Assessing EU Funding for R&D for Poverty-Related and Neglected Diseases

Research report commissioned by the EACH Coalition

Report developed by:

SEEK development
STRATEGIC AND ORGANIZATIONAL CONSULTANTS

POLICY CURES
Investing for Impact in R&D for Poverty-Related and Neglected Diseases: Assessing the European Union’s funding schemes

Research report commissioned by the EACH Coalition

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About the EACH Coalition
6.5 million people die from neglected infectious diseases every year but only 4% of new drugs and vaccines approved between 2000-2011 were developed to address these diseases. The European Advocacy Coalition for Global Health R&D (EACH), an informal group of organisations with interest and expertise in advocacy for research for global health has come together to address the imbalance in funding for global health innovations. The EACH coalition campaigns for a more enabling funding environment for global health innovations at EU level and advocates for the adoption of norms that ensure that final products are suited for patients’ needs in developing countries and made accessible and affordable in an equitable manner for all, when developed with support from the EU.

The partners behind this initiative are Aeras, DNDi, DSW, Global Health Advocates France, HAI, Medicines for Malaria Venture, PATH, Results UK and TB Alliance, who collectively commissioned SEEK Development and Policy Cures to prepare this report. The authors of this report and the EACH Coalition would like to thank all of the individuals, organisations, EU officials and Member State representatives who contributed their time and expertise.
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### Acronyms and Abbreviations

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<th>Acronym</th>
<th>Description</th>
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<tr>
<td>AMR</td>
<td>antimicrobial resistance</td>
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<tr>
<td>CORDIS</td>
<td>Community Research and Development and Information Service</td>
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<td>DALY</td>
<td>disability-adjusted life year</td>
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<td>EC</td>
<td>European Commission</td>
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<td>EDCTP</td>
<td>European &amp; Developing Countries Clinical Trials Partnership</td>
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<td>EDCTP1</td>
<td>EDCTP Phase 1: 2003 - 2014</td>
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<td>EDCTP2</td>
<td>EDCTP Phase 2: 2014 - 2024</td>
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<td>EFPIA</td>
<td>European Federation of Pharmaceutical Industries and Associations</td>
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<td>ERC</td>
<td>European Research Council</td>
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<td>EU</td>
<td>European Union</td>
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<td>FP</td>
<td>Framework Programmes for Research and Innovation</td>
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<td>GA</td>
<td>General Assembly</td>
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<td>H2020</td>
<td>Horizon 2020</td>
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<tr>
<td>HIV/AIDS</td>
<td>Human Immunodeficiency Virus/Acquired Immune Deficiency Syndrome</td>
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<td>IMI</td>
<td>Innovative Medicines Initiative</td>
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<td>IP</td>
<td>intellectual property</td>
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<td>IPR</td>
<td>Intellectual Property Rights</td>
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<td>MS</td>
<td>Member State</td>
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<td>MSC</td>
<td>Marie Sklodowska-Curie actions</td>
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<td>NID</td>
<td>neglected infectious disease</td>
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<tr>
<td>NTD</td>
<td>neglected tropical disease</td>
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<tr>
<td>PanACEA</td>
<td>Pan-African Consortium for the Evaluation of Antituberculosis Antibiotics</td>
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<td>PDP</td>
<td>product development partnership</td>
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<td>PRINDs</td>
<td>poverty-related and neglected diseases</td>
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<td>PSIA</td>
<td>Participating States Initiated Activities</td>
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<td>R&amp;D</td>
<td>research and development</td>
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<td>SAC</td>
<td>Scientific Advisory Committee</td>
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<td>SME</td>
<td>small and medium-sized enterprises</td>
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<td>SRA</td>
<td>Strategic Research Agenda</td>
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<tr>
<td>TB</td>
<td>tuberculosis</td>
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<td>UK</td>
<td>United Kingdom</td>
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<td>US</td>
<td>United States</td>
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<td>WHO</td>
<td>World Health Organization</td>
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Substantial achievements were made in the last decade in research and development (R&D) of health technologies for poverty-related and neglected diseases (PRNDs). However, there is still a significant lack of medical tools to tackle these diseases, including HIV/AIDS, malaria, tuberculosis, and lesser-known infectious diseases, which together kill an estimated 6.5 million people in low- and middle-income countries annually, and affect more than 1 billion people globally. Many PRNDs pose a threat to Europe, but the world’s poorest populations are disproportionately affected. To achieve the Sustainable Development Goals (SDGs) — particularly SDG 3: “Ensure healthy lives and promote well-being for all at all ages” — it is of paramount importance that we reduce this disease burden. This will require the development of new drugs, vaccines, diagnostics, vector control products, and other health technologies, and public-sector support is needed for their development. This report assesses which of the relevant European Union (EU) funding mechanisms are best suited to successfully support R&D for new health technologies for PRNDs. Whilst the report’s main aim is to assess the suitability of EU funding mechanisms for advancing PRND R&D and to suggest what needs to be improved, it also reviews the EU’s support for new tools to counter antimicrobial resistance, which has become a growing threat in recent years, and which faces some of the same challenges to innovation as PRND R&D.

Two characteristics distinguish the PRND R&D process. First, because PRNDs disproportionately affect the world’s poorest populations, there is limited to no commercial market for health technologies to address these diseases. Thus, the public sector needs to provide funding for R&D to deliver these tools. Second, as products of public investment, the new tools should be global public goods. They must be appropriate, affordable, and accessible for the people who need them.

The EU is the third largest public funder of neglected disease R&D, as defined in the G-FINDER report, accounting for 3.7% of global public financing for PRND R&D in the period between 2007 and 2014. It ranks slightly behind the UK government (3.9%), and a long way behind the US government (46%). The vast majority of funding is delivered through the EU’s three funding mechanisms: (1) Framework Programmes for Research and Innovation (FP)/Framework Programme health-related calls for proposals; (2) the European & Developing Countries Clinical Trials Partnership (EDCTP); and (3) the Innovative Medicines Initiative (IMI). This report assesses how these mechanisms are placed to fund PRND R&D and where there is need for improvement.

The main conclusion is that the impact of the EU’s past investments could have been greater if the programmes had been better tailored to account for the distinctive characteristics of PRNDs. The latest iterations of the EU funding mechanisms include several significant improvements that could promote effective PRND R&D, but not all changes were entirely positive, and major gaps remain. Each mechanism’s improvements and remaining gaps are examined in detail in the analysis below.

The product development process begins with early-stage research, and carries through to clinical trials, regulatory approval, registration, and uptake by national health care systems. Unlike R&D for diseases with a commercial market, PRND R&D relies on public and philanthropic funding to support candidates beyond the early stage of research, all the way through costly late-stage clinical trials. EU funding has supported basic and early-stage
research for both PRNDs and other diseases, but this support needs to be available for product developers conducting late-stage R&D for PRNDs as well. It also needs to take into account that only very limited global capacity exists, and where it does, it might not be located centrally in Europe, but rather, focused on countries with the greatest disease burden.

One of the primary reasons the EU’s funding mechanisms fail to promote effective development of global health technologies is that the EU pursues conflicting aims with its investments. On the one hand, it seeks to promote global health and recognises the need for new medical tools. On the other hand, it implements this aim under its research and innovation framework, whose primary focus is to promote economic competitiveness and growth.

The result of this divergence is reflected in many of the shortcomings of the EU’s mechanisms assessed here:

- PRND R&D is complex and demanding, making coordination and contributions from research institutes, industry, nongovernmental organisations, and academia important. Restrictive eligibility criteria, such as on organisation type, forms of cooperation, geographic origin, and co-funding arrangements, hamper the EU’s ability to select and financially support the best projects. This is especially pertinent for late-stage PRND R&D and translational research. Narrow selection criteria restrict applications from product developers and especially from product development partnerships because of their portfolio approach, since the EU funds only individual projects. Lengthy application processes may restrict applications from smaller organisations, including small pharmaceutical and biotechnology firms, which do not have the capacity for or experience with these processes.

- The technologies developed for global health purposes need to be appropriate, affordable, and accessible to be effective, but EU funding mechanisms fail to demand and monitor this. There are no mandatory conditions on affordability, accessibility, and suitability in the respective governing documents, Work Programmes, strategic business documents, or calls for proposals (“calls”). This is a significant shortcoming in the EU’s support for PRND R&D. Without mandatory provisions on access, the goal of reaching the people in greatest need cannot be achieved. The EU urgently needs to commit to making the results of its funded R&D accessible to all.

**Recommendations**

To improve the effectiveness of EU funding and to address the gaps stated above, we recommend that the European Commission develop a comprehensive PRND R&D funding strategy with clear objectives and an implementation plan, focused on delivering appropriate and accessible new health technologies to achieve the EU’s global health aims. The strategy should:

- Cover the full product development cycle and all diseases and technologies relevant to the EU’s global health priorities, whilst reflecting the differences between PRND R&D and other innovation supported by the EU.
• Entrench comprehensive provisions for both patient and data access, especially through calls and their evaluations. This is vital to ensure that the outputs of EU-funded research can directly improve global health, and to facilitate improved collaboration within consortia.

• Improve the existing mechanisms and generate greater synergies between them. This can be achieved by:
  
  - Supporting the transition of PRND projects funded under FP calls to EDCTP2 (where eligible), including through the provision of bridge funding, and providing funding for late-stage development of those projects ineligible for EDCTP2.
  
  - Relaxing eligibility requirements for future PRND-related calls to facilitate the involvement of organisations with PRND product development experience, and reducing restrictions on the location and origin of consortia members under EDCTP2, to accommodate consortia that manage larger projects and portfolios.
  
  - Improving alignment of IMI2 priorities with PRND needs. In principle, the mechanism would be suitable to support PRNDs since the World Health Organization’s Priority Medicines for Europe and the World 2013: Update features in IMI2’s Strategic Research Agenda. Yet, PRNDs are currently not a focus. If the mandate reflected PRND R&D needs more strongly, IMI2 could become a strong mechanism of support for PRND R&D.
The last decade has seen increased investments in global health research and development (R&D) to address the needs of poor and marginalised populations, and impressive gains in tackling global health problems. Despite these advances, however, there is still a significant lack of new tools to diagnose, prevent, and treat poverty-related and neglected diseases (PRNDs), such as HIV/AIDS, malaria, tuberculosis (TB), sleeping sickness, and worm and parasitic infections. (For the purposes of this report, PRNDs refer to the 35 neglected diseases listed in detail in Appendix 1.) Tackling these diseases by producing and distributing appropriate medical tools will be crucial to achieving the Sustainable Development Goals, but funding for R&D for tools to diagnose, treat, and prevent PRNDs is not proportionate to their global public health importance. R&D in this area is chronically underfunded, primarily because the target beneficiaries are the world’s poorest and most marginalised people; thus, the commercial market is limited, even though the diseases cause a tremendous annual death and disability toll. It is estimated that PRNDs are responsible for more than 6.5 million deaths in the developing world, and more than 300 million disability-adjusted life years. A 2013 study reported in The Lancet found that 26 PRNDs contributed to 14% of the global disease burden, but received only 1.4% of global health-related R&D expenditure. The European Union (EU) is the third largest public funder of PRND R&D worldwide. Between 2007 and 2014, it provided 3.7% of global PRND R&D funding, as well as €263 million for antimicrobial resistance (AMR).

The primary purpose of this report is to review the conditions put in place by EU funding schemes to stimulate the development of adapted, affordable, and accessible tools to diagnose, treat, and prevent PRNDs. Specifically, this report aims to address three overarching questions:

1. Which mechanisms within relevant EU programmes are best suited to promote the development of new health technologies to address PRNDs?
2. Will these mechanisms ensure that these tools are affordable, accessible, and suitable for patients most in need?
3. How can the mechanisms be improved?

Whilst the report focuses on EU funding mechanisms for PRND R&D under the EU’s research programme, Horizon 2020, it also reviews the EU’s support for new tools to counter AMR, which poses a significant threat to populations (and health systems) in developing countries. However, we note that this EU-funded AMR R&D activity, whilst likely to be of benefit to developing countries, is largely being conducted to address the health needs of high-income countries. All PRND-specific AMR R&D has been included in the PRND totals.

* Disability-adjusted life years (DALYs) refers to single ‘healthy’ life years lost in a population. Accumulated across a population, they allow for an estimation of the burden of a particular health issue, such as diseases. DALYs are the sum of years of life lost due to premature mortality in the population and years of life lost due to disability for people living with the consequences of disease.
◊ The study includes 26 of the PRNDs listed in Appendix 1.
** G-FINDER and CORDIS data are in 2014 EUR prices; i.e., adjusted for currency and inflation. The programme budget values used are those stated by the organisation and have not been adjusted.
1.1 Methodology

We conducted a comprehensive analysis of financing flows and a desk review of relevant primary and secondary documents, including calls for proposals, governing statutes, and reports, as well as external evaluations and position papers from advocacy groups and think tanks. In addition, we conducted 12 semi-structured interviews with representatives of the European Commission (EC), European & Developing Countries Clinical Trials Partnership (EDCTP), product development partnerships (PDPs), nongovernmental organisations, the pharmaceutical industry, and the media (see Appendix 2 for details on the interviewees).

Product developers

Product developers encompass all actors that engage in producing new health technologies. These may include large international pharmaceutical corporations and small and medium-sized biotechnology companies, as well as PDPs.

PDPs are nonprofit organisations that develop new and improved medical tools through partnering with the public and private sectors, and by combining both public and philanthropic funding. They manage a portfolio of different products using commonplace management approaches, but select candidates on the basis of public health returns rather than commercial returns.6
2. What is the EU’s strategy for promoting product development for global health?

The EU has no explicit strategy or work plan that addresses global health. However, it does have a clear commitment to advance global health R&D, which has been articulated in various documents. Two strategic documents are particularly relevant for the EU R&D funding landscape for PRNDs:

1. Global health policy, as outlined in a report by the EC to the Council of the European Union on the EU’s role in global health.\(^7,8\)

2. Europe 2020, the EU’s ten-year growth strategy.\(^9\)

The EU’s global health policy includes a clear commitment to R&D. The Council of the European Union has stated that the EU is committed “to [promoting] effective and fair financing of research that benefits the health of all”.\(^8\) It also highlights that research priorities should focus on those interventions with the “biggest impact on public health”, and that “access and innovation need to be addressed simultaneously”.\(^7\) There is a clear commitment to global health R&D, yet it is only one priority amongst many and no action plan has been developed.

The primary objective of the EU’s R&D strategy, the Innovation Union, is to promote economic growth through innovation.\(^10\) It has no goals at the strategic level related to global health or PRND R&D in particular. The Innovation Union is part of Europe 2020, the EU’s strategy to achieve “smart, sustainable, and inclusive growth”. Innovation is identified as the main driver of economic growth within the EU.\(^10\) A core mechanism to promote innovation is the series of Framework Programmes for Research and Innovation (FP), initiated in 1984. The current (eighth) edition is called Horizon 2020. It is by far the largest programme and focuses on three key areas: Excellent Science, Industrial Leadership, and Societal Challenges.\(^11\)

This strategic orientation towards growth through innovation can be traced all the way through to health R&D. Amongst the Societal Challenges, Societal Challenge 1, Health, Demographic Change and Wellbeing, includes the objective to “improve lifelong health and well-being of all”.\(^12\) However, it also has the strategic goal to promote growth, create jobs, and establish Europe as a leader in the field. This challenge also references HIV/AIDS, TB, malaria, emerging epidemics, re-emerging infectious diseases, and the growing AMR threat, and highlights that European R&D efforts need to foster cooperation with developing countries and involve all stakeholders to address “global challenges, […] deliver better health and well-being for all, and position Europe as a leader in the rapidly expanding global markets”.\(^12\) No reference is made to unmet public health needs as drivers for public investment. Nor does the challenge mention tackling market failures or calls for publicly funded medical tools to be affordable, suitable, and accessible. Yet it does emphasise the need to ensure the competitiveness of the European industry.\(^12\)

Thus, at the strategic level, EU support for R&D is primarily geared toward the overarching goal of economic growth. Global health does not play a significant role at this level. This is especially problematic for PRND and AMR R&D as it is unlikely to be seen as a major driver for European competitiveness and economic growth. Hence, R&D for PRNDs and AMR will likely be subordinated to other goals that are perceived to be more conducive to achieving economic goals.
3. Overview of EU funding for R&D and the place of PRNDs

Horizon 2020 has a budget of nearly €80 billion\textsuperscript{13} for the period 2014-2020 and is the primary vehicle through which the EU seeks to promote research and innovation. Since the commencement of the FP in 1984, each iteration has included at least one theme related to health, most recently: Life Sciences in FP 6; Health in FP 7; and Societal Challenge 1, Health, Demographic Change and Wellbeing, in Horizon 2020.

Most funding for PRND and AMR R&D has been channelled through Framework Programmes, either directly through their multi-annual Work Programmes, or through the Innovative Medicines Initiative 1 (IMI1) and EDCTP1 strategic initiatives (see Figure 1). Both initiatives fit within Societal Challenge 1 but operate under different models, have their own budgetary powers, are funded through the biannual Societal Challenge 1 Work Programmes, and have specific objectives, as described below.

Funding for PRND R&D is potentially available through other themes of Horizon 2020 (and its predecessors), including the European Research Council, Marie Skłodowska Curie Actions, and the Executive Agency for Small and Medium-sized Enterprises and Research Infrastructures, as well as from other EU directorates (e.g., Directorate-General for International Cooperation and Development). However, these alternative sources are not evaluated further in this report as they have provided less than 1% of historical EU PRND and AMR R&D investment.\textsuperscript{14}

\textbf{Figure 1.} Structure of EU funding for PRND R&D under Horizon 2020.
The tables below summarise the key features of the three funding mechanisms discussed in this report.

**Table 1. Horizon 2020 Work Programmes under Societal Challenge 1: Health, Demographic Change and Wellbeing.**

| **Objectives** | • Improve health and well-being outcomes; promote healthy and active ageing; promote market growth, job creation, and the EU as a global leader in the health arena. |
| **Scope** | • Full spectrum of health research.  
• Primary focus on health challenges faced by the European population; also covers diseases with a high global health burden.  
• Open to global participation; funding available only to the 28 EU Members States plus Horizon 2020 Associated Countries (see Appendix 3 for a list of Associated Countries), developing countries, and the United States (special exemption under Societal Challenge 1).  
• Target of at least 20% of Societal Challenge 1 budget to benefit small and medium-sized enterprise participants.1,15 |
| **Budget** | • €5.0 billion available for Societal Challenge 1 Work Programme calls for the period 2014-2020, from a total Societal Challenge 1 budget of €7.5 billion. The remaining €2.5 billion is budgeted for IMI, EDCTP, and Active and Assisted Living.  
• €1.2 billion of the €5.0 billion is budgeted for 2014-2015 priorities and €934 million for 2016-2017 priorities. |
| **Sources of funding** | • EU funding under Horizon 2020 (administered by the Directorate-General for Research and Innovation).  
• Requirement for co-funding from the applicants in most cases. |
| **Form of R&D investment** | • Two-year Work Programmes; open competitive calls on defined strategic priorities.  
• Primarily grant funding: two to five years; common range €3 to €12 million per project.  
• Consortia approach: minimum of three partners from three EU Member States (commonly ten to 20 partners).  
• Non-grant funding, for example the Horizon Prize for better use of antibiotics. |
| **Relevance of PRNDs to overall scope of mechanism** | • PRNDs are a fraction of the scope of Societal Challenge 1, but are explicitly acknowledged, as well as being the subject of specific calls.  
• Annual PRND R&D funding of more than €85 million in previous Framework Programmes. |
| **PRND scope** | • All PRNDs are within scope, although specific priorities are defined only in individual calls. |

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§ Small and medium-sized enterprises: Small pharmaceutical and biotechnology companies with revenues of less than US$10 billion per annum and which conduct the majority of their business in one country.

**\*\* This is the maximum amount of the EU’s financial contribution, to equal the contributions of Participating States.**

○○ Any legal entity other than a Member or a constituent/affiliated entity of a Member, may apply to become an Associated Partner. Previous examples include charities and organisations working in sectors related to health care.
OVERVIEW OF EU FUNDING FOR R&D AND THE PLACE OF PRND S

This is the maximum amount of the EU's financial contribution, to equal the contributions of Participating States.

Any legal entity other than a Member or a constituent/affiliated entity of a Member, may apply to become an Associated Partner. Previous examples

Small and medium-sized enterprises: Small pharmaceutical and biotechnology companies with revenues of less than US$10 billion per annum and which

• All PRNDs are within scope, although specific priorities are defined only in individual calls.
• Annual PRND R&D funding of more than €85 million in previous Framework Programmes.
• Non-grant funding, for example the Horizon Prize for better use of antibiotics.
• Consortia approach: minimum of three partners from three EU Member States (commonly ten to
• Primarily grant funding: two to five years; common range €3 to €12 million per project.
• Two-year Work Programmes; open competitive calls on defined strategic priorities.
• Requirement for co-funding from the applicants in most cases.

EU funding under Horizon 2020 (administered by the Directorate-General for Research and

€5.0 billion available for Societal Challenge 1 Work Programme calls for the period 2014-2020,
• Target of at least 20% of Societal Challenge 1 budget to benefit small and medium-sized
• Open to global participation; funding available only to the 28 EU Members States plus Horizon
• Primary focus on health challenges faced by the European population; also covers diseases with a
• Full spectrum of health research.
• Improve health and well-being outcomes; promote healthy and active ageing; promote market

Table 2. European & Developing Countries Clinical Trials Partnership 2.

| Objectives | • Accelerate the development of new or improved health technologies for PRNDs in sub-Saharan Africa. |
| Scope | • Drugs, vaccines, microbicides, and diagnostics.  
• Sub-Saharan Africa.  
• Clinical trials (Phases I–IV), with a focus on Phases II and III.  
• Capacity-building; regulatory-strengthening. |
| Budget | • Approximately €1.4 billion for the period 2014-2024 (including third-party funding). |
| Sources of funding | • €683 million from the EU under Horizon 2020 Societal Challenge 1 strategic initiatives.  
• €683 million (cash or in-kind) from EU Participating States.  
• Goal of €500 million additional investment (cash or in-kind) from other funders. |
| Form of R&D investment | • Annual work plans.  
• Open competitive calls.  
• Two to five grants per call.  
• Project duration of up to 36 months.  
• Consortium approach. |
| Relevance of PRNDs to overall scope of mechanism | • PRNDs are the primary focus (including research capacity-building for countries with highest PRND burden). |
| PRND scope | • HIV/AIDS, TB, malaria and other neglected infectious diseases (see Appendix 1 for diseases). |

Table 3. Innovative Medicines Initiative 2.

| Objectives | • Promote collaborative projects between industry, academia, and others to hasten the development of new medicines; enhance the competitiveness of the European health care sector; address the challenges facing the European health care system. |
| Scope | • Primarily pre-competitive research aimed at facilitating the R&D process rather than product development.  
• Disease priorities defined by the World Health Organization’s Priority Medicines for Europe and the World: 2013 Update, but primarily those that affect the health of Europeans or the European health care industry. |
| Budget | • €3.3 billion for the period 2014-2024. |
| Sources of funding | • €1.6 billion from the EU under Horizon 2020 Societal Challenge 1 strategic initiatives.  
• €1.4 billion (in-kind) from European Federation of Pharmaceutical Industries and Associations (EFPIA) companies (EU multinational corporations).  
• €213 million (in-kind) from others (non-EFPIA industry). |
| Form of R&D investment | • Open and competitive calls for proposals.  
• EU provides grant funding (typically €2 to €25 million) to recipients; academia, research organisations, patient organisations, and small to medium-sized enterprises (SMEs) are eligible.  
Pharmaceutical companies (non-SMEs) are ineligible.  
• Recipients form a consortium with EFPIA companies; may also include Associated Partners. |
| Relevance of PRNDs to overall scope of mechanism | • Limited relevance, with some exceptions:  
- AMR is one of 11 European Health Priorities addressed by IMI2.  
- Ebola+ programme announced in response to 2014 epidemic.  
- Possible non-disease-specific pre-competitive vaccine research is another of the 11 priorities. |
| PRND scope | • Technically, all PRNDs are eligible.  
• In practice, primarily AMR and Ebola. (TB is the only other PRND to receive IMI funding.) |
4. EU support for PRND and AMR R&D: How has it fared so far and what is the outlook?

4.1 Overview of EU funding provided for PRND and AMR R&D

European public organisations provided nearly 15% of global PRND R&D investment from 2007 to 2014. The majority of this (70%) was contributed by public organisations in Member States, whilst one quarter came from the EU. Overall, the EU directly contributed 3.7% of global PRND R&D investment between 2007 and 2014. (See Figure 2.)

Framework Programme investment was cyclical, in line with the timing of the various programmes; FP 6 ran from 2002 until 2006, but disbursements continued until 2012; FP 7 ran from 2007 to 2014; and Horizon 2020 began in 2014 but with minimal investment in PRNDs in its first year. Funding for EDCTP was relatively stable from 2009 to 2013, with smaller disbursements at the beginning and end of the cycle (2007-2009 and 2014). IMI spending increased over the past three years, driven by two large AMR grants. (See Figure 3.)

Figure 2. The EU’s contribution to global PRND R&D, 2007-2014.

MS: Member States.

 Including academic institutions, government research organisations, public sector and public pharmaceutical companies from European countries (EU Member States as well as non-Member States), including EU.

 Figure excludes AMR, as AMR is not included in G-FINDER.

 Figures include projects within Framework Programmes 6 and 7, Horizon 2020, and other programme funding.
The majority (75%) of EU investment in PRND and AMR R&D was directed through Framework Programme health-related calls for proposals. Figure 4 shows the focus and size of each mechanism.
4.2 Review of past programmes

**Work Programmes under Horizon 2020**

Between 2007 and 2014, three-quarters of all EU funding for PRND R&D came from the Work Programmes of FP 6, FP 7, and Horizon 2020—a total of €788 million.

FP 7, which ran between 2007 and 2014, was the source of two-thirds of all Work Programme funding for PRNDs (€511 million, 65%). FP 6 calls finished in 2006 but disbursements continued after the end of the programme.

**Figure 5.** Work Programme spending for PRND and AMR R&D, 2007-2014.


Work Programme funding was heavily focused on AMR, malaria, TB, and HIV/AIDS.

Despite the broad scope of the Framework Programmes, AMR, malaria, TB, and HIV/AIDS collectively received 80% of all funding between 2007 and 2014, €631 million of the €788 million total. The remaining €158 million (20%) was shared amongst other PRNDs. Of these, only kinetoplastids and helminths received 5% or more of all PRND and AMR R&D Work Programme funding. (See Figure 6.)
Work Programme funding was almost exclusively for basic and early-stage research

The majority (74%) of FP 7 Work Programme funding for PRND R&D was for basic and early-stage research, compared to 6% for late-stage research. This is typical of science and technology agency funding, which is largely driven by scientists engaged in basic research, with minimal focus on advancing candidates through the research pipeline. The focus of Work Programme funding on basic and early-stage research is not restricted to PRNDs; it reflects a funding approach that is primarily designed for a market-based system, which aims to create knowledge and promising leads, with the assumption that late-stage development and commercialisation will be funded by the private sector. Whilst this may be appropriate for diseases for which a commercial market for products exists, the assumption does not hold for PRNDs. PRND projects that do not fall within the scope of EDCTP—for example, trials that are not conducted in Africa, or research for diseases that are not within EDCTP’s scope (malaria, HIV/AIDS, TB, and neglected infectious diseases (NIDs) (see Appendix 1)), are at risk of not progressing to late-stage product development because industry will not pick up the projects for commercialisation, leaving them reliant upon public or philanthropic support.

Only a small proportion of Work Programme funding went to organisations with product development expertise

The focus on upstream research is reflected in the recipient breakdown of Work Programme PRND R&D funding. Just 11% (£12 million) of 2014 funding went to small and medium-sized enterprises (SMEs), despite there being a clear SME participation target of 15% for FP 7, and the adoption of specific measures in the 2010 and 2011 Work Programmes to strengthen SME engagement.

Product developers are, by definition, focused on results, so they could be expected to be attractive targets for investment under the 2010 EU budget review, which recommends that
EU budget expenditure be “[focused] on instruments with proven European added value, becoming more results-driven and leveraging other public and private sources of funding”. However, PDPs have not received significant funding from the EU; less than 1% (€0.7 million) went directly to PDPs in 2014. Once again, we are reminded that global health objectives are not seen to align with objectives of economic growth and competitiveness.

Multiple potential barriers to SMEs’ and product developers’ participation have been identified. Many of these are not specific to PRND R&D, and were highlighted in the interim evaluation of FP 7, whilst some are particularly relevant for product developers with a PRND focus. These include:

- Complexity of the application process.
- Long average time-to-grant under the FP 7 Health theme (351 days).
- Lower than average success rates for SMEs (17% compared to 19% to 22% average success rate).
- Although some calls specifically target PRNDs, other, open calls pit PRNDs against diseases that have greater relevance for Europe, making it difficult for PRNDs to compete.
- Requirements for co-funding.

**European & Developing Countries Clinical Trials Partnership 1**

EDCTP1 was established in 2003 with three specific objectives: (1) coordinate and integrate European national programmes on EDCTP-related activities into a joint programme; (2) strengthen clinical research capacities in sub-Saharan Africa, especially for conducting clinical trials against poverty-related diseases; and (3) support clinical trials of new or improved drugs and vaccines against HIV/AIDS, malaria, and TB in sub-Saharan Africa, with a focus on Phase II/III trials.

EDCTP has three funding schemes (see Figure 7):

- Integrated Activities—projects are selected, administered, and funded by EDCTP.
- Participating States Initiated Activities (PSIA)—funded by the Participating States through cash or in-kind contributions. These activities are included in the EDCTP’s work plan but administered by the Member States.
- Joint Activities—involve EDCTP and other funders such as Participating States or third parties. Calls can be jointly launched through EDCTP and third parties, or EDCTP can issue a call for co-funding of joint activities.

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For the 2014 G-FINDER data, the EC was able to report the amount per participant, but prior to this they only reported the coordinator breakdown, which does not enable us to assess the level of funding going to PDPs over the entire funding period.

Defined as the time elapsed from deadline of a call for submission of proposals to signature of the grant agreement.
However, PDPs have not received significant funding from the EU; less than 1% (€0.7 million) identified. Many of these are not specific to PRND R&D, and were highlighted in the interim.

Although some calls specifically target PRNDs, other, open calls pit PRNDs against diseases that have greater relevance for Europe, making it difficult for PRNDs to compete.

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Of the €212 million disbursed by EDCTP1 from 2003 to 2012, 78% (€166 million) went to clinical trials; the remainder was invested in capacity-building, ethics, and similar programmes. Between 2007 and 2014, spending was relatively evenly distributed between TB (€73 million, 35%), HIV/AIDS (€66 million, 32%), and malaria, which received slightly less (€48 million, 23%). From 2007 to 2014, funding targeted late-stage clinical R&D, which received 87% of product R&D funding (€164 million).

EDCTP1 prioritised improving collaboration and facilitating research capacity-building in African countries, in alignment with its original objective. Between 2007 and 2014, the majority (€135 million, 65%) of PRND R&D investment was given to African recipients.

EDCTP1 funding was spread very thinly

The 2014 review of EDCTP1 recognised the discrepancy between the cost of clinical trials and the typical size of EDCTP grants. The average grant size for EDCTP1-funded clinical trials was €3.2 million, considerably less than the amount needed to conduct trials (often in the tens of millions of Euro, depending on the phase and product). This is particularly true for Phase III trials, which are the most costly, running into the hundreds of millions of Euro. This discrepancy means that researchers must find co-funding, or seek alternative funding. The review recommended that EDCTP focus its efforts on a smaller number of larger projects, rather than a large number of small projects, to optimise the integration of research efforts.

It is commendable that the scope of EDCTP2 has expanded to include neglected diseases and more research phases, but there are concerns that even with the very significant budget increase from EDCTP1 to EDCTP2, the grants will remain too small and EDCTP will not be able to contribute meaningfully to funding Phase III research and registration.

This section focuses on the pooled funding administered by EDCTP.

Figure 7. EDCTP funding structure.

![EDCTP funding structure diagram]

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It is commendable that the scope of EDCTP2 has expanded to include neglected diseases and more research phases, but there are concerns that even with the very significant budget increase from EDCTP1 to EDCTP2, the grants will remain too small and EDCTP will not be able to contribute meaningfully to funding Phase III research and registration.
EDCTP1’s structure limited its ability to integrate with product developers

Despite being the primary mechanism for EU support for clinical development of new PRND products, EDCTP1 allowed limited involvement of industry partners, PDPs, and other product developers. Between 2007 and 2014, SMEs and product developers each directly received less than 1% of EDCTP1 funding, at €2.7 million and €1.4 million respectively. Most funding went to academic institutions (€140 million, 67%).

Structural issues played a major part in this. For example, there is one requirement that the project coordinator has to be employed by a public institution, and another that requires every EDCTP1 project be co-funded by at least two EDCTP European Economic Interest Group Member States. Small, inflexible grants provided only for short periods (two to three years) also made EDCTP1 not particularly well suited for funding product developers.

EDCTP1 began to respond to many of these criticisms regarding financing and the small size of grants for expensive research stages in 2007 with a brokered call for TB drug development, for which a consortium of groups could apply jointly for a drug development grant, as opposed to applying competitively. There were multiple aims of the call: to make sure enough funding was available for relevant trials, and to develop a portfolio, build capacity, and develop a drug development consortium that would be suitable for future projects. As a result, EDCTP1 provided €27 million in funding to the Pan-African Consortium for the Evaluation of Antituberculosis Antibiotics (PanACEA), alongside funding leveraged from PanACEA’s partners, including the Bill & Melinda Gates Foundation, the TB Alliance (a PDP), and government funders.

Innovative Medicines Initiative 1

IMI contributed €60 million in funding to PRND and AMR R&D from 2007 to 2014, representing only 7% of the EU’s share of IMI1’s total budget (€1.2 billion). The vast majority (79%) of IMI’s very limited PRND funding went to academic institutions rather than SMEs or product developers.

IMI has historically demonstrated little interest in most PRNDs

IMI’s primary purpose is to improve the health of the European population by promoting solutions that make the European health care industry more competitive. PRNDs are not a natural fit; therefore, it is not surprising that more than 75% of IMI’s €60 million AMR and PRND R&D investment between 2007 and 2014 went to AMR (€47 million). AMR poses a major threat to global public health and is currently a field of under-investment that can benefit from the diverse skills offered by collaborations. IMI invested €13 million in PRND R&D, funding just two in-scope projects: the PreDiCT-TB consortium of 21 leading European industry and academic research partners in TB, and RAPP-ID (rapid point-of-care test platforms for infectious diseases). Without a specific mandate or separate budget line, PRNDs appear unlikely to receive the focused attention needed to help form public-private consortia to develop innovative new products.
4.3 Which of the current EU financing mechanisms is best suited to support R&D for PRNDs?

The degree to which PRNDs are a focus varies across the mechanisms. EDCTP2 has the strongest focus, as its specific objective is to support R&D for most of these poverty-related and neglected diseases. Compared to EDCTP1, its scope has been broadened to include other neglected diseases in addition to HIV/AIDS, TB, and malaria, as well as to include all clinical trial phases. Horizon 2020’s Health, Demographic Change and Wellbeing challenge does not feature PRNDs on a strategic level, but one or two PRND-specific calls have been issued within each of its biannual Work Programmes. IMI2 does not have a strategic focus on PRNDs either, yet it recently provided support to PRND R&D through a call for proposals for medical interventions against Ebola and other filoviral haemorrhagic fevers, although this Ebola-related support is not part of IMI2’s Strategic Research Agenda (SRA).

The EC took into account the research activities and agendas of EDCTP2 and IMI2 when drafting the Work Programme for Horizon 2020 Societal Challenge 1, in order to avoid overlaps and create synergies. However, interviewees suggested there is little coordination between the mechanisms, and we could not find robust evidence for such coordination.

Nor does Horizon 2020’s overall legal framework include any binding provisions that ensure that tools developed with EU support are accessible, affordable, suitable, and acceptable to populations in resource-poor settings. This conflicts with the EU’s strategy, which stresses the need for wide and affordable access to global health products. The legal framework requires open access only to results in scientific publications. To promote open access to research data, the EC introduced the Open Research Data Pilot, which does not yet apply to Societal Challenge 1 projects.

Lastly, although the award criteria are identical across all three mechanisms—(1) excellence, (2) impact, (3) quality and efficiency of the implementation—they are defined slightly differently within each mechanism, and might be further differentiated within Work Programmes or specific calls. In general, however, these criteria do not pose a hurdle to PRND R&D, but do not specifically further it either. Where the differentiations within Work Programmes or calls might have a potential impact on PRND R&D is analysed below.

**Societal Challenge 1: Horizon 2020 Work Programmes**

Through the Work Programmes of Horizon 2020’s Societal Challenge 1, the EU pursues the objectives of improving health and well-being outcomes; promoting healthy and active ageing, market growth, and job creation; and positioning the EU as a global leader in the health arena.

**Scope and focus**

PRND R&D is not specifically prioritised within Societal Challenge 1, nor in the two Work Programmes issued so far (2014/2015 and 2016/2017). Yet, specific calls within the two Work Programmes have focused on PRNDs: the development of vaccines against TB...
The Societal Challenges 1 Work Programme does not entail provisions for affordable access or suitability.

EU SUPPORT FOR PRND AND AMR R&D: HOW HAS IT FARED SO FAR AND WHAT IS THE OUTLOOK? (2014),**** HIV/AIDS (2015), and malaria and/or NIDs (2016).33 The broadening of scope in terms of diseases makes Horizon 2020 more suitable to fund PRND R&D since it can in principle provide funding for all of them. However, the broadening of scope was not accompanied by an increase of the indicative budget.

Given the fact that PRNDs are included only in specific call topics, the Work Programme drafting process is of particular importance. It is critical that experts in global health and product development, spanning the full spectrum of research—including the regulatory requirements of late-stage R&D—provide input on the specific challenges of PRND R&D during the development of Work Programmes. The lack of inclusion of product development expertise has been criticised in the past. The EC signs off on all Work Programmes but engages in stakeholder consultations and with the Advisory Group for Health, Demographic Change and Wellbeing, which suggests priority areas for the Work Programme.30 The Advisory Group has a broad membership that includes academia, patient organisations, international organisations, and the private sector; some members have product development and global health backgrounds.***,**** The inclusion of such R&D expertise can be evaluated as a first step toward placing stronger emphasis on specific requirements for PRND product development.

Interviewees highlighted the lack of synergy with the other two main mechanisms during the drafting of the Work Programme. The EC attempted to avoid overlap and to create synergies;30 however, there is no indication that increased strategic coordination has occurred. This lack of strategic coordination becomes apparent when studying the three PRND-relevant calls, which all focus on early-stage development; there is no mechanism to ensure that research will move candidates along the pipeline; for example, by providing follow-up funding under EDCTP2. The EC is taking steps in this direction, but these still need to be institutionalised. In all three calls, the EC asked applicants to develop strategies on how to advance their R&D after funding ended, and to incorporate this pathway as an integral part of their proposal. For instance, in the HIV/AIDS call, the EU asked for the “successful proposal to continue its vaccine development in the context of […] EDCTP”.33 Slightly weaker language was used in the malaria call, suggesting that moving candidates along the pipeline should be undertaken within the context of EDCTP, if appropriate.33 In the TB call, the EU requested proposals that incorporated a pathway and commitment to become part of the Global TB Vaccine Partnership and to continue the vaccine development within the context of the initiative, in collaboration with EDCTP.33 This would potentially enable the global funding community, including the EC, to take a portfolio approach, with common milestones and criteria, which could accelerate the development of TB vaccines. The EU has taken initial steps to increase coordination by requiring organisations to chart their plans for the full product development cycle. However, this does not address the lack of overarching strategic coordination across mechanisms.

****** Geneviève Inchauspe, Transgene, part of Institut Mérieux, a publicly traded French biopharmaceutical company focused on discovering, developing, and manufacturing targeted immunotherapies for the treatment of cancer and infectious diseases.
****** Switzerland is associated only with the “Excellent Science” pillar, containing the European Research Council, Future and Emerging Technologies, Research Infrastructures, and the Marie Skłodowska Curie Actions; the actions under the specific objective “Spreading excellence and widening participation”; and the Euratom Programme and the activities carried out by the European Joint Undertaking for ITER and the Development of Fusion for Energy for 2014-2020. See: http://ec.europa.eu/research/participants/data/ref/h2020/grants_manual/hi/3cpart/h2020-hi-list-ac_en.pdf, accessed 17 February 2016.
Access provisions

The only binding provisions related to access are those requiring guaranteed access to scientific publications. There are no provisions for affordable access or suitability. None of the relevant Work Programmes or calls include access requirements. Only one call provided some guidance on access: the 2016 call for the development of vaccines against malaria and/or NIDs asked that proposals take into account that vaccine candidates need to be adapted to the specific requirements of resource-poor settings. The call also asked that proposals include an assessment of the affordability of the vaccine products and their acceptability and suitability for the target group(s).33

We analysed Horizon 2020’s Regulation of Establishment;12 model grant agreements; the intellectual property (IP) guideline document, “Your guide to IP in Horizon 2020”;35 Work Programmes; and relevant calls in 2014, 2015, and 2016 for any provisions or language on accessibility, affordability, and suitability, and also used the interviews to check for any requirements. Overall, there are no mandatory or specific access provisions included in calls or the Work Programmes and there is no indication that they are part of the formal evaluation process. The inclusion of language around access in the 2016 call marks a slight improvement over those under the 2014-2015 Work Programme.

Other barriers and incentives for PRND R&D

- Eligibility to receive funding based on geographic location is a potential challenge for effective PRND R&D. Organisations not based in a EU country, a Horizon 2020 Associated Country (Appendix 3),36 or a specifically listed country37 are not automatically eligible for funding. This provision excludes applicants from countries such as Japan, India, South Korea, and Switzerland from funding.36 Organisations based in the United States are eligible for funding due to a special provision in Societal Challenge 1.33 This is a positive step, but the exemption of many other important stakeholders based on their geographic location is not conducive to effectively supporting the global effort of PRND R&D.
Complexity of the application process, long average time-to-grant, and low success rates are potential barriers for SMEs and other product developers.

- Award criteria do not incentivise PRND R&D but also do not pose a formal barrier: especially in regard to the definition of the "impact" criterion, global health goals are not included. Instead, in the case of Societal Challenge 1, the impact criterion reflects the overall objectives of the Challenge and emphasises innovation capacity and competitiveness of companies. This is not conducive to supporting PRND R&D, and might even disadvantage it, since applicants compete with a high number of competitors from areas outside the PRND area. Many of these may be seen to more effectively advance the EU's economic goals.

- Complexity of the application process, long average time-to-grant, and low success rates are potential barriers for SMEs and other product developers, instead favouring academic research institutes. Many interviewees highlighted these as hurdles. There are indications that Horizon 2020 has reduced the complexity of its application process. In addition, the average time-to-grant has decreased from nearly 12 months in the previous period to a maximum of eight months. However, the application process is still costly, and the odds of getting a Horizon 2020 grant were lower in its first 14 months than they had been under FP 7, at around 14% compared to 19% to 22%. The remaining complexity can still be a hurdle for entities with limited capacity and resources, especially when considering the moderate chances for success.

- The new SME instrument is a potential source for PRND R&D funding. It has a budget of about €3 billion for 2014-2020 and is restricted to SMEs, and can be used to support PRND R&D. The ongoing ADVANTAGE project, for example, uses funding from the SME instrument to develop TB diagnostics.
EDCTP2 aims to accelerate the development of new health technologies for PRNDs, making it the EU’s most relevant funding mechanism for PRND R&D.

**Scope and focus**

PRND R&D is at the core of EDCTP2’s mandate. It is the only mechanism for which PRND R&D is central. The Strategic Business Plan defines EDCTP2 as a research platform for clinical and operational trials against PRNDs.

Whilst PRND R&D features in EDCTP2’s scope and priorities, product development expertise is not adequately represented in the institutions that shape EDCTP2’s priorities. The General Assembly (GA), which drafts the Strategic Business Plan, is the ultimate decision-making body, and, together with the Scientific Advisory Committee (SAC), shapes priorities. Whilst the GA features representatives of all Participating States, the SAC is composed of scientists only. A review of SAC member profiles revealed that they seem to have limited product development experience, raising concern that product development may receive less attention than needed.

EDCTP2 has taken an important step toward ensuring that the mechanism’s R&D priorities are aligned with developing countries’ health priorities. African Participating States are now full members, and are equally represented in the GA. EDCTP2’s legal status was changed to make this possible. Interview partners noted that European states will, however, likely remain more influential, as they provide the lion’s share of funding to the mechanism. Yet, a greater inclusion of African members may lead to more pronounced consideration of the suitability of products.

EDCTP2’s ability to set its priorities independently is limited by funding constraints. Of the €57 million provided by the Participating States for the implementation phase in 2015, only €10.5 million in cash was earmarked for allocation to EU-funded projects. The remaining €46.5 million comprised in-kind contributions within the PSIA. This weakens EDCTP2’s overall funding volume and its ability to deploy its funding strategically, since, for example, late-stage clinical trials are very expensive. The limited cash available to EDCTP2 could result in oversubscribed calls and dilution of funding. This was a problem under EDCTP1, and brokered calls were introduced to address the problem. The PanACEA groups set a precedent for joint applications for drug development grants. According to EDCTP2’s Strategic Business Plan, this approach was one of the main innovations of EDCTP1. Brokering is a potential way to support clinical trials, especially costly Phase III trials. Overall, higher cash contributions from Participating States would enable EDCTP2 to deploy its funding more strategically toward effective development of health technologies for PRNDs.

EDCTP2 continues EDCTP1’s geographic focus on sub-Saharan Africa and Europe. This limited geographic focus reduces EDCTP2’s effectiveness in addressing global diseases such as malaria, a huge burden in Africa but a disease that occurs around the world. It also creates a blind spot for PRNDs that affect only areas outside of sub-Saharan Africa.

**European & Developing Countries Clinical Trials Partnership 2**

EDCTP2 aims to accelerate the development of new health technologies for PRNDs, making it the EU’s most relevant funding mechanism for PRND R&D.
By broadening its scope to include all research stages and NIDs, in addition to HIV/AIDS, TB, and malaria, EDCTP2 has increased its ability to effectively support PRND R&D. Interviewees argued that the broadened focus has helped to bring "more and much needed" flexibility. This is a positive development.

EDCTP1 prioritised support for clinical trials in Phases II and III. However, in reality, focus on the two phases was not pronounced: 50% of all clinical trials within EDCTP1 related to Phases II and III, and 30% to Phases I and IV. The remaining 20% were projects that referred to two phases, discontinued trials, and unclassified trials. EDCTP2 explicitly broadens the scope to include clinical trial Phases I and IV, but according to the work plan, it will continue to focus more on clinical trial Phases II and III. This focus is problematic, as coordination between mechanisms is limited, making it difficult to move one or several candidates from one stage to another.

**Access provisions**

Applicants are not required to meet any provisions for access to research data or for developing affordable, accessible, and suitable products. EDCTP1 included an Intellectual Property Rights (IPR) policy containing access provisions, but it is no longer in force. Whilst being criticised for not placing enough emphasis on access rights, it did require all research products to be accessible and affordable in resource-poor settings and granted EDCTP a broad license to the patented results, which it could invoke to promote access. The situation has worsened under EDCTP2, which has no access to provisions at all, and only general IPR provisions for Horizon 2020 apply.

We reviewed the founding documents, the model grant agreement, EDCTP's former IPR policy, and individual calls concerned with research and innovation for new medical tools, and raised the subject in all relevant interviews. Because the general objective of EDCTP2 is to promote the development of "accessible, suitable and affordable medical interventions for poverty-related diseases", these aspects are considered in the evaluation of proposals. Still, there is no legal requirement to ensure that these aspects are meaningfully addressed by funded projects.
Other barriers and incentives for PRND R&D

When looking at other potential barriers to successful support of PRND R&D, the eligibility and award criteria are important factors.

• EDCTP2’s eligibility criteria echo the geographic disease focus on sub-Saharan Africa. This is problematic because many diseases are global and can be addressed only through a global effort. The criteria also differ significantly from the Horizon 2020 criteria. For EDCTP2, at least one of the partners needs to be based in a sub-Saharan African country, and two other entities must be based in two different European Participating States. Organisations that are not based in sub-Saharan Africa or Europe can participate but cannot receive funding, which hinders PRND R&D progress for many diseases.

• Product development aspects do not feature prominently enough in the evaluation of proposals, which depends purely on scientific excellence of individual projects. According to some of the interviewees, impact criteria seem less important. This is problematic, because valuable improvements to medicines may not be ground-breaking scientifically yet very useful for developing a product of high global health relevance.

• There likely is a lack of product development expertise in the evaluation of proposals under EDCTP2. The proposals are subject to a peer review by a panel of scientists whose names are not disclosed (not even in an aggregated form as for Horizon 2020), making it difficult to gauge whether product development expertise features prominently enough. A number of our interview partners inferred from the reviews they received that it was unlikely that enough reviewers were close to the product development process.

• Industry is now able to participate more easily in EDCTP2 and can receive funding. The 2014 evaluation of EDCTP1 recommended that the private sector be involved more strategically. Forums like "Post-Registration Medicinal Products Safety Monitoring in sub-Saharan Africa", a capacity-building collaboration between EDCTP2 and the European Federation of Pharmaceutical Industries and Associations (EFPIA), and several stakeholder meetings with industry representatives, have intensified the cooperation. This is a positive development, since PRND R&D benefits from the involvement of the private sector.
IMI2 is a so-called “joint undertaking” between the EC and the pharmaceutical industry, represented by EFPIA. The objective of IMI2 is to promote collaborative projects between industry, academia, and others to accelerate the development of new medicines, enhance the competitiveness of the European health care sector, and address the challenges facing the European health care system.

Scope and focus

PRND R&D is not a priority of IMI2. The SRA sets general priorities for IMI2 and includes a reference to the World Health Organization’s (WHO) *Priority Medicines for Europe and the World: 2013 Update*, but it limits the focus to diseases that have an impact on Europe. This reference suggests that IMI2 has become slightly more aligned with WHO’s priorities compared to the first iteration. It is a positive development that vaccines have become distinct research priorities and that HIV, TB, malaria, and other NIDs are identified as a challenge to Europe.

The Ebola+ call, the only call relevant to PRND R&D under IMI2 so far, was not based on the SRA but can be understood as a one-off investment, although initially there were plans to add another round. It is providing funding for clinical trials in Phases I, II, and III. This call shows that IMI2 can be flexible, as the annual work plan was amended and calls were evaluated in a fast-track one-stage process. However, it has not led to a strategic focus on PRNDs.

IMI2 places a focus on pre-competitive research to strengthen European pharmaceutical competitiveness, which may disadvantage product developers working on PRND R&D. A number of interviewees confirmed that this focus is a challenge for PRND R&D, since its potential to boost competitiveness is lower than for diseases with a strong commercial market.

Priority-setting is dominated by EFPIA stakeholders, which largely represent the commercial pharmaceutical industry. The SRA was developed in a consultative process by members of EFPIA. Based on those priorities, call topics are designed in annual work plans by EFPIA companies interested in participating in the research area. The final selection must be approved by the governing board, comprising five EFPIA representatives and five representatives from the EC. This gives EFPIA considerable influence, which was criticised in the second interim evaluation of IMI1. This issue has not been addressed.

It seems unlikely that funding opportunities for PRND R&D will increase unless PRNDs are more strongly integrated into IMI2’s priorities. Broader participation of different stakeholders focusing on PRND R&D in the priority-setting process would be a necessary first step.

***** EFPIA represents 33 national associations and 39 pharmaceutical companies operating in Europe.
R&D for PRNDs is not a priority of IMI2.

Access provisions

There are no provisions in IMI2 for the affordability of end products to meet patients’ needs, or open access to research results. Only the very general provisions of Horizon 2020 apply. The Ebola+ call did not contain binding access provisions either. It included language calling for provisions on affordable access for possible future topics (e.g., rapid diagnostic tests and therapeutic products for Ebola). The call mandated, however, that proposals include plans for setting up a “central information repository” with the purpose of sharing data between consortia working on Ebola and ensuring that data would remain accessible after the project.

We analysed the Council Regulation establishing IMI2, the model grant agreement, and the interim evaluation of its first iteration, as well as the Ebola+ programme call provisions and other language on access, affordability, and suitability of research results or medical tools developed. We also addressed questions on access in our interviews.

Other barriers and incentives for PRND R&D

• Eligibility is restricted to a specific geographic location, which is a challenge. The Horizon 2020 eligibility criteria also apply to IMI2; however, organisations based in the United States are excluded from funding. This means that important product developers are excluded from funding, limiting the effectiveness of IMI2 to support global health R&D projects.

• Award criteria within IMI2 do not incentivise PRND R&D, focusing instead on European health challenges and on fostering European competitiveness. The three general criteria of Horizon 2020 are further specified in IMI2’s Manual for Submission, Evaluation, and Grant Award. They remain very general and reflect the general objectives of IMI2. Impact, for example, is partly defined as contribution to European citizens’ health and well-being and the strengthening of competitiveness. This may disadvantage projects focusing on PRND R&D since they compete with a very large commercial industry.
5.1 Key findings

The EU has a global health policy that acknowledges the importance of R&D and a comprehensive research and innovation strategy. It does not have a global health R&D strategy. As a result, R&D funding is allocated in line with EU research and innovation priorities that are primarily dedicated to promoting economic growth through innovation, rather than health goals.

Despite the fact that each of the main EU PRND R&D funding mechanisms has worked to address criticisms from earlier iterations, all three have significant shortcomings. Overall, the EU funds R&D for PRNDs in much the same way as it funds R&D for other diseases and places a strong focus on early-stage development. Whilst this may be suitable for diseases with commercial markets, it is problematic for PRND R&D, which requires public funding throughout the entire research cycle.

The Framework Programmes now contain attempts to improve coordination with other mechanisms, such as EDCTP. Entities outside the EU and Associated Countries (Appendix 3) are eligible to receive funding, which is conducive to a global health R&D agenda. There are still many areas that require improvement. The lack of focus on product development in the relevant Work Programmes and calls remains; the emphasis is almost entirely on basic and early-stage research. This is coupled with the very limited strategic and overarching coordination with other mechanisms to move candidates along the pipeline and on to the next research stage.

EDCTP2 is also an improvement over EDCTP1 in some aspects. The partner base is widened, and industry now can receive funding. African partners have become official members of the GA. It has also tested new approaches, including brokered calls for proposals to leverage more funding to finance costly Phase III trials. Furthermore, EDCTP2 has formally extended its focus to all clinical trial phases. However, a focus on clinical trial Phases II and III remains, and coordination with other mechanisms to move candidates to the next stage has not improved. EDCTP2 still has a geographic focus on sub-Saharan Africa and Europe and cannot fund global efforts to tackle global diseases. Restrictive eligibility criteria hamper EDCTP’s ability to contribute to these global efforts, since a variety of potential contributors is prohibited from receiving funding. Lastly, Participating States have provided the majority of their funding as in-kind contributions, which weakens EDCTP’s ability to deploy its funding strategically. It also limits EDCTP2’s overall cash budget, meaning there is less funding to be distributed to applicants.

IMI2’s objectives are to address health challenges in Europe and strengthen Europe’s competitiveness. Yet IMI2’s model could, in principle, be a suitable mechanism to support PRND R&D. It is a public-private partnership that can leverage the comparative advantages of different players, including industry. However, major changes would be required at a strategic level, since addressing PRNDs is not part of IMI2’s mandate, and in the decision-making processes, to give non-EFPIA stakeholders opportunities for meaningful input. There is no strategic focus on PRNDs and only limited coordination with the two other mechanisms analysed in this report. Furthermore, it is problematic that the call topics are driven by EFPIA, as it represents industry interests, rather than global health priorities.
In addition, there are no binding provisions in any of the mechanisms that ensure PRND R&D funded through the EU will produce accessible, affordable, suitable, and acceptable products for populations in resource-poor settings or that research data will be openly accessible. Finally, the EU has not incorporated the principles of its global health policy, which stresses the need for wide and affordable access to global health products, into its innovation strategy. This way, PRND R&D funding that is distributed is not necessarily aligned to the projects that will create the most appropriate products for PRNDs.

5.2 Recommendations

Which of the mechanisms are best suited to support PRND R&D?

- Work Programmes under Horizon 2020’s Societal Challenge 1 are best suited to fund early-stage R&D, as early-stage research is a clear priority of Horizon 2020. It reflects the archetype of science and technology that places a focus on investigator-driven basic research with little consideration for advancing candidates along the pipeline and translational work that will ultimately lead to innovative health products. Work Programmes can, in principle, provide funding for late-stage research, yet there has been little funding for product development thus far.

- EDCTP2’s explicit purpose is to support R&D for PRND, and it is best suited for later-stage research since the mechanism is geared toward bridging the funding gap between early- and late-stage research. It allows for substantial flexibility as it now issues broader calls that are not focused on specific diseases. Funding can also be accessed by industry. EDCTP2 is the only mechanism with the objective to help develop accessible, suitable, and affordable health tools for many PRNDs, even if specific access provisions have been abolished. To leverage additional funding, EDCTP has started to use brokered calls that offer an interesting model for co-funding resource-intensive projects.

- IMI2 is not well suited to fund PRND R&D since its current mandate is to address health challenges in Europe and strengthen Europe’s competitiveness, even though it clearly places global health threats like HIV/AIDS, TB, and malaria within the European context. IMI2 does not focus on specific diseases or tools but prioritises pre-competitive research that may indirectly advance health technologies for PRNDs. IMI2’s recent investment in Ebola tools was not driven by its SRA and can be considered a one-off investment.

What should be improved?

We recommend that the EC develop a comprehensive PRND R&D funding strategy in order to improve the EU’s overall support for PRND R&D and to address the gaps of each mechanism. The strategy should focus on delivering appropriate and accessible new tools to achieve the EU’s global health aims, and should contain clear objectives and an implementation plan. Such an approach would also enable the EU to take part in global R&D platforms such as the WHO’s Consultative Expert Working Group on Research and Development. The strategy should:
KEY FINDINGS AND RECOMMENDATIONS

- **Cover the full product development cycle and all diseases and technologies relevant to the EU’s global health priorities.** Product development differs from basic research, as the latter is investigator driven and not product oriented. The EC should include product development expertise to tailor its support to the specific needs of product developers. More emphasis should be placed on the applicant's portfolio, rather than the strict focus on the individual project.

- **Entrench comprehensive and binding provisions on access.** Binding provisions on how to ensure patients' access to medical tools and access to research data should be in place for all R&D projects funded through the EU. Firm requirements need to be in place from early and basic research onward so that publicly funded R&D will eventually lead to products that will benefit target populations, including those in resource-poor settings. This is vital to ensure that the outputs of EU-funded research directly impact global health, and to facilitate improved collaboration within consortia.

- **Improve existing mechanisms and synergies by:**
  - **Supporting the transition of PRND projects from one mechanism to another along the R&D pipeline and providing bridge funding.** Products need to transition from Horizon 2020 Work Programme funding for early-stage R&D to EDCTP2 support (where eligible) for late-stage trials. In addition, funding is needed for late-stage development of projects that are not eligible for EDCTP2 funding. Horizon 2020 should develop an approach to proceed with non-African products and ensure they can receive support through better coordination between the three funding mechanisms.
  - **Relaxing some requirements for future PRND-related calls.** Relaxed requirements will facilitate the involvement of relevant product development organisations, and reduced restrictions on the location of consortia members will enable EDCTP to accommodate consortia that manage larger projects and portfolios. This is important because PRNDs are global problems that need a global response. By relaxing geographic eligibility criteria for researchers and product developers, the existing mechanisms can more effectively contribute to the development of medical tools against PRNDs.
  - **Improving alignment of IMI2 priorities with PRND needs.** In principle, the mechanism could be well suited to support PRND R&D since it is a public-private partnership that can effectively support collaborative projects. The IMI2 SRA refers to features of the WHO’s *Priority Medicines for Europe and the World: 2013 Update.* However, PRNDs currently are not a focus. If they were to become one, IMI2 could become a suitable mechanism to support PRND R&D. This is especially pertinent as IMI2 has a strong focus on product development.
The following table shows the poverty-related and neglected diseases included in the scope of G-FINDER, the 2013 study reported in *The Lancet*, the European & Developing Countries Clinical Trials Partnership (EDCTP) neglected infectious diseases (NIDs) list, and the World Health Organization’s (WHO) list of neglected tropical diseases (NTDs).

<table>
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<tr>
<th></th>
<th>G-FINDER</th>
<th>Lancet</th>
<th>EDCTP NIDs</th>
<th>WHO NTDs</th>
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<td>HIV/AIDS</td>
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<td>Dengue</td>
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<tr>
<td>Lower respiratory infections</td>
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<td>Cryptococcal meningitis</td>
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<td>Buruli ulcer</td>
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Appendix 2.
List of interviewees

• Helle Aagaard, EU Policy and Advocacy Advisor, Médecins Sans Frontières
• Lluis Ballell-Pages, Open Lab Head and DDW External Opportunities Director, GlaxoSmithKline
• Richard Bergström, Director General, European Federation of Pharmaceutical Industries and Associations
• Willo Brock, Senior Vice President for External Affairs, TB Alliance
• René Coppens, Director of Resource Mobilisation, Tuberculosis Vaccine Initiative
• Dr. Ruxandra Draghia-Akli, Director Responsible for Health, Directorate-General for Research and Innovation, European Commission
• Anne Hradsky, Advocacy Coordinator, Global Health R&D, Deutsche Stiftung Weltbevölkerung
• Dr. Stefan Jungbluth, Head of Business Development, European Vaccine Initiative
• Nicola Kuhrt, Editor in Chief, Deutsche Apotheker Zeitung, Online
• Dr. Line Matthiessen, Head, Unit Fighting Infectious Diseases and Global Epidemics R&D, Directorate-General for Research and Innovation, European Commission
• Dr. Ole Olesen, Director of North-North Cooperation, European & Developing Countries Clinical Trials Partnership
• Jérôme St-Denis, Senior Advocacy & Resource Mobilization Officer, Foundation for Innovative New Diagnostics
As of 1 December 2015, the following countries are Associated to Horizon 2020:

- Albania
- Bosnia and Herzegovina
- Faroe Islands
- Iceland
- Israel
- the former Yugoslav Republic of Macedonia
- Moldova
- Montenegro
- Norway
- Serbia
- Switzerland (partial association)
- Turkey
- Ukraine


14 Policy Cures. Original analysis based on G-FINDER survey data and CORDIS data.


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European Commission; 2015.


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Assessing EU Funding for R&D for Poverty-Related and Neglected Diseases

Research report commissioned by the EACH Coalition