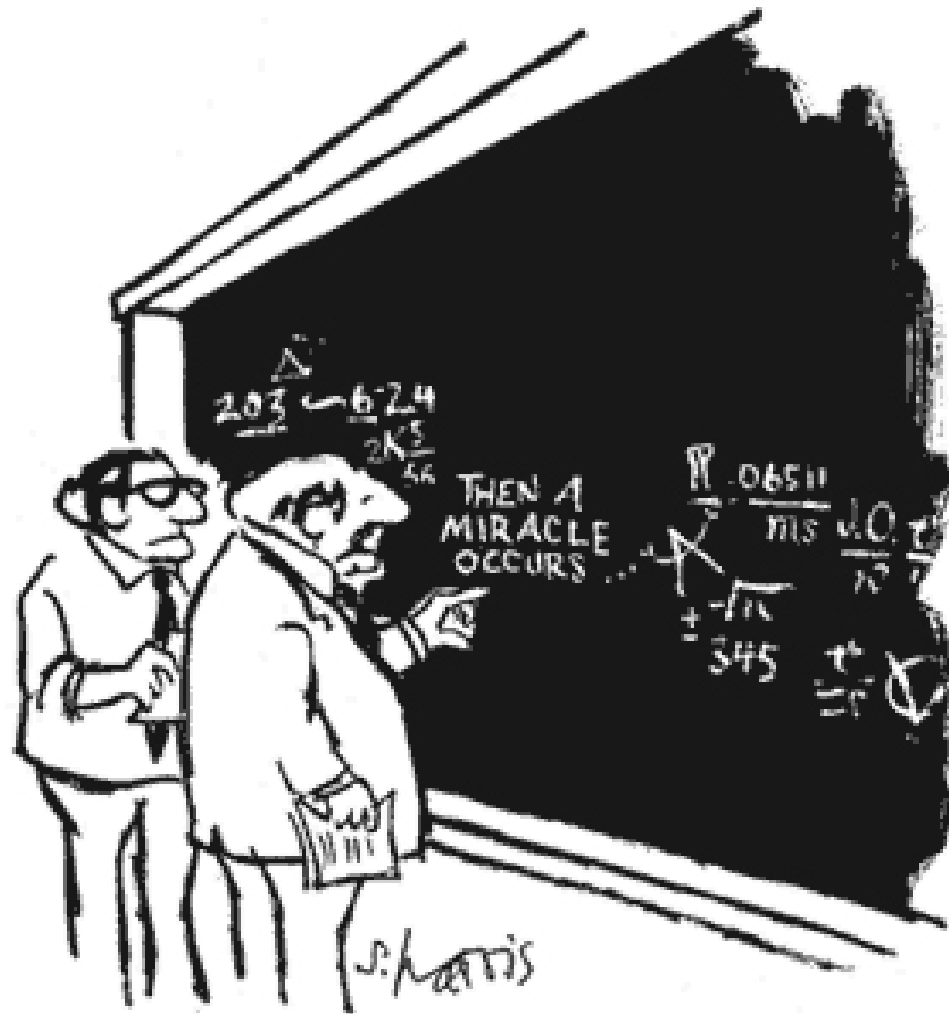


How to Teach and Train Innovation: US Approach

Alan C. Yeung MD
Li Ka Shing Professor of Medicine
Division of Cardiovascular Medicine
Department of Bioengineering
Stanford University

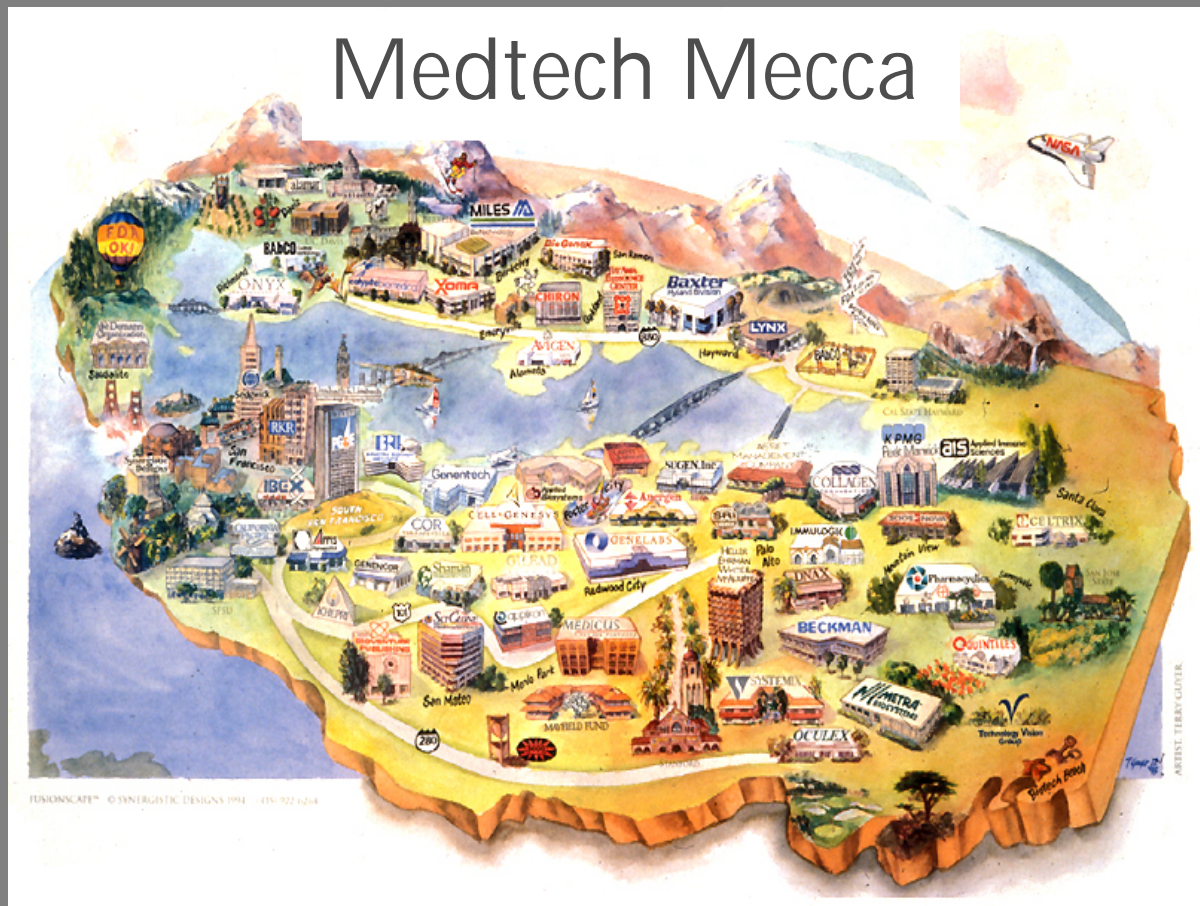




"I THINK YOU SHOULD BE MORE EXPLICIT HERE IN STEP TWO."

The San Francisco Bay Area has the highest concentration of new biotech and medtech companies in the world

Medtech Mecca



J. Abele, C. Alferness, P. Arensdorf, P. Auerbach, D. Auth, M. Baker, J. Bakker, L. Barish, A. Belson, M. Berman, A. Bianchi, N. Blevins, L. Bottorff, K. Bowsher, R. Buyan, B. Byers, J. Capek, M. Carusi, T. Chou, K. Connors, B. Constantz, R. Croce, R. Curtis, M. Cutkosky, M. Dake, A. de Bord, M. Deem, J. Delagardelle, D. Donohoe, D. Echt, D. Feigal, R. Ferrari, F. Fischer, R. Fisher, T. Fogarty, G. Foster, J. Garfinkle, M. Garrison, J. Geriak, G. Gershony, H. Gifford, J. Gill, J. Gold, J. Gordon, G. Graham, J. Green, J. Grossman, E. Grube, D. Gruenfeld, L. Guterman, S. Hamade, W. Hawkins, M. Hendricksen, J. Hickey, T. Hinohara, R. Hirsch, E. Hlavka, D. Hoffmeister, L. Hogle, H. Holstein, M. Horsewski, S. Hossainy, K. Im, M. Imran, F. Ingle, P. Jackson, J. Jacobs, W. Jaeger, R. Jaffe, J. Jove, S. Jvanuskos, A. Kaganov, D. Kaley, F. Kelley, K. Kelley, F. Khosravi, G. Kiman, T. Koller, E. Kosynas, M. Lachman, J. Jacob, G. Lamorecht, J. Lamson, J. Lasersohn, S. Latterman, T. Lefteroff, M. Lesh, A. Macfarlane, W. Maloney, J. Mandato, J. Maroney, D. Mauney, A. May, M. Mayer, C. McGlynn, L. Michael, T. Mills, N. Mourlas, D. Murphy-Chutorian, J. Nehra, C. Nelson, W. New, S. Oesterle, J. Onopchenko, M. Paganini, J. Palmaz, O. Palmer, T. Kim Parnell, R. Perkins, T. Petersen, D. Piacquad, H. Plain, M. Raab, G. Rao, A. Rasdal, R. Reiss, G. Robertson, D. Roeder, E. Rogers, S. Rowinski, G. Rubin, S. Salmon, W. Samson, J. Schox, M. Selmon, J. Shapiro, J. Shay, T. Simons, J. Simpson, Y. So, F. St. Goar, B. Starling, B. Stern, M. Sugarman, R. Sutton, J. Swick, R. Tabibiazar, K. Talmadge, L. Tannenbaum, R. Thomas, S. Toyloy, S. Turnbull, J.S. Uy, B. Vale, S. Van Bladel, C. Vidal, M. Wan, K. Wasserstein, K. Widder, A. Will, J. Wilson, S. Wolf, T. Wollaeger, P. Young, R. Z...

Real-World Mentors



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... & others

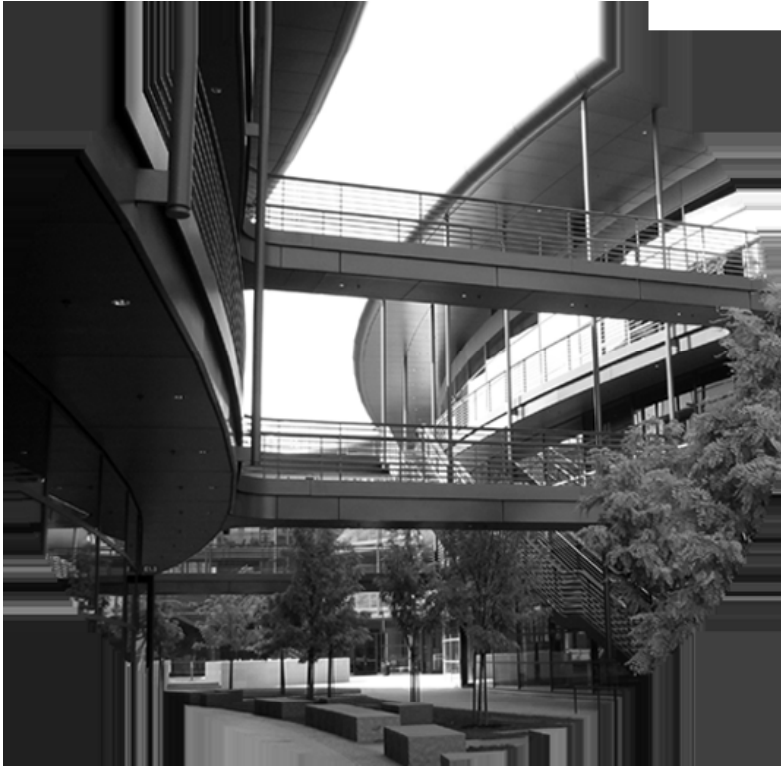
Mission

*To develop leaders in biomedical
technology innovation*

Educate. Collaborate. Innovate.



Program in Biodesign (Bio-X)



needs **invent**
med tech patent
license collaborate
cost effective
surgical innovation
license **Stanford**
FDA discovery
technology transfer

ethics & policy prototype reimbursement
specialty innovation teamwork outcomes

Biodesign Faculty Leadership



P Yock
Founder,
Director



T Krummel
Co-Director

Core Faculty



T Andriacchi



S Delp



G Gurtner



P Wang



S Zenios

Ethics, Policy



R Popp
Director

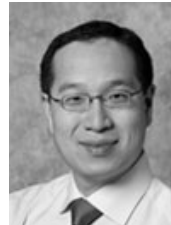
Fellowship



J Makower
Mentor
Co-
Founder



Todd
Brinton
Fellowship
Director



Chris Shen
Mentor

Stanford-India Biodesign



Raj Doshi
Exec Director
(U.S.)



Balram
Bhargava
Exec Director
(India)

Collaboratory



Craig Milroy
Director

medtech vs. biopharma

	medtech	biopharma
Disciplines	mech eng elect eng med/surg business	chem eng comput sci biology genetics business
Innovation Process	needs-driven	discovery plus need

2 months clinical immersion...



Start With “Boot Camp”



- Intensive introduction to clinical field
- Lectures by clinical faculty
- Engineering & business overview
- Team building

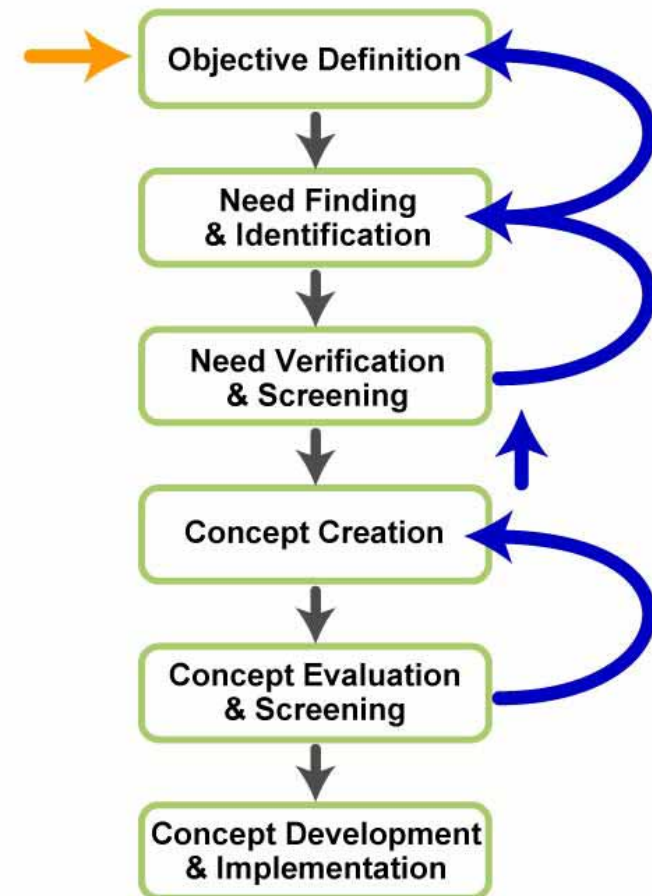


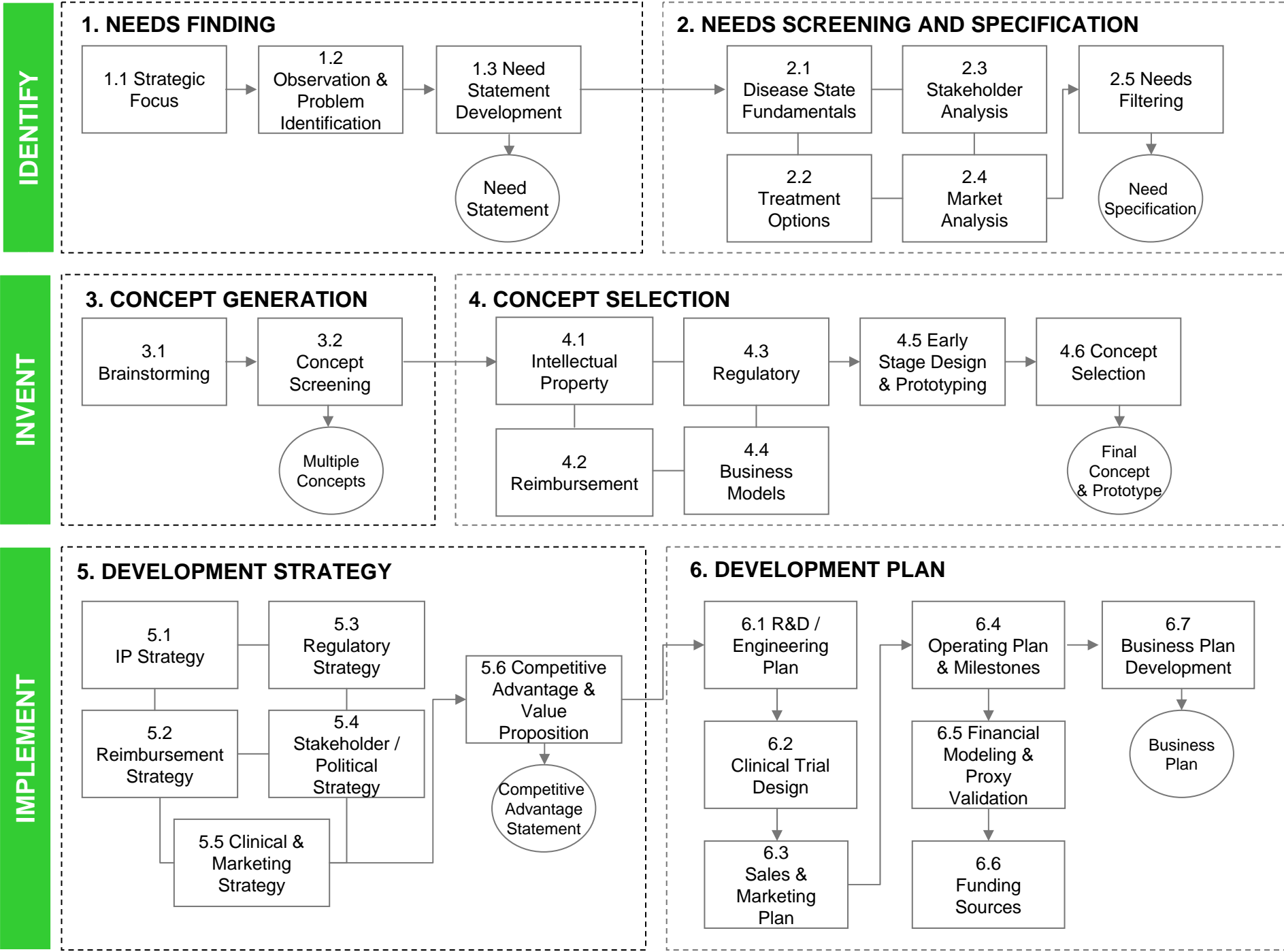
Clinical Immersion

- Team “lives” in hospital and clinics
- Observe with fresh eyes, ask “naïve” questions
- Develop list of >200 needs



Innovation Program Fundamental Approach





IDENTIFY

INVENT

IMPLEMENT

Needs Finding

Observation



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Biodesign Innovation

Needs Finding-Validation

- ❖ Needs Finding begins with observation
 - Observe patient care and management
- ❖ Problems are identified through observations
OBSERVATIONS NEEDS
- ❖ Needs are clearly identified problems with well defined desired outcomes

*Two Important Principles:

1) Fully understand the need and specifications prior to embarking on the process of finding a solution

2) Differentiate needs from solutions



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Biodesign Innovation

Understanding the Need

- ❖ Observe patient care
 - Seeking care
 - Receiving care
 - Recovering from care
- ❖ Ask questions
 - What do stakeholders need?
- ❖ Competing Outcomes?



Biodesign Innovation

Need Statement

- ❖ Isolate the single need that has the best chance of addressing the problem, driving a desired outcome, and supporting a reasonable market opportunity
- ❖ Capture need in one sentence statement.
- ❖ Focus on goal or endpoint, not problem.
 - ❖ Do not reference current solutions!



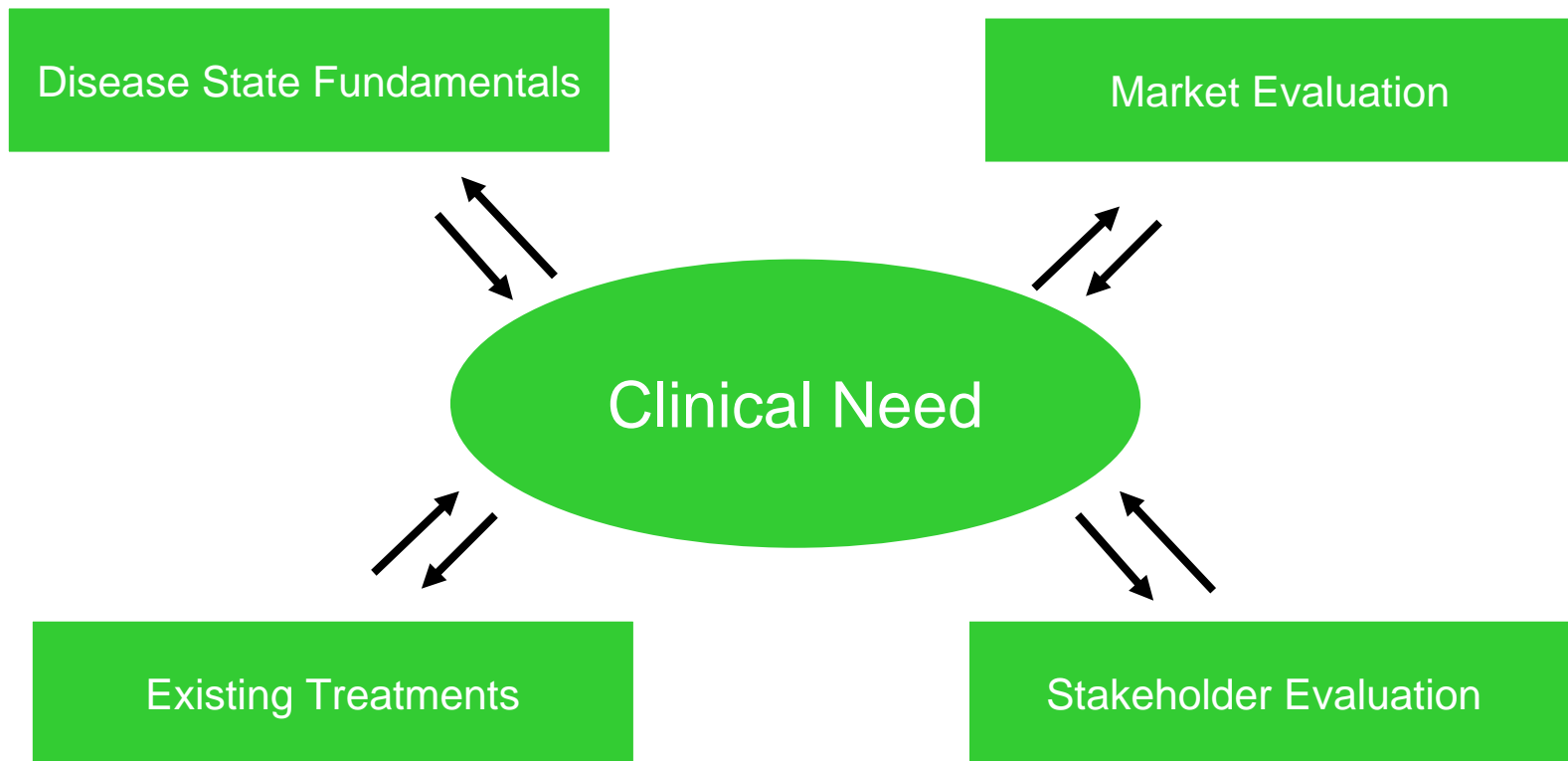
Biodesign Innovation

Desired Outcomes	As Measured By...
Improved clinical efficacy	Treatment success rates in clinical trials
Increased patient safety	Rate of adverse events in clinical trials
Reduced cost	Total cost of procedure relative to available alternatives
Improved physician/facility productivity	Time and resources required to perform procedure
Improved physician ease of use	Solution of complex workarounds and/or the simplification of workflow
Improved patient convenience	Frequency and occurrence of required treatment, change in treatment venue (inpatient versus outpatient, physician's office versus home), etc.
Accelerated patient recovery	Length of hospital stay, recovery period, and/or days out of work



Biodesign Innovation

Early Steps to Innovation



Need Specification

- Verify & Validate
- Quantify the Potential Benefit
- Develop Criteria for Screening
- **Rank the Needs**
- **Create A Written Need Specification**



Identify at least 200 needs...

Microsoft Access - [Need Data - Table (Replicated)]

Type a question for help

Need Statement	Pathology	Date Need Identified	
* stabilize DBS electrode after implantation to prevent migration	Neurodegenerative diseases	10/28/2004	
* a microscope configuration that allows for more natural angle of gaze while not interfering with surgical field	Surgical Tools	9/26/2004	-ask neurosurgeons if they do have problem
* a system for motion tracking that allows for accurate ankle measurement during dorsal flexion	Movement Disorders	9/28/2004	
* Method to find needles that have fallen on the floor	Surgical Tools	9/29/2004	
* method to prevent reperfusion-related secondary injury after stroke has occurred	Cerebrovascular Diseases	10/28/2004	- under what circumstances do you go in
* a technology to recreate/repair the sinuses so that surgeons can access areas beneath it or that have encrusted	Tumor	10/21/2004	- no idea if this is a need or incidence
* be able to drive stimulating electrode to exact same location/tract as the electrophysiology electrode in a microscope	Neurodegenerative diseases	10/28/2004	what about the stimulating electrode is in a microscope
* an endoscope-based approach to brain surgery that allows for better hemostasis and suction/irrigation than current	Unspecified	10/25/2004	- talk to surgeons more about why they do it
* Need to make "artificial" tracheoesophageal speech less cumbersome and easier for the patient	ENT	9/30/2004	-interview a couple of pts: how difficult is it
* need for a method to determine patient's responsiveness using something other than pain so as to reduce pain	Neuromonitoring	9/26/2004	- do patients remember the pain of a hard
* VP shunt: more reliable way than landmarks to get the needle into ventricle	Hydrocephalus	10/25/2004	-find out if camera-guidance is the norm in
* Surgical suite that allows surgeons/assistants of different heights to optimize use of steps, table height such as	Surgical Tools	10/3/2004	- how many OR's in the US?
* stimulation method to recruit muscles in a graded fashion to allow more complex/smooth motions such as walking	Rehabilitation	9/23/2004	gr
* an instantaneous, fool-proof method to provide every instrument with a suction source, eliminating the need for	Surgical Tools	10/17/2004	
* a method to identify a mass from surrounding tissue for more precise extraction and preservation of healthy tissue	Tumors	9/23/2004	
* A tool or method to speed up the 'peeling' of the tumor capsule away from the brain without traumatizing the brain	Tumors	9/23/2004	gr
* a retraction device that does not reflect, which might be less distracting for the operator	Surgical Tools	10/13/2004	- find out if reflection is a significant issue
* method to increase acute stability of ossicle prosthetics	ENT	10/13/2004	
* a method to align patients head and spine perfectly so that when looking at the ct/mri scans, do not need to	Neuromonitoring	10/7/2004	- need is primarily for neuroradiology
* Means to monitor (long-term) the occurrence/severity/duration of seizures in epileptic patients	Paroxysmal Disorders	9/30/2004	
* A nerve conduction needle that can be safely inserted to allow stimulation of the lumbosacral plexus	Neuromonitoring	9/26/2004	- find out why this this is considered dangerous
* a method to thicken or generate a capsule around the tumor to aid in surgical removal	Tumors	9/23/2004	gr
* Need to be able to pull up on smooth surface even if going perpendicular to it (forceps)	Surgical Tools	10/3/2004	- confirm how much this is a big deal
* diagnostic method to determine the likelihood that an aneurysm will rupture pre-operatively	Cerebrovascular Diseases	9/27/2004	- ask physicians if they had this test, and
* a method to mark the surgical incision site that does not get wiped off when the surgery site is sterilized.	Surgical Tools	10/13/2004	- ask how often errors result from the marking
* need for markerless motion analysis that will allow high resolution measurement of joint angles during walking	Movement Disorders	9/27/2004	
* a method to sterilize an instrument very quickly when it is urgently needed in surgery	Surgical Tools	10/17/2004	
* method to transplant fat and prevent resorption	ENT	10/25/2004	-find out amount of cases that actually need
* a method to allow airway maintenance/suctioning of patients outside of the ICU.	Unspecified	10/27/2004	
* a method to remove an aneurysm without temporarily occluding proximal vessels	Cerebrovascular Diseases	9/23/2004	- find out what the negative consequences
* a method to prevent a mobilized embolism from traveling to brain causing a stroke.	Cerebrovascular Diseases	9/23/2004	gr
* assistive communication devices that are more intuitive to learn/use	Rehabilitation	10/3/2004	- what is the patient impact currently as a
* an IR transmitter that serves as a universal remote for assistive devices, to increase patient mobility	Rehabilitation	10/28/2004	
* faster and safer method to gain access to brain for surgery	Craniotomy	9/23/2004	gr
* a dissection tool that utilizes finger tip pressure instead of one that utilizes pressure on the back of the finger	Surgical Tools	10/3/2004	- does ANYONE think that there is a problem
* a neuromonitoring probe that does not need to be held for one minute and which does not cause any trauma	Cerebrovascular Diseases	10/17/2004	- find out the official name of this test
* way to evaluate integrity of carotid "seal" quickly and reliably	Cerebrovascular Diseases	10/13/2004	- ask if this is a problem
* provide greater stability for the burr-hole drill at different angles and positions	Surgical Tools	9/23/2004	gr
* system to provide power to instruments/machines anywhere in the room with minimal clutter and less limitation	Surgical Tools	9/27/2004	-how many OR's in US
* Need to quantify blood loss from sponges	Surgical Tools	10/3/2004	
* a hearing aid that alleviates any negative social stigma associated with having a hearing deficit	ENT	10/28/2004	
* a method to rapidly decompress the spine in spine trauma cases and the cord is compressed due to swelling	Trauma	10/27/2004	- what are the inherent limitations
* method to keep scalp incision and cranial bone hydrated during long surgeries	Surgical Tools	10/3/2004	- if this is an issue, is the current solution

Record: 14 | Database View

A method to select top needs...

Needs entry

Need

Need ID: 323 Scope: Mix Date: 8/23/2005 Clinical immersion:

Need statement: A safe, effective method to reduce the apnea and hypopnea episodes experienced by a patient with obstructive sleep apnea/hypopnea syndrome.

Source: Meeting w/ Jackler Pathology: OSA

Attending: Class: ENT

Notes:

References Validation

Scores

Absolute market size	12M	Additive score (0-10)	6.9	Top 100	<input checked="" type="checkbox"/>
Market size	5	Regression score	m 7.0	Top 50	<input checked="" type="checkbox"/>
Impact to patient	3	Additive rank	67	Top 22	<input checked="" type="checkbox"/>
Impact to HCP	4	Regression rank	m45	Class	<input type="checkbox"/>
Financial impact	1				
Global incidence	5				

Brainstorming

Need specification: [Need specs\OSA - Need Specification.doc](#) Requirements Concepts

SIP 2005-2006

Record: 323 of 389

Brainstorm solutions for the best needs



“Given enough time, sugar and caffeine, you will invent something”

Concept Development



- Brainstorm
- Prototype
- In-Vivo / In-Vitro Modeling
- Screen Based On Criteria
- **Create A Concept Specification**



Business/Project Planning











- Financial Modeling
- Funds Forecasting
- Research Strategy
- Marketing Strategy
- Clinical/Regulatory Strategy
- Ethical Considerations
- Management Planning
- **Business/Project Plan**











Biodesign Innovation Class and GSB



Initial Fellow and Student Companies

	Biodesign Year	Clinical Status	Business Status
	1-F	OUS, US	Acquired
	1-F	OUS, US	Acquired
	1-C	OUS, US	Acquired
	2-F	OUS, US	Acquired
	2-C	OUS	Series B
	5-C	Preclinical	Series A
	5-F	OUS, US	Series B
	5-C	OUS	Series B
	6-F	Preclinical	SBIR Ph. 1
	6-C	Preclinical	Series A

Newer fellow and student companies (partial list)

	Biodesign Year	Clinical Status	Business Status
	6-F	OUS	Series A
	6-C	Preclinical	Seed
	6-C	OUS	Series B
	6-F	FIH	Seed
	7-F	Preclinical	Seed
	8-I	Preclinical	India "SBIR"
	8-F	Preclinical	Seed
	8-F	Preclinical	Seed

Technology Translation Metrics

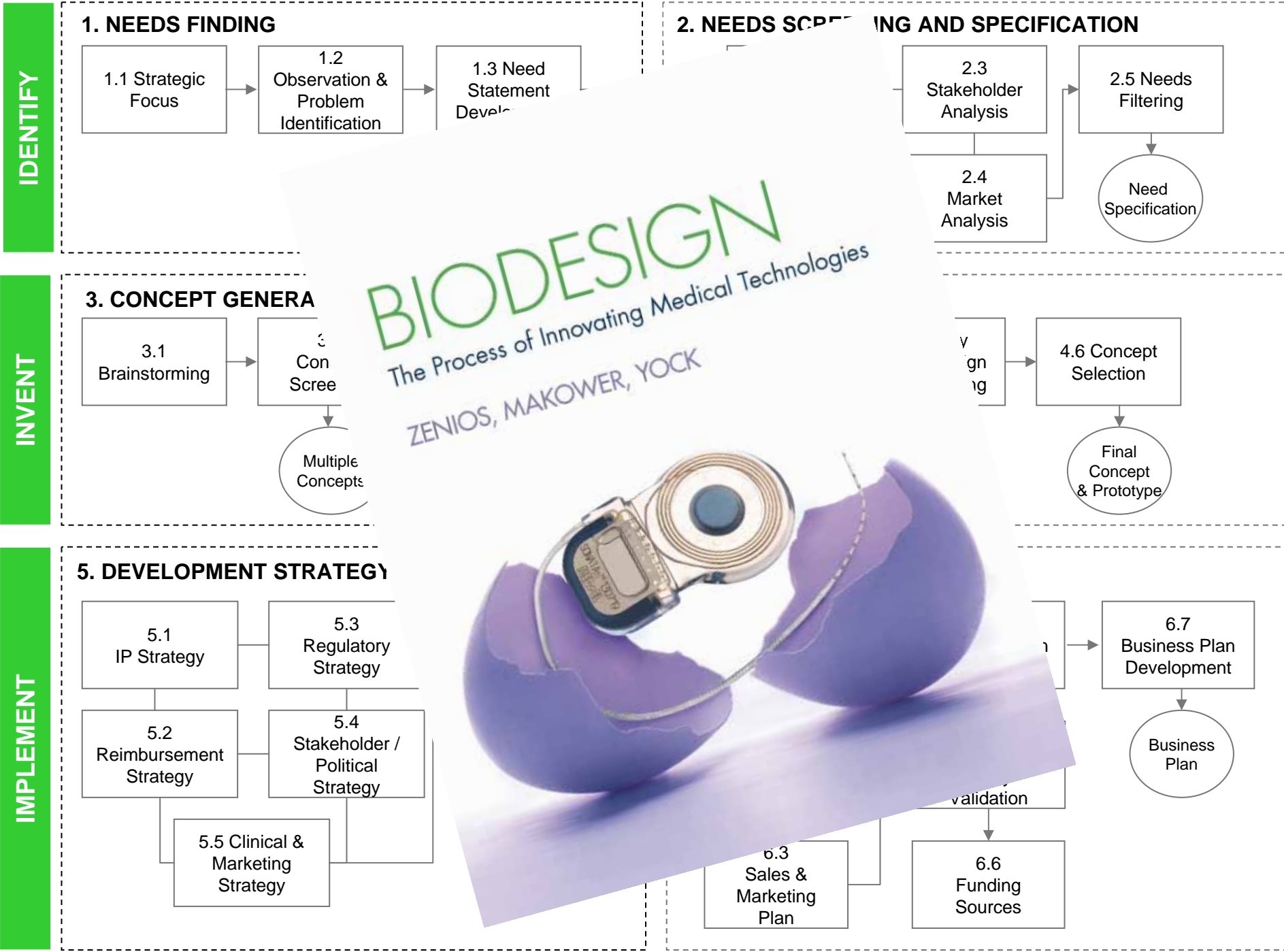
As of May, 2010:

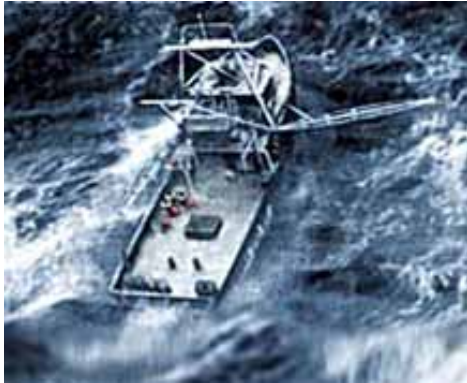
- over 35,000 patients treated
- 291 new jobs created
- over 200 patents filed by fellows





Our real “product”





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 – A.I.



Opportunities...

2. Global focus

- BRIC countries
- value-driven innovation

Strategic Centers for Biodesign

