



CASE STUDY

Saving the Lives of the Most Vulnerable - With Financial Returns

GHIF: An Innovative Funding Structure Tackles Neglected
Diseases Around the World

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IFC

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ABOUT THE CASE STUDY

Expanding access to quality and affordable health care is a central element to eliminating extreme poverty and promoting shared prosperity. The World Bank Group has a goal to end preventable deaths and disability through Universal Health Coverage (UHC). In many developing countries, governments do not have the capacity to service the entire population and private health care providers often play a critical role in meeting societal needs.

IFC's health practice is developing case studies that demonstrate the ability of the private sector towards achieving global and national health care goals. Through a focus on efficiency and innovation, certain business models can provide better outcomes at a lower overall cost to society.

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Photo © PAHO/WHO

Haitian woman taking Euvichol during a cholera vaccination campaign. Figuers, Sud Department, Haiti, November 9, 2016

AN ORAL CHOLERA VACCINE STEMS AN EPIDEMIC

“Our house flew away,” Ismir Pierre Vannel explained to an Al Jazeera reporter, “We are not even sure in which direction it went. It took to the sky and we lay on the ground with our little baby and our children.”¹ The fury of Hurricane Matthew’s 145 mph (230Km/h) winds were no match for the Haitian communities living under tin roofs. On October 4, 2016, the storm wiped out entire villages across southwestern Haiti, the poorest nation in the Western Hemisphere. An estimated 1,600 lives were lost to the storm. The relief efforts for two million people was an immense challenge for this country of limited resources. The storm leveled about 200,000 homes, destroyed latrines and health clinics, razed entire crops, and floodwaters overran villages. People lost everything - their homes, food, clothes, and access to safe drinking water.

Dr. Jean Daniel Legare from Doctors without Borders explained in an interview with CBS News, “They drank the only water they could find – the water from the river - that’s how they are getting cholera.”² In the aftermath of a catastrophe of this scale, the lack of clean drinking water - already a problem - became exacerbated as the flooding contaminated the drinking water. With an inadequate water and sanitation infrastructure, Haitian doctors warned of a second cholera crisis.

Cholera, an infectious bacterial disease contracted from drinking contaminated water, can spread like wildfire. Even healthy people who have consumed tainted water can die within hours. This was not the island nation’s first experience with the disease. In the seven years since the 2010 earthquake, 9,000 lives have been lost to cholera and another 800,000 people have been infected. The post-storm conditions were ideal for fecal matter, containing cholera, to leech into the water supply. Fear ripped through villages like shock waves – and those fears were grounded. Days after the storm, over 1,000 children were sick and suspected of having contracted cholera.

The Haitian government requested international assistance and the World Health Organization (WHO) Global Task Force for Cholera Control mobilized a response. By October 27, EuBiologics, a cholera vaccine-manufacturing company had shipped one million doses of the vaccine to Haiti. Dr. Pape Faye of the Pan American Health Organization (PAHO) said, “Vaccination campaigns were organized. People who lost everything desperately wanted to get the vaccine. There was great demand for the vaccine.” One month after the storm, about 730,000 people had received



Photo © PAHO/WHO

At midday in Figuers, a rural area in the Sud Department of Haiti, nurse Orcel Naika set up a vaccination post by the shore. In less than three hours, her brigade vaccinated more than 250 people against cholera.

¹ AJ+ (Al Jazeera) “Our house flew away.” October 28, 2016.

² Haiti in Ruins after Hurricane Matthew, CBS Evening News, October 11, 2016

one dose of an oral cholera vaccine. By year end, another 40,000 had been vaccinated. The balance was stored to defend against future outbreaks. Ideally, two doses should be given (2.6 million doses would have been needed for the affected area in Haiti alone) but given the global shortage, one dose has been shown to provide some effective protection.

Dr. Curt LaBelle, Managing Partner of the Global Health Investment Fund's (GHIF's) investment management company said, "The global supply of cholera vaccines had dropped to such low levels that it was not possible to meet the demand of just one country in the event of an outbreak. If we had not invested in 2014 in EuBiologics, a company that manufactures oral cholera vaccines, it would not have been able to finish its manufacturing process and scale it up so that they could supply millions of doses per year. In fact, EuBiologics had only obtained WHO prequalification approval nine months before the storm struck. GHIF's support facilitated EuBiologics' efforts to supply the Haitian people with oral cholera vaccines to help combat a second epidemic."

Photo © GHIF



"If we had not invested in 2014 in EuBiologics, a company that manufactures oral cholera vaccines, it would not have been able to finish its manufacturing process and scale it up so that they could supply millions of doses per year."

Dr. Curt LaBelle

Cholera and other communicable diseases are largely under control in industrialized countries where it represents about seven percent of the burden of disease; however, infectious diseases are still serious health concerns in emerging markets. It is 66 percent of the disease burden in Sub-Saharan Africa alone. Fifteen million people die annually from infectious diseases, and these tend to affect vulnerable populations where there is limited capacity to pay for treatment. The perception that it wasn't financially viable to invest in research and development of cures for infectious diseases predominantly affecting poor people grew over time and dampened production, leading to global neglect of a set of diseases suffered by people living in developing countries.

The Bill and Melinda Gates Foundation ("BMGF") believed it could be possible to address these diseases and generate reasonable profits. The foundation explored various financing models, which could enable sustainable development of low-cost products. In 2012, under the sponsorship of BMGF, the non-profit Global Health Investment Fund (GHIF) was launched to make these investments.

GHIF is a novel social impact fund established to finance the development of drugs, vaccines, and diagnostic tests for diseases that disproportionately burden low and middle income countries. In 2013, IFC played a catalytic role by committing \$10 million of equity in the fund. This enabled GHIF to attract other investors and surpass its funding target. By year end, GHIF had attracted a diverse group of investors, allowing it to raise \$108 million of capital. It began investing in companies in 2014—one of which was EuBiologics, the cholera vaccine maker.

As of December 2016, GHIF had invested in seven companies for development and manufacture of treatments for diseases such as cholera and river blindness, as well as diagnostic tests for tuberculosis, HIV, malaria, dengue, preeclampsia and gestational diabetes. GHIF's most recent investment is financing further development of Tribendimidine, a drug to combat soil-transmitted helminth infections. These parasitic worms are among the most common infections found in poor communities, and affect nearly 900 million children worldwide. By year end, three portfolio companies had commercialized products, three were in clinical trials, and one was in the pre-commercialization stage prior to roll out. Another deal should close in the first quarter of 2017, and GHIF expects two additional investments later in 2017. These investments would fully commit the fund.

GHIF measures results on a “double bottom line” of social impact and financial results. To date, results are positive. Although three products—cholera vaccine, HIV diagnostic, and the malaria diagnostic—are in the early stages of commercialization, GHIF-supported companies and projects have already saved an estimated 4,200 lives and improved quality of life for an estimated 1.5 million people (data as of November 2016). By 2025, it expects to save 140,000 lives and improve 10.9 million lives annually. In terms of financial performance, the fund’s portfolio companies are generating revenues and increasing in value, and EuBiologics completed a public offering in January 2017. GHIF’s investors have made unrealized returns comparable to the Standard and Poors (S&P) 500 Index.

More broadly, GHIF’s investments are helping to end a global shortage of cholera vaccines and enabling cheaper, more effective diagnostic tests for HIV and malaria, providing more accurate results and reducing healthcare costs. Since a number of GHIF’s investee company’s products help children, KfW Development Bank believes that “GHIF’s investments can make significant contributions to the goal of cutting child mortality in half by 2030.”³ In addition, KfW notes that four of these seven investments by GHIF directly address the targets established by the United Nations Sustainable Development Goals.



Photo © PAHO/WHO

Children at cholera vaccination campaign site. Figuers, Haiti.

³ KfW Development Bank Project Information. KfW Review of GHIF Performance, December 21, 2016.

KEY SUCCESS FACTORS

GHIF is demonstrating that it is possible to have social impact and it expects to generate reasonable financial returns for investors. The keys to its success are the investor guarantee mechanism, affordable pricing, and partnerships.



PARTIAL LOSS GUARANTEE TO INVESTORS. Given the Fund’s novel approach and lack of a proven track record, the investor guarantee mechanism was an essential element in raising capital. The Gates Foundation and the Swedish International Development Cooperation Agency (Sida) provide investors with a partial loss guarantee. In the event of a loss, the guarantors fully assume the first 20 percent of loss. Above that amount, the guarantors share the risk equally with investors. A total of about \$65 million of investors’ capital, out of \$108 million, is protected through this mechanism, significantly improving the risk-return balance of the fund and making it more attractive to investors.



AFFORDABLE PRICING. GHIF ensures that its social impact goals are achieved through “Global Access Commitments,” which legally obligate the investee companies to price their products at affordable rates in developing countries. Prices are agreed with GHIF and are well below developed world market prices. GHIF believes that companies can sell products very cheaply, and generate profits through high volumes, which can still lead to attractive exits through IPOs, acquisitions by larger companies, or milestone payments or royalties.

The most innovative financing example is piloted by Medicines Development for Global Health (MDGH), a GHIF investee company that is developing a drug for the treatment of Onchocerciasis, also known as River Blindness. The product is expected to be donated to eradication campaigns, which might not seem like a sustainable business approach. Still, the company hopes to earn a transformative return by auctioning its United States Food and Drug Administration (US FDA), Priority Review Voucher (PRV), a priority place in line for US FDA regulatory review of any drug, to the highest bidder. Developers can earn a PRV by receiving FDA approval for a new therapy targeting neglected tropical diseases or rare pediatric diseases. Several vouchers have recently been sold for \$200 million or more (See Chapter 4.) Importantly, capital from the sale of a PRV will be set aside to procure the drug so that it can be donated in endemic areas. This PRV model is expected to also finance Tribendimidine, a drug that combats soil-transmitted helminth infections (parasitic worms).



PARTNERSHIPS. Success has been built on a series of partnerships with investors, investee companies, and organizations in order to complete the manufacturing process, conduct clinical trials, and get products to market. J.P. Morgan and the Gates Foundation played a key role in developing and structuring the concept. Investors, including IFC, GCC, Merck, AXA, Pfizer and others, played a role in providing industry expertise, developing impact metrics, and identifying opportunities. GHIF’s “Charitability Oversight Committee” comprised of select stakeholders in the Fund, guides management on its social impact goals. Through its relationships with the WHO, Gavi, (formerly known as the Global Alliance for Vaccines and Immunizations), and others, GHIF helps its investee companies navigate the international regulatory and commercialization landscape to ensure supported products are readily accessible to public health systems in developing countries. Partnerships have been essential to the success of this effort every step of the way.



Photo ©GHIF

Malaria testing with Access Bio diagnostic tool in Uganda

THE GENESIS OF GHIF

One sunny day in 1993, Bill Gates was reading an article in the New York Times and was shocked to learn that a deadly diarrheal disease, Rotavirus, was killing half a million children every year. Flabbergasted that such a travesty could possibly go by unnoticed, he confirmed the phenomenon in a World Bank report. He began to investigate further and realized that huge market failures - where capitalism does not provide sufficient incentives for the private sector to invest in life-saving treatments - were at the root of the problem. “Many in the drug industry weren’t keen on trying to develop a new vaccine just for poor countries because of the uncertainty they could charge enough to recoup research and development costs.”⁴

Gates decided that he had to take action. Inspired by David Rockefeller’s style of philanthropy, Gates went on to tackle global problems that are neglected by the private sector and governments through the Bill & Melinda Gates Foundation (BMGF) that he founded in 2000. A decade into funding grants for research and development on global health, many products were approaching the final phases of development and commercialization, and staff began to talk about how to support the next stages.

GHIF’s Dr. LaBelle explains, “There was an interest in moving projects that had gotten to an advanced level of development and hand them off to another funding source, with the hope that they would become self-sustaining - but this had never been tried before and there was a lot of doubt that it could be successful.”

As BMGF explored possible approaches, initial thoughts were to take a few specific projects that were under development such as an anti-diarrheal drug, a cholera vaccine, and a tuberculosis test, and package them into one fund. But it became clear that it would be too difficult to do three deals simultaneously. Furthermore, this approach would limit the number of opportunities that could be supported. So BMGF thought bigger. Instead of investing in specific opportunities, they decided that it would be more practical to create a larger vehicle where they could invest in these projects, as well as other opportunities that would arise over the next five years. By 2010, they started to brainstorm with J.P. Morgan about creating a vehicle that would pair the Gates Foundation expertise in health with J.P. Morgan’s expertise in structuring traditional investment vehicles to fund global health.

BMGF did not want a traditional investment fund, because they feared that investment priorities would overtake social impact. It wanted to ensure that it got true impact commitments from its investee companies, so they decided to use traditional investment tools in new ways. BMGF decided to create a social impact investment fund, having concluded that it was the best mechanism to ensure a social return to neglected populations, and a financial return to its investors.



Photo ©Kjetil Ree

Bill and Melinda Gates decided to create a social impact investment fund that ensured a social return to neglected populations, and a financial return to its investors.

⁴ The Obscure Bug that Set off Bill Gates, Awakening a Geeky Giant, Humanosphere, September 9, 2011.

<http://www.humanosphere.org/global-health/2011/09/rotavirus-the-deadly-bug-that-set-off-bill-gates-and-woke-a-geeky-giant/> Last visited on January 26, 2017

With the concept in place, BMGF recruited investors. Initially, the thought was to crowdsource funds from hundreds of individuals and family offices, but they ended up pursuing larger investors. BMGF felt a need to provide investors with some level of comfort to entice them to join, given the untested ideas on the table. GHIF was new, a social impact fund for neglected diseases had never been tried before, and there was no track record. Gates decided to sweeten the deal with a risk guarantee that would partially protect investors from a loss. This was viewed as more valuable than if Gates had simply become an investor alongside the others.

Even with the guarantee, when GHIF approached investors, it was a hard sell, said Glenn Rockman, a Partner in GHIF's investment management company. "You had to sell every investor on the business model and the team that would be executing it. It was not as easy as had been expected to raise the funds and the process took two years to meet fundraising targets."

Bill Gates' star power was helpful in getting an audience, but it was not enough to close investments. It took a lot of time and energy to court investors. By 2013, GHIF concluded its fundraising activities with several high profile institutions, governments, and companies to raise \$108 million of capital. Alongside IFC, other investors were AXA, BMZ (German Federal Ministry for Economic Cooperation and Development) acting through KfW Development Bank, Children's Investment Fund Foundation (CIFF), Grand Challenges Canada, GlaxoSmithKline (GSK), J.P. Morgan, Merck, The Pfizer Foundation, and Storebrand. They committed financing of between US\$2 million and US\$20 million each to GHIF. Several individual investors and family offices together committed more than \$14 million.



Photo © GHIF

GHIF visited a site in India to conduct diligence on Tuberculosis



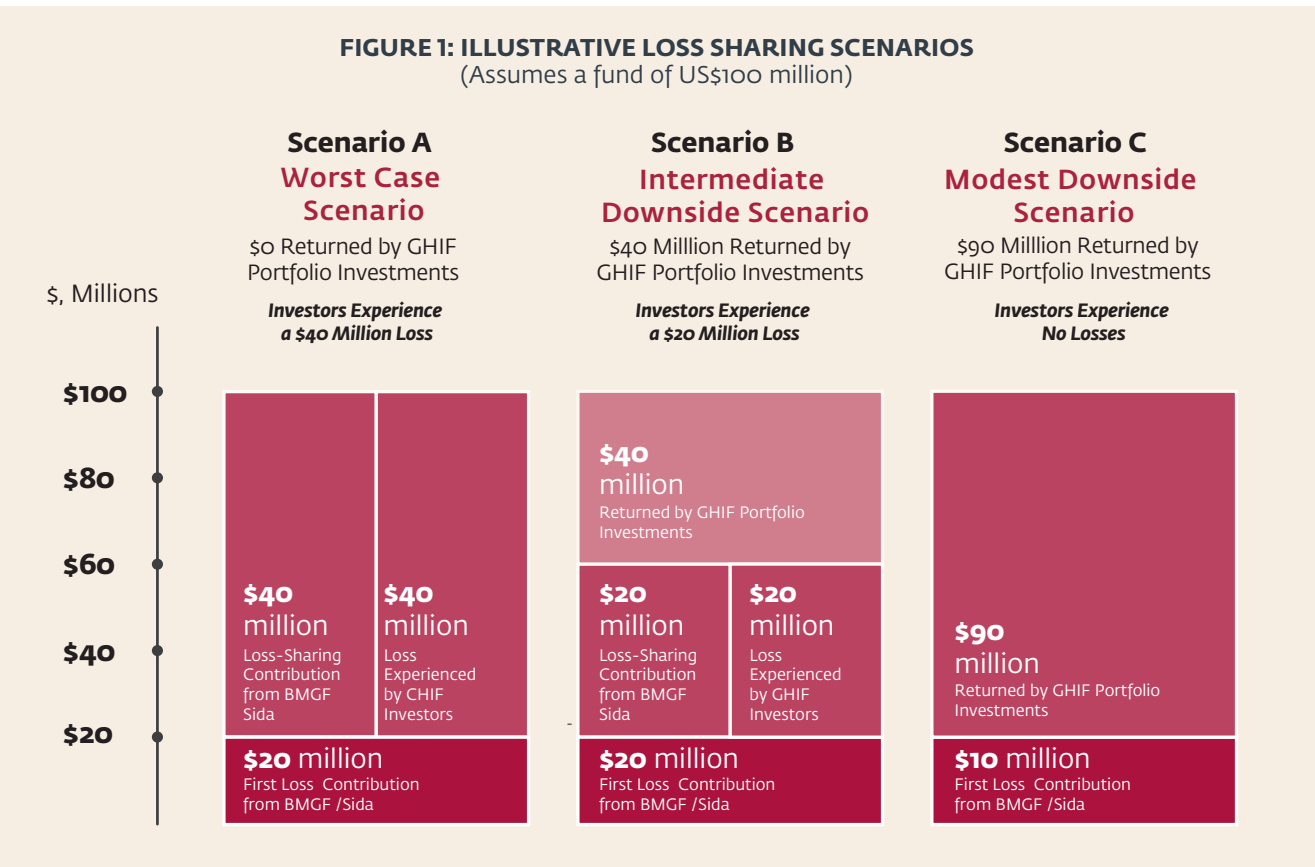
Photo © GHIF

The maternal health ward at a hospital in Hyderabad, India. BD and DiabetOmics are running a clinical study on a prospective pre-eclampsia and gestational diabetes diagnostic.

HOW THE GUARANTEE MECHANISM WORKS

The guarantee mechanism that provides downside protection from losses was essential to attracting investors said Dr. LaBelle. “Even if we were the worst fund and lost every single penny, investors would still get 60 percent of invested capital back. The BMGF and Sida are the guarantors that fund the downside protection. The guarantors assume the full risk of loss up to 20 percent of invested capital. Once this is exhausted, then the guarantors share the losses with investors. Thus, with a fund size of \$108 million, just under \$65 million is covered by the guarantee mechanism. We don’t think it will need to be used, but it does provide comfort to investors”

To help investors evaluate risk, GHIF illustrates three different loss sharing scenarios, based on a \$100 million portfolio. Note the actual fund size is US\$108 million. Figure 1, below illustrates the three scenarios. In Scenario A, the worst case scenario, if the portfolio lost all invested capital, the guarantors would contribute up to \$20 million to cover all of the first loss. For the remaining 80 percent of losses, investors and GHIF would split those losses equally on a pari-passu basis. Rather than losing the full \$80 million, investors would experience a loss of \$40 million and the other \$40 million would be covered by the guarantors.



Scenario B assumes an intermediate loss of 60 percent. Again the guarantors cover the first \$20 million of losses. The remaining \$40 million of losses would be shared between the guarantors and the investors evenly, so that investors would assume \$20 million of losses. Scenario C assumes a modest loss of \$10 million of invested capital. These losses would be fully covered by the guarantors and investors would not experience any loss.

How the Fund Makes Money

Although GHIF was designed to provide affordable financing to support global health product development, it aims to generate a financial return for investors that is in line with standard market returns. A financial return would be realized at the time when investment assets held by the fund are sold. This could take the form of an initial public offering, an acquisition by a larger company, receipt of milestone or royalty payments, or a PRV sale. For the fund as a whole, after payment of any outstanding fees and expenses have been settled, any profits are shared between investors and GHIF. At that time, investors will earn 80 percent of the profits. Twenty percent of the profits will remain in GHIF's ecosystem and may be reinvested in a second fund that has yet to be structured.



Photo © GHIF

AccessBio Biosensor is for quantitative G6PD deficiency testing. It tests for a genetic condition that makes it dangerous to take certain types of malaria medicines and is necessary for the rollout of a new one-dose cure for *p. vivax* malaria.



Photo © Jerome Starkey

Kenyan children playing near the river are susceptible to blindness.

ENSURING AFFORDABILITY FOR THE POOREST POPULATIONS

Striking a balance between making its drugs, vaccines, and diagnostic products affordable, all while generating financial returns, may not sound like an easy task. After all, affordable products in a developing world context typically need to be priced in pennies rather than in dollars.

To ensure social impact, GHIF legally requires investee companies, through Global Access Commitments, to commit to making their products available to the developing world at an affordable price. This is typically cost-plus pricing or capped pricing that is decided jointly with GHIF. The commitments remain in force in the event that a company is acquired. These commitments have resulted in the world's least expensive WHO prequalified oral cholera vaccine. Previously, the prevailing price for the oral cholera vaccine in resource-limited settings was \$1.85 per dose. After EuBiologics entered the market, the average price procured by UNICEF fell to \$1.77 per dose in 2016, and the company has committed to offer the vaccine at \$1.00 per dose or lower in the future.

"This can be tricky because the margins for these products are lower but the companies are prepared to make these types of commitments," said Mr. Rockman. To make the products affordable, companies must adopt a low price, high volume business model, or an alternate revenue source strategy. While many were skeptical that this could be sustainable, GHIF is experimenting with the latter as an innovative approach for Onchocerciasis.

Onchocerciasis, or river blindness, is designated by the WHO as a neglected tropical disease which affects nearly 37 million people, most of them in Sub-Saharan Africa. The simple bite of a black fly that lives near the banks of a river can transmit the disease with devastating effects of blindness or impaired vision, severe itching and other debilitating symptoms. Many affected persons become socially isolated and lose their ability to work and care for their families. Affected villages tend to suffer poverty and famine. Treatment of the disease has made great strides, thanks to a generous donation program run by Merck, but tens of millions are still infected or at risk. A non-profit company called Medicines Development for Global Health (MDGH), has been working on a new treatment, moxidectin, which could eradicate the disease as well as address other conditions such as scabies and head lice.



Photo ©GHIF

"The returns that could be made possible from the PRV incentive program can completely transform the ability to invest in neglected diseases. Any company that is pursuing a neglected tropical disease or rare pediatric indication, could potentially benefit from the financial windfalls of the voucher program."

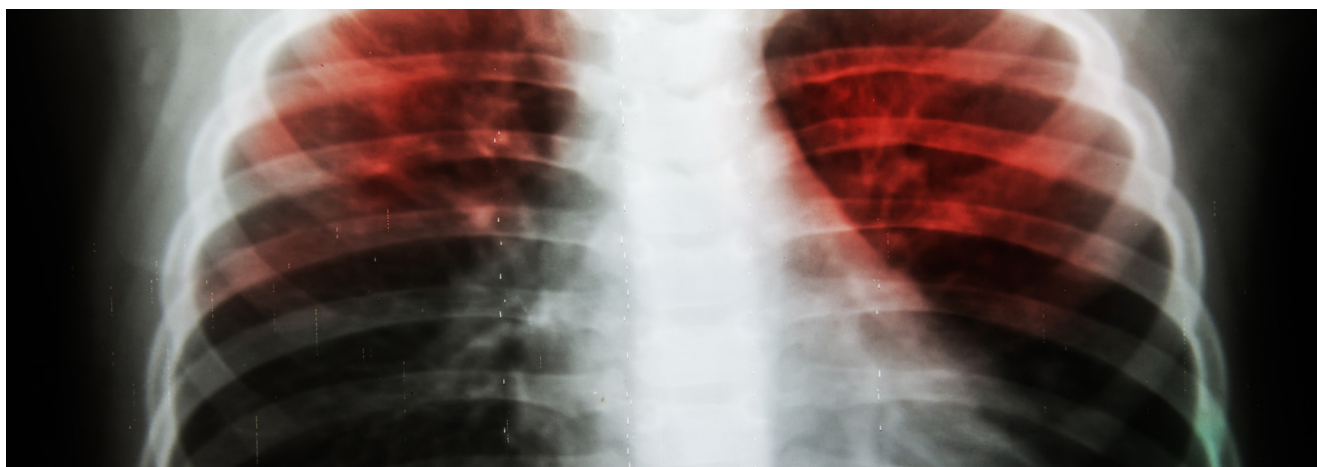
Glenn Rockman

According to GHIF's 2015 Annual Report, "Moxidectin had long been considered a possible game changer in the treatment and potential eradication of river blindness, but its development had stalled due to the lack of a viable commercial market." GHIF went on to invest \$10 million to support manufacturing, clinical trials, and registration process of the drug. If successful, MDGH has committed to deliver moxidectin for river blindness on a cost recovery basis, in addition to donating large quantities of moxidectin if the Priority Review Voucher (PRV) payback structure proves successful. While initial estimates of financial returns were modest, the financial incentives created by FDA's PRV program can be transformational for this drug.

The PRV is an incentive program introduced in 2007 by the United States Congress to encourage pharmaceutical companies to develop drugs for neglected tropical diseases, mostly occurring in the developing world, or for rare pediatric diseases in the United States. Companies engaged in the development of drugs to address these illnesses are eligible to be reviewed by the FDA on a priority basis. In addition, if the drug is approved by the FDA, the company will earn a PRV that can be sold to another company that is seeking FDA approval for any drug on a fast-track basis. The PRV allows the purchaser's product to be reviewed faster than those in the standard line. For companies seeking to be first to market, the voucher makes a huge difference, often shaving off four months of the review process. There is a market demand for the PRVs, and the last PRVs sold have raised over \$200 million each, with the highest achieving a \$350 million sales price. Curt sees the PRV program as creating a paradigm shift for funding research of many neglected tropical diseases.

"Without the PRV, neglected diseases are very difficult to make financial returns because the people that suffer the conditions can't even afford basic services let alone access to Western pharmaceuticals," said Mr. Rockman. "The returns that could be made possible from the PRV incentive program can completely transform the ability to invest in that space. Any company that is pursuing a neglected tropical disease or rare pediatric indication, could potentially benefit from the financial windfalls of the voucher program, so there is nothing precluding any other investors and many have been pursuing these vouchers," he said. He does caution, however, that "anything that is legislated by Congress can always be changed or eliminated so investors have to have a high degree of risk tolerance."

GHIF takes this program a step further and agrees with its portfolio companies that they will set aside capital to bring these drugs to the intended populations with the PRV proceeds. If MDGH is able to obtain a voucher that will sell at comparable levels, the company could then use those resources to push out the product into the field. In addition, it will give the company the resources to pursue registration of moxidectin for scabies and head lice.



Pulmonary tuberculosis.

Photo © toeytoey



Photo © World Bank

South African woman that is HIV positive

IMPACT MODELING APPROACH

Given the priority of achieving social impact, GHIF takes a comprehensive approach to impact modeling. As it is evaluating each investee company's social impact potential, it looks at the condition it is addressing and the proposed intervention to assess how the product will bring value. For example, Atomo Diagnostics developed a rapid diagnostic test platform for global health applications such as HIV, malaria, Ebola, dengue fever and others. While there are already diagnostic tests available on the market, Atomo's product is distinguished for its ability to reduce error rates and improve accuracy. Clinical literature has found a rapid diagnostic test error rate ranging from 10 percent to 50 percent.

An HIV diagnostic test is not complicated, but there are several steps involved. The healthcare practitioner uses a lancet to prick the finger, takes a blood sample, applies it to a test strip and adds a solution to get a determination of positive or negative. In areas where healthcare workers are not well trained, common in the developing world, the multiple steps create room for errors, which may result in a false negative or false positive – results that could be devastating to the patient.

Atomo developed a device that simplifies all the steps. The device pricks the finger and automatically draws in the blood to the test strip, dramatically reducing the test error rate. With a more accurate test, the patient can get treatment sooner. With a correct diagnosis, the contagion effect on the general population and healthcare workers can also be reduced. GHIF believes that this tool is very unique, that it could be adapted to dengue, malaria and other conditions, and that it is scalable. By reducing errors in tests, eliminating waste, and introducing self-testing, GHIF hopes that this product will also result in overall savings to health system in several countries.

To measure the potential impact that its products will have on the market, GHIF looks at a variety of factors. It develops a unique “impact thesis,” or impact objective for each investee company. (See Figure 2). The definition of how a life is impacted is tailored to the individual product. In the case of Atomo, this is to “improve error rates on tests for HIV, malaria, and dengue.” GHIF defines this objective according to two impact metrics “lives improved” and “lives saved.” For Atomo “lives improved” is defined as “patients avoiding inaccurate test results due to the Atomo test.” “Lives saved” is defined as “patients for whom early, correct diagnosis would avert death.”

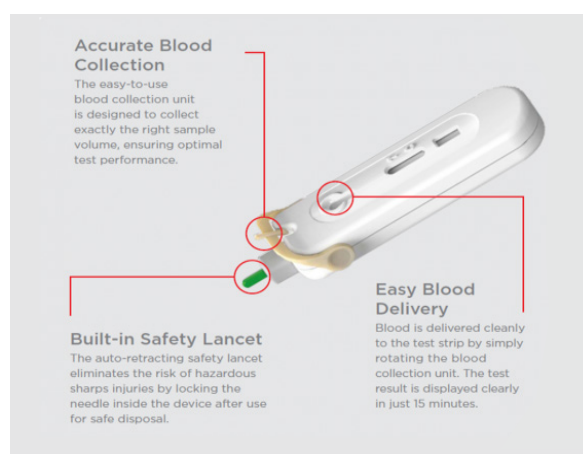


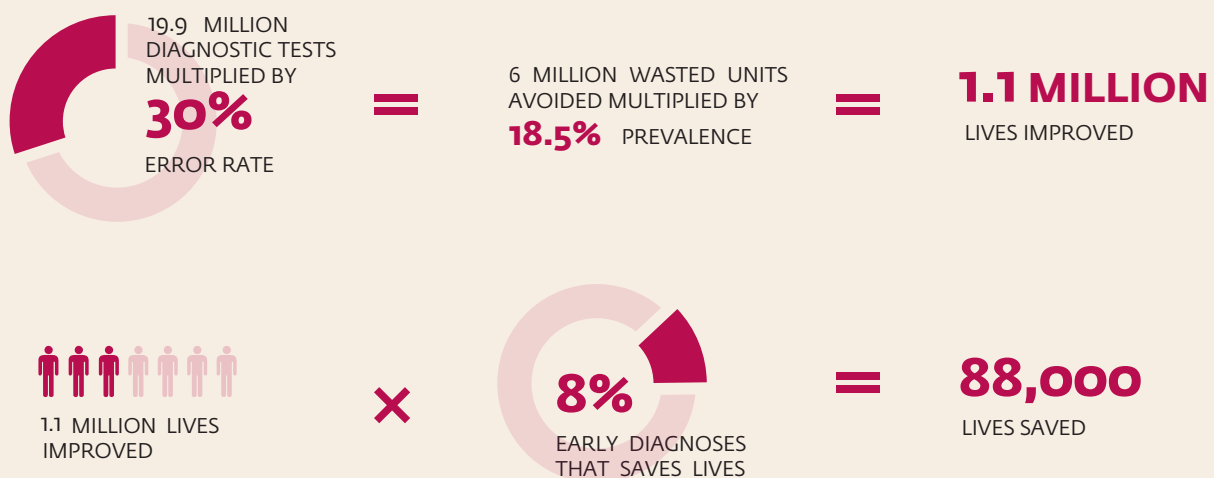
FIGURE 2: GHIF IMPACT MODELING APPROACH

| Investment | Impact thesis | Impact metric | Definition | Result (2025) | Cost per Metric |
|------------|--------------------------------------------------------|----------------|-------------------------------------------------------|---------------|-----------------|
| Atomo | Improves error rates on test for HIV, malaria & dengue | Lives improved | Patient avoiding inaccurate test result due to Atomo | 1,117,993 | \$ 5.60 |
| | | Lives saved | Patient for whom early, correct diagnosis would avert | 88,321 | \$ 70.84 |

It then estimates target results to be achieved on an annual basis by 2025, or when a company or project reaches scale. In the Atomo example, it estimates that about one million lives will be improved and that about 85,000 lives will be saved annually when the product sales reach scale.

Although each impact model has its own nuances, lives improved is generally calculated by multiplying the number of products sold by the local prevalence rate of the target condition. To calculate lives saved, it takes the number of lives improved and multiplies it by metrics such as case fatality rate or percent of early diagnoses or treatments that save lives. (See Figure 3)

FIGURE 3: IMPACT RESULTS CALCULATIONS FOR ATOMO

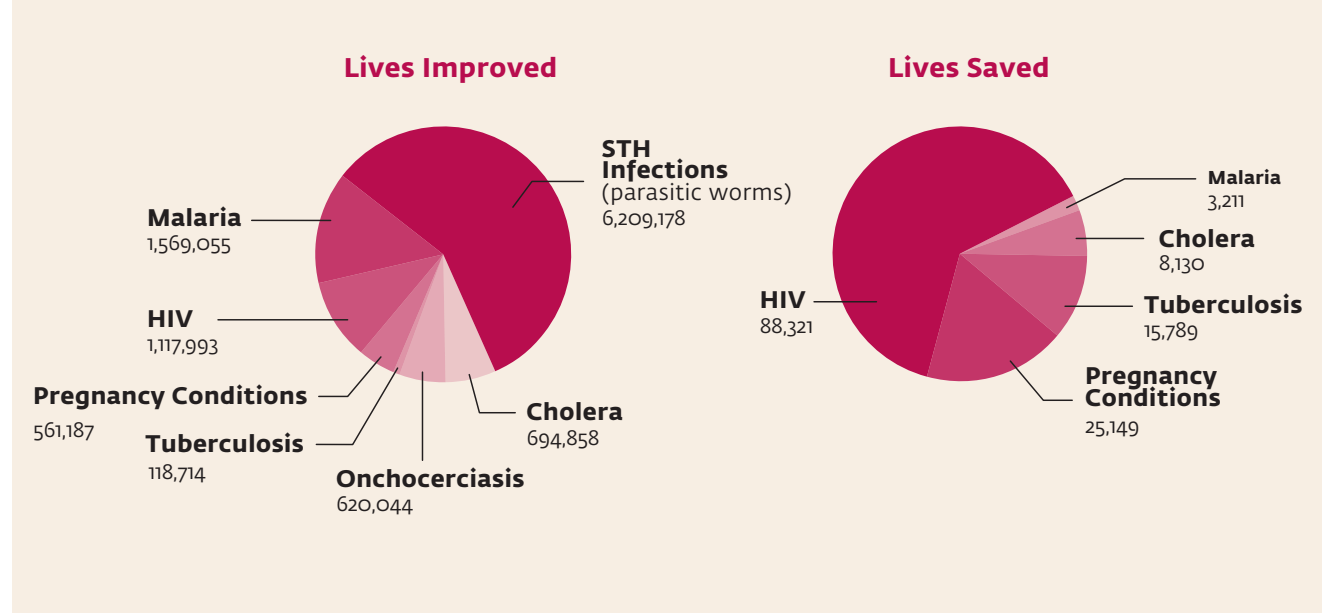


GHIF uses sales figures to calculate impact because the investee companies are the manufacturers and do not control usage. Data is based on actual sales, which becomes a proxy to calculate the number of patients benefited. Regarding the figures for local prevalence, incidence, case fatality rates, and estimates on future deaths, these are obtained from the WHO, Gavi, and research organizations.

In order to calculate the cost per metric for lives improved and lives saved for each product, GHIF takes the total cost of the aggregate number of products sold at scale and divides that by the selected impact metric. GHIF has identified a few general trends that would be expected. Conditions with high incidence rates and high fatality rates have a lower cost per life improved and saved. Meanwhile conditions that are not as prevalent, and have a lower case fatality rate have a higher cost per metric.

In terms of overall results, by 2025, which is approximately 10 years from the initial investments, GHIF estimates that the products in its current portfolio will each year save the lives of 140,000 people and improve the lives of 10.9 million people who are suffering from malaria, HIV, tuberculosis, cholera, onchocerciasis (river blindness), and pregnancy-related conditions. (See Figure 4). However, the overall impact of these drugs, vaccines, and diagnostic tests could be much broader given that diseases may be eradicated and successful approvals may also pave the way to spin off related products that treat other medical conditions. Consequently, these figures could be conservative estimates and the long-term effects may be much greater. In one month in Haiti alone, nearly 800,000 lives were touched.

FIGURE 4: ESTIMATED ANNUAL IMPACT BY 2025



THE FUTURE FOR GHIF

In the future, GHIF wants to scale and expand the model. In a year or two, it will review the portfolio and identify which interventions were most cost effective, as measured by lives saved per dollar, and the impact on its double bottom line. It anticipates raising capital for a successor fund. The initial investment vehicle sunsets after 10 years; however, two vehicles could exist simultaneously. In addition, it plans to optimize areas that have proved successful. Given the enormous needs, GHIF expects that it will continue to focus on drugs, vaccines, and diagnostics for neglected diseases in emerging markets.



Photo © Maggie Hallahan, MHPV/ OlysetNet

A girl in Senegal is protected while under a mosquito net but one day she may need a malaria test.

THE ROLE OF IFC

Prior to the establishment of GHIF, the Gates Foundation and IFC had joined forces to support a number of projects, thus the relationship was already well established between two partners with a shared mission to create impact where it is needed most.

Given that part of GHIF's mission is making investments in vaccines and pharmaceuticals for emerging markets, and that IFC had investments in companies such as Bharat Biotech, an Indian vaccine-manufacturing company working on an affordable Rotavirus vaccine, IFC's experience in the same field was very relevant and attractive to GHIF. Furthermore, having IFC come on board as a limited partner in the fund was an endorsement of GHIF, given IFC's size and reputation. This association enabled GHIF to attract other investors and surpass the \$100 million target.

Typically, IFC does not invest in early-stage ventures without a proven track record and does not take exposure to product development risk. In this case, IFC became comfortable with the terms of the investment, since Gates was providing the downside protection.

In addition to direct financial support, IFC also contributed its expertise in the structuring of protective covenants and terms for investments that made them more secure and brought them into conformity with international best practices. The biggest direct contribution has been on environmental and social safeguard issues. GHIF has referred all due diligence review for all prospective investments to IFC.

IFC was interested in doing business with GHIF because it was an opportunity to invest in an innovative fund for the development of drugs for neglected diseases. GHIF brought an excellent fit with IFC's strategy of reducing the overall health burden that developing countries experience, and where the poorest are especially vulnerable. Furthermore, it complemented IFC's strategy to deliver quality and affordable healthcare services and products to improve health outcomes, and implicitly, economic outcomes.

From a development impact perspective, IFC was very interested in the impact of approved drugs, vaccines and diagnostic tests that would benefit millions of patients, especially vulnerable populations, children, and pregnant women. Furthermore, IFC was particularly interested in the demonstration effect that a social impact investment fund could have. If successful, GHIF's model could be replicated more broadly in the health sector as well as in other sectors.



Photo ©GHIF

"This innovative Fund is mobilizing financing for medical advances that could potentially save millions of lives," said World Bank President Jim Yong Kim. "It shows that we can align the needs of investors with the need for cures for diseases which cause so much suffering in developing countries."



Photo © PAHO/WHO

Haitian girls at a cholera vaccination site

CONCLUSION

GHIF took a chance in the belief that it could change the lives of people suffering from neglected diseases and do so with financial returns. Without GHIF, many of the drugs, vaccines, and medical devices, would not have received the late-stage financing necessary to commercialize its products.

Although it is still early in the life of GHIF, there is growing evidence that it is possible to develop treatments and diagnostic tests that address neglected diseases, while at the same time generating meaningful social impact, reducing costs to healthcare systems, and delivering competitive financial returns to investors. While there is no guarantee that the entire portfolio is going to succeed, GHIF is beginning to see tangible evidence of investee companies that are becoming profitable while creating social benefits.

GHIF hopes to demonstrate the commercial viability of providing health services to underserved populations through innovation. It is pushing the boundaries of traditional revenue models, all while setting affordable prices in some of the most difficult markets across the globe. It further hopes to stimulate other entrepreneurs who were dubious, to pursue their products through alternative avenues, rather than focusing efforts solely on scarce grants.

Perhaps most importantly, GHIF is bringing tangible medical solutions, hope, and dignity to neglected communities. It is improving their chances of survival and even helping to eradicate some of the worst diseases on earth.

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