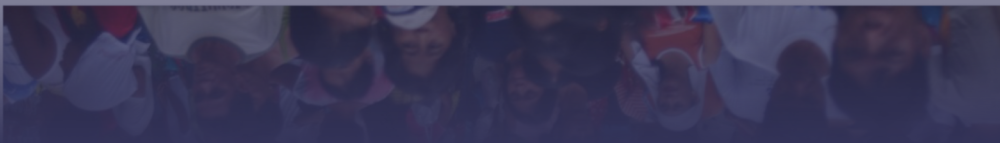


INCENTIVES FOR GLOBAL HEALTH

Health Impact Fund Pilot Proposal



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Executive summary

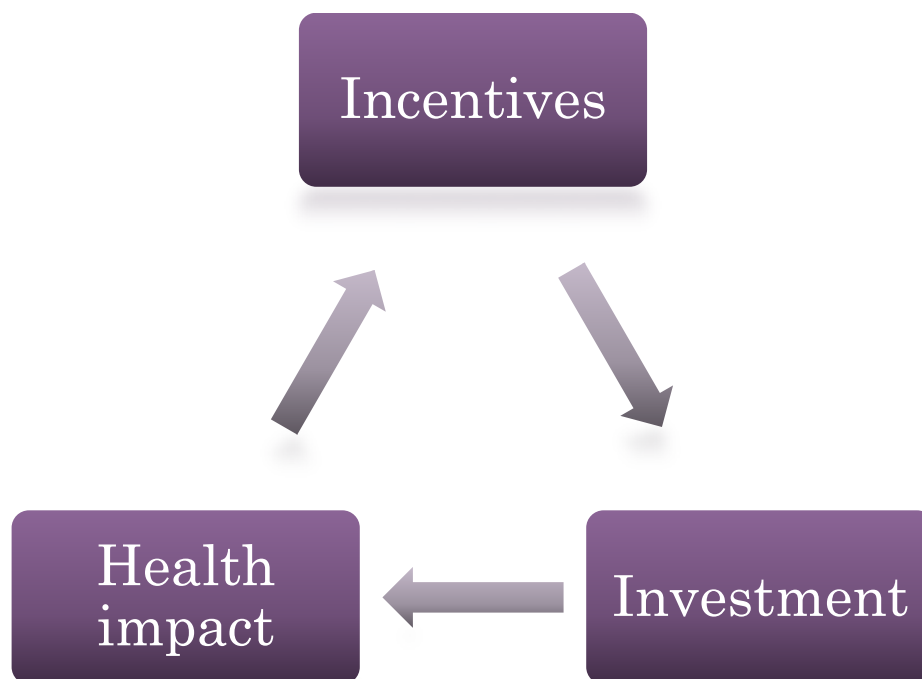
The Health Impact Fund (HIF) is intended to provide competitive returns to firms that develop drugs and vaccines to treat the diseases mostly prevalent in low- and middle-income countries. A smaller version – the HIF Pilot – could effectively demonstrate viability of this approach. The benefits of supporting the HIF Pilot are

- Helping to kickstart a transformative, sustainable solution to generate incremental revenues from therapies targeted at developing countries
- Helping to launch an institution that would increase commercial incentives to develop therapies for neglected diseases
- Leading a highly visible, innovative global public health initiative

The most effective HIF Pilot would be funded in the range of \$60m - \$200m, ideally with funding from several sources including foundations and governments.

The HIF Pilot would be a competition for pharmaceutical manufacturers to achieve health impact through an innovative drug, vaccine, delivery mechanism or formulation used mainly in low- and middle-income countries (a “project”). Firms would be invited to bid through a Request for Proposals; successful proposals would become eligible for rewards based on health impact achieved through the initiative. The available reward pool would be divided among the accepted projects in proportion to the health impact achieved by each.

The HIF Pilot would create incentives for investment into improving the health of poor people.



HIF Pilot design and terms

a. Summary

Incentives for Global Health (IGH), funded by donations from industry, governments and foundations, would conduct a competition for pharmaceutical firms to achieve health impact in low- and middle-income countries (“LMICs”) through pre-specified projects. The donations would fund a reward, to be allocated on the basis of health impact achieved during a defined period of time (e.g. 3 years) through each project. This competition would constitute the HIF Pilot.

b. Request for Proposals

IGH would issue a Request for Proposals. Firms wishing to compete would submit a proposal, describing a proposed initiative, its anticipated impact on health, and how health impact could be assessed. IGH would evaluate the proposals on the following criteria:

- Anticipated impact on health
- Innovation
- Ability to measure impact reliably and consistently
- Improved access to the therapy

IGH would, in collaboration with its partners, select the leading proposals in order to limit the number of competitors dividing the reward.

c. Examples of projects

The kinds of projects that firms could undertake to achieve health benefits include:

- Formulation and supply of a heat-stable drug or vaccine appropriate for use mainly in LMICs
- Formulation and supply of a fixed-dose therapy for use mainly in LMICs
- Formulation and supply of a pediatric dose of a drug for use mainly in LMICs
- Development and supply of a new product (drug or vaccine) suitable for use mainly in LMICs
- Development and use of a new distribution or treatment protocol suitable for use mainly in LMICs
- Development and supply of a diagnostic increasing the effectiveness of a drug for use mainly in LMICs

This list is indicative only of the kinds of projects that could be undertaken. Firms would be encouraged to consider broadly how to overcome the barriers they face for their products to achieve maximum health impact.

d. Competition to achieve health impact

After the selection process, successful proposals would compete for health impact rewards. At defined intervals, the impact of each firm’s initiative will be assessed in terms of QALYs or a similar measure. Each proponent would receive a share of the total reward proportional to the health impact of its project. The HIF Pilot will last for a fixed total period of time, e.g. 3 years.

e. Terms

1. Proponent eligibility

Eligibility would be restricted to pharmaceutical firms wishing to supply a new product, or increase access to or availability of a patented product, in LMICs. IGH would be the final arbiter of proposal eligibility. An eligible firm could partner with another firm or organization to undertake the project.

2. Project eligibility

Proponents would establish the terms of the project, including territorial extent, products or diseases covered, activities involved, and duration up to three years. The project would, however, be required to increase availability of and access to a new pharmaceutical product, including vaccines and drugs, within a pre-specified set of low- and middle-income countries. Firms would be expected to maximize access to the product being evaluated within the territorial limits and duration of the proposed project. Proposals should include a plan explaining how access will be maximized.

3. Project entry

IGH would create a project assessment expert committee to evaluate proposals. The expert committee would include experts with relevant field expertise, and would be selected to minimize conflicts of interest. The expert committee would select proposals based on criteria specified in the RFP, including expected impact, access terms, and ability to assess impact.

In order to ensure that all proponents were committed to the process, there would be a further stage. Selected proponents would be informed of the number of other selected proposals, as well as their geographic scope and medical indication. The proponents would then have the chance to accept to continue in the competition or to withdraw. If any proposal were withdrawn, IGH might add one or more new proposals, and then again invite proponents to accept or withdraw. Once all selected proponents had accepted, contracts would be signed, proponent identity and the general project scope of the proposals would be published, and the competition would begin.

Each selected proponent would have up to one year to start its project. This would give firms flexibility to develop their projects, recognizing that some projects would likely be “shovel-ready” and others still in development.

4. Assessment

IGH would commission the Institute for Health Metrics and Evaluation (IHME) to measure and assess project outcomes on a basis that allowed, to the greatest extent possible, for a fair comparison across different proposals. The process for evaluating health impact would likely vary across proposals. Because measurement of health impact is complex and health benefits are often specific to each therapy, proponents would be requested to explain how their proposal could be assessed, including specifying (and justifying) a correspondence between measurable outcomes and QALYs or healthy year equivalents. Firms would have the opportunity to comment on a draft evaluation of health impact. IHME would, however, be the final arbiter of assessment methodology and health impact assessed.

Assessment would rely on existing data from clinical trials complemented by newly collected data on real-world compliance, access, volume, patient characteristics and therapeutic outcomes. The HIF

Pilot would not require new clinical trials to assess effectiveness but mainly monitor how each drug is being used in each setting.

5. Reward payments

IGH would pay out the entire reward payment, divided between the proponents on the basis of total measured health impact of each proposal, within one year of the end of the HIF Pilot. Firms would not be compensated for any project costs. Rewards paid would be based only on assessed health impact of the project.

Subject to credible evidence of success in an interim assessment, IGH would pay out up to 30% of the total reward payments following the first 18 months of the competition. Any payments made on the basis of the interim assessment would be subtracted from the final reward payment due at the end of the competition. Interim payments would, however, not be repayable except in cases of fraud and/or intentional misrepresentations on the part of the proponent.

Notwithstanding the above, no proponent would be paid a final reward exceeding a maximum payment per unit of health impact achieved (e.g. \$8,000 per QALY). If, because of this condition, there were any funds remaining following payment for all projects, these funds would be donated to [the Global Fund].

The total reward payment would be equal to the funding given for the HIF Pilot, less the expenses of managing the competition and assessing health outcomes.

It is anticipated that the World Bank would be the trustee of funds, and responsible for payment of rewards according to the contracts and the determination of health impact as assessed by IHME.

6. Termination

A proponent would be able to terminate its participation in the competition by sending notice of withdrawal. In this case, the proponent would forfeit the right to any payment under the competition; it would also be liable for any costs of assessment of its project incurred by IHME up to the time of termination. If termination were to occur after an interim payment had been made, the proponent would have to repay the interim payment.

If a proponent failed to make a good faith effort to achieve the access/availability plan outlined in its proposal, IGH would possibly, following a warning, and consultations with the company, retain a third party to mediate. If this were unsuccessful, IGH may disqualify the proponent from the competition. In this case, the proponent would forfeit the right to any payment under the competition.

7. Confidentiality

Proposals would be confidential, including the identities of proponents and their projects. Summaries of accepted proposals and the identities of proponents would be published by IGH. Highlights of projects would be publicized, in collaboration with proponents. IGH would also publish final summaries of projects' health impact, including a discussion of assessment methodologies and outcomes by country.

8. Other terms

Legal jurisdiction

Rights of appeal quite limited.

Why the HIF Pilot?

a. The Health Impact Fund offers a way forward

Traditionally, there has been little commercial incentive for pharmaceutical firms to invest in solving health problems that are specific to LICs. Effective demand is extremely weak, even where the health benefits are substantial, since poor people typically lack insurance and cannot pay high prices. Organizations such as the Global Fund, GAVI, and PEPFAR have helped increase access to older (and occasionally newer) drugs and vaccines, but have not created a climate that favors investment in new therapies; their mandate is to achieve the maximum health gains given their budgets, and this has necessarily precluded paying for performance.

The Health Impact Fund (HIF) offers a new model that encourages firms to invest in developing therapies that achieve significant health gains among the poor. The HIF would offer pharmaceutical firms a choice of whether to sell their drugs in the usual way, or to register with the HIF. Registered drugs would be eligible for health impact rewards paid by the HIF, based on the assessed global health benefits of each registered product. Firms, in exchange, would be required to sell registered products at the cost of production. Funding for rewards would come from governments, proportional to national income. A reasonable scale for the HIF to achieve its goals of stimulating innovation to tackle the most important diseases affecting people in low- and middle-income countries is approximately \$6bn per year in rewards. The HIF would not have any impact on intellectual property; it would be a reimbursement mechanism for drugs and vaccines for which the therapeutic value is large but the commercial value is small. The HIF would be a permanent institution that would enable firms to achieve a competitive (or at least meaningful) return from investments in neglected diseases and other health conditions principally prevalent in low- and middle-income countries.

For more on the HIF proposal, see www.healthimpactfund.org.

The HIF Pilot would be a demonstration project for the HIF, and is not intended to replicate it in terms of its incentives on developing new drugs. Instead, it would be focused on demonstrating the feasibility of rewarding new drugs based on assessed health impact. The HIF Pilot would establish the groundwork needed to make a push to fund the HIF permanently at a scale that would make a real difference to the health of the world.

b. The HIF is good for the world – and for pharmaceutical companies

There are many worthy initiatives for increasing access to drugs in low- and middle-income countries. The HIF is the only one that offers a way of rewarding firms for developing new products to treat diseases specific to, or mainly prevalent in, these countries.

Other initiatives fall into one of several groups:

Large-scale purchase and provision of (mainly generic) drugs

Global Fund; Unitaid; PEPFAR; GAVI; Clinton Foundation

Even when these organizations purchase patented products, they tend to do so at generic prices.

Licensing advocacy

Medicines Patent Pool; various civil society organizations focused on compulsory licensing

This approach does not create incentives to develop new drugs or vaccines.

Product Development Partnerships

TB Alliance; Medicines for Malaria Venture

These organizations, funded substantially by the Gates Foundation, collaborate with pharmaceutical companies to develop new drugs within their areas of specialization. Pharmaceutical partners typically retain commercial rights in high-income countries in exchange for sharing their product library or other research contribution. Generally, commercial returns are not substantial.

Notably, none of these initiatives offers pay-for-performance or creates a competitive environment. Pay-for-performance is essentially the mechanism that is used very successfully for pharmaceuticals generally: drugs that have a large impact on health tend to generate high profits. Whether the system of determining price is formalized – as in the UK – or informal and set through negotiation – as in the US – the underlying principle is that insurers and patients look for value in the product being offered. Products with high perceived value and large volume can earn substantial profits.

The pharmaceutical market in high-income countries is also inherently competitive. Innovative firms compete to develop new, valuable products and then to achieve high utilization. Competition is important since it pushes firms to achieve a high level of performance and innovation. Competition and pay-for-performance together drive firms to be efficient in their allocation of capital. Unfortunately, these principles are not applied in the development or supply of pharmaceuticals in low-income settings, because the market is not lucrative, and the existing alternative initiatives do not reward firms for value.

The HIF is designed to introduce the two principles of pay-for-performance and competition into the development and supply of drugs and vaccines mainly used in low- and middle-income settings. Through the HIF, firms would be motivated to deliver value in a competitive environment.

This would be good for the world, since the existing system of drug development and supply is very productive and delivers enormous value to humanity. The HIF could extend these same benefits into disease areas where well-targeted investment could make a significant difference.

The HIF would also be good for pharmaceutical companies, since it would open up new commercial opportunities, aligning social goals of improved health in all corners of the world with the corporate mandate to earn a return for investors.

The competition is not designed so that one firm wins and another loses, in that firms are competing with different proposals and investments, different therapeutic classes and geographies. All the participating firms win by achieving a measurable improvement in human health.

c. Who is Incentives for Global Health?

Incentives for Global Health is US-registered non-profit focused on promoting the Health Impact Fund proposal. The President is Aidan Hollis, Professor of Economics at the University of Calgary. He is assisted by a group of staff and volunteers, as well as an international advisory board.

International Advisory Board

Noam Chomsky	<i>Institute Professor Emeritus, MIT</i>
John J. DeGioia	<i>President, Georgetown University</i>
Ruth Faden	<i>Director, Berman Institute of Bioethics, Johns Hopkins University</i>
Paul Farmer	<i>Harvard Medical School; co-founder, Partners in Health</i>
Robert Gallo	<i>Institute of Human Virology</i>
Paul Martin	<i>Former Prime Minister of Canada</i>
David Haslam	<i>Chair, UK National Institute of Health and Clinical Excellence</i>
Christopher Murray	<i>Director, University of Washington Institute for Health Metrics and Evaluation</i>
Baroness Onora O'Neill	<i>House of Lords; former British Academy President & Newnham College Principal</i>
Sir Gustav Nossal	<i>Former Director, Hall Institute of Medical Research, University of Melbourne</i>
James Orbinski	<i>Former International President, Médecins Sans Frontières</i>
Sir Michael Rawlins	<i>Former Chair, UK National Institute of Health and Clinical Excellence</i>
Jan Rosier	<i>Professor of Biotech Business, former VP of Janssen Drug Development</i>

Karin Roth	<i>Former Member of the German Parliament</i>
Amartya Sen	<i>Nobel Prize in Economics; Professor, Harvard University</i>
Peter Singer	<i>Professor, Princeton University</i>
Judith Whitworth	<i>Former Chair, WHO Advisory Committee on Health Research</i>
Heidemarie Wieczorek-Zeul	<i>Former German Minister of Economic Cooperation and Development</i>
Richard Wilder	<i>Associate General Counsel, Bill and Melinda Gates Foundation</i>
Formerly:	
Kenneth J. Arrow	<i>Nobel Prize in Economics; Professor Emeritus, Stanford University</i>

d. Supplementary information on the HIF

For a **comprehensive set of documents** on the HIF, see www.healthimpactfund.org.

A good **video** describing the HIF idea can be found at <https://www.youtube.com/watch?v=rTMqGbTNkNg>

What **others are saying**:

German Social Democratic Party, [Motion](#) (16 June 2010)

“The German Bundestag calls on the Federal Government ... to actively support the pilot phase of the HIF under the auspices of the Global Fund, and to financially and actively support and promote the establishment of a HIF, tested through evidenced efficacy.”

Renewed with [Bilateral Support in the Bundestag](#), 19 May 2015

[Liberal \(Venstre\) Party of Norway](#) (June 2015)

An international Health Impact Fund (HIF) should be established as a supplement to the current patent system. Through HIF pharmaceutical companies can voluntarily register their drugs and commit to making them available at the lowest price against payment of support over ten years from the Fund on the basis of major health impact their drugs have. This gives companies incentives to develop medicines for those with the greatest health needs and not only those with the greatest purchasing power.

Sachin Chaturvedi, Director General at the Research and Information System for Developing Countries, New Delhi, in the [Daily Mail](#) of India:

“It is a reward system based on objective assessment. It can be seen as an alternative to compulsory licensing and can facilitate affordable access.”