

Clearing Commercialization Hurdles

August 29, 2012

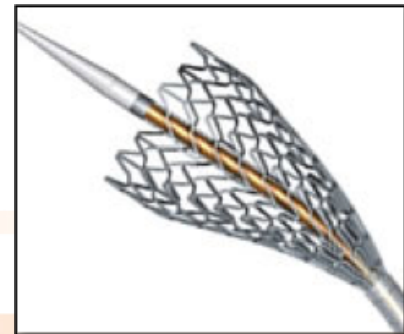
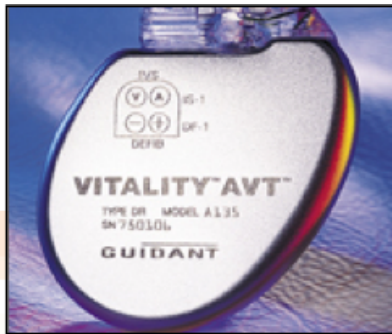
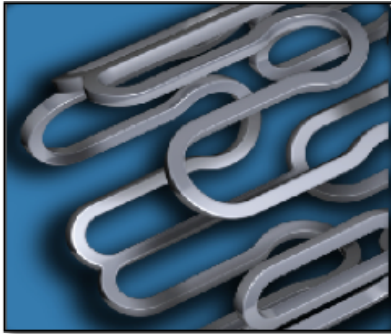
J. Greg Davis

Founder & CEO, MedCelerate



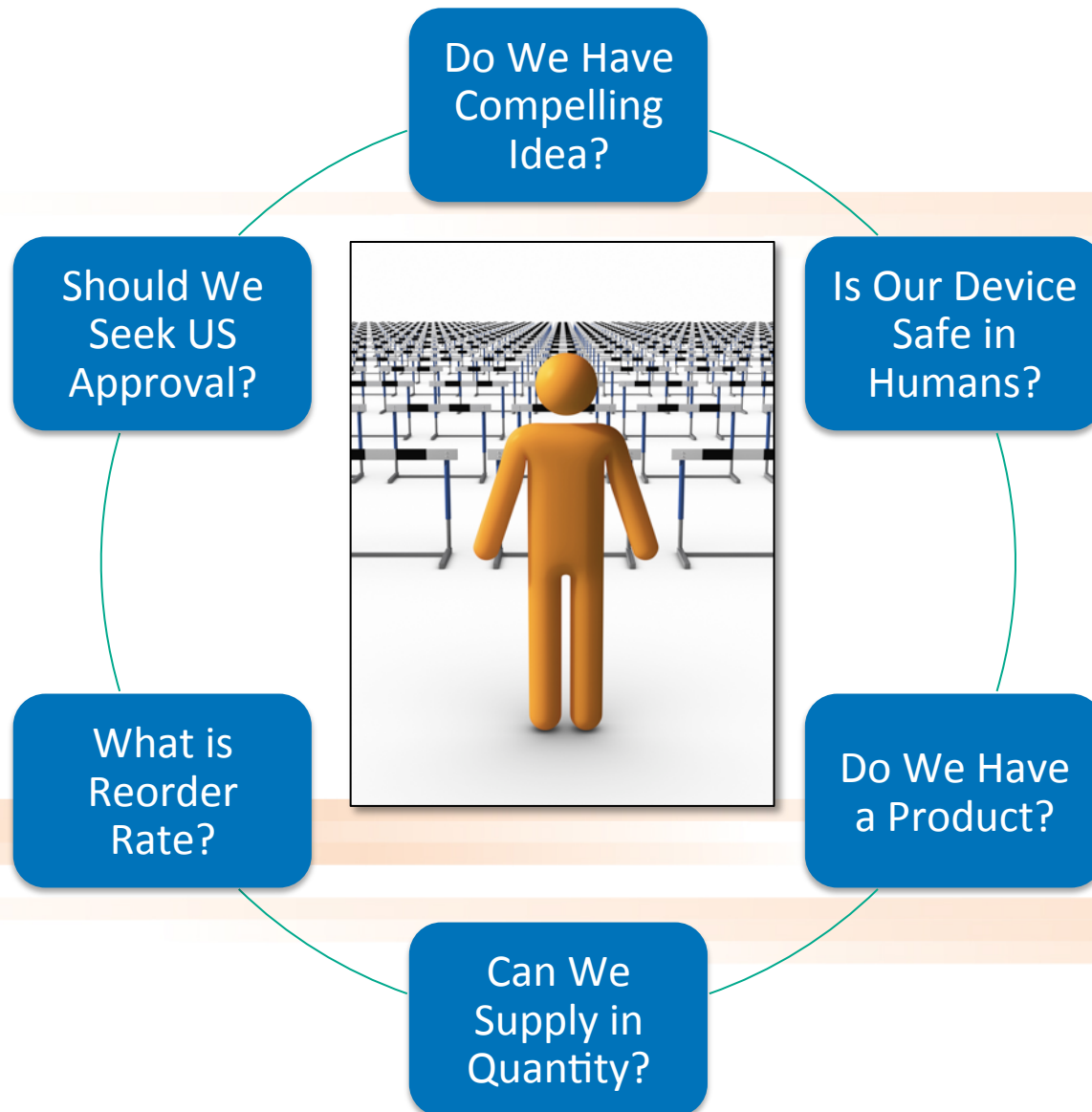
My Device Background

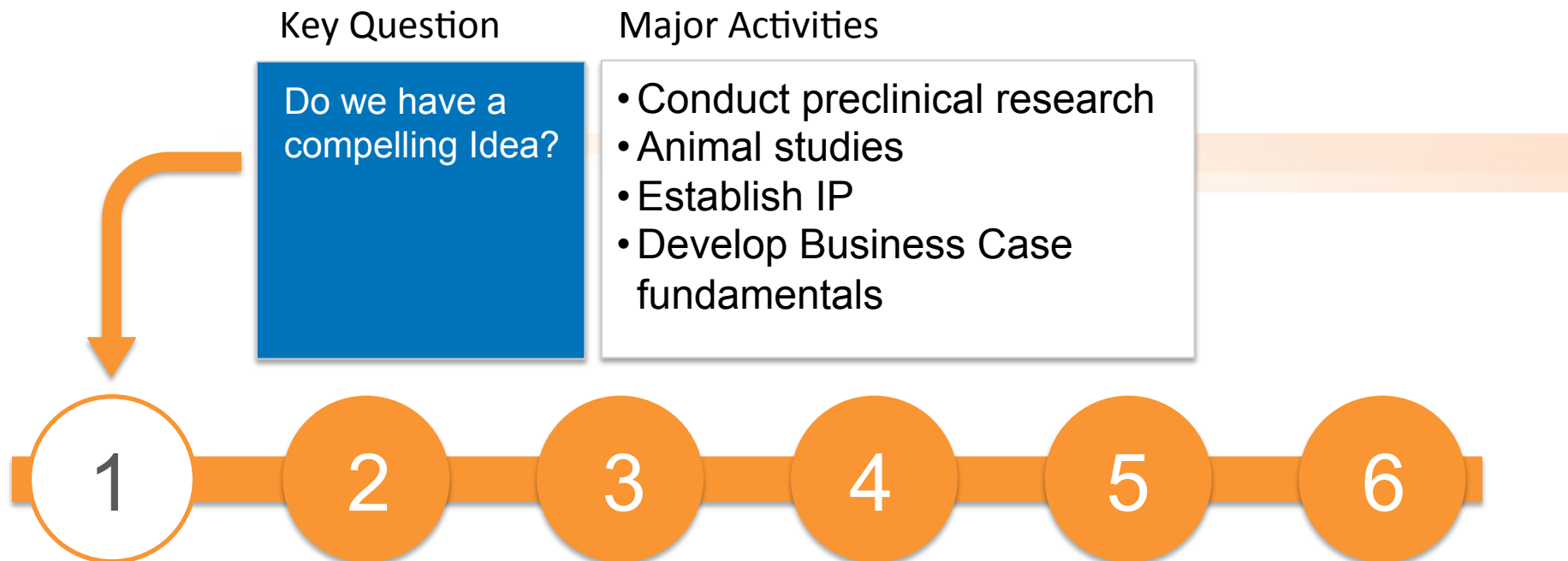
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Fundamental Questions

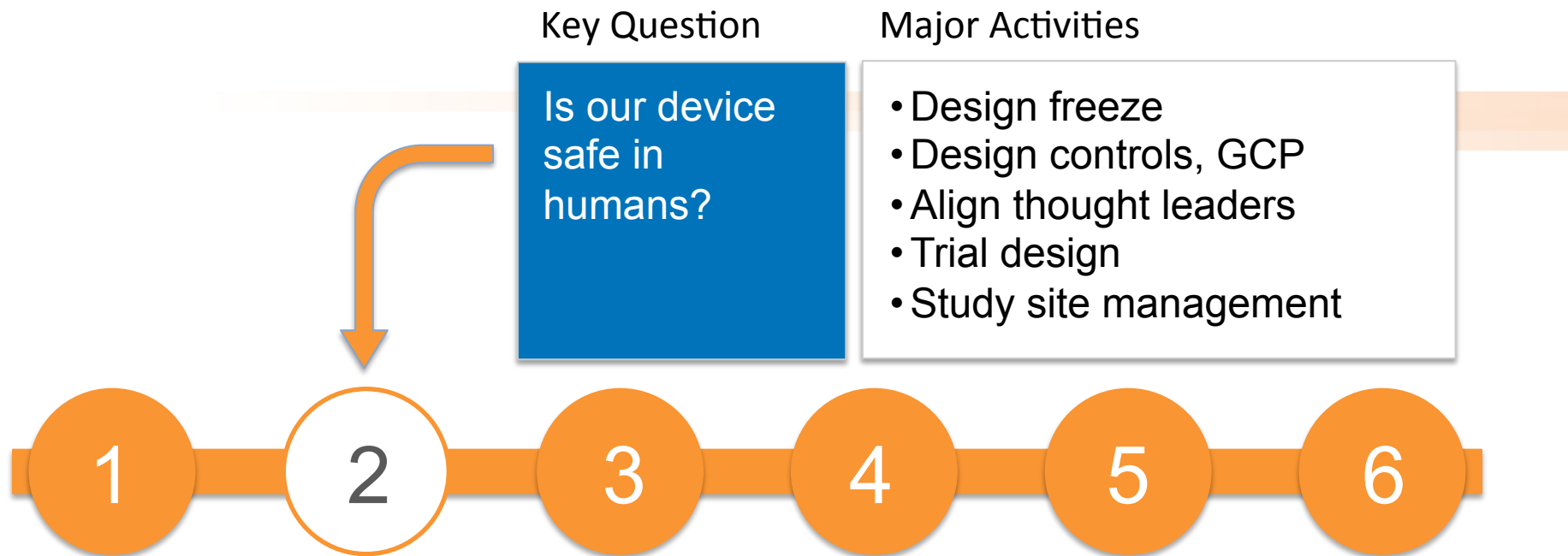
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Lessons Learned

- ✓ Start virtual, run silent, be capital efficient
- ✓ Learn how to iterate and fail quickly
- ✓ Study long-term trends in healthcare and impact on your technology
- ✓ Identify up front how your product will save health care system money



Lessons Learned

- ✓ Lay solid Quality System foundation early
- ✓ Know and understand regulatory requirements
- ✓ Consider using European CRO with relevant device experience
- ✓ Continue staying lean and focused

Blessing and Curse of CE Mark Approval

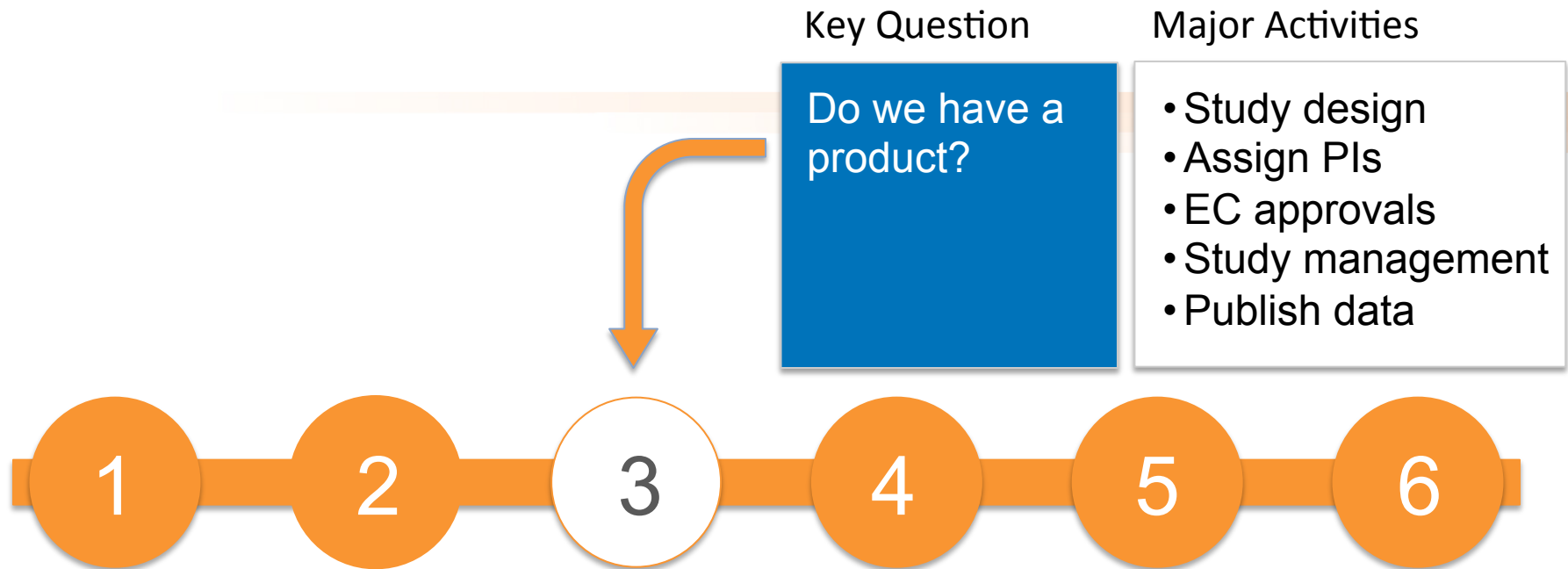
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	EU Regulatory Class	# of Patients	Trial Region
Cardiovascular	III	30	Europe
Peripheral Artery	IIb	11	South America
GERD	III	24	South America
Venous Disease	IIb	11	Caribbean
Cardiovascular	III	25	Europe

- Limited clinical experience, with small number of KOLs, does not guarantee product viability

Post-Market Clinical Studies

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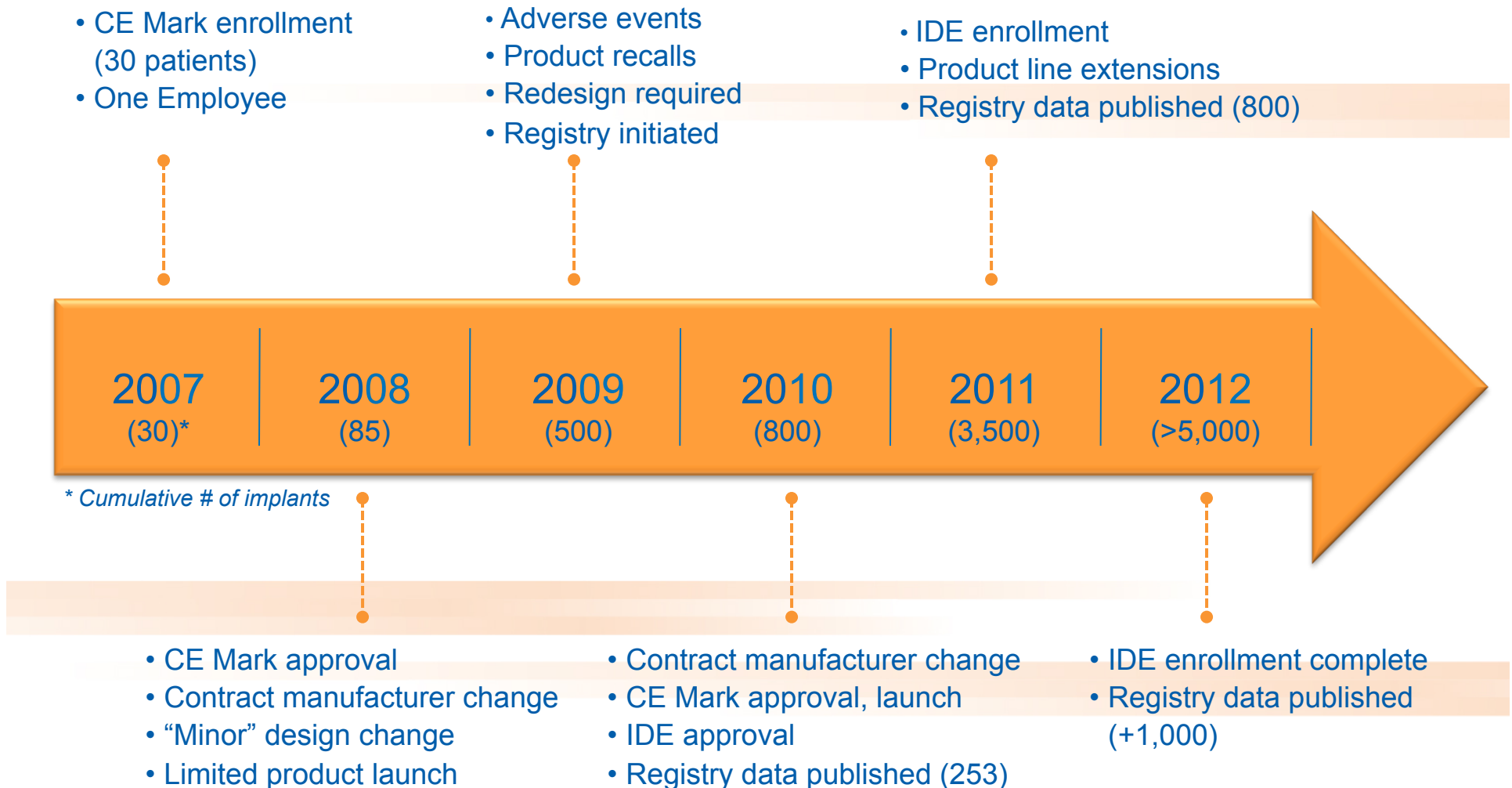
Lessons Learned

- ✓ Build clinical experience to gain understanding of product limitations
- ✓ Customer usage may lead to another product iteration
- ✓ Will inform about market development and physician training requirements
- ✓ Despite limitations, clinical data is powerful

Building Clinical Data Set Post-CE Mark

- Case Study

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Supply Chain Scale-Up

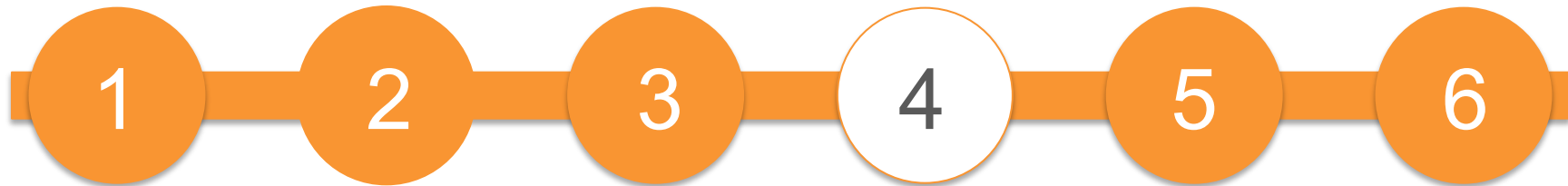
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Key Question

Can we supply in quantity?

Major Activities

- Identify CMOs or scale in-house mfg.
- Improve yields
- Additional CE Mark
- Logistical support

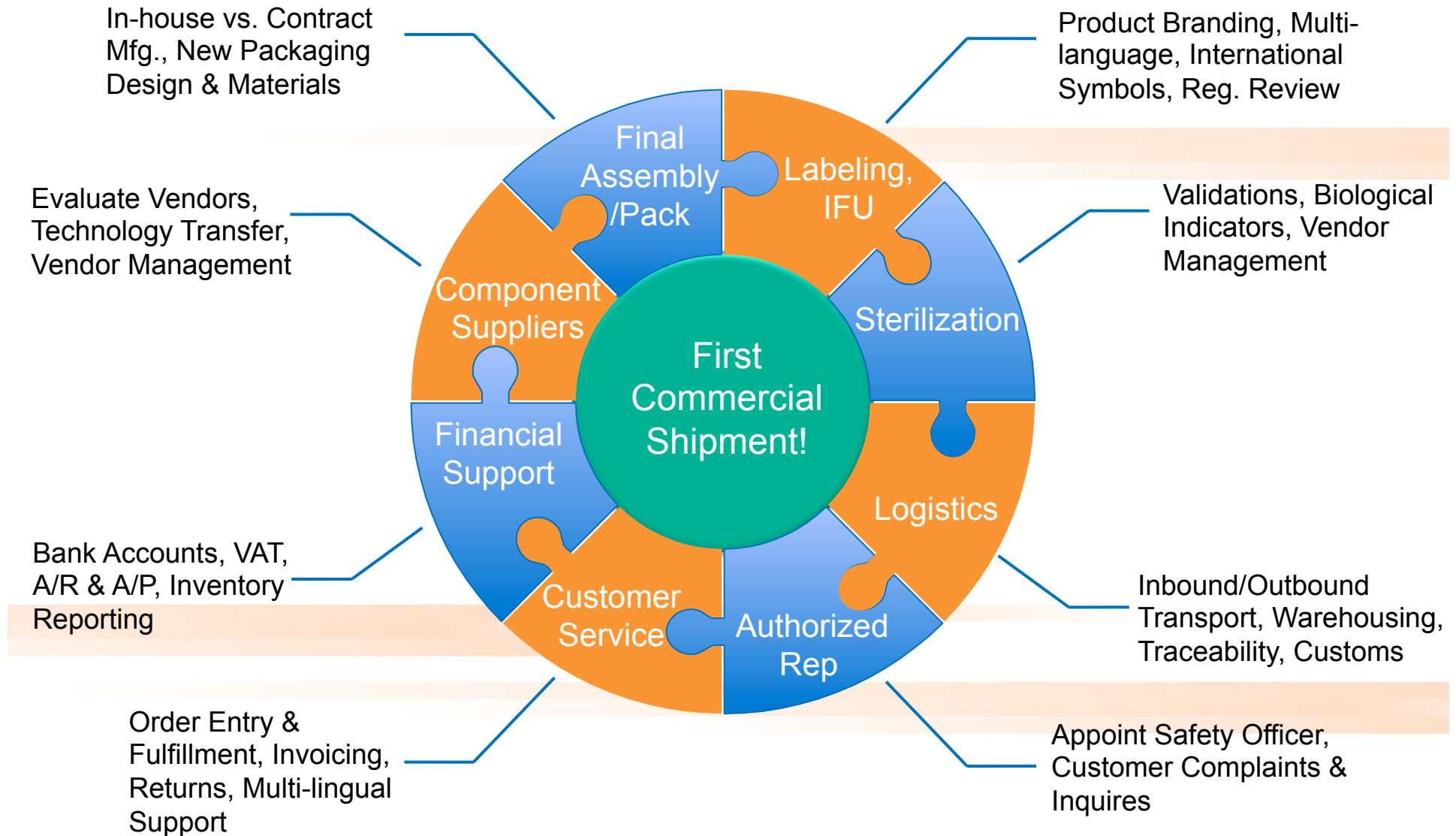


Lessons Learned

- ✓ Making 50 is not the same as making 500 or 5,000!
- ✓ Weigh pros & cons of in-house vs. contract manufacturing
- ✓ Consider using EU-based contract manufacturers
- ✓ Limit number of partners – must be profitable for them as well

Delivering Robust Product Supply Requires Time & Teamwork

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Building Capable Supply Chain

- Case Study

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	Pre-CE Mark (Q1 2011)	Post-CE Mark (Today)
Manufacturing	<ul style="list-style-type: none"> • U.S. component mfgs • Adhesive, kitting & pack in CA • Sterilization in CA 	<ul style="list-style-type: none"> • Product made in Ireland • Adhesive production in NC • Sterilization in Belgium • EU Operations Director (Irish)
Labeling/IFU	<ul style="list-style-type: none"> • English only • Generic labeling 	<ul style="list-style-type: none"> • 8 languages • New branding, Venaseal®
Logistics	<ul style="list-style-type: none"> • Non-existent 	<ul style="list-style-type: none"> • NL distribution center (outsourced)
Authorized Rep	<ul style="list-style-type: none"> • Non-existent 	<ul style="list-style-type: none"> • Emergo - NL
Customer Service	<ul style="list-style-type: none"> • Non-existent 	<ul style="list-style-type: none"> • Multi-language call center - NL
Financial Support	<ul style="list-style-type: none"> • U.S. bank account 	<ul style="list-style-type: none"> • 3 EU bank accounts • In-depth VAT analysis

Product Transformation

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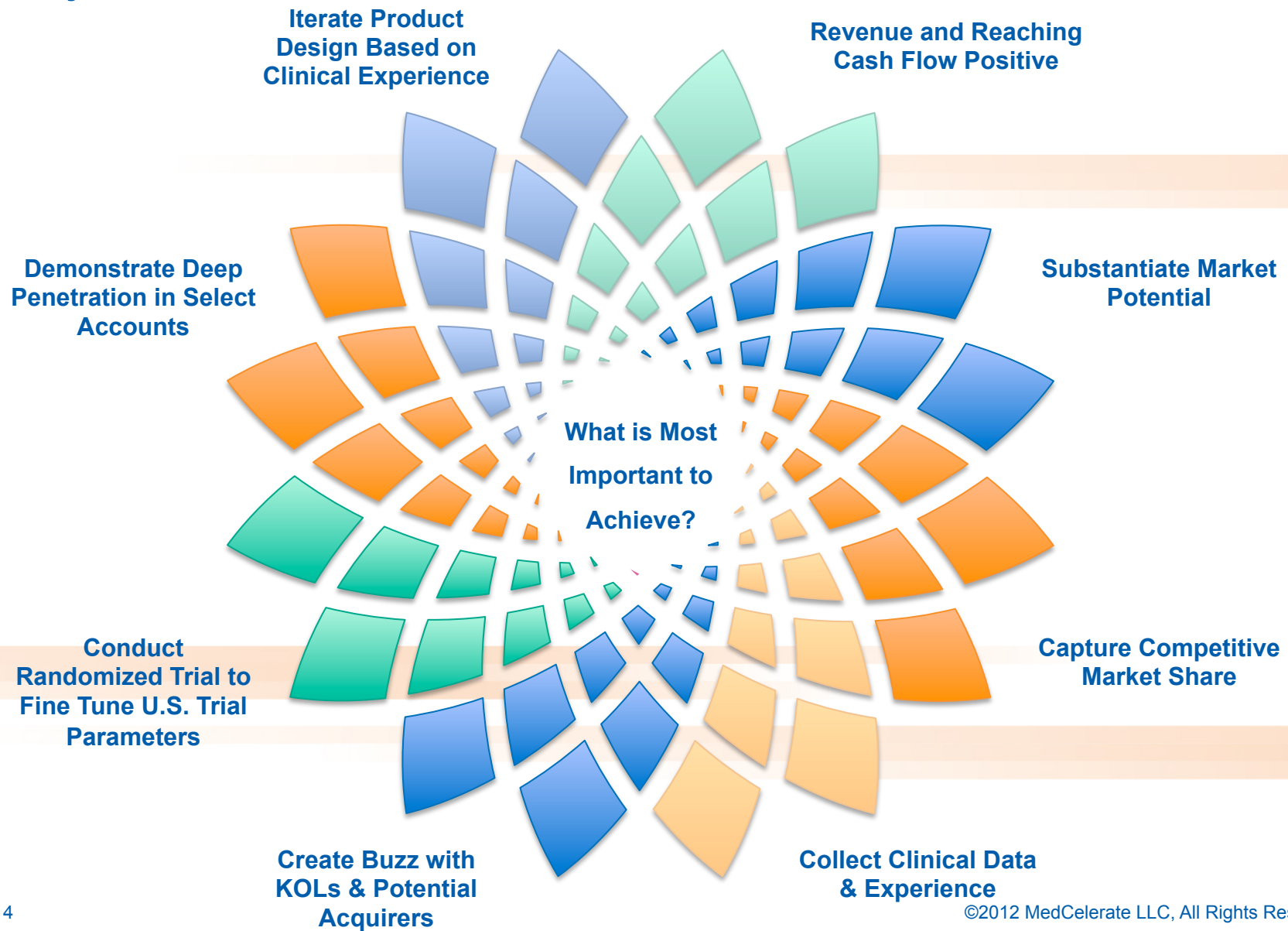


Lessons Learned

- ✓ Start with basic question: “What are we trying to achieve?”
- ✓ Your exit potential heavily tied to account level product adoption
- ✓ Stay focused on limited number of countries/accounts
- ✓ Resist temptation to add new markets opportunistically

Chasing Conflicting Commercialization Objectives

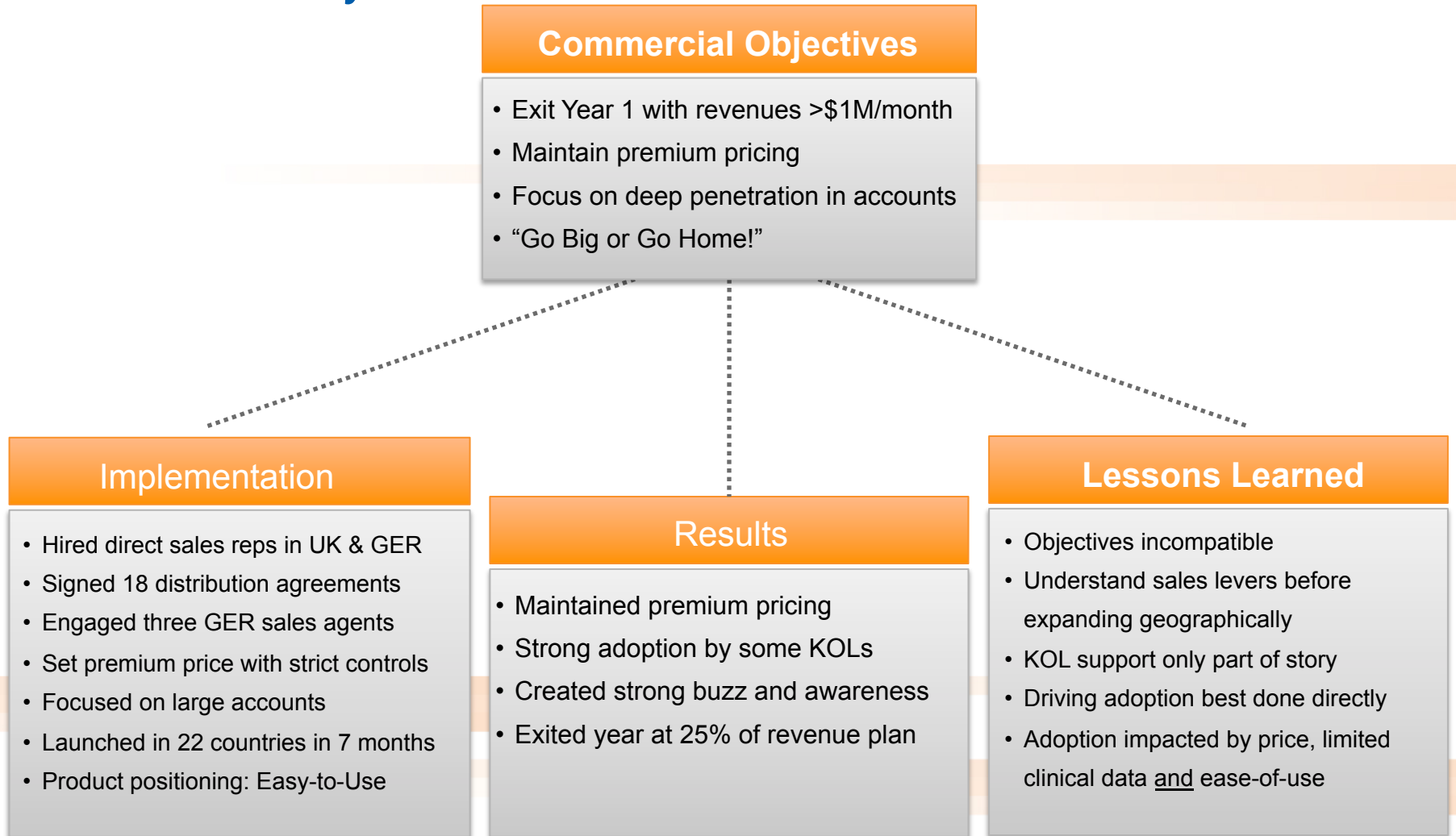
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Chasing Conflicting Objectives

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Deciding Approach to Customer: Distributors versus Direct Employees?

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Product Profile

- Changing clinical practice?
- Physician learning curve?
- Market development?
- Gross margin?
- Niche product?

Commercial Objectives

- Alignment with objectives?
- Revenue ramp?
- Investor patience/dry powder?
- U.S. market strategy?

Market Dynamics

- Local tenders?
- Hospital payment terms?
- Number of accounts?
- Geographical spread?
- Reimbursement?

Distributor Capabilities

- Customer relationships?
- Technical expertise?
- Financial stability?
- Product portfolio?
- Interest/desire?

Distributor as Commercial Partner

- Case Study

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Strategy

- Involved early in commercial planning
- Open and frequent communication to build trust
- Collaboration on programs aimed at our commercial objectives
- Open about company's progress towards major milestones
- Offered equity investment opportunity
- Joint visibility with KOLs

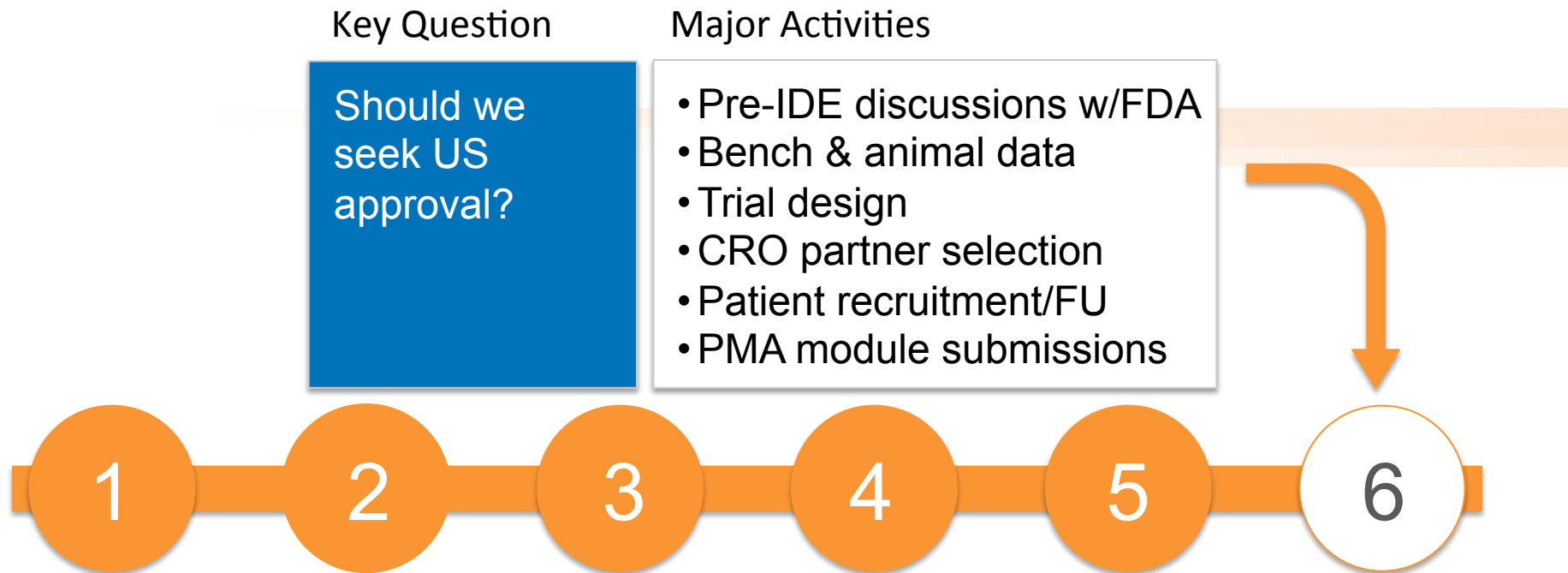


Results

- Remained with us during 10-month redesign effort
- Consistently achieved/exceeded quarterly sales targets
- Produced strong product adoption in key accounts
- Award for outstanding sales & clinical support performance, 2011

U.S. PMA Approval

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Lessons Learned

- ✓ Expensive, time-consuming, potentially risky
- ✓ Enrollment will take longer than you project
- ✓ Strategic acquirers happy to stay on sidelines
- ✓ Assess investors' dry powder to reach PMA approval

Key Takeaways

- Focus on how technology will save HC system money from Day 1
- CE Mark does not mean you have product
- Clinical data, not revenues, should be initial focus
- Don't underestimate supply chain complexities
- Align commercial objectives, focus on few
- Validate sales levers before expanding
 - "It's all about what happens at the account level"*
- Have ability to see FDA trial to completion

GOOD LUCK!