
Report by the Secretariat

INTRODUCTION

1. In resolution WHA65.22 the Health Assembly requested the Director-General to hold an open-ended meeting of Member States¹ that will thoroughly analyse the report and the feasibility of the recommendations proposed by the Consultative Expert Working Group on Research and Development: Financing and Coordination (CEWG), taking into account, as appropriate, related studies as well as the results from national consultations and regional committee discussions. This background paper provides Member States with options relating to the areas covered in the resolution, namely the monitoring of research and development (R&D) expenditures; research coordination and financing of R&D for Type II and III diseases; and specific R&D needs of developing countries in relation to Type I diseases.
2. In order to address the various aspects of the resolution this paper is divided into three parts.
3. Part 1 is a brief assessment of past and current efforts at monitoring R&D resource flows and the potential for tangible advancement in this area. It also explores how a global observatory for health R&D could be planned in a gradual manner.
4. Part 2 describes different levels of organization required to coordinate R&D as a spectrum of efforts from simply sharing information more systematically through to the management of joint activities with differing degrees of commitment, complexity and governance. It then sets out options for consideration in discussions on moving towards greater and better coordination.
5. Part 3 describes a number of possible mechanisms for financing health R&D and the different instruments that might be considered in order to establish such a mechanism, illustrated with existing examples.

¹ And, where applicable, regional economic integration organizations.

PART 1

MONITORING R&D FLOWS

Background

As highlighted in the CEWG report,¹ the picture of how much the world is spending on health R&D for medical technologies is incomplete. This is mainly due to an absence of capacity at national level for collecting and reporting such data.² Although there are many disease-focused surveys on R&D and a few initiatives that collect information on health R&D resource flows at a global or regional level, obtaining accurate estimates is hampered by the absence of national data and the lack of good practice and standards for reporting investments on R&D.^{3,4,5}

This means that current efforts to track and map global health research investments are incomplete, resource-intensive, unsustainable and reliant on mathematical extrapolations to fill in blank data. It is therefore difficult to compare findings across surveys and across years.

The resulting challenge needs to be addressed in order to align, or even begin to coordinate, at a global level, health R&D investments with public health priorities. For example, one area to improve is the classification of research data, as suggested by the European Science Foundation, to an internationally agreed standard.⁶ There are many opportunities for innovation in this area; the Internet offers the potential to create more efficient ways to share and collate information that were not available to previous initiatives.⁷

It should also be noted that even an accurate record of financial flows provides only one piece of the information needed to provide a comprehensive picture of the R&D landscape. New sources of information are now available online including research publications, clinical trial registries and patent data. These related sources of information are dispersed and need to be brought together, as envisioned under the global strategy and plan of action on public health, innovation and intellectual property. These varied sources have both strengths and weaknesses. For example, although research papers are an excellent source of detail on the nature of the investigations undertaken, on existing collaborations and on a country's science base, there is no standard for reporting a research paper, the paper can be published many years after the research has been completed, and the research that is published is mainly the research that is publically funded and biased towards positive results.

¹ Documents A65/24; Annex and A65/24 Corr.1.

² Global Forum for Health Research: Monitoring financial flows for health research series. 2001–2009.

³ http://g-finder.policycures.org/gfinder_report/.

⁴ <http://www.healthresearchweb.org/>.

⁵ <http://lattes.cnpq.br/>.

⁶ Health Research Classification Systems – Current Approaches and Future Recommendations European Science Foundation Science Policy Briefing 43 <http://www.esf.org/publications.html>.

⁷ Terry RF et al. Mapping global health research investments, time for new thinking – A Babel Fish for research data. Health Research Policy and Systems September 2012, 10:28 doi:10.1186/1478-4505-10-28.

Clinical trial registration has created a new online resource. Since 2000, the number of registered clinical trials has increased dramatically. There are currently over 200 000 records available through the WHO International Clinical Trial Registration Platform (ICTRP).¹ Trials are reported in a standard way, and their registration ensures that research from both the public and private sector is recorded, even if the final trial outcome remains unpublished. A limitation is that trials only cover one aspect of health technology development.

While some resources exist already (for example WIPO Gold for patent data²) others still need to be created in order to establish a more comprehensive picture of R&D. For example, sources of data covering the product pipeline, human resources in health R&D and overviews of the research institutes within a country, the available research networks in disease areas or a complete picture of active public–private partnerships.

OPTIONS

Three options are presented, in view of the above considerations. These options represent linked stages along a continuum towards better monitoring of R&D financial flows, not distinct and separate options. In order to achieve improvements in monitoring, Member States will need support in building their capacity to manage and report on their own R&D data.

Option 1: Improve the reporting and sharing of ad hoc surveys

The monitoring of health R&D will continue through existing surveys, most of which are ad hoc projects undertaken by academic groups, nongovernmental organizations and international bodies, including WHO technical programmes. These are usually focused on a specific disease or set of diseases (for example the work undertaken by the G-Finder survey) and serve their own communities. There is no inventory of all these efforts. A voluntary online repository could be established in which the results of individual surveys are made available and facilitate sharing or analysis. In addition reporting could be standardized – for example there are standards to report a clinical trial – and a resource similar to the WHO International Clinical Trial Registry Platform (ICTRP) could be developed to bring these reports together in one place.

In addition to an inventory adaptations could be sought in the regional and global R&D surveys that are regularly undertaken, for example by OECD or UNESCO. Although these provide a good model for undertaking R&D monitoring, they do not provide specific data on health research related to the required disease types that are the focus of the CEWG report. These surveys would need to be developed considerably if they are to serve an expanded purpose.

An online repository is a relatively easy option to create. A single repository, if well populated and managed, may encourage the development of good practices for reporting. However, without standards, comparability between surveys would remain difficult to achieve. Moreover, surveys are labour intensive and require considerable financial resources. For example the G-Finder survey, one of the most comprehensive surveys on R&D in neglected diseases, is supported by private funds (the Bill & Melinda Gates Foundation).

¹ <http://www.who.int/ictrp/en/>.

² <http://www.wipo.int/wipogold/en/>.

Previous global health R&D surveys have been undertaken by the Global Forum for Health Research and funded by the World Bank. However, the Global Forum has struggled to secure sustainable support for this work. It has now been merged with the Council on Health Research for Development, but there are no known current plans to undertake a new global survey, nor are there any resources available to sustain such work in the short or longer term.

Option 2: Develop standards and seek a harmonized approach in monitoring

Work needs to be undertaken to define more precisely the scope of R&D monitoring efforts, identify which diseases should be covered, and decide how financial flows should be reported.

During consultations at the regional committees, several Member States requested definition of the scope of monitoring efforts and of which diseases to focus on.¹ The CEWG report refers to the typology of diseases, as introduced by the Commission on Macroeconomics and Health, and as elaborated in the report of the Commission on Intellectual Property Rights, Innovation and Public Health (Type I, II and III diseases). These disease type definitions have not previously been mapped systematically against actual diseases. In order to inform discussion on the monitoring of resource flows for R&D and the mapping of the current situation, the Secretariat has developed a working list of which diseases might be grouped under the three types. This uses the Disability Adjusted Life Years (DALYs) from the Global Burden of Disease Report (2004). Further explanations and details are available on the PHI web site.²

Work is needed to develop standards in the classification of R&D as recommended by the European Science Foundation building on the work of the UK Clinical Research Collaboration. This could utilize disease classifications (ICD) and combine them with a description of the purpose of the research, for example as described in the WHO strategy on research for health.³

A parallel approach would be to investigate how computer translation technology could be used to analyse the text or data within locally reported or existing resources and automatically translate that to an international standard. This is one of the innovative approaches that could be investigated, thus providing a new method for work in this area.

Standards would improve the quality and comparability of surveys. Developing them requires significant organization to ensure they are appropriate in scope and fit for purpose. An automated approach warrants investigation as a pilot as this could allow the local recording of data with global reporting via translation. A pilot could be undertaken within the surveys that exist now and this approach is being considered by the G-Finder survey. However adoption will require a credible process and WHO may be an appropriate body to convene such work.

¹ Reports from the 2012 regional committee meetings, including related resolutions adopted by regional committees, are provided separately, see document A/CEWG/2, and document A/CEWG/2 Add.1.

² <http://www.who.int/phi/CEWG>.

³ <http://www.who.int/phi/implementation/research/en/index.html>.

Option 3: Develop a global Observatory on health R&D

The most structured approach in this area, and one recommended by the CEWG report, would be to create a global resource, a global R&D Observatory (working title), that could provide the focus for monitoring financial flows for health R&D and integrate these with the other information sources referred to above. A global resource, built on regional hubs, could also work on the generation of standards and provide technical support to improve research governance at the national level. The Observatory effectively brings options 1 and 2 together.

The functions of such an Observatory could include:

- monitoring and reporting on financial flows in support of global health R&D related to Types II and III diseases and the special R&D needs of Type I;
- integration of information on R&D financial flows with the product pipeline and other resources that support innovation and access to medical technologies;
- provision of information, reports and analysis to inform policy-makers, donors and researchers with a special focus on developing countries and global health;
- creation of a space in which to convene stakeholders virtually and in regional and global meetings;
- collection, dissemination and development of good practice, norms and standards; and
- support at the national level to build capacity in the monitoring, stewardship, governance and management of R&D and innovation for improved access.

The information and data available on the R&D Observatory would enable all users to:

- analyse data on financing for global health R&D;
- produce analysis to inform national R&D portfolios management;
- guide R&D priority-setting at different levels;
- benchmark activities with other users; and
- monitor and evaluate trends against national, regional and global strategies.

Finally, as appropriate, the Observatory could generate the analysis to support a mechanism of coordination. This could take the form of regular global reports, for example recommending research priorities, an action that was endorsed in the WHO strategy on research for health by the Sixty-third World Health Assembly.¹

¹ See document WHA63/2010/REC/1, resolution WHA63.21 and Annex 7.

The technical challenges to the establishment of such an Observatory are significant and, to add value, a global platform of this type requires a long-term commitment and sustainable sources of support. Answering the sustainability question is a key to success.

The development of a global Observatory could be approached in a phased way with three steps:

- (1) A research phase to understand user (e.g. governments, researchers, research funders, civil society, the private sector) needs, identify the incentives to support the initiative and analyse how existing initiatives might be integrated or scaled up to meet user requirements. The global Observatory needs to build on the principle of harvesting data wherever possible rather than being the primary collector or generator of data through surveys.
- (2) A planning phase to develop an approach from existing structures or the design of an appropriate institutional mechanism and sustainable systems of support.
- (3) A pilot testing phase to create the necessary technology and design of the platform.

The regional committees raised the following points with regard to monitoring and any potential health R&D Observatory:

- Any new global Observatory should be housed within existing structures (i.e. no new institutional structure to be established).
- The governance needs to be regionally representative.
- The global Observatory could build on national and regional observatories.
- Wherever possible data should be harvested rather than created from new.
- The global Observatory needs to have a credible mandate to develop new standards to facilitate collection of data.
- Technical assistance will be needed to support Member States in better managing their national health R&D portfolio.

In Europe, Orphanet, funded jointly by the European Commission, INSERM (the French National Institute of Health and Medical Research) and the French Directorate General for Health, provides a recent example of how a portal might add value to research, diagnosis, product development and treatment in a defined disease area. Orphanet is the reference portal for information on rare diseases and orphan drugs, for all audiences.¹

Any efforts to improve global monitoring and reporting would benefit from improved capacity at Member State level to manage their national health R&D portfolio. Whereas technical support is available at the level of a research institute or academic unit to undertake research, there are far fewer resources to support the establishment of national research governance capacity. Some work is being undertaken by the Council on Health Research for Development with the Health Research Web to

¹ http://www.orpha.net/consor/cgi-bin/Education_AboutOrphanet.php?lng=EN.

create a platform to allow the reporting of data.¹ The identification of a package of support for Member States would create some of the necessary incentives for Member States to engage in the reporting of data to a global survey if, at the national level, there is a perceived benefit in doing so.

A global R&D Observatory needs to be credible, representative and mandated to develop appropriate standards. This suggests a role within the established mechanisms of WHO, given its partnerships with respected governance arrangements and multi-donor support. Based on the work of G-Finder and the existing observatories in WHO on health statistics an annual operating budget of approximately \$2.5 million would be needed.

¹ <http://www.healthresearchweb.org/>.

PART 2

COORDINATING HEALTH RESEARCH AND DEVELOPMENT

Background

Coordination in health R&D at a global level has been a long stated and often repeated objective as evidenced by the history of initiatives in this area, many of which were reviewed in the CEWG report. The report suggests that the availability of a pooled source of funding is a facilitating factor in coordination as it provides an incentive for the various stakeholders of R&D to align their programmes and so maximize access to a finite envelope of resources. However, there are a number of steps towards improved coordination that can be achieved by better sharing of information, active coordination through research networks, or managed coordination through joint planning and prioritized allocation of resources. The Secretariat has identified those steps towards improved coordination, described below.

Sharing of information: Sharing of information is the first step towards coordination. Systematic sharing of information between R&D actors can for example take advantage of the Internet at marginal cost. This information can be organized on web sites, in publications, research registries and databases, preferably according to pre-defined criteria.

Joint priority-setting: Numerous global prioritization exercises are conducted for specific diseases or specific product categories (e.g. for the development of a malaria vaccine), many of them under the auspices of WHO. Prioritization exercises for R&D on all or some types of diseases have also been conducted at national, subregional and regional levels and many examples were cited by the regional committees. There is no accepted gold standard for setting priorities but a review of the approaches undertaken can describe common themes of good practice.¹

Joint planning and action: This is the most formal managed expression of coordination. Joint planning and action is already a reality in several specific disease areas but no such mechanism exists for R&D across a broader spectrum of disease.²

These levels of coordination activity occur widely throughout various disease-focused groups and research networks, however they are weak and largely absent at the global level. At a national level there are numerous R&D and health R&D strategies. Certain country blocs, for example the European Union, have invested considerable resources in the creation of regional health R&D strategies and mechanisms to fund them such as the Framework Programme and the European Research Council.

Regional committees raised the following points with regard to coordination:

- Any advisory mechanism put together to facilitate prioritization and coordination should be regionally representative and include key stakeholders from national and donor communities.

¹ Viergever et al. A checklist for health research priority setting: nine common themes of good practice. Health Research Policy and Systems 2010 8:36.

² See for example the Malaria Vaccine Technology Roadmap produced by the Malaria Vaccine R&D Funders' informal group (2006).

- Prioritization should be based on the best available evidence drawing on global and regional R&D observatories.
- Existing structure should be built on and utilized.
- Coordination should take place under the auspices of WHO, with potential involvement of other United Nations agencies.

OPTIONS

Options to improve coordination are set out below. They correspond to the three levels of coordination described above: improving information, agreeing priorities and establishing joint planning mechanisms. As in Part 1, the three options represent gradual improvements along a continuum rather than separate approaches to coordination.

Option 1: Coordination through open and timely information sharing

Greater coordination could occur as a natural progression resulting from improvements in monitoring as discussed in Part 1. Objective and accurate information on R&D investments and gaps provided through an online resource, such as the inventory of surveys, could in time influence R&D actors and funders to concentrate efforts where they are most needed. Member States would also be in a better position to articulate their national health R&D priorities. This would be particularly beneficial for those Member States where a large proportion of research is funded by external sources.

The best improvement in sharing of information would require an active approach that would need resources and a clear programme of work. An Observatory would provide the most structured approach to the collation and dissemination of this type of data.

The baseline source of data remains within Member States and so capacity in the governance of health R&D will need to be supported at national level to ensure quality data are generated to enable sharing.

Option 2: Coordination through an agreement of priorities

The agreement of priorities and road maps is well established in specific disease areas and includes many that have been endorsed in resolutions by the World Health Assembly. What is largely absent is regular and focused attention to health R&D issues globally. If the monitoring of R&D resources can be improved, it would provide the resource for many stakeholders to undertake national, regional and global analyses to monitor the commitments and strategies of Member States and donors to meet the priorities identified. A global advisory body that is representative and well respected could also use such a resource to provide a regular opinion on global health R&D and evidence-based recommendations for action.

Such a global advisory body could in principle be hosted by a number of institutions. The CEWG report emphasizes the potential value of a reconstituted Advisory Committee on Health Research (ACHR) as an advisory mechanism at a global level. Certainly ACHR has demonstrated in the past an

ability to identify priority areas and to instigate programmes to meet those priorities.¹ It was instrumental in the creation of global research programmes, including the Special Programme of Research, Development and Research Training in Human Reproduction (HRP) and the Special Programme for Research and Training in Tropical Diseases (TDR). Over time these programmes have each developed their own advisory boards and scientific advisory panels. The technical programmes of WHO have around 20 R&D advisory committees in the different research and disease areas. A reconstituted ACHR could draw its membership from these existing committees, which are representative of regions, scientific disciplines and gender, and could ensure appropriate input from civil society and the private sector.

The proposed global advisory body could also be informed, as discussed in the CEWG report, by a network (or forum) of national research funding institutions, for example research councils. The running cost of such an advisory mechanism, based on an ACHR model that had resources to commission studies, would be close to US\$ 2 million per year. Any impact would, however, require a readiness to take into account the recommendations of the global advisory mechanism by state and non-actors in the area of R&D into neglected diseases.

Option 3: Managed coordination through joint planning and action

Joint planning and targeted initiation of research activities is a higher level of research coordination building on the previous levels. It requires information sharing and the existence of a respected decision mechanism that identifies research priorities and gaps. In addition, in order for joint planning and action to have substance, those decisions need to be made in relation to the allocation of resources. Within a specific disease or health condition a number of models exist and are referred to in Part 3 and in the Annex.

Should Member States decide to put in place a funding mechanism that would ensure availability of resources to finance R&D for Type II and Type III diseases and the specific R&D needs of developing countries in relation to Type I disease, one route for deciding on allocation would be through existing programmes that already have appropriate governance mechanisms in place.

TDR, for example, could be tasked to play a role as a manager of a joint workplan as it already has a mandate for neglected diseases. Indeed, TDR was created to facilitate research and capacity-building in the area of Type III (and to a lesser extent Type II) diseases. It also benefits from an established governance structure that incorporates partners from the World Bank, UNICEF and UNDP and has representatives from both the developed and developing world on its scientific and advisory committees, as well as from civil society (see Annex).

¹ The ACHR is the oldest WHO committee, established in 1956 to advise the Director-General on global health research issues. See: World Health Organization. *A history of the Advisory Committee on Health Research 1959–1999*. http://whqlibdoc.who.int/publications/2010/9789241564113_eng.pdf.

PART 3

FINANCING MECHANISMS

Background

At the conclusion of the discussion on the global strategy and plan of action on public health, innovation and intellectual property by the Health Assembly, the issues on financing remained unresolved. The Expert Working Group (EWG) and the CEWG were established in order to address element 7 of the strategy which aims to “... *secure adequate and sustainable financing for research and development, and improve coordination of its use, where feasible and appropriate, in order to address the health needs of developing countries*”.¹

The CEWG recommended that all countries should commit to spend at least 0.01% of GDP on government-funded R&D devoted to meeting the health needs of developing countries. These additional funds were to be used to fund all phases of R&D in the public and private sector as well as public–private partnerships to address identified health needs of developing countries using in particular open approaches to R&D and prize funds.

To meet this target the CEWG recommended an increase of national financing of health R&D, and the pooling of a portion of these contributions by governments into an international financing instrument that could also be open to additional voluntary public, private and philanthropic contributions. In order to ensure a sustainable and appropriate level of funding, the CEWG recommended that Member States enter into binding commitments through an international treaty, i.e. a system of assessed or otherwise obligatory contributions.

During the regional committee meetings, a number of Member States raised the possibility of establishing a voluntary funding mechanism, but no clear picture emerged from these discussions. This section of the background paper presents a number of options on how the increase of funding of R&D related to Type II and Type III diseases and the specific R&D needs of developing countries in relation to Type I diseases could be approached.

Pooling funds at an international level

In order to meet the 0.01% target recommended by the CEWG, Member States would have to increase their overall investment in health R&D that is directed to the health needs of developing countries. This could be realized through an increase of national spending, in line with resolution WHA65.22, in which the Health Assembly calls upon Member States, the private sector, academic institutions and nongovernmental organizations to increase investments in health research and development related to Type II and Type III diseases and the specific research and development needs of developing countries in relation to Type I diseases.

Better monitoring of current health R&D and resource allocation as well as improved coordination of R&D through the implementation of some of the options described in Part 1 and 2 of this paper could contribute to a more efficient and targeted resource allocation at national level.

¹ See resolutions WHA61.21 and WHA63.28.

A number of different options are available for pooling a certain part of the funds at a global level through an international mechanism. Indeed, the set up and functioning of financing instruments and mechanisms differ significantly in different areas (see examples in the Annex).

The Global Fund to Fight AIDS, Tuberculosis and Malaria and the GAVI Alliance are standalone foundations not linked to any organization or international convention. Initially, however, both were hosted by international organizations that provided administrative services. This is still the case for UNITAID. Some international research programmes, such as the Special Programme of Research, Development and Research Training in Human Reproduction (HRP), the UNICEF/UNDP/World Bank/WHO Special Programme for Research and Training in Tropical Diseases (TDR) and the International Agency for Research on Cancer (IARC), are embedded within existing international organizations. Others are linked to a convention under which they perform a specific function such as the Multilateral Fund for the implementation of the Montreal Protocol on Substances that Deplete the Ozone Layer (Multilateral Fund).

There are also major differences in the way the different vehicles raise funds. Most of the existing mechanisms provide for voluntary contributions, with different scales of commitment:

- Totally voluntary: TDR, HRP, the International Vaccine Institute (IVI) as well as Product Development Partnerships (PDPs).
- Voluntary based on replenishment model (not enforceable pledges; donors fix themselves the amount of pledges) and/or innovative financing mechanisms: the GAVI Alliance, the Global Fund, UNITAID.
- Assessed contributions based on United Nations scale of assessments or other assessments: the Multilateral Fund, IARC.
- Obligatory assessed contributions based on average national income: European Molecular Biology Laboratory (EMBL).

Truly voluntary models can therefore be found both in mechanisms set up by soft law instruments (like resolutions), such as HRP or TDR, as well as mechanisms that were set up by an international binding instrument (hard law), such as IVI. The establishment by a convention thus does not mean necessarily that financing commitments are obligatory. On the other hand, a mechanism such as IARC that was set up by a resolution provides for assessed contributions that are fixed based on the average net national income of Participating States. Mechanisms set up by soft law instruments can have relatively strong financial obligations.

The choice of the instrument also depends on the actors involved. An international convention can only be negotiated by governments which, by signing and ratifying become Parties to the convention. Membership is thus limited to state actors and governing bodies consist of representatives of the Parties. Soft law instruments in comparison allow the inclusion of non-state actors, including in governing bodies, and more nuanced decision-making processes. They often represent a coalition of particularly ambitious and engaged actors that want to move forward, a good example being UNITAID.

Overall, four models of international financing instruments can be distinguished (Table 1).

Table 1: Models of international financing instruments

Financial commitment	Soft law (e.g. a resolution)	Hard law (e.g. a convention)
Voluntary, including through innovative financing mechanisms	Model 1: e.g. GAVI Alliance; Global Fund to Fight AIDS, Tuberculosis and Malaria; UNICEF/UNDP/World Bank/WHO Special Programme for Research and Training in Tropical Diseases; UNITAID, International AIDS Vaccine Initiative	Model 2: e.g. Consultative Group on International Agricultural Research; International Vaccine Institute
Mandatory: assessed contributions by Members	Model 3: e.g. International Agency for Research on Cancer	Model 4: e.g. Multilateral Fund; European Molecular Biology Laboratory

OPTIONS

Should Member States decide to set up one or more international funding vehicles, these can be either based on newly-established instruments (option 1) or within existing instruments (option 2). Some pros and cons for these two options are discussed below.

(1) Establishing a new financing mechanism

One option to pool funds on an international level could be achieved through the establishment of an international financing mechanism as recommended by the CEWG. Based on the examples further described in the Annex, four different models can be distinguished (see Table 1 above). The pros and cons of such solution are discussed in the CEWG report. The regional committees mentioned the possibility of regional instruments, and examples for such regional approaches already exist, such as the EMBL. In principle, the options for establishing a regional mechanism are the same as for a global mechanism. Regional approaches may be particularly appropriate to approach health challenges or diseases that are specific to a certain region. The time required and the transaction costs incurred for any global or regional mechanism would depend on what type of mechanism was chosen.

(2) Using an existing vehicle

Instead of creating a new mechanism, Member States could also decide to use an existing mechanism to pool funding at an international level. Subject to the agreement of the governing bodies in principle, any existing organization could be tasked with the mission to manage pooled funds and create an international mechanism to finance health R&D dedicated to the specific health needs of developing countries. For example, WHO Member States could create a new budget line within TDR's Trust Fund, decide to expand the mandate of IARC or try to expand the mandate of other existing mechanisms to include additional disease areas, for example the GAVI Alliance, the Global Fund, and UNITAID, or of one of the existing product development partnerships. The obvious advantage of using an existing organization or programme would be the limited transaction costs and the fact that less time would be lost than in the creation of a new instrument.

Whatever form is chosen, a number of factors are critical for the success of any new financing mechanism, including:

- political commitment for the establishment of the mechanisms and its mission, or for the adaptation of an existing mechanism;
- governance should be inclusive and represent the interests of policy-makers, researchers and developers, funders and beneficiaries of research;
- a broad, stable and predictable financial basis and a financial structure that minimizes procedural obstacles for contributors;
- a clearly defined, focused and realistic objective of the mechanism and a clear implementation model; and
- an effective system of monitoring of disbursement of funding and evaluation of success.¹

Final comments:

In conclusion, although this paper presents options towards better monitoring and coordination of R&D, those options represent different positions on a scale of improvements rather than discrete approaches. The first level of information-sharing is a prerequisite before moving to prioritization or joint planning. The extent of information-sharing directly affects the utility of the outcomes from the prioritization/joint planning. Moreover, a respected advisory mechanism can facilitate credible global R&D coordination through evidence-informed recommendations. These would guide, but not instruct, individual funders to match priorities according to their remit, noting that each actor/agency is expected to have different roles and focuses, and that R&D coordination can empower the different roles. Finally, the establishment of a financial instrument would require mechanisms to identify R&D priorities through improved monitoring. Investments prioritized in a transparent and evidence-informed way would support effective coordination. A balanced consolidation of the three elements – monitoring, financing and coordination – would form the basis of a new global framework for R&D on Type II and Type III diseases and on the specific R&D needs of developing countries in relation to Type I diseases.

¹ See: WHO, Conference of the Parties to the WHO FCTC, Review of existing and potential sources and mechanisms of assistance, A/FCTC/COP/1/4, 9 January 2006.

ANNEX

**EXAMPLES OF EXISTING MECHANISM FOR FINANCING
GLOBAL INTERVENTIONS OR FUNDING RESEARCH**

This annex describes examples of different existing financing and research mechanisms. The examples provided are not limited to mechanisms financing R&D, but include mechanisms financing the procurement of medical products, as well as mechanisms that were set up not only to disburse money for research, but also to conduct or coordinate research.

FINANCING VEHICLES**The GAVI Alliance**

The GAVI Alliance was established by a meeting of the provisional (Proto-) Board in 1999¹ as an alliance of public and private sector organizations, institutions and governments, including the Bill & Melinda Gates Foundation, UNICEF, the World Bank, WHO, vaccine manufacturers, nongovernmental organizations and research and technical health institutes, in order to increase access to immunization in poor countries. The Secretariat of GAVI was first housed by UNICEF in Geneva under the name Global Alliance for Vaccines and Immunization. In 2008, GAVI and the Vaccine Fund (GAVI's financial vehicle) were reorganized under the GAVI Alliance brand, and registered as a foundation under Swiss law. The GAVI Alliance generated 37% of its funding in 2000–2010 from innovative financing mechanisms, which include the International Finance Facility for Immunization and an Advance Market Commitment for pneumococcal vaccine.² The GAVI Alliance also receives direct voluntary contributions from a variety of donors. Following its first pledging conference, GAVI reported pledges of US\$ 4.3 billion bringing available resources for the period 2011–2015 to a total of US\$ 7.6 billion.³

The Global Fund to Fight AIDS, Tuberculosis and Malaria

Established in 2002 through a Framework Document,⁴ the Global Fund is a multi-stakeholder international financing institution. Its mission is to attract, manage and disburse funds to finance technically sound and cost-effective interventions for the prevention, treatment, care and support of people infected with HIV/AIDS, tuberculosis and malaria in countries in need. The Global Fund today is totally independent from any international organization. Initially however, the Global Fund was operating under an Administrative Service Agreement with WHO. In 2009, the Fund separated from WHO and was registered as a foundation under the laws of Switzerland.⁵ The Global Fund is financed

¹ Decision GAVI/99.01.

² <http://www.gavialliance.org/about/gavis-business-model/securing-predictable-financing/>.

³ GAVI Alliance Press Release, Donors commit vaccine funding to achieve historic milestone in global health, 13 June 2011, <http://www.gavialliance.org/library/gavi-documents/funding/june-2011-pledging-conference--key-outcomes-for-2011-2015/>.

⁴ The Global Fund for AIDS, Tuberculosis and Malaria, The Framework Document, 2001, <http://www.theglobalfund.org/en/library/documents/>.

⁵ The Global Fund for AIDS, Tuberculosis and Malaria, By-laws, 2011, <http://www.theglobalfund.org/en/library/documents/>.

through contributions from governments, private sector, social enterprises, philanthropic foundations and individuals, with funding from donor governments representing the largest source of income. As at January 2011 pledges from the public sector amounted to US\$ 28.3 billion (95 % of all pledges since its inception in 2002) and pledges from the private sector and from innovative financing initiatives constituted the remaining 5% (or US\$ 1.6 billion). 97.5% of all public sector contributions in 2009 came from 19 OECD Development Assistance Committee members.¹ Contributions are mobilized through a periodic replenishment model in three-year intervals, complemented by additional ad hoc contributions. Each donor arranges its contribution independently, but is usually making a pledge over a certain period in time. Pledges are public, legally non-binding statements on planned contributions² and not all pledges necessarily materialize into contributions. The Global Fund replenishment model is thus totally voluntary, but commitments are made over a three-year time period which allows financial planning over this period.

The Multilateral Fund for the implementation of the Montreal Protocol on Substances that Deplete the Ozone Layer

In the area of the environment, the Multilateral Fund for the implementation of the Montreal Protocol on Substances that Deplete the Ozone Layer (Multilateral Fund) was the first financial mechanism to emerge from an international treaty in 1991 dedicated to reversing the deterioration of the Earth's ozone layer. It is financed by contributions from industrialized countries on the basis of the United Nations scale of assessments which define the scale of contributions of United Nations Member States in percentages of the budget due by each Member. The Parties to the Montreal Protocol decide upon the programme budget of the Multilateral Fund for each fiscal period and upon the percentage of contributions of the individual Parties thereto (Article 10 of the Montreal Protocol). Accordingly the Fund is replenished on a three-year basis by the donors. The total budget for the 2012–2014 triennium is US\$ 450 million.³

UNITAID

UNITAID is an international drug purchasing facility using innovative financing mechanisms. It was created through a Memorandum of Understanding (MoU) signed by the governments of Brazil, Chile, France, Norway, and the United Kingdom of Great Britain and Northern Ireland in 2006. UNITAID has its own governing bodies and a distinct financial structure. It is hosted by WHO, which provides administrative support and facilities. Between 2007 and 2012, UNITAID has raised approximately 65% of its funding through solidarity contributions on airline tickets collected in nine UNITAID member countries. Additional funds come from voluntary regular budget contributions from members, partly in the form of multi-year funding pledges with one country allocating part of its tax on carbon dioxide emissions to UNITAID every year. Since its establishment in 2006 to the end of 2011, UNITAID had mobilized contributions from 17 donors of US\$ 1.6 billion.⁴

¹ <http://www.theglobalfund.org/en/about/donors/public/> (last visited 21.08.2012).

² The Global Fund, Governance Handbook: Financial Resources, page 5.

³ <http://www.multilateralfund.org/default.aspx>.

⁴ UNITAID Annual Report 2011, http://www.unitaid.eu/images/Annual_Report_2011/UNITAID_AR2011_EN.pdf.

INTERNATIONAL RESEARCH ORGANIZATIONS AND THEIR FINANCING

European Molecular Biology Laboratory

The European Molecular Biology Laboratory (EMBL) was set up in 1973 by an international treaty¹ and has a distinct legal personality. It conducts fundamental research as a result of cooperation among European countries. The EMBL operates through five laboratories in Europe where it performs basic molecular biology research. The EMBL had a budget of € 171 million in 2011 with 55% stemming from Member States. Under the treaty establishing the EMBL, each Member State contributes annually to the capital expenditure and to the operating costs of the Laboratory. The amount of contributions is fixed in accordance with a scale that is calculated every three years based on the average net national income of each Member State (Article X of the Agreement). Member States who are in arrears in the payment of contributions can lose their right to vote (Article VI(6)(a) of the Agreement).

International Agency for Research on Cancer

The International Agency for Research on Cancer (IARC) was created in 1965 as a specialized institution within WHO based on Article 18(1) of the WHO Constitution by World Health Assembly resolution WHA18.44. The objective of IARC is to promote international collaboration in cancer research. Any Member State of WHO can notify its intention to take part in IARC and to become a Participating State. IARC receives regular contributions from its Participating States who, by joining IARC, accept the obligation to contribute annually. Annual contributions are determined by the Governing Council of IARC based on the approved budget (assessed contributions), allowing coverage of all administrative services and permanent activities of the Agency.² Special IARC projects are financed from additional grants or special contributions that are truly voluntary. The regular budget for the 2010–2011 biennium was € 37.91 million. Voluntary contributions amounted to € 14.95 million.³

International Vaccine Institute

The International Vaccine Institute (IVI) is an international institution, with a legal identity, which is researching and providing training and technical assistance in the area of vaccines based on the needs of developing countries. IVI was set up by an international treaty⁴ that currently has 16 Parties from different regions. Funds are generated through voluntary contributions from Parties, non-Parties and other donors who are free to determine their level of contributions.

¹ Agreement establishing the European Molecular Biology Laboratory, http://www.embl.de/aboutus/general_information/organisation/hostsite_agreement/index.html.

² IARC, Statute, Rules and Regulations, 13th edition, 2011, <http://governance.iarc.fr/ENG/Docs/StatuteEnglish.pdf>.

³ GC/54/9, 16/04/2012, Biennial Financial Report, http://governance.iarc.fr/GC/GC54/En/Docs/GC54_9.pdf.

⁴ Agreement on the Establishment of the International Vaccine Institute: http://www.ivi.int/html/themes/www/download/Establishment_Agreement.pdf.

MIXED MODELS: CONDUCTING RESEARCH AND ADMINISTERING A FUND

CGIAR – Consultative Group on International Agricultural Research

The Consultative Group on International Agricultural Research (CGIAR) consists of the CGIAR Consortium and the CGIAR Fund. The CGIAR Consortium of International Agricultural Research Centers, established through an international agreement in 2011,¹ is an international organization made up of 15 international agricultural research centres, dedicated to reducing rural poverty, increasing food security, improving human health and nutrition, and ensuring more sustainable management of natural resources. The Consortium is the umbrella organization of the 15 research centres coordinating donors and recipients of funds. The Agreement expressly states that it does not impose any financial obligations on the Parties. The CGIAR Fund is a multi-donor trust fund that finances the CGIAR research. Contributions to the CGIAR Fund are voluntary, but the minimum contribution is US\$ 100 000. Donors conclude legally binding contribution agreements with the Trustee. Thus, in comparison to pledges, donor commitments are binding once agreed.² The CGIAR Consortium was initially created (in 1971) through a resolution as an informal network of the 15 research centres, and became an international organization only forty years later following negotiation of an international agreement that is currently open for signature.³

International AIDS Vaccine Initiative

The result of a meeting organized by the Rockefeller Foundation in Bellagio, Italy in 1994, the International AIDS Vaccine Initiative Inc. (IAVI) is a public–private product development partnership that was founded in 1996 as a global not-for-profit organization working towards the development of safe and effective HIV vaccines that are available and accessible to all who need them. IAVI is a corporation registered in the United States (Delaware State).⁴ IAVI conducts intramural research in addition to funding other research organizations to fulfil its mission. It is financed through donations of governments, private individuals, corporations and foundations. IAVI's Innovation Fund established in 2008 supports short-term, high-risk, proof-of-concept studies on promising technologies' applicability to AIDS vaccine development. IAVI's budget in 2011 amounted to US\$ 83.2 million.⁵ While IAVI was the first international product development partnership (PDP) established to drive R&D for medical products adapted to the needs of developing countries, the last two decades have seen the establishment of many other PDPs, either as independent not-for-profit public–private foundations (e.g. the Medicines for Malaria Venture – MMV), as European economic interest groups (e.g. the European Vaccine Initiative – EVI) or as programmes within nongovernmental organizations (e.g. the Meningitis Vaccine Programme – MVP, a 50/50 partnership between WHO and PATH, USA).

¹ http://library.cgiar.org/bitstream/handle/10947/2592/Agreement_establishing_the_Consortium_of_International_Agricultural_Research_Centers_as_an_International_Organization.pdf?sequence=4.

² The standard agreement in CGIAR Fund Governance Framework, http://www.cgiarfund.org/how_the_fund_works.

³ As at September 2012 the agreement had been signed by four countries.

⁴ Amended and Restated By-laws of the International AIDS Vaccines Initiative Inc., <http://www.iavi.org/Who-We-Are/Leaders/Governance/Pages/default.aspx>.

⁵ IAVI, 2001 Annual Progress Report, http://www.iavi.org/Information-Center/Publications/Documents/APR_2011_FINAL_LoRes.pdf.

UNICEF/UNDP/World Bank/WHO Special Programme for Research and Training in Tropical Diseases and Special Programme of Research, Development and Research Training in Human Reproduction

The Special Programme of Research, Development and Research Training in Human Reproduction (HRP) established in 1972 and the UNICEF/UNDP/World Bank/WHO Special Programme for Research and Training in Tropical Diseases (TDR), established in 1975 by resolution WHA27.52, are examples of specific programmes that have been created within an existing international organization, but with their own distinct governing bodies deciding research priorities and fund allocation.

TDR aims to develop new and improved tools and approaches for the control of infectious diseases of poverty and to strengthen the research capacity of affected countries. It both conducts research and acts as a funder of research conducted by others. In 1978, through a Memorandum of Understanding (MoU), TDR founded its structure on the basis of cosponsorship by UNICEF, UNDP, the World Bank and WHO. The programme has its own governing bodies, but it is hosted in WHO, which acts as the executing agency of the programme. Its total funding in the 2010–2011 biennium was US\$ 94.4 million with a majority (67%) coming from governments. High-, middle- and low-income countries contribute resources to the TDR Trust Fund. For many years TDR itself undertook product R&D in the area of neglected tropical diseases, however it now concentrates on implementation research and research capacity-building activities.

Table 2: Overview of existing financing and research mechanisms

	Generation of funds	Founding Instrument	Legal form	Membership/Partners
Consultative Group on International Agricultural Research	Voluntary with minimum contribution of US\$ 100 000	CGIAR Consortium: international treaty CGIAR Fund: Decision of Board of the World Bank	IGO World Bank is trustee	Consortium: 15 International Agricultural Research Centers Agreement: four signatories as at September 2012
GAVI Alliance	Voluntary and innovative financing mechanisms	Decision by the provisional Board	Foundation under Swiss law	Partnership model, including United Nations organizations, governments, industry, foundations and other stakeholders
European Molecular Biology Laboratory	Compulsory assessed contributions	International treaty	IGO	20 Member States
International Agency for Research on Cancer	Assessed and voluntary contributions	World Health Assembly resolution	WHO Agency	22 Participating States

	Generation of funds	Founding Instrument	Legal form	Membership/Partners
International AIDS Vaccine Initiative Inc.	Voluntary contributions	The result of a Rockefeller meeting in Bellagio, registered as a Corporation	Corporation under US law, Delaware	The membership of the Corporation shall at all times consist of the directors of the Corporation ¹
International Vaccine Institute	Voluntary contributions	International treaty	IGO	16 Member States
Multilateral Fund to the Montreal Protocol	Assessed contributions	International treaty (Montreal Protocol)	Fund	Parties of the Montreal Protocol
Special Programme for Research and Training in Tropical Diseases	Voluntary contributions	World Health Assembly resolution/MoU	Hosted by WHO with own governing body (JCB)	Sponsors of TDR are UNICEF/UNDP/World Bank/WHO. Additional members of JCB are Member States and the civil society
Global Fund to Fight AIDS, Tuberculosis and Malaria	Voluntary contributions under triennial replenishment model	Framework Document	Foundation under Swiss law	Multistakeholder international financial institution bringing together governments, civil society groups, private sector, United Nations agencies and other players
UNITAID	Innovative financing mechanisms and voluntary contributions	MoU	Hosted by WHO with own governing body	International Drug Purchasing Facility created by Brazil, Chile, France, Norway, United Kingdom of Great Britain and Northern Ireland supported in 2012 by 29 countries and the Bill & Melinda Gates Foundation

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¹ Article 1 of the Amended and Restated By-laws of the International AIDS Vaccines Initiative Inc., <http://www.iavi.org/Who-We-Are/Leaders/Governance/Pages/default.aspx>.