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# **DRAFT WORKING PAPER 3<sup>1</sup>**

## FINANCING MECHANISMS FOR HEALTH R&D

#### **Executive Summary**

This Working Paper further explores the option of using and adapting an existing instrument to increase funding of R&D for diseases disproportionately affecting developing countries on a global level. It is a follow-up to the Report outlining potential options for the creation of a fund for the financing of R&D that the WHO Secretariat had prepared for the open-ended meeting of Member States held in November 2012. The paper identifies a number of mechanisms that could be suitable starting points and presents possible criteria that could be used to assess the suitability of a range of existing mechanisms.

#### **Goal & Background**

WHO Member States, throughout the development of the Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property<sup>2</sup> had identified the need for sustained efforts to ensure that newly replenished pipelines deliver the kind of breakthrough products that are needed. At the conclusion of the negotiations however, the issue remained unresolved. The Expert Working Group (EWG) and later the Consultative Expert Working Group on Research and Development: Financing and Coordination (CEWG) were thus established in order to address this remaining open issue contained in element 7 of the strategy which aims to "… secure adequate and sustainable

<sup>2</sup> WHA61.21 and WHA62.16.

<sup>&</sup>lt;sup>1</sup> In order to deepen the analyses presented in the Background document prepared for the open-ended meeting of Member States in November 2012 - where the report and the feasibility of the recommendations proposed by the Consultative Expert Review Group's report were discussed - the WHO Secretariat has developed draft Working Papers focusing on four main elements: the global observatory for health research and development (R&D); R&D coordination and prioritization; R&D financing; and options for demonstration projects. The Working Papers are drafts and will be revised based on feedback received.

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".<sup>3</sup>

Based on this mandate, the CEWG in 2012 recommended the creation of a new pooled financing mechanism. These funds were proposed to be used to fund all phases of R&D in the public and private sector as well as public–private partnerships addressing the identified health needs of developing countries. Moreover, 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 open also to additional voluntary public, private and philanthropic contributions. The report of the CEWG was discussed by WHO Member States in November 2012.<sup>4</sup> In preparation ahead of this meeting, the WHO Secretariat had prepared a Report outlining potential options for the creation of such a fund for the financing of R&D for diseases disproportionately affecting developing countries.<sup>5</sup>

## Existing financial mechanisms for health R&D

The Report of the Secretariat discussed how the increase of R&D funding 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. The Report presented two options:

- establishing a new instrument or
- using an existing instrument

The report included some arguments for both of the aforementioned options. This paper follows up on this Report and further discusses the possibility of using and adapting an existing instrument to pool funding for research at a global level. Such a mechanism would have to be able to

- receive voluntary funding from a variety of sources, including WHO Member States, and
- manage funds that are disbursed to private and/or public entities for the financing of research in various areas of diseases disproportionately affecting developing countries.

The mechanism would not be tasked with the identification of research priorities. This would instead be one of the outcomes of the work of a possible Global Observatory for Health R&D (see Working Paper 1).

<sup>&</sup>lt;sup>3</sup> See resolutions WHA61.21 and WHA63.28

<sup>&</sup>lt;sup>4</sup> See http://www.who.int/phi/cewg/en/index.html

<sup>&</sup>lt;sup>5</sup> See http://www.who.int/phi/1-cewg\_secretariat\_paper-en.pdf

To explore the suitability of existing mechanisms to be developed into a new financing mechanism, those existing mechanisms which should be taken into account must be ascertained. This paper starts from the assumption that suitability for such a task – financing R&D in the area of health – would require some health expertise. The paper thus focuses on existing mechanisms in the area of health. There are a number of existing international or regional mechanisms that finance health R&D, including the UNICEF/UNDP/World Bank/WHO Special Programme for Research and Training in Tropical Diseases (TDR), the International Agency for Research on Cancer (IARC) and a number of product development partnerships (PDPs – see the list in the Annex 1). Some of these mechanisms are pooling resources to fund research, while others, such as certain PDPs, are themselves managing product development and are therefore involved in carrying out or managing health research. Nevertheless, using and adapting existing PDPs could be an option and thus some PDPs have been included in this assessment (PATH, MMV and DNDi) in order to establish the extent to which these might represent a suitable starting point. This is not meant to exclude other PDPs, but should highlight the possible role of PDPs.

Given the goal to establish an international mechanism, the assessment is limited to existing international or regional mechanisms and does not include national mechanisms. However, it does not only focus on existing health research mechanisms, but includes existing international mechanisms for the procurement of health products, namely the Global Fund to Fight AIDS, Tuberculosis and Malaria, GAVI, and UNITAID.

A possible future mechanism could also be composed of two entities: a trust fund hosted by a development bank, whose function would be purely fiduciary and who would release funding following instructions of the second element of the mechanism, which would constitute the governance and decision making organ. Such arrangement has been used already, e.g. during the first years of the GAVI Alliance, the Vaccine Fund was responsible for the finances, while the Alliance Board – hosted by UNICEF – was the decision-maker.

Annex 2 provides factsheets on each of the mechanisms that have been included in this assessment, containing the relevant information.

## Assessment criteria

Prior to exploring and evaluating the suitability of these mechanisms for the scaling up of financing of R&D for diseases disproportionately affecting poor people, a key question is to identify a set of criteria that can be used as a proxy. The following criteria were identified:

- Adaptability: can the mechanism easily be adapted to take up the global funding of health R&D or would this require a long process, e.g. ratification by Members?
- Scope of research:
  - Disease areas covered: disease areas/diseases covered

- **Technologies covered:** scope and spread of medical technologies researched
- **Geographical scope:** if and to what extent the mechanism is geographically limited regarding its activities and implementation
- **Governance:** is the governing structure inclusive regarding Member States representing both funders and beneficiaries as well as other stakeholders, e.g. civil society and industry?
- **Experience in funding R&D:** Experience of financing research projects includes the identification of the areas of research, allocation and monitoring of funding external research projects.
- **Experience in managing R&D:** Experience in managing research projects. For example, PDPs typically identify particular R&D projects, e.g. a diagnostic for TB or a paediatric version of an existing ARV and are managing the research often by mandating external entities to do the required R&D.
- **Transparency:** are the criteria used to distribute funding and the minutes of governing body meetings publicly available?

The following table assesses existing mechanisms against the described criteria. It uses a scale between:

RED: criteria not fulfilled, e.g. RED in the column of "Disease areas covered" would signify that the mechanism does not cover any of the diseases disproportionately affecting developing countries.

YELLOW: criteria partly fulfilled, e.g. in the column of "Disease areas covered" YELLOW would signify that the mechanism already covers some of the diseases disproportionately affecting developing countries, for example TB and malaria.

GREEN: criteria fulfilled, e.g. in the column of "Disease areas covered" GREEN would signify that the mechanism already covers most diseases disproportionately affecting developing countries.

WHITE: result of investigation not yet known.

#### World Health Organization (WHO)

#### Department of Public Health, Innovation and Intellectual Property

	Adaptabi lity	i Scope of research		Geograp hical	Experien ce in	Experien ce in	Inclusive governan	Transparency	
		Disease areas covered	Technolo gies covered	coverage	funding R&D	managin g R&D	ce structure	Criteria to distribut e funding publicly available	Minutes of governin g body meetings publicly available
ANDI									
DNDi									
EMBL		n.a.							
GAVI Alliance									
Global Fund									
IARC									
IVI									
ΜΜΥ									
РАТН									
RBM									
WHO/TDR									
UNITAID									

n.a.: not applicable

#### Assessment

The table provides only a very preliminary and incomplete assessment with some columns remaining blank for the time being. It does not claim to be an exact science, but rather means to provide a qualitative indication on which mechanisms would be more suitable than others.

The question of when a governance structure is inclusive was among the most difficult to answer. Mechanisms scored green when funders and beneficiaries as well as other stakeholders such as civil society and industry were included in the governance structure.

The assessment will be finalized once the criteria have been refined and finalized and the table has been filled in completely.

#### **Annex 1: Product Development Partnerships**

In 2011, funding to PDPs involved in research into neglected diseases totalled US\$ 451.4 million. This represented 14.8 per cent of global funding for research on neglected diseases. Four PDPs – PATH, Medicines for Malaria Venture, the International AIDS Vaccine Initiative and the Aeras Global TB Vaccine Foundation – accounted for over half of all PDP funding (Moran et al., G-Finder – Global Funding of Innovation for Neglected Diseases, 2012<sup>6</sup>).

#### HIV/AIDS

- International AIDS Vaccine Initiative IAVI
- International Partnership for Microbicides
- South African AIDS Vaccine Initiative

#### Malaria

- Malaria Vaccine Initiative
- Medicines for Malaria Venture (MMV)

#### Tuberculosis

- Aeras Global TB Vaccine Foundation
- Foundation for Innovative New Diagnostics
- Global Alliance for TB Drug Development
- Tuberculosis Vaccine Initiative

#### Other partnerships include

- Drugs for Neglected Diseases Initiative (DNDi)
- Institute for OneWorld Health
- PATH
- International Vaccine Institute
- Infectious Disease Research Institute
- Innovative Vector Control Consortium
- Sabin Vaccine Institute
- European Vaccine Initiative.

**Source:** WHO, WIPO, WTO, Promoting Access to Medical Technologies and Innovation, Geneva 2013

<sup>&</sup>lt;sup>6</sup> <u>https://g-finder.policycures.org/gfinder\_report/</u>

#### **ANNEX 2: Included Financing Mechanisms**

This Annex contains factsheets on the various mechanisms included in this paper. The information is based on the FACTSHEETS ON FUNDING AND RESEARCH MECHANISMS<sup>7</sup> prepared by the WHO Secretariat for the open-ended meeting in November 2012. The information has been completed with a view to the identified criteria. In some instances information still needs to be completed. Factsheets on PATH, DNDi, and MMV have been added, but still need to be checked with these organizations.

<sup>&</sup>lt;sup>7</sup> http://www.who.int/phi/2-funding\_mechanism\_factsheets\_6nov12.pdf

	African Notwork for Drug and Vaccine Innovation (ANDI)
Name Established	African Network for Drug and Vaccine Innovation (ANDI) 2008, transferred to Africa in 2011
Headquarters	Addis Ababa, Ethiopia
Mandate	ANDI supports and promotes African-led health product innovation for the discovery, development and delivery of drugs and diagnostics for neglected tropical diseases. African Innovation Fund (AIF) is embedded within the financial structure of ANDI.
	ANDI was set up as a project under the auspices of the WHO through the Special Programme for Research and Training in Tropical Diseases (TDR), Regional Office for Africa (AFRO) and Regional Office for Eastern Mediterranean (EMRO), along with the African Development Bank (AfDB), the European Union (EU) and several national African institutions.
Founding	WHO <u>Resolution WHA62.161</u>
document	
	The framework to drive health product innovation, of which ANDI is a part, is derived from the Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property (GSPA-PHI) (WHA.61.21). A strategic and business plan for ANDI was developed in 2009 <sup>8</sup> .
Legal entity	ANDI is hosted by the United Nations Economic Commission for Africa (UNECA) <sup>9</sup>
-	in Addis Ababa, Ethiopia, where it is expected to function as an Intergovernmental Organization.
Membership (geographical coverage)	The ANDI Board is discussing possible future memberships by African countries based on annual contribution.
Governance	There are three structures playing different roles in ANDI's governance. These are the Board, the
	Scientific and Technical Advisory Committee (STAC), and the host agency UNECA.
	The Board is the highest governing body of ANDI. It comprises representatives from North, South,
	East, West and Central African regions, independent health experts, the African Diaspora and key intuitional partners including UNECA, WHO and AfDB. The STAC is an independent body that
	provides technical support to the ANDI Board and Secretariat. The STAC provides an annual review of ANDI's technical activities and makes recommendations. It also supports the transparent review, selection and implementation of projects. UNECA as the host agency provides administrative oversight of ANDI.
Diseases and	Technologies: medicines, vaccines, diagnostics, including health tools based on traditional medicine
technologies	
covered	Disease areas: neglected tropical diseases
Funding	Presently ANDI is supported through voluntary contributions by various stakeholders.
	Potential sources of funding include traditional donor-based support and innovative health financing.
	ANDI presently holds a Trust Fund at UNECA where contributions are deposited and used for ANDI
	activities following the administrative processes of UNECA. ANDI is actively seeking donations. An
	endowment fund is expected to be set up in due course. The main challenge for ANDI at present is
	financial and human resources. ANDI obtains funding from the EU and ongoing support from WHO through TDR, AFRO and EMRO as well as support from UNECA.
Experience in	To be completed.
funding and managing R&D	To be completed.
Criteria to	Not available on the website.
distribute	
funding publicly available	

<sup>&</sup>lt;sup>8</sup> <u>http://www.andi-africa.org/index.php/aboutus/strategy</u>

<sup>9</sup> www.uneca.org

## World Health Organization (WHO) Department of Public Health, Innovation and Intellectual Property

Minutes of	Summaries of annual ANDI Stakeholders Meetings are available on the website.
governing body	http://www.andi-africa.org/index.php/news-events/stakeholder-meeting/past-meetings/4th-andi
meetings	
publicly	
available	
Website	http://www.andi-africa.org/
	http://www.who.int/tdr/publications/documents/sbp_andi.pdf

Name	Drugs for Neglected Diseases Initiative (DNDi)
Established	2003
Headquarters	Geneva, Switzerland
1	<ul> <li>DNDi has regional offices at the following locations:</li> <li>Kinshasa, Democratic Republic of the Congo (Project Support Office)</li> </ul>
	• New York, USA (Affiliate)
	Nairobi, Kenya
	New Delhi, India
	Pulau Pinang, Malaysia
	Rio de Janeiro Brazil
	• Tokyo, Japan
Mandate	DNDi's mandate is to develop new drugs, or new formulations of existing drugs, for patients suffering from the most neglected communicable diseases. Acting in the public interest, DNDi aims to bridge existing R&D gaps in essential medicines for these diseases by initiating and coordinating medicine
	R&D projects in collaboration with the international research community, the public sector, the pharmaceutical industry, and other relevant partners.
	While using the existing support capacities in countries where the diseases are endemic, DNDi helps to build additional capacity in a sustainable manner through technology transfer in the field of medicine R&D for neglected diseases.
Founding document	DNDi was founded under the DNDi Charter.
Legal entity	DNDi is an independent, not-for-profit foundation under the Swiss Civil Code.
Membership	DNDi operates under a not-for-profit model. The founding partners are primarily from the public sector:
(geographical	Indian Council of Medical Research; Kenya Medical Research Institute; Médecins Sans Frontières;
coverage)	Ministry of Health of Malaysia; Oswaldo Cruz Foundation/Fiocruz (Brazil). The World Health Organization Special Programme for Research and Training in Tropical Diseases (TDR) is a Permanent Observer.
	DNDi has various types of agreements with its partners worldwide, such as Research Services Agreements, Material Transfer Agreements, Research and License Agreements, Collaboration Agreements, Clinical Trial Agreements, and Financial Agreements. Partners include pharmaceutical companies, biotechs, universities, research institutes, national research centres, NGOs, international organizations, hospitals, Ministries of Health, and governmental organizations.
Governance	The DNDi Executive Team is governed by the Board of Directors with the Scientific Advisory Committee, Audit Committee and Executive Board Committee. The Executive Team implements the R&D strategy, manages the global portfolio, allocates resources, fundraises, and advocates.
Diseases and	Technologies: medicines
technologies covered	Disease areas: neglected diseases, including leishmaniasis, human African trypanosomiasis (sleeping sickness), chagas disease, malaria, paediatric HIV, and specific helminth infections
Funding	DNDi receives funding from different sources, including governments, international organizations, founding partners who provide ongoing support, private foundations, large donors, and individuals.
	DNDi has invested EUR 120 million between 2003 and 2011 and has secured EUR 218 million out of the EUR 400 million needed to fund approximately 55% of its estimated needs by 2018.
Experience in	To be completed.
funding and managing R&D	
Criteria to distribute	Not available on the website.
funding publicly available	
Minutes of	Not available on the website.
governing body meetings publicly available	
Website	http://www.dndi.org/
** CDS11C	http://www.andi.org/

Name	European Molecular Biology Laboratory (EMBL)
Established	1974
Headquarters	EMBL operates from five locations in Europe:
-	Heidelberg, Germany - main laboratory
	• Hinxton, UK - European Bioinformatics Institute (EMBL-EBI)
	• Grenoble, France - research and services for structural biology
	• Hamburg, Germany - research and services for structural biology
	<ul> <li>Monterotondo, Italy - Mouse Biology unit</li> </ul>
Mandate	Co-operation among European States in fundamental research, development of advanced
	instrumentation and advanced teaching in molecular biology as well as in other areas of related
	research, and to focus on work not normally or easily carried out in national institutions. The result of
	the experimental and theoretical work of the Laboratory shall be published or otherwise made generally
	available.
Founding	International Agreement adopted at the European Molecular Biology Conference by 10 European
document	countries in 1973.
Legal entity	The Laboratory was established as an intergovernmental institution with legal personality (Article XI of
	the Agreement).
Membership	Austria, Belgium, Croatia, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Israel, Italy,
(geographical	Luxembourg, the Netherlands, Norway, Portugal, Spain, Sweden, Switzerland, United Kingdom,
coverage)	Australia (Associate Member).
Governance	The EMBL is led by the Director General who is appointed by the Governing Body which is also the
	Council (representatives of all Member and associate Member States).
Diseases and	Technologies: not focused on any particular technology; research in molecular biology
technologies	
covered	Disease areas: basic research not focused on a specific disease area
Funding	Annual contributions at a scale fixed by the Council based on average net national income for the last
	three years.
	The Laboratory is financed in three ways:
	Financial contributions from Member States
	<ul> <li>Gifts by Member States in addition to the financial contributions</li> </ul>
	<ul> <li>Any other resources, gifts by private organizations and individuals</li> </ul>
	• Any other resources, girts by private organizations and individuals
	As per Article X of the Agreement, Member States shall contribute annually to the capital expenditure
	and to the current operating expenses of the Laboratory an aggregate amount of convertible funds in
	accordance with a scale which shall be fixed every three years by the Council by a two-thirds majority
	of all the Member States, and shall be based on the average net national income at factor cost of each
	Member State for the three latest preceding calendar years for which statistics are available.
	Failure to fulfill obligations under the Agreement may deprive Members of membership by decision of
	the Council taken by a majority of two-thirds of all the Member States (Article XVI of the Agreement).
	The Laboratory had a budget of €171 million in 2011 with 55% contributions from Member States.
Experience in	To be completed.
funding and	
managing R&D	
Criteria to	Not available on the website.
distribute	
funding publicly available	
Minutes of	Not available on the website.
governing body	
meetings	
publicly	
available	
Website	http://www.embl.de/aboutus/index.html

## World Health Organization (WHO) Department of Public Health, Innovation and Intellectual Property

Name	GAVI Alliance
Established	2000
Headquarters	Washington DC, USA; Geneva, Switzerland
Mandate	The mission of the GAVI Alliance (formerly the Global Alliance for Vaccines and Immunization) 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 programmes. GAVI was launched in 2000 to fund the procurement and delivery of vaccines for the world's poorest
	countries. It combines major players into a single decision-making body.
Founding document	GAVI was established by a Meeting of the Proto-Board in Seattle, State of Washington on 12 July 1999 (See Decision <u>GAVI/99.01</u> ) 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, NGOs and research and technical health institutes. In 2008, the GAVI Alliance, the GAVI Fund (a non-profit organization based in the United States) and
	the GAVI Foundation were reorganized under the GAVI Alliance brand, using the GAVI Foundation's legal platform.
Legal entity	The GAVI Alliance is a Foundation under Swiss law with international institution status and has Public Charity status in the United States.
Membership (geographical coverage)	GAVI operates under a partnership model, which includes UN organizations, governments, industry, foundations and other stakeholders.
	As of 2013, up to 68 countries were eligible for GAVI's support, e.g. for hepatitis B vaccine.
Governance	The GAVI Alliance Board is the supreme governing body. It comprises: four permanent members, WHO, UNICEF, the World Bank and the Bill and Melinda Gates Foundation; GAVI Alliance CEO (non-voting); nine independent individuals; and representative seats from developing (5) and industrialized (5) governments; vaccine industries in developing (1) and industrialized (1) countries; research and technical institutes (1); and civil society organizations (1).
Diseases and	Technologies: vaccines
technologies covered	Diseases include: pneumonia, rotavirus, hepatitis B, Hib antigens, measles, meningitis A, human papillomavirus, yellow fever
Funding	The International Finance Facility for Immunization (IFFIm) uses legally-binding commitments of up to 20 years from donor governments to sell bonds in the capital markets, making funds available for GAVI programmes.
	The Advance Market Commitment (AMC) incentivises the research, development and manufacture of vaccines through legally-binding commitments signed by donors to provide the vaccines at a long-term, affordable price to developing countries.
	Under the GAVI Matching Fund, the Department for International Development (DFID) and the Bill & Melinda Gates Foundation match contributions to GAVI from corporations and foundations.
	Direct contributions: from 2000-2010 63% funding were direct contributions, primarily from governments and the Bill & Melinda Gates Foundation, while 37% came from innovative finance. Since 2000 GAVI has committed expenditure of US\$7.2 billion.
Experience in funding and managing R&D	To be completed.
Criteria to distribute funding publicly available	Not available on the website.
Minutes of governing body meetings publicly	GAVI publishes minutes of Board and committee meetings on its website. http://www.gavialliance.org/library/minutes/
available Website	http://www.gavialliance.org

#### The Global Fund to Fight AIDS, Tuberculosis and Malaria (Global Fund) Name Established 2002 Headquarters Geneva, Switzerland Mandate The Global Fund is an international financing institution based on a unique partnership between governments, civil society, the private sector and affected communities. The Global Fund was created to raise, manage and disburse large amounts of additional financing to fight three of the world's most devastating diseases, and to direct those resources to areas of greatest need. The Framework Document of the Global Fund and the By-Laws are the governance documents of the Founding Global Fund.<sup>10</sup> When the Global Fund was created it entered into an Administrative Services document Agreement (ASA) with the WHO, whereby the WHO Secretariat provided administrative and financial services to the Global Fund, including employment of staff. Effective from 1 January 2009, the Global Fund ended the ASA and became an autonomous organization, with all staff members becoming employees of the foundation (17th Board Meeting, Geneva, Decision Point GF/B17/DP20). Legal entity The Global Fund is registered as a Non-Profit Foundation in Switzerland and is recognised as an International Organization by national governments (Article 1, By Laws). It has Public Charity status in the United States. It has signed a Headquarters Agreement with Switzerland and enjoys the same privileges and immunities as other international organizations within that country. The World Bank is the trustee of funds contributed to the Global Fund (Article 16, By Laws). Membership The Global Fund operates as a multi-stakeholder international financial institution which brings together implementing government bodies, national civil society groups, and the private sector, (geographical coverage) development partners (UN Agencies and bilateral agencies), and, in particular, communities affected by the diseases. The Global Fund distributes funding to eligible countries according to disease areas using certain criteria. As of 2012, more than 120 countries were eligible for grants. Governance The main governing body of the Global Fund is the Board which consists of representatives of both donor and recipient countries, civil society, private sector, private foundations and the community affected by these diseases. The Country Coordinating Mechanism (CCM) operates as a national-level partnership of all key stakeholders which submits proposals to the Global Fund while nominating the entities responsible for implementation of the grants (the Principal Recipients). The CCM is also responsible for overseeing the implementation work of the Principal Recipients. The Secretariat is responsible for day-to-day operations including resource mobilization, managing grants, providing financial, legal and administrative support. The Secretariat is headed by an Executive Director. The Technical Review Panel is a group of independent international experts in these three diseases who review funding proposals and make recommendations to the Board. Approximately every 30 months, the Global Fund convenes a broad group stakeholders meeting in a Partnership Forum. **Diseases and** Technologies: medicines, vaccines, diagnostics, insecticide-treated bed nets technologies covered Disease areas: AIDS, tuberculosis, malaria Funding of the Global Fund comes from voluntary financial contributions from all sectors -Funding governments, the private sector, social enterprises, philanthropic foundations and individuals. Funds are mobilized through a periodic replenishment model. Under the replenishment model, each donor fixes independently their contribution, but is usually making a pledge over a certain period in time. Pledges are public, legally non-binding statements on planned contributions to the Global Fund.

<sup>&</sup>lt;sup>10</sup> <u>http://www.theglobalfund.org/en/library/documents/</u>

	The current replenishment cycle covers the period 2011-2013; planning for the Fourth Replenishment
	will commence in early 2013.
Experience in	To be completed.
funding and	
managing R&D	
Criteria to	The Global Fund's Eligibility, Counterpart Financing and Prioritization Policy explains the criteria of a
distribute	country's eligibility for funding.
funding publicly	
available	
Minutes of	Minutes of Board meetings are available on the website.
governing body	http://www.theglobalfund.org/en/board/decisions/
meetings	
publicly	
available	
Website	www.theglobalfund.org

Name	International Agency for Research on Cancer (IARC)
Established	1965
Headquarters	Lyon, France
Mandate	IARC is an inter-disciplinary agency bringing together skills in epidemiology, laboratory sciences and biostatistics to identify the causes of cancer so that preventive measures may be adopted and the burden of disease and associated suffering reduced.
	The Agency's work has four main objectives: monitoring global cancer occurrence; identifying the causes of cancer; elucidation of mechanisms of carcinogenesis; and developing scientific strategies for cancer control.
Founding document	WHO Resolution WHA18.44 as a WHO agency, May, 1965
Legal entity	The IARC is part of the WHO (WHO Agency).
Membership	IARC's membership includes 22 countries: the five founding Countries, Germany, France, Italy, the
(geographical	United Kingdom and the United States of America, plus Australia, Austria, Belgium, Canada,
coverage)	Denmark, Finland, India, Ireland, Japan, the Netherlands, Norway, Republic of Korea, Russian
	Federation, Spain, Sweden, Switzerland and Turkey.
Governance	IARC's general policy is directed by a Governing Council, composed of the Representatives of Participating States and of the Director-General of the WHO.
	The IARC also has a Scientific Council that evaluates IARC's activities, and makes recommendations on the programme of permanent activities. <sup>11</sup>
Diseases and	Technologies: epidemiology, laboratory sciences, biostatistics; cancer research to identify the causes of
technologies covered	cancer, early detection of cancer, and evaluation of prevention strategies
	Disease areas: cancer
Funding	IARC activities are mainly funded by regular contributions from its Participating States who by joining IARC accept the obligation to contribute annually. Assessed contributions are determined by the Governing Council of IARC in accordance with the approved budget, thus allowing to cover all administrative services and permanent activities of the Agency. Special IARC projects are financed from additional grants or special contributions that are in comparison completely voluntary (voluntary contributions). The regular budget for the 2010-2011 biennium was €37.91 million. Voluntary contributions amounted
	to €14.95 million. <sup>12</sup>
Experience in funding and	To be completed.
managing R&D Criteria to	Not available on the website.
distribute	not available off the website.
funding publicly	
available	
Minutes of	Minutes of governing body meetings are available on the website.
governing body	http://governance.iarc.fr/
meetings	
publicly	
available	

<sup>&</sup>lt;sup>11</sup> IARC, Statute, Rules and Regulations, 13th edition, 2011 <u>http://governance.iarc.fr/ENG/Docs/StatuteEnglish.pdf</u>

<sup>&</sup>lt;sup>12</sup> GC/54/9, 16/04/2012, Biennial Financial Report, <u>http://governance.iarc.fr/GC/GC54/En/Docs/GC54\_9.pdf</u>

# World Health Organization (WHO) Department of Public Health, Innovation and Intellectual Property

Name	International Vaccines Initiative (IVI)
Established	
	Seoul. South Korea
Headquarters Mandate	
Mandate	The IVI is an international centre of research, training and technical assistance for vaccines needed in
<b>F B</b>	developing countries.
Founding	Founded under <u>The Establishing Agreement</u> <sup>13</sup> , the IVI was created pursuant to the initiative of the
document	UNDP under Article 5 of the <u>Vienna Convention of 1969</u> . <sup>14</sup> It is located in Seoul, South Korea, which
	is the host country for the IVI. (See also the <u>Constitution</u> of the IVI).
Legal entity	International Organization with juridical personality ( <u>Article II, Constitution</u> <sup>15</sup> ).
Membership	Member States: 33 Signatories, 17 Parties, and the WHO.
(geographical	
coverage)	
Governance	The governing bodies of the IVI comprise the Board of Trustees and the Scientific Advisory Group.
Diseases and	Technologies: vaccines
technologies	
covered	Disease areas: infectious diseases, with a focus on neglected diseases
Funding	The IVI has diverse donors including governments (even those who are not signatories or parties to the
U	IVI), foundations, public sector institutions and international organisations, private sector and even
	individuals.
Experience in	To be completed.
funding and	
managing R&D	
Criteria to	Not available on the website.
distribute	
funding publicly	
available	
Minutes of	Not available on the website.
governing body	
meetings	
publicly	
available	
Website	www.ivi.int

<sup>13</sup> http://www.ivi.int/html/themes/www/download/Establishment\_Agreement.pdf

<sup>&</sup>lt;sup>14</sup> http://untreaty.un.org/ilc/texts/instruments/english/conventions/1\_1\_1969.pdf

<sup>&</sup>lt;sup>15</sup> http://www.ivi.int/html/themes/www/download/Constitution.pdf

Name	Medicines for Malaria Venture (MMV)
Established	1999
Headquarters	Geneva, Switzerland
Mandate	The mandate of MMV is to reduce the burden of malaria in disease-endemic countries by discovering, developing and facilitating delivery of new, effective and affordable antimalarial medicines.
Founding	http://www.mmv.org/sites/default/files/uploads/docs/about_us/history/mmv_october_1999.pdf
document	
Legal entity	MMV initially operated from within the WHO TDR and later was established as a foundation under Swiss law.
Membership (geographical coverage)	MMV operates as a not-for-profit public-private partnership. It was launched in 1999, with initial seed finance by Switzerland, UK, Netherlands, the World Bank, and Rockefeller Foundation.
	MMV has partnerships with the private sector (biotech and pharma), public sector (research and academic institutions), governments, international organizations, NGOs, non-profit organizations, and clinical centres in endemic countries.
Governance	MMV is governed by a Board of Directors, the highest policy and decision-making body of MMV which ensures that MMV's objectives are efficiently executed by the management. MMV has established a Board of Directors in North America, which supports MMV's Corporate Development activities in the USA.
	The Expert Scientific Advisory Committee (ESAC) helps identify the best projects worthy of inclusion in the MMV portfolio and monitors progress through an annual review of all projects. The Access & Product Management Advisory Committee (APMAC) advises MMV on its global access activities to ensure timely and effective delivery of new antimalarial drugs in malaria endemic countries. The Global Safety Board (GSB) ensures adherence to scientific and ethical principles.
Diseases and technologies	Technologies: medicines
covered	Disease areas: malaria
Funding	MMV has received funding and support from government agencies, private foundations, international organizations, corporations, corporate foundations, and private individuals. These funds are used to finance the MMV portfolio of R&D projects and to support specific, targeted access interventions that make it easier for vulnerable populations to access MMV products.
Experience in funding and managing R&D	To be completed.
Criteria to	Not available on the website.
distribute	
funding	
publicly	
available	
Minutes of	Not available on the website.
governing body	
meetings	
publicly	
available	
Website	http://www.mmv.org

## World Health Organization (WHO)

Name	PATH (Program for Appropriate Technology in Health)
Established	1977
Headquarters	Seattle, Washington, USA
neuuquurters	Source, Hushington, OSH
	PATH has offices in 41 cities in 21 countries, located across Africa, Asia, Europe, Eastern Europe,
	North America, and Latin America.
Mandate	The mandate of PATH is to improve the health of people around the world by advancing technologies,
	strengthening systems, and encouraging healthy behaviours. PATH responds to the spectrum of global
	health needs, with a particular focus on emerging and epidemic diseases, health technologies designed
	for low-resource settings, safer childbirth and healthy children, health equity for women, and basic
	protection of vaccines for women and children.
Founding	See "The birth of PATH": http://www.path.org/about/birth-of-path.php
document	
Legal entity	PATH is an international non-profit organization with public charity status in the US.
Membership	PATH has partnerships with the WHO, UNICEF, the UN Population Fund, government ministries,
(geographical	community groups, other NGOs, foundations, and private firms.
coverage)	
	PATH initiatives reach more than 70 countries worldwide.
Governance	PATH's executive team consists of the president, CEO, four vice presidents, and a general counsel.
Diseases and	Technologies include: vaccines, diagnostics, nutrition technologies, safe birth and newborn health
technologies	technologies, safe injection, and safe water
covered	
	Disease areas include: HIV/ AIDS, malaria, tuberculosis, influenza, diarrhoea, rotavirus, malnutrition,
	safe childbirth, postpartum haemorrhage, newborn death, safe abortion, cervical cancer, avian flu,
<b>T I</b>	meningitis, respiratory syncytial virus, and pneumonia
Funding	Sources of funding are foundations, governments, NGOs, non-profit organizations, international
	organizations such as the WHO, and individuals.
	Project-specific grants make up more than 95 per cent of operating funds. PATH's 2012 budget was
	US\$ 305 million.
Experience in	To be completed.
funding and	
managing R&D	
Criteria to	Not available on the website.
distribute	
funding publicly	
available	
Minutes of	Not available on the website.
governing body	
meetings	
publicly	
available	
Website	http://www.path.org

Name	Roll Back Malaria Partnership (RBM)
Established	1998
Headquarters	Geneva, Switzerland.
neuuquarters	General, Switzenand.
	Branch offices are located in the following locations: New York, USA; Nairobi, Kenya;
	Yaoundé, Cameroon; Gaborone, Botswana; Dakar, Senegal.
Mandate	RBM Partnership is a global Partnership to implement coordinated action against Malaria. The overall
Wanuate	strategy of the RBM program is to reduce malaria morbidity through universal coverage as the goal and
	by strengthening health systems. The Partnership was founded by the Director-General of WHO with
	UNICEF, UNDP and the World Bank.
Founding	Memorandum of Understanding between the Partnership and WHO <sup>16</sup> , RBM Partnership By Laws and
document	RBM Partnership Operating Framework. <sup>17</sup> The Partnership is currently hosted under the WHO, which
uocument	provides the hosting arrangements for the Partnership Secretariat, and also administrative and fiduciary
	support and facilities.
Legal entity	The Partnership is hosted by WHO
Membership	The Partnership brings together a range of constituencies, i.e. malaria-endemic countries, multilateral
(geographical	development partners, the private sector, foundations, researchers and academia, non-governmental
coverage)	organizations, OECD Donor countries and Ex-Officio Members.
Governance	RBM functions through a Board, an Executive Committee, and a Secretariat. The Board is represented
Governance	by 21 voting members who serve as representatives of their constituencies and 5 non-voting ex officio
	members.
	The 21 Board members include representatives from countries in Africa (Togo, Congo, Kenya,
	Mozambique), South East Asia (Thailand), South Asia (India); Latin America and Caribbean (Brazil);
	OECD Donor Countries (France, United Kingdom, United States); International organizations
	(UNICEF, UNDP, WHO); civil society (Friends of the Global Fund Africa, Management Sciences for
	Health); the private sector (Sumitomo Chemical, GlaxoSmithKline; and foundations (Bill & Melinda
	Gates Foundation).
	Further information is available on the website.
	www.rollbackmalaria.org/mechanisms/partnershipboard.html
Diseases and	Technologies: medicines, insecticide-treated mosquito nets, rapid diagnostic tests (RDT), insecticides
technologies	
covered	Disease areas: malaria
Funding	The Partnership does not directly finance malaria prevention, control and treatment but works through
J	its partners to co-ordinate global actions in these areas. The main sources of funding for efforts to
	prevent, control and treat malaria are the Global Fund, the World Bank, and the OECD.
Experience in	To be completed.
funding and	
managing R&D	
Criteria to	Not available on the website.
distribute	
funding publicly	
available	
Minutes of	Minutes of Board meetings are available on the website.
governing body	http://www.rbm.who.int/mechanisms/partnershipboard.html
meetings	
publicly	
available	
Website	http://www.rbm.who.int/

<sup>&</sup>lt;sup>16</sup> <u>http://www.rbm.who.int/mechanisms/index.html</u>

<sup>17</sup>http://www.rbm.who.int/mechanisms/partnershipboard.html

Name	The Special Programme for Research and Training in Tropical Diseases (TDR)
Established	1978
Headquarters	Geneva, Switzerland
Mandate	The Special Programme for Research and Training in Tropical Diseases (TDR) is a global programme of scientific collaboration that helps coordinate, support and promote global research efforts to combat infectious diseases of the poor and disadvantaged and promote the translation of innovation to health impact in disease endemic countries. TDR is co-sponsored by the United Nations Children's Fund (UNICEF), the United Nations Development Programme (UNDP), the World Bank and WHO; it is hosted by WHO, its executing agency, and operates within a broad framework of intergovernmental and interagency cooperation and participation.
Founding	WHO Resolution WHA27.52 <sup>18</sup>
document	Memorandum of Understanding <sup>19</sup> , 1978, (amended 1988, 2003, 2006 and 2008)
Legal entity	It is a joint venture, co-sponsored (financed and governed) by UNICEF, UNDP, the World Bank and WHO. WHO is the executing agency of TDR.
Membership (geographical coverage)	Governments and other cooperating parties, including non-governmental organizations, are eligible for membership on the TDR Joint Coordinating Board (JCB). The JCB consists of 34 members, including one non-governmental organization.
Governance	TDR is governed by three bodies: The Joint Coordinating Board (JCB), The Standing Committee and the Scientific and Technical Advisory Committee (STAC) The JCB usually meets once a year. It comprises Government representatives from donor countries; government representatives from each of WHO's six regions; other collaborating parties of TDR, which may include non-governmental entities, and TDR's 4 co-sponsoring agencies, UNICEF, UNDP, the World Bank and WHO. The Standing Committee oversees the management and financing of TDR and comprises the four co- sponsors - UNICEF, UNDP, the World Bank and WHO. The STAC meets on an annual basis and oversees TDR's scientific activities. The STAC reports to the JCB.
Diseases and	Technologies: medicines, vaccines, diagnostics
technologies covered	Disease areas: infectious diseases of poverty including African trypanosomiasis, chagas, dengue, Helminths, leishmaniasis, malaria, onchocerciasis, schistosomiasis, TB/HIV co-infection, tuberculosis
Funding	Governments and international agencies, other public groups such as philanthropic foundations, non- governmental organizations and private companies make voluntary contributions to TDR.
Experience in funding and managing R&D Criteria to	To be completed. Not available on the website.
distribute funding publicly available	
Minutes of governing body meetings publicly available	Summaries of the following governing body meetings are available on the website.   The Joint Coordinating Board (JCB) <a href="http://www.who.int/tdr/about/governance/jcb/en/">http://www.who.int/tdr/about/governance/jcb/en/</a> The Standing Committee <a href="http://www.who.int/tdr/about/governance/standing_committee/en/">http://www.who.int/tdr/about/governance/jcb/en/</a>
Website	http://www.who.int/tdr/

<sup>&</sup>lt;sup>18</sup> <u>http://www.who.int/tdr/about/governance/documents/wha27-52/en/index.html</u>

<sup>&</sup>lt;sup>19</sup> <u>http://www.who.int/tdr/documents/mou\_08\_eng.pdf</u>

## World Health Organization (WHO) Department of Public Health, Innovation and Intellectual Property

Name	UNITAID
Established	2006
Headquarters	Geneva, Switzerland
Mandate	UNITAID is an innovative financing initiative for global health, established to provide sustainable, predictable and additional funding to significantly impact market dynamics to reduce prices and improve access to high quality medicines, diagnostics and related commodities for the treatment of HIV/AIDS, malaria and tuberculosis, primarily for populations in low-income and lower-middle income countries.
Founding document	The governments of France, Chile, Brazil, Norway, and the United Kingdom signed a Memorandum of Understanding (MoU) at the United Nations on September 19, 2006.
Legal entity	The <u>UNITAID Constitution</u> <sup>20</sup> was adopted 6 July 2011 by the Executive Board. UNITAID is hosted by WHO.
Membership (geographical coverage)	Countries become UNITAID Members by adhering to the principles of international solidarity and innovative financing.
	UNITAID currently has 29 members – 28 countries and the Bill & Melinda Gates Foundation. The countries that are members of UNITAID include Brazil, Chile, France, Norway, United Kingdom, Cyprus, Luxembourg, Spain, Republic of Korea, South Africa, Benin, Burkina Faso, Cameroon, Republic of Congo, Ivory Coast, Gabon, Liberia, Madagascar, Mali, Morocco, Mauritius, Namibia, Niger, Central African Republic, Senegal, Sao-Tomé-e-Principe, Togo and Guinea.
Governance	The Executive Board is the decision-making body for UNITAID. It comprises 12 members, one representative nominated by each of the five founding countries (Brazil, Chile, France, Norway, and the United Kingdom); one representative of African countries designated by the African Union; one representative of Asian countries; one representative of Spain; two representatives of relevant civil society networks; one representative of the constituency of foundations and one representative of the WHO.
Diseases and	Technologies: drugs, diagnostics
technologies	
covered	Disease areas: HIV/AIDS, malaria, tuberculosis
Funding	UNITAID is funded by innovative mechanisms such as the solidarity (air ticket) levy and carbon taxes. Together these account for 72% of its total funding. The remaining 28% of the funding comes from voluntary budgetary contributions from Member States and foundations. Member countries decide what rate and for which ticket class the solidarity contributions apply. It is added to existing national airport taxes through law or decree. <sup>21</sup>
	France, United Kingdom and Norway are the top three donors to UNITAID. As of June 2012, nine countries are implementing the solidarity levy to contribute to UNITAID. According to the information available to the Secretariat, at least five other countries are in an advanced stage of adopting it. Since 2006, donors have contributed a total of US\$1.6 billion to the UNITAID trust fund.
Experience in funding and managing R&D	To be completed.
Criteria to distribute funding publicly available	The Proposal Review Committee (PRC) considers the following eligibility criteria when proceeding to the selection of proposals: Impact on health, market dynamics, use of innovation, geographical area, target population, budget estimate, time needed to reach expected impacts on health and market, transition feasibility, complementarity with other international health initiatives and other relevant criteria.
	Further information is available on the website. <u>http://www.unitaid.eu/en/component/content/article/16-home/997-advisory-group-on-funding-priorities-agfp</u>

<sup>20</sup> <u>http://www.unitaid.eu/images/governance/en\_constitution\_rev6july2011.pdf</u>

<sup>21</sup> UNITAID Annual Report 2011

## World Health Organization (WHO) Department of Public Health, Innovation and Intellectual Property

Minutes of	Minutes and resolutions of Executive Board meetings are available on the website.
governing body	http://www.unitaid.eu/en/governance-mainmenu-4/resolutions-mainmenu-34
meetings	
publicly	
available	
Website	www.unitaid.eu