Bio Events International Convention

Bio Entrepreneurship Boot Camp

R&D Marketing Interface

Session 6

June 12 & 13, 2022

#BIO2022

R&D Marketing Interface

Biotechnology Entrepreneurship Boot Camp
BIO International Convention
June 12, 2022

Dr. Thani Jambulingam Ph.D.,
Professor, Pfizer Fellow, Arrupe Research Fellow
Department of Pharmaceutical and Healthcare Marketing
Erivan K. Haub School of Business
Saint Joseph's University
Philadelphia, PA 19131

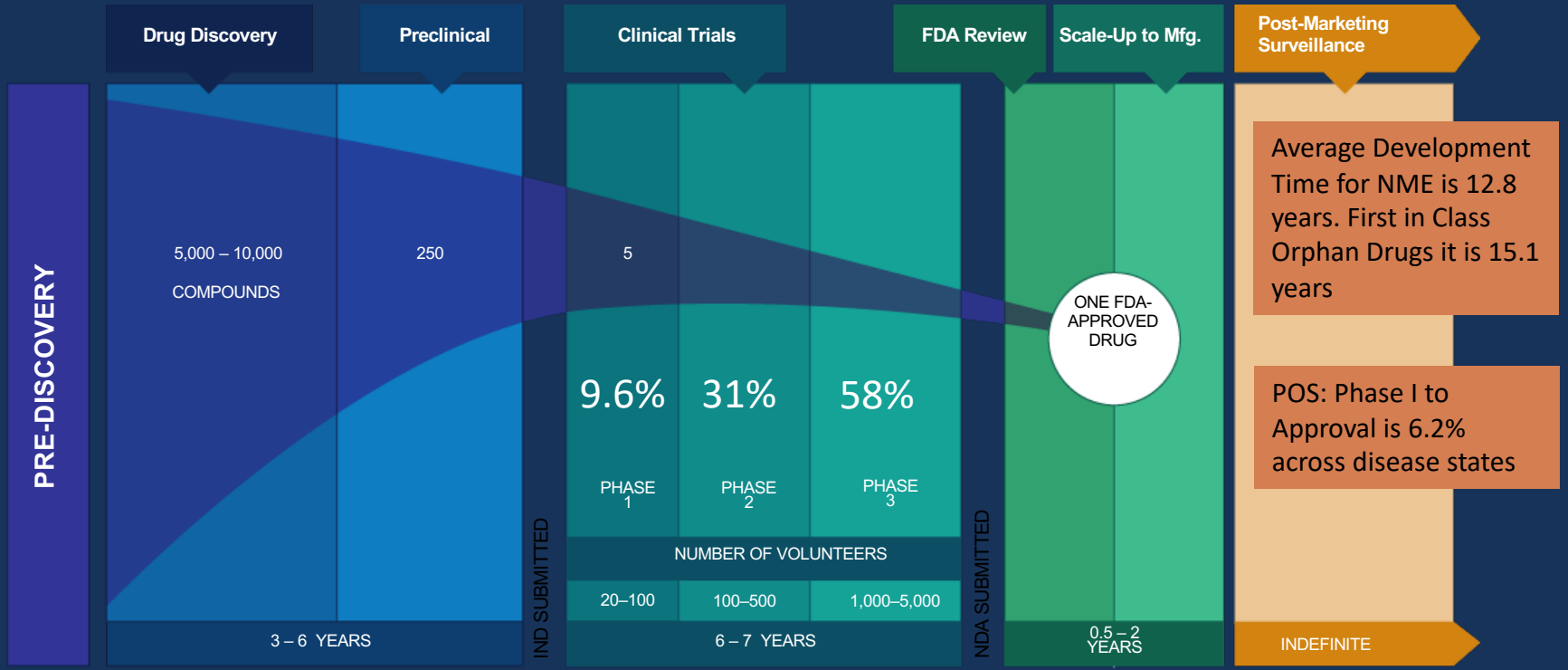
Learning Objectives

- Highlight the importance of commercial team input into product development strategy in a early stage biotech/medical device company
- Understand the role of marketing in early stage companies to shape the product life cycle to achieve the best commercial success.
- Describe the process of creating a commercially appealing target product profile (TPP).
- Learn how to develop a TPP framework to deliver better outcomes.

Trends

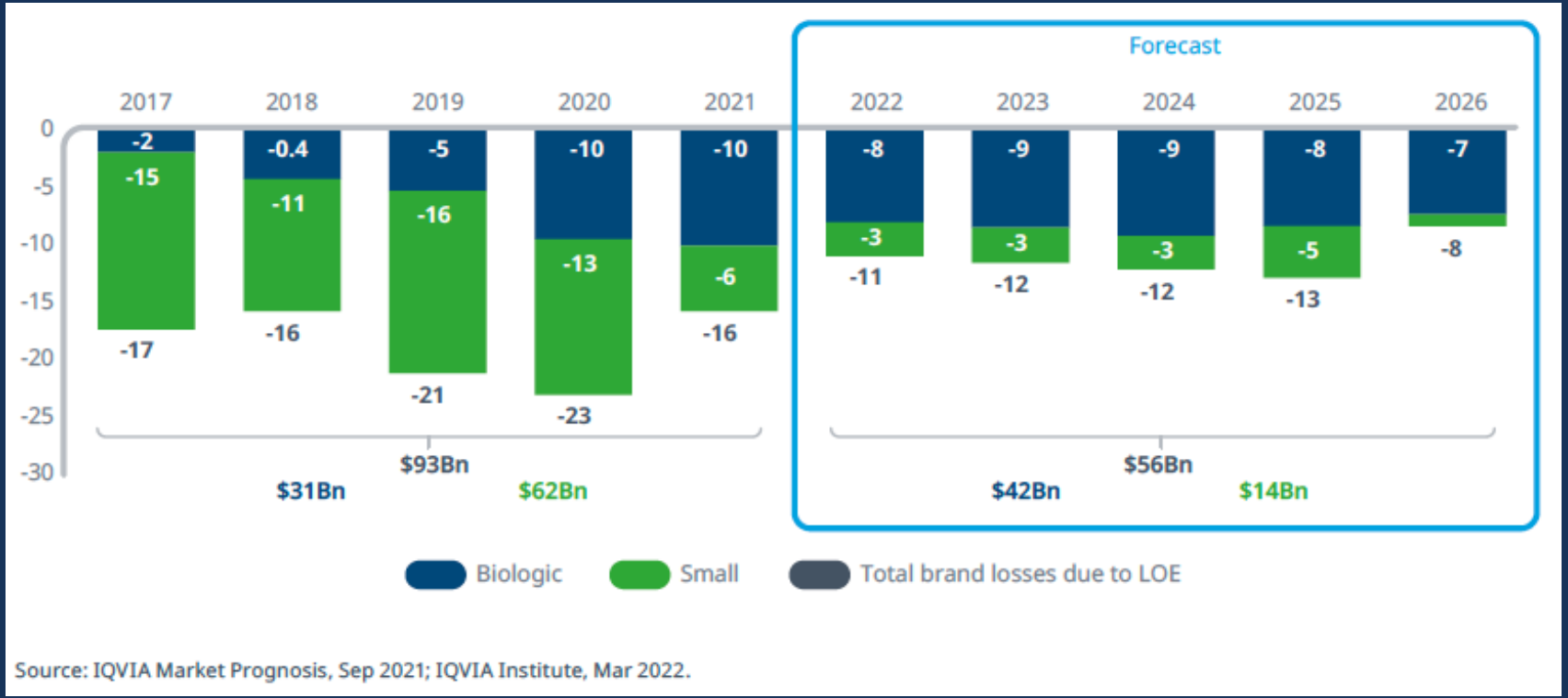
- Health care priority: cost control, access and price transparency
- Consumerism will influence healthcare decisions
- Decreasing access to physicians
- Shifting power balance toward payers
- Reimbursement models focus on value/outcome
- Growth of alternative delivery models and partnerships
- Digital transformation enhancing patient centricity and engagement

DEVELOPING A NEW MEDICINE TAKES AN AVERAGE OF 10–15 YEARS



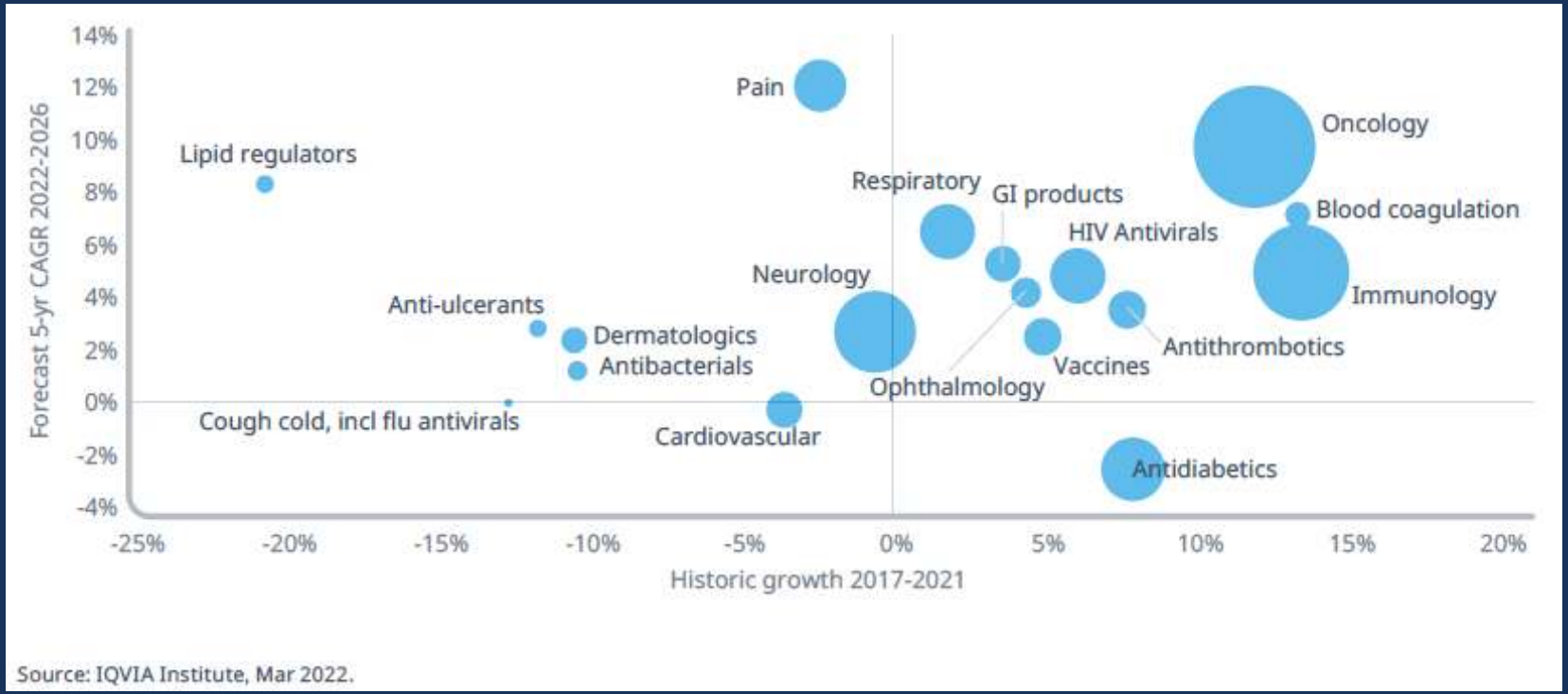
Sources: Drug Discovery and Development: Understanding the R&D Process, www.innovation.org; CBO, *Research and Development in the Pharmaceutical Industry*, 2006, Tufts Center for the Study of Drug Development, Impact Report May/June 2018, Clinical Development Success Rate 2006-2015, Biotechnology Industry Organization, 2006, Wong C.H., Siah K. W. "Estimation of Clinical Trials Success Rates and Related Parameters, Biostatistics , 20: 273-286, 2019

Pharma Loss of Exclusivity



Source: IQVIA Market Prognosis, Sep 2021; IQVIA Institute, Mar 2022.

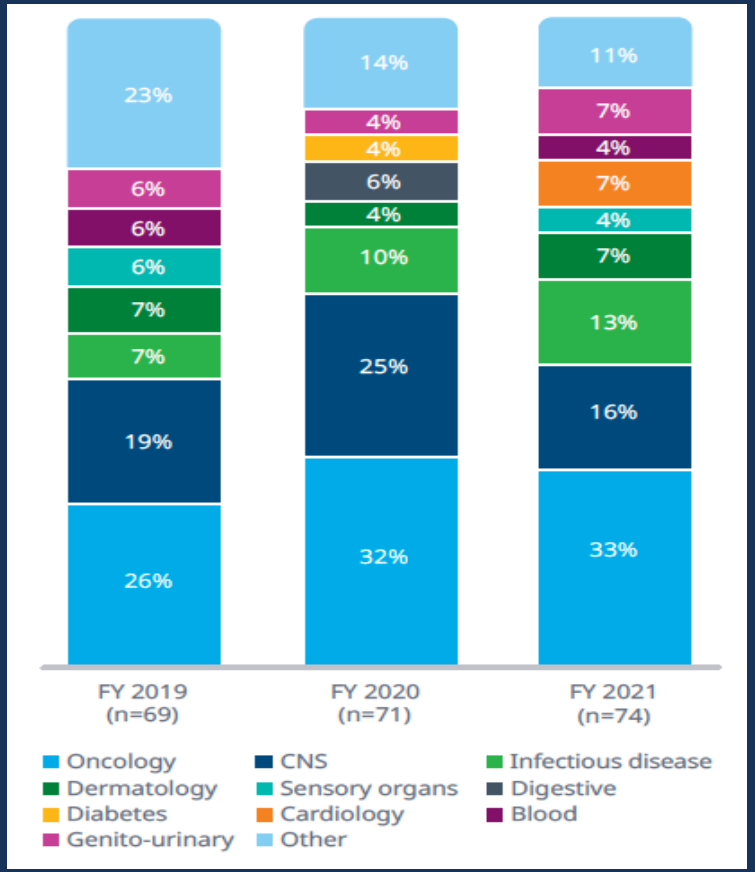
Net Spending Growth for Leading Therapy Areas



Source: IQVIA Institute, Mar 2022.

Breakdown of Launches by Therapy

#BIO2022



Source: IQVIA US Launch Quarterly May 2022

Innovative Product

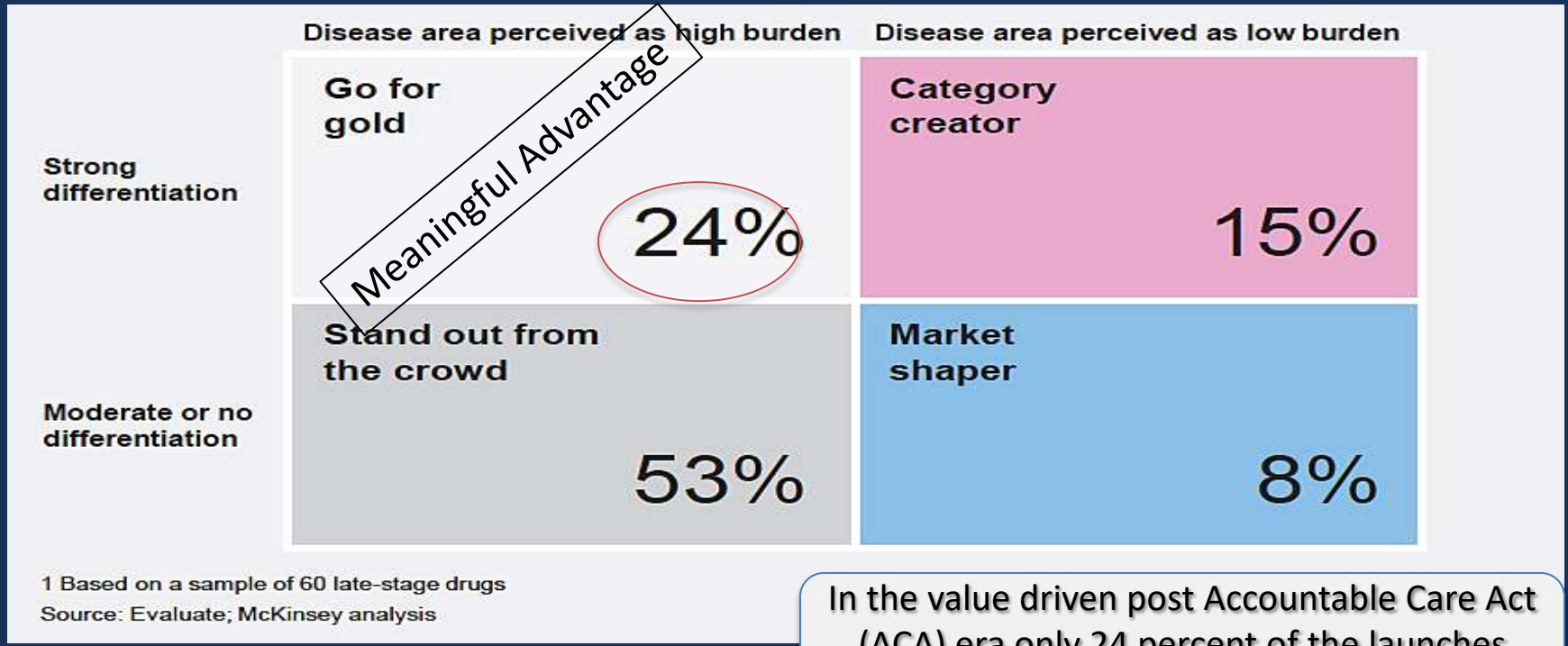
A differentiated product (solution) that offers a meaningful advantage (value) over existing treatments for a given condition

How can marketing shape the product?

Objectives, 4 P's, A's of Marketing

Objectives	4Ps	4As
Address Unmet Needs	Product	Acceptability
Value to Payers	Price	Affordability
Create Convenience	Place	Accessibility
Communication of Value	Promotion	Awareness

What Proportion of the Launches are Innovative?

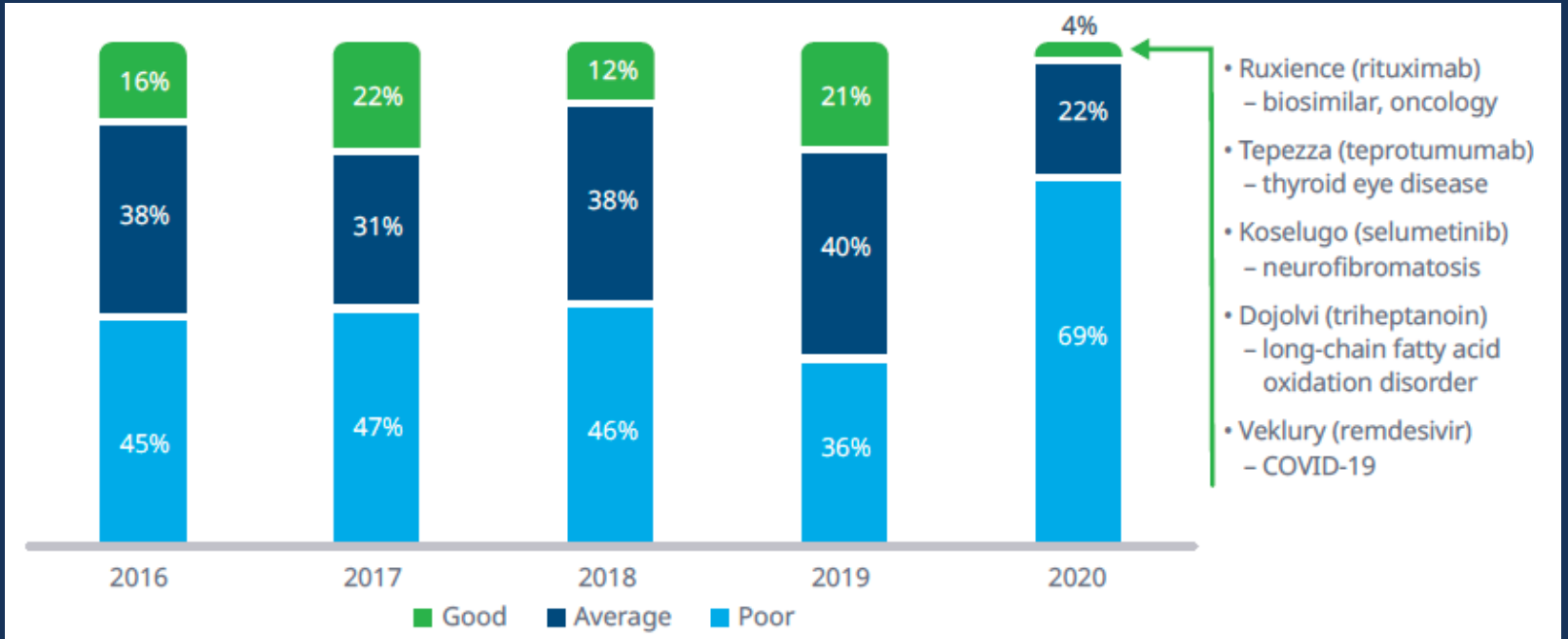


In the value driven post Accountable Care Act (ACA) era only 24 percent of the launches would be truly innovative

Source: Beyond the Storm: The Launch Excellence in the New Normal, McKinsey Report 2013, pp.6

Rating Share of Launch Products

#BIO2022

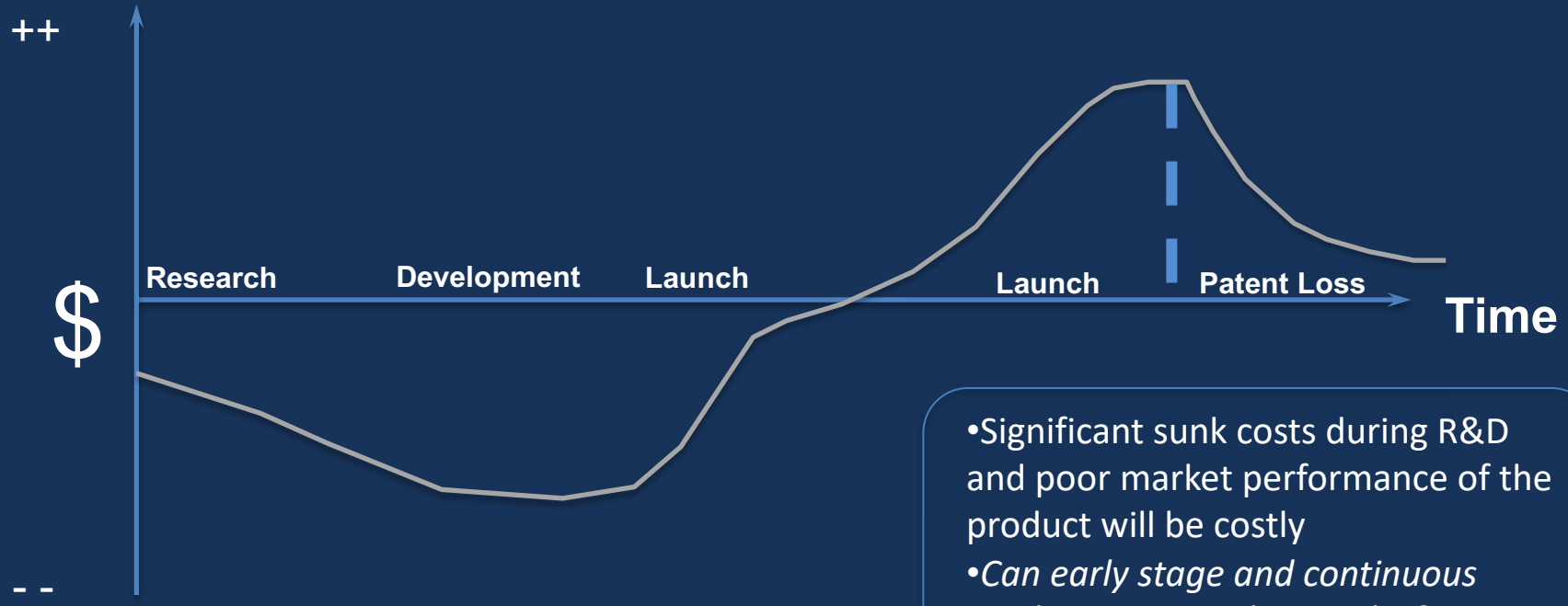


Source: National Sales Perspective, Launch MVP, Center of Launch Excellence, IQVIA

Notes: Includes Hepatitis C products. Launch performance is determined at month twelve by four criteria: share achievement, competitive rank, promotion-to-gross-sales ratio and gross sales.

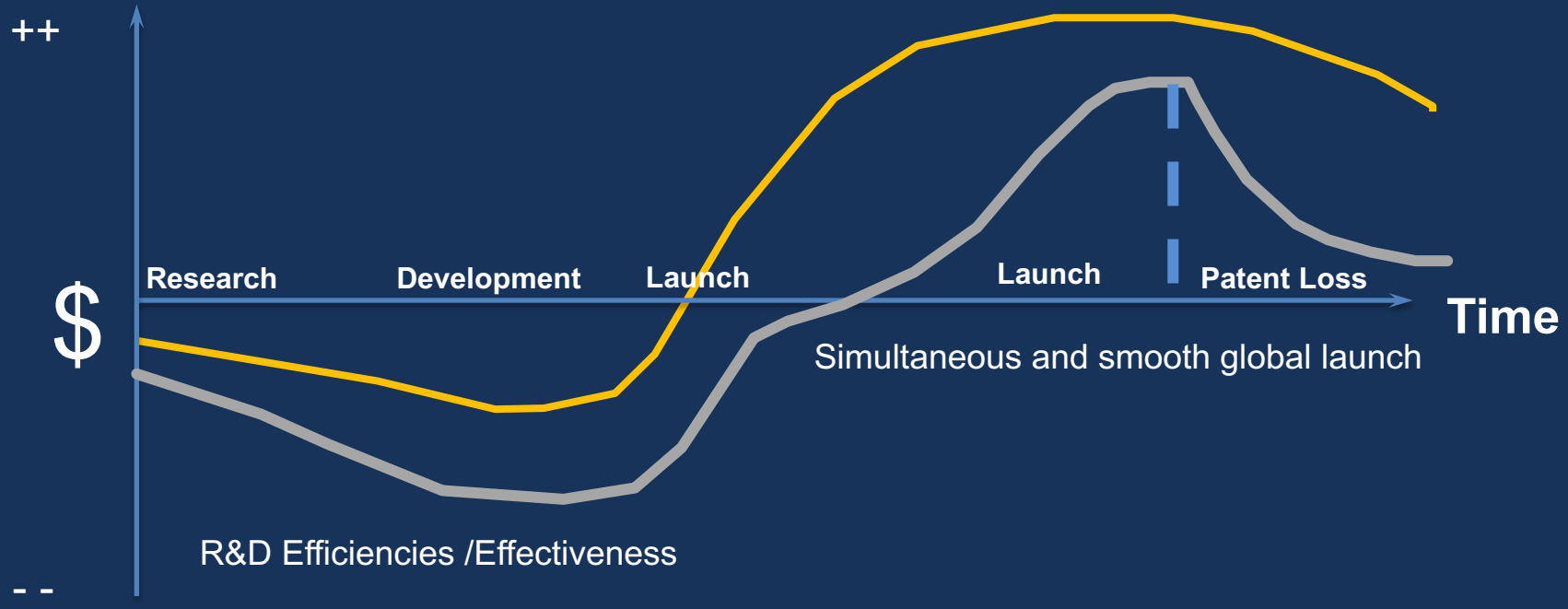
Source: IQVIA US Launch Quarterly May 2022

How to Improve the Probability of Success?

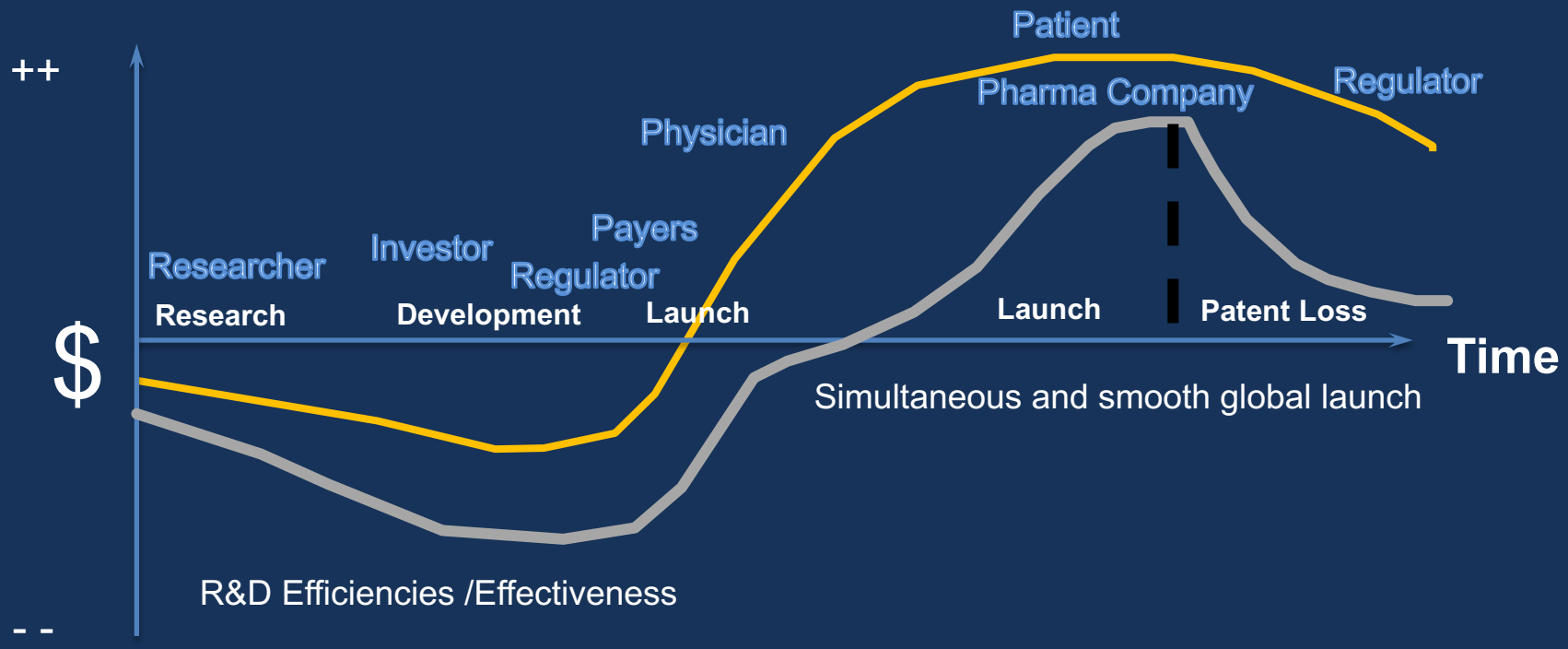


- Significant sunk costs during R&D and poor market performance of the product will be costly
- *Can early stage and continuous marketing input change this?*

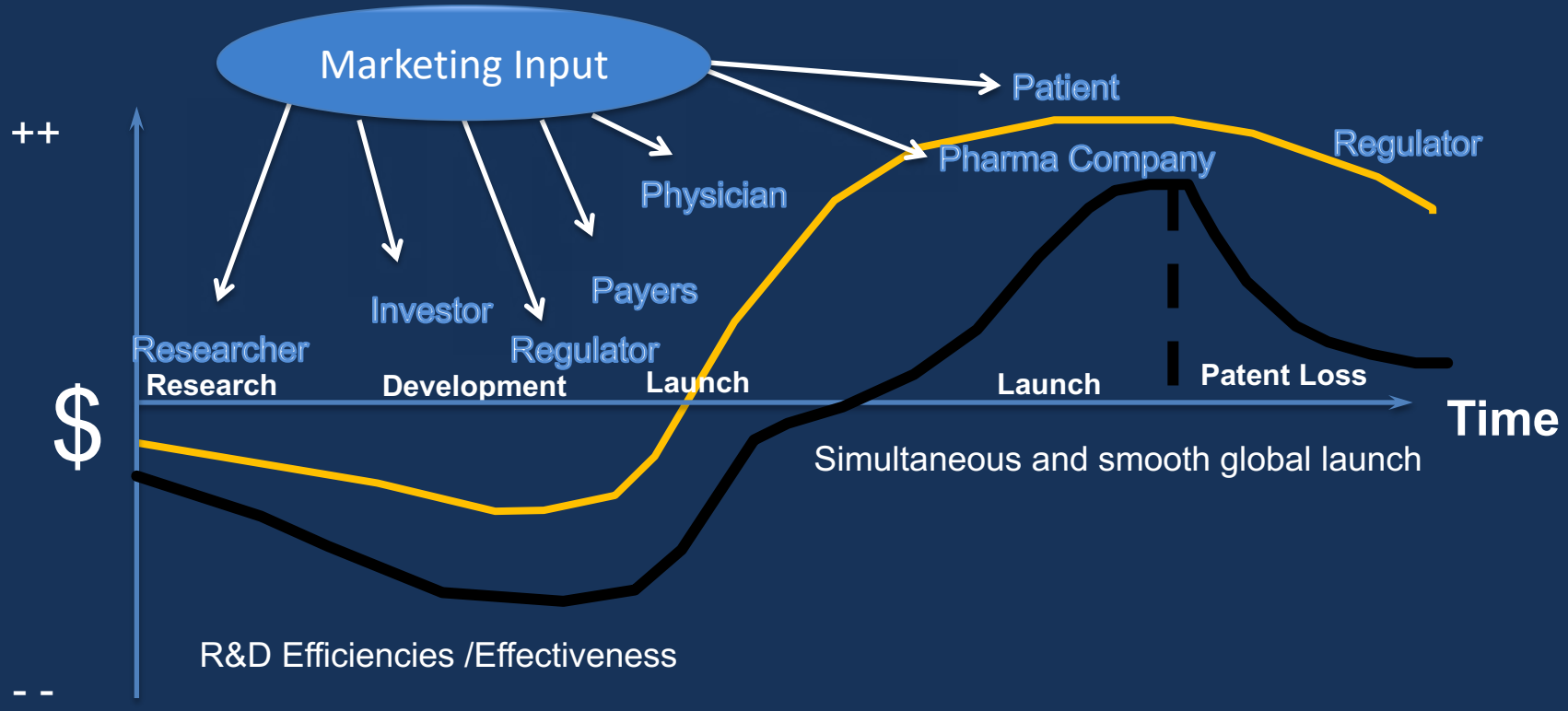
Ideal Product Life Cycle



Meeting Stakeholders Needs



Early Marketing Input Can Improve Product Success



Early Marketing Input Can Improve Product Success

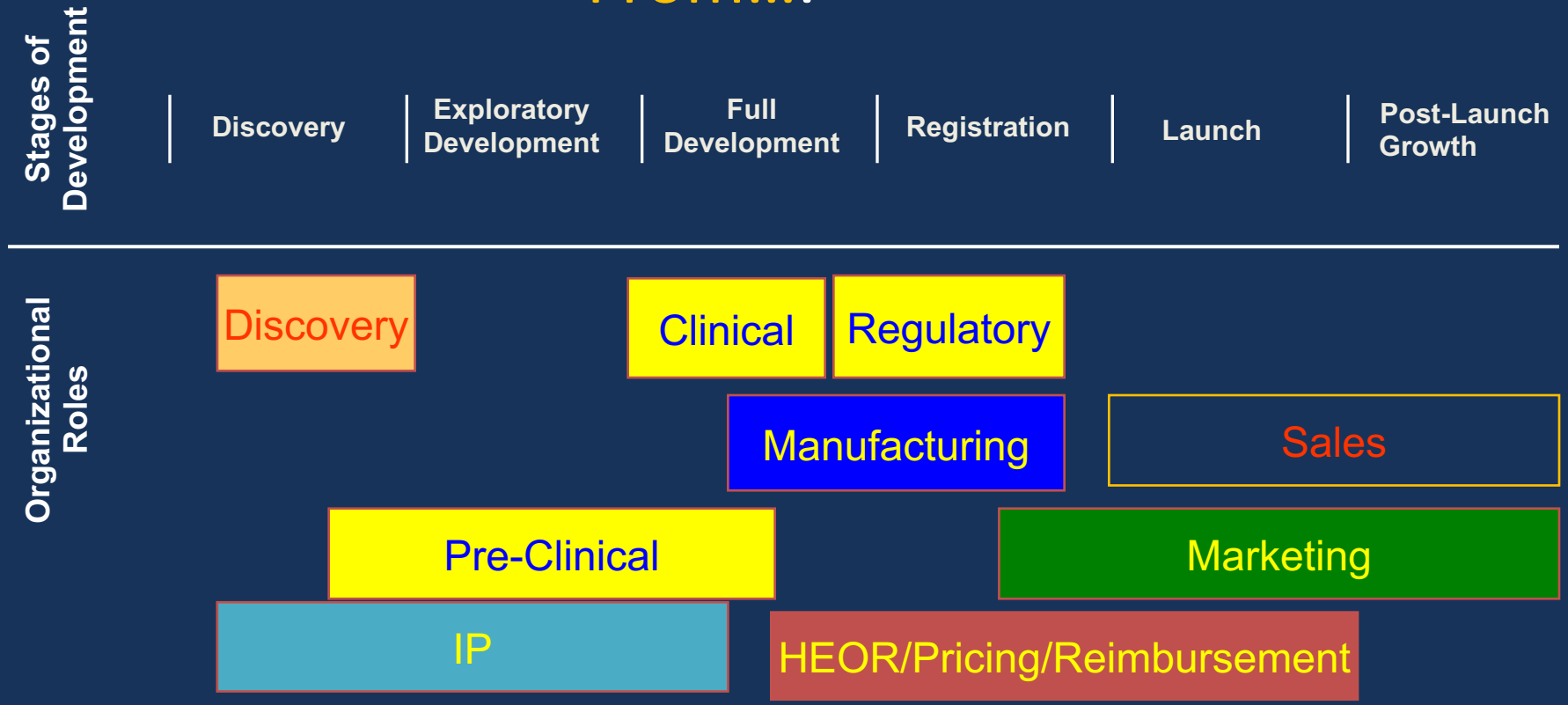
#BIO2022

						Launch	Growth			
					Submission	Launch/Adoption Tracking	Longitudinal Tracking	Maturity		Rejuvenation
					Pricing Finalization	Promotional ROI Analyses	Patient Studies	Licensing/ Acquisition		Line Extension Optimization
				Phase III	Launch/Adoption Forecast	Message Recall Studies	Patterns of Therapy	Franchise Optimization	Decline	Competitive Recall Response Modeling
				Positioning Studies	ATU Studies	Perceptual Mapping	Consumer Satisfaction Testing	Promotional Sensitivity	Erosion Tracking	
			Phase II	Promotion Message Development	Market/Competitive Assessment	Validate / Modify Promotions	Defense Planning	Cannibalization Planning	Franchise Optimization	
			Optimize Targeting Strategy	Line Extension Analyses	Journal Ad/CME Testing	Customer Satisfaction Testing	Pricing Reevaluation Study	Forecasting	Pricing Re-evaluation	
		Phase I	Licensing/ Co-promotion Study	DTC Message Development	Promotional ROI Analyses	Competitive Reaction Analyses	Promotional ROI Analyses	Divestiture/Generic Planning	Line Extension Launch Tracking	
		Positioning: Physician Testing	Physician-Patient Pricing Study	Positioning Finalization	Promotional Material Testing	ATU Studies	Line Extension Launch Planning	Line Extension Launch Planning		
	Development	Market Assessment	Post Efficacy Forecast	Market/Competitive Assessment	Formulary/Tier Analysis	Relaunch & Repositioning	Sales Forecasting	Brand/Generic Erosion Trending		
	Copayment MCO Market Analysis	Global Pre-efficacy Forecast	Detailed Patient Segmentation	Educational Needs Assessment	Pharmacist Research	Line Extension Research Update	Competitive Defense Strategy	New Indication Research		
Discovery	Pricing Range Study	MCO/Value Pricing Study	Detailed Physician Segmentation	Call Plan and Targeting	Early Sampling Value Study	Pull-through Effectiveness				
Market Size & Opportunity	Patient Segmentation	Optimize Market Coverage	Branding Development	Identify Early Adopters	Optimize Sampling Coverage	Spillover Analysis				
Market Assessment	Thought Leader Analysis		Product Profiling	Parallel Behavior Modeling	Inventory Mgmt Assessment	Value Added Program ROI		TOOLBOX	Predictive Modeling	Factor Analyses
Physician Segmentation			Initial Sales Force Sizing	Sales Force Sizing & Deployment	Monitoring Program Development	Contract Monitoring		Diagnosis/Treatment protocols	Therapeutic Class Studies	Discriminant Functions
Pre-efficacy Forecast			Managed Care Landscape	Contracting and Rebates	Coupon Tracking	Pharmacy Program Intervention ROI		Patient Diagnosis Database	Primary Market Research	Econometric Modeling
Determine Value of a Patient				Sales Incentive Compensation	Relevant Benchmarking	DTC ROI		Ad Hoc Primary Research	Promotional Response	Event Modeling
Cost of Illness Economic Analysis				Prescriber Base Analysis	Local Health Market Influence Study			Patient Flow Analysis	Copay/Coupon ROI	Time Series Modeling
Risk - Productivity Analysis				Patient Tracking Audits	Reach & Frequency Study			Revealed Preference	Patient Longitudinal Tracking	Adoption Analysis
Unmet Product Needs				Persistency Studies	Sales Force Effectiveness			Multi-therapy Analytics	Managed Care Analytics	Physician Segmentation
				Patient Simulation Studies				Persistency / Compliance	Forecasting/Lifetime value of a Patient	TOOLBOX

What will Collaboration Achieve…?

#BIO2022

From….



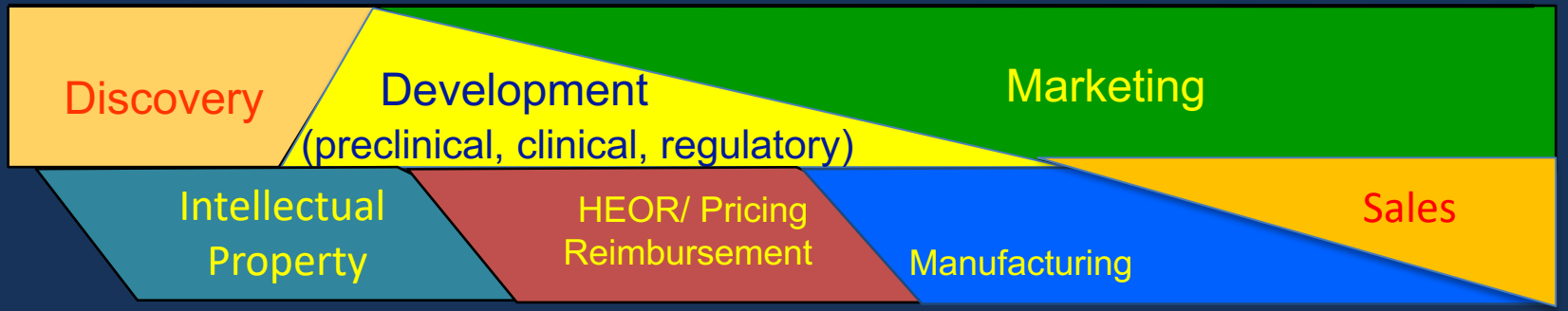
What will Collaboration Achieve…?

To….an Integrated Model

Stages of Development

Discovery	Exploratory Development	Full Development	Registration	Launch	Post-Launch Growth

Organizational Roles



Upstream Role of Marketing is Critical for developing an Ideal Label and Product Success!

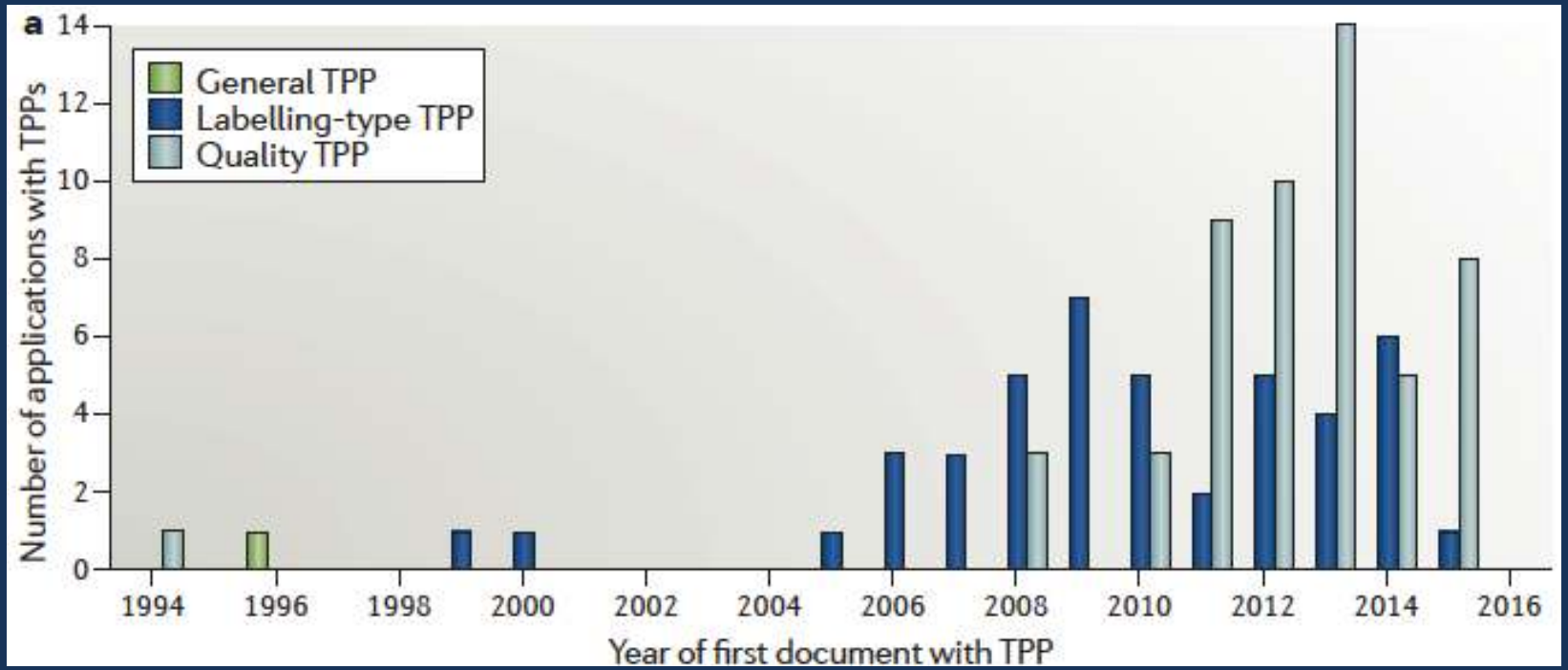
Marketing Facilitate Cross-Functional Decisions

Source: Jambulingam, T. (2018), The R&D Marketing Interface in BioPharma and MedTech, Journal of Commercial Biotechnology, 24(1), 48-55.

What is TPP?

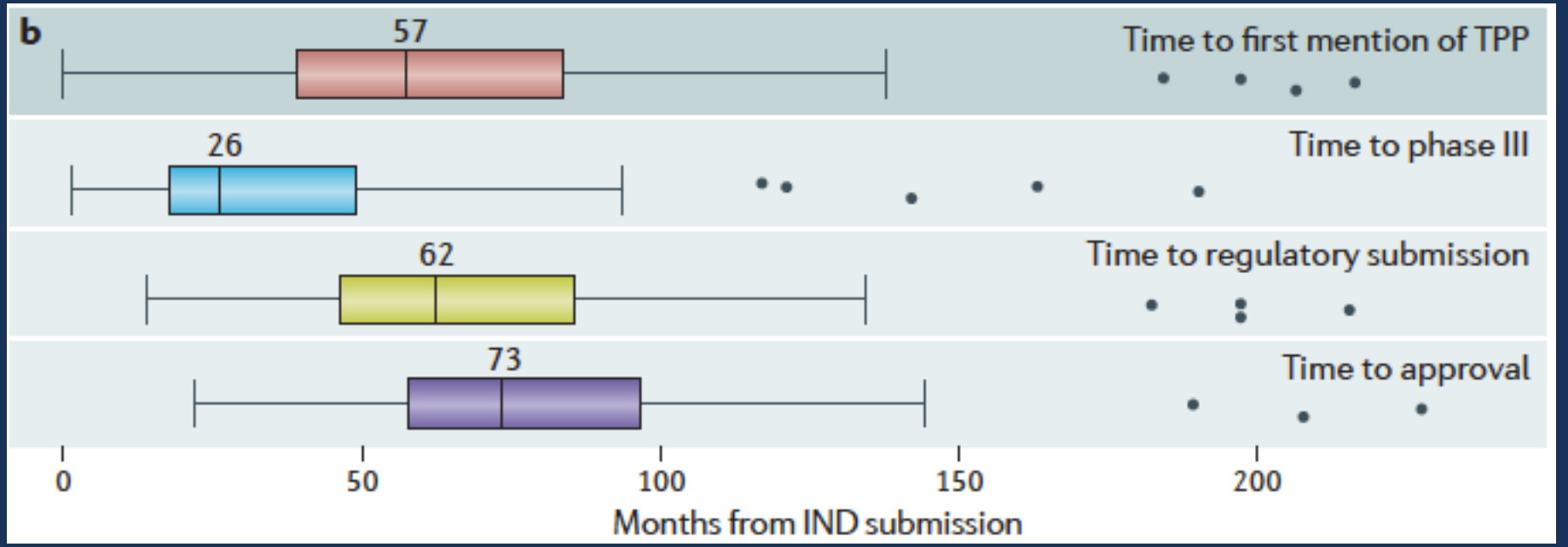
- In 2007 FDA created a guidance document on TPP as a strategic process development tool to facilitate effective communication between the industry and review staff
- TPP is the directional tool that has a significant impact on the drug development process and in particular, its marketing organization
- TPP convert discoveries into companies!
- Marketing as part of commercial team can shape the TPP

Research shows TPP is valuable but underused



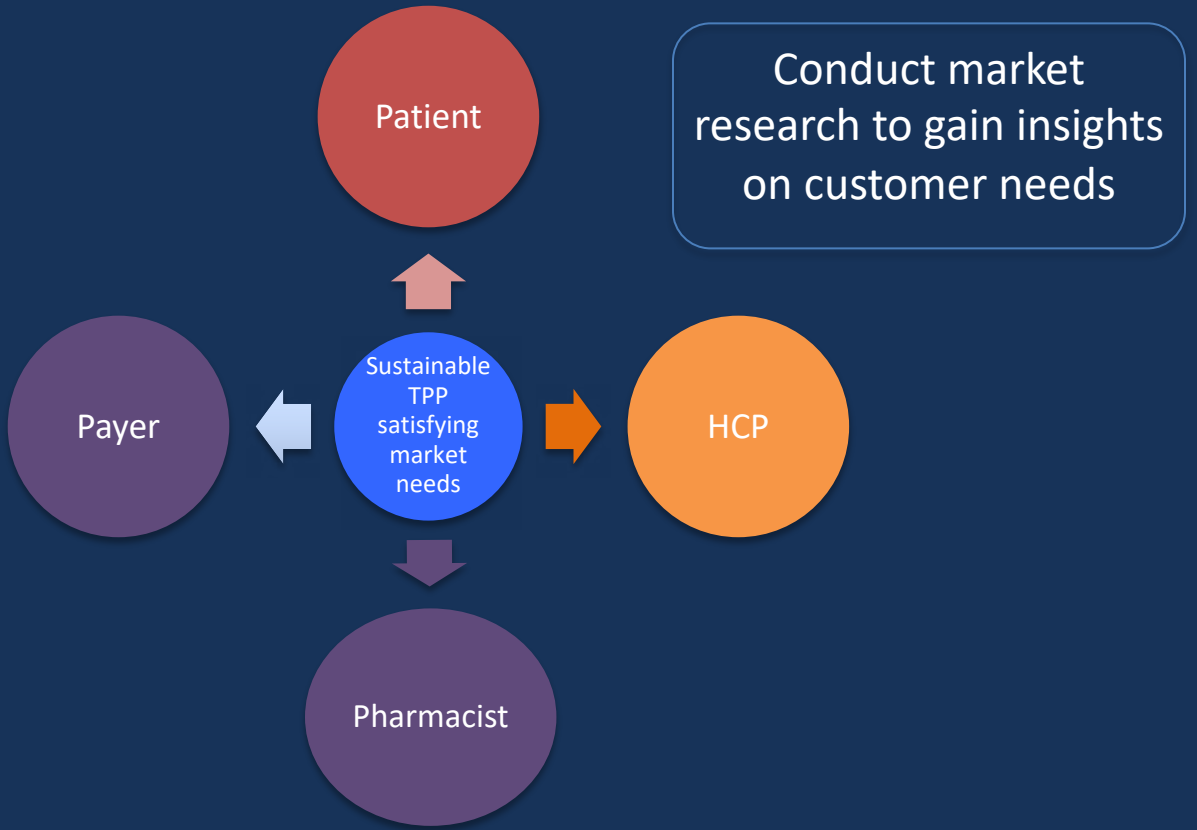
Source: Tyndall et.al. The TPP as a tool for regulatory communication: advantageous but underused, Nature, March 2017, pp. 156

Research shows TPP Valuable but Underused



Source: Tyndall et.al. The TPP as a tool for regulatory communication: advantageous but underused, Nature, March 2017, pp. 156

Start with end in mind: How should the label look to meet customer needs ?



How can TPP be shaped by Marketing?

TPP

- Indication
- Dosage form
- Dose, frequency
- Differentiation
  - Efficacy
  - Safety
  - Economic

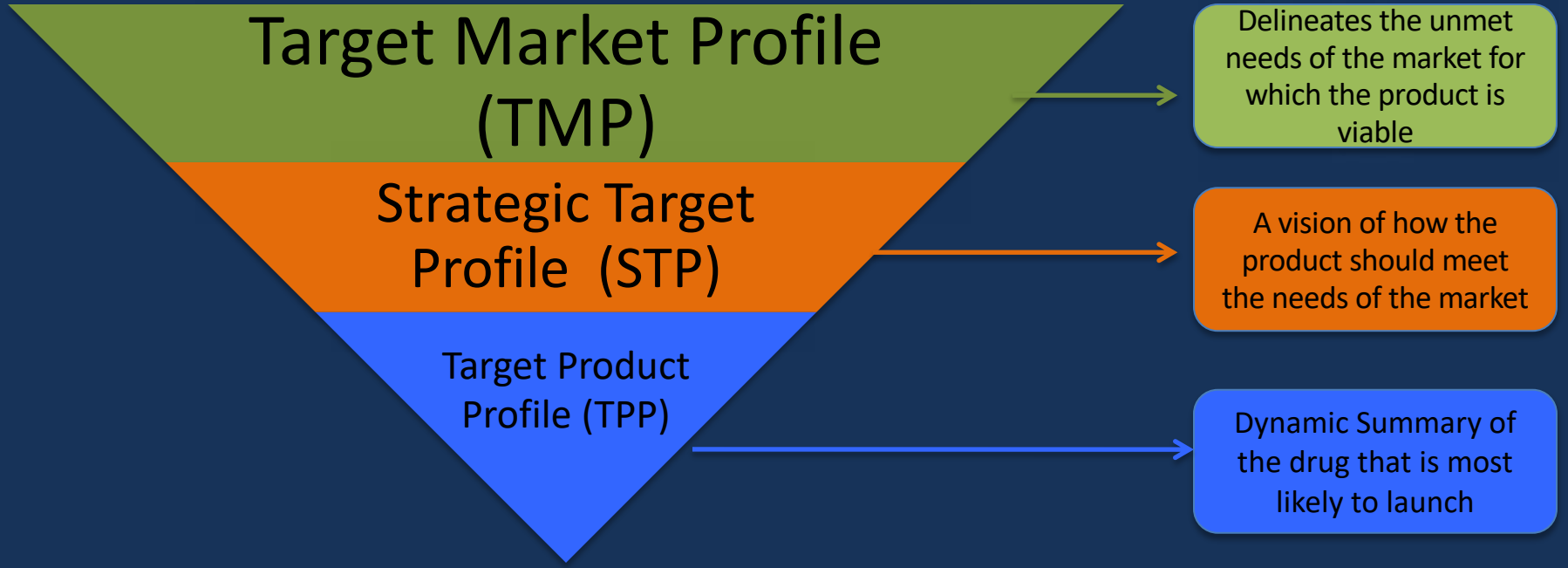
Attributes Shaped by Marketing

- Proposed indication
- Develop formulation
- Develop trade-dress
- Establish efficacy/superiority
- Establish safety advantage
- Develop for pediatric use
- Pharmacoeconomic data

Who should work together?

Goal: To deliver strong development plan with superior clinical performance, patient benefit and health economic value

STRATEGIC FRAMEWORK



Source: Tebbey, Paul W. and Charles Rink, "TPP: A Renaissance for its Definition and Use, Journal of Medical Marketing, Vol. 9 (4), 301-307.

Strategic Framework

	Target Market Profile (TMP)		
Purpose	Captures all the key information about the market		
Content	Therapeutic areas/diseases • Unmet Need • Patient Populations • Drivers of use • Competitive assessment • Economic cost of disease		
Rigidity	Create before the STP or TPP Details are updated as findings emerge, but core facts change only in response to major market events		

Strategic Framework

	Target Market Profile (TMP)	Strategic Target Profile (STP)	Target Product Profile (TPP)
Purpose	Captures all the key information about the market	A vision for a product that will meet the needs of the market	
Content	Therapeutic areas/diseases • Unmet Need • Patient Populations • Drivers of use • Competitive assessment • Economic cost of disease	Target attributes (desired profile) • Value drivers/Positioning • Global Reach • Pricing/Reimbursement • Patient Share • Revenue – Profitability • Pharmacoeconomics • Investments (R&D, COGS, SGA) • Cost of goods • Licenses, Royalties	✓Positioning ✓Global Sales Forecast ✓Developmental Logic ✓Regulatory and Reimbursement Strategy ✓Product Value
Rigidity	Create before the STP or TPP Details are updated as findings emerge, but core facts change only in response to major market events	Set at the beginning of clinical development and updated only when necessitated by changes in the TMP	

Strategic Framework

	Target Market Profile (TMP)	Strategic Target Profile (STP)	Target Product Profile (TPP)
Purpose	Captures all the key information about the market	A vision for a product that will meet the needs of the market	A record of the drug that is most likely to launch
Content	Therapeutic areas/diseases • Unmet Need • Patient Populations • Drivers of use • Competitive assessment • Economic cost of disease	Target attributes (desired profile) • Value drivers • Global • Pricing/Reimbursement • Patient Share • Revenue – Profitability • Pharmacoeconomics • Investments (R&D, COGS, SGA) • Cost of goods • Licenses, Royalties	Indications and usage (label) • Dosing and administration • Contraindications • Warnings and precautions • Adverse reactions • Description • Clinical Pharmacology • Clinical Studies • Storage and handling
Rigidity	Create before the STP or TPP Details are updated as findings emerge, but core facts change only in response to major market events	Set at the beginning of clinical development and updated only when necessitated by changes in the TMP	Updated as clinical and pharmacologic findings emerge and in response to guidance from regulatory authorities

Questions that needs to be asked and answered during the TPP process

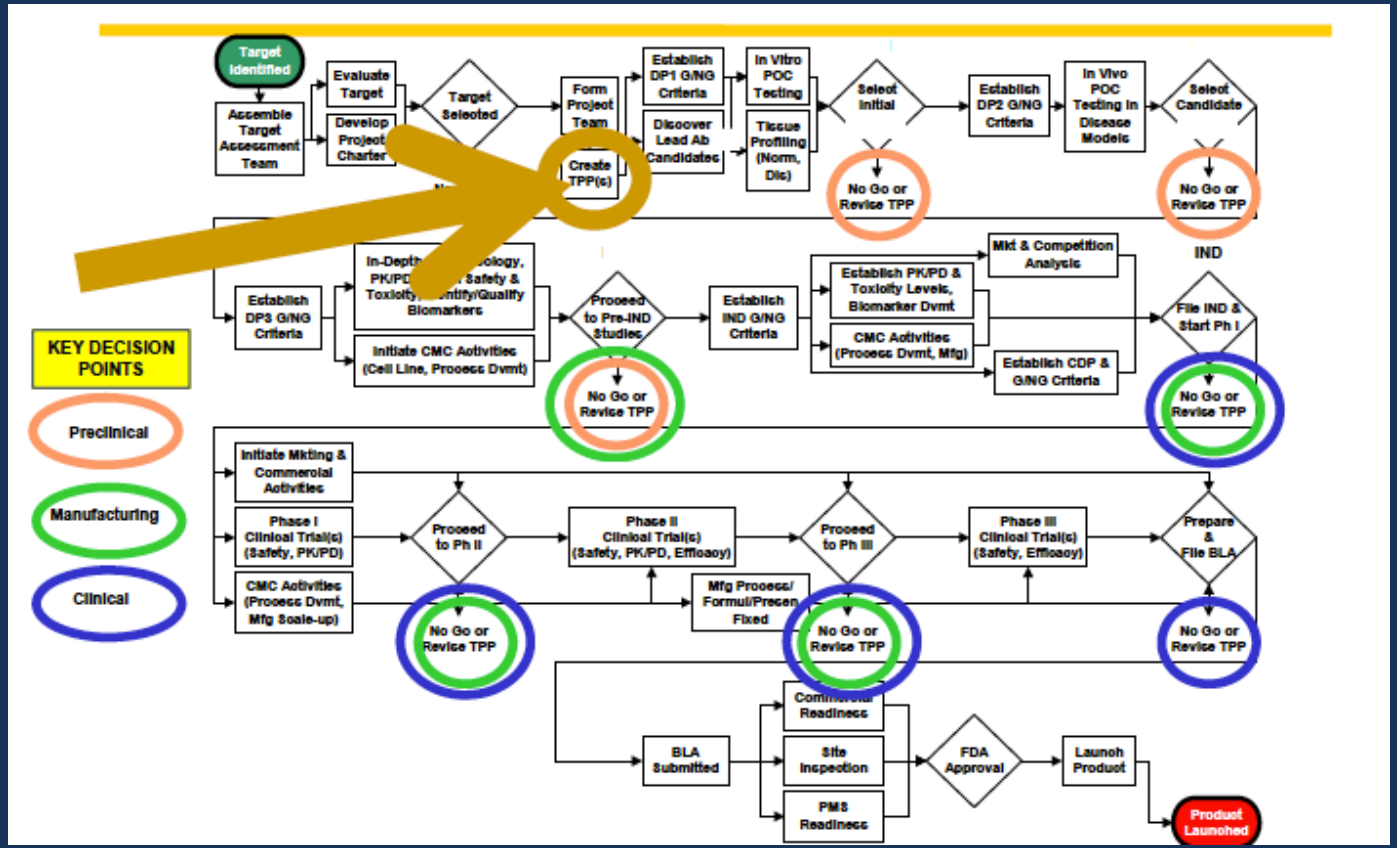
- What is the product description?
- What data or literature is available for review for the various indications and claims?
- What is the unmet need, clinical benefit or value to others?
- Will the product be used for a new or existing procedure?
- What is the standard of care (SOC) for this indication?
- What is the future direction of SOC?
- What is the market potential for each indication and claim?
- What is the probability of success for each indication and claim?
- What are the product's possible differentiating features and will they be obsolete in 5 years?
- What are all of the possible indications for this product (neurovascular, pulmonary, peripheral vascular, gastrointestinal, etc.)?
- What are all of the possible differentiating claims?
- Can premium pricing be justified?
- If so, will payors directly reimburse?
- How is the competitor successful?
- Where does the competition fall short?
- Does IP exist or can it be created?
- Can exclusivity be achieved with a more complex regulatory or clinical strategy?
- If so, what is the company's tolerance or resource availability for such complexity?
- What are the COGS?
- How do development costs compare against five-year return on investment (ROI)?
- How does the net present value (NPV) or ROI compare against other projects?

Source: Begin with End in Mind – White Paper Premier Research, 2015

Portfolio Optimization – Go/No Go

- Specification – TPP – Current, Minimal, Ideal & Expected
- Resources – Manpower and Cost
- Timeline – Milestone Schedule
- Risk – Probability of Success (Technical, Commercial)

TPP in Go/No Go Decisions



Sample TPP

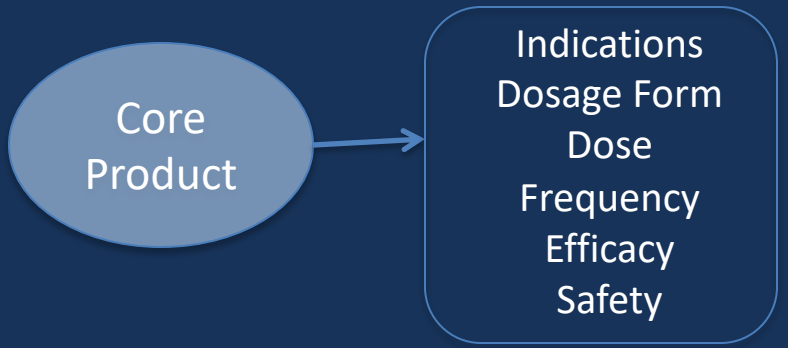
Product Properties	Minimum Acceptable Result	Ideal Results
Primary Product Indication	Relief of pain symptoms in diabetic neuropathy	Relief of symptoms in neuropathic pain syndromes
Patient Population	Adults with diabetes who experience moderate to severe pain	Adults with diabetes who experience moderate to severe pain
Treatment Duration	Chronic	Chronic
Delivery Mode	Subcutaneous injections	Subcutaneous injections
Dosage Form	Prefilled vials with liquid	Prefilled vials with liquid
Regimen	Once every month	Once every 2 months
Efficacy	A 40% decrease in pain score in 30% of patients	A 70% decrease in pain score in 50% of patients
Risk/Side Effect	Devoid of local injection effect and clinically significant CNS side effect	Devoid of local injection effect and any CNS side effect
Therapeutic modality	Antibody	

Source, https://neuroscienceblueprint.nih.gov/sites/default/files/documents/Example_TPP_508C.pdf accessed June 2, 2022

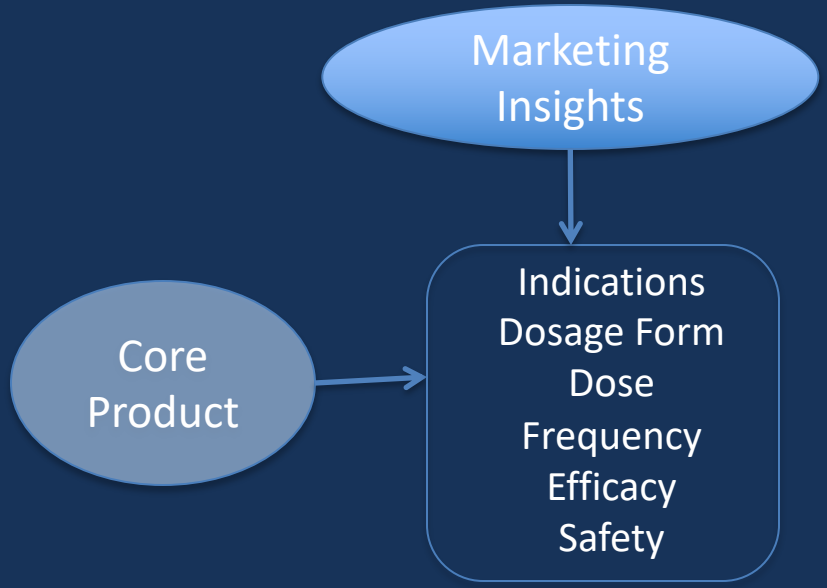
Best Development Strategies…

- Use the strategic framework (TMP, STP) to shape TPP and define clinical and commercial value
- TPP provides developmental logic and saves cost to drug discovery and development program and meet the needs of the market place
- Encourages right dialog within the company and with the FDA to optimize label and promotability for commercial success
- The ideal development strategy identify key milestones -critical times, when the ability of a project to attain its TPP can be assessed - and establish “go / no go” success criteria

Marketing Create “Beyond the Pill” Solution

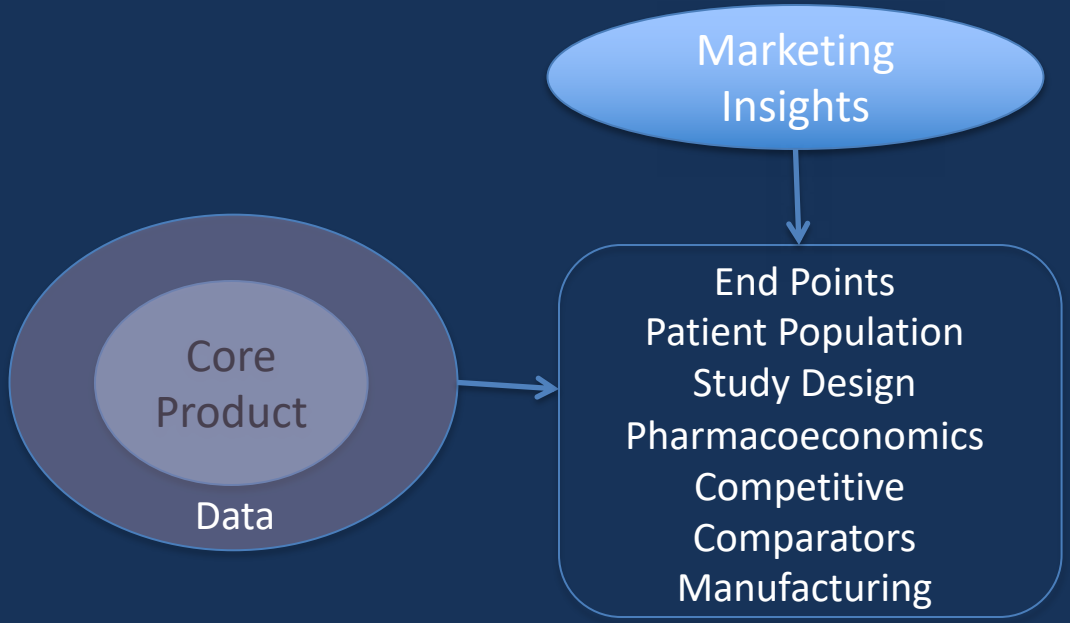


Marketing Create “Beyond the Pill” Solution

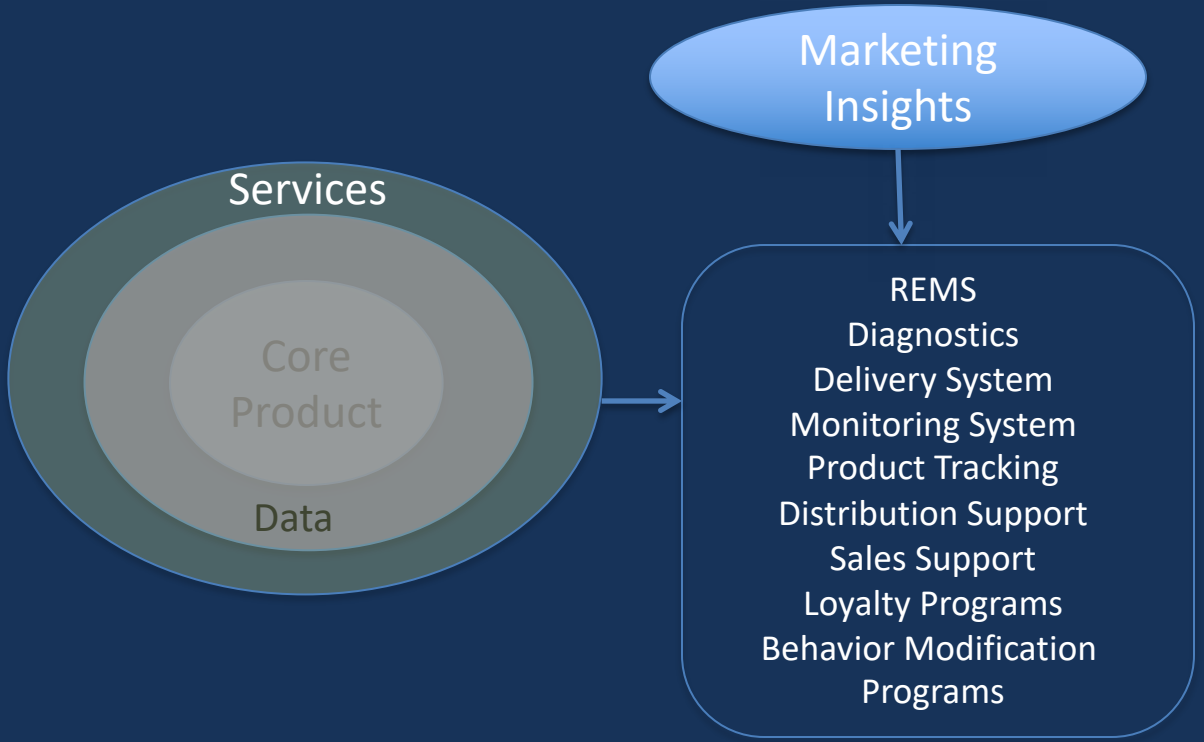


Marketing should shape the “Label” for the product

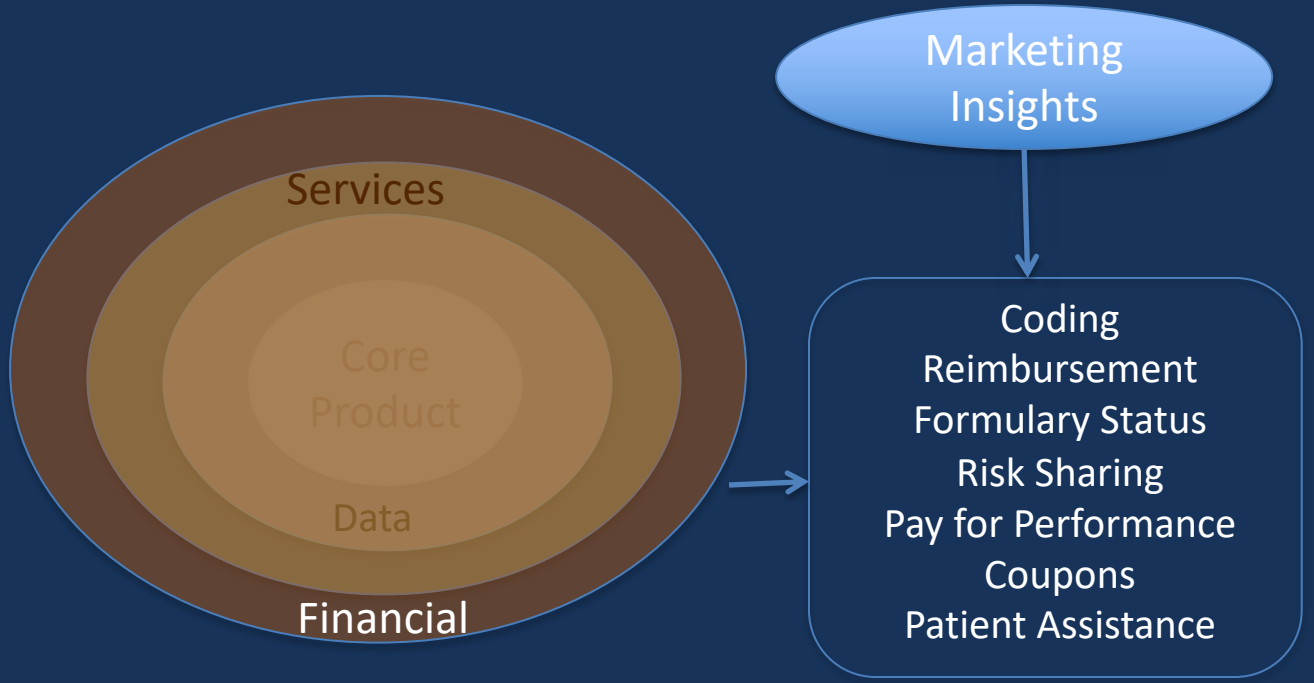
Marketing Create “Beyond the Pill” Solution



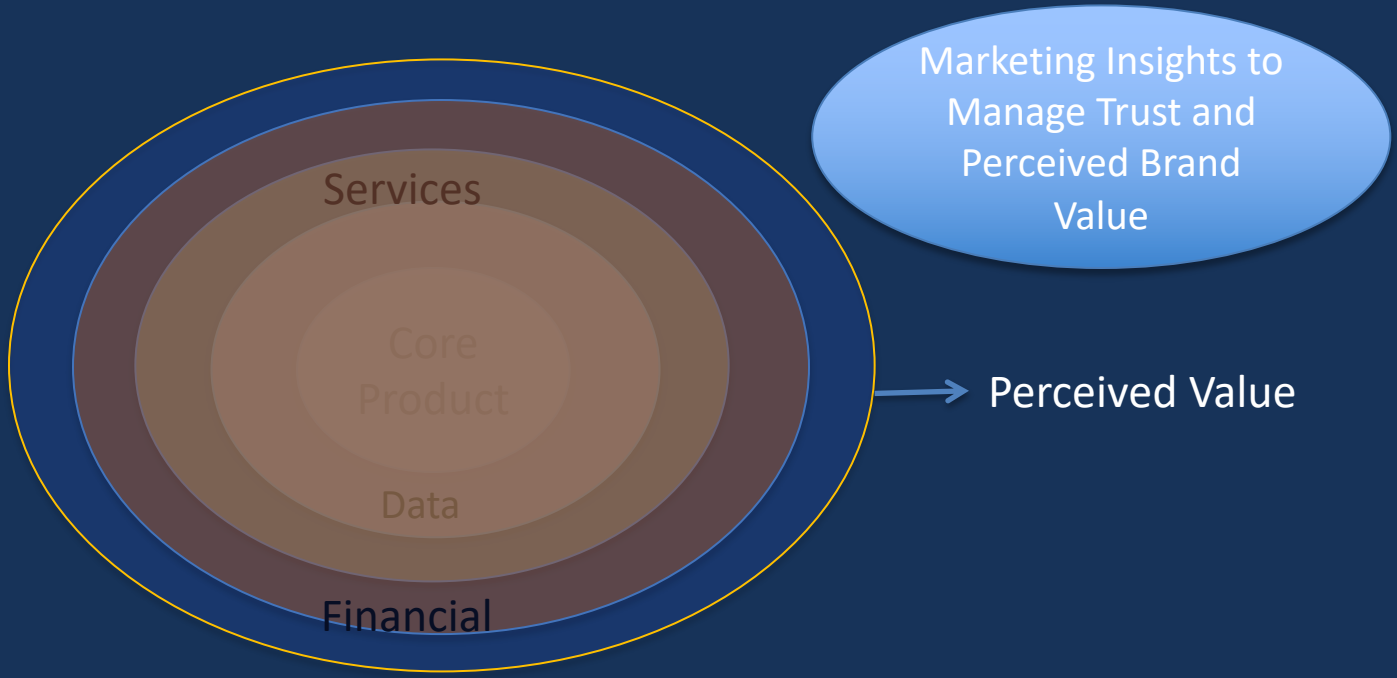
Marketing Create “Beyond the Pill” Solution



Marketing Create “Beyond the Pill” Solution



Marketing Create “Beyond the Pill” Solution



Final Remarks

- Start with end in mind
- Strengthen the R&D Marketing (Commercial) interface
- Assemble cross functional commercial development team
- Assign a marketing manager to the development team
- Incorporate market research and competitive intelligence in clinical trial planning and label development
- Engage payers early on to get valuable input in development
- Success is when the final version of TPP is similar to the annotated draft labeling!

Bio Events International Convention

Questions???