External Medical Affairs:
Considerations and Best Practices in 2017

Monica Kwarcinski, PharmD
Head of Medical Affairs
Purdue Pharma L.P.

Disclosure Statement

- Employee of Purdue Pharma L.P.
- Opinions expressed during this presentation are my own and do not necessarily represent the views of Purdue Pharma L.P.

Medical Communications Landscape

Increased Government Scrutiny

Actions by medical and scientific affairs professionals continue to be heavily scrutinized by government prosecutors and subject to "regulation" through:

- **Corporate Integrity Agreements,**
- **Plea Agreements**
- **Consent Decrees**

Trends of Increased Focus

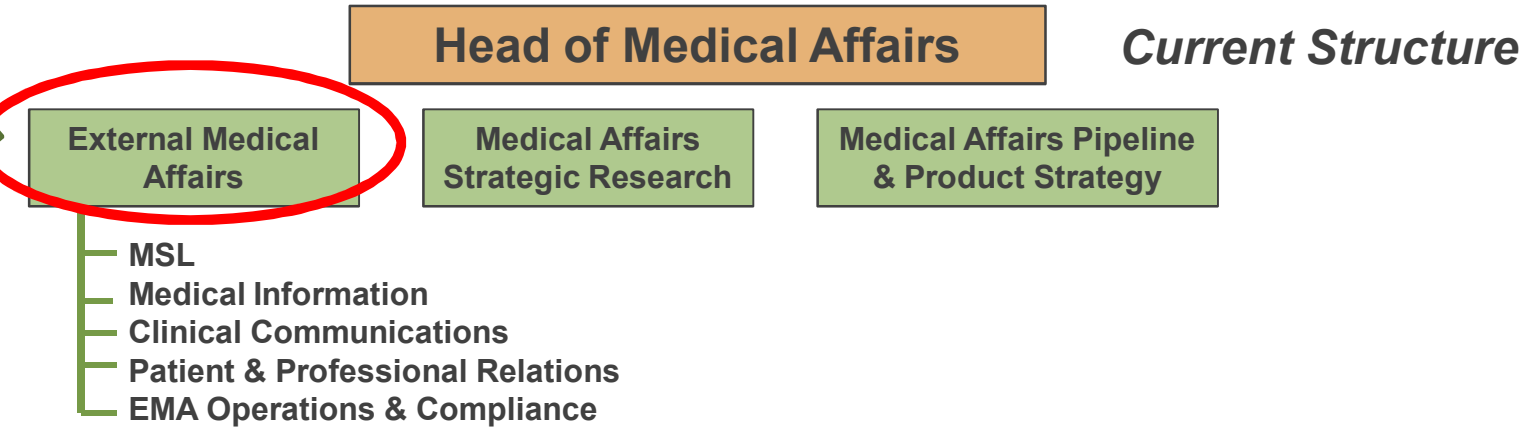
Interactions between medical affairs personnel and

- **Government payers**
- **Managed care organizations**
- **Institutional formulary committees**
- **Professional associations**
- **Patient advocacy groups**

- **Dissemination of off-label information via MSLs and Medical Information Departments**
- **Investigator Initiated Research**
- **Health Economic and Outcomes Research**
- **Publication activities**
- **Reimbursement Hubs**

Purdue Medical Affairs

- ✓ All customer facing groups
- ✓ Some overlap and synergies in job responsibilities
- ✓ Some redundancy of operational work



Purdue External Medical Affairs (EMA)

Medical Information

- Call Center
- Product Inquiries
- Standard Response Documents / FAQ
- OTC Promotional Review
- Compendia Review

Medical Science Liaisons

- Managed Markets Customer Interactions
- Branded / Non-Branded Education
- HCP outreach
- Support Pipeline

Patient & Professional Relations

- Patient and Professional Associations Strategy & Execution
- Professional Contact outreach
- Professional Contact Database Management
- Advisory board development
- Medical Affairs Congress coordination and strategy

Clinical Communications

- Develop Communication Tools for External Medical Affairs
- Identify Data & Education Gaps
- AMCP Dossier
- Sales & MSL Training
- Rx Promotional Review
- MSL Back-up
- Call Center Backup

Operations & Compliance

- SOP
- Compliance
- Document Maintenance
- Training
- Systems Administrator / Support
- Medical Inquiry Triage
- Administrative Support

Considerations: Off-label Inquiries

- Does everyone have the same interpretation of the FDA draft guidance* on responding to unsolicited requests for off-label information?
- Do you know the number of off-label requests your company receive per product?
  - What percentage are rep facilitated inquiries?
- Review existing procedures for responding to unsolicited requests for off-label information
  - Private versus Public (e.g. Product Theaters at Congresses)
  - Medical Information Booths, formulary presentations, promotional presentations
  - Enclosures of clinical reprints (copyright, Sunshine Act)
  - Non-promotional in tone or presentation
    - *MSL slide presentation color?*
    - *Do you include product logo in MSL presentations?*

 * http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM285145.pdf

Considerations: Off-label Inquiries

- Review inquiry documentation expectations
  - Are all verbal off-label inquiries and responses being documented (e.g. formulary presentations, physician group presentations)?
  - Free text responses or drop down / pick lists

- Are Medical Affairs, Medical Information, MSLs processes consistent for responding to off-label requests? If not why not?

- Do your responses include non-biased information or data including data not supportive or that cast doubt on the safety or efficacy of that use?

2016 Medical Communications Survey: Processes and Compliance Practices

When responding to a medical inquiry do you cite or discuss conflicting data on the topic?

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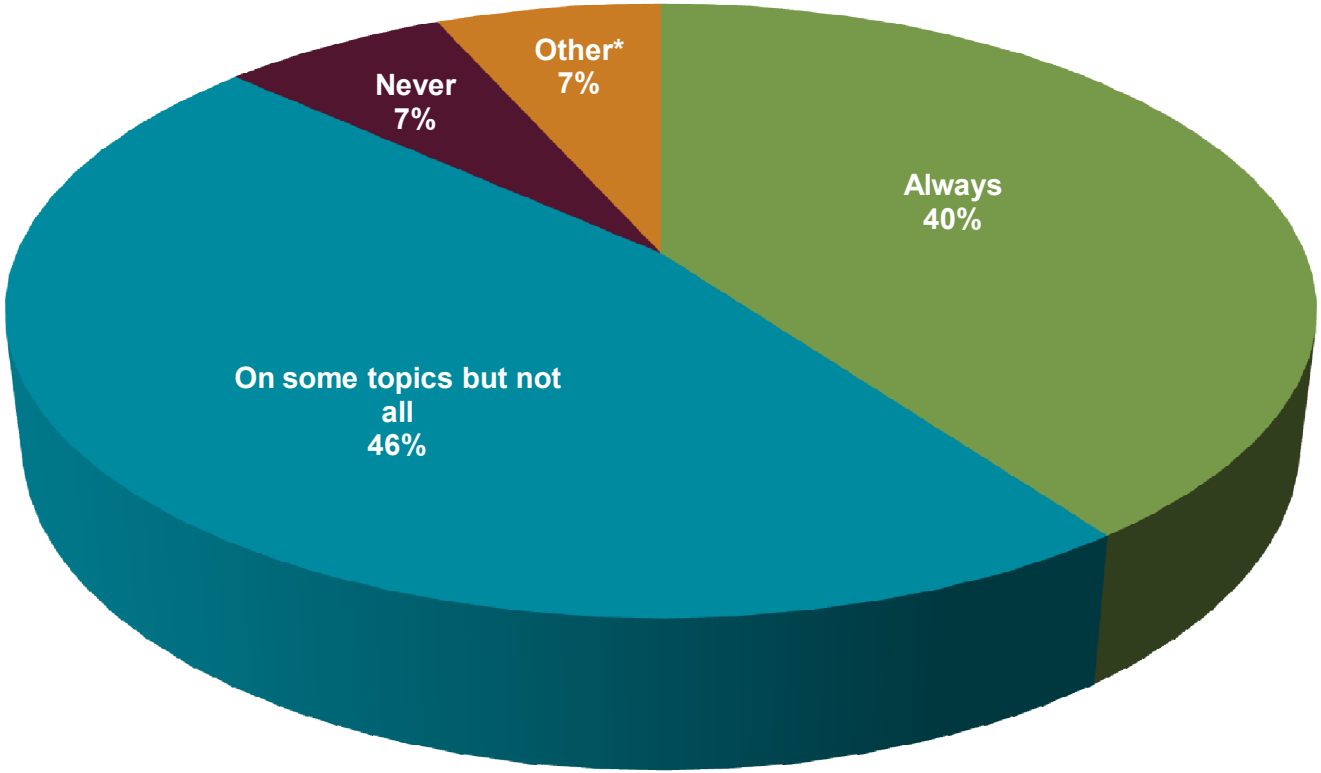


*Other Response:

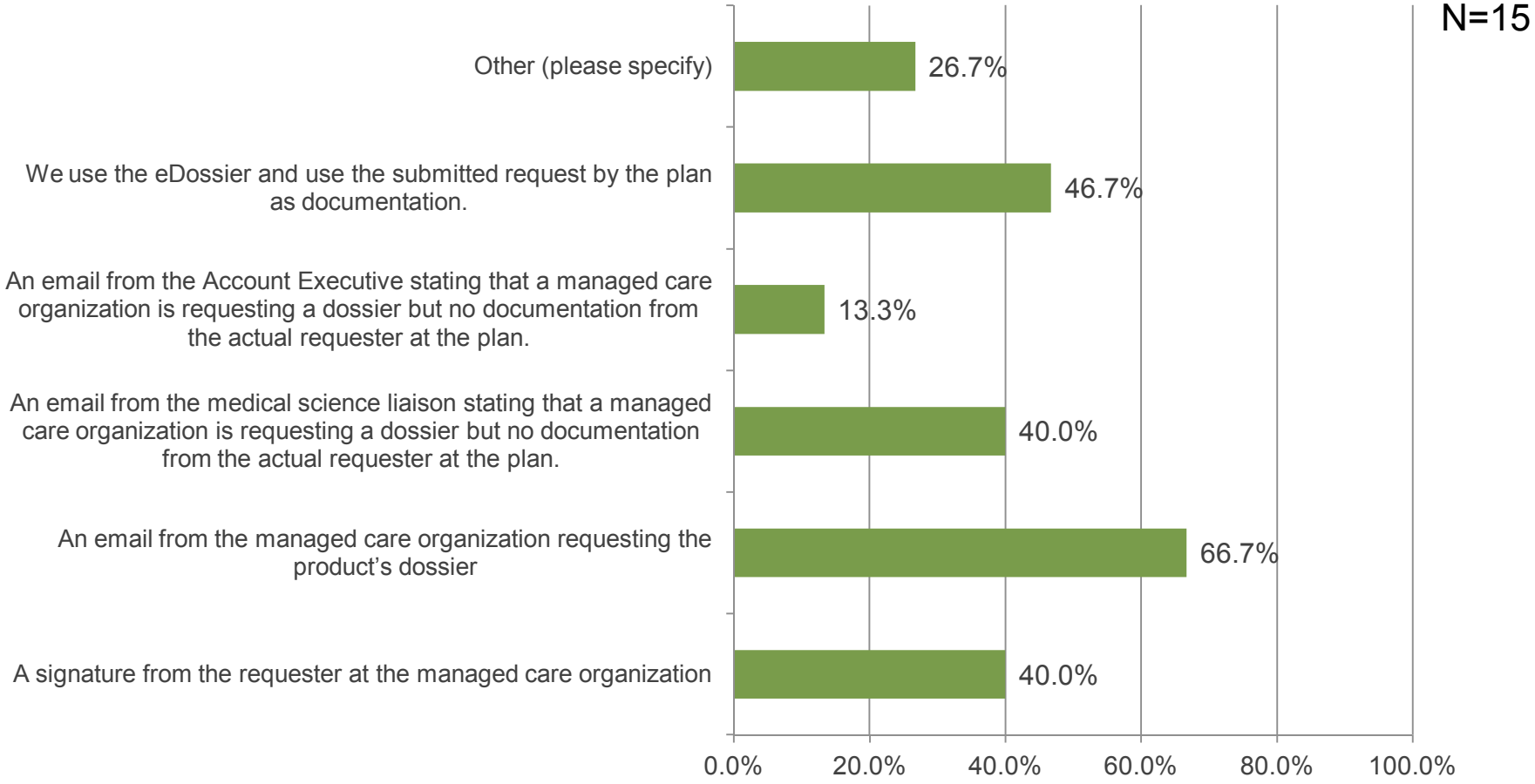
- We present all available data on topics, including positive, negative, and neutral results

Considerations: Managed Care Requests

- AMCP Dossier
  - Request Process
  - Documentation of request
  - Data consistent with response documents?
  - Requests for data updates
- Unsolicited requests for clinical presentations
  - Documentation of request
  - Is the presentation specific to the request, balanced?
  - Is the clinical presentation non promotional?
    - Do slides use brand colors or product logo?
  - Documentation of Q&As

2016 Medical Communications Survey: Processes and Compliance Practices

What type of documentation is required in order to fulfill an unsolicited request for a product's AMCP dossier? (Check all that apply)



Sales Representative Facilitated Requests

2016 Medical Communications Survey: Processes and Compliance Practices

What percentage of inquiries related to your US products are submitted to the Medical Information Department by your sales force on behalf of a healthcare professional?

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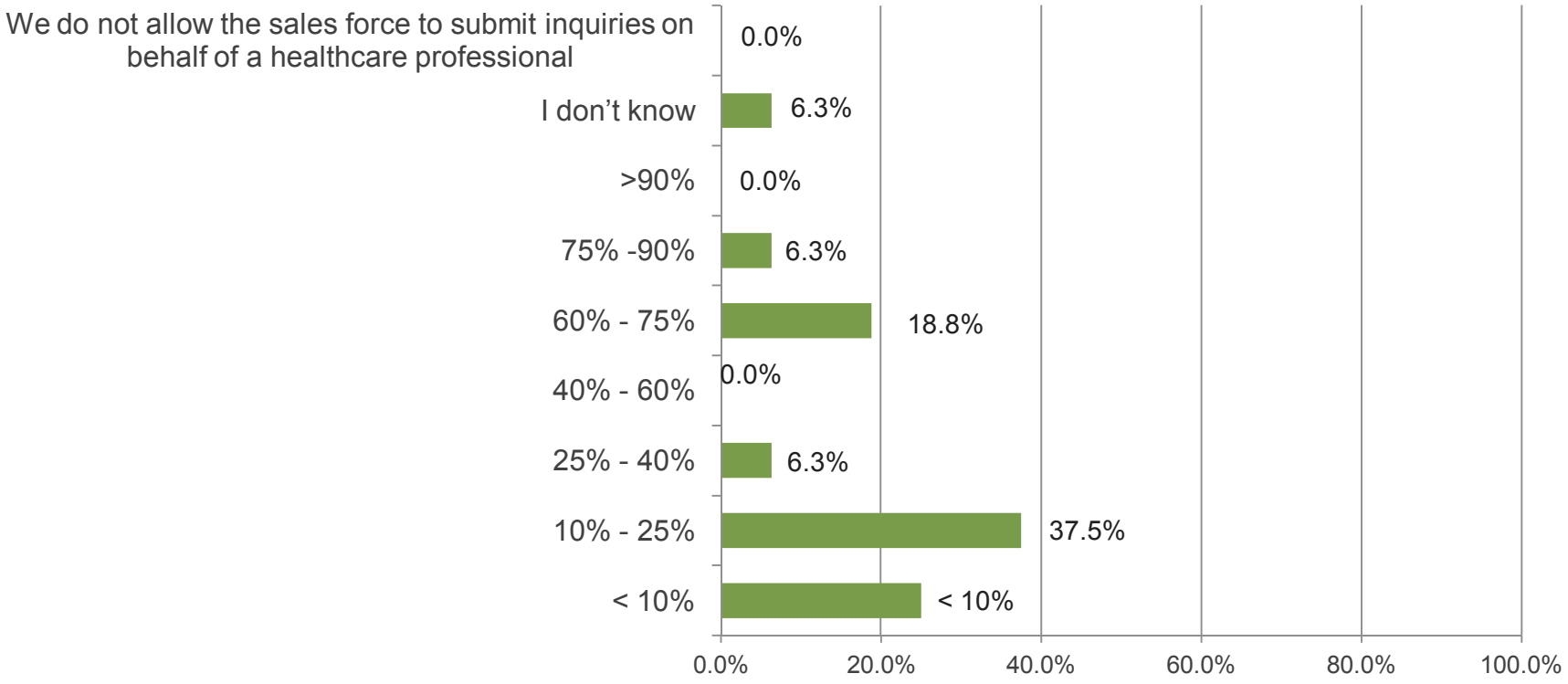
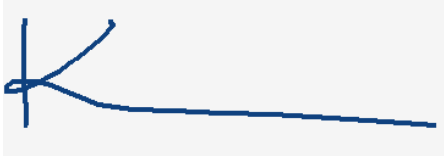
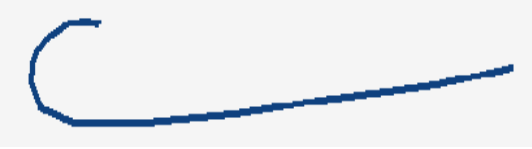


Sales Representative Facilitate Requests: Where do I sign?

- Sale representative facilitated requests
  - Are signatures required?
    - How do you verify signatures?
    - What is the escalation plan if issues arise with the signatures?

  - Do reps get a copy of the response?
    - Are the copies watermarked?

2016 Medical Communications Survey: Processes and Compliance Practices

When an inquiry is submitted by a member of the sales force on behalf of a healthcare professional, is the healthcare professional's signature required?

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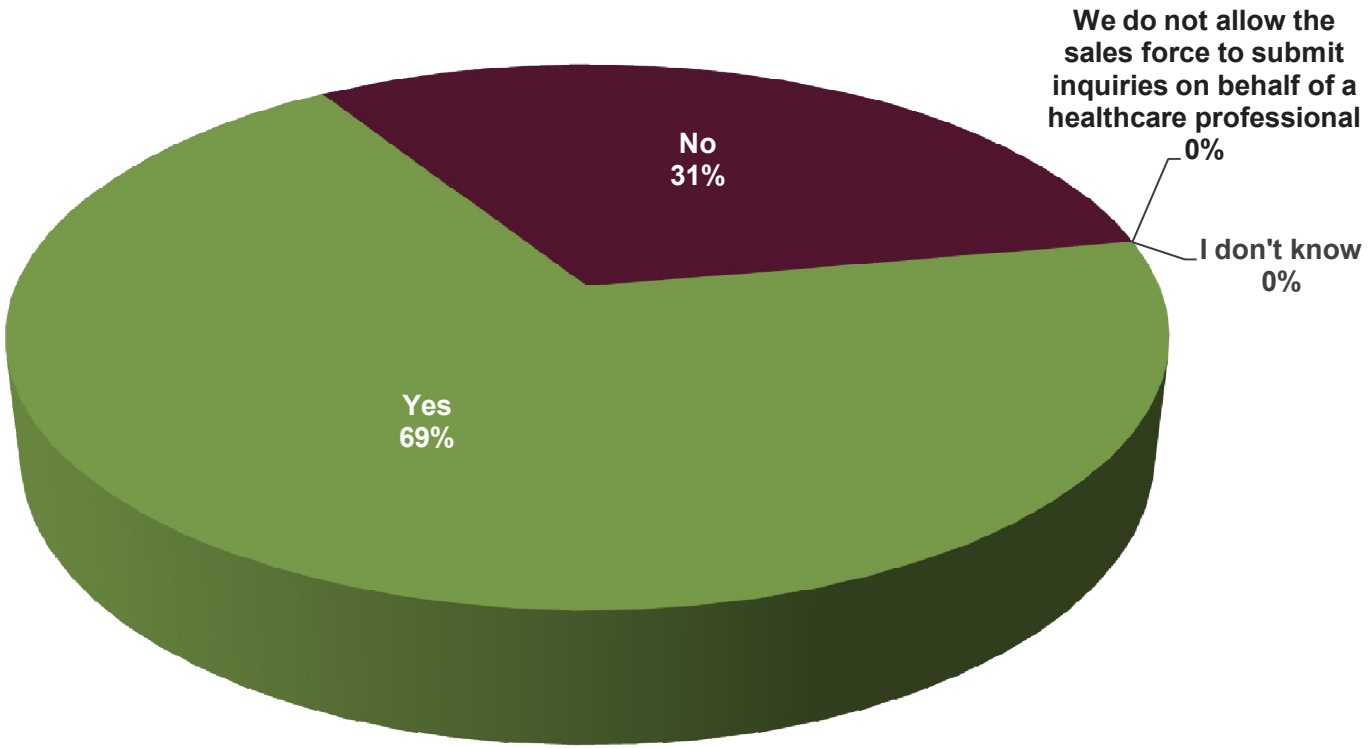

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Does the Sales Representative who submitted an unsolicited request for medical information on behalf of a healthcare professional receive a copy of the response letter?

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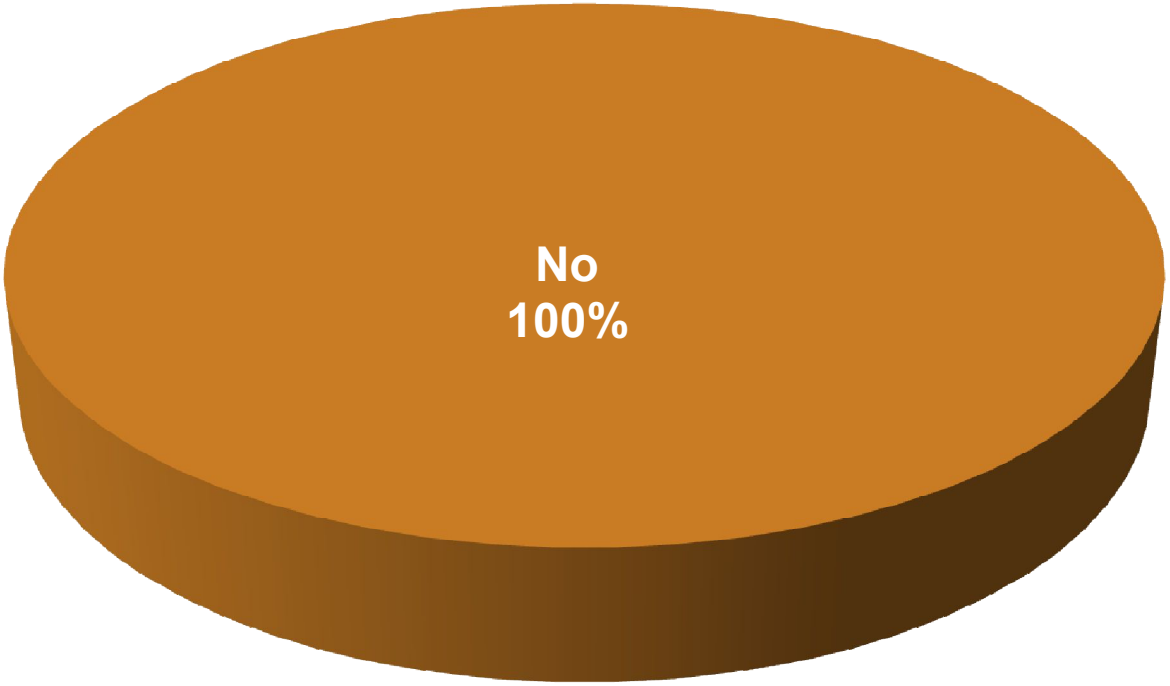

Considerations: Inquiry Analysis

- Rep Facilitated Inquiries Analysis
  - Obligation in some CIAs
  - Off-label inquiries
    - How many is too many?
    - How often are inquiries analyzed?
      - Weekly
      - Monthly
      - Quarterly
    - Do you have an escalation process is an issue arises?
  - Product comparison inquiries
  - Adverse events / safety profile Inquiries
  - What about the reps that never submit an inquiry?

Medical Inquiries: Data Collection Considerations

Data	Draft Guidance	CIA	Sunshine
Name	X	X	X
Address	X	X	X
Requester Type (HCP, Patient)	X	X	X
NPI# or HCP License #			X
Date	X	X	X
Question	X	X	
Whether it is an off-label question	X	X	
Response	X	X	
Value of Materials Provided			X
Follow-up questions from requestor	X		
Name of Sales Rep if Rep Facilitate or interacted with requestor		X	

http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM285145.pdf
https://oig.hhs.gov/compliance/corporate-integrity-agreements/cia-documents.asp
Federal Register Vol 78: No 27;February 8, 2013 p. 9458-9528

Inquiry Data Capture Considerations

- Are you documenting enough information with each inquiry?
- Multiple inquiries by one requester
  - Are you splitting out and tagging each inquiry?
- Do you have right topics to accurately tag your inquiries?
  - Too few
  - Too many
  - Do you have inquiry tagging/coding conventions?
  - What is the process if no topic exists for an inquiry?

Inquiry Data Capture Considerations

- Off-label inquiries
  - What is considered an off-label inquiry?
    - Can you easily report on off-label inquiries received?
- Adverse events / product complaints reconciliation
- Reprints distributed – Sunshine Act
- Staff training on data capture and tagging

2016 Medical Communications Survey: Processes and Compliance Practices

For individuals outside of Medical Information who respond to requests for off-label information where are these requests and responses documented?

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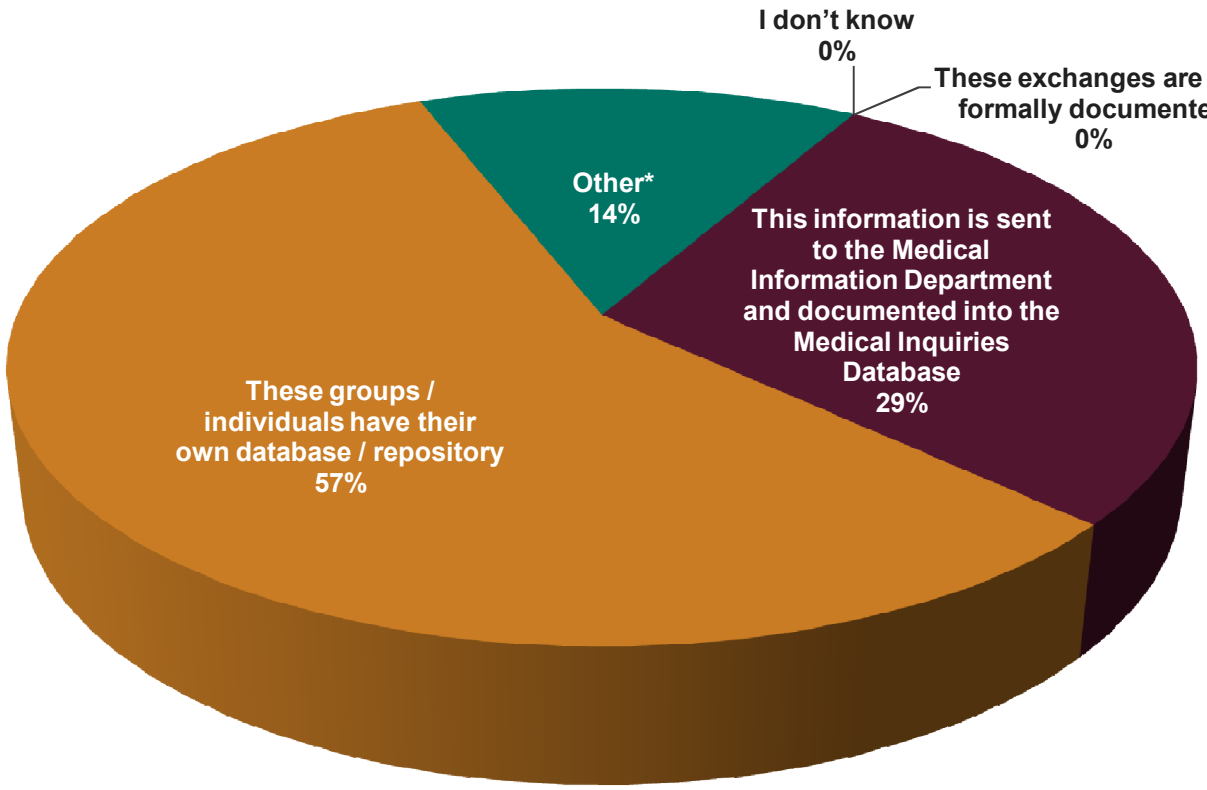

*Other Responses:

- Not sure how all the groups are documenting, but some groups do have their own database/repository
- MSLs are capturing inquiries in their own database however, clinical leaders who may speak to physicians informally at medical meetings are likely not documenting interactions.

Data Integration and Insights

Inquiry Auditing and Monitoring

How are cases audited/monitored?

- Review of cases within the inquiry management system
  - Percentage of cases
  - By product
  - By topic
- Review of recorded calls
  - Was the response complete?
  - Was the response accurate?
  - Did it provide appropriate balance?
- Did the response answer the question asked?
  - Written Responses

Who does the auditing/monitoring?

- Internal staff
- Management
- Call Center Vendor
- Independent vendor
- Healthcare Compliance

How often should you audit

- Daily
- Weekly
- Monthly

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What percent of inquiries are reviewed/QA'd?

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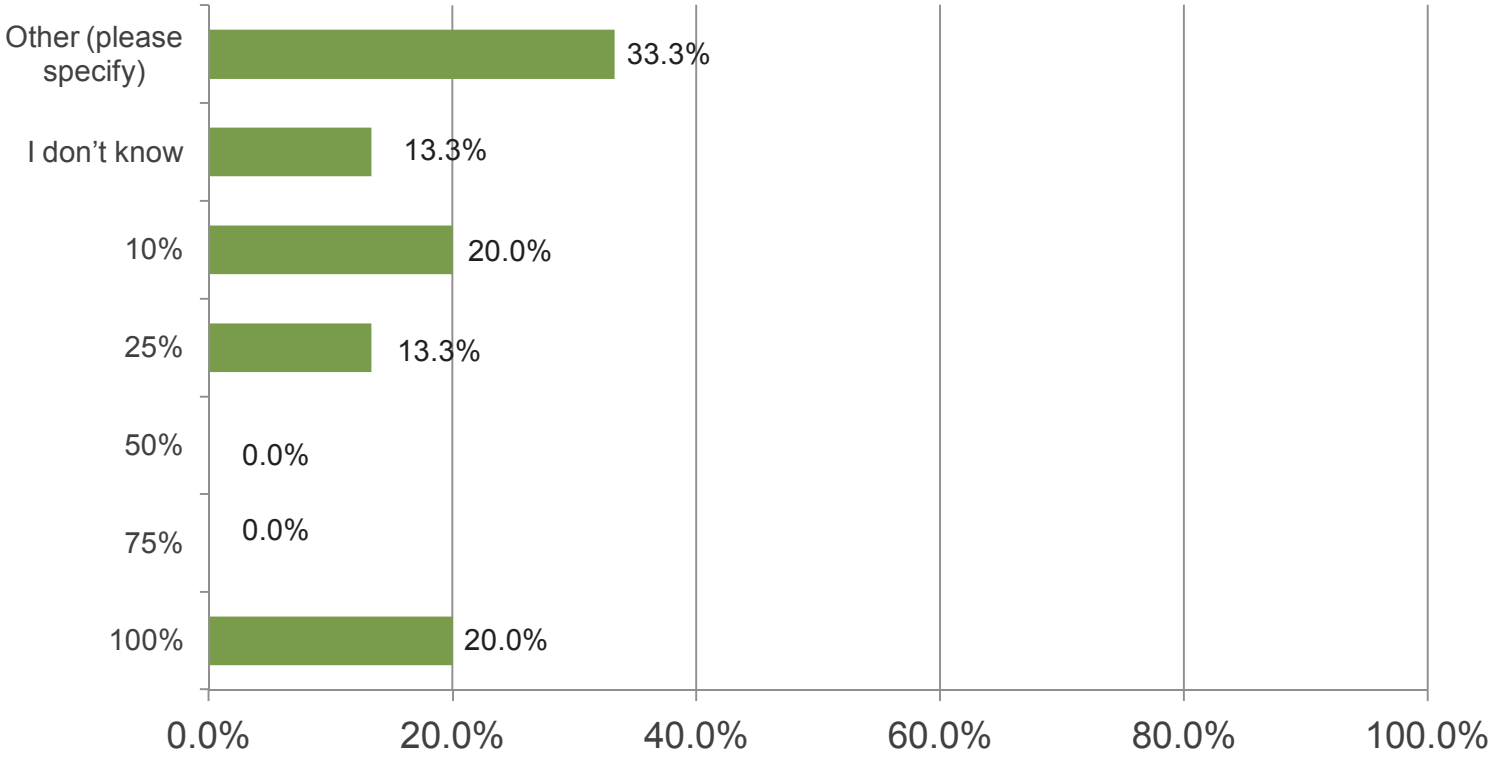

2016 Medical Communications Survey: Processes and Compliance Practices

If yes what percent of inquiries are reviewed/QA'd?

*Other responses:

- Vendor management reviews 10-20% percent of inquiries for each Medical Information Specialist, and 100% for new MISs. Vendor also has peer-to-peer review of all queries. Sponsor has access to vendor's MI database and conducts spot checks of cases. Vendor also provides weekly call recordings for review by Sponsor Med Info therapeutic leads and management team.
- <10%
- 1-2%
- About 2%
- 5% for AEs and 1-2% for accuracy of response

Staff Training

Staff Training

Initial Training

- SOPs/ Written Procedures
- Product Training
- Inquiry submission
- Database Training
  - Documentation of inquiries and responses
- External Training

Ongoing Training

- Written procedures updates / deviations
- Full Prescribing Information updates
- Recent product publications
- New / updated Standard Responses /FAQs
- Database upgrades
- Disease state and competitor updates
- Proper inquiry / response documentation and tagging

External Training

- Medical Communications
- Presentations Skills
- Medical Writing
- Phone Skills

Staff Training Curriculum

- Professionals
- Management
- Non-exempt

Initial Product Training (Professional Staff)

- Disease State
- Guidelines
- Full Prescribing Information
  - Previous versions - what has changed
- Clinical Studies
  - Published, data on file, on-going trials
- Product Standard Responses
- Product FAQs
- REMS (if applicable)
- Identifying and reporting AEs and PQCs
- Who will conduct the training?
- Will there be a competency check?
  - Oral test
  - Written test (open book?)
  - Role play
  - Call shadowing / call monitoring

Don’t forget to document your training!

Contact Information

Monica Kwarcinski, PharmD

Head of Medical Affairs

Purdue Pharma L.P.

Monica.Kwarcinski@pharma.com

203-588-7534 office phone