AN EQUAL OPPORTUNITY

ACHIEVING ACCESS 2030

Financing the Strategic Workplan to Address Global Health Research & Development Needs

“Needs-driven innovation is a priority for WHO and for countries.”

Marie-Paule Kieny
Assistant Director-General, WHO
The strategic workplan to improve monitoring and coordination, and to ensure sustainable funding for health research and development was endorsed by all WHO Member States\(^1\) in May 2013 as a follow-up to the Report of the Consultative Expert Working Group on Research and Development: Financing and Coordination.\(^2\)

Full implementation of the strategic workplan requires commitment from Member States to adequately and sustainably fund its objectives. To date, contributions have totalled only US$ 12.7 million, leaving a funding gap of US$ 72.3 million.

**Existing Donors to the Strategic Workplan**

Brazil  
France  
Germany  
India  
Norway  
South Africa  
Switzerland  
United States of America

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WHO/EMP/IAU/2017.01
**Why Financing the Strategic Workplan is a Good Investment**

- **Member State-Driven**
  
  WHO-managed, giving Member States an active role to monitor progress and influence priorities

- **Cost-Effective**
  
  It utilizes existing structures and mechanisms within WHO and does not require the creation of a new hosting structure

- **All-In-One**
  
  Data analysis, priority setting and implementation are integrated into the same mechanism

- **Relevant**
  
  In keeping with the 2030 agenda of leaving no one behind, it targets neglected diseases affecting the poorest populations with the least voice

- **Empowering New Donors**
  
  All donors are welcome, including countries not typically active in multilateral initiatives, such as low- and middle-income countries
US$ 72.3 million in new funding is needed to meet the objectives of the strategic workplan in addition to the US$ 12.7 million already assured for 2014-2017.*

*As of December 2016
FUNDING NEEDS (2014-2017)

1. Improve MONITORING of health R&D
   - US$ 8.8 million

2. Improve COORDINATION of health R&D
   - US$ 0.4 million

3. Ensure SUSTAINABLE FUNDING for health R&D
   - US$ 63.1 million

TOTAL
- US$ 27,000,000
- US$ 85 million

12% of US$ 72.3 million
<1% of US$ 72.3 million
87% of US$ 72.3 million
**Innovative Solutions to Save Lives through Health Research and Development**

**STRATEGIC GOAL**

To develop and deliver health products that address the health needs of developing countries.

**OBJECTIVES**

1. Improve **MONITORING** of health R&D
2. Improve **COORDINATION** of health R&D
3. Ensure **SUSTAINABLE FUNDING** for health R&D
In May 2013, the World Health Assembly adopted resolution WHA66.22, which endorsed a strategic workplan to improve monitoring and coordination and to ensure sustainable funding for health research and development. By adopting the resolution, WHO Member States committed to share responsibility for implementation of the strategic workplan as a step toward achieving the goal of development and delivery of affordable, effective, safe and quality health products for which existing market mechanisms fail to provide incentives for health research and development. The resolution also urged Member States to strengthen health research and development capacities, increasing investments in health research and development for diseases disproportionately affecting developing countries.

Despite these great achievements, significant challenges remain. Gains in life expectancy and quality of life are unequally shared or distributed between low-, middle-, and high-income countries. Troubling disparities in the burden of disease are, in part, attributed to the lack of adequate investment in research and development to address the specific health needs of low- and middle-income countries.

The strategic workplan represents an important step in orienting global health research and development toward priorities that align with unmet needs. Investments in health research and development promise to accelerate progress toward universal health coverage and achievement of the health-related Sustainable Development Goals.

Scientific progress and advances in health technologies - new medicines, vaccines, and diagnostics - have contributed to unprecedented improvements in health outcomes. Development of the smallpox vaccine, the world’s first vaccine, led to the global eradication of smallpox as one of the greatest achievements in public health. Antibiotics revolutionized healthcare, saving millions of lives worldwide, extending healthy life expectancy, and improving the quality of life for countless others. Investments in research and development have resulted in novel, life-saving therapies for the treatment of HIV, cancer, diabetes, and heart disease, for example.
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Improve

MONITORING

of health R&D
The Global Observatory on Health Research and Development is a centralized and open-data platform hosted at WHO that aims to collate, monitor and analyse information on health research and development. The Observatory will contribute to the identification of gaps and opportunities for health research and development and help define priorities for new research and development investments. In its first phase, the Observatory integrated available data on funding for health research and development, health products in the pipeline, clinical trials and research publications.

**Disease-Specific and Country-Specific Overviews of Health R&D**

To better inform future health research and development investment decisions, the Observatory will generate overviews of the status of health research and development by disease and by country. These analyses will contribute to the priority-setting mechanism as part of the coordination objective of the strategic workplan as well as support local capacity strengthening.

As a global point of access for relevant data on health research and development, the Observatory will also develop norms and standards for classification of health research and development, including common reporting formats, in order to collect and collate information systematically.
Improve COORDINATION of health R&D
Global demand for better coordination of health research and development uniquely intersects with WHO’s constitutional mandate to act as the coordinating authority on international health work. In order to maximize synergies, the WHO Expert Committee on Health Research and Development will provide technical advice on the prioritization of global health research and development based on the public health needs of developing countries.

The Committee’s advice will be based on the data and analyses provided by the Observatory and complemented by regional and national strengthening of health research and development capacities. Recognizing the inter-linkage of monitoring, coordination and financing and to facilitate transparent decision-making, the Observatory and the Committee will work together with the Scientific Working Group of a voluntary pooled fund, which is described in objective three of the strategic workplan.
SUSTAINABLE FUNDING
for health R&D

Ensure
**Action**

**Voluntary Pooled Fund to Support Research and Development**

As agreed by Member States, a dedicated budget stream was established to finance the strategic workplan. This budget line is managed by UNICEF/UNDP/World Bank/WHO Special Programme for Research and Training in Tropical Diseases (TDR). To ensure sustainable funding for health research and development, TDR further explored the possibility of hosting a pooled fund for voluntary contributions to finance development of needed health products, diagnostics, vaccines and treatments, from promising leads through to the launch of a new product.¹

To enable transparent, objective and non-political decision-making, a Scientific Working Group would be responsible for the management of the health product projects portfolio, including detailed analyses of the research and development landscape; the identification of project types with high feasibility and impact potential; the development of calls for proposals; the monitoring and evaluation of projects; and the financing recommendations of selected projects.

In order to accelerate and fill the gaps in the research and development pipeline for diseases primarily affecting low- and middle-income countries, TDR concluded that a fund size of US$ 100 million or more per year would be necessary to reduce the gaps in research and development and produce the results in product development that are needed to have and impact on the targeted diseases. Subject to the availability of new funding, TDR can adapt the mechanisms it has in place to accommodate a new financial mechanism to support health research and development.
Interim Phase

1. Improve MONITORING of health R&D
2. Improve COORDINATION of health R&D
3. Ensure SUSTAINABLE FUNDING for health R&D
HEALTH RESEARCH AND DEVELOPMENT DEMONSTRATION PROJECTS

As an interim phase to demonstrate the effectiveness of alternative, innovative and sustainable financing and coordination approaches to address identified R&D gaps, the WHO Secretariat in conjunction with experts and Member States identified six health research and development demonstration projects. These projects are aimed at developing health technologies for diseases that disproportionately affect developing countries and for which identified research and development needs remain unaddressed due to market failures. Each of the six projects are at different stages of implementation and are briefly described in the next section.

Demonstration Project Selection Criteria

- address identified research and development gaps related to discovery, development and/or delivery, including promising product pipelines, for diseases that disproportionally affect developing countries, particularly the poor, and for which immediate action can be taken;
- utilize collaborative approaches, including open-knowledge approaches, for research and development coordination;
- promote the de-linkage of the cost of research and development from product price; and
- propose and foster financing mechanisms including innovative, sustainable and pooled funding.

Ad-hoc Committee on Health Research and Development

The Ad-hoc Committee was established in 2015 with representation from all WHO regions. The Committee meets to review progress of the demonstration projects and of the Observatory. It makes recommendations for approval by the TDR Joint Coordinating Board on allocation of available funds in line with the objectives and the stage of implementation of each project.
Development of Easy-to-Use and Affordable Biomarkers as Diagnostics for Type II and III Diseases

This project aims to deliver simple, affordable, sensitive, and specific field diagnostics for the prevention and control of diseases affecting mostly developing countries.

Exploiting the Pathogen Box: An International Open-Source Collaboration to Accelerate Drug Development in Addressing Diseases of Poverty

This project aims to deliver new drug discovery projects for numerous neglected diseases that disproportionately affect developing countries and for which identified research and development gaps remained unaddressed due to market failures.

The Visceral Leishmaniasis Global Research and Development and Access Initiative

This project addresses some of the critical research and development gaps in order to provide supporting tools to meet the WHO elimination goals for visceral leishmaniasis.
**Multiplexed Point-of-Care Test for Acute Febrile Illness**

The project aims to deliver a low-cost, multiplex point-of-care diagnostic test for the differential diagnosis of fever/sepsis, thus enhancing treatment options and reducing inappropriate use of antibiotic drugs.

**Project Proponent**
Translational Health Science and Technology Institute, India

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**Development of a Vaccine Against Schistosomiasis Based on Recombinant Sm14, a Member of the Fatty Acid Binding Protein Family: Controlling Transmission of a Disease of Poverty**

The objective of this project is to develop the recombinant Sm14 protein as an anti-Schistosomiasis and potentially a multi-valent, anti-helminth vaccine.

**Project Proponent**
Oswaldo Cruz Foundation, Brazil

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**Demonstration of the Potential of a Single-Dose Malaria Cure of Artemether-Lumefantrine Through Reformulation in a Nano-Based Drug Delivery System**

The primary objective is to demonstrate the potential of a single-dose cure (or at least a reduced dosage form) for artemether-lumefantrine.

**Project Proponent**
Council of Scientific and Industrial Research, South Africa
“With the launch of the Sustainable Development Goals, we have committed to achieving health for all. Promoting innovation and access to medicines is the necessary first step.”

Malebona Precious Matsoso
Director General of Health, South Africa
QR Codes to Key Documents

4. http://apps.who.int/iris/bitstream/10665/204522/1/9789241510295_eng.pdf?ua=1
5. http://www.who.int/phi/OEM_Reporting_template_DevEasyUseAffordableBiomarkers.pdf?ua=1
6. http://www.who.int/phi/OEM_Reporting_template_ExploitingPathogenBox.pdf?ua=1
10. http://www.who.int/phi/OEM_Reporting_template_Vaccine_against_schistosomiasis.pdf?ua=1

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