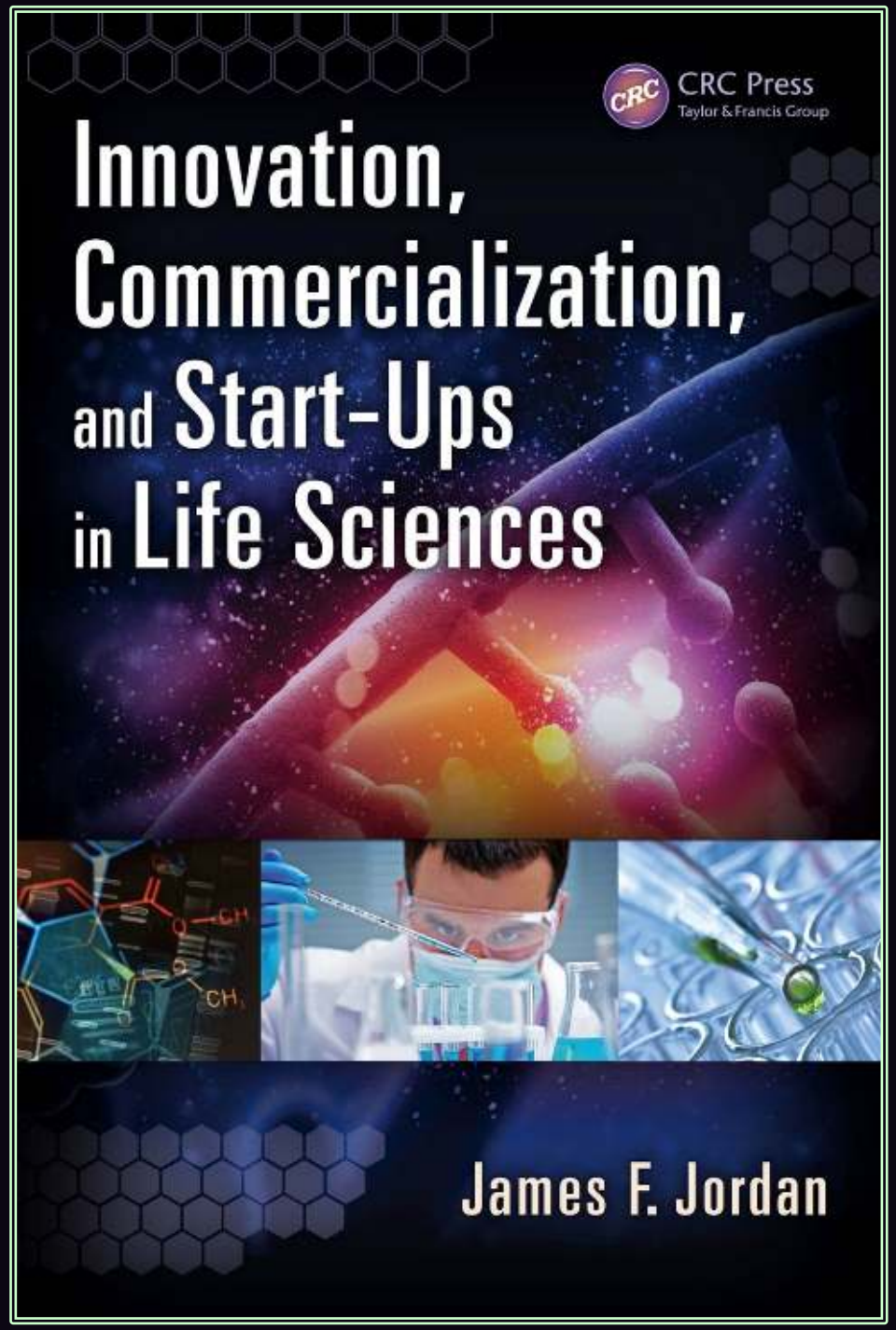
Biotechnology Entrepreneurship Boot Camp

Positioning Life Science Companies For Accurate Valuation & Strong Exit


CRC Press
Taylor & Francis Group
Innovation, Commercialization, and Start-Ups in Life Sciences
James F. Jordan

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Uncovering your Exit Triggers

Part 1 – Innovation is a Process of Connected Steps

Part 2 – Investment Must Be Connected to Exit

Part 3 – Align With the Industry Norms

Part 4 – A Startup Must Tell a Compelling Story

Aligning Objectives & Concerns
Customer = Investor = Acquirer

A poorly planned and ill-provisioned journey ↑ probability of failure

Navigational instruments ascertain position & direction to a destination

Waypoints are planned milestones to re-provision ($) & capture value

Planning & provisioning are aided through the use of tools

Objective: Provide Tools for Accurate Valuation & Strong Exit

1

Find **BENCHMARK**

- Evaluate by comparison

2

To uncover the **STANDARD**

- A measure, norm or model in comparative evaluation

3

Through use of **TOOLS**

- An implement to carry out a particular function

4

To obtain **KNOWLEDGE**

- Acquired understanding through facts, information or experience

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Uncover the standards by addressing constituency objectives & concerns

	Customer	Investor	Acquirer
Objectives	• Outcomes = ↑Access + ↑Quality + ↓Cost	• IRR, ROI, Multiples • Placement amount	• Price/Earning Ratio • Revenue/margin accretion • Market share
Concerns	• <u>Produce multi-year, accretive revenue stream</u> - Clinical trial participation - New procedures (aka robotics) • <u>Attain top-tier operating margins</u> - Multi-year agreements (formulary) - Reimbursement category PPV - Predictable horizontal/longitudinal costs - Sustainability of NewCo • <u>Capture regional market-share</u> - Technology guarantee - Clinical trial access	• Portfolio balance & timing • Validation of business model • Validation of product category • Venture capital requirements • Inability to participate in later rounds • Implications of public financing	• Aligned business models • Defend/expand existing categories • Enter new categories/markets • Formulary competitiveness • Maintain/improve financial ratios • Salesforce leverage

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Tools reveal standards so you can plot a winning strategy

- **Valuation Milestones**: A review of standard, not comparatives, avails and aligns valuation and fundable milestones with those of investors and acquirers
- **Disease State Fact Book**: Distinguish the difference between an incremental market improvement and a monumental innovation
- **Industry Life Cycle**: Incumbent's resist acquiring until their existing investment is threatened or expiring
- **Purchase Trigger Database**: Reliance on an early exit is misplaced if uninformed, know your acquirer's habits

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Let’s look at an example

- Each life sciences vertical differs
  - Pharmaceutical
  - Diagnostics
  - Medical Devices
  - Healthcare IT
- Each product category may differ
  - Cardiovascular
  - Cancer
- Each regulatory category may differ
  - 510k
  - PMA

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Data points from Venture Source & Pitchbook

Note:
- 2011 Venture Data Set for regional companies
- F = Fundable milestone – move to next class
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Valuation standards define your waypoints

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Series A - in millions		
Pre-Money	Capital Raise	Post-Money
2.7	1.3 +/- 1	4 +/-2

|---------- 11 months +/- 2.4 ----------|

- Creat proof of concept (F/V)
- Commercialization plan vaibility (F/V)
- Buildout technical team (V)

Series B - in millions		
Pre-Money	Capital Raise	Post-Money
8.0	4 +/- 1.9	12 +/- 4.3

|---------- 14 months +/- 2.5 ----------|

- Attain regulatory pathway (V)
- 1st in-human data/ start clinical trial (F/V)
- Design System Audit (V)

Series C - in millions		
Pre-Money	Capital Raise	Post-Money
15.9	8.9 +/- 3.5	24.8 +/- 7.6

|---------- 15 months +/- 3.4 ----------|

- Commercial approval - OUS (V)
- Regulatory trial approval - US (F/V)
- Launch US trial (V)
- Hire sales & marketing team (V)

Series D - in millions		
Pre-Money	Capital Raise	Post-Money
32.1	11.6+/- 5.9	43.7 +/- 15

|---------- 20 months +/- 8.7 ----------|

- Regulatory approval - US (F/V)
- Launch US product (V)
- US Revenue in excess of $xxM run-rate (F/V)
- Demonstrate viability of 2nd product (V)

Series E - in millions		
Pre-Money	Capital Raise	Post-Money
62.0	16. +/- 5.9	78.3 +/- 24

- Demonstrate hockey-stick revenue growth (F/V)
- Pass cash-flow BE Point (F/V)
- Regulatory trial path 2nd product - US (V)

Exit Details		
Capital Raise	Exit Value	Months
54 +/- 15	107 +/- 43	72 +/-21.6
Multiples	CAGR %	
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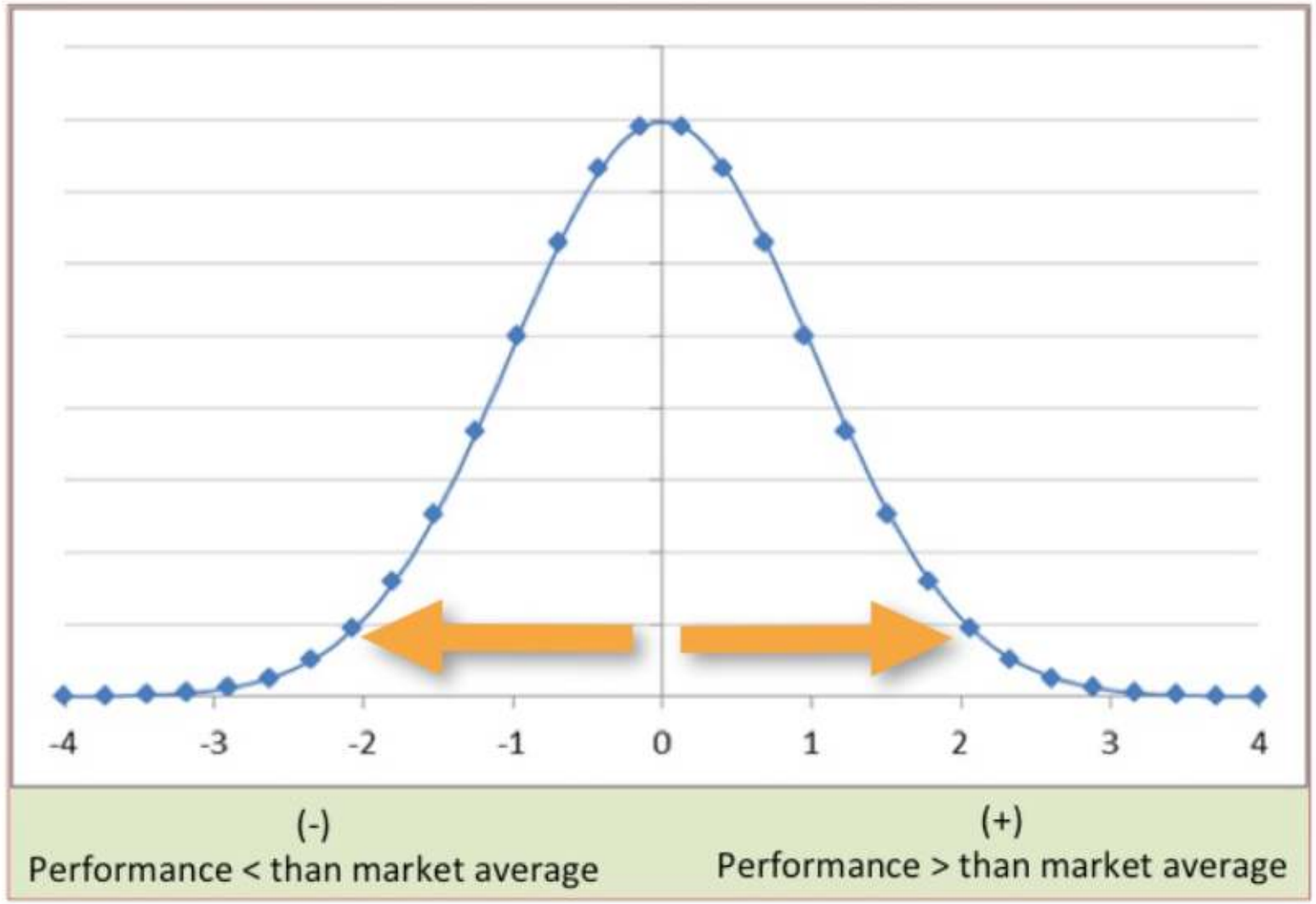
Standard deviation is a measure used to quantify dispersion



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A value milestone increases company value

|---------- 11 months +/- 2.4 ----------|

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A fundable milestone allows movement to next investor class

|---------- 14 months +/- 2.5 ----------|

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VENTURE FUNDS
BANKS
FAMILY AND FRIENDS
INVESTMENT SOURCES
INSTITUTIONAL INVESTORS
ANGELS
GOVERNMENT GRANTS

Valuation standards define your waypoints (Medical Device)

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Early exits are not always practical

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Valuation standards for a Therapeutic

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Seed Round - in millions		
Pre-Money	Capital Raise	Post-Money
6.5 +/- 2.3	0.9 +/- 0.8	7.4 +/- 3.1

|---------- ~15 months ----------

- Proof of concept with IND candidates
- Selection of clinically relevant animal model(s)

1st Round - in millions		
Pre-Money	Capital Raise	Post-Money
9.6 +/- 7	6.9 +/- 7.7	16.5 +/- 14.7

|---------- ~19 months ----------

- Rodent and non-rodent tox da
- Selection of IND enabling compound

2nd Round - in millions		
Pre-Money	Capital Raise	Post-Money
35.7	13.2 +/- 13.9	48.9 +/- 13.9

|---------- ~17 months ----------

- Human safety (Phase I)

3rd Round - in millions		
Pre-Money	Capital Raise	Post-Money
50.0	17.3 +/- 17	67.3 +/- 17

|---------- ~13 months ----------

- Efficacy studies in patients
- Patient dose range studies (Phase IIb)

4th Round - in millions		
Pre-Money	Capital Raise	Post-Money
148.3	29.8	178.1

- Phase III

Exit Details		
Capital Raise	Exit Value	Months
~70	~226.7	~60 - 84 months

Biotechnology Entrepreneurship Boot Camp

Tools reveal industry standards so you can plot a winning strategy

- **Valuation Milestones**: A review of standard, not comparatives, avails and aligns valuation and fundable milestones with those of investors and acquirers
- **Disease State Fact Book**: Distinguish the difference between an incremental market improvement and a monumental innovation
- **Industry Life Cycle**: Incumbent's resist acquiring until their existing investment is threatened or expiring
- **Purchase Trigger Database**: Reliance on an early exit is misplaced if uninformed, know your acquirer's habits

Biotechnology Entrepreneurship Boot Camp

Determine if a technology is an innovation or a modification

DISEASE STATE FACT BOOK

Row #			Base Year	Year 2
1	Disease Prevalence	Portion of the population found to have the condition (1 in 1000)	24,652,555	25,268,869
2	Incidence %	Percentage of new cases (generally a year)		20%
3	Incidence	Occurrence of new cases since last time periodlater year or in a period of time (generally a year)		5,053,774
4	Percentage Recurring	Percentage of population with a reoccurring event in a given year		20%
5	Prevelance Population	[Disease prevalence less incidence] x percentage recurring		4,043,019
6	Number Diagnosed	Number diagnosed patients (the act of identifying trateable disease)		9,096,793
7	Diagnosis Rate %	Number diagnosed/disease prevalence (this included incident patients)		36.0%

			Medical Therapy	CABG	Inteventional Procedure
8	Procedural Approaches	Diagnostic, Medical Devices, Pharmaceutical, Long-term Care, Rehabilitation, etc.			
9	Procedure/Service Approach %	The percent of diagnosed cases that would use this product/service	84.5%	3.5%	12.3%
10	Number of Procedures/Services	Number of diagnosed x procedure/service approach %	7,687,700	318,388	1,119,815

			Stent	Guide Catheter	Guide Wire
11	Type of Products/Sub-services	List the individual products or services performed			
12	Units per Procedure/Service	Example: 2 Stents per Procedure, 30 pills per cycle, 30 days in long-term care	2.2	1.75	1.1
13	Market Units/Services	Number of Procedures x Units per Procedure/Service	2,463,593	1,959,677	1,231,797
14	Average Revenue per Event	Revenue value per event or service - note revenue by manufacturer would be different than at the hospital level	$ 550.00	$ 9.87	$ 6.93
15	Market Dollars or Cost	Maket Units x Average Price	$1,354,976,390	$ 19,342,008	$ 8,536,351

Factors that increase market value

1.	Disease Prevalence	Portion of the population found to have the condition (1 in 1000)
2.	Incidence %	Percentage of new cases (generally a year)
3.	Incidence	Occurrence of new cases since last time period — later year or in a period of time (generally a year)
4.	Percentage Recurring	Percentage of population with a recurring event in a given year.
5.	Prevalence Population	[Disease prevalence less incidence] x percentage recurring
6.	Number Diagnosed	Number diagnosed patients (the act of identifying treatable disease)
7.	Diagnosis Rate %	Number diagnosed/disease prevalence (includes incident patients)
8.	Procedural Approaches	Diagnostic, Medical Devices, Pharmaceutical, Long-Term Care, Rehabilitation, etc.
9.	Procedure/Service Approach %	The percentage of diagnosed cases that would use this product/service
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The factors that increase market value

DISEASE STATE FACT BOOK

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8	Procedural Approaches	Diagnostic, Medical Devices, Pharmaceutical, Long-term Care, Rehabilitation, etc.	Medical Therapy	CABG / Inteventional Procedure
9	Procedure/Service Approach %	The percent of diagnosed cases that would use this product/service	84.5%	3.5% / 12.3%
10	Number of Procedures/Services	Number of diagnosed x procedure/service approach %	7,687,700	318,388 / 1,119,815

			Stent	Guide Catheter	Guide Wire
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14	Average Revenue per Event	Revenue value per event or service - note revenue by manufacturer would be different than at the hospital level	$ 550.00	$ 9.87	$ 6.93
15	Market Dollars or Cost	Maket Units x Average Price	$1,354,976,390	$ 19,342,008	$ 8,536,351

A 4% change in diagnosis rate can increase the market by 11%

DISEASE STATE FACT BOOK

Row #		Year 2				Year 2			
1	Disease Prevalence	25,268,869				25,268,869			
2	Incidence %	20%				20%			
3	Incidence	5,053,774				5,053,774			
4	Percentage Recurring	20%		5%		25%			
5	Prevelance Population	4,043,019				5,053,774			
6	Number Diagnosed	9,096,793				10,107,548			
7	Diagnosis Rate %	36.0%		4%		40.0%			
8	Procedural Approaches	Medical Therapy	CABG		Inteventional Procedure	Medical Therapy	CABG		Inteventional Procedure
9	Procedure/Service Approach %	84.5%	3.5%		12.3%	84.5%	3.5%		12.3%
10	Number of Procedures/Services	7,687,700	318,388		1,119,815	8,541,888	353,764		1,244,239
11	Type of Products/Sub-services			Stent	Guide Catheter	Guide Wire		Stent	Guide Catheter	Guide Wire
12	Units per Procedure/Service			2.2	1.75	1.1		2.2	1.75	1.1
13	Market Units/Services			2,463,593	1,959,677	1,231,797		2,737,326	2,177,418	1,368,663
14	Average Revenue per Event			$ 550.00	$ 9.87	$ 6.93		$ 550.00	$ 9.87	$ 6.93
15	Market Dollars or Cost			$1,354,976,390	$ 19,342,008	$ 8,536,351		$1,505,529,323	$ 21,491,120	$ 9,484,835
					1,382,854,750				1,536,505,277	
						153,650,528				

A 1.2% procedural shift can change the market dollars by 10%

DISEASE STATE FACT BOOK

Row #		Year 2
1	Disease Prevalence	25,268,869
2	Incidence %	20%
3	Incidence	5,053,774
4	Percentage Recurring	20%
5	Prevelance Population	4,043,019
6	Number Diagnosed	9,096,793
7	Diagnosis Rate %	36.0%
8	Procedural Approaches	Medical Therapy / CABG / Inteventional Procedure
9	Procedure/Service Approach %	84.5% / 3.5% / 12.3%
10	Number of Procedures/Services	7,687,700 / 318,388 / 1,119,815
11	Type of Products/Sub-services	Stent / Guide Catheter / Guide Wire
12	Units per Procedure/Service	2.2 / 1.75 / 1.1
13	Market Units/Services	2,463,593 / 1,959,677 / 1,231,797
14	Average Revenue per Event	$ 550.00 / $ 9.87 / $ 6.93
15	Market Dollars or Cost	$1,354,976,390 / $ 19,342,008 / $ 8,536,351
		1,382,854,750

		Year 2
		25,268,869
		20%
		5,053,774
		20%
		4,043,019
		9,096,793
		36.0%
		Medical Therapy / CABG / Inteventional Procedure
		84.5% / 2.0% / 13.5%
		7,687,700 / 181,936 / 1,227,157
		Stent / Guide Catheter / Guide Wire
		2.2 / 1.75 / 1.1
		2,699,746 / 2,147,525 / 1,349,873
		$ 550.00 / $ 9.87 / $ 6.93
		$1,484,860,398 / $ 21,196,075 / $ 9,354,621
		1,515,411,094

132,556,345

Market factors that attract acquirers

Factors that increase market value: (all tides rise boats)

- Diagnosis rate
- Procedure rate
- Units p/procedure

Factors that require taking share: (fighting incumbents)

- Type of products
  - —Category transitions
- Market units
- Average selling price
- Market dollars

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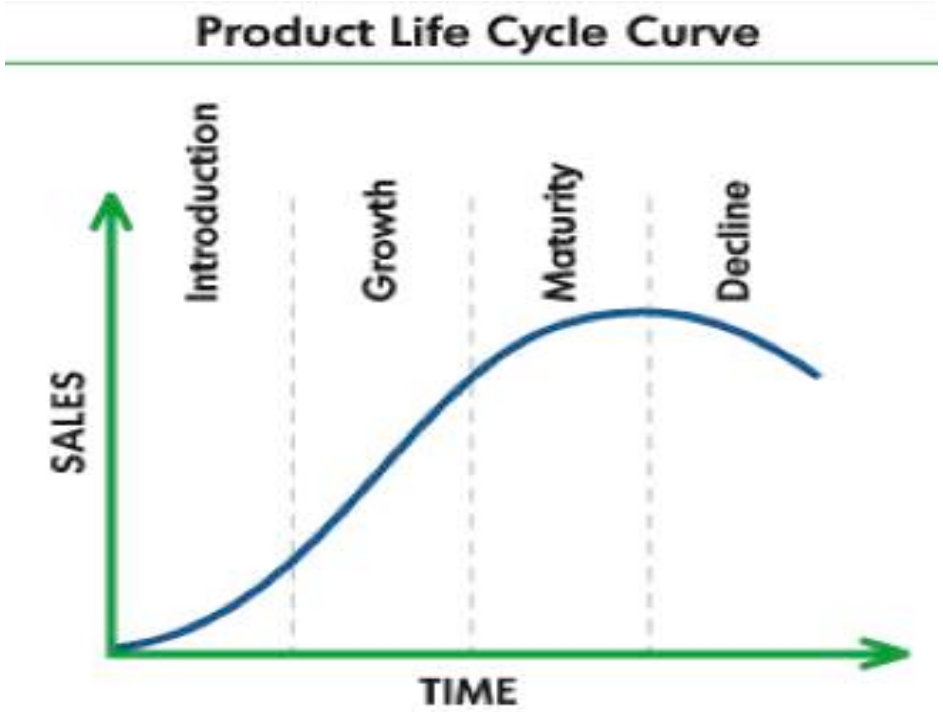
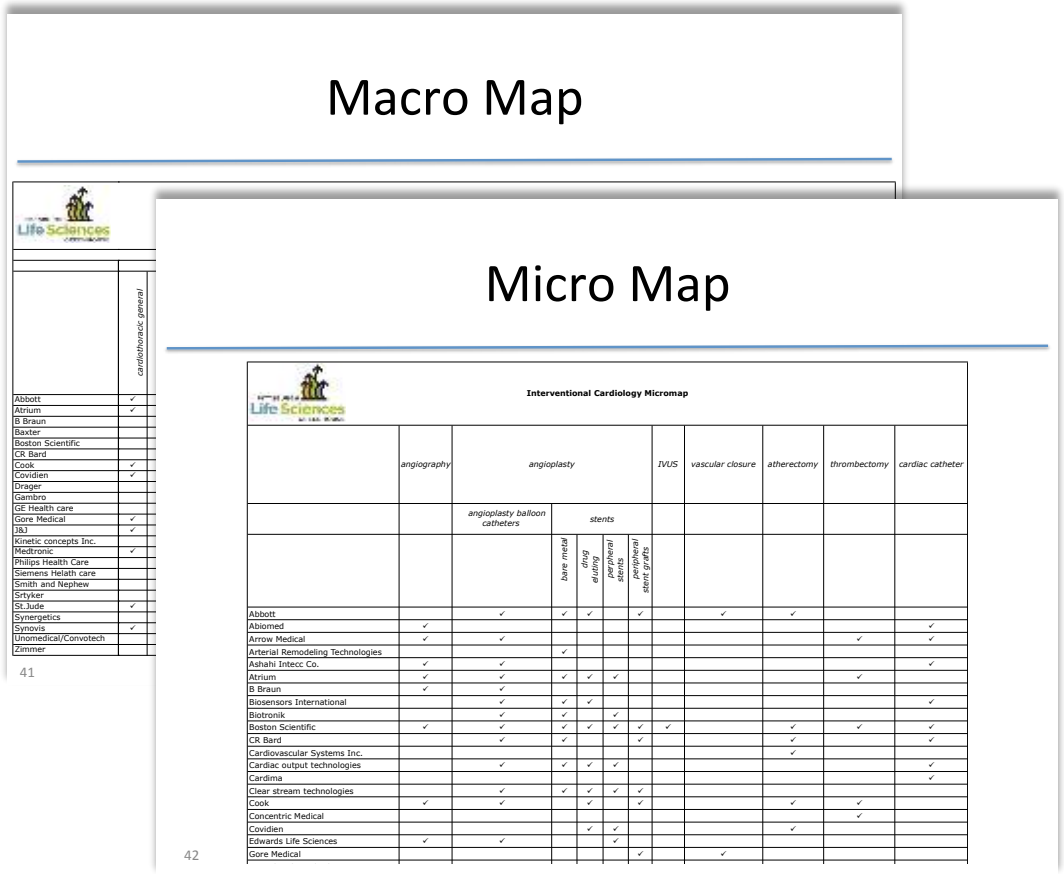
Biotechnology Entrepreneurship Boot Camp

Determine an industry's readiness



Macro Map

Micro Map



Life Sciences

	cardiothoracic general
Abbott	✓
Atrium	✓
B Braun	
Baxter	
Boston Scientific	
CR Bard	
Cook	✓
Covidien	✓
Drager	
Gambro	
GE Health care	
Gore Medical	✓
J&J	✓
Kinetic concepts Inc.	
Medtronic	✓
Philips Health Care	
Siemens Helath care	
Smith and Nephew	
Srtyker	
St.Jude	✓
Synergetics	
Synovis	✓
Unomedical/Convotech	
Zimmer	

41

Life Sciences

Interventional Cardiology Micromap

	angiography	angioplasty					IVUS	vascular closure	atherectomy	thrombectomy	cardiac catheter
		angioplasty balloon catheters	stents								
			bare metal	drug eluting	peripheral stents	peripheral stent grafts					
Abbott		✓	✓	✓		✓		✓	✓		
Abiomed	✓										✓
Arrow Medical	✓	✓								✓	✓
Arterial Remodeling Technologies			✓								
Ashahi Intecc Co.	✓	✓									✓
Atrium	✓	✓	✓	✓	✓					✓	
B Braun	✓	✓									
Biosensors International		✓	✓	✓							✓
Biotronik		✓	✓		✓						
Boston Scientific	✓	✓	✓	✓	✓	✓	✓		✓	✓	✓
CR Bard		✓	✓		✓				✓		✓
Cardiovascular Systems Inc.									✓		
Cardiac output technologies		✓	✓	✓	✓						✓
Cardima											✓
Clear stream technologies		✓	✓	✓	✓	✓					
Cook	✓	✓		✓		✓			✓	✓	
Concentric Medical										✓	
Covidien				✓	✓				✓		
Edwards Life Sciences	✓	✓			✓						
Gore Medical						✓		✓			

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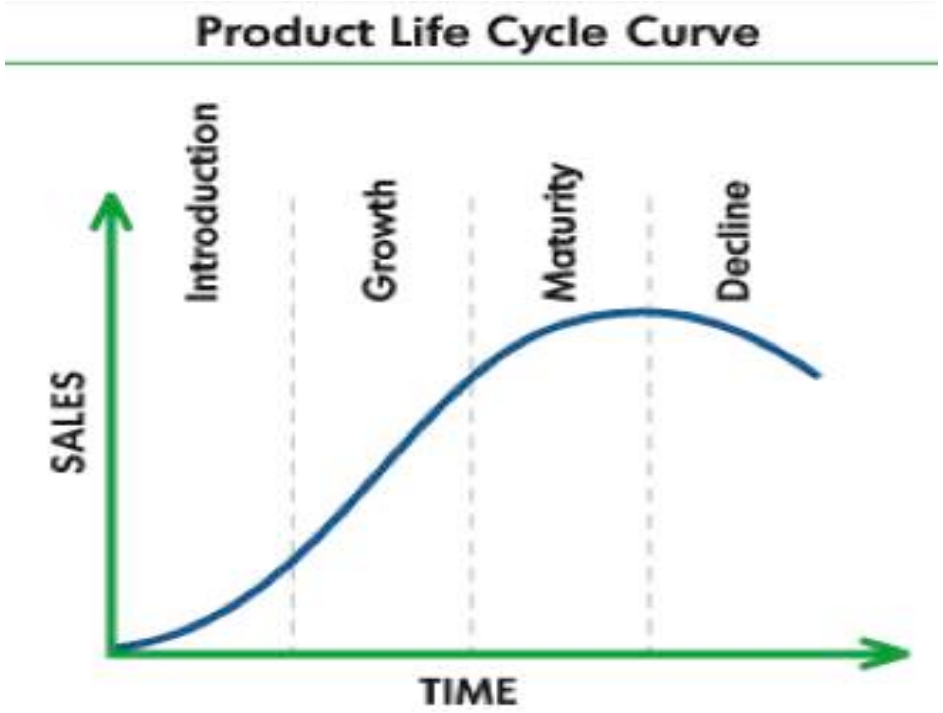
Biotechnology Entrepreneurship Boot Camp

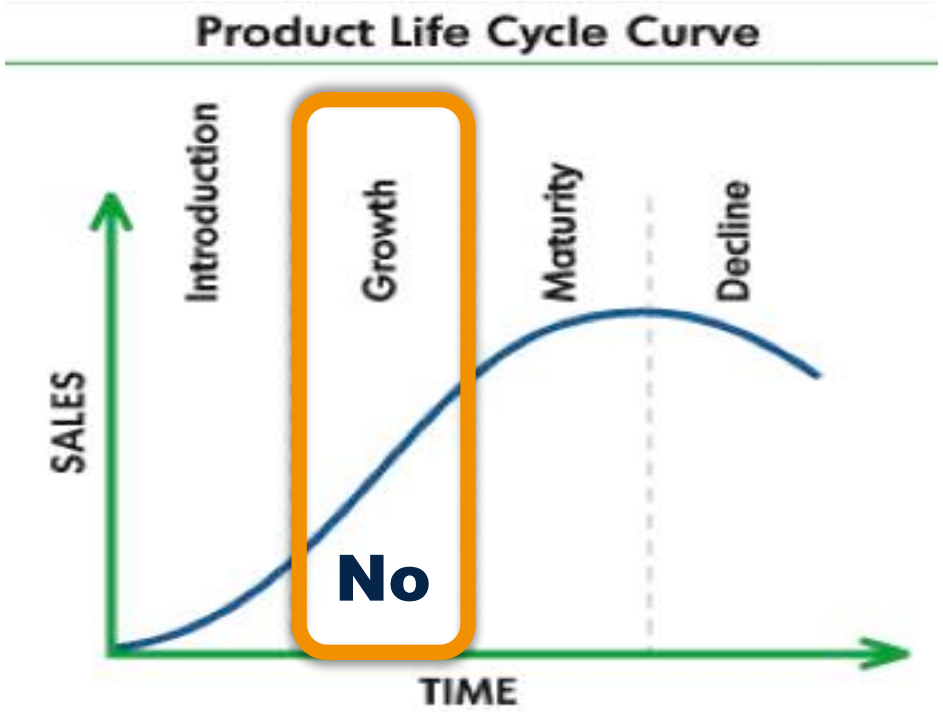
Determine an industry's readiness



Wang developed the CRT Word Processor
61% CAGR between 1979-1984

Biotechnology Entrepreneurship Boot Camp

Industry & companies in a growth phase will fight a category shift



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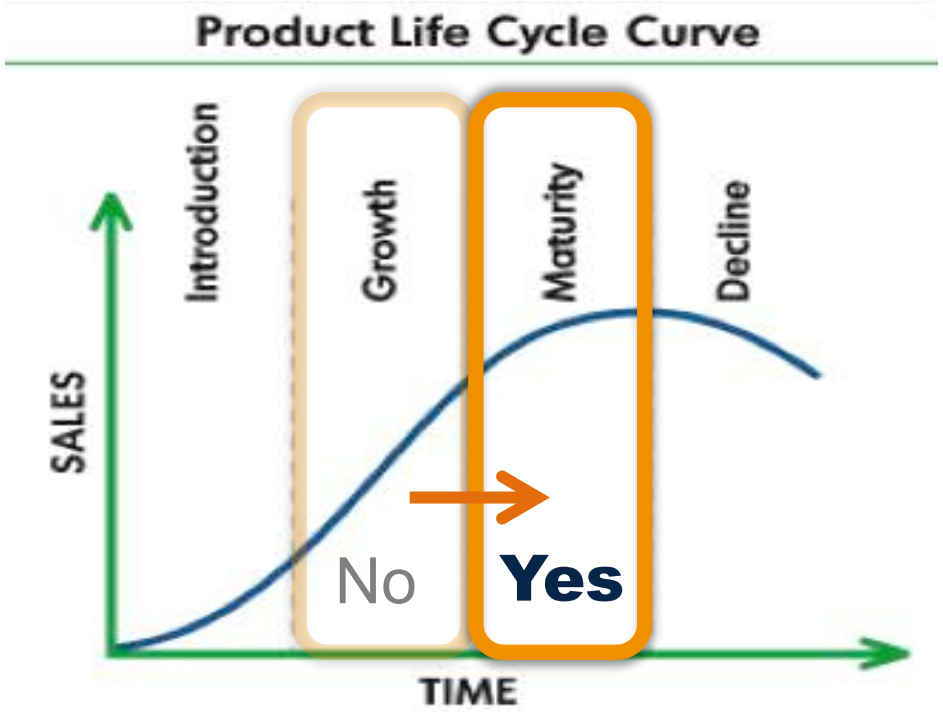

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Biotechnology Entrepreneurship Boot Camp

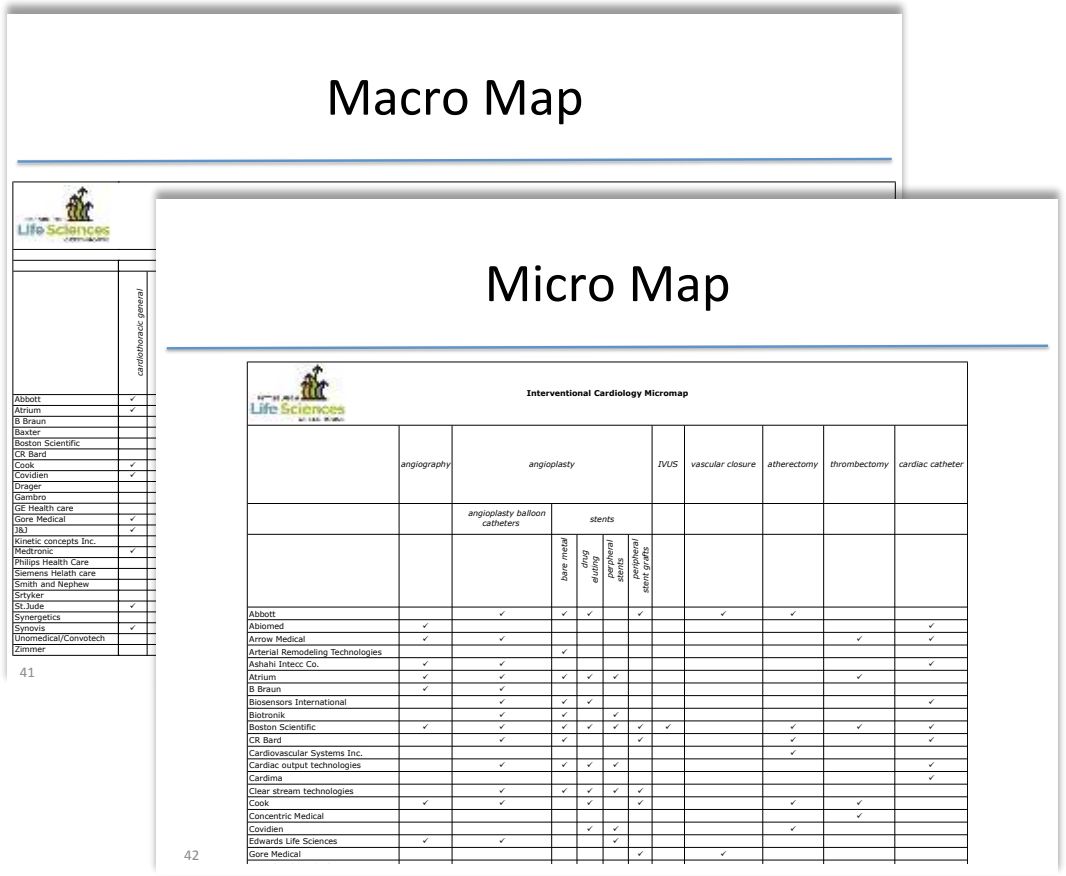
Macro/Micro maps help uncover industry readiness

Thermo Fischer Acquirers PPD for $17.4 billion

Baxter Acquirers Hillrom for $10.5 billion

Steris and Cantel Medical stock deal for $4.6 billion

Boston Scientific aquires Baylis Medical for $1.75 billion



Macro Map

MEDICAL DEVICE INDUSTRY MACRO MAP

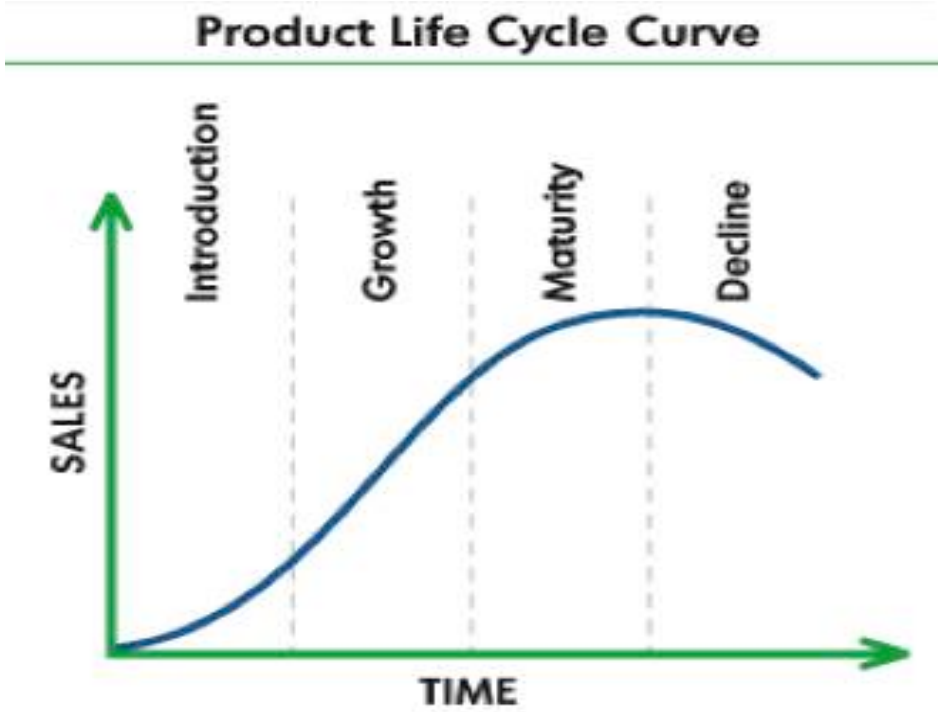
	HOSPITALS																													
	Operating Room														Multi speciality						ICU/CCU	Laboratory based				Specialty					
	cardiothoracic general	*colon rectal*	*otolaryngiology*	*orthopedic*	*plastic surgery*	*ophthalmology*	*ob-gyn*	*general laproscopy*	*general-other*	*Vascular*	*urology*	*endoscopy*	*neurology*	*Robot assisted/image guided*	*anasthetics*	*respiratory devices*	*hemostats*	*tissue sealants*	*adhesion prevention*	*monitoring systems*		*Interventional cardiology*	*Interventional radiology*	*Electrophysiology*	*Interventional neurology*	*CRM*	*Radiology(imaging)*	*Renal*	*Neurology*	*Infusion systems*	*wound care and management*
Abbott	✓					✓				✓							✓					✓	✓								✓
Atrium	✓								✓	✓												✓									
B Braun										✓					✓							✓	✓					✓	✓	✓	✓
Baxter															✓		✓	✓	✓									✓		✓	✓
Boston Scientific		✓					✓		✓		✓	✓	✓									✓	✓		✓	✓					
CR Bard			✓	✓					✓	✓	✓	✓					✓					✓	✓	✓		✓		✓			✓
Cook	✓	✓					✓		✓	✓	✓	✓										✓	✓							✓	
Covidien	✓	✓	✓				✓	✓	✓	✓	✓	✓	✓			✓		✓	✓		✓	✓	✓		✓	✓	✓	✓		✓	✓
Drager															✓	✓				✓											
Gambro																												✓			
GE Health care			✓				✓		✓		✓			✓	✓	✓				✓	✓		✓	✓		✓	✓					
Gore Medical	✓	✓		✓					✓	✓			✓									✓	✓	✓						✓	
J&J	✓			✓	✓	✓	✓	✓	✓		✓		✓									✓	✓		✓	✓			✓	✓	✓
Kinetic concepts Inc.							✓				✓																				✓
Medtronic	✓		✓	✓							✓										✓	✓				✓			✓	✓	
Philips Health Care															✓					✓							✓				
Siemens Helath care															✓	✓				✓		✓		✓			✓				
Smith and Nephew				✓								✓																			✓
Srtyker				✓								✓	✓	✓						✓	✓						✓			✓	
St.Jude	✓	✓												✓								✓		✓		✓			✓		
Synergetics													✓																		
Synovis	✓				✓		✓	✓	✓	✓	✓		✓																		
Unomedical/Convotech																✓					✓		✓						✓	✓
Zimmer				✓																						✓					

Micro Map

Interventional Cardiology Micromap

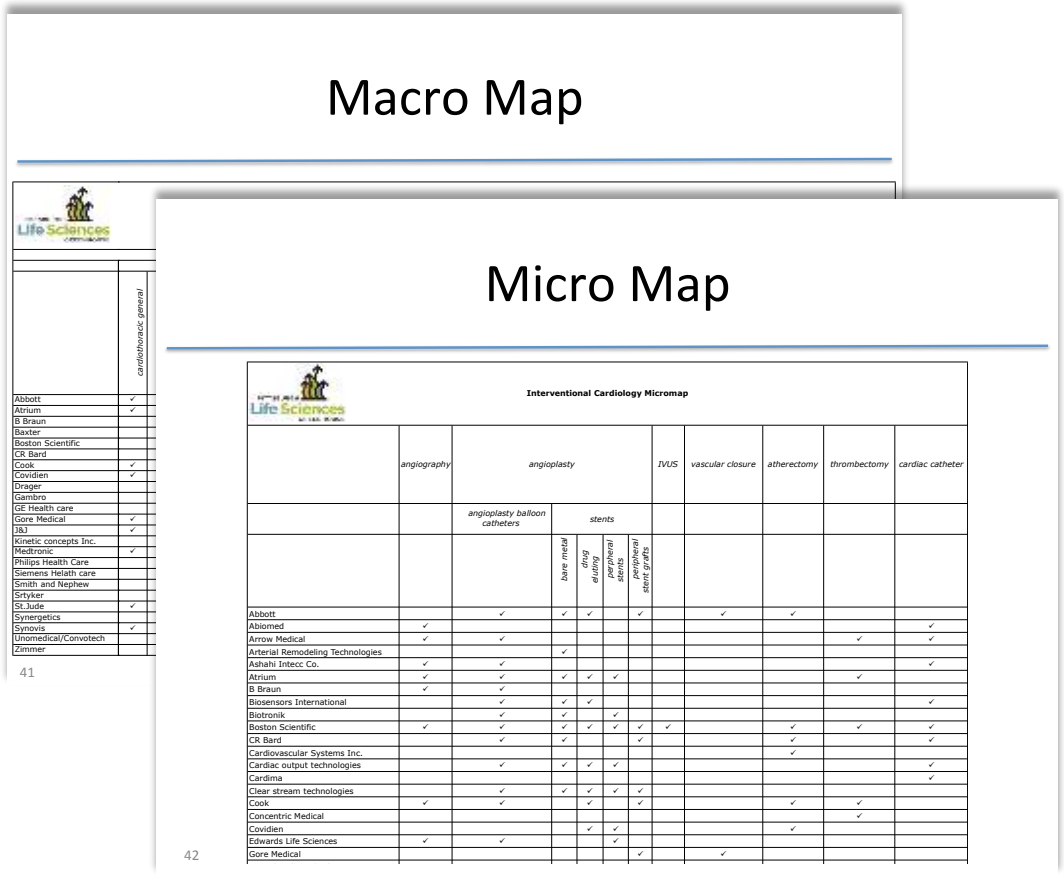
	angiography	*angioplasty*					*IVUS*	*vascular closure*	*atherectomy*	*thrombectomy*	*cardiac catheter*
		angioplasty balloon catheters	*stents*								
			bare metal	*drug eluting*	*perpheral stents*	*peripheral stent grafts*					
Abbott		✓	✓	✓		✓		✓	✓		
Abiomed	✓										✓
Arrow Medical	✓	✓								✓	✓
Arterial Remodeling Technologies			✓								
Ashahi Intecc Co.	✓	✓									✓
Atrium	✓	✓	✓	✓	✓					✓	
B Braun	✓	✓									
Biosensors International		✓	✓	✓							✓
Biotronik		✓	✓		✓						
Boston Scientific	✓	✓	✓	✓	✓	✓	✓		✓	✓	✓
CR Bard		✓	✓			✓			✓		✓
Cardiovascular Systems Inc.									✓		
Cardiac output technologies		✓	✓	✓	✓						✓
Cardima											✓
Clear stream technologies		✓	✓	✓	✓	✓					
Cook	✓	✓		✓		✓			✓	✓	
Concentric Medical										✓	
Covidien				✓	✓				✓		
Edwards Life Sciences	✓	✓			✓						
Gore Medical						✓		✓			

Determine an industry's readiness



Macro Map

Micro Map



Life Sciences

	cardiothoracic general
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Drager	
Gambro	
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Arrow Medical	✓	✓							✓	✓
Arterial Remodeling Technologies			✓							
Ashahi Intecc Co.	✓	✓								✓
Atrium	✓	✓	✓	✓	✓				✓	
B Braun	✓	✓								
Biosensors International		✓	✓	✓						✓
Biotronik		✓	✓		✓					
Boston Scientific	✓	✓	✓	✓	✓	✓		✓	✓	✓
CR Bard		✓	✓		✓			✓		✓
Cardiovascular Systems Inc.								✓		
Cardiac output technologies		✓	✓	✓	✓					✓
Cardima										✓
Clear stream technologies		✓	✓	✓	✓	✓				
Cook	✓	✓		✓		✓		✓	✓	
Concentric Medical									✓	
Covidien				✓	✓			✓		
Edwards Life Sciences	✓	✓			✓					
Gore Medical						✓	✓			

42

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Biotechnology Entrepreneurship Boot Camp

62% of PMAs are acquired after FDA approval

Note:
- 2011 Venture Data Set
- Sample size = 18
- Most likely less today before PMA

Series A - in millions		
Pre-Money	Capital Raise	Post-Money
2.7	1.3 +/- 1	4 +/-2

|---------- 11 months +/- 2.4 ----------|

Series B - in millions		
Pre-Money	Capital Raise	Post-Money
8.0	4 +/- 1.9	12 +/- 4.3

|---------- 14 months +/- 2.5 ----------|

Series C - in millions		
Pre-Money	Capital Raise	Post-Money
15.9	8.9 +/- 3.5	24.8 +/- 7.6

|---------- 15 months +/- 3.4 ----------|

7 (38%) acquired before regulatory approval

Series D - in millions		
Pre-Money	Capital Raise	Post-Money
32.1	11.6+/- 5.9	43.7 +/- 15

|---------- 20 months +/- 8.7 ----------|

Series E - in millions		
Pre-Money	Capital Raise	Post-Money
62.0	16. +/- 5.9	78.3 +/- 24

Exit Details		
Capital Raise	Exit Value	Months
54 +/- 15	107 +/- 43	72 +/-21.6
Multiples	CAGR %	
2.2 +/- 0.7	14.8 +/- 7.6	

- Regulatory approval - US (F/V)

11 (62% acquired after regulatory approval

62% of PMAs are acquired after FDA approval

Note:
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- Sample size = 18
- Most likely less today before PMA

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|---------- 11 months +/- 2.4 ----------|

Series B - in millions		
Pre-Money	Capital Raise	Post-Money
8.0	4 +/- 1.9	12 +/- 4.3

|---------- 14 months +/- 2.5 ----------|

Series C - in millions		
Pre-Money	Capital Raise	Post-Money
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|---------- 15 months +/- 3.4 ----------|

7 (38%) acquired before regulatory approval

Series D - in millions		
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32.1	11.6+/- 5.9	43.7 +/- 15

|---------- 20 months +/- 8.7 ----------|

Series E - in millions		
Pre-Money	Capital Raise	Post-Money
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Exit Details		
Capital Raise	Exit Value	Months
54 +/- 15	107 +/- 43	72 +/-21.6
Multiples	CAGR %	
2.2 +/- 0.7	14.8 +/- 7.6	

- Regulatory approval - US (F/V)

11 (62% acquired after regulatory approval

A value proposition must address constituency objectives & concerns

- Identify constituency measures of success
- Valuation standards define your waypoints
- Distinguish innovation from improvement
- Determine an industry's readiness to change
- M&A history defines triggers (timing)

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Questions?

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