Translational Medicine Symposium 2013: The Roller Coaster Ride to the Clinic
Translational Medicine Connects the Problem to the Solution

- Every step in developing a device or drug must be evaluated in light of the clinical problem
Academic Scholarship is Evolving

- **Traditional Model**
  If you get grants, publish in top journals and win awards, other faculty will respect you

- **Evolving Model**
  If your scholarship has a positive impact on other people, you will earn their respect

*Students* are the key to the culture change
Who are the Academic Entrepreneurs?

They are students and faculty who:

- Identify and solve real world problems
- Translate basic science to applied technology
- Create products as well as papers
- Strive to understand business of science
- Understand marketing and customers are key
Translational Activities Are Scholarly

- Translational research – applying basic knowledge to real world needs
- Translational teaching – applying educational methods to real world needs
- Translational service – engaging in activities responsive to real world needs

*Impact* is the unifying feature
Translation Requires Focus
The View is Great from 20,000 Feet
Translation Requires Energy

Unstable intermediate states

Financing and FDA approval

Start up company

Business

Bedside

Money

Bench

Time
The Path to Product is Not Linear
The Challenges Can Appear Insurmountable
The Competition May Seem Very Close
Disasters Await the Unwary
The Destination Can be Obscured
The Landscape is Complex....
....But Patterns Emerge
At the End of the Day You Can Succeed!
Design Criteria for a Clinical Biomaterial

- Meet needs of end-users: scientists, patients, physicians
- Simple, effective composition
- Simple to use
- Easy to manufacture under GMP
- Clear path to regulatory approval
- Reimbursable by health payers

Clinically useful products

Research use and veterinary products

The Translational Imperative

*Embrace complexity*

*Engineer versatility*

*Deliver simplicity*

Today’s Program

11:30 – 12:00 Arrive and collect box lunch
12:00 – 12:20 Introduction
12:20 – 1:00 Identifying the Clinical Problem
1:00 - 1:40 Intellectual Property
1:40 - 2:20 Preclinical Development
2:20 - 2:40 Break
2:40 - 3:20 Regulatory Pathway
3:20 - 4:00 Business Strategy & Financing
4:00 - 4:40 Clinical Development and Trials
4:40 - 5:20 Product Development
5:20 – 5:40 Open discussion and closing remarks
Tomorrow’s Program

08:15 – 08:45   Continental breakfast
08:45-10:15    First group of student elevator pitches
10:15 – 10:30   Break
10:30 – 12:00    Second group of student pitches