Leveraging the pre-approval information safe harbor to accelerate patient access

March 14, 2024

2:00-3:00 pm ET

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Speakers

Moderators

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Panelists

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Cencora

Jenna Dale, MBA
Associate Director, Market Access & Commercialization
Cencora

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Payer and Health Outcomes Liaison

Learning objectives

1. Understand how pre-approval information exchange (PIE) has been leveraged by biopharma companies to communicate with healthcare decision-makers through various channels
2. Explore the impact of effective PIE strategies on stakeholder engagement and decision-making
3. Discuss potential solutions for challenging areas in PIE such as FDA expedited approval pathways and availability of economic/pricing data
4. Understand how digital solutions can be leveraged for PIE and its implications for communication with stakeholders

Cencora is a leading expert in PIE

Cencora staff have been involved in PIE Policy and Implementation since 2016

3 

National Manufacturer-Payer Forums on PIE/HCEI

9 

AMCP PIE/HCEI Webinar Speaker/Moderator

50+ 

PIE Webinars Hosted or Produced since 2021

64 

PIE Projects

7 

Peer-Reviewed PIE/HCEI Posters, Abstracts, Publications

33 

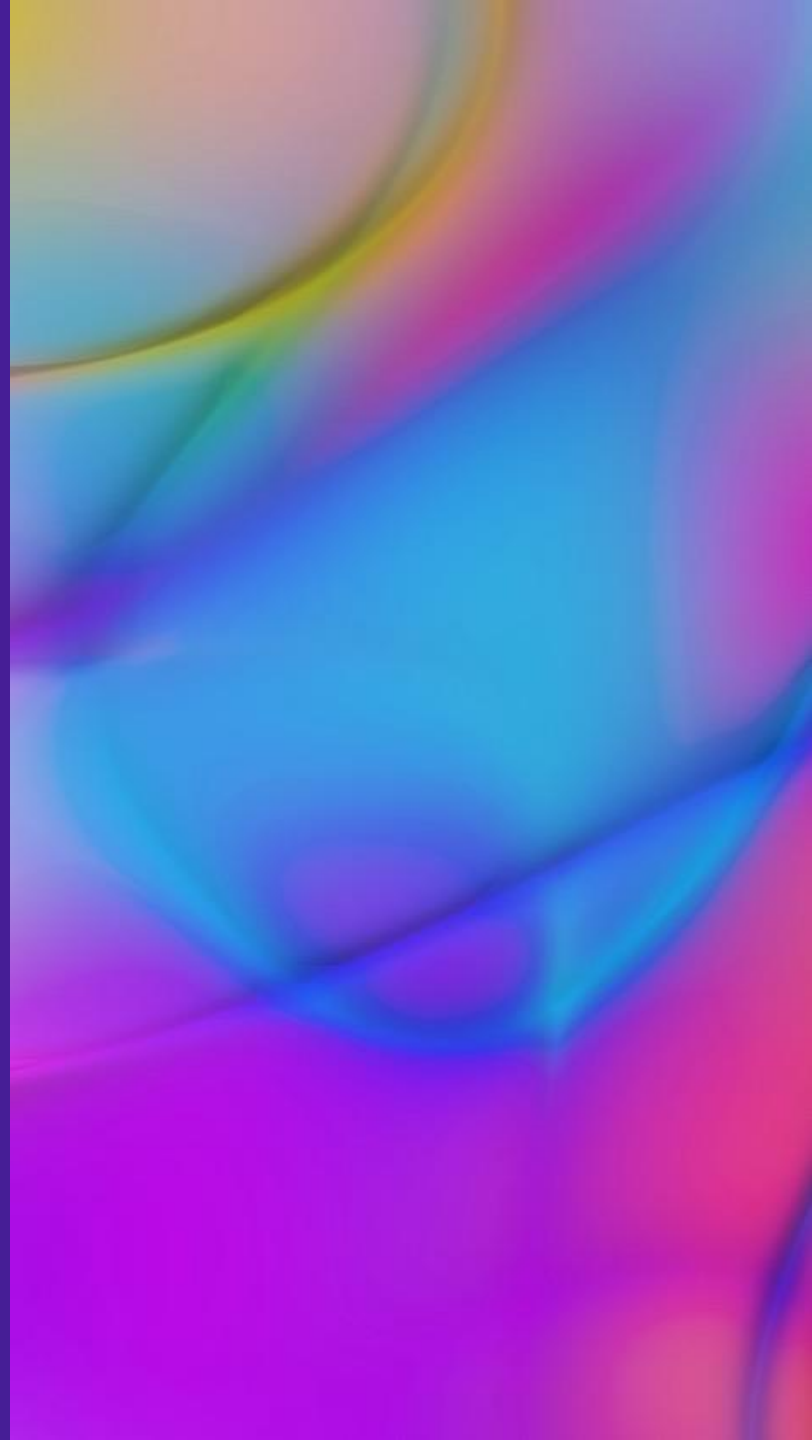
PIE Manufacturer Clients

4 

PIE/HCEI National Training Programs

In partnership with AMCP

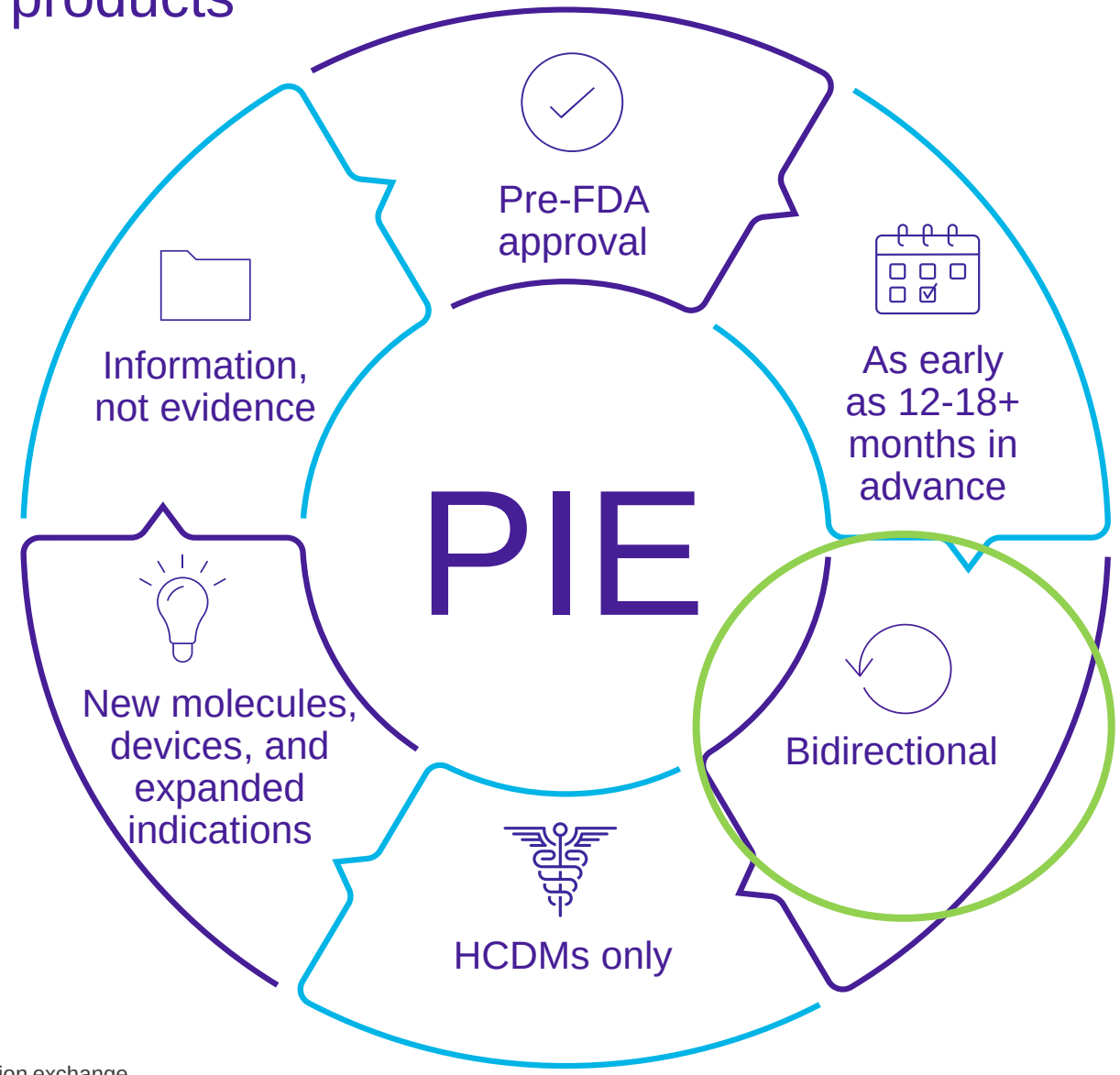
Overview of research trends on how HCDMs are utilizing pre-approval information



PIE is an opportunity for manufacturers to **engage proactively** with healthcare decision-makers (HCDMs) about pipeline products

What is PIE?

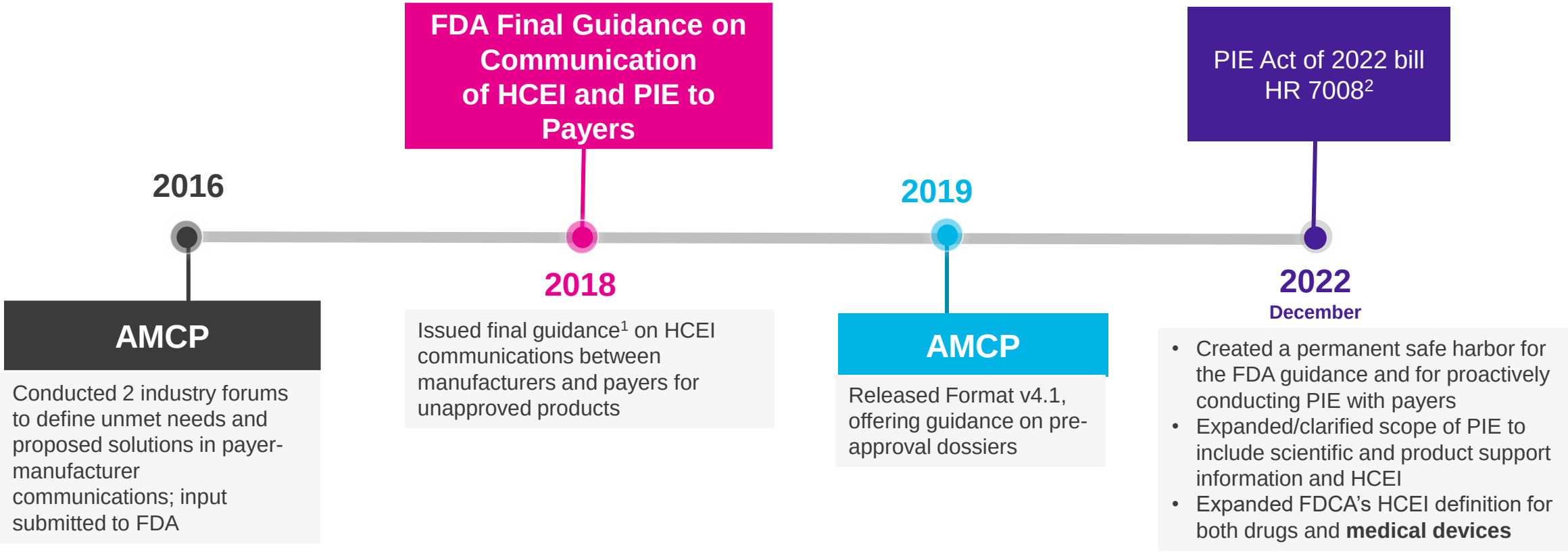
- Truthful, non-misleading pre-approval communication between biopharmaceutical companies and population HCDMs
- Remember: “E” stands for “exchange”—an opportunity to gain feedback and insights



Key: FDA – Food and Drug Administration; HCDM – healthcare decision-maker; PIE – pre-approval information exchange.

Reference: Consolidated Appropriations Act, 2023, HR 2617 (§3630), 117th Cong. Facilitating exchange of product information prior to approval. Accessed January 17, 2023. https://www.congress.gov/bill/117th-congress/house-bill/2617/text.

The Pre-approval Information Exchange Act of 2022 was introduced to make the FDA 2018 guidance and proactive communication **permanent through statute** and to clarify economic data questions



Key: FDA – Food and Drug Administration; FDCA – Food, Drug & Cosmetic Act; HCEI – healthcare economic information; PIE – pre-approval information exchange.

References: **1.** US 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 January 17, 2023. https://www.fda.gov/media/102683/download. **2.** Pre-approval Information Exchange Act, 2022 HR 7008 (§810), 117th Cong. Facilitating the exchange of information prior to approval. Accessed January 17, 2023. https://www.congress.gov/bill/117th-congress/house-bill/7008/text?r=4&s=1.

The Consolidated Appropriations Act, 2023, outlines **who** is eligible to receive PIE

PIE audience

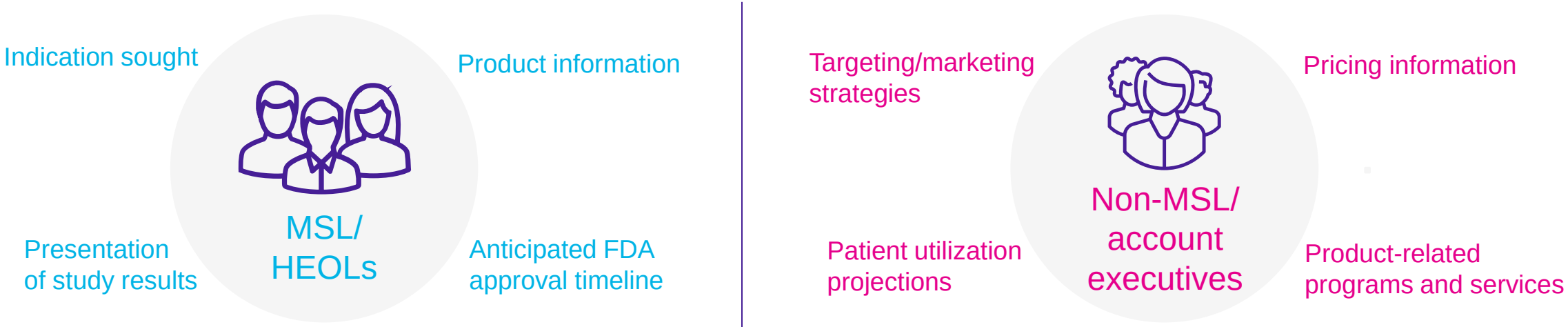
- Public or private sector payers and formulary committees (eg, pharmacy and therapeutics committees)
- Drug information centers
- Technology assessment committees
- Pharmacy benefit managers
- Third-party administrators
- Other multidisciplinary entities that, on behal of healthcare organizations, review scientific and/or technology assessments to make drug or device selection or acquisition, formulary management, and/or coverage and reimbursement decisions on a population basis

Reference: Consolidated Appropriations Act, 2023, HR 2617 (§3630), 117th Cong. Facilitating exchange of product information prior to approval. Accessed January 17, 3, 2023. https://www.congress.gov/bill/117th-congress/house-bill/2617/text.

The Consolidated Appropriations Act, 2023, did **not** provide guidance on **who** should deliver PIE on behalf of the manufacturer[1]

Biopharma company PIE presenters

- Payers may prefer clinical/product information to be provided by medical personnel[2]; it is important to understand that medial science liaisons (MSLs) and health economic and outcomes liaisons (HEOLs) are firewalled from discussing certain information



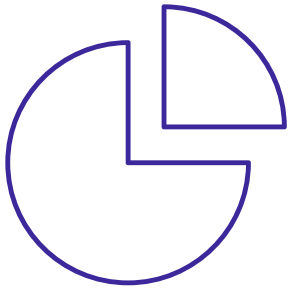
Key: HEOL – health economic and outcomes liaison; MSL – medial science liaison.

References: **1.** Consolidated Appropriations Act, 2023, HR 2617 (§3630), 117th Cong. Facilitating exchange of product information prior to approval. Accessed January 17, 3, 2023. https://www.congress.gov/bill/117th-congress/house-bill/2617/text. **2.** Dodda S, Bannister B, Hydery T, Gorey C, Dunlap S, Mody L. Best practices in designing preapproval information engagements for US health care decision makers. *J Manag Care Spec Pharm*. 2023 Mar;29(3):245-250.

A gap remains between what payers consider necessary PIE and what's available from biopharma companies

Nearly half of annually surveyed HCDMs perceive a gap
between the PIE needed to make formulary decisions and what PIE is available

Top reported gaps in PIE



- **Product pricing information**
- **Place in therapy**
- **Patient utilization projections**
- **Anticipated timeline to approval**

All HCDMs surveyed believe that
closing the PIE gap would *improve* their decision-making ability

47% of surveyed HCDMs perceive a PIE gap, 100% of HCDMs surveyed that closing the PIE gap would improve their decision-making ability
Key: HCDM – healthcare decision-maker; PIE – pre-approval information exchange.
Reference: Cencora. PIE and HCEI Managed Care Trends Report. 2023. N=45.

AMCP pre-approval dossiers and **PIE webinars** are top resources utilized by HCDMs in formulary decision-making

Resources for preapproval information

- **AMCP pre-approval dossiers**
- **AMCP PIE webinars**
- **Pre-approval presentations/videos**
- **Posters/abstracts of clinical trial results**

Key: HCDM – healthcare decision-maker; PIE – pre-approval information exchange.

Reference: Cencora. Data on file. 2022. N=17.

The most valuable types of pre-approval information prior to phase 3 results are **indication**, **unmet need**, **clinical trial information**, and **regulatory timeline**

Appropriate types of information

- Product information
- Indication sought
- Presentation of study results
- Anticipated FDA approval timeline
- Patient utilization projections
- Pricing information
- Targeting/marketing strategies
- Product-related programs and services

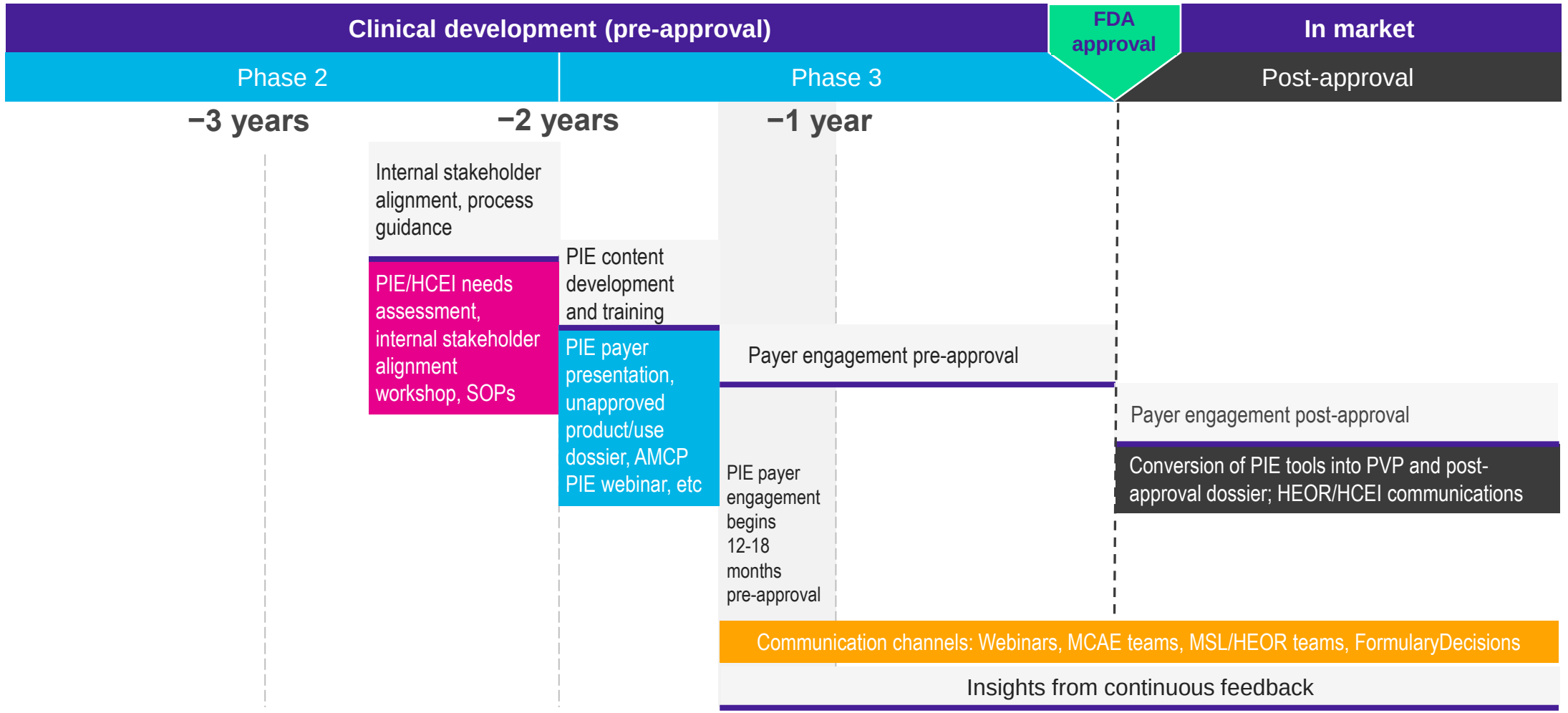
Other recommendations

- Information must be unbiased, factual, accurate, and not misleading
- Clear statement that product is under investigation
- Disclose stage of development
- Follow up with payers as information becomes outdated

Prior to availability of a product's phase 3 data (ie, approximately 1-2 years prior to FDA approval), what type of pre-approval information would you find valuable to receive about the product and/or related information?

References: **1.** Cencora. Data on file. 2023. N=45. **2.** Consolidated Appropriations Act, 2023, HR 2617 (§3630), 117th Cong. Facilitating exchange of product information prior to approval. Accessed January 17, 2024. https://www.congress.gov/bill/117th-congress/house-bill/2617/text.

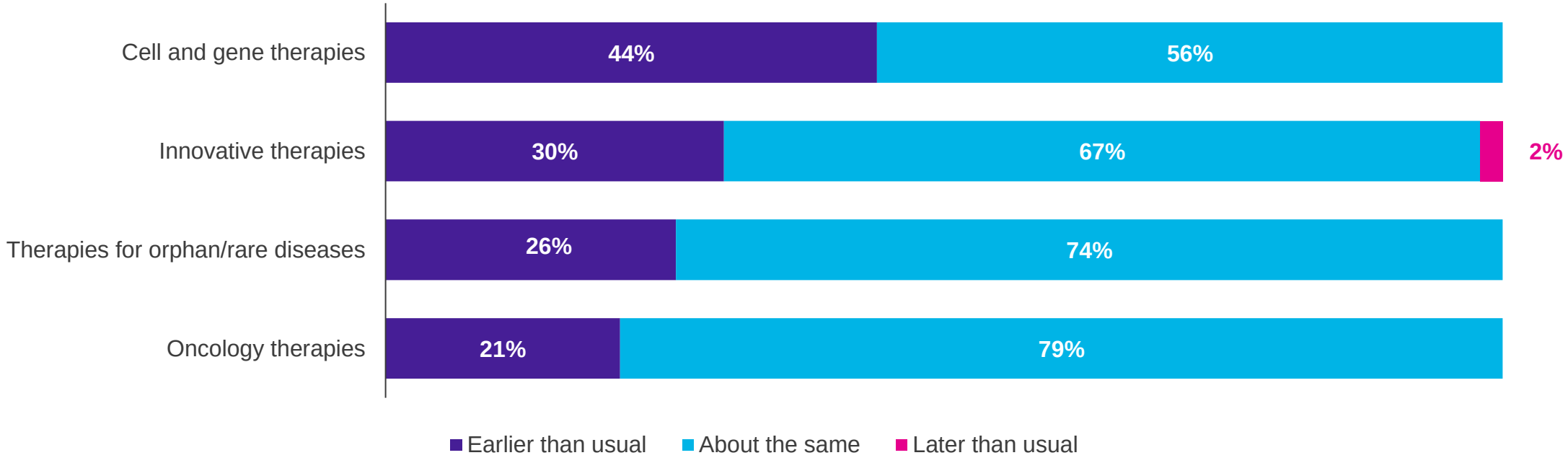
Biopharma companies that are **new to PIE** should allocate **at least 9-12 months** for planning and development prior to their initial PIE engagement/release of PIE data



Key: FDA – Food and Drug Administration; HCEI – healthcare economic information; MCAE – managed care account executive; MSL – medical science liaison; PIE – pre-approval information exchange; PVP – payer value proposition.

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



Reference: Cencora. Data on file. 2021. N=43.

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

A **comprehensive** HCDM engagement strategy requires both **traditional** and **digital** channels

Traditional, face-to-face channels for **engagement remain critical**

Digital channels augment reach and meet customers where they are

100% of HCDMs surveyed agree that it is **important for biopharma companies to include both traditional and digital channels** when communicating product-related information[1]

FormularyDecisions®

FormularyDecisions is a fit-for-purpose digital channel offering biopharma companies access to HCDM audiences

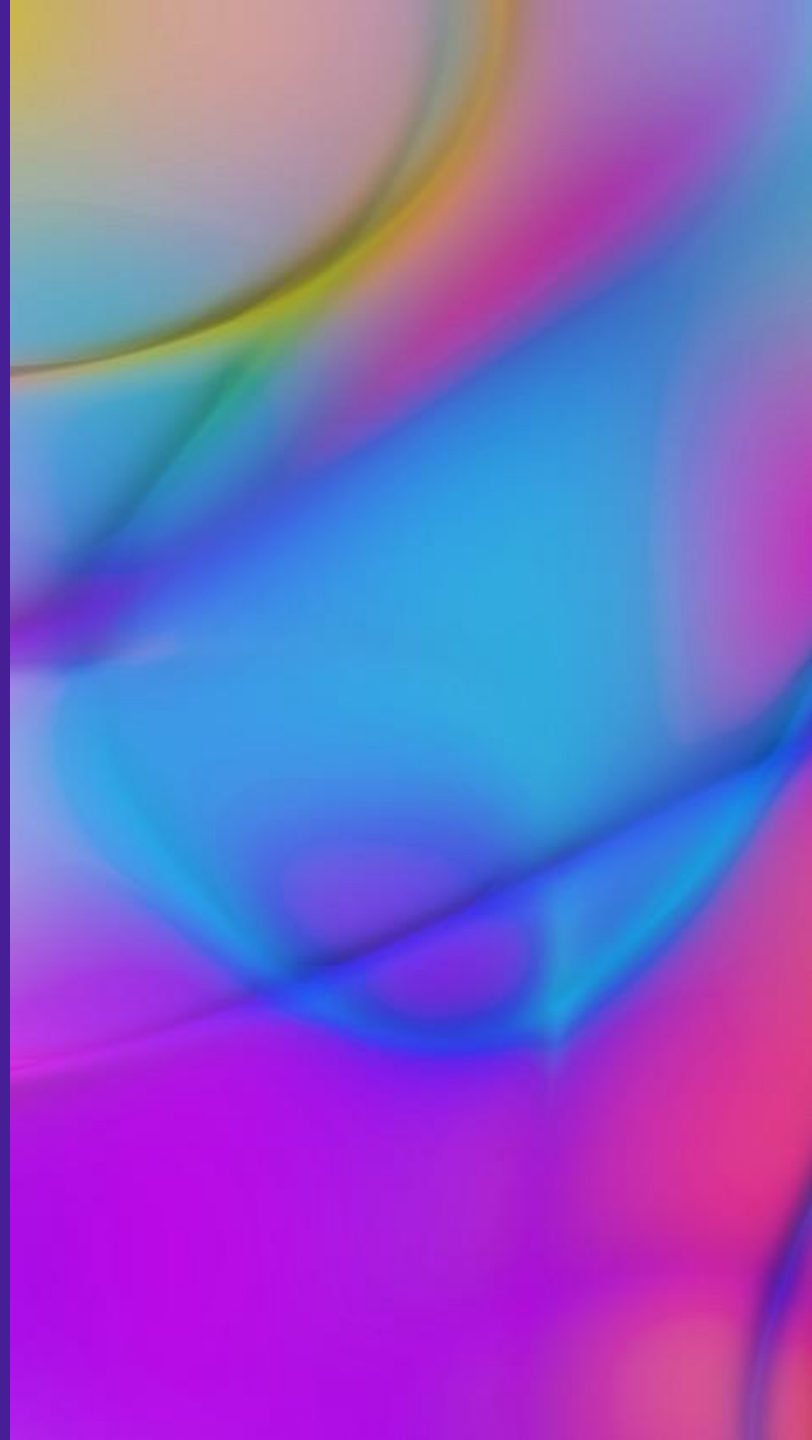
1. Cencora. Data on File. 2022. (N=17)

In summary, access to pre-approval information is crucial for both HCDMs and biopharma manufacturers as it s**treamlines the formulary review process** and positions products for **market success**

Benefits of engaging in PIE	
HCDMs	**Biopharma companies**
Comprehensive understanding of product (pricing, safety, and efficacy data, place in therapy)	Effective communication of product value to support informed decision making
Streamlined formulary review process and expedited patient access to novel therapies	

Reference: Dodda S, Bannister B, Hydery T, Gorey C, Dunlap S, Mody L. Best practices in designing preapproval information engagements for US health care decision makers. J Manag Care Spec Pharm. 2023;29(3):245-250.

For inquiries on the FormularyDecisions platform or questions related to preapproval information exchange (PIE) between payers and biopharma companies, email our team at Charles.Dragovich@cencora.com



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