Product Development for Tech and Life Science Startups

Cliff Emmons

https://www.linkedin.com/in/cliff-emmons/

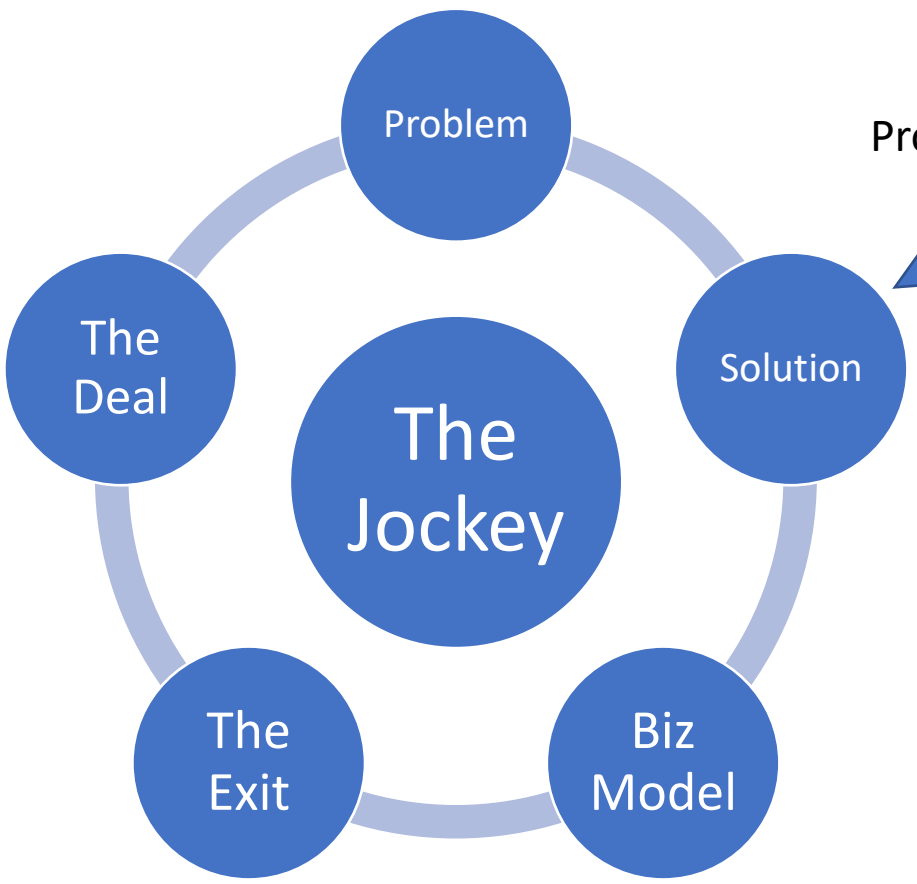
President & Founder, Accelerated Healthcare Innovations, LLC

Panelist Background & Today's Goals

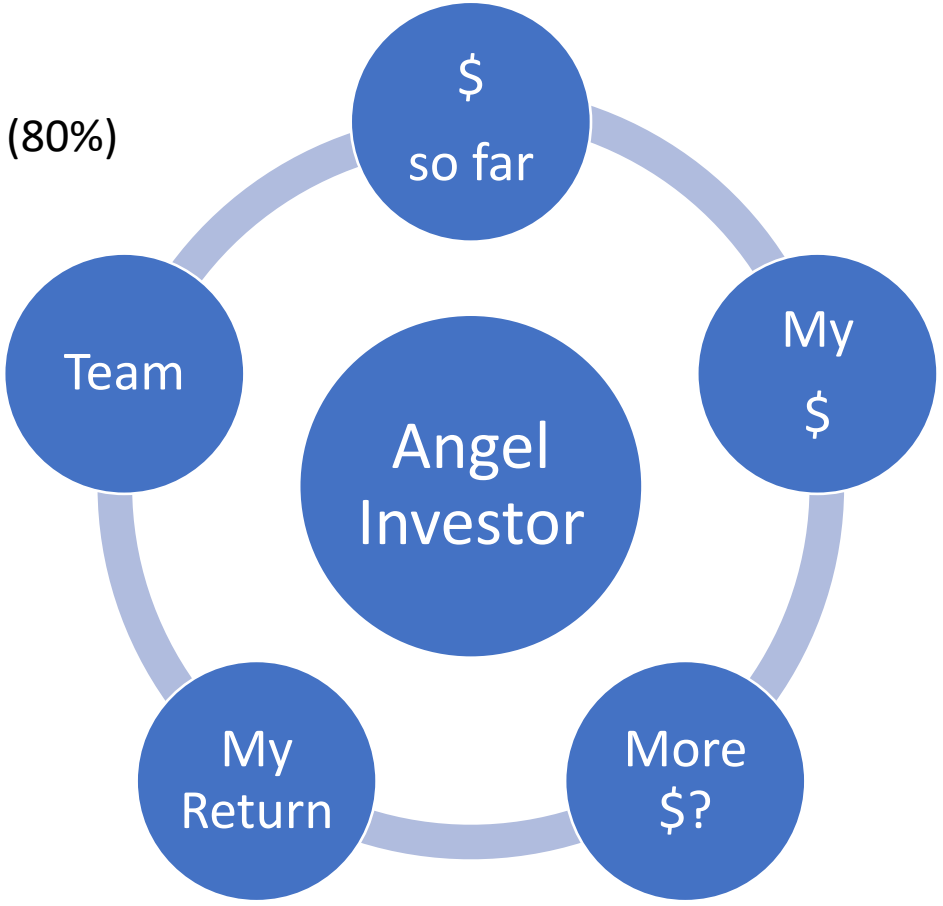
- Who's Cliff?
  - Engineer, Corporate VP R&D, Entrepreneur, Angel Investor, Advisor/ Consultant
  - Pragmatic Idealist (JFK quote)
- Why should you listen to him?
  - Inventor - Patent holder of 1 Billion USD ARR product
  - Leader - Founded a Half-Billion USD "Internal Startup" at Fortune 500 Med Tech
- Goals for today?
  - Investor's perspectives on PD WRT a complete Investment Thesis
  - Tips on weaving PD into your Startup Story, and vice-versa (Interdependence)
  - PD and The Pivot

Communicating Value Proposition to Angels

80/20 Rule for Product Development



Product Development (80%)



The Entrepreneur's Story …

… The Angel Investor's Perspective

R&D, Tech Dev, Product Development

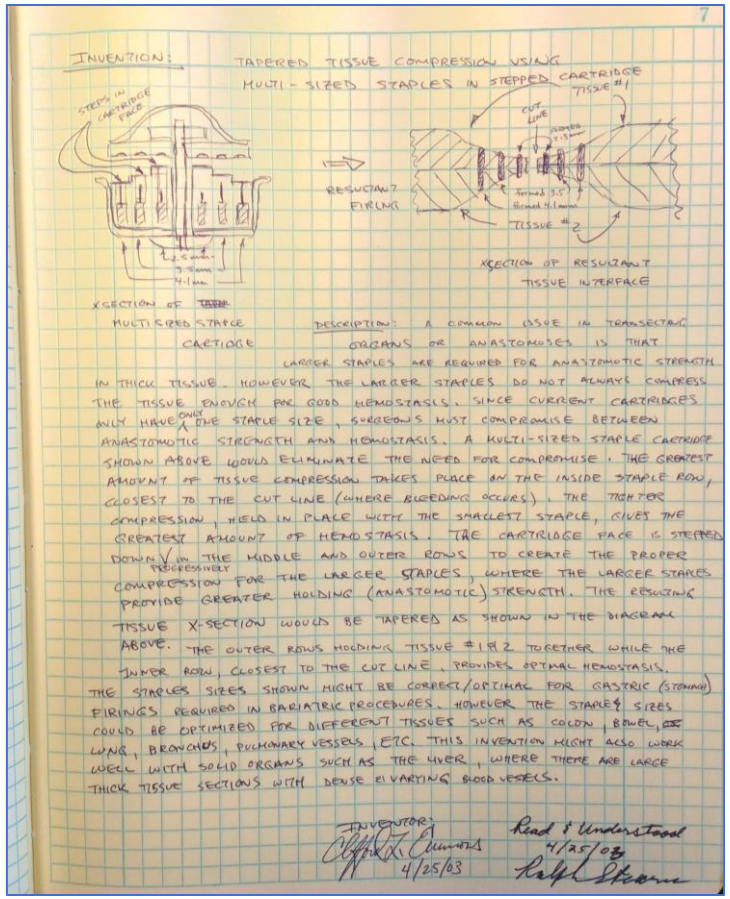
- Key elements & practices of COV / MDT investment in Organic Growth
  - Lessons to apply to Start-Ups

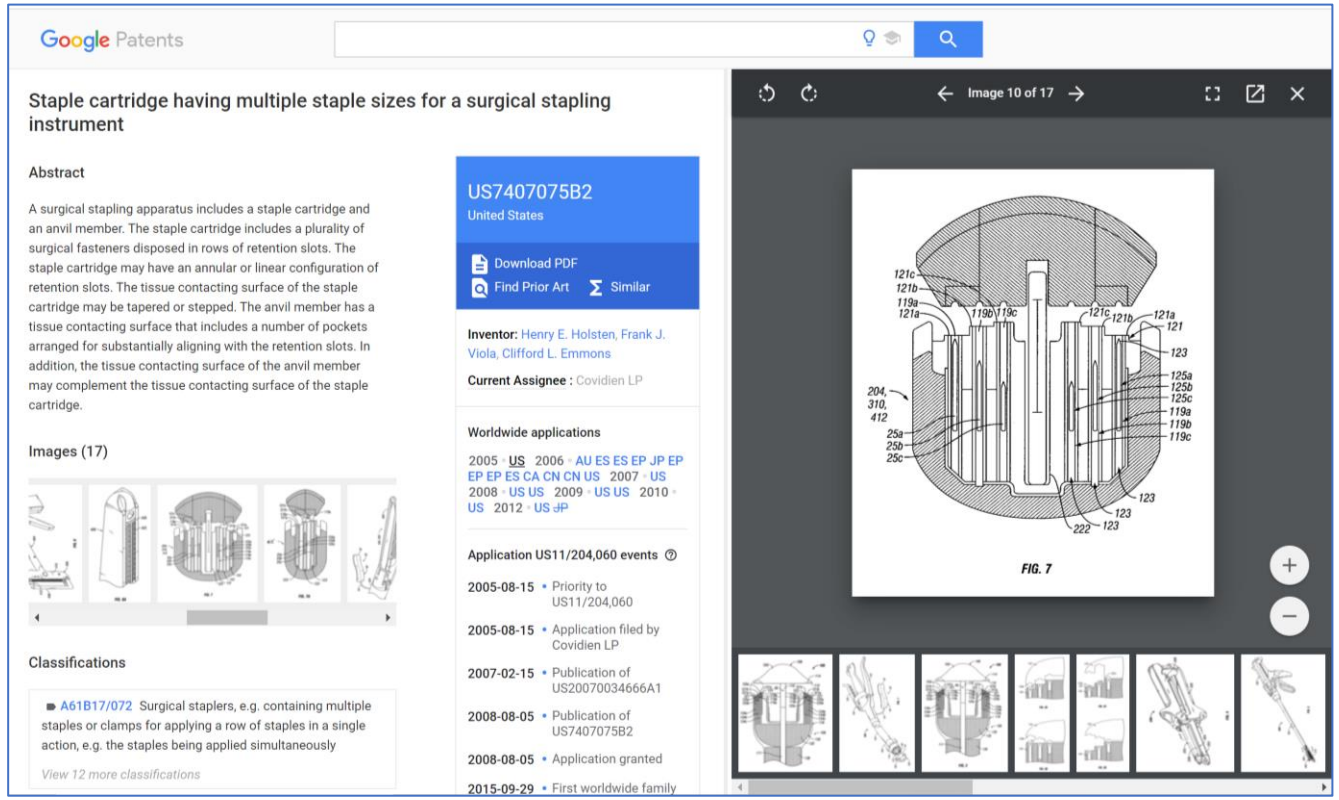
  - Regulatory Path impact Product Development Costs
    - Contrast of COV & MDT - % R&D
      - Development Costs of 510K Class 2 vs PMA Class 3

  - Technology Development vs Product Development
    - Technology Development
      - Feasibility, Proof of Concept, Early Prototypes
    - Product Development
      - Design Thinking, Voice-Of-Customer, Ethnographic Studies, Human Factors
        - Key: “The Un-expressed Unmet Need”
      - PMO, Design For Excellence Tools, Commercialization

Idea to Intellectual Property (IP) to Product

- Engineering Notebook (Idea Disclosure) to Utility Patent





Clinical – Regulatory – Risk versus Reward

Including Impact on Product Development

2015–1H 2019	Stage at Exit	Median Invested ($M)	Median Upfront ($M)	Median Upfront Multiple	Median Total Deal ($M)	Median Total Deal Multiple	Median Time to Exit (Years)
510(k) M&As 39 Exits	36 / 2 / 1	$46	$110	3.4x	$140	4.7x	8.9
De Novo 510(k) M&As 4 Exits	4	$46	$360	4.6x	$435	6.1x	8.8
PMA M&As 31 Exits	5 / 14 / 12	$51	$200	3.4X	$315	5.8x	6.7

Source: Silicon Valley Bank 2019 Healthcare Report

HC Stakeholders

Complete VoC

REGULATORY APPROVAL ISN'T ENOUGH

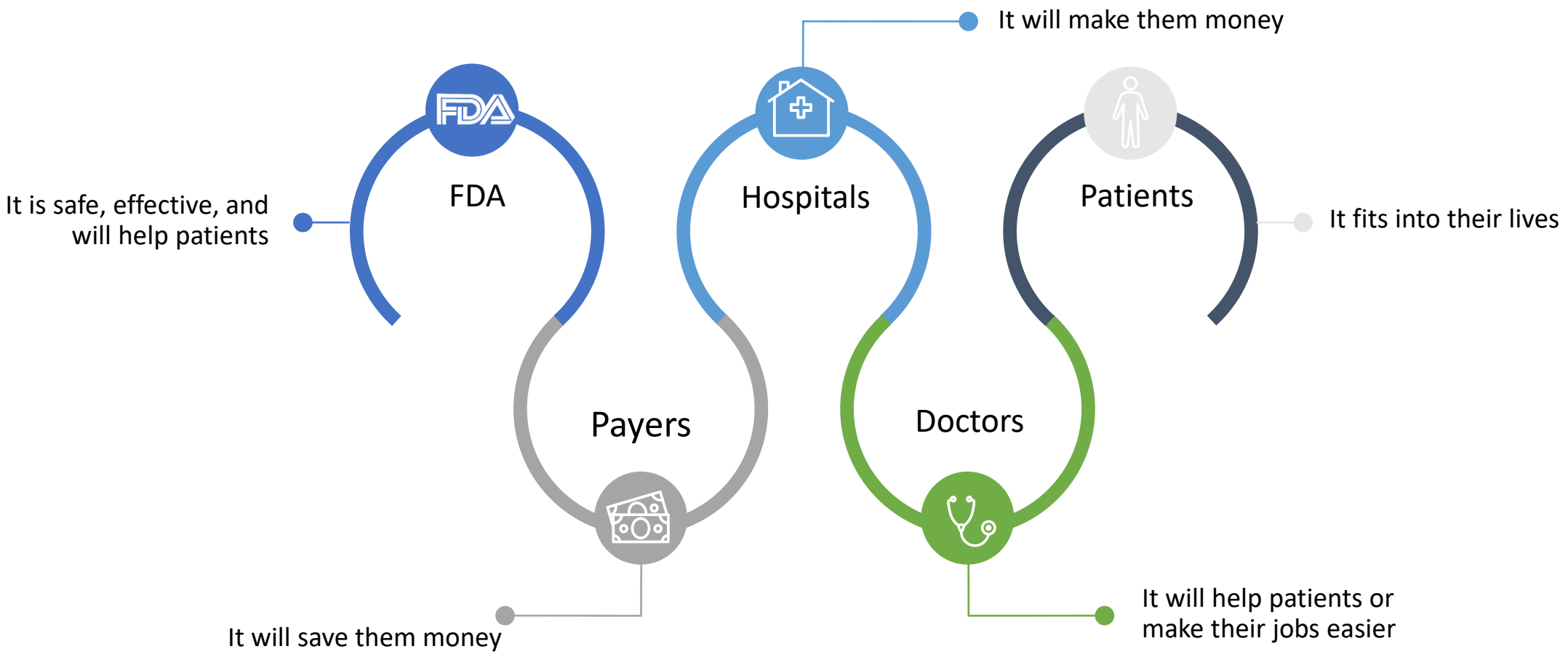
One-third of all approved medical devices don't make money

There are large number of factors that you need to consider before making critical business decisions

Groups that you should keep in mind

1. **Regulatory**
   FDA
2. **Payers**
   Medicare/Medicaid and health insurance
3. **Hospitals**
   Administration
4. **Doctors**
5. **Patients**
6. **Strategic Partners**
   Licensing, acquisition, and joint venture targets
7. **Investors**

Healthcare Stakeholders' Perspectives



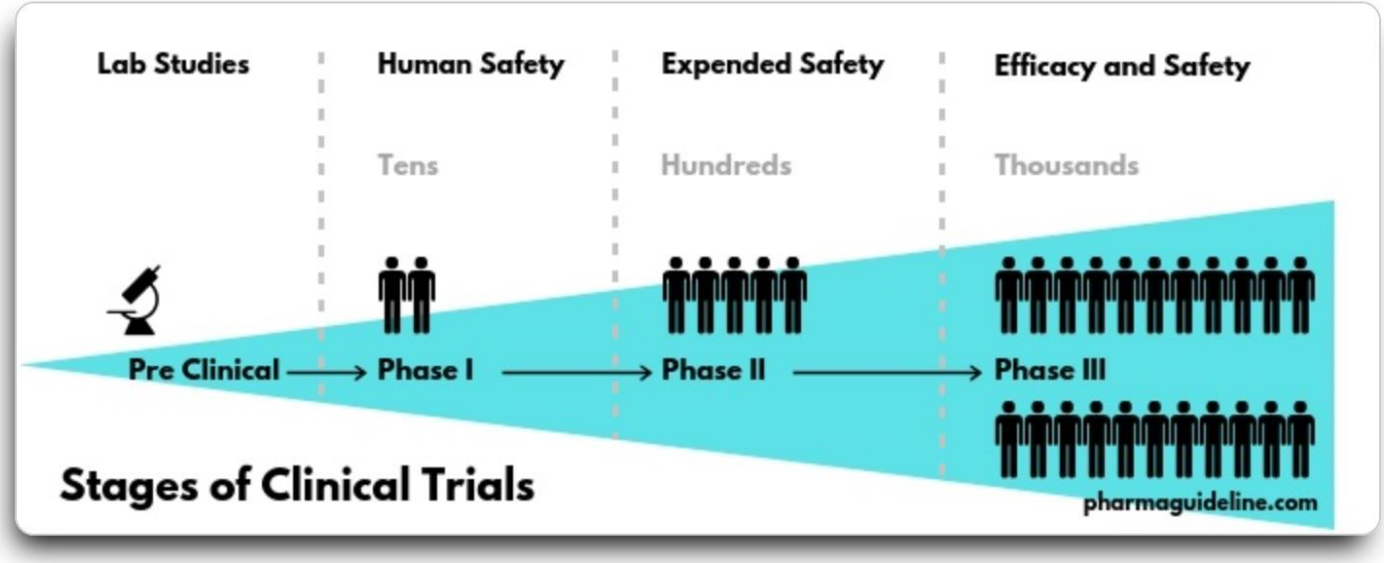
Note: There are more factors that influence adoption, but these are major drivers. Eg. healthcare economics can also impact decision making for payers.

Manufacturing

- Supply Chain
- Local vs Global
- Scalability

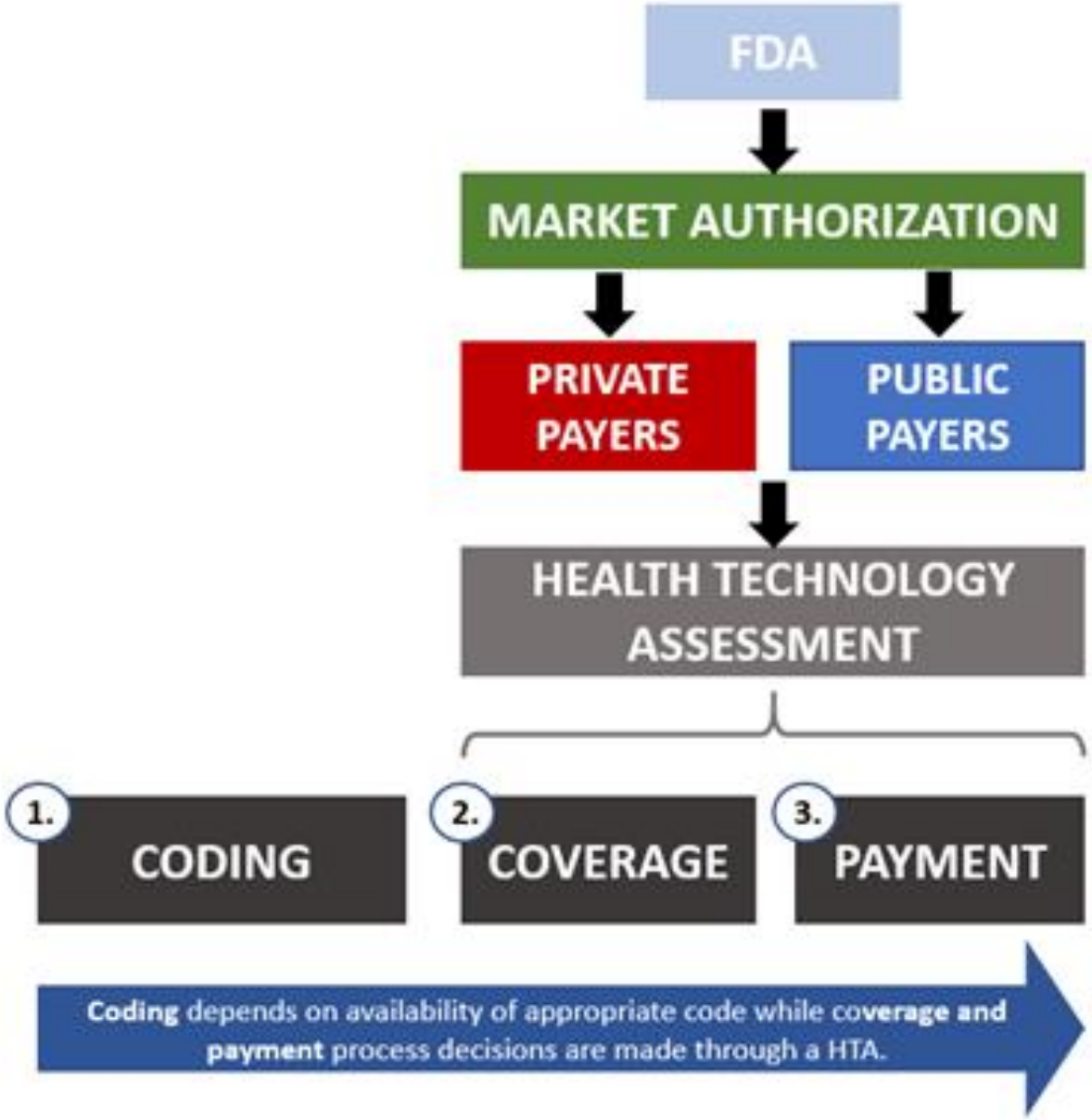
Clinical Studies

- PMA (Pre-Market Authorization)
- (or) Claims Expansion
- (or) Market Traction

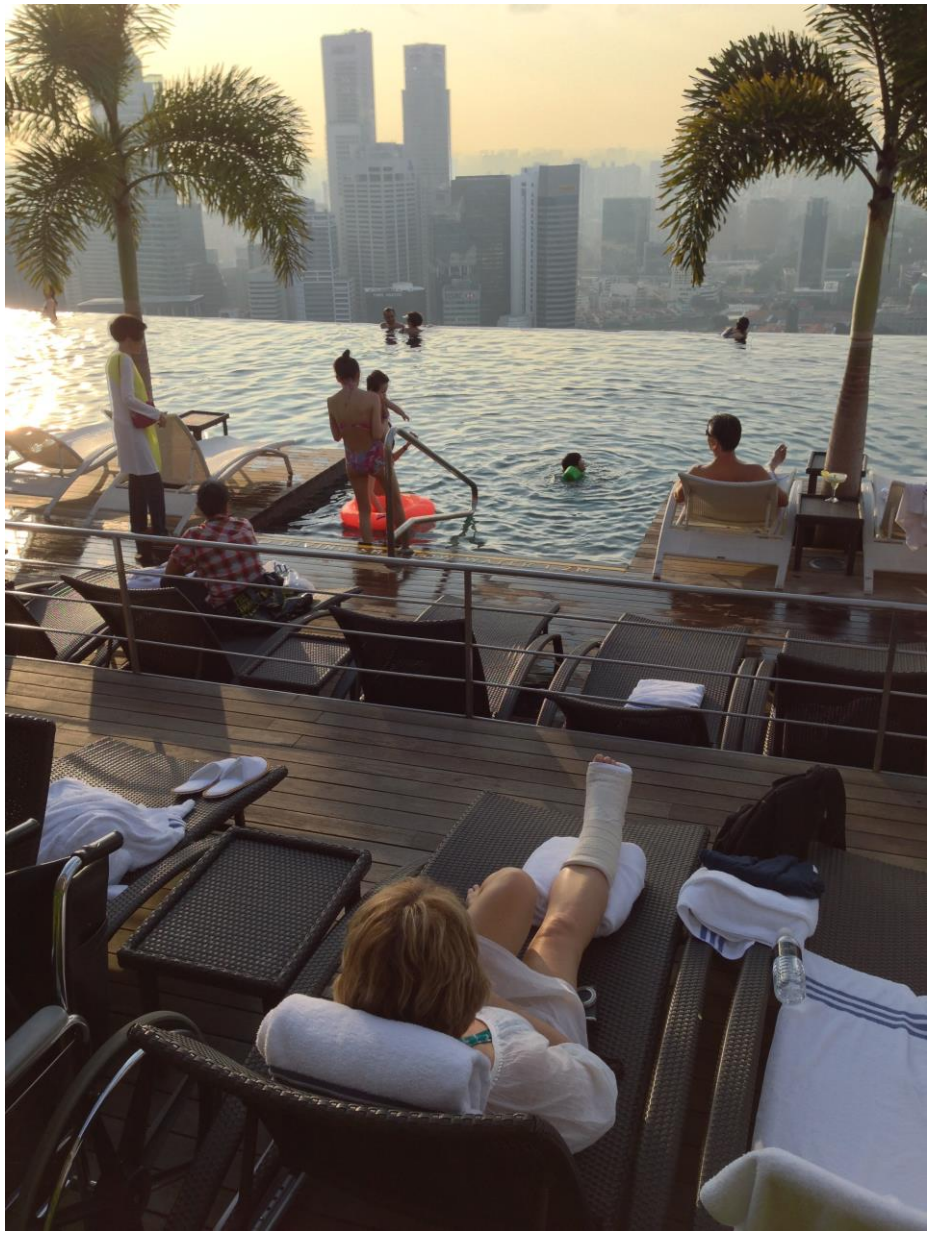


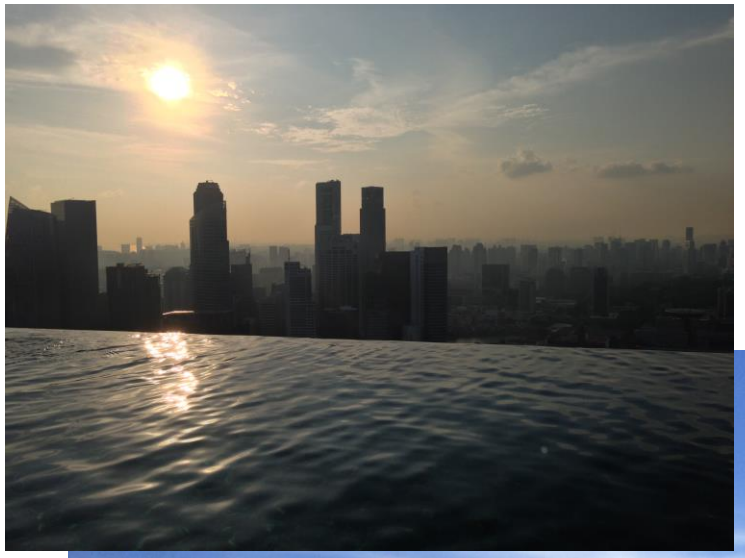
Reimbursement

- Healthcare Economics
  - Value Proposition
- CMS
  - Centers for Medicare & Medicaid Services
  - CPT Codes



Q & A





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