

# “Applying the Biodesign process for medical device innovations in India – Advances & Challenges”

**Dr. Jagdish Chaturvedi**

## **Abstract**

The Biodesign innovation process is a structured process to develop new medical technologies. It has been developed to help both amateur and experienced innovators to reduce their risk of failure. This process was developed in Stanford University's Program called Biodesign and serves as the foundation to the text book Biodesign: The Process of Innovating Medical Technologies.

The Biodesign process is designed to analyze unmet validated clinical needs and uses a structured filtering process to find the most compelling and impactful needs those are worth solving. Keeping in mind factors such as stakeholder's involved, business models, regulatory pathway and reimbursement strategy, creative solutions for the top unmet need are created by multidisciplinary teams. This process is different from what most organizations follow which is to develop a technology and find a right problem to solve using the technology in the healthcare system.

The Biodesign process has worked well for many medtech start up companies in the west but has been challenging to apply when implemented in the Indian healthcare setting. The reasons for this being a diverse public and private healthcare system where more than 70% of the population pays out of pocket and poor database of diseases. With limited regulatory processes, poor IP protection law enforcement, limited mature business models and unpredictable stakeholder's it makes implementing some of the processes used in Biodesign rather challenging.

We have analyzed these challenges and revised the Biodesign process to better suit the Indian healthcare scenario. This talk highlights how these changes can improve the innovation ecosystem in our country

## **Keywords**

Biodesign, Medical device technology, innovation, Indian healthcare ecosystem

## **Full text, with all subsections and illustrations**

### *Presentation outline:*

- Speakers contribution & experience in the field
- Overview of healthcare innovations ecosystem in India
- Challenges while implementing the Biodesign process
- Advances in implementing a structured innovation process
- Key takeaways

### *Speaker profile:*

Dr. Jagdish Chaturvedi, Director Clinical Innovations and Partnerships, InnAccel.

An ENT surgeon, a Stanford-India Biodesign Fellow 2012 and an MBA in Entrepreneurship and hospital management (NIBM).

Core expertise lies in the process of identifying and analyzing unmet clinical needs for quick development of low-cost and high quality medical devices, and teaching/ training the Biodesign process.

Designed and executed the Stanford India Biodesign internship program in 2012 and is currently spearheading the Affordable Indian Medtech (AIM) fellowship program at InnAccel.

Has provided consulting services for unmet need analysis for both large and small MedTech companies in India since 2012.

Dr. Chaturvedi has developed 13 medical technologies (Intellectual Property/Patents) and 1 teaching methodology. 5 of which have been licensed to Indian companies, 4 have developed start up companies and 1 has developed into a Phd research project.

### *Current innovative ecosystem in India:*

India ranks 66 out of 142 countries  
Switzerland-1  
UK-3  
USA-5  
China-7  
Singapore-8  
Israel-14  
Germany-15  
Korea-18  
Yemen-142

*Possible reasons why people in India choose not to innovate:*

Don't think it's their responsibility  
Don't know how to go about the process  
No time  
Waiting for western technology  
Don't think it's important

*Myths around MedTech Innovation in India:*

It's a complete change in field  
It's never ending research  
The chances for success is low  
It requires a lot of investment money  
No money or very late returns in this field  
Ideas cannot be patented  
If a similar solution exists then patent cannot be filed  
Innovation can't be taught or learnt

*Advantages of being a healthcare innovator:*

Development of a new skill  
Ability to invent independently  
Filing of intellectual property (Counts as a publication)  
Added weightage for fellowships/courses/jobs abroad  
Ability to impact large populations by improving healthcare  
Huge long term or upfront revenues  
Increasing job opportunities for Indian employees

*Situation is changing: India's decade of innovation is 2010-2020:*

"The country must develop an innovation ecosystem to stimulate innovations. Innovators must be challenged to produce solutions to our society needs. And innovative solutions with potential must be nurtured and rapidly applied."  
– Prime Minister Manmohan Singh

*Stanford India Biodesign (SIB) Program:*

The SIB program is a Biomedical Technology Innovation program of the Department of Biotechnology, Ministry of Science & Technology, Government of India, implemented at AIIMS - New Delhi, and IIT-D in collaboration with the Stanford University (USA) and in partnership with Indo-US Science and Technology Forum. Biotech Consortium India Limited (BCIL) with necessary experience and expertise in IP management and technology-transfer domain is the management agency of this program.



Stanford University, CA



AIIMS, New Delhi



IIT Delhi



The SIB runs an annual fellowship program, which trains a multidisciplinary team on the Biodesign process by having them train at Stanford University on the Biodesign process and implement it in India at AIIMS hospital in New Delhi and IIT Delhi.

Shown below is an outline of the Biodesign process



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*Challenges in applying the Biodesign process in the Indian healthcare setting:*

The Biodesign process has worked well for many medtech startup companies in the west but has been challenging to apply when implemented in the Indian healthcare setting. The reasons for this being a diverse public and private healthcare system where more than 70% of the population pays out of pocket and poor database of diseases. With limited regulatory processes, poor IP protection law enforcement, limited mature business models and unpredictable stakeholder's it makes implementing some of the processes used in Biodesign rather challenging.

*Specific challenges*

- 1. Clinician Involvement:** In India clinicians are over worked and not many are willing to disturb their clinical practices to spend time in innovating medical devices. The SIB program takes in one clinician to train in the Biodesign process and during this time the clinician needs to discontinue from their clinical work. Forming a startup company after that is even more difficult as it takes 2-3 years of commitment for a clinician to help in development of the product and taking it towards clinical testing.

**Finding accurate data:** A large portion of the filtering process is strongly dependent on clinical data, which is not easily available for Indian clinical conditions. This makes the inventors add their bias and prevents them from carrying out an efficient filtering process to reach a real compelling need.

**Stakeholder analysis:** In India there are different stakeholders in diverse healthcare settings. It is not easy to understand these stakeholders without being involved in the clinical setting for a few weeks. Understanding this aspect of the process is probably the most challenging to carry out in India.

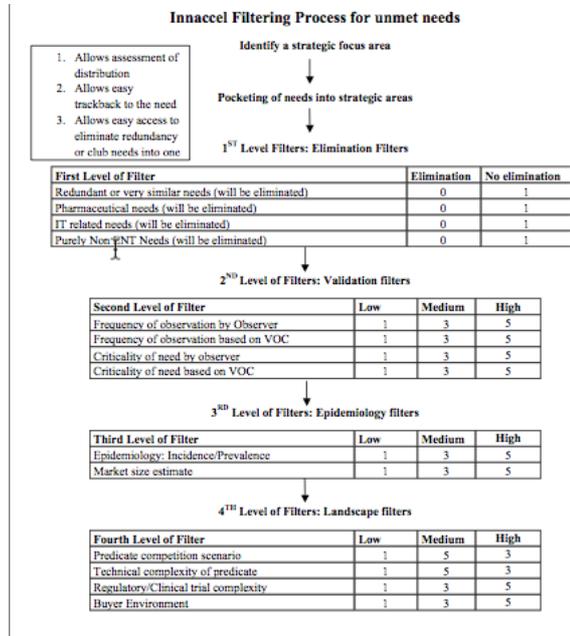
**Capital raising:** There are various government grants available for Medtech innovations and are easily accessible as well. However start up companies who have managed to successfully raise large capital from these grants, they are often over entangled in following processes of writing applications and reports in order to avail sanction of funds that are often staged on receiving deliverables. Applying the Biodesign process in addition to this has lead to teams taking longer to complete their milestones and slows down the solution from reaching the market.

*Advances in the Biodesign process:*

**Increasing clinical involvement:** In the modified Biodesign process we are involving clinician clinicians who have been trained to apply the Biodesign process without discontinuing their clinical commitments and having them remain integral to the hospital they are employed in. This makes it easier for clinicians to be involved in the process and interact with engineers and designers from the team.

**Collecting better data:** In the process of making clinical observations the teams are now trained to create an Observation Docket which includes collection of lengthy & detailed clinical observations with 8 key parameters such as frequency of the problem, criticality of the problem, cost to the patient, incidence/prevalence of the problem in literature, patient pathway, treatment gap, need statement and problem statement.

**Stakeholder analysis:** In order to understand the stakeholders better, structured voice of customer studies were included in the form of Voice of Customer (VOC) validation and these were incorporated in the filtering process. This became a part of a pre calibrated filtering criteria (15 criteria/ 4 levels) which is designed to find high impact unmet clinical needs.



In addition a detailed market assessment, stakeholder & business model analysis is carried out with senior experts in order to help incorporate these into concepts while selecting the most appropriate solution for the problem.

**Advances in capital raising:** Increasing access of innovators to private funding in the form of VC funding through medtech accelerators is a new model to raise capital and receive management expertise along with access to resources such as prototyping labs, expert mentorship and clinical access. This allows quick cash flow into the start up company and allows for better management of usage of the capital.

*Current opportunities to learn and apply the Biodesign process:*

Stanford India Biodesign fellowship and Internship program

## InnAccel's Affordable Innovations in MedTech Entrepreneurship program

### *Key Take-away's:*

- Biodesign process is an efficient process used to innovate medical technologies
- The healthcare ecosystem in India is mature enough to apply the Biodesign process as is
- Key challenges are clinician access, acquiring accurate data, stakeholder analysis and raising capital
- Making subtle changes in the process minimizes these challenges
- There is now an increase in opportunities for learning and implementing the Biodesign process

### **References**

Biodesign: The Process of Innovating Medical Technologies.

Author's personal experiences from following the Biodesign process at SIB and for the AIM entrepreneurship program

### **Author's biography (200 words)**

Dr. Jagdish Chaturvedi, Director, Clinical Innovation and partnerships at InnAccel, Bangalore is an ENT surgeon by training (St. John's Medical College, Bangalore), a medical device innovations expert (Stanford India Biodesign fellow 2012) and an MBA in entrepreneurship and hospital management (National Institute of Business Management). Apart from being an

actively practicing ENT surgeon (currently with Apollo Hospitals, Bangalore), Dr. Chaturvedi has been involved in inventing numerous low cost medical devices since the past few years. His first invention involved conceptualizing and developing a low cost portable tri-purpose multiscope

ENT recorder while partnering with a design firm in Bangalore (ICARUS). Further in the space of ENT, Dr. Chaturvedi has co-invented Nasoplast, an epistaxis controlling device and NoXeno - an easy to use nasal foreign body extractor.

In addition, through the Stanford India Biodesign Fellowship program 2012 and while structuring and executing the Stanford India Biodesign Internship program 2013, Dr. Chaturvedi has co-invented 10 other low cost medical devices in other fields (gastroenterology, pulmonology and community medicine) within a short span of 3 years. 5 out of these have been successfully licensed out to MedTech industries (Both large and small) for further development and commercialization.

Dr. Jagdish Chaturvedi continues to contribute to the affordable healthcare space by supporting his colleagues in similar inventions and is currently an integral part of an indigenous MedTech accelerator based out of Bangalore called InnAccel which is creating opportunities to support entrepreneurs and start up companies working in the affordable healthcare innovations ecosystem in India.

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