The Biodesign Process:
From Needs Finding to Commercialization

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Founder, Chief Scientific Officer, Ventus Medical
Mission

To develop leaders in biomedical technology innovation

Educate. Collaborate. Innovate.
Innovation is a discipline that can be learned!
The process ...

identify

invent

implement
Key stages

- needs finding
- needs screening & specification
- concept generation
- concept selection
In a nutshell:

needs finding

needs screening & specification

concept generation

concept selection

program launch
Technology Looking for Application (TLA):
2 months clinical immersion...
Identify at least 200 needs...
A method to select top needs…
Brainstorm solutions for the best needs

“Given enough time, sugar and caffeine, you will invent something”
1. NEEDS FINDING

1.1 Strategic Focus
1.2 Observation & Problem Identification
1.3 Need Statement Development

2. NEEDS SCREENING

2.1 Disease State Fundamentals
2.2 Treatment Options
2.3 Stakeholder Analysis
2.4 Market Analysis
2.5 Needs Filtering

3. CONCEPT GENERATION

3.1 Ideation & Brainstorming
3.2 Concept Screening

4. CONCEPT SELECTION

4.1 Intellectual Property Basics
4.2 Regulatory Basics
4.3 Reimbursement Basics
4.4 Business Models
4.5 Prototyping
4.6 Final Concept Selection

5. DEVELOPMENT STRATEGY & PLANNING

5.1 IP Strategy
5.2 R&D Strategy
5.3 Clinical Strategy
5.4 Regulatory Strategy
5.5 Quality & Process Management
5.6 Reimbursement Strategy
5.7 Marketing & Stakeholder Strategy
5.8 Sales & Distribution Strategy
5.9 Competitive Advantage & Business Strategy

6. INTEGRATION

6.1 Operating Plan & Financial Model
6.2 Business Plan Development
6.3 Funding Sources
6.4 Licensing & Alternate Pathways
## Initial Fellow and Student Companies

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<th>Biodesign Year</th>
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<th>Business Status</th>
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### Newer fellow and student companies (partial list)

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Technology Translation Metrics

As of May, 2010:

• over 35,000 patients treated
• 291 new jobs created
• over 200 patents filed by fellows
A perfect storm for medtech innovation in the U.S.?

- unpredictability of FDA
- reimbursement reform
- diminished venture funding
- physician/industry alienation
Opportunities...

1. Technologies that take cost out of system
   - keep patients out of hospital
   - “downshift” delivery across provider spectrum: specialists – generalists – nurses – aids
Opportunities…

2. Global focus

• BRIC countries

• value-driven innovation
Strategic Centers for Biodesign
About SSB

Singapore Stanford Biodesign is an innovative new program that seeks to nurture and train the next generation of Asian medical device innovators through a hands-on fellowship that will be based in Singapore.

We’re Hiring!

The Singapore Stanford Biodesign Program is currently searching for outstanding candidates for the part-time position of Program Director. Click here to find out how to apply!

SSB Official Launch

The Singapore-Stanford Biodesign Program will be officially launched on 29th January 2010.

Highlights from the Launch Ceremony will be made available. Stay tuned!

Latest News

25 Jan 2010

An informational session will be held on 30th January 2010 for interested Program Director candidates.

25 Jan 2010

The official launch of the SSB program will take place on 29th January 2010. This invitation-only event will see the gathering of members from Singapore’s medtech community as well as participants from NUS, NTU, hospitals and institutions.
Singapore Stanford Biodesign Fellows 2011

Henry HO
Urology

Fiona LOKE
Electrical Engineering

Iris TAN
Mechanical Engineering

Anthony TANG
General Surgery
Stanford India Biodesign

The goal of Stanford-India Biodesign is to train the next generation of medical technology innovators in India. This is facilitated through a fellowship, internships and events.

Funded by the Department of Biotechnology, Ministry of Science and Technology, Government of India, Stanford University, and other supporters, the SIB Fellowship Program is centered in New Delhi and administered as a collaboration between Stanford University, the Indian Institute of Technology Delhi, and the All India Institute of Medical Sciences (AIIMS) in partnership with the Indo-US Science & Technology Forum.

NEWS

- We're pleased to announce our selection for the Stanford-India Biodesign Interns for 2011. They are
  - Prashant Soni: MTech Material Science, IIT Bombay, (Sponsored by Stryker)
  - Nitin Aggarwal: BTech ENTC Engg, BITS Dubai, (Currently working with CBME, IIT Delhi)
  - Pragun Goyal: BTech CS, IIT Delhi (Hearing Screener Device Project)
  - Reshma Maurya: BTech Bio Engg, MDES, IIT Kanpur
  - Chandini Kabra: BDES, Symbiosis
  - Sonakshi Pandey: BDES, Symbiosis

May 10, 2011 5:30 - 7:00 pm
Innovator's Workbench
The 2nd in our 2011 series features Ezekiel J. Emanuel, Chair of the Clinical Center Department of Bioethics at the National Institutes of Health. For the past two years, Dr. Emanuel has been on detail to the Office of Management and Budget working on health care reform issues.

May 23, 2011 - Application Due
Stanford-India Biodesign Fellowship
The Stanford-India Biodesign (SB) Fellowship seeks to train and nurture the next generation of Indian medical device innovators at Stanford and in India.
SIB and SSB: Creating A Community

Physicians

Venture Capitalists

Regulatory Experts

Educators

Entrepreneurs

IP Professionals

Reimbursement Experts

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A few examples
India Biodesign: Intraosseous access

Developed market device
From a student Biodesign/ME team…

The $20 Knee

Tens of thousands of amputees in the developing world wear an inexpensive prosthetic called the Jaipur Foot. But poor patients who lose a knee joint have few options: a titanium replacement can cost $10,000, and crude models don’t work very well. Now a team of Stanford engineering students has designed a knee that’s not only dirt cheap — just $20 — but also mimics the natural joint’s movements. Developed with the Jaipur Foot group, the Jaipur Knee is made of self-lubricating, oil-filled nylon and is both flexible and stable, even on irregular terrain. The device is being tested in India; more than 300 people have been fitted so far.
Invention Awards: An Inexpensive, Portable Ventilator

An inexpensive portable ventilator designed to save lives during a pandemic

By Elizabeth Svoboda  Posted 05.28.2010 at 9:50 am  4 Comments

Air Supply: Matthew Callaghan’s OneBreath is portable and just a fraction of the cost of conventional ventilators, making it ideal for use during a pandemic.
Provent Sleep Apnea Therapy

photo courtesy of the American Sleep Apnea Association

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Provent Therapy Mechanism

**Inspiration**

- MicroValve opens
- Airflow is nearly unobstructed, allowing for normal breathing

**Expiration**

- MicroValve closes, directing air through small air channels, increasing resistance
- Expiratory resistance creates EPAP and maintains pressure in airway until next inspiration
RANDOMIZED TRIAL OF NOVEL EPAP DEVICE FOR TREATMENT OF OSA

A Novel Nasal Expiratory Positive Airway Pressure (EPAP) Device for the Treatment of Obstructive Sleep Apnea: A Randomized Controlled Trial

Richard B. Berry, MD; Meir H. Kryger, MD; Clifford A. Masico, PhD
1Division of Pulmonary, Critical Care, and Sleep Medicine, University of Florida, Gainesville, FL; 2Gaylord Sleep Medicine, Gaylord Hospital, Wallingford, CT; 3Chicago Sleep Group of Suburban Lung Associates, Elk Grove Village, IL.

Study Objectives: Investigate the efficacy of a novel nasal expiratory positive airway pressure (EPAP) device as a treatment for obstructive sleep apnea (OSA).


Setting: 19 sites including both academic and private sleep disorder centers.

Patients: Obstructive sleep apnea with a pre-study AHI ≥10/hour.

Interventions: Treatment with a nasal EPAP device (N = 127) or similar appearing sham device (N = 123) for 3 months. Polysomnography (PSG) was performed on 2 non-consecutive nights (random order: device-on, device-off) at week 1 and after 3 months of treatment. Analysis of an intention to treat group (ITT) patients completing week 1 PSGs (EPAP N = 119, sham N = 110) was performed.

Measurements and Results: At week 1, the median AHI value (device-on versus device-off) was significantly lower with EPAP (5.0 versus 13.8 events/h, P < 0.0001) but not sham (11.6 versus 11.1 events/h, P = NS); the decrease in the AHI (median) was greater (−52.7% vs. −7.3%, P < 0.0001) for the ITT group. At month 3, the percentage decrease in the AHI was 42.7% (EPAP) and 10.1% (sham), P < 0.0001. Over 3 months of EPAP treatment, the Epworth Sleepiness Scale decreased (69 ± 4.7 to 7.2 ± 4.2, P < 0.0001), and the median percentage of reported nights used (entire night) was 88.2%.

Conclusions: The nasal EPAP device significantly reduced the AHI and improved subjective daytime sleepiness compared to the sham treatment in patients with mild to severe OSA with excellent adherence.


Keywords: Obstructive sleep apnea, expiratory positive airway pressure, CPAP.

A small study published in the April issue of Sleep Medicine says that a new device is effective for some patients who can't tolerate CPAP.

Good Night's Sleep by a Nose

By Linda Jarvis

Snoring and waking up at night are common nighttime annoyances, but for many, they are signs of a major health problem—sleep apnea. A number of companies are marketing nasal devices to treat the disorder. Scientists say the nose is more effective than a mouth, says Dr. Nyenta, president of the American Academy of Sleep Medicine and director of the Sleep Therapy Center in Atlanta. He noted that new devices have been developed over the past few years and have been shown to be effective in a broad range of patients.

The product is a patch that adheres to the inside of the nose, which is placed on the skin every night. The patch is designed to help the nose breathe more comfortably, reducing the number of times the patient stops breathing per hour decreased to 12 from 32 at the end of five weeks.

A 220-patient study, published April 1 in the Journal of Sleep Research, showed that the product was effective in the treatment of sleep apnea.
Advanced Technology Ventures
Alloy Ventures
Delphi Ventures
DeNovo Ventures
Frazier Healthcare Ventures
Interwest Partners
Kleiner, Perkins, Caufield & Byers
Mohr Davidow Ventures
Montreux Equity Partners

New Enterprise Associates
New Leaf Venture Partners
ONSET Ventures
Prospect Venture Partners
Sanderling Ventures
Split Rock Partners
Synergy Life Science Partners
Three Arch Partners
US Venture Partners
Versant Ventures
Biodesign Fellowship Alums 2001-2009