

Leverage Clinical Insights from the Field to Inform Medical Strategy

Kent Christopherson, PhD

Senior Medical Director, Global Medical Affairs

Orchard Therapeutics

Medical Affairs Strategic Summit

April 11-14, 2022, New Brunswick, NJ

Disclaimer

This presentation was prepared or accomplished by Kent Christopherson, PhD in his personal capacity. The opinions expressed in this presentation are the author's own and do not reflect or represent those of other people, employees, institutions, organizations, or companies.

The contents of this presentation represents the views of the presenter and do not necessarily reflect the views of the presenters' employer, Orchard Therapeutics.

Key Considerations



Uncover the value of clinical insights from the field



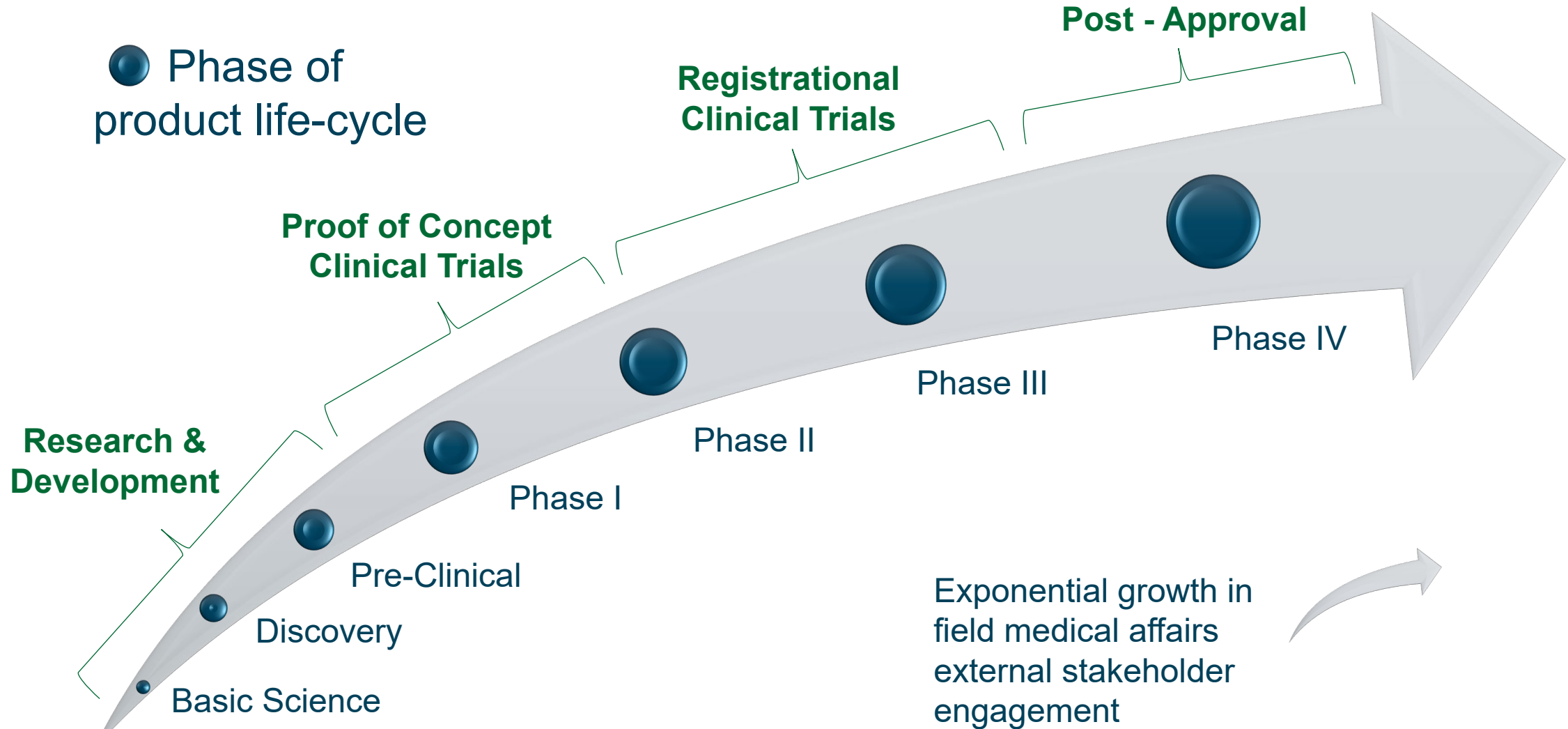
Understand the importance of collecting quality clinical insights



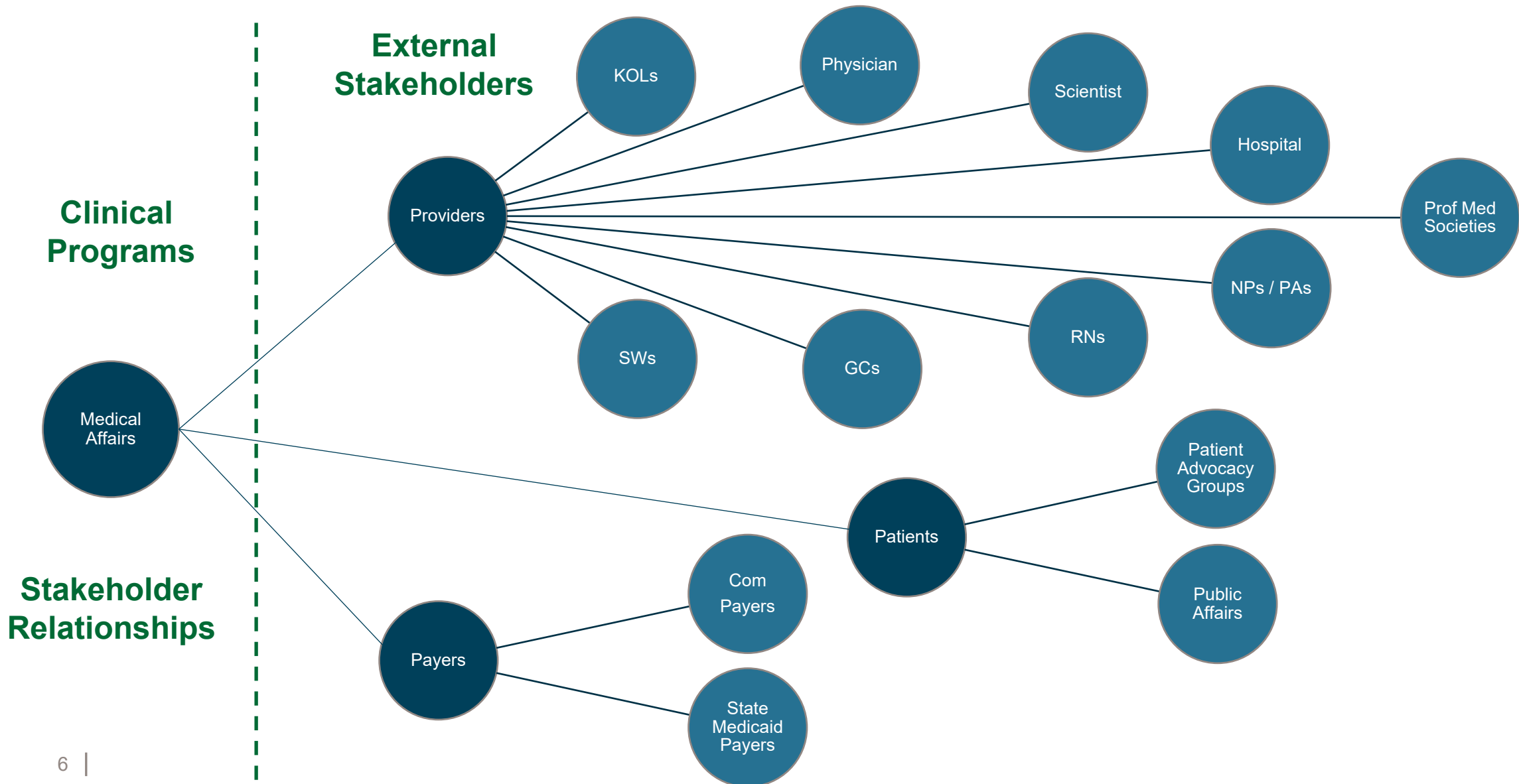
Explore how pull through of clinical insights can drive strategy

Value of Clinical Insights From the Field

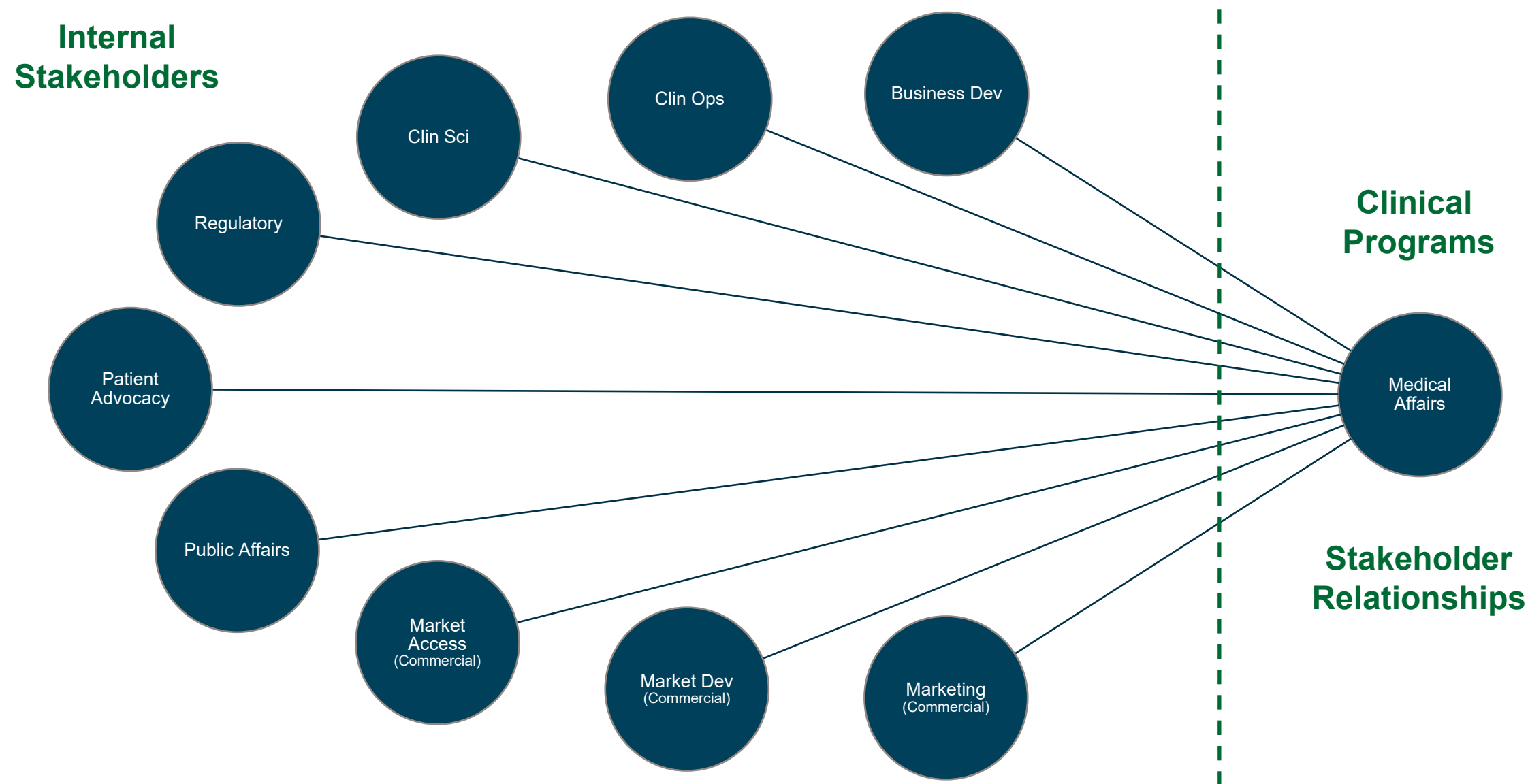
Medical Affairs – Role in the Product Life Cycle



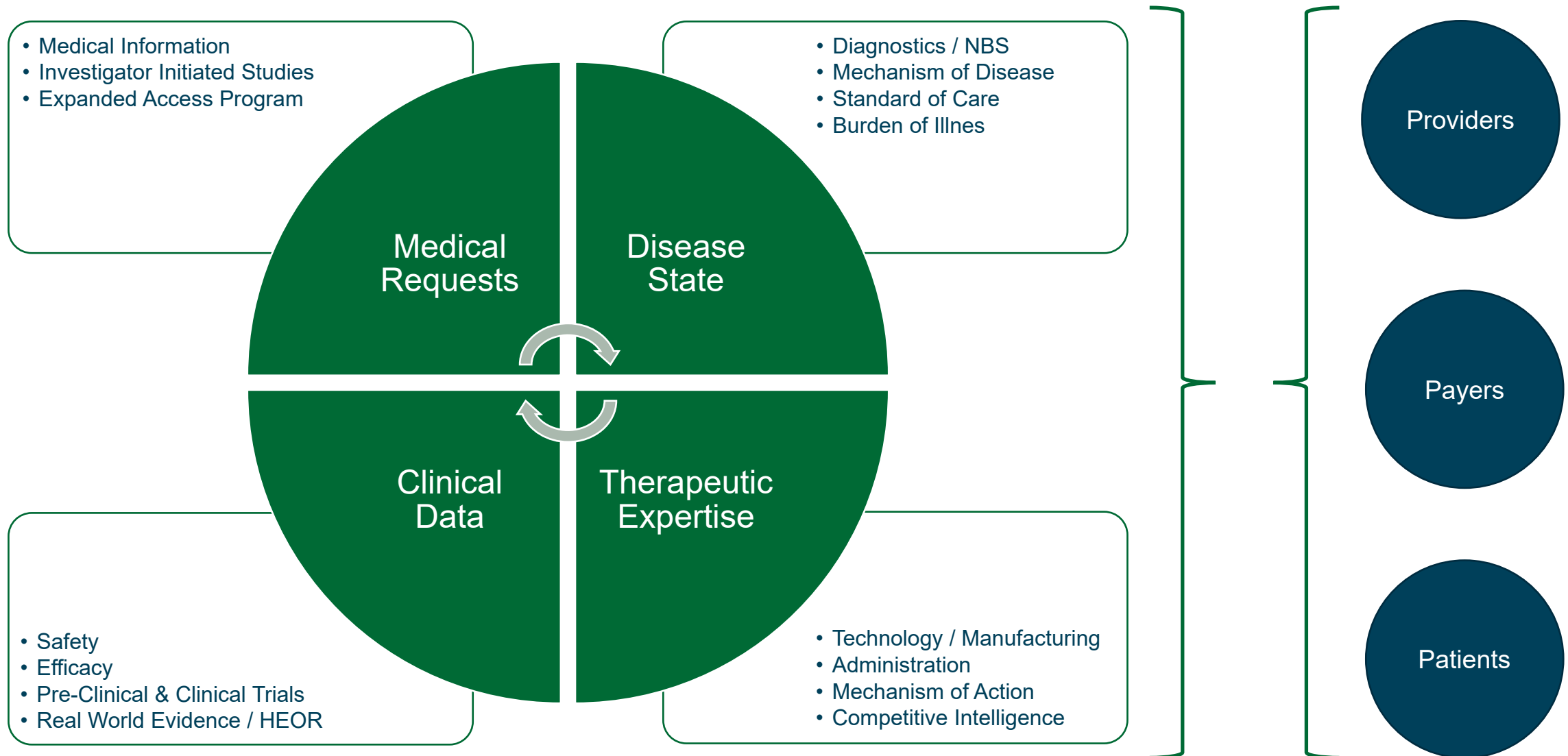
Medical Affairs – External Stakeholders



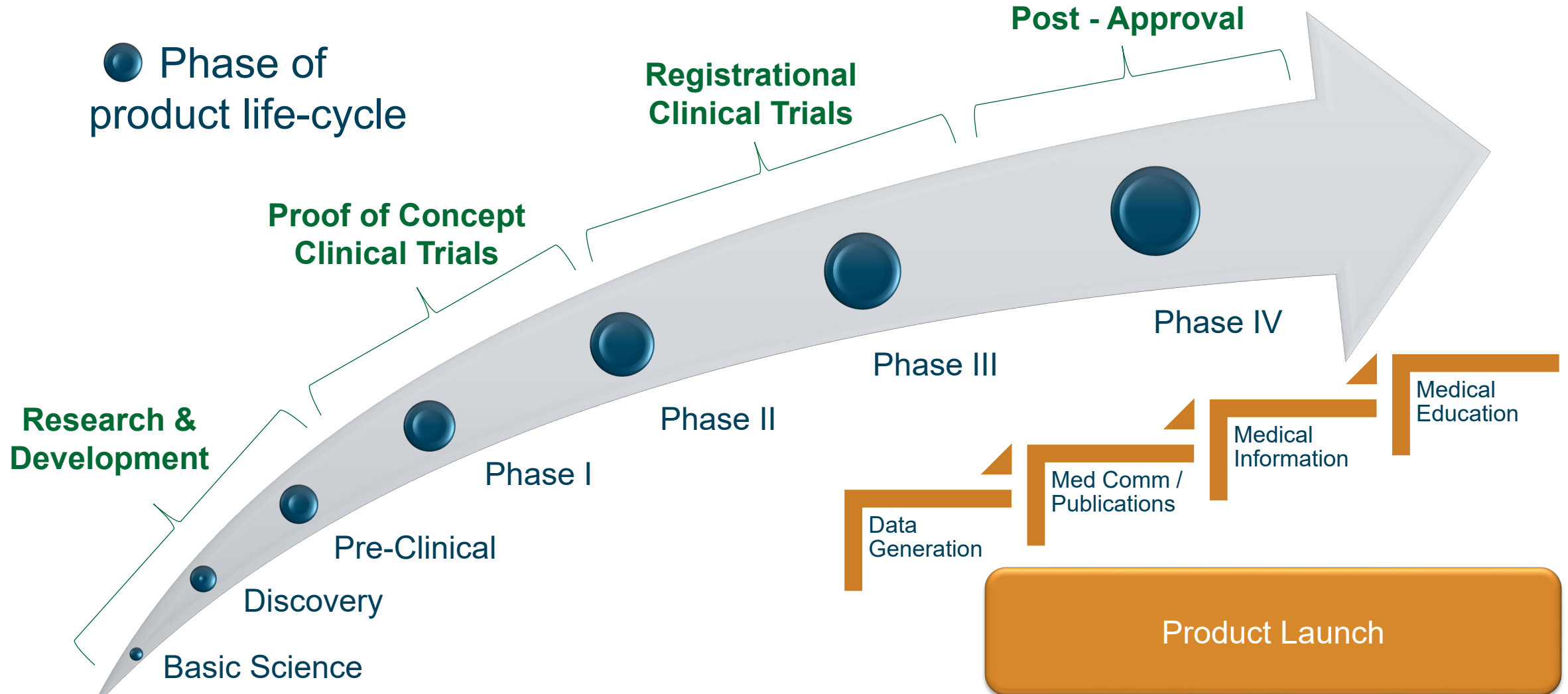
Medical Affairs – Internal Stakeholders



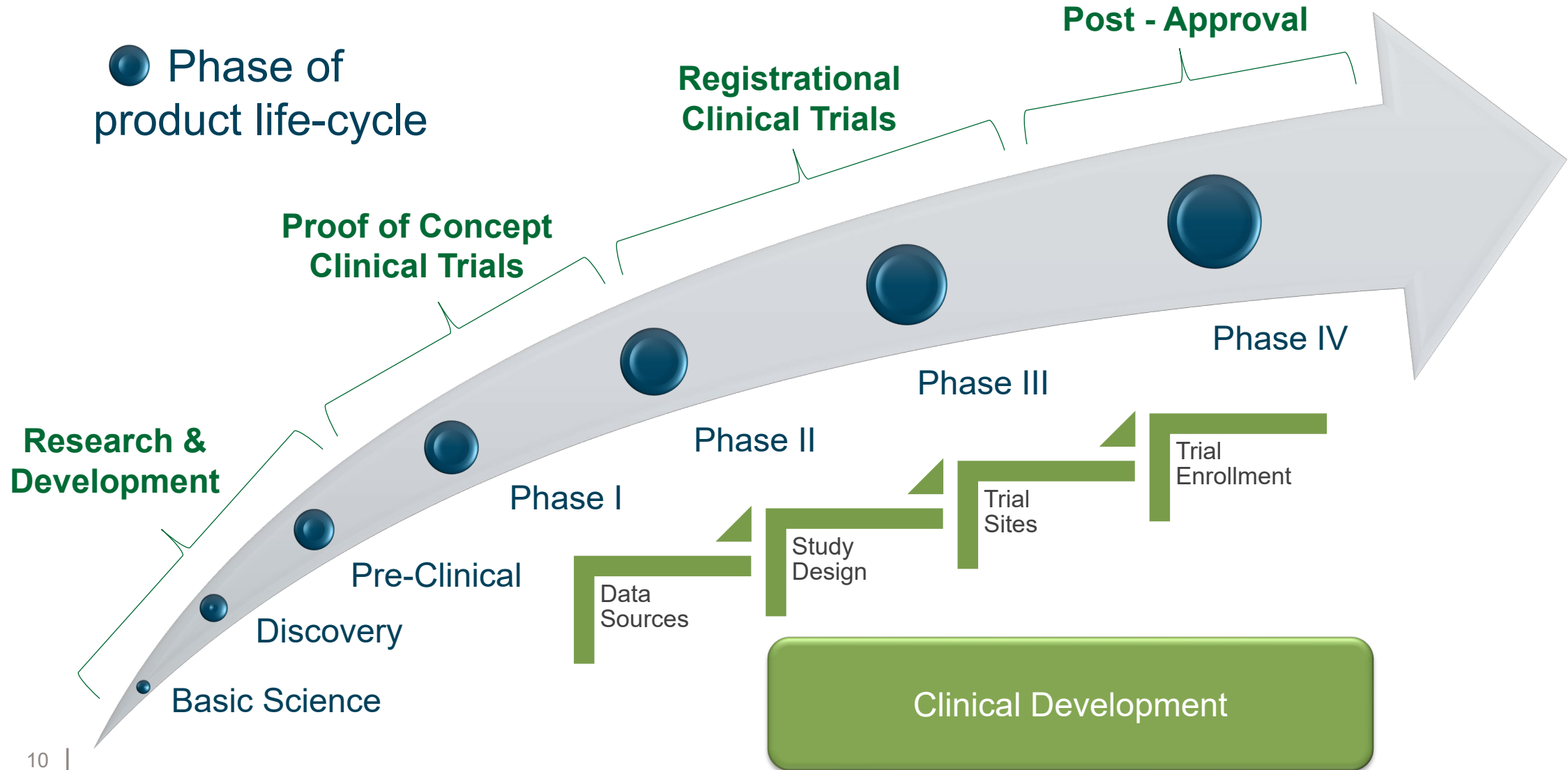
Medial Affairs – In-Depth Complex Knowledge



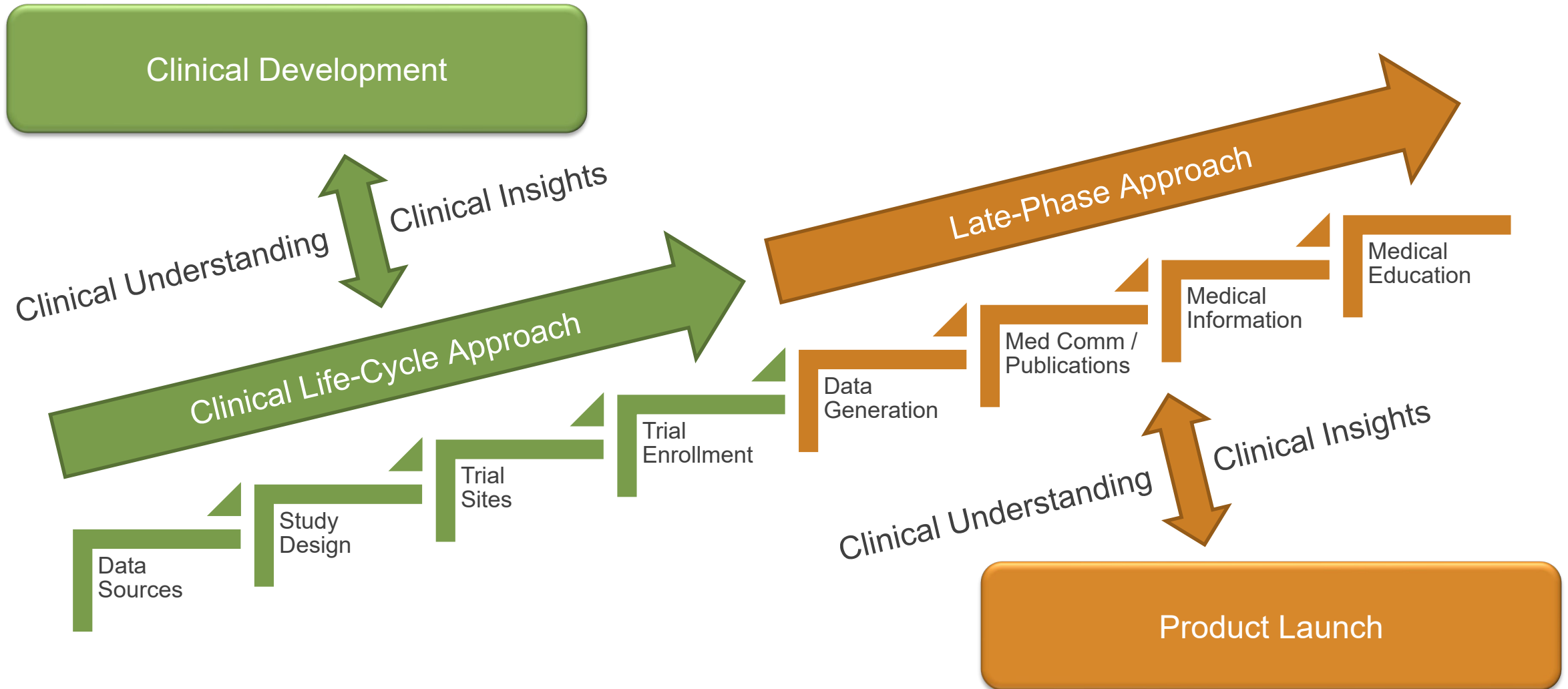
Medical Affairs – Product Launch / Late-Phase



Medical Affairs – Clinical Development



Medical Affairs – Value Throughout the Product Lifecycle



Medical Affairs – Uniquely Positioned to Provide Value

Throughout the
Product
Life Cycle

- Research & Development
- Proof of Concept Clinical Trials
- Regulatory Clinical Trials
- Post Approval

At the
Intersection of
Knowledge and
Experience

- Disease State
- Therapeutic Expertise
- Clinical Data
- Medical Requests

Where Clinical
Discussions are
Occurring

- Data Sources and Data Generation
- Study Design, Trial Sites, and Trial Enrollment
- Med Communication, Publications, and Med Information
- Medical Education

Importance of Collecting Quality Clinical Insights

Clinical Insights – Purpose, Topics, and Definition

Perceived Purpose

- Gather reliable information, data points, or trends
- Understand perceptions or sentiment
- Currency or representation of value of Medical Affairs

Perceived Topics

- Disease, unmet need, burden of illness
- Provider, payer, and patient therapeutic landscape
- Specific research, trials, products, or competitors
- Other relevant, timely, or unexpected information

Definition of Clinical Insights

- Clinical and Scientific Information that Informs Strategy

Clinical Insights – ARE

ARE Associated with:

- Disease state
- National Health System
- Company products
- Competitors' products

ARE Aligned with Policy/Principles:

- Conducted with integrity and in a professional manner
- In line with corporate values
- Abide with applicable laws and regulations

ARE Aiding:

- Medical strategy and tactics
- Clinical strategy and research priorities
- Overall corporate or program strategy

Clinical Insights – ARE NOT

ARE NOT Associated with:

- General discussion details or notes
- Derived from rumor or hearsay
- Field staff thoughts, opinions, or other personal comments

ARE NOT in Conflict with Policy/Principles:

- Gossip or innuendo
- Unprofessional references
- Non-compliant details

ARE NOT Distracting or Misinforming:

- For the internal decision-making processes
- For ongoing or future strategy and tactical discussions

Clinical Insights – Capturing a Great Insight

Building Great Insights Takes Practice

“I am not a fan of the existing disease sub-type classification.”

“I am not a fan of the existing disease sub-type classification. Severity is not dependent on one mutation.”

“I am not a fan of the existing disease sub-type classification. The score is low until the wheels fall off. Severity is not dependent on one mutation.”

“I am not a fan of the existing disease sub-type classification. The score is low until the wheels fall off, then it is high. Severity is not dependent on one mutation.”

“I am not a fan of disease sub-type classification. The score is low until the wheels fall off, then it is high. Also, you could have a low score with other dreadful clinical manifestations. Severity is not dependent on one mutation vs another.”

Building Great Insights Utilizes Multiple Skill Sets

Clinical Insights – Best Practices

DO

- Enter insights as soon as possible after interaction
- Capture as much of an exact quote as possible
- Minimize summarization or paraphrasing

DO NOT

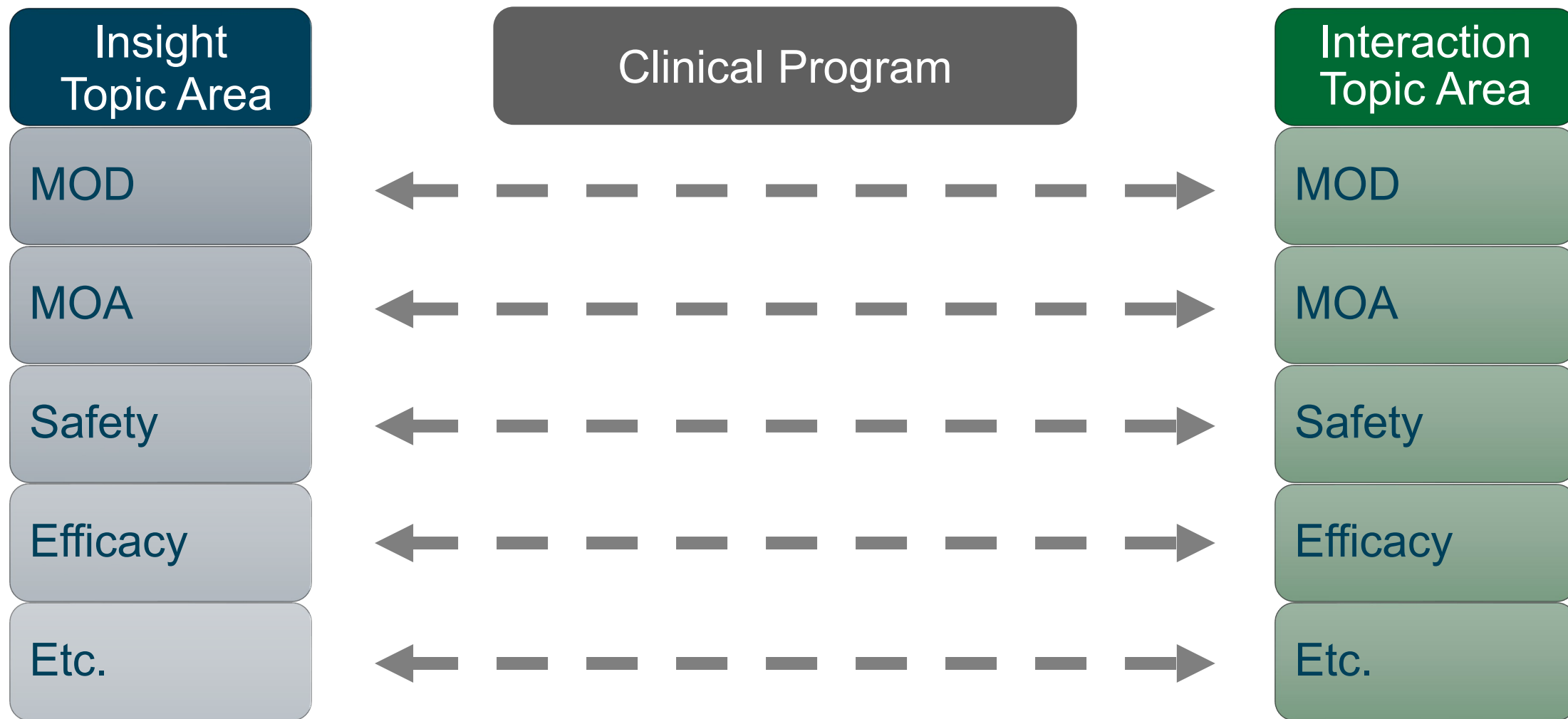
- Add extra commentary
- Include specific names of HCPs in the quote
- Include Adverse Event reporting

Remember

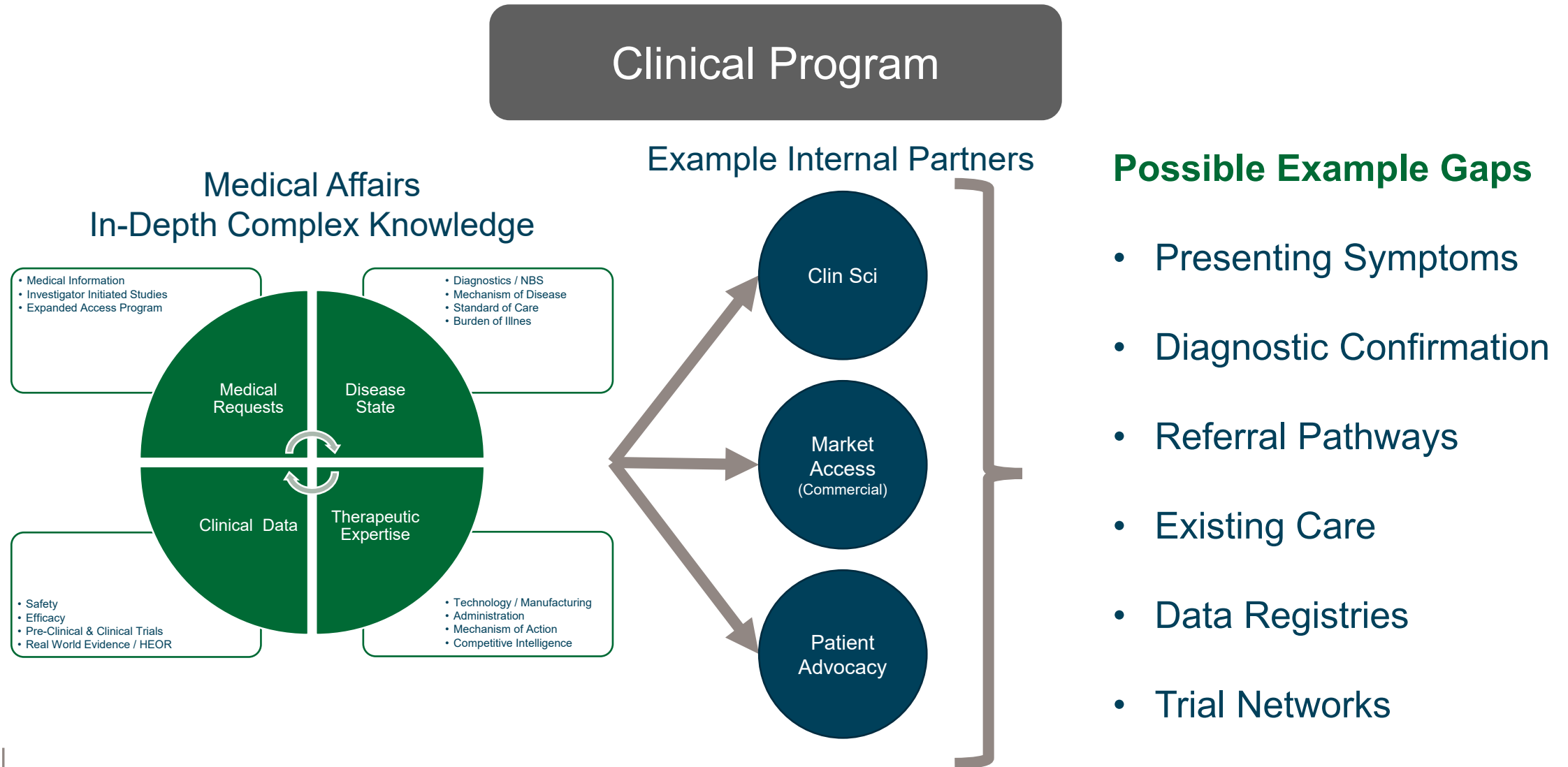
- Clinical Insight collection and documentation is a component of every interaction

How Pull Through of Clinical Insights Can Drive Strategy

Pull Through – Establish Consistent Topic Areas



Pull Through – Define Current Informational Gaps

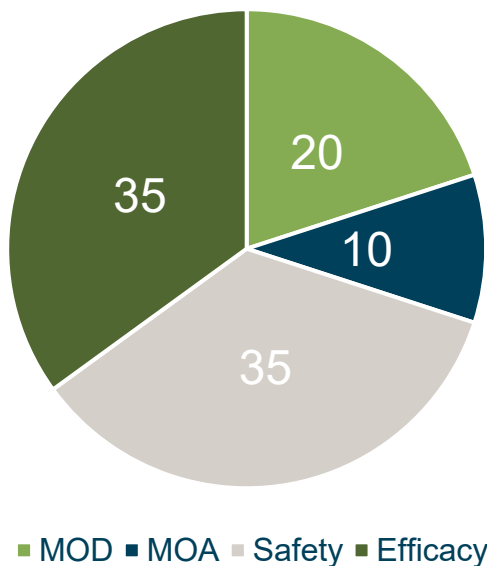


Pull Through – Disease Specific Insight Summary

Insights by Topic Area	Examples	
	Themes	Verbatims (Quotes)
MOD	Theme 1 (clinical development)	Example 1-A (from trial site KOL)
MOA		Example 1-B (from referring HCP)
Safety	Theme 2 (medical affairs)	Example 1-C (from referring KOL)
Efficacy		Example 2-A (from KOL physician)
Etc.	Theme 3 (programmatic)	Example 2-B (from non-KOL physician)
		Example 3-B (from non-physician HCP)
		Example 3-A (from referring HCP)
		Example 3-B (from HCP working with payer)
		Example 3-C (from HCP working with pt. advocacy)

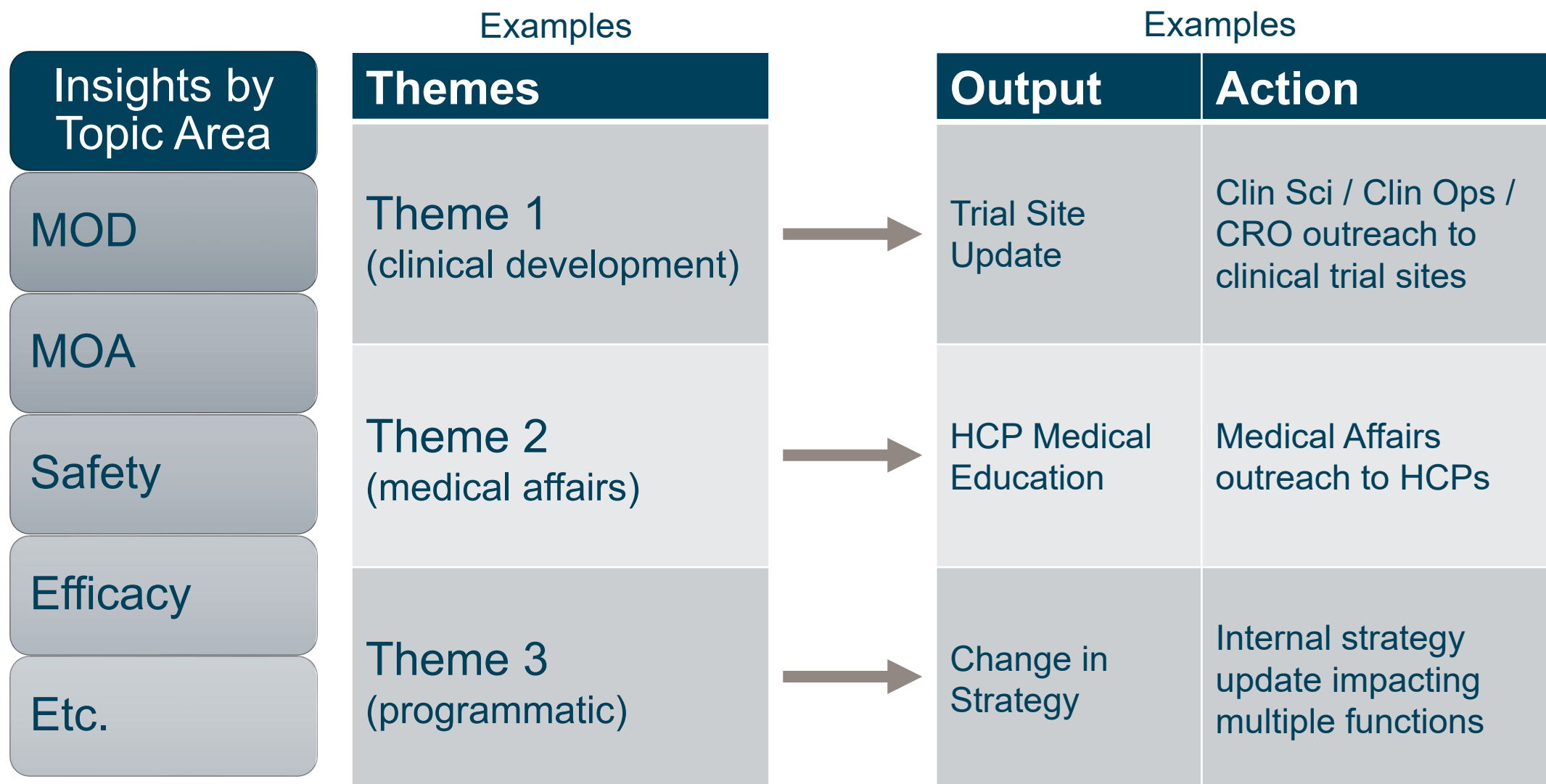
Pull Through – Cross-Functional Insight Summary

**Insights by
Topic Area
(percentage)**

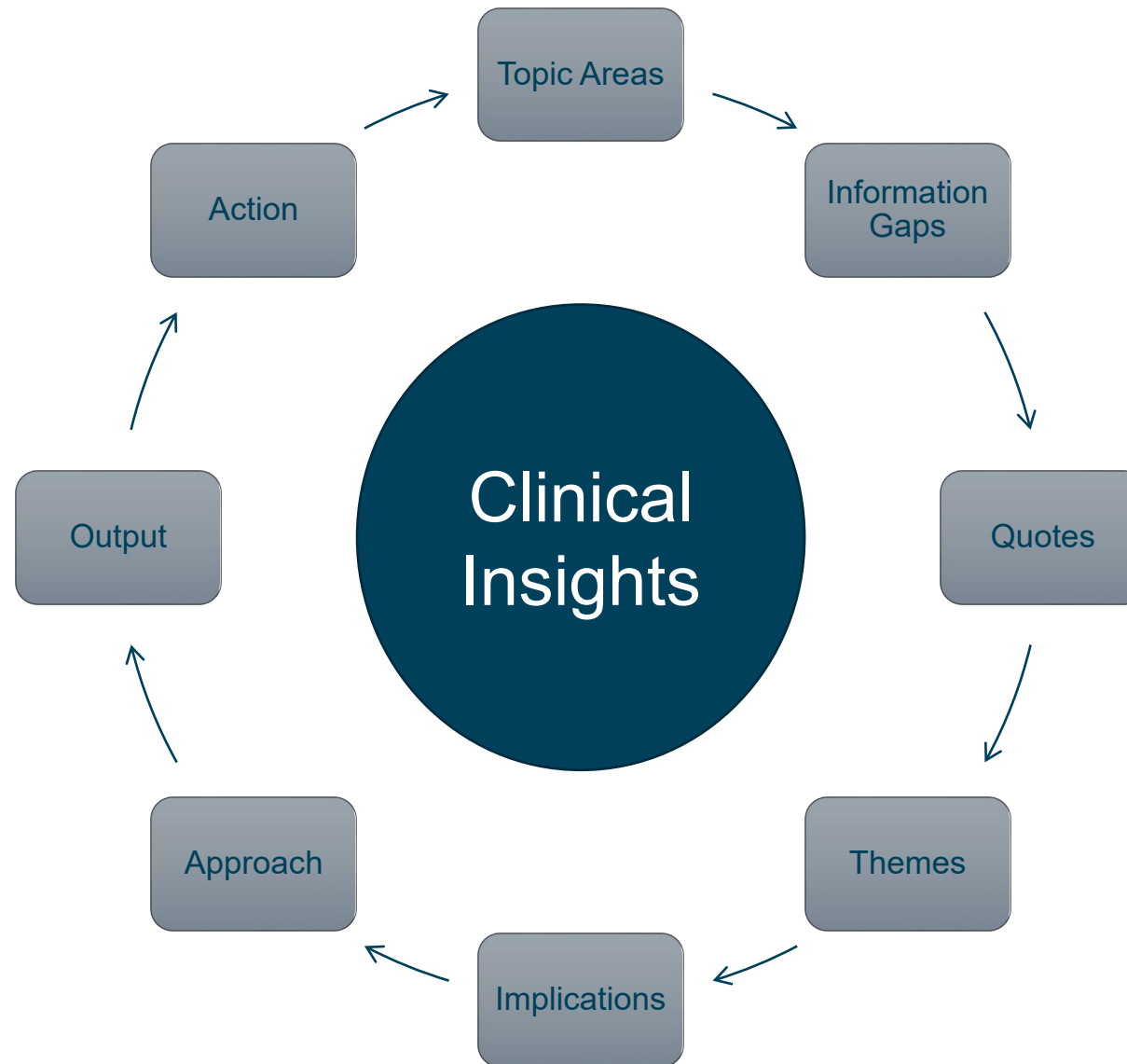


Examples	Examples	Examples
Themes	Implications	Approach
Theme 1 (clinical development)	Implications for clinical development	Internal communication Re: clinical development strategy or tactical plan
Theme 2 (medical affairs)	Implications for medical affairs	Recommended changes or additions to medical affairs strategy and/or tactical plan
Theme 3 (programmatic)	Implications for overall program	Internal escalation and communication Re: overall program strategy

Pull Through – Disease Specific Insight Summary



Pull Through – Results in Impact on Strategy



Questions

