

22nd Annual Conference of the National Task Force
on CME Provider/Industry Collaboration

COLLABORATING TO IMPROVE PROFESSIONAL EDUCATION AND HEALTH OUTCOMES



Current Perspectives and Trends in Commercial Support of CME: Perspectives from Industry

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Disclaimer

- The comments and contents of today's discussion on the PACME Benchmarking Working Group Surveys are those of the presenters and are solely based on the survey data and its interpretation.
- Comments do not represent individual company perspectives or data.
- Survey results are a sampling and for information purposes only.

PACME Benchmarking Working Group

- Co-Chair, Kristan Cline, Janssen Scientific Affairs, LLC
- Co-Chair, Sharon Park, Astellas Pharma Global Development, Inc.,
- Peg Bollella, sanofi-aventis U.S.
- Sue Garnett, Celgene
- Kevin Harris, Millennium: The Takeda Oncology Company
- Patty Jassak, Astellas Pharma Global Development, Inc.
- Samantha Lansdowne, Daiichi Sankyo, Inc.
- Pamela Mason, Astra-Zeneca
- Suzette Tomaska, Purdue Pharma L.P.

PACME and Alliance for CME Leadership:

- Hilary Schmidt, sanofi-aventis U.S., PACME Chair
- Germaine Aprill, PACME Chair-Elect
- Debrah Fisher, Manager, Member Services, Alliance for CME

PACME Benchmarking Work Group

- Benchmark practices and processes related to industry funding of educational grants
 - Company processes and policies
 - Budget trending
 - Compliance
 - Communications with providers
 - Educational outcomes assessment
 - Monitoring supported activities
 - Industry IME department educational/training needs

How do Industry Supporters...

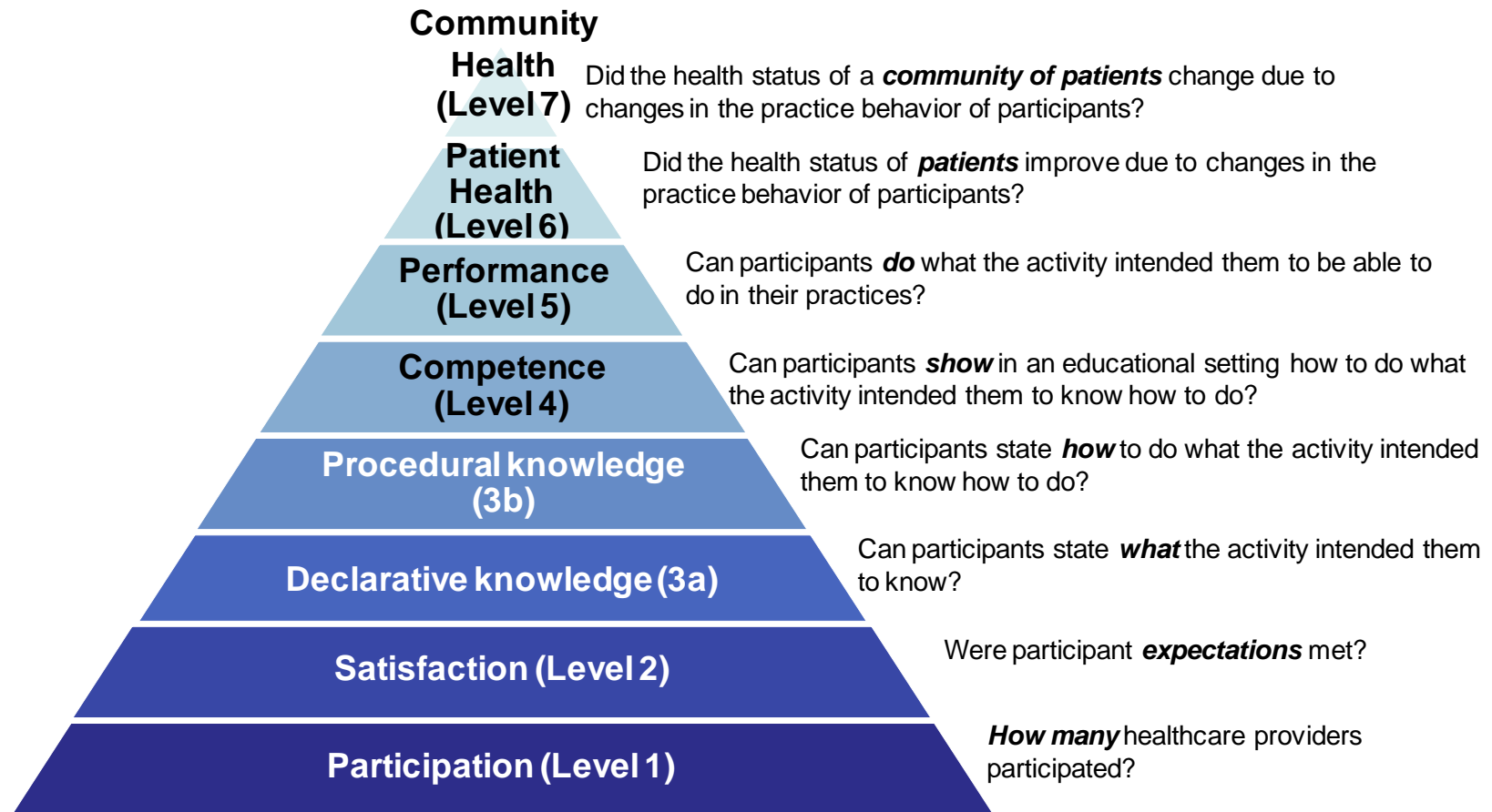
- ...evaluate the potential that a grant request will improve healthcare provider performance and quality of patient care?
- ...evaluate the balance, educational quality, and scientific accuracy of supported activities?
- ...uphold the independence of supported education?
- ...assess appropriate use of funds?

Surveys Fielded

- Annual Benchmarking Survey
 - Fielded April 2010
 - 53 questions; Response Rate: 59% (32/54)
- Educational Outcomes, Planning, and Assessment Survey
 - Fielded December 2010
 - 26 questions; Response Rate: 38% (21/56)
- Monitoring Survey
 - Fielded March 2011
 - 33 questions, Response Rate: 50% (27/54)
- Second Annual Benchmarking Survey
 - Fielded July 2011
 - 54 questions, Response Rate: 50% (28/56)
 - Note, due to a skip pattern error there were 6 surveys that were incomplete

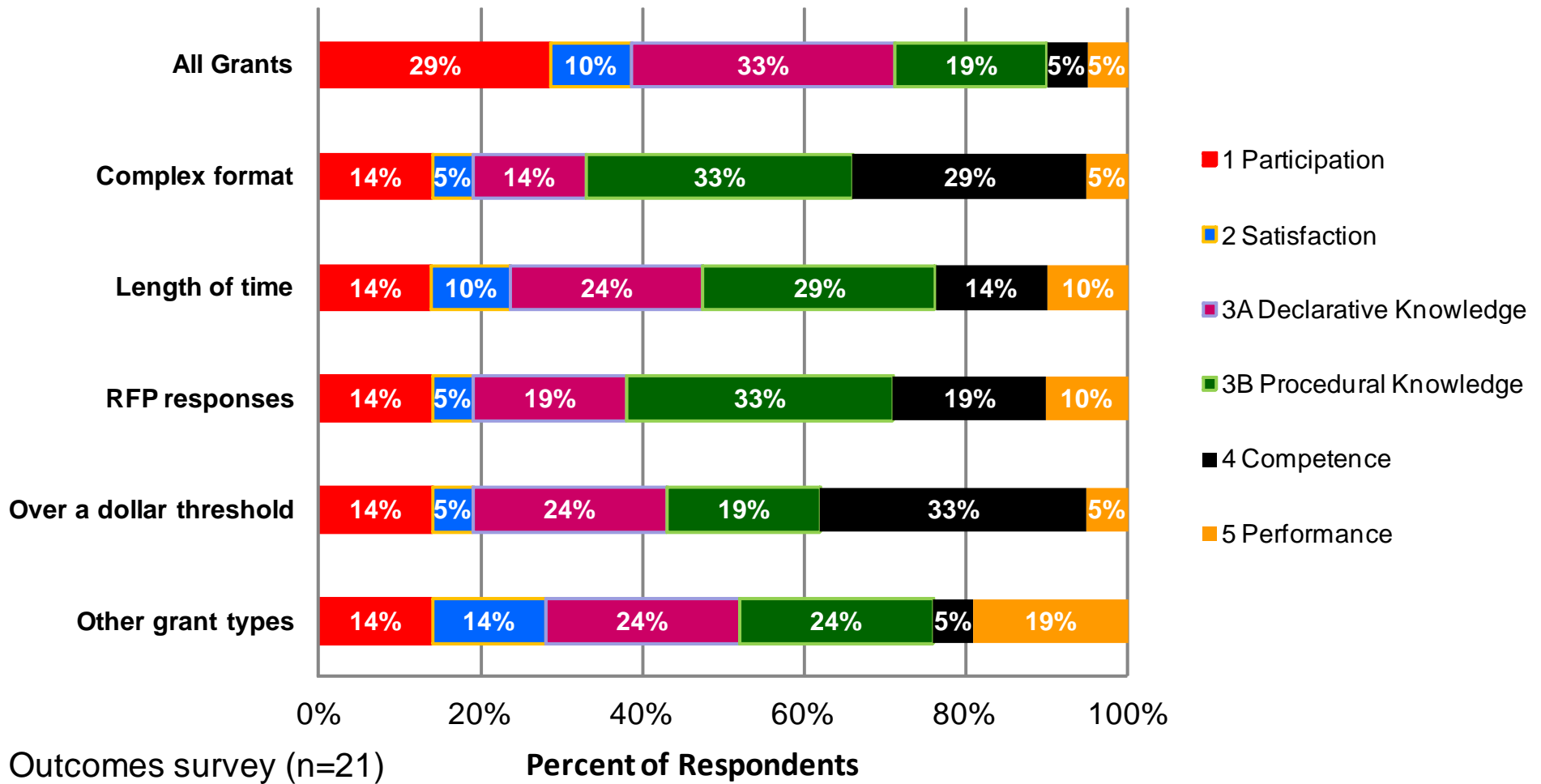
Evaluation of Grant Applications and Potential for Educational Effectiveness

Measuring IME Quality and Impact

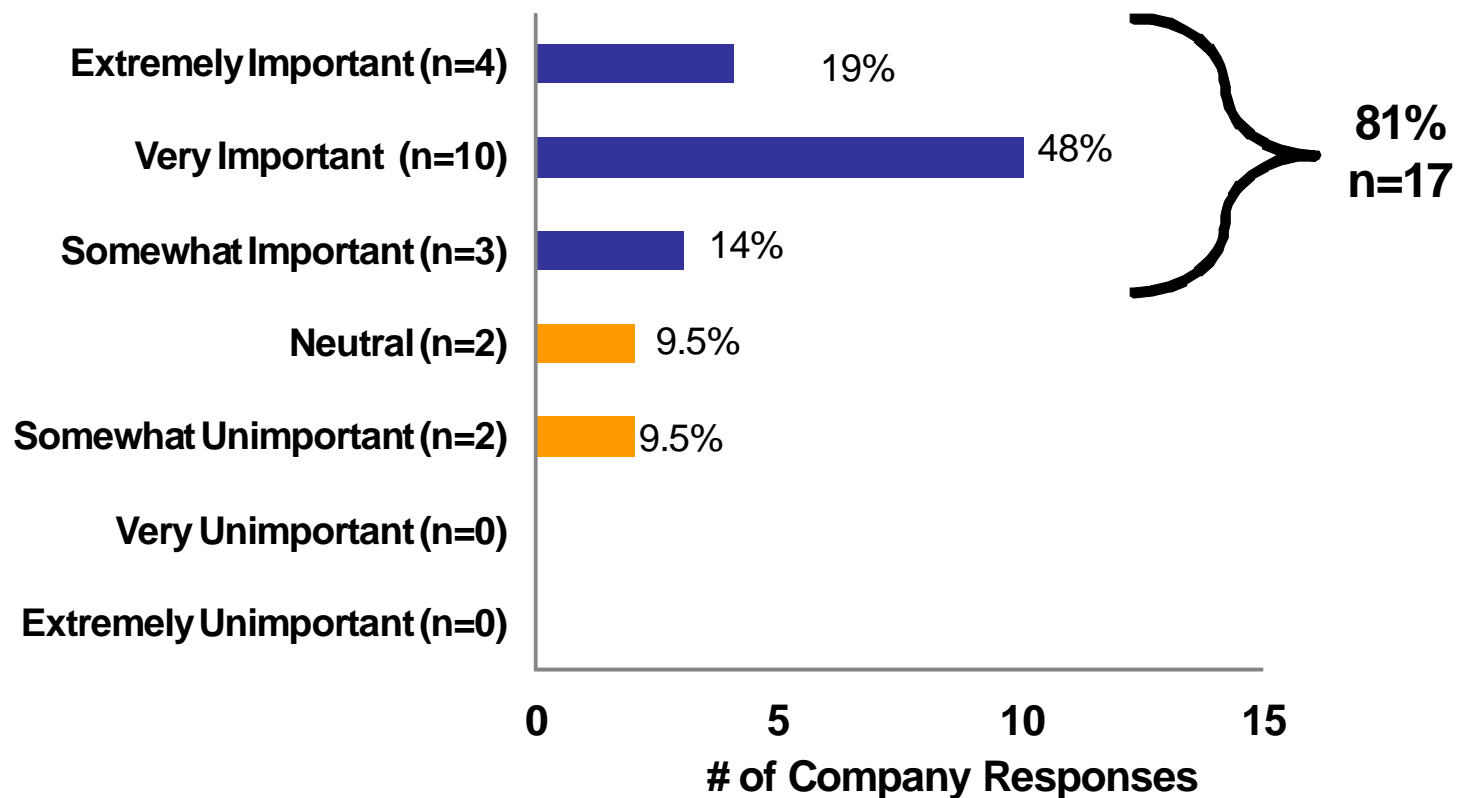


Moore DE Jr, Green JS, Gallis HA. Achieving desired results and improved outcomes: integrating planning and assessment throughout learning activities. *JCEP*. 2009 Winter;29(1):1-15.

Companies Expect a Minimum Level of Outcomes

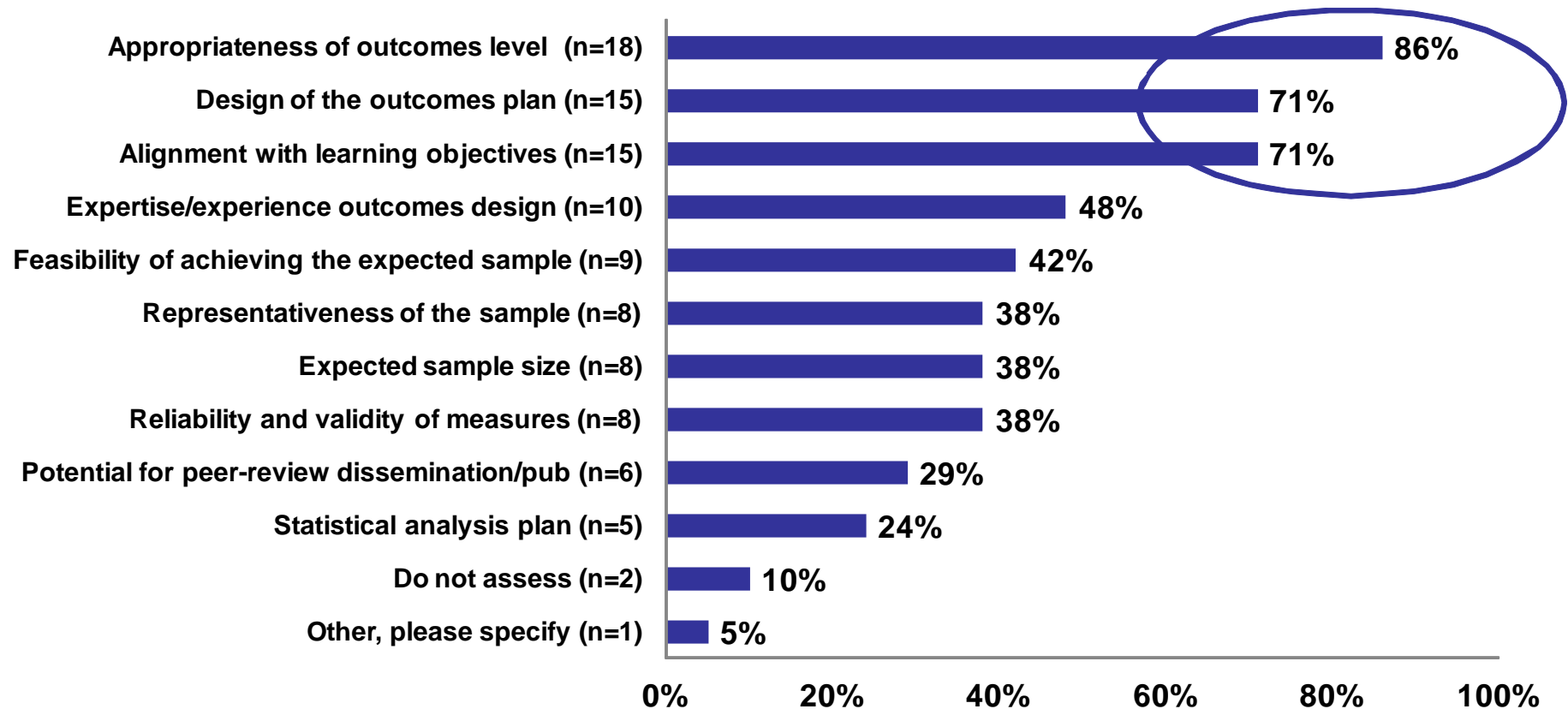


Importance of Outcomes Assessment Plan Quality on Funding Decisions



Outcomes survey (n=21)

Criteria Used to Assess Outcomes Assessment Plan Quality



Outcomes survey (n=21*)

* Due to an Error in the questionnaire, 5 respondents could select only 1 response

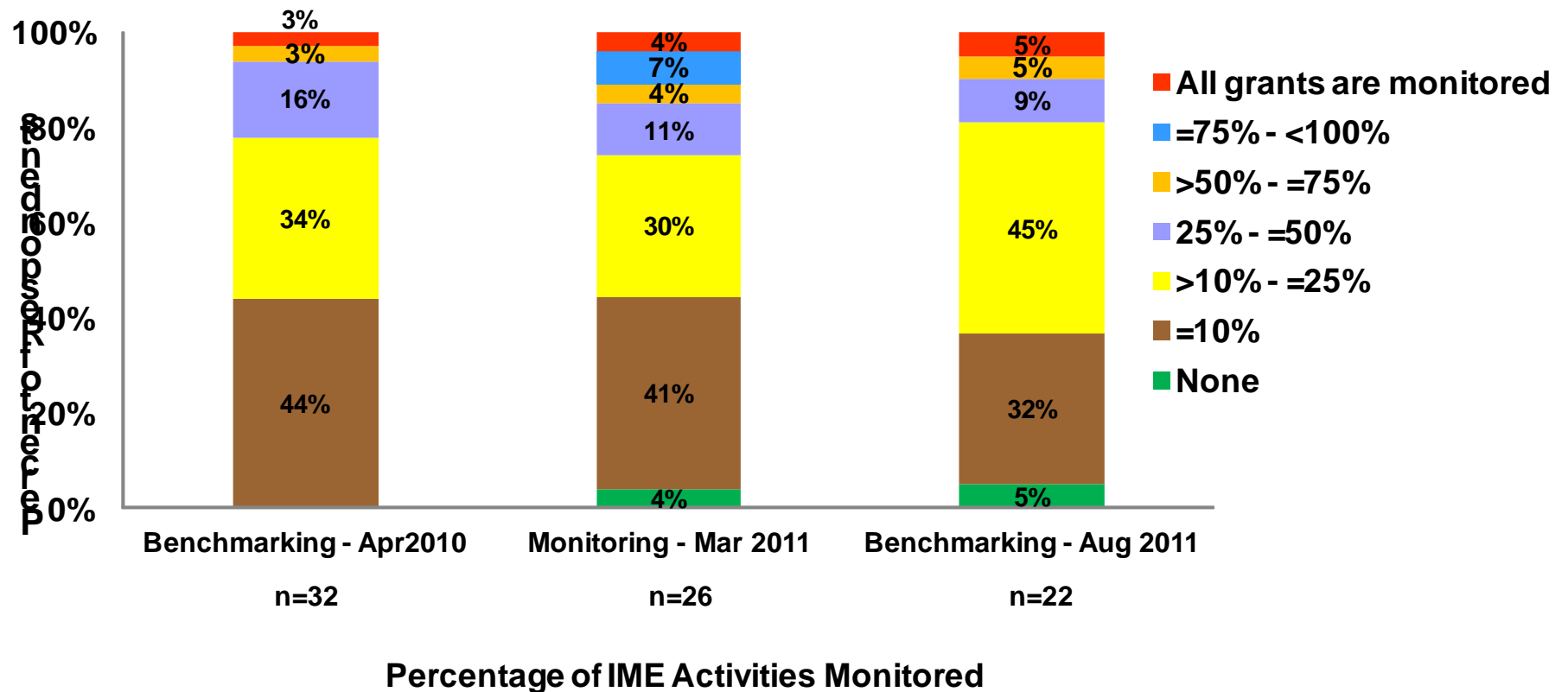
Evaluation of Balance, Educational Quality, and Scientific Accuracy

Most Companies Monitor Supported Activities

- Company personnel attendance or completion of activities to assess whether the supported activity is accurate, evidence-based, unbiased, and aligned with the approved grant request (consistent with ACCME guidelines).
 - 96% (n=26) monitor some supported activities
 - 62% (n=16) require (LOA or website) that the commercial supporter reserves the right to monitor supported IME activities
- Monitoring is performed by:
 - IME department staff (85%; n=22)
 - Field Medical Liaisons (54%; n=14)
 - Medical & Scientific Affairs (38%; n=10)
 - Compliance (31%; n=8)

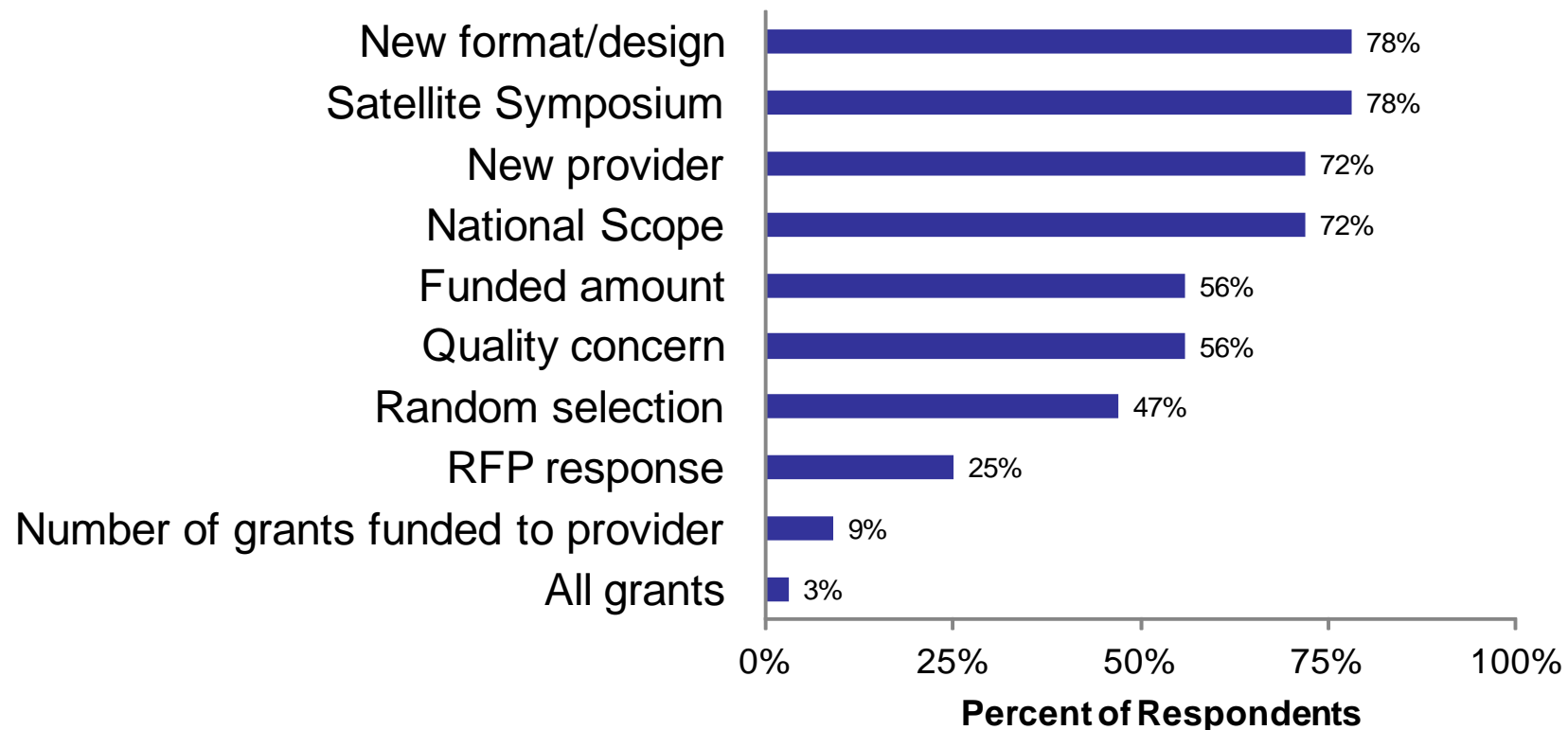
Monitoring survey (n=27)

Increasing Proportion of Activities are Monitored



Criteria to Select Activities for Monitoring

Percent Rated as "Very" or "Somewhat" Important



More than 1 answer possible

Monitoring survey (n=27)

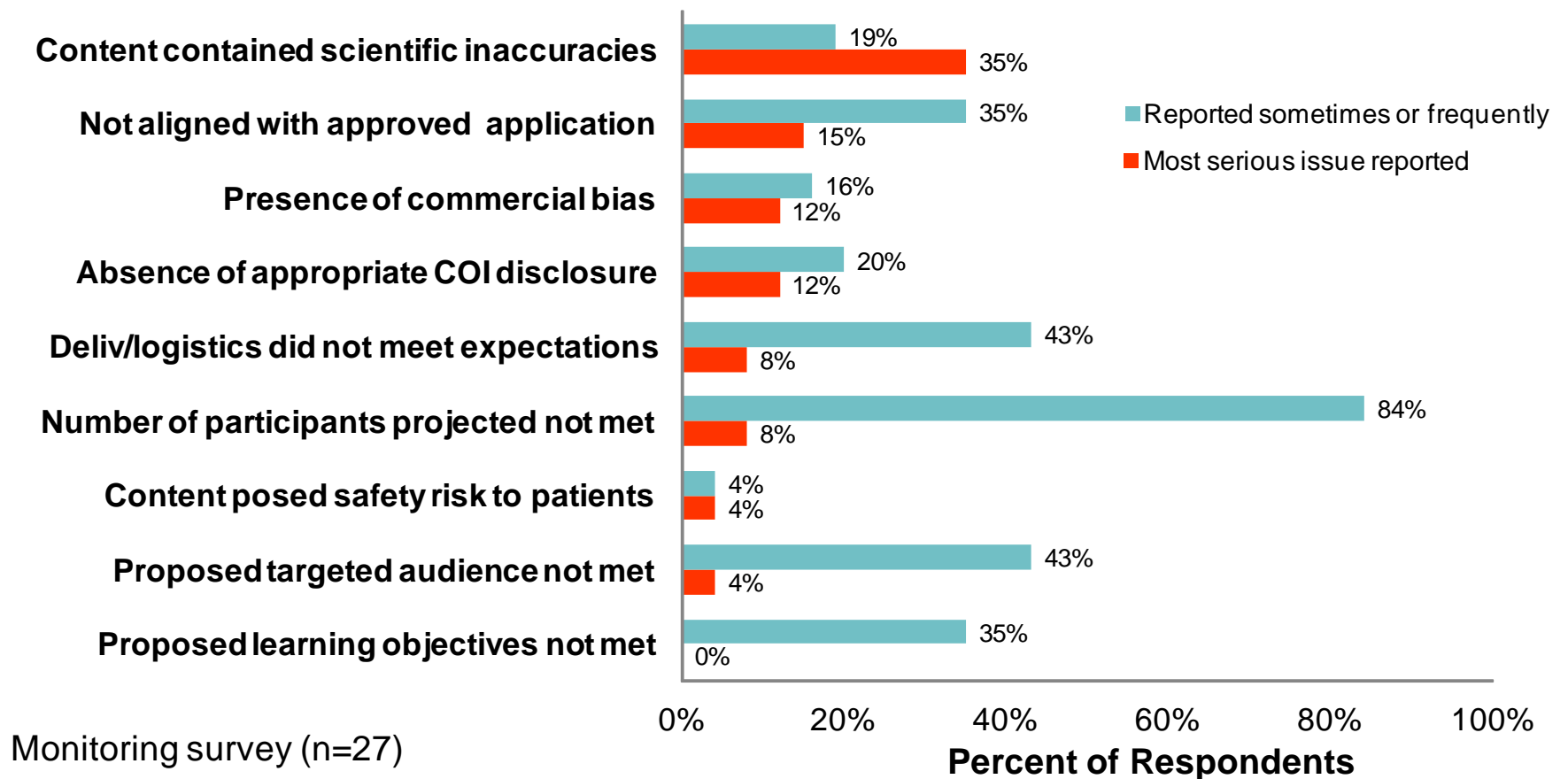
Routinely Monitored Elements

	n	%
Educational objectives were met	24	92%
Consistent with PhRMA, ACCME and company guidelines	23	88%
Presence of bias	22	85%
Appropriate disclosures are made	20	77%
Number of participants	18	69%
Discussion of off label use of treatments is clearly identified	17	65%
Capability and knowledge of faculty	17	65%
Appropriateness of venue	15	58%
Content accuracy	14	54%
Presentation of safety data for all therapeutic options discussed	12	46%
Participant composition (MDs, RNs, PharmD, etc.)	10	38%
Other, please specify	3	12%

More than 1 answer possible

Monitoring survey (n=27)

Issues Reported “Sometimes” or “Frequently” Most Serious Issues Reported



Post Activity Action and Communication of Findings

Actions Taken by Companies: Post Activity Completion

- Activity not aligned with approved grant application (methods, design, and content)
 - 38% (n=10/27) verbally communicate to provider
 - 23% (n=6/27) send a written communication to provider
 - 31% (n=8/27) unable to receive new grant funds
 - 19% (n=5/27) notify internal legal/compliance
- Final outcomes assessment plan not aligned with approved application*
 - 100% (n=16/16) consider when evaluating new requests
 - 75% (n=12/16) require a rationale
 - 44% (n=7/16) report discrepancy internally

Outcomes survey (n=21)

Monitoring survey (n=27)

*Question asked for companies (n=16) that reconcile the outcomes plan

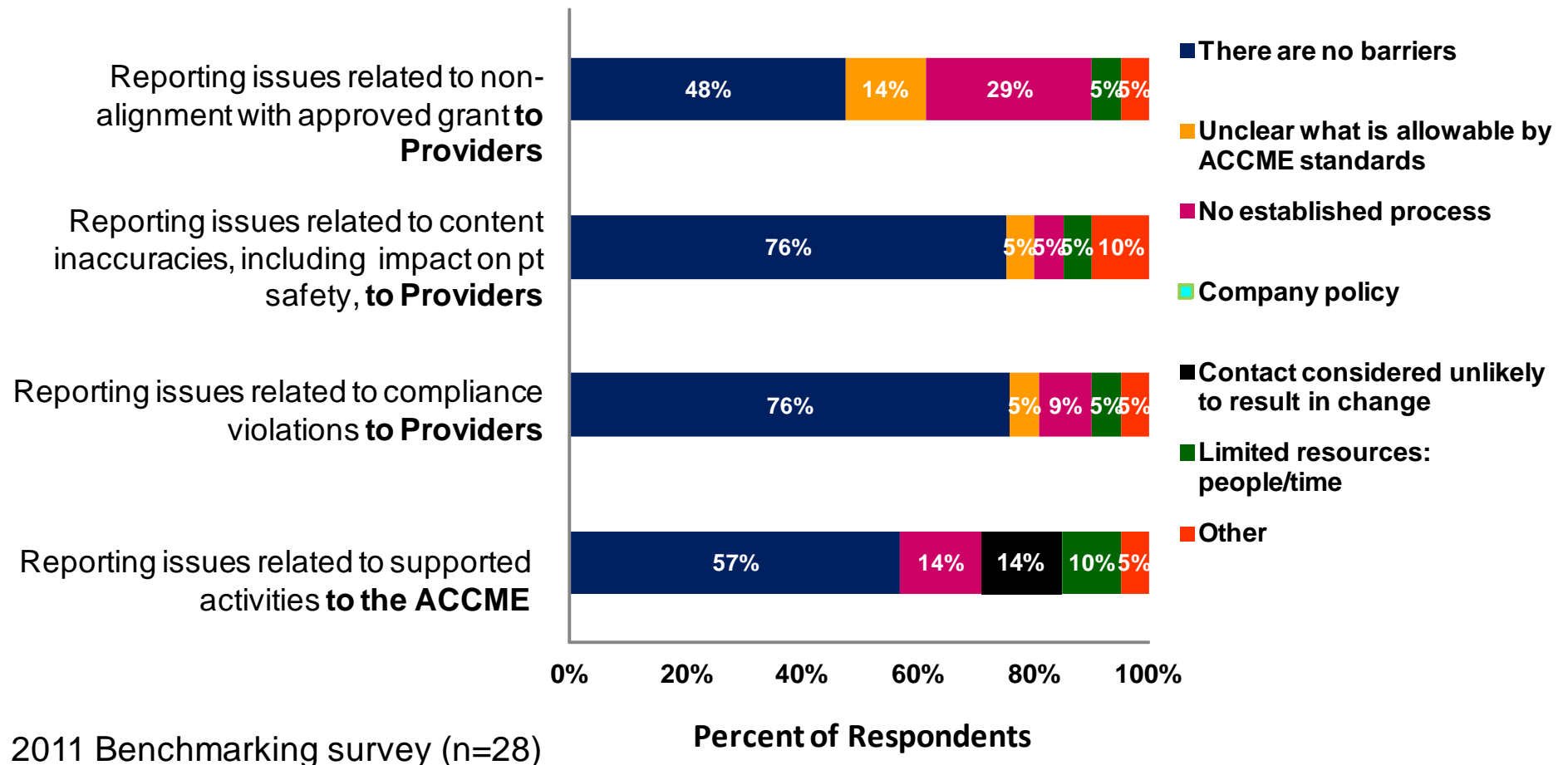
Actions Taken Following Monitoring Findings

Actions Taken By Commercial Supporters									
	Do not communi- cate	Notify ACCME	Notify internal legal/co mpliance	Grant recipient to return funds	Unable to submit new requests	Unable to receive funding for new requests	Written communi- cation to Provider	Verbal communi- cation to Provider	Other
<u>Absence of an appropriate conflict of interest disclosure</u>	15% (4)	8% (2)	19% (5)	0% (0)	0% (0)	12% (3)	38% (10)	42% (11)	15% (4)
<u>Presence of commercial bias (assessed by company personnel)</u>	12% (3)	8% (2)	27% (7)	0% (0)	0% (0)	19% (5)	54% (14)	38% (10)	8% (2)
<u>Content contained scientific inaccuracies</u>	8% (2)	4% (1)	31% (8)	0% (0)	4% (1)	15% (4)	62% (16)	35% (9)	15% (4)
<u>Content included inaccuracies that posed a safety risk to patients</u>	8% (2)	27% (7)	38% (10)	0% (0)	4% (1)	27% (7)	62% (16)	42% (11)	19% (5)

Monitoring survey (n=27)

PLEASE NOTE: More than 1 response allowed for each question

Assessment of Barriers Related to Reporting Findings



Actions Taken When Supported Activities Fail to Meet Established Standards

- Most companies do not report barriers to communicating findings
 - May be more established processes for communicating content inaccuracies and compliance violations
 - Some companies unsure of communication boundaries or do not have an established process
- Commercial Supporters address serious issues in a variety of approaches
 - May reflect differences in how companies assess compliance risks
 - Trending to more formal (written) communication where there are safety and compliance concerns
 - Results are not inclusive of all possible actions

Industry is Actively Committed to Assuring that Supported Education is Impactful, Accurate, and Balanced

- Well established grant processes and trained personnel that promote quality education and compliance
- Emphasis is placed on outcomes planning and reports
 - Likelihood/actuality of improving healthcare provider competence/performance, and quality of patient care
 - Companies have increasing sophistication in evaluating both the outcomes plan and the qualifications of the provider responsible for outcomes
- Monitoring is a key component of the grant process
 - Fiduciary responsibility, evaluate balance, educational quality and scientific accuracy of supported activities
 - Compliance and safety are the most important part of monitoring

Thank You!