The Innovation Cycle—Translating Research Outcomes to the Marketplace

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The Innovation Cycle in Healthcare Technologies

- I have been immersed in this Innovation Cycle for more than three decades.
- Founded AMO in the late 1970’s
- Founded Chiron Vision in the late 1980’s
- Entered Venture Capital in the late 1990’s
- Co-founder of Versant in 1999
- Over 50 novel products developed and commercialized
  - Eight 510ks, 53 PMAs/NDAs
Innovation Cycle – Healthcare Technologies

1. Observation & Invention
2. Product Dev/Pre-Clinical
4. FDA Approval
5. CE Mark/OUS Market Dev.
6. Iterate/Refine
7. Iterate/Refine
8. Human Proof of Concept
Principles of Innovation

• Focus on important issues (big markets)
  – Identify the value drivers
  – Find where innovation will be rewarded

• Seek the truth
  – Making progress is an iterative process
  – Seek and be open to independent input and findings
  – Don’t process information through a narrow filter
Principles of Innovation.....

• Be disciplined
  – Being methodical and thorough pays off

• Try things
  – When in doubt…try it
  – Don’t be frozen by the uncertain or unknown

• Be willing to fail
  – It will happen….dust yourself off and move forward
Principles of Innovation.....

• Don’t be paralyzed by mistakes
  – Learn from them
  – Apologize and move on

• Be skilled
  – Identify the skills and expertise required
  – Develop or find the requisite skills
  – Mobilize these resources and focus relentlessly on the problem
Principles of Innovation…..

- Be aggressive and confident…but not arrogant
  - Being passive does not work
  - Arrogance does not work
- Professionalism pays off
  - Take the high road
Where Does Innovation Happen?

- Wherever the innovators are….and where the culture fosters innovation
- Culture of Innovation
  - Knows that innovation drives value
  - Does not punish mistakes
  - Knows it is NOT just about MY ideas…others’ ideas have merit
  - Balances internal with external innovation (corporate)
  - “Not invented here” attitude stifles innovation
Innovation Cycle-Key Contributors

1. Inventor-scientist/entrepreneur/team
2. Clinician-early adopter
3. Financial Partner--Venture Capitalist, etc.
4. Industry leaders- commercial team
Key Contributors-Roles and Attributes

1. Inventor-scientist/entrepreneur/team
   - Breakthrough idea that is unique, protectable, not a “me too”
   - Does not accept the current state
   - Develops/tests/reduces to practice
   - Amazing problem solving skills
   - Puts concept to strong challenges
   - Skilled, relentless, listens, responds, inspires…. 
   - Makes others around him/her better
Key Contributors-Roles and Attributes

1. Inventor-scientist/entrepreneur/team

2. Clinician-early adopter
   - Clinical, medical expert
   - Open minded—"sure I will try it....."
   - Constructively critical
   - Real world assessment…does it work, no kidding..
   - Helps position the innovation in the OR and/or practice
   - Judges whether it is “better medicine and better business”
Key Contributors-Roles and Attributes

1. Inventor-scientist/entrepreneur/team
2. Clinician-early adopter
3. Financial Partner--Venture Capitalist, etc.
   - Brings Money
   - Thought partner to the team
   - Constructive engagement….part of the solution, not part of the problem----don’t panic!!
   - Accesses network for building team, finding needed expertise and additional capital
   - Enables exit path….IPO, sale or strategic partnership
Key Contributors - Roles and Attributes

1. Inventor-scientist/entrepreneur/team
2. Clinician-early adopter
3. Financial Partner--Venture Capitalist, etc.
4. **Industry leaders- commercial team**
   - Global market presence
   - Culture which fosters innovation….allows mistakes
   - Balances inside versus outside innovation
   - Operationally skilled and organized to commercialize new products globally
   - Drives adoption, assures access for customers and patients
Innovation Cycle-Key Key Contributors

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Innovation Cycle Timeline – Healthcare Technologies

1. Observation/Invention – 1-3 yrs
2. Product Dev/Pre-Clinical Phase – 1-3 yrs
3. Human Proof of Concept – 1-3 yrs
4. Refinement – 1-2 yrs
5. FDA Study - 1-2 yrs 510K, 4-6 yrs PMA
6. CE Mark/OUS Market Dev
7. FDA Approval / U.S. / Launch
8. Successful Global Commercialization
Times Have Changed…. Healthcare Innovation Cycle….Then and Now…

- Era
- Time to US launch
- Role of Europe/OUS
- Reimbursement
- Technology Availability
- Cost
- Market size

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<td>Time to US launch</td>
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Innovation in Healthcare Technologies

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Innovation in Healthcare Technologies

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• Resources focused where they are rewarded
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• Still immense unmet needs
Innovation in Healthcare Technologies

- Times have changed....challenging, but still attractive
- Resources focused where they are rewarded
- Key Constituents....entrepreneurs; clinicians; VCs and Industry.....stronger and more connected than ever
- Still immense unmet needs
- Innovation in healthcare technologies remains highly active
Innovation in Healthcare Technologies

- Thanks to all who remain committed.....because when we do well, many people benefit
Thank you....