

# **A Translational Checklist; Building Value for Your Cardiovascular Research Ideas**

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# Presentation Outline

1. The Medical Automation Research Center introduction
2. Basic research vs innovation
3. Why invent?
4. Pre-disclosure activities
5. Intellectual property
6. Coauthors vs coinventors
7. Financial incentives for inventors
8. The invention to disclosure process; building value through:
  1. Standardizing your product (GMP, GLP)
  2. Obtaining technology development grants and contracts (the STTR)
  3. Networking with companies (the NDA)
  4. Customer base (the MTA)

# The Medical Automation Research Center

*“Improving healthcare quality and efficiency through the development of advanced technologies”*

A multidisciplinary research and innovation center that focuses on inventing and developing medical and biotechnologies



# A Typical MARC Project

## The Automated Biorepository

- DNA, RNA, and plasma protein aliquoting and storage
- \$235,000 grant (North Shore Long Island Medical Center)
- \$250,000 grant from Aventis Behring
- System has been functioning for 5 years at the North Shore Hospital
- Building a 1M system in N. VA With Merck as a partner



# Our Long Range Mission:

To Develop Technology to Enable Personalized and Affordable Medicine

Genomic Screen

↳ Data Interpretation

↳ Smart House Monitoring

↳ Early Warning of Disease Onset



Proteomic Screening



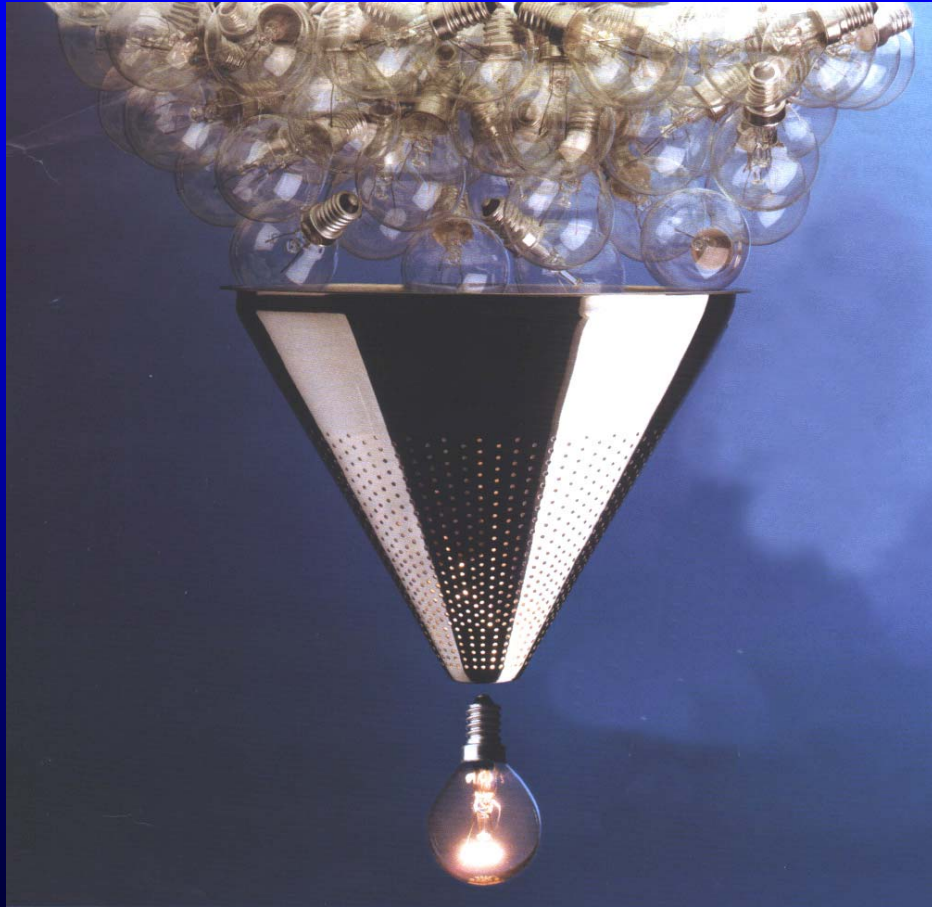
Personal Health Improvement



Appropriate and Cost Justified Health Intervention



# How Did We Develop the MARC “Translational Checklist”?



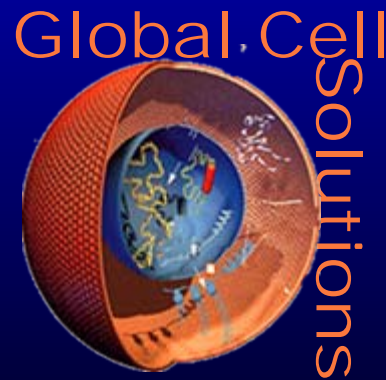
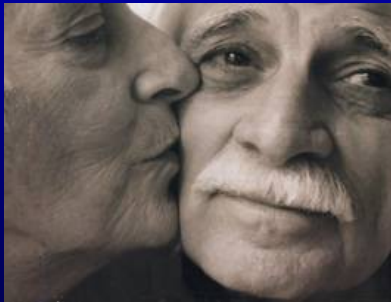
## Minimal Checklist

- Large market potential
- Significant margins
- Intense need
- Business acceptance
- Purchase reimbursable by CMS/Insurance

# MARC Spin-Out Portfolio



Home Guardian, LLC



# Medical Automation Systems



Laboratory reporting and remote process control software

# The Association for Laboratory Automation (ALA)

LabAutomation  
Annual  
Conference  
attendance 6,000

LabFusion  
Conference in  
Boston, June  
2004

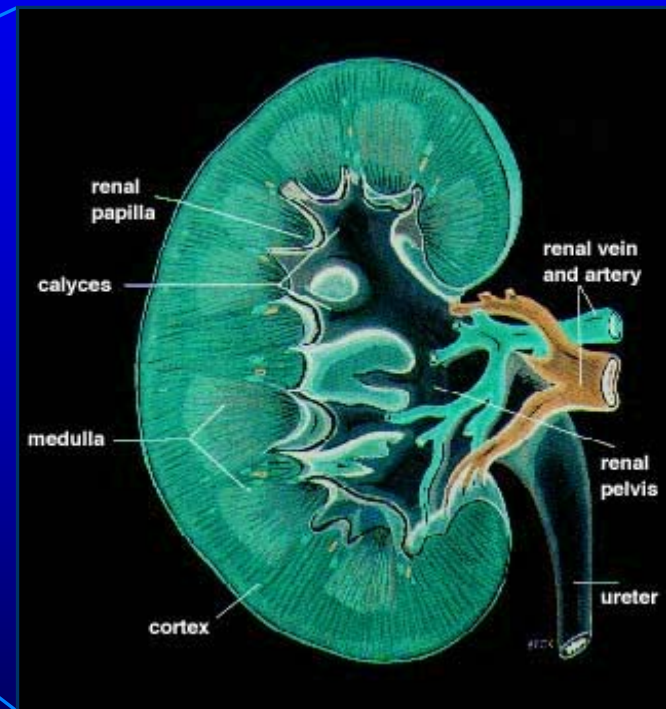
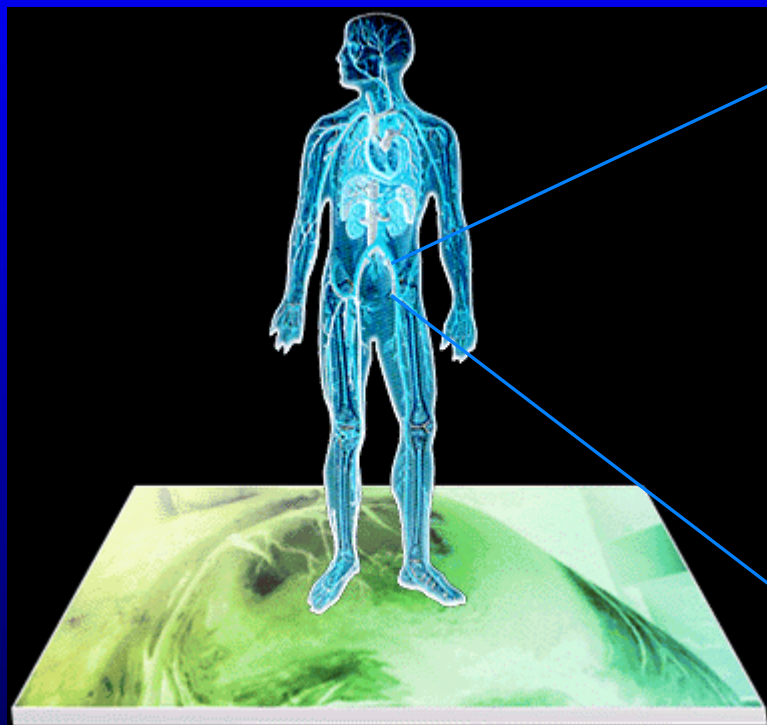


The Journal of the Association for Laboratory Automation  
“JALA”, circulation 10,000

# BIOPHILE, Inc.

- Automated medical specimen storage system
- Compound delivery for high throughput screening

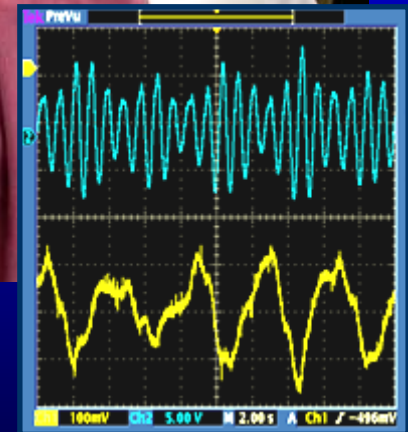




**Hypogen researchers are the first to associate hypertension with specific gene variants in the kidney**

# Home Guardian (Project)

- Passive eldercare technologies
- Bed monitor for pulse and breathing
- Gait monitor
- Bathroom scale that determines blood pressure

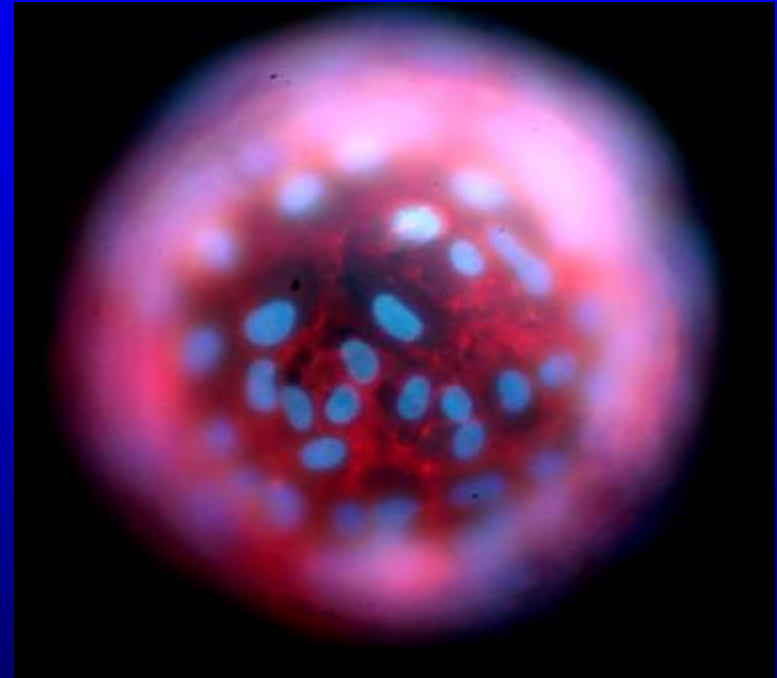


Processed vibration signal gives pulse rate and respiration



# Global Cell Solutions (Project)

- Global Cell Solutions (project)
  - Replacement human cells
  - Automated cell culture
  - Increases cell productivity by over 400 fold
  - Improves phenotype
  - **Questionable IP protection**



Global Cell Solutions microcarriers enabling automated cell culture

# Basic Research vs Innovation

- Research

- scientific excellence
- broad dissemination of results
- sharing of research tools
- engaging in productive research collaborations
- ensuring the highest standards of scientific standards and conduct

- Innovation

- Conveyance of technological innovations from one party to another with the goal of continued development and commercialization



# Basic Research vs Innovation

- Research\*
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- Innovation\*
  - Conveyance of technological innovations from one party to another with the goal of continued development and commercialization
- PPG Dopamine and Angiotensin Receptor Interactions in Genetic Hypertension
- RO1 Dopamine-1 Receptor Defect in Hypertension
- Hypogen, Inc.
  - Molecular diagnostic SNP panel to predict hypertension and salt sensitivity
  - Refinement of the therapeutic antisense for hypertension and salt sensitivity

\*Source: The NIH technology transfer web site

# Why Invent?

“Inventing  
can revitalize  
your research  
career.”



# Personal Incentives

- Inventing is “fun”
  - Submarine patents, infringement, theft
- Tax advantages to patent income
- Independence from grant writing
- Ability to internally fund R21 type projects
  - new, exploratory and developmental research projects



# Consumers Deserve Access to Good Ideas



- Bayh-Dole Act (law PL 96-517), - a federal law passed in 1980 giving universities commercial rights to discoveries made with public money, but also requiring them to make sure those discoveries are diligently commercialized.

# The Value of Innovation Varies Between Academic Organizations



# Universities Drive Innovation

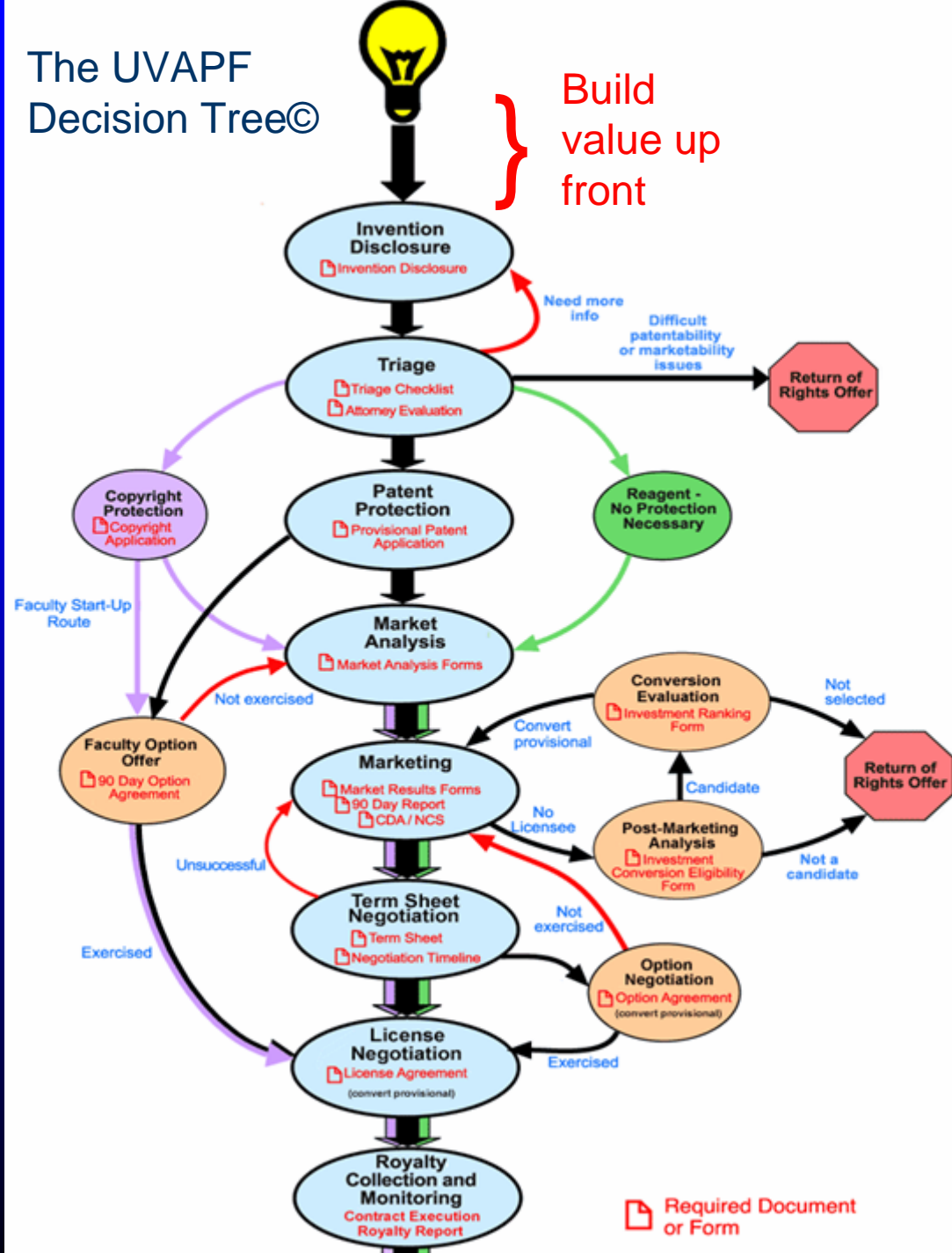
- Academia beats out corporate inventing by 51
- Despite difficult economic conditions, U.S. patent applications were up 13.6 percent, licenses and options increased 15.2 percent, and license-related income was up 11.9 percent in 2003
- Highest cited patents are all held by US universities (MIT/Harvard in the lead)

Source: The Association of University Technology Managers, a Northbrook, Ill.-based nonprofit organization

# Pre-disclosure

- Significant value can be added prior to disclosure
- Added value
  - Improves chance of patentability
  - Enhances interest from outside parties
  - Improves license terms for UVA

## The UVAPF Decision Tree©



# Spinning-out is not for Everyone

- Bookkeepers, Accountants and Tax
- Banking
- Early Stage Funding and infrastructure support
- Lawyer services
  - Incorporation, Corporate documents, equity distribution
- Marketing & strategy
- Patents and other forms of IP
  - Patent disputes
- Pitching to Sources of Capital
  - Angels and Angel networks
  - Venture Capital



# Intellectual Property: Why Protect Your Ideas?

- The desire of the private sector to commercialize your inventions rests on the economic viability of those inventions, and thus depends on solid patent protection in the major world markets

# Intellectual Property

- A successful patent will be novel, useful, and nonobvious. To be patentable, an invention must also belong to one of the following broad categories: a process, a machine, a method to manufacture, a composition of matter, or any new and useful improvement thereof.

# The Basics of Protecting Your IP

- Write it down
  - Bound notebook without intervening pages
  - Date
  - Witnesses
  - Lock it up
- Keep it secret until it has been disclosed
  - Publishing and presenting
  - The Non-disclosure agreement (NDA)
- Trade secrets
- Writing the disclosure
  - **Background**
  - Drawings
  - Claims



# Broad Statements in Background Can Enhance Your Claims

“The increased avidity of the renal proximal tubule for sodium in hypertension may be caused by defective renal paracrine action of dopamine. Dopamine causes a decrease in sodium reabsorption. Thus a defect in the action of dopamine would lead to an increase in sodium reabsorption and hypertension.”

Claim 55. (NEW) A method of identifying individuals predisposed to a decreased ability to excrete an acute or chronic sodium load, comprising

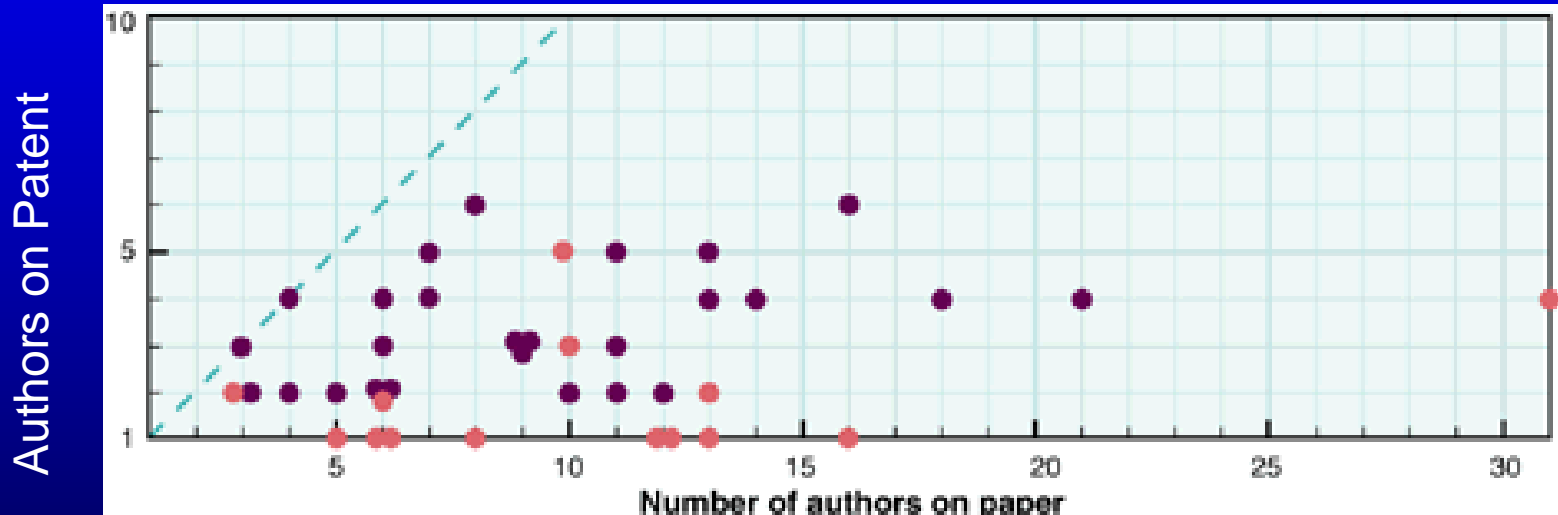
# Beware of Visitors to Your Lab

- The UVAPF NDA
- Trade Secrets
- Discussions at conferences
- Discussions with colleagues



# Coauthors are not Necessarily Coinventors

- Ducor P. Coauthorship and coinventorship. *Science*, Vol. 289, 11 Aug 2000, pp. 873-875.



Red indicates 14 article-patent pairs in which the first, the last, or authors in both positions on the paper were not mentioned as inventors on the corresponding patent.

# Financial Incentives for Inventors: Is It Worth the Effort?

- IP can have significant value
  - Cal Tech receives over \$100M/yr in royalty income
- IP royalty income can support research
  - Adenocard has put over a \$ million into basic research at UVA (1)
  - Total royalty income from IP nationwide was \$1.1 billion in 2001 (2)
- IP royalty income can add to the personal wealth of investigators

1. UVAPF personal communication

2. T. Agres, "The fruits of university research," *The Scientist*, 17(14) 55-6, July 14, 2003.



# Royalty Income

- Inventor share
  - 50% of the first \$99,000
  - 30% of \$100,000 - \$299,000
  - 25% of \$300,000 - \$999,000
  - 15% of > \$1M
- Tax breaks on royalty income
  - Federal tax code A-6105 (Specific income items not included in determining “net earnings from self-employment.”)
  - Awards received by an individual
    - **In settlement of a patent suit**
    - **Royalties received under a license agreement for a patent**



# Pre-Marketing Your Ideas

- IP does not generate value without customers
  - Peer reviewed publication
  - Sharing your technology through Material Transfer Agreements with other researchers
  - Vendors of similar technology that visit your place of work
    - Sales people
    - Invitations to VPs for business development
  - Scientific conferences
    - Presenting your discovery in scientific forums
    - Providing workshops
    - Hosting your own mini-conference
  - Trade shows
    - Networking and discussions with vendors (keep the NDA handy)
  - Invited articles in trade journals

# Industrializing Your Product

- Engineering design vs market need
- Elegant vs functional
- User interface
- Reproducibility
- Manufacturability
- Testing it on your colleagues
- Testing it against your competitors

# Moving Your Therapeutics Closer to Market

- Adsorption, Distribution, Metabolism, Elimination (ADME)
  - Cell models
- Clinical trials
  - Phase I
  - Phase II

# Competitive Landscape

Function/Attribute	Competitor 1	Competitor 2	Your Invention
Explain why your invention is best			

# Cell Culture Competitive Landscape

Function/Attribute	SoloHill Engineering	Amersham	Global Cell Solutions
Bouyant, paramagnetic microspheres	Yes	No	Yes
Shear free cell culture	No	No	Yes
Optically clear	No	No	Yes
Can be fully automated	No	No	Yes

# Return on Investment

- Calculate how much less expensive your method is compared to the competition
- Demonstrate how long it would take a laboratory to recoup an investment in your IP
- Demonstrate other less obvious cost benefits

# Technology Transfer Leadership

- Who understands the technology best?
- Who is available to transfer knowledge to the licensing party?
- Is there anyone who has a sense of the market to assist the licensing party with sales opportunities?
- Is there anyone who is interested in cycling off/on campus?

# Summary of Key Milestones

- IP
- Technical feasibility
- Initial product development
- Customers
- Return on investment

# Incubator Checklist

- ✓ Receptionist, bookkeeper
- ✓ Conference Room (access to a large center)
- ✓ Audio-Visual Equipment
- ✓ Copy Center
- ✓ Kitchen Facilities
- ✓ Secured Facility with 24/7 Access
- ✓ Financial Lending Resources
- ✓ Advisory Board/Mentoring Program
- ✓ Local Networking Activities
- ✓ Access to Local Universities, Colleges and Research Establishments

# UVA Resources

- UVA Patent Foundation
  - Robert S. MacWright, J.D./ Ph.D.  
Executive Director and CEO
  - John Breen  
Senior Patent Counsel
  - Robert Decker  
Patent and General Counsel
- Spinner
  - For profit subsidiary of UVAPF – Bob S. MacWright, CEO
- Darden Business School
  - Batten Center for Entrepreneurial Research
    - Speaker series
    - Business concept and business plan competitions
    - Darden Progressive Incubator
- Office of the Vice President for Research

**For More Information Contact:**

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# Take Home Remuneration From a \$1M Invention



■ Incremental Income ■ Cumulative Income

# Royalty Distribution

<b>Patent Royalty Distribution Schedule (as of April 1, 1997):</b>					
<b>Total Royalty Income</b>	<b>Inventor Income</b>	<b>Inventor Research</b>	<b>Patent Foundation</b>	<b>Inventor School</b>	<b>Scholarly Activities Fund</b>
1 - 99,999	50	7.5	42.5		
100,000 - 299,999	30	20	42.5	7.5	
300,000 - 999,999	25	15	40	10	10
above 1,000,000	15	15	40	20	10

Ref: UVAPF web site