



PIE Webinar

Leveraging the latest payer and manufacturer insights to enhance your company's pre-approval information exchange strategy

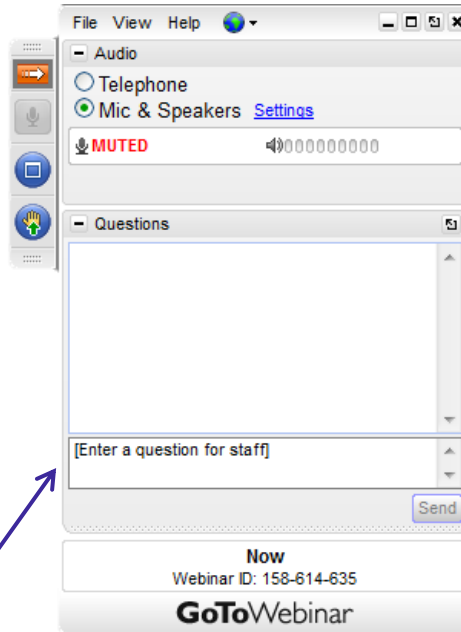
Wednesday, March 23, 2–3pm



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

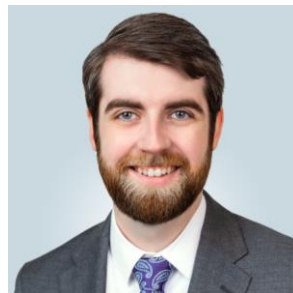
Speakers and Panelists



Charlie Dragovich,
BSPHarm
Senior Director & Client
Strategist,
Value & Access Team
Xcenda



Lisa Cashman, PharmD
Chair, Format Executive
Committee
AMCP



Adam Colborn, JD
Senior Manager, Policy and
Government Relations
AMCP

Webinar learning objectives

- Understand the evolving pre-approval information needs of payers in planning for the approval of new drugs and devices
- Review how manufacturers are developing tactics based on the Food and Drug Administration (FDA) guidance to provide payers information needed to plan for a new product approval
- Resolve ambiguity and misperceptions regarding the FDA manufacturer guidance on PIE
- Evaluate sample tactics currently being used by manufacturers and payers to evaluate pre-approval information

Checking your knowledge of PIE



True or False:

The FDA guidance specifically states that PIE is not considered promotional.



True or False:

It is estimated that over 50% of companies have procedures in place to conduct PIE.



True or False:

Account Executives, such as National Account Directors, are prohibited from discussing PIE with payers.



True or False:

No biopharmaceutical companies have been able to provide information regarding pricing until after FDA approval.



True or False:

Patient utilization projections are listed as one of the data sets that manufacturers may provide payers as part of PIE.

Speaker



Adam Colborn, JD

Senior Manager, Policy and
Government Relations

AMCP

Just introduced: Pre-approval Information Exchange Act (H.R. 7008)



- Introduced March 9 by Rep. Brett Guthrie (R-KY-02)
- Bill aimed at codifying and clarifying 2018 FDA guidance on PIE
- Top-level summary:
 - Creates legislative safe harbor for proactive PIE
 - Requires certain disclosures (not FDA approved, timeline for submission, etc)
 - Expands scope of communicable information to include HCEI and new indication-only studies
 - GAO report on PIE utilization to begin 5 years and 6 months after enactment
- Intended to attach to PDUFA VII, part of March 17 UFA hearing
- Next milestone: Mark-up in May (exact date TBD)
- New AMCP PIE Coalition to support this legislation

AmerisourceBergen

Xcenda

Presenters



Charlie Dragovich, BSP Pharm

Senior Director & Client Strategist,
Value & Access Team

Xcenda



Lisa Cashman, PharmD

Chair, Format Executive Committee

AMCP

AmerisourceBergen

Xcenda

PIE Implementation Across the Industry

Insights From the 2021 Xcenda PIE
Manufacturer and Payer Survey



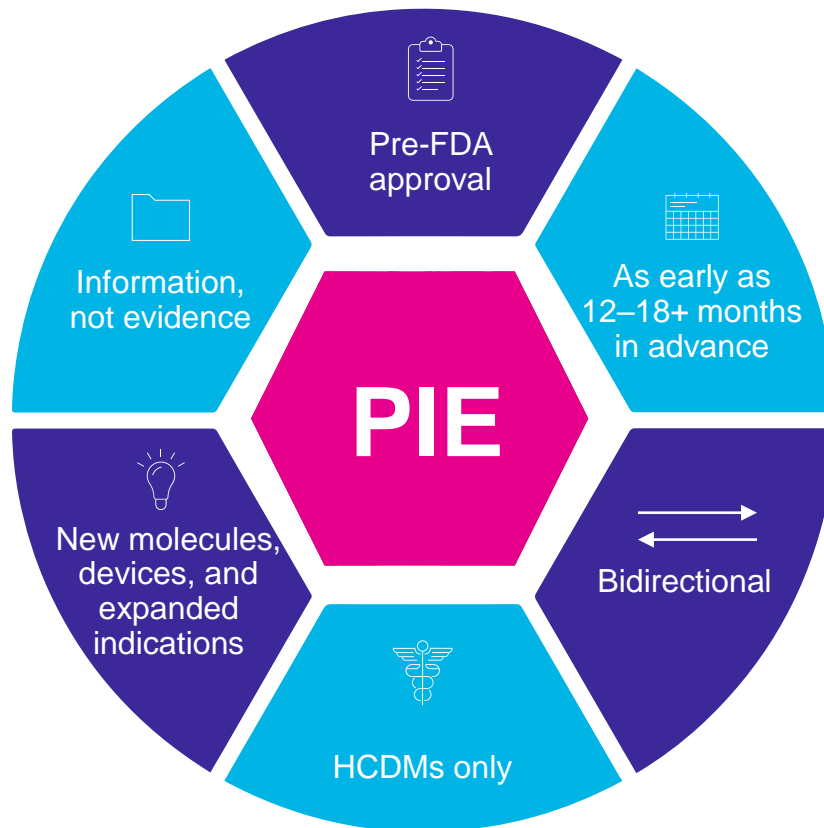
Quick review: What is PIE?



Opportunity for manufacturers to engage proactively with HCDMs about their pipeline products



Truthful, nonmisleading pre-approval communication between biopharmaceutical companies and population HCDMs

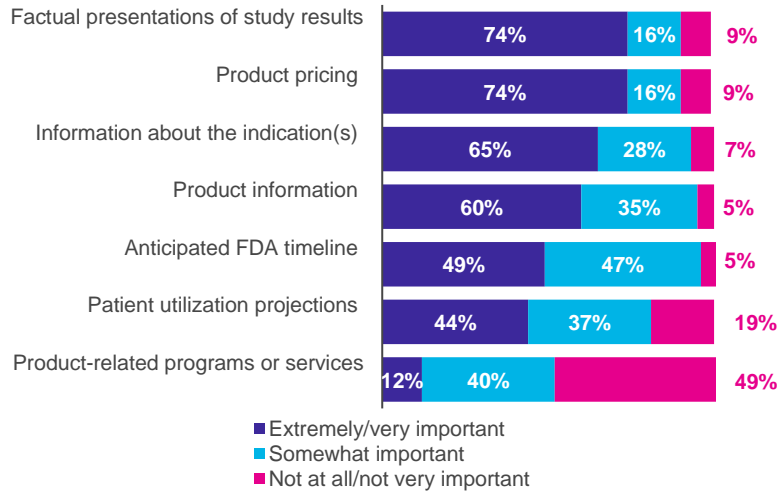


Key: HCDM – healthcare decision maker.

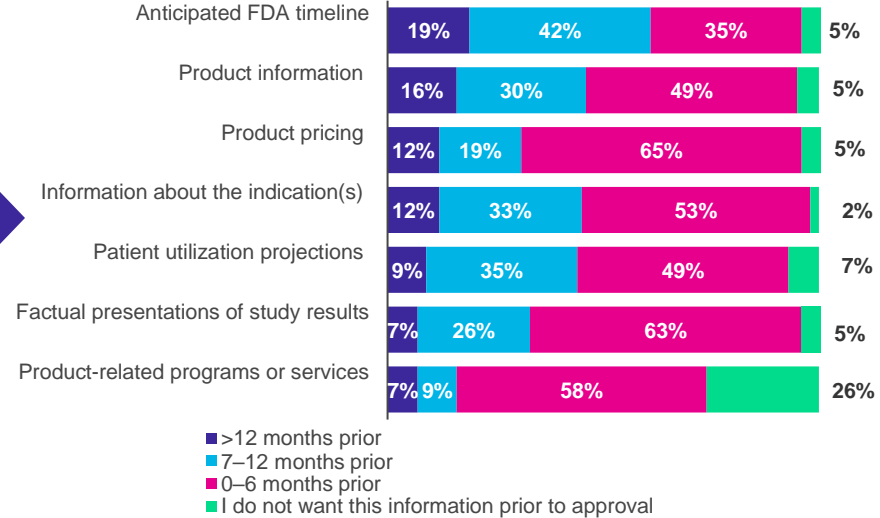
Source: Food and Drug Administration. Drug and device manufacturer communications with payors, formulary committees, and similar entities – questions and answers. Guidance for industry and review staff. June 2018. Accessed December 12, 2019. <https://www.fda.gov/media/102683/download>

Factual presentations of study results and product pricing are extremely important to receive proactively; more than 80% of respondents prefer timing up to 12 months prior to approval

Importance of receiving information proactively and prior to approval



Timing for receiving information



N=43

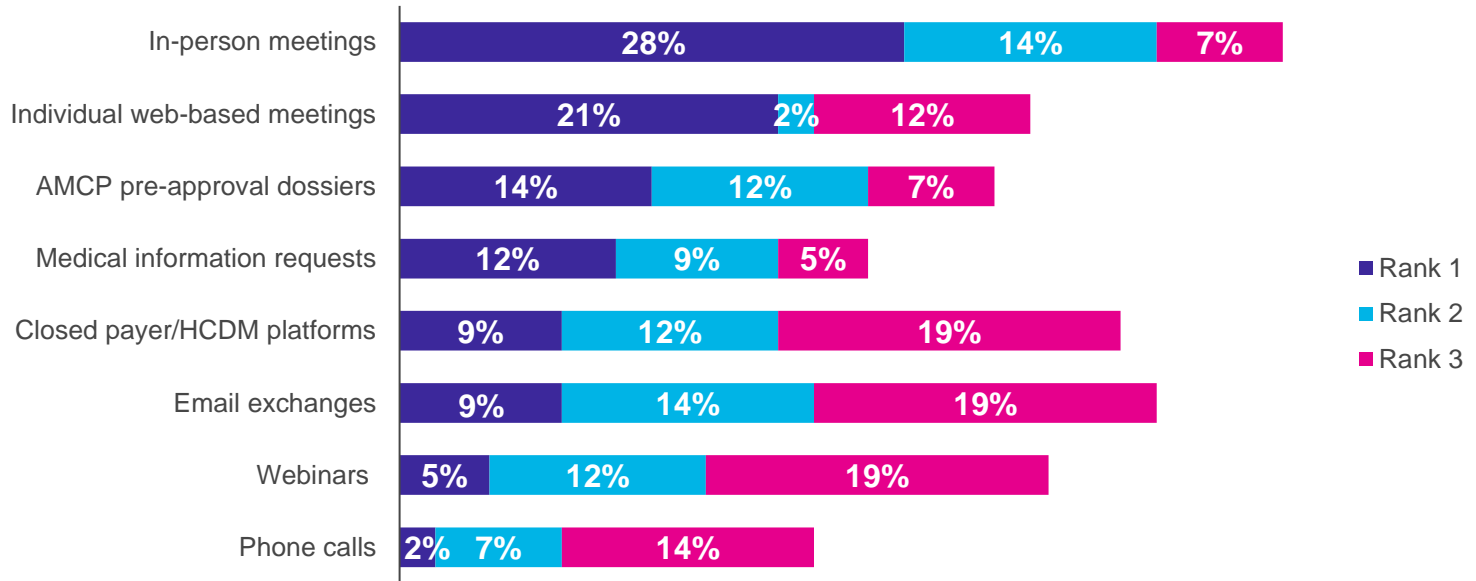
Q16a. For each of the following, please rate the level of importance to your organization in receiving this information proactively and prior to approval from a manufacturer.

Q16b. For each of the following, please indicate when you would like to receive the information, considering the availability of the information prior to approval.

The wording of response options to Q16a and Q16b were shortened for graphing purposes.

The top preferred method for manufacturer representatives to conduct PIE with payers is **in-person meetings**, followed by **individual web-based meetings**

Pre-approval communication preferences

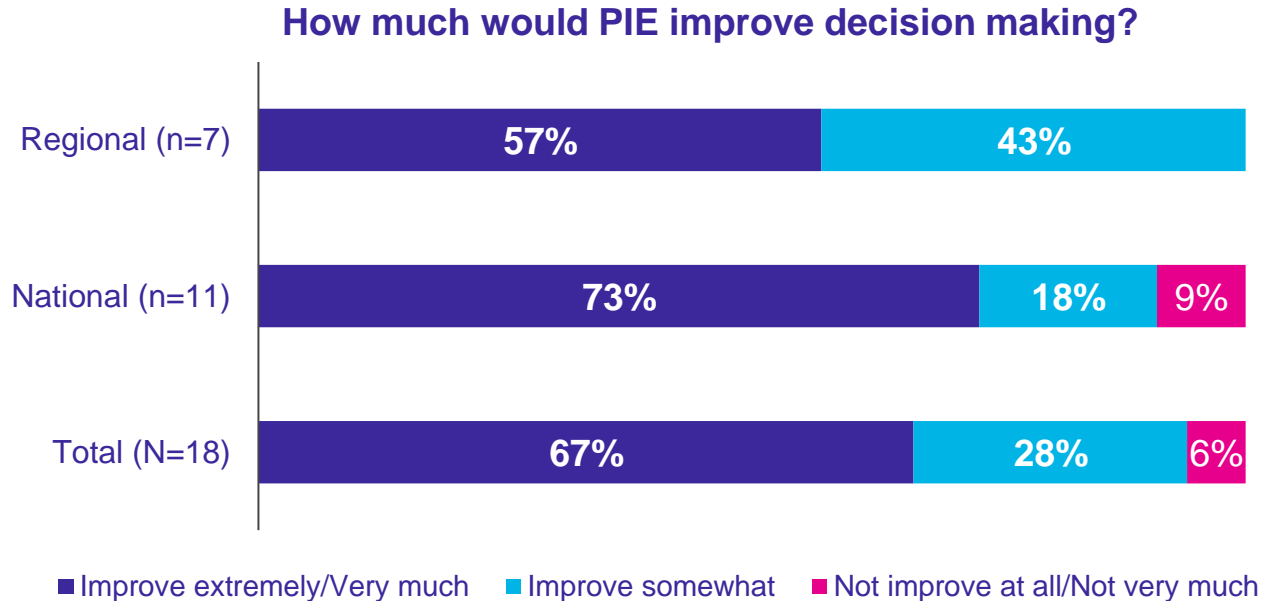


N=43

Q17. Please rank order your preferred ways to communicate with manufacturer representatives regarding PIE.

Note: "Closed payer/healthcare decision maker platform" refers to the FormularyDecisions platform. It was not defined in the survey (but will be in the future).

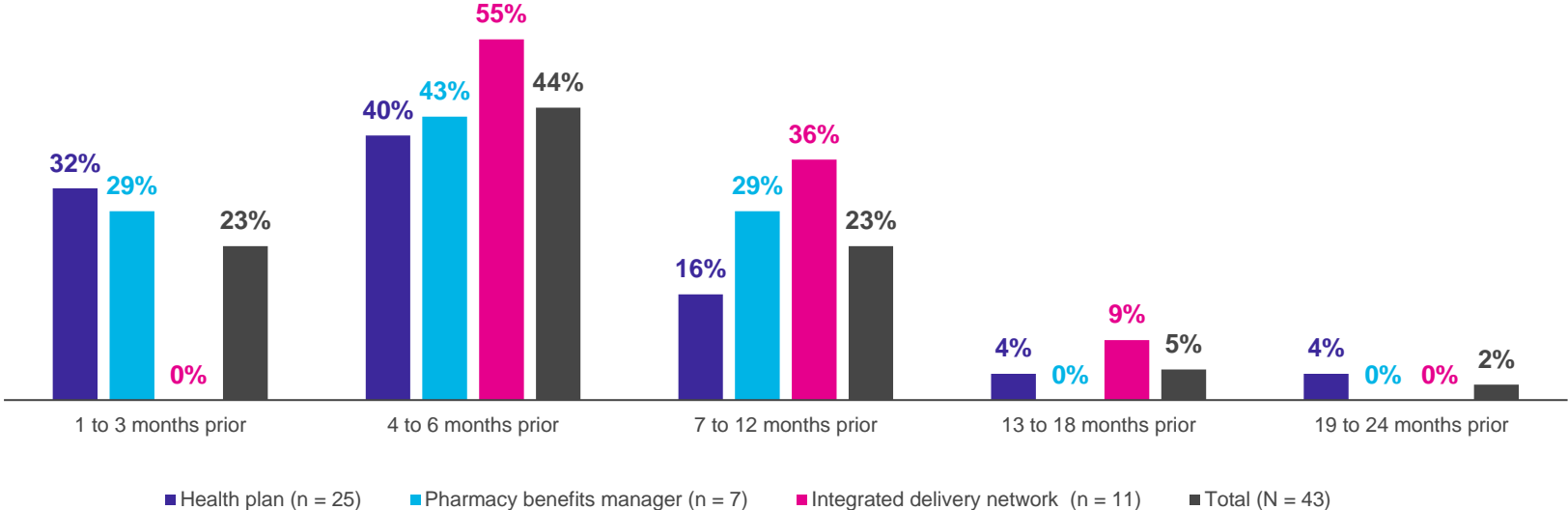
Many payers believe that formulary decision making would be very much or extremely improved by leveraging PIE to close information gaps



Q20. If the **gap is closed** between the pre-approval information you need and that which is available about **unapproved products** or **unapproved uses of approved products (ie, PIE information that you need is available)**, to support formulary decision making, how much would it improve your formulary decision-making ability?

Most respondents (67%) preferred to receive PIE 4 to 12 months before approval

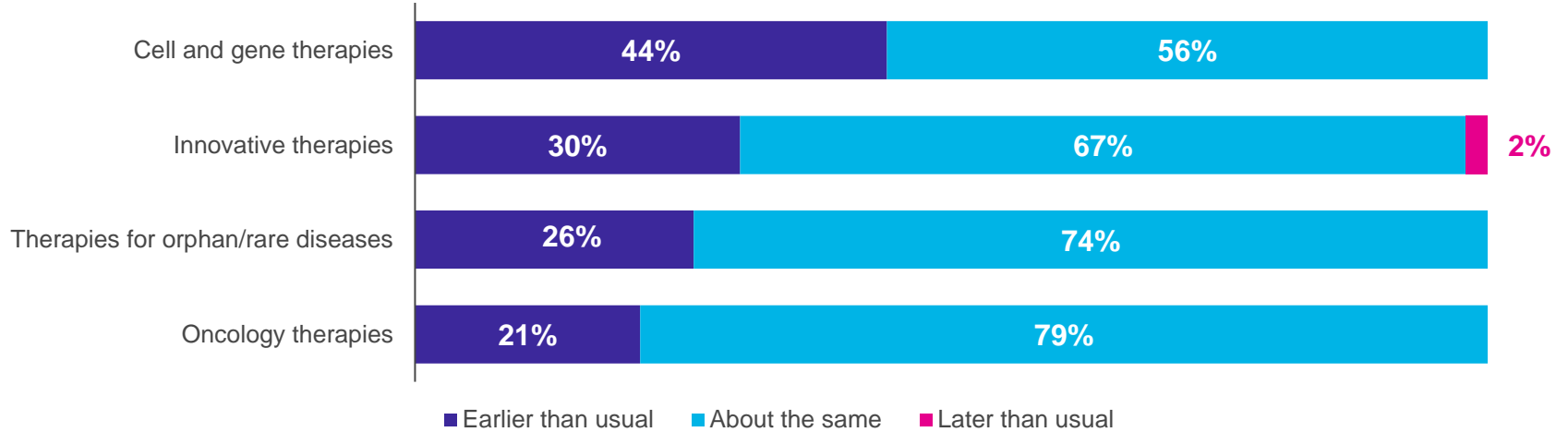
Timing on receiving pre-approval information overall and by organization type



N=43
 Q21. In general, how early would your organization like to receive pre-approval information from a manufacturer prior to anticipated approval? Please select one best answer.
 Note: Reason for not wishing pre-approval information provided was because they "do not review or make any decisions at that time."

Over a third of payers would like PIE earlier for **cell and gene therapy**, followed by **innovative therapies**, **rare disease**, and **oncology**, compared to other categories

Timing difference on PIE based on therapies

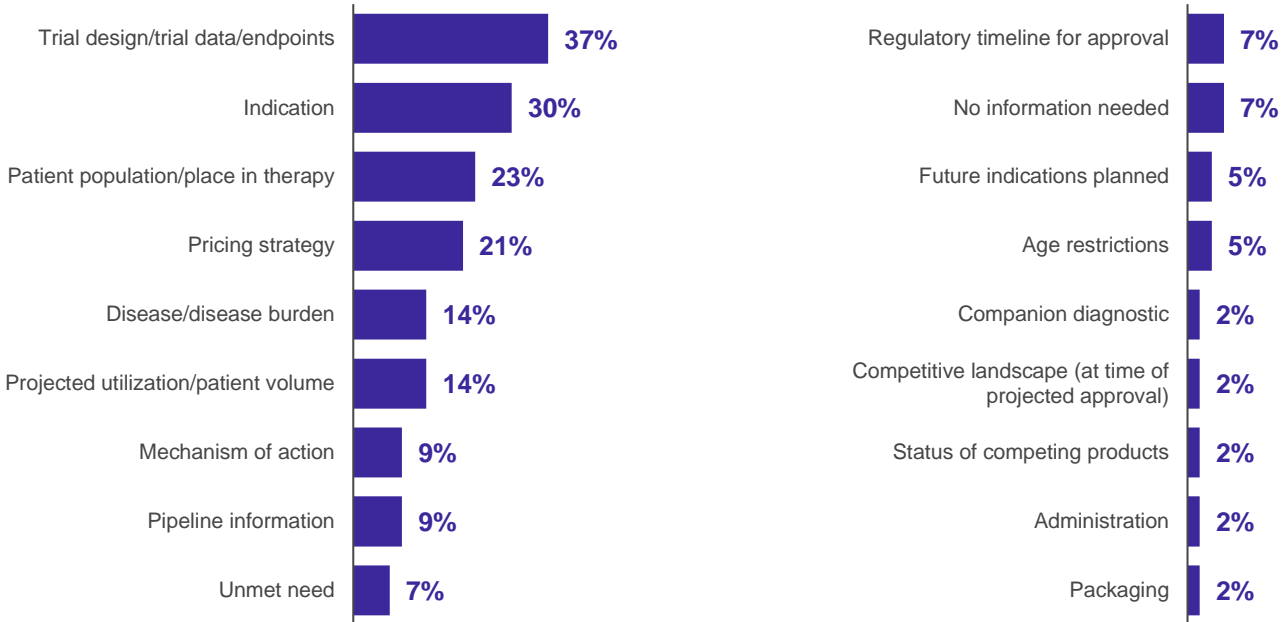


N=43

Q22. How does the timing of your organization's request for pre-approval information change for different therapies?

The most valuable pre-approval communication prior to phase 3 results are information on the trial, indication, place in therapy, and pricing

Type of valuable pre-approval information pre-phase 3



N=43

Q23. Prior to availability of a product's phase 3 data (approximately 1–2 years prior to FDA approval), what type of pre-approval information would you find valuable to receive about the product? Please provide a few examples.

Open-ended responses were hand-coded into thematic categories. Percentages were calculated by summing the number of respondents who endorsed that thematic category divided by the total number of respondents (ie, 43).

AmerisourceBergen

Xcenda

Common misperceptions regarding PIE implementation



Common misperceptions on the FDA guidance and PIE



Only clinical data
are allowed or
wanted



The FDA considers
PIE promotional



Only medical
teams may
present PIE
information to
HCDMs

Common misperceptions on the FDA guidance and PIE



A pre-approval dossier cannot be proactively disseminated because it is a “dossier”

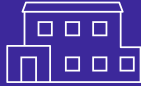


Pre-approval dossiers are large, expensive documents



Payers only want the price of the unapproved product or unapproved indication

Common misperceptions on the FDA guidance and PIE



Manufacturers are not providing any pricing information during PIE



“The sooner I provide payers information, the sooner they will restrict access to the product”



Posters and abstracts don't meet PIE guidelines



The FDA guidance is very clear that PIE is not considered “promotional”

FDA does not intend to object under 21 CFR 312.7(a) or 21 CFR 812.7(a) to such communications, nor to use such communications as evidence of a new intended use.

FDA also does not intend to enforce any applicable postmarketing submission requirements for these materials.

AmerisourceBergen

Xcenda

Questions and discussion



Questions & discussion



- What do you need help with regarding PIE adoption for your company?
- What's preventing your organization from fully implementing PIE?

AmerisourceBergen

Xcenda

Common tools and resources used to conduct PIE



Most common PIE assets and communications vehicles used by manufacturers to conduct PIE



Key assets

- Pre-approval presentation
Disease state/burden of illness presentation
- Pre-approval dossier
- PIE webinar
- Clinical data flashcard



Key communication vehicles

- Live and virtual meetings
- Non-personal communication
- FormularyDecisions[®] platform
- AMCP PIE webinar

Remember:

PIE is pre-approval information **exchange**

A significant value in pre-approval discussions is to obtain feedback from payers on specific data/information that are important for reviewing the product post-approval.

PIE presentations & flashcards

Facilitating discussion and feedback

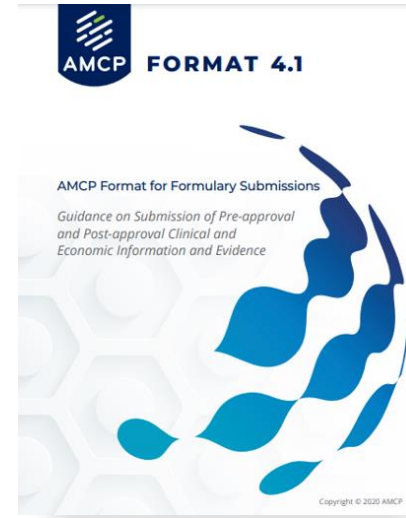
- Data assessment & review
- Content development
- Content approval
- Presenter training



Pre-approval dossiers

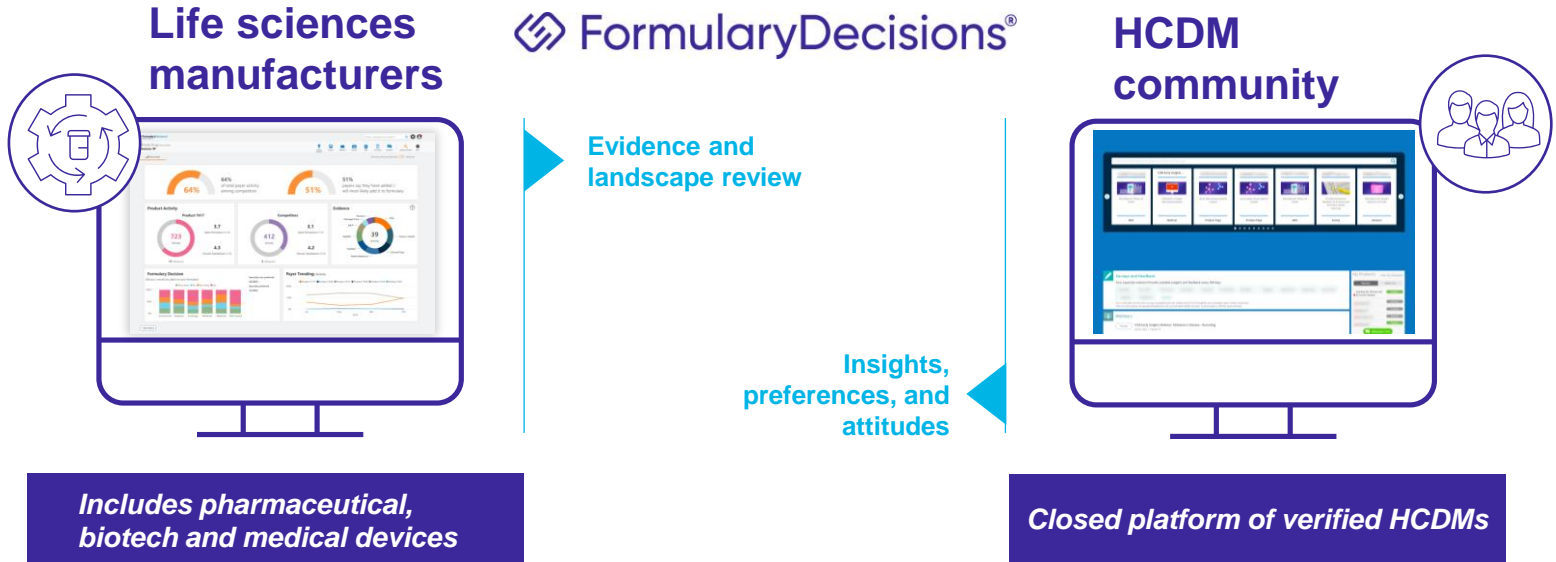
Providing HCDM comprehensive pre-approval information

- Data collection and analysis
- Content development
- Content approval



FormularyDecisions

Providing a qualified audience for PIE that aligns with the FDA 2018 guidance



FormularyDecisions provides qualified HCDMs access to PIE materials

- Unapproved product/indication eDossier
- Resource center
- AMCP PIE webinars

AMCP PIE webinars

Expanding your reach with nonpersonal communication of PIE through FormularyDecisions

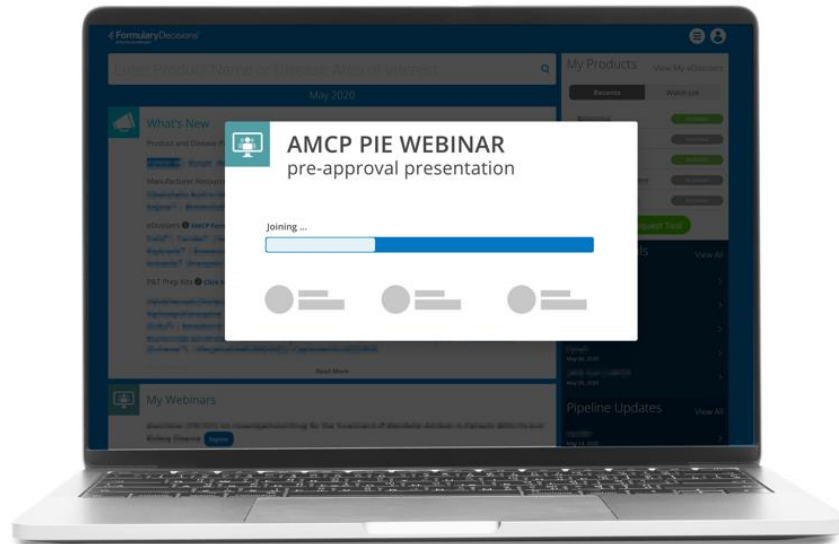
Present pre-approval information to payers on your product to prepare the market for launch

Integrated in the FormularyDecisions platform, home of AMCP eDossiers

Attendees are vetted HCDMs only^a

Access hard-to-reach payers and generate follow-up meetings for your field teams

Raise awareness through AMCP and FormularyDecisions promotional channels



^a Attendees must meet criteria for HCDMs, consistent with Section 3037 of the 21st Century Cures Act and FDA Final Guidance on payer communications.

Questions & discussion



- What questions do you have about specific resources developed for PIE?
- What questions do you have about personal or nonpersonal communication of PIE?

Closing

Final questions or requests for information

Thank you