Out in Front – Effective Pre-approval Communication with Payers

June 2, 2020

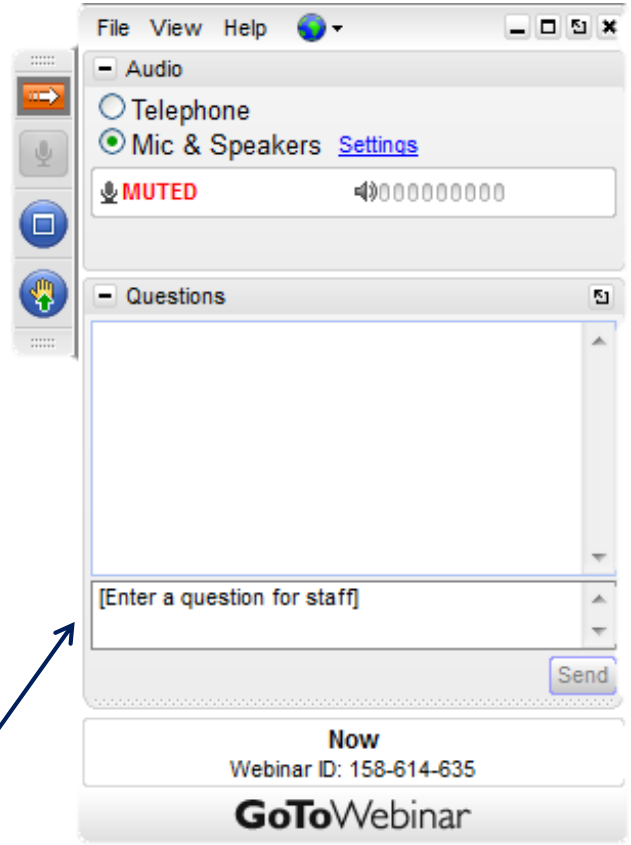
AMCP

Optimizing medicine.
Improving lives.

Disclaimer

Organizations may not re-use material presented at this AMCP webinar for commercial purposes without the written consent of the presenter, the person or organization holding copyright to the material (if applicable), and AMCP. Commercial purposes include but are not limited to symposia, educational programs, and other forms of presentation, whether developed or offered by for-profit or not-for-profit entities, and that involve funding from for-profit firms or a registration fee that is other than nominal. In addition, organizations may not widely redistribute or re-use this webinar material without the written consent of the presenter, the person or organization holding copyright to the material (if applicable), and AMCP. This includes large quantity redistribution of the material or storage of the material on electronic systems for other than personal use.

How to Ask a Question



Type your question in the 'Questions' area

AMCP

Panelists

Lisa Cashman, PharmD,
Vice President, Specialty Solutions,
MedImpact Healthcare Systems

Laura Randa, Vice President
Market Access, HEOR and
Public Policy, Mycovia
Pharmaceuticals

Jay Jackson, PharmD, MPH,
Senior Vice President,
Consulting, Xcenda

Moderator

Laurie Fazio,
Head, FormularyDecisions
Market Access Solutions &
Growth Strategies

Webinar Overview

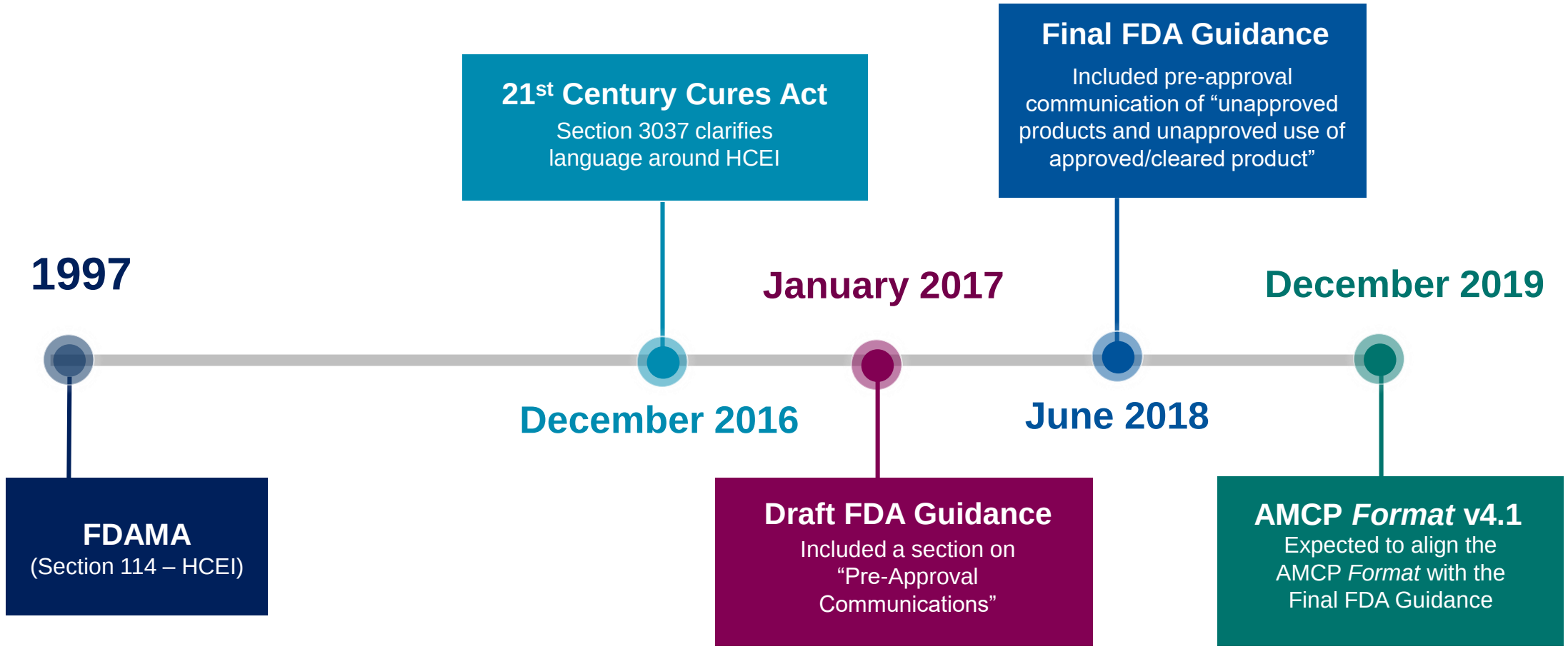
In this session, you will learn:

- The latest research, industry trends and guidelines around pre-approval information exchange (PIE)
- Payer perspectives on PIE that are impactful in their decision making
- Manufacturer best practices and processes for PIE to meet the needs of payers
- Virtual opportunities for key stakeholders to connect and share critical product information

Polling Question

What is your level of experience with PIE?

Legislative Evolution of PIE and HCEI Communication



Key: FDAMA – Food and Drug Administration Modernization Act; HCEI – healthcare economic information; H.R. – House Resolution; PIE – pre-approval information exchange.

Role of PIE in product development

FormularyDecisions℠ AmerisourceBergen

Manufacturers

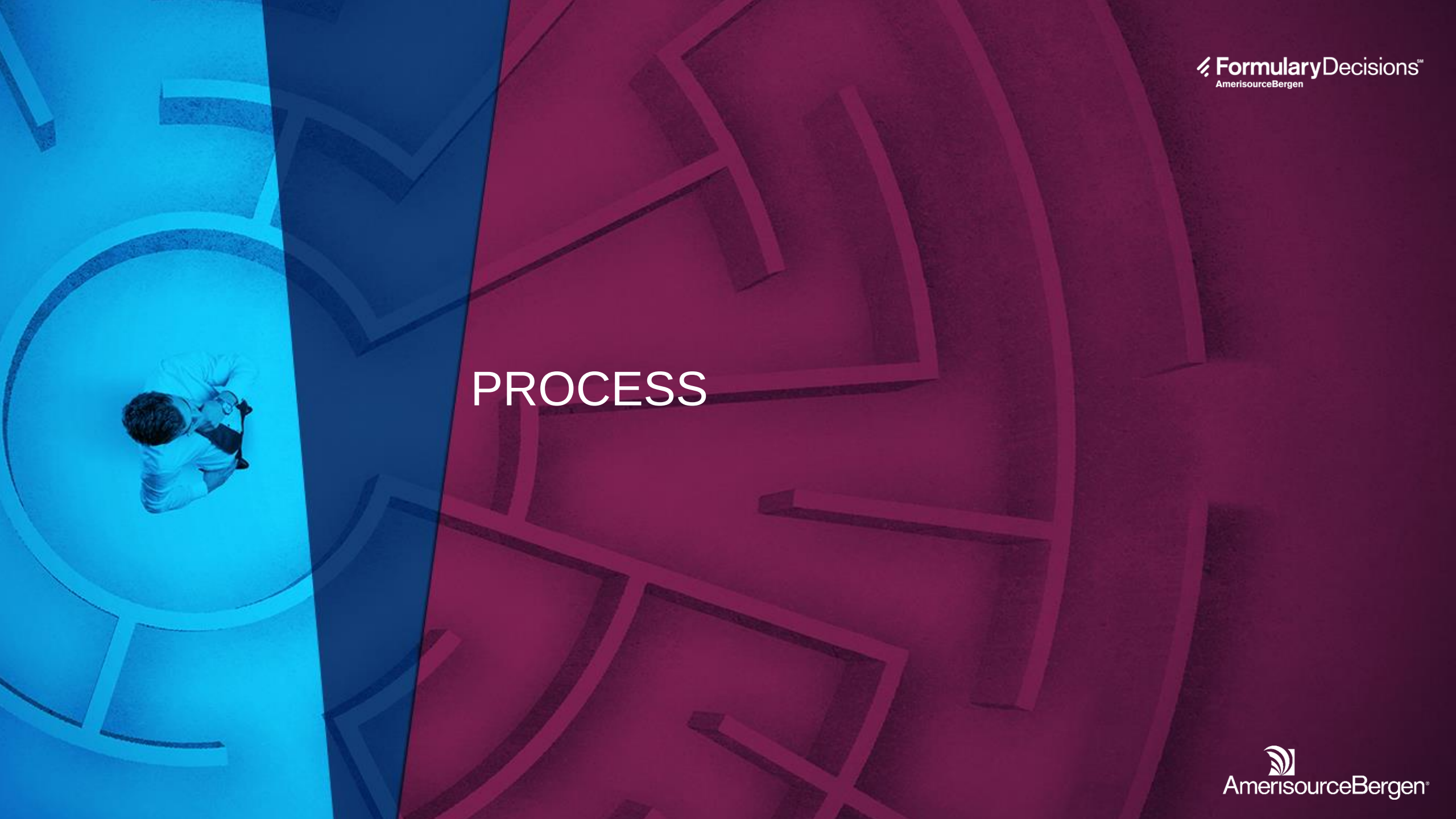
PIE addresses 3 imperatives for manufacturers:

- Allows manufacturers to communicate unbiased, factual, accurate, and non-misleading information on products or indications that have not yet been approved
- Sharing information early may result in a “place saved at the table” for their product(s)
- Opportunity for earlier communication of the product’s value story and positioning

Payers

PIE addresses 3 imperatives for payers:

- Enables accurate budgeting and forecasting for intended plan year
- Supports the opportunity to explore value-based contracting and payment models
- Allows preparation for expedited approval pathway therapies, as well as the opportunity to discuss and prepare for other innovative therapies

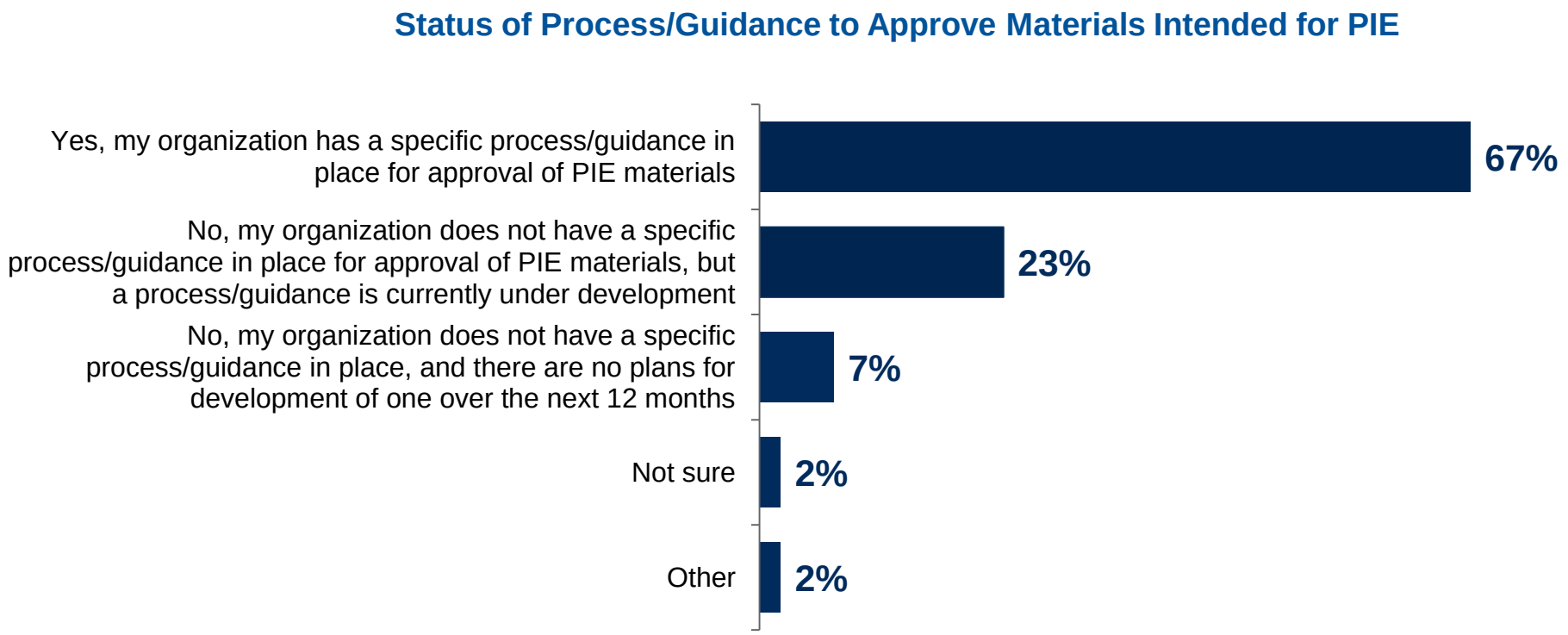


PROCESS

FormularyDecisions℠
AmerisourceBergen

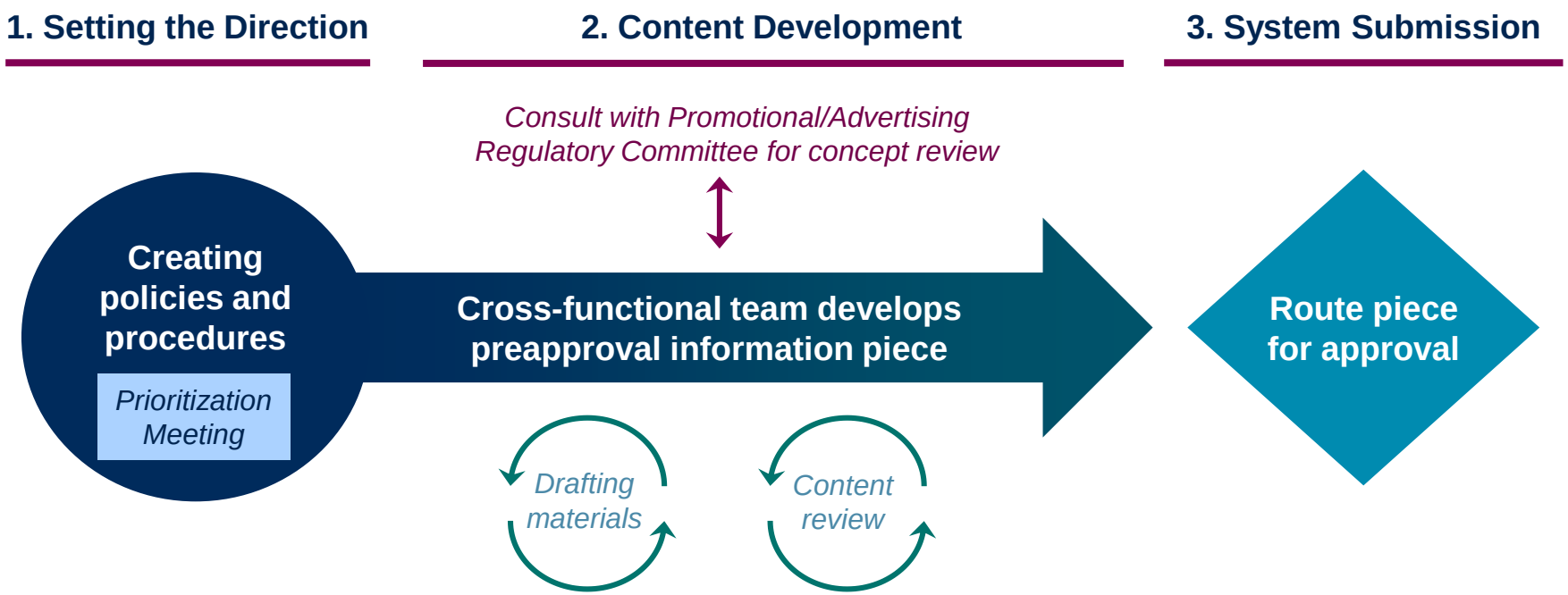
AmerisourceBergen®

Two-thirds of manufacturers have a process/guidance for approval of PIE materials



Note: Percentages may not total 100% due to rounding. 1 respondent selected “Other” (No, my organization does not have a specific process/guidance in place for approval of PIE materials, but we would like to develop one).
N=57.
Q18d. Is there a specific process/guidance (eg, standard operating procedure, formal committee) in place within your organization to approve materials intended for PIE?

Illustrative PIE Operating Procedure

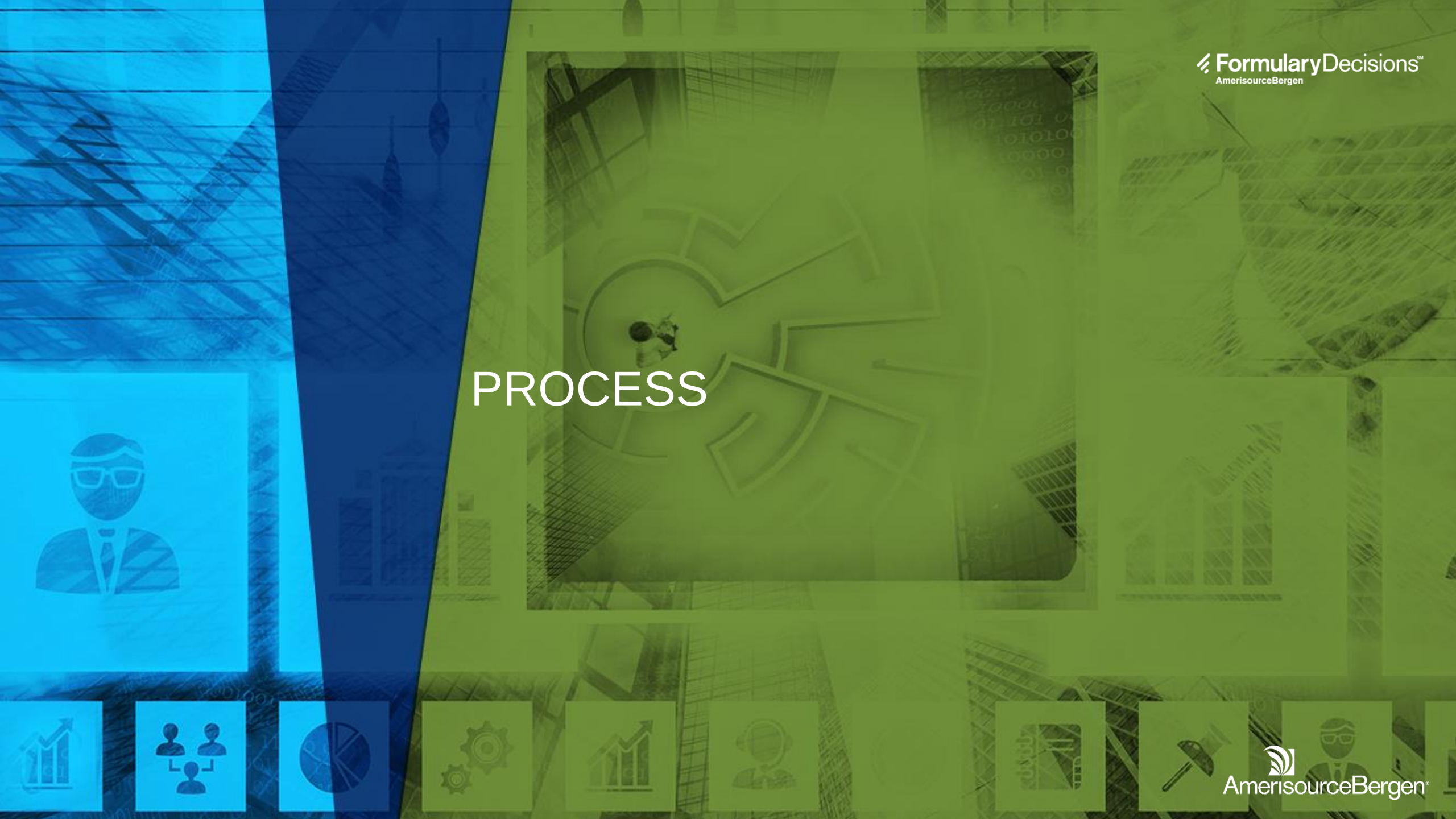


Potential interaction points between content creators and reviewers

Potential interaction point between teams and Medical, Legal, Regulatory and Promotional/Advertising Regulatory Committee

FormularyDecisions℠
AmerisourceBergen

PROCESS

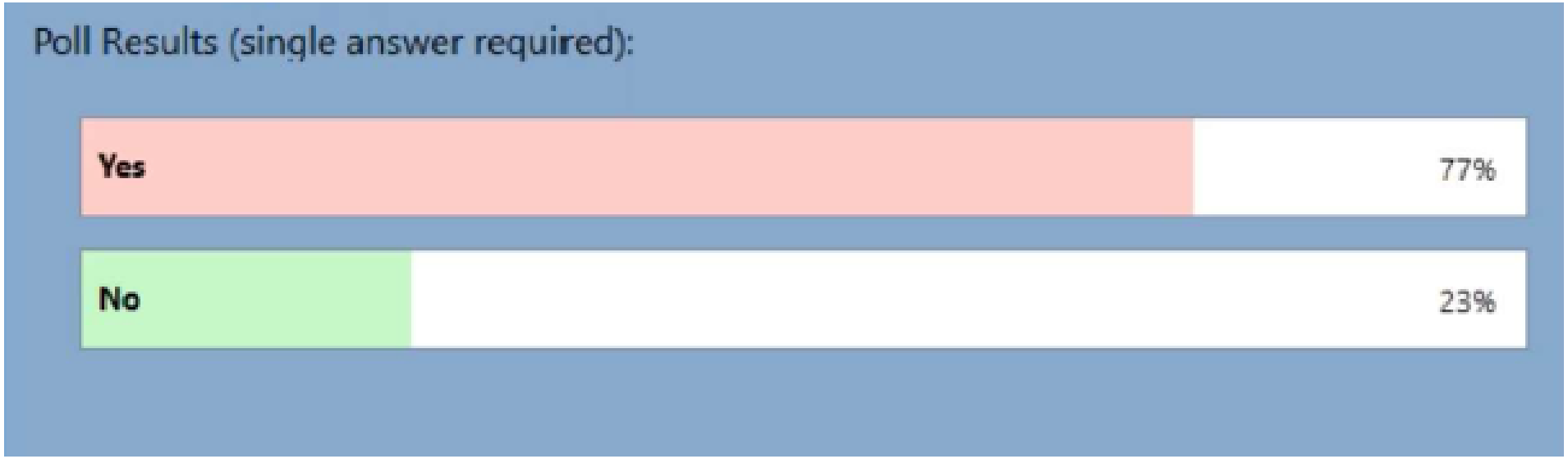


AmerisourceBergen®


FormularyDecisions℠
AmerisourceBergen
PLANNING
AmerisourceBergen®

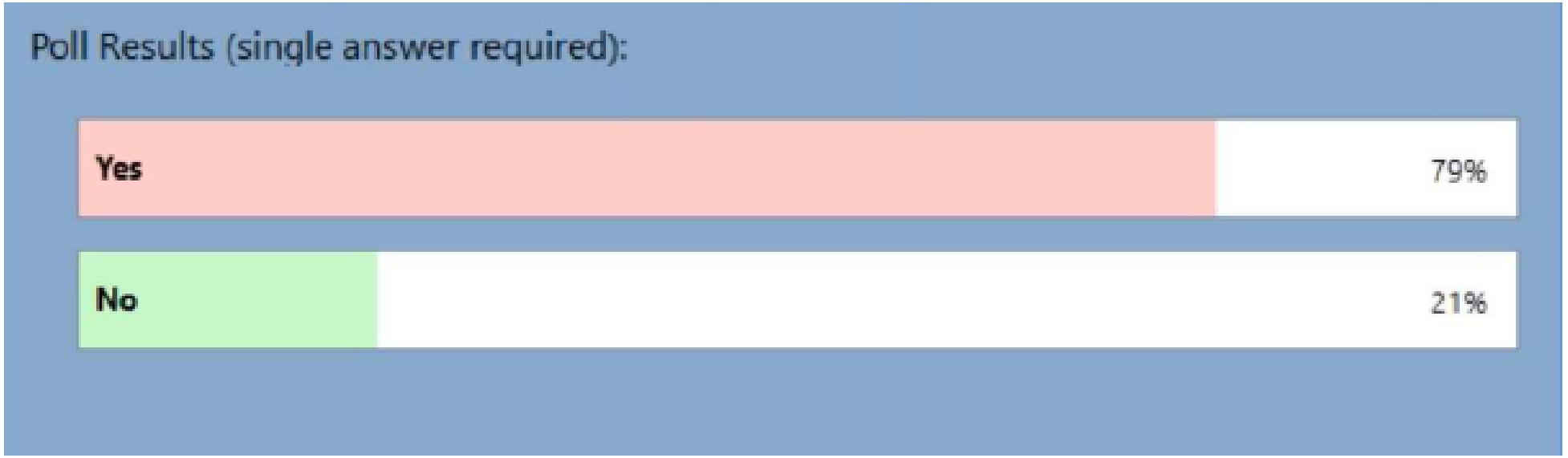
Polling Question for Manufacturers

Have you included PIE in your launch strategy?



Polling Question for Payers

Is there is a gap between the PIE you require and the information you are currently receiving from manufacturers?

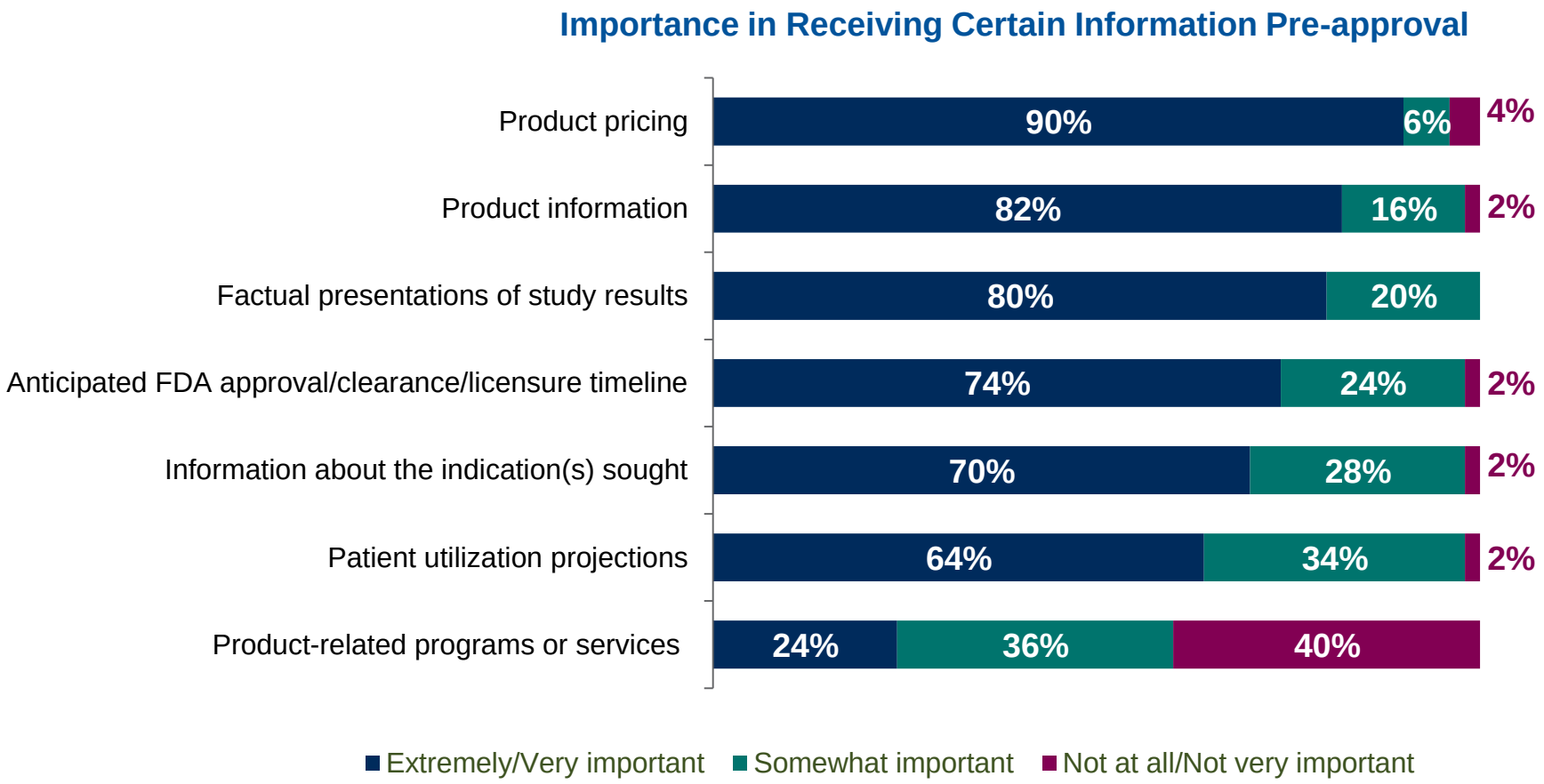


Considerations for PIE roadmap

Manufacturers should engage with payers at least 12–18 months in advance of FDA approval to better understand payer needs

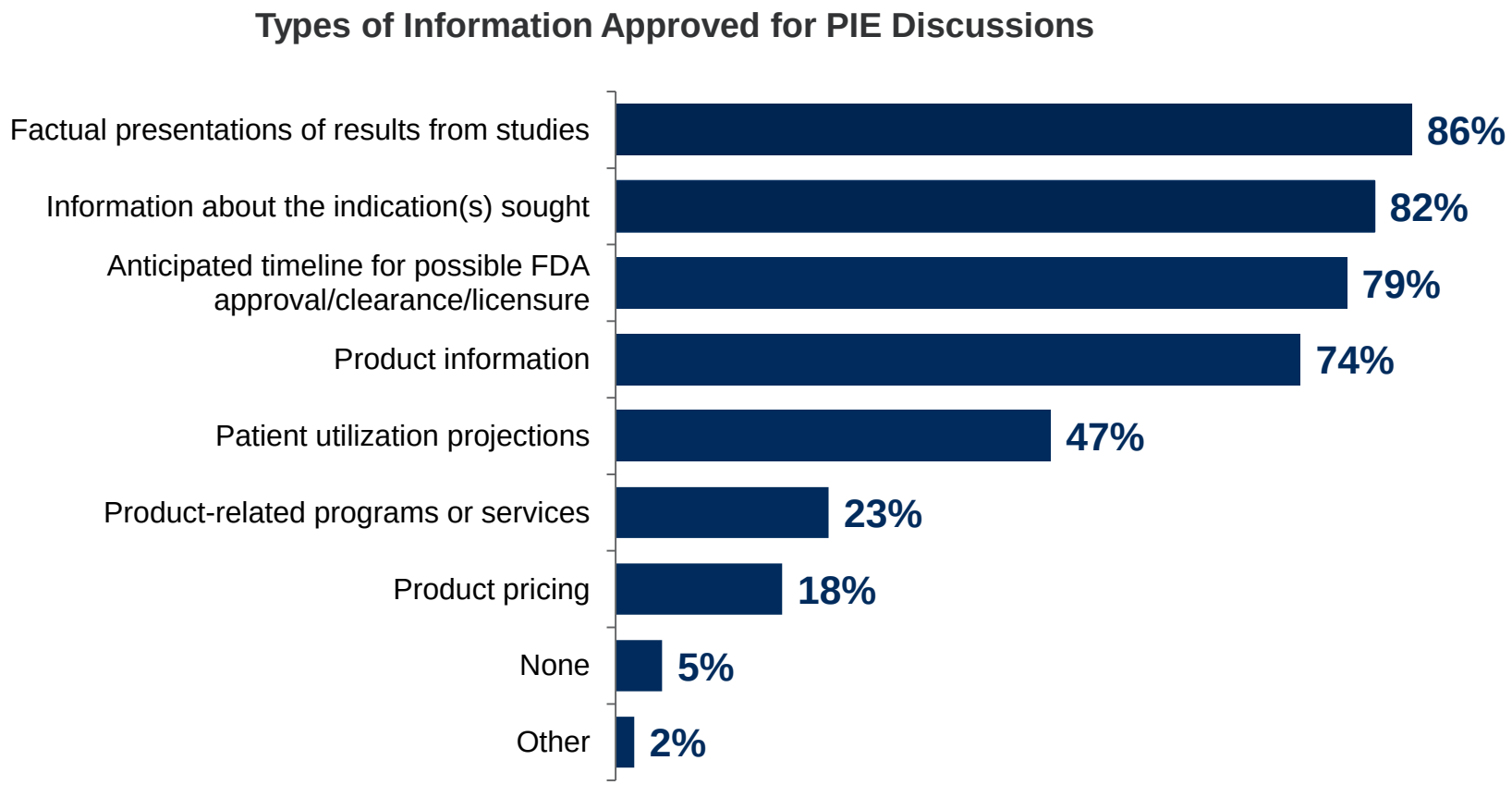

FormularyDecisions℠
AmerisourceBergen
EXECUTION OF PIE
AmerisourceBergen®

Payers consider product pricing, general product information, and study results the most important types of pre-approval information



Note: Percentages may not total 100% due to rounding.
N=50.
Q16a: For each of the following, please rate the level of importance to your organization in receiving this information proactively and prior to approval from a manufacturer.

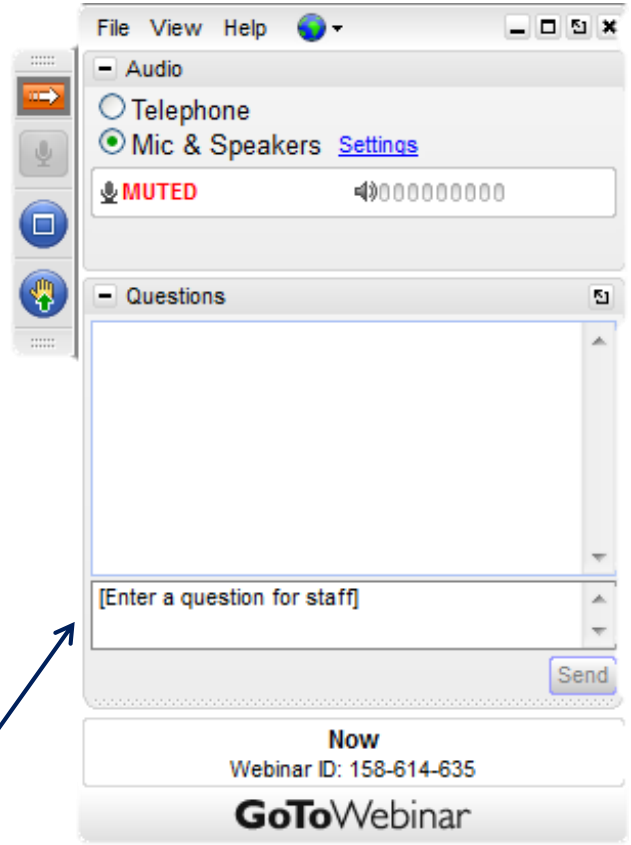
What manufacturers are delivering…



Note: 1 respondent selected “Other” (Distribution strategy/REMS plans [if applicable]).
N=57.
Q20. Which, if any, of the following types of information about investigational products are approved in your organization for PIE discussions with eligible entities?

Questions?

How to Ask a Question



Type your question in the 'Questions' area

AMCP

What do the next 3-5 years look like?

AMCP

Thank You

Lisa Cashman, PharmD,
Vice President, Specialty Solutions,
MedImpact Healthcare Systems

Laura Randa, Vice President
Market Access, HEOR and
Public Policy, Mycovia
Pharmaceuticals

Jay Jackson, PharmD, MPH,
Senior Vice President,
Consulting, Xcenda
Jay.Jackson@xcenda.com

Laurie Fazio,
Head, FormularyDecisions
Market Access Solutions &
Growth Strategies
Laurie.Fazio@xcenda.com

FormularyDecisions℠
AmerisourceBergen

For inquires on the FormularyDecisions platform or questions related to PIE, please:

- Email us at insights@xcenda.com
- Contact us at xcenda.com

AmerisourceBergen®

For a list of upcoming webinars, visit www.amcp.org/calendar

AMCP