Stanford India Biodesign
Enabling MedTech Future in India
Program and Innovations

A Department of Biotechnology, Ministry of Science and Technology, Government of India initiative
Mission

To develop leaders in biomedical technology innovation in India.

To identify unmet clinical needs and develop solutions for India.

To help develop low cost, high quality devices for medically underserved populations.

To develop the Indian MedTech innovation ecosystem.

Stanford India Biodesign Fellowship

Stanford India Biodesign, started in 2008, is an initiative to catalyse the medical technology innovation in India and help address the needs of the medically underserved. SIB is a collaboration between the All India Institute of Medical Sciences (AIIMS), Indian Institute of Technology (IIT) Delhi, and Stanford University. SIB is supported by the Department of Biotechnology, Government of India, the Indo-US Science & Technology Forum, foundations, medical technology companies, venture capital firms and individuals. Biotech Consortium India Limited (BCIL) has been actively involved in consultation over intellectual property, fund syndication and technology transfer.

SIB offers a multidisciplinary, team-based, one to two year fellowship program that trains the future leaders of the Indian medical technology industry. Housed jointly at Stanford and New Delhi, the Fellowship trains future innovators with engineering, design and medicine backgrounds to identify major healthcare needs in India and develop solutions that are cost-effective and widely deployable across a broad socioeconomic spectrum. SIB Fellows commit to remain in India at the completion of the program, with the intent of returning to academia, creating entrepreneurial ventures or joining medical technology companies.

A distinctive feature of the Program is its focus on innovation and technology transfer. SIB’s methods and courses are based on methodologies developed at Stanford, but are customized for the needs of India. The curricula developed by SIB will be freely accessible to other Indian institutions, helping to facilitate broader medical technology educational exchange.

The MedTech Summit, now in its fourth year is an annual showcase of medical technology in India hosted by SIB in Delhi. It is attended by innovators, industry leaders and key opinion leaders of the medtech sector.
biodesign process

IDENTIFY
- Needs Finding
  - Observations
  - Need Statements

INVENT
- Concepts
  - Brain Storming
- Concept Selection
  - Intellectual Property
  - Regulatory Risks
  - Business Model
  - Prototyping

IMPLEMENT
- Development Strategy
  - IP Strategy
  - Regulatory Strategy
  - Stakeholder Strategy
  - Marketing Strategy
- Development Plan
  - Manufacturing
  - Clinical Trials
  - Business Operations
  - Plan Finance

Faculty

India
- Balram Bhargava, MD
  Executive Director (India), Stanford India Biodesign;
  Professor of Cardiology, All India Institute of Medical Sciences
- Alok Ray, PhD
  Director (India), Stanford India Biodesign;
  Professor, Centre for Biomedical Engineering, Indian Institute of Technology Delhi
- Sandeep Singh, MD
  Associate Director (India), Stanford India Biodesign;
  Associate Professor of Cardiology, All India Institute of Medical Sciences

Support

India
- Rajani Sethi
  Program Assistant, Stanford India Biodesign
- Rita Luthra
  PA, Department of Cardiology, All India Institute of Medical Sciences

Stanford
- Paul Yock, MD
  Director, Stanford Biodesign;
  Professor of Medicine and Bioengineering, Stanford University
- Rajiv Doshi, MD
  Executive Director (US), Stanford India Biodesign
  Consulting Assistant Professor of Medicine, Stanford
- Uday Kumar, MD
  Associate Director Curriculum, Global Biodesign
  Lecturer in Bioengineering, Stanford University
- Anurag Mairal, PhD
  Associate Director Program Development, Global Biodesign
Emergency Medicine

2008 Fellows

Prior to joining the Stanford-India Biodesign fellowship, Nish developed and commercialized several innovative medical technologies for the US, European and Japanese markets. Some of the products that Nish has been involved with include: the first FDA approved drug coated stents (Cypher), inflatable bone tamp for kyphoplasty, bioresorbable stents for BPH, neurovascular coils, guiding catheters, spinal implants, expandable valvulotomes and carotid shunts. He has cross-functional leadership experiences from LeMaitre Vascular, Cordis, Vcube (co-founder), Kyphon (acquired by Medtronic) and ConSure Medical (co-founder).

While pursuing the biodesign fellowship, Nish along with his colleagues identified a latent need in incontinence care. Together, they have developed a novel medical device in India that has global potential. For their innovative solution for incontinence care, Nish was recognized as one of the Top 35 innovators under the age of 35 in India (MIT TR35 Award for Medicine). His start-up, ConSure Medical, was recently recognized as one of the Top 75 startups in India to bet on by DARE magazine.

Nish graduated with a BS in Plastics Engineering from the University of Massachusetts at Lowell, where he was also a varsity athlete (crew). He has multiple patents issued or pending for various vascular, orthopedic and critical care devices.
Srinivas has over ten years experience in the design and development of medical device technologies. He joined GE Medical Systems working initially in Nuclear Medicine for the Starcam Range of products and then joined Diagnostic X-ray where he worked in software for a Digital detector tester. As a member of the Global Diagnostic team, Srinivas worked on system control and platform software for GE’s X-ray products and made significant contributions to the Atlas and Calypso system platforms which are used in GE’s invasive cardiology, mammography and diagnostic X-ray products.

Srinivas’ area of work includes designing software for system control and communication frameworks using distributed computing and real time system technologies. He served as software architect for surgical C-arms and navigation system and as a Lead System Designer for Primary Care Group. Srinivas has developed and patented the idea of a distributed user interface that enables multiple user interfaces for medical imaging systems. He has a patent pending for his development of a new method and apparatus for control of a cinematography X-ray image viewer in surgical X-ray. Srinivas has achieved DFSS Six sigma Black belt for developing highly reliable products.

Srinivas received his BE Degree from University Visveswaraya College in Electrical and Electronics Engineering.

Jayant is a product designer who has worked on various products from medical diagnostic equipments to automotive parts. His expertise includes articulating customer requirements, design conceptualization, and engineering of the concept to the point of implementation of the product through manufacturing.

Jayant joined GE Healthcare Bangalore in 2003. For GE he worked extensively on the Mobile Rad system where his responsibilities included conceptual design, prototyping for technical feasibility and successful demonstration of the resulting technology. On the Hawkeye X-ray generator he provided conceptual design, prototyping, analysis and validation, and ensured smooth integration into the Infinia-a nuclear imaging device. Jayant received an award of excellence for his work on this product. Previously Jayant worked at Mahindra Automobiles, where he designed and developed an instrument panel for a rural utility vehicle and redesigned a brake system, which allowed easier assembly and reduced the cost of manufacture.

Jayant is a Stanford India Biodesign Fellow at All India Institute of Medical Sciences, New Delhi since 2008. He is working on affordable medical devices for developing markets. Jayant has a Bachelors degree in mechanical engineering from Government College of Engineering Pune and Masters of Design from Indian Institute of Science Bangalore. He also studied in the Norwegian Science and Technology University under the Indo-Norwegian Student Exchange Program.
Amit is a cofounder of Consure Medical which is developing a novel and disruptive technology for fecal incontinence. Before this Amit was part of the Stanford India Biodesign fellowship program where he focused on identifying and developing solution for the unmet clinical needs of the developing world. A prolific industrial designer and engineer, Amit started his career as a freelance designer consulting for organizations ranging from Indian Railways to small and medium scale enterprises looking for innovation as a competitive tool. He soon formalised it by cofounding CreogenX, an early stage product design and development firm focusing on medical devices.

Passionate of design and innovation Amit studied mechanical and automation engineering at undergraduate level. His research projects included the development of a robotic document management system and a novel device for absolute squareness calibration of Master Cylinder at National Physical Laboratory, Delhi. Amit has experience in developing medical devices both in simple, high volume disposable device space like safety catheters and balloon inflation device and complex capital tools like multi-band ligator for laparoscopic surgery.

Amit received M.Des. in Industrial Design from the Indian Institute of Technology Delhi and has a B.Tech. in Mechanical & Automation Engineering. Long term, Amit want to bring best medical care to masses by innovating and engineering medical technology to cater the unique needs of the developing world.

Sandeep is working as an interventional cardiologist at a premier tertiary care hospital. He earned his MBBS and MD Medicine from Maulana Azad Medical College, (University of Delhi) and then completed three years of advanced training (DM) in cardiology from GB Pant Hospital, University of Delhi. As a medical student, he received several honors for his academic performance, including the Mohan Lal Nayar award for best senior resident in cardiology, the Roll of Honor for best medical student and merit-cum-scholarships for admission to the MBBS.

Sandeep is actively involved in various multi-center trials on cardiac devices and has authored more than 50 peer-reviewed publications in the field of cardiology. He also held the position of Editorial Secretary for the Indian Heart Journal and is a life member of the Cardiological Society of India.

Sandeep harbours the passion of innovating simple and cost-effective devices. His postdoctoral certification in the Stanford-India Biodesign (SIB) Program in the year 2008 gave him the platform to be co-inventor of many such devices. In addition, being a faculty at SIB, his role is to strengthen the roots of biodesign process and to mentor the trainees and fellows in India.
A Novel Device for Intraosseous Access

Inventors: Sandeep Singh MD, Srinivas Jaggu, Jayant Karve

Accessing circulatory system is critical to resuscitation of patients in emergencies such as cardiac arrest, trauma, pediatric, and dehydration, when reaching veins is difficult. Existing solutions are expensive; require power supply and need trained manpower; all particularly difficult in resource constrained settings.

IntraOz provides a novel solution that effectively addresses these needs; an inbuilt detection mechanism will reduce procedural time and complications. This is achieved with a simple manual mechanism, which makes it reliable and cost effective.

Milestones & Accomplishments
- Several design concepts were generated; provisional applications have been filed for the novel concepts.
- Initial prototyping of the concepts was done at Stanford India Biodesign facility.
- Non-clinical testing of the prototypes was conducted on simulated models, and on small animals at AIIMS.
- Design revision and prototype development is in progress with the global team.
- Initial pre-clinical planned on human cadaver and have AIIMS approval for the first phase

Innovation: 2008 Fellows

A Novel Way to Manage Fecal Incontinence

Inventors: Sandeep Singh MD, Amit Sharma, Nishith Chasmawala

Fecal incontinence, the inability to control the release of the flatus or stool, is a ubiquitous clinical problem. In addition to its clinical sequelae, studies have shown that the cost of care for each fecal incontinent patient is about $10,000/year. These costs are associated with the increased risk of acquiring pressure ulcers (22 times), prolonged length of stay (4 – 7 days) and increased utilization of hospital resources (nurses, cleaning aids, laundry staff).

The prevalence of fecal incontinence is 58% among intensive care unit (ICU) patients, 33% among general ward patients, 50% among patients in psychiatric wards and 10 – 46% among patients in skilled nursing/long-term care facilities. With these prevalence rates, in US alone there are 16 million patients that are incontinent for 5 – 45 days every year.

In collaboration with key opinion leaders in gastroenterology from Stanford University & AIIMS, a team of SIB fellows have developed a self-expanding device with a unique placement, deployment and withdrawal mechanism. Unlike competitive products, our novel device will be indicated for non-ambulatory patients across all care facilities.

Competitive Advantages:
- Developed for all stool types
- Developed for all sphincter tone
- Sanitary and hygienic insertion mechanism
- Small insertion and profile diameter
- Requires minimal training for use
- Eco-friendly design

Product Commercialization Status:
- Prototype development completed
- Proof of concept established with bench-top models.
- Safety established in a successful “first-in-man” study at AIIMS.
- Strong patent portfolio protected globally with PCT application.
- Contract manufacturing vendors indentified.
- Safety and efficacy study in target population (in progress).
- Next milestones include Regulatory approval and distribution partnership.

Innovation: 2008 Fellows

A Novel Device for Intraosseous Access

Inventors: Sandeep Singh MD, Srinivas Jaggu, Jayant Karve

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Darshan Nayak is a Stanford India Biodesign Fellow and a physician trained at the Grant Medical college and Sir J.J. Hospital in Mumbai, India. He graduated with degrees in General Surgery and Internal Medicine. While in medical school, he worked with Dr. S. Natarajan, a renowned vitreo-retinal surgeon on the development of Indigenous subretinal implant to treat patients with Retinitis Pigmentosa.

Darshan is passionate about inventing medical devices and developing high quality, affordable medtech solutions for developing countries. While interning at J.J. hospital in Mumbai, he worked on a approach for measuring blood analytes and developed a working prototype to measure hemoglobin. The work led to the formation of a startup which is now incubated at the Center for Innovation, incubation and Entrepreneurship at the Indian Institute of Management, Ahmedabad. Darshan is also an J.R.D Tata Trust and Sir Ratan Tata Trust scholar.
Pulin, a 2009 Stanford India Biodesign Fellow, is a product designer with three years of experience in creating a broad spectrum of products. He received his graduate degree in Product Design from Centre for Product Design and Manufacturing, Indian Institute of Science, Bangalore. He is a mechanical engineer from the University of Pune, India.

Pulin started his career as an Executive Design Engineer working on vapor absorption machines in Thermax Ltd for two years immediately following his undergraduate degree. As a graduate student, he interned with Design Geneva, a design studio focused on innovative product development, where he gained valuable experience in designing products for the real world. Pulin has a patent pending for a portable washing machine developed for rural India, as part of his work during graduate school. Later he worked in Ashok Leyland, a leading automobile industry in India, as a product designer in styling department.

Pulin is passionate about designing medical devices to solve unmet healthcare needs of Indian market. At Stanford India Biodesign, he is focused on developing affordable health care solutions for India as well as other developing countries. He enjoys touch of clay, smell of wood, heat of melting iron and clanking sound of metals to give shape to his ideas in the workshop.

Rahul Ribeiro is a 2009 Stanford India Biodesign Fellow. He is working on the design and development of medical devices for the Indian population. He also currently holds the position of Assistant Professor in the Mechanical Engineering Department at the Indian Institute of Technology Delhi.

After completion of his Bachelors degree in Marine Engineering from the Marine Engineering and Research Institute, Kolkata, Rahul worked for a few years in the merchant navy as a marine engineer. His interest in a career in research led him to a masters degree in Mechanical Engineering at the Texas A&M University, where he focused on Materials for Aerospace applications. His interest in biomedical research for the disabled led him to pursue a doctoral program in Orthopedics, also at the Texas A&M University. His doctoral research involved the tribological and nano-mechanical investigation of bone joint repair materials.

He has seven journal publications to his credit as well as several conference proceedings publications. He also holds an Outstanding Young Faculty Fellowship Award from the Indian Institute of Technology, Delhi.
Asokan is a Fellow at Stanford India Biodesign, and an academician with interests in the design of mechatronic and robotic systems. Asokan received his Ph.D in Mechanical Engineering from the Indian Institute of Technology Madras, India in the year 2000. He then spent six years as a researcher at the Robotics Research Center, Nanyang Technological University, Singapore, working in the area of mechatronic systems and robotics. Asokan joined the Indian Institute of Technology (IIT) Madras as an Assistant Professor in the Department of Engineering Design in 2006. At IIT Madras, his areas of teaching and research interests include product design, engineering system design, and robotics.

One of his design projects won the Design Innovation Award at the Brunnel Design show held in London in 2007. Asokan has published more than 25 papers in international journals and conferences and has filed two patents, one each in India and Singapore. He holds a concurrent appointment as visiting fellow at the University of New South Wales, Australia.

At Stanford India Biodesign, Asokan strives to combine the modern technology and design methodologies with affordability to develop state-of-the-art medical devices to meet the Indian health care needs, thus contributing to the medtech revolution in India.

**Innovation: 2009 Fellows**

**A Novel Pre-Hospital Trauma Care device**

Inventors: Darshan Nayak, Asokan Thondiyath, Pulin Raje and Rahul Ribeiro

In any trauma case, the most common extremity injuries are fractures, dislocation, sprain, strain or contusions resulting from either blunt, penetrating or crush type of injuries. The pre-hospital care infrastructure is not well developed in India. Also, after ABC and spine immobilization, injuries of the extremity are hardly taken seriously in pre-hospital setting. The risk of aggravating the injury is very high during transportation to the nearest hospital, transferring patient from an ambulance to gurney, gurney to bed etc. In order to prevent the situation of major complications in such cases, it is necessary to develop methods/devices which reduce the possibility of further injury to a patient who has suffered a limb injury. Realizing this unmet clinical need and based on our observation, we are focusing on emergency care of traumatic extremity injuries.

In an acute setting, some of the problems in administering effective pre-hospital care for extremity injuries are:

- Difficulty in distinguishing between different types of injuries such as fractures, dislocation, sprains, just based on clinical presentation, in the pre-hospital setting.
- Difficulty in quickly assembling of a temporary device for immobilization with enough support such that no further harm is caused to the patient.
- Lack of understanding of the different techniques practiced in managing a closed vs open extremity injury fracture in a prehospital setting.
- Lack of re-usability and re-configurability of immobilization devices.

Based on this understanding we are developing a novel device for immobilization of the injured limb in a cost-effective way.
Gita is a Physiatrist working in the field of Rehabilitation Medicine for over a decade. She has been engaged with patient care, teaching, training and research at All India Institute of Medical Sciences, New Delhi, India, during the above period. The challenges arising from the variety of medical problems that are addressed as part of clinical duties, and those put forth by the inquisitive students and patients have helped her in exploring innovative ideas, and in developing solutions such that treatment of conditions is undertaken and rehabilitation service designed to simultaneously address quality of life aspects.

Further, she has published many articles in national and international journals and presented papers and received awards for the work. The themes include outcomes in rehabilitation to developing newer techniques and devices for training and assistance for persons with impairments. She is actively involved in the process of developing better technological solutions for efficient and effective patient care.
Ritu Kamal is a 2010 Stanford India Biodesign Fellow. Her background is in Bioengineering, in which she has a Masters from the University of Pennsylvania. She graduated from Princeton University in 2007 with a B.S.E. in Electrical Engineering. Post graduation, she received a fellowship from Princeton-in-Africa and spent a year in South Africa working in health care delivery, specifically in maternal health, and HIV/AIDS prevention from mothers to new-born children. While at Princeton, she cofounded a program that now sends Princeton graduates to India to work with various development-oriented groups. Ritu is committed to engaging with the Indian healthcare system in entrepreneurial ways and leveraging technology to reduce disease burdens in the developing world.

Ritu is also the author of two books on Indian philosophy and science. The first book, Panch Kanya, was nominated for the International IMPAC Dublin Literary Award, 2002 and is in its second edition. The second book Prapanch Kanya, a sequel to the first, was published in January 2008.

Pushkar Ingale is a 2010 Stanford-India Biodesign Fellow. Pushkar graduated with a Bachelors degree in Mechanical Engineering from Pune University and has a Masters degree in Industrial Design from Industrial Design Center (IDC), Indian Institute of Technology Bombay. A project on rural health care in his design school led to his interest in developing medical device solutions.

Pushkar started his career with a two year experience working with Sandvik Asia Ltd in their Coromant Sales and Marketing Division. During his design schooling he got a chance to do his internship with Design Directions, a leading design studio in India, focused on designing of Medical Devices. After his design education he gained valuable experience styling motorcycles for Rajaji Auto Ltd. He continued his efforts in design by partnering in a start up, communication and identity design studio - YeOH. Pushkar continues to be excited about helping new innovators and entrepreneurs create a larger impact, by designing a lasting experience around their products and services.

He is also a recipient of the Forbes Marshall Award for his engineering degree project. Working as a teaching assistant at IITB, he has helped compile a book titled “What is Design?”
Nitin is a 2010 Stanford-India Biodesign Fellow, and is excited to use the intersection of technology, design and business to create solutions and opportunities.

Nitin went to study Engineering from the National Institute of Technology in Bhopal. He authored guidebooks for math and engineering students. He secured third place in the Mathematics Olympiad at the state level during his school studies. His quest of finding out new perspective to look at things and creation has driven him to join Design school.

He went on to do his Post Graduation from National Institute of Design (NID) India with major in Industrial Design. There he developed several Products and worked on toys and games for the developmental and educational needs of children. He also simultaneously worked on some of the research projects of NID in the craft and technology sector.

Always passionate about advanced forms and transportation, Nitin designed bicycles for small towns in one of this project, with India’s leading bicycle manufacturer. He then worked as an Automobile designer in India and Japan for three years with Maruti Suzuki, where he worked in the compact car segment for India. The unique combination of analytical concepts and sensitive Design education equip him with the required skills to provide creative solutions for the real world problems.

His other interests lie in cooking, traveling, Theatre (performing arts) and Humor.

Stanford India Biodesign Internship

With the idea of propagating the Biodesign philosophy and process widely beyond the fellowship, a three month internship program was started at the SIB center in All India Institute of Medical Sciences. Interns work on one of the many clinical needs observed by the fellows during their problem identification phase. The fellows mentor them throughout the process. Most interns are fresh graduates from engineering, design or medical background and work together as a multi-disciplinary team to come up with novel solutions. The internship program has also had interns from the sponsoring industries with the idea of taking back the Biodesign Innovation process to their respective jobs in the industry.

2008 Internship Program

Interns
- Ashwin Udupa
- Abhinav
- Dinesh Sharma
- Isha Wadhawan
- Meghna Sareen
- Shruti Mullick
- Simerjeet Singh

Projects
- A cheaper and efficient way to do Retinal Scan.
- A better way to conduct Epidural Access.
- A way to contain and estimate the Blood Loss.

2009 Internship Program

Interns
- Pooja Singh
- Satish Regode
- Satyashodhan Patil
- Pankaj Vyas
- Mansi Aggarwal
- Shitij Malhotra
- Pooja Manchanda
- Kundan Krishna

Projects
- A better way to conduct Patient Transfer.
- A novel way to treat Deep Vein Thrombosis.

2010 Internship Program

Interns
- Sourav Mishra
- Nisha Munjal
- Prashant Borkar
- Gaurav Kulkarni

Projects
- A way to remove tenacious mucous from severe COPD patients
Advisors

India
M. K. Bhan, MD
Secretary, Department of Biotechnology, Ministry of Science and Technology, Government of India
Jayesh Bellare, PhD
Professor, Indian Institute of Technology Bombay
R. C. Deka, MD
Director, All India Institute of Medical Sciences
V.M. Katoh, MD
Director General, Indian Council of Medical Research
D.R. Mehta
Founder, Bhagwan Mahaveer Viklang Sahayata Samiti
Arabinda Mitra, PhD
Executive Director, Indo-US Science & Technology Forum
Surendra Prasad, PhD
Director, Indian Institute of Technology Delhi
T. S. Rao, MD
Advisor (Medical), Department of Biotechnology, Government of India
Alka Sharma, MD
Joint Director, Department of Biotechnology, Government of India
Poornima Sharma, PhD
CEO, Biotech Consortium India Limited
Srikumar Suryanarayanan, MD
Director General, Association of Biotechnology led Enterprises of India

Stanford
John Abele, PhD
Founder, Boston Scientific Corporation
Thomas Fogarty, MD
Inventor, Embolectomy Balloon Catheter
David Green
MacArthur Fellow, Founder, Project Impact, Inc.
Harry Greenberg, MD
Sr. Associate Dean for Research, School of Medicine, Stanford University
Mir Imran
Inventor, Founder, CEO, Incube Laboratories
Stephen MacMillan
CEO and President, Stryker Corporation
Philip Pizzo, MD
Dean, School of Medicine, Stanford University
James Plummer, PhD
Dean, School of Engineering, Stanford University
Hira Thapliyal, PhD
Founder, ArthroCare Corporation

Mentors
Ramesh Agarwal, MD
Assistant Professor, Division of Neonatology, Department of Pediatrics, All India Institute of Medical Sciences
Praveen Aggarwal, MD
Professor Incharge, Department of Emergency Medicine
All India Institute of Medical Sciences
Vinod Bhutani, MD
Professor of Pediatrics-Neonatology, Stanford University
School of Medicine, Lucile Packard Children's Hospital
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Medical Director, Stanford University
Emergency Department
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Associate Professor, Gastroenterology
All India Institute of Medical Sciences
M. C. Mishra, MD
Head and Professor, Surgery
Jay Prakash Narayan Apex Trauma Center, All India Institute of Medical Sciences
Sujoy Pal, MD
Assistant Professor, Gastrointestinal Surgery
All India Institute of Medical Sciences
Pankaj Jay Pasricha, MD
Professor, Medicine - Gastroenterology & Hepatology
Professor (By courtesy), Surgery, Stanford Hospital
Vinod Paul, MD PhD
Head, Department of Pediatrics & WHO Collaborating Centre, All India Institute of Medical Sciences
Peush Sahni, MD
Additional Professor, Gastrointestinal Surgery
All India Institute of Medical Sciences
Pravin Soni, PhD
VP, Pharmaco
Serial Entrepreneur
Sakti Srivastava, MD
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Stanford Hospital
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