

Pharma Compliance Webinar

*Leading Forum on Pharmaceutical and
Medical Device Legal and Compliance Issues*

Tuesday, June 7, 2016 • 1:00 pm (Eastern)



Welcome to the Pharma Compliance Webinar

Medical Affairs Compliance - Lessons Learned and Best Practices



Featured Presenters

WEBINAR FACULTY

 <p>Brian J. Conner Director, Huron Consulting Group, Former Sr. Director, Asst. Compliance Officer, Global Compliance, Shire Pharmaceuticals, Atlanta, GA</p>	 <p>Kevin L. Espinoza, MBA Global Vice President, Ethics & Compliance, BTG International, Former R&D Compliance Officer, Forest Laboratories (now Allergan), Durham, NC</p>
 <p>Kevin Ryan, JD, MS Senior Director, Compliance: New Products, Novo Nordisk, New York, NY</p>	 <p>Brian A. Bohnenkamp, MHA, JD Partner, King and Spalding LLP, Washington, DC (Moderator)</p>

Disclaimer: Speakers' remarks are their personal opinions, and should not be considered to represent the position of their current or former employers.

Agenda

1:00 pm **Welcome, Introduction and Overview of Legal Framework and Landscape**

Brian Bohnenkamp

1:20 pm **Strategic Planning and the Interface between Medical Affairs and Marketing**

Brian Conner

1:40 pm **Customer-Facing Medical Affairs Roles: Medical Affairs Interactions with HCPs and Managed Markets Accounts**

Kevin Ryan

2:00 pm **Medical Affairs: Operations and Measurement**

Kevin Espinoza

2:20 pm **Q&A**

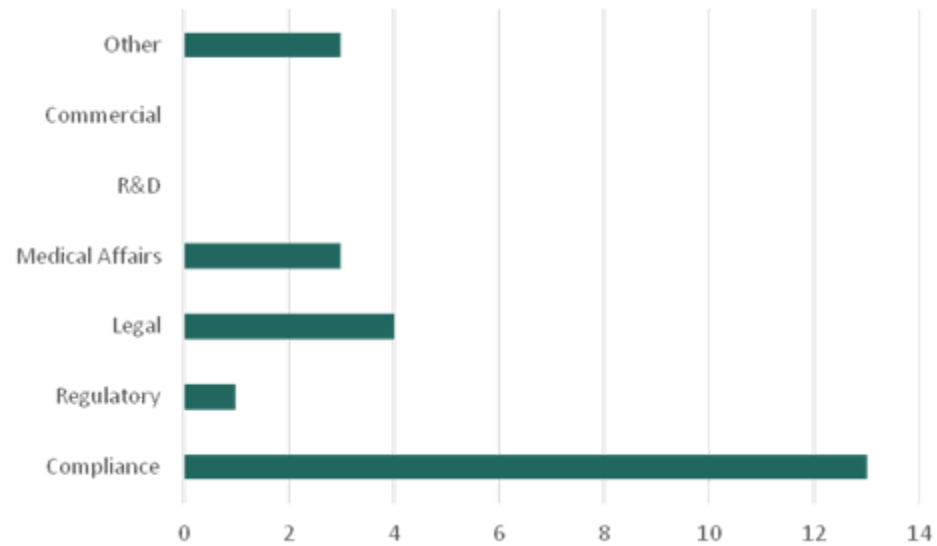
2:30 pm **Webinar Adjournment**

Who's on the Line?

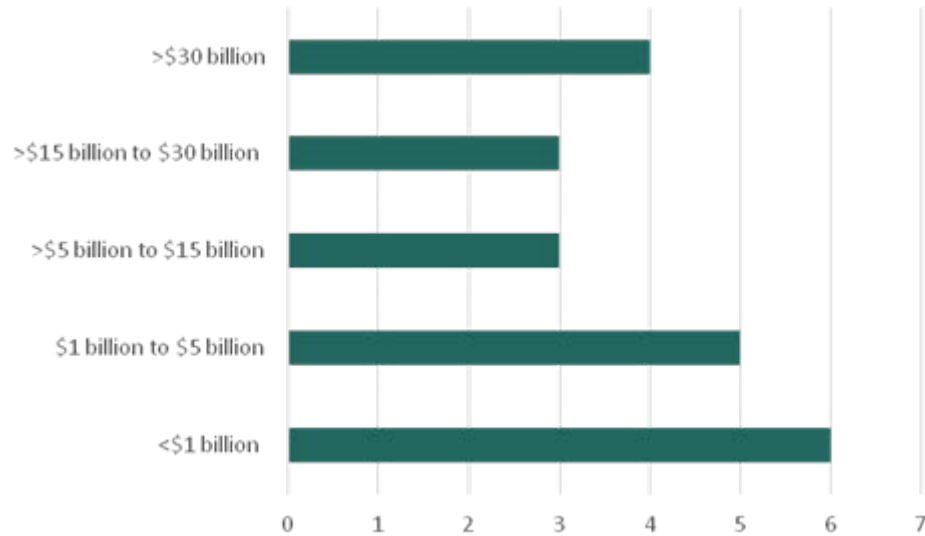
A few polling questions...

Note: Individual responses will be protected for anonymity. Only aggregate data will be reported and made available after the webinar concludes. Benchmarking is conducted solely to provide industry benchmarks regarding compliance program issues. There is no purpose to agree among companies on any specific compliance policy or procedure. Companies should decide on their own how to develop and implement their compliance programs.

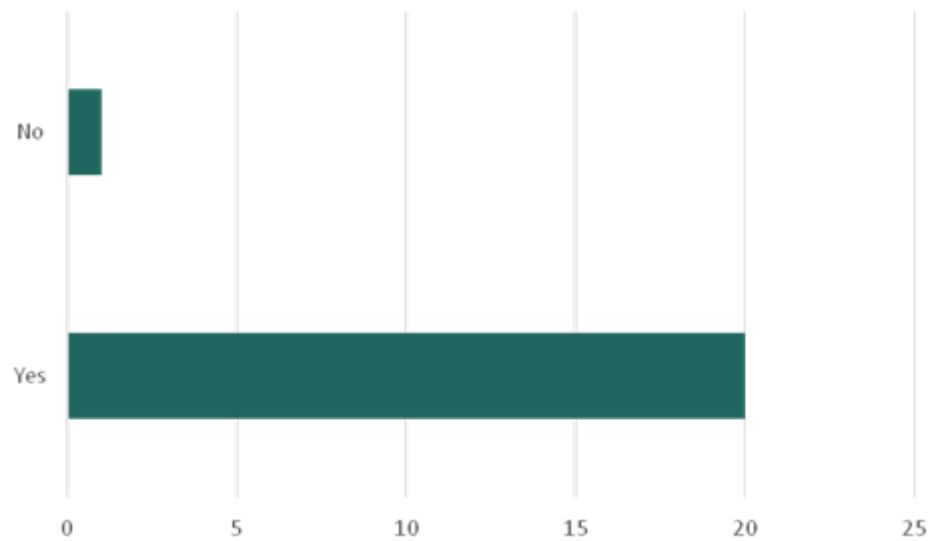
POLL 1: What's your role?



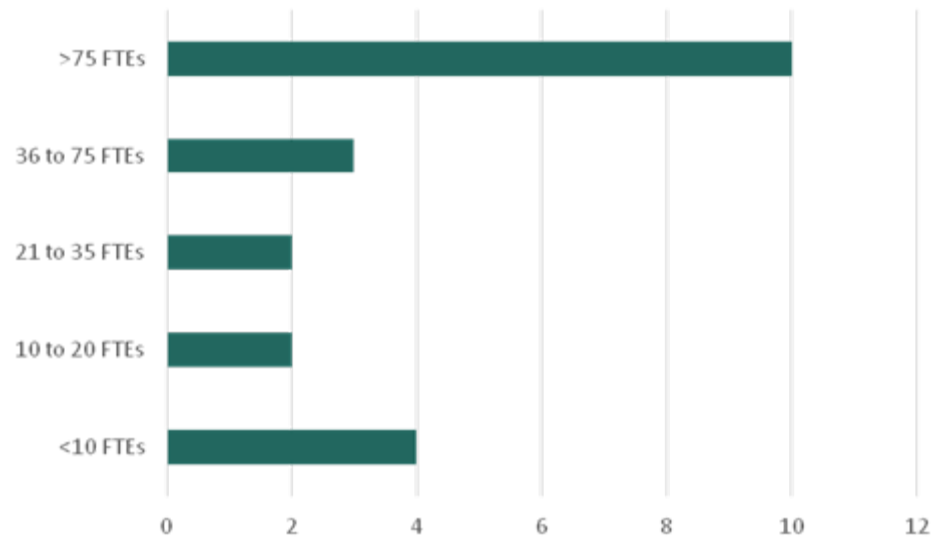
POLL 2: How big is your company in terms of annual revenue (roughly)?



POLL 3: Does your company have a distinct Medical Affairs Department?



POLL 4: How many FTEs work in US Medical Affairs function? (even if not a distinct Medical Affairs dept)



Overview of Legal Framework and Landscape

Brian Bohnenkamp

Medical Affairs is Not Special

- “FDA holds the medical affairs department to the same standards as it does sales reps. It’s important to keep from blurring the lines between promotion and responses to unsolicited requests.”
- “Just because you have a person with a different hat in a different booth, if they are promoting a drug [providing off-label information is still] against the law.”



Tom Abrams,
Director of FDA's
Office of Prescription Drug
Promotion (OPDP)

Overview of Legal Framework

No statutory or regulatory requirement to have a Medical Affairs department or function

As a general matter, the same laws and regulations apply to Medical Affairs personnel that apply to Sales and Marketing personnel. This includes, but is not limited to:

- The Food, Drug, and Cosmetic Act
- The Anti-Kickback Statute

A primary purpose of Medical Affairs should be to help ensure that non-promotional interactions remain appropriately non-promotional and are not tainted by Sales and Marketing considerations or influence

- Company organizational structure, processes, and incentives also should be designed and administered to avoid inappropriate influence or the appearance of inappropriate influence

Promotion

vs. Scientific Exchange

No official FDA definition

Generally, would include express or implied written or oral statements distributed to or made to customers and/or patients by a company or its representatives with the intent to proactively communicate attributes (e.g., safety, effectiveness, indication, etc.) of company-promoted products and their use

Examples:

- Sales aids, brochures, notes, email messages, blog postings, social media, website materials, videos, etc.
- Proactive statements made during in-person, phone, or email discussions with HCPs

No official FDA definition

Typically understood to refer to the dissemination and discussion of scientific research / medical findings, without making promotional claims about a product

Examples of practices commonly understood to be scientific exchange:

- Responding to unsolicited requests for off-label information in accordance with FDA draft guidance
- Distributing scientific and medical publications on off-label uses in accordance with FDA draft guidance
- Providing financial support for independent medical education programs
- Appropriate scientific discussions at legitimate scientific or medical conferences
- Scientific advisory meetings/focus groups, in appropriate circumstances and with limitations
- Appropriate communications intended for recruitment of clinical investigators and study subjects

First Amendment Cases

United States v. Caronia (2d Cir. 2012)

- Construes misbranding provisions not to criminalize truthful, non-misleading speech about off-label uses to avoid First Amendment violation

Pacira v. FDA (S.D.N.Y.) (dec. action, settled in 2015)

- Settlement with FDA permits company to market product for specific procedures not limited to those studied in the product's pivotal trials

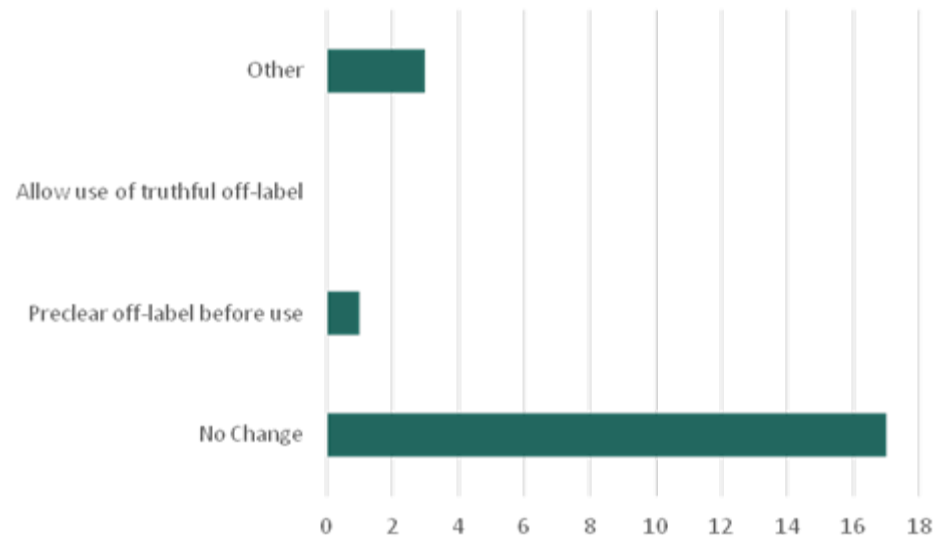
Amarin v. FDA (dec. action, settled 2016)

- Settlement with FDA provides that Amarin may engage in “truthful and non-misleading speech promoting the off-label use of [the product] . . . , and under *Caronia*, such speech may not form the basis of a prosecution for misbranding”

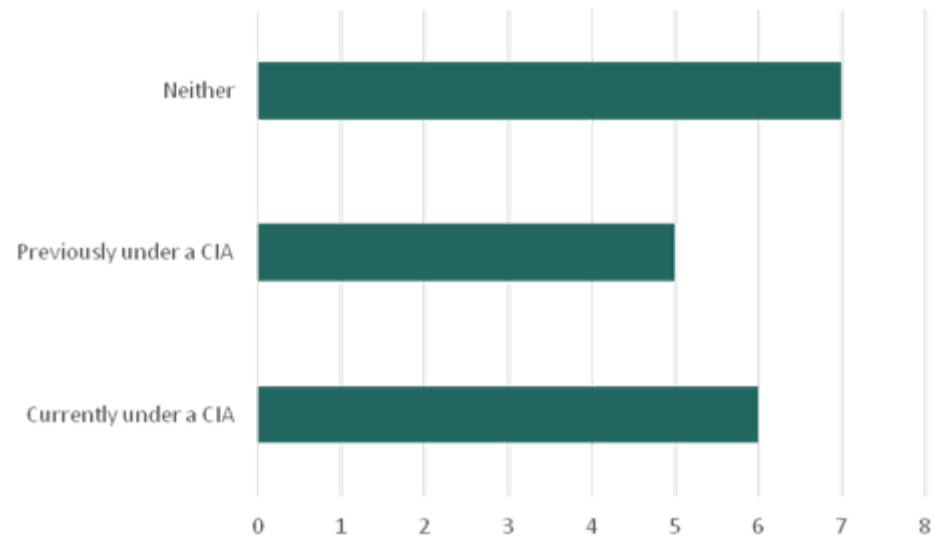
United States v. Vascular Solutions, Inc. (W.D. Tex.) (acquittals in 2016)

- Jury instructions stated: “It is also not a crime for a device company or its representatives to give doctors wholly truthful and non-misleading information about the unapproved use of a device. If you find that VSI's promotional speech to doctors was solely truthful and not misleading, then you must find the Defendants not guilty of the misbranding offense.”

POLL 5: In response to the court decisions regarding the First Amendment, what changes in compliance rules is your company considering:



POLL 6: What status applies to your company:



Enforcement Examples

U.S. enforcement authorities are sensitive to Medical Affairs departments engaging in improper Sales or Marketing activities and/or being inappropriately influenced by Sales and Marketing considerations

Settlements involving Medical Affairs activities have included allegations of, among other things...

- Promoting MSLS based on ability to sell
- Funding CME on off-label uses and creating and controlling content
- Training MSLS to prompt off-label questions
- Paying HCPs to speak on off-label uses
- Developing KOLs to support and promote off-label uses
- Using advisory boards to promote off-label uses
- Using IIS grants to promote off-label uses
- Ghostwriting articles on off-label uses
- MSLS accompanying sales reps on in-office visits and providing presentations on off-label uses
- Creating teams of Reimbursement, Sales, and Medical personnel to track off-label promotion and use and to target HCPs for visits by MSLS
- Preparing and publishing a misleading journal article that misreported clinical trial results
- Publicizing and circulating positive study results and failing to discuss negative study results

CIA Requirements

Many recent CIAs require manufacturers to implement at least some of the following measures:

- Creation of policies/procedures to control provision of off-label information by Medical Affairs personnel
- Creation of policies/procedures to require sales reps to refer requests for off-label information to Medical Affairs
- Development and maintenance of inquiries databases to track and monitor HCP requests for off-label information and company responses
- Policies/procedures related to the manner and circumstances under which Medical Affairs personnel participate in meetings or events with HCPs (either alone or with sales reps or account executives) and the role of the Medical Affairs personnel at such meetings or events
- Representations that Sales and Marketing departments have no involvement in medical education grants or charitable contribution requests, and that all such grants requests will be processed in accordance with standardized criteria developed by Medical Affairs
- Requirements to develop annual publication plans and establish a publication monitoring program

Strategic Planning and the Interface between Medical Affairs and Marketing

Brian Conner

Commercial and Medical Affairs Alignment

What is the appropriate firewall between Medical Affairs and Commercial?

The changing healthcare environment has encouraged the formation of independent Medical Affairs departments

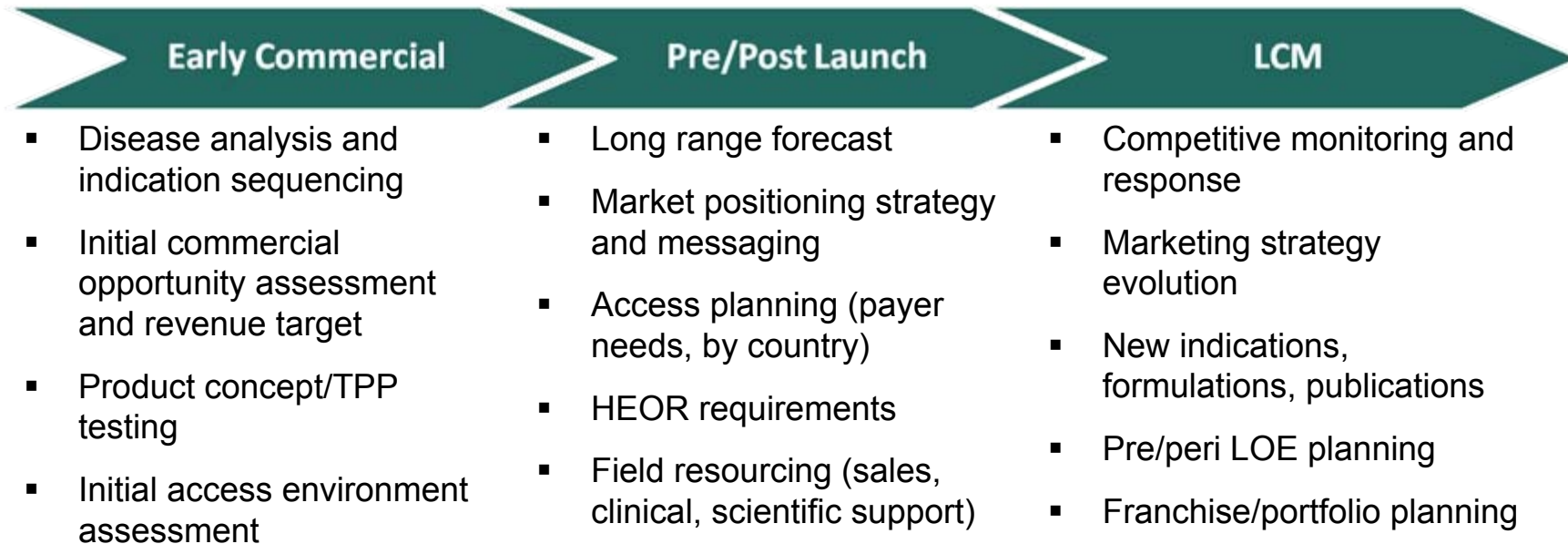
There is not a rigid set of requirements that dictate how a Medical Affairs department should look or operate

As a result, the industry has developed a wide variety of models, all seeking to address intensified public and regulatory scrutiny

Typical models:

1. Prohibit all communication between medical affairs and commercial
2. Allow open communication between medical affairs and commercial
3. Establish guardrails and protocols to allow compliant communication between medical affairs and commercial

Commercial and Medical Affairs Alignment



Medical Affairs Functions (Examples)		
<ul style="list-style-type: none"> ▪ Clinical Context/Expertise 	<ul style="list-style-type: none"> ▪ Medical Education 	<ul style="list-style-type: none"> ▪ Scientific Communications
<ul style="list-style-type: none"> ▪ Investigator Management/IIS 	<ul style="list-style-type: none"> ▪ MSL Management 	<ul style="list-style-type: none"> ▪ Surveillance
<ul style="list-style-type: none"> ▪ KOL Engagement and Relations 	<ul style="list-style-type: none"> ▪ Publications 	<ul style="list-style-type: none"> ▪ Trial Design and Demonstration

Commercial and Medical Affairs Alignment

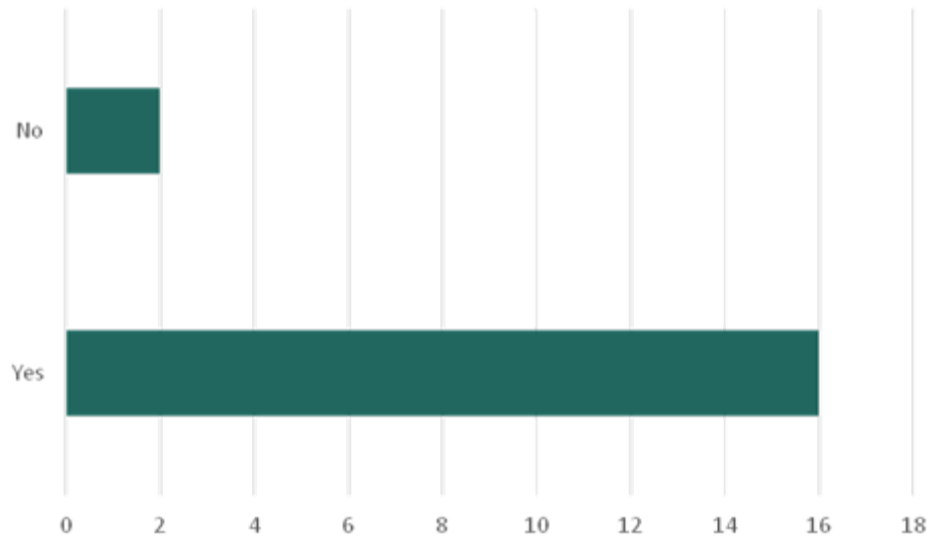
Key Life Sciences Trends

- More aggressive and sophisticated access management
- Outcomes metrics being used more broadly (indications, payers)
- Provider integration and IT investment as enabler of HECON--and new payer audience
- Emergence of new decision-makers (e.g. hospital admin, hospitalists, patients/ advocacy, etc.)
- Increasingly patient centric (and longitudinal) approach to care delivery
- Increasing biopharma and medtech reliance on emerging markets

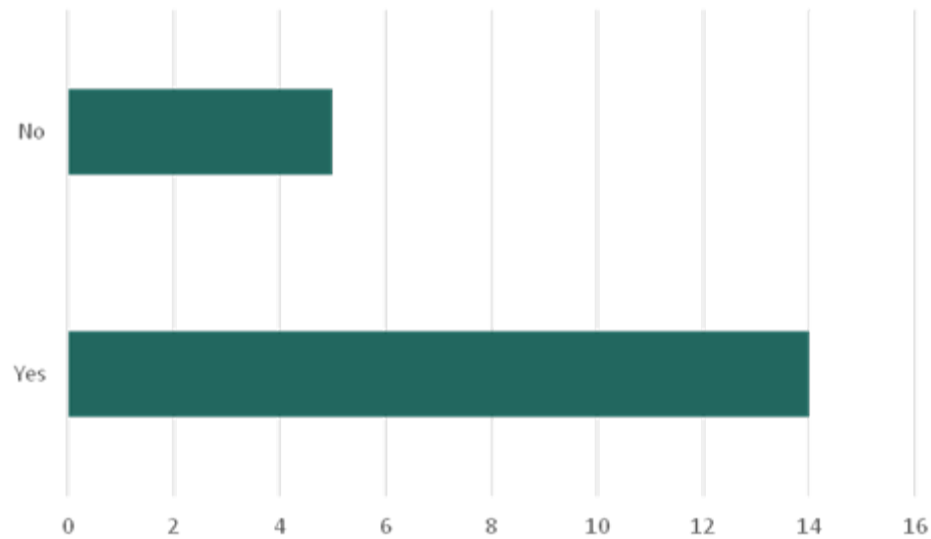
Medical Affairs Imperatives

- Address shift in definition of value and associated information requirements
 - Engage new stakeholders and tailor content of communication accordingly
 - Embrace “patient journey” approach
 - Understand and harness new, digital media channels where appropriate
 - Build expertise and structure organization in a way that addresses needs (region specific)
- ...execute in an increasingly rigorous and transparent regulatory environment***

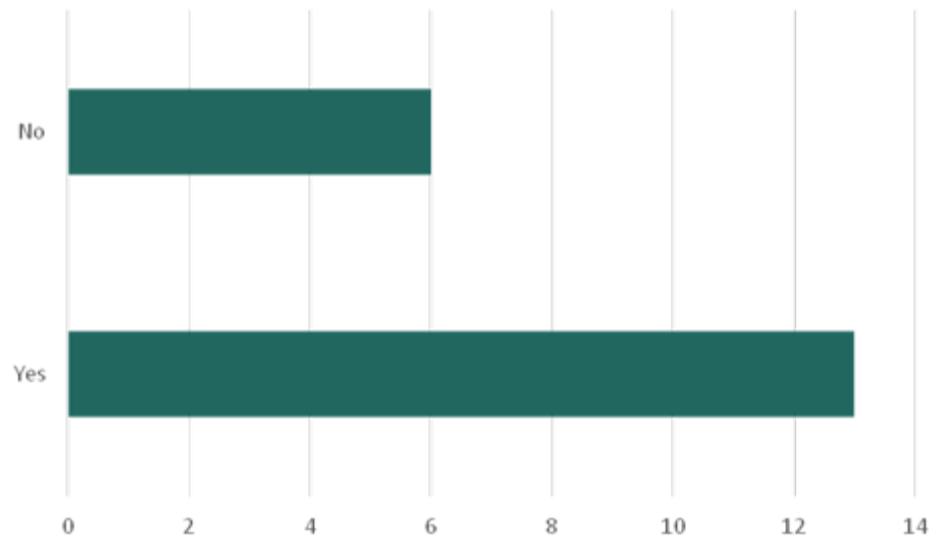
POLL 7. Does the current strategy for your Commercial activity align with the Medical Affairs Dept?



POLL 8: *Does Medical Affairs provide input into Commercial strategic planning?*

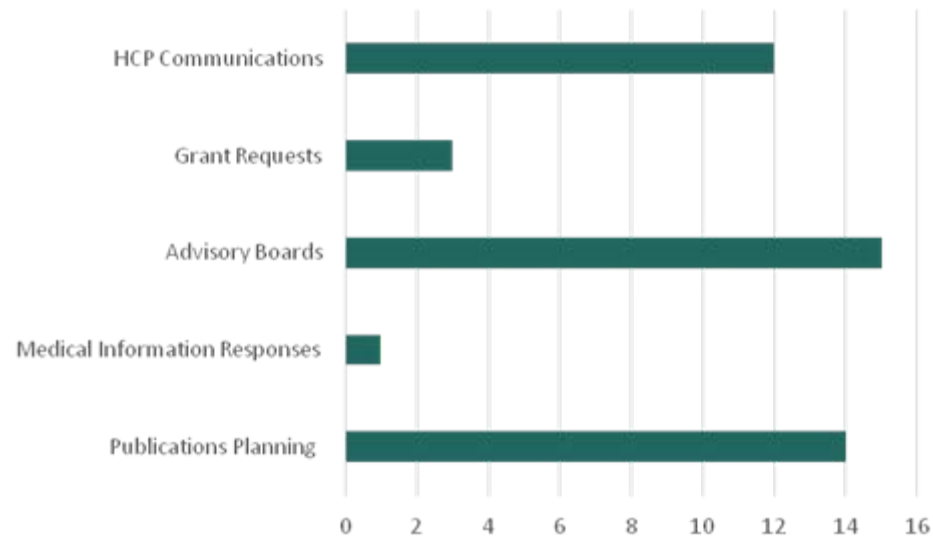


POLL 9: *Does Compliance have a role in the strategic planning process?*



POLL 10: *If Commercial and Medical align on strategic planning, does it cover specific issues such as:*

Select all that apply:



Customer-Facing Medical Affairs Roles: Medical Affairs Interactions with HCPs and Managed Markets Accounts

Kevin Ryan

Field Medical Interactions Basics

Growing focus of enforcement authorities on Field Medical activities *and communications*; U.S. prosecutors and whistleblowers attempting to build cases of improper product promotion

U.S. enforcement authorities sensitive to potential for Field Medical teams to inappropriately circumvent restrictions under the guise of “*scientific exchange*,” AKA “*white coat marketing*.”

Scientific Exchange

FDA expects Scientific Exchange to be a balanced, unbiased, straightforward presentation of the data, and its purpose should be to advance scientific knowledge and discussion by disseminating scientific findings; not to create product demand. As such, information should be truthful, complete, and scientifically accurate, unbiased, non-misleading and lack promotional intent, tone, or context.

True scientific exchange does not include promotional product claims or commercial objectives.

Limits of Scientific Exchange:

- Cannot promote off-label uses, but may respond to unsolicited questions about off-label uses.
- Cannot not solicit or encourage HCPs to request off-label information.
- Off-label inquiries should be referred to the Medical Affairs department or to an MSL.
- Information used to respond to unsolicited off-label requests should be internally reviewed
- If MSLs are treated as sales reps, they cannot respond to unsolicited requests for off-label information.

Field Medical Activities: Best Practices?

MSLs should be separate and independent from the Sales organization.

- Joint meetings with Commercial
- Exceptions

MSLs should report into Medical Affairs

- Small companies

MSLs should neither engage in, nor have any connection with promotion, promotional activities, or promotional presentations.

- Speaker training, speaker programs, post approval/pre-launch

MSLs should not share with commercial colleagues the subject matter or content of discussions with HCPs in response to unsolicited requests for off-label information or regarding customer research interests or participation in clinical studies.

- Trending, practice habits, ongoing site issues

Field Medical Activities: Best Practices?

MSLs may proactively call on HCPs and/or accounts to discuss on-label, non-promotional product and disease state information.

- Review

MSLs may also proactively call on HCPs, investigators, and health care organizations to discuss potential areas of interest and participation in company-sponsored clinical trials and externally sponsored studies, as well as to understand HCP capabilities, expertise, and affiliations.

- Information sharing

Joint Visits

Introductory visits

- New to role
- Who records the call? Who gets to be substantive?

Ambassador Meetings

- Neutral content, not related to products, company specific

Cross-functional meetings

- Accounts, SPs, SDs
- Product vs. non-product

Formulary meetings

- Related vs. actual meeting

Upper management

Considerations for Managed Market Accounts

Role of Field Medical vs. traditional “customers”

Requests for more in-depth information

- Deep clinical or HEOR information
- “Super Rep”

Specialty vs. “Big Pharma”

- Time constraints
- Multiple roles

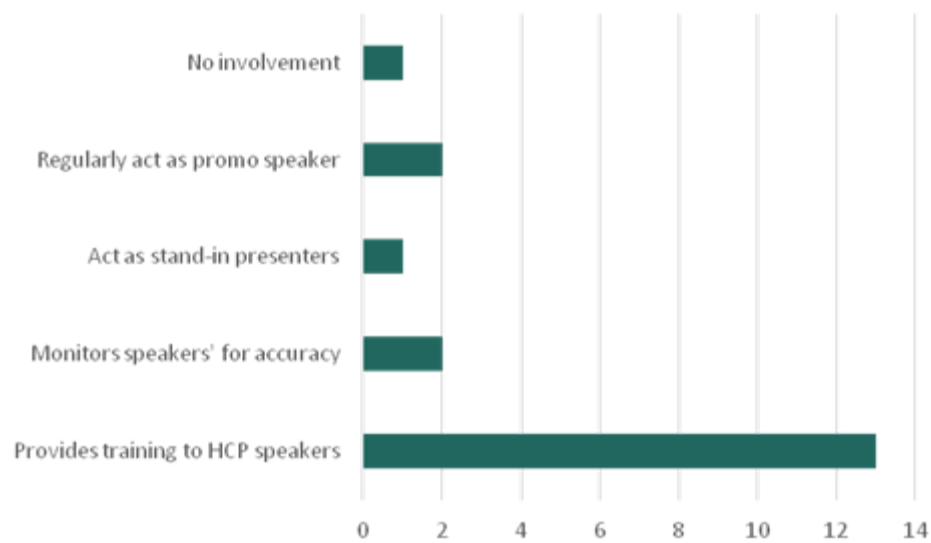
“Scientific exchange” vs. “business terms”

Collaboration vs. Partnering

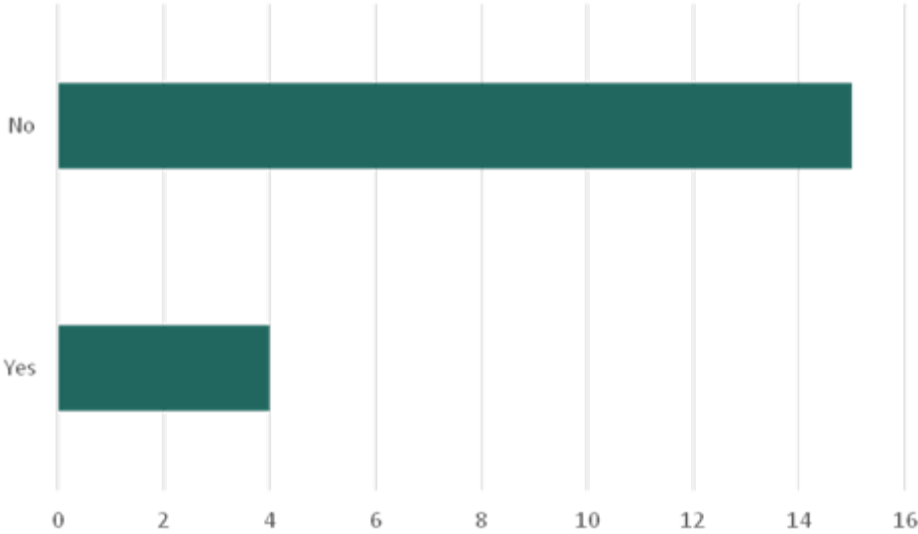
Value should be a four letter word

POLL 11: *What involvement does your Field Medical team have with promotional speaker programs?*

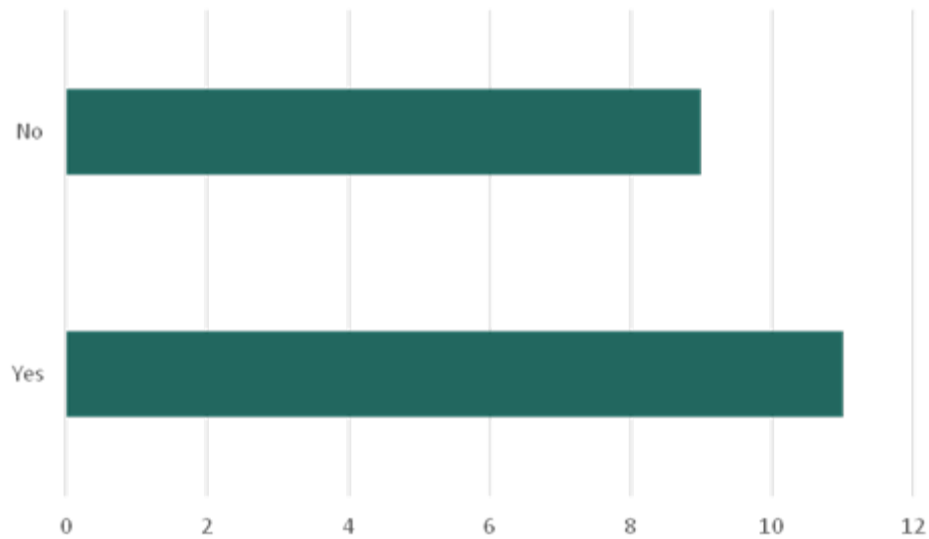
(select all that apply)



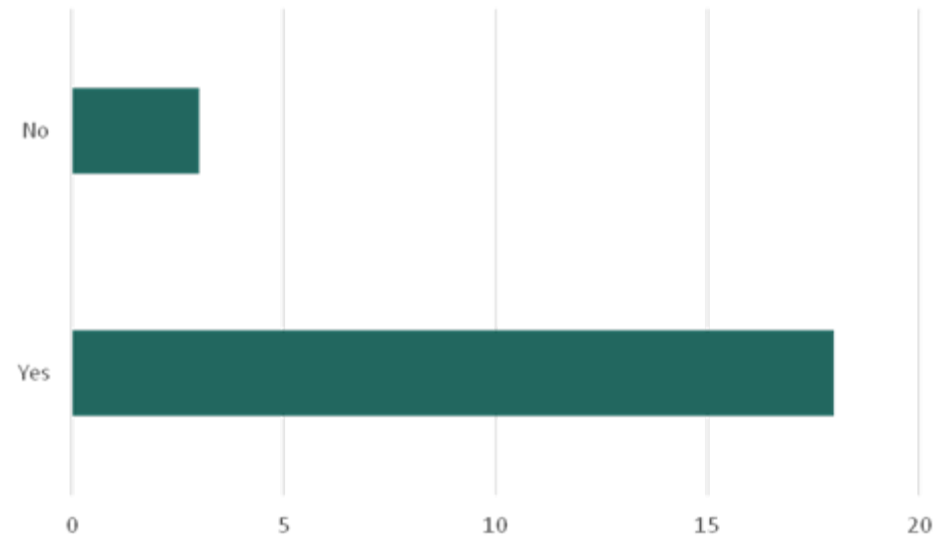
POLL 12: Does your Field Medical team conduct joint visits with any Commercial functions beyond introductory?



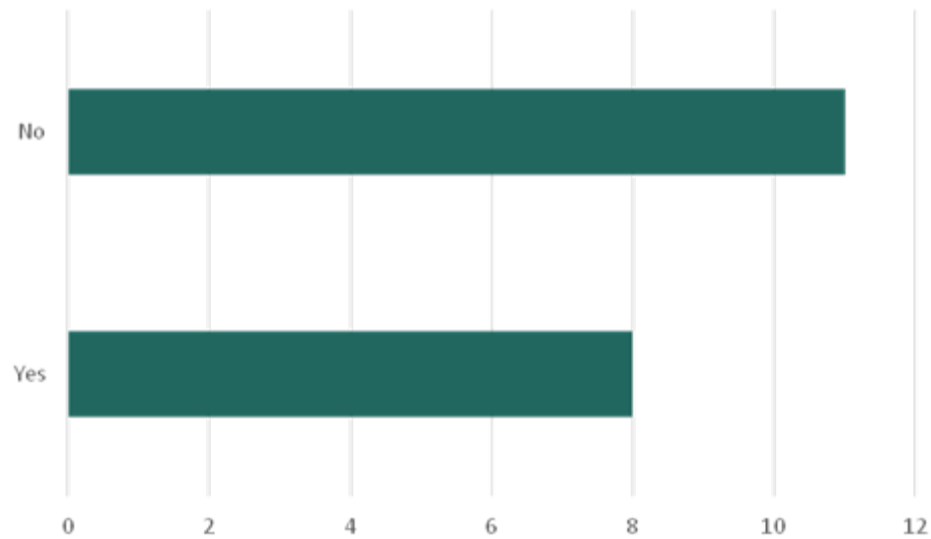
POLL 13: *Do you have a Field Medical team that specializes in reimbursement or managed markets?*



POLL 14: *Does your Field Medical team understand their role within the organization?*



POLL 15: *Does the rest of your organization understand the role of Field Medical?*



Medical Affairs: Operations and Measurement

Kevin Espinoza

Key Questions for Medical Affairs Operations

- What is the value of Medical Affairs to *the organization* and how does *the organization* measure it?
- How much or how little are Medical Affairs activities directed by commercial?
- What is the relationship with R&D, particularly around achieving R&D objectives?
- Are Medical Affairs contributions tangible and measurable?
- Are there clear key performance indicators for internal and field-based Medical Affairs teams?

Medical Affairs Objective: Listen more & talk less

1. Identify knowledge gaps in clinical practice
2. Embrace Scientific Exchange & Role in R&D organization
3. Establish formal feedback channels/processes to communicate clinical insights to inform various internal activities:
 - Publications
 - Clinical Trials
 - Life Cycle Planning
 - Brand (including Payer) Strategy
 - Market Research & Competitive Intelligence
 - Health Economics & Outcomes Research (HEOR)
 - Payer collaboration initiatives
4. Develop a deeper understanding of patient needs

Measurements of Effectiveness

Field-Based Medical Teams

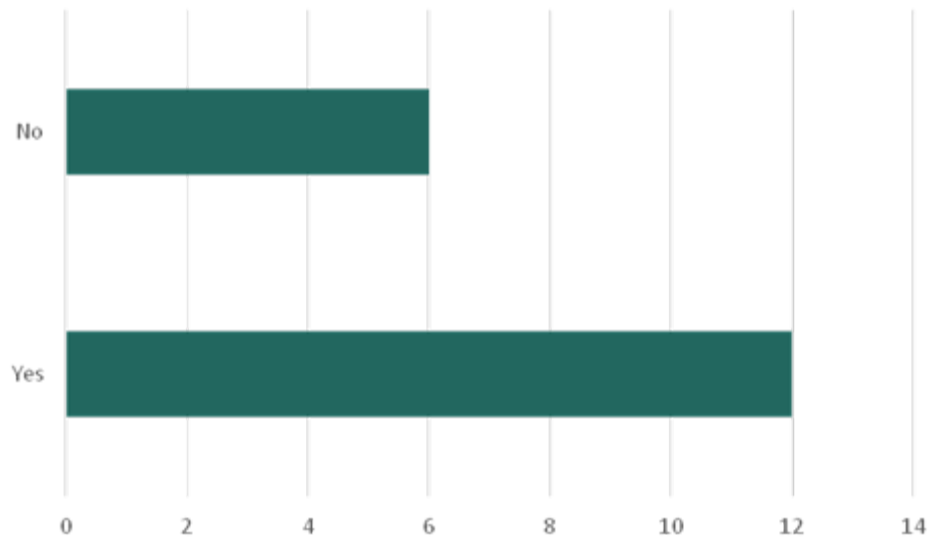
1. MBOs, including special projects
2. Observed Performance by supervisors
 - HCP/HCO visits; HCP Speaker Training
 - Internal training
3. Knowledge Assessments
(Compliance incorporated)
4. Internal reports & presentations to stakeholders
5. External Expert HCP Surveys
 - Demonstrated Medical expertise
 - Investigator Initiated Trials Support
6. R&D Site Support as directed by clinical
7. Compliance to SOPs & training deadlines

Internal Medical Affairs Teams

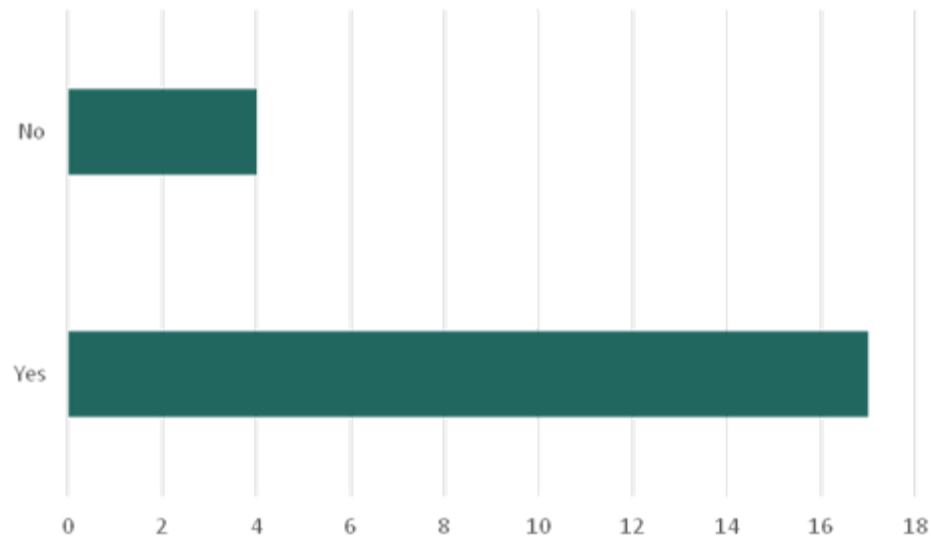
1. Response/processing metrics (dashboard)
 - Educational Grant requests
 - Investigator Initiated Trial requests
 - Medical Information (SRLs)
 - Surveillance
2. Supervisor & stakeholder evaluation of contribution to plans/planning processes
 - Franchise and Brand
 - Clinical (e.g. patient/investigator recruitment)
 - HEOR studies and Health Tech Assessments
 - Competitive intelligence (e.g. congresses)
 - Advocacy & Publication
 - External expert training & development
3. Publication Plan execution
4. MBOs & special projects completion

POLL 16: Do your field-based medical teams routinely produce formal reports?

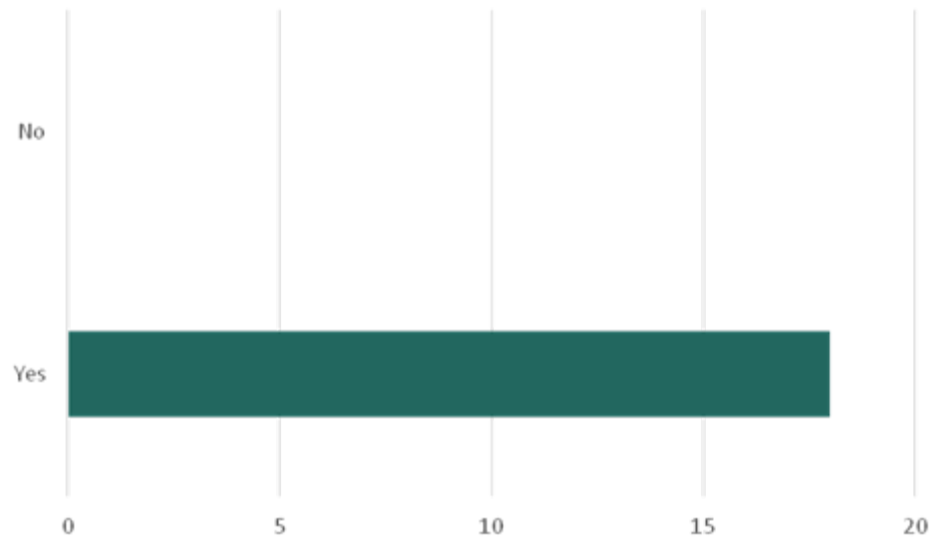
(e.g. on clinical insights, HCP knowledge gaps, competitive intelligence)



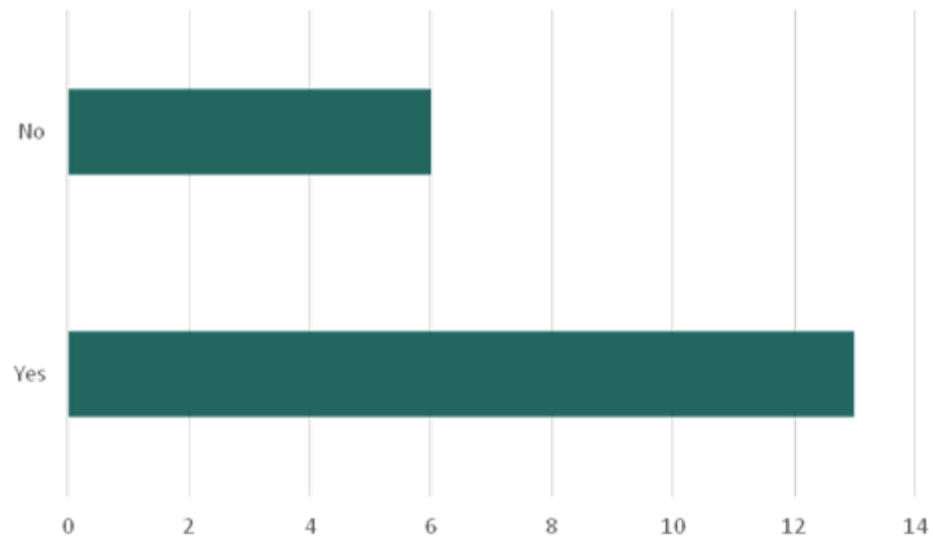
POLL 17: Is your MA organization involved in company sponsored clinical trial activities?



POLL 18: Does your MA organization contribute to the brand/franchise planning process?



POLL 19. Does your IMA organization track and publish their KPI performance (e.g. dashboard)?



Q & A

**Thank you for Participating in
Today's Webinar!**
