

NCAI-CC

NIH Center for Accelerated Innovations
at Cleveland Clinic



Key Resources in Biomedical Product Development

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Business Model - Definition

- What does it mean to have a **Business Model**?
- A business model describes the **rationale** of how an organization **creates**, **delivers**, and **captures value**, in economic, social, cultural or other context [Medical].
- So, what are the **Most Important Resources** required to make the **Business Model work**?

Key Resources

- What are the key resources does your Value proposition require?
- What competencies, assets and resources underpin your Business Model?
- What are the key resources that drive your business?

Medical Devices

Intellectual Property

Regulatory & Reimbursement Strategy

Proof of Concept

Bench Testing

Non-GLP Animal Studies

Product Optimization

V&V Testing

GLP Pre-Clinical Val.

First in Man

Unmet Clinical Need Definition

Functional Testing

MVP Testing

Product Design Input Defined

Pilot Manufacturing

Acute Safety and Efficacy Studies

510(k), PMA, CE-Mark, etc...

MVP Definition

Mechanical Testing

Safety Studies

Design Iterations for Optimization

BioCompatibility

Chronic Safety and Efficacy Studies

Feasibility Studies

Chemical Testing

Efficacy Studies

COGS Studies

Sterilization Validation

Customer Feedback

R&D Manufacturing Process

Human Usability Studies

Packaging Validation & Labeling

Business Plan Development

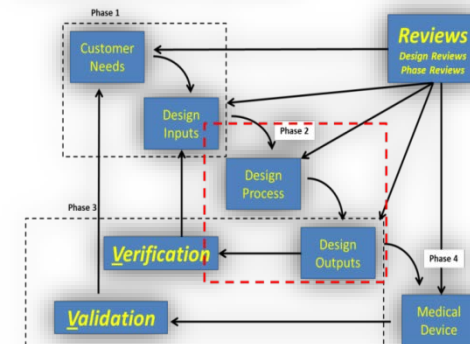
R&D Manufacturing Procedures

Real-Time and Accelerated Aging

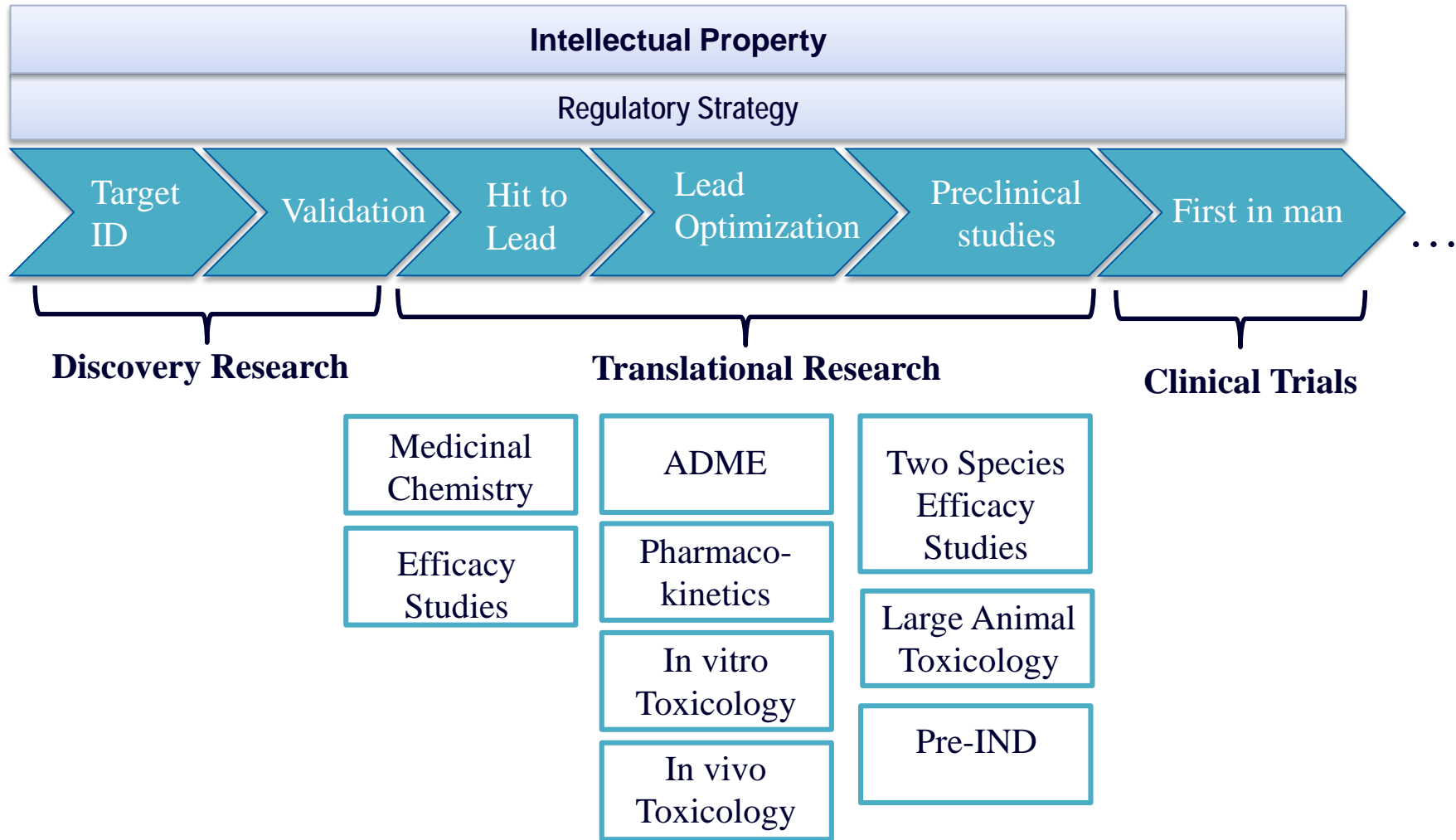
R&D Inspection Procedures

Sterilization Method

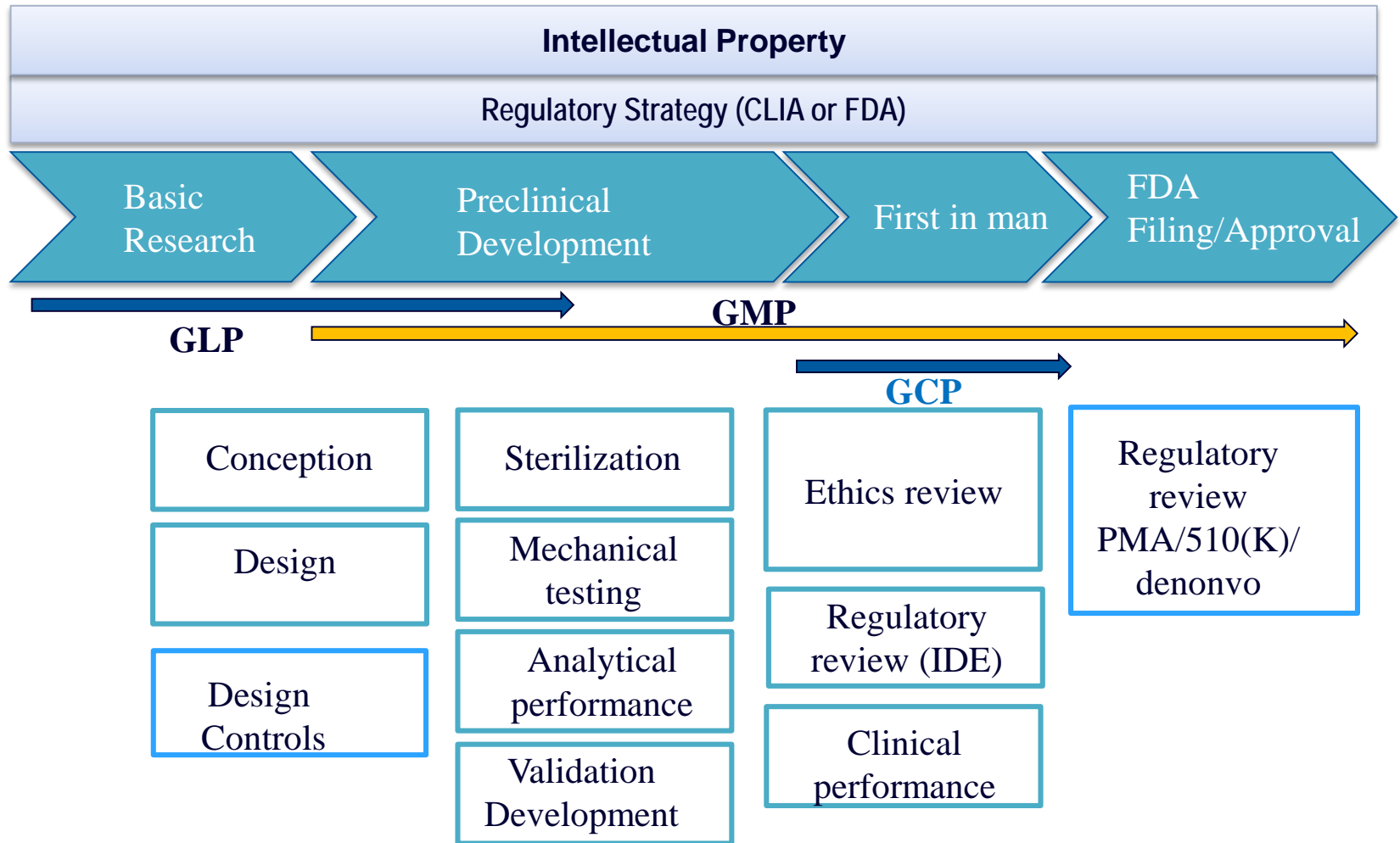
Design Controls Waterfall



Therapeutics Projects



In vitro Diagnostics Products



Critical Startup Resources

- Financial
- Physical/Tangible
- Intellectual Property / Intangible
- Human Capital

Financial Resources

INCREASE COST OF CAPITAL

- Self-Funding
- Friends
- Family
- Crowdfunding
- Angels
- Grants

Lower Magnitude

- Venture Capital
- High Net Worth
- Angels
- SBIR/STTR
- SBA.

- Venture Capital
- Corporate Funding
- Venture Debt
- Bank Financing
- Lease-lines
- Factoring
- Vendor Financing

High Magnitude

Financial Resources

FINANCING

- Friends
- Family
- Crowdfunding
- Angels
- Venture Capital
- Corporate Partners
- SBIR/STTR Grants
- SBA

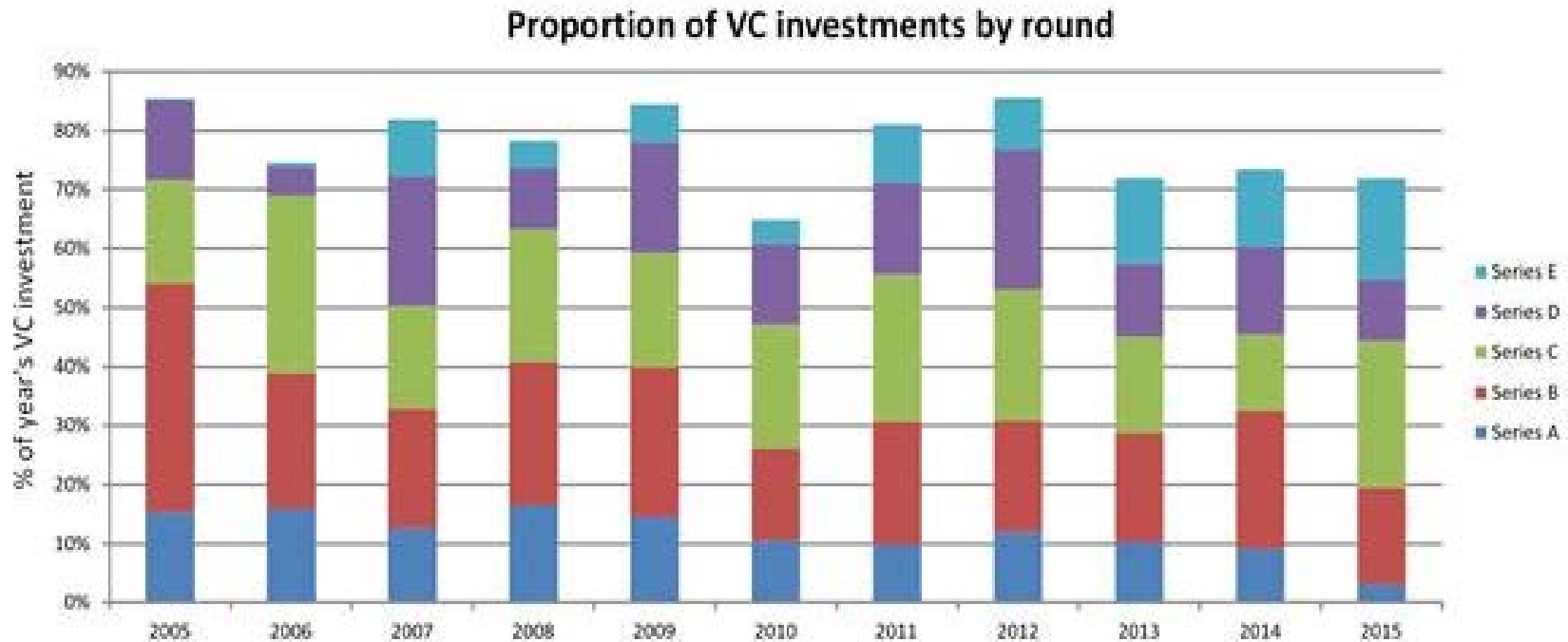
OPERATING

- Lease-Lines
- Venture Capital
- Factoring
- Vendor-Financing
- Corporate Partners
- SBIR/STTR grants
- SBA

Current Fundraising Environment

- Weaker funding outlook for biomedical technologies.
- Existing financial models have collapsed and new models are being explored.
- Number of VCs down > 60%
- Amount of available cash down >60%
- Available cash being used to support existing portfolio companies.

Here are the numbers...



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Tactics to Raise Funds

- Start with Angels and Angel Groups
- Seek knowledgeable investors
- Don't get too hung up on valuation and terms
 - Strong partners are invaluable in tough times
- Agree on major milestones and definitions
- Syndicate strength is a critical resource
 - Avoid a single investor; seek multiple investors

Critical Startup Resources

Financial

Physical/Tangible

Intellectual Property / Intangible

Human Capital

Physical/Tangible Resources

- **Company facilities:**
 - What is the best place to locate your company's Headquarters?
 - Where are you going to do most of the work?
 - Single or multiple
 - Office Space, Laboratories, Warehouse, Manufacturing
- **Products/ Services:**
 - What is the best geographical location to access relevant services?
 - Warehouse spaces location.
- **Physical goods are capital intensive:**
 - Therapeutics (high capital) vs. Software Development (low capital)
 - How do you organize your finances (leasing, lease-to-buy, buying)?
 - How do you scale up the business? R&D manufacturing using physical goods vs. full-scale manufacturing?
 - Examples:

Physical/Tangible Resources

- Virtual medical device companies can sometimes skirt the need for physical infrastructure
 - Management in separate locations
 - Outsourced R&D
 - Outsourced low volume manufacturing
 - Outsourced clinical trial run by a CRO
- Understanding how to transition from a virtual company to brick-n-mortar.
- Virtual company model works best for “pure product” plays where company is “built to flip”
 - Limits exit possibilities since essentially no Plan B

Critical Startup Resources

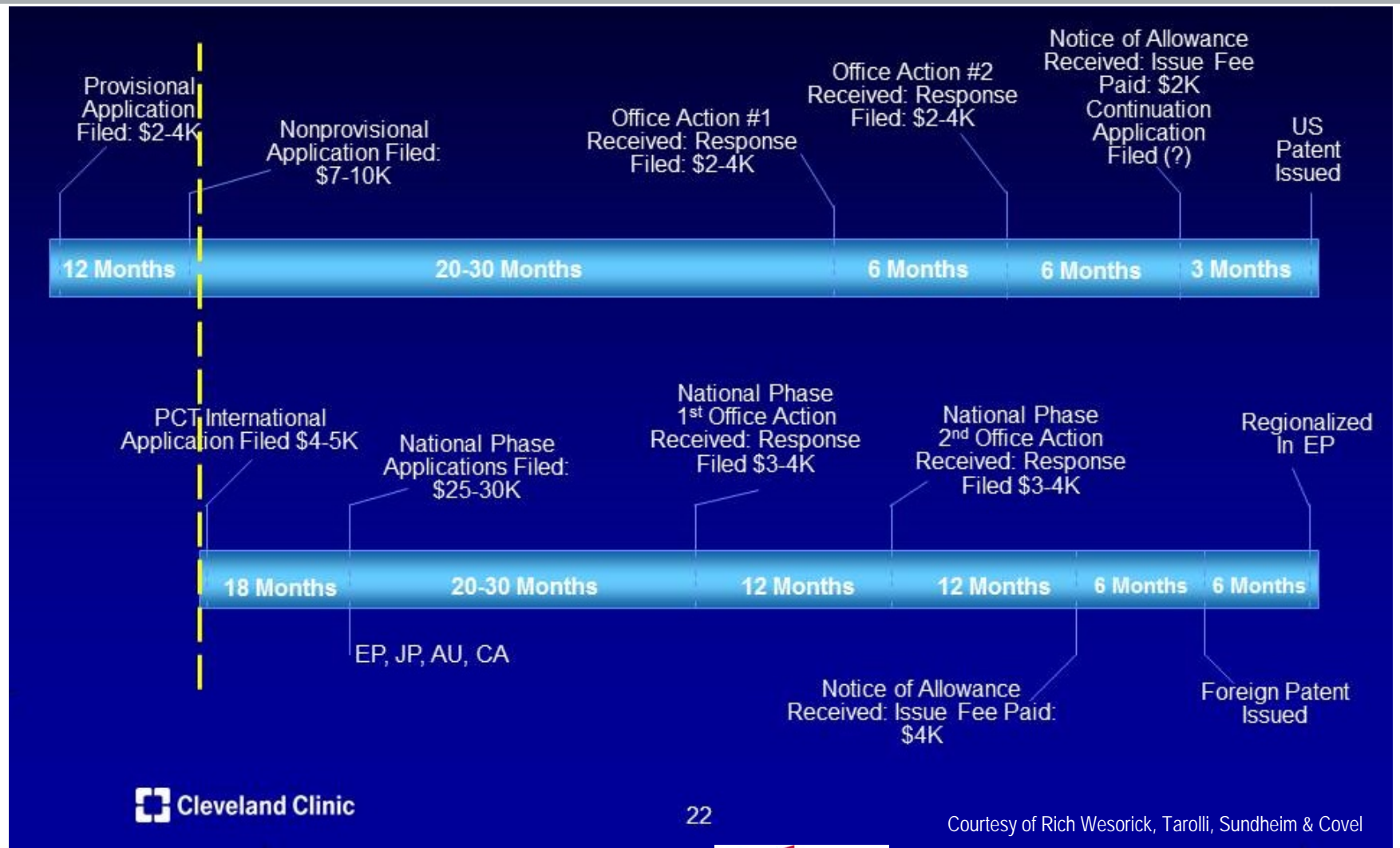
- Financial
- Physical/Tangible
- Intellectual Property / Intangible
- Human Capital

Intellectual Property

- Intellectual Property creates value

Type	Protectable	Examples
Trademark	Branding	Marks, logos, slogans
Copyright	Creative Work	Software, films, music, websites
Trade Secrets	Secrets of Value	Private Tech, contacts, formula
Contracts	Contract-Defined	Technology, business info
Patent	Inventions	New Technology

Patent Prosecution Timeline



Critical Startup Resources

- Financial
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Human Resources - Business Success

- Finding Qualified & Motivated Employees
 - Critical importance of an A-Team
 - Surround yourself with experienced consultants
- Build a corporate culture embodying the team's essence.
- Some resources focus on Business Success
 - Clinical, Scientific and Business advisors
 - Executive Chairpersons

Human Resources – Advisors vs. Investors

- Advisors – People you need to help advance your company's success.
- Founders fail when they believe their visions are facts.
- Listening to experienced advice can help you sort out the whether your vision is a hallucination.
- Get an advisory board for customer development
- Investors are your employer.

Early Stage Human Resources

INCEPTION

- Founder(s)
- Hands-on Person
- Patent Lawyer
- Regulatory Advisor
- Reimbursement Advisor
- Key Opinion Leader(s)

SERIES A

- Founders
- Management Team
- Executive Chairperson
- Scientific Advisory Board
- Hands-on engineers
- Patent Lawyer
- Regulatory Advisor
- Reimbursement Advisor
- Key Opinion Leaders
- Principal Investigators

Concluding Questions

- What is your Minimum Viable Product?
- How many staff members do you need for your business?
- How many are hired as FTE? Consultant?
- Do you need a physical location or can you be virtual?
- What is your Product Development Plan?
- What are your milestones?
- How much money do you need to achieve your milestones?
- What is your contingency funding needs?
- What equipment do you need? and at what stage in development?
- What is your ASP? And what is your COGS?
- What milestone do you need to achieve for follow-on funding?

HOW MUCH \$\$ DO YOU NEED?

GCIC

Global Cardiovascular Innovation Center

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NIH Center for Accelerated Innovations
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Thank you

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