Breaking the Silo Mentality
Working With Opinion Leaders

Kashif Chaudhry

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Objectives

Share a view on the changing environment impacting the pharmaceutical industry and KOL relationships

Discuss key imperatives and learnings for success in the future

Share a high level approach for moving forward

Contents

The Changing Environment
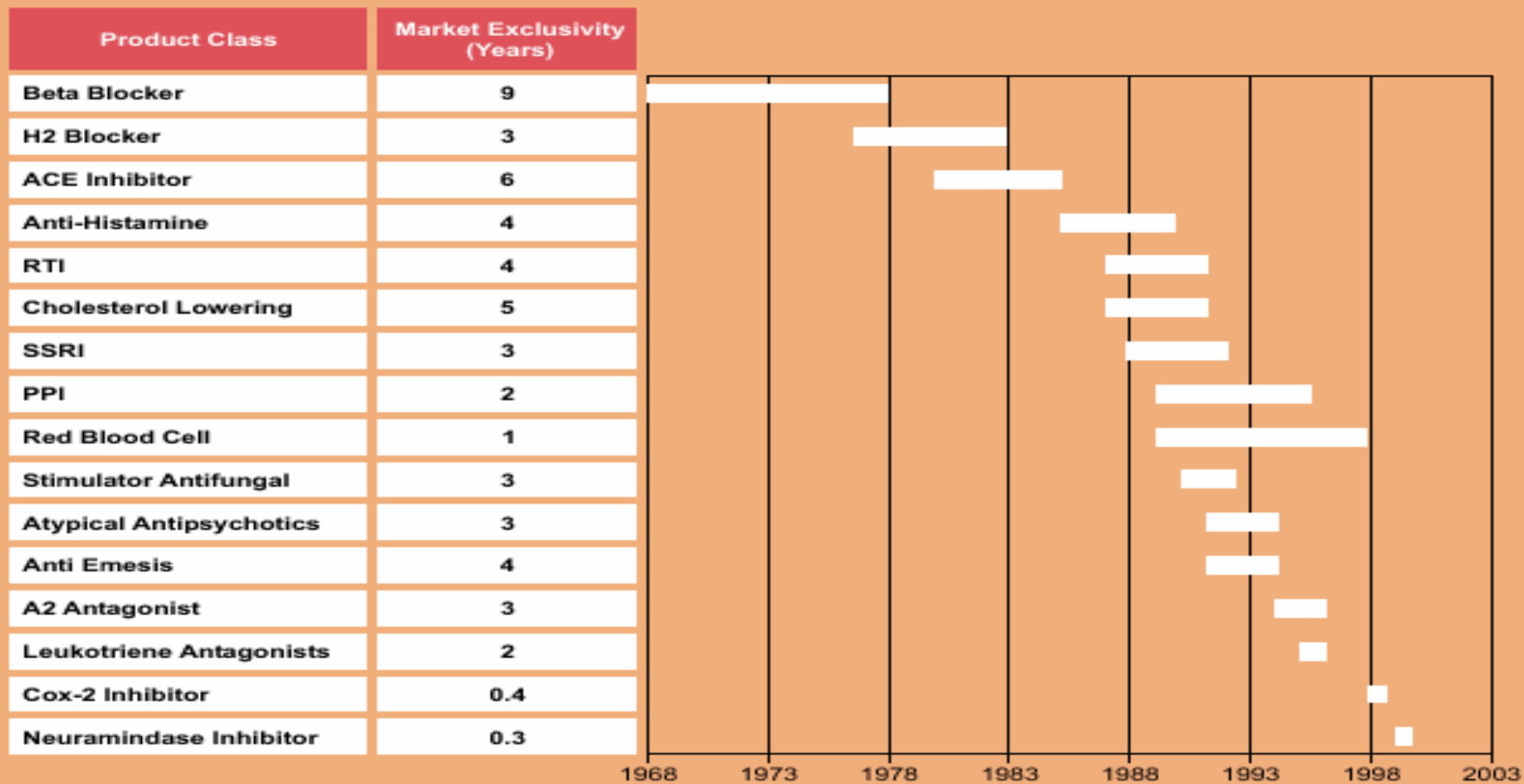
Key Learnings

How to Move Forward

The Changing Environmental Context

The industry is becoming increasingly competitive and exclusivity periods are reducing

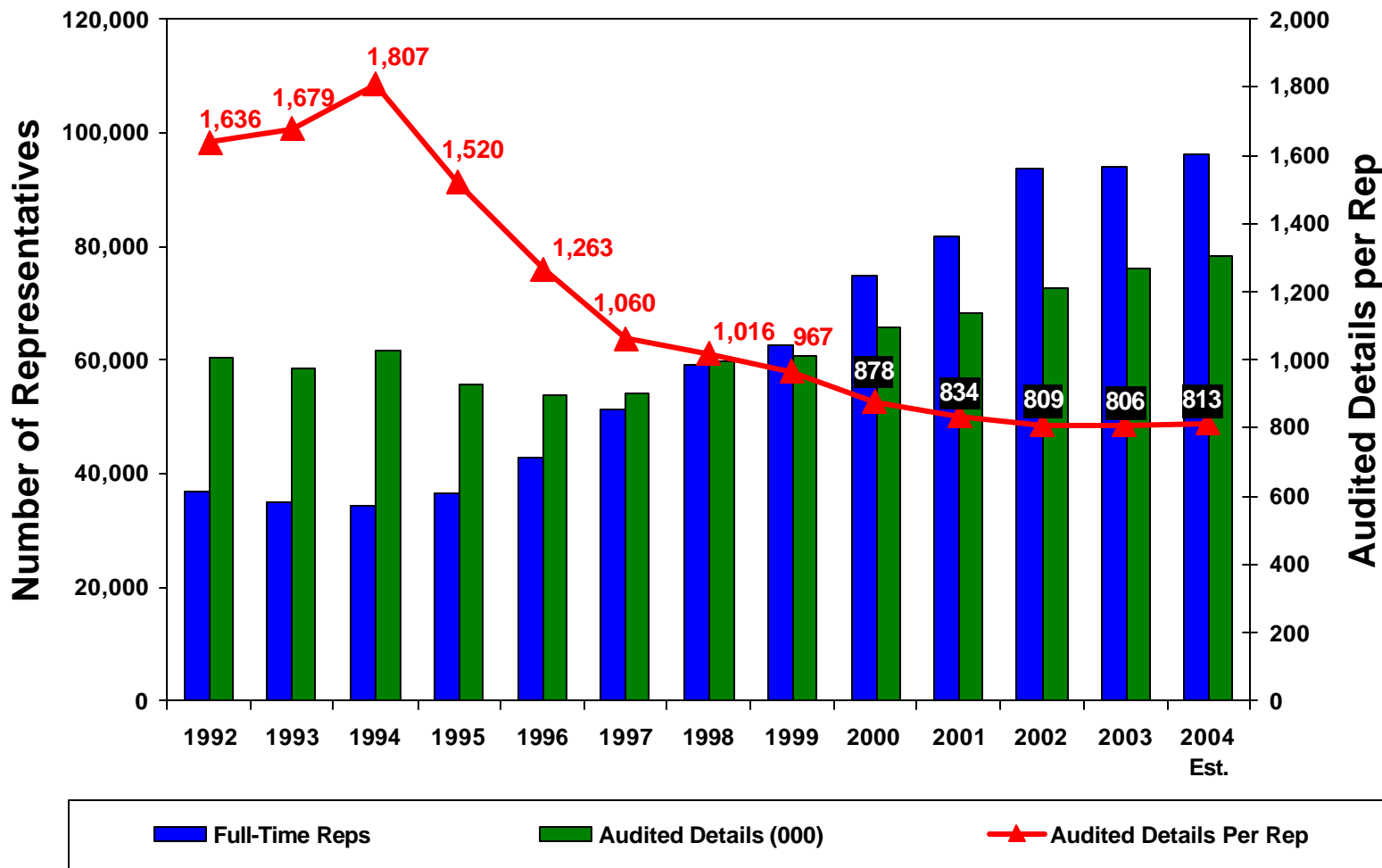The key traditional channel to the customer (the sales rep) is starting to show diminishing returns

The interactions with KOLs are increasingly multi-dimensional, across the life-cycle, and subject to increasing regulatory scrutiny

The Clock Speed of the Industry is Increasing

Product Class	Market Exclusivity (Years)
Beta Blocker	9
H2 Blocker	3
ACE Inhibitor	6
Anti-Histamine	4
RTI	4
Cholesterol Lowering	5
SSRI	3
PPI	2
Red Blood Cell	1
Stimulator Antifungal	3
Atypical Antipsychotics	3
Anti Emesis	4
A2 Antagonist	3
Leukotriene Antagonists	2
Cox-2 Inhibitor	0.4
Neuramindase Inhibitor	0.3

Source: PhRMA, 2001.

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The Industry's Key Channel to the Customer Is Showing Diminishing Returns

Chart showing Number of Representatives (left axis, 0 to 120,000) and Audited Details per Rep (right axis, 0 to 2,000) by year from 1992 to 2004 Est.

Audited Details Per Rep values:
- 1992: 1,636
- 1993: 1,679
- 1994: 1,807
- 1995: 1,520
- 1996: 1,263
- 1997: 1,060
- 1998: 1,016
- 1999: 967
- 2000: 878
- 2001: 834
- 2002: 809
- 2003: 806
- 2004 Est.: 813

Legend: Full-Time Reps | Audited Details (000) | Audited Details Per Rep

Complexity of KOL Touch-Points Requires Strong Coordination Across the Organization
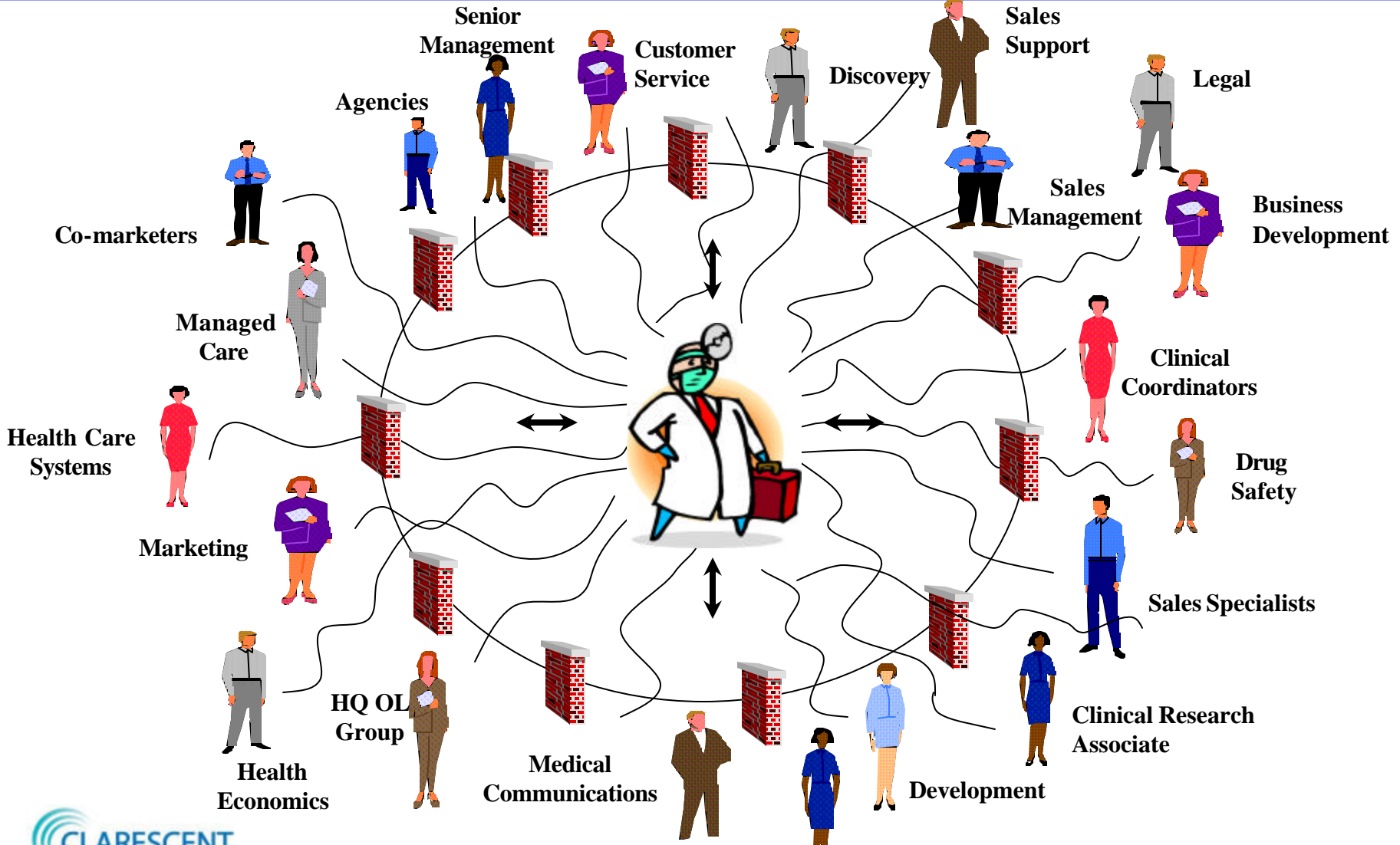
# Contents

The Changing Environment

Key Learnings

How to Move Forward

The Evolving Paradigm of KOL Relationship Management

Yesterday's Paradigm

- Engage a KOL in as many activities as possible

- Decentralized and ad-hoc decision making on how and where to engage the KOL

- Do as much as possible with one KOL

- Internal silos own and manage the KOL relationships at different points in the life-cycle
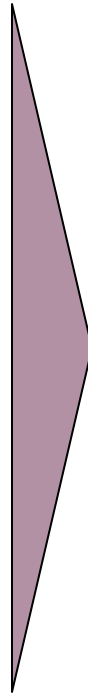
Today's Paradigm

- KOL segmented and integrated based on expertise

- Centralized functionality for coordinated KOL management

- Broad bench of KOL pool

- More strategic targeted and pro-active approach to working with KOLs

- Policies and processes to manage conflicts of interest, capitation requirements and perceptions

- KOL knowledge management system to increase transparency

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Enable Consistent KOL Interactions Across the Organization

Marketing and Sales

Medical Affairs and MSLs

Discovery / Research & Development

Healthcare Policy

Coordinating Across Tactics For Consistent Communications

JAN | FEB | MAR | APR | MAY | JUN | JUL | AUG | SEP | OCT | NOV | DEC

Congress Leadership Meeting

Congress Cons. / Board Mtg

Congress Cons. / Board Mtg

Consultant Teleconf

Marketing Consulting Board

Consultant Teleconf

Congress Leadership Meeting

Consultant Teleconf

PR Campaign

Publication Author
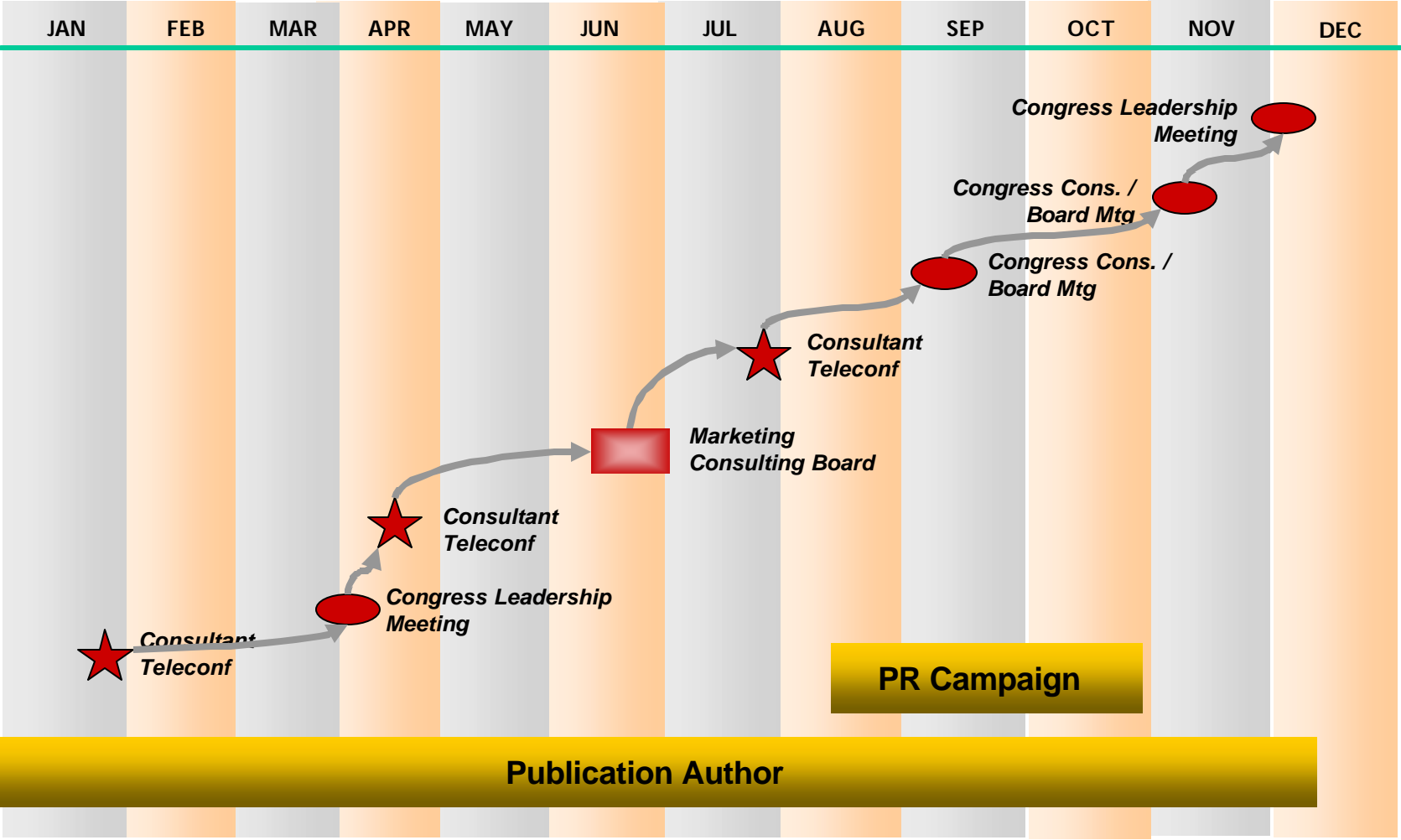
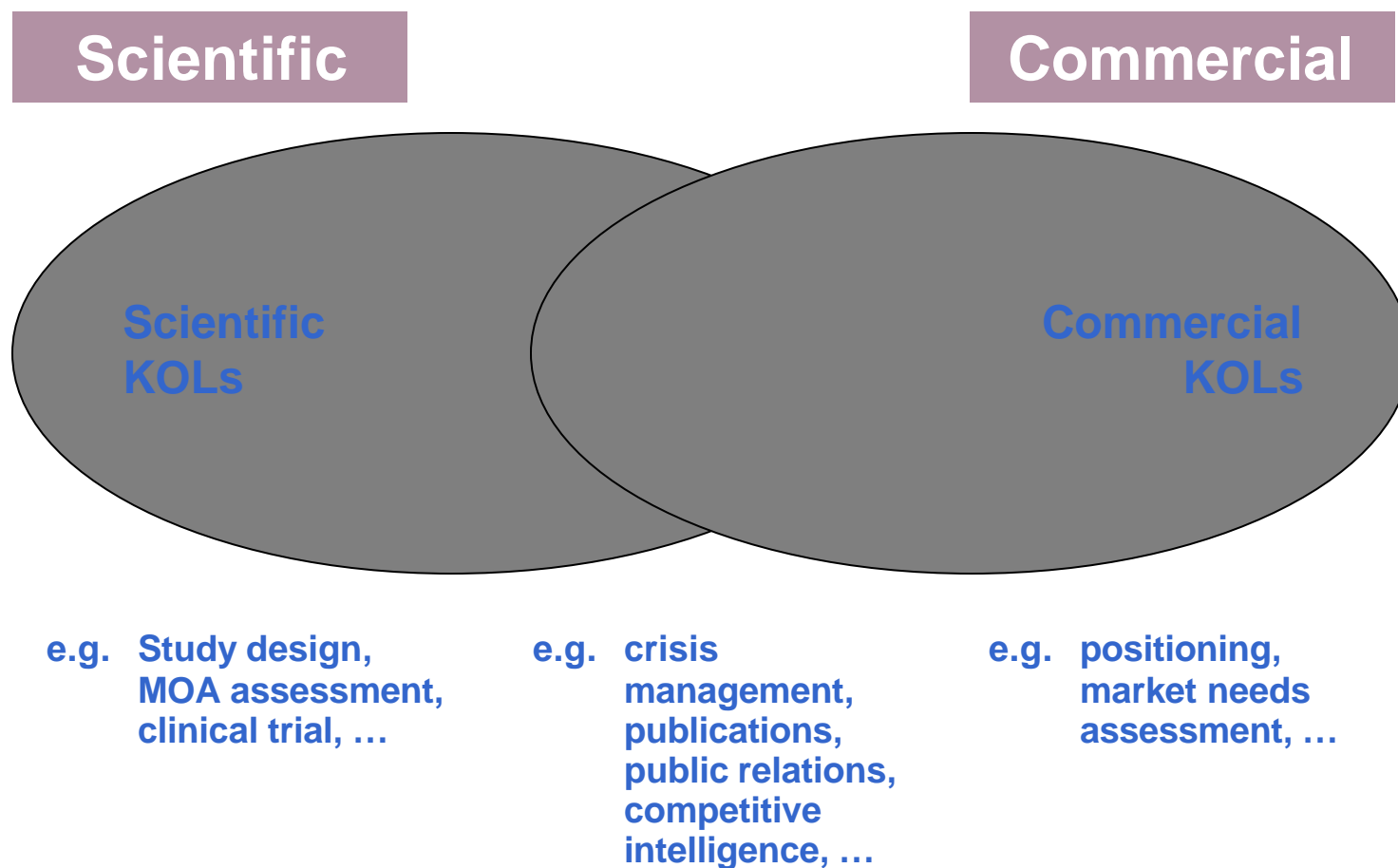# Key Elements of A Successful KOL Relationship Management Program

- Proactive strategic planning and involvement across the life-cycle

- Consistency of interactions through policies, code of conduct, processes and SOPs

- Centralized accountability for coordination with distributed relationship managers

- Clear definition of roles and responsibilities across the organization

- Internal alignment around a broad synchronized communications plan with KOLs

- Transparency across the organization

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Consistency Of Interaction May Be Achieved Through Policies and Processes

- The need for a consistent approach to interactions with Opinion Leaders is based on the potential for an Opinion Leader to be involved in multiple research, clinical, or commercial projects with different personnel.

- Policy, interaction guidelines and processes ensures that all employee interactions with Opinion Leaders conform with all applicable laws, regulations, industry guidelines, and company standards related to research and development, sale and marketing

Commercial and Scientific Perspectives Need to Be Balanced Across the Life-cycle

Opinion Leader Assets

Scientific

Commercial

Scientific KOLs

Commercial KOLs

e.g. **Study design, MOA assessment, clinical trial, …**

e.g. **crisis management, publications, public relations, competitive intelligence, …**

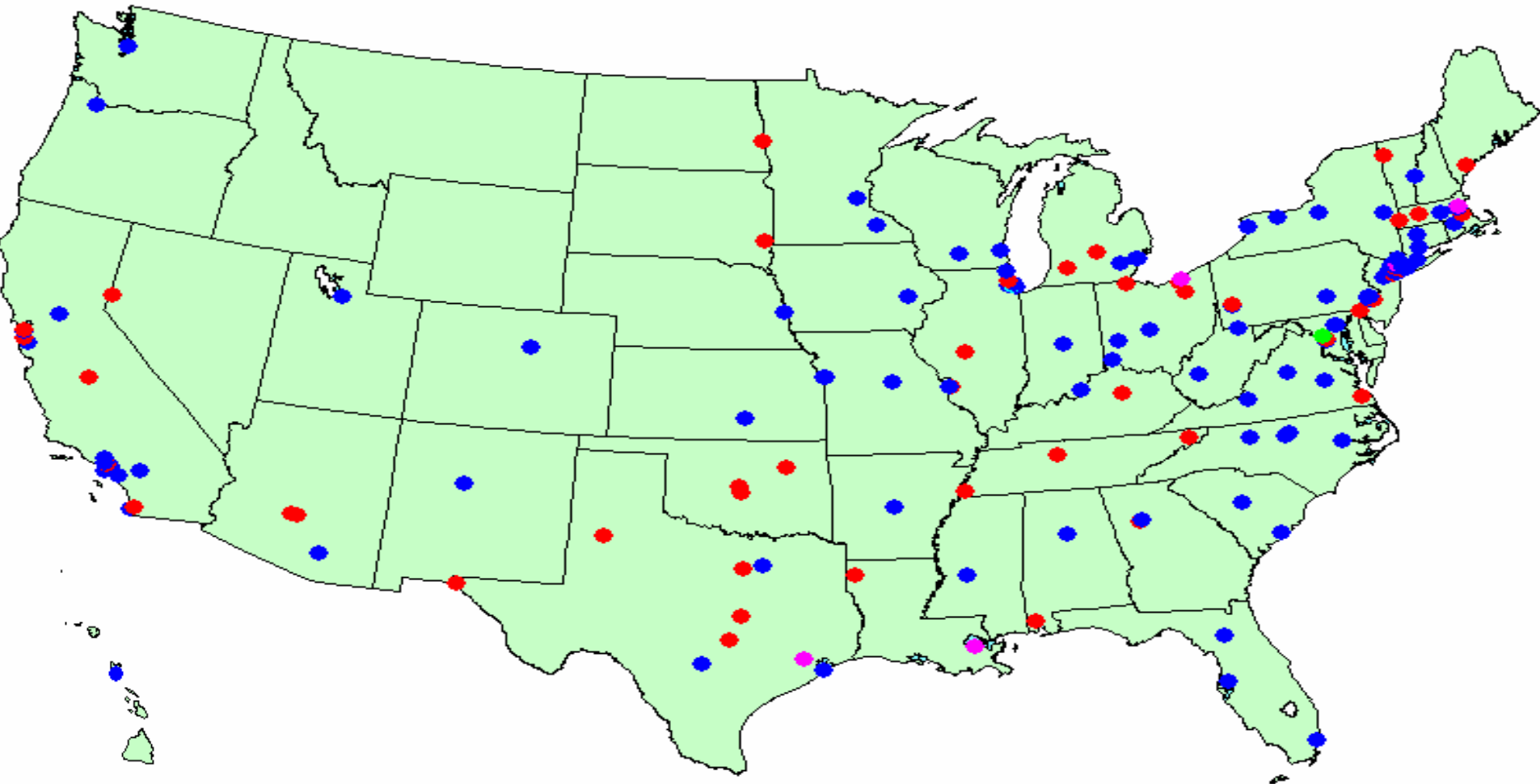e.g. **positioning, market needs assessment, …**

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KOL Involvement Across the Life-cycle Requires Proactive Planning and Management

OL Involvement by Lifecycle Phase

Exploratory, Discovery, Pre-Development, Phase 0	Phase 1/2	Phase 2/3	Registration	Market
	Clinical Trials	Clinical Trials		

Strategy

- Consult on unmet needs
- Consult on disease burden

- Consult on future therapeutic area, trends, and new technologies
- Consult on target market
- Consult on target product profile
- Advise on key aspects of disease (ie safety, measures, etc.)
- Consult on licensing and divestment of products
- Consult on clinical development plan

- Consult on protocol design
- Advise on regulatory strategy
- Advise on competitive positioning (strategy and products)
- Advise on product positioning and messages

- Advise on lifecycle management
- Advise on value proposition to managed markets
- Consult on issues analysis and management

- Write expert reports

- Consult on risk management programs

Operations

- Communicate discovery results
- Communicate on concept (disease state and platform)

- Serve as Investigators (phase 1 to 4)
- Advise on clinical trial execution and operations
- Review trial data

- Support Sales training

Communication

- Potentially contribute to independent publications

- Communicate trial results
- Educate on disease stat

- Advise on communications strategy and tactics
- Advise on public relations
- Potentially deliver medical education

- Participate in Visitor Speaker Bureau (VSB)
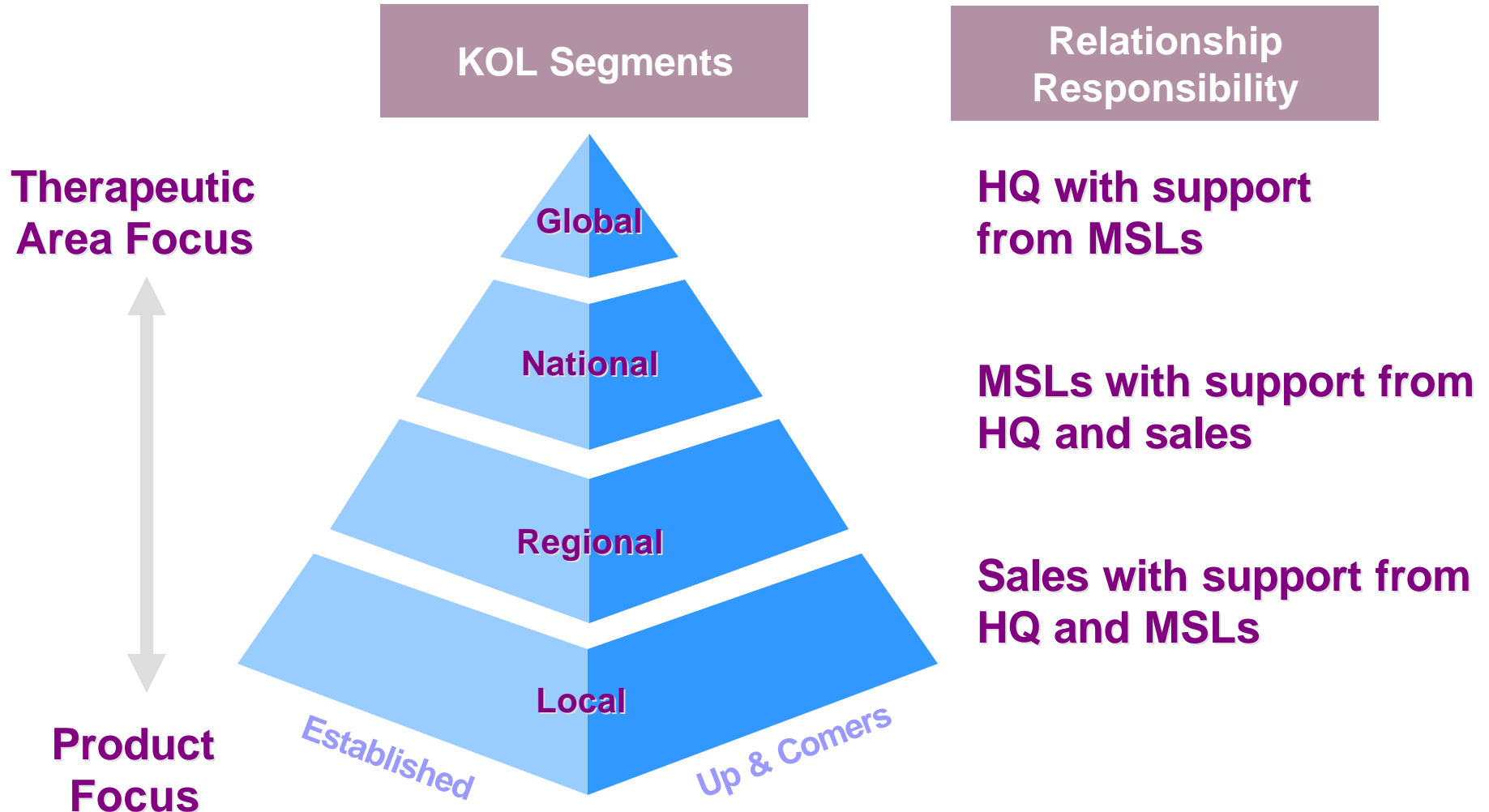
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Geography Adds Another Dimension of Complexity In Managing KOL Relationships

Centers of Excellence

Clear Roles and Responsibilities are Required in Managing KOL Relationships

KOL Segments

Relationship Responsibility

Therapeutic Area Focus

Global

HQ with support from MSLs

National

MSLs with support from HQ and sales

Regional

Sales with support from HQ and MSLs

Local

Established

Up & Comers

Product Focus

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Transparency Of Interactions May Be Achieved Through a Database Solution

Develop a phased database solution:

- Focus on gathering inventory of KOL relationships across the organization and build a database around capturing these and making them transparent

- Define accountabilities to maintain the database and link it into existing processes (e.g. investigator selections, advisory board development, …)

- Link the database to transactional systems to provide transparency on KOL investment from both a business perspective and a compliance perspective

Pitfalls to Avoid

- High turnover in KOL relationship management positions

- Inexperienced people in KOL relationship management positions

- Allowing long-term KOL relationships to expire

- Lack of clarity of KOL relationship management governance

- Lack of strategic plans by KOL segment

- Lack of transparency around KOL interactions across the organization

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Contents

The Changing Environment

Key Learnings

How to Move Forward

Path Forward For Breaking Down the Silos – Defining a KOL RM Program

1. **Assessment of your organizational context**
   - Science vs marketing coordinated
   - Centralized or decentralized with distributed capabilities
   - MSL access

2. **Define the capabilities**
   - Define the organizational construct (e.g. centralized by therapeutic area)
   - Develop policy, key processes, and roles & responsibilities
   - Develop a centralized knowledge database system
   - Define strategic plans, key success measures and metrics
   - Gain buy-in

3. **Make it a part of required business operations**
   - Embed the processes across the organization
   - Follow up on agreed upon metrics

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Thank You! Questions?

Kashif Chaudhry
Clarescent LLC
+1 610 570 3859
Kashif.Chaudhry@clarescent.com

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