



Become a Biotech or MedTech Entrepreneur

Presented by:

Thani Jambulingam Ph.D.

June 1–2, 2024

[#BIO2024](#) [#StandUpForScience](#)

Session 5: Translating Strategy into Execution with a Target Product Profile (TPP)

Become a Biotech or MedTech Entrepreneur
BIO International Convention
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Dr. Thani Jambulingam Ph.D.,
Professor, Pfizer Fellow, Arrupe Research Fellow
Department of Pharma and Healthcare Business
Erivan K. Haub School of Business
Saint Joseph's University
Philadelphia, PA 19131



Learning Objectives

- Understanding the importance and components of TPP
- Role of market research and competitive intelligence in TPP development
- R&D and Marketing collaboration in creating an effective TPP
- Finalizing the TPP and ensuring alignment with company goals

Key Healthcare 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

A business enterprise has two--and only two--
basic functions: Innovation and Marketing.
Innovation and Marketing produce results; all
the rest are costs."

Peter Drucker



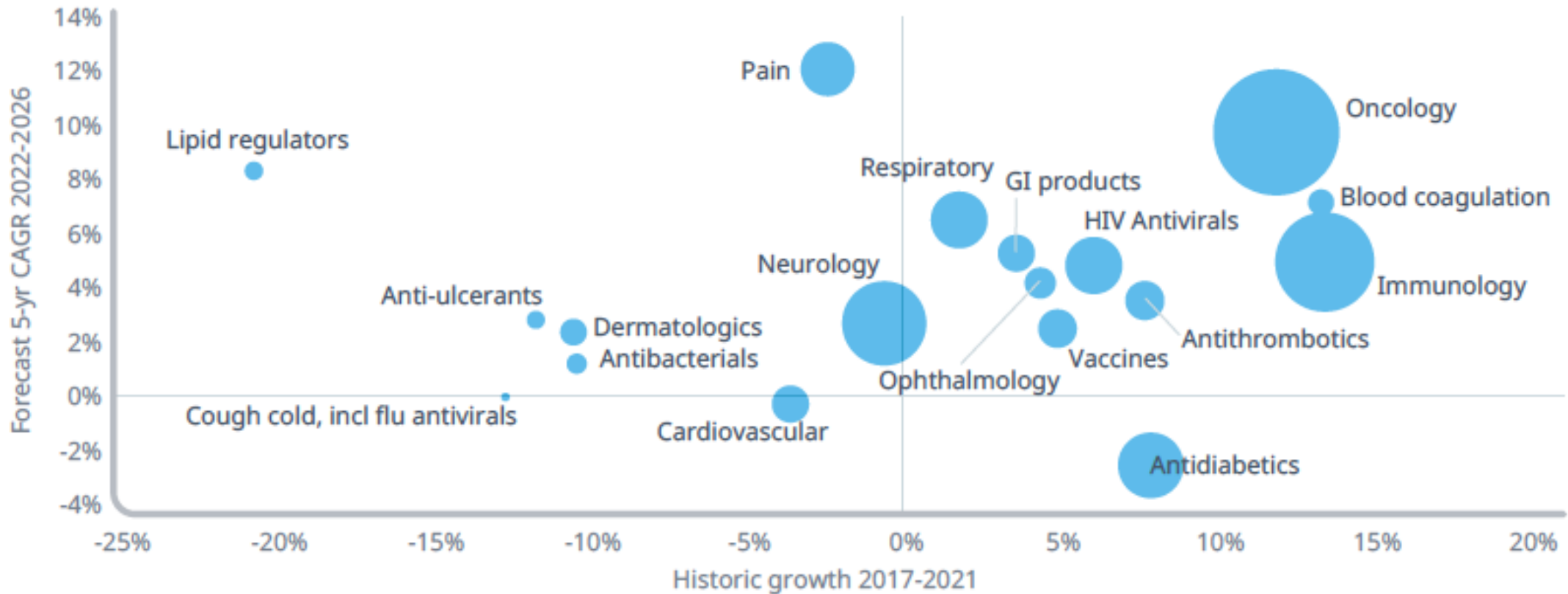
R&D: DEVELOPING A NEW MEDICINE TAKES AN AVERAGE OF 10–15 YEARS



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



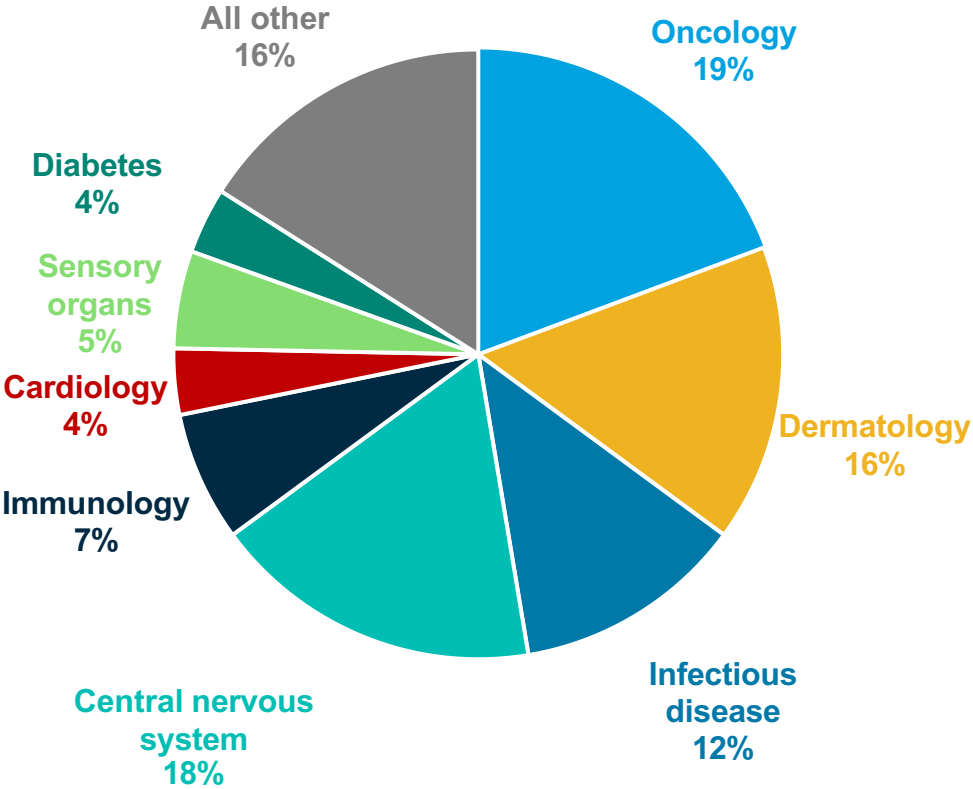
Net Spending Growth for Leading Therapy Areas



Source: IQVIA Institute, Mar 2022.

Lilly's Mounjaro is the best-selling launch product of 2022, followed by Genentech's Vabysmo for wet macular degeneration

2022 – 57 Launches



2022 – Top 10 Performers

| Product | Company | Indication | Launch date | First year gross sales |
|---|-------------------|-------------------------------|-------------|------------------------|
| Mounjaro <i>tirzepatide</i> | Eli Lilly | Type 2 diabetes | Jun-22 | \$7.2B |
| Vabysmo <i>faricimab</i> | Genentech | Wet macular degeneration | Feb-22 | \$632.4M |
| Opdualag <i>nivolumab/relatlimab</i> | BMS | Metastatic melanoma | Mar-22 | \$304.1M |
| Radicava <i>edaravone</i> | Mitsubishi Tanabe | Amyotrophic lateral sclerosis | Jun-22 | \$165.9M |
| Bebtelovimab <i>monoclonal antibody</i> | Eli Lilly | COVID-19 | Aug-22 | \$156.9M |
| Tezspire <i>tezepelumab</i> | Amgen | Severe asthma | Jan-22 | \$156.2M |
| Vyvgart <i>efgartigimod alfa</i> | Argenx | Generalized myasthenia gravis | Jan-22 | \$151.6M |
| Adbry <i>tralokinumab</i> | Leo Pharma | Atopic dermatitis | Feb-22 | \$145.3M |
| Kimmtrak <i>tebentafusp</i> | Immunocore | Uveal melanoma | Feb-22 | \$101.3M |
| Leqvio <i>inclisiran</i> | Novartis | Atherosclerosis | Jan-22 | \$59.1M |

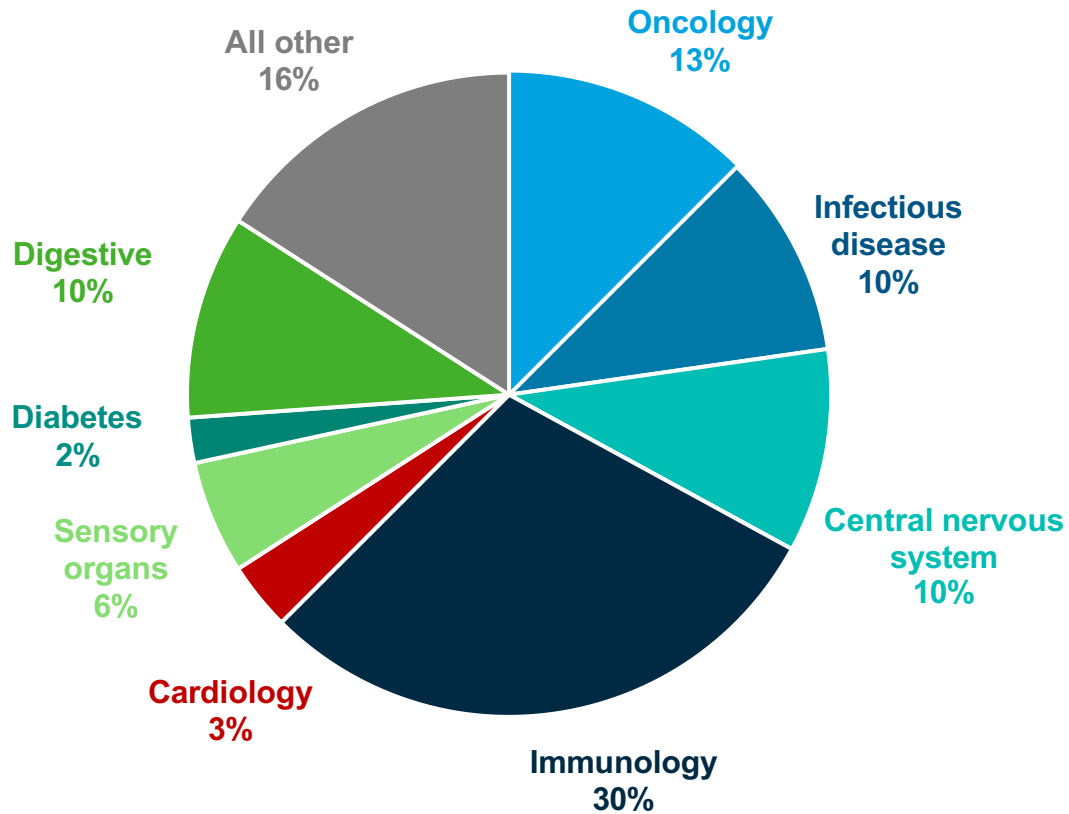
Source: National Sales Perspective; Launch Center of Excellence, IQVIA
Notes: All sales values are USD.



2023 sales have been dominated by GSK's RSV vaccine, Arexvy

Lilly's Zepbound for obesity is having a strong launch, surpassing \$1 billion in sales within four months

2023 – 84 Launches



2023 – Top 10 Performers

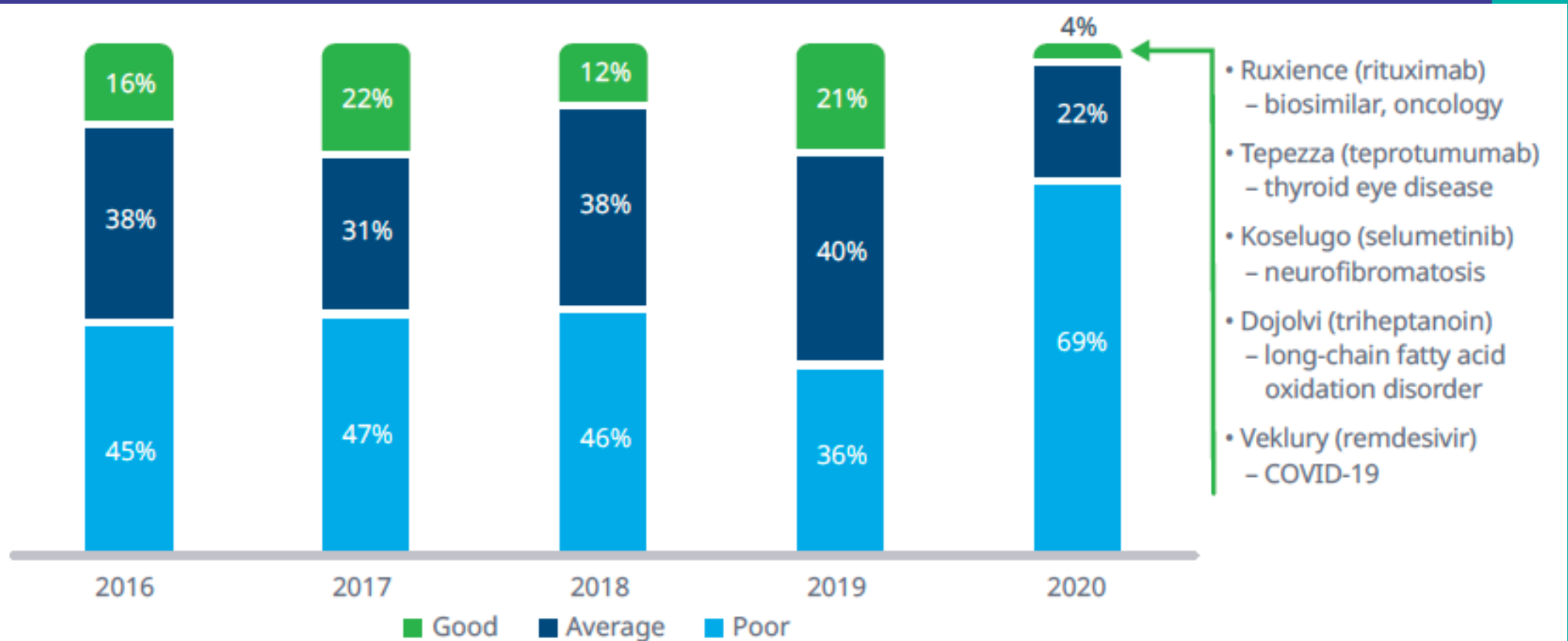
| Product | Company | Indication | Launch date | First year gross sales (as of Mar-24) |
|---|---------------|---|-------------|---------------------------------------|
| Arexvy <i>RSV vaccine</i> | GSK | Prevention of LRTD caused by RSV (60+ y/o) | Jul-23 | \$1.96B |
| Abrysvo <i>RSV vaccine</i> | Pfizer | RSV vaccine (gest. age 32-36wks, 60+ y/o) | Jul-23 | \$1.06B |
| Zepbound <i>tirzepatide</i> | Lilly | Obesity | Dec-23 | \$1.05B |
| Altuviio <i>Antihemophilic factor recombinant</i> | Sanofi | Hemophilia A | Apr-23 | \$263.9M |
| Beyfortus <i>nirsevimab</i> | Sanofi | RSV vaccine Pediatrics 0-24m | Sep-23 | \$248.0M |
| Miebo <i>perfluorohexyloctane ophthalmic solution</i> | Bausch + Lomb | Dry eye disease | Sep-23 | \$162.6M |
| Elahere <i>mirvetuximab soravtansine</i> | Immunogen | Ovarian, fallopian tube and peritoneal cancer | Mar-23 | \$160.9M |
| Orserdu <i>elacestrant</i> | Stemline | ER+ / HER2- breast cancer | Feb-23 | \$158.4M |
| Amjevita <i>adalimumab</i> | Amgen | CD, PsA, PsO, RA, UC | Feb-23 | \$118.4M |
| Jaypirca <i>pirtobrutinib</i> | Eli Lilly | Mantle cell lymphoma | Feb-23 | \$82.5M |

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

Notes: All sales values are USD. CD = Crohn's disease; LRTD = lower respiratory tract disease; PsA = psoriatic arthritis; PsO = plaque psoriasis; RA = rheumatoid arthritis; UC = ulcerative colitis; y/o = years old



Rating Share of Launch Products



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.

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 |

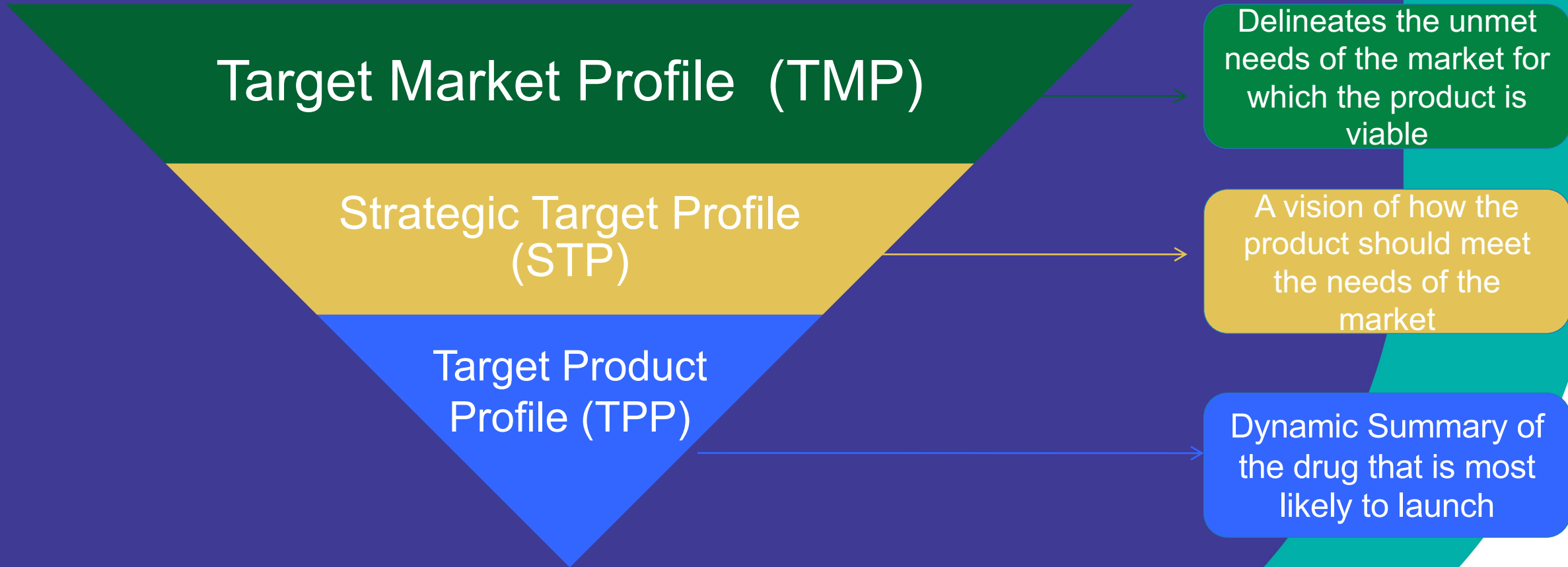
What is Target Product Profile (TPP)?

- 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

Importance of TPP

- TPP serves as a blueprint for the development, regulatory approval and commercialization of a pharma, biotech and medical device product
- It defines the desired attributes, characteristics and intended use of the product based on market needs, regulatory requirements and strategic objectives
- TPP guides decision making, resource allocation and strategic planning throughout the product life cycle, from pre-clinical development to post-market launch

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 | <p>Therapeutic areas/diseases</p> <ul style="list-style-type: none">• 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 | <ul style="list-style-type: none"> ✓ Positioning ✓ Global Sales Forecast ✓ Developmental Logic ✓ Regulatory and Reimbursement Strategy ✓ Product Value |
| Content | Therapeutic areas/diseases <ul style="list-style-type: none"> • Unmet Need • Patient Populations • Drivers of use • Competitive assessment • Economic cost of disease | Target attributes (desired profile) <ul style="list-style-type: none"> • Value drivers/Positioning • Global Reach • Pricing/Reimbursement • Patient Share • Revenue – Profitability • Pharmacoeconomics • Investments (R&D, COGS, SGA) • Cost of goods • Licenses, Royalties | |
| 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) |
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| Content | Therapeutic areas/diseases <ul style="list-style-type: none"> • Unmet Need • Patient Populations • Drivers of use • Competitive assessment • Economic cost of disease | Target attributes (desired profile) <ul style="list-style-type: none"> • Value drivers • Global • Pricing/Reimbursement • Patient Share • Revenue – Profitability • Pharmacoeconomics • Investments (R&D, COGS, SGA) • Cost of goods • Licenses, Royalties | Indications and usage (label) <ul style="list-style-type: none"> • 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 |

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How can TPP be shaped by Marketing?

TPP

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



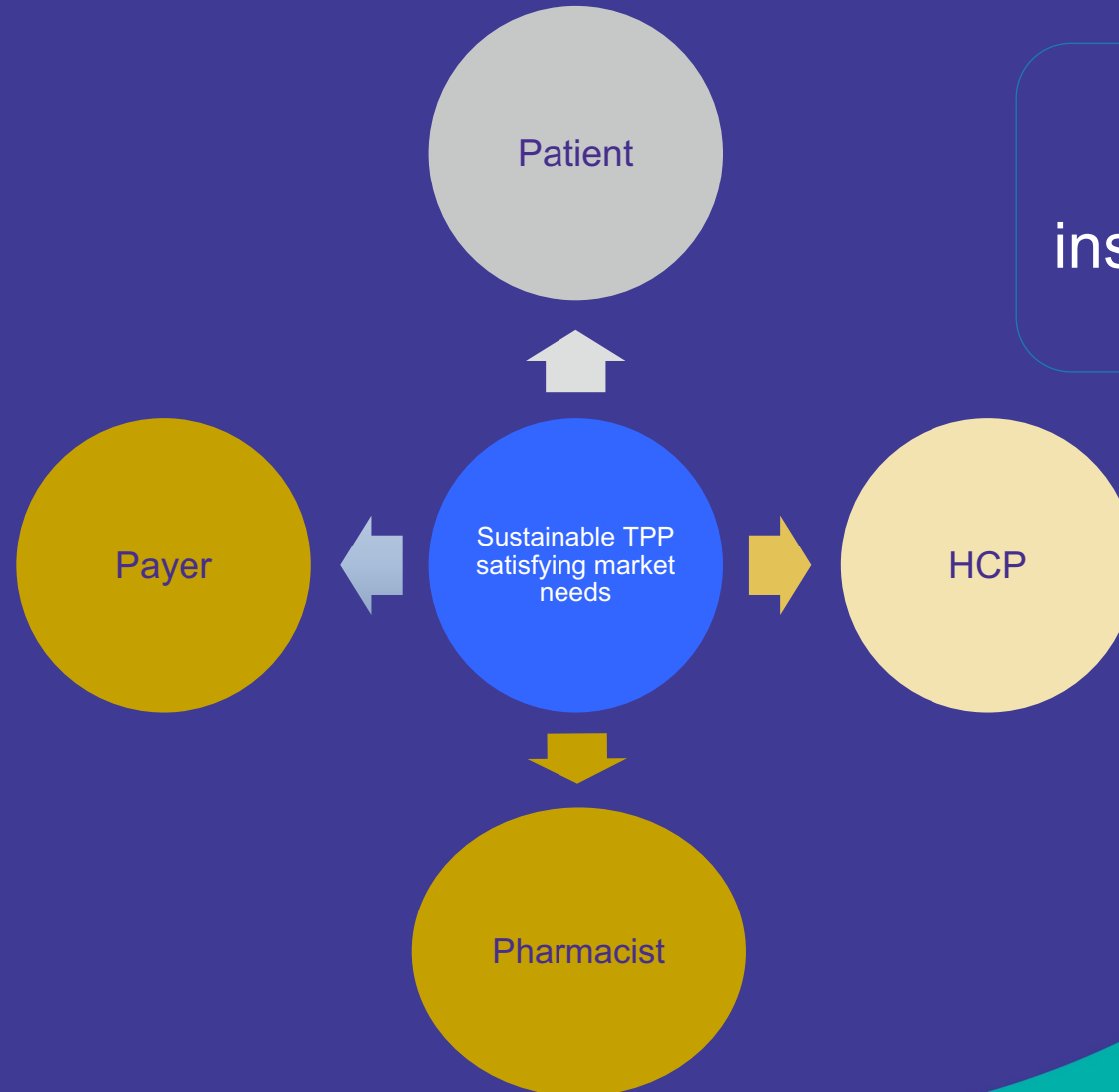
Attributes Shaped by Marketing

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

Role of market research and competitive intelligence in TPP development

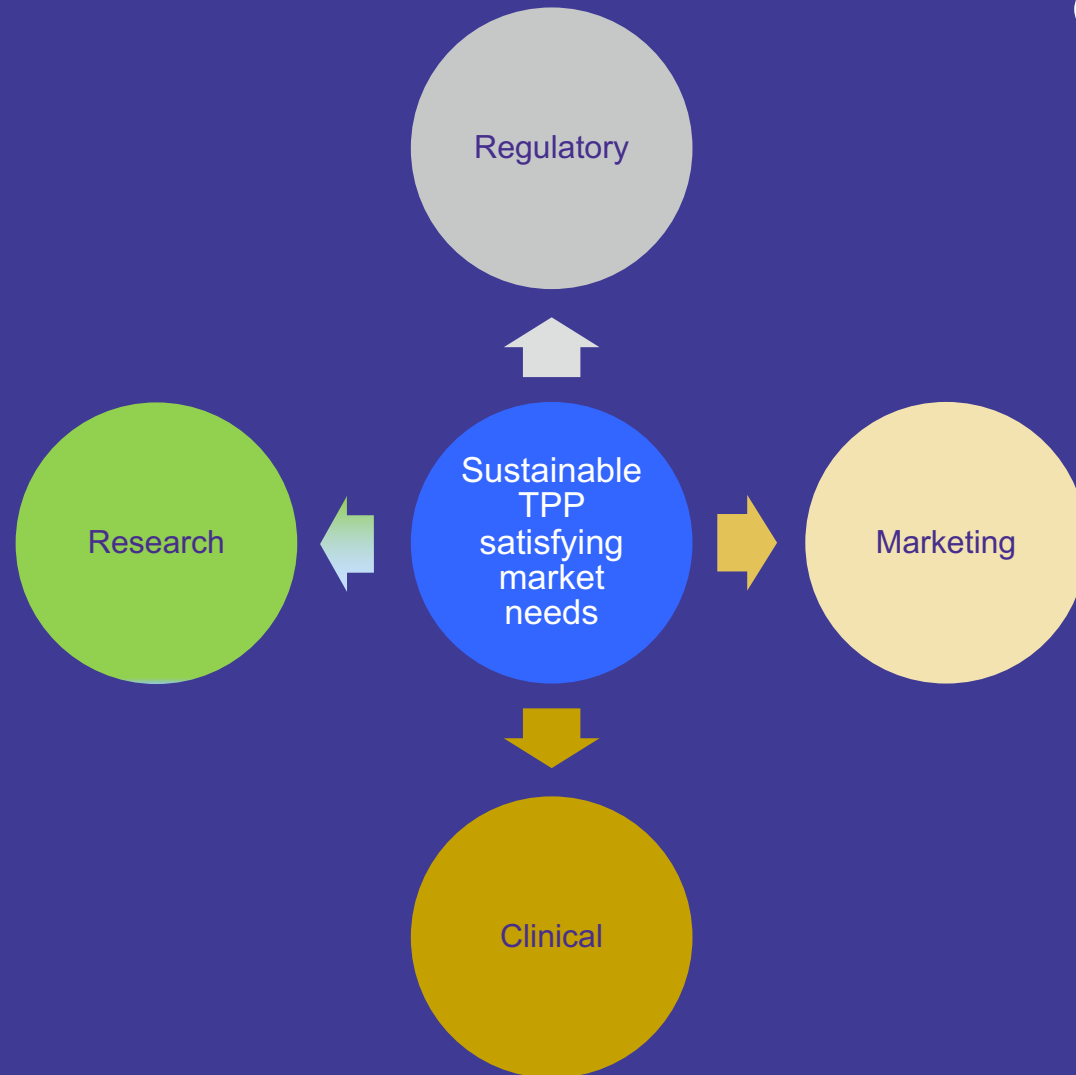


Start with end in mind: How should the label look to meet customer needs ?



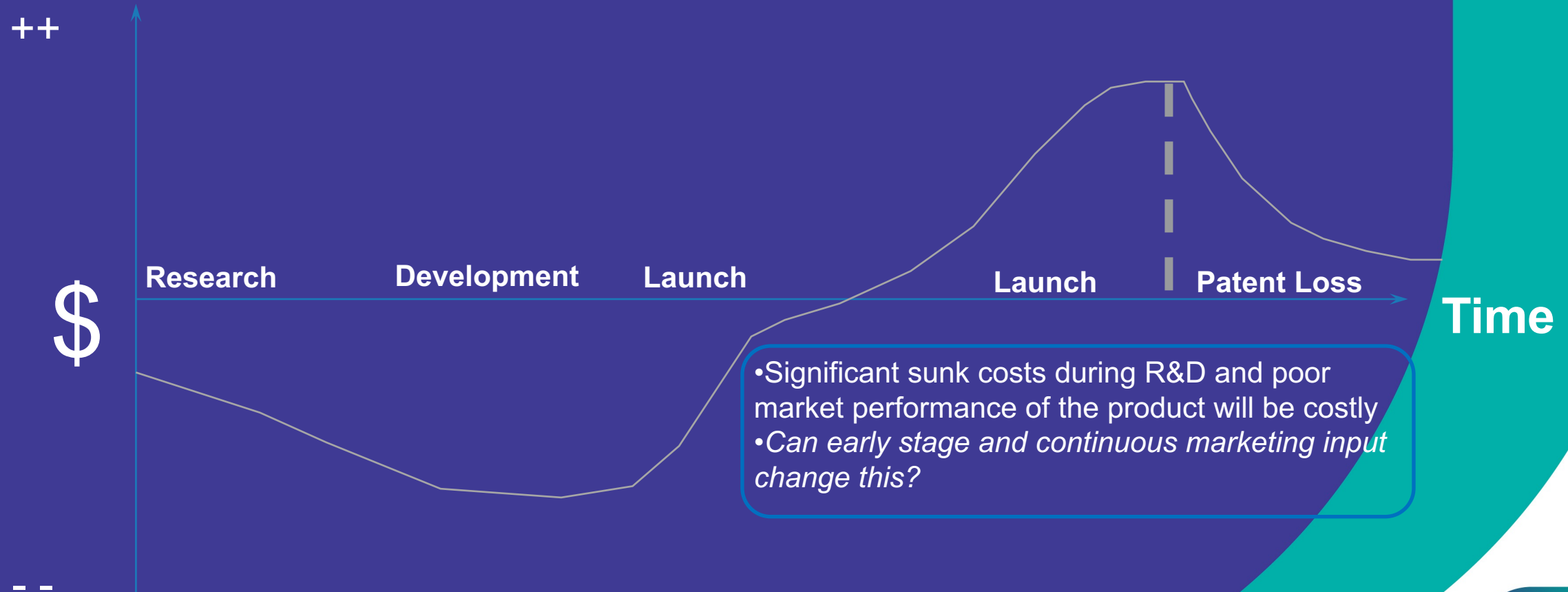
Conduct market research to gain insights on customer needs

Who should work together?

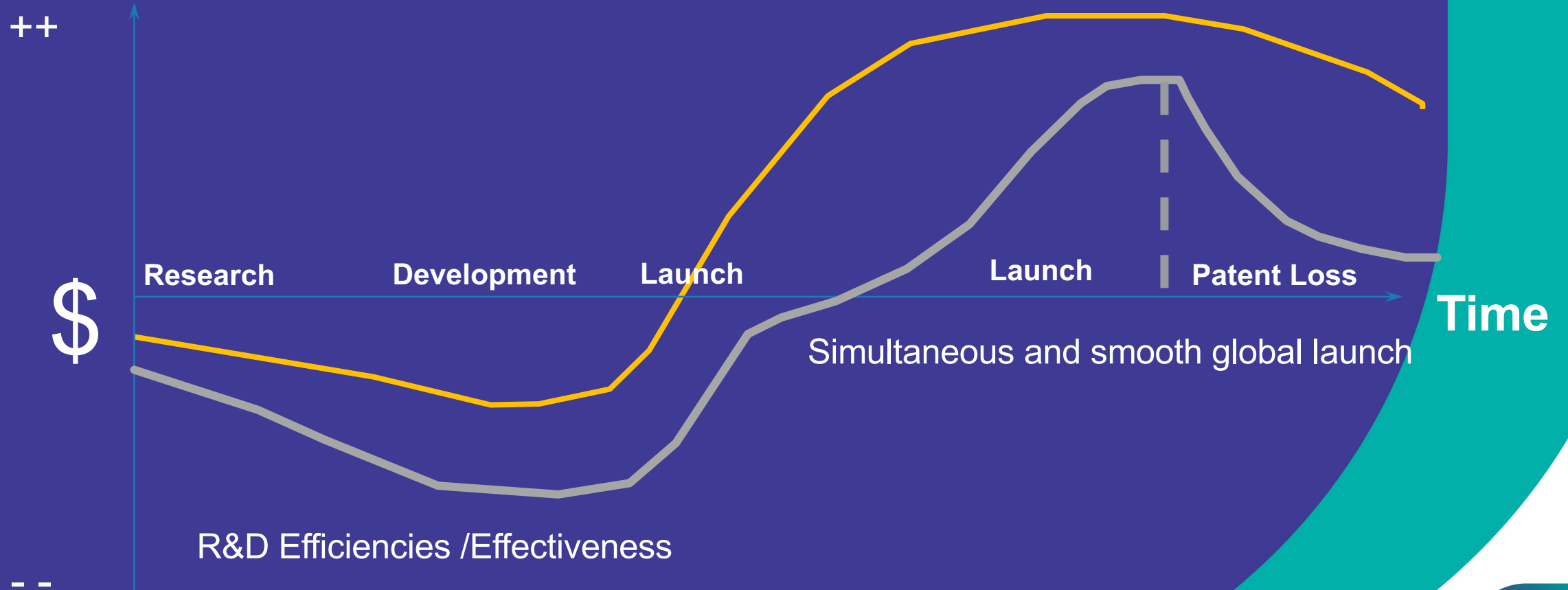


Goal: To deliver strong development plan with superior clinical performance, patient benefit and health economic value

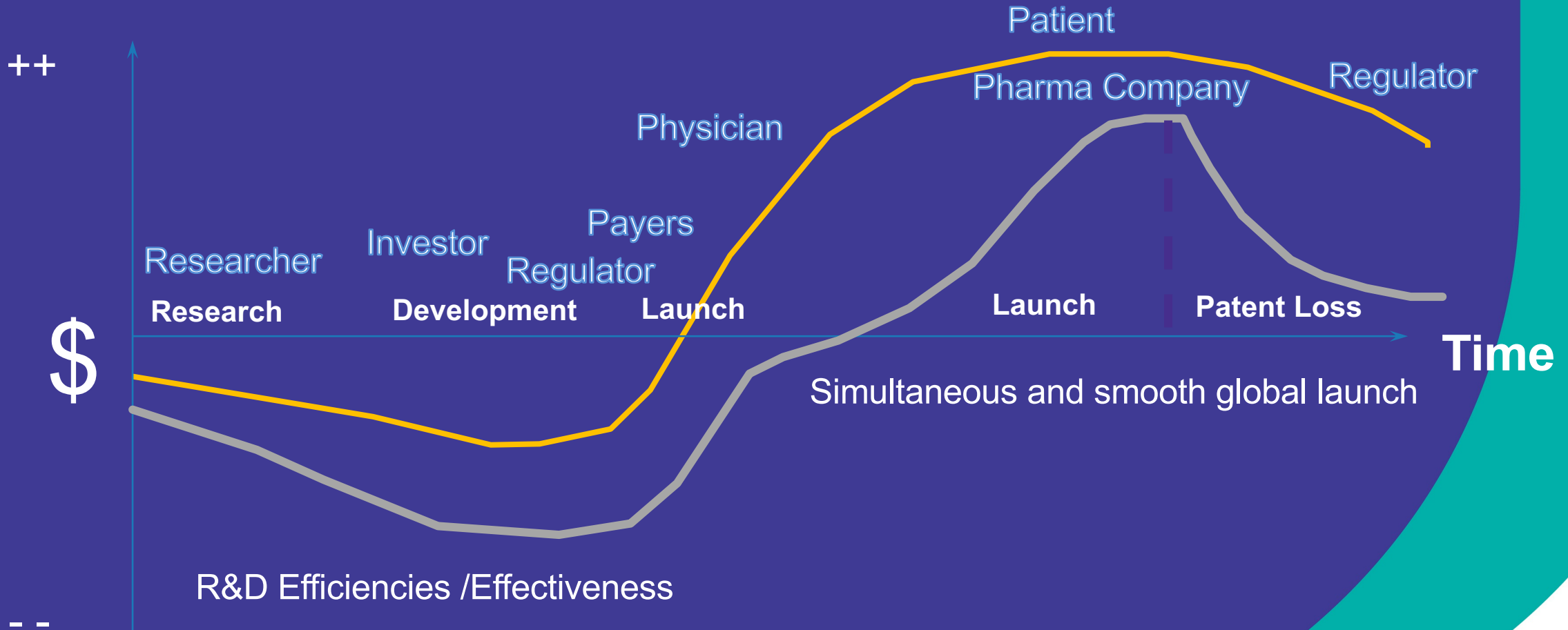
How to Improve the Probability of Success?



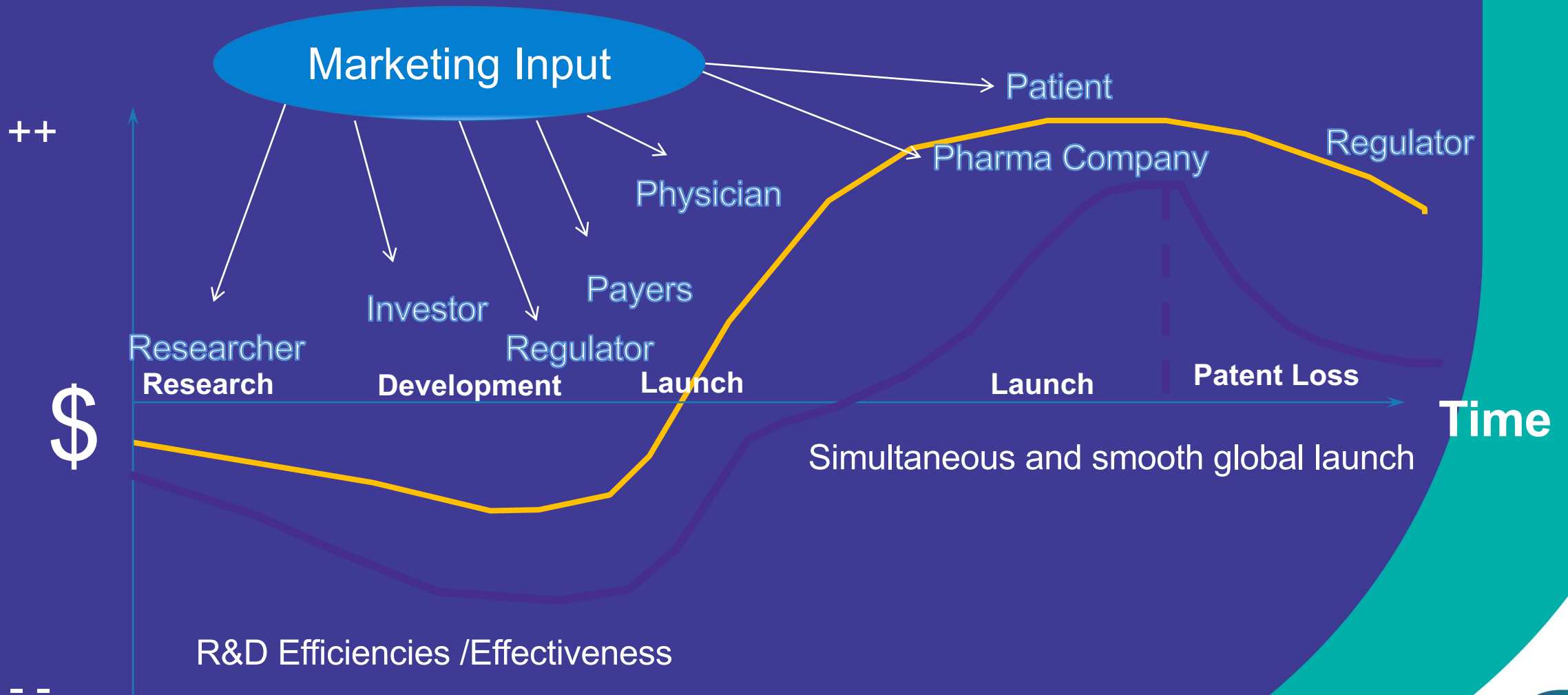
Ideal Product Life Cycle



Meeting Stakeholders Needs



Early Marketing Input Can Improve Product Success



Early Marketing Input Can Improve Product Success

| | | | | | | Submission | Launch | Growth | | | | | |
|-----------------------------------|-------------------------|--------------------------|---------------------------------|---------------------------------|-------------------------------------|-----------------------------------|-------------------------------|-------------------------------|----------------------------|--------------------------------|--------------------------------|---|------------------------|
| | | | | | | | 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 |

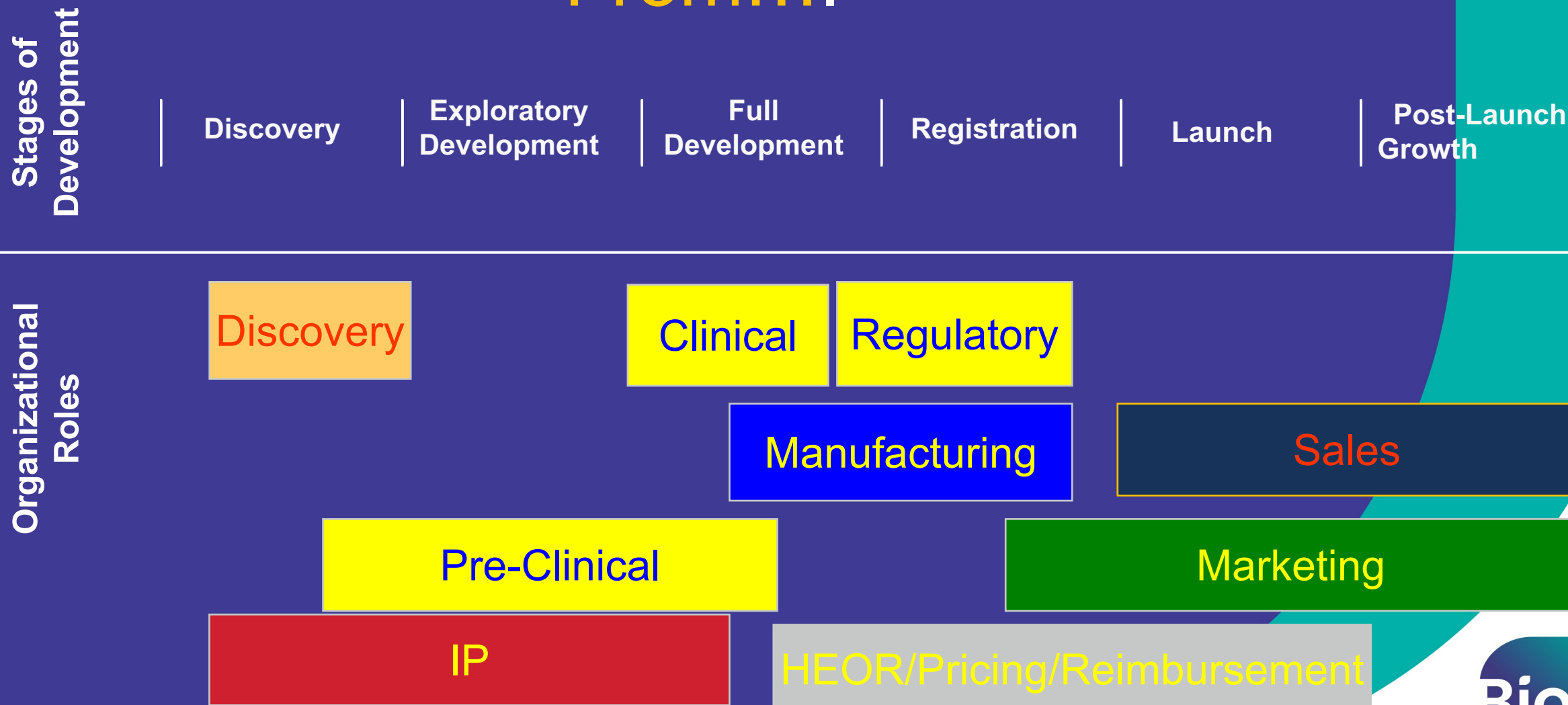


R&D and Marketing collaboration in creating an effective TPP



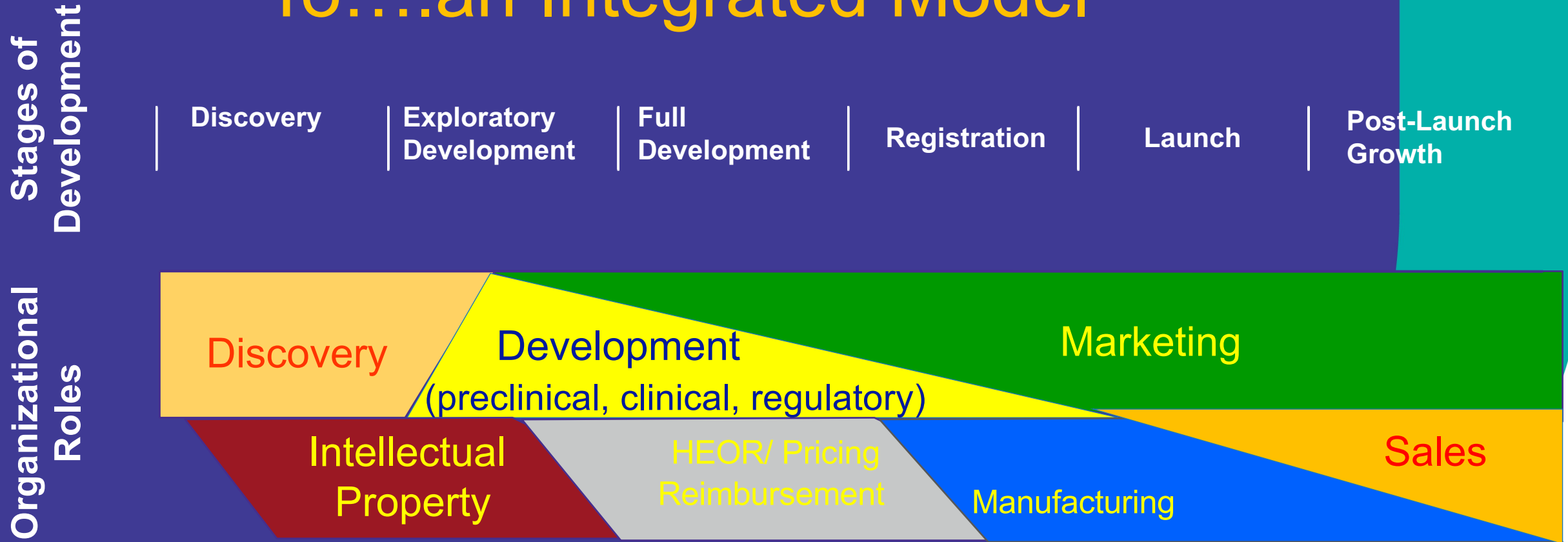
What will Collaboration Achieve...?

From....



What will Collaboration Achieve...?

To....an Integrated Model



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.

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

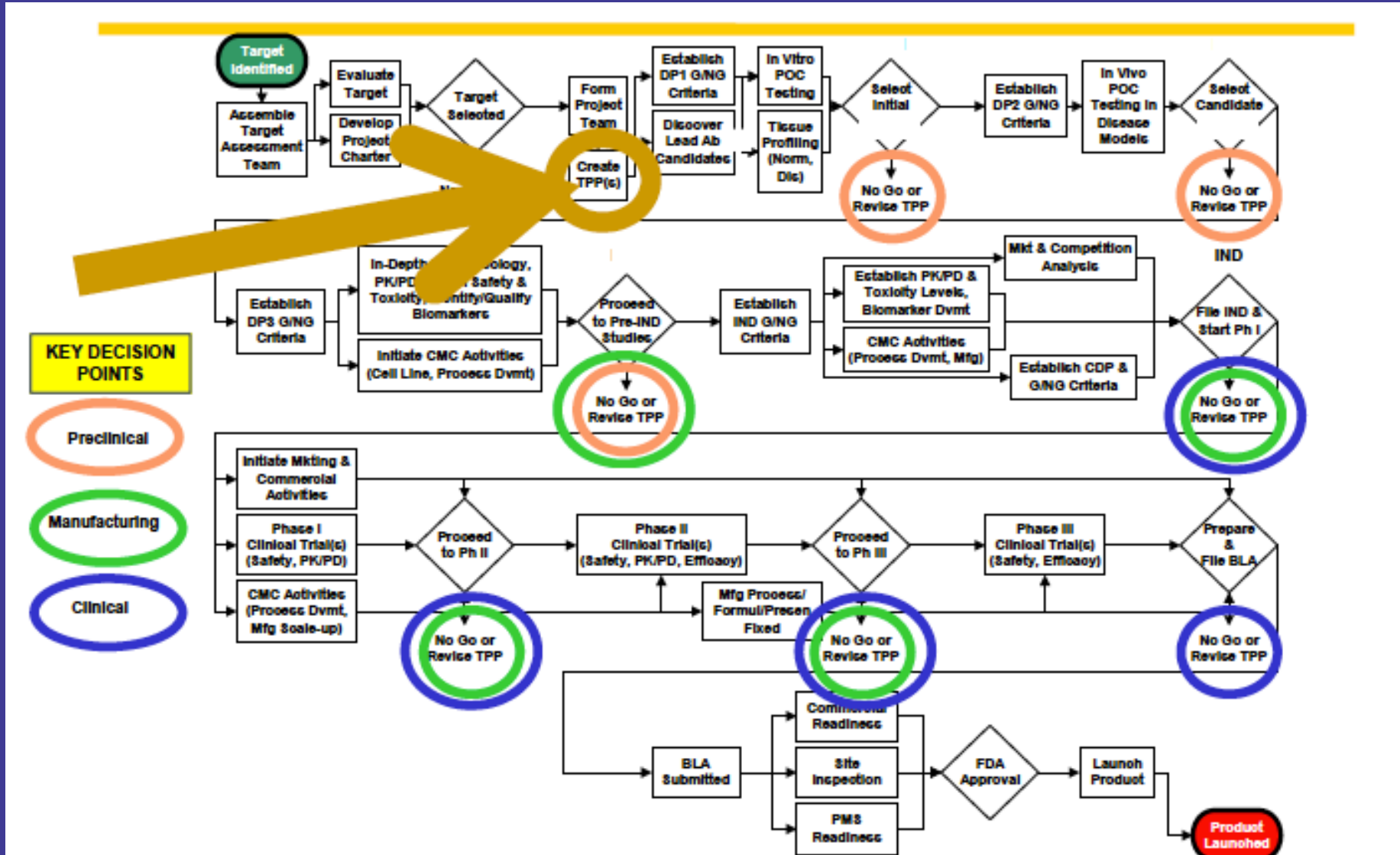
- What is the product description?
- What data or literature is available for review for the various indications and claims?
- What is the unmet need, clinical benefit or value to others?
- Will the product be used for a new or existing procedure?
- What is the standard of care (SOC) for this indication?
- 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 | |

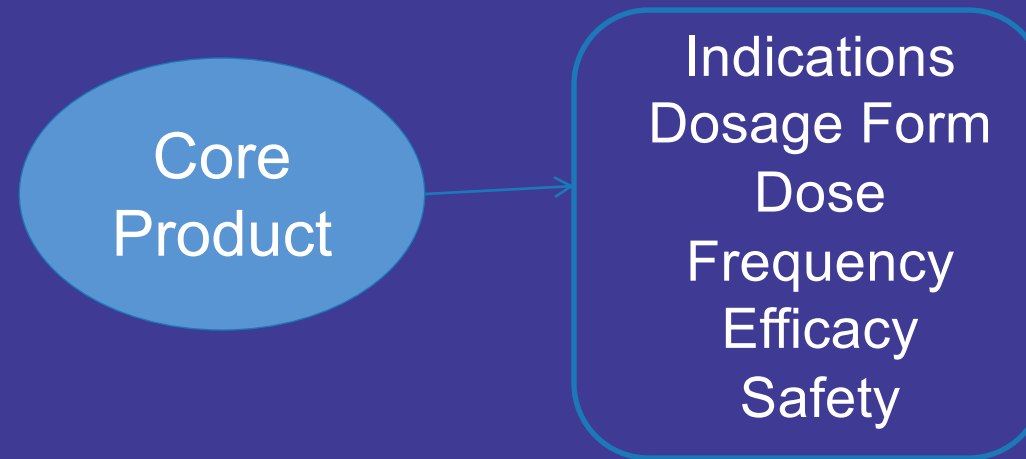
Source, https://neuroscienceblueprint.nih.gov/sites/default/files/documents/Example_TPP_508C.pdf accessed June 2, 2022



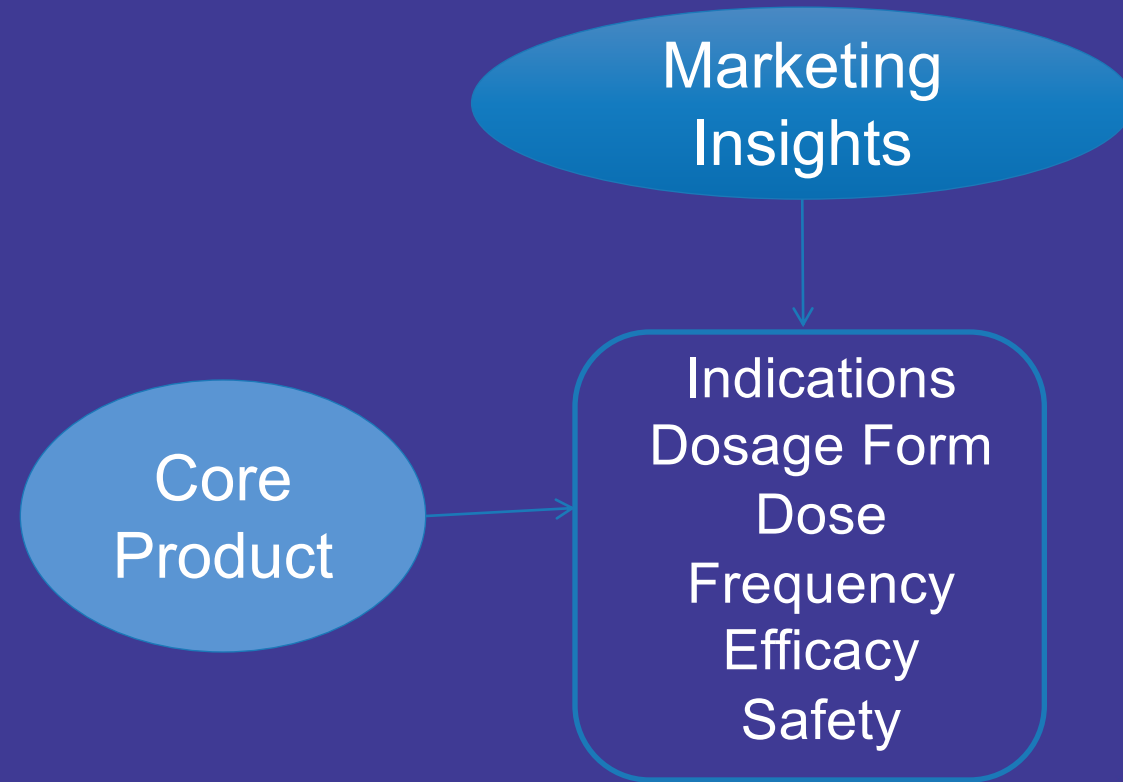
Best Development Strategies...

- 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

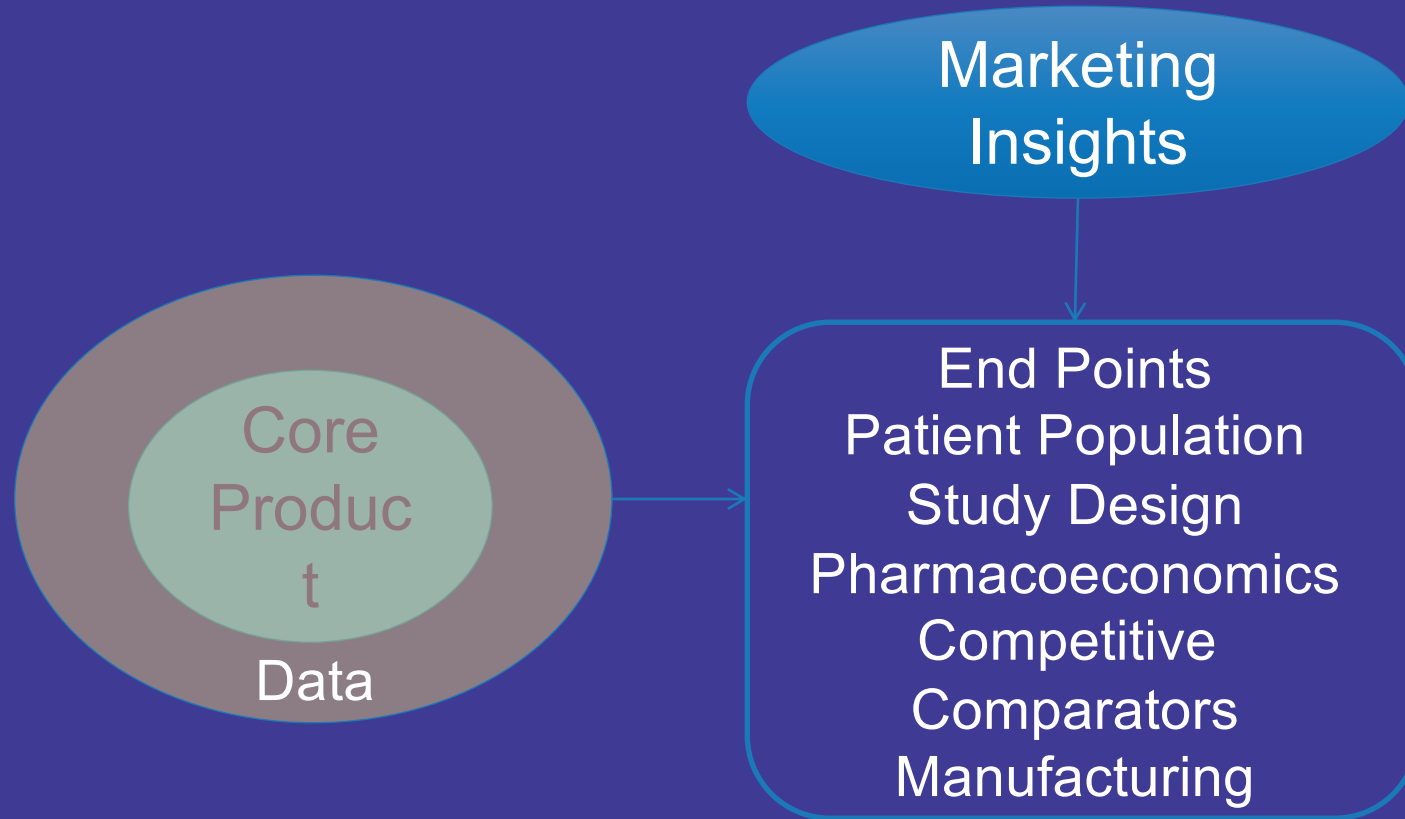


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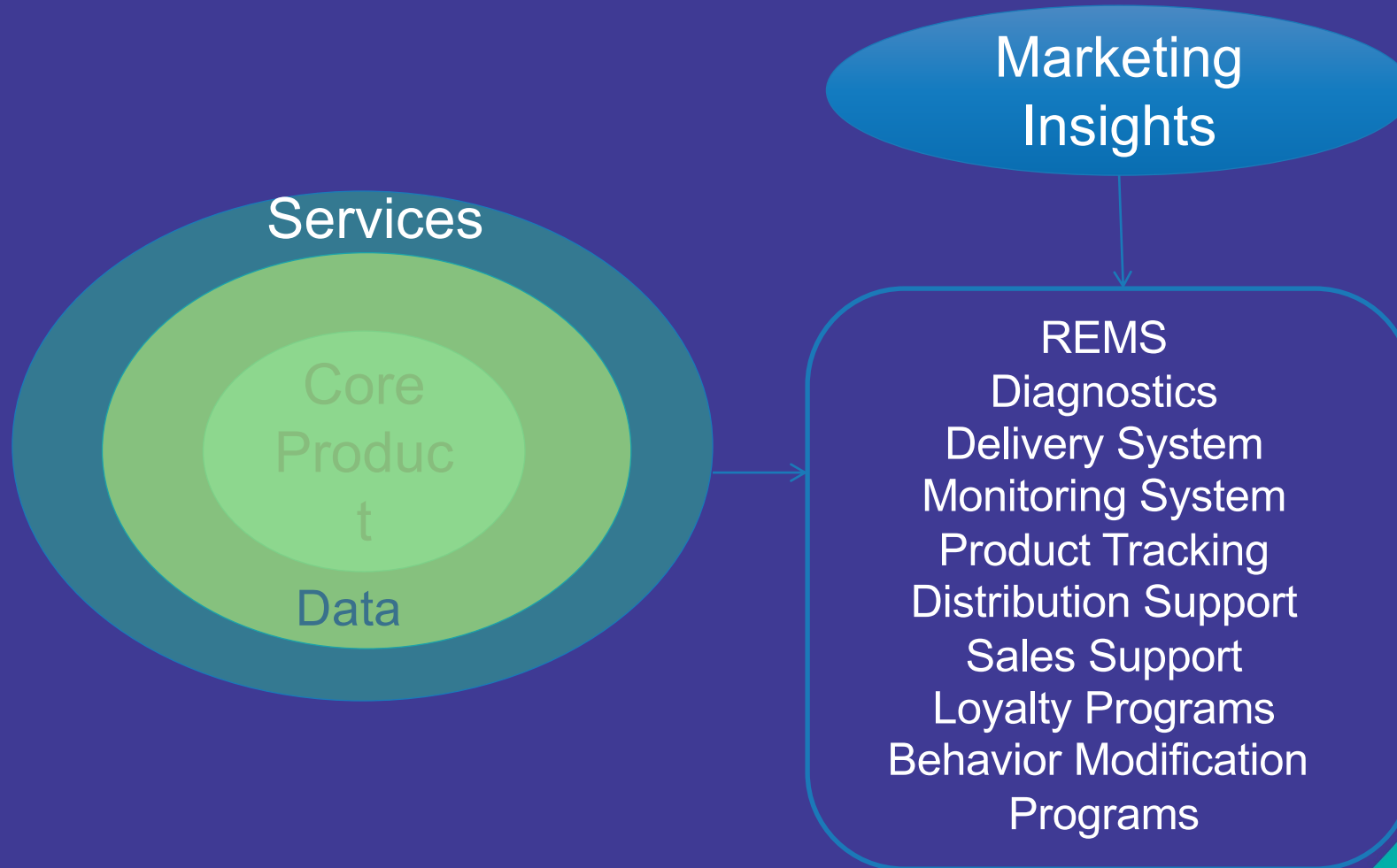


Marketing should shape the “Label” for the product

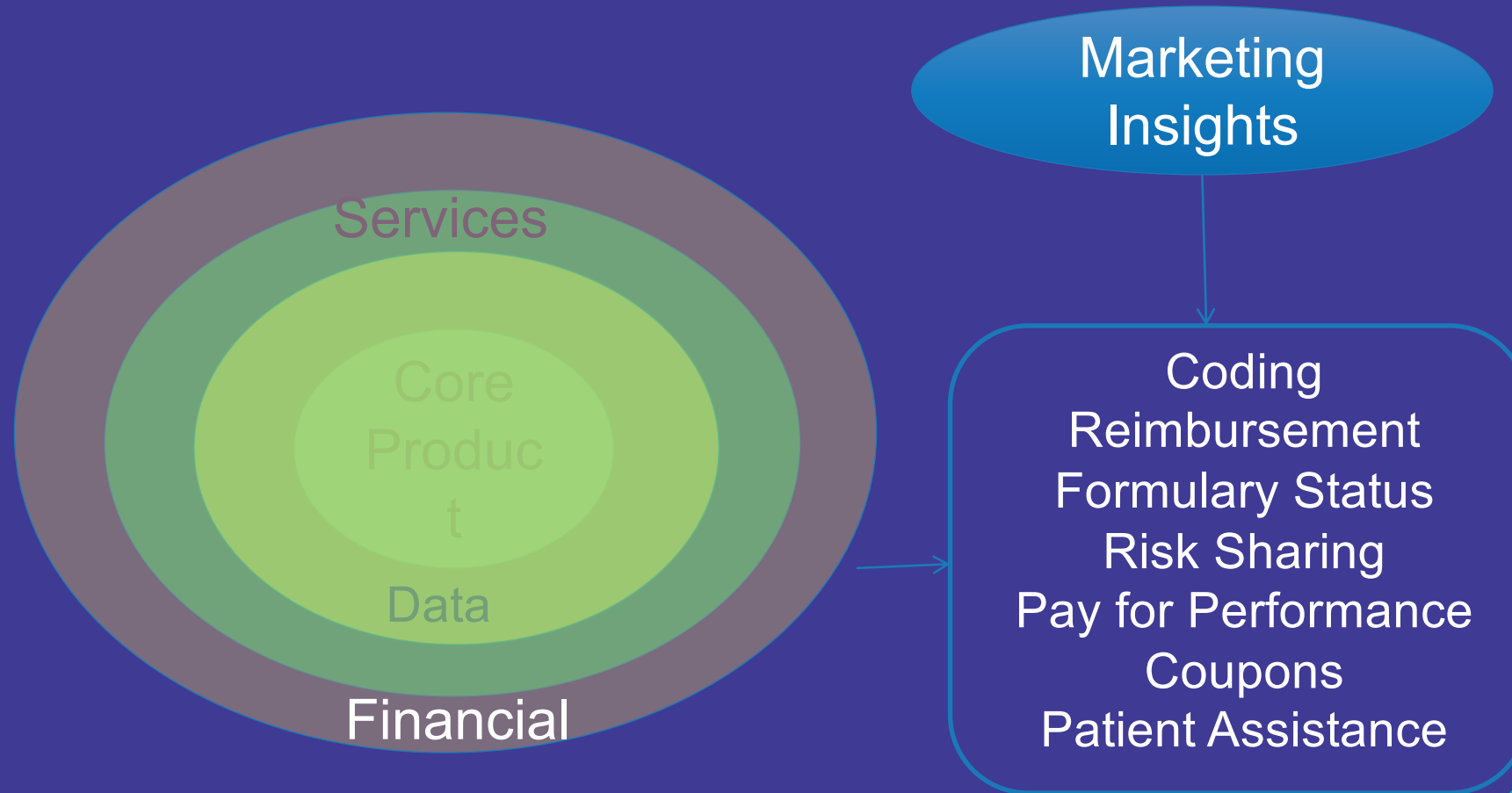
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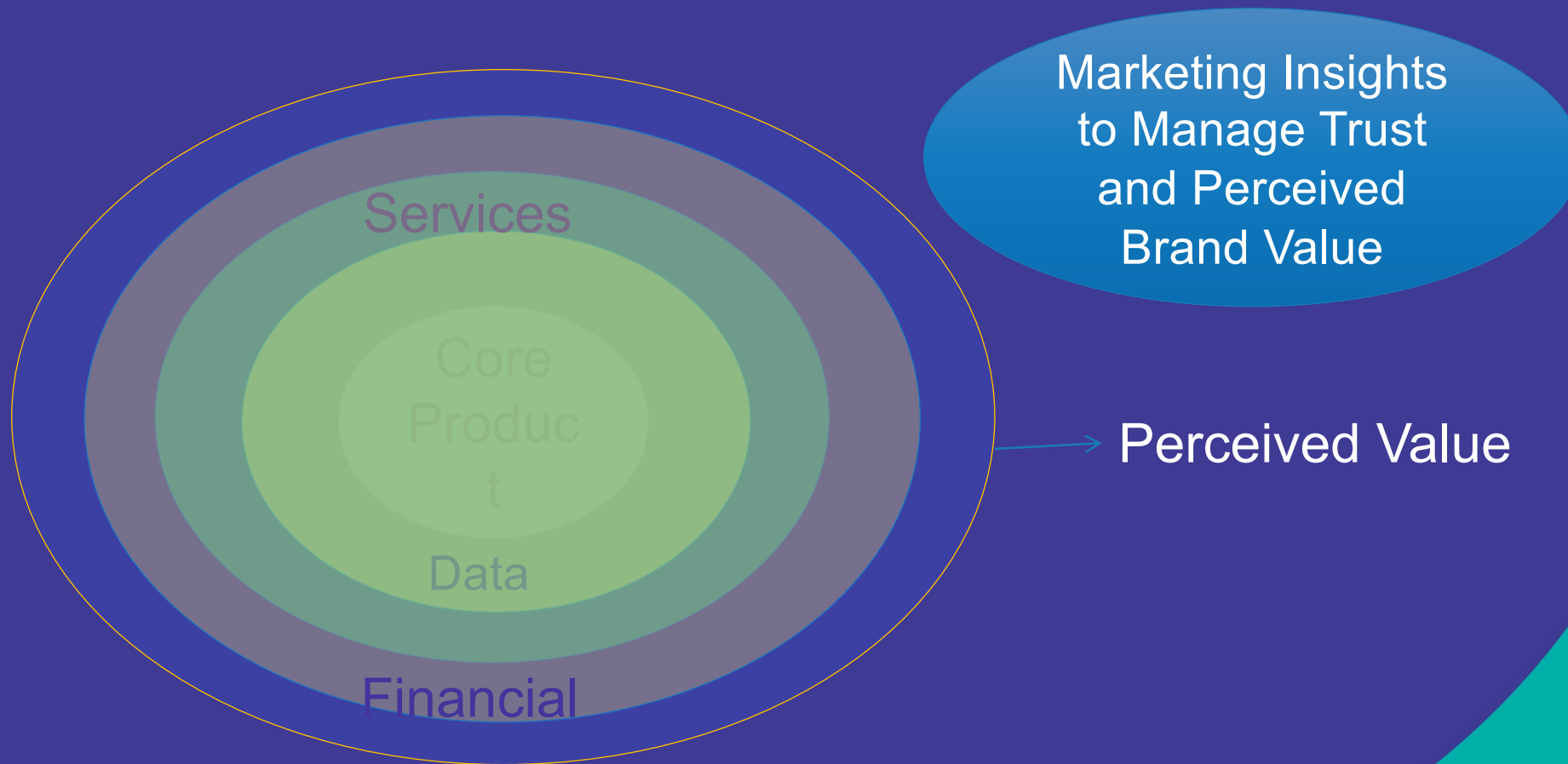
Marketing Create “Beyond the Pill” Solution



Marketing Create “Beyond the Pill” Solution



Marketing Create “Beyond the Pill” Solution



Finalizing the TPP and ensuring
alignment with company goals



Alignment with Goals

- **Strategic Alignment:** The TPP outlines the desired attributes and characteristics of the product that the company aims to develop. It helps align the strategic goals of the company with the specific needs of the market, ensuring that the product under development meets the identified unmet medical needs or market opportunities.
- **Focus and Prioritization:** By defining the key features, indications, patient populations, and clinical endpoints for the product, the TPP helps the start-up company focus its resources and efforts on the most promising opportunities. It enables prioritization of development activities and allocation of resources based on the desired product profile and market potential.
- **Decision Making:** The TPP serves as a reference point for decision making throughout the product development process. It helps the company evaluate and prioritize potential development paths, regulatory strategies, and investment decisions based on their alignment with the target product profile and strategic objectives.
- **Resource Planning and Budgeting:** The TPP provides a roadmap for the development timeline, milestones, and resource requirements needed to achieve the desired product profile. It helps the start-up company estimate the budget, personnel, and infrastructure needed for product development and commercialization, enabling effective resource planning and allocation.



Alignment with Goals

- **Regulatory Strategy:** The TPP informs the regulatory strategy for the product by outlining the intended use, indication, patient population, and clinical trial endpoints required for regulatory approval. It helps the company design and execute clinical development programs that are aligned with regulatory requirements and expectations, minimizing regulatory risks and delays.
- **Market Access and Commercialization:** The TPP informs the commercialization strategy for the product by defining the target market, positioning, pricing, and market access considerations. It helps the company identify key stakeholders, understand customer needs, and develop value propositions that differentiate the product in the market, ultimately supporting successful market entry and adoption.
- **Communication and Collaboration:** The TPP serves as a communication tool for internal stakeholders, external partners, investors, and regulatory agencies. It helps ensure alignment and clarity of purpose across the organization and facilitates collaboration with partners and stakeholders involved in product development, regulatory interactions, and commercialization efforts.
- TPP provides a **strategic framework and roadmap** for guiding the development, regulatory approval, and commercialization of a product, helping start-up companies navigate the complex and competitive landscape of the pharmaceutical and biotech industries with clarity, focus, and efficiency.



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!

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Questions???

