

# **DEVELOPING EFFECTIVE COMMERCIAL/MEDICAL BOUNDARIES IN INTERACTIONS WITH HCPs**

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**FROILAN G. AGATEP  
MERCK, INC.  
SUB-REGIONAL COMPLIANCE OFFICER, SEA**

## Objectives

- To provide Medical and Commercial personnel with a framework on how to interact in a manner consistent with evolving best practices in the global pharmaceutical industry
- To ensure that medical activities are non-promotional, thereby mitigating risks of violating laws and codes that govern product promotion, bribery and corruption, and research



## Risks (examples)

- Educational grants, sponsorships, healthcare professionals (HCP) consulting agreements used as tools to drive sales
- CME fundings used as platform to communicate promotional messages
- Disguised clinical trials (e.g. “seeding studies”)
- Use of MSLs to facilitate off-label promotion
- Disease awareness activities for purpose of generating prescription



## **Boundaries (In General)**

- Allocation of roles to Commercial and Medical and provide for proper interactions and collaborations (e.g. Who should or should not initiate certain activities, provide inputs and support?)

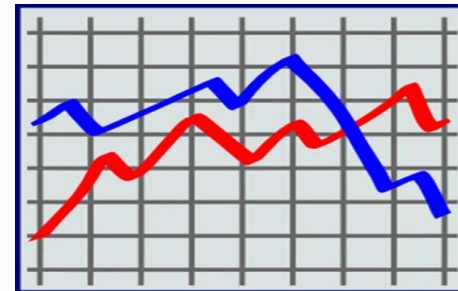
- Medical should be responsible for clinical research, publications, educational support strategy, medical donations, as well as for any other non-promotional activities with medical content

- Commercial should not identify potential HCPs or institutions for medical consulting, educational needs, donations or grant-making activities unless requested by Medical

- Commercial personnel may provide administrative assistance to medical projects under the supervision of Medical

## Boundaries (In General)

- Boundaries must be reflected in the organization reporting lines and allocation of projects and budgets
  - Medical personnel should not report directly to Commercial
  - Medical should have a plan separate from Commercial's "brand plans"
  - Separation of medical and commercial budgets
- Medical employee and consultant compensation/ evaluations should not be based on the volume of product sales or delivery of promotional messages



Hello Froilan Agatep

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- › CLEAR User Guide
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- › Items Lists
- › Fair Market Value and CAPs
- › CLEAR News Archive
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- › my Workflow
- › Reporting HUB
- › Quick Finder
- › Useful Links

## CLEAR

Compliance Electronic Approval Center

### Procedures



### my Tasks



### Responsibilities



### Maintenance



### Search all



### I want to plan . . .

› [an event](#)

› an interaction connected to an event

› a stand-alone interaction

- › Internal Event (Merck Serono Sponsored Program)
- › Participation in Third Party Event
- › Advisory Board



## Communications with HCPs

- Medical communications with HCPs should focus on scientific, medical or educational content (joint calls by sales reps and MSLS should be avoided)
- Commercial personnel should not respond to questions about unapproved uses of products; such questions should be referred to Medical for appropriate action



## Clinical research

- Commercial should have no role in developing clinical study protocols, recruiting patients, providing experimental drugs, developing or analyzing data, retaining clinical trial consultants or contract research organizations, or drafting clinical study reports and publications





## Publications

- Scientific publications, materials and communications intended for distribution through a promotional channel (e.g., via the sales force) should be subject to internal review and approval before use
- Ghostwriting by any employee or vendor acting on a company's behalf should not be permitted





**Thank You!**