e.g., a joint decision-making process, a pooled fund, multistakeholders involvement)
- What level of cooperation among states (the 4 'C's) should the platform be designed to promote? (e.g., communication – information sharing, collaboration – joint funding)

### Question Set 2: Demonstration Projects

The resolution requests WHO to “facilitate the implementation of a few health R&D demonstration projects to address identified gaps which disproportionately affect developing countries, particularly the poor and for which immediate action can be taken”. Given there is broad consensus for initiating demonstration projects:

- Should the demonstration projects focus on providing some 'quick wins' or incorporate more comprehensive functions?
- What criteria for selection of these projects should be used?
- Which implementation mechanisms should be thought through when deciding on and implementing demonstration projects? (e.g., advisory mechanism, decision-making mechanism, financing mechanism)
- How can the key functions and level of cooperation discussed in the questions above be mapped to the stylized options for phase 1 (demonstration projects) described above, if at all? (e.g., Option A1 - Coordination Mechanism for Priority Disease R&D, Option B1 – Joint Programming on Priority Disease R&D, Option C1 – Joint Funding for Priority Disease R&D)

### Question Set 3: Role of WHO

Some have suggested that it would be preferable to rely on existing institutions if possible, especially WHO, given its normative mandate, governance structure, and role as an arena for

intergovernmental negotiations on health issues.<sup>29</sup>

- What should the role of WHO be in the establishment and operations of a global platform for health R&D?
- What should the responsibilities of the WHO Secretariat be?
- What is the role, if any, of WHO governing bodies, i.e. EB and WHA?
- What other existing institutions/organizations/groups may be utilized?

### Question Set 4: Learning from the Past

In the current stage of discussions, some have expressed support for relying on existing structures in a time when the multitude of actors in the global health architecture and other limitations are of concern. However, there are also challenges related to utilizing existing structures, including incompatible scope or missions. Currently there is no single organization that is well suited to carrying out the functions discussed above. A technical expert meeting<sup>27</sup> recommended two general approaches: either the mandates and resources of existing entities would need to be amended to take on these new functions, or a new organization(s) would need to be created. As we review existing institutions to assess their suitability to perform the required functions of health R&D:

- What are the potential success stories/models that are most relevant? (e.g., UNITAID's innovative financing mechanism, GEF's replenishment model, CGIAR's different funding windows)
- What should the role of existing organizations other than WHO be? (e.g., TDR, UNITAID, COHRED, Global Fund, research funders (NIH, Wellcome, Gates), etc.)
- Should we rely on existing structures to build the R&D platform? If so, which ones, and how?
  - Unified model: use one organization (new or existing)
  - Network model: use several organizations working together under an overarching governance arrangement

### Question Set 5: Learning from the Present

Evaluation is an important part of planning, as it would provide an understanding of what worked and what did not. During and after the implementation of the platform, it is important to assess the effectiveness of the system through an evaluation. The outcomes would contribute to organizational learning on effectiveness and provide evidence for future decision-making.

- How can we identify and measure the impact of establishing the platform?
- What are some potential measures of success of a global R&D platform?

29 Röttingen, J.A., Moon, S., Tangcharoensathien, V., Hoffman, S. (2012) Multi-stakeholder Technical Meeting on Implementation Options Recommended by the WHO Consultative Expert Working Group on Research & Development (CEWG): Financing and Coordination at the Rockefeller Foundation Bellagio Center, 16-19 October 2012. <http://globalhealth.harvard.edu/sites/globalhealth.harvard.edu/files/Meeting%20Report%20FINAL.pdf> (see Appendix III for more detail on the meeting outcome related to the role of existing structures)

The goal of the workshop was to explore ideas for securing collective action towards a credible platform for monitoring, coordinating, and financing R&D for the health needs of low- and middle-income countries. This background paper explored potential approaches for identifying and implementing demonstration projects and sustained solutions, and described the various possible implementation mechanisms and different levels of cooperation. We also presented examples of the governance and financing structures of existing international organizations and offered suggestions for how a new health R&D platform could build on these experiences. With the passage of Resolution WHA 66.22 and decision point WHA 66(12), the concepts proposed in this paper and the topics discussed in the workshop could be valuable in taking concrete steps towards building a stronger global R&D system, including but not limited to the technical consultative meeting envisioned for late 2013.

A summary report of the workshop is available at:

[http://graduateinstitute.ch/webdav/site/globalhealth/shared/1894/Events/Events%202013/PolicyBrief\\_Health%20R%26D%20as%20a%20Global%20Public%20Good\\_2013.pdf](http://graduateinstitute.ch/webdav/site/globalhealth/shared/1894/Events/Events%202013/PolicyBrief_Health%20R%26D%20as%20a%20Global%20Public%20Good_2013.pdf)

## Appendices

# Appendix I. Background Information on Institutions for International Cooperation

### GAVI Alliance

Main Source: GAVI Website, Bezanson & Isenman (2012), E2Pi (2012)

#### Background

GAVI was launched in 2000 to fund the procurement and delivery of vaccines for the world's poor. The mission of the organization is "to save children's lives and protect people's health by increasing access to immunization in poor countries." GAVI raises funds for immunization and forwards resources directly to developing country governments, relying on country-based systems and partners to deliver its program.<sup>30</sup>

#### Operational Mechanisms

- Decision-making body: GAVI Board
  - GAVI's initial governance body included four separate boards, with one to ensure multi-stakeholder inclusiveness (advisory & decision-making mechanism), another to monitor fiduciary accountability (commitment mechanism), a third to maintain budgetary control and a fourth to enhance financial management integration (financial mechanisms). In 2008 an independent review concluded that roles and responsibilities at various levels of the organization was inadequately defined.<sup>31</sup> GAVI's governance design caused confusion the roles of each board, and that the complexity of the arrangement not only caused significant inefficiencies in both time and money but also blurred accountability lines.<sup>32</sup> GAVI later switched to a single governing body and established a hybrid model for the board, which includes two-thirds constituency-determined board members and one-third independent members. A 2010 evaluation of the organization concluded that the new board structure brought about significant improvements, but that its size of 28 board members and its dominant constituency character made decision-making processes "more bureaucratic and inefficient."<sup>30</sup> Issues around potential conflicts of interest were also raised, as some constituency members were also recipients of GAVI funding.<sup>29,30</sup>
- Advisory: GAVI's Independent Review Committee (IRC) reviews proposals and annual progress reports based on technical criteria and provide funding recommendations to the

30 WHO. (2012). [http://www.who.int/phi/2-funding\\_mechanism\\_factsheets\\_6nov12.pdf](http://www.who.int/phi/2-funding_mechanism_factsheets_6nov12.pdf)

31 GAVI. (2008). GAVI First Evaluation Report. <http://www.gavialliance.org/results/evaluations/gavi-first-evaluation-report/>

32 Bezanson, K., Isenman, P. (2012) Governance of New Global Partnerships: Challenges, Weaknesses, and Lessons. Center for Global Development.



Board. The technical experts in the committee conduct peer review and assessments of funding applications for the different types of GAVI activities and progress reports submitted by countries.<sup>33</sup>

## Fiscal Mechanisms

- GAVI's two financing streams, innovative finance and direct contributions account for 37% and 63% respectively of the Alliance's overall funding portfolio.<sup>34</sup>
  - Direct contributions include grants and agreements from donor governments, and personal and private sector philanthropy facilitated by the GAVI Campaign.
  - Innovative financing mechanism includes the Matching Fund program, International Finance Facility for Immunisation (IFFIm) and the Advance Market Commitment (AMC). The Matching Fund program is supported by UK's Department for International Development (DFID) and by the Bill & Melinda Gates Foundation. The private sector partner makes a financial pledge to GAVI, which then works with the organization to explore ways to engage its customers, employees, business partners and others to contribute through the Matching Fund. Between now and 2015, every donation to GAVI through the Matching Fund is matched either by DFID or by the Gates Foundation. As of January 2013 the total amount raised was US \$78 million.<sup>35</sup> IFFIm relies on long-term pledges from donor governments to sell "vaccine bonds" in their financial markets, thus making funds available for GAVI.<sup>36</sup> AMC for vaccines was designed as a "pull mechanism" to encourage the development and production of affordable vaccines for the poor. In the pilot AMC for pneumococcal vaccine, donors committed funds to guarantee the price of vaccines once they are developed. These strong financial commitments provided vaccine producers with the incentive to invest in R&D and sign a legally binding commitment to provide the vaccine at an affordable price for a defined period.<sup>37</sup>

## Accountability Mechanisms<sup>38</sup>

- The Office of Internal Audit is an independent and objective entity designed to improve the operations of GAVI. Its scope includes auditing not only the Secretariat but also the programs and activities of GAVI's grant recipients and partners. It also oversees GAVI's Transparency and Accountability Team, which conducts reviews of cash programs and investigates any cases of possible misuse of GAVI funds.

33 E2Pi. <http://globalhealthsciences.ucsf.edu/sites/default/files/content/ghg/e2pi-gavi-profile.pdf>

34 <http://www.gavialliance.org/funding/how-gavi-is-funded/>

35 <http://www.gavialliance.org/library/news/press-releases/2013/gavi-alliance-significantly-expands-private-sector-involvement-in-saving-lives/>

36 <http://www.iffim.org/about/overview/>

37 <http://www.gavialliance.org/funding/pneumococcal-amc/how-the-pneumococcal-amc-works/>

38 <http://www.gavialliance.org/about/governance/internal-audit/>

## The Global Fund to fight HIV/AIDS, Tuberculosis and Malaria

Main Source: GFATM Website, Bezanson & Isenman (2012), E2Pi (2012)

### Background

The Global Fund is an international financing institution and a global public-private partnership dedicated to attracting and disbursing resources to prevent and treat HIV and AIDS, TB and malaria. The Global Fund promotes partnerships among governments, civil society, the private sector and affected communities.

### Operational Mechanisms

- Decision-making body: the Global Fund Board
  - Within the Board, representatives of the corporate sector, private foundations, non-governmental organizations and communities affected by the three diseases hold equal decision-making power with government representatives.<sup>39</sup>
  - The Board provides direction and oversees the development and implementation of a multiyear strategy. It builds on a series of regional consultations held with a broad range of stakeholders, including representatives from implementing countries, partner organizations and experts from the Technical Review Panel (TRP).
  - One independent evaluation reported that the unique set up of the GFATM governance structure had been an important factor in the organization's success in resource mobilization, but its "partnership and constituency-based membership had not added significant value in terms of agreed roles and responsibilities, divisions of labor or durable agreements."<sup>40</sup> As a result, the fund underwent significant organizational and structural modifications, including the replacement of its Chief Executive.<sup>38</sup>
- Advisory and decision-making process: Country Coordinating Mechanisms (CCMs), composed of representatives from governments, donor agencies, NGOs, academia, patient groups, and the private sector, are responsible for designing and submitting proposals. After an initial screening by the Secretariat for timeliness, completeness, and eligibility, the TRP reviews proposals based on defined criteria (such as soundness, feasibility, value for money, and potential for sustainability and impact) and makes a recommendation to the Board.

### Fiscal Mechanisms

- Financing
  - Between 2002 and 2011, the vast majority of pledges (about 95%) came from rich

39 [http://www.theglobalfund.org/documents/core/guides/Core\\_GovernanceHandbookSection10overview\\_Handbook\\_en/](http://www.theglobalfund.org/documents/core/guides/Core_GovernanceHandbookSection10overview_Handbook_en/)

40 Bezanson, K., Isenman, P. (2012) Governance of New Global Partnerships: Challenges, Weaknesses, and Lessons. Center for Global Development.

governments, with the top ten donors accounting for almost 85% of all contributions and the top 20 donors comprising over 98% of all contributions.<sup>41</sup>

- The main financing source comes from its Voluntary Replenishment Mechanism, which is an instrument to raise funds from public and private donors. It involves a donor forum where donors discuss the operations and effectiveness of the organization, consider its funding needs, and make financial pledges for the next three years. Before the replenishment mechanism was introduced in 2004, all contributions were made on an ad-hoc basis, which currently still exist but serve as a complement to the replenishment model.<sup>42</sup>
- Funding:
  - In the new funding model two types of funding mechanisms are available:<sup>43</sup>
    - Indicative funding is derived from an allocation formula for each country and adjusted based on pre-defined qualitative criteria. It represents predictable funding to support countries' priority interventions and activities.
    - Incentive funding is a separate reserve of funding that rewards well-performing programs with a potential for increased, quantifiable impact, and encourages ambitious requests. It is made available, on a competitive basis, to applicants whose requests are based on robust national strategic plans or a full expression of prioritized demand for strategic interventions.
  - The Grants Approvals Committee determines final funding amounts, and whether or not a country will be awarded additional incentive funding.

## Accountability Mechanisms<sup>40</sup>

- All approved proposals, grant agreements and progress reports are required to be made available on the Global Fund website, as well as Board documents and decisions.
- Office of the Inspector General (OIG): The OIG is an independent unit reporting directly to the Board. It is responsible for providing objective assurance over all operations and programs, and puts special emphasis on fighting fraud, corruption, and abuse of funds. It also has the capability to independently carry out audits and investigations within countries.

41 E2Pi. <http://globalhealthsciences.ucsf.edu/sites/default/files/content/ghg/e2pi-global-fund-profile.pdf>

42 E2Pi. <http://globalhealthsciences.ucsf.edu/sites/default/files/content/ghg/e2pi-global-fund-profile.pdf>

43 <http://www.theglobalfund.org/en/accesstofunding/faqs/#112>

## UNITAID

Main Source: UNITAID Website, UNITAID 5-Year Summary (2012), Silverman (2012)

### Background

UNITAID performs innovative financing mechanisms to increase funding for greater access to treatments and diagnostics for HIV/AIDS, malaria and tuberculosis in low-income countries. According to UNITAID, it is the first global health organization to use “buy-side market leverage” to make life-saving health technologies more effective and accessible.<sup>44</sup>

### Operational Mechanisms

- Decision-making: UNITAID is governed by a 12-member Executive Board that is responsive to the Consultative Forum, composed of a broader group of contributors, beneficiaries, and partners, which provides feedback and advice back to the Executive Board.
- Advisory and decision-making processes:<sup>45</sup>
  - The Secretariat first uses “landscape analysis” of three focus diseases to develop a list of potential funding opportunities, and creates a short list of strategic priorities based on Strategy criteria, funding availability, and the organizational portfolio principles.
  - An Advisory Group on Funding Priorities (AGFP) assists the Board in identifying potential high-impact investment areas, which then is adopted as the focus of Request for Proposals (RFPs). AGFP recommends and the Board selects and approves strategic priorities or calls for proposals. The Secretariat then issues a call for proposals each year based on this decision.
  - Once proposals are submitted to UNITAID, Proposal Review Committee (PRC), composed of external experts, is charged with evaluating funding requests against organizational strategic objectives, and making overall recommendations for Board consideration.
  - The PRC’s recommendation, along with resource availability will feed into the Executive Board’s final decision on whether or not to fund a project.
  - Note that at its most recent meeting in June 2013, the Board decided to disband the AGFP and restructure the PRC.
- UNITAID also accepts unsolicited letters of intent twice yearly, which is intended to “maintain UNITAID’s ability to fund innovative proposals, and flexibility.”
- 2011 DFID Multilateral Aid Review criticized the funding process, noting that “UNITAID does not yet have a credible framework for choosing between and prioritizing which proposals are funded and which are not. A ‘first come, first served’ approach once resources are available and without prioritization has potential for significant opportunity costs and is a real weakness.”<sup>46</sup>

44 <http://www.unitaid.eu/en/who/about-unitaid>

45 Silverman, R. (2012) UNITAID – Background paper prepared for the Working Group on Value for Money: An Agenda for Global Health Funding Agencies. Center for Global Development.

46 *ibid*

## Fiscal Mechanisms

### → Financing

- Funded primarily by a levy on airline tickets (approximately two-thirds of all donor funding between 2006 and 2011), UNITAID's revenue seemed closely tied with performance of the airline industry. Although this reliance on airline tax was initially aimed to provide a steady and consistent funding source, some have suggested that since air travel is a luxury good, it is highly vulnerable to economic fluctuations. According to a report by the Center for Global Development, UNITAID's revenues fell 21% between 2008 and 2009, while overall development assistance for health globally rose 3% during the same period.<sup>47,48</sup> The most recent UNITAID 5-year evaluation report describes this heavy reliance on airline tax as "a double-edged sword", since there is a risk that this tax will not continue to provide secure and sustained financing. It suggests UNITAID to consolidate its other donor funding and explore more financing beyond the airline tax.<sup>49</sup>
- France contributed 62% of UNITAID's cumulative revenue between 2006 and 2011, followed by the UK at 16%. The high-income country donors and the Gates Foundation were responsible for more than 95% of UNITAID's funding. LMICs, including founding members Brazil and Chile, have contributed less than 5% of the organization's total funding.<sup>50</sup>
- UNITAID has investigated other innovative fundraising mechanisms, such as the Millennium Foundation that launched a pilot of MASSIVEGOOD, a web platform to enable voluntary micro-donations through travel booking services. However, the program was discontinued in November 2011 due to "no sufficient enough returns for such a micro philanthropy initiative in today's economic climate."<sup>51</sup>

### → Funding

- UNITAID works through a number of programmatic partners, which are primarily multilaterals and large foundations (40+% to CHAI)<sup>52</sup>, though the list has expanded recently entities such as NGOs, Product Development Partnerships (PDPs), private firms, and foundations.
- UNITAID is able to make long-term purchasing commitments and therefore able to drive price reductions through bulk purchasing, mainly due to the fact that its funding is "considered to be predictable and immune from annual political fluctuations."<sup>53</sup>

47 Silverman, R. (2012) UNITAID – Background paper prepared for the Working Group on Value for Money: An Agenda for Global Health Funding Agencies. Center for Global Development.

48 UNITAID, however, states that the funding has remained stable in the past five years, and strongly suggesting that innovative financial mechanisms can "weather an economic storm" (UNITAID Annual Report 2011)

49 ITAD. (2012). UNITAID 5 Year Summary. <http://www.unitaid.eu/images/Five-year-evaluation/5YE%20Exec%20Summary-UNITAID%202012-12-03%2016h00.pdf>

50 Silverman, R. (2012) UNITAID – Background paper prepared for the Working Group on Value for Money: An Agenda for Global Health Funding Agencies. Center for Global Development.

## Accountability Mechanisms

Its transparency policy states that UNITAID “is to operate in a transparent and accountable manner, and will make the fullest disclosure of records possible.”<sup>51</sup> Its decisions and activities are made public via its website.

The Secretariat monitors partners on outputs and evaluates impact through periodic reviews and evaluations, which are planned in collaboration with partners, taking into account the specific disease area, project timeline, and partner restrictions.

Its constitution mandates that all projects be subject to an independent performance evaluation.

## Consultative Group on International Agricultural Research (CGIAR)

Source: All information excerpted from the CGIAR official website

### Background

CGIAR is a global partnership that connects research organizations working on agricultural development. Its organizational goals are to reduce rural poverty, increase food security, improve human health and nutrition, and ensure more sustainable management of natural resources. It is carried out by 15 Centers that are members of the CGIAR Consortium, in close collaboration with hundreds of partner organizations, such as national and regional research institutes, civil society organizations, academia, and the private sector. The Research Centers generate and disseminate knowledge, technologies, and policies through the CGIAR Research Programs, while the CGIAR Fund provides reliable and predictable multi-year funding to “enable research planning over the long term, resource allocation based on agreed priorities, and the timely and predictable disbursement of funds.”<sup>52</sup>

### Operational Mechanisms

→ Advisory and decision-making of the Consortium:<sup>53</sup> The Consortium Board leads the CGIAR Consortium, sets policies, and is responsible for the attainment of the CGIAR Consortium’s purpose. It sets the science strategy across the group and ensures CGIAR Research Programs cohere and interact. The Board also decides on the priorities for funding and how funds should be allocated across the Centers and Research Programs. Where appropriate the Board takes guidance from the Independent Science and Partnership Council (ISPC), which is a panel of leading scientific experts in the field.

51 [http://www.unitaid.eu/images/governance/transparency\\_policy.pdf](http://www.unitaid.eu/images/governance/transparency_policy.pdf)

52 CGIAR website: [www.cgiar.org](http://www.cgiar.org)

53 <http://www.cgiar.org/cgiar-consortium/>

- Advisory and decision-making of the Fund:<sup>54</sup> The Fund Council includes 22 members, composed of donor countries, multilateral and global organizations, and representatives from the South. For Window 1, the Council's takes decisions on resource allocation on behalf of all Fund donors.. For Window 2, the Council plays an equalizing role, advising donors to channel part of their resources to underfunded programs in the event that one or more Research Programs is overfunded (see below for details on the "Windows"). It is also responsible for appointing the ISPC.
- The Funders Forum, a biennial gathering of all donors, sets the CGIAR's strategic direction.

### **Fiscal Mechanisms<sup>55</sup>**

- Financing and funding: Fund donors may designate their contribution to one or more of three funding "Windows":
  - Window 1 - the least restricted type of funding. The Fund Council sets overall priorities and makes specific decisions about the use of Window 1 Funds such as allocation to CRPs, payment of System Costs and any other use required to achieve the CGIAR mission;
  - Window 2 –designated by Fund Donors to one or more specific CRPs. For each approved CRP, a sub-account is created to which donors may allocate funds. Once Window 2 funds are allocated to a given CRP, they flow to the Lead Center implementing the CRP;
  - Window 3 –the most restricted type of funding, consisting of funds that Fund Donors wish to allocate to specific Centers. Neither the Consortium nor the Fund Council makes decisions about the use of Window 3 funds. Within 2 years after the CGIAR Fund's establishment, the Fund Council will review the use of Window 3 in consultation with the Consortium Board.
- The CGIAR encourages Fund Donors to provide predictable funding to the Centers through the CGIAR Fund, rather than directly in the form of bilateral grants.
- To receive funding, CGIAR Research Programs are required to set their expected achievements and provide verifiable targets against which progress can be measured and monitored. By linking funding to results, the Fund aims to give donors better value for money and ensure that research translates into tangible benefits for its beneficiaries.

### **Accountability Mechanisms<sup>56</sup>**

CGIAR Policy for Independent External Evaluation addresses the independent external evaluation of the CGIAR and of its ongoing and completed policies, programs, and institutional entities. The CGIAR Independent Evaluation Arrangement (IEA) conducts the evaluations.

54 <http://www.cgiar.org/who-we-are/cgiar-fund/>

55 *ibid*

56 <http://www.cgiar.org/who-we-are/independent-evaluation-arrangement/>

## Global Environment Fund (GEF)

Source: All information excerpted from the GEF official website and GEF 2013 Replenishment Report

### Background

The Global Environment Facility was founded by the World Bank, the United Nations Development Program (UNDP), and the United Nations Environment Program (UNEP) in 1991 as an independent financial mechanism “to unite countries in partnership with international institutions, civil society organizations, and the private sector to address global environmental issues while supporting national sustainable development initiatives.”<sup>57</sup> It also serves as financial mechanism for the following conventions: Convention on Biological Diversity (CBD), United Nations Framework Convention on Climate Change (UNFCCC), UN Convention to Combat Desertification (UNCCD), Stockholm Convention on Persistent Organic Pollutants (POPs), and Montreal Protocol on Substances that Deplete the Ozone Layer (MP).<sup>58</sup>

### Operational Mechanisms

- Decision-making body: The GEF Council is the main governing body of the GEF. It functions as an independent board of directors, with primary responsibility for developing, adopting, and evaluating GEF programs. Council members representing 32 constituencies (16 from developing countries, 14 from developed countries, and two from countries with transitional economies) meet twice each year for three days and also conduct business by mail. All decisions are by consensus.
- Advisory: The Scientific and Technical Advisory Panel (STAP) provides strategic scientific and technical advice to the GEF on its strategy and programs. The Panel consists of six members who are internationally recognized experts in the Fund’s key areas of work, and are supported by a network of additional experts.
- When the GEF was first established, member countries chose to tap into the strengths of three founding organizations (the World Bank, UNDP, and UNEP) to implement its projects, rather than construct a new organization. The three organizations were appointed as GEF Agencies to create project proposals and supervise or implement approved projects. In 1999, an additional seven executing agencies were added: the Asian Development Bank, the African Development Bank, the European Bank for Reconstruction and Development, the Food and Agriculture Organization, the Inter-American Development Bank, the International Fund for Agricultural Development, and the United National Industrial Development Organization. The GEF provides an administration fee to GEF agencies, equal

57 GEF website: [www.thegef.org](http://www.thegef.org)

58 Although not linked formally to the Montreal Protocol, GEF supports implementation of the Protocol in countries with economies in transition.



to about 10 percent of GEF financing, to cover the costs of project preparation and supervision. GEF agencies are expected to leverage their respective comparative advantages in GEF projects. For example, the comparative advantage of UNEP is listed as “catalyzing the development of scientific and technical analysis and advancing environmental management in GEF-financed activities,” that of UNDP as “developing and managing capacity building programs and technical assistance projects”, and that of the World Bank as “developing and managing investment projects.” In integrated projects that include elements of expertise that are lacking in one GEF agency, that agency is expected to partner with another agency so that all aspects of the project will be managed well.<sup>59</sup>

## Fiscal Mechanisms

- The GEF is a partnership designed to provide primarily grant resources, thus the GEF Trust Fund requires periodic replenishment. The World Bank as Trustee for the GEF is responsible for mobilizing replenishment resources by convening meetings of participants to agree on the size and strategy for each four-year replenishment period.
- During the negotiating sessions, participants agree on a set of policy reforms to be undertaken, a document to guide the programming of resources, and a level of resources that the GEF will aim to provide to recipient countries during the replenishment period. The negotiation sessions also provide an opportunity for donors to review organizational performance and progress, and decide on future programming and strategic directions.. The size of a given replenishment depends on a number of factors, such as the estimated overall funding requirements for approved future programming, donors’ priorities, and their ability to fund the replenishment. A unique design of GEF’s replenishment model is that donor pledges are then formalized by the deposit of an Instrument of Commitment (IoC), which constitutes a legally binding obligation on the part of the donor to pay the specified amount. Due to national constraints some donors are not able to offer legally binding IoCs for the entire replenishment period, therefore they may deposit a Qualified IoC with the Trustee, agreeing to pay a part of their contribution without qualification while the rest remains subject to enactment by national legislative approval. The donor is then expected to obtain approval for the full amount of its contribution by the same payment dates applicable to unqualified IoCs.<sup>60</sup>
- *GEF Burden-sharing Framework (excerpt from GEF Replenishment document 2013):* “Burden sharing” refers to the sense of “fairness” in sharing the financial responsibility of a multi-lateral effort. The goal of burden sharing in the GEF is to ensure adequate funding for the intended objectives. Principles guiding a burden-sharing framework are transparency,

59 [http://www.thegef.org/gef/gef\\_agencies](http://www.thegef.org/gef/gef_agencies)

60 GEF Replenishment: Overview of Financial Structure 2013. <http://www.thegef.org/gef/sites/thegef.org/files/documents/GEF-6%20Replenishment%20Financial%20Structure.pdf>

equity, and ability to pay. Burden-sharing frameworks can vary over time and across institutions, as donors reach funding agreements on the basis of a variety of factors. At the outset, donors usually begin from share levels in the previous replenishment, which reflect past budgetary decisions and replenishment considerations. This reference point is what has come to be known as “basic shares”. Traditionally, these basic shares have not been a matter of negotiation in the GEF. Changing donor budgetary circumstances and priorities, however, may be reflected in “actual donor shares”, which are the basic shares enhanced by additional and supplementary contributions. When the Fund was first established, its donors agreed to use the shares from the IDA10 Replenishment Resolution as the basis for establishing initial basic shares for the GEF replenishment. The initial basic shares did not add up to 100%. This was intentional, to leave space for new or supplemental contributions by recipients, participating non-recipient donors and not-yet-participating non-recipient donors. These basic shares continued to be used as the reference point for the last four replenishment negotiations.

- *Minimum contribution (excerpt from GEF Replenishment document 2013)*: While there is no minimum amount established to contribute to the GEF, the practice since the second round of replenishment has been that a donor would be expected to contribute at least SDR<sup>61</sup> 4 million to participate in the replenishment discussions. Five countries provided the minimum contribution of SDR 4 million to the most recent replenishment (GEF-5): Luxembourg, New Zealand, Nigeria, Pakistan and Portugal.
- *Donor Instrument of Commitment (excerpt from GEF Replenishment document 2013)*: Donor pledges are formalized by the deposit of an Instrument of Commitment (IoC) with the Trustee, which constitutes a legally binding obligation on the part of the donor to pay the total amount specified. Some donors are not able to provide legally binding IoCs for the entire replenishment period; they may deposit a Qualified IoC with the Trustee, agreeing to pay a part of their contribution without qualification while the remainder is still subject to enactment by their legislature of the necessary appropriation legislation. A donor depositing a Qualified IoC undertakes to exercise its best efforts to obtain legislative approval for the full amount of its contribution by the same payment dates applicable to unqualified IoCs, as set out in a replenishment resolution.
- *Funding (excerpt from GEF website)*: GEF funding shall be made available for activities within the focal areas in accordance with the following eligibility criteria:<sup>62</sup>
  - GEF grants that are made available within the framework of the financial mechanisms of the conventions shall be in conformity with the eligibility criteria decided by the Conference of the Parties of each convention
  - All other GEF grants shall be made available to eligible recipient countries and, where

61 The SDR or Special Drawing Right is a currency basket consisting of fixed proportions of the EUR, JPY, GBP, and the USD.

62 [http://www.thegef.org/gef/country\\_eligibility](http://www.thegef.org/gef/country_eligibility)

appropriate, for other activities promoting the purposes of the GEF and any additional eligibility criteria determined by the Council. A country shall be an eligible recipient of GEF grants if it is eligible to borrow from the World Bank (IBRD and/or IDA) or if it is an eligible recipient of UNDP technical assistance. GEF grants for activities within a focal area addressed by a convention but outside the framework of the financial mechanism of the convention, shall only be made available to eligible recipient countries that are party to the convention concerned.

- GEF concessional financing in a form other than grants that is made available within the framework of the financial mechanism of the conventions shall be in conformity with eligibility criteria decided by the Conference of the Parties of each convention. GEF concessional financing in a form other than grants may also be made available outside those frameworks on terms to be determined by the Council.

## Accountability Mechanisms

- The Evaluation Office<sup>63</sup> (excerpt from GEF website)
  - The office was established under the GEF with the role of ensuring the independent evaluation function within the GEF. It sets minimum requirements for monitoring and evaluation, ensures oversight of the quality of M&E systems at program and project levels, and shares evaluative evidence within the GEF. The Office is also responsible for undertaking independent evaluations that involve a set of projects from more than one Implementing or Executing Agency.
  - It supports knowledge sharing and follow-up of evaluation recommendations. It works with the GEF Secretariat and the GEF Agencies to establish systems to disseminate lessons learned and best practices emanating from M&E activities and provides independent evaluative evidence to the GEF knowledge base.
  - It promotes accountability for the achievement of GEF objectives through the assessment of results, effectiveness, processes, and performance of the partners involved in GEF activities. GEF results will be monitored and evaluated for their contribution to global environmental benefits.

63 [http://www.thegef.org/gef/evaluation\\_office](http://www.thegef.org/gef/evaluation_office)

# Appendix II. Implementation Mechanisms

**Table 4: Implementation Mechanisms – Options**

		Levels of Cooperation	
		Coordination	Collaboration
Normative		Coordinated efforts (e.g. a platform for discussing and coordinating priorities)	Hammonized or joint efforts (e.g. joint programming with common decisions but separate funding)
		<ul style="list-style-type: none"> <li>→ None</li> <li>→ Ad hoc</li> </ul>	<ul style="list-style-type: none"> <li>→ None / ad hoc</li> <li>→ Well-defined mission, vision, goals, principles, norms etc</li> <li>→ Promote knowledge sharing, network building</li> <li>→ Facilitate collaboration between research entities</li> <li>→ Encourage adherence to quality standards</li> </ul>
Advisory	Who	<ul style="list-style-type: none"> <li>→ Between funders and/or recipients</li> <li>→ Between governments and civil society/public</li> </ul>	<ul style="list-style-type: none"> <li>→ Well-defined mission, vision, goals, principles, norms etc</li> <li>→ Efforts to engage multistakeholders</li> <li>→ Promote knowledge sharing, network building</li> <li>→ Facilitate collaboration between research entities</li> <li>→ Encourage adherence to quality standards</li> </ul>
		<ul style="list-style-type: none"> <li>→ Ad hoc</li> <li>→ Bilateral agreement</li> </ul>	<ul style="list-style-type: none"> <li>→ Advisory group (delegation)</li> <li>→ Technical experts</li> <li>→ Representative from each stakeholder</li> <li>→ All stakeholders: member states and/or non-state actors</li> </ul>
Decision Making	Who	<ul style="list-style-type: none"> <li>→ Ad hoc</li> <li>→ Bilateral agreement</li> </ul>	<ul style="list-style-type: none"> <li>→ Ad hoc</li> <li>→ Joint group agreement</li> </ul>
		<ul style="list-style-type: none"> <li>→ Between funders and/or recipients</li> </ul>	<ul style="list-style-type: none"> <li>→ Predetermined priority-setting criteria</li> <li>→ Consultation processes</li> <li>→ Board members (delegation)</li> <li>→ Member state representatives and/or non-state actor representatives</li> <li>→ All stakeholders: member states and/or non-state actors</li> </ul>
Administration	How	<ul style="list-style-type: none"> <li>→ Mutual agreement</li> </ul>	<ul style="list-style-type: none"> <li>→ Joint group agreement</li> </ul>
		<ul style="list-style-type: none"> <li>→ Self-organizing</li> </ul>	<ul style="list-style-type: none"> <li>→ Delegated</li> <li>→ Unanimous or consensus model</li> <li>→ Majority or supermajority voting</li> <li>→ Modified voting system (e.g. based on financial contribution)</li> <li>→ International organizations (new or existing)</li> <li>→ Sub-agencies under existing organizations</li> <li>→ Joint ventures</li> <li>→ Coordinated self management (no institutional processes or activities)</li> </ul>

Operational Mechanisms

Levels of Cooperation		Collaboration	
	Coordination		
	Coordinated efforts (e.g. a platform for discussing and coordinating priorities)	Harmonized or joint efforts (e.g. joint programming with common decisions but separate funding)	Collective efforts (e.g. pooled funding mechanism)
Dispute	<ul style="list-style-type: none"> <li>→ None</li> <li>→ Ad hoc</li> </ul>	<ul style="list-style-type: none"> <li>→ Ad hoc</li> <li>→ Mandatory dispute resolution process</li> </ul>	<ul style="list-style-type: none"> <li>→ Ad hoc</li> <li>→ Mandatory dispute resolution process</li> </ul>
Learning	<ul style="list-style-type: none"> <li>→ None</li> <li>→ Ad hoc</li> </ul>	<ul style="list-style-type: none"> <li>→ Ad hoc</li> <li>→ Separate learning processes</li> </ul>	<ul style="list-style-type: none"> <li>→ Systematic review and reporting of feedbacks</li> <li>→ Continuous improvement of processes and policies</li> </ul>
Financial	<ul style="list-style-type: none"> <li>→ Separate financial mechanisms</li> </ul>	<ul style="list-style-type: none"> <li>→ Separate financial mechanisms</li> </ul>	<ul style="list-style-type: none"> <li>→ Pooled fund                             <ul style="list-style-type: none"> <li>→ All Member States agree on a new pooled financing mechanism</li> <li>→ A smaller group of countries could create a mechanism in which other countries may later opt to participate</li> </ul> </li> </ul>
Financing	<ul style="list-style-type: none"> <li>→ Separate financing mechanisms</li> </ul>	<ul style="list-style-type: none"> <li>→ Separate financing mechanisms</li> </ul>	<ul style="list-style-type: none"> <li>→ Voluntary discretionary contributions</li> <li>→ Voluntary multi-year contribution</li> <li>→ Voluntary contribution based on a soft norm</li> <li>→ Voluntary pledges based on achievement of a collective goal (e.g. financing level, matched funding by others, number of countries contributing)</li> <li>→ Mandated assessed minimum contributions and additional voluntary contribution</li> <li>→ Mandated assessed contributions</li> </ul>
Funding	<ul style="list-style-type: none"> <li>→ Separate funding mechanisms</li> </ul>	<ul style="list-style-type: none"> <li>→ Separate funding mechanisms</li> </ul>	<ul style="list-style-type: none"> <li>→ Investment / venture capital model (owner/partner)</li> <li>→ Infrastructure (investment in processes, eg. patent pool)</li> <li>→ Pull mechanisms (eg. incentives, prizes, market or procurement commitments)</li> <li>→ Push mechanisms (eg. grants)</li> </ul>
Auditing	<ul style="list-style-type: none"> <li>→ Separate auditing processes and requirements</li> </ul>	<ul style="list-style-type: none"> <li>→ Separate auditing processes and requirements</li> </ul>	<ul style="list-style-type: none"> <li>→ Consolidated processes &amp; standards for auditing</li> <li>→ Systematic review &amp; reporting of financial health</li> </ul>

Levels of Cooperation		
	Coordination	Collaboration
	Coordinated efforts (e.g. a platform for discussing and coordinating priorities)	Harmonized or joint efforts (e.g. joint programming with common decisions but separate funding)
Commitment	<ul style="list-style-type: none"> <li>→ None</li> <li>→ Declarations</li> <li>→ Contracts</li> </ul>	<ul style="list-style-type: none"> <li>→ Joint declarations</li> <li>→ Contracts</li> </ul>
Compliance	<ul style="list-style-type: none"> <li>→ None</li> <li>→ Political pressure</li> </ul>	<ul style="list-style-type: none"> <li>→ None</li> <li>→ Political pressure</li> <li>→ Economic sanctions</li> </ul>
Transparency	<ul style="list-style-type: none"> <li>→ Ad hoc</li> <li>→ Voluntary information sharing</li> </ul>	<ul style="list-style-type: none"> <li>→ Voluntary information sharing</li> <li>→ Mandated information sharing</li> </ul>
Oversight	<ul style="list-style-type: none"> <li>→ Ad hoc</li> <li>→ Self-report</li> <li>→ Civil society</li> </ul>	<ul style="list-style-type: none"> <li>→ Self-report</li> <li>→ Peer review</li> <li>→ Expert review</li> <li>→ Civil society</li> </ul>
Appeal	<ul style="list-style-type: none"> <li>→ None</li> </ul>	<ul style="list-style-type: none"> <li>→ Ad hoc</li> <li>→ Appeals / revision mechanism for non-members</li> </ul>
		Collective efforts (e.g. pooled funding mechanism)
		<ul style="list-style-type: none"> <li>→ Declarations</li> <li>→ Institutional reforms</li> <li>→ Contracts</li> <li>→ Conventions</li> <li>→ Political pressure</li> <li>→ Economic sanctions</li> <li>→ Institutional consequences</li> <li>→ Legal processes</li> <li>→ Mandated information sharing</li> <li>→ Coordinated reporting process</li> <li>→ Publicity</li> <li>→ Self-report</li> <li>→ Peer review</li> <li>→ Expert review</li> <li>→ Civil society</li> <li>→ Ad hoc</li> <li>→ Appeals / revision mechanism for non-members</li> </ul>

Accountability Mechanisms

## Appendix III. Excerpt of the Bellagio Meeting Report <sup>64</sup>

Multi-stakeholder Technical Meeting on Implementation Options Recommended by the WHO Consultative Expert Working Group on Research & Development (CEWG): Financing and Coordination at the Rockefeller Foundation Bellagio Center, 16-19 October 2012

### Section G. FORMS: INSTITUTIONAL/ORGANIZATIONAL OPTIONS

Form should follow function. After identifying and describing the functions which will be necessary in a new framework for global health R&D, the next question is how they should be structured in an institutional arrangement. The new global functions will need to be carried out by an organization. In general there are many arguments in favor of relying on existing structures in a time when the multitude of actors in the global health architecture, the complexity of relationships between them, and budget constraints are of concern. However, there are also challenges related to utilizing existing structures. These include incompatible scopes or missions. Changing the roles or mandates of existing organizations may also pose institutional political challenges, which can be more complicated than establishing a new framework.

Some participants argued that it would be preferable to rely on existing structures if possible, and some highlighted the role that WHO could and should play, given its mandate, governance structure and role as an arena for intergovernmental negotiations. (Notably, new funding would be required if WHO were tasked with this role.) Others argued for identifying different alternatives. However, it was clear that there is no single organization that, with its current mandate and form, is today perfectly suited to carrying out the three functions described above. Therefore, either the mandates (and related resources) of existing organizations would need to be amended or transformed to take on these new functions, or a new organization(s) would need to be created.

Two general approaches to form emerged from the discussions:

- Unified model: use one organization
- Network model: use several organizations working together under an overarching governance arrangement

If the unified model is chosen there are again two options: either to use an existing organization or to establish a new one. We have listed the options identified at the meeting in the table below:

64 Röttingen, J.A., Moon, S., Tangcharoensathien, V., Hoffman, S. (2012) Multi-stakeholder Technical Meeting on Implementation Options Recommended by the WHO Consultative Expert Working Group on Research & Development (CEWG): Financing and Coordination at the Rockefeller Foundation Bellagio Center, 16-19 October 2012. <http://globalhealth.harvard.edu/sites/globalhealth.harvard.edu/files/Meeting%20Report%20FINAL.pdf>

	Model	Existing	New
<b>Within WHO</b>	Secretariat function with ear-marked trust fund	WHO Secretariat	WHO secretariat, but with specific governance arrangements
	Conference of parties (convention model)	n.a.	Secretariat
	Special program (TDR-like model)	TDR	New co-sponsored special program
	Sub-agency (IARC-like model)	n.a.	New sub-agency
	Partnership (UNITAID-like model)	UNITAID	New partnership
<b>Outside WHO</b>	A global fund (GFATM-like model)	n.a.	New global health R&D fund
	Intergovernmental organization (IGO)	World Bank trust fund (CGIAR-like model)	New intergovernmental organization (CERN or EMBL-like model)
	Non-governmental organization (NGO)	COHRED	New non-governmental organization (GFHR-like model)

Which option to choose depends on several factors and criteria, guided not only by evidence, but also by the political will of Member States in negotiations. Is it important to link it to WHO? The clear tendency in the meeting was that it was seen as preferable to narrow down to options within WHO given that they could satisfy other requirements. There were concerns regarding challenges to establishing a new organization outside of WHO. There was also a strong emphasis on the role of governments in both ownership and governance, therefore making an NGO-model less likely. The most viable option outside of WHO would therefore perhaps be a World Bank trust fund-model.

The question of whether to use existing structures within WHO depends on whether such structures could modify their mandates and accommodate several new functions. This will partly depend on whether the organization could be reformed or (more likely) transformed by its governing body. This is relevant for both TDR and UNITAID, which would both need to expand their scope by focusing on a much broader range of diseases and, for UNITAID, an earlier part of the product development value chain. In particular, a new financing mechanism (whether in an existing organization or established separately) may require specific governance arrangements that give sufficient influence to those who contribute funds.



A narrower list of options for a financing mechanism may therefore be warranted:

- WHO secretariat, but with specific governance arrangements
- TDR or new co-sponsored special program
- UNITAID (or analogous partnership)
- World Bank trust fund
- New WHO sub-agency (like IARC or the UNESCO Institute for Statistics)
- Secretariat of a COP (Conference of Parties to a convention)

However, as mentioned, another alternative is a networked model where different organizations take the responsibility for different functions. There are many options with such an approach, including:

- Monitoring/Global Observatory
  - WHO
  - TDR
  - WHO collaborating center (at academic institution)
  - COHRED
- Coordination and priority setting
  - WHO
  - TDR
- Financing/pooled funding mechanism
  - WHO secretariat, but with specific governance arrangements
  - TDR
  - UNITAID
  - World Bank trust fund
  - GFATM (or analogous new organization)

For coordination and priority setting we have limited options to those within WHO given the importance of securing links to Member States for normative functions such as identifying needs and priorities. In addition, we note that there are currently ongoing assessments of the role of partnerships within WHO. Unlike special programs like TDR which are seen as intrinsically part of WHO's programmatic framework, partnerships are seen as less closely-linked to WHO's overall governance. A special program model with specific governance arrangements may be the most suitable approach in the current environment.

The challenge of a networked model is to make it work as one system. This will likely require joint governance mechanisms to make sure that the functions are linked and that there are not too many transaction costs arising from coordination among them.

