Translating Academic Concepts to Commercial Medical Products:
A Complex Academic/Industrial Partnership

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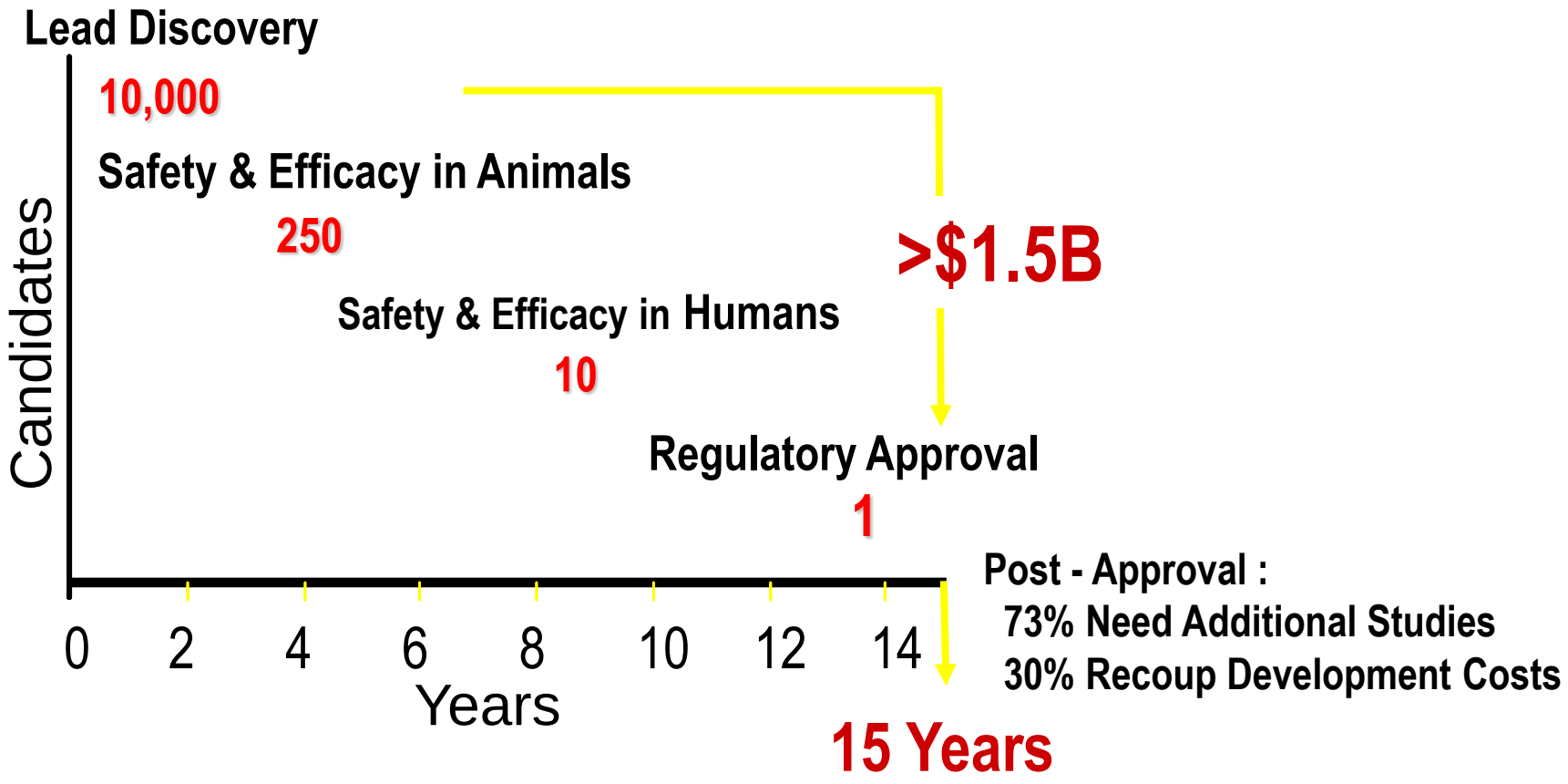
Focus: Medical Product Development

Outline

- Medical Product Costs, Development Protocol
- Medical Product Resourcing: Hypothetical Case
- Product Selection Criteria
- Concluding Remarks

Development Costs
Pharmaceuticals/Biopharmaceuticals



Center for Study of Drug Development, Tufts University, 2003 - 2005
G. Neill, J&J, AIMBE, Feb. 20, 2011

Typical Development Costs for New Class III Medical Device (Rough Estimate)

- Preclinical Costs- $10-$20M
- Clinical/Regulatory Costs- $20-$40M
- Sales, Marketing, Finance, Etc.- $10-$20M
- Manufacturing Development- $10-$15M
- Total Costs to Launch- $50-$95M

Timescale: 5-10 Years

A Kaplan et al,, Circulation, 2004; 109; 3068-3072 and Personal Estimates, 2007.

Efficiency of Corporations, 2011*
(Net Cost Per Employee for Operations)

2011

R-E/# = Cost / Employee

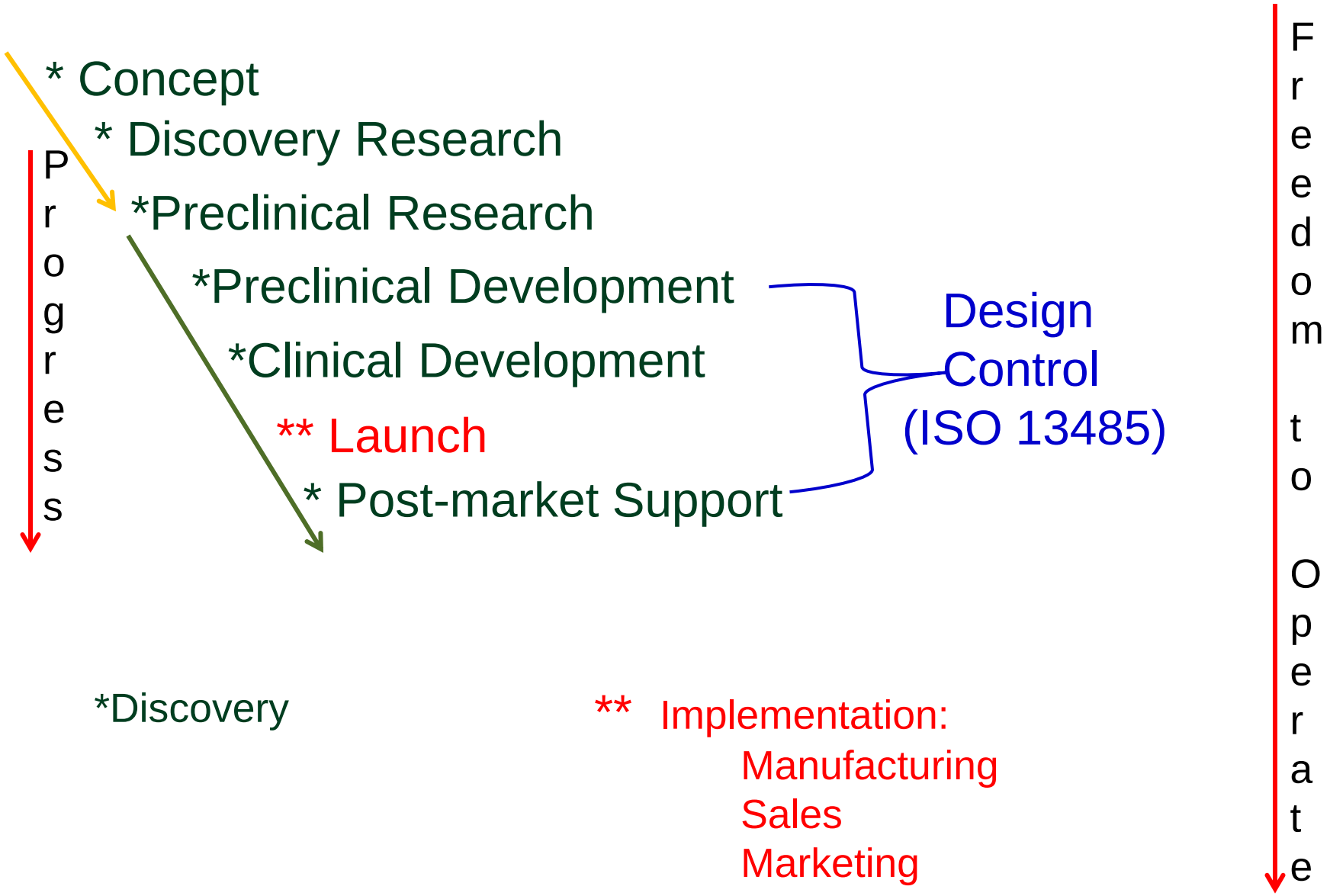
Firm	Revenues (R)	-	Net Earnings (E)	/	Employees (#)	2011	2009	2007
Medtronic	$15.9 B	-	$3,1 B	/	45,000	$285,000	$327,000	$297,000
Boston Sci.	$ 7.6 B	-	$0.44 B	/	24,000	$298,000	$354,000	$354,000
C.R. Bard	$2.9 B	-	$0.33 B	/	12,100	$212,000	$188,000	$176,000
J&J	$65.0 B	-	$9.7 B	/	117,900	$469,000	$351,000	$435,000
(Genzyme**	$ 4.0 B	-	$.32 B	/	10,000	$368,000	$371,000	$406,000)
Amgen	$15.3 B	-	$3.7 B	/	17,600	$659,000	$560,000	$663,000
Novartis	$58.6 B	-	$13.5 B	/	123,700	$399,000	$440,000	$261,000

Focal, Inc.(1992-2001), Peak Burn Rate/Peak # Employees:~$19M/125 = ~$152,000

**Data for 2010, Last year of Genzyme independent operations

*Sources: Corporation Websites, Annual Reports

Product Development Pathway



Hypothetical Case:
New Biologic/Device Combination Product

Assumptions:

- Existing Delivery Matrix/ Recombinant Natural Protein (e.g., BMP-2)
- ~$200 Million Development Costs
- Initial R&D with VC, “Angel,” or Government Funding
- Initial Funding Only Covers Discovery Research + Limited Preclinical Research
- Follow-On Funding needed to Bridge Discovery → Development

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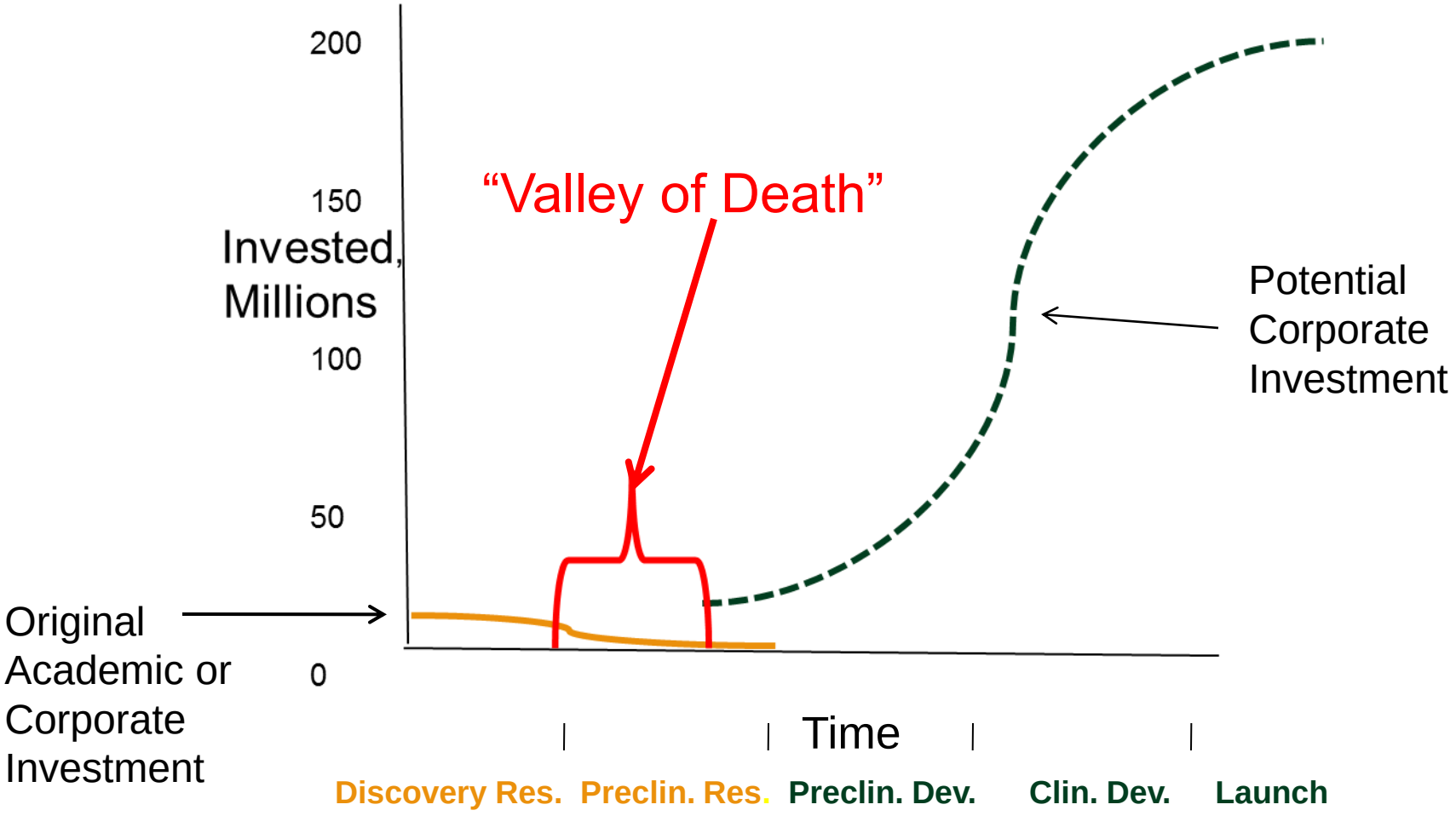
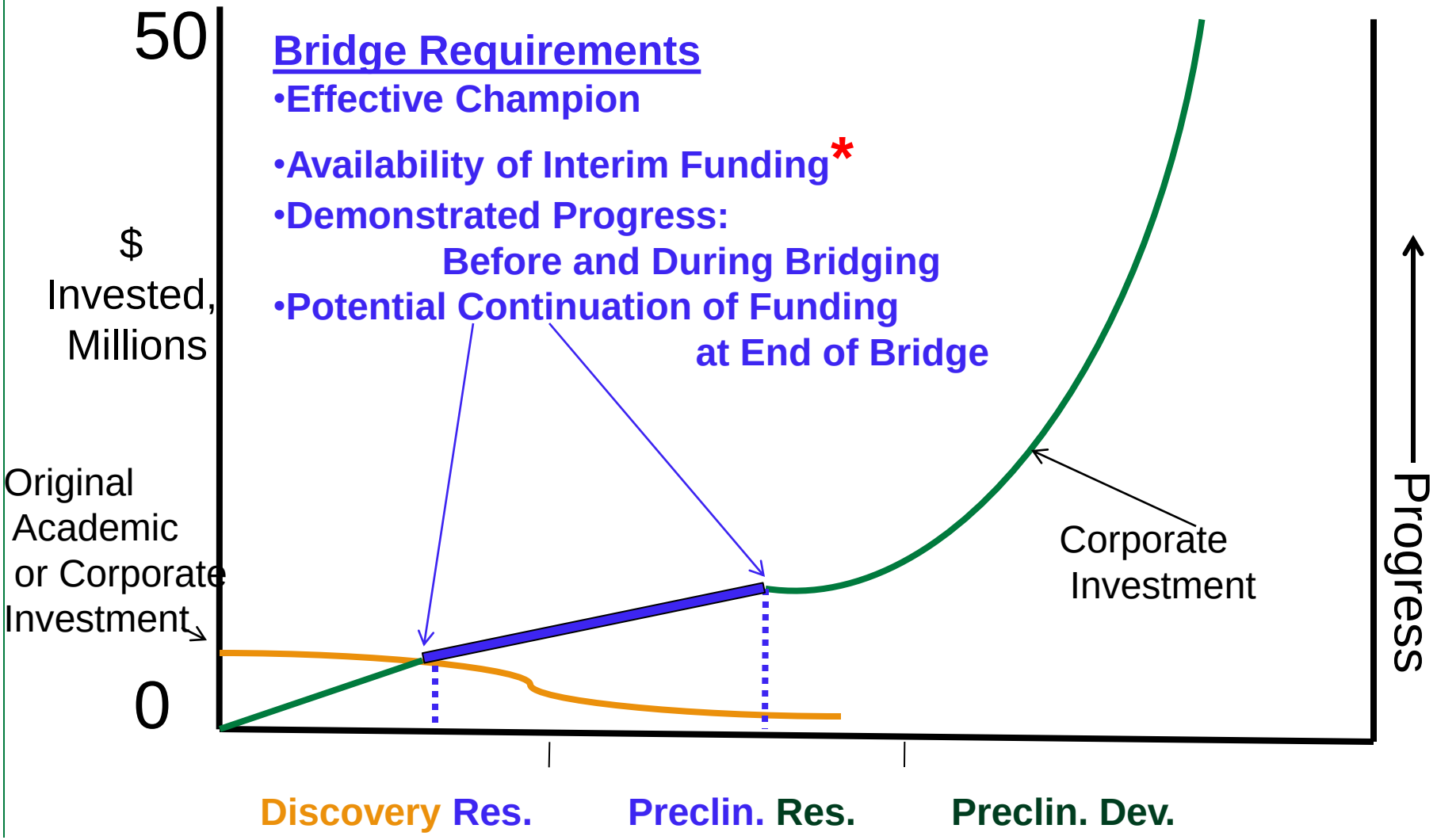
Most Product Development Fails in the “Valley of Death”

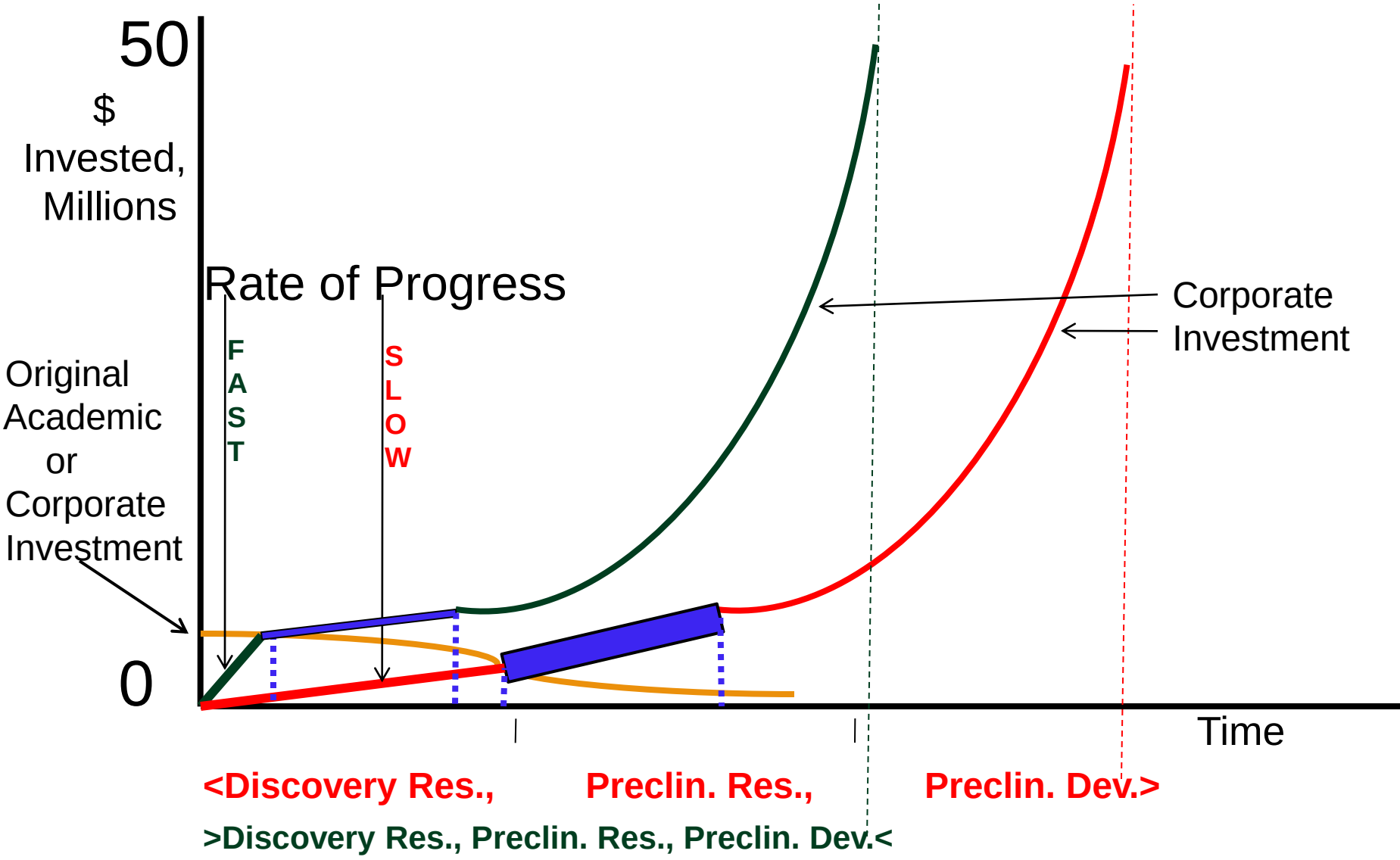


Bridging "Valley of Death"



*VC, Government, "Angel," Foundation, Corporate, University, Etc.

Translation Requirements



Product Development: Selection Criteria

- Mission, Vision, Culture
- Product Mix Strategy
- Fiscal “Health,” (Finances, Stock Movements, Etc.)
- Maturity: Start-up $\longrightarrow$ Mature
- Potential Adoption Curve
- Market Potential
- Reimbursement Potential
- Intellectual Property, Internal or External
- Competition
- Project Champion
- Staff Capabilities: Lab, Clinical, Manufacturing (Scalability), Sales, Marketing, Etc.
- Availability of Staff for Project, Staff Mix
- Availability of Materials, Products from Outside
- Physical Plant: Equipment, Space, Etc.
- Project Costs
- Timing Considerations: Handoffs, Funding, Regulatory, Clinical, Marketing, Etc.
- Publication Strategy
- Business Climate: Economic, Societal, Regulatory, Liability, Image, Morale, Etc.
- Exit or Survival Strategy

Strategic Product Choices

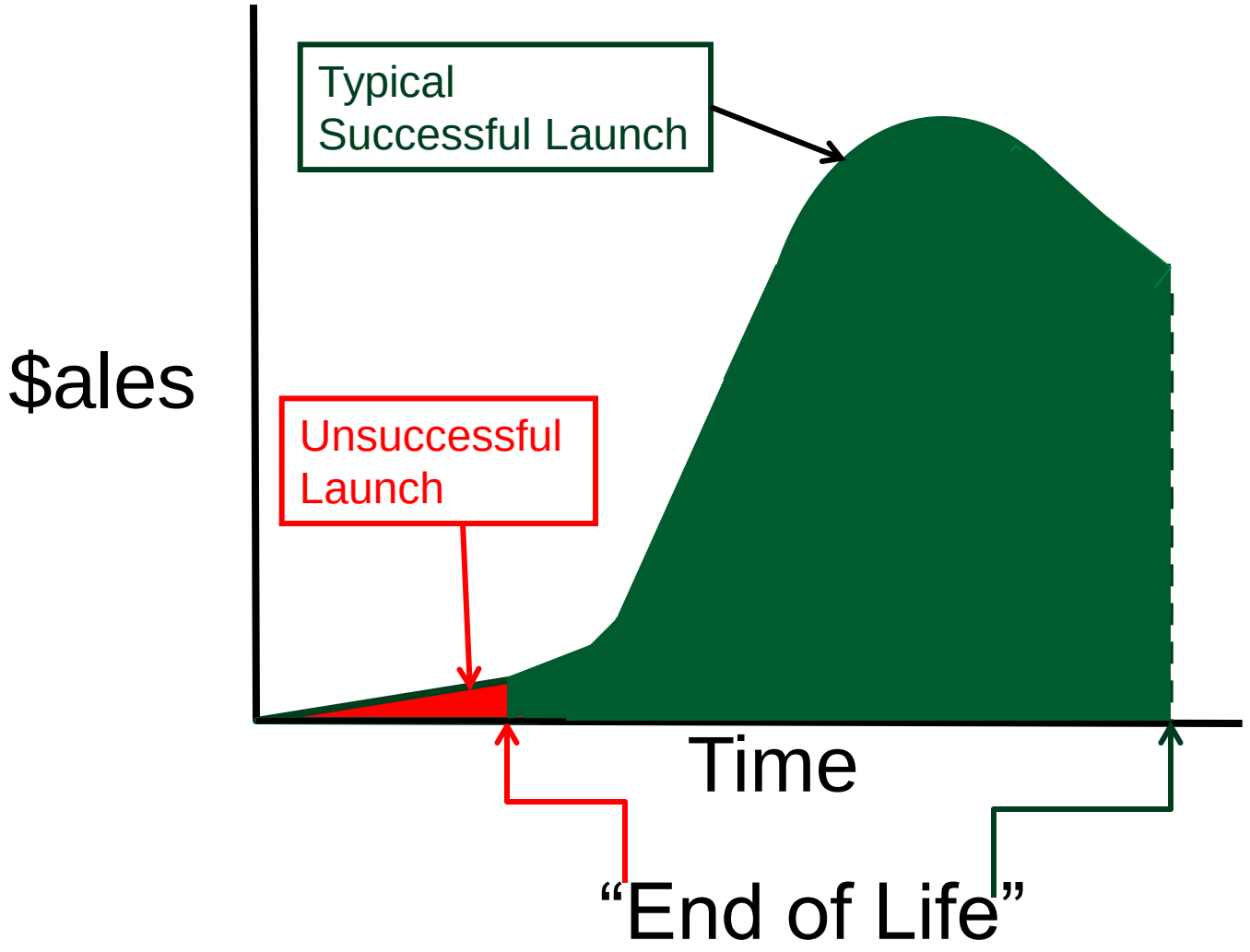
	Comparing 2 Products
Market	# Patients
Product Sophistication	High-Low
Development Costs	$$$-$
Regulatory Pathway	PMA-501K
Implementation	Elective-Imperative
Utilization	%
Unit Price	$
Market Potential	$
New Product Intro	Timing
Implications	Product Improvements, Pipeline , etc

Limits to Value of Academic Licenses

Comparing Academic vs. Corporate Investment

- University vs Corporate Expenditures
- Funding Sources, University vs. Company
- Contribution of University vs. Company to Intellectual Property
- Stage of Development at Time of Licensure
- Totality of Licenses for Product
- Projected Revenues and Profits at Time of Licensure
- Degree of Risk Assumption by Company
- Profitability of Product when Marketed

Product Adoption Curve



Concluding Remarks

If medical product is goal:

- Be product-focused from the start
- Select product/project based on meeting Product Development Selection Criteria *a priori*
- Urgently make as much progress as possible with initial funding
- Appoint effective, articulate “Champion” to advance project, develop bridge funding, strategic partners
- Use “bridge” funding to make maximum product-oriented progress
- Collaborate with strategic partner during project transfer and for problem solving thereafter if applicable
- Have realistic expectations of state of progress and value of technology if academic-corporate transfer: Medical products may be derived from many patents
- Expect goals, project plans and evaluations to be driven by quality system (e.g. ISO 13485) imperatives in development stage
- Realize that, no matter how great the staff and promising the product, most programs change original direction, but:
- The experience, knowledge and reputations gained are never lost for future enterprises.

Thank You

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