SOCIAL INNOVATION IN HEALTH INITIATIVE

Credit: Embryyo Technologies, India, 2015

# EMBRYYO TECHNOLOGIES

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| **CONTINENT** | Asia |
| **COUNTRY** | India |
| **HEALTH FOCUS** | General, Tuberculosis |
| **AREAS OF INTEREST** | Medical technology, Health research |
| **HEALTH SYSTEM FOCUS** | Medical products and technologies |

# EMBRYYO TECHNOLOGIES, INDIA

Embryyo Technologies is a private medical device and technology innovation company, based in Pune, India, specializing in low-cost, context-appropriate, user-centred interventions in the field of public health.

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# ABBREVIATIONS

| | |
|---|---|
| BIRAC | Biotechnology Industry Research Assistance Council (India) |
| BRIC | Brazil, Russia, India and China |
| CE | Conformité Européenne (European Conformity) |
| CEO | Chief Executive Officer |
| CIIE | Centre for Innovation, Incubation and Entrepreneurship |
| CTO | Chief Technology Officer |
| DOTS | Directly Observed Treatment-Short Course |
| DPwB | Digital Patient-wise Box |
| FDC | Fixed Dose Combination |
| FDI | Foreign direct investment |
| IITs | Indian Institutes of Technology |
| INR | Indian Rupee |
| IP | Intellectual Property |
| LED | Light Emitting Diode |
| MDR-TB | Multi-drug Resistant Tuberculosis |
| NTD | Neglected tropical disease |
| PPD | Product development partnership |
| RNTCP | Revised National Tuberculosis Control Programme |
| R&D | Research & development |
| TB | Tuberculosis |
| TB-CCTV | Embryyo's Innovative TB Solution |
| TBHV | TB Health Visitor |
| US$ | United States dollar |
| USAID | United States Agency for International Development |
| WHO | World Health Organization |

# CASE INTRODUCTION

In recent years, there has been increasing recognition of the importance of medical devices and other non-pharmaceutical health-related technologies to all aspects of health care (Sinha & Barry, 2011). Despite advances in health technology, there are many diseases for which inadequate or few technologies exist that can reduce their burden on health (Sinha & Barry, 2011). There are also significant challenges in financing and delivering technologies to those who need them. In India, most medical devices manufactured are exported, while 75% of the medical devices used in the country are imported (Deloitte, 2010). About 70% of complex medical devices sit inoperable at their destinations in developing countries (WHO, 2011). Creating appropriate products for low-resource settings requires not only a rethinking of what is considered a health technology, but also cross-disciplinary innovation and in-depth understanding of the needs of each country.

Embryyo Technologies (Embryyo) is a private medical device and technology innovation company, based in Pune, India, specializing in context-appropriate, user-centred interventions in the field of public health. Its mission is to create breakthroughs in science, technology, research and design while solving the toughest challenges in global health to enable maximum impact in a sustainable way. Embryyo designs a wide range of low-cost, portable innovations, including devices for blood plasma separation for point of care diagnostics, non-invasive bilirubin assessment in neonates, respiration rate diagnostics and a LED-based neonatal phototherapy system. To illustrate Embryyo's approach to the design of such devices, this case study will chronicle the development of its TB-CCTV system. Embryyo's TB-CCTV is a novel drug adherence monitoring system, which enables the identification of non-compliant tuberculosis (TB) patients in almost real time in India. The TB-CCTV has been designed and tested, but not yet commercialized or widely manufactured.

The Embryyo case study illustrates how research funding can support start-up companies in low- and middle-income countries to develop and test new low-cost, context-appropriate technology innovations. These creative young companies often require tailored business support and guidance to get the innovations into the local market while retaining affordability of the product. The case study also shows how location-specific needs assessment and user-centred design can ensure that more appropriate devices reach people in need, and prevent the adoption of ineffective or inappropriately costly technologies that could divert resources from other critical health care areas (Sinha & Barry, 2011).

*We fundamentally believe that good health is the primary signature of prosperity for any individual, their families, and the nation at large... with these kind of initiatives we are contributing our bit to health as well as economy.* (Nishant Kumar & Prateek Jain, Co-founders, Embryyo)

# 1. INNOVATION AT A GLANCE

## Organization Details

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|---|---|
| Organization name | Embryyo Technologies |
| Founding year | 2014 |
| Founders' names | Nishant Kumar (CEO) and Prateek Jain (CTO) |
| Founders' nationality | Indian |
| Current head of organization | Nishant Kumar |
| Organizational structure | For-profit, private limited company |
| Size (Embryyo staff) | 15 |

## Innovation Value

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|---|---|
| Value proposition | Low-cost, context-appropriate and user-centred medical devices and technologies developed in and for resource-constrained settings to address key public health challenges. |
| Beneficiaries | Low-income beneficiaries of affordable medical technology products. E.g. TB-CCTV system designed for patients of district level TB units. Embryyo still at the research and development stage so no reported beneficiaries beyond the user-testing groups. |
| Key components | • Comprehensive, user-centred needs assessments conducted.<br>• Affordable, context-appropriate technological solutions designed.<br>• Leverages existing public health infrastructure where possible and appropriate<br>• Incorporates a mixed funding model, utilizing different grants for specific projects. |

## Operational Details

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|---|---|
| Main income streams | Grants from Grand Challenges in TB Control (Bill & Melinda Gates Foundation and USAID); however, profits expected once products have been validated and commercialized |
| Annual expenditure | 3 600 000 INR (US$ 55 638) |
| Cost per person served | Depends on the technology. The TB-CCTV system costs 2 000 INR (US$ 31) for four treatment cycles. |

## Scale and Transferability

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| Scope of operations | R&D operations based in Pune, India |
| Local engagement | Integrated in local innovation ecosystem, via Venture Centre, CIIE, and IKP Knowledge Park. Conducted Phase 1 testing of TB-CCTV at Talera Hospital in Pune. |
| Scalability | Each device has its own scaling requirements and considerations, but are all designed to be transferable to similar settings. E.g. the TB-CCTV system was designed for and alongside the nationally rolled out TB DOTS programme, allowing for transferability across Indian states. |
| Sustainability | • Raised grant funding for R&D, investor funding to be raised for commercialization;<br>• Fast-prototyping of multiple ideas to reduce dependence on individual products and increase chances of developing break-through solutions. |

# 2. CHALLENGES

With a population of more than 1.2 billion, India is the world's largest democracy, and the world's fourth-largest economy. In the past few years, average life expectancy in India has more than doubled, literacy rates have quadrupled, a sizeable middle class has emerged and several globally recognized pharmaceutical, steel, space and information industries have been established. The growth of India's middle class has meant the emergence of several million new health care consumers looking to opt out of India's public hospitals and instead pay for private health care services (Richman et al., 2008). Private Indian hospitals generally provide world-class services at far lower prices than in the United States and Europe, and this has stimulated growth in medical tourism and further growth in the private health care sector (Chinai & Goswami, 2007). Private health care in India is often associated with innovation, and, given fixed pricing schemes, Indian hospitals have managed to build capital, labour and systems investment strategies to maximize quality of care within pricing constraints. In addition, many Indian firms self-manufacture medical equipment, which facilitates further innovation and cost reduction (Richman et al., 2008).

For decades, technological change and innovation, driven by research and development (R&D), have been important sources of productivity growth and increased welfare (Edquist, 2000), and there is a high correlation between countries with significant economic improvement and substantial investment in R&D. India has attracted substantial foreign direct investment (FDI) in R&D, reflecting broader trends towards offshoring in developed countries (United Nations, 2005). Opinions differ on the degree to which transnational corporation (TNC) R&D activities help in building up local technological capacity in a host country. On one hand, TNC's presence in developing countries may result in desirable forms of economic activities. However, these foreign R&D units sometimes create high-technology enclaves with limited diffusion of knowledge into the economy, and FDI into R&D may divert scarce local R&D resources of host countries from local firms and research institutions (United Nations, 2005).

In recent years, there has been increasing recognition of the importance of medical devices and other non-pharmaceutical health-related technologies to all aspects of health care (Sinha & Barry, 2011). In 2007, for example, the World Health Organization (WHO) issued the first global directive on medical devices, recognizing that, like medicines, many health technologies are indispensable. The availability of these new technologies holds great promise for addressing important diseases in developing countries, especially since, despite recent advances in health technology, there remain many diseases for which there are inadequate or few technologies that can reduce their burden on health, for example in HIV, malaria, tuberculosis and neglected tropical diseases (NTDs) (Sinha & Barry, 2011).

There are many challenges in financing and delivering these technologies to those who need them. In India, most medical devices manufactured are exported, while 75% of the medical devices used in the country are imported (Deloitte, 2010). About 70% of complex medical devices sit inoperable at their destinations in developing countries (WHO, 2011). Creating appropriate products for low-resource settings requires not only a rethinking of what is considered a health technology, but also cross-disciplinary innovation and in-depth understanding of the needs of each country. Location-specific needs assessment can ensure that more appropriate devices reach people in need, and prevent the adoption of ineffective or inappropriately costly technologies that could divert resources from other critical health care areas (Sinha & Barry, 2011).

While the Indian market for medical devices and technologies is among the top 20 in the world by market size, the per capita spend on medical devices in India is the lowest among BRIC countries, and this current under-penetration of medical devices in India represents a sizeable growth opportunity (Deloitte, 2016). This potential in the medical devices sector is acknowledged by its inclusion in the Make in India initiative, a

programme launched by Prime Minister Narendra Modi in September 2014 as part of a wider set of nation-building initiatives devised to transform India into a global design and manufacturing hub (Make in India, 2016). It represents an opportunity to stimulate indigenous manufacturing and realize the twin objectives of accessibility and affordability (Deloitte, 2016).

The international development community has also launched several product development partnerships (PDPs), recognizing the potential of medical devices and technologies in improving health outcomes. The single largest donor is the Bill & Melinda Gates Foundation, with additional support provided by the World Bank, other foundations, and bilateral donors. The PDPs promote collaboration between public and private sector institutions in developed and developing countries, addressing a wide range of diseases and working on accelerating the development of drugs, vaccines, diagnostics and other technologies (Moran et al., 2009). The PDPs are not-for-profit entities operating with philanthropic funds and forming collaborative partnerships with private sector health technology corporations to design and implement product development programmes for specific health technologies (Mahoney, 2011).

In addition to India's reputation as a centre of technological innovation, recent years have also seen India become known as a hub of social innovation, addressing social problems such as the lack of high-quality education, limited access to clean water and hygiene, and inadequate nutrition. Improved outcomes are being achieved at a low cost per client, with the use of diverse business models (Nee, 2015).

# 3. INTERVENTION AND IMPLEMENTATION

Embryyo Technologies (Embryyo) is a private medical device and technology innovation company, based in Pune, India, specializing in context-appropriate, user-centred interventions in the field of public health. Its mission is to create breakthroughs in science, technology, research and design while solving the toughest challenges in global health to enable maximum impact in a sustainable way. Embryyo designs a wide range of low-cost, portable innovations, including devices for blood plasma separation for point of care diagnostics, non-invasive bilirubin assessment in neonates, respiration rate diagnostics and LED-based neonatal phototherapy. To illustrate Embryyo's approach to the design of such devices, this case study will chronicle the development of its TB-CCTV system. Embryyo's TB-CCTV is a novel drug adherence monitoring system which enables the identification of non-compliant tuberculosis (TB) patients in almost real time in India. The TB-CCTV has been designed and tested, but not yet commercialized or widely manufactured.

## 3.1. NEEDS ASSESSMENT

Embryyo's design process begins with an extensive needs assessment, which involves interactions with end users and "gemba walks", where the Embryyo team spends time in the locations where the devices will be used to understand the needs and constraints of the environment and people. Research is also conducted to get a complete picture of the challenge. For the TB-CCTV system, the needs became clear.

India has the highest TB burden in the world, with an estimated annual incidence of 2 million to 2.3 million cases and 150 000 to 350 000 deaths annually (WHO, 2014a). Effective TB control requires swift diagnosis and the completion of a six-month treatment (WHO, 2014b). However, the Indian health care delivery system is fragmented, with a variety of public and private providers (Das et al., 2007). On average, TB patients interact with three different health providers, delaying appropriate TB diagnosis by almost two months (Sreeramareddy et al., 2014).

The Directly Observed Treatment-Short Course (DOTS) is an internationally recognized public health strategy for the identification and treatment of TB, administered across the Indian public health system according to the Revised National Tuberculosis Control Programme (RNTCP). The DOTS treatment regimen is divided into two phases: 1) Intensive Phase (two months), during which the patient must visit a DOTS centre on alternate days and take medication in the presence of the provider; and 2) Continuation Phase (four months), during which the patient must visit a DOTS centre once a week to receive a new blister pack of TB medication comprised of three pills to be taken in the presence of the provider, and then taking the remainder of the week's medication at home. Medication is supplied in a Patient-wise Box that contains blister sheets for the full treatment course, and is stored at a DOTS centre. A DOTS provider at each centre manages the distribution of medication amongst patients.

Many challenges accompany this process:

- **Patient compliance:** Studies of TB patients in India have reported non-adherence rates between 20% and 50% (Jaggarajamma et al. 2007; Kulkarni et al. 2013).
- **Lack of information**: The DOTS system employs TB Health Visitors (TBHVs), who are responsible for identifying non-compliant patients, counselling them and ensuring they complete treatment. Currently, TBHVs can only identify non-compliant patients through the DOTS provider and random checks. During the Intensive Phase, compliance data are available every two days, corresponding to the patient's scheduled visit to the DOTS centre. Patients who do not show for treatment can be contacted by the TBHVs. However, during the Continuation Phase, this reduces to a single weekly interaction.
- **Severe consequences:** Non-compliant patients will become infectious again, endangering others in their communities. Moreover, they are at high risk of developing Multi-drug Resistant Tuberculosis (MDR-TB), which requires two years of treatment.

Dr Rajabhau Yeole, a RNTCP consultant working on behalf of the WHO, highlighted the desperate need for novel and accurate techniques in TB control. *"Our incidence of cases is very slowly declining. If we go at this rate, then it will be a very long time. Innovation research is very much needed in this TB programme, then only can we accelerate progress."* (Consultant, RNTCP) The urgency for health innovation and health system strengthening to combat TB is echoed throughout India. In 2015, India's government launched a Call to Action for a Tuberculosis Free India, which has attracted the support of stakeholders from both the public and private sectors (Deshpande 2015).

TB spreads very quickly, particularly in India's densely populated urban slums. Dr Hodgar Balasaheb, District TB Officer at Pune's Talera Hospital, says his unit sees around 2 000 TB patients annually, with 30% coming from slums. Mr Sachin Patil, a DOTS supervisor at the same facility, highlighted some of his daily challenges: *"I would like to meet the patient at the time of his missing a dose, but I never understand how many patients have missed it today, how many patients have missed their dose yesterday, I don't know."* (Supervisor, DOTS) Because the system is entirely paper-based, Patil has to visit every individual DOTS centre and view every patient's treatment card in order to identify non-compliant patients. He explains that each missed dose increases the patient's conviction that they do not need the medication if there are no immediate negative effects. They do not realize that a relapse takes time to become symptomatic.

### 3.2. PROBLEM SET REDUCTION

Based on this needs assessment, the Embryyo team identifies core elements of the problem and identify specifications that need to be met in a solution design. For example, for the TB-CCTV system, the following problem set reduction was specified:

- **Real-time monitoring**: Bring the latency of information about the patient from seven days to one day.
- **Zero-patient burden:** The patient should be a passive recipient of the solution and should not be required to exert additional effort to make

the solution work. Research has shown that interventions with a self-monitoring component are likely to require greater investment into appropriate community education and are likely to be less scalable (Garber et al, 2004; Wilson et al, 2009).

- **Work-flow efficiency**: Empower the health system with data-driven decision making tools and fit within existing structures to reduce burdens and create an efficient workflow.

### 3.3. SOLUTION DESIGN

The TB-CCTV was purposefully designed for integration into the existing workflow of the DOTS programme. Collaboration with Pune's Talera Hospital highlighted the inefficiencies of the paper-based system and the need for actionable information to inform targeted response to non-compliance. As the team of innovators highlight, *"We haven't really attempted to build a fundamentally new system … [but] to study the inefficiencies in the existing system and … build the right solution which addresses those inefficiencies."* (Embryyo Design Team)

Embryyo's TB-CCTV system consists of three main elements:

*Digital Patient-wise Box (DPwB)*

The DPwB is a digital version of the Patient-wise Box, which contains TB medication for an individual patient. It has 42 slots for blisters packs: 24 for the Intensive Phase and 18 for the Continuation Phase. A GSM circuit records when a blister pack is removed and then sends an SMS to a central server. The DPwB is kept at the DOTS Centre throughout the duration of the regimen.

*Figure 1: Digital Patient-wise Box*

*BoxRx*

The BoxRx (the name stems from the Rx symbol used to denote medical prescriptions) is a compact and robust device that fits a single blister pack (i.e. one week of medication during the Continuation Phase) that is preloaded by the DOTS provider each week and sent home with the patient. The BoxRx works by utilizing a circuit printed onto a tearable substrate, where the conductive tracks are aligned with the positions of the pills. When a pill is forced out of the blister, it tears through the substrate and breaks the circuit. In this way, the BoxRx records the exact time that each individual pill is removed from the blister and sends this data to a central server. Although it cannot ensure that the tablet is swallowed, it will indicate if a tablet is forgotten (i.e. not removed from the pack to begin with).


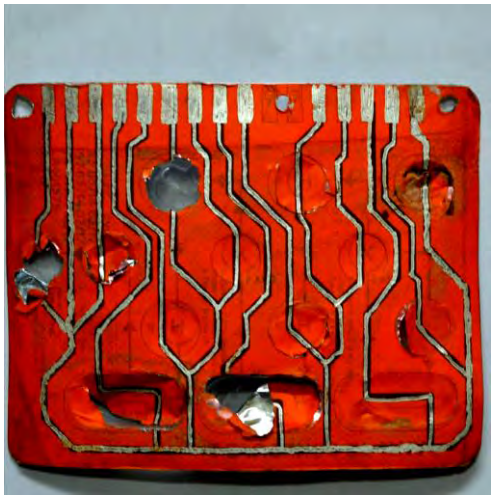

*Figure 2 and 3: Embryyo's Mobile Box and printed circuit behind TB medication blister*

*Mobile Applications*

A suite of mobile and web-based applications has been developed to connect various stakeholders in the TB control system with the data generated from the DPwB and the BoxRx. Currently, the DOTS provider can connect to the mobile application to identify patients who have missed a dose and notify the TBHV.

# 4. ORGANIZATION AND PEOPLE

Two young Indian engineers, Nishant Kumar and Prateek Jain, founded Embryyo in 2014. They shared a profound passion for innovation and dedication to help society. *"We were rich in ideas in the sense of what is practical for the existing [problems]... So we wanted to build technologies for today, not for 20 or 30 years down the line."* (Nishant Kumar, Co-founder, Embryyo) The name is intended to elicit a vision for a space where "ideas for a healthier planet" can be seeded and imagination can overcome frustration with the lack of appropriate health care solutions. They have built Embryyo into a medical devices innovations laboratory, where the team develops rapid-prototype medical devices with the potential to address some of the most urgent health challenges in India. With its lean start-up approach, Embryyo "seeds" new ideas and quickly create initial prototypes, whilst flexibly iterating its technologies side-by-side with the user. *"The message that we want to communicate to any policymakers, as innovators trying to solve this problem, is ...that we will see multiple [challenges] but we have the capacity to adapt and design a solution."* (Nishant Kumar, Co-founder, Embryyo)

The company's employees are mainly university graduates, enthusiastic about making a difference and driven to excel at their first job. *"People from different backgrounds – mechanical, electrical, software, mobile applications, and product design – are coming together, glued by a medical problem, and creating a product ... [They are] a team of impatient optimists, bubbling with ideas at a very high rate ... trying to convert the top line ideas into real tangible products ... With these kinds of initiatives, we are contributing our bit to health as well as economy."* (Nishant Kumar, Co-founder, Embryyo) With 15 employees, Embryyo keeps the key product development activities in-house: technical specifications; design and prototype building; and mobile application development. Beyond this, Embryyo seeks external input for additional expertise: a local science incubator manages patent applications and a collaborative start-up handles back-end software development. Additionally, the team has established key partnerships with academic groups (IIT Bombay and National Chemical Laboratory) and clinical teams (Narayana Health, All India Institute of Medical Science and Sassoon Hospital).

# 5. BUSINESS MODEL

Embryyo is a lab accelerating ideas for health innovation, committed to taking its products to *"at least the full stages of clinical trials and market readiness."* (Kumar & Jain, Co-founders, Embryyo) Currently Embryyo's focus is on the design and prototyping stages, not the commercialization and distribution stages. Moving forward, Embryyo plans to explore three routes to market for its products: 1) licensing the IP to a third party; 2) creating spin-out entities; or 3) managing the full commercialization process in-house. This move will require a restructuring of investment strategies and funding models, which the team is currently exploring.

Unlike many other biotech companies rising through Silicon Valley or London, Embryyo has adapted a mixed funding model, leveraging

philanthropic grants to fund the development of affordable solutions to public health challenges, before engaging with investors who can support commercialization. The Economic Times in India commented on this business model: *"No one would have been interested in him [Kumar] then, as he was setting up an R&D lab without revenue models. Within a year of its formation, Kumar's company has US$ 300 000 in the bag. His funders are the Tata Trust, the Gates Foundation and the Department of Biotechnology."* (Pulakkat 2015)

In late 2013, Embryyo received a Phase 1 grant from the Grand Challenges TB Control Programme, which is supported by the Bill & Melinda Gates Foundation and USAID. Over the course of six months, Embryyo developed and tested a prototype for the BoxRx. In early 2015, Embryyo was awarded Phase 2 funding (selected as one of four out of the original 14 teams), enabling it to conduct a multicentre trial on 200 patients over the full duration of TB treatment. This study commenced in December 2015.

The Grand Challenges platform also facilitated mentorship by experts, advising the team on gaps and opportunities in the public health system, as well as connecting them with appropriate hospital partners for their Phase 1 study. Jain summarized the significance of this milestone: *"Getting an entry into these systems is so tough that if you don't have a cooperative medical officer then you won't be able to proceed."* (Prateek Jain, Co-founder, Embryyo)

Currently, the cost of the TB-CCTV system has been brought down to 2 000 INR (US$ 31) with a lifetime of four treatment cycles per patient. The solution is expected to introduce substantial cost savings, as treatment for each newly infected TB patient costs the health system between 10 000 and 15 000 INR (US$ 154 to US$ 232), and the two-year treatment for Multidrug-resistant TB (MDR-TB) costs 200 000 INR (US$ 3 087). Costs are anticipated to be covered by the health system; a different financial model might be required if the solution is also administered through private providers.

# 6. OUTPUTS AND OUTCOMES

## 6.1. IMPACT ON HEALTH DELIVERY

Embryyo's devices are designed to provide high-quality, low-cost, context-appropriate alternatives for resource constrained settings. Data-driven health care is an aspiration in resource-rich settings which use advanced health technologies. Simultaneously, the rise of mobile technology has enabled resource-poor settings to leapfrog inefficiencies and deliver evidence-based care (World Economic Forum "Health Systems" 2014).

The TB-CCTV system has the potential to achieve similar outcomes, as it allows for real-time monitoring of a patient's adherence to treatment. This could transform the decision-making process of TBHVs into a streamlined interaction with patients. Potential future improvements include collecting data to track infection outbreaks and monitoring behavioural changes in patients as they interact with the mobile platform. In effect, the DOTS programme is multilayered, and Embryyo's solution is carefully sandwiched between these layers to optimize health care delivery.

## 6.2. COMMUNITY AND BENEFICIARIES

Embryyo involves its end users in the design and testing process to make sure maximum benefits accrue to the intended beneficiaries and that their input is considered and incorporated throughout.

As an example, the TB-CCTV system has been designed to benefit two groups of beneficiaries: 1) health providers delivering TB care through the DOTS programme; and 2) patients undergoing TB treatment. Because Embryyo has yet to complete the multicentre evaluation, evidence on beneficiary impact remains anecdotal thus far.

For health-care providers, the solution allows TBHVs to monitor patient compliance in almost real time and prioritize visits with non-compliant patients. It provides providers with data-driven evidence to resolve the existing ambiguity of self-reported patient compliance. A DOTS provider who participated in the Phase 1 study shared his experience: *"It is not possible for me to reach each and every [patient] … every day… That is why this system, this mechanism, will provide the information … so when so many patients are missing today … I will take the proper reaction at that time."* (Provider, DOTS) The TB-CCTV system streamlines a currently labour-intensive, paper-based system, fast-tracking what used to be substantial delays in reporting of non-compliant patients. During the study, the overseeing TB officer observed that his staff was already operating within "sophisticated dynamic structures" and could adapt to the technology with training.

For TB patients, the product facilitates targeted interaction with the DOTS programme, driven solely by their level of treatment adherence. The digital infrastructure allows the patient to remain passive, mitigating the challenges of compliance and self-reporting. In the long term, this could reduce development rates of MDR-TB. An interview with the wife of a patient currently trialing the BoxRx pilot described: *"This problem is very difficult for us… The stigma, the society view, is very tough for us."* The wife described her fear of being identified as a TB patient, forcing her to travel to the furthest DOTS centre to ensure that nobody could know where she was going or what she was doing. The design of the BoxRx has the potential to resolve some of this tension. With good adherence monitored by the system, there may be less a need for frequent TBHV patient visits.

### 6.3. ORGANIZATIONAL MILESTONES

Embryyo's success story starts with its incubation at Pune's Venture Centre in 2013. The Venture Centre is India's largest science business incubator, supporting early-stage ventures through services and resources that include: access to advanced facilities for scientific experiments, mentorship from domain experts, accounting and legal services, and support with Intellectual Property (IP) filing. Similarly, through the Centre for Innovation, Incubation and Entrepreneurship (CIIE) and the IKP Knowledge Park, Embryyo has accessed a large network of advisors and mentors.

Other important milestones include Embryyo's participation in the Startup Leadership Programme and support from India's Biotechnology Industry Research Assistance Council (BIRAC) and the Innovate for Digital India Challenge. Recently, the team presented at the Private Sector Innovation Working Group event, organized by Every Woman Every Child at the launch of the Global Strategy for Women's, Children's and Adolescents' Health.

## 7. SUSTAINABILITY AND SCALABILITY

As an organization, Embryyo is too young to predict the sustainability of its model for seeding innovation through a mixture of grants and investment. Its strategy of driving various ideas simultaneously reduces dependency on individual projects and sustains operations through a bigger pool of funds. This approach also maximizes the number of ideas in design stage and increases the chances of identifying breakthrough innovations. However, the next few years are crucial, as broader uptake of the technology by the health system and Embryyo's ability to start generating revenue from sales will be tested. Longer-term investment streams are needed for getting products to market, which is another factor for sustainability that Embryyo should explore. This is a particularly important issue to address as there are funding gaps between R&D phases and commercially viable rollout of products, especially for low-profit technologies designed for the public sector.

The RNTCP is rolled out across the whole of India and its implementation is governed by a set of predefined national standards pertaining to staffing structure, medical supplies and treatment protocol (DOTS Guidelines, India, 2010). This presents a potential scaling opportunity for novel solutions which capitalize on this standardized infrastructure (Sachdeva et al. 2012). To best accommodate the intricacies of the DOTS programme, Embryyo's solution has undergone numerous iterations, incorporating the needs of patients and DOTS providers. Through this human-centred design approach, Embryyo's solution has been optimized for the RNTCP, making it potentially scalable across India. However, the multicentre study will be needed to fully evaluate this scalability. The non-negotiable components of the TB-CCTV system essential for its functioning are: 1) a public health infrastructure to follow up with non-compliant patients (TBHVs or equivalent); 2) access to TB medication; and 3) access to a mobile network.

Embryyo's ambition to scale its solution across India and internationally has driven the team to subject its products to a stringent process of future-proofing. For example, the challenge of mobile connectivity has been addressed by: 1) collecting data on telecom providers in each new area; and 2) integrating a microcontroller into the pill box to store data until a network signal is picked up. Similarly, the team has designed the product to accommodate, with minimal changes, the introduction of a Fixed Dose Combination (FDC) treatment. In a recent policy document by the RNTCP, FDC has been recommended to potentially simplify the treatment process, as it combines the current multidrug approach into a fixed dose (WHO 2014b). Finally, the two-year longevity of the DwPB can be extended, since the cardboard box can be cheaply replaced (at time of research, for less than 25 INR, or US$ 0.4), re-using most of the electronics and internal setup. Finally, Embryyo ensures that all its products are built towards a CE approval (showing that the product complies with the essential requirements of the relevant European health, safety and environmental protection legislation), which would allow access other markets in the future.

# 8. KEY LESSONS

## 8.1. IMPLEMENTATION LESSONS

### *Getting started*

Embryyo's development phase shows the need for urgency, agility and inclusiveness in the social innovation process, summarized by Kumar's favorite quote: *"I have been impressed by the urgency of doing: knowing is not enough, we must apply; being willing is not enough, we must do"*, and his fundamental belief: *"It's only after you convert your idea into something tangible that you realize the full potential of the idea ... Hence, being willing is not enough; you must go out and try."* (Nishant Kumar, Co-founder, Embryyo)

### *Maintaining efforts*

Despite some failures, Embryyo's consistent process of evolution and maturation proactively engages stakeholders throughout the whole value chain, from patients and doctors to public health experts and investors. An idea at conception rarely resembles itself at maturity, requiring an agile and human-centred approach to turn a research invention into an innovation. Embryyo has excelled in this area.

Embryyo's team has learned how to "walk in the shoes of the beneficiary". Jain has spent days accompanying TBHVs on their daily travels to visit TB patients. He has sat quietly for hours observing the shame with which TB patients hide their medication to avoid social stigma, the reluctance with which they often visit the DOTS centre, and the hardships associated with paying for transport for six months and losing wages. As Jain puts it, *"Working with clinicians helped in making [him] quite practical"*, realizing that the *"device can do a*

*part of it",* but its integration should be leveraged to drive behavioural change (Prateek Jain, Co-founder, Embryyo). Consequently, the team has been working on various gamification ideas to better connect with the patient. This interaction with beneficiaries has transformed the engineers into social innovators.

*Overcoming challenges*

Social innovators working in health often find themselves unequipped to develop and execute a well-structured and data-rich clinical study to fully assess impact. Trying to develop this expertise in a rushed manner could deliver substandard results. To overcome this, Embryyo contracts the services of a commercial biostatistics entity whose service covers the full design of study protocol, consent forms, ethical approval documentation, data collection framework and statistical analysis of outcomes. While this service can be unaffordable for social innovators, costs can be offset by absorbing monitoring and evaluation into the data collection process. More importantly, Embryyo's team acknowledges the need to incorporate these costs into grant applications, emphasizing impact assessment as an integral part of the study execution.

A conversation with two senior health programme implementers from PATH India highlighted a related issue, namely the lack of appreciation for impact assessment and research amongst some entrepreneurs in India. *"Start-up entrepreneurs … are true believers in their innovation and they resent [external people] coming in and telling them they need to do research… The thing is, if impact evaluation is linked in the minds of the start-up to managing a user base by showing how impactful your value proposition or innovation is… and then by carrying on doing this kind of research, you will end up nursing your user base. I think that's the way to put it."* (Programme Implementers, PATH India) Embryyo has grounded this belief in evidence-based product creation, situating itself not just as a start-up but as a true innovation lab.

## 8.2. PERSONAL LESSONS

India is a country where science and technology are often placed on a pedestal: the most reputed network of universities, the Indian Institutes of Technology (IITs), exist across the whole country and attract a phenomenal number of applicants each year (the acceptance ratio is 2%) (Priceonomics, 2013). However, combining engineering and business to deliver social innovation in health is an unconventional choice, riddled with social pressures and personal sacrifices. For Kumar and Jain, this has meant giving up a stable corporate career, investing personal savings and readjusting family expectations. Therefore, they stress the importance of shared values among co-founders: *"We fundamentally believe that good health is the primary signature of prosperity for any individual, their families, and the nation at large … with these kind of initiatives we are contributing our bit to health as well as economy."* (Kumar & Jain, Co-founders, Embryyo)

Kumar and Jain also stress the importance of proximity, suggesting that innovators should be intimately familiar with an industry's operational capacities and mechanisms. During an internship at a hospital in Munich, Germany, Kumar observed the facility's state-of-the-art infrastructure but its low number of patients. *"In India it is almost always the opposite – resource constrained with a lot of patients to cater to,"* he argued. This initial experience forged his determination to be a *"knowledge sponge in the medical devices and medical technology domain",* taking up employment with some of the market leaders in the field (Co-founder, Embryyo). This experience allowed him to build a professional network and equip himself with skills that have been invaluable.

# CASE INSIGHTS

1. Research funding can support start-up companies in low- and middle-income countries to develop and test new low-cost, context-appropriate technology innovations. However, these creative young companies often require tailored business support and guidance to get innovations into the local market while retaining affordability of the product.

2. Involving the end user in the design and testing of new technologies enables tailored, context-appropriate solutions for challenges faced in health care delivery, and leads to products that are more affordable and relevant for the situation. Location-specific needs assessment can ensure that more appropriate devices reach people in need, and prevent the adoption of ineffective or inappropriately costly technologies that could divert resources from other critical health care areas (Sinha & Barry, 2011).

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