



Technology Development and
Market Research
in the MedTech Industry



**Vicky Hunsicker Sanko
& Dan Maehren**

The Next Phase Consultancy, Inc.



Discussion Outline:

- How is the medtech industry defined?
- What does The Next Phase do? And how does it do it?
- How did Dan and Vicky begin working together? And what are we working on?
- What are the stages of technology development?
- Assessing the Market: Where can YOU find the information YOUR team requires?
- What advice can Dan offer YOU on Group Projects?
- What has Dan gained from his experience with The Next Phase?
- Questions and Answers

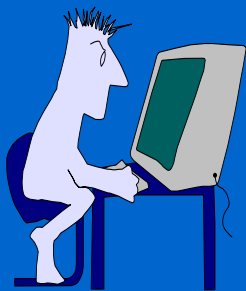
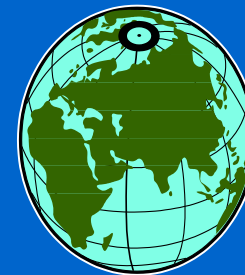
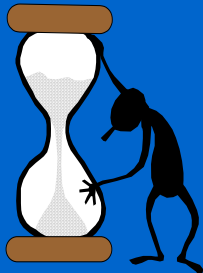


Definitions:

- Biotechnology (biotech)
- Biomedical (biomed)
- Pharmaceutical (pharma)
- Medical Device (med device)
- MedTech
- natural biochemical sources or processes
- biological medical applications
- typically artificial chemical drug sources
- electromechanical systems - instruments, equipment, disposables
- biotech, biomed, pharma & med device



What do We do?





What DO We do?

- **MedTech & Technology Business Development:**
 - **Early Stage Technology & Product Development**
 - + **Situational Market Analysis* (SMA*)**
 - + **Product Marketability Assessments* (PMA*)**
 - + **Product Definition Development**
 - + **Early Stage Business & Marketing Strategies**
 - **Technology Alliances & Business Development**
 - + **Strategic Partnering**
 - + **Business Plan Development**
 - + **Opportunities Screening**
 - + **Due Diligence Investigations**
- **Multiclient Reports in Cardiac & Vascular Medicine**
- **TNP's website: www.TheNextPhase.com**



How do We do it?

- Independent consultant - The Next Phase Consultancy, Inc.
- **Begin with a Project Plan!!**
- Secondary market research:
 - Internet
 - Industry-specific and market niche journals
 - Trade groups & government agencies
 - Industry-specific directories
 - Technical research - patents, technical journals
 - Customer needs (Clinical articles & clinical trials)
- Primary market research:
 - Informal & formal in-person interviews
 - Telephone & mail surveys
 - Focus groups
 - Expert panels



Typical TNP Project Plan

<u>Information Type</u>	<u>Timing</u>	<u>Source</u>
1 - Overall Market Understanding	few hours to day or so - to refine strategy	Internet, business journals - popular & industry specific
2 - Business & Commercial Information	few hours to week	Above plus industry - specific directories, financial reports, investor relations, etc.
3 - General Technology	few days to week or so	Above plus technical journals, patent investigation
4 - Technology applied to a specific field	few days to week or so	Above plus customer-specific journals, patent investigation
5 - Customer's uses, needs & wants	few weeks to months	Above plus customer-specific: journals, informal and formal primary market research, Internet chat groups
6 - Competing technologies' impact	few weeks to months	All of above
7 - Beyond - Regulatory, government & economic issues	few days to weeks	FDA, FYI reports, the MDDI "Gray Sheets", other expert consultants, other journals



How do We do it? +

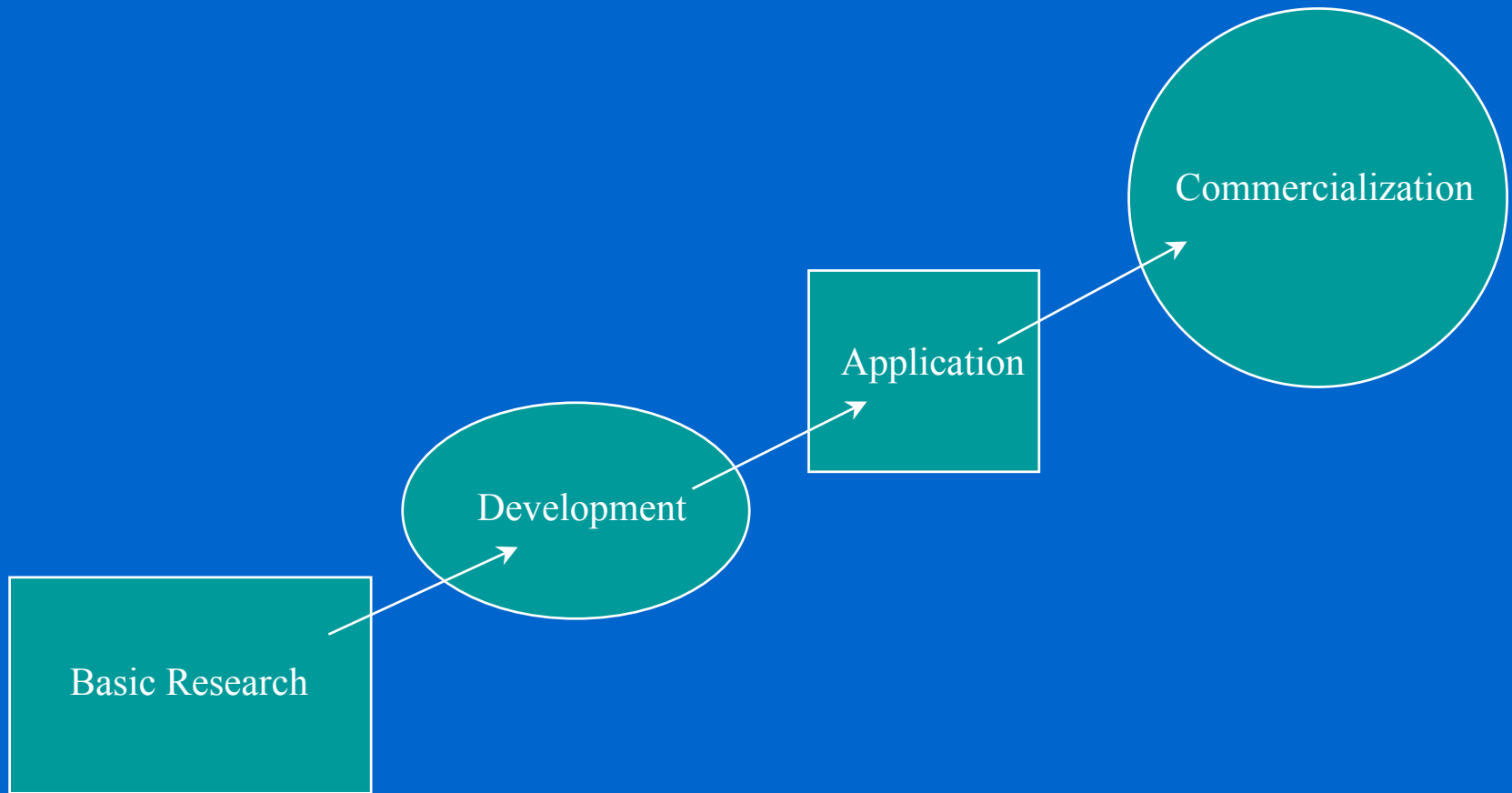
- **PRECISELY DEFINE the PROBLEM & view it as your client or an investor would**
- **Perform a MARKET SITUATION ANALYSIS to IDENTIFY the OPPORTUNITIES:**
 - key issues & trends
 - competing technologies
 - government issues
 - customer needs & wants
 - economic climate
 - fiscal issues
 - competitor position
 - regulatory issues
 - etc.
- **ASSESS - How, where and how well does your product or technology fit in this marketplace?**
- **Customer needs analysis - required performance & function**
- **CUSTOMER REQUIREMENTS DEFINITION (CRD) – your product's specific performance, features & benefits**
- **Project market potential, business and financial RISK & RETURN**
- **Evaluate all of the above at each key stage in a technologies' or products' development or life cycle**



Technology Development in Medtech vs. ROW

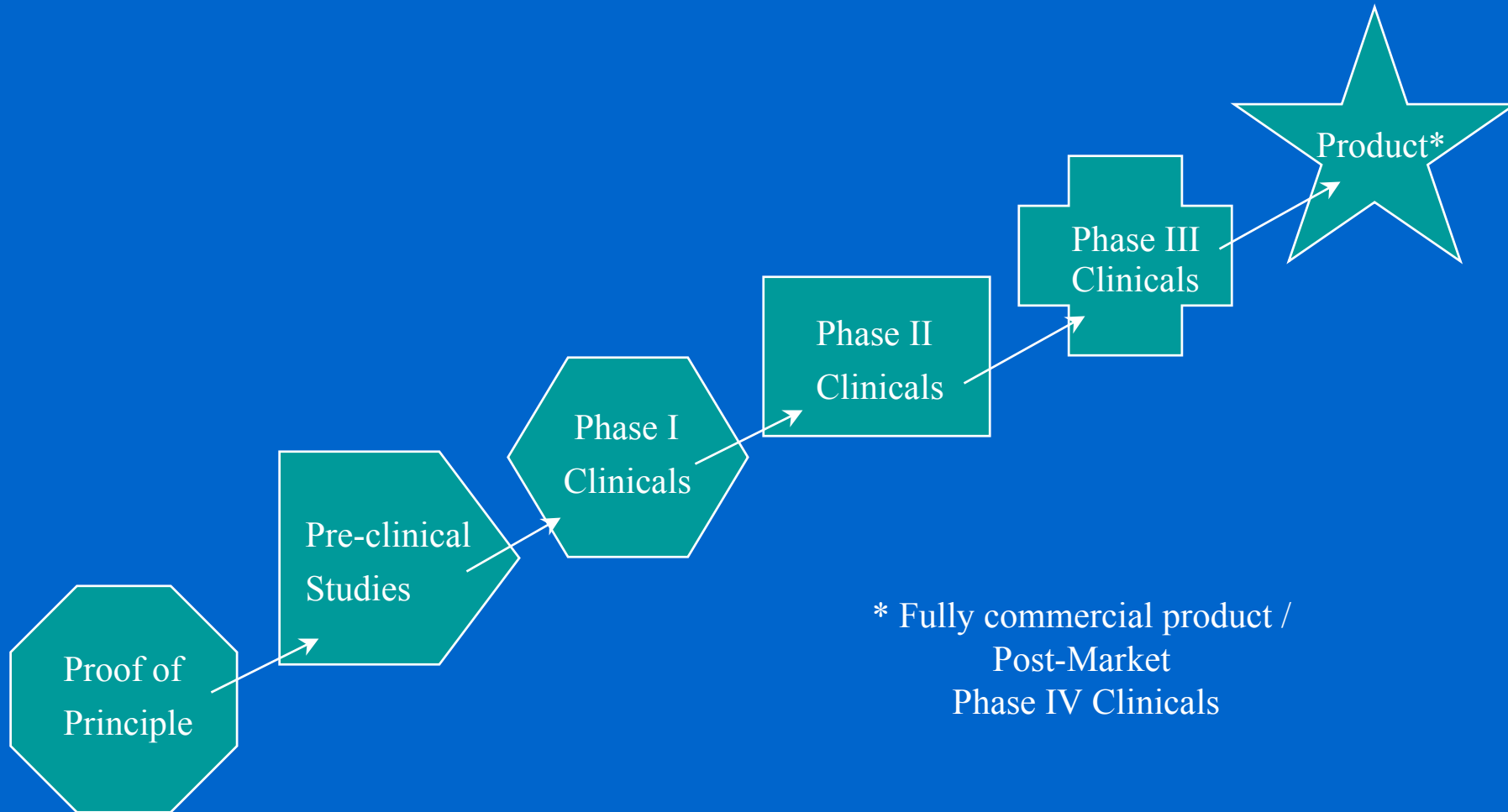


Technology Development Cycle





Medtech Development Cycle



* Fully commercial product /
Post-Market
Phase IV Clinicals



NewTech Group Project



Helpful Hints from Dan

Helpful Hints

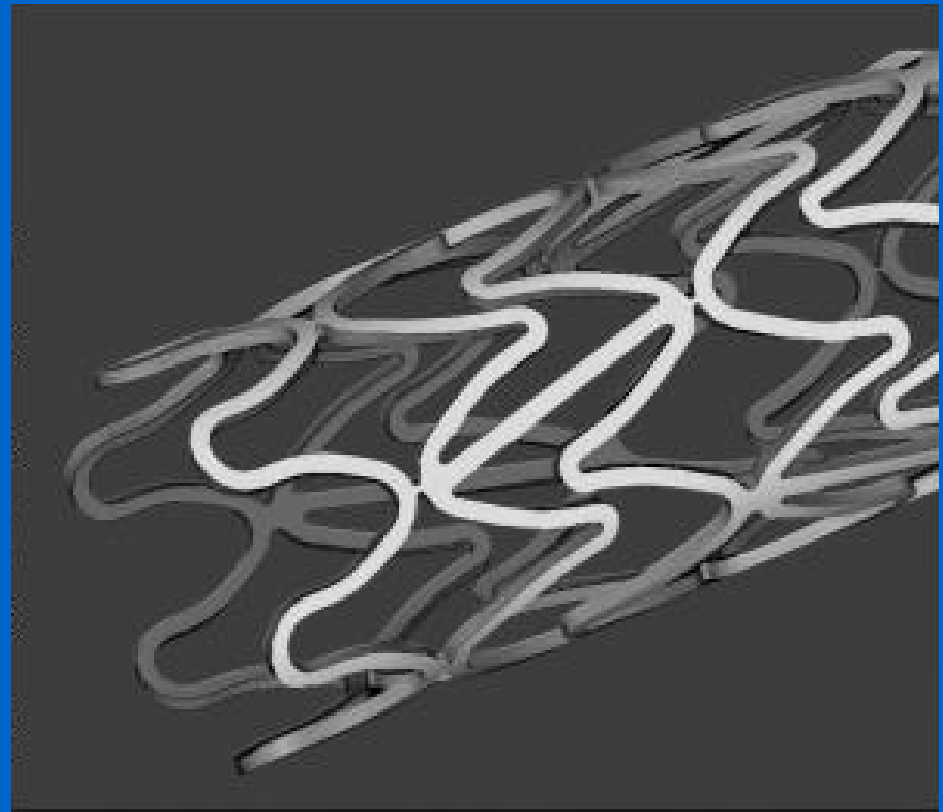
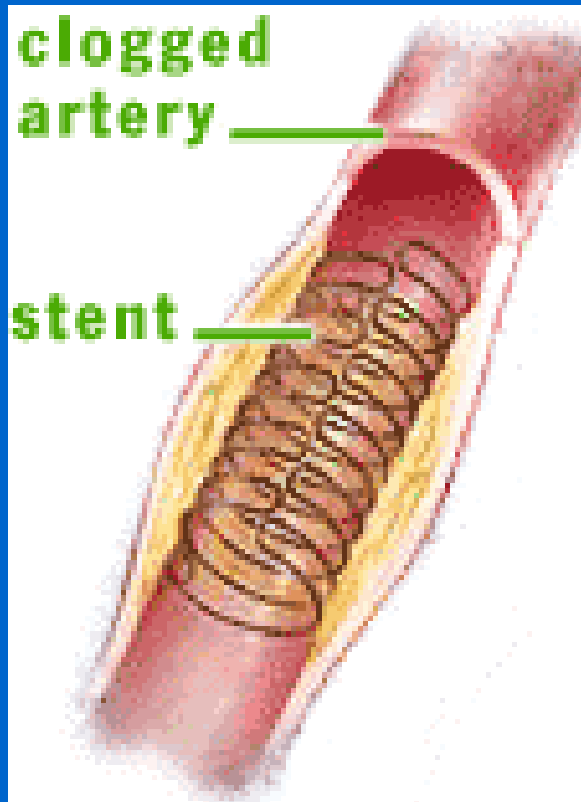
- **Start early**
- **Focus your topic**
- **Produce a project plan**
- **Keep everyone on the same page**
- **Set up interviews early**

Helpful Hints

- **Use your student status**
- **Use (but don't abuse) Alan**
- **Exploit the strengths of your group**
- **Be creative with your presentation, have fun, and be BOLD**
- **...Start Early**



The Technology of Coated Stents





The Technology of Coated Stents

The Problem: RESTENOSIS

TNP identified 135 separate technologies that address this problem

This includes over 65 different vascular stents

30 coated stent products in development

20 drug coatings and carriers

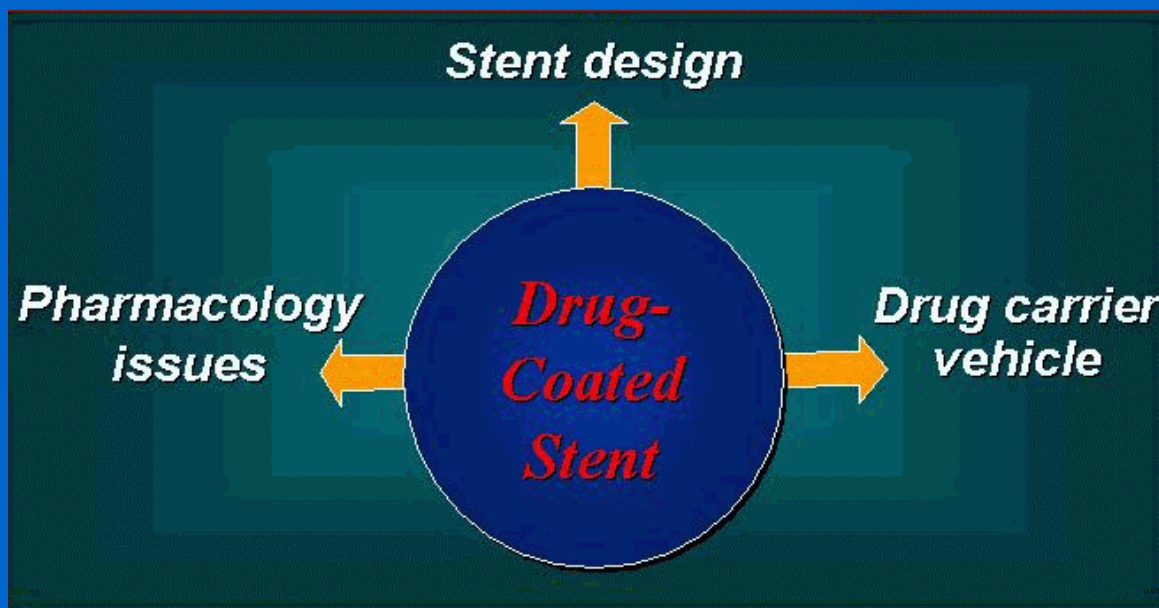
Only 2 drug coated stents have demonstrated zero percent restenosis rates in animal models and early human clinical trials

Leading Edge Technologies

Could this be the Silver Bullet?



The Technology of Coated Stents





Q & A





THE END!





CV - Leading vs. Bleeding Edge

- **PTCA PTA Balloon Catheters**
- **Stents**
- **Coated Stents – Anti-Restenosis**
- **Atherectomy Systems & Laser Systems**
- **Radiation Therapies (Brachytherapy)**
- **Imaging Systems**
- **Less Invasive CV Surgical – MICS, MIDCAB, Port Tech, etc.**
- **Gene Therapy**
- **Aging “Gold Standard”**
- **Leading → Bleeding**
- **New Leading**
- **Leading & Bleeding**
- **Bleeding**
- **Bleeding → Now Leading**
- **Leading**
- **Promise to be Leading**



Future of Medtech

- Next 1 to 5 years:
 - Wide adaptation of drug formulations & drug/device system to:
 - * allow local drug delivery – coated stents
 - * improve drug/device efficacy – drug delivery catheters
 - Continued first releases of biotech-produced drugs
- Next 5 to 10 years:
 - Phase-out of brachytherapy in cv medicine
 - “Gentle” energy-enabled drug delivery in cv medicine – ultrasound, electropulsation, etc.
 - Wider understanding of the human genome
- Next 10 to 25 years:
 - Initial introductions of gene-based (DNA & RNA) systems to mitigate diseases at their genetic roots
 - Displacement of selected traditional therapeutic products – medical devices and systemically delivered drugs