# Global Health Commercialization & Funding Roundtable

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The Cambridge Global Health Commercialization & Funding Roundtable was held as a two-day conference at the Institute for Manufacturing April 19-20, 2012. The meeting concentrated on exploring innovation for global development in the area of healthcare. The Roundtable brought together global health entrepreneurs, investors/funders and other participants comprising an “innovation ecosystem”, such as civil society, member states and researchers, to explore business models in discovery, development and delivery of global health innovations.

The Roundtable conference focused on tuberculosis [TB] an age-old infectious disease that still claims 1.8 million lives per year, and yet is curable with the tools and technologies available today. Entrepreneurs, as agents of change, have historically demonstrated ability to link supply and demand in new ways. Since the year 2000 and the declaration of the Millennium Development Goals, there has been increased economic support to accelerate innovation for tuberculosis prevention and treatment. New public-private partnerships have formed and new innovators have joined the fight against TB.

We, the conference organising team, are delighted to use this conference report as a tool to encourage discussion on the importance of entrepreneurs and the role they play in accelerating health innovations. Global health in not a challenge that can be tackled alone and we hope that the Roundtable conference, the material on our website www.bit.ly/ghcfroundtable, and this report can build on existing partnerships, bridge gaps and initiate new collaborations.

Best Regards,

Julia Fan Li, Priya Khetarpal, Tomas Niklitschek, Nicole Person-Rennell, Diana Pirjol, and Anne Radl

“There is the need for governments in the north and south, pharmaceutical companies, scientists and other stakeholders, to consider how disease which disproportionately affect developing countries could best be addressed, and to seek solutions.”

Objectives

• To share knowledge of existing business models from technological innovators in developed and emerging economies

• To stimulate new thinking by catalytic resource providers of both grant and investment-funding

• To encourage awareness and public engagement on the issue of innovative financing for global health
Fundamental Problem

The drive to host and organise the Global Health Commercialization & Funding Roundtable was motivated by the fundamental challenge facing global health: the global disease burden is not distributed equally. Communicable, maternal, perinatal and nutrition-related diseases (classified as diseases of poverty) add up to over 50% of the disease burden of developing countries — nearly ten times higher than their burden in developed countries. There is a clear lack of economic incentives for innovation in research and development (R&D) for diseases that disproportionately affect the poor. Just over $2.5 billion was invested into R&D for new neglected disease products in 2007. This makes up approximately 1.6% of the estimated $160 billion global R&D spend for health. Medical research and development is inherently expensive and patients in developing countries may have little means to pay. The life-sciences product development cycle is costly and resources for commercialization are underprovided in resource-poor settings.

Turning of the tide

Recognizing the importance of good health in breaking out of abject poverty, the United Nations designated three out of the eight Millennium Development Goals (MDGs) to be specifically health focused (child health, maternal health, combating HIV/AIDS and other infectious diseases). There is also acknowledgement that a foundation of good health contributes to all other MDGs, global security and peace. With the declaration of the Millennium Development Goals and the creation of the Global Fund to fight HIV/AIDS, Tuberculosis and Malaria, neglected diseases have received increased global resources. Development assistance for health has risen from $5.6 billion in 1990 to $21.8 billion in 2007. Increasingly, private philanthropic foundations have contributed towards global health assistance, reaching 27% ($5.2 billion) of the $21.8 billion in 2007.

UN Secretary-General Ban-Ki Moon implored the crowds at the World Economic Forum in Davos in 2012 “that we have the moral and social imperative to innovate”. But the question is, who innovates in global health? We propose that entrepreneurs are the innovators; entrepreneurs are integral to discovery, development and delivery of global health innovations.
Entrepreneurs as agents of change

Lack of effective demand and purchasing power by marginalized patients has led to commercial neglect of diseases of poverty. Entrepreneurs, as agents of change, have historically demonstrated the ability to exploit neglected opportunities associated with human need and link demand and supply in new ways. To serve patients in low and middle-income markets, new innovations are required in all stages of the innovation value chain of discovery, development and delivery. Governments and public health systems cannot achieve health progress alone and need to collaborate with other participants including entrepreneurs.

The incentives for innovation are evolving for global health entrepreneurs. Low and middle-income markets and developing countries are emerging as sources of market growth and entrepreneurial opportunities. Base of Pyramid (BOP) studies show that although spending by households in developing countries is small compared to the developed world, the aggregate GDP of the most populous developing nations is over $12.5 trillion. The BOP market on health spending is estimated to be a $158.4 billion USD opportunity. Given the increasing trends in development funding for health and new market-based commercial opportunities, there have been a proliferation of innovative financing mechanisms to encourage public and private sector collaboration for health innovations.

Entrepreneurial activity in global health has been exhibited in both small start-ups and large multinational firms. Entrepreneurs and the private sector have entered the global health ecosystem through new organizations, partnerships or product/service innovations to cater to new customers. In addition global coordination bodies have been established to oversee international innovation workstreams such as the United Nations joint program on HIV/AIDS, the StopTB Partnership and the Roll-back Malaria Partnership.

The burden of disease directly impacts economic development and it is known that weak health systems help perpetuate the poverty cycle. These problems are seldom viewed as amenable to entrepreneurial solutions. However, throughout history entrepreneurs have demonstrated the ability to harness opportunities to meet unfilled needs. Entrepreneurs initially propelled industrial innovations such as the railroads, and those of science-based businesses, such as DuPont AT&T (Bell Laboratories) and General Electric. Yet in new science-based businesses, such as the life-sciences, the convergence of science with business has presented difficulties in long-term innovation management. How science-based entrepreneurs discover and develop opportunities that lie beyond the pull of existing markets is a question that calls for focused evidence.
Initiating the Roundtable

The Global Health Commercialization & Funding Roundtable was initiated to bring together global health ecosystem participants to explore business models in discovery, development and delivery of global health innovations. The conference examined current partnerships between resource providers and entrepreneurs and explored the dynamics of these relationships. In the context of tuberculosis, the Roundtable shared business models and promising innovations relating to vaccines, pharmaceuticals, and diagnostic technologies. The keynote address, given by Dr. Ellen Strahlman, Global Head of Neglected Tropical Diseases for GlaxoSmithKline, offered insights into investing in diseases of poverty, including tuberculosis, and benefiting the global community while pursuing excellence as a company. Five conference panels highlighted different funding models and identified challenges for attracting funding and engagement on tuberculosis. Furthermore, through use of social media, visual representation of conference ideas and lively Q&A sessions, the conference aimed to raise awareness of global health.

Please see Appendix I for the list of expert participants of the Roundtable. The structure of the Roundtable was split into two days: Day 1 aimed to cover depth of issues and stimulate discussion between experts across the global health ecosystem using a Delphi focus group. Day 2 aimed to cover breadth of issues across intervention areas in tuberculosis and stimulate discussion among conference participants and attendees.
The Global Health Commercialization and Funding Roundtable created a unique opportunity to exchange experiences and ignite new ideas, bringing together innovators from both developed and developing countries with a range of ecosystem participants, from academics to investors to member state representatives. Three facilitators encouraged discussion and participation on Day 1: Julia Fan Li and Elizabeth Garnsey from the University of Cambridge and Mia Eisenstadt from Reos Partners.

The Innovation Value Chain

The context of health innovations for tuberculosis was set using the theoretical tools of the innovation value chain and the global health innovation ecosystem. All innovations start as seed ideas. Scholars have termed the process of transforming an idea into something a customer can use, the innovation value chain. The innovation value chain integrates idea discovery, idea development and idea delivery. These functions can be assigned to different participants in the value chain or take place in an integrated organization that carries them out internally. A company’s capacity to innovate is only as good as the weakest link in the chain. This notion is built upon the manufacturing value chain concept of mapping out processes to transform raw materials into finished goods. Figure 1 below shows the innovation value chain as applied to healthcare. It embeds a translation process from scientific discovery to use, with intermediary phases in clinical development to test efficacy and safety and delivery processes to reach patients.
Generating value inside the innovation ecosystem

Business strategies are embedded in the business models which management chooses to pursue. Each business either “explicitly or implicitly employs a particular business model that describes the design or architecture of the value creation, delivery and capture mechanisms it employs. The essence of a business model is in defining the manner by which the enterprise delivers value to customers, entices customers to pay for value, and converts those payments to profit.” An illustration of how a business model can generate value for a firm is illustrated below.

![Value Generation Cycle](image)

**Figure 7:** The value generation cycle. Adapted from Garnsey, et al., 2006

Every entrepreneurial organization, whether new or established, is continuously building, reconfiguring and designing its resource base. Firms originate to take advantage of some unique knowledge, but continual learning and strengthening of resources is central to firm development and survival. Along with the basic requirements of money, people and information, healthcare ventures are established to respond to unmet medical needs.
Value created and captured by each participant in the global health ecosystem can be a combination of financial, technical and social value. Lepak’s (2007) review proposes two conditions for value creation: first, the monetary amount exchanged must exceed the producer’s costs of creating the value and second, the value enjoyed by the consumer must be perceived to be better than the consumer’s closest alternative. The financial value captured by the firm is the difference between exchange value and production cost. In addition, intangible value can be built, in the form of knowledge and skills. Social value is created through the matching of innovation to an unmet customer need and results in positive externalities that benefit society.

All ventures require the re-investment of value created and captured back into the original business to sustain operations. Technology firms usually invest all retained earnings back into new technology development, as innovation is the key differentiation between competitors. The reinvestment into the firm encourages the development and retention of human capital and technology; in the case of social enterprises, the scale-up of impact.

The U-Process of Understanding and Solving Complex Problems

Building on the theoretical frameworks presented in the morning of Day 1, the global health ecosystem participants engaged in a group activity in the afternoon that focused on solving complex problems.

To foster an atmosphere for creativity, Mia Eisenstadt, of Reos Partners and Julia Fan Li of University of Cambridge led participants through a thought-exercise on the creative process of innovation, called the U-process. The U-process has been used by leading social change and academic institutions in the past to help diverse groups of people find new solutions to complex social problems. The key steps to the U-process are to re-perceive the situation and then to act from a new understanding.

Participants were placed into groups that would maximize contributions from different perspectives, informed by a range of backgrounds, to catalyze new ways of perceiving and solving a problem. Each group consisted of an academic, an entrepreneur, and investor and/or a donor, and various ecosystem participants. Additionally, these roles were variously filled by participants from “developed” and “developing” countries, which shed light on how different resources and regulations come into play in bringing a global health innovations to target markets.
Each of the five groups was randomly allocated a different resource scenario, and given autonomy to choose which disease they wanted to concentrate on, their method of intervention (e.g. vaccines, drugs, diagnostics, delivery) and geographic scope. Each group was asked to consider some of the following questions in developing their business model for global health innovations:

- Stemming from your business model, what results do you expect?
- What other resources do you need to bring to bear for the model to succeed (technical, human, financial)?
- Who will be the partners? What are their roles?
- Who will be the supporters, who will be the barriers?
- What are the barriers to implementation?
- How will you create value from this model and how will you capture value?
- How will you evaluate your success or failure?

The participants were encouraged to build both a descriptive model (through brainstorming on paper) and a tangible model through use of various objects that were made available by the facilitators. The tangible models allowed for increased creativity in thinking, especially for members who work best away from traditional paper forms. The global health experts were selected for their interest in global health innovations and thus started the exercise with a common purpose in mind.
Scenario 1

GLOBAL HEALTH INNOVATION IN A BRICS-LEVEL EMERGING COUNTRY WITH EVOLVING RESOURCES

1 Academic (N), 1 Entrepreneur (N), 1 Entrepreneur (S), 1 Investor (S), 1 Ecosystem Participant (S)*

This group chose to introduce a novel TB vaccine in Brazil as their hypothetical scenario. They began with some assumptions: the vaccine had originated elsewhere in the world and had already been approved in other territories. Their business model would look specifically at how the vaccine could be introduced and delivered to the Brazilian Market.

They chose a joint venture model. The resources brought into the joint venture by the vaccine originator were the vaccine itself, intellectual property (IP) and capital.

For both political and regulatory reasons, they chose to partner with a local manufacturer. In this way, they were able to add manufacturing infrastructure to their resources. By partnering with a local manufacturer, they also hoped to gain local insights into navigating bureaucratic hurdles and accelerating the process of vaccine introduction, adoption and delivery. In parallel, they needed to overcome regulatory hurdles and other barriers to entry: initially through clinical trials, and then through post-marketing licensing studies. To introduce the vaccine to Brazil, they needed to demonstrate cost-effectiveness, particularly as they hoped for its incorporation into national immunisation schedules. There would be additional discussions required to get the vaccine adopted after the initial private sector launch. To ensure effective delivery of the vaccine, they required the engagement of patient advocacy groups to help overcome local apprehension of the vaccine and make people aware of its benefits.

In terms of actual delivery, the group adapted a social franchising model to a Brazilian context. Doing this, they also hoped to secure support from philanthropic foundations, replicating real life partnerships that already exist in practice. Value would be returned to the vaccine originator in the form of commercial returns from the sales of vaccines to private markets, and subsequently public markets. Value would be returned to the end users—the vaccinated patients—as well as to the Brazilian government, who would derive public health benefits, and decrease public health costs.

*N” and “S” designate whether the participant is working in the “global North” or “global South.” These terms are often used to describe the state of economic development in place of “developed” and “developing” or “high-, middle- and low-income.” The global North roughly corresponds to “developed;” “high- and middle-income countries;” while the “global South” roughly maps onto “developing;” “middle- and low-income countries.” These terms are used to evoke the geographic location, as well as the economic state, in which each participant is working.
Scenario 2
GLOBAL HEALTH INNOVATION IN LOW-INCOME COUNTRY WITH LIMITED RESOURCES

1 Academic (N), 1 Entrepreneur (N), 1 Donor (S), 3 Ecosystem participants (N)

This group chose to set their business model in Bangladesh, and focused their presentation on production of safe, efficacious and affordable TB drugs. How can the proposed business model ensure that drugs would be delivered to local populations safely and securely, without fraudulent substitution? The first issue to consider was how to produce quality TB drugs cheaply operating from within Bangladesh.

Their model encouraged a company from a neighbouring country (i.e. India)—preferably an external generics manufacturers of anti-TB drugs of high standards—to come into the country and set up generic manufacturing. The incentives for this company to set up external manufacturing in Bangladesh would be threefold: 1) financial, allowing access to a new market; 2) social, to alleviate that suffering was believed to be a powerful enabler; 3) novelty, setting up manufacturing capacity in a less developed country would be innovative. Potential diaspora populations could be included to provide expertise, institutional networks and knowledge. This business model has the potential to be a self-contained start-up situation.

With the prospect of financial and social returns to investors, there is also both the potential for the growth of new political leadership—but also for corruption. There was debate amongst the group about the role of government in setting up the external manufacturing company. Whilst the wary wanted to keep them at a distance, there was a unanimous recognition that they needed to be involved on some level, to ensure that all the hoops that would inevitably put in the way could be overcome swiftly.

The external manufacturing company would need resources—mainly raw materials, which they hoped to secure at relatively low costs. Additionally, the company needed multiple supply routes and multiple means of distribution to get their drug into local communities, acknowledging that no single way would reach all.

In light of their focus on delivering quality-assured, safe drugs to local populations, they needed incentives and enablers to encourage sustainable local community distribution. As the company was set up to provide drugs that are of highest quality, but cheaper than any other drugs being imported, quality assurance and transparency needed to be an integral part of their evaluation.
The group members emphasised that their model should generate offerings that were transferable to other low-income countries, and they believed the best way to do that was through research outputs. The evaluation of health service base, of potentially clinical trials, of use of these generics in multidrug regimens as well as standard treatment—all of this research would add value. In Bangladesh, research outputs could feedback both into the use of the drug, and also how the company was working with community.

Lastly, the team wondered if the model could be rolled out to address different diseases. The chronic non-communicable diseases that are co-morbidities of infectious diseases have increasingly become an area of concern in developing countries as their impact on populations becomes more apparent. If this model proved successful for the production and delivery of generic TB drugs, perhaps it could be used to produce and distribute generic drugs for noncommunicable diseases in the future.

The photograph below depicts team members working on Scenario 2, brainstorming on paper and using the tangible objects to make business models.
Scenario 3

GLOBAL HEALTH INNOVATION IN A BRICS-LEVEL EMERGING COUNTRY WITH A DOUBLE BURDEN OF NON-COMMUNICABLE DISEASES (NCDs)

1 Academic (N), 1 Entrepreneur (S), 1 Investor (S), 1 Donor (N), 1 Ecosystem participant (N)

The hypothetical setting for this scenario was Brazil, with a disease concentration on diabetes, which is often a co-morbidity factor of TB. The team looked for gaps in the diabetes treatment chain and asked what were the most pressing unmet medical needs. Their answer was an early diagnostic test that would alert individuals at risk for developing diabetes or in the early stages of the disease. These individuals could then receive consultation on measures that would prevent exacerbating the disease.

The novel technology proposed was for a diagnostic test to measure two kinds of haemoglobin in the blood. The advantages of an early diagnostic blood test, over a (fasting) oral glucose were thought to be many: oral glucose tests are difficult, time-consuming, expensive and impractical. An easy-to-use early diagnostic test would not only give individual patients the information they needed to make preventative lifestyle changes, but would also provide a more accurate overview of population health, thus appealing to physicians, epidemiologists and public health scientists.

The basic science—the proof of principle—has already been established for the haemoglobin test; relatively little input would be needed in this part of the investment chain. Development would be needed to turn the lab test into a commercially viable diagnostic test: cheap, easy to use and accessible to a large number of people. This would require a lot more investment—most likely from different streams. Multiple technical partners would be prerequisite in developing the product in different ways. Even under the best circumstances, many elements of chance and risks would have to be factored into investment decisions.

The target market for the diagnostic test would be the BRICS countries at first. Before going to market, the team envisioned strong developmental interactions with high-income countries. This developmental interaction would lead to a product, which would flow downstream to low-income countries. Once the product had been developed, it would need to pass quality assurance tests such as WHO certification.
Even with the positive development of an early diagnostic test, there could be unintended negative consequences. By making a test widely available, widespread interventions to combat the disease would need to follow. Current interventions against diabetes are not particularly successful. The key to the success of this test would be that it worked for “early” stages of diabetes, when there are still a plethora of different preventative solutions—such as dietary changes and increased physical activity—to enact before recourse to expensive or ineffective drugs. Moreover, a diagnostic test could provide patient incentive to adhere to interventions, as they would be able to measure the interventions success or failure through repeated tests, with the consequence of halting the disease’s advancement, or hastening it. Although interventions will never be 100% effective, any impact would contribute to prevention of a diabetes epidemic, even if it were only 5-10% of people who take up an intervention, and lead to decreased susceptibility of TB.

In regard to the finances of the business model, there was an acknowledgement of possible price inflation in high income countries. Additionally, to offset some of the development costs, the portable devise could eventually be used to diagnose different diseases, using differently priced cartridges—those for diseases like stroke and cancer costing more. In high-income countries, the device may even be sold at a retail price to individual consumers; whereas in BRICS countries, devices would be used in clinics to diagnose local populations.

The diagram below illustrates the tangible model that the team built. The alarm bells signal non-communicable disease burdens hitting developing country health systems and diversity of interventions required for diabetes. The model proposed by team members in Scenario 3 concentrated on an early-stage detection innovation to reduce the looming health burdens.
Scenario 4
GLOBAL HEALTH INNOVATION IN A HIGH-INCOME COUNTRY WITH MORE RESOURCES

1 Academic (N), 1 Entrepreneur (S), 1 Entrepreneur (N), 1 Investor (N)

This group began with some prefatory remarks, which set the scene for their business model: If you can develop a business in a high-income country, there’s profit to be made, but process can be slow and getting a product to market can take a long time. In the developing world, there are more people, and although the profits are lower, there are still profits to be made. Thus, the same business set in the developing world would be a lower-margin model but with higher volume sales. Innovation enters the scene with the idea that you can leverage the speed with which you can get things done in the developing world, to build a business and make profits in both developing and developed countries.

To illustrate this model, the group chose to look at a new approach to TB diagnostics—although the same approach could be applied to vaccine manufacturing with a little adjustment, and potentially drugs with more adjustments. The group chose India as a geographic example.

The standard approach to developing a new TB diagnostics test would be to bring the product to the US (or any high-income) market, get it approved by regulatory authorities like the FDA, and then think about how to open up a market for your product in the developing world. By turning this standard model on its head, taking the product to the developing world market first, and then to the developed world, there is the potential for a “win” for the company and end users in both markets.

Steering the development of a diagnostic test towards the developing world, the group focused on bringing it quickly to market through accelerated regulatory processes. This did not mean that the quality of the product would be compromised in any way; the product would still go through robust clinical trials, but in developing countries—or perhaps simultaneously in developing, BRICS and developed countries to create a pooled safety data package to support the regulatory process. Additionally, basing the factory in a developing country would provide relatively cheap labour, and keep production costs low, while driving economic growth and job opportunities in that country.
The business model proposed to optimize the factory, lower production costs, de-risk the technology, continue to seek regulatory body approval in other markets and implement a quality assurance system. In doing these things, they could then leverage the strengths they would have now built through bringing this product to market in a constrained setting, to bring this product to market in high income settings, and collect greater profit. Low profits from developing countries would ultimately be leveraged to make even higher profits in the developed world.

This model can be continually used to bring new products to the developing world first, for example diagnostics for maternal health, and then to the developed world as well. This model only works for dual markets for the same products. However, if the production/manufacturing processes can be refined, it can be leveraged to supply other products for high-income markets. For example, after manufacturing a vaccine for TB, the process can be adjusted for low cost vaccine production, and can be employed to bring other vaccines to market in the US or Europe at a much higher margin, thereby continuing to drive higher returns and higher margins in the developing world.

The figure below is an illustration of the group’s tangible model, informed by the text description of the model and presented in visual form.

The diagram illustrates the dual market approach by the high-income country innovator to capitalize on efficiency and social impact. The diagram emphasizes the business strategy of selling products at lower margin and higher volume to ensure financial sustainability for the health innovator and maximize number of patients helped.
Rather than focus on TB, this group chose to look at innovation in nutrition through a hypothetical international coordinating body which they called “Nutrition Alive.”

They began by outlining the services an international coordinating body could provide to a variety of stakeholders: governments, researchers, health care providers, non-governmental and civil society organisations, foundations and private companies. One of the most important ways that an international coordinating body captures and creates value is through data collection: bringing together data from all over the world, standardizing it, normalizing it, publishing it and “making some noise” about it.

Data collection is integral to international norm setting, an extremely important function done by these coordinating bodies. An example of a norm setting tool is the mid-upper arm circumference body-mass-index bands universally used to monitor malnutrition in children. When malnutrition occurs, a coordinating body also helps set norms for interventions, such as therapeutic foods.

An international coordinating body has a more omniscient global view and can forecast problems that may arise in the future, such as droughts and other disease-specific burdens, and give early warning to donor communities. Early warning of a problem on the horizon can also add value to the private sector, in helping to identify markets for specific products that will be needed to address it. Data can also be used to rate and reward or admonish countries that are doing well or poorly in providing for the good nutrition of the population.

Although data is rarely thought of as a battery, it can indeed spark advocacy. When “Nutrition Alive” or WHO issues a report, it can ignite news coverage, advocacy, and draw public attention to push for change. There is also an important role to play for an international coordinating body to facilitate engaging the private sector, by helping to create more opportunities for private sector involvement in solving global health problems, like malnutrition.
But how to turn a profit doing these things—or to generate sustainable financial returns? An international coordinating body does not easily fit into a traditional business model, where outputs are financially rewarded. Coordinating bodies may need to go around each year with “hats out” collecting contributions from donor governments to keep their doors open. The group posed the question of whether there are ways to break this cycle at donor dependency.

One way that international coordinating bodies could engage businesses is in promoting the societal endorsement of tiered pricing structures. If a coordinating body can use data to demonstrate the impact of an intervention, and be a source of advocacy and endorsement for governments to adopt a tiered pricing strategy for the intervention, it could attract capital and business into it. This would be an opportunity for coordinating bodies to act more like GAVI Alliance, and to use their data to drive a larger discussion about equity and effectiveness among popular society. Securing societal endorsement of tiered pricing structures for interventions could not only be an innovative way to improve global health, but could also help to draw investment into the coordinating body. Other ideas focused more on how to monetise the core business of data collection:

- While the data collected by international coordinating bodies is a hugely valuable, it needs to remain free and open to access by research and public health communities. In general, what is made easily available to the broader public is highly aggregated. What is made available to qualified academics and public health professionals is disaggregated. Perhaps organisations that “qualified” or were recognized by the coordinating body as commercial companies could pay to access the disaggregated data.

- Coordinating bodies could find ways to curate, analyse and market disaggregated data and sell tailored reports to commercial companies. There are for-profit consultancies that provide this service, using publically available data. An international coordinating body could consider working on the peripheries in this capacity, to sustain core activities. A peripheral arm of an international coordinating body could also tender for funds from major donors to pursue “trendy” areas of research, which could support core activities as well.

- Coordinating bodies could also collect data to sell league tables to consumers, rating companies on a health index. Companies are often rated in consumer league tables in areas such as sustainability—why not for the ways in which they are “healthy” and contribute to “healthy” development in the areas of the world in which they operate? Even if coordinating bodies freely provided this information, it may help to drive positive reinvestment into the infrastructure of communities where companies operate and sell their products, as well as increased social responsibility in product development and delivery.

- It was suggested that more value could be generated to the coordinating body if they established some kind of reciprocity, whereby companies receive free information and, in turn, participate in more board and sponsored activities.

- Another way that commercial companies could add value to coordinating bodies, would be to agree to share any findings that emerge from usage of the coordinating bodies’ data set, thereby constantly enhancing the data set, and ensuring that no one company has a monopoly on information derived from public data sets.

- Lastly, international coordinating bodies could take on the roles of resource centres, asking for payments from governments and companies to access specialists’ advice on pertinent issues.
A layer of systems thinking was integrated into the Roundtable by inviting a graphic designer to ‘visually harvest’ the discussions, debates and models generated throughout the two days. The wall-long mural drawn by the artist captured proceedings for immediate feedback for the participants and facilitators during refreshment and lunch breaks. The mural was also prominently displayed during Day 2 of the Roundtable where the public was invited to post comments on it via post-its to encourage interactive discussion. Day 1 and Day 2 visual harvesting diagrams by artist Quoc Dang are available in full PDF on the conference website: www.bit.ly/ghcfroundtable.
Dr. Ellen Strahlman delivered the keynote speech for the Global Health Commercialization & Funding Roundtable titled: “Doing well by doing good: The contributions of the pharmaceutical industry to global health” at the conclusion of Day 1. Dr. Strahlman outlined the contributions of GSK and other pharmaceutical companies to global health. She described the three primary GSK contributions as: business practices, research and development and humanitarian programs. GSK is engaged in a HIV medicines joint venture with Pfizer and also has a operating unit concentrated on developing countries that re-invests 20% of profits to improve health systems in the low-income countries where GSK works. GSK conducts R&D and offers tiered pricing for vaccines to developing countries. Dr. Strahlman emphasized that GSK and other pharmaceutical firms recognize that a healthy society contributes to good business and that health innovations need to be provided to all.
Day 2

Day 2 was an open conference day for the Global Health Commercialization & Funding Roundtable with over 100 attendees. The day consisted of five expert panel discussions: Funding, TB Delivery and Social Entrepreneurship, TB Vaccines, TB Drugs and TB Diagnostics.

Tuberculosis is known as the poor man’s disease. It is easily spread in dense urban areas with poor ventilation and sanitation. TB is low on the innovation radar screen because it is curable with current tools and technologies. However, it sadly ranks as the leading cause of death from a curable infectious disease. There is a clear gap in TB healthcare delivery.

Tuberculosis is caused by a bacterium called *Mycobacterium tuberculosis*, which enters through the respiratory tract and primarily affects the lungs, but can also affect almost any tissue or organ of the body. It is estimated that one-third of the global population is infected with the bacteria. A healthy human immune system can kill the bacteria and clear the infection, making the individual asymptomatic and non-infectious. However, in immuno-suppressed humans, the immune system is unable to clear the infection and the bacteria remains in the body; between 5 and 10 percent of those infected with the bacteria will develop active TB disease. If the bacteria are not contained, the disease will progress to active TB. Without adequate treatment, the infection can fatally damage the patient’s lungs. *Mycobacterium tuberculosis* is spread from person to person through airborne particles and is most prevalent in crowded spaces. If active TB is left untreated, a single person can infect an additional 10-15 people per year. The following Day 2 summaries feature seven world-leading TB innovators working to fight tuberculosis and the business models used to enable their work in this important area.
Panel I
GLOBAL HEALTH FUNDING: GRANTS & FUNDING

Panel I focused on global health funding with grants and investments. During the session, different business models using grants, social and traditional investment organisations were analysed. Panellists described the roles and impacts of early stage investment in the scaling up of global health ventures in and for developing countries. Funders recognise the structural/logistical and financial gaps entrepreneurs face during product development; considerations of local and international resources are required to accelerate the innovation value chain.

Chair: Christopher (Edge) Egerton-Warburton, Partner, Lion’s Head Capital Partners

Panellists: Vinay Nair, Business Development – Europe, Acumen Fund; Sev Vettivetpillai, CEO, Aureos Advisers Ltd; Bina Rawal, Head of Clinical Development, Wellcome Trust; Kim Tan, Chairman, SpringHill Management Ltd; Mark Braganza, Principal, TPG Biotech LLP.

• Vinay Nair opened the session by introducing the different business models between traditional venture capital and social venture capital.
• Sev Vettivetpillai discussed the most important healthcare problems in Africa regarding services and infrastructure.
• Bina Rawal summarised how technology transfer is helping medical research to move towards a commercial stage.
• Kim Tan explained the role of work opportunites in social rehabilitation to improve the whole healthcare environment and the challenges with basic services in rural areas.
• Mark Braganza ended by discussing the relevance of logisitics and distribution models from the developed world to emerging economies and vice versa.

“This is about building companies and revenues so countries are able to grow and ultimately become self-sufficient”

Christopher Egerton-Warburton, Lion’s Head Capital Partners
Points made by the panellists:

**Vinay Nair: Acumen Fund**

- Acumen’s mission is to create a world beyond poverty. Acumen is built around three major pillars: social enterprises, emerging leaders, and breakthrough ideas.

- While most traditional venture capital firms (VCs) are looking to maximise their financial return, their philanthropic counterpart is only focused on social return without taking risks to leverage projects that “don’t” need to generate profits. Acumen works in the middle of this dichotomy.

- Acumen’s work strategy is based around patient capital. It allows the organisation to work with entrepreneurs providing the capital and the post management support required to achieve a sustainable business model.

- In 2011, “innovation” was the 2nd most used word in LinkedIn - just behind “extensive experience”- therefore it seems important to understand how this concept can have a direct impact on people. One way this can be achieved is by creating business models where people are no longer treated as passive recipients of aid, but as customers with opportunities and demands for quality services.

- There is a link between the Innovation Value Chain - Discovery, Development, and Delivery- and the business model that pioneers use: Blueprint, Validation & Preparation, and Scale-up. However, in the middle of this route there is a funding gap, or a “pioneer gap,” and this is where philanthropy-backed patient capital can play an important role.

- Therefore, it is important to understand that grants and philanthropy can support private investment to allow entrepreneurs to reach a high value stage where growth capital might be needed.

**Sev Vettivetpillai: Aureos Advisers Limited**

- Aureos is focused on healthcare because they saw the need to bring medical care to workers and families. This is partly because insurance policies were expensive and limited due to the lack of an audit track at the hospital level.

- As an initiative from the International Finance Corporation (IFC) and the Bill and Melinda Gates Foundation, three specific measures were established to improve healthcare access:
  1. Work between the World Bank and local governments to advance healthcare policies.
  2. Provide financing in terms of debt and other source of capital to healthcare businesses through banks.
  3. Get capital from a typical commercially driven firm to provide risk capital to scale up businesses.

- The need for private capital and institutions with local expertise led Aureos to become the first fund where financial return is combined with the creation of services and goods to bottom of the pyramid (BOP) markets.

- Aureos wants to improve infrastructure and provide quality services - one of the most important problems in Africa - by backing projects in the development and delivery stages.
Aureos has been able to manage the largest supporting platform for projects in sub-Saharan Africa. They have set a global advisory board for the healthcare industry, where they look to:

1. Get the low-hanging fruit in these countries and start funding them to scale up.
2. Bring successful models from India, China, and the UK and transplant them using grant funding to set the right atmosphere in emerging countries to test new technologies.

The independence of the Wellcome Trust sets a unique position that allows project backing without any investors, politics, or social pressure.

They work under the concept of patient capital and in a close relationship with the people on their projects.

The Technology Transfer Division is one the three major funding units. It is the youngest and has the mission of maximising the impact of medical research by accelerating its access to the marketplace.

The division's focus is to provide early stage investment and the division funds gaps, such as the “pioneer gap.” Funding decisions are driven by public good rather than commercial return; however, they look to achieve a fair return on investment (ROI).

The fund has supported more than 200 projects with a very wide range of capital provided. Since the division’s creation, £350 million has been committed and £150 million has been leveraged from other sources. Their exit opportunities have been mainly through mergers and acquisitions, out-licensing, and products launched.

Almost a quarter of the backed projects are targeted towards developing nations’ health needs with approximately £33 million committed in this area. As an important example, India has been a hub for technology development. Joint ventures (JV) for the creation of vaccines between Merck and the research and development (R&D) for affordable healthcare agreements have taken place.

The methodology to achieve this has been similar to what venture capitalists (VCs) have implemented. Due diligence, governance and management are no different.
Kim Tan: SpringHill Management Limited

- SpringHill is focused on the question: Can we use enterprises to tackle social needs? By utilising their social venture capital arm, the company looks to maximise financial, social and environmental return.
- Their approach to work in the healthcare sector is by investing in businesses where health is an indirect, but important, project component.
- Social therapy has been one of the key concepts to implement in areas where mental health is an important burden for local communities. Project Hagar has integrated more than 600 women into society through employment and NGOs which provide continuous help for an adequate reincorporation.
- One of its most promising technologies is the “3 Stone Technology” for cooking which has a direct impact on health and deforestation. Created and manufactured in Kenya, it is a fuel efficient cook stove that saves 50% of charcoal and reduces smoke and toxins by 85%.
- The most important driver for healthcare is prevention. Therefore, the priorities respectively should be in providing clean water, improving housing, sanitation and energy accessibility.

Mark Braganza: TPG Biotech LLP

- TPG has achieved wide participation in the healthcare space by using three different arms: Capital, Growth, Biotech. The company is amongst the most active healthcare investors, with over $5.3 billion of equity committed in 30+ companies in the last 5 years.
- By recognising that delivery mechanisms and environment conditions are very different, it has been possible to create adequate business models from developed economies using a pharmacoeconomic approach to balance their investment.
- While TPG are looking for products with a direct application to traditional emerging markets, they also want to take the technology into western markets. Likewise, they focus their investment on the development of logistics and distribution businesses.
- At the same time, they are also looking to translate products that have worked in traditional markets and take them to emerging ones.
- Logistics, scale and requirements are different in different geographical contexts; however, if there is good reason why a technology should be adopted, a sustainable approach should be sought to incorporate new products and services.
Points discussed in the Q&A session:

- Vinay Nair highlighted that one important challenge in his daily work is to find entrepreneurs who have passed the blueprint stage and have started to create a sustainable commercial model. Regarding the interaction between grants and investments, he mentioned that in many social projects, an enterprise-based solution might be impracticable because of the required volumes or market development. Consequently, there is a previous stage where the necessary demand needs to be created without a revenue model, and it is here where grants can have a major role before or in parallel to an investment stage.

- Bina Rawal discussed how The Wellcome Trust model is focused in funding mainly R&D and requires rigorous quarterly audit procedures to check resource allocation. Additionally, she expressed that the biggest challenge for the institution is to work where no distribution channels have been established.

- Mark Braganza emphasised that to scale up projects, it is critical to pick ventures where they can really see a well-informed and enthusiastic innovator who has demonstrated that the business can work. As a consequence, they support projects to then attract more funding and mentoring in logistics across different sectors.

- Sev Vettivetpillai mentioned that the biggest issue in emerging markets is a lack of investors willing to support small companies, which employ the vast majority of the population. Regarding potential accountability issues, the major problem is in how you measure the financial support in the field. It is a problem of cost-effectiveness and selection of the right measurement tools.

- For Kim Tan the main challenges are in the human and patient capital resources for small and medium enterprises, since all the factors that make a company grow are related to people. There is a shortage of motivated and talented individuals to manage these investments. On the other hand, a general local challenge for developing countries is the proportion of informal business. It is necessary to increase the tax base which will allow governments to sustain schools and hospitals and to gain independence from donor aid.
Panel II

TB OVERVIEW AND SOCIAL ENTREPRENEURSHIP IN TB DOTS DELIVERY

Panel II brought together perspectives from TB epidemiologists and delivery innovators to discuss the current global state of TB and effective directly observed treatment short-course (DOTS) delivery, the official WHO-recommended TB treatment. Representatives of the World Health Organisation, Operation ASHA, and the Michael and Susan Dell Foundation engaged in discussions around existing and evolving methods of DOTS delivery and funding. Operation ASHA, an NGO founded in India in 2006, serves a population of over 5 million slum dwellers in India, and a further 1 million in Cambodia using a scaleable, reputable, low-cost model to deliver TB medicines. The Dell Foundation, a funder of Operation ASHA, was established in 1999 and began making grants and investments to support child-related healthcare and education programmes across the USA, South Africa and India in 2003.

Chair: **David Brown**, Advisor, One World Health

Panellists: **Christopher Dye**, Director of Health Information in the Office of HIV/AIDS, Tuberculosis, Malaria and Neglected Tropical Diseases, World Health Organisations (WHO), **Shelly Batra**, President, Operation ASHA, **Urvashi Prasad**, Programme Officer, Michael and Susan Dell Foundation

- David Brown opened the panel by reminding the audience of Mark Braganza’s statement during Panel I: “Innovation in delivery may be just as important as innovation in technology”.
- Chris Dye contributed extensive knowledge of international policies and targets, giving an overview of TB.
- Shelly Batra showed how policies worked in practice, sharing her views on the importance of accountability and the methods that the organisation uses to achieve this, as well as what needs to be done in order to reduce the prevalence of TB in the future.
- Urvashi Prasad closed the panel by sharing her views from a donor perspective, explaining how programmes are chosen for funding and how accountability is achieved.
Christopher Dye: World Health Organisation

- Since 1990 the number of TB cases recorded has increased from 7 million to 9 million. Although the number of cases is now falling slowly by 1-2% annually, this rate is far below the expected 10%.

- There are two possible theories as to why the rate is not falling quicker:
  1. We are unable to stop the transmission of TB from existing cases
  2. The infection in those already infected by TB is accelerating rapidly towards active disease

  The former is the biggest problem. There are a number of additional risk factors that could increase the chances of contracting TB and are hindering efforts to prevent transmission.

- The number of routinely reported TB cases follows the pattern of cases of HIV prevalence and incidence with a time delay of 3-4 years.

- The relative risk of active TB for diabetics is 2-3 times that of non-diabetics, and it is expected that 1 in 5 cases of TB in India will be attributable to diabetes by 2030.

- Many health centres in developing countries provide a hub for infection to spread as contagious TB patients wait to be seen by a health worker in crowded waiting rooms.

- The main reasons for our inability to stop transmission are because we are not applying the tools we have effectively enough and we do not have enough sufficiently effective tools.

- The MDG targets for 2015 provided an enormous boost to TB prevention programmes, forcing organisations to look harder at prevalence and incidence as clear targets — aiming to halve 1990s rates by 2015 and reduce case incidents to less than 1 per million by 2050.

- The MDG target of reducing mortality is likely to be met everywhere except the region of Africa, and the target for reduced prevalence is likely to be met only in the Americas and Western Pacific regions.

- Eliminating TB by 2050 requires a 20% annual reduction or 1000 fold reduction in TB cases. Using current tools, an annual reduction of 10% can be achieved in areas where drugs and good health systems are available; therefore new technologies are required to meet the target.

- There are no international milestones set between 2015 and 2050; intermittent targets are required to measure success.

- The USA and most of Western Europe is in the elimination phase.
Shelly Batra: Operation ASHA

- 25% of the world’s TB burden is in India, causing indirect costs of £190 million in loss of wages and costing the Indian economy approximately £14 billion.

- DOTS alone is not sufficient to curb the TB epidemic; electronic data sets are needed to facilitate accuracy and analysis of data.

- The Indian government has an effective TB control programme aiming to reduce the prevalence of TB, but both diagnosis and treatment lack sufficient resources. Centres in which patients can take medication under direct observation are scarce and too far for many patients to travel. This prevents patients from seeking treatment; others take medication for 6 weeks and stop taking it because they think they have recovered.

- Operation ASHA has established DOTS centres in remote areas run by local people. They bring costs down via community empowerment programmes.

- Programmes are self-sustaining through systems such as paying an incentive to community health workers employed by the organisation for case-finding and tracking default patients and returning them to the system. Counsellors are sent to specialised training camps before working in local communities. Using these methods, Operation ASHA has been able to reduce the default rate of patients to 3% compared to 60% for other organisations.

- Governments, organisations and donors should invest because, although there is no direct financial return, there is a strong social return exceeding 3500% on investment, increasing productivity and annual income, effectively adding to the economic well-being of the country.

- Programmes aim to enforce accuracy and adherence through the use of fingerprint scanners which remove errors and corruption at the point of data entry. The software is open-source and can be transferred across the medical world and beyond. It runs on commercially available software and hardware, and a text-free version is being developed.

- Integrating technology into healthcare systems can significantly improve accountability, but requires adequate communication to eliminate concerns of staff members. Sufficient training and resources should be present to ensure any technical difficulties can be overcome. Theft of hardware represents a real threat, and therefore sufficient security systems should be introduced to minimise risk.
Urvashi Prasad: Michael and Susan Dell Foundation

- There are three main aspects to the funding model used by the foundation: funding criteria, funding tools, and the role of the funder post-investment.
- The foundation funds programmes based on the following criteria: the programme must address a problem that is fundamental to improving the health outcomes of children in the target segment; the proposed solution must be sustainable, and therefore must have substantial government-backing or market-based support; the programme must deliver an intervention that is already proven and cost-effective; the outcomes must be measurable and should determine whether “the pill actually gets to child it was meant to get to.”
- Operation ASHA meets the necessary criteria – it addresses big health problems, extensively leverages government resources and funds, extends the government’s system to areas it would not otherwise meet, uses practical technology, and adopts cost-effective therapy for TB treatment.
- Funding tools need to match the type of project – specific instruments used should lead to sustainable improvements at the organisation or project level.
- The funder’s role post-investment should ensure that value continues to be added after investments are made, whether this is to help organisations scale-up or leverage government policies and connections.
- Donors should work with their partners in order to produce the best operational model and investigate how they can work with institutions to strengthen the model.
- The Michael and Susan Dell Foundation’s support of Operation ASHA has two main aims: to help them expand by strengthening existing systems and processes; and improving and optimising their distribution channels to meet working capital requirements.
Points discussed in the Q&A session:

- MDR-TB is falling on large scales in some regions including China. Once Estonia broke away from the Soviet Union, it reduced MDR-TB at a faster rate than drug-sensitive TB. Focus should be on drug-sensitive TB which is not being treated effectively in many parts of the world, and correct weighting should be given to various factors affecting proliferation depending upon the region—e.g. TB related to HIV is only a big problem in Africa.

- There is no effective vaccine for TB — BCG prevents severe and fatal forms of TB, but does not prevent other types. Therefore more research into drugs and vaccines is needed and misuse needs to be prevented.

- Accelerating active case finding by mobilising communities should be done. However, in practice it is hard to do affordably and effectively. It is difficult to identify who will get TB. Only 1/10 of those who become infected with tuberculosis will develop active disease and it is impossible to tell who of those infected will develop active tuberculosis.

- Working with local communities is necessary and this can be done via educating counselors to recognise symptoms; however TB is not a highly clustered disease so this may still only represent a small number of overall cases.

- Sustainable development strongly focusing on environmental issues is likely to dominate the agenda for Rio +20. WHO need to send out the message to include TB in a realistic and educated way, by using elimination targets and thresholds carefully, backed by clear programmes of technological implementation.

- Most of the programmes the Michael and Susan Dell Foundation supports are funded in collaboration with other organisations, so often they find appropriate programmes via their partners. Networks with other institutional funders gives the foundation access to good organisations.

- Organisations which require funds will be actively looking for donors and will try and choose those who value the same important objectives.

“TB everywhere is TB anywhere - we need education programmes that target whole communities”

Shelly Batra, Operation ASHA
Panel III
TB VACCINES

The contribution of effective partnerships between TB vaccine entrepreneurs development and public-private funders was discussed during Panel III.

Chair: Ann Ginsberg, Vice President of Scientific Affairs, AERAS

Panellists: Adam Stoten, Deputy General Manager, Oxford Emergent Tuberculosis Consortium (OETC); Zhongming Li, CEO and President of Shanghai H&G Biotechnology; Suresh Jadhav, Executive Director of Serum Institute of India Ltd (SII).

- Ann Ginsberg set up the broader context of TB, discussing the need for new TB vaccines and the position that AERAS and three entrepreneurs on the panel occupy in the larger ecosystem.
- Adam Stoten discussed how the concept of joint venture was formed leading to the formation of OETC and some of the challenges expected in the future during phase III trials.
- Zhongming Li summarised how the Chinese government has provided funding and resources for him to conduct the phase I trial of Ag85a vaccine.
- Suresh Jadhav ended the panel presentations by discussing the efficiency and safety of the VPM1002 vaccine together with the role that collaborative partners have played in developing the vaccine at SII.

“For the vaccine to reach the people, there needs to be political will!”

Suresh Jadhav, Serum Institute of India Ltd
Points made by the panellists:

**Ann Ginsberg: AERAS**

- Ann Ginsberg started the presentation with the question: Why do we still have a growing TB epidemic when there has supposedly been a TB vaccine since 1921?

- According to the latest data, the current vaccine, BCG, is the most widely used vaccine in the world, with an estimated 3 billion doses given since 1921. Unfortunately, the BCG vaccine is unreliable for preventing latent TB infection and adult pulmonary infections and is not recommended for HIV positive children as they can develop a disseminated BCG infection (BCGosis).

- There is a need for new vaccines that are safer and more effective in preventing TB in children, adolescents and adults including those with HIV. New vaccines are currently being developed and these have the capacity to reduce the burden that MDR/ XDR-TB places on patients, health systems and society.

- Currently, the most advanced vaccines in the TB pipeline are those in phase IIb, as is the case for OETC. However, lack of funding and expertise are major challenges faced by biotech companies throughout product development.

- AERAS, a non-profit product development organisation, founded in 2003 and located in the United States, is doing everything from discovery to regulatory approval, including post approval trials, commercialisation, coordinating funding, and gathering expertise from public and private sectors to move novel candidates through the TB pipeline.

**Adam Stoten: Oxford Emergent TB Consortium**

- Adam Stoten mentioned that OETC is in the development stage of the vaccine MVA85A (phase IIb trial), a viral vaccine that aims at boosting the immune responses in those previously vaccinated with BCG.

- He described how OETC was formed in 2008 as a joint venture between Isis innovation at Oxford University and the UK subsidiary of Emergent BioSolutions. As part of the venture, Oxford University provided intellectual property as well as scientific, clinical and funding contributions. Meanwhile, Emergent has provided the funding and commercial vaccine development expertise. Together, the joint venture consortium attracted funding from the Wellcome Trust, European Clinical Trial Partnership and AERAS.
Zhongming Li: Shanghai H&G Biotechnology

Zhongming Li founded Shanghai H&G Biotechnology, which is now developing the Ag85a, a plasmid DNA vaccine in conjunction with first line anti-TB drugs. The initiative started as a reaction to the high burden of MDR-TB cases and to the lack of accessibility to the anti-TB second-line drugs in China.

A major role was also played by the Shanghai Government, which is funding the testing of the new vaccine as part of the National Eleventh Five-year Plan and Twelfth Five-year Plan. However, the funding is conditional on whether the results are showing efficacy and safety.

The company is also able to make use of the Shanghai Zhangijang Biopharm incubator and Wuhan Guanggu Biopharm incubator in order to cut costs. Collaboration with AERAS for the phase I clinical trial was also established.

It was estimated that the phase I clinical trial could be started next year and was concluded that further financing and partnership is needed.

The plan to commercialise and deliver the vaccine has put in place two additional agreements between OETC and Emergent and AERAS:

Emergent has received the rights to commercialise and sell the vaccine in the developed world.

AERAS has received the rights to commercialise and distribute the vaccine in developing world. In return, AERAS has provided funding for phase IIb trial and access to the clinical trial in South Africa.

It was concluded that progressing the pipeline is still challenging despite the support offered by AERAS in South Africa, and continuing funding is necessary to continue with phase III trials.
Suresh Jadhav: Serum Institute of India Limited

- Suresh Jadhav opened the session by mentioning the position of SII as the number one biotech company in India and the world’s largest BCG vaccine producer. SII has a licensed capacity to produce and distribute 90-95 million doses per year of BCG vaccine to the government of India and to UN Agencies.

- He mentioned that SII is now developing a prime vaccine labelled VPM1002. So far, the vaccine has been used as a prime and booster dose and was safe and efficient during Phase I trials conducted in Germany and South Africa. Phase II trials are currently being undertaken in infants.

- SII partners include: Bill & Melinda Gates Foundation, Sabin Vaccine Institute, Merck etc. Collaboration was also established with VPM Germany for the BCG vaccine candidate, VPM 1002, and this is seen as crucial for gaining access to new bio-processing technologies.

- SII hopes that public sector funders and public-private partnerships will continue to play a major role in advancing R&D and in building product development and manufacturing capabilities.
Points discussed in the Q&A session:

- Currently, the method of action for new vaccines is unknown. Further details on the difficulties of developing a business model for a tool with unknown workings were requested. In response to this question Adam Stoten acknowledged that the understanding of the underlying biology is poor and in this type of situation he suggested to make use of the resources that already exist. The studies on efficacy currently conducted should help understand some of the biological mechanisms related to TB and if unsuccessful, there is a broader value offered by these trials to enable development of a more rational vaccine.

- It was further added by Ann Ginsberg that it is a stepwise process, and it is hoped that the first round of efficacy trials will help to identify biomarkers of efficacy that will help design faster trials.

- A member from the audience acknowledged that vaccine development is highly expensive, has high risks, has high impact and has low financial returns. When asked where the money should come from to fund R&D, Zhongming Li said that H&G Biotech intellectual property was transferred to China to get the funding. The trials will be further sponsored by the government only if it shows efficacy data. With good data, big companies may also start to invest.

- Adam Stoten further added that funding should come from both the public and private sectors and this is mostly conditional on the clinical efficacy of the candidate vaccine. In attracting private partners, each entrepreneur should consider how they can add value beyond TB for the partners.

- Furthermore, Suresh Jadhav emphasised that the chances of investing in the candidate vaccines could increase if WHO would take the BCG vaccine out of the market.

- Finally, Ann Ginsberg concluded that development of TB vaccines is still risky. AERAS could play a role of de-risking a project by helping in the early stages both through technical expertise and by bringing in government and private partners.

- Ann Ginsberg commented that a first vaccine will likely be ready by 2020. It was further added by Zhongming Li this could happen even earlier for those who are interested in taking part in the trial.
Panel IV
TB DRUGS

Panel IV illuminated academic entrepreneurship and corporate entrepreneurship in the areas of TB drug discovery. Panellists described innovative partnerships in R&D funding and collaboration within the EU framework and within a UK consortium of scientists. A retired pharmaceutical executive from AstraZeneca discussed the background due diligence of how AZ Bangalore came to be a centre of excellence for TB drug discovery within a large multinational corporation. Finally, the Cambridge Enterprise representative provided additional examples of academic entrepreneurship on how technologies spin out from academic labs to be commercialised and delivered in the real world.

Chair: Richard Jennings, Deputy Director, Cambridge Enterprise

Panellists: Chris Abell, Professor of Biological Chemistry, University of Cambridge, Geoff Coxon, Lecturer in Medicinal Chemistry, University of Strathclyde / Tuberculosis Drug Discovery UK, Barry Furr, Llangarth Ltd, Former Chief Scientist of AstraZeneca

- Chris Abell opened the panel with an example of academic entrepreneurship of applying novel technology in drug discovery. He introduced the concept of fragment-based drug discovery and how it can be applied to TB drug discovery in particular.
- Geoff Coxon described a step-change in academic thinking about drug discovery and the need to work in collaboration across scientific disciplines and engage with policy makers to mobilise resources.
- Barry Furr offered a personal perspective on how AstraZeneca, a multinational pharmaceutical firm established a TB centre of excellence in India. He became involved in TB drug discovery from his time as Chief Scientist of AstraZeneca until his retirement in 2005.
- Richard Jennings shared examples of what is happening with collaborative research at Cambridge and how academics can contribute to discovering and commercialising research into real products with benefits.
Points made by the panellists:

**Chris Abell: University of Cambridge**

- Chris founded Astex Pharmaceuticals in 1999 with other Cambridge co-founders focused on applying novel technology of fragment-based drug discovery to oncology targets using protein crystallography. This technique allows for rational design of potential drug candidates.
- The success of this technique has allowed Astex Pharmaceuticals to generate one Investigational New Drug (IND) per year and now have 6 fragment-based compounds in clinical trials.
- Based on proven technology, his lab is now collaborating with EU Framework partners on applying fragment-based drug discovery techniques to TB drug discovery based on TB structural genomics. EU projects NM4TB (new medicines for TB) and MM4TB (more medicines for TB) are successfully delivering new compounds into the global TB pipeline. Alongside leading researchers, these EU project partners also include private sector partners such as AstraZeneca Bangalore and Sanofi-Aventis.
- The lab is also collaborating with the Bill & Melinda Gates Foundation, Dundee University, partners in South Africa and pharmaceutical companies in using these techniques for screening large compound libraries of pharmaceutical and agrochemical companies in hopes of finding targets that have potency in killing *mycobacterium tuberculosis*.
- The lab recognises that the intensity in TB drug discovery research lags behind those for diseases like cancer and diabetes; however, it is encouraged by pharma involvement.
- The TB drug discovery community, as a whole, is struggling to define what a good target is in TB. There is a shortage of good targets and technology can be better used if those targets can be clarified.

**Geoff Coxon: University of Strathclyde**

- Geoff Coxon emphasised that novel TB drug treatments need to be shortened to fewer pills, and shorter regimens. This message must be shared with politicians and policy makers; it is not good enough if academics work in silos and they are the only ones equipped with the knowledge.
- He explained the initiation and subsequent implementation of the TB Drug Discovery UK collaboration. It was founded in 2009 after engaging with Members of Parliament and its goal is to engage the UK in coordinated TB research and maximise the UK’s contribution to global efforts to facilitate drug development and provide new drugs in the clinic.
- The consortium collaboration has identified a new class of anti-TB agents and works closely with the All-Party Parliamentary Group (APPG) on TB to act as key experts to provide evidence and blueprints to help guide UK research. It also holds key collaborations with TB Drug Alliance on a global level and significant UK outreach achieved with 40+ researchers engaged in collaboration.
- The collaboration has successfully bid for funding from EU Innovative Medicines Initiative to invest additional funds in fundamental TB drug discovery.
Barry Furr: Llangarth Ltd

- Barry outlined the corporate history of innovation for diseases of the developing world by ICI (UK) and emerging country molecular biology collaborations by Astra (Sweden) prior to their merger to become AstraZeneca in 1999.

- He described his responsibilities as Chief Scientist and Head of Project Evaluation post-merger, which included evaluating AstraZeneca Bangalore. His initial findings were that the quality of the science was good in Bangalore; however, the site lacked strategic leadership and had too many projects with inadequate resources.

- He recommended keeping the site open, but instilling strong local leadership and giving the scientists a core focus to establish credibility and reputation. A new laboratory was established for AZ Bangalore concentrating on TB research in 2003 and it has now evolved into a centre of TB drug discovery excellence, engaged in many global partnerships.

- Strengths of AZ Bangalore included excellent human resources with technical expertise and a strong work ethic, purpose built research facilities and access to AZ corporate technologies and capabilities as well as leading science from Indian public science institutes.

- Weaknesses of AZ Bangalore included limited history of drug development activities and lack of corporate incentives to increase R&D budget due to constraints on delivering shareholder value as a public company.

Richard Jennings: Cambridge Enterprise

- Cambridge Enterprise is a 100% owned subsidiary of the University of Cambridge. Its role is to disseminate the results of research and transfer the technology if commercial channels are the best way of getting results to society. There is a need to use tech transfer activities to make money for the university, but in most cases, the monetary amount is small and the ultimate driver is to create societal value that allows applicable research to be shared.

- Academics are very entrepreneurial and are constantly applying for new grants, hiring people, mentoring people and collaborating with peers on a global basis to peer-review work and debate, discuss and push innovations. Many important discoveries are unexpected and often arise from long periods of fundamental research.

- Universities are good at partnership and collaborations because of two reasons a) academics have great networks which they naturally bring as assets to universities and b) universities act as a neutral platform for these collaborations to take place.
Points discussed in the Q&A session:

- Is anybody funding the basic research needed to develop assays to find the right therapeutics? The correct assays are absolutely essential. Geoff Coxon affirmed that there is EU-funded work in this area.

- Barry Furr stated the need to conduct more research on how TB reservoirs remain in human macrophages for long periods without proliferating.

- It was reminded by the moderator, Richard Jennings, that Geoff Coxon’s talk was a great example of key people triggering relationships and leveraging resources to push innovation further into development phases.

“Academics can strengthen the TB drug discovery approach by working together across scientific disciplines and providing sound evidence to policy makers.”

Geoff Coxon, University of Strathclyde
Panel V

TB DIAGNOSTICS

Partnerships’ contribution to innovation was a key focus of the fifth panel of the day. Diagnostic technology development presents many challenges for innovators, especially in the field of tuberculosis. According to WHO in 2009, the TB global case detection rate was just 63%. Because of the challenges of current diagnostic capabilities, including the challenges of separating latent from active TB, as well as diagnosing TB in children and immunocompromised patients, the fifth panel focused on what progress has been made in partnerships for innovation as well as how to use these partnerships for progress.

Chair: Bill Rodriguez, co-founder and CEO of Daktari Diagnostics

Panellists: Steven Nelson, Vice President, Business Development, Cepheid, Romain Prieur, Senior Manager for Tuberculosis, Cepheid, Lakshmi Sundaram, Advocacy Officer, Foundation for Innovative New Diagnostics (FIND), Chandy Nair, Director and CEO, Bigtec Labs, Ruth McNerney, Senior Lecturer in Pathogen Biology and Diagnostics, London School of Hygiene and Tropical Medicine (LSHTM).

- Steven Nelson and Romain Prieur worked together to represent Cepheid, introducing Cepheid’s history as a fully integrated molecular diagnostics company that revolutionised diagnostics with GeneXpert, a technology endorsed by the WHO for applications such as the diagnosis of TB. Steven Nelson opened by discussing Cepheid’s recent growth areas and explaining some of Cepheid’s initial partnerships for the development of GeneXpert assays and technology. Romain Prieur continued by explaining in detail some of the improvements made in diagnosis of TB with the use of GeneXpert.
- Lakshmi Sundaram discussed FIND’s work as a sustainable collaborating and funding body and talked about her work in providing the necessary expertise, capacity and facilities needed to drive the diagnostic development process.
- Chandy Nair provided insight from collaborations in molecular diagnostic technology in India and creating a multi-disciplinary team to address new technology needs.
- Ruth McNerney highlighted some challenges and complications in academics and diagnostics as well as the importance of bringing an integrated approach to tuberculosis and global health.
Points made by the panellists:

Steven Nelson: Cepheid

- Cepheid has over 3000 GeneXpert Systems installed around the world in developing and developed countries. They also have growing applications in women’s health and have 11 FDA cleared tests.

- The benefits of the GeneXpert as an innovative diagnostic test for TB include its nested Polymerase Chain Reaction (PCR) design, its use of four (or more) modules that work independently, lack of contamination by use of disposable cartridges and design that is easy for deployment and scaling. Additionally, results—including Rifampin resistance—are available for patients in less than two hours.

- Cepheid’s successful history of partnerships can be seen through the development of the MTB/RIF Assay. This began in 1999 with development of the GeneXpert System and partnering with the Alland Lab (UMDMJ) on developing the MDR-TB assay. Collaboration with grant funding came with the National Institutes of Health (National Institute of Allergy and Infectious Disease) with two grants for sample processing for rapid PCR TB detection and cartridge development. Additional funding came from FIND in 2006. FIND’s partnership with Cepheid is continuing with a grant for development of the GeneXpert HIV-VL test.

Romain Prieur: Cepheid

- WHO endorsed the GeneXpert® MTB/RIF System in 2010 and since that time, rapid expansion of the instrument has occurred, with distribution of 611 instruments placed since November of 2010. WHO has been monitoring the roll-out and adoption of the system in the field.

- FIND partnered with Cepheid to negotiate lower prices for high burden developing countries (HBDC) for the Xpert® MTB/RIF assay and GeneXpert® IV System. This includes 145 countries with customers such as government funded institutions, NGOs & UN related organisations, registered not-for-profit humanitarian organisations, and donor agencies. Romain Prieur stressed that this is the same system/product as used in the developed world, so the price negotiations did not compromise quality of the product.

- Cepheid is reaching out as a company and partnering with programs in HBDCs to deploy GeneXpert in novel ways, including:
  - Riders for Health’s initiative in Lesotho, a mobile testing program
  - Tutu Tester in South Africa, a mobile testing unit
  - Solar powered GeneXpert systems in Uganda
**Lakshmi Sundaram: FIND**

- FIND was set up to address problems with the lack of diagnoses in HBDC countries due to the lack of appropriate diagnostic technology. FIND assists with product development and funding. The foundation is currently working on malaria, sleeping sickness and other neglected tropical diseases in addition to TB.

- Along with working with Cepheid on pricing for developing countries, FIND looks at concepts and work to develop tools in context. For example, with malaria, there was difficulty with a lancer for producing a blood droplet for smear. FIND assisted in developing and publishing a new tool that has been utilised to solve this problem. In this case, a seemingly insignificant change led to big improvements in this bottleneck situation.

- FIND (and those working in TB diagnostics generally) need more monetary resources to continue work. As highlighted by the Treatment Action Group, an organisation that analyses funding for R&D, $48 million USD were spent in 2010 on TB R&D, but the global plan to stop TB identifies a need for $340 million USD per year to achieve targets for tools. This is only 14% of the target!

**Chandy Nair: Bigtec Labs, Bangalore**

- Bigtec Labs started with collaboration between Chandy Nair, with his life sciences background, and partners in IT, creating a multi-disciplinary team.

- Bigtec is an idea-to-product company, not a product-to-market company. The primary focus is on sensing applications in healthcare and Bigtec utilises a collaborative development model, primarily working with academia.

- Bigtec’s vision for product development includes developing low cost, small, handheld, battery powered products with minimal footprint and minimal training required. The realisation for this vision came with a handheld PCR, the “TrueLab” for diagnosis of certain infectious diseases. The “TrueLab” microPCR platform is 850g, operates with a smart phone and disposable PCR chip, can run on battery for eight hours, offers results from a sample in 45 minutes, and has dual channel, real-time quantitative fluorescence detection. The Truenat MTB focuses on TB diagnosis.

- After a CSIR-NMITLI (government) soft loan in 2006, Bigtec partnered in a joint venture with Tulip Group in 2011, an Indian manufacturing group with national and international distributors, to bring “TrueLab” to market. Molbio Diagnostics was created from this joint venture.

- Current challenges for Bigtec include funding, characterise sample banks, unclear regulatory strategies, and reaching public and private sector markets.
Challenges for diagnostics include university support, funding, and the need for better links with technologists. With insecure medical research funding, it is difficult to plan. TB diagnostics funding has decreased during 2009, whereas funding for vaccines, basic science and drugs increased.

Generally, we also need more published work on point of care tests. From January 2008 through August 2011, 262 articles were published on Interferon Gamma Release Assays, which are not recommended by the WHO for use in high burden countries, but only 12 articles published on point of care tests.

To address TB, we need an integrated approach that is appropriate for the setting. Investment in health should bring education, social equality programs, nutrition and health into packages for countries. Furthermore, because TB is strongly linked with poverty, an integrated approach for improving TB and health is necessary. Academia’s role is in advocacy, advising, information provision, education and training.

TB diagnosis is a complicated journey, encountering many barriers and confounding conditions, including: a failure to seek diagnosis or diagnostic dropout due to lack of awareness, social exclusion, lack of access, stigma, inconvenience, or cost; health system failure or technology failure due to lack of trained staff, lost results, lack reagents/kits, inadequate specimens, lack of robustness, and poor sensitivity/specificity.

A proper point of care test would overcome many of these problems.

Exciting developments in TB diagnostics include new technologies, like nano-sensors, and the move toward active case finding.
Points discussed in the Q&A session:

- Michael Norman from Globalbio acknowledged the difficulty of working in TB diagnostics, especially the difficulties of making a sustainable business out of TB diagnostics.

- In response to a question asking about needs, the panellists were unified in a call for more funding in line with Bill Rodriguez’s comment that “whatever you’re talking about, you’re talking about money.”

- Ruth McNerney, when asked if the world was ready for point of care tests, said that the world is ready for a good point of care test to replace serology and other poor tests.

- Romain Prieur and Chandy Nair, when asked about readerless technology, responded that they were not in the instrument free business. Lakshmi Sundaram pointed out that although instrument free diagnostics would be ideal, this presents quite a scientific challenge. She advocated for a pragmatic approach that identifies the difference in needs at various levels of the health care system as well as the need to work with different partners to apply tools to all levels. Ruth McNerney added that some developments are close to instrument free, but that preparing the sample of sputum is the most challenging part. Finally, Bill Rodriguez identified that the tools that appear simple take considerable, complicated development and usually require trade-offs. Also, if the government wants epidemiological data, electronics can be a positive aspect in assisting with reporting. One audience member pointed out that from the venture capital world, point of care testing is heading toward devices (for example for identifying HIV) as more people are nervous about making an important diagnostic decision based on simple methods.

- Chandy Nair explained Bigtec’s government support as well as the need for a different game in funding for public health problems.

- Romain Prieur talked about the challenges with the multitude of process for quality work in different countries and the large costs associated with it.

“You can’t differentiate health from everything else …TB stops children going to school, stops education, its stops you growing, it stops you investing in your family, I don’t think we can pull global health and development apart. I think we’ve got to stop saying: education’s over there, health’s over there, agriculture is over there. When we start bringing in together packages that are appropriate for a country, then I think we’ll start to make more progress.”

Ruth McNerney, LSHTM
Appendices

Appendix 1: Participant List

- University of Cambridge: Elizabeth Garnsey, Christopher Abell, Jaideep Prahbu
- Oxford-Emergent TB Consortium (OETC): Adam Stoten
- Shanghai H&G Biotechnology Ltd: Li Zhongming
- Cepheid Inc: Steven Nelson, Romain Prieur
- Bigtec Labs, Bangalore/Molbio Diagnostics, Goa: Chandrasekhar Nair
- GlaxoSmithKline: Ellen Strahlman
- Operation ASHA: Shelly Batra, Sandeep Ahuja
- Serum Institute of India Limited: Suresh Jadhav
- Aureos Capital Partners: Sev Vettivetpillai, Geetha Tharmaratnam
- Acumen Fund: Vinay Nair
- SpringHill BioVentures: Kim Tan
- World Health Organization: Christopher Dye
- Foundation for Innovative New Diagnostics (FIND): Lakshmi
- Michael and Susan Dell Foundation: Urvashi Prasad
- London School of Hygiene and Tropical Medicine (LSHTM): Ruth McNerney
- Cambridge Enterprise: Richard Jennings
- Daktari Diagnostics: Bill Rodriguez
- David Brown, Scientific Adviser, One World Health
- Wellcome Trust: Bina Rawal
- AERAS TB Vaccine: Ann Ginsberg
- TPG Biotech LLP: Mark Braganza
- Results UK: Aaron Oxley
- University of Strathclyde/Tuberculosis Drug Discovery (TBD): Geoffrey Coxon
- Rwanda High Commission: Patrick Gihana-Mulenga
- Lions Head Global Partners: Christopher Egerton-Warburton
- Brazilian Embassy: David Sena
- UK National Health Service: Marc Lipman
- Mia Eisenhardt, Reos Partners
- Quoc Dang, Goldsmiths College
- Llangarth Ltd, former Chief Scientist at AstraZeneca: Barry Furr
Appendix 2: Roundtable Poem

TB - it seems to me that you’re the disease that we’ll never beat,
and that forever your killing spree will make tears stream down my cheeks as I watch television screens.

But actually I believe that equality in health can be achieved,
but in solving it, it isn’t just wealth or expertise that we need.

Because although those like Bill and Melinda are the flood “Gates” for aid,
there are still people dying out there every single day.

All the same, if we engage we can bring about change.

From individuals to states and large business chains,

Innovation leads to instigation of immunisation in the world’s worst off nations.

What I’m saying is corporations need cooperation with health organisations and patrons and people stationed in affected places.

These “partner-ships” we start sailing are research enabling. Favouring vaccinations that are life-saving and ultimately changing the face of global health implementation.

There is no room for ego in our health ecosystems, and the catalyst for justice and access for all is for all to be called to listen.

Enlisting the mixing of public and private business and bodies,
it’s bound to make some progress in ridding tuberculosis from people’s bodies.

So embody this vision for health provision and make the decision to stand there,
working together to eradicate these diseases forever under one banner.

Global help for global health is the least we can do,

TB or not TB? That is the question and the answer is you!

Written for the Global Health Commercialization & Funding Roundtable by:

Megan Beech, Poet / Spoken-Word Artist, April 2012
BIBLIOGRAPHY


Reos Partners prior engagements of the U-process in solving complex problems include the World Wildlife Fund, sustainable food systems and improving education systems.

Julia Fan Li is currently a PhD candidate in Technology Management at the University of Cambridge. She completed her undergraduate education with a dual concentration in finance and immunology from the University of British Columbia. She worked as a Chartered Accountant with KPMG LLP's biotechnology practice. Her public sector experience include research projects on the Access to Medicines Index, hospital capital expenditure analysis in Rwanda and working as a technical officer with the World Health Organization and GAVI Alliance. Julia has worked at the intersection of business and science on four continents and recognizes both the challenges and opportunities in global health.

Priya Khetarpal is currently finishing her MEng in Manufacturing Engineering at the University of Cambridge. She has a strong interest in International Development, and in 2010 she spent three months volunteering in Kenya working for the charity Kenya Education Partnerships (KEP), and has since been a branch treasurer and now finance manager of the charity. Throughout her time in university, she has actively pursued her passion in the third sector, as president of the Cambridge branch of Engineers Without Borders (EWB), and most recently becoming a founding member of Charity Change. Her next move is a 6 month EWB placement in Peru.

Tomas Niklitschek is currently completing an MPhil in Bioscience Enterprise at the University of Cambridge. He is a bioprocess engineer motivated by social- and science-related entrepreneurship development. From Chile to the UK he has successfully collaborated with different life sciences companies and learnt from great lecturers, conferences and new friends. He believes that developing nations can incorporate external aid and investment to create a platform of knowledge and pursue more equitable economic growth. In the future, he would like to be working with local entrepreneurs moving their ventures to an international and sustainable scale.

Nicole Person-Rennell is currently pursuing her masters degree in public health at the University of Cambridge. She will return to her third year of medical school in the USA at the Mayo Clinic College of Medicine in August 2012, where she is currently on an academic leave of absence to pursue her enthusiasm for public health. She graduated from Barrett, the Honors College at Arizona State University in 2009 with a BA in Global Studies. She is passionate about women's health and currently is researching domestic violence in pregnant women. She also enjoys dancing, singing, reading, and the rare sunny day in England!

Diana Pirjol is currently doing her MPhil in Epidemiology at the Institute of Public Health, Cambridge. For her thesis she is looking at the epidemiological evidence around parity and the risk of cardiovascular disease. She also has a large interest in pricing and market access strategies for biotech products. Previously, she has undertaken a Masters degree in Management and Health Policy in Amsterdam, the Netherlands, where she was involved in a number of projects ranging from health technology management assessment to policy analysis impact on corporate performance. She enjoys traveling, reading and dancing.

Anne Radl is currently the Projects Manager at the Humanitarian Centre, an international development network affiliated with the University of Cambridge. As part of her work, she runs the Cambridge Global Health Year, which brings together NGOs, researchers, entrepreneurs, business leaders, students and consultants working to address global health issues. Previously, she was the Volunteer Services Manager at a San Francisco-based NGO, Shanti, which provides support and wellness services for people living with life-threatening illnesses. Before this, she served as a Community Health Educator in the United States Peace Corps.
The IfM

The IfM is part of the University of Cambridge’s Department of Engineering. Its activities encompass research, education, consultancy services and courses that aim to provide a clear understanding of the challenges facing manufacturing today. The IfM works closely with industry at regional, national and international level providing strategic, technical and operational expertise to help companies to grow and to become more competitive. This work brings benefits to both parties. Industry receives practical solutions based on the latest applied research. The university receives live feedback to help set the agenda for new research and an income stream to assist in funding future research activities.

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