Saving Lives and Creating Impact:
EU investment in poverty-related neglected diseases
DSW (Deutsche Stiftung Weltbevoelkerung) is an international development and advocacy organisation founded in 1991 as a non-profit foundation in Hannover, Germany in the fields of global health, and sexual and reproductive health and rights (SRHR). DSW focuses on development programmes, advocacy, and awareness raising. Headquartered in Hannover, DSW also maintains four country offices in Ethiopia, Kenya, Tanzania, and Uganda, as well as liaison offices in Berlin, Germany, and Brussels, Belgium.

Policy Cures
Policy Cures is an independent not-for-profit group with offices in Sydney and London, providing research, information, decision-making tools and strategic analysis for those involved in the creation of new pharmaceuticals for global health. The Policy Cures team has focused exclusively on product development related to global health since 2004, from R&D activities and portfolios, to developers, business models, funding, incentives, pricing and access issues.

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The views expressed are those of the authors.

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<thead>
<tr>
<th>Acronym</th>
<th>Description</th>
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<tr>
<td>ACCD</td>
<td>Catalan Agency for Development Cooperation</td>
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<tr>
<td>ACT</td>
<td>Artemisinin-based combination therapy</td>
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<td>AECID</td>
<td>Spanish Agency for International Cooperation for Development</td>
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<td>AMC</td>
<td>Advance Market Commitment</td>
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<td>BMBF</td>
<td>German Federal Ministry of Education and Research</td>
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<td>BMZ</td>
<td>German Federal Ministry for Economic Cooperation and Development</td>
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<td>DANIDA</td>
<td>Danish International Development Agency</td>
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<td>DFID</td>
<td>UK Department for International Development</td>
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<td>DGDC</td>
<td>Belgian Directorate-General for Development Cooperation</td>
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<td>DGIS</td>
<td>Dutch Directorate-General of Development Cooperation</td>
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<td>DNDi</td>
<td>Drugs for Neglected Diseases Initiative</td>
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<td>EC</td>
<td>European Commission</td>
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<td>EDCTP</td>
<td>European and Developing Countries Clinical Trials Partnership</td>
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<td>EU</td>
<td>European Union</td>
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<td>FIND</td>
<td>The Foundation for Innovative New Diagnostics</td>
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<td>FP</td>
<td>Framework Programme for Research and Technological Development</td>
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<tr>
<td>GAVI</td>
<td>The GAVI Alliance (formerly The Global Alliance for Vaccines and Immunisation)</td>
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<td>GFC</td>
<td>Global financial crisis</td>
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<td>GDP</td>
<td>Gross domestic product</td>
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<td>GSK</td>
<td>GlaxoSmithKline</td>
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<td>HIV &amp; AIDS</td>
<td>Human Immunodeficiency Virus and Acquired Immunodeficiency Syndrome</td>
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<td>MDR-TB</td>
<td>Multidrug-resistant tuberculosis</td>
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<td>MDG</td>
<td>Millennium Development Goal</td>
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<td>MMV</td>
<td>Medicines for Malaria Venture</td>
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<td>MRC</td>
<td>Medical Research Council</td>
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<td>OECD</td>
<td>Organisation for Economic Cooperation and Development</td>
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<td>PRND</td>
<td>Poverty-related and neglected disease</td>
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<td>PDP</td>
<td>Product development partnership</td>
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<tr>
<td>R&amp;D</td>
<td>Research and development</td>
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<td>S&amp;T</td>
<td>Science &amp; technology</td>
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<tr>
<td>SIDA</td>
<td>Swedish International Development Agency</td>
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<td>SME</td>
<td>Small and medium-sized enterprise</td>
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<td>SRHR</td>
<td>Sexual and reproductive health and rights</td>
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<td>TB</td>
<td>Tuberculosis</td>
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<tr>
<td>WHO</td>
<td>World Health Organization</td>
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<tr>
<td>WHO/TDR</td>
<td>World Health Organization Special Programme for Research Training in Tropical Diseases</td>
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<tr>
<td>XDR-TB</td>
<td>Extensively drug-resistant tuberculosis</td>
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EXECUTIVE SUMMARY

Poverty-Related and Neglected Diseases (PRNDs) are infectious diseases that disproportionately affect the world’s poorest populations, where the private sector does not have enough of an incentive to develop urgently needed new products. Europe plays a critical role in developing new PRND products that are saving millions of lives and millions of euros in the world’s poorest countries. Funding from the European Union (EU), which includes funding from both the European Commission (EC) and Member States, has increased in recent years and has been essential to bringing these new products to market. However, with austerity measures and budget cuts rife across Europe, it is now timely to re-examine the case for EU investment in PRND research and development (R&D).

This report assesses the impact of EU funding for PRND R&D, highlighting the return on investment for both developing countries and the EU, and the EU’s ongoing role in funding PRND R&D.

WHAT HAS THE EU INVESTED IN PRND R&D?

The EU is a major funder of PRND R&D, with the EC and Member State governments contributing almost a quarter (22%) of government PRND R&D investment worldwide and 15% of total global investment. EU governments contribute an average €341 million a year to developing new PRND products, with nearly three-quarters (73%) of this provided by Member States, and just over a quarter (27%) provided by the EC.

But EU investment in PRND R&D is still low overall, and is not spread equally between Member States. EU funding for PRND R&D is only 0.0024% of the EU’s combined GDP. The contributions of Member States vary greatly - Sweden, Ireland and the UK are the most generous funders (investing over 0.0045% of their GDP), while others such as Finland and Italy invest less than a tenth as much (investing 0.0004% and 0.0002% of GDP respectively). Germany, the EU’s largest economy, has typically contributed towards the lower end of the scale (investing just 0.0007% of GDP), but has recently increased its commitments to PRND R&D.

EU investment supports research into 31 PRNDs, with three-quarters of funding (76%) going to three diseases – HIV & AIDS, tuberculosis (TB) and malaria. The EU also invests fairly evenly across all stages of product development (basic research, discovery & preclinical research, and clinical development), although there has been a recent shift away from clinical development in favour of basic research – a concerning trend, given the number of PRND products entering late-stage clinical trials.

EU investment, both by the EC and EU Member States, has been vital to supporting the innovative and highly successful PDP model – EU governments have contributed or committed over half of all government funding to PDPs from their inception through to 2019.

WHAT ARE THE BENEFITS OF EU INVESTMENT IN PRND R&D?

EU funding for PRND R&D has delivered enormous health, economic and societal benefits for both developing countries and for Europe.

Benefits for developing countries – saving lives and building the next generation of researchers

The EU’s investments in PRND R&D are on course to save millions of lives and euros in the developing world. European funding has contributed to the creation of 43 new products that are already improving health and productivity in developing countries while reducing healthcare costs and helping to alleviate poverty. These include new malaria drugs especially designed for children, and a pneumonia vaccine that includes developing country strains (the latter is estimated to save up to seven million lives by 2030).
Europe is playing a critical role in generating PRND products for the future. EU researchers are working on almost 150 PRND products in development (40% of all products in the pipeline), some of which promise equally impressive health benefits. These include new TB vaccines, malaria drugs that are safe for pregnant women, and the first-ever vaccines for malaria, dengue fever and HIV.

EU investment is building the next generation of developing country researchers, putting these countries on a more sustainable footing. European funding has a strong focus on building research capacity in developing countries, including training researchers and supporting institutions. This builds long-term economic value through the creation of highly-skilled jobs and high-quality infrastructure. The EDCTP has supported over 300 postgraduate trainee positions, and consistent and long-term support from a range of EU governments has enabled institutions such as the UK Medical Research Council (MRC) Gambia Unit, the Medical Research Unit, Albert Schweitzer Hospital in Gabon and the Manhiça Health Research Centre in Mozambique to become world-class research centres.

Benefits for Europe – jobs and investment, integration, and protecting European citizens

Investment in PRND R&D is an investment in European jobs and growth. Sixty-six cents of every euro invested by EU governments in PRND R&D is reinvested back into European laboratories, universities and companies. EU PRND R&D investment created over 13,000 jobs in Europe between 2002 and 2010 – many of these being exactly the kind of the smart, high-value jobs sought by the EU growth strategy (Europe2020).

Government funding for PRND R&D generates a net benefit to Europe’s economy. Each euro invested by EU governments generates a further €1.05 in investments into Europe from companies, philanthropic organisations and other governments, many of these based outside Europe. These investments support thousands of European jobs and contribute to the high quality of European PRND R&D.

EU investment is maintaining Europe’s position as a leader of PRND research and innovation. Europe has a long tradition of conducting PRND R&D, focusing on scientific excellence. Europe is home to many of the world’s leading specialised tropical medical institutes - including Sweden’s Karolinska Institute, France’s Institut Pasteur, the London School of Hygiene and Tropical Medicine, and Germany’s Bernard Nocht Institute - which have been the source of many critical scientific breakthroughs in global health, and whose scientists have received five Nobel Prizes for infectious disease research.

PRND R&D funding promotes integration between European countries. More than three out of four PRND projects involving a European partner are collaborative, promoting integration and partnership across the EU. The EDCTP, an organisation set up by the EC, is a flagship initiative for integration, involving cooperation between 14 Member States and two EU Associated Countries to support clinical trials for HIV & AIDS, TB and malaria in sub-Saharan Africa. The EDCTP has supported 57 clinical trials and 196 projects involving 211 research institutions across Europe and sub-Saharan Africa. For the EDCTP specifically, each euro invested by the EC has also generated a further €1.50 in PRND investments from Member States, philanthropic organisations and industry, both inside and outside Europe.

European-based pharmaceutical companies and small and medium enterprises (SMEs) are the industry leaders in PRND R&D. Europe has been highly successful in integrating the private sector into the PRND R&D landscape, and in attracting industry investments in Europe. European companies invest six times more in PRND R&D, relative to annual revenues, than their U.S. counterparts. Europe is home to a significant industry base, with five Europe-based multinationals (AstraZeneca, Bayer Healthcare Pharmaceuticals, GlaxoSmithKline, Novartis and Sanofi) and over 25 European SMEs working in the field.

The EU’s investment in PRND R&D is protecting Europe’s global health security. New PRND products also protect European populations. Cases of PRNDs (such as TB, Chagas’ disease and worm-based infections) are reported in Europe (particularly in Southern and Eastern Europe), and new PRND products will help to prevent and treat these diseases in European citizens. Importantly, new products will ensure that European populations are protected from the spread of other PRNDs (such as dengue fever).
DISCUSSION

Increased PRND R&D investment under Horizon 2020 will result in increased benefits for developing countries and for Europe. EU investment in PRND R&D achieves all the goals of Horizon 2020 – scientific excellence, growth, industrial leadership, job creation, integration, and health and societal benefits. Increased investment will support Europe’s world-leading institutions and continue to attract high-quality industry PRND R&D investments into Europe. Greater funding will also sustain new, highly-skilled research jobs, encourage integration between Member States through partnerships, and protect European populations from new and existing PRNDs.

EU investment in PRND R&D has many distinctive and valuable features. Fostering these will maintain Europe’s competitive advantage and deliver more new products more quickly. EU funding for PRND R&D emphasises collaboration and partnerships (most prominently through championing the highly successful PDP model and through the EDCTP), focuses on scientific excellence and capacity building in developing countries, and has been effective in bringing industry to the table. These are essential pillars of Europe’s competitive advantage and should continue to feature in, and to shape, future EU investment.

The EU can secure greater value for money by addressing specific shortcomings in its investment approaches. Reducing existing inefficiencies in EU funding – by reducing conditionality, taking a more results-driven approach to collaboration, streamlining funding processes and increasing coordination – will substantially increase the return on investment for both developing countries and the EU, meaning more lives and dollars saved for each euro invested.

RECOMMENDATIONS

1. The EU should increase its investments in PRND R&D under Horizon 2020.

2. The EU should retain and foster the distinctive benefits of its approach to funding PRND R&D, including a focus on collaboration and partnerships, supporting capacity building in developing countries, promoting institutional excellence and integrating industry.

3. The EU should improve specific aspects of its investment in PRND R&D, to ensure greater efficiency, impact and value. This can be achieved through streamlining conditions and processes, taking a more results-driven approach to collaboration and increasing coordination at all levels.
INTRODUCTION

Poverty-Related and Neglected Diseases (PRNDs) remain an enormous problem in the developing world, causing widespread human suffering and impeding economic growth. Each year, PRNDs cause 13.7 million deaths and the loss of 377 million years of healthy and productive life worldwide. Tragically, much of this is preventable with existing tools, but new tools are still needed – children still die from malaria due to lack of a vaccine, and adults still die from tuberculosis (TB) because treatment is too complex and difficult to deliver in the developing world, or because TB is not properly identified in the first place.

In addition to the human toll, the burden of PRNDs impacts the economies of developing countries through lost productivity and high healthcare costs, trapping countries in a cycle of low growth. Some of these diseases, including HIV & AIDS and TB, strike down individuals in their most productive years, leaving workplaces without staff and forcing children out of school to care for their sick parents. Children are also kept out of school by their own illness – many PRNDs, such as diarrhoeal diseases and bacterial pneumonia, primarily affect children – meaning that the next generation of children never reaches their full potential. Malaria is estimated to cost Africa over $12 billion per year in direct economic losses, while TB is expected to cost the world’s poorest countries $1-3 trillion over the next decade.

PRNDs are infectious diseases that affect the world’s poorest populations, where the private sector does not have enough of an incentive to develop urgently needed new products, such as vaccines for malaria and HIV & AIDS, or adequate treatments for sleeping sickness. PRNDs include the ‘big three’ – HIV & AIDS, malaria and TB – as well as lesser-known diseases such as dengue fever, Chagas’ disease, diarrhoeal diseases and worm infections, which together kill millions of people each year (see full list of PRNDs in the Methodology). There is no paying market for products for these diseases, unlike diseases such as diabetes and cancer which have a large market in the developed world. The lack of a market incentive to develop new products results in these diseases and the communities they affect being ‘neglected’.

Addressing PRNDs is an essential part of global development efforts, as PRNDs are both a cause and consequence of poverty in developing countries. The Millennium Development Goals (MDGs) recognise the vital connection between health, poverty alleviation and development. Three of the eight MDGs are focused squarely on improving health (reduce child mortality; improve maternal health; and combat HIV & AIDS, malaria and other diseases), and many PRNDs are directly exacerbated by factors addressed through other MDGs (for example, combating malnutrition). Although not included in this report, sexual and reproductive health and rights (SRHR), including family planning (FP), also have important links with PRNDs; crucially, PRNDs such as HIV & AIDS, malaria and anaemia-inducing parasitic diseases are a significant cause of maternal mortality. Therefore, combating PRNDs and advancing SRHR is critical to improving global health overall.

In recent years, increased investment in PRND research and development (R&D) by European funders and other donors has gone hand-in-hand with renewed scientific interest in these diseases. Greater investment has started to usher in new technologies that are already saving millions of lives, and often also millions of euros – just as polio and measles vaccines did for previous generations. The need for new products has also seen the creation of innovative, smarter ways of working on these problems, including Product Development Partnerships (PDPs) (partnerships that combine private sector, government, academic and philanthropic resources and expertise) and the European and Developing Countries Clinical Trials Partnership (EDCTP).
Despite these advances, improving the health of the world’s poorest populations cannot be achieved without continued support for the development of new tools to address PRNDs. Tools to prevent, diagnose and treat PRNDs are often still lacking (for example, there is no HIV or malaria vaccine, and no treatment for dengue fever), or existing tools are unsuitable for developing country populations (for example, TB treatment regimens still require months or years of multi-drug therapy). In the absence of a commercial market for these products, targeted investments in PRND R&D by governments, philanthropic organisations and the private sector are critical, driving the development of new and better tools that will save lives and support healthy communities.

EUROPE’S ROLE IN FUNDING R&D

This report analyses European investment in product development R&D for PRNDs for the four years from 2007 to 2010. European investment in PRND R&D is complex, with many funding mechanisms across the government, private and philanthropic sectors. On the government side, PRND research and innovation is funded in two ways – directly by EU Member States (for example, through national aid or science & technology agencies) or by the European Commission’s (EC’s) overarching research Framework Programmes, which are funded by the EC’s overall budget and also include contributions from Member States. The current EC programme – the Seventh Framework Programme for Research and Technological Development (FP7) – runs until 2013, and will be replaced by the new, seven-year Horizon 2020 funding programme in 2014. Co-funding arrangements, where the EC and Member States contribute joint funding, also exist (for example, the EDCTP).

In addition to governments, Europe-based philanthropic organisations and pharmaceutical companies are key investors in PRND R&D. Some philanthropic organisations, such as the UK’s Wellcome Trust, have a long history of funding PRND R&D and building research links with developing countries. The private sector, including both multinational and smaller biotechnology and pharmaceutical firms, also increasingly contributes to PRND research and innovation, using their own resources and expertise to develop PRND products such as HIV vaccines. Many PRND R&D projects, such as those conducted by PDPs and the EDCTP, receive funding from a combination of all three sources – government, philanthropy and industry – highlighting the importance of partnership at all levels.
Europe plays a vital part in creating new products for neglected disease patients, in particular through European Union (EU) funding of Poverty-Related and Neglected Disease (PRND) research and development (R&D). EU funding includes both funding from the European Commission (EC) and Member States.

From 2007 to 2010, the EU invested an average €341 million a year in R&D to develop new tools to prevent, diagnose and treat HIV & AIDS, malaria, tuberculosis (TB) and other PRNDs that continue to claim the lives of millions in the developing world. Individual Member States accounted for nearly three-quarters (73%, €248m) of this investment, while the European Commission (EC), as the largest single funder, provided just over a quarter (27%, €93m).

Government funding is crucial to PRND product development, which – by definition – has an insufficient commercial market to attract R&D by private industry. Two-thirds of all PRND R&D funding is from governments and the EU plays a critical role in this, providing 22% (€341m a year) of government funding globally, equivalent to 15% of all funding for PRND R&D.

The EU invests an average €341 million a year in PRND R&D

Fig 1. EU Investment in PRND R&D (2007-2010)

Fig 2. Global PRND R&D funding (2007-2010)

* In this report, the European Union (EU) includes both the European Commission (EC) and EU Member States
The largest funders in the EU are the EC, the UK and France, who collectively provided more than two-thirds of all EU PRND R&D funding. Other notable EU Member State funders are the Netherlands, Sweden and Germany, who along with the UK and France share a rich tradition in tropical medicine and neglected disease research. The EC’s contribution is particularly significant as it spends a high proportion of its R&D budget on PRND R&D – although the EC only manages about 5% of total EU government spending on R&D, it contributes over a quarter (27%) of EU government spending on PRND R&D.

However, investment in PRND R&D varies widely between Member States: some, like Finland, Italy and Portugal, contribute relatively little and fund only sporadically; while 14 EU countries - Austria, Bulgaria, Cyprus, Czech Republic, Estonia, Greece, Hungary, Latvia, Lithuania, Malta, Poland, Romania, Slovakia, Slovenia - provide virtually no funding for PRND R&D.

As governments across Europe implement austerity measures in a bid to resolve the debt crisis, it is particularly striking that the EU’s investment in PRND R&D has come at a small cost to the European taxpayer, leaving room for increased commitments. Between 2007 and 2010, the EU invested an average of just 0.0024% of GDP into PRND R&D, although the burden of investment was not shared evenly among Member States. Sweden, the UK and Ireland all punched above their weight relative to their GDP, while Finland and Italy languished towards the bottom of the chart. While Germany has also been a low funder in the past, we note their recent commitment to a four-year, €20 million investment into PRND R&D, specifically for Product Development Partnerships (PDPs) and particularly focused on tropical diseases and diseases that affect children, such as malaria. This commitment is one of the four pillars of Germany’s funding concept for PRNDs.

Fig 3.
Top 10 EU funders
(2007-2010)

Fig 4.
PRND R&D investment
as a percentage of GDP
(2007-2010)

vi Product development partnerships combine private sector, government, academic and philanthropic resources and expertise to create new products for PRNDs.
For the most part, Member States that make the most meaningful contribution to PRND R&D are those that share a long cultural and historical association with the developing world, often borne out of former colonial ties. Indeed, there is a strong correlation between PRND R&D funding and historical colonial interests in regions affected by PRNDs (Asia, sub-Saharan Africa, Latin America). Of the EU countries with former colonies in sub-Saharan Africa, Asia or Latin America, only Portugal does not fund PRND R&D. Moreover, the three largest funders in absolute terms (UK, France and the Netherlands) also governed the largest colonial populations.

Despite its global contribution, the EU still lags a long way behind the U.S. in terms of PRND R&D funding. The U.S. (with a GDP that is 90% of the EU’s) invests four times as much as the EU in relative GDP terms, and twice as much relative to overall R&D expenditure (0.32% vs 0.14%). Some middle-income countries are also catching up fast; Brazil and India already contribute more in relative GDP terms than France, Germany and Spain and are not far short of the EU average in relative GDP terms.

Since the onset of the Global Financial Crisis (GFC), many OECD governments, including several in Europe, have scaled back funding for PRND R&D. For some Member States, the impact of the GFC has been immediate and dramatic. Prior to the GFC, Ireland was by far the biggest contributor to PRND R&D in GDP terms; however, in the wake of the GFC, both Belgium and Ireland made large cuts to their funding commitments to PRND R&D. In 2010, the UK was the only EU Member State to increase funding for PRND R&D (up 15%).

EU funding comes from both science and technology (S&T) and aid agencies. S&T agencies, such as the German Federal Ministry of Education and Research (BMBF) and the UK Medical Research Council (MRC), account for nearly two-thirds of EU funding (62%, €191m per year), with the remaining third (38%) provided by development and aid agencies.

The remit and mandate of S&T and aid agencies are usually very different, and this is reflected in their very different funding patterns. S&T agencies have a long-term time horizon that is more resilient to changes in the external environment, while aid agencies are more focused on short-term results and more susceptible to political considerations. As such, aid agencies have fared worse than their S&T counterparts since the GFC, with cuts across the board to development budgets in most Member States except the UK. This reflects a wider trend, with drops in aid agency funding accounting for over 60% of the PRND R&D funding drop in many high-income countries in 2010. In Europe, these included cuts from the Dutch Directorate General of Development Cooperation (DGIS, down €6.4m, -38%), the Swedish International Development Agency (SIDA, down €7.6m, -41%) the Spanish Agency for International Cooperation for Development (AECID, down €5.9m, -51%), the Danish International Development Agency (DANIDA, down €2.5m, -49%), the French Ministry of Foreign and European Affairs (down €1.5m, -63%) and the Belgian Directorate-General for Development Cooperation (DGDC, down €1m, -42%). Although the German Federal Ministry for Economic Cooperation and Development (BMZ) also registered a drop in funding in 2010, it was encouraging to see that the German Federal Ministry of Education and Research (BMBF) included, for the first time in 2011, a dedicated budget line to supporting PDPs for PRND R&D, as part of Germany’s four-pillar funding concept for PRNDs.

The U.S. invests four times as much as the EU in GDP terms’
The EU supports scientific research into a broad range of PRNDs, with three-quarters of this funding going to HIV & AIDS, TB and malaria. EU investment\(^7\) is fairly equal between these three diseases, unlike the U.S., where HIV & AIDS dominate the government’s R&D investment.

Until the financial crisis, the EU also funded fairly consistently across the R&D value chain - from basic research to increase our scientific understanding of diseases; through discovery and preclinical research to translate that knowledge into potential products; to clinical research to test new diagnostics, vaccines and drugs in humans.

Between 2007 and 2010, the EC was the second-largest funder of basic research in Europe after the UK, and the top funder of discovery and preclinical as well as clinical research. The European and Developing Countries Clinical Trials Partnership (EDCTP), in particular, has been critical in driving clinical research funding by both the EC and Member States, and is responsible for over one-third of all EU funding in this area.

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\(^{7}\) In this report, the European Union (EU) includes both the European Commission (EC) and EU Member States

\(^{*}\) Other includes funding for salmonella infections, bacterial pneumonia & meningitis, leprosy, trachoma, Buruli ulcer, rheumatic fever and core funding to multi-disease R&D organisations

Core funding to the EDCTP has been apportioned to HIV & AIDS, TB and malaria based on EDCTP expenditure
However, PRND R&D funding patterns have changed significantly since 2009 as Member States have shifted resources into basic research, which is usually done by domestic academics; and away from clinical development, which usually takes place in the developing countries most affected by PRNDs. This shift is unrelated to product development needs; indeed, if these needs were our only guide we would have expected significantly increased clinical funding since 2009 as new malaria, TB and HIV products moved into costly late-stage clinical trials. In this environment, initiatives such as the EDCTP (which focuses on Phase II and Phase III clinical trials for these three diseases) become particularly important, demonstrating the added value of pooled funding mechanisms coordinated by the EC.

Like the U.S., the largest share of PRND R&D funding from EU Member States goes to academic and research institutions (56%), more often than not in the funder’s home country. However, in stark contrast to the U.S., EU Member States have also been keen supporters of Product Development Partnerships (PDPs), with Member States providing half of government funding commitments to PDPs from their inception through to 2019, compared to 31% from the U.S. government.

There are currently more than 20 vaccine and drug candidates in Phase III trials, including three HIV vaccines, four malaria drugs, a malaria vaccine and a TB vaccine.

**Fig 7.**
EU investment by R&D stage (2007-2010)

**Fig 8.**
Trends in EU Member State investment by R&D stage (2007-2010)

**HOW IS EU FUNDING DISTRIBUTED?**
EC investment (€373 million from 2007-2010) supported a wide range of organisations, including academic organisations, industry, PDPs and the EDCTP. In all, 73% of EC funding went to academic and research organisations – including small and large pharmaceutical and biotechnology companies (10% of overall funding, or €37 million) – with most of the remainder going to the EDCTP (22%).

PDPs have also benefited from EC support – the EC has been the largest government funder of the Tuberculosis Vaccine Initiative (TBVI) and the European Vaccine Initiative (EVI), and has committed over €88 million to nine PDPs, from their inception through to 2019.
EU investment in PRND R&D is making a real difference in developing countries. The health impacts of new products developed with EU support are already evident – pneumococcal conjugate vaccines are saving hundreds of thousands of lives, and new formulations of malaria drugs are allowing more children to reach adulthood. Promisingly, this trend looks set to continue. Of the 43 products that were registered in the last decade and over 350 that are currently in development, 43% involved European developers, the majority of whom were partially or fully funded by European funders. These products have already saved millions of lives, and often also millions of euros.

EU investment also benefits the economies of developing countries, with new products increasing productivity and saving costs for overstretched health systems. Promoting healthy communities in the developing world helps to alleviate poverty and makes those countries more competitive on the world stage. Investment in PRND R&D lays the foundation for long-term economic value to developing countries by building research capacity and creating sustainable, high-quality institutions across sub-Saharan Africa and Asia. Collaborations between EU and developing country institutions are already resulting in valuable contributions to the scientific knowledge base, including through clinical trials for malaria drugs and vaccines in sub-Saharan Africa.

In the last decade, 43 new diagnostics, vaccines and drugs have been registered to tackle a wide variety of PRNDs, with European organisations playing a pivotal role in many of these.

**Malaria**

Malaria infects more than 216 million people each year and is responsible for the deaths of an estimated 655,000 people, mostly children living in Africa. Around 40% of the world's population are at risk of contracting malaria. Malaria is preventable and treatable, but the emergence of drug-resistant malaria parasites has rendered the old generation of antimalarial drugs ineffective.

Novartis, a Europe-based pharmaceutical company, partnered with Chinese scientists at the Beijing Institute of Science and Technology to develop Coartem®, the first artemisinin-based combination therapy (ACT), with a cure rate in excess of 95%. Novartis later collaborated with a Swiss-based PDP, the Medicines for Malaria Venture (MMV), to develop Coartem® Dispersible, the first water-dispersible ACT specifically designed for children. The collaboration was funded by several EU Member States and Associated Countries including Ireland, the Netherlands, Spain, the UK and Switzerland.

French-based pharmaceutical company Sanofi partnered with two Europe-based organisations, the Drugs for Neglected Diseases Initiative (DNDi) and World Health Organization Special Programme for Research Training in Tropical Diseases (WHO/TDR), to develop the first fixed-dose ACT formulation for children. The fixed-dose combination pill, ASAQ, is simple to administer and improves patient compliance, which is critical to avoid the risk of resistance.

Importantly for developing country populations, ASAQ is available in four different presentations (for infants, toddlers, children and adults). Initially, Sanofi manufactured ASAQ in Morocco, but the manufacturing technology was later transferred to the Zenufa Group in Tanzania to establish a second manufacturing plant. Under the auspices of its Impact Malaria programme, Sanofi provides ASAQ at a ‘no profit-no loss’ price to public organisations in endemic countries and to international institutions. The collaboration was funded by several EU Member States including France, the Netherlands, Spain and the UK and the EC through the Fifth Framework Programme for Research and Technological Development (FP5).
Sigma-Tau, an Italian SME (small and medium-sized enterprise), partnered with MMV and the University of Oxford to develop Eurartesim®, another simpler-to-use ACT. Initial studies were conducted in Vietnam at a site funded by the UK-based Wellcome Trust. The collaboration was originally proposed by the then-Italian Minister of Health and funded by Ireland, the Netherlands, Spain, UK and Switzerland, in addition to philanthropic foundations. Eurartesim® was the first antimalarial to be approved by the European Medicines Agency in October 2011, and Sigma-Tau and MMV are currently developing it in a paediatric formulation.

These malaria drugs are already having positive health impacts on the ground. Since 2001, Novartis has provided more than 400 million Coartem® treatments on a not-for-profit basis through an agreement with the World Health Organization (WHO), saving an estimated 1 million lives; 137 million treatments of Coartem® Dispersible have been delivered to 35 malaria-endemic countries since the product was launched in 2009; over 150 million treatments of ASAQ have been distributed in 30 African countries by Sanofi on a not-for-profit basis; and Eurartesim® is now being delivered to Cambodia, the first malaria-endemic country to receive the new drug.

Pneumonia

Bacterial pneumonia (pneumococcal pneumonia) kills more than half a million children under five each year, more than any other disease. While an effective pneumonia vaccine has been widely used in Europe since 2000, it was not suitable for use in developing countries since it did not include the most common strains of developing world pneumonia.

EU governments and industry have played an important role in developing a lower-cost pneumonia vaccine that includes developing country strains. In 2009, the Italian and UK governments committed €465 million and €355 million respectively to the Advance Market Commitment (AMC), an innovative financing mechanism designed to incentivise vaccine manufacturers to develop vaccines for developing country use. In response to the AMC, GSK Biologicals, based in Belgium, developed Synflorix®, the first pneumococcal conjugate vaccine to receive WHO prequalification for use globally. Synflorix® is now being rolled out in national immunisation campaigns across the developing world, with GSK Biologicals providing 480 million doses to vaccinate 160 million children in developing countries by 2023. The health impacts of this are enormous, with pneumococcal conjugate vaccines estimated to save 900,000 lives by 2015 and up to 7 million lives by 2030.

Case study: The meningitis A vaccine

During the dry season, 430 million people in a region known as the ‘meningitis belt’, live in fear of a meningitis epidemic. Meningococcal meningitis causes high fever, vomiting, headaches and stiffness of the neck, and is spread by sneezing, coughing, or sharing eating utensils. One in 10 people die within a few days of developing symptoms, and one in five is left with permanent life-limiting disabilities such as mental impairment, deafness or epilepsy.

The public health response to meningitis outbreaks has typically been too little, too late. The disease spreads too quickly to make early diagnosis and treatment a viable option. Instead, countries have relied on emergency immunisation campaigns triggered at the first sign of an epidemic. Unfortunately, by the time these control measures were rolled out, thousands may already have died. Between 1999 and 2003, an estimated €130 million was spent on emergency vaccination, yet epidemics still occurred and thousands still died.

The new meningitis A vaccine

The World Health Organization (WHO) and PATH, an international non-profit organisation, founded the French-based Meningitis Vaccine Project (MVP) to develop a new low-cost long-lasting vaccine, with funding from the Bill & Melinda Gates Foundation.
MVP established key partnerships to assist in the development of the new vaccine, with European researchers and developers playing a critical role. SynCo Bio Partners, a Dutch vaccine manufacturer, supplied the technology for one of the main components of the vaccine, and played a key role in meeting the price per dose target. Aérial, a French company based in Strasbourg, provided expertise in the formulation of the vaccine. The Serum Institute of India, one of the world’s largest producers of vaccines, agreed to manufacture the new vaccine at a cost that no manufacturer in the developed world could match. The U.S. Food and Drug Administration donated a technology critical to creating a more effective vaccine and provided technical support. The new vaccine was tested and licensed initially in India, and in 2010, a new meningitis A conjugate vaccine - the first vaccine developed specifically for sub-Saharan Africa - was ready to be rolled out.

In December 2010, national immunisation campaigns commenced in Burkina Faso, Mali and Niger to vaccinate infants, children and young adults against meningitis with MenAfriVac™. In less than one month, 19.5 million people were vaccinated. European donors participated in the successful rollout of the vaccine – for example, the Spanish Agency for International Development (AECID) provided financial support for the coordination of the vaccine’s introduction.

The impact of the new meningitis A vaccine

Since its introduction in early 2011, the impact of the new meningitis A vaccine has been dramatic. In the 2011 epidemic season, there were no cases of meningitis A among people who were vaccinated. The unprecedented success of MenAfriVac™ prompted a second wave of vaccination campaigns in Chad, Cameroon and Nigeria using vaccine supplies procured by the GAVI Alliance (formerly the Global Alliance for Vaccines and Immunisation). To date, more than 54.5 million people have received the vaccine. The target is for all 26 countries in the “meningitis belt” to be vaccinated by 2016.

EU investment is also contributing to the creation of the largest-ever pipeline of new products to tackle poverty-related and neglected diseases. There are currently over 350 PRND candidates in development (including vaccines, other preventive technologies such as microbicides, diagnostics and drugs) and European researchers and developers are involved in over 40% of these. Many candidates will fail at the early hurdles, as is normal in pharmaceutical development but - if funding is sustained - others will succeed in the next decade, bringing profound benefits to developing countries. There are approximately 20 PRND vaccine and drug candidates currently in Phase III trials (the last stage of development, and the phase with the highest success rates), including three HIV vaccines, four malaria drugs, a malaria vaccine and a TB vaccine.

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**EUROPE IS HELPING TO DEVELOP THE LARGEST-EVER PIPELINE OF NEW PRND PRODUCTS FOR DEVELOPING COUNTRIES**

EU involvement in PRND projects in the pipeline

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> Malaria (19)  
> HIV & AIDS (18)  
> Other PRNDs (16)  
> TB (12)  
> Diarrhoeal diseases (8)

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> Malaria (17)  
> Leishmaniasis & Chagas’ (9)  
> Other PRNDs (9)  
> TB (6)

---

> Sleeping sickness (10)  
> TB (9)  
> Other PRNDs (7)  
> HIV & AIDS (5)  
> Leishmaniasis & Chagas’ (3)

---

HIV Microbicides  
Diagnostics  
Drugs  
Vaccines

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*The GAVI Alliance is a public-private partnership that finances and supports delivery of vaccines for children in the world’s poorest 70 countries*

*The product pipeline includes all PRND products currently in development, from early discovery to registration*

*Based on a previous Policy Cures report. See Appendix 1 for details*
The examples below show the potential impact of Europe’s contribution to this pipeline, even at current average EU funding levels of only 0.0024% of GDP.

**Preventing Buruli ulcer**

Buruli ulcer is a highly neglected disease that occurs in more than 33 countries (predominantly Western Africa), leading to disfiguration and functional impairment. It typically affects the rural poor, with the highest number of cases in children under 15 years of age. Treatment is difficult and often requires surgery, as well as skin grafting and long courses of antibiotics.

The EC and other European funders are among the largest investors in R&D for Buruli ulcer. Under the Seventh Framework Programme (FP7), the EC has invested €4.6 million in BuruliVac, a consortium to identify and develop new vaccine candidates. The consortium includes 16 institutions across Europe and Africa. Recent findings have shown that several vaccine candidates work well in preclinical studies.

**Preventing dengue epidemics**

Dengue fever is a mosquito-borne viral infection that usually causes a flu-like illness but that can develop into severe or haemorrhagic dengue, which kills between 12,500 and 25,000 people each year, and hospitalises half a million more. In recent decades, dengue epidemics have become more common and dengue is now the leading cause of serious illness and death among children in some parts of Asia and Latin America. There is currently no effective treatment for dengue and no dengue vaccine.

The French pharmaceutical company Sanofi is currently developing a new dengue vaccine, which is the most advanced vaccine candidate in the pipeline. The vaccine is currently in Phase III clinical trials, and is likely to be launched in 2014. Sanofi expects to produce about 100 million doses a year, enough to protect around 33 million children.

**Preventing leishmaniasis**

Leishmaniasis causes large skin lesions and, in its more severe form, can damage internal organs such as the spleen and liver. The disease is transmitted by sandflies and occurs across Africa, South America and the Middle East.

Under the Seventh Framework Programme (FP7), the EC is supporting two research consortia to develop a vaccine against human leishmaniasis, representing about half of the leishmaniasis vaccine candidates in active development. With a total EU contribution of approximately €6 million, the two consortia, LeishDNAvax and Rapsodi, have each taken a new vaccine candidate through preclinical development and are now ready to initiate clinical trials.

**Preventing malaria during pregnancy**

Malaria threatens about 125 million pregnancies around the world each year and, as a result, 10,000 women and up to 200,000 babies die in Africa alone. To reduce this risk, pregnant women are given Intermittent Preventative Treatment with sulfadoxine–pyrimethamine (SP) during pregnancy, however this approach is now under threat due to emerging SP-resistance.

MMV, a Swiss-based PDP, Pfizer and the London School of Hygiene and Tropical Medicine are working to develop AZCQ, a combination tablet of azithromycin and chloroquine, both of which have been proven safe in children and pregnant women. AZCQ is in Phase Ib/II trials and is planned to be submitted through the European Medicines Agency’s Article 58 mechanism to facilitate developing country approval and use. The governments of Ireland, the Netherlands, Spain, the UK, Switzerland and the U.S. and other donors are providing funding for the development of AZCQ.

**Preventing schistosomiasis infections**

Schistosomiasis is a chronic disease, caused by exposure during agricultural and domestic activities to parasitic worms that live in the water. At least 230 million people require treatment for schistosomiasis each year, mainly in sub-Saharan Africa. Currently, only a fraction of these receive treatment, mainly through annual mass drug administration programmes, where at-risk populations are treated for a number of neglected tropical diseases at the same time (regardless of whether they have the disease or not). Mass drug administration is effective and inexpensive, but can become a burden on health systems because of the sheer scale of need.

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xiv Article 58, established by the European Medicines Agency, was designed to assist developing country regulators by providing a reliable scientific opinion on the safety, efficacy and quality of new products intended for use outside the EU.
French and Belgian developers are collaborating to develop the most advanced vaccine candidate for schistosomiasis currently in the pipeline. Bilhavax is undergoing Phase III clinical trials in Senegal, and is a result of a partnership between Inserm (the French biomedical and public health research institution), Eurogentec (a Belgian-based biotechnology company) and the Institut Pasteur de Lille. Two regional governments – the Council Regional Nord-Pas de Calais (France) and the Walloon Region (Belgium) – are funding this project, together with Inserm.

Preventing Tuberculosis

TB has re-emerged as a leading cause of death, this time concentrated in the developing world. In 2010, 8.8 million people became ill with TB and 1.4 million died. It is estimated that TB will cost the world’s poorest countries $1-3 trillion over the next decade.

People with HIV are particularly susceptible, being 20-30 times more likely to develop TB. TB is the leading cause of death among those with HIV and is responsible for half of all AIDS-related deaths in sub-Saharan Africa. In recent years, drug-resistant forms of TB have also emerged. These forms of TB – known as multidrug-resistant (MDR) and extensively drug-resistant (XDR) TB – are extremely difficult and expensive to treat.

Oxford-Emergent Tuberculosis BioSolutions and Aeras, a U.S.-based PDP, are working together to develop the most advanced TB vaccine candidate (MVA85A) to date. It was originally developed at the University of Oxford, with funding from the EC’s Seventh Framework Programme (FP7), the UK MRC and the Wellcome Trust, and is now in Phase II clinical trials in The Gambia and South Africa. Additional funding for these trials is being provided by the governments of Denmark, the Netherlands, Norway and the U.S., as well as by the Bill & Melinda Gates Foundation.

The EC is now funding four of the six TB vaccine candidates in Phase II trials globally, which involve both industry (GlaxoSmithKline (GSK), Crucell) and developing country partners (such as the Kenya Medical Research Institute).

There is growing recognition of the long-term value of building research capacity in developing countries, and of technology transfer to the South. Europe’s PRND R&D investment is contributing directly and significantly to these efforts.

Some of the leading research institutions in sub-Saharan Africa and Asia have a rich tradition of tropical medicine research, which has been supported by European donors. The UK MRC has been conducting clinical research in the Gambia since 1947. Currently, the MRC Gambia Unit has around 750 staff – including over 600 Gambians – making it the third largest employer in the country. The unit represents the UK’s single largest investment in tropical medicine research in a developing country. Similarly, the Ifakara Health Institute in Tanzania was born out of a partnership with the Swiss Tropical and Public Health Institute that spans more than five decades. Ifakara is now supported by Ireland, the UK and Norway in addition to Switzerland.
The EU’s PRND investment is also developing the next generation of research leaders through the support of postgraduate trainee positions. For example, the EDCTP has supported 38 senior fellows, 5 career development fellows, and around 95 PhD and 165 Masters students, the majority from developing countries.

Increasingly, PRND R&D funded by the EU Member States and the EC is being conducted by European institutions in partnership with institutions in the countries that are affected by neglected diseases. These partnerships enable developing country and European institutions to exchange knowledge, and allow research and training activities to be conducted at the heart of the problem. Many of these involve long-term partnerships that deliver impressive results. In particular, these partnerships have been critical to ensuring that many new PRND products reach the market quickly; without strong counterparts in the developing world, many products would not have passed through the clinical development phase so rapidly.
Developing country research institutions are also playing an increasingly central role in developing new global health products. For instance, the Manhiça Health Research Centre in Mozambique, built with funding from the Spanish Agency for International Development (AECID) and the Catalan Agency for Development Cooperation (ACCD), was selected as one of the trial sites for the clinical development of the malaria drugs Coartem® and Eurartesim®, while 11 sites in seven sub-Saharan African countries are currently conducting clinical trials of the new RTS,S malaria vaccine, including Kilifi in Kenya (UK Wellcome Trust supported) and the Hospital Albert Schweitzer in Gabon (working with the University of Tübingen, Germany)\(^1\). The EC’s Directorate-General for Development and Cooperation (EuropesAid) has also supported the development of PRND R&D capacity in developing countries. For instance, €5 million was contributed to develop clinical trial capacity and monitoring facilities at sites in South Africa and Senegal in order to conduct Phase I, II and III trials for the leading TB vaccine candidate MVA85A.

<table>
<thead>
<tr>
<th>Institute</th>
<th>Research Partnerships with Developing Countries</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bernhard Nocht Institute for Tropical Medicine (Germany)</td>
<td>Jointly runs the Kumasi Centre for Collaborative Research (KCCCR) in Tropical Medicine together with the Ghanaian Ministry of Health and Kwame Nkrumah University, conducting field and laboratory research on malaria, TB, river blindness and Buruli ulcer. The KCCR hosts graduate students from the Kwame Nkrumah University as well as researchers from the Bernhard Nocht Institute and the University of Bonn.</td>
</tr>
<tr>
<td>Heidelberg University (Germany)</td>
<td>Longstanding partnership with Centre de Recherche en Santé de Nouna (CRSN) in Burkina Faso; CRSN has since expanded into a national centre for biomedical, clinical, health systems and environmental research with diverse partners in the North and South. Division of Clinical Tropical Medicine coordinates a partnership program through the Ghanaian-German Centre for Health Research at the University of Ghana, where interdisciplinary teams of German and African researchers work in tandem on a range of PRND projects.</td>
</tr>
<tr>
<td>Institut Pasteur (France)</td>
<td>Institut Pasteur International Network consists of 32 institutions on 5 continents, hosting 8 WHO collaborating centres and employing 2600 staff of more than 60 nationalities(^2). Yellow fever vaccine was developed at the Institut Pasteur in Dakar; Nobel prize-winning research on typhus was done at the Institut Pasteur in Tunisia.</td>
</tr>
<tr>
<td>Institute of Tropical Medicine Antwerp (Belgium)</td>
<td>Co-founder of the European Developing Countries Clinical Trials Partnership (EDCTP). Prepares approximately 60 PhD candidates from developing countries yearly (more than 95% of students go back to their country of origin after graduation)(^2).</td>
</tr>
<tr>
<td>Liverpool School of Tropical Medicine (United Kingdom)</td>
<td>Established the Centre for Neglected Tropical Diseases, which serves as the Secretariat for the Global Alliance to Eliminate Lymphatic Filariasis. Key partner in the Malawi-Liverpool Wellcome Programme, which has become an internationally-renowned research and training centre.</td>
</tr>
<tr>
<td>London School of Hygiene and Tropical Medicine (United Kingdom)</td>
<td>80 funded Research Centres, groups and collaborative partnerships across Africa, the Americas, Europe and Asia(^2). Runs the Malaria Centre, which hosts the largest number of malaria researchers and students in Europe. Trained more than 20,000 LSHTM alumni who are working in more than 180 countries worldwide(^2).</td>
</tr>
<tr>
<td>Statens Serum Institute (Denmark)</td>
<td>Participates in a number of PRND research partnerships, including the Tuberculosis Vaccine Initiative, NEWTBVAC and EDCTP.</td>
</tr>
<tr>
<td>Swiss Tropical and Public Health Institute (Switzerland)</td>
<td>Built up Ifakara Health Institute (IHI) in Tanzania from a field site in 1957 to its present-day status as an eminent African health research organization. Capacity building in East Africa for sleeping sickness control, which culminated in the foundation of the Eastern Africa Network for Trypanosomiasis (EANETT). Conducts series of advanced courses in International Health attended by more than 150 students yearly from home and abroad, in collaboration with Ifakara(^2).</td>
</tr>
</tbody>
</table>

Table 1. Key European and developing country research partnerships
Table 2.
Examples of developing country involvement in PRND product R&D

<table>
<thead>
<tr>
<th>Institute/Research Centre</th>
<th>Key European partners</th>
<th>Trials of PRND products registered</th>
<th>Trials of PRND products still in development</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ifakara Health Institute (Tanzania)</td>
<td>Irish Aid, UK DFID, Norwegian NORAD, Swiss SDC, EDCTP</td>
<td>Coartem Dispersible®, Pyramax®</td>
<td>The RTS, S malaria vaccine for pregnant women, Evaluating 10 new TB diagnostics, A new TB drug</td>
</tr>
<tr>
<td>International Centre for Diarrhoeal Disease Research (ICDDR,B) (Bangladesh)</td>
<td>Swedish SIDA, UK DFID, Swiss SDC</td>
<td>Oral rehydration therapy and zinc therapy for diarrhoea, Dukoral® (cholera vaccine), Rotarix™ (rotavirus vaccine), Invented and patented a novel diagnostic method for TB</td>
<td>The RTS,S malaria vaccine for pregnant women, A new TB vaccine, Malaria drug (fomosidomycin-clindamycin)</td>
</tr>
<tr>
<td>Manhiça Health Research Centre (CISM) (Mozambique)</td>
<td>Spanish AECID and ACCD, EDCTP</td>
<td>Eurartesim® (malaria drug), Coartem Dispersible®(malaria drug)</td>
<td>The RTS,S malaria vaccine for pregnant women, A new TB vaccine, Malaria drug (fomosidomycin-clindamycin)</td>
</tr>
<tr>
<td>Medical Research Council (MRC) Gambia Unit (Gambia)</td>
<td>UK Medical Research Council, EDCTP</td>
<td>Hib vaccine, Pneumococcal conjugate vaccine, MenAfriVac (meningococcal vaccine), Pyramax® (malaria drug)</td>
<td>A second generation malaria vaccine, Two new TB vaccines</td>
</tr>
<tr>
<td>Medical Research Unit – Albert Schweitzer Hospital (Gabon)</td>
<td>German BMBF, EDCTP</td>
<td>Malarone (malaria drug), LapDap (malaria drug), Coarsucam® (malaria drug), Pyramax® Artesunate injection (malaria drug)</td>
<td>A second generation malaria vaccine, New malaria drugs (tafenoquine; fomosidomycin-clindamycin), A new TB drug</td>
</tr>
</tbody>
</table>

Irish Aid, Spanish AECID and ACCD, Swedish SIDA, UK DFID, Norwegian NORAD and Swiss SDC are the aid/development cooperation agencies in their respective countries. The German BMBF is the German Federal Ministry of Education and Research.

These achievements demonstrate that European support is successfully building research capacity in developing countries, paving the way for a more inclusive and sustainable PRND research landscape.
As austerity measures are implemented across Europe in response to the sovereign debt crisis, it has become increasingly necessary to rationalise EU investment in PRND R&D, not just in terms of the health and economic benefits to developing countries, but also in terms of the economic return to Europe itself. The collateral benefits of PRND R&D to Europe are often overlooked in favour of the humanitarian impact of those investments on communities in the developing world. However, in this economic climate, it is important to consider the impact of the EU’s financial commitments to PRND R&D on European growth and competitiveness, as well as the health benefits to European populations.

The link between economic growth and investment in research and innovation is well established\textsuperscript{23}. Indeed, investment in R&D is often hailed as a smart growth strategy – one that can increase Europe’s competitiveness in the global marketplace while at the same time addressing critical health and societal challenges. But does the link between R&D investment and growth hold true for PRND R&D? More broadly, what return on investment has Europe’s funding of PRND R&D generated in terms of Europe’s own overarching goals of scientific excellence, collaboration and integration, industrial leadership, and societal and health benefits?

The majority of Europe’s PRND R&D funding is reinvested into European economic activity

Europe’s PRND R&D investment has contributed to the creation of technologies that not only save lives and money in the developing world, but have also generated significant value within Europe. Between 2007 and 2010, for every euro that Member States and the EC gave to PRND R&D, approximately 66 euro cents were reinvested back into Europe, going to researchers and product developers working in European laboratories, universities and companies to unravel the science of PRNDs and develop new products to combat them.

Each euro invested into PRND R&D by European governments leverages an equal or greater investment by others into Europe

Not only do 66 cents of each euro invested by Europe go back into Europe, but each euro of European government PRND R&D investment generates a further €1.05 in investments into Europe from companies, philanthropic organisations and other governments, many of these based outside Europe\textsuperscript{xv}. In other words, Europe’s governments are in substantial net gain for every euro they spend on PRND R&D.

\textsuperscript{xv} See Appendix 1, ‘External, industry and philanthropic investment leveraged by EU PRND government funding’ for analysis methodology
PRND R&D has created thousands of European jobs

Europe’s PRND R&D investment has created well over 13,000 European jobs. As noted, around two-thirds of EU government investment into PRND R&D goes back into Europe. This investment created around 13,000 jobs in academic and research institutions, PDPs and private companies between 2002 and 2010\textsuperscript{xvi}.

Many additional European jobs were created as a result of leveraged investments from companies, the philanthropic sector and other government funders. For example, the TB Vaccine Initiative, a PDP based in the Netherlands, estimates that its operations have created at least 1,200 direct jobs in the EU\textsuperscript{xvii}; while GSK, a UK-headquartered multinational pharmaceutical company, employs around 120 scientists at its Tres Cantos Medicines Development Campus in Spain, which focusses on developing PRND products, including for malaria and TB.\textsuperscript{35}

Europe has a unique history in PRND research and innovation that has spanned decades. European tropical medicine institutions – many established in the nineteenth century - have been responsible for some of the most important scientific breakthroughs in PRND research, including for HIV, TB, malaria and neglected tropical diseases (see Table 3).

Europe’s tropical institutes identified the pathogens responsible for malaria, HIV and sleeping sickness; shed light on how filariasis, river blindness, malaria and typhus were transmitted; and pioneered technologies to combat diseases such as TB and yellow fever.

These tropical medicine institutes form the backbone of a thriving network of PRND researchers across Europe and, along with the European-based PDPs, pharmaceutical companies and SMEs, ensure Europe’s competitiveness in global health R&D.
<table>
<thead>
<tr>
<th>Institute</th>
<th>Key scientific achievements in infectious diseases and PRNDs</th>
</tr>
</thead>
</table>
| **Bernhard Nocht Institute for Tropical Medicine** (Germany)             | Produced some of the earliest findings related to life cycles of parasitic worms in the 1930s, which have proved crucial for understanding schistosomiasis transmission  
|                                                                          | Identified the coronavirus as the cause of the 2003 SARS outbreak and publicised all findings necessary for diagnosis on the same day without claiming any intellectual property rights; developed a diagnostic kit with partners a few weeks later for worldwide distribution  
|                                                                          | Discovery of ‘merosomes’, a previously-unknown life cycle stage of malaria parasites  
| **Institut Pasteur** (France)                                            | Discovered pasteurisation  
|                                                                          | First vaccines for: anthrax, rabies, TB, yellow fever  
|                                                                          | 4 Nobel Prizes related to infectious disease research:  
|                                                                          | • 1907 for research on role of protozoans as disease agents  
|                                                                          | • 1919 for discoveries on immunity and role of antibodies  
|                                                                          | • 1928 for discovery of typhus transmission mechanism  
|                                                                          | • 2008 for discovery of HIV virus as the cause of AIDS  
| **Institute of Tropical Medicine Antwerp** (Belgium)                    | Discovery of Ebola virus  
|                                                                          | Discovery of Leishmania ‘super’ parasites as the first known organism to couple acquired drug resistance to higher resistance against human immune system  
| **Liverpool School of Tropical Medicine** (United Kingdom)              | Identification of the mosquito as malaria vector  
|                                                                          | 1902 Nobel Prize for Ronald Ross’ work on malaria  
|                                                                          | Created the Innovative Vector Control Consortium (IVCC) – the only PDP working on vector control products  
|                                                                          | Discovered that onchocerciasis (river blindness) is transmitted by blackflies; first discovery that ivermectin (current-day treatment) prevented river blindness in cattle  
|                                                                          | Shed light on how filariasis (type of parasitic worm infection) and onchocerciasis are transmitted  
|                                                                          | Collaborative investigation of the first Ebola epidemic  
| **London School of Hygiene and Tropical Medicine** (United Kingdom)     | Carried out seminal “malaria hut” experiment as first evidence of malaria-mosquito theory  
|                                                                          | Led first trials of insecticide-treated-nets to control the spread of malaria  
|                                                                          | Discovery of trypanosomes as the cause of sleeping sickness  
|                                                                          | First comprehensive study to establish link between HIV and TB  
| **Statens Serum Institute** (Denmark)                                   | Led the production and supply of vaccines for European epidemics in the 1920s and 30s (diphtheria; tuberculosis; pertussis; foot-and-mouth disease; tetanus)  
|                                                                          | Founded the International Salmonella Center which serotyped more than 2000 types of salmonella  
| **Swiss Tropical and Public Health Institute** (Switzerland)            | Conducted first studies of controlled human malaria infection (CHMI) in African populations, a critical component of targeting malaria drug and vaccine development for endemic country use  
|                                                                          | Discovery of important genetic mutations allowing tuberculosis to become multidrug-resistant  
|                                                                          | Elucidation of the mechanisms of drug resistance in African trypanosomes, which are responsible for many PRNDs including Chagas’ disease and sleeping sickness  

**Table 3. Key achievements of top EU PRND research institutes**
Partnerships between European researchers and developing country institutions increasingly contribute to maintaining this competitiveness. European researchers benefit in many ways from their collaborations with developing country counterparts — gaining close, on-the-ground knowledge of the diseases; acquiring up-to-date information on implementation challenges; and receiving valuable input on essential steps in the product development process, including developing the Target Product Profile. These benefits apply to European researchers across all sectors — whether in an academic institution or working for industry.

We noted earlier Europe’s role in creating new PRND products for the developing world. However, Europe’s impact in other areas of PRND research is also dramatic. Europe’s pre-eminent position as a discoverer and publisher of new knowledge was confirmed by a 2012 report, showing that the EU-27 was responsible for 31% of reviews and articles on neglected tropical diseases in 2011 — and as high as 35% if EU Associated Countries are included. A 2008 study on global malaria research outputs painted a similar picture, with Europe generating 36% of all scientific articles and reviews on malaria. However we note that, for both neglected tropical diseases and malaria, Europe’s knowledge lead is diminishing, with Brazil and India rapidly moving up the publication scale with 16% and 8% respectively of global malaria articles and reviews.

**Fig 14. Examples of top EU PRND research institutes**

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One of the overarching goals of the EC’s Seventh Framework Programme (FP7) and its Horizon 2020 successor is the promotion of integration and partnership across the EU. Indeed, one of the conditions of EC grants is collaboration with other EU-based institutions in order to facilitate and maintain European networks.

Evidence suggests this goal has been fully realised, with an examination of all PRND products in development showing that 77% of projects that involve a European partner are collaborative in nature, spanning multiple research sectors and geographic borders.

**Example 1: European Solutions Enterprise on Neglected Diseases (euSEND)**

European Solutions Enterprise on Neglected Diseases (euSEND) was established in 2010 with a start-up grant from Dutch Ministry of Health. euSEND plays ‘matchmaker and portfolio manager’ for public-private research consortia in neglected diseases and is itself a partnership between several Dutch organisations: TI Pharma (Dutch public-private partnership); the Academic Medical Center (public research); Royal Tropical Institute (KIT); Roland Berger Strategy Consultants (Dutch office); Amsterdam Institute for Global Health and Development.

Current projects include:

- a rapid field test for trachoma (the Foundation for Innovative New Diagnostics (FIND) + Royal Tropical Institute (KIT))
- identification of TB biomarkers to be used in future diagnostic development (FIND + KIT + Leiden University)
- searching for better, more useful diagnostic targets in leishmaniasis-infected patients (FIND + KIT + Eiken Institute)

**Example 2: European Vaccine Initiative**

The European Vaccine Initiative (EVI) is a European Economic Interest Group funded by the EC and Member States, which brings together the European academic research community with clinical networks and industry to develop effective, accessible and affordable vaccines against diseases of poverty. EVI was established by Stockholm University (Sweden) and Heidelberg University (Germany) but now also includes the Biomedical Primate Research Centre (Netherlands); Jenner Vaccine Foundation (UK); National Institute for Public Health and the Environment (Netherlands); and Royal College of Surgeons (Ireland). EVI is currently funding five PRND vaccine candidates.

**Example 3: Vakzine Projekt Management GmbH**

Vakzine Projekt Management GmbH (VPM) is a start-up funded by the German Federal Ministry of Education and Research (BMBF) to coordinate and finance preclinical and clinical development of promising vaccine candidates from German laboratories. VPM acquires the rights to promising candidates and develops them in cooperation with a pool of partners (predominantly German SMEs). Currently, VPM is focused on bringing the TB vaccine candidate VPM1002 through clinical trials.

**Example 4: EVIMalar (formerly BioMalPar)**

The European Virtual Institute of Malaria Research (EVIMalaR) is a Network of Excellence funded by the EC’s Seventh Framework Programme (FP7), which seeks to integrate and coordinate malaria research around the world. Formerly known as BioMalPar under the EC’s Sixth Framework Programme (FP6), the network has a strong European focus, with 56 of its 62 partners located across 10 European countries, and coordination services provided by the University of Glasgow in the UK. Part of the network’s focus is on ensuring that Europe is a world leader in the biology of the malaria parasite, particularly in the areas of immunobiology and vector-parasite interactions. EVIMalaR has significantly increased coordination between institutional laboratories within Europe and with developing country partners, and plays an active role in training students and advancing the research base (EVIMalar members have published approximately 400 publications).
The European and Developing Countries Clinical Trials Partnership (EDCTP) was established by the EC in 2003 to support the development of vaccines, microbicides, diagnostics and drugs for HIV & AIDS, malaria and tuberculosis in sub-Saharan Africa. The EDCTP is a partnership between 14 EU Member States plus two EU Associated Countries (Norway and Switzerland), and 47 sub-Saharan African countries.

The EDCTP promotes a more integrated approach to health research by allowing the EC to fund research programmes undertaken jointly by several Member States (providing, for the first time, a mechanism to improve coordination between the EC and Member States), while also facilitating partnerships with their sub-Saharan African counterparts. The EDCTP was designed to pool resources from the EC, the EU Member States and EU Associated Countries and third parties including industry and other non-governmental R&D funding agencies.

**Achievements**

After a difficult start from mid-2003 to 2006, when legal and administrative limitations hampered the EDCTP’s ability to deliver on its mandate, substantial progress has been achieved including:

- **Securing buy in and fostering collaborations between EU Member States and sub-Saharan African countries:** At the end of 2011, EDCTP-funded projects were being conducted in 29 sub-Saharan African countries with participation of 14 Member States, involving 211 research institutions in Europe and sub-Saharan Africa.

- **Leveraging investments from EU Member States and other third parties:** At the end of 2011, EC investment in the EDCTP (€142.5m) had leveraged €132 million from Member States and €81 million from third parties including PDPs, philanthropic organisations and industry. In other words, each euro invested by the EC generated a further €1.50 in investments from Member States and third parties (93 and 57 euro cents, respectively). Over half of third-party investments came from PDPs (54%), nearly one-third (32%) from philanthropic organisations based outside Europe, such as the Bill & Melinda Gates Foundation, but only 11% from industry.

- **Advancing the development of new products for PRND while creating capacity in sub-Saharan African countries:** At the end of 2011, the EDCTP had supported 57 clinical trials and funded 196 projects, including 64 to strengthen ethics review capacity.

- **Encouraging sub-Saharan African ownership, stewardship and leadership:** Sub-Saharan African researchers and policy makers are now represented in all EDCTP governing bodies including the General Assembly, the Partnership Board and the Developing Countries Coordinating Committee; and over 70% of all EDCTP-funded activities are led by sub-Saharan African researchers.

### Case study: the EDCTP

European pharmaceutical companies and SMEs are the industry leaders for PRNDs, working to create products in many neglected disease areas where there is no viable commercial market. European pharmaceutical companies and SMEs invested on average €178 million a year in PRND R&D between 2007 and 2010, a remarkable six times more relative to annual revenues than their U.S. counterparts - EU firms invested 0.18% of their annual revenues into PRND R&D, while U.S. firms invested only 0.03%. European pharmaceutical firms are also widely engaged in PRND R&D, with five Europe-based multinationals and over 25 European SMEs working in the field, accounting for nearly two-thirds (64%) of global industry investments in PRND R&D.

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xxi Original design envisioned total contributions of €600m (€200m from the EC, €200m from Member States and €200m from other public or private funds)

xxii See Appendix 1, ‘EU Member State and third-party funding leveraged by EDCTP’ for analysis methodology

xxiii Ethics review capacity refers to the ability of institutions to carry out ethical reviews of clinical trials. This involves research ethics committees reviewing proposals for, and monitoring the conduct of, clinical trials.
Several European multinationals have also invested significantly in setting up neglected and tropical disease research centres, focused on finding new PRND treatments and preventives. These include GSK’s Tres Cantos Medicines Development Campus in Spain; the Novartis Vaccine Institute for Global Health in Italy and the Novartis Institute for Tropical Diseases in Singapore, focussed on malaria, TB and dengue; Sanofi’s Access to Medicines department with specific initiatives on malaria, TB, leishmaniasis, sleeping sickness, Chagas’ disease and Buruli ulcer.

The underlying motivations driving European-based industry investments in PRND R&D vary between companies but their research programmes are facilitated by several common factors: proximity to European tropical medicine institutes and to a pool of PRND researchers; Europe’s long-standing political and cultural interest in the developing world and the need to address PRNDs; and proximity to PDPs and other public-private partnership models, many of which are based in Europe.

In the last decade, EU-based industry has played a significant role in bringing PRND products to market. This work is predominantly conducted in partnership with others, including PDPs and public institutions (for example, the creation of Coartem®, ASAQ, Eurartesim and others as discussed above). Additional examples of PRND products developed with industry involvement include:

**Primo Star iLED (LED fluorescence microscopy for TB diagnosis)**

Conventional microscopes are the mainstay for TB diagnosis in developing countries. However, fluorescence microscopy (FM) detects 10% more TB cases and is four times faster than normal microscopy. A German company, Carl Zeiss MicroImaging GmbH, developed the Primo Star iLED system, employing a new FM technology called LED-FM, which is specifically adapted for use in resource-poor settings. Together with the Swiss-based PDP, the Foundation for Innovative New Diagnostics (FIND), the diagnostic was evaluated across nine countries and resulted in the WHO recommending the use of LED FM over conventional microscopy. FIND negotiated with Carl Zeiss to provide the new diagnostic at preferential prices to 74 disease-endemic countries, and supported the scale-up of LED FM use in these countries. LED technology also has promise as a diagnostic for other infectious diseases including malaria, leishmaniasis and Chagas’ disease of Latin America.

**Rotarix®**

Rotarix® is a vaccine developed by UK-based GSK that targets rotavirus, a common cause of severe gastroenteritis in children under three. Rotavirus is responsible for the deaths of more than 450,000 children every year - virtually all in developing countries. Rotarix® was first licensed in Mexico, is now available in more than 100 countries and has been prequalified by the WHO for use by international procurement agencies, including the GAVI Alliance. GAVI estimates that rolling out the rotavirus vaccine to the poorest countries could prevent an estimated 180,000 deaths, avert 6 million clinic and hospital visits and save $68 million annually in treatment costs in GAVI-eligible countries alone.

**PRND R&D investment also saves lives and money in Europe**

EU investment in PRND R&D protects EU populations, as PRNDs occur in Europe as well as in developing countries. New PRND products improve the prevention and treatment of diseases that already exist in Europe, but also prevent the spread of new diseases to European populations - meaning that investment in PRND R&D is also an investment in Europe’s global health security.

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The GAVI Alliance is a public-private partnership that finances and supports delivery of vaccines for children in the world’s poorest 70 countries

Only some countries are eligible for support by GAVI. Eligibility is determined by Gross National Income (GNI) per capita levels
Helminth infections (eg. roundworm, whipworm, tapeworm and other parasitic worms)
- Other parasite infections (eg. leishmaniasis, Chagas’ disease)
- Tuberculosis (prevalence >1%)

There are 49 new TB cases and seven TB deaths every hour in Europe

PRNDs particularly affect two areas of Europe:
- In Eastern Europe, TB remains a serious problem, with some of the highest rates of drug-resistant TB in the world (see case study below). Likewise, high rates of parasitic infections still occur in Eastern Europe: soil- and food-based worm infections, some of which have been linked to childhood development and cognitive delays, are particularly important public health threats. Roundworm affects up to 16% of children in Poland, and up to 23% of preschool children in Estonia suffer from pinworm infections.
- In Southern Europe, other parasitic infections are emerging as a significant health issue. Leishmaniasis has been reported in Spain, Portugal, France, Italy and Greece, with 700 new cases occurring annually across Southern Europe. Chagas’ disease is present in both Spain and France and is related to immigration from Latin America27.
Tuberculosis remains a serious health issue in Europe, resulting in 49 new cases and seven deaths every hour across the region. With the vast majority of TB cases arising during people's most productive years, the economic cost is extremely high, estimated at €750 million per year to the EU.

Of particular concern is the emergence of new, drug-resistant strains of TB, known as multidrug-resistant (MDR) and extensively drug-resistant (XDR) TB, which are extremely difficult and expensive to treat. Treatment for MDR-TB (defined as resistance to standard first-line TB drugs) takes up to 24 months, has significant side effects and - worst of all - often fails, with four out of every 10 patients dying despite treatment. European countries, particularly former Soviet Union countries, have some of the highest proportions globally of MDR-TB, with 29% of new TB cases in parts of Russia showing multidrug-resistance, 26% in Belarus and 18% in Estonia. XDR-TB (where both first- and second-line TB treatments are ineffective) is also emerging as a worrying problem, with 20% of MDR-TB cases in Estonia and 15% of MDR-TB cases in Latvia reported as XDR-TB (compared to the global average of 5%). The costs of treating drug-resistant forms of TB, which can be thousands of times more expensive than regular treatment, mean the costs of TB to Europe are at risk of multiplying at an alarming rate.

Fortunately, progress is being made towards better tools to detect and treat TB, MDR-TB and XDR-TB. The Foundation for Innovative New Diagnostics (FIND), a PDP based in Switzerland, has co-developed a new TB diagnostic called Xpert® MTB/RIF, together with Cepheid (a U.S. private company). This test is significantly better than previous tests in detecting drug-resistant forms of TB and diagnosing TB in HIV patients, allowing TB-infected patients to start appropriate treatment on the day they first present with potential TB symptoms. New drugs in the pipeline, such as PA-M-Z, a combination of two new drugs (PA-824, developed by the TB Alliance, a U.S.-based PDP, and moxifloxacin, developed by the German company Bayer Healthcare Pharmaceuticals) and pyrazinamide, promise to shorten the treatment of drug-resistant TB from two years to four months, dramatically reducing the cost of MDR-TB treatment. Data from initial trials of PA-M-Z suggest that it could reduce the cost of MDR-TB treatment by 90%, from €1,600-€7,200 per patient to just €250 for the drugs alone. Shorter, simpler and more affordable treatments for MDR-TB and XDR-TB will allow European countries to scale up treatment for drug-resistant TB patients, something that is extremely difficult with current tools.

Protecting at-risk EU populations, who live in or travel to developing countries, is also important in containing new disease threats. With high travel and immigration rates – EU citizens take over 90 million trips outside the EU each year, and 31.4 million EU residents were born outside the EU – there is a considerable risk of introducing PRNDs to Europe. For example, Chagas’ disease was introduced into Spain through migration from Latin America, resulting in over 6,000 cases in Spain today. Defence personnel stationed overseas are particularly at risk, with 68,000 European troops abroad in 2009. European troops have been deployed to countries such as Chad, the Congo and Guinea-Bissau, which are high-risk for PRNDs compared to other EU deployment areas.
With its world-class research institutions and committed private sector, Europe is leading the world in many areas of PRND research and innovation. The €341 million invested in PRND R&D each year by EU Member States and the EC also generates considerable value for developing countries and Europe itself.

For the developing world, this investment has generated new scientific knowledge and contributed to the creation of many of the 43 new products that are already delivering health benefits to developing country populations. Products such as the pneumococcal conjugate vaccine, the meningitis A vaccine and new antimalarials have already saved the lives of millions of people living in the poorest countries in the world, and millions of dollars for their governments and for international donors. The development of new PRND products also contributes significantly to achieving the MDGs – improving health worldwide by combating diseases such as HIV & AIDS and malaria, as well as contributing to SRHR and poverty alleviation. The 359 additional products now in the development pipeline promise to deliver further health benefits, with dramatic improvements expected from new TB treatments and new vaccines for HIV, malaria and dengue. For instance, modelling has suggested that an HIV vaccine with even 50% efficacy provided to just 30% of the population could reduce the number of new HIV infections in the developing world by a quarter over 15 years, preventing 5.6 million new infections\textsuperscript{50}. This could go a long way to meeting the current Joint United Nations Programme on HIV/AIDS (UNAIDS) goal of averting 12.2 million new infections by 2020 at a cost of $19.8 billion\textsuperscript{51}.

In addition, PRND R&D funding also offers strong positive returns on investment for Europe. European PRND R&D funding increases the credibility and scientific excellence of European research institutions and supports the European project by engendering strong collaborative networks between research and industry sectors and Member States. Importantly, PRND R&D investment creates new European jobs and encourages investment in Europe - two-thirds of the EU's PRND R&D investment goes directly back to European researchers and developers and, more tellingly, each euro invested by the public sector in Europe leverages an additional €1.05 in investment from companies, philanthropic organisations and other governments. In short, European governments and the EC have a net economic gain from every euro they invest.

Investment in PRND R&D achieves all the goals of Horizon 2020 – scientific excellence, growth, industrial leadership, job creation, integration, and health and societal benefits. It also creates a win-win situation for both the EU and the developing world, creating reciprocal benefits that go well beyond health alone.

EU investment in PRND R&D is distinctive in many ways, and these unique features are often its real strengths. European funding emphasises collaboration and partnerships, including through the EDCTP research consortia (often involving academic institutions and national research institutes) and through championing the successful PDP model\textsuperscript{xxvi}. Investment by EU donors increasingly takes into account what developing countries want and need, and focuses on the quality (not just the quantity) of R&D outcomes. Crucially, Europe has shown the world that industry can play an important role in developing PRND products, with a strong industry presence that funds six times more PRND R&D than its U.S. counterparts, in relative terms. These are all essential pillars of Europe’s competitive advantage, and should continue to shape future EU investment and Europe’s interaction with the rest of the world.

\textsuperscript{xxvi} Member states have supported the PDP model globally while the EC has only supported EU-based PDPs
Collaboration and partnerships

Collaboration is central to the EU investment model, including EC-funded calls for proposals under the Seventh Framework Programme (FP7) and the EDCTP, resulting in partnerships that allow sharing of knowledge and technologies. As a leading EU government funder has noted, “collaboration is built into the way European funding operates – the model is collaborative to start with”. More than three out of four PRND projects involving a European partner are collaborative in nature, allowing researchers to leverage the expertise of different sectors (academic organisations, industry and PDPs). Emphasis is placed on collaboration between EU organisations and, increasingly, on collaboration between EU institutions and developing country institutions. The EDCTP is steadily proving itself as a successful example of collaboration between the EC, Member States and sub-Saharan African countries – establishing new North-South networks, improving coordination between European national programmes, and enabling the EC to leverage €1.50 in investments from Member States, philanthropic organisations and industry for each euro invested\(^\text{xxvii}\) (an even higher amount than the €1.05 leveraged by EU government investment in PRND R&D generally\(^\text{xxviii}\)).

Europe’s focus on collaboration has also helped to foster the PDP model, which leverages the expertise and resources of government, industry and philanthropic institutions, resulting in increased time and cost efficiencies. EU Member States and the EC have accounted for over half of government funding commitments for PDPs from their inception through to 2019 (56%, €850m)\(^\text{xxix}\). Notably, European PDP funding sources are highly concentrated with nearly three-quarters coming from the UK (37%, €314m), Dutch (26%, €221m) and Irish (11%, €92m) aid agencies (as of 2009). The EC also primarily targets EU-based PDPs – indeed, U.S.-based PDPs have received only 11% of the PDP funding committed by the EC during this period.

As a result of the EU’s consistent support, PDPs now play an essential role in bringing new global health products to market – PDPs were responsible for over 40% of products registered between 2000 and 2011\(^\text{xx}^\text{xx}\) (including the TB diagnostic Xpert® MTB/RIF, and the antimalarial drugs Coartem®, ASAQ and Eurartesim®). This has benefited thousands of developing country patients – for instance, the Xpert® MTB/RIF test (co-developed by Swiss-based PDP FIND and a U.S.-based SME, Cepheid), is expected to triple the numbers of patients diagnosed with drug-resistant TB and double the diagnosis of TB in HIV-infected patients.

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\(^{xxvii}\) See Appendix 1, ‘EU Member State and third-party funding leveraged by EDCTP’ for analysis methodology
\(^{xxviii}\) See Appendix 1, ‘External, industry and philanthropic investment leveraged by EU PRND government funding’ for analysis methodology
\(^{xxix}\) These figures include both disbursed funding and committed funding to PDPs
Building capacity in developing countries

EU funding for PRND R&D is notable for its strong focus on benefits to developing countries, and particularly on building research capacity in these countries. This means that EU investment is more likely to ensure that local researchers and institutes are able to play an increasingly important role in developing new PRND products. Consistent and long-term support from a range of EU governments has enabled leading research institutes in Asia and sub-Saharan Africa, such as the Ikafara Health Institute in Tanzania, the International Centre for Diarrhoeal Disease and Research in Bangladesh and the Manhiça Health Research Centre in Mozambique, to train high-quality postgraduate researchers and build world-class research institutions. Importantly, many of these partnerships are conducted in a spirit of genuine reciprocity – for example, a joint Gambian Government/MRC Scientific Partnership Committee serves as a mechanism for the Gambian Government to play a key role in determining the MRC Gambia Unit’s strategic direction. The EDCTP also encourages developing country partners to set priorities through their representation on EDCTP governing bodies. This established tradition of interaction with developing countries is described by industry experts as “a huge advantage”, resulting in greater knowledge and expertise.

Quality research

European investment emphasises high-quality research. Europe is home to some of the oldest and most highly regarded global health research institutes in the world, including France’s Institut Pasteur, the Royal Tropical Institute in Amsterdam, the Bernard Nocht Institute for Tropical Medicine in Germany, the Liverpool & London Schools of Tropical Medicine in the UK and the Swiss Tropical Institute of Public Health. Their focus on excellence is clear in their numerous scientific breakthroughs (identifying the cause of sleeping sickness, developing the first vaccine for TB) and Nobel prizes (identifying the mosquito as the carrier of malaria).

Integrating industry

Equally importantly, Europe has led the way in integrating the private sector into the PRND R&D landscape. Europe-based companies account for two-thirds of global industry PRND R&D investments, and invest far more of their annual revenues in PRND R&D than their U.S. counterparts. Much of this work is conducted in collaboration with PDPs and public institutions and researchers, which makes Europe’s talented pool of researchers and its interest in the developing world a key drawcard for industry. As a result, industry has located key PRND R&D investments in Europe, including GSK’s leading Tres Cantos facility in Spain (a specialist, industry research facility focused on developing products for PRNDs, including malaria and TB) and the Novartis Vaccines Institute for Global Health in Italy (an institute to develop effective and affordable vaccines for PRNDs, including salmonella infections and meningitis).

Although EU PRND R&D investment has been successful in building partnerships, establishing quality institutions and bringing industry to the table, there are aspects that can be improved. Funding from Europe is highly concentrated and is still too low. Reducing inefficiencies in EU funding – by reducing conditionality, taking a more results-driven approach to collaboration, streamlining funding processes and increasing coordination – will substantially increase the return on investment for both developing countries and the EU, meaning more lives and dollars saved for each euro invested.

Funding needs to increase

Horizon 2020 provides an opportunity for Europe to invest more in an area where it is competitive, has a strong comparative advantage, and – because of its strong PRND research and industry base – creates a positive net economic benefit from every public euro invested. This is particularly so, as Europe’s own public funding is well below what it should be. The U.S. invests four times as much as the EU in relative GDP terms (0.0098% of GDP is spent on PRND R&D in the U.S., compared to 0.0024% of GDP in the EU).

The EU spends more on the Common Agricultural Policy in two days than it spends in a year on PRND R&D. Most EU Member States contribute little or nothing to PRND R&D, most Member State funding to the EDCTP comes from a handful of EU countries and more importantly, many relatively large European economies are still contributing at fairly low levels. With current funding at a mere 0.0024% of GDP, and with each euro invested creating more jobs and investment than it costs the EU itself - Europe can and should invest more in PRND R&D. Doing so will benefit not only developing countries, but European countries where PRNDs still exist such as those facing drug-resistant TB in Eastern Europe.
Reduce funding conditionality

Reducing unnecessary conditions for EC funding will ensure the best research candidates are prioritised. Currently, organisations seeking funding under the EU Seventh Framework Programme (FP7) and the EDCTP face a wide range of conditions that effectively exclude some participants (for example, PDPs based outside Europe) or force participants into consortia that may not be the best or most efficient. These conditions include a high minimum number of participants, eligibility restrictions, and requirements for representation from several Member States. For example, the ‘Research for SMEs’ programme under the Seventh Framework Programme (FP7) requires projects to include at least three independent SMEs established in three different countries, as well as two additional research and technological development (RTD) participants (universities, academic organisations and companies). Many researchers and the PDPs find it impossible to fulfil these conditions, and doing so may not be the most efficient way to achieve the desired outcome of developing new products to address PRNDs. Likewise, co-funded EDCTP projects require participation by at least two European countries, with each country having different rules on eligibility and the type and amount of co-funding available. In the majority of cases, co-funding is only available to universities or institutes in that European country, excluding participation by organisations outside that country (and certainly outside Europe) which could be better positioned to strengthen the project.

Collaborate for results, not for its own sake

Revisiting some of these conditions and taking a more results-driven approach to collaboration are essential if Europe is to support the best research. Although the EU’s focus on collaboration is one of its strengths, it can often be implemented in a counterproductive way, forgetting that the purpose of collaboration is to leverage expertise and deliver greater impact. As a leading funder has observed, “too much emphasis is placed on the partnership itself rather than results or impact”. This leads to projects with extraordinarily high numbers of partners – some Seventh Framework Programme (FP7) projects have up to 26 participants – making coordination unwieldy and costing valuable time and euros. A more results-driven approach to collaboration will also recognise that the investigator-led consortium model is not necessarily ideal for all stages of the pipeline. Although suited to basic research, fast-evolving product pipelines require a more flexible approach, including the ability to constantly reprioritise and to contract with partners based on emerging needs. This portfolio-based approach, used by PDPs, has proven more efficient and more successful in the discovery, preclinical and clinical stages, with its focus on moving products through the pipeline and capitalising on each partner’s competitive advantage.

Decrease administrative timeframes

Shortening the time taken for funding to start flowing, by streamlining administrative processes and reducing decision-making timeframes, will mean that researchers can start delivering results more quickly. On average, it takes 348 days from the close of calls for proposals under Seventh Framework Programme (FP7) to the signature of the grant agreement, and participants have highlighted time-to-grant length as a significant concern in a recent FP7 monitoring report. EDCTP participants have also found administrative procedures to be “too bureaucratic and long”, due to lengthy application and review processes. Research funding requires greater flexibility.

Better coordination for better results

There is also a need to improve coordination between Member States, and between Member States and the EC. Some efforts have been made to work together and avoid duplication, including the EDCTP Joint Call by States and the coordination by the PDP Funders Group, which has agreed common reporting procedures among donors to minimise the burden on PDPs. However, participation in these coordination efforts is uneven and siloed approaches still persist. For example, France and Italy mostly fund PRND R&D within their own countries – 84% and 66% of funding respectively remains within their own borders.
Coordination can be improved by supporting existing pooled mechanisms and considering what more could be done. After a difficult start, the EDCTP is demonstrating that pooled funding mechanisms can be an effective means of coordination, although there is still room for improvement. In particular, if the EDCTP is to be a successful example of increased coordination, it would benefit from greater industry participation (industry only accounts for 11% of third-party investments to the EDCTP), broaden Member State funding and participation, and increase integration through joint proposals, common funding pots and other initiatives. In a climate of scarce resources and with many PRND products approaching expensive late-stage clinical trials, the increased efficiency of pooled funding becomes particularly important. If the EC can initiate more pooled funding mechanisms, drawing on the success of the EDCTP, it will demonstrate that the EC - along with the U.S. government and the Bill & Melinda Gates Foundation - is one of the few global groups who genuinely have the capacity to provide substantial funding and technical resources for PRND R&D.

Other levels of coordination that would improve the EU’s return on investment include coordination within Member States, and between EU and non-EU partners. Improved alignment between aid and science & technology agencies within Member States (for example, through a taskforce where both agencies are represented) could identify synergies and ensure the right balance between development funding and basic research funding. Similarly, coordination between EU funders and researchers and U.S. counterparts could be further improved. Collaborations such as the recent memorandum of understanding between the Dutch-based Tuberculosis Vaccine Initiative (TBVI) and the U.S.-based Aeras to jointly develop a common portfolio of new TB vaccines, and the formal cross-disease collaboration between the International AIDS Vaccine Initiative and Aeras to share information about TB and HIV vaccines, show that coordination is possible. This sort of alignment should be strongly encouraged.
The EU, including the EC and its Member States, should be proud of what its investment in PRND R&D has achieved: high-quality research institutions, strong partnerships that lead to successful products, increased research capacity in developing countries and impressive industry integration.

However, the return on PRND R&D investment to the EU and developing countries could be improved by implementing the following recommendations:

1. The EU should increase its investments in PRND R&D under Horizon 2020

   The benefits of EU funding for PRND R&D are clear in both the developing world and in Europe. With hundreds of promising products in the pipeline and with the budget for Horizon 2020 set to increase by 60% (from €50bn to €80bn), this is an opportune time to boost investments in PRND R&D. The EC should increase its PRND R&D investments by at least the same 60% increase as applied to the overall proposed Horizon 2020 budget.

   To develop a broad and sustainable funding base, all Member States should share responsibility for funding PRND R&D, including through funding collaborative mechanisms such as the EDCTP and PDPs as well as their own national research institutions.

2. The EU should retain and foster the distinctive benefits of its approach to funding PRND R&D

   EU investment in PRND R&D is distinctive in many positive ways – it focuses on collaboration and partnerships, promotes institutional excellence and capacity building in developing countries and attracts industry participation.

   Future investment should continue to promote all these aspects. Opportunities to do so include encouraging stronger industry relationships with the EDCTP and bringing more European countries into this mechanism.

3. The EU should improve specific aspects of its investment in PRND R&D, to ensure greater efficiency, impact and value

   To deliver better value for money, the EU should:

   - streamline conditions and processes to ensure the best research candidates are prioritised, including by:
     - removing unnecessary funding conditions
     - encouraging collaboration driven by results, not for its own sake
     - shortening the time for funding to start flowing (to 100 days, as proposed under Horizon 2020, or less)
   - increase coordination at all levels, including
     - between Member States, and between Member States and the EC (e.g., through pooled funding mechanisms like the EDCTP)
     - within Member States, particularly between science & technology and aid agencies
     - between EU and non-EU partners, including between EU- and U.S.-based PDPs.
APPENDIX 1.
METHODOLOGY

REPORT SCOPE

This report analyses European policy and investments in R&D for PRNDs (Poverty-Related and Neglected Diseases) during 2007-2010. Our scope for PRND R&D is based on the scope for the Global Funding of Innovation for Neglected Diseases (G-FINDER) survey, which was determined by a global advisory group and stakeholder network, and as defined below:

- Drugs, vaccine, diagnostics, microbicides and vector control products across 31 diseases
- All types of product-related R&D including basic research, discovery and preclinical, clinical development, Phase IV, pharmacovigilance studies and baseline epidemiological studies

While we recognize the importance of non-communicable diseases, sexual and reproductive health and rights (SRHR) and family planning in low- and middle-income countries, as well as other related activities such as implementation research and capacity building, these are outside the scope of this report. We also exclude non-pharmaceutical tools for the diseases covered, such as bednets or circumcision, as well as general therapies such as nutritional supplements.

DATA COLLECTION

Primary financial investment data was extracted from the G-FINDER databases\(^{xxxii}\) and reported in 2007 euros. This was done to make the data comparable across the four years and to avoid conflating real year-on-year changes with changes due to inflation. Analysis of European government R&D funding for PRNDs used the following definitions throughout the report:

- **EC funding**: consists of funding disbursed by the Directorate-General for Research and Innovation, European Commission (EC)
- **Member State funding**: consists of self-funding and grant funding originating from public sector government in EU-27 countries
- **EU funding**: consists of Member State funding plus EC funding

Other specific datapoints were provided by the EC, the European and Developing Countries Clinical Trials Partnership (EDCTP), European Vaccine Initiative (EVI), Tuberculosis Vaccine Initiative (TBVI), the Bill & Melinda Gates Foundation and Thomson Reuters. These included:

- Number of European jobs created by EC-funded health research projects between 2002 and 2010\(^{xxxiii}\)
- Member State and third-party contributions to the EDCTP\(^{xxxiv}\)
- Number of publications on neglected tropical diseases in 2011
- Government funding commitments to Product Development Partnerships (PDPs) supported by the Bill & Melinda Gates Foundation since inception through to 2019
- Government funding commitments to EVI and TBVI since inception

Qualitative policy data was obtained through desk-based research, and supplemented by communications with specific institutes or organisations mentioned in the report.
<table>
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<tr>
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<th>Drugs</th>
<th>Vaccines (Preventive)</th>
<th>Diagnostics</th>
<th>Microbiotics</th>
<th>Vaccines (Therapeutic)</th>
<th>Vector Control Products</th>
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Table 4. G-FINDER diseases, products and technologies

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<tr>
<th>Adjuvants and immunomodulators</th>
<th>Delivery technologies and devices</th>
<th>Diagnostic platforms</th>
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</table>
ANALYSIS

- **European involvement in the PRND product pipeline** was analysed based on a compilation of global health products and developers in a previous Policy Cures report\(^{xxxv}\).

- **External, industry and philanthropic investment leveraged by EU PRND government funding** was calculated as a ratio:

  The total amount of additional PRND R&D investment in EU-based recipient organisations from sources other than EU government funding (private industry based in and outside of Europe; philanthropic foundations based in and outside of Europe; and non-European governments) to Total PRND R&D funding from the EU and associated countries (Iceland, Norway, Switzerland)

- **Percentage of global industry funding coming from EU-based firms** was calculated as:

  The percentage of all industry funding for PRND R&D coming from firms headquartered in Europe

- **Jobs created by PRND R&D investment** was calculated through an extrapolation:

  - We first determined the number of jobs created by EC-funded PRND R&D projects based on the jobs created by EC-funded health research projects, assuming that the number of jobs created is directly proportional to the magnitude of R&D investment
  - This number was then extrapolated to jobs created by PRND R&D projects funded by Member States, assuming that Member State-funded projects created the same number of jobs per unit of investment as EC-funded projects
  - The numbers of jobs created by EC- and Member State-funded projects were multiplied by the ratio of funding flows to EU institutions to total funding, assuming that the ratio of funding flows to EU institutions reflects the ratio of jobs created in EU institutions

- **EU Member State and third-party funding leveraged by the EDCTP** was calculated as a ratio:

  The total amount of Member State and third-party funding to the EDCTP to Total amount of EC funding to the EDCTP

LIMITATIONS

The key limitation concerns potential gaps in the financial investment data. In particular, the G-FINDER data does not capture investments made by smaller European funders of PRND R&D who do not participate in the yearly G-FINDER surveys\(^{xxxvi}\).
## APPENDIX 2. ADVISORY COMMITTEE MEMBERS

<table>
<thead>
<tr>
<th>Organisation</th>
<th>Title</th>
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<tbody>
<tr>
<td>Jean-François Alesandrini</td>
<td>Drugs for Neglected Diseases Initiative (DNDi) Fundraising and Advocacy Director</td>
</tr>
<tr>
<td>Sarah Ewart</td>
<td>The Bill &amp; Melinda Gates Foundation Senior Program Officer, Global Health Program (formerly)</td>
</tr>
<tr>
<td>Prof. Dr. Bruno Gryseels</td>
<td>Institute of Tropical Medicine Antwerp Director</td>
</tr>
<tr>
<td>Sue Kinn</td>
<td>UK Department for International Development (DFID) Research Manager &amp; Chair of the PDP Funders’ Group</td>
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<tr>
<td>Line Matthiessen</td>
<td>Directorate-General for Research and Innovation, European Commission (EC) Head of Unit, Infectious Diseases</td>
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<tr>
<td>Ellen Strahlman</td>
<td>GlaxoSmithKline (GSK) Senior Vice President and Head of Global Neglected Tropical Diseases Unit</td>
</tr>
<tr>
<td>Anna Wang</td>
<td>The Bill &amp; Melinda Gates Foundation Consultant</td>
</tr>
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REFERENCES


52. Saving lives and creating impact: why investing in global health research works. Global Health Technologies Coalition / Policy Cures; 2012.