

## **CASE STATEMENT**

**The Global Health Innovation Quotient Prize:  
A Milestone-Based Prize to Stimulate R&D for Point-of-Care Fever Diagnostics**

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### **I. Misdiagnosed Fever is an Urgent Threat to Child Health**

- **Children brought to clinics in developing countries often present with general symptoms, including fevers that could be caused by a wide range of diseases – malaria, pneumonia, HIV/AIDS and others.** Clinicians are often unable to isolate the root cause of illness and have difficulty making an accurate diagnosis to determine the appropriate treatment needed to save a child's life.
- **The misdiagnosis of fever is a growing global health challenge. Clinical misdiagnoses contribute to the deaths of the nearly 3 million children under five who are lost to malaria and bacterial pneumonia each year.** The vast majority of these deaths occur in developing countries, and a significant portion could be avoided with timely and accurate diagnosis.
- **Many clinicians across Africa, Asia and Latin America do not have the tools they need to definitively diagnose their pediatric patients.** These individuals are often forced to make their best guess according to the World Health Organization's presumptive diagnostic guidelines, rather than relying on a definitive diagnosis.
- **Sometimes, a clinician's educated guess will save a child's life. Other times, a child will die for lack of appropriate diagnosis and treatment.** The introduction of rapid diagnostic tests for malaria in some regions has helped. But in the absence of point-of-care (POC) diagnostic tests, clinicians are unable to differentiate between all the causes of fever and cannot reliably provide the right treatment.
- **In addition, without the aid of modern diagnostic technologies, clinicians often indiscriminately prescribe antibiotics.** This trend has led to dangerous increases in antibiotic resistance, which has increased the cost of fighting infectious diseases and potentially undermines investments made to increase access to drugs.

### **II. A Point-of-Care Fever Diagnostic Could Save 350,000 Lives Annually**

- **BIO Ventures for Global Health (BVGH) is a non-profit organization that works to save lives by enabling the biopharmaceutical industry to engage in global health R&D. BVGH consulted with more than 80 leading global health and industry stakeholders to identify a POC diagnostic that could help prevent the misdiagnosis of fever.** These interviews were conducted with diagnostic companies, biotechnology investors, global health leaders, clinicians in low-resource settings and academic experts.
- **A POC diagnostic that could test for a range of diseases and differentiate the causes of fever could save the lives of hundreds of thousands of children in developing countries.** Such a tool would enable doctors and clinicians to offer more accurate and timely diagnoses, thereby reducing ineffective treatments and the overuse of unnecessary antibiotics.

#### **Impact of a POC Fever Diagnostic**

- **350,000 children** under 5 saved annually
- **Up to 20% reduction** in child mortality due to pneumonia
- **15% reduction** in antibiotic prescriptions for bacterial pneumonia in India per year
- **35M fewer** inappropriate prescriptions in India per year

- **BVGH estimates that such a diagnostic could reduce pediatric pneumonia deaths by up to 20%, saving more than 350,000 lives per year.** In India alone, BVGH estimates that a POC fever diagnostic would result in 35 million fewer inappropriate antibiotic prescriptions for bacterial pneumonia per year – a 15% reduction.
- **Despite the immense need for a POC fever diagnostic, industry investments to develop such products remain limited, largely due to a lack of attractive markets and financial returns.** Only 4% of total R&D funding for neglected diseases in 2009 was directed toward diagnostics<sup>1</sup>. While a POC fever diagnostic could save hundreds of thousands of lives, industry is unlikely to invest resources in developing these products without a meaningful incentive.
- **BVGH has consulted with 20 small to mid-size biotechnology companies, and many reported they were unable to invest in neglected disease R&D without a compelling potential for financial returns.** These biotech firms remain the center of new product innovation for global health, but they often lack sufficient resources to make the necessary investments in global health R&D.

### **III. The Global Health Innovation Quotient Prize (IQ Prize) Can Engage Industry in the Development of a POC Fever Diagnostic**

#### ***IQ Prize Overview:***

- **The lack of a robust market to support the POC fever diagnostic is not an insurmountable barrier. BVGH has designed the IQ Prize, a ‘pay-for-success’, milestone-based prize to help address this challenge.** This innovative approach will help smaller and mid-size companies overcome barriers to investing in the development of such a diagnostic by reimbursing and rewarding developers as they complete specific milestones along the product development process (as opposed to a prize that only rewards innovation at the end). This strategy will also help mitigate the risks and offset the opportunity costs of development for this purpose.

#### **Impact of a Milestone-Based Prize**

- **Up to \$150 million** required over 8 years
- **2 new products** likely developed
- **\$2-\$5 target price** for diagnostic end product
- **80 leading stakeholders** consulted in designing this prize



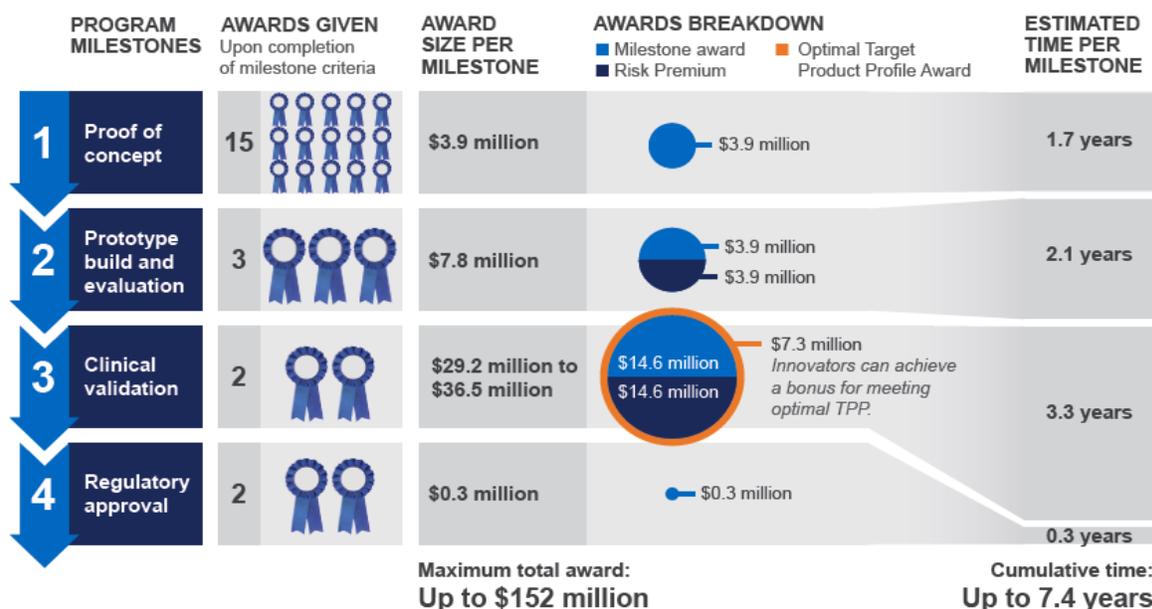
- **The anticipated result of the IQ Prize is the development of two effective POC fever diagnostic products developed by separate biotech firms within 8 years.** In order to be rewarded with milestone payments, the target products will be low-cost, portable, simple to use and durable enough to withstand resource-poor environments.
- **Donor commitments are needed to fund a prize competition that would lead to development of these diagnostics, which could help save more than 350,000 lives in developing countries per year.** It would make a particularly large impact in sub-Saharan Africa and India, where up to 220,000 and 175,000 lives, respectively, could be saved if the diagnostics were universally adopted.
- **Investing in the IQ Prize could result in significant value-for-money. Donors who fund the prize only pay for meaningful results achieved during the product development cycle by a number of developers, thereby mitigating risk.** Because the milestone-based nature of the prize encourages the pursuit of multiple technologies and strategies throughout the development process, and rewards only those who succeed at each level, donors don't have to ‘pick winners’ in advance. This increases the breadth of

innovative approaches applied to the problem, and therefore success.

- **At the same time, the ‘open competition’ structure provides reasonable returns that help overcome barriers to entry and motivate private firms to invest in global health R&D.** This will lead to greater biotech engagement in the field and a broader pool of innovative approaches to product development. More than 10 companies have already signaled their interest in participating in such a mechanism.

**Design of the IQ Prize:**

- **BVGH developed the IQ Prize through consultations with more than 80 leading stakeholders,** including diagnostic companies, biotechnology investors, global health leaders, clinicians in low-resource settings, and academic experts. A high-level industry working group was convened to validate the prize structure as well as key assumptions in the financial analysis.
- **BVGH’s IQ Prize is designed to lead developers toward creating a critically needed POC fever diagnostic.** BVGH has developed four clearly defined R&D milestones in pursuit of this goal – 1) proof of concept, 2) prototype build and initial clinical performance evaluation, 3) clinical validation in the field, and 4) regulatory approval.
- **BVGH worked with industry to develop sophisticated product specifications – called a ‘target product profile’ (TPP) – to ensure the resulting product meets the needs of endemic country health providers and patients.** The TPP is ambitious but technologically feasible. At minimum, it calls for the diagnostic test to be able to differentiate between malaria, bacterial pneumonia and other bacterial infections by testing for multiple pathogens, each with 90-95% sensitivity. It takes into account the operational requirements needed for low-resource settings, and sets a target price of US \$2-5 for the assay itself. The TPP was vetted by a group of **12** for-profit companies.
- **At the beginning of the competition, a number of companies, mostly small to mid-sized biotech firms, will enter and invest time and resources to achieve incentive milestones.** Companies that successfully reach a milestone are awarded gradually increasing cash prizes, which fund the next stage of work and provide cost recovery (and for the more challenging milestones, a risk premium) ahead of product completion. The following graphic outlines the stages of the incentive:



- **There are a maximum number of awards allocated to each milestone, based on an assumed rate of attrition among participating firms.** BVGH estimates that a minimum of approximately 19 innovators will be needed to enter, with 15 successfully reaching the first milestone, in order for 2 products to succeed at the final milestone (see chart above for assumed attrition rates).
- **An independent expert advisory group would judge whether milestones are achieved according to the TPP.** The size and number of awards at each stage would be predetermined based on the recovery of average costs for that phase of development, with a risk premium appropriate to that phase.
- **We anticipate that two companies will succeed in passing the fourth and final milestone** to achieve the design of a POC diagnostic that is accurate, inexpensive, portable, simple enough to be used by minimally trained health workers, and rugged enough to withstand low-resource settings.

#### ***Cost-Effectiveness and Sustainability:***

- **To implement the milestone-based prize, donor support of up to \$150 million over 8 years is needed.** Donors only pay for milestones achieved, so \$150 million is the maximum cost at the current estimates of dollars per award, and numbers of awards.
- **A detailed analysis conducted by BVGH has demonstrated a resulting diagnostic would be cost effective, especially in sub-Saharan Africa and India.** For a price of \$2-\$5 per diagnostic, the POC diagnostic would be cost effective in sub-Saharan Africa and India in line with commonly accepted World Bank standards (\$150 per life-year saved), and would lead to substantial impact, particularly in rural areas.
- **The IQ Prize was also designed to be a transparent and sustainable strategy for product development.** BVGH understands that the development of new products is only one part of the equation, which is why the IQ Prize has a built-in access plan to address affordability, supply and distribution of the POC diagnostic once it's developed. The following strategies will help ensure the incentive's success:
  - ***Participant Eligibility:*** Clear eligibility requirements to screen willing diagnostic participants, including demonstrated expertise in relevant product development and sufficient resources to engage in the competition, either alone or with identified partners.
  - ***Incentive Governance:*** A program secretariat or other body will manage the incentive program on behalf of the prize sponsors, directing the flow of funding and managing contractual relationships and communications with developers. An Expert Advisory Group that includes developing country diagnostic experts would support the secretariat, and act as the objective judges of whether milestones are successfully reached.
  - ***Approach to Intellectual Property:*** The prize mechanism also takes a unique approach to intellectual property by protecting against the potential default of firms. To receive an award, a firm must agree to pursue the next milestone in good faith, or grant the sponsor a non-exclusive, limited use license of the resulting technology. This will protect donor investment while allowing the developer to retain ownership of their intellectual property.
  - ***Access Provisions and Supporting Interventions:*** BVGH has developed a number of strategies to ensure the resulting diagnostic tools will be accessed in developing countries. The POC diagnostic must satisfy regulatory requirements under the EU CE Mark (and any local requirements, prior to distribution in a given country) and be priced between \$2 and \$5 (exclusive of any required "box" or

base equipment). Developers are required to submit a plan for manufacturing and distribution of the final product.

#### **IV. The IQ Prize Can Encourage Additional Global Health R&D in the Future**

- **BVGH believes that the IQ Prize for a POC fever diagnostic could save hundreds of thousands of lives in developing countries, and help curb the spread of antibiotic resistance, at a reasonable cost in a relatively short period of time.** The IQ Prize can deliver significant value-for-money to donors, engage the biotech sector in global health R&D and produce products that can bring significant benefits to developing country clinicians. More detailed information on the prize for a POC fever diagnostic can be found in BVGH’s full donor proposal.
- **A successful pilot project would show the effectiveness of milestone-based prizes to stimulate development of a lifesaving global health product—and could be a new and effective model to stimulate development for other crucial tools for developing countries.** The global community has recently begun to recognize the potential value of prizes to stimulate innovation. BVGH’s IQ Prize moves this concept forward by providing concrete and appealing incentives for biotech companies to become engaged in global health R&D.
- **There is a significant need for a wide variety of new drugs, vaccines and diagnostics needed to meet developing country health needs.** BVGH believes that milestone-based prizes are an innovative strategy to help industry meet these needs, and bring life-saving new products to those most in need.

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<sup>i</sup> Policy Cures. 2010 G-FINDER Report – Neglected Disease Research and Development: Is the Global Financial Crisis Changing R&D? Accessible from: [http://www.policycures.org/downloads/g-finder\\_2010.pdf](http://www.policycures.org/downloads/g-finder_2010.pdf)