

Inventor Stages of Development



Outline

1. Idea
2. Patent
3. Money
4. Prototypes and Studies
5. The Next Level
6. Real Funding
7. Human Trials
8. Exit Strategy
9. Final Product and Marketing Strategy



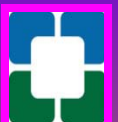
1. IDEA

- There is no bad idea, and no idea is too goofy to think of, you may be just before your time.
- Colleagues may be skeptical – that is natural – have thick skin.
- CCF innovations will guide you through stages if you are committed to the project.



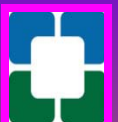
2. Patent

- Do not be surprised if someone else thought of it first. See if you have a different slant.
- Do a brief search yourself
 - Look in filed not just issued patents
 - Uspto.gov
 - A good patent lawyer will help.



3. Money

- Different Routes
 - Traditional NIH grants. This is a different path.
 - Angel Investors – bet on jockey, not the horse.
 - Alternative sources – state of Ohio, military
 - NIH SBIR/STTR
 - Venture Capital
 - Major medical company – office of business development. Need to get to senior people.
- Business plan – how are you going to get there and how much?



4. Prototypes and Pilot Studies

- Try it your self first - finding the right engineer is not easy.
- Outside contracting engineers saves time and money for recruiting.
- Pilot study – animal short term feasibility
 - Paper work takes time due to regulations
- GLP – Good Laboratory Practice
 - A highly scrutinized accounting required by FDA
 - Expensive, so do non GLP pilot first as a change means you need to start over.
 - There are private GLP company auditors for hire.
 - Several contract GLP facilities exist



5. The Next Level

- Go or No go
- What if, and If then
 - Think ahead
- Hiccups – expect them, have thick skin if the concept works



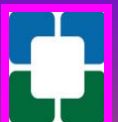
6. Real Funding

- What does it takes to get a product to market
 - In the US 30-40 million for an SFA/peripheral stent
 - Pharma – 100+ million
- VC – mature money
 - Adds more value
 - They take more
- Medical Device Companies
 - Can not own more than 12% per SEC regulations



7. Human Trials

- Get regulatory advise early
- First in Man – usually South America (Asia)
- European CE mark
- US
 - 510 – usually no human trials
 - IDE/PMA – human trials
- CROs



8. Exit Strategy

- Be careful what you disclose to companies and investors
 - NDAs and CDAs are not enough
- Investment Bankers



9. Final Product

- Can not change
- Need regulatory advise
- Design history file – keep good records from day one



My Mistakes and Advise

1. Personnel –
 - CEO is really a manager – creative and honest
 - All personnel - age not a requirement, experience helpful, but potential and intelligence most important
 - Do not just fill a slot
2. Cut Losses early
3. Homeruns are rare – stay with it and be involved as much as you can. Take ownership of the project.

