

Business of Science: Pharma Brand Team and HEOR

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iJOBS Alumni

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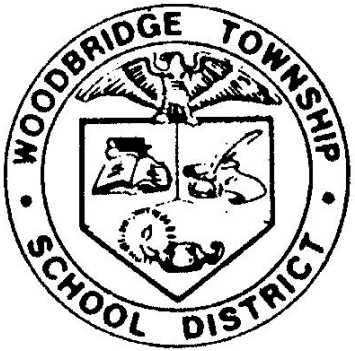
Agenda

- Objective & Introduction
- Pharma Brand/Asset Team Deep Dive
- Role of HEOR on Brand/Asset Team
- HEOR Case Study Breakouts
 - Value Proposition Development
 - Evidence Generation Plan
- Closing

Today's Objective

- Learn about the business side of pharma, focusing on brand team
- Understand the role of HEOR in generating evidence
- Explore areas of HEOR through 2 case studies

Introduction



K-12



BS



PhD



CENTER FOR
ADVANCED
BIOTECHNOLOGY
AND
MEDICINE

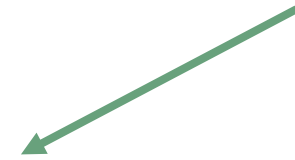
Rutgers Biotechnology
Training Program



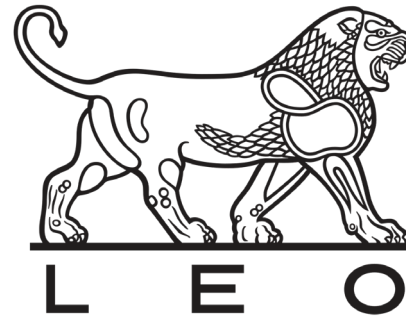
RUTGERS
Graduate School of
Biomedical Sciences



Intern



Director, Global Value,
Evidence & Outcomes -
Specialty



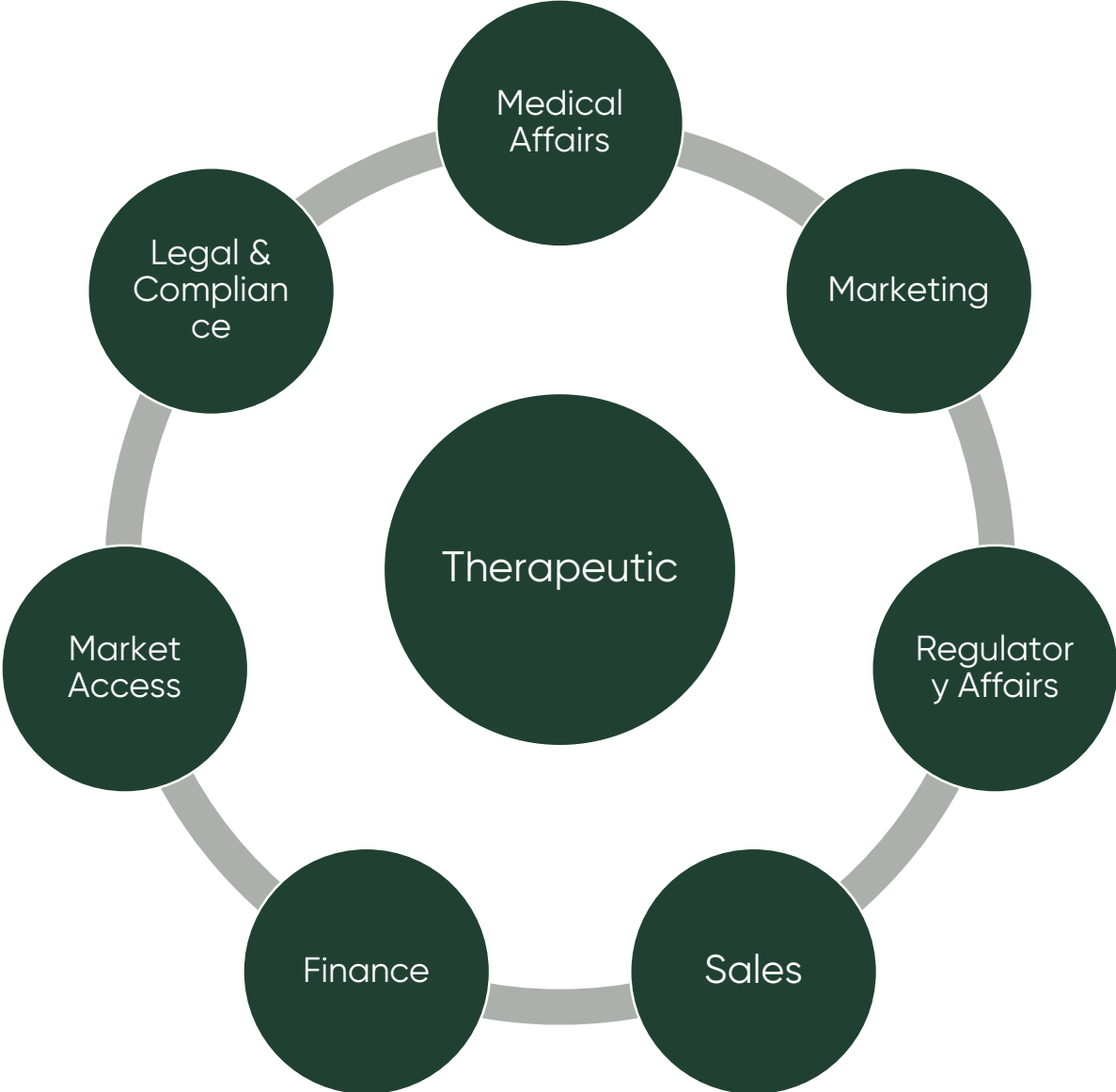
Manager, Scientific Affairs
Senior Manager, HEOR

Asset/Brand Teams

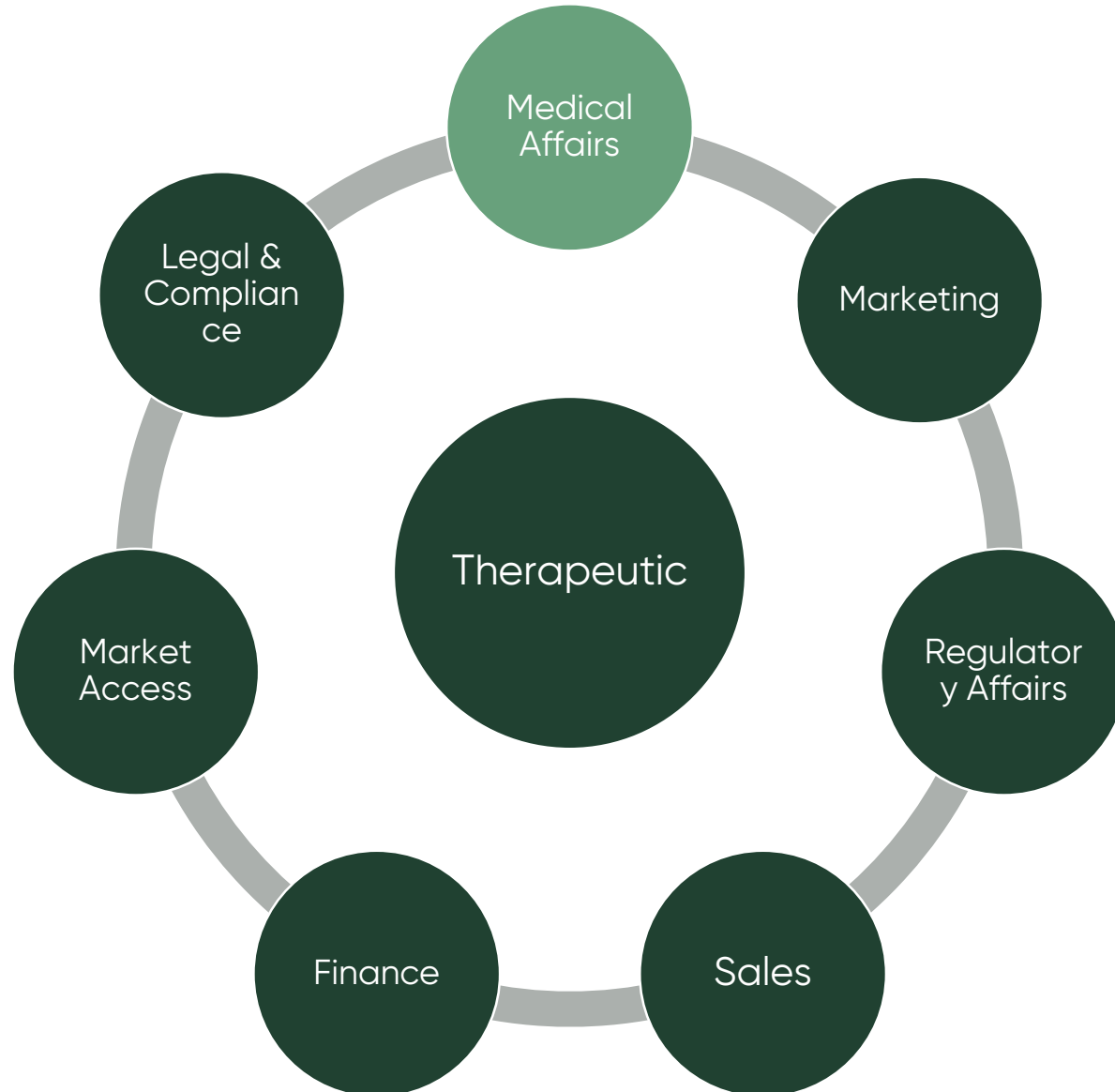
What are they?

- Functions dedicated to supporting the launch and continued post-marketing development of therapeutic assets
- Significant cross-functional and matrix collaboration between functional areas
- Developing strategy, evidence and messaging about a product
- Engaging with key customer segments
 - Key opinion leaders
 - Health care providers
 - Health systems
 - Regulatory agencies (TBD)
 - Payers
 - PBMs
 - Patients/patient groups

Functional Areas on Brand Team



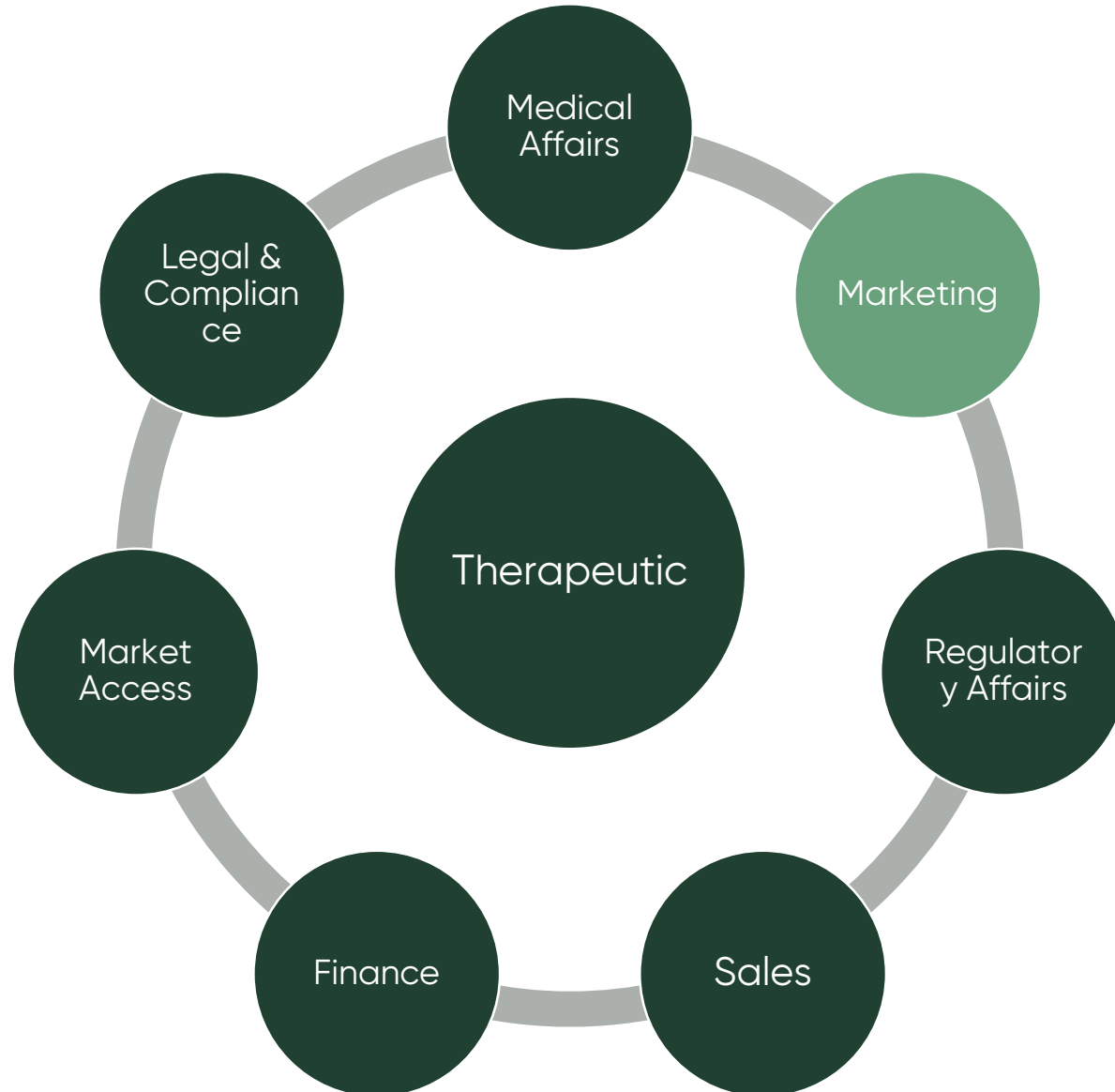
Functional Areas on Brand Team



Medical Affairs

- **Medical Director** – lead medic or scientist, key internal strategy experts
- **MSL team** – supports engagements with HCPs and KOLs on disease state education, off-label use
- **Payer MSLs** – supports understanding of disease state and product by payers
- **Publications** – supports medical communication of data at conferences and journals
- **Medical Information** – unbiased information on medical data of product
- **Business Operations & Excellence** – monitor activity of all functions to maintain caliber of excellence

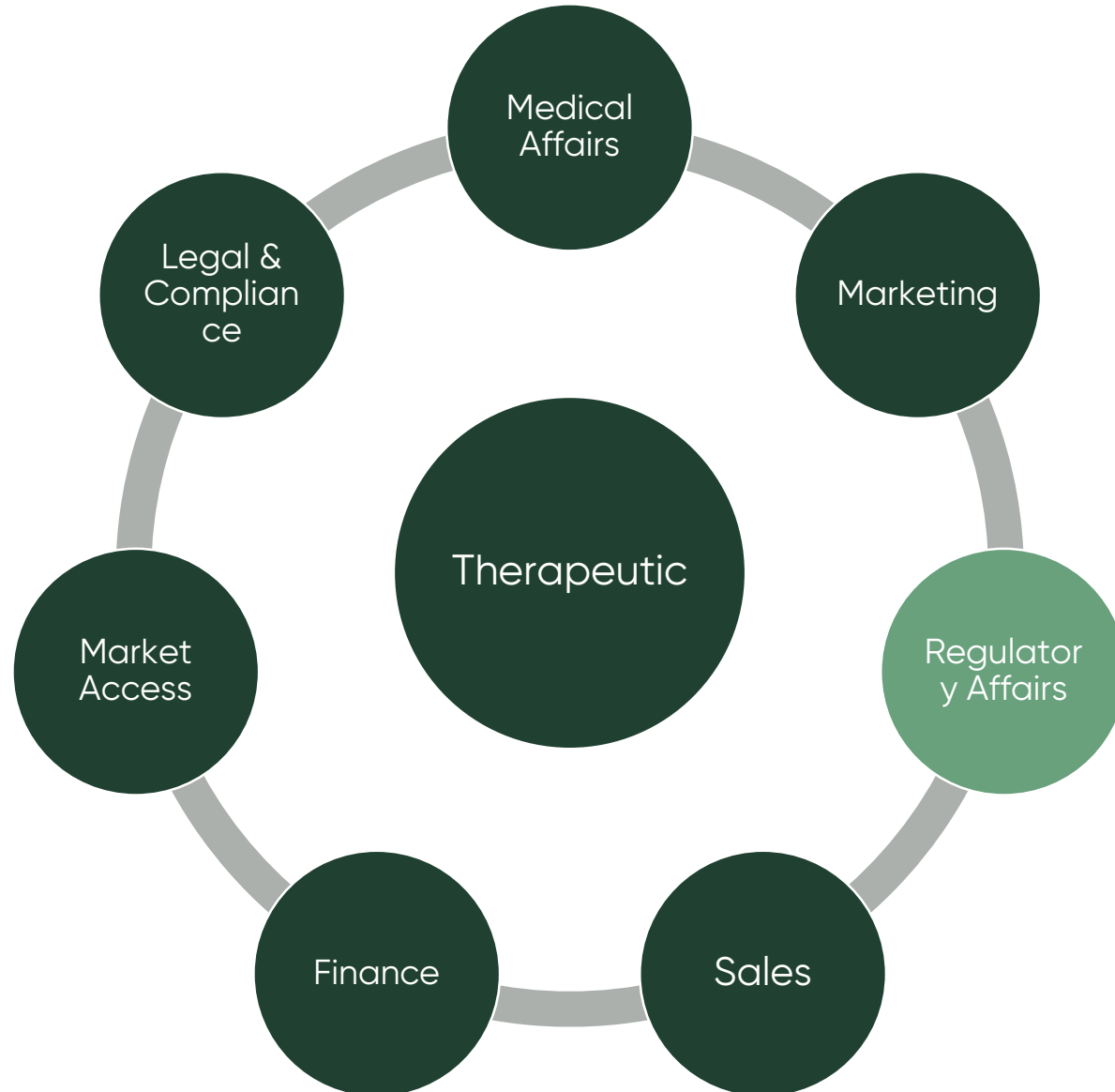
Functional Areas on Brand Team



Marketing

- **Lead Marketer** – responsible for developing marketing strategy and messages
- **Digital Marketing** – identifying customer segments and digital content
- **DTC Marketing** – direct to consumer marketing channels (TV, print, etc)
- **Congress Management** – unbranded and branded presence at key scientific congresses
- **KOL Management** – field support for sales and marketing outreach
- **Forecasting** – develop sales forecast, market share, and GtN

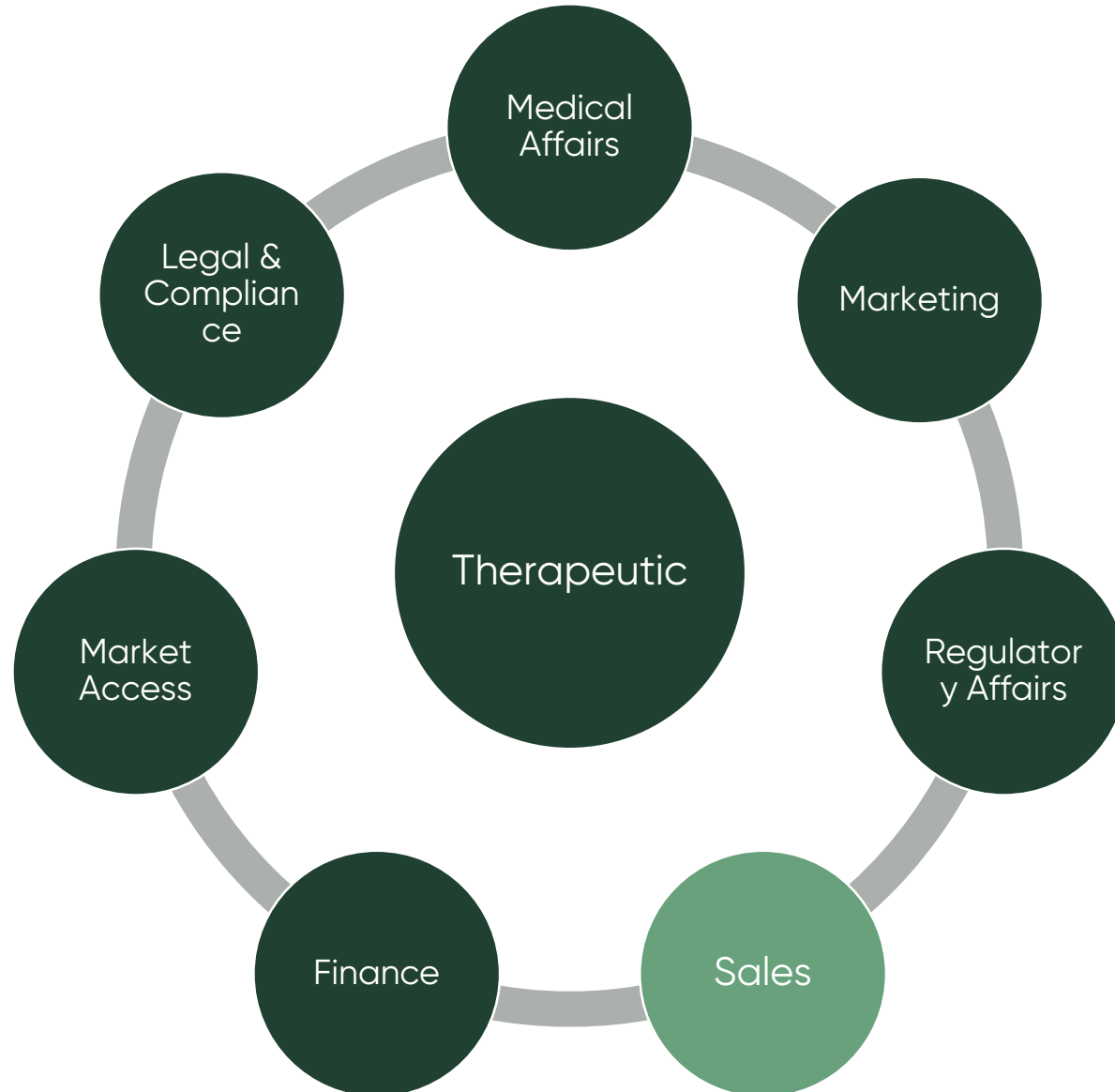
Functional Areas on Brand Team



Regulatory Affairs

- **Regulatory Lead** – responsible for communicating with regulatory agency on data, evidence, trials, documents, etc
- **Labeling** – develops regulatory label with the clinical R&D team and brand team
- **Promotional Review** – ensures all external communication are factual and per local regulatory guidance
- **Packaging** – ensures appropriate packaging and content

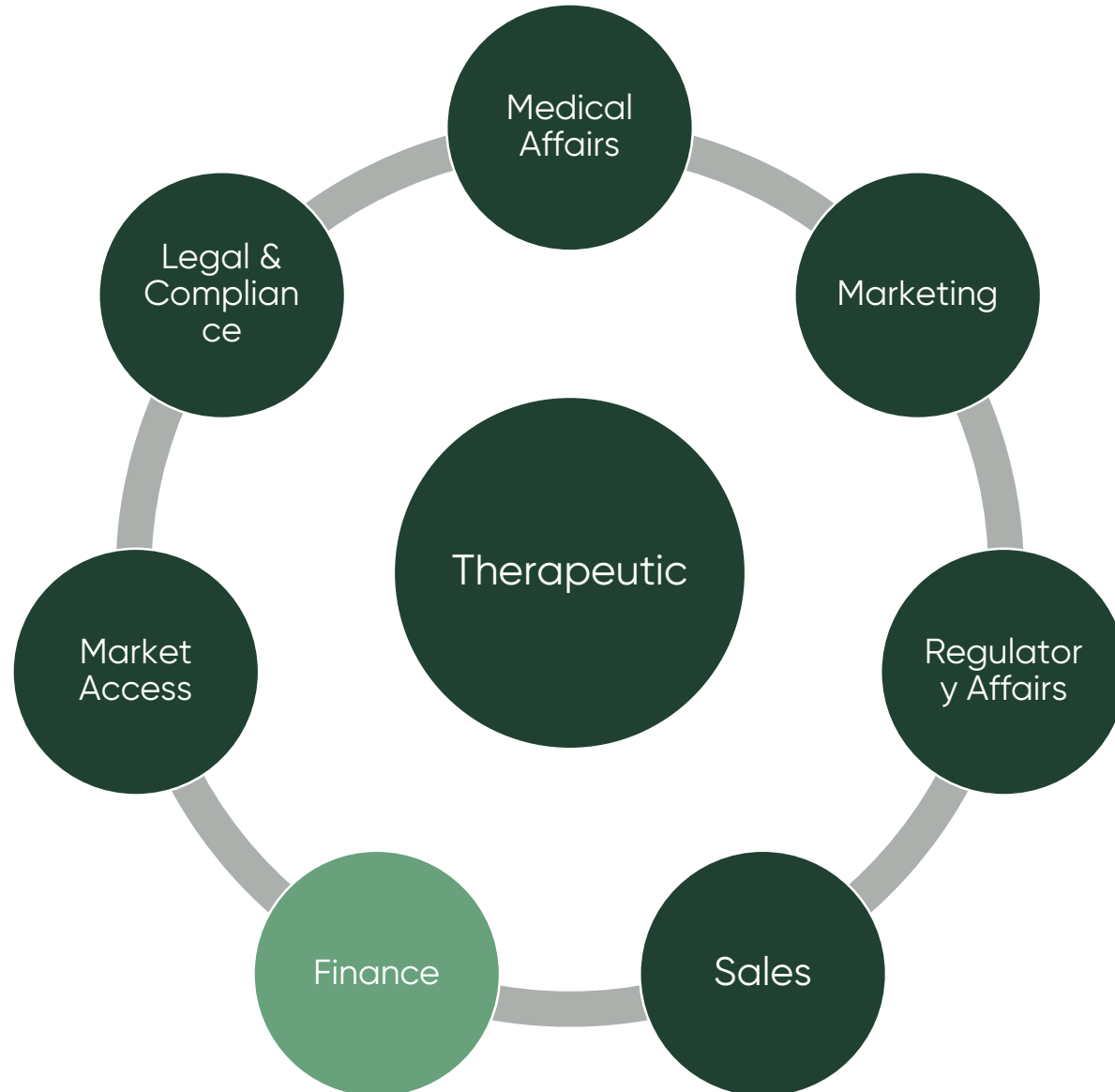
Functional Areas on Brand Team



Sales

- **Sales Team** – area manager, district manager, sales reps engaging with prescribers (ultimate money-makers)
- **Sales Operation** – provide support to field team (fleet, materials, expenses, call planning, etc)
- **Sales Training** – provide therapeutic, product, and competitive business training to sales reps
- **Sales Support** – everything else

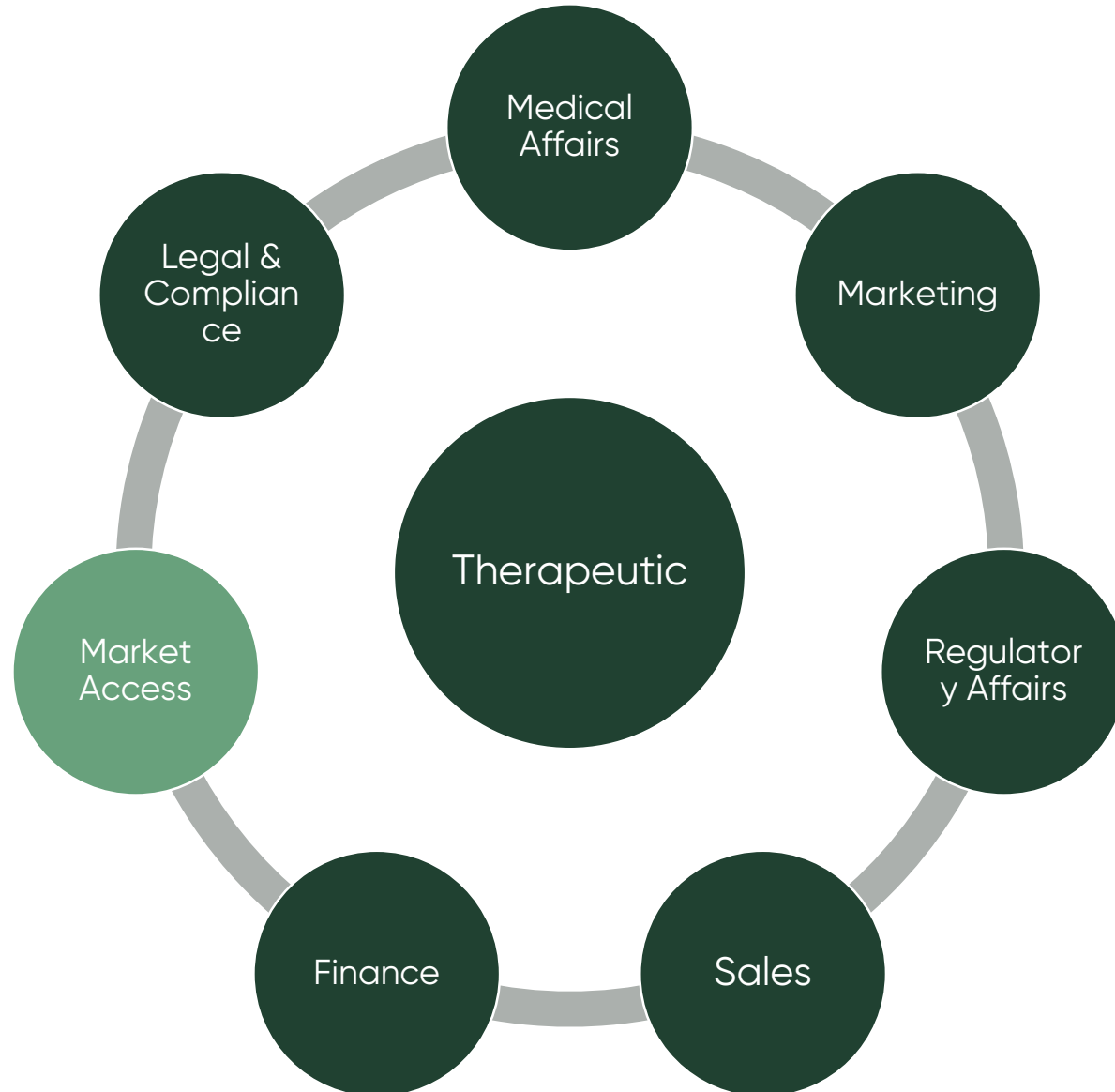
Functional Areas on Brand Team



Finance

- **CFO** – manages all finances for brand team on long term basis; provide ROI analyses
- **Finance Operations** – budget and track money spent versus forecasting; maintain P&L
- **Accounts Payable** – process and pay invoices based on projects completed
- **Procurement** – help all business functions attain goods and services at best price

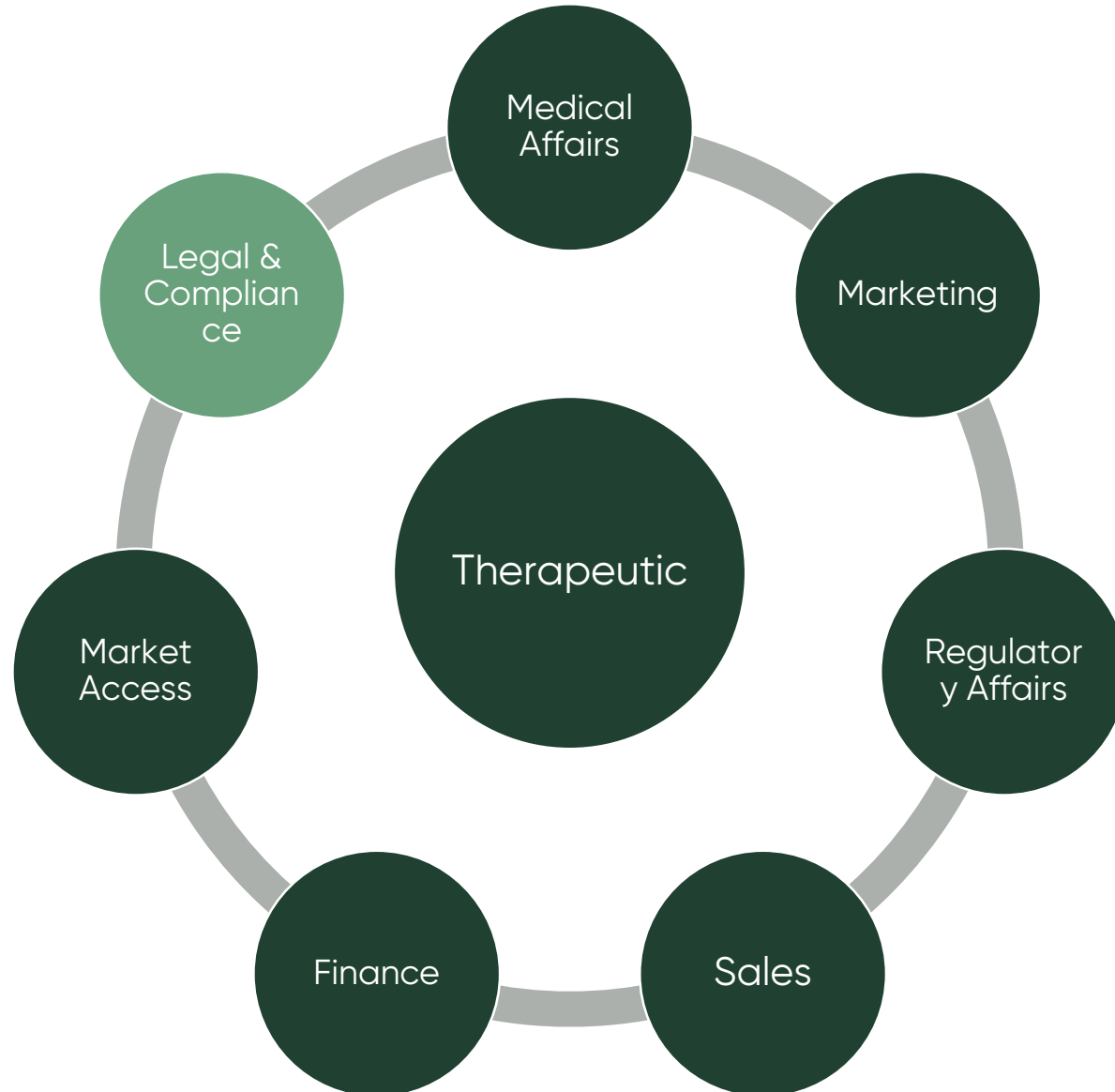
Functional Areas on Brand Team



Market Access

- **Payer Marketing** – developing strategy and materials for payers
- **Patient Support** – helps patients with the cost of medication and support in attaining it
- **Account Management** – field based team managing payer accounts
- **Contracting** – develops contracts with payers to cover medication (net cost, rebates, terms)
- **HEOR** – develop evidence to support the value proposition of a product beyond RCT data
- **Patient Advocacy** – partnering with patients to understand patient perspective

Functional Areas on Brand Team



Legal and Compliance

- Makes sure everyone is conducting business with the right ethics in a legal and compliant manner
- Keep organization abreast of developments in laws, regulation, and guidance that dictate business conduct

Health Economics & Outcomes Research

Evidence-based research discipline on cost and effectiveness of medical interventions

Health Economics (COST)

- Study of the cost of medical intervention for patients, payers, and society
- Understanding budgetary impact of medical intervention on hospitals, insurance companies, and patients
- Defining cost-effectiveness of therapies and interventions based on societal norms
- Economic burden and healthcare resource utilization of NOT treating a disease or condition

Outcomes Research (EFFECTIVENESS)

- Evaluating effectiveness and safety of therapies and interventions
- Generating real world evidence to support the effective utilization of therapies (treatment patterns)
- Understand physician treatment patterns
- Define patient heterogeneity and effectiveness of therapies (non-responders, super-responders)

Health Economics & Outcomes Research

Developing Evidence to Support Differentiated Value Proposition to HCPs and Payers

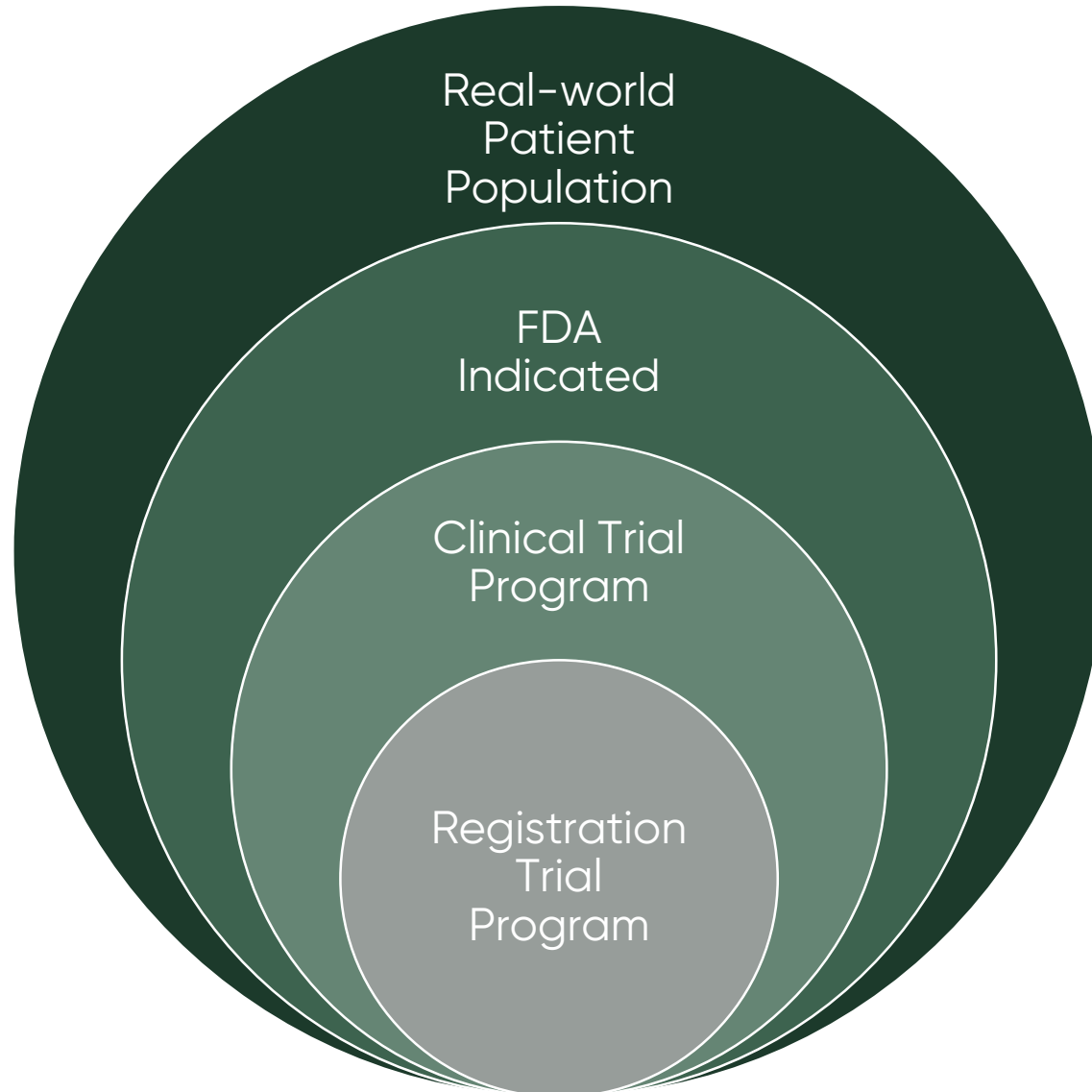
Value Proposition Development

- What clinical and economic value does your product bring to patients, healthcare providers, and payers?
 - Unmet need, efficacy, safety, price/cost offsets, budget impact, patient satisfaction, physician utilization
 - Who are the external stakeholders, how do we communicate this info to them, and why?

Evidence Generation

- **Pre-launch (defining market need)**
 - What are the current unmet needs not being fulfilled by available therapies?
 - What are some of the 'issues' with current therapies? (ex. not safe, not effective, costly, cumbersome for pts)
- **Post-launch (understanding your product)**
 - How does a drug perform in the real-world outside of a VERY controlled trial?
 - What is the real-world effectiveness of a drug?
 - Is the way physicians prescribing the therapy appropriate for the patient population?
 - FDA Post-Authorization Safety Study (PASS)

Patient Populations



Registration Trial Population

Patients REQUIRED by FDA to demonstrate efficacy and safety

Clinical Trial Population

All manufacturer sponsored trial populations

FDA Indicated

No restriction on inclusion/exclusion criteria as in clinical trials

Real-world Patient Population

Any patient the physician would prescribe the therapy for (off-label, pediatric, geriatric, etc)

Case Study 1

Value Prop Development

September 30, 2020

Case Study 1: Developing a Value Proposition for *Reslizumab*

- Review the phase 3 data for *reslizumab* for treatment of severe asthma
 - <https://www.sciencedirect.com/science/article/pii/S0012369216457156>
- *DO NOT read the entirety of the article (due to time constraints)*
- Focus on the template in developing the value proposition for reslizumab to demonstrate the value to a payer to cover the drug on their formulary (and for patients to get it when prescribed)
- In addition, identify areas where you don't have evidence to support a component of the value proposition. How can you generate evidence to support the utilization of this therapy?
- An example of a fictitious product, Grafisis™, is provided as a starter

Value Proposition - *EXAMPLE*

**Unmet
Need**

Psoriasis is a chronic, inflammatory skin disease affecting 3 million adults. Topical corticosteroid therapies are effective in 80% of patients, but 20% of moderate-severe psoriasis require additional, systemic agents.

MOA

Grafisis™ is a biologic targeting the IL-12 cytokine, a key driver implicated in psoriasis etiology. Grafisis™ is a first-in-class biologic that targets the p40 subunit of IL-12, with significant binding affinity.

Efficacy

Grafisis™ treatment for 16 weeks in moderate-severe adult psoriasis patients resulted in 73% of patients achieving PASI90, and maintained response in 65% of patients for 52 weeks. Patients reported significant and maintained reductions in itch and quality of life as early as week 1.

Safety

Treatment related adverse events with Grafisis™ treatment was comparable to placebo. Adverse events led to treatment discontinuation in 4% of patients.

Cost

Adding Grafisis™ to a formulary will result in a net-neutral budgetary effect. The cost-per-responder is lowest for Grafisis™ amongst other systemic agents for psoriasis due to high and sustained efficacy.

Value Proposition - *Reslizumab*

Unmet
Need

A

MOA

B

Efficacy

C

Safety

D

Cost

E



Case Study 2

Evidence Generation

September 30, 2020

Case Study 2: Evidence Generation Needs for *EXHALA*®

Challenge:

You work at a pharma company developing a once daily treatment of severe asthma, *EXHALA*®

There is limited comparator data from the Phase 3 program (only placebo controlled), and payers are questioning the value of your product in comparison to other therapies on the market

There are already twice-daily 'gold standard' treatments that show good efficacy in phase 3 trials

Compliance and outcomes of gold standard treatments unknown

Task:

You are the lead of the Integrated Evidence workstream (comprised of medical, marketing, market access, and regulatory)

You are tasked with working with this cross functional team in identifying HEOR study ideas that you can execute to:

- 1. Differentiate your product vs others*
- 2. Drive economic value for your product*
- 3. Secure insurance company coverage*

Focus on key areas of HEOR studies outlined on previous slides (cost, outcomes, value prop, and real-world evidence)

Fill out the below

Study Idea	Rationale	Expected Outcome
Understand compliance of gold standard treatments in the real world	Limited understanding of how compliant patients are to twice-daily treatment for asthma	Low compliance of gold standard due to twice-daily treatment, leaving opportunity for EXHALA®