Bio

Biotechnology
Innovation Organization

Become a Biotech or MedTech Entrepreneur

Presented by:

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#BIO2025 #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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Session Objectives

Understand TPP's Strategic Role

Learn how TPPs fit within the strategic document ecosystem.

Master Key Components

Identify essential elements of effective TPPs.

Adapt Across Venture Stages

Tailor TPPs from early project to mature company.

Craft Investor Narratives

Transform technical details into compelling investment stories.

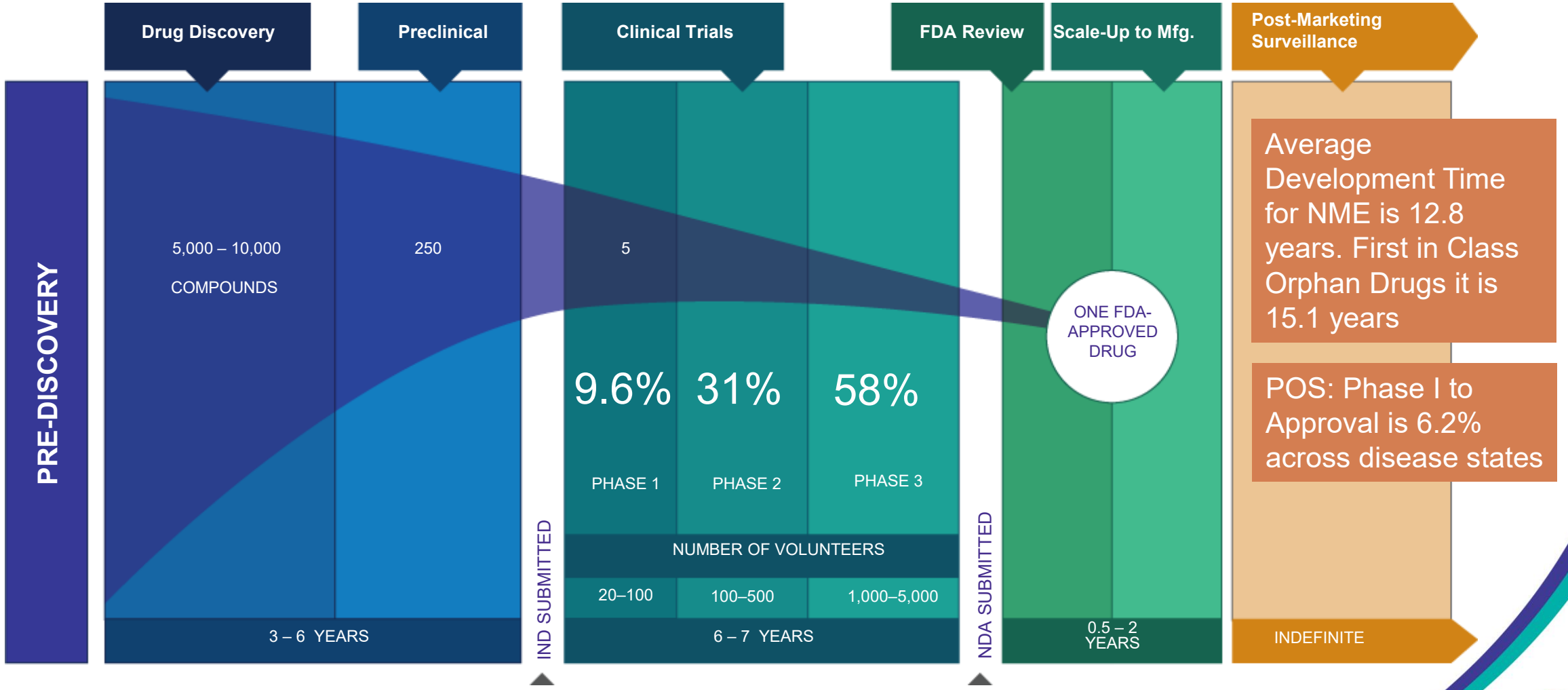
Key Healthcare Trends

- Health care priority: cost control, access and price transparency
- Consumerism will influence healthcare decisions
- Shifting power balance toward payers
- Health systems consolidate — and rationalize
- Reimbursement models focus on value/outcome
- Growth of alternative delivery models and partnerships
- Growth of precision medicine
- Digital transformation from AI experiment to infrastructure

Innovative Product

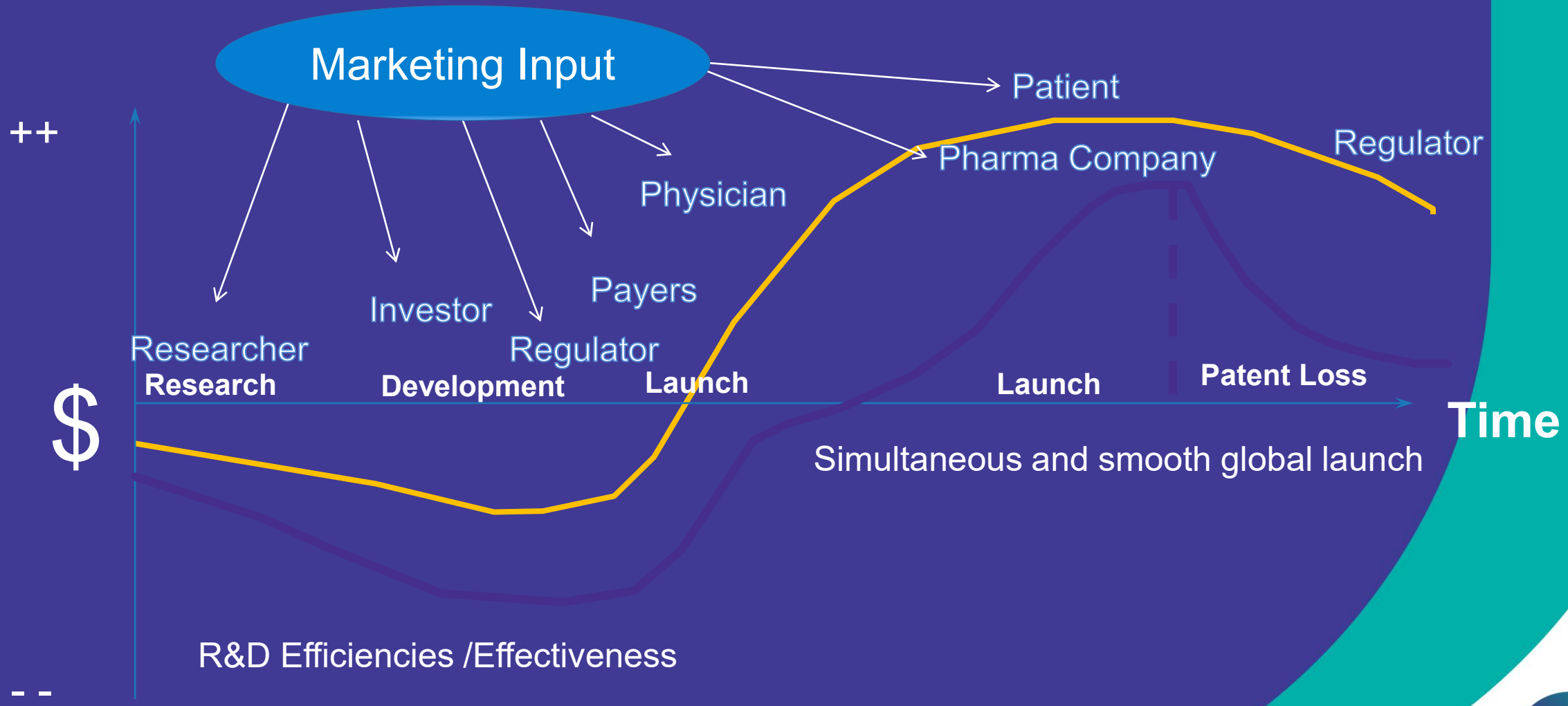
A differentiated product (solution) that offers a meaningful advantage (value) over existing treatments for a given condition

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

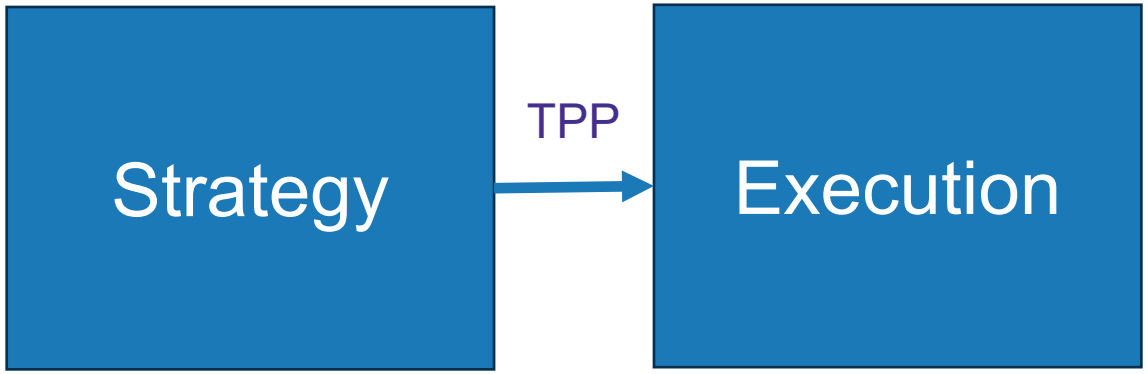
Early Marketing Input Can Improve Product Success



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!

Strategic Role of Target Product Profile



TPP Outlines Product Specification that….

Meet Clinical, Customer and Market Needs

Align Development with IP, Clinical, Regulatory, Manufacturing & Commercialization

Core Components of a TPP

Product Concept

Who it helps and why it matters

Target Population

Who exactly is it for

Efficacy Targets

What it needs to do (min/target/stretch)

Safety Profile

Acceptable risks and monitoring

Mechanism of Action

How does it work?

Dosing/Administration

How it will be delivered and used

Pricing/Reimbursement

Commercial access and payer fit

Differentiation

Why it's better than alternatives

IP/Exclusivity

Protection and lifecycle planning

Regulatory Pathway

Approval strategy and milestones

Manufacturing/Supply

Scalability and quality

Efficacy Targets - Threshold vs. Ideal

1

Ideal Goal

Transformative improvement that redefines standard

2

Target Profile

Differentiated position with clear advantage

3

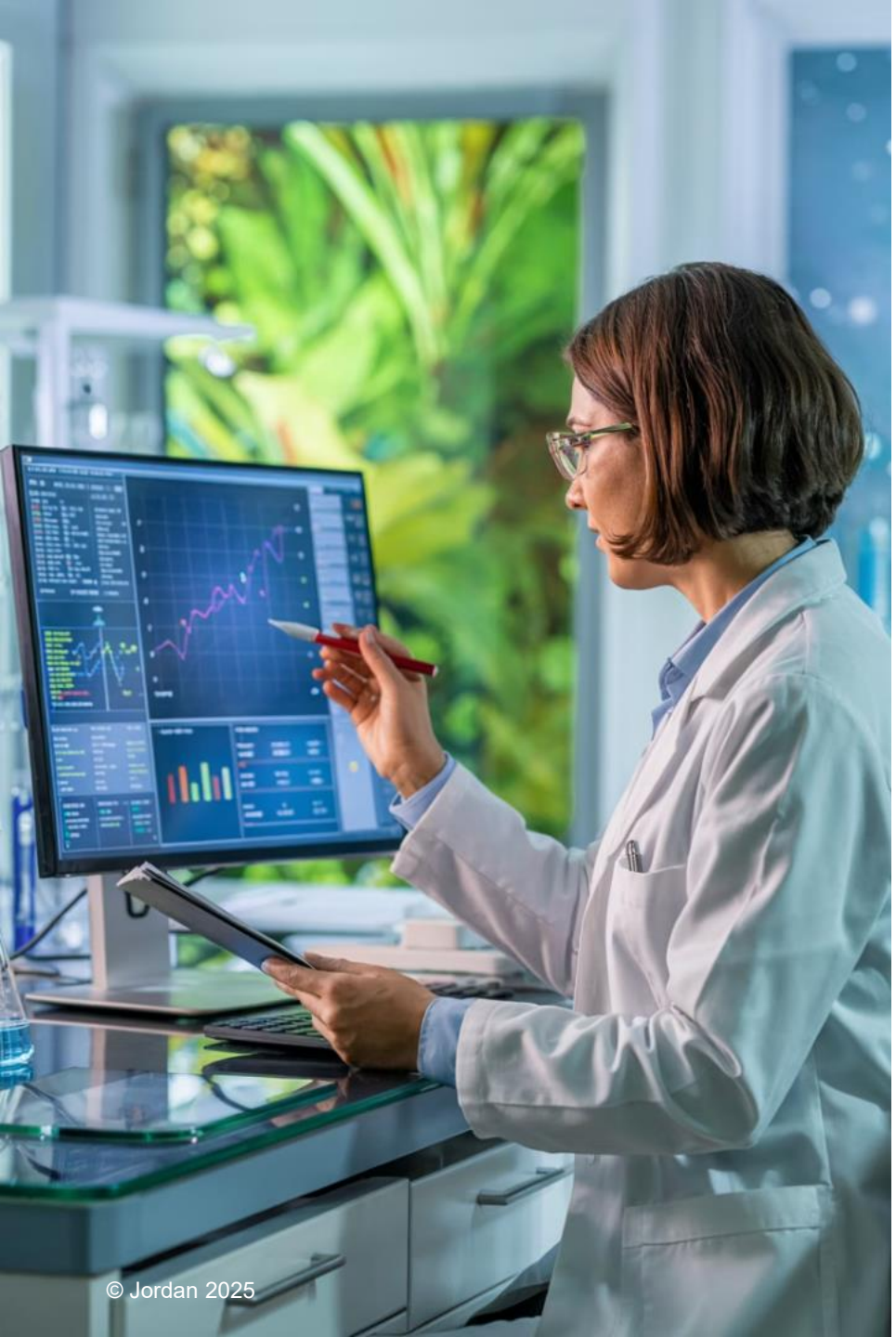
Competitive Benchmark

Current standard of care performance

4

Minimum Acceptable

Required for approval and commercial viability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Key TPP Attributes by Therapeutic Area

Therapeutic Area	Critical TPP Attributes	Value Driver
Chronic Diseases	Superior safety, Reduced monitoring, Improved adherence	Safety and convenience often often outweigh efficacy gains
Acute Conditions	Speed of onset, Higher response rate, Shorter duration	Rapid resolution and high success probability
Rare Diseases	Transformative efficacy, Novel mechanism, Durable response	Dramatic efficacy at disease mechanism level
Oncology	Overall survival, Progression-free survival, Biomarkers	Extending life while maintaining quality

The Strategic Document Ecosystem

Document	Purpose	Primary Audiences
Target Product Profile (TPP)	Defines success criteria with clear label claims	Team, regulators, partners, investors
ÎØÖÑÞÑP GÑQÑÕÕÓÖÑŌP ÎÕMŌ	Maps technical and and scientific validation	Team, advisors, investors
Commercialization Plan	Defines customer reach and adoption scaling	Team, payers, partners, investors
Business Plan	Maps operations, team, funding, financials	Ì MŌMŊÑÖÑŌÞÆ ÒÕQÑCÆPÖØÕŒÆ ÓMØPŌÑØŒÆ
Investor Pitch Deck	Synthesizes compelling funding story	Angels, VCs, corporate venture arms

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Use the TPP To…

Make go/no-go decisions

Evaluate opportunities against strategic criteria

Align cross-functional teams

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Guide regulatory strategy

Define clear path to approval

Pitch to investors or acquirers

Communicate value proposition clearly

The 80-20 Principle in TPP Development

Identify your non-negotiables early — startups demand tough choices

Focus on Critical Few

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- Ruthless prioritization over "wish lists"
- Resource allocation follows value creation
- Strategic differentiation requires focus

The Pareto Principle applied to TPP development ensures resources target the attributes that matter most.

TPP Changes by Startup Stage

Project: technology component requiring integration/licensing

Validate scientific tech + IP fit for licensing

Product: standalone solution positioned for acquisition

Develop full solution with exit in mind

Company: a platform with a multi-product roadmap and independent growth potential

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Strategic Innovation Approaches

Create New Category

Pioneer entirely new market segment segment

- Example: PD-1/PD-L1 inhibitors created immuno-oncology
- Best for: Company with platform technology

Split & Grow Category

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- Example: Herceptin for HER2+ breast breast cancer
- Best for: Product with clear biomarker/segmentation

Collapse Value Chain

Eliminate inefficiencies in delivery/distribution

- Example: Direct-to-consumer diagnostics
- Best for: Product or Company with operational innovation

The Tyranny of Novelty

Distinct mechanism of action

Differentiation at molecular or biological level

Transformative patient impact

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Strategic novelty

Not superficial differences from competitors

Mechanistic distinctiveness

Innovation bedrock that drives unique value

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Common Pitfalls

Static Document Syndrome

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Scientific Myopia

Solution: Include commercial & payer input

Market Blindness

Solution: Stay on top of competitors

Overbuild

Solution: Align with resources and stage

Strategic Leverage Points

TPPs as Negotiation Tools

Structured with tiered outcomes, outcomes, TPPs create natural anchor points. These drive more more favorable deal terms with partners or acquirers.

The "Reverse TPP" Method

Identify what strategic acquirers acquirers want based on their pipeline gaps. Engineer your TPP to TPP to fit that gap precisely.

Geographic Adaptability

[illegible]

Hidden Pitfalls to Avoid

Regulatory Benchmark

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The Entrenchment Problem

TPPs create dangerous organizational inertia. Build explicit "pivot explicit "pivot triggers" that mandate reassessment at key key thresholds.

Competitive Intelligence Gap

Most TPPs neglect projections of competitor progress. By By launch, landscapes evolve beyond initial TPP targets.

TPP Signaling

Investors evaluate what you emphasize versus what you omit. omit. These choices signal your market understanding.

Common TPP Misalignments

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TPP-Market Disconnect	Product customers don't want or won't pay for	F ÖÕÑÞÑP POÖŽÖÞNJO ÖMØÓÑPØÑCEÑMØÑOÉ QVÕÔNMPÑ RÒPO ÷HÎ ICE MÕÑ ÓMŘÑØCE
TPP-Regulatory Mismatch	Clinical endpoints don't align with regulatory precedent precedent	ĜÕNJMNJÑØÑNÞÕMPÖŽŘ MNJÑÕÑÒÑCEÑMØŘÉ MÕÔNJÕ RÒPO ÑCEPMNÕÒŒÐÑÑ ÓMPORMŘCE
TPP-Resource Incongruence	Product costs more to develop than available funding	Right-size TPP to funding reality; prioritize critical attributes

TPP Evolution Over Time

Early Stage

Aspirational but grounded in rationale

Mid Stage

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Late Stage

Ready for launch, access, and lifecycle planning

TPP & The Triple Balancing Triangle™

Acquirers

Creating strategic value that will lead to acquisition

Investors

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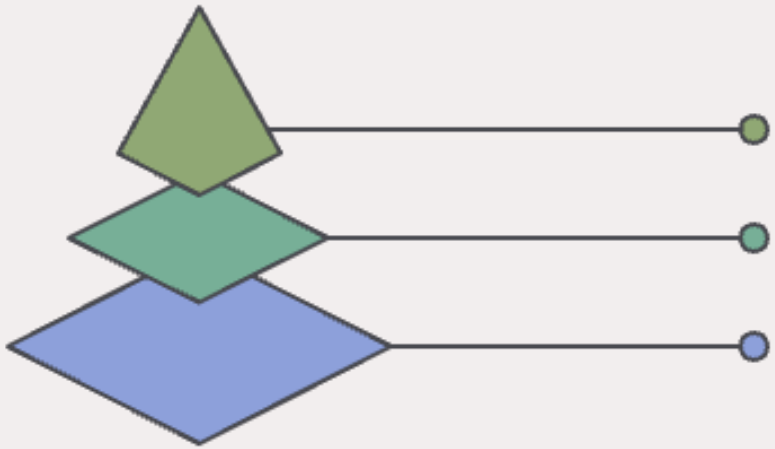
Customers

Building products that solve real problems and deliver value

Miss any corner of this triangle, and your startup collapses.



Acquirers
Strategic fit, Scalability, Lifecycle value

Investors
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Customers
Patients, Providers, Payers

Target Product Profile Alignment:

Advanced Triangle Dynamics

TPP Signaling

What you emphasize reveals your team's understanding

Stakeholder-Specific TPP Versions:

Maintain core consistency with tailored emphasis

Counter-Positioning Strategy

Position your product to make competitive response difficult

Real-World Example: Herceptin®

Targeted Population

Identified HER2-positive breast cancer patients as distinct subset

Strategic Focus

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Regulatory Success

Streamlined approval through clear definition of target population

Commercial Success

Established personalized medicine paradigm and became blockbuster

Cautionary Tale: Biogen's Aduhelm

Regulatory Success

FDA approval based on surrogate endpoint data

TPP-Market Misalignment

Failed to address payer and provider concerns

Pricing Issue

$56,000 annually faced Medicare resistance

Commercial Failure

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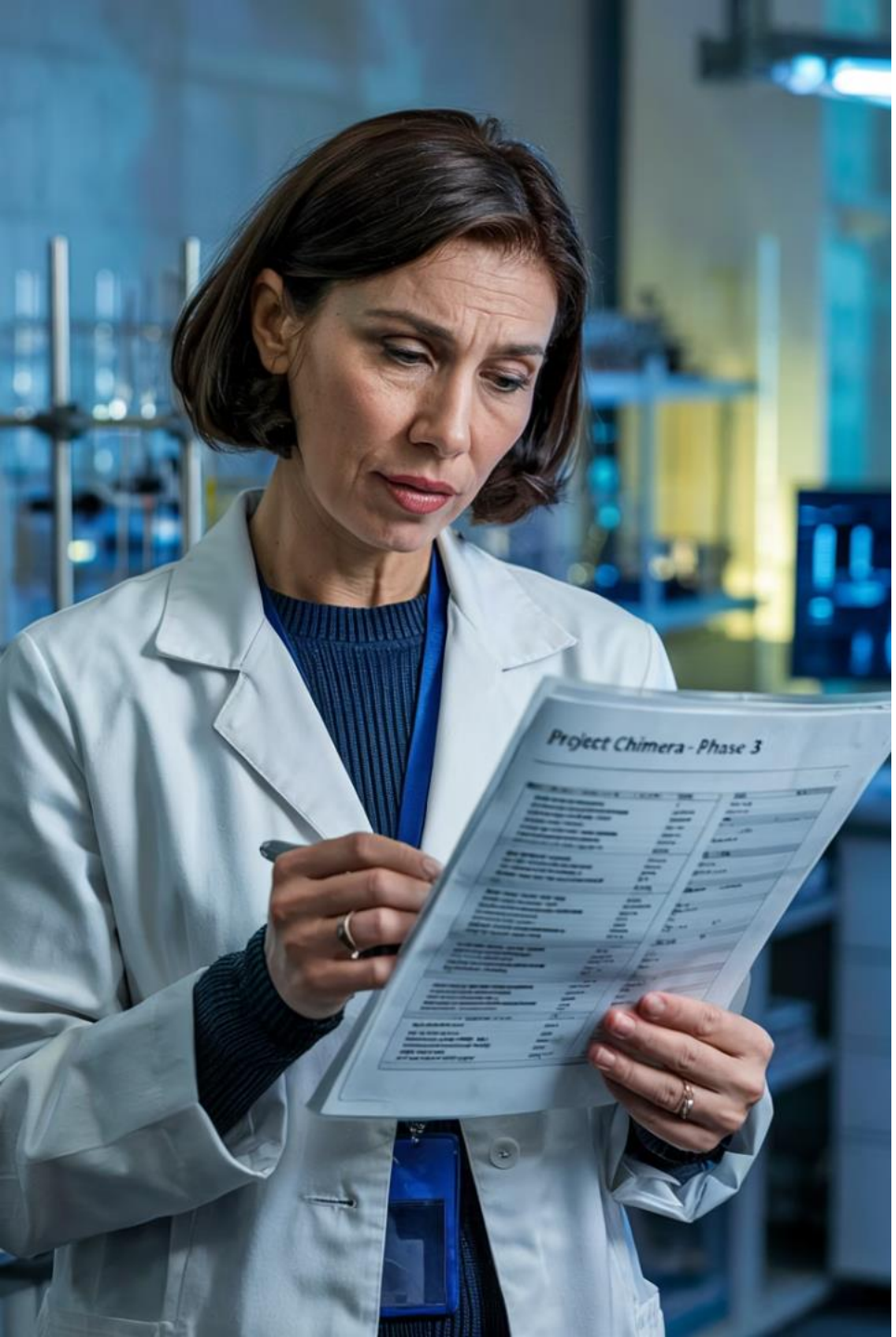

Evaluating Your TPP: Self-Assessment Guide

1 **The Scientific Reality Test**

Is there compelling scientific rationale? Do preclinical data support the target attributes?

2 **The Commercial Viability Test**

Does it address an unmet need? Is the differentiation meaningful to prescribers and patients? and patients?

3 **The Competitive Sustainability Test**

How will the landscape evolve? Will differentiation remain relevant at launch?

4 **The Resource Alignment Test**

Do you have the capabilities? Is capital requirement aligned with funding prospects? prospects?

5 **The Regulatory Feasibility Test**

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6 **The Triple Balancing Triangle Test**

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Key Takeaways

Strategic Foundation

TPPs serve as the foundation for compelling pitches

Classification Matters

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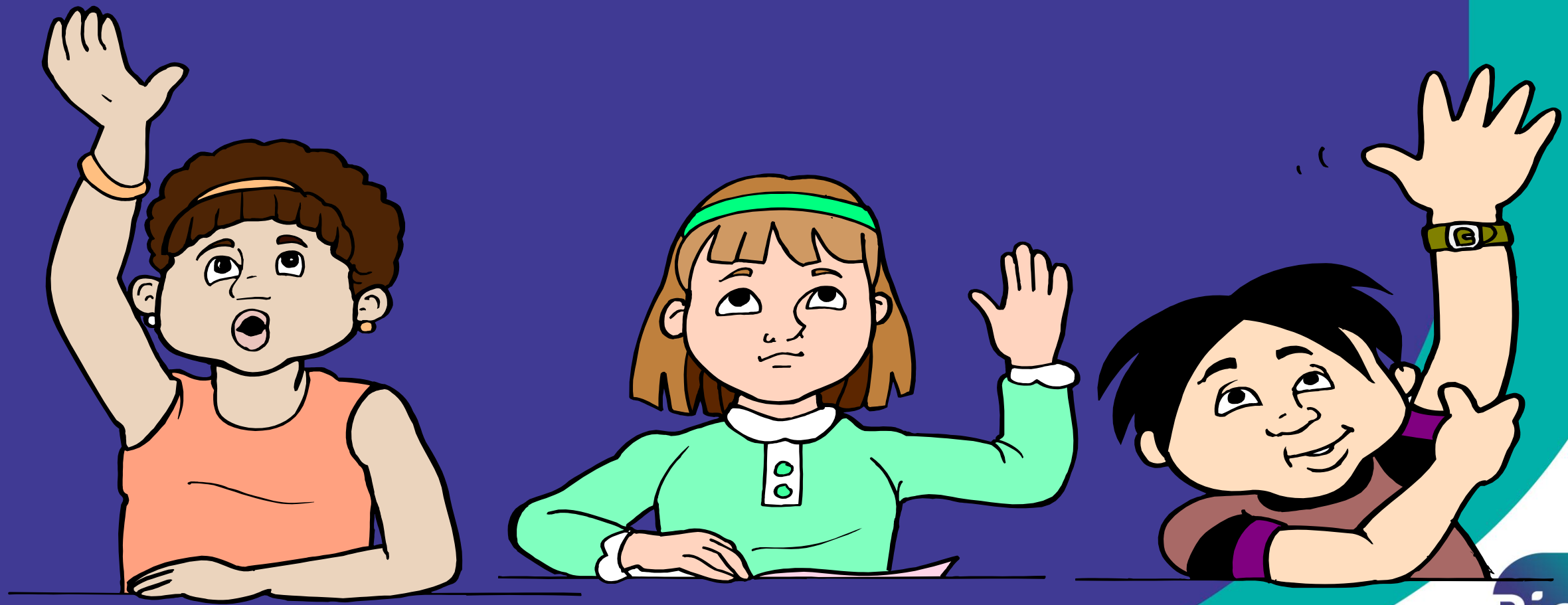
Focus on What Matters

The 80-20 principle applies to both TPPs TPPs and pitches

Strategic Novelty

Core differentiation investors value

Questions???



Case Study: Target Product Profile (TPP): Next-Generation Metabolic Agent to Surpass Mounjaro

Product Name (Code): [To Be Determined]

Indication: Chronic weight management in adults with obesity or overweight and comorbidities (e.g., type 2 diabetes, hypertension, dyslipidemia)

Product Description

Attribute	Target	Minimum Acceptable
Product Class	Triple receptor agonist (GLP-1/GIP/Glucagon) or oral small molecule	Enhanced GLP-1R agonist
Formulation	Oral tablet or once-monthly injection	Weekly subcutaneous injection
Route of Administration	Oral or subcutaneous	Subcutaneous only
Mechanism of Action	Triple incretin pathway or dual incretin + SGLT2 activity	Dual GIP/GLP-1 RA

Indication and Usage

- Chronic weight management in:
  - Adults with BMI ≥30 kg/m², or
  - BMI ≥27 kg/m² with at least one weight-related comorbidity
- Adjunct to reduced-calorie

Dosage and Administration

Attribute	Target	Minimum Acceptable
Dosing Frequency	Once monthly (injectable) or once daily (oral)	Once weekly (injectable)
Titration	Minimal or none required	<6 weeks titration phase
Dose Adjustments	Based on response/tolerability	Limited titration flexibility

Efficacy Targets

Endpoint	Target	Minimum Acceptable
Mean Weight Loss at 72 weeks	≥25% of baseline body weight	≥20%
Time to 10% weight loss	≤16 weeks	≤24 weeks
A1C Reduction (T2D patients)	≥2.5% absolute drop	≥2.0%
% Achieving ≥15% WL	≥75% of patients	≥60%
Maintenance of Weight Loss	≥90% at 1 year after cessation	≥70%

Safety and Tolerability

Attribute	Target	Minimum Acceptable
GI Side Effects (N/V/D)	<10% incidence, mostly mild	<20%, dose-dependent
Pancreatitis Risk	No increased risk over placebo	Comparable to GLP-1 RA class
Hypoglycemia	Rare in non-diabetics	<2% without insulin use
Cardiovascular Profile	CV risk reduction shown in long-term trial	CV safety demonstrated

Differentiation vs. Mounjaro

Dimension	Mounjaro (Tirzepatide)	Next-Gen Product TPP Target
MOA	Dual GIP/GLP-1 RA	Triple GIP/GLP-1/Glucagon or small molecule
Administration	Weekly subcutaneous injection	Monthly injectable or oral
Mean WL (SURMOUNT-1)	~22.5% at 72 weeks	≥25%
Diabetes A1C drop	~2.5% in SURPASS trials	≥2.5% or equal
Onset of effect	Weight drop begins by week 8	Detectable by week 4
Nausea/Vomiting	~18–30% during titration	<10%
Oral option	No	Yes (optional but advantageous)
Cost-effectiveness	High list price ($1,000+/month)	Improved access or formulary coverage

Intellectual Property Strategy

Attribute	Target Approach
Composition of Matter	Novel NCE or new class of oral small molecules/agonists
Method of Use	Broad coverage for obesity, diabetes, and cardiometabolic conditions
Formulation Patents	Enhanced delivery technology (e.g., oral peptide stabilization, depot formulation)
Manufacturing IP	Proprietary synthesis process or biomanufacturing platform
Patent Life Expectancy	≥20 years from earliest filing (with extensions/Orange Book listings)
Global Filing Strategy	U.S., EU, China, Japan, South Korea, Brazil, and India
FTO and Competitive Surveillance	Conducted regularly to identify risks and block competition
Lifecycle Management	Combination therapies, new indications, pediatric exclusivity, device-paired delivery

Clinical strategy

Attribute	Target Approach
Phase 1 Objectives	Safety, tolerability, PK/PD in healthy & obese volunteers
Phase 2 Design	Dose-ranging, weight loss efficacy, A1C lowering in T2D and non-T2D
Phase 3 Pivotal Trials	Head-to-head vs. tirzepatide or semaglutide; long-term safety extension
Population Focus	Diverse BMI and metabolic phenotypes; balanced gender & ethnicity representation
Biomarker Subgroup Analysis	Glycemic control, baseline GLP-1R expression, weight loss response predictors
Adjunct Therapies Tested	Lifestyle interventions, metformin co-administration, digital health tools
Global Trial Sites	North America, EU, Asia-Pacific (focus on high-burden obesity geographies)

Regulatory Strategy

Attribute	Target
Regulatory Pathway	505(b)(1) NDA (global pivotal trials)
Designations	Fast Track, Breakthrough, PRIME (EU)
Primary Comparator	Tirzepatide (Mounjaro) or Semaglutide (Wegovy)
Endpoints	% weight loss, metabolic improvement, QoL
Study Duration	≥72 weeks + long-term extension

Commercial & Access Strategy

Attribute	Target
Launch Pricing (U.S.)	≤$900/month or value-based agreement
Payer Access Strategy	Formulary Tier 2 or outcomes-based rebate
Patient Adherence	≥85% persistence at 12 months
Health Equity Focus	Efficacy across ethnicities and BMI strata

Aspirational Claims (Pending Validation)

- Superior weight loss vs. Mounjaro in head-to-head study
- Well-tolerated with low nausea and minimal titration
- Once-monthly or oral delivery with equal or greater metabolic control
- Proven benefit in maintaining weight loss post-discontinuation
- Demonstrated cardiovascular event reduction in high-risk patients

Q&A