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Benchmarking Medical Publication Policies, Procedures, and Practices Across Pharmaceutical Companies

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- The views expressed in this presentation are our personal views and do not necessarily represent the views of sanofi-aventis US.

Background

- Industry sponsored peer-reviewed publications
 - Under increased scrutiny
 - Processes have been initiated to increase transparency
- Benchmarking industry processes will:
 - Support standardization of best practices
 - Help improve overall credibility of industry-sponsored publications

Objective

- To establish a benchmark for pharmaceutical industry publication standards and processes

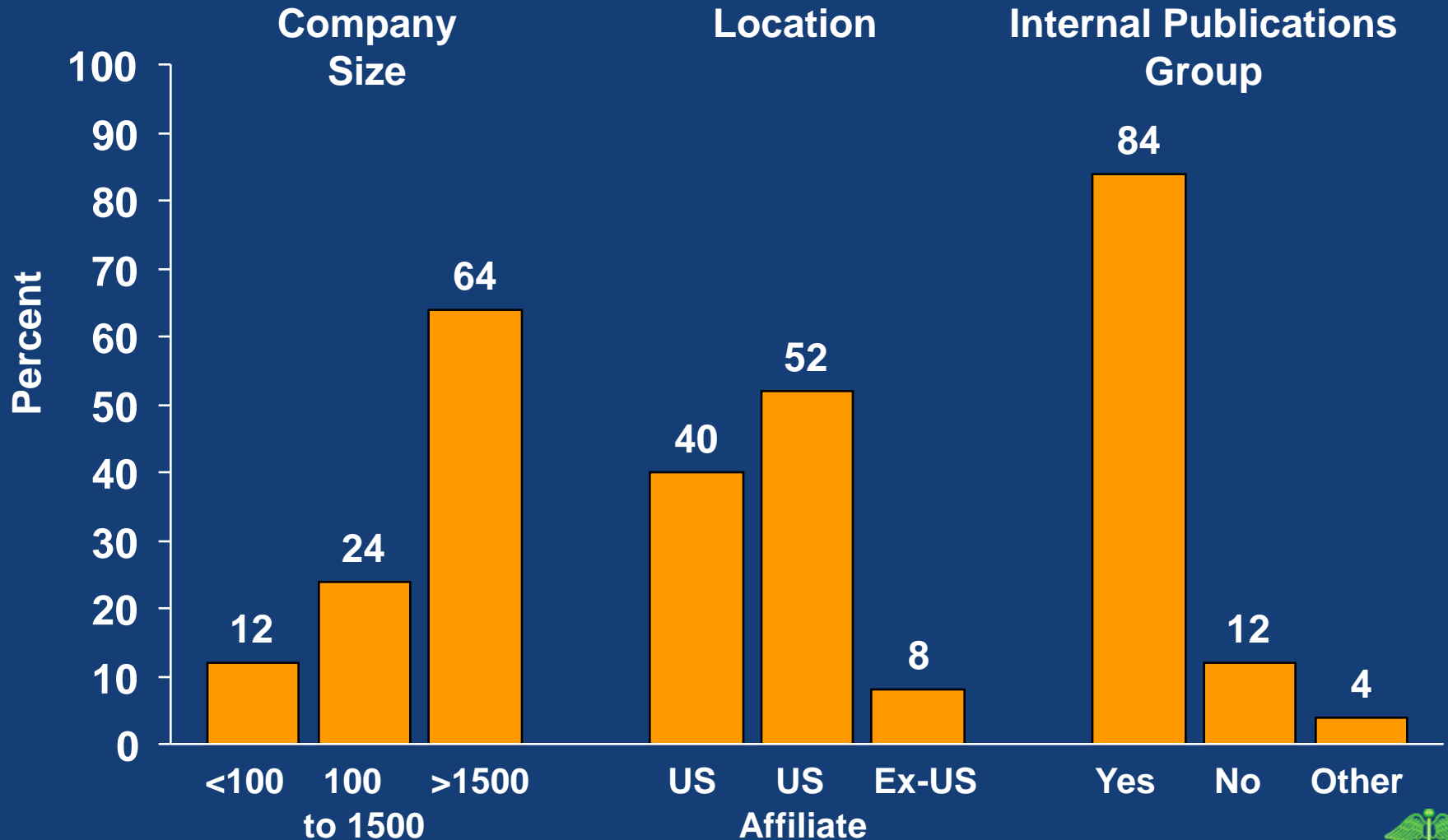
Methodology

- 22-item/5 domain internet-based anonymous survey
 - Demographics
 - Authorship
 - Transparency
 - Publications planning process
 - Documentation & archiving

Recruitment & Response

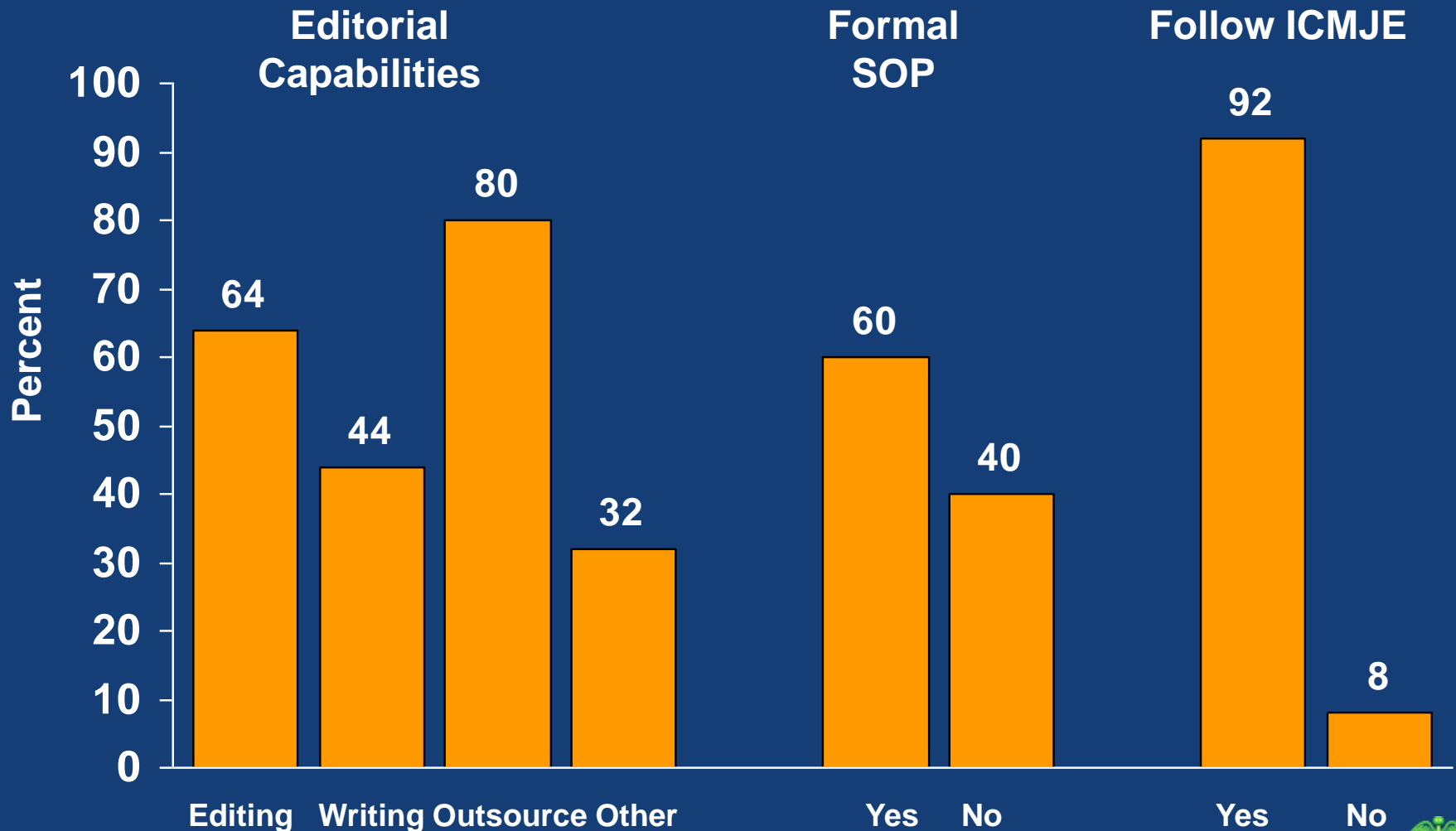
- Sent to 63 US-based pharmaceutical companies
 - Two waves over 2 weeks
 - Publication department heads & managers
 - Representative publication manager when no dedicated publications department was identified
 - One survey per company
 - ISMPP members
- 39.7% (25/63) responded

Demographics



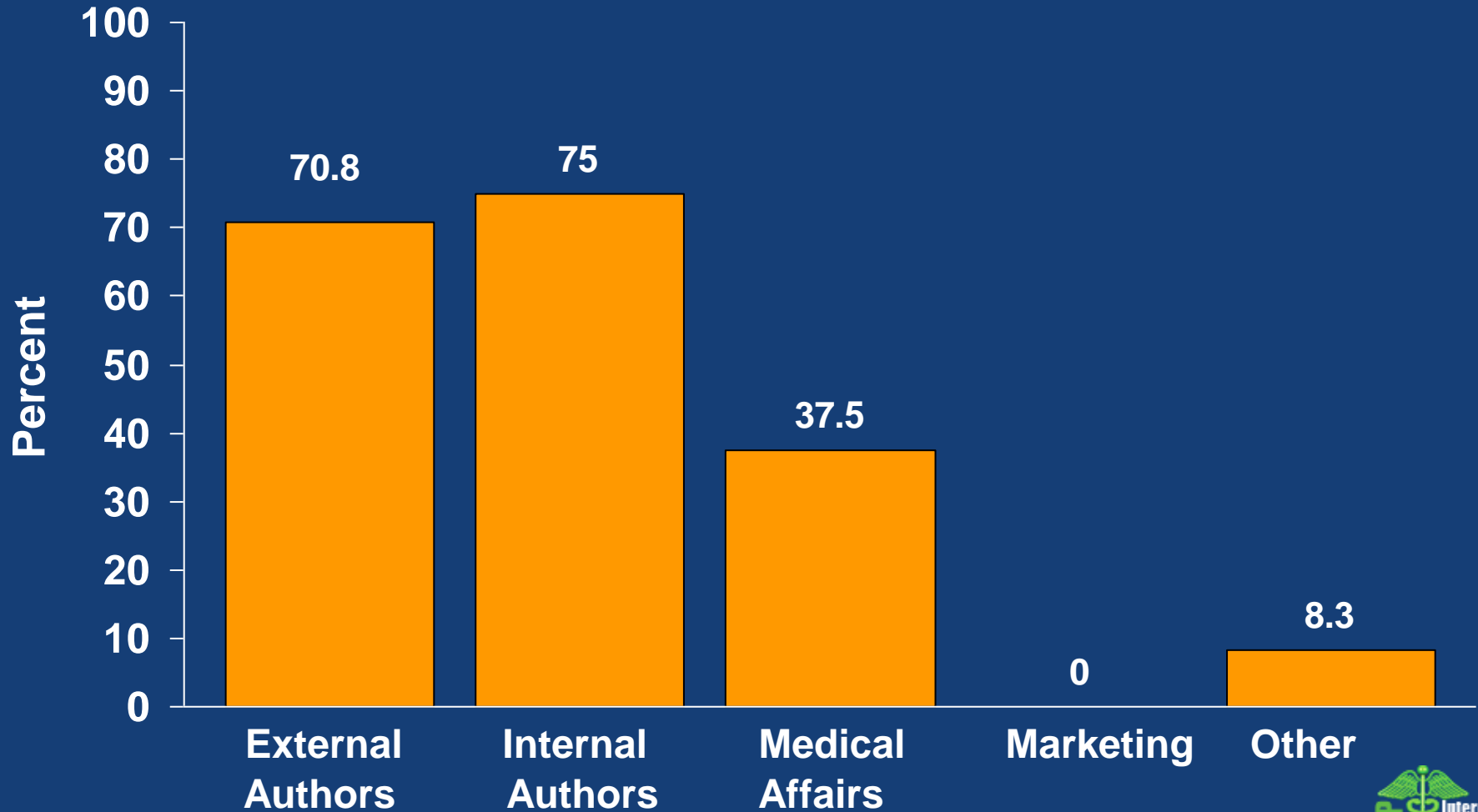
N = 25

Characteristics



N = 25

Who Drives Content?



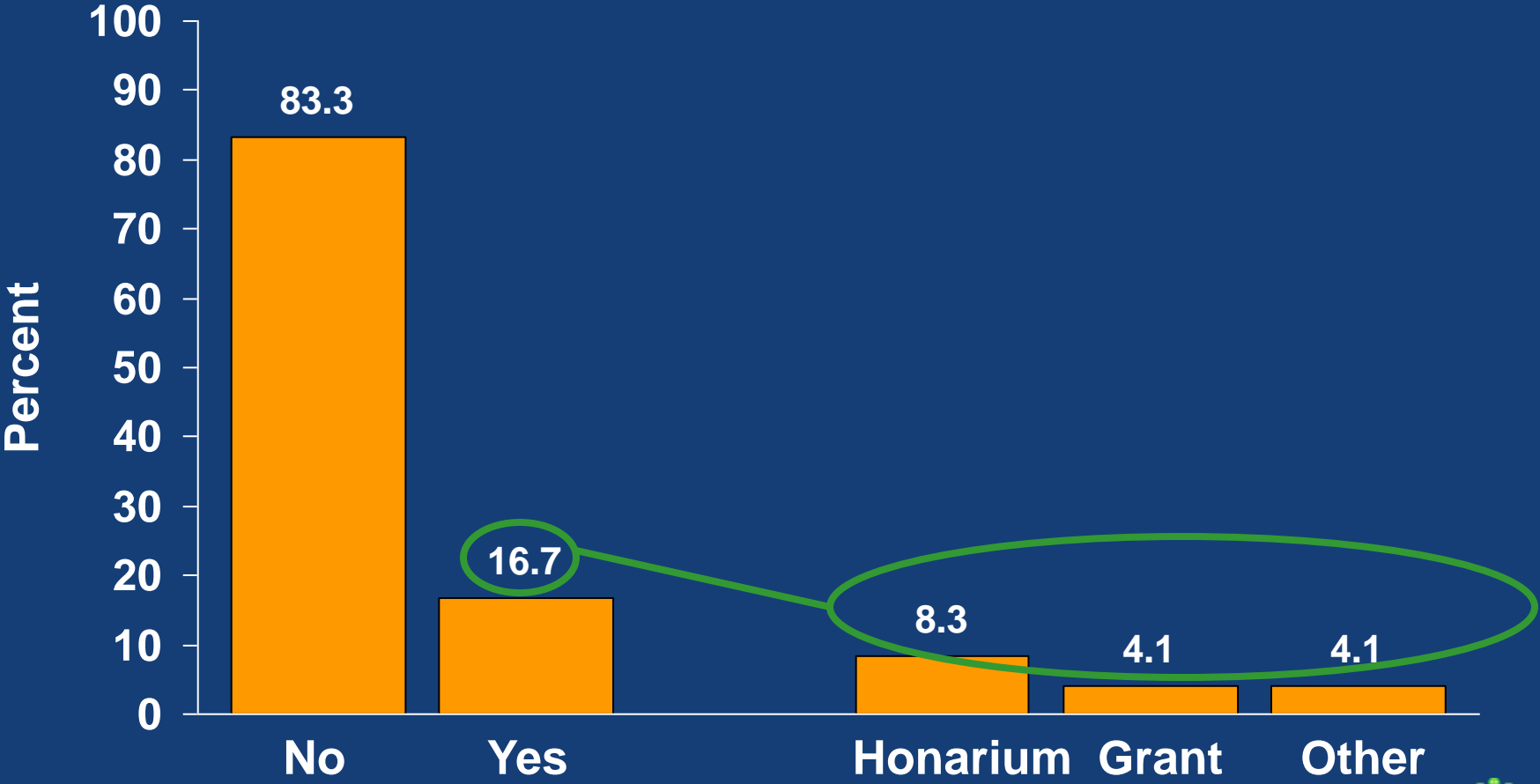
All that applied were marked (n = 24)

Point of Author's Involvement in Development

| Response | Percent |
|-----------------|---------|
| Concept | 91.6% |
| Outline | 8.3% |
| Completed draft | 0.0% |

N = 24

Author Compensation



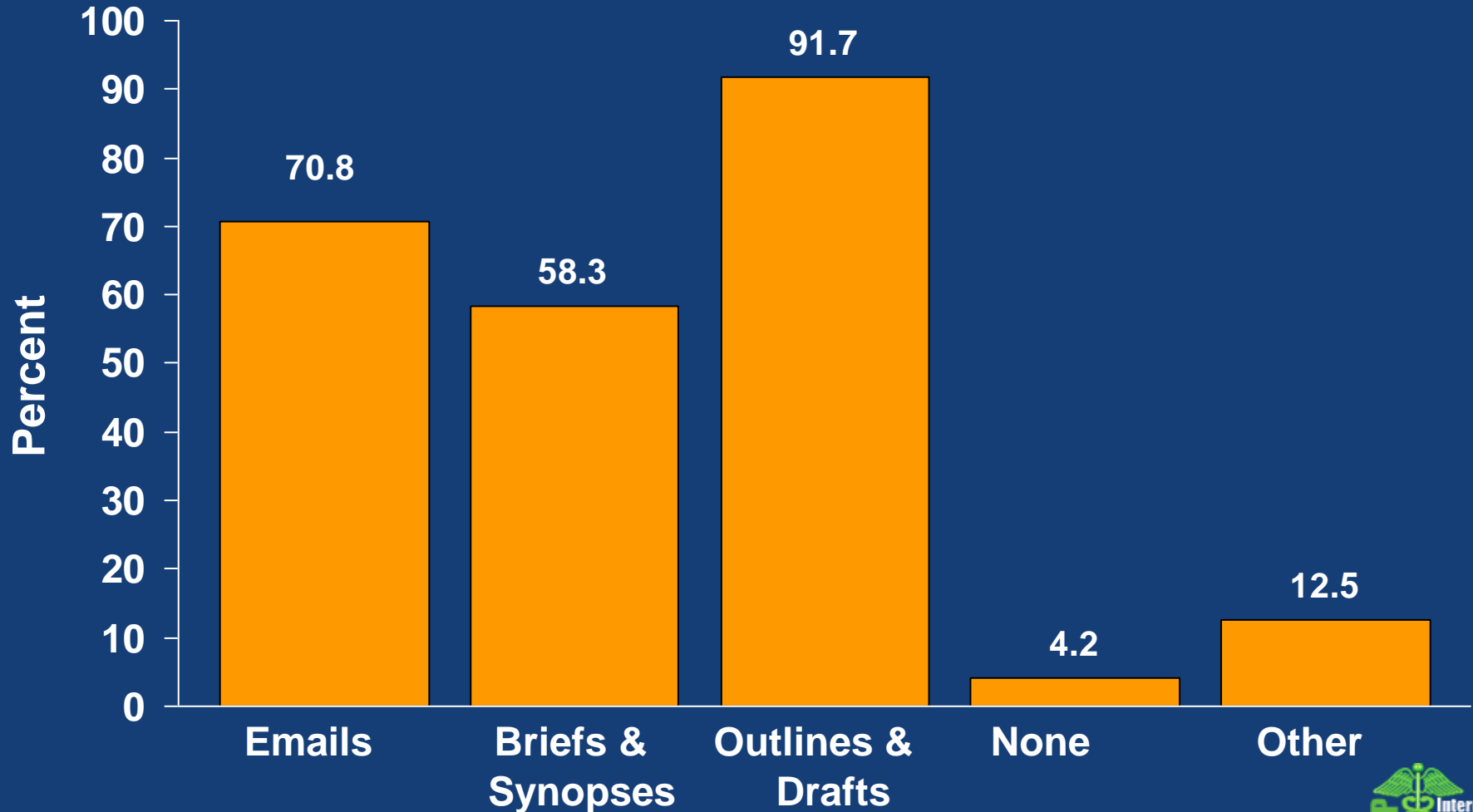
N = 24

Author's Input Captured

| Response | Percent* |
|------------------------|----------|
| Email | 79.2% |
| Verbal exchange | 70.8% |
| Formal signed document | 50% |
| Other | 25.0% |

*All that applied (n = 24)

Documenting Authors' Input



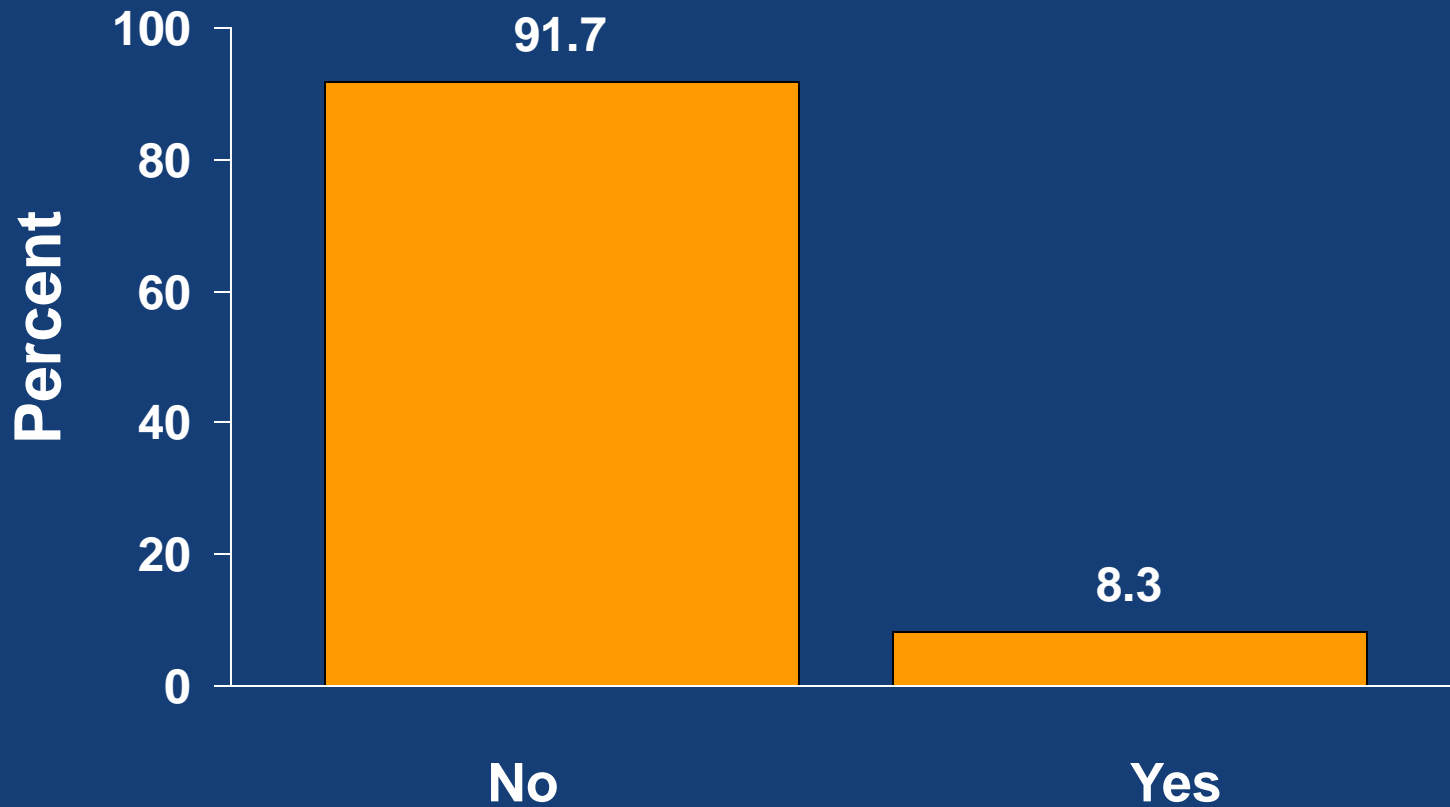
All that applied were marked (n = 24)

Disclosure Statement

| Response | Percent* |
|--|----------|
| Yes | 91.7% |
| No | 8.3 |
| Disclosure Statement Specifics | |
| Study Funding | 100% |
| Editorial Support Funding | 77.3% |
| Medical Writer Funding | 77.3 |
| In-house writer/editor acknowledgement | 77.3 |

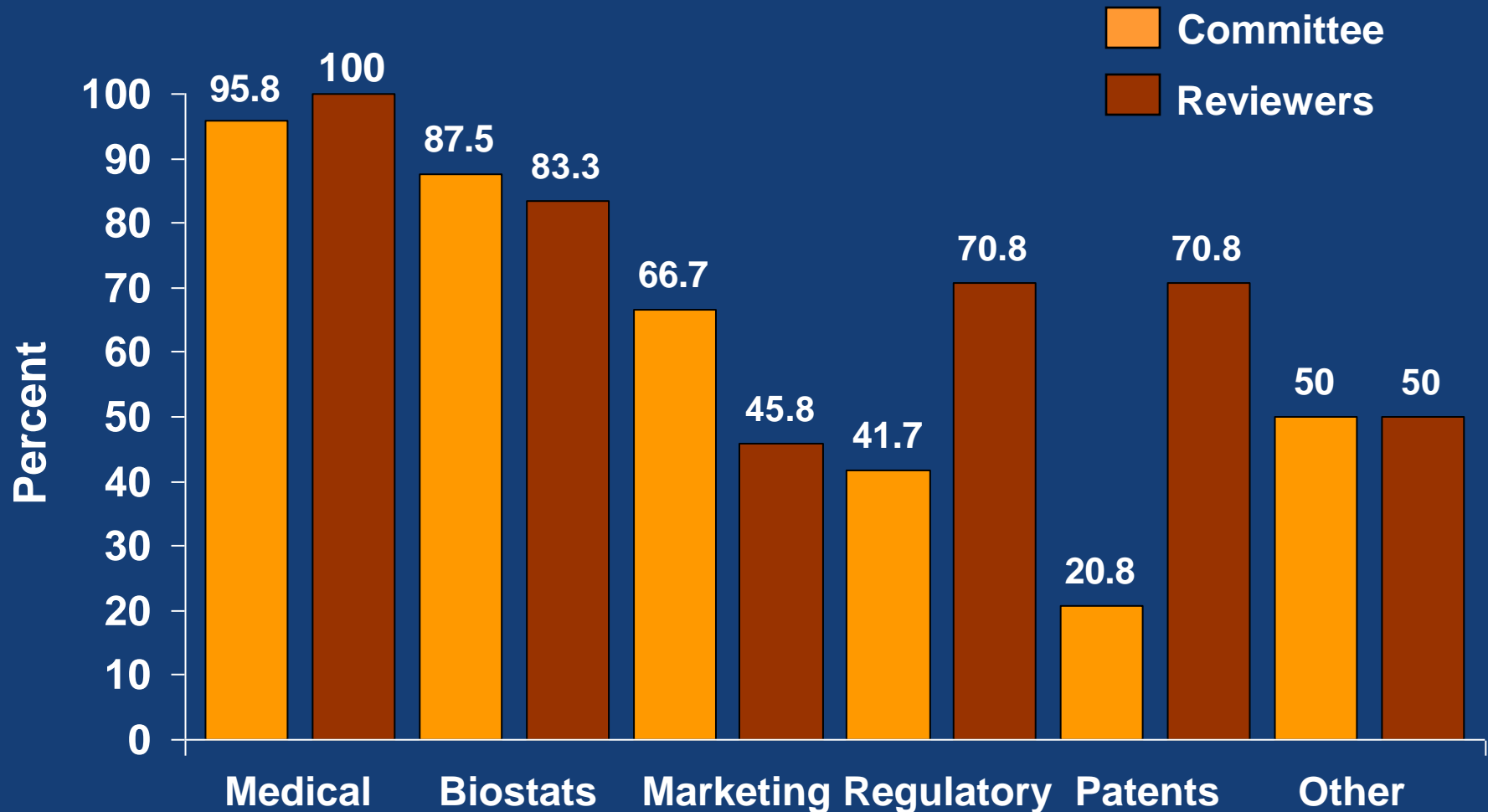
*All that applied were marked (n = 24)

Internal Author Limits



N = 24

Publication's Committee Members and Reviewers



All that applied were marked (n = 24)

Strategy & Tactical Development

| Response | Percent* |
|---------------------------------|----------|
| Medical Objectives | 87.5 |
| Independent Gap Analysis | 75.0 |
| Editorial Board Recommendations | 58.3 |
| Marketing Objectives | 54.2 |
| Field Medical Input | 54.2 |
| Other | 29.2 |

*All that applied were marked (n = 24)

Archiving

| Response | Percent* |
|--------------------------------|----------|
| In-house central archives | 65.2 |
| External communications agency | 39.1 |
| Stored locally on computer | 34.8 |
| Other | 21.7 |
| Off-site central archive | 17.4 |

*All that applied were marked (n = 24)

Internal Auditing Process



N = 24

Limitations

- Small sample size (N=63)
- Limited to ISMPP members
- Limited number of questions and domains
- Questions limited by a lack of common terminology

Next Steps

- Expand survey
 - Include non-ISMPP members
- Expand focus to include medical communication agencies
- May consider conducting annual survey to gather longitudinal data on current medical publication practice

Areas for Concern and Improvement

- Transparency statement acknowledging:
 - Editorial support funding
 - Medical writer funding
 - In-house writer/editor
- Publication Committee
 - Unable to assess marketing's role
 - Was it limited to broad strategic discussions
- Publications Review
 - Marketing's involvement is a risky practice
- Auditing process
 - 63% did not have an internal process
 - Not having an internal audit is a risky practice

Conclusions

- First step in establishing a benchmark
- Respondants/ISMPP members are striving towards standardized best-practices despite negative perceptions
- Room for improvement