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**Objectives**

- Learn the basics of biodesign in engineering solutions for clinical medicine
- Understand obstacles in entrepreneurship
- Empower your ideas to become products and know that time is on your side

In this case-based course, we will review one retina specialists journey into medical device from idea creation, engineering and commercialization highlighting the principles of biodesign. The goals of the course are to encourage other retina specialists to consider taking the next step into entrepreneurship.

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**Disclaimer**

- This is my story and one that is not even a success story
- The goal is to encourage you to consider executing the idea that you have
- My knowledge is biased into medical device, not pharma or apps
- I am not any different than anyone else in this room, grit is defining characteristic

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### An Idea

- Patients complained all the time about PI and how their eyes were irritated
- Patients asked for a "good rinse" and a "rinse under my lid"
- How do we create a "good rinse"

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### Biodesign

- An **innovation process** that applies:
  - **engineering**
  - **medicine**
  - **and business principles** to develop new medical technologies and healthcare solutions.

It focuses on(1) **identifying unmet clinical needs first, (2) designing solutions, and (3) bringing them to market** efficiently.

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### Unmet Clinical Needs

- We are experts in this area
- We experience every day – patients will tell us to our faces what the unmet needs are
  - Complaints are opportunities
- Issues that we as physicians have may not be shared with other physicians – lean on colleagues to spitball ideas

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### Unmet Clinical Needs: How I did it?

- Go to work every day
- Listen to patients over and over and over
- Ask what worked and what didn't with their rinse
- Ask what a good rinse was and what the effects were

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### Designing Solutions

- Iterative design and prototyping
  - Fail Fast
  - Refine quickly
- Remember to think about Intellectual Property Protection
  - Provisional Patent

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### Designing Solutions-How I did it?

- Printed a preliminary design off of a sketch I had
- 3D Printed next iteration with design engineering team
- Used that for preliminary data collection
- Refined design based on feedback of patients but also other physicians

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### Bringing to Market

- Regulatory Pathway – FDA, CE Mark
- Reimbursement Strategy – OOP, Insurance Coverage, DME
- Market Adoption – Patient Education, Physician Education/Training

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### Bringing to Market – How I did it

- Regulatory Strategy
  - Employed a regulatory consultant
  - FDA Class I – reduced regulatory burden
- Reimbursement Strategy
  - Evaluated similar procedures, trends of reimbursement, current landscape
  - Needs to be feasible for patient, physician and practice
- Market Adoption
  - Commercialization strategy assistance

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**Challenges**

- Cost/Funding
- Regulatory Hurdles
- Adoption Barriers
- Life

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**Challenges – How I did it**

- Cost/Funding
  - Self vs Capital/PE
- Regulatory Hurdles
  - Class I
- Adoption Barriers
- Time
- Life

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**Adoption Barriers – How I did it**

- RS in private practice are not custom to charging out of pocket which was model of reimbursement I devised
- Not the right customer
  - Listened to patient in trial, actually improved Dry Eye Syndrome symptoms
    - Background knowledge in DED/Clinical Trials –Restasis® clinical trial end points
- Shifted to DED/Anterior Segment for most commercial activity
  - RS in Government/VA Systems still a viable option → Federal Contract obtained
  - Shifting into premium IOL market?
- Barriers breakdown when (1) patient has an exceptional experience (2) doctor has positive feedback from patient in medical device.

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**Time**

- The runway to commercial product will take 2-3x longer than any time you predict.
- Formula 409 concept (409 iterations to get to magic)



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**Life**

- High stress
- No clear path; very different than pathway from college→med school→residency→fellowship→Attending
- 72% of entrepreneurs struggle with Mental Health
  - High Uncertainty
  - Loneliness/Isolation
- No is the most common word you will hear
- [Burn Rate](#) by Andy Dunn good resource

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**Pop Quiz**

- Name the three people who were in the slides.

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**You have time.**

- They all began their entrepreneurship journey at various stages in their life.
- Ina Garten: Worked at White House, at 30 years old bought Barefoot Contessa store, at 51 wrote her first cookbook, at 53 filmed first episode for Food Network.
- Ron Popell: Grew up in entrepreneurship, in his 30s showcased Veg-O-Matic, at 63 he had the showtime rotisserie
- Martha Stewart: A stockbroker at 26, at 36 began her catering business, 41 her first book, 56 when she started Martha Stewart Omnimedia

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