“I HAVE AN IDEA”
A PRIMER ON MEDICAL TECHNOLOGY INNOVATION IN ACADEMIA

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STANFORD SCHOOL OF MEDICINE
Disclosures

No relevant COI for this topic
CAN YOU DESCRIBE A FEW DEVICE ADAPTATIONS/ “MACGYVERISMS” THAT YOU’VE SEEN OVER THE YEARS?
HOW MIGHT YOU CAPTURE THOSE AND MAKE THEM A REALITY?
Objectives

- Develop recognition of a clinically relevant problem that is in need of innovation
- Recognize the challenges of brainstorming solutions and identify ways to brainstorm effectively
- Identify methods by which most academic institutions approach creation and ownership of intellectual property
- Describe the options for early prototypes including 3-D printing and low volume manufacturing
- Appraise the risks and benefits of start-ups, licensing and other modes of commercialization while working within academia
A medical device is an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals.
TRENDS IN INDUSTRY

• Wireless devices
• Combination products
• “Wearables”
• Home and personal health
ASSESSING CLINICAL NEED

- Will the healthcare system be better off?
- Is there a known or likely risk in target modulation?
- What will the risk-to-benefit ratio be? Is it acceptable?
- Will the delivery choice be acceptable to the patient?
- To the provider?
- Will this be reimbursed by 3rd party payers?
SCHNOZZLE™
NASAL IRRIGATION ADAPTER

- Smooth Rounded Tip
- Internally Threaded Luer Lock for Safety
- High Flow Irrigation Port Gentle Flow

Fits any Standard Luer Lock Syringe

- Simple & Fast
- Upper Airway Clearance
- Flushes Nasal Secretions
- Positive Pressure Irrigation
- Fits Any Luer Lock Syringe
- Alternative to Suctioning
- Kid (& Adult) Friendly
ASSESSING CLINICAL NEED AND IDEATION

• What unmet medical need will the product address?
• What clinical problem are we solving?
• Why would a patient use our product?
• Why would a prescriber order our product?
• Will the patient be better off? Would this device reduce risk for other patients?
• Would this device add to staff satisfaction?
• Would this device help meet regulatory metrics?
WHAT IS INTELLECTUAL PROPERTY?

• Intellectual property ("IP") is the general term for intangible property rights which are a result of intellectual effort

• Patents, copyrights, trademarks and trade secrets are the main ways of protecting IP

• At colleges and universities, IP most frequently refers to patentable inventions and copyrightable works created by faculty, students, and staff

• Ownership and revenue sharing policies vary by institution
What is the policy of your institution?
WHAT IS A PATENT?

• Agreement between the US government and the inventor(s)
• The inventor describes to the public what the invention is, how to make it, and how to use it
• A patent provides its owner with the right to exclude others from practicing the patented invention, but it does not necessarily grant the patent owner the right to practice the patented invention
• A patent is property and can be bought, sold, willed, pledged as collateral, or anything else one can do with their property
• Everyone who is designated as an owner of a patient can fully make use of the patent
INVENTORSHIP

• Determining inventors on a patent application is distinctly different from naming authors on a publication; it has a strict legal meaning.

• Incorrectly including or excluding an inventor can potentially invalidate a patent.

• Determination is made by patent counsel, not by OTD, principle investigators (PI’s), department heads, etc.

• Only those individuals that have made independent, conceptual contributions to the claimed invention are entitled to be named as inventors.
Inflatable nasal packing device with two non-elastic, flexible bags oversized relative to nasal cavities

US 7108706 B2

ABSTRACT

An inflatable nasal packing device, and method of use, for insertion in a patient's nasal cavity to control bleeding or epistaxis. The device includes a flexible insertion tube, a first inflatable bag attached to and surrounding an anterior section of the tube, and a second inflatable bag attached to and surrounding a posterior section of the tube. The tube has three lumens for providing separate fill passageways to the two bags to allow independent filling and pressurization and for providing an air passageway through the device even when the bags are inflated. Both bags have walls of non-elastic, flexible material with fixed surface areas defining interior volumes when inflated that are larger than the anterior nasal cavity and the posterior nasal cavity and nasopharynx.
# FDA Device Classification

## TABLE 1 Classes of Medical Devices

<table>
<thead>
<tr>
<th>Class</th>
<th>Risk</th>
<th>Regulatory Pathway</th>
</tr>
</thead>
<tbody>
<tr>
<td>Class I (e.g., gauze, toothbrushes)</td>
<td>Low risk of illness or injury</td>
<td>75% are exempt from approval</td>
</tr>
<tr>
<td>Class II (e.g., suture, needles)</td>
<td>Moderate risk of illness or injury</td>
<td>The majority will have to go through a PMN application</td>
</tr>
<tr>
<td>Known Class III (e.g., pacemakers, ventilators)</td>
<td>Significant risk of illness or injury</td>
<td>Has a predicate device and may be able to undergo PMN rather than the full PMA process</td>
</tr>
<tr>
<td>New devices classified as Class III by default</td>
<td></td>
<td>If low or moderate risk, investigator may petition to have them classified as &quot;de novo&quot; devices, and they may be able to undergo a PMN process rather than full PMA process</td>
</tr>
</tbody>
</table>

PMA = pre-market approval; PMN = pre-market notification.
COMMERCIALIZATION

• A license agreement is used to permit another party to make, use, and sell an invention. Most licenses are with existing companies.

• Licenses are granted usually by the Board of University, but negotiations are the responsibility of technology development staff.

• Any eventual license revenues are distributed according to the Board’s rules and policies.
DEVICE: WOUND DRESSING WITH MANUKA HONEY
MANUKA HEALTH NEW ZEALAND LTD.
ATTN: DAVID BECHTEL
1011 U.S. HIGHWAY 22 SUITE 200
BRIDGEWATER NJ 08807-2950

510(k) NO: K133729 (Traditional)
PHONE NO: 908 429-9202
SE DECISION MADE: 23-JAN-15

510(k) STATEMENT
PROTOTYPING

• Just draw!
• CAD design
• 3D Printing
  • University
  • Commercial
• Small volume manufacturers
• Injection molding
• Makerspaces – mock up of a variety of materials
• Lego, clay, pipe cleaners, homeworkshop, trips to hardware/hobby/craft stores

MIT Little DEvices Lab, Photo by Sam Ogden, Discover Magazine
A FEW WORDS ABOUT 3D PRINTING

http://themetapicture.com/3d-printers-go-way-back/
https://www.baldengineer.com/3d-printer-tips.html
### Medical Device Industry Ecosystem

<table>
<thead>
<tr>
<th>Components</th>
<th>Device Maker</th>
<th>Marketer</th>
<th>Healthcare Provider</th>
<th>Insurance</th>
<th>End Users</th>
</tr>
</thead>
<tbody>
<tr>
<td>OEM LPC w/ RF</td>
<td>Design and integrate components</td>
<td>Brands, sells, distributes, services</td>
<td>Uses data, recommends, prescribes</td>
<td>Certifies and covers purchase</td>
<td>End users &amp; Caregivers</td>
</tr>
<tr>
<td>Devices</td>
<td>Phillips</td>
<td>Phillips – Motiva</td>
<td>Civil Facilities</td>
<td>Private</td>
<td></td>
</tr>
<tr>
<td>• Phillips</td>
<td>• iCare</td>
<td>• Health Hero Network</td>
<td>• Hospitals</td>
<td>• Private Plan</td>
<td></td>
</tr>
<tr>
<td>• Cybernet Medical</td>
<td>• Andromed</td>
<td>• I-Med</td>
<td></td>
<td>• Group Coverage</td>
<td></td>
</tr>
<tr>
<td>• Aerotel</td>
<td>• Cybernet</td>
<td>• Carelink</td>
<td></td>
<td>• United Health</td>
<td></td>
</tr>
<tr>
<td>• Viterion</td>
<td>• Cybernet</td>
<td>• AMD Telemedicine</td>
<td></td>
<td>• BlueCross</td>
<td></td>
</tr>
<tr>
<td>• Orizon</td>
<td>• Cybernet</td>
<td>• Honeywell HomMed</td>
<td></td>
<td>• Kaiser</td>
<td></td>
</tr>
<tr>
<td>• STMicroelectronics</td>
<td>• Cybernet</td>
<td>• McKesson Extended Care</td>
<td></td>
<td>• Aetna</td>
<td></td>
</tr>
<tr>
<td>Sensors</td>
<td></td>
<td></td>
<td></td>
<td>Public</td>
<td></td>
</tr>
<tr>
<td>• Medlab</td>
<td>Software</td>
<td></td>
<td></td>
<td>• VA</td>
<td></td>
</tr>
<tr>
<td>• Teledyne</td>
<td>• 2nd Opinion</td>
<td></td>
<td></td>
<td>• Medicare</td>
<td></td>
</tr>
<tr>
<td>• Micro-epsilon</td>
<td>• AHECAN</td>
<td></td>
<td></td>
<td>• Medicaid</td>
<td></td>
</tr>
<tr>
<td>Research Agencies</td>
<td>• Wellogic</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• CRSTI</td>
<td>• TMA Medical</td>
<td></td>
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<td></td>
<td></td>
</tr>
</tbody>
</table>

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- Begin with industry value chain
- Identify major categories of industry participants, including regulatory and support entities and define their roles at each level of value chain
- Within each category, identify the key players (generically or in detail)
- Identify network of existing relationships
Summary

• Know the regulations within your university
• Do a prelim patent search for prior art
• Employ the assistance or guidance of your technology development office
• Recognize ways to prototype and options, including 3D printing
• Identify avenues and the reality of funding
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