Impact of COVID-19 on Global Medical Affairs Compliance Panel

Medical Affairs Professional Society | 2020

>> NOW SPEAKING: **Erinn Hutchinson**
Moderator, PwC

The views expressed in this Webinar are those of the presenters, and are not an official position statement by MAPS, nor do they necessarily represent the views of the MAPS organization or its members.

Introductions

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Introductions

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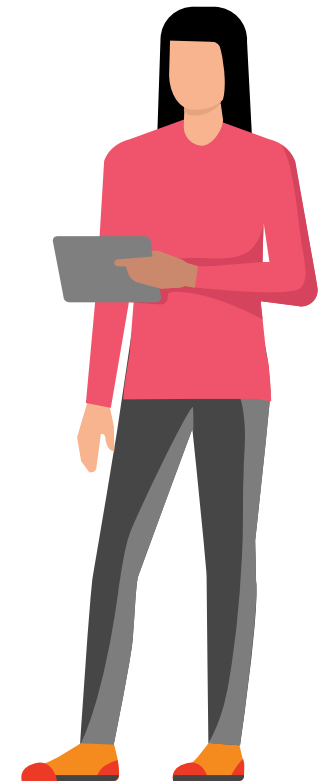
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Agenda

▶ Introduction and background **(10 mins)**

▶ Scenarios **(30 mins)**

▶ Key learnings and Q&A **(20 mins)**

Polling question #1

What is your role / functional team?

a. Field based Medical / Medical Science Liaison

b. Medical Director / Manager

c. Medical Information

d. Scientific Communications

e. Compliance / Legal

f. Commercial (Sales, Marketing)

Polling question #2

What are the concerns or challenges your company faces as it considers new ways of working during this pandemic? Please select all that apply.

a. Interactions with HCPs (e.g., Off Label, False Claims)

b. Interactions with patients

c. Transfers of Value (e.g., Anti-kickback/ABAC risk, provision of hospitality)

d. Privacy & Cyber-Security

e. Regulatory

f. Dissemination of information

Polling question #3

What has been the most significant impact of the COVID-19 pandemic on your company so far?

a. Providing patient support including access related concerns

b. Disruptions to how companies interact with HCPs

c. Impact to studies/patient enrollment

d. Delays in product launches

e. Manufacturing and supply concerns

f. Inability to provide product information to customers

Polling question #4

What is the primary type of support your Compliance teams are providing to address COVID-19 concerns?

a. Navigating Business Exceptions

b. Business Continuity

c. Policy / Guidance Updates

d. Updated Monitoring Approach

e. Communications / Training

f. COVID-19 Risk Assessment

g. Industry Alliances

How can we leverage an algorithm or framework to help us navigate these new compliance risks?

- **Think (innovatively)**
  - What outcome are we looking to achieve with the activity/interaction?
  - How can we minimize risk to the organization?
  - Due to time sensitivity, what activities can be fast-tracked or co-created?

- **Engage**
  - Who is responsible for making the decision and who should be consulted or informed?
  - What changes need to be made to remain in compliance?

- **Ask**
  - Does this activity/interaction "pass the red face test"?
  - Do you have the ability to execute on compliance requirements?

- **Monitor**
  - What worked well and what didn't?
  - How might we do things differently?

Scenario: Field Medical Interactions

Scenario description

Business Issue:
Field based teams are looking for different ways to interact with customers virtually given the lack of ability to visit offices or travel.

Key Question: How can field-based medical personnel continue to fulfill their role in the Medical Affairs organization?

Panel discussion questions

1. What are some **compliance risks** that must be taken into consideration?
2. How do you manage obtaining signatures? What are the rules around meals?
3. How are virtual-joint interactions managed?
4. What are some global issues (eg, differences in technology, access) that should be taken into consideration as we think about the changing ways of working?

Scenario: External Funding

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Scenario description

Business Issue:

Previously approved IME grants have been modified (eg, format changed from in-person to virtual) in response to COVID-19. There is also increased demand for donations to support COVID-19 activities.

Key Question: How can companies provide the appropriate level of oversight for external funding requests**?**

Panel discussion questions

1. What are some **compliance risks** that must be taken into consideration? Where can there be flexibility?
2. Is your review and approval process manual (ie, requiring wet signatures) or is the workflow automated? Does the change in the format of the IME event warrant additional approval?
3. Is there a possibility to expedite donation requests?
4. How do you manage due diligence for new contractors? Is there a process for assessing whether contracts etc. should be modified?

Scenario: Medical Information or Communication

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Scenario description

Business Issue:

Call centers responsible for responding to unsolicited requests are closed / or your organization has experienced a reduction in workforce.

Key Question: How do companies manage the potential impact of a reduced workforce despite increased demands?

Panel discussion questions

1. What are some **compliance risks** that must be taken into consideration?
2. How do you manage responding to the increased demand for more information? What additional controls must be put in place.
3. Are there considerations to use a mobile/ digital tool? If so, how do you track 'virtual' unsolicited requests and the responses?

Scenario: Collection of Data (Data Privacy)

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Scenario description

Business Issue:

As we move to virtual activities, there are more tools to collect data on HCPs and patients. This information may be used to obtain useful medical insights.

Key Question: How do we manage external information (ie, data) received through our digital communication channels?

Panel discussion questions

1. What are some **compliance risks** that must be taken into consideration?
2. What data is appropriate to collect, use or distribute?
3. What are the security and privacy concerns? What is the global impact of our decisions?
4. How should companies respond to inquiries received via social media platforms?

Key Takeaways

- As Medical Affairs quickly pivot to evolve operational activities to a virtual environment, Compliance must get involved early to set the tone
- Medical Affairs should consider…
  - Evaluating their current medical strategy / plan and determine what tactics to start, stop or continue
  - Review existing policies and procedures and assess whether the existing controls are sufficient
  - Evaluating whether manual processes could be automated