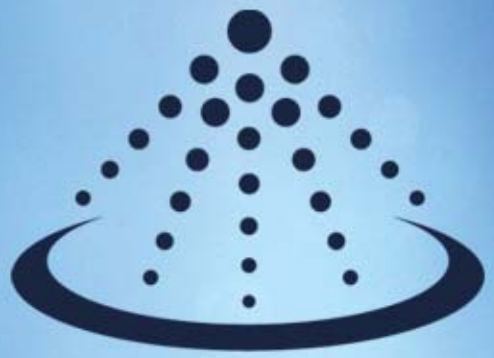

CSA

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CryoSprayAblation™ System

The ***SuperCool*** Choice™

Medical Device Product Development In the New Millennium: Bootstrapping 101

BIO IT Coalition Meeting

November 14, 2007

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"Hell, there are no rules here -- we're trying to accomplish something."

Thomas A. Edison, American Inventor

(1847 - 1931)

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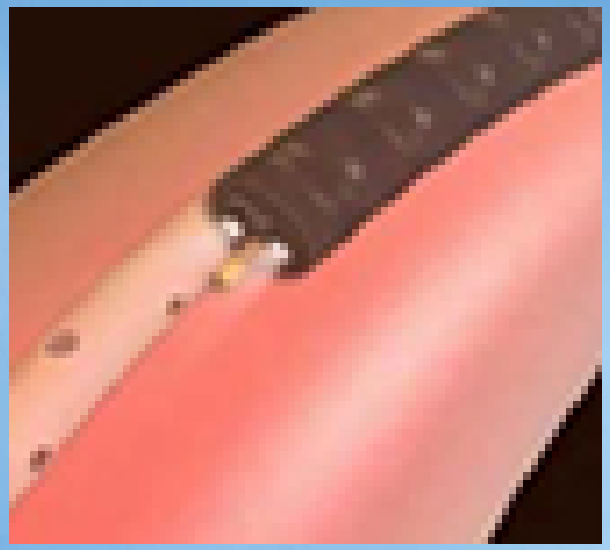
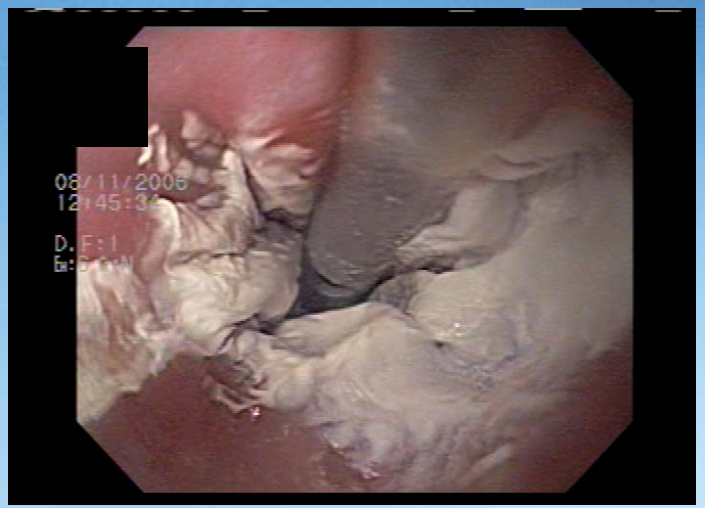
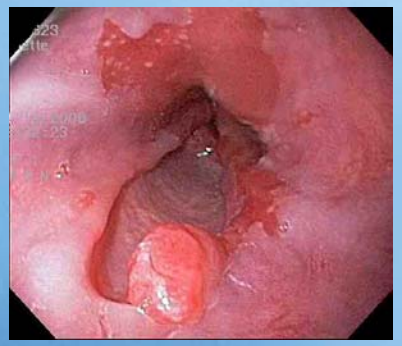
Cryo-Spray Ablation™







Before ***After***

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Classical Product Development

Design and Development Planning
- **Gantt Chart**
- **Assign Responsibilities**

Design Inputs
- **User Needs, Transferred into a Marketing Specification**
- **Set Target Specifications**

Design Process

Design Outputs
- **Concept Generation, Selection, Testing**
- **Initial Prototyping, Technical Modeling**
- **Product Testing**
- **Refine Design**
- **Design for Manufacturing**

Design Transfer
- **Initial Production Run**

Design Validation

****Design Reviews, Risk Analysis and Verification occur during the entire process.**

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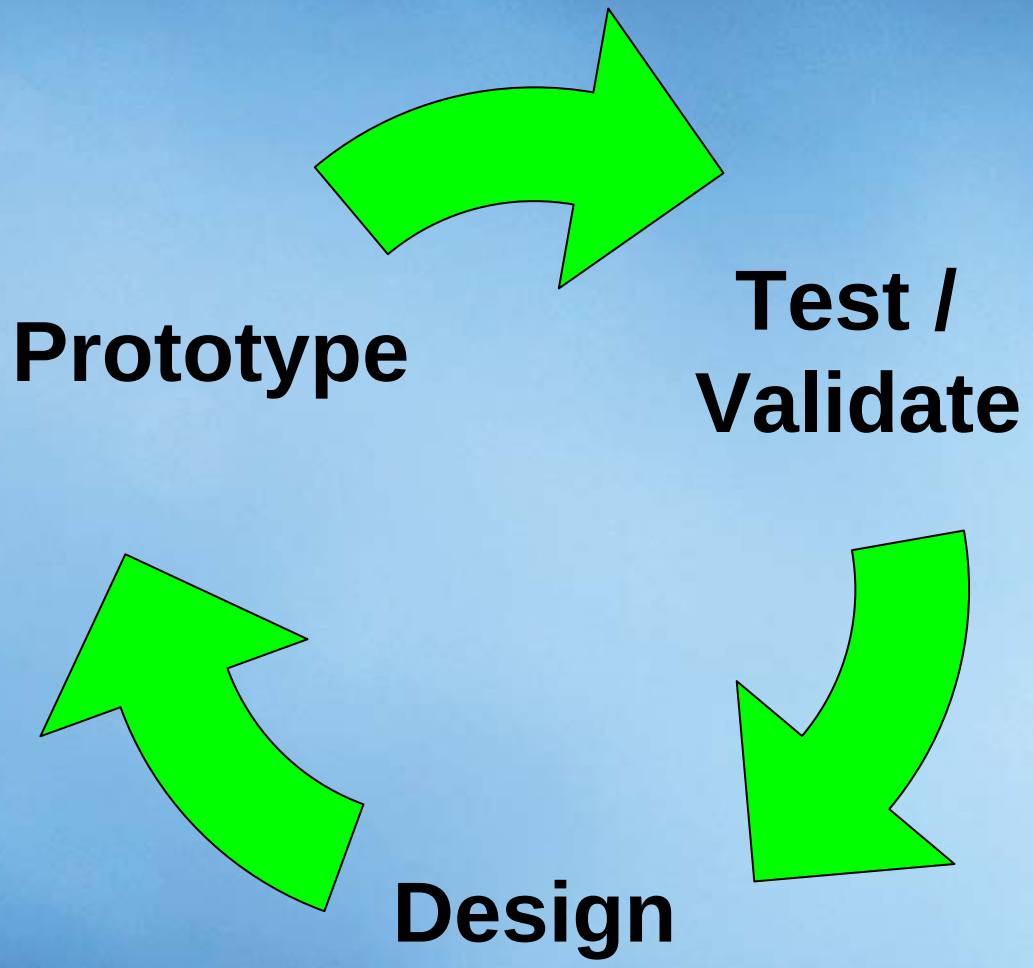
Product Development Lifecycle (by Tim)



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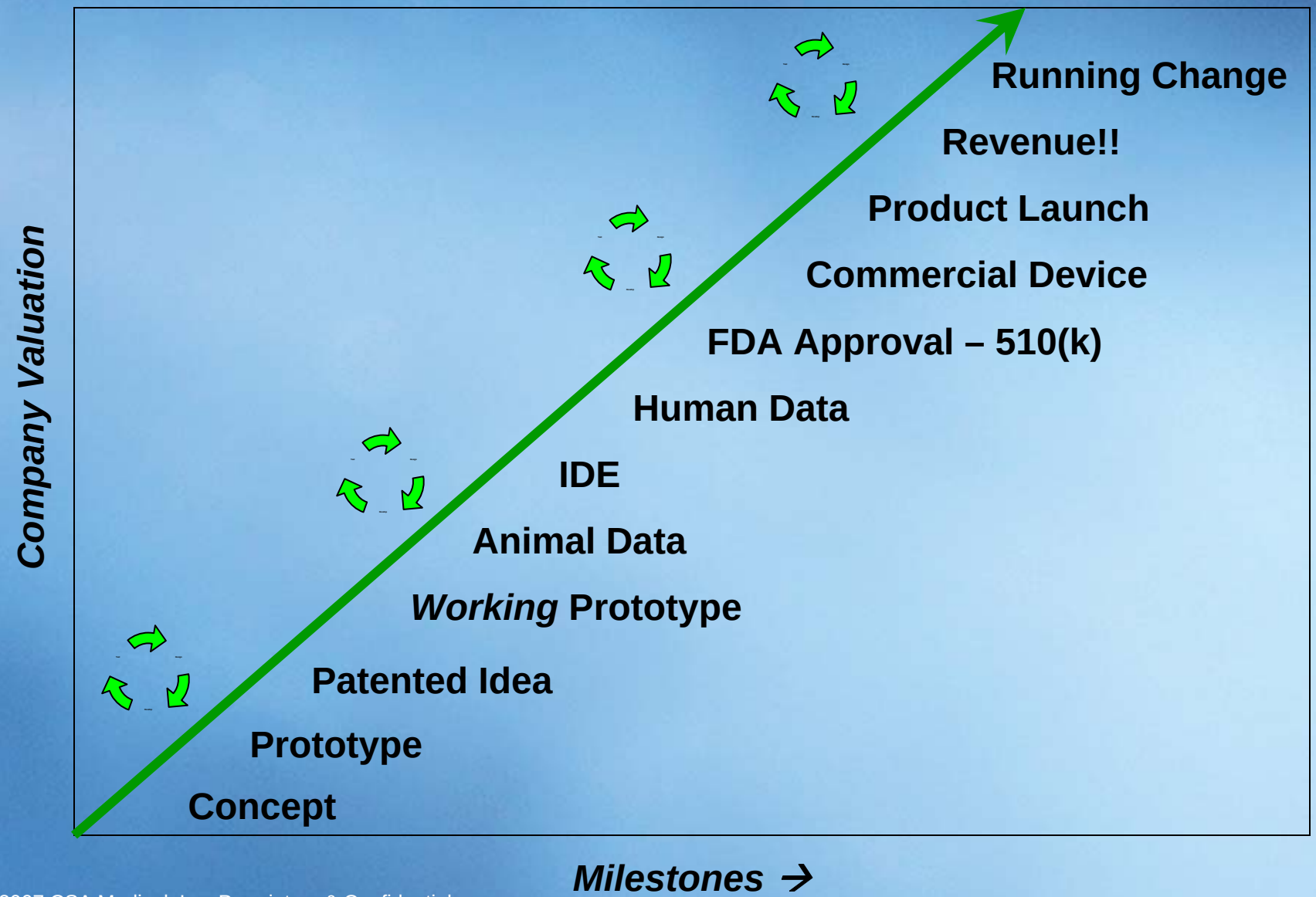
Milestone Valuation Model – Medical Devices



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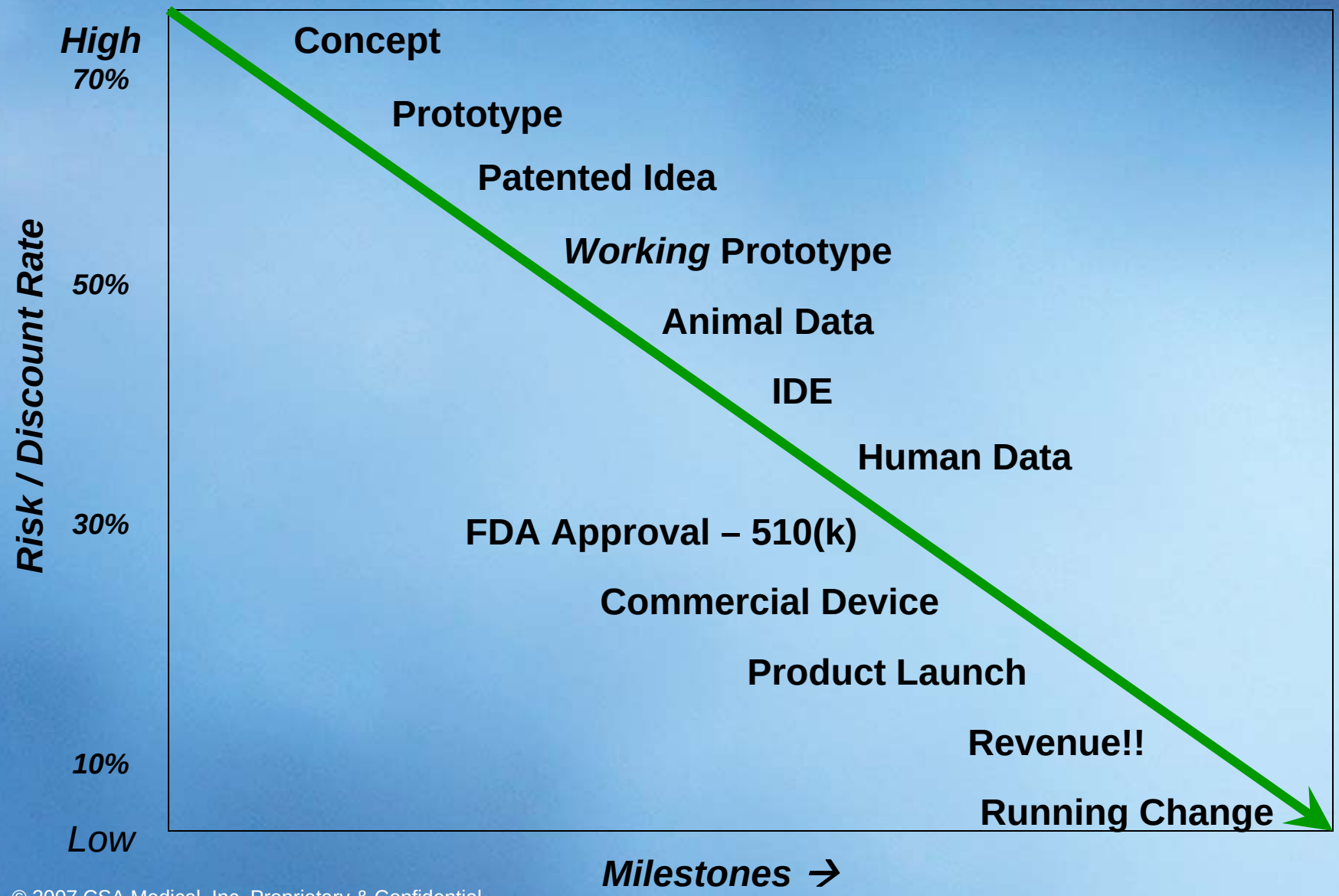
Milestone Discount Rate Model – Medical Devices



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The First Device – Concept Prototype

Prototype

Concept

Company Valuation

Milestones →

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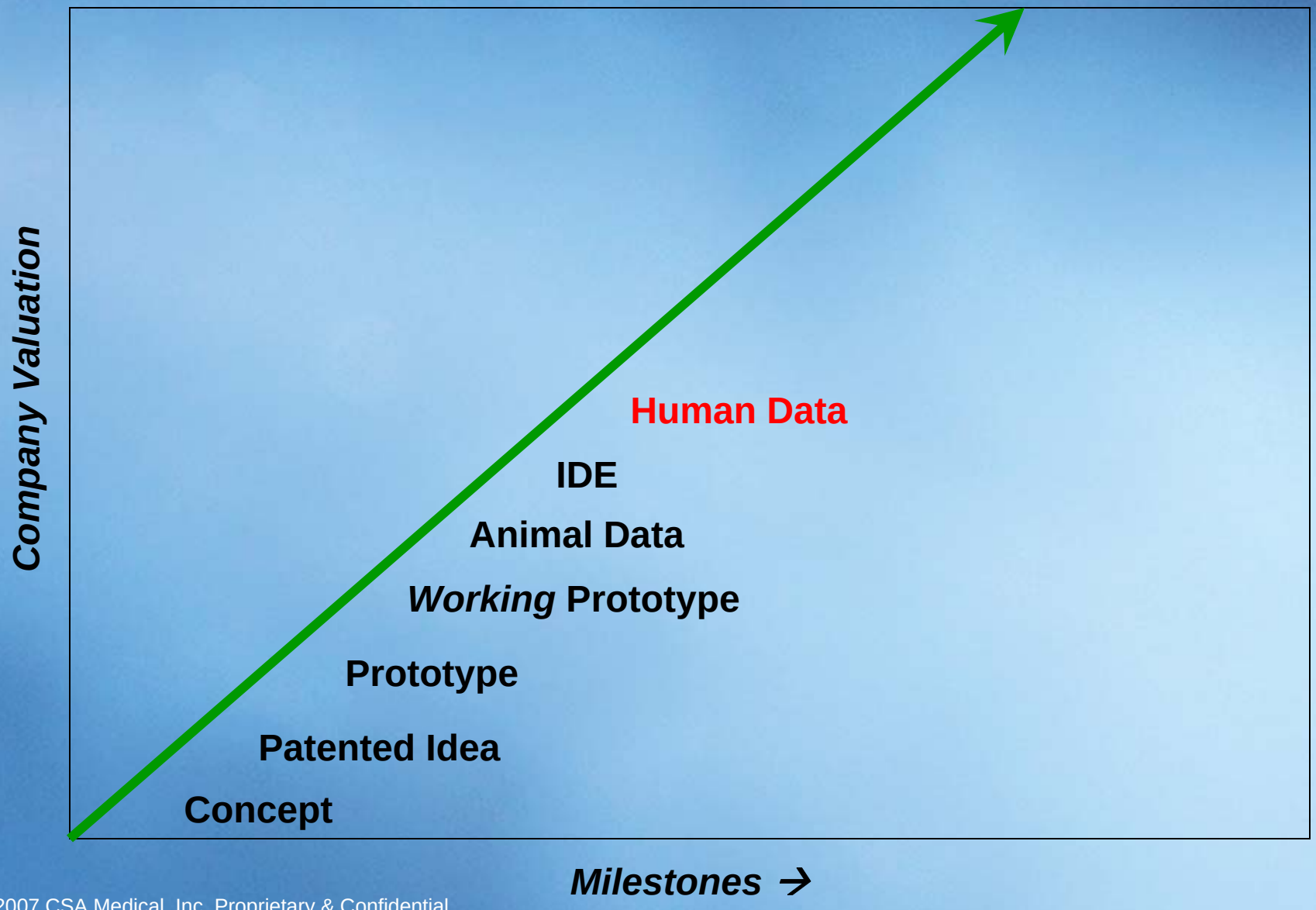
Milestone Valuation Model – Human Data



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The Second Device - Feasibility

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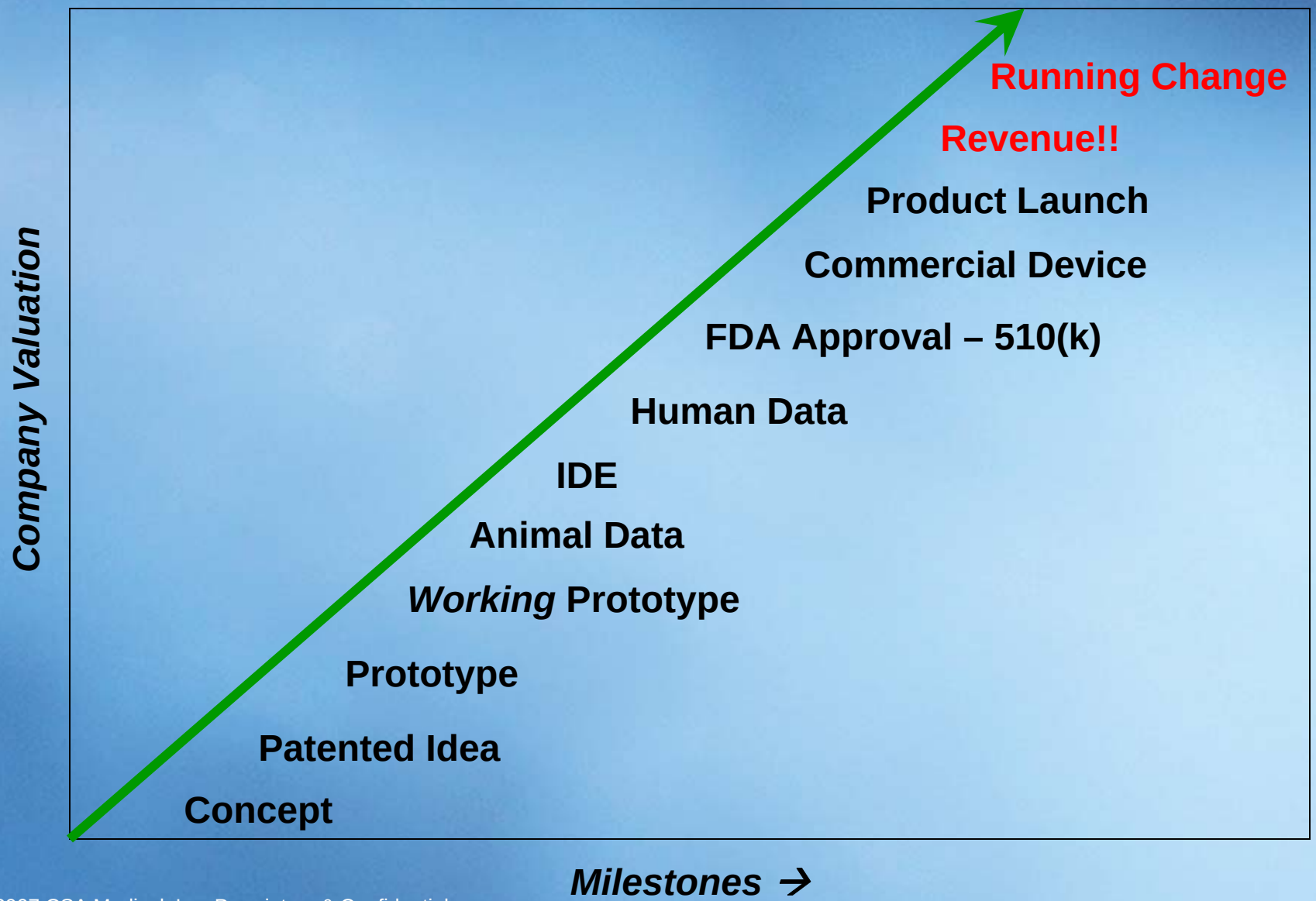
Milestone Valuation Model – Revenue!!!



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The Third Device - Commercial

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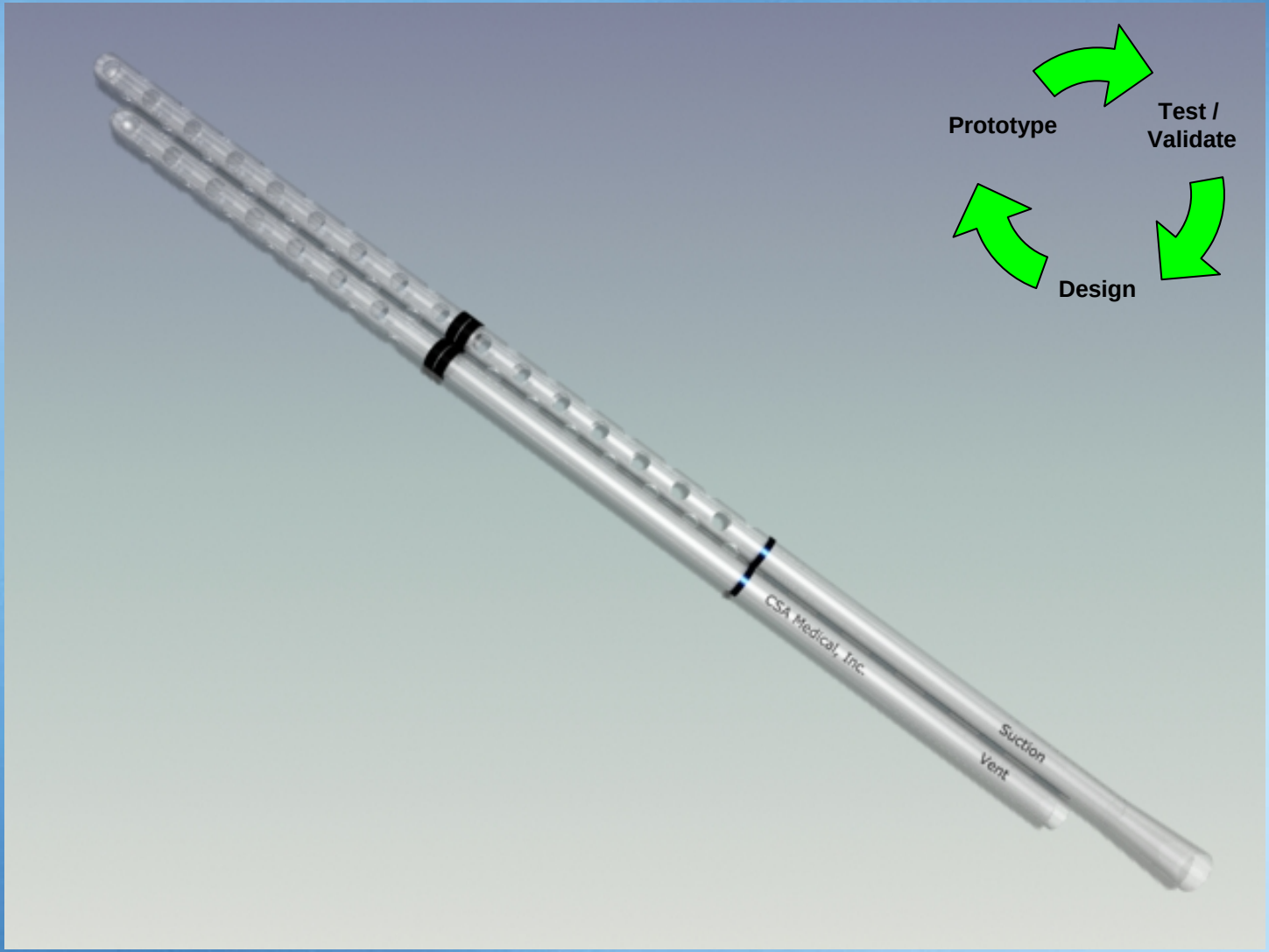
Future Development



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Lessons Learned

Identify the key value driving milestones on your path.

Hit the milestones….then negotiate!

Time is more valuable than money.
- Competition is hungry
- Market demands rapid change
- Technology is evolving fast

Money is a commodity, brains are of real value.

An idea is worth a dollar, implementation of the idea is worth a million dollars.

Have fun!

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