Product Innovations in Respiratory Care

NCRSC Conference
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Vice President of Innovation

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Goals for Today

- **Generate Excitement** about medical product innovation
  - Professional
  - Personal
- **Outline a Process** for inventing and developing new product ideas
  - Definitions
  - Best Practice
  - Pitfalls
- **Provide Resources** to help you pursue your new ideas

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Agenda

- **Introductions**
- **Excitement** — Why should we encourage product innovation from health systems?
- **Process** — What are the steps to commercializing a new medical product?
- **Resources** — Where do we go from here?

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ibiliti Supports Medical Technology in North Carolina

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ibiliti Board Members

Board Member	Experience
Greg Davis, Chairman	Former CEO Tryton Medical, Guidant
Sam Taylor, Vice Chairman	President, NCBIO
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Tim Gupton	Partner, HPG
Matt Jennings	CEO Phillips Medisize, former Teleflex, BioEnterprises
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Barry Myers	Prof. Duke, EIR Pappas
Troy Nagle	Prof. UNC/NCSU
Bob Wilhelm	Prof. UNCC
Mary Beth Thomas (observer)	NC Biotechnology Center

Dan Deaton
Vice President Innovation

- 15 years of development experience in high growth environments (12 Years in Respiratory)
- Director of Product Development, Oriel Therapeutics (Sandoz/Novartis)
- Kos Pharmaceuticals (Abbott)
- Magnetic Imaging Technologies (GE Healthcare)
- BS/MS Mechanical Engineering NC State University
- MBA University of North Carolina Chapel Hill

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Our Programs

AdvantageWest • Asheville Chamber of Commerce • BD Technologies
G3 Medical • Gilero Biomedical • JNJ COSAT • North Carolina Biotechnology Center
Phillips-Medisize • Polylinks • RAPID Prototyping Center • Synecor
Western Carolina University

MICA makes new medical solutions a reality for patients.

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Why do we need more innovators from within healthcare?

- **Financial Pressures** on Hospitals and RC Departments:
  - Increasing Costs
  - Decreasing Revenue
  - Changes in payor mix and reimbursement
- New products and processes can **improve healthcare delivery**:
  - Better outcomes and safety
  - Better patient experience
  - Increased efficiency
  - Lower Costs
  - **A Culture of Innovation**

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Healthcare Trends: Leading Health Systems are **Investing in Innovation**

Innovation Programs

- Summa Health
- MedStar Health
- **Novant Health**
- **Mission Health**
- **Carolinas Healthcare**

Venture Capital Funds

- Mass General and Brigham and Womens ($35M, 2007)
- **Rex Healthcare ($10M, 2012)**

10 ** Representative Samples Only*

Why Respiratory Therapists Can Be Great Inventors:

- Improvising to Solve Clinical Problems: A Daily Event!
- High degree of technical training
- Specialization
- Familiar with continuous quality improvement process and the scientific method
- "Part of the current federal stimulus package is aimed at spurring medical research, and the National Institutes of Health (NIH) is getting ready to issue at least $200 million for research projects; including those specifically related to Respiratory Care" (NIH Grants, 2009 AARC Website)
- Precedent……Other RT's have done this!

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Examples of Successful RT Inventions:

- Continuous Infusion Nebulizer
- Negative pressure ventilation and resuscitation system
- Closed Suction Catheter
- Endotracheal Tube with Subglottic suction
- Finger Guard for Arterial Puncture
- Stethoscope which merges sound waves
- High Flow Oxygen Delivery System
- Continuous Cuff Pressure Regulating Device

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MICA: Case study for Product Innovation

MICA
MEDICAL INNOVATION AND COMMERCIALIZATION ALLIANCE OF WESTERN NORTH CAROLINA

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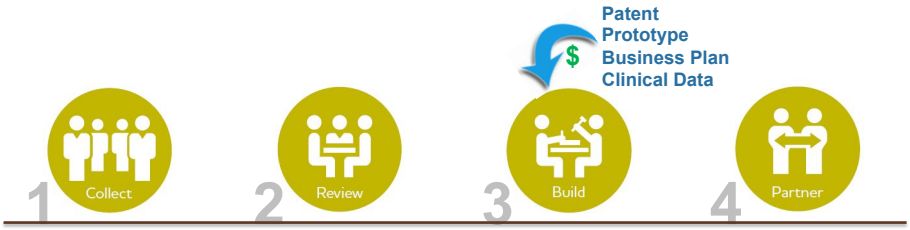
MICA Product Commercialization Process



Ideas best suited for this program are medical devices, diagnostics, hospital equipment/supplies, and healthcare information technology —engineered products and services that can be approved and available to patients in less than 24 months.

Panels of industry leaders from across the country help us select the most promising ideas for development. This invaluable feedback is shared with all of the inventors that participate in the program.

Working with engineers, prototyping experts, manufacturers, regulatory, clinical and reimbursement professionals, we develop the product and gather data needed to make the product real as quickly and cost-effectively as possible.

With product data in hand, we showcase the innovations to companies and people who have the expertise to market and sell them.

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Methods to Invent: **Flash of Genius**

Tips from a President (Anesthesia Products Company):

- Stick to products you know
- Think "T-tube" type products (Single patient use, Low cost, Disposable)
- Don't try to invent a new ventilator—start small!

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Methods to Invent: **Creative Clinical Problem Solving**

- Identify a **Problem or Need** first - later, work on a solution that meets criteria for a new product
- This Method allows you to generate a list of potential inventions and then iterate through these solutions

Inventor Tip:

During a routine clinical day, listen out for the "magic words" that identify problems to be solved:

- **"Why don't they invent …."**
- **"How can we do …."**
- **"If I only had a …. this would be easier"**

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Methods to Invent: **Creative Clinical Problem Solving**

- Examples of North Carolina Products

XEROS DRY MOUTH PUMP

Cancer Survivor, Al Toman
Swansboro, NC

HENSLER SURGICAL

Physician Assistant, Sean Hensler
Wilmington, NC

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After Inventing: **Write it Down**

- **The Inventors notebook**:
  - Keep a list of potential design solutions
  - Add and subtract items from the list based on prior art, marketing research, and experimentation
  - Record sketches, drawings, experiments, data, and any other notes on the invention
- **Sign and Date entries**
  - Have a witness co-sign entries

Note
- US is now "First to File" (used to be "First to Invent")
- Somewhat diminishes the importance of notebooks, but this is still a good practice

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Review and Research

- **Research Prior Art**
- Look carefully at **Competitive Products**
- Consider the market size
- Consider the possible paths to a commercial product
- Consider: Why might insurance companies or hospitals pay for this new product?

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Build: The Critical Elements

- **Intellectual Property (IP): Protect your idea**
- **Design and Prototype**
- **Business Plan**
- **Clinical use data**

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Intellectual Property (IP)

Patent
Prototype
Business Plan
Clinical Data

- **Patent:** A right granted by the government which gives its holder the right to exclude others from making, using, or selling an invention for a period of time (20 years in US)
  - **Utility Patent**: Covers structure and/or function of a useful process, machine, article of manufacture, or composition of matter
  - **Design Patent**: Covers design of product only (not as strong as utility patent)
- **Copyright:** Right given to a composer, author, or artist to exclude others from publishing or copying work
- **Trademark:** Word, phrase, symbol or design, or a combination thereof, that identifies and distinguishes the source of the goods of one party from those of others

TM ®
© SM

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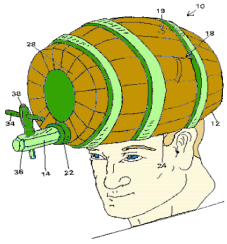
Is this a patentable idea?

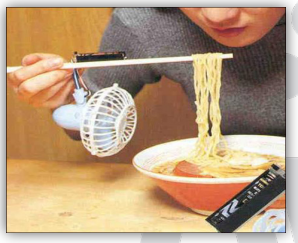
Collect Review **Build** Partner

Patent
Prototype
Business Plan
Clinical Data

In order to be a patentable idea – an invention has to meet the following 3 criteria:

- **Useful**
- **Novel**
- **Not Obvious**





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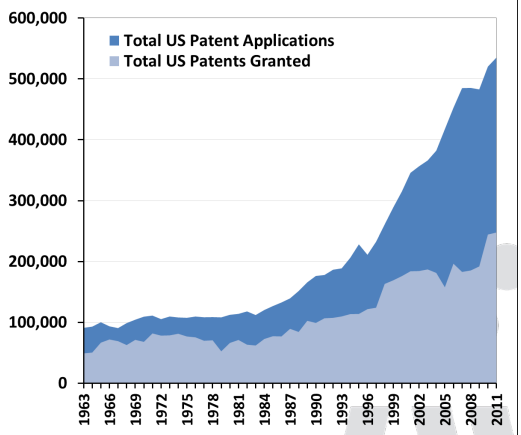
IP Process

Collect Review **Build** Partner

Patent
Prototype
Business Plan
Clinical Data

Step 1: Research Prior Art

- Competitive Products
  - Product Catalogs
  - Buying Guides
  - Vendors expos
- Patents and Applications
  - USPTO.gov
  - Google Patents
  - Patentstorm.com



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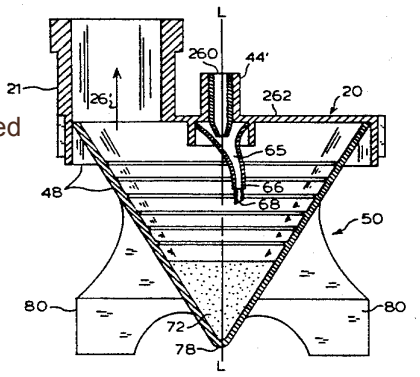
IP Process

Patent
Prototype
Business Plan
Clinical Data

Step 1: Research Prior Art
Step 2: Draft Invention Disclosure

- Summary of Invention
- Other Patents you have discovered
- Sketches and drawings
- Lab Data
- Any other uses
- (Reference Inventors Notebook)



(Dry Powder Nebulizer, courtesy of Dr. John Riggs, RRT, FAARC).

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IP Process

Patent
Prototype
Business Plan
Clinical Data

Step 1: Research Prior Art
Step 2: Draft Invention Disclosure
Step 3: Contact Patent Lawyer

- Seek out Medtech Experience
- Qualified professional:
  - Can conduct a search
  - Provide a report of findings
  - File a patent application with **formal claims**
  - Typically will file a Provisional Patent that allows 1 year to assess market prior to finalizing
- Prosecute patent (2-4 years)

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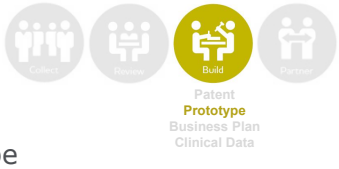
Design and Prototype



- Proof of Concept (POC) models may be made with metal, plastic, modeling clay, existing parts, hardware store parts, etc
- It will be helpful to engage a mechanical designer to provide options for a given product concept
- Working with a manufacturer (plastic molder, machine shop) often also informs the design
- Design Prototyping has become an industry (3D printing, quick turn parts, etc.)

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Business Plan Development

Executive Summary
- Keys to Success
- Objectives

1. **Company Summary**
2. **Product Description**
3. **Market Analysis Summary**
   - Focus on Competition
   - Market Trends
   - Pricing Strategy
4. **Development Strategy**
   - Regulatory Approach
   - Clinical Trial Needs
   - Reimbursement
5. **Management Summary**
6. **Financial Plan**
   - Milestone Driven

Target Audience
- You!
- Potential Investors
- Potential Acquirers

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Clinical Use Data

Laboratory proof that the device works

- In Vitro (in lab – observation)
  - Mechanical performance
  - Usability
  - Reliability
  - Intended Use
- In Vivo
  - Animal Data ($)
  - Human Data ($$$)

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Partner

- **Licensing:** a formal agreement where buyer receives permission to make and sell your invention in return for agreed terms (i.e. licensing fee, legal expenses, royalty %)
- **Sale** of Invention: Buyer acquires all rights to product for up front fee

Potential Buyers

- Medical Technology Companies (including competitors!)
- Manufacturers
- Entrepreneurs and Investors

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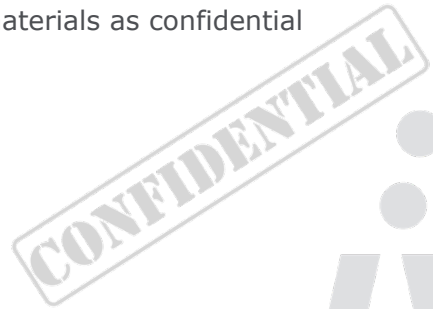
Partner

Note on Confidentiality

- Throughout development of a new product idea, keep idea and all discussions confidential
- Only discuss the idea with a potential acquirer under a confidentiality agreement
- Mark written description materials as confidential



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Need	Why should we encourage product innovation from health systems?
Process	What are the steps to commercializing a new medical product?
Resources	Where do we go from here?

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Summary Messages

1. **Actively look** for new product ideas
2. **Research** the idea and try to find if the invention has been made or documented before
3. **Reach out** in the community to take advantage of the focused resources available to guide you through this process
4. **Don't gamble** your life savings, home, etc. to finance your invention - look for partners and programs to support you and reduce risk
5. **Have Some Fun!**

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North Carolina Resources for RT Innovators

- Peers
- Health System
- Universities
- Nonprofit Groups:
  - ibiliti
  - North Carolina Biotechnology Center
  - Small Business and Technology Development Center (SBTDC)
  - CED, BIG, others (Regional Entrepreneurial Groups)

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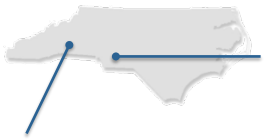
Healthcare Innovation Programs in North Carolina



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- Mission Health
- ibiliti (NC COI for Medical Devices)
- Asheville EDC
- Western Carolina University
- www.mica-wnc.com

Edison NATION MEDICAL

- Carolinas HealthCare
- Edison Nation
- Enventys
- http://edisonnationmedical.com

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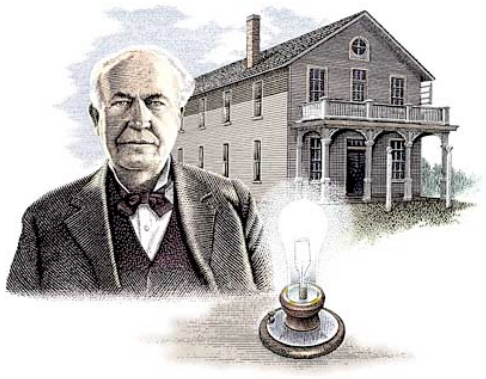

"Genius is one percent inspiration and ninety-nine percent perspiration"

Thomas A Edison

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Discussion and Questions

- Generate Excitement about Innovation
- Outline a Process
- Provide Resources

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