

# Disciplined Innovation: From Concept to Market in Medical Technology

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**Objective:** Provide an overview of how YOU can move a concept to market with the Chrysalis Process

# Introduction

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**Mark Gardner**  
Founder and Managing  
Partner



**Brendon Pittman**  
Founder and Partner



**Darryl Barnes**  
Founder and Partner



**Benjamin Tramm**  
Founder and Partner

# Professional Experience

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- ✓ Chief Technology Officer and Founder at Sonex Health, Inc.
- ✓ Partner and Co-Founder at Chrysalis Incubator
- ✓ 25+ years of clinical experience
- ✓ Groundbreaking projects



# Inventions and Innovations

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## ✓ Inventions

- Technology to treat carpal tunnel syndrome (UltraGuideCTR™), trigger finger syndrome (UltraGuideTFR™), tendon, bone and other soft tissue problems (Tenex TX System)
- AI-enabled Learning Management System: UltraGuideCo-Pilot™

## ✓ Innovations

- Importance of disciplined approach in developing medical technologies



# Why a Disciplined Approach?

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- ✓ Phase Zero process
- ✓ Foundation of successful projects
- ✓ Systematically addressing unmet medical needs



PHASE ZERO:  
SETTING UP FOR  
SUCCESS



PHASE ONE:  
STRUCTURING FOR  
SUCCESS



PHASE TWO:  
BUSINESS  
BLUEPRINT



PHASE THREE:  
SECURE FUNDING  
AND PLAN FOR  
LAUNCH

Is there an **unmet clinical need?**

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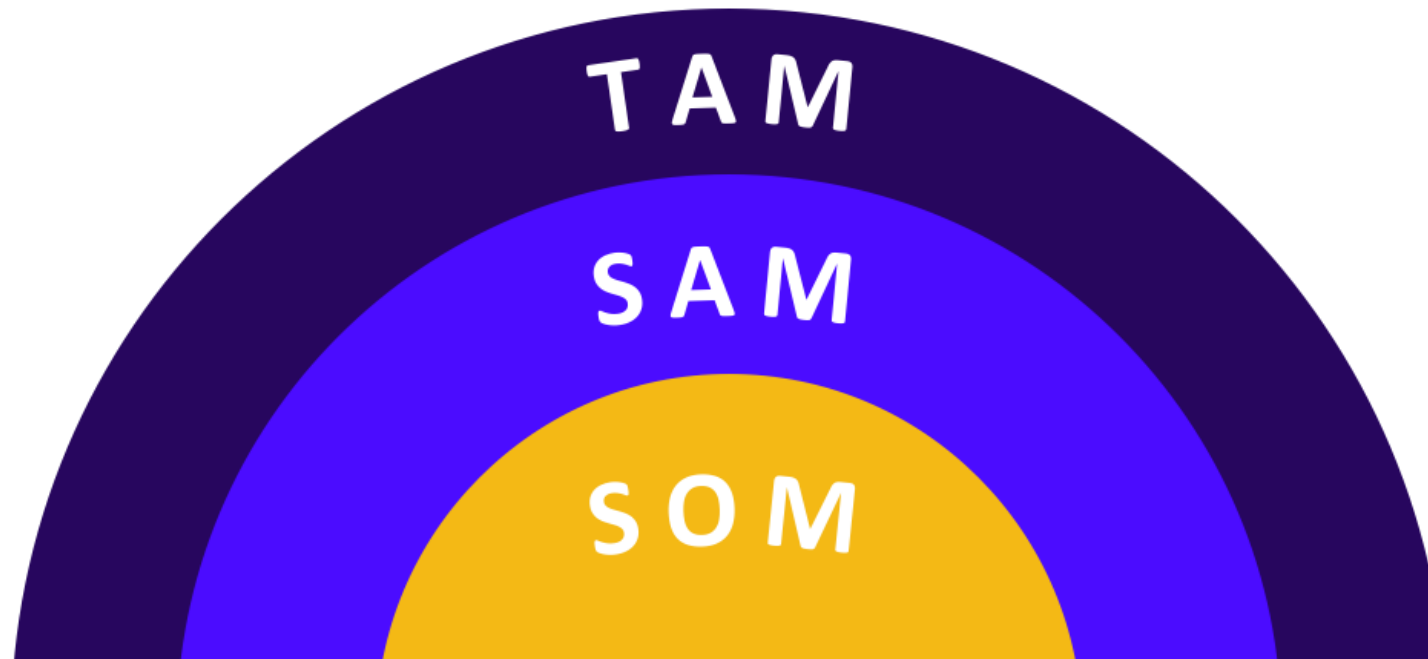
Whether it's a sketch on a napkin, patent, or prototype, have you defined and substantiated the unmet need?



# Is there a market?

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- ✓ Have you calculated the disease cascade and continuum of care?
- ✓ Have you determined **prevalence** and **incidence**?
- ✓ What is the Total Addressable Market, Serviceable Addressable Market, and Serviceable Obtainable Market?





# How do you develop the right solution?

- ✓ Human-centered design
- ✓ Meeting the needs of patients and HCP's
- ✓ Innovation and collaboration



# How do you apply for a patent?

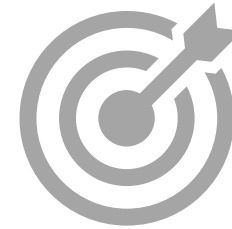
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Define the functions of the concept/products that will need patent protection



Confirm the ability to get the proper patents to continue



Conduct a competitive analysis

# How do you **finalize** the concept/product?

- ✓ Rapid prototyping
- ✓ Robust IP Strategy
  - Confidentiality and ownership considerations
  - Patentability analysis and landscape analysis
  - Contracts/agreements and IP protection
- ✓ HCP input



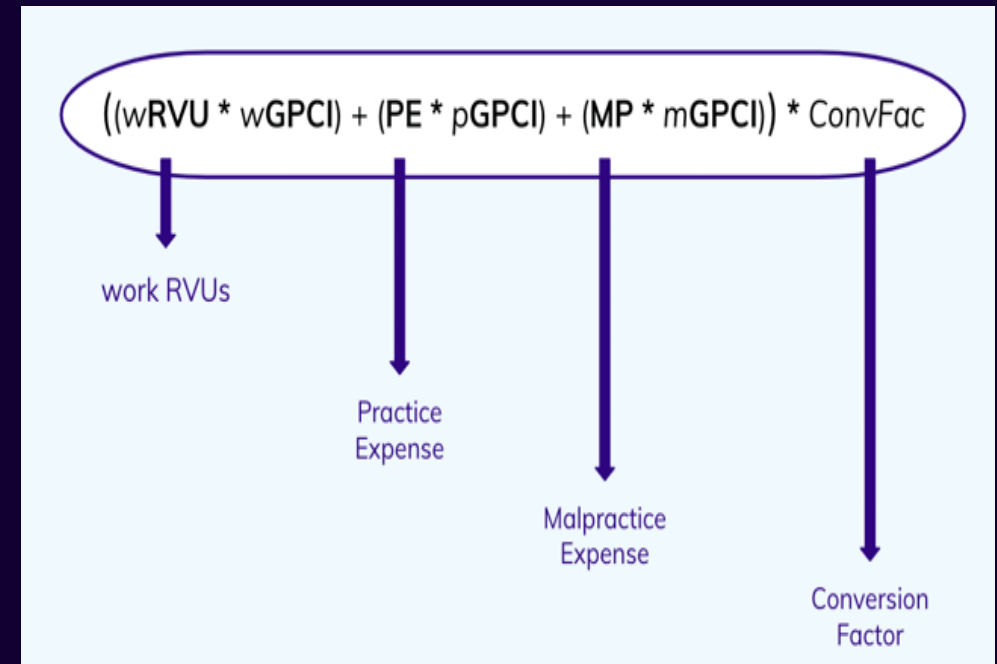
# When do you start to think about **FDA**?

- ✓ Look at Regulatory
- ✓ How will FDA regulate your future product?
  - Is it a medical device? A drug? A combination of the two? Is some other product class involved, e.g., a cosmetic?
- ✓ What “class” does the medical device fit into? Class I, II, or III?
- ✓ Will FDA require 510(k)- or De Novo- clearance, or a PMA-approval, or is the device waived?
- ✓ How much time and money is required depending on the class?
- ✓ What quality management system (Part 820) requirements exist?
- ✓ What do you need to start doing now in terms of planning?



# How do you determine the reimbursement pathway?

- ✓ Do you have a new product?
- ✓ Or is it like something that already exists?
- ✓ If your product is new, how will it be paid for?
- ✓ Who will pay for your product and/or service?
- ✓ Does adequate coding, coverage, and payment already exist?
- ✓ Or do you have something that the world has never seen for which you will have to forge a new pathway to reimbursement?



# Is clinical evidence needed for every product?

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✓ What evidence is needed?



✓ Animal, Cadaver, Human requirements based on regulatory path

# What will **investors** look for?

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Carefully crafted  
strategies



Robust pitch deck





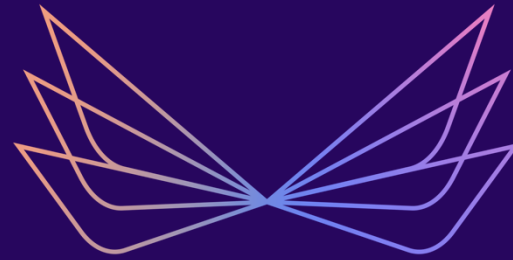
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# Thank You

[chrysalisincubator.com](http://chrysalisincubator.com)







# Questions

[info@chrysalisincubator.com](mailto:info@chrysalisincubator.com)

612.382.7584

# Appendix

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# Marketing Strategy

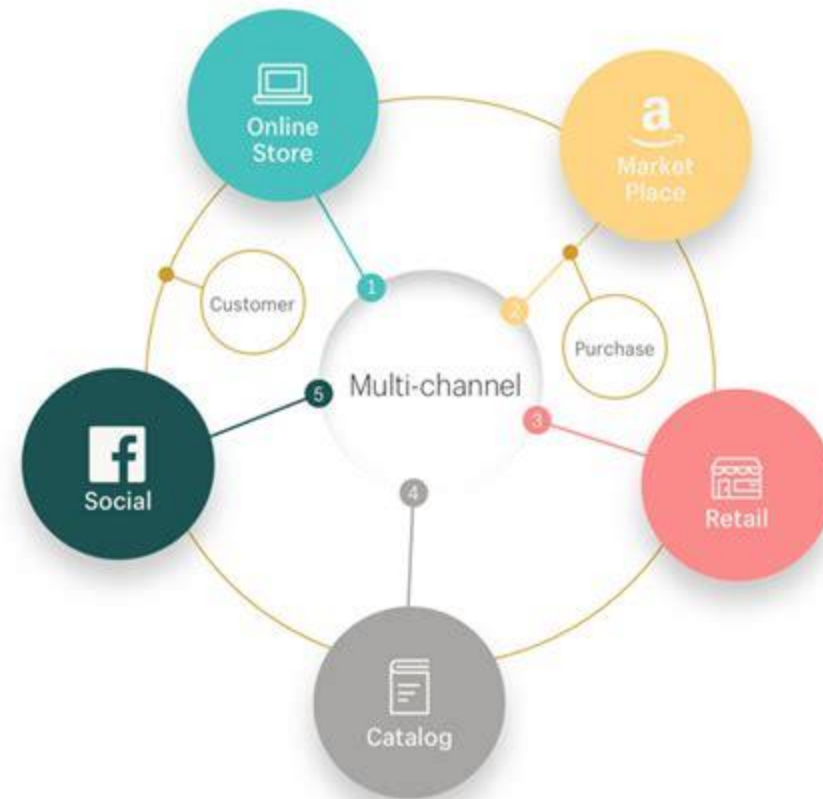
- ✓ Identify target audience
- ✓ Model market opportunity
- ✓ Ensure market validation
- ✓ Crafting compelling value proposition
- ✓ Developing marketing claims

Rogers's Innovation Adoption Curve



# Sales and Distribution Strategy

- ✓ Selecting distribution channels
- ✓ Complying with legal and regulatory requirements
- ✓ Maximize market penetration via multi-channel strategies



# Competitive Advantage Strategy

- ✓ Identifying competitors' offerings
- ✓ Developing competitive positioning
- ✓ Creating FDA cleared messaging



# Reimbursement

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- ✓ Do you have a new product?
- ✓ Or is it like something that already exists?
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- ✓ Who will pay for your product and/or service?
- ✓ Does adequate coding, coverage, and payment already exist?
- ✓ that the world has never seen for which you will have to forge a new pathway to reimbursement?

# Conclusion

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- ✓ Thank you for joining us today!
- ✓ Insights into our disciplined approach and expertise at Chrysalis Incubator
- ✓ Visit [www.chrysalisincubator.com](http://www.chrysalisincubator.com) for more information

# R&D Strategy

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- ✓ Human-centered design
- ✓ Meeting the needs of patients and healthcare providers
- ✓ Innovation and collaboration



# Clinical Strategy

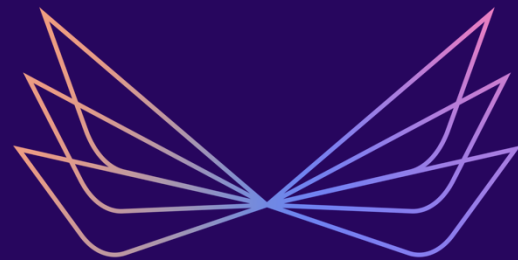
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- ✓ Integrated clinical evidence strategy
- ✓ Aligning clinical strategies with regulatory requirements
- ✓ Managing risks through systematic planning

# Intellectual Property (IP) Strategy

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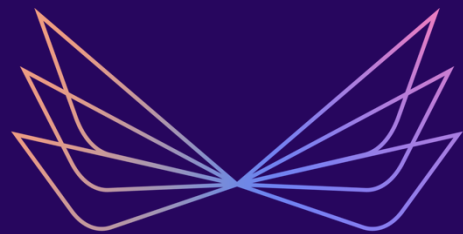
- ✓ Keep it secret
- ✓ Consult with an IP attorney
- ✓ Consider patent protection
- ✓ Ensure you own it
- ✓ Consider landscape and freedom to operate analysis



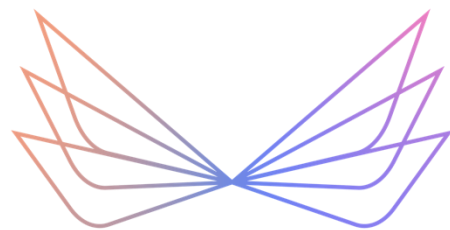
Questions



Questions



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