

# The Role of Medical Affairs in Shaping Brand Development

**PRINCETON PHARMA  
COMPLIANCE CONFERENCE**

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# Key Themes

- Changing Environment – Changing Roles for Medical Affairs
- Medical Affairs and Its Partners – How the Elements of the Company Differ
- Clinical Commercial Optimization – Planning vs. Reaction
- Enablers and Obstacles

# Medical Affairs and HCC

- Clinical commercial optimization requires specialized skills, involvement beginning in development and extending through life cycle.
- A mastery of HCC facilitates not only legal and ethical behavior but also commercial success.

# Changing Environment – Changing Roles

1. What we demonstrate is what we can say – label, publication, evidence-base.
2. HCC codifies business ethics and good science – neither meets universal agreement.
3. Pipeline, development costs, margins – the product/molecule life cycle value.
4. Customer types, customer expectations.

# Medical Affairs and Partners – Time & Space\*

<u>Division</u>	<u>Time</u>	<u>Focus</u>
Research Development	3-10 Years +	Drug to Development Approval
Medical Affairs	Crisis-7 Years	Life Cycle
New Product	2-3 Years	Launch
Brand	¼ - 1 Year	Market & Share
Sales	Week – 1 Year	Comp. Plan

\* Rough examples for discussion.

# Clinical Commercial Optimization Planning Steps

- Understand molecule, clinical issues, customer drivers.
- Early advice from experts, KOL's, promotional partners.
- Develop clinical, epidemiologic, outcomes, and publication plan.
- Influence requires expertise – team may evolve.
- Execution requires expertise – team may evolve.
- Information must be in place to permit appropriate adoption, including CME.
- Flexibility – new data, new technology, competitive activity.

- As customers consolidate, evidence is demanded, and regulation clarifies, Medical Affairs role will grow in life cycle planning, execution, communication, and episodic issue management.
- Each product/molecule must be characterized appropriately and developed to its optimal extent. A skilled and enabled Medical Affairs function is the best investment for the foreseeable future.