

# Best Practices for Commercially Driven Product Development

*Biotech Entrepreneurship Seminar Series*  
*8 November 2023*

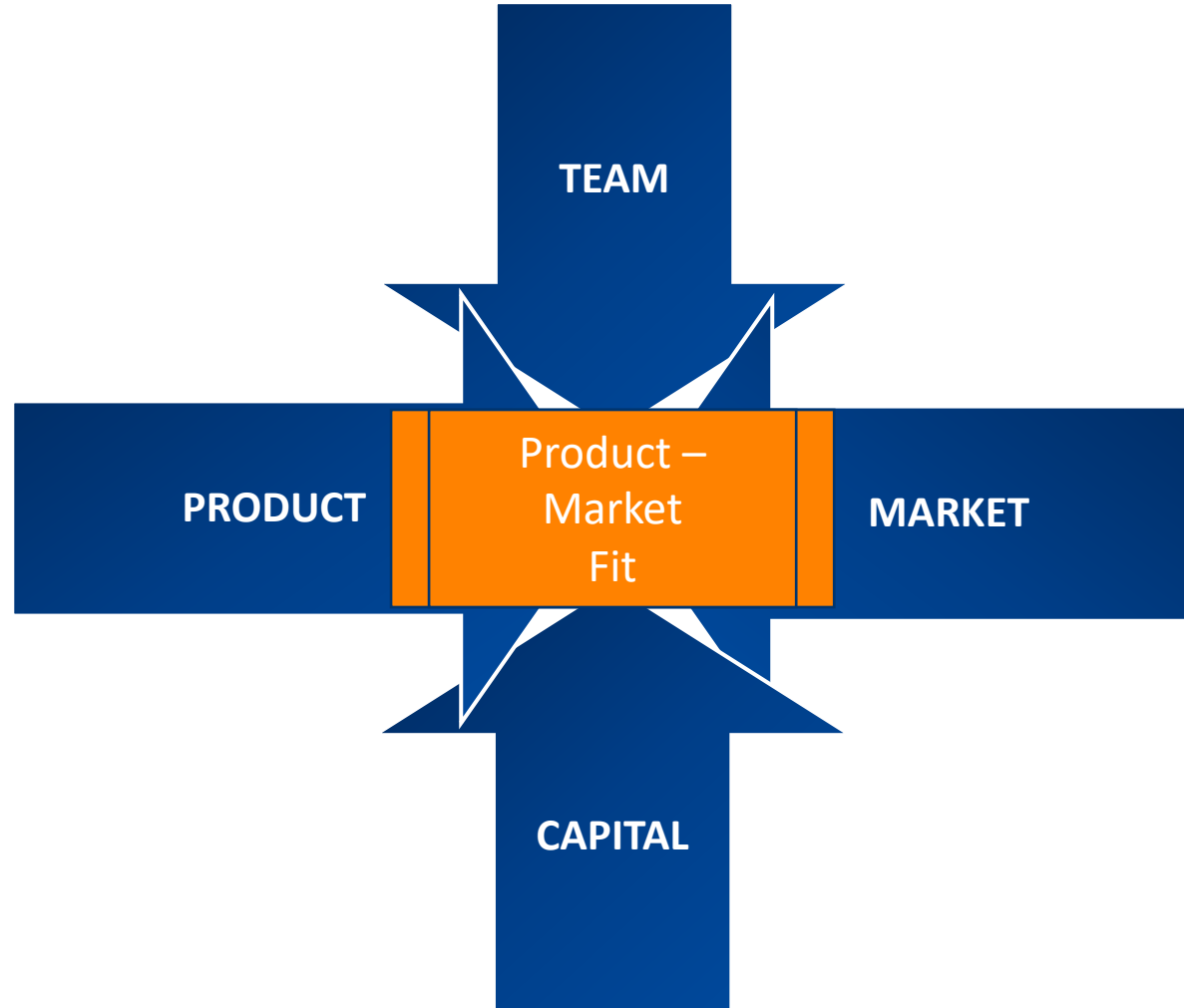
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UMB EIR / TEDCO Site Miner

## Expanding on Product-Market Fit → Developing Commercially Successful Products



Entrepreneurs must convince professional investors of that your company / product will provide an attractive return on investment.

## Expanding on Product-Market Fit → Developing Commercially Successful Products



Developing “Commercially Successful” products requires not only an understanding of the “product–market fit”, but real, in-depth insights on the unique environment into which the product will launch.

*“Product–Market-Channel” Fit*

# Commercialization in the US Biopharmaceutical Market

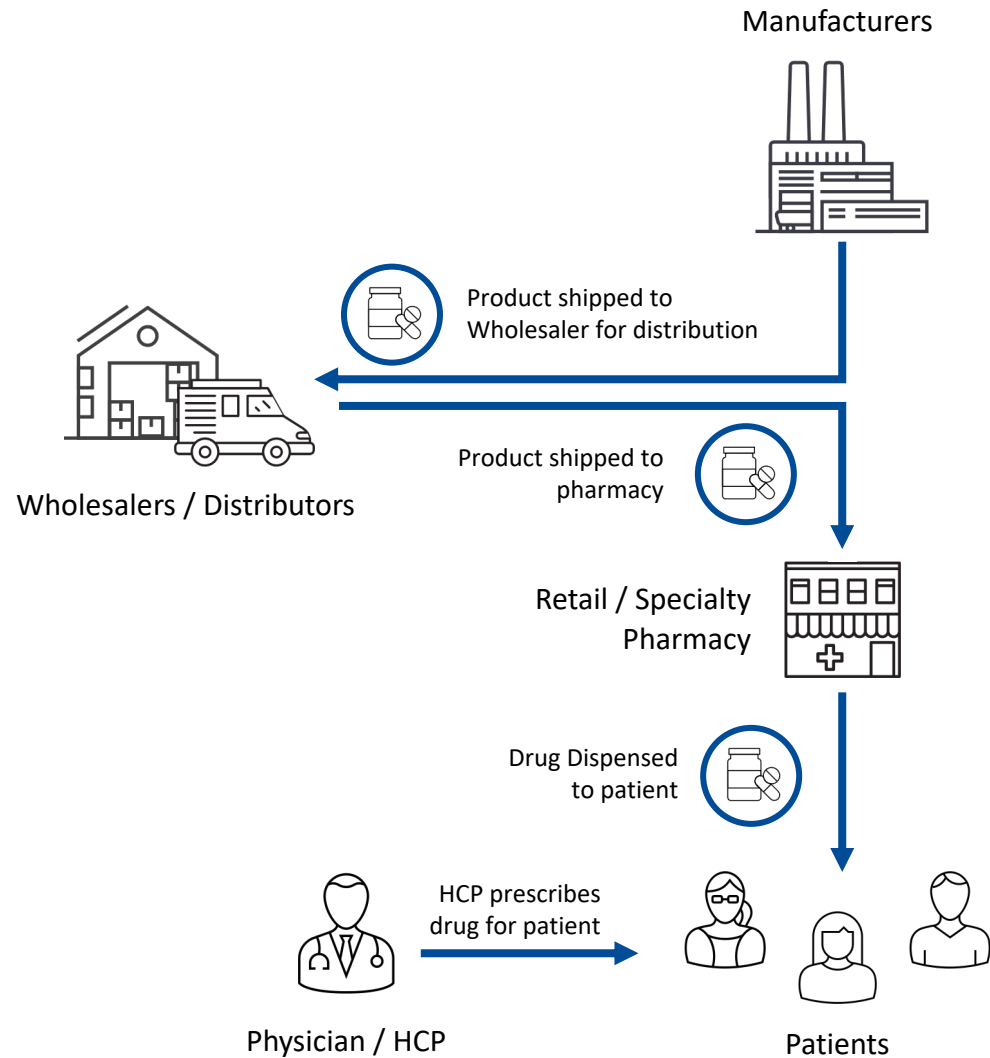


What stakeholders are involved in the commercialization of biopharmaceutical products?

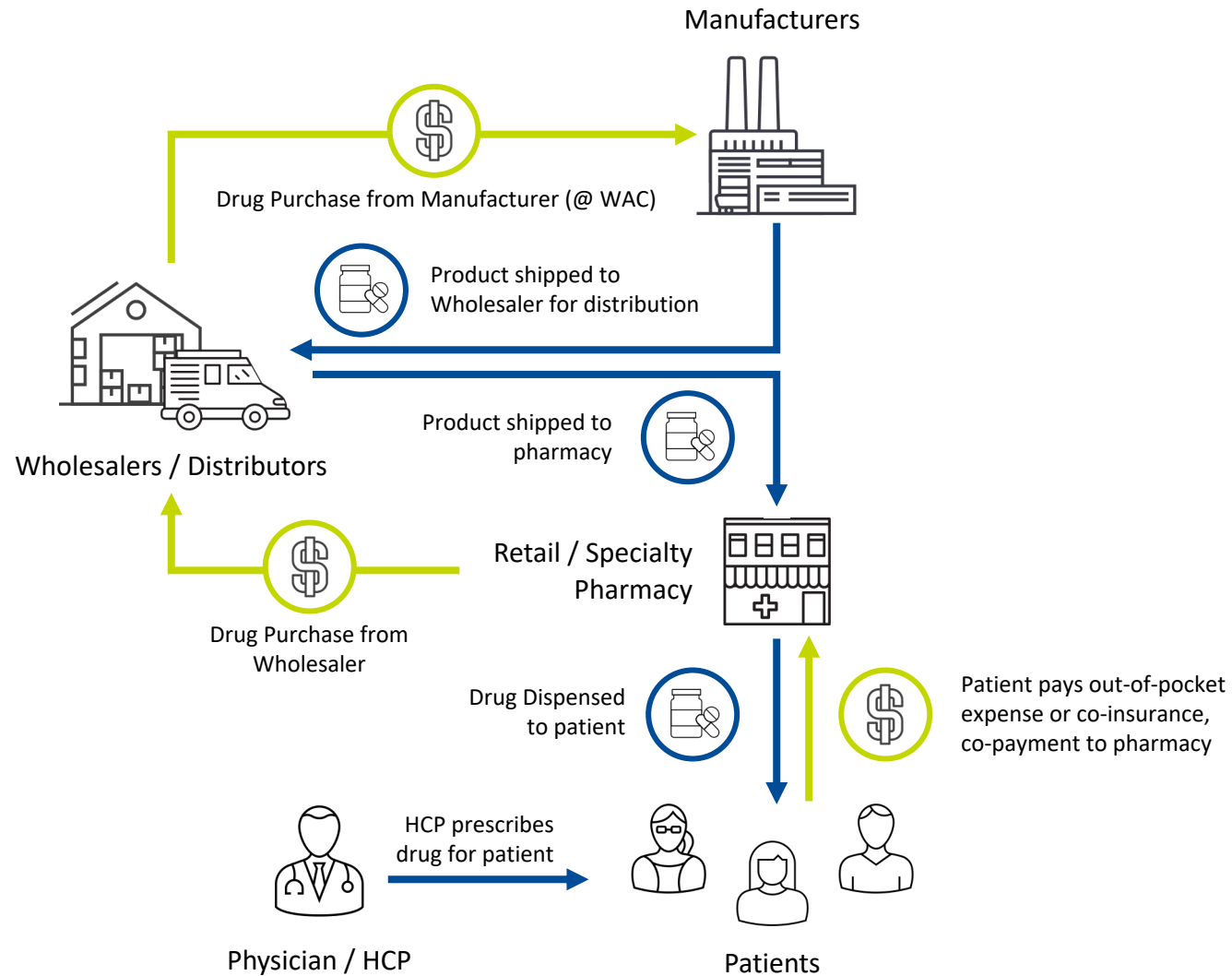
How are drugs transferred from the manufacturer to the patient?

How are manufacturers compensated for the products and how are the other commercial stakeholders paid for their services / roles?

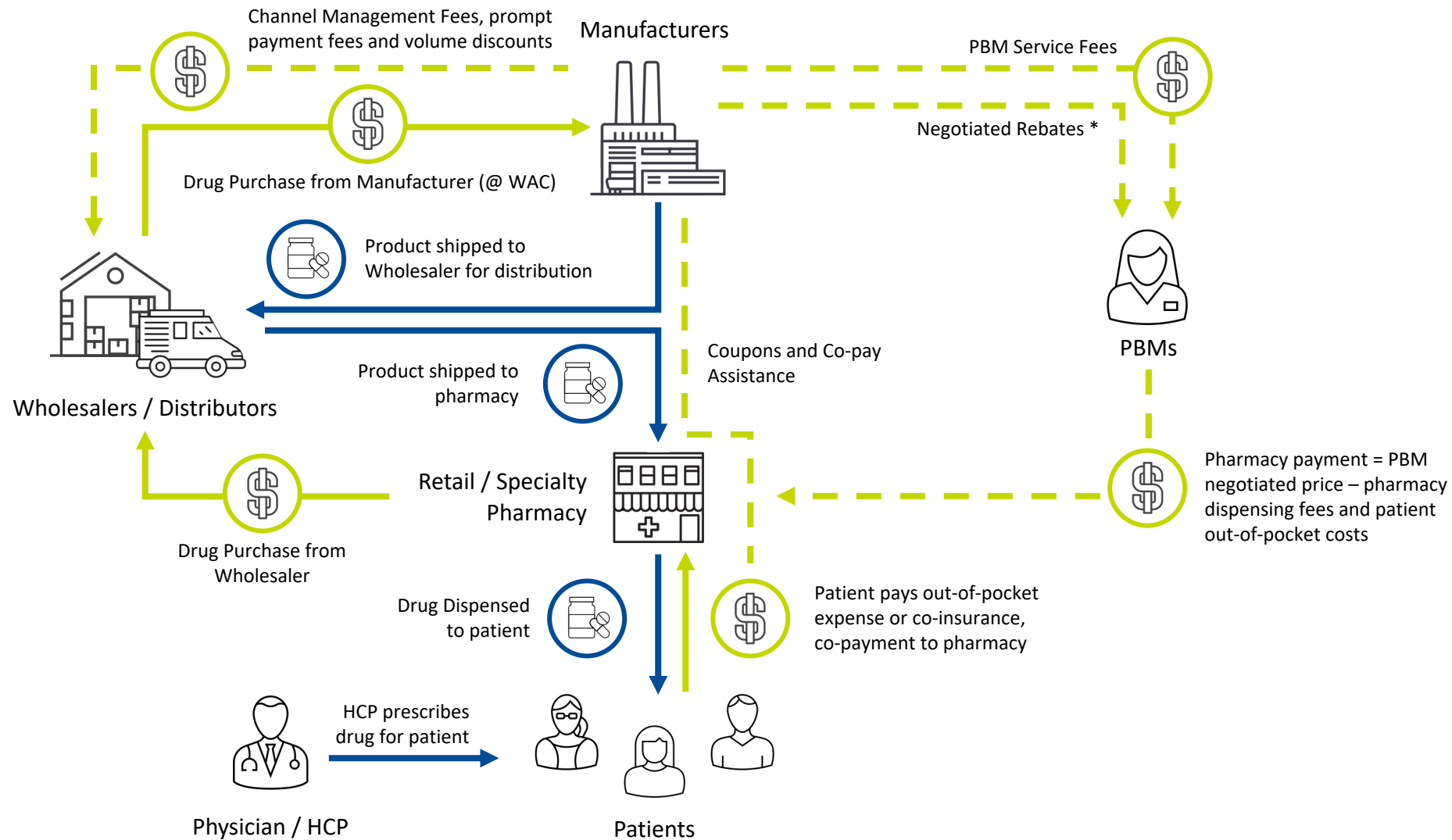
# US Biopharmaceutical Market: Distribution of Products



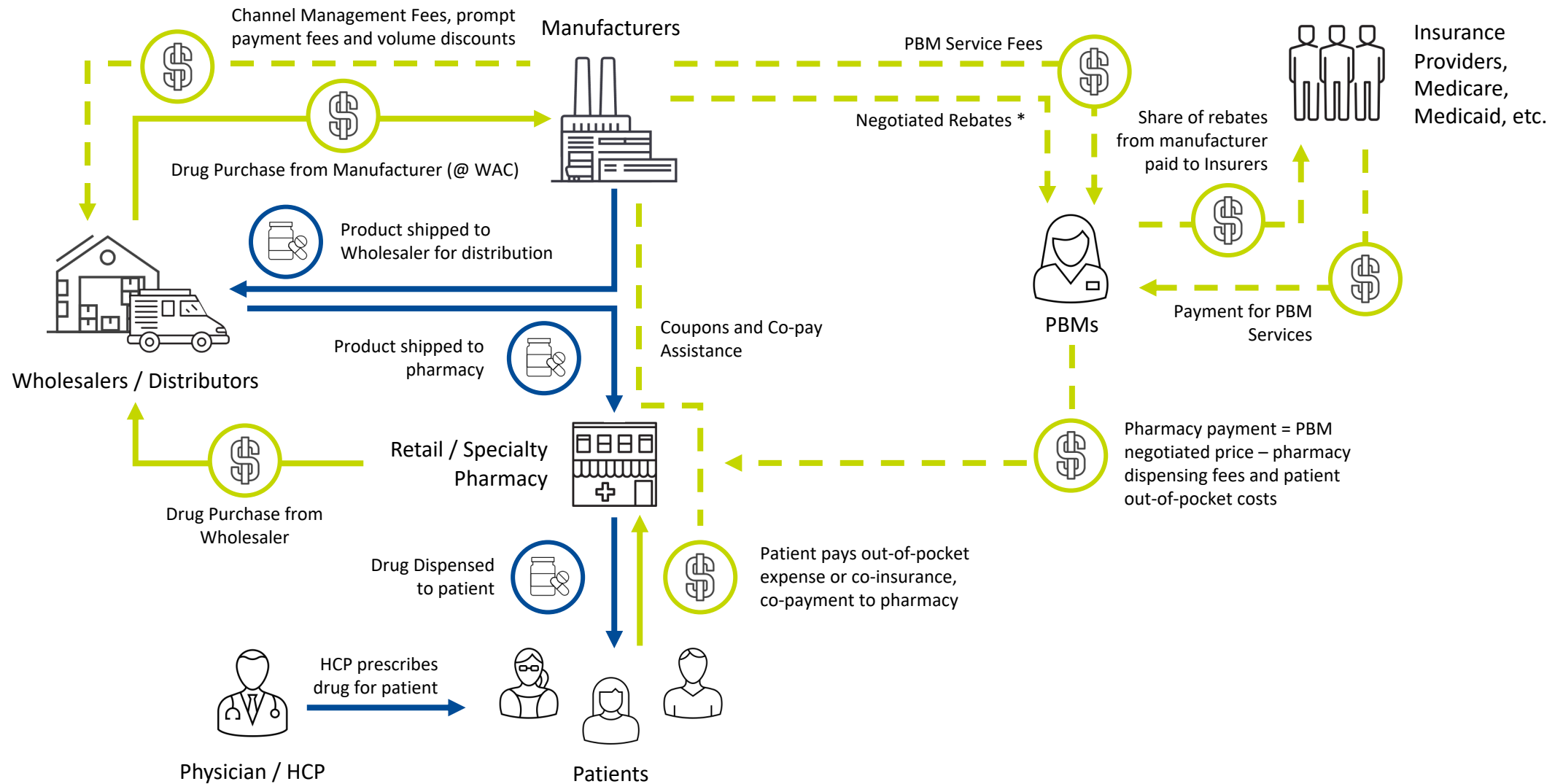
# US Biopharmaceutical Market: Payment for Products



# US Biopharmaceutical Market: Rebates and Service Fees



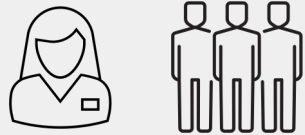
# US Biopharmaceutical Market: Insurance Providers





# Commercial Stakeholders Have Diverse Needs / Expectations

## Typical Goals / Expectations of Drug Product



**Insurers, Payors  
and PBMs**

- Provide access to medically necessary drugs;
- Minimize overall formulary expenses;
- **Maximize Revenue!!!**



**Physicians and  
HCPs**

- Achieve positive health outcomes for patients;
- Confidently prescribe products that have meaningful efficacy and limited risk of side effects or AEs;
- **Easy access / No hassles in fulfilling Rx (i.e., limited office work required (no prior authorizations, etc.))!!**

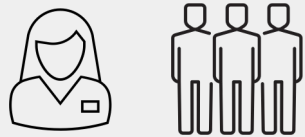


**Patients and  
Caregivers**

- Improved health
- Easy access to medication;
- **Take medications that provide meaningful efficacy with limited risks of side effects or AEs;**
- **Limited out of pocket costs!!**

# Commercially Successful Products Address Those Needs

## Typical Goals / Expectations of Drug Product



**Insurers, Payors  
and PBMs**



**Physicians and  
HCPs**

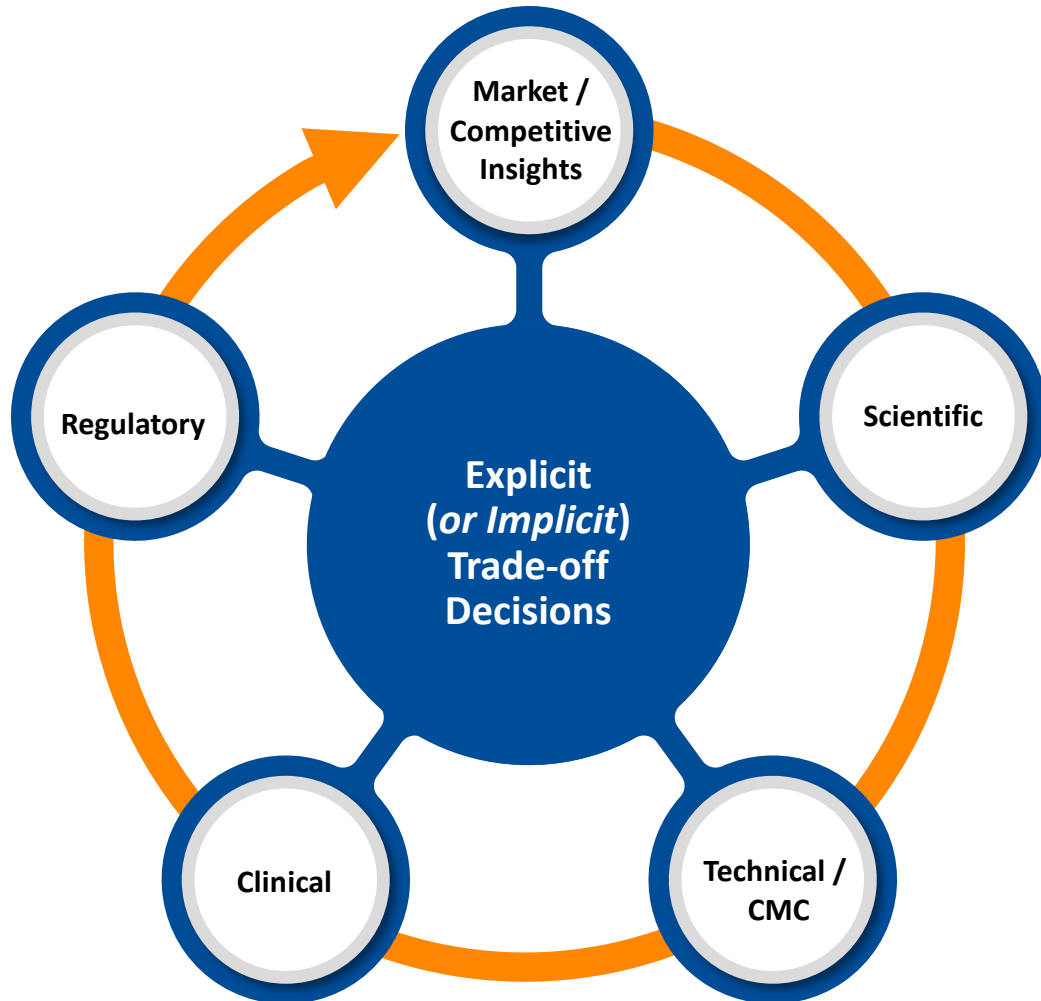


**Patients and  
Caregivers**

To develop commercially successful products, companies need to understand the diverse needs of potential stakeholders and make well-informed tradeoff decisions that address these needs and maximize the potential return on investments required for development.

# Principles of Commercially-Driven Product Development

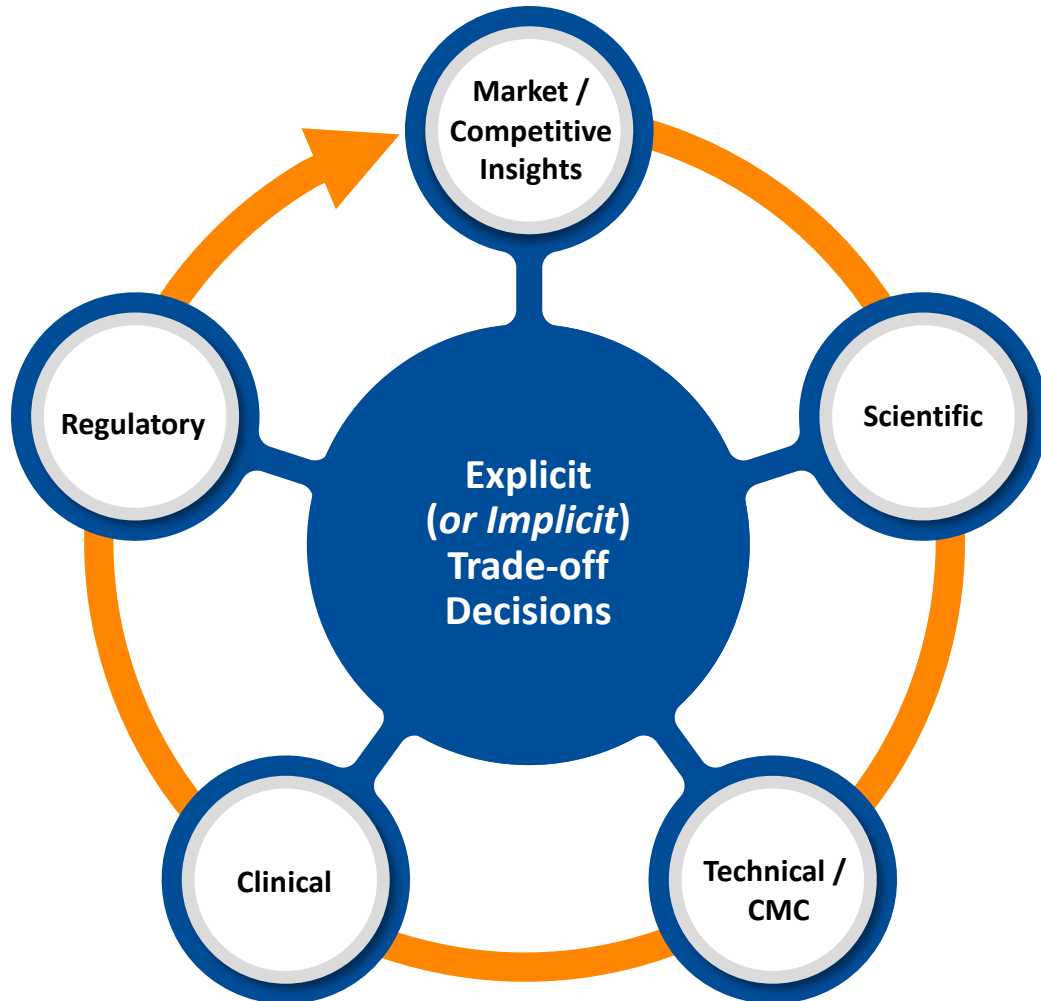
Development and Commercialization Timeline



- Developed w/ comprehensive input
- Defined by clear trade-off decisions
- Iterative & Constantly Evolving

# Principles of Commercially-Driven Product Development

Development and Commercialization Timeline



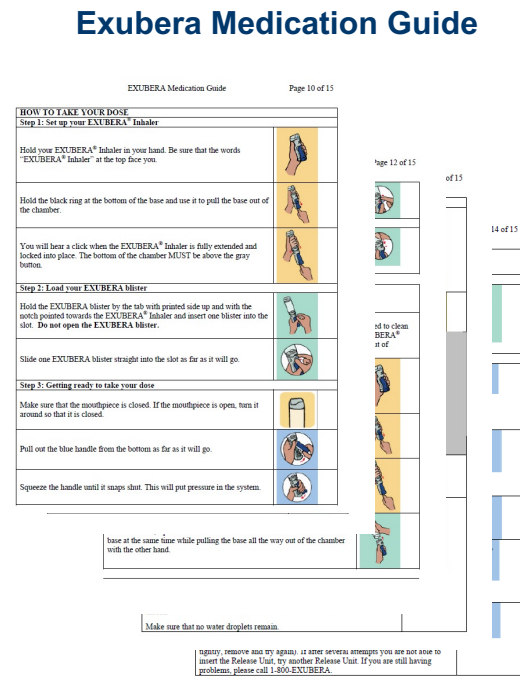
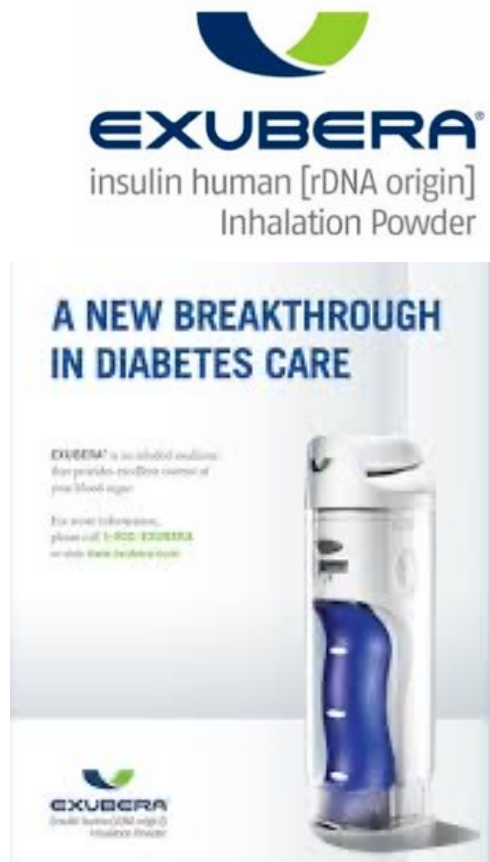
The decisions that ultimately determine any product's development strategy can be summarized by the answers to two simple questions:

Where will we play?

How will we win?

# Why is this important?

## Flawed Market Insights Can Lead to Catastrophic Failure



- In 2006, Pfizer purchased the rights to Exubera® (inhaled insulin) from Sanofi for \$1.4B; The product was expected to be a multi-billion (\$) game-changer
- “Needle Phobia” was real (for a subset of patients) but discretion and flexibility of dosing were prioritized by all
- At launch, Exubera® was universally panned by patients; The device was recognized as being unnecessarily complex, bulky and extraordinarily difficult to use;
  - Exubera® had limited dose flexibility; higher doses could take several minutes to manipulate the device for multiple blister packs
- Exubera® generated a total of ~\$12M in worldwide sales before being withdrawn from market and Pfizer realized a loss of ~\$2.8B

# Why is this important?

Funding is a competitive game

No No No No No No No No  
No No No No No No No No  
No No No No No No No No  
No No No No No No No Yes  
No No No No No No No No  
No No No No No No No No  
No No No No No No No No

## Why is this important?

Funding is a competitive game



of start ups ever  
receive VC funding

## Why is this important?

Funding is a competitive game

**0.05%** of start ups ever  
receive VC funding



## How Many Early-Stage CEOs Pitch Their Product / Company ...



**An investment in our company / product  
will provide you with an attractive risk-  
adjusted ROI**

## How Early Stage CEOs Should Pitch Their Product / Company ...

**This is HOW and WHY an investment in our company / product will provide you with a SUPERIOR risk adjusted ROI when compared to all of the other investments that are being evaluated**

# Best Practice for Commercially Driven Product Development:

## 1. Use Strategic Tools and Develop a Target Product Profile (TPP)

### Frameworks and Decisions Defining a Commercially-Driven Product Development Strategy



#### Target Market Definition

*What indications, patients and patient types will we prioritize?*



#### Patient Journey & Stakeholder Needs Assessment

*What factors result in patients receiving medical treatments? What are the (prioritized) unmet needs of stakeholders (patients, providers, and payors) within our target market? Which unmet needs will motivate future behavior?*



#### Competitive Analysis

*What products will be competing in our target market when we launch? How will our product be differentiated from current and future competition?*



#### Payor / Value Analyses

*What benefits will our product provide? How will we articulate the value of these benefits to payors? How can we ensure that patients will have access our product?*

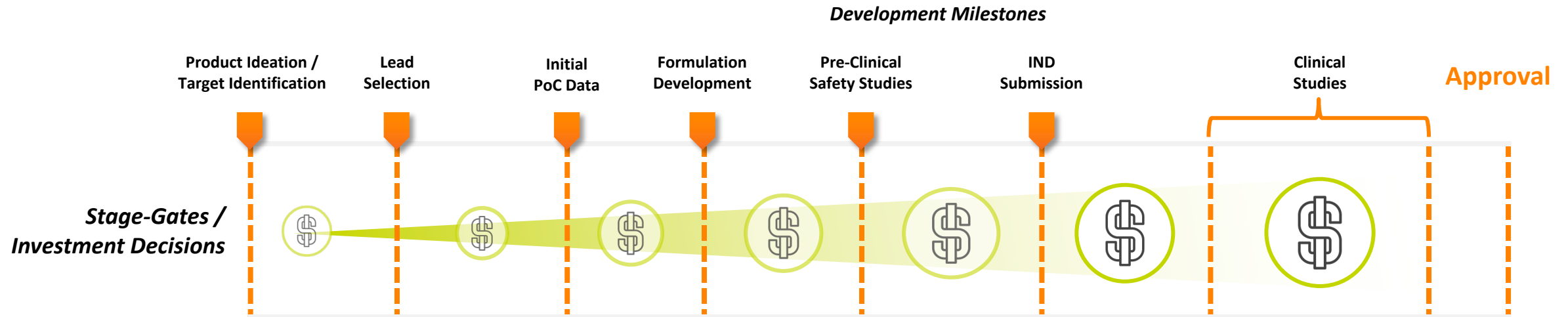
### Target Product Profile



- Framework that synthesizes commercial, regulatory, scientific and medical input
- Defines prioritized (achievable) labeling claims that optimally differentiate product
- Regularly updated to serve as guide for design of ongoing clinical trials and labeling negotiations with FDA

# Best Practices for Commercially Driven Product Development:

## 2. Inform Stage Gate Decisions with “Stage Appropriate” Strategy Refresh



Required Investments:



Product development is usually advanced through a series of stage-gates which typically involve increasing levels of investments in the program. Each of these stage-gates should be informed by a pragmatic assessment of product value as well as an understanding of resources required to monetize subsequent investments.

# Best Practices for Commercially Driven Product Development:

## 3. Determine / Utilize Appropriate Levels of Rigor for Decision-Making

### Low Level of Rigor

#### Typical Situations of Use:

*Low levels of rigor can be used for high-level evaluations of opportunities, as a “gut check” for early assessments or as a refresh on a previously-made, well-informed, low-risk decision.*

#### Level of Insights:

- Where possible, internal insights and expertise are leveraged to develop initial hypotheses;
- Hypotheses are tested with readily available secondary data sources (literature and online databases) and, if needed to further enhance confidence, limited qualitative market research.
- If conducted, qualitative research projects will be focused in scope and/or limited in scale (e.g., shorter interviews (30-45 minutes) with small group of KOLs or <10 HCPs)

### Moderate Level of Rigor

#### Typical Situations of Use:

*Moderate levels of rigor are typically used to initially define upcoming strategic decisions or to inform a strategic choices not associated with major investments; Moderate levels of rigor can also be utilized to reassess previous decisions challenged by new data or insights.*

#### Level of Insights:

- Qualitative research is typically conducted with specificity and focus in targeted questions and/or with targeted stakeholders. .
- More complex interviews and methodologies utilized (longer interviews (45 - 60 mins), deeper discussions, more respondents (n = 10-15 per segment).
- Simple online surveys can be used to quantify opportunities or specific points of differentiation.

### Significant Level of Rigor

#### Typical Situations of Use:

*Significant rigor should be applied to companies seeking to make formal go / no-go decisions or pivotal decisions directly associated with significant investments and/or clinical milestones.*

#### Level of Insights:

- Significant qualitative and/or quantitative research is typically conducted to ensure executive and board-level confidence with pivotal decisions and significant program investments.

# Resources for UMB Faculty Entrepreneurs and Startups: OTT can help identify potential sources of funding / collaborators

- University-Based Grants & Resources
- State Funds
- Federal Grants
- Other Sources
  - Non-Profit Foundations
  - Sponsored research & industry collaborations



**I-CORPS**

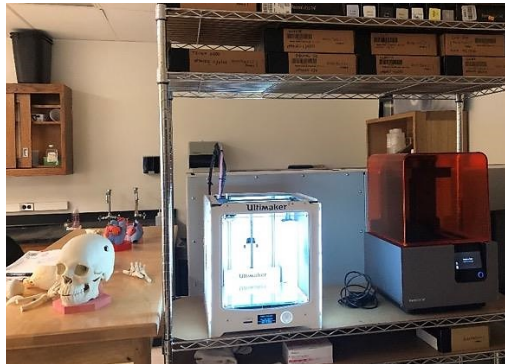


# Resources for UMB Faculty Entrepreneurs and Startups: Physical Facilities



## UMVB Wet Laboratory

- Opened 2019 (UM BioPark; 650 ft<sup>2</sup>)
- Molecular & cell biology capabilities
- TRP expansion for UMB inventors (& Biorepository storage)



## UMVB Prototyping Laboratory

- Opened 2021 (Bressler Bldg)
- Design, 3-D printing & tooling capabilities
- Facilitates rapid concept creation

Coming in 2024: 4 MLK !!!



# Resources for UMB Faculty Entrepreneurs and Startups: EIRs with Deep Knowledge and Expertise



**DARRYL CARTER, MD**  
*Entrepreneur-in-Residence*  
*Venture Advisor*



**RAHUL SINGHVI, ScD, MBA**  
*Entrepreneur-in-Residence*  
*Venture Advisor*



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