"We Need to Talk!" Using the AMCP *Format* 5.0 to Facilitate More Effective Evidence-Based Discussions with US Payer Audiences

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Presenters and discussants

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Fast Facts!

- What is the AMCP *Format* and what is new in Version 5.0?
- What *Format* best practices and challenges have been identified?
- How can we better support effective, *bidirectional* communication?

What is the AMCP *Format* for Formulary Submissions?

- Created in 2000 with the goals of:
  - Improving the timeliness, scope, quality, and relevance of clinical and economic evidence provided by manufacturers to HCDMs
  - Streamlining the evidence and information acquisition and review process for HCDMs
- Key sections of the AMCP *Format*:

1.0 Executive Summary of Clinical and Economic Value

2.0 Product Information and Disease Description

3.0 Clinical Evidence

4.0 Economic Value and Modeling Report

5.0 Additional Supporting Evidence

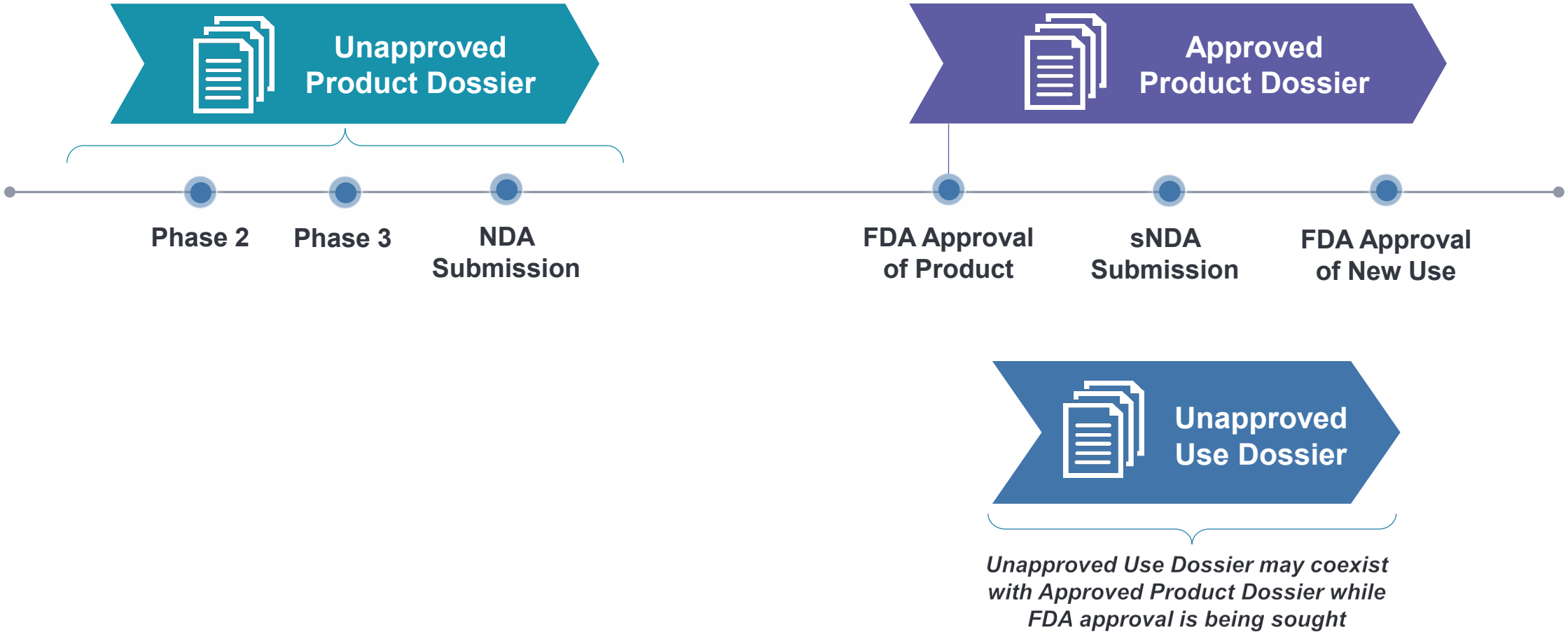
AMCP Format for Formulary Submissions 5.0

jmcp.org

Guidance on Submission of Pre-approval and Post-approval Clinical and Economic Information and Evidence

Key: AMCP, Academy of Managed Care Pharmacy; HCDM, health care decision maker

When are AMCP dossiers created and disseminated?



Key: AMCP, Academy of Managed Care Pharmacy; NDA, new drug application; FDA, Food and Drug Administration; sNDA, supplemental new drug application.
Adapted from Hoye-Simek A, Penley B, AMCP Annual Meeting, New Orleans, 2024.

What is new in AMCP *Format* 5.0?

1

Digital therapeutics

- Outlines unique evidentiary needs for digital therapies (DTx)
- Provides guidance on dossier format for DTx
- Outlines DTx-specific considerations regarding:
  - Privacy and data security
  - Engagement
  - Screenshots

2

Health disparities

- Provides guidance on incorporating health disparities information:
  - Addressing health disparities in the *Disease Description* section
  - Evidence recommendations for including health disparities considerations
  - Additional supporting evidence

3

Streamlining dossiers

- Encouraging brevity!
- "Right-sizing" the *Disease Description* section
- Encouraging use of internal hyperlinks rather than duplicating content
- Use of external hyperlinks where plausible for:
  - Product information
  - External websites
  - Relevant guidelines

4

Preapproval information exchange

- Aligns AMCP guidance on preapproval information exchange (PIE) with relevant legislation (PIE Act)
- Reinforces appropriate **proactive** engagement with health care decision makers in the preapproval space
- Provides timeline, content, and engagement recommendations to foster an ongoing scientific dialogue

5

Incorporating RWE

- Supports increased emphasis on including RWE in relevant dossier sections
- Provides additional guidance on where and what types of RWE should be included to support key sections:
  - Clinical Evidence
  - Economic Value and Modeling Report

The AMCP *Format* for Formulary Submissions remains the industry standard for communicating clinical and economic information to address the critical evidence expectations of US health care decision makers

AMCP *Format* for Formulary Submissions, Version 5.0, 2024.

Panelists Reactions

What are your thoughts on AMCP *Format* 5.0?

What key supply-side issues need to be addressed?

What best practices have been identified?

What best practices have been identified?

Comprehensive, yet concise

Provided in a timely fashion

Transparent, evidence-based clinical and economic value presentation

Follow the *Format*!

Adapted from Hoye-Simek A, Penley B, AMCP Annual Meeting, New Orleans, 2024.

Optimizing AMCP Dossier Value

- Overcoming Perceived Limitations

Length & Ease of Use

- Limit repetition through internal document linking
- Utilize infographics & charts/tables to facilitate data presentation
- Keep core sections concise, with links to supplementary supportive data in appendices

Relevance & Completeness

- Tailor to product, disease area, audience, and therapeutic landscape in a bespoke approach
- Include RWD where available
- Link reference list to primary source locations

Timing

- Provide pre-approval dossiers 6 – 12 months ahead of anticipated product approval
- Target more timely dossier release upon FDA product approval
- Managing updates in pre- and post-approval timeframes

Manufacturer Bias

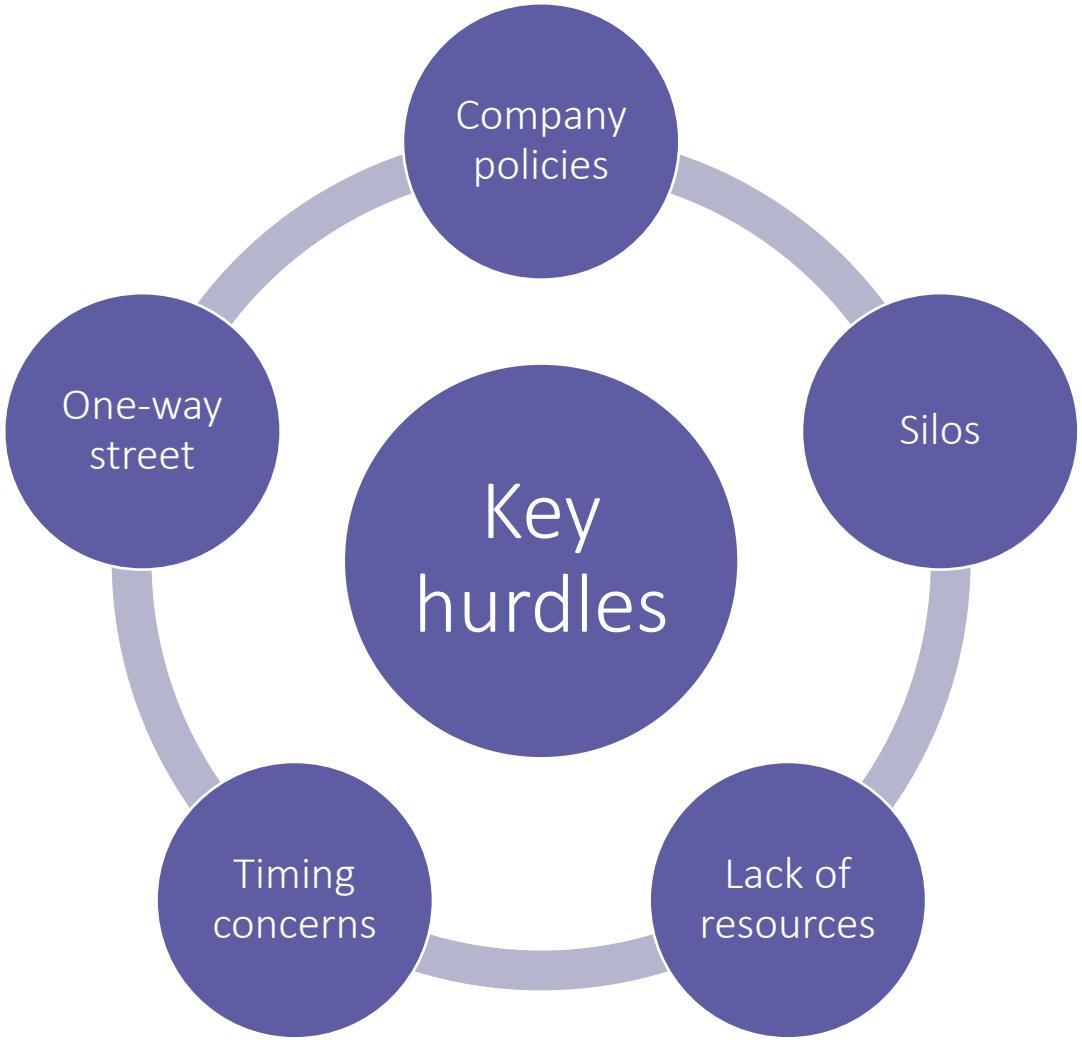
- Incorporate feedback from dossier users
- Integrate transparency, e.g. including economic model assumptions & limitations
- Provide objective rationale for inclusion of studies

Key: RWD, real world data; FDA, Food and Drug Administration.

What gets in our way?

(Let's talk about it)

Common obstacles in facilitating timely scientific dialogue with US payer audiences



Discussion Topics

- How can we start the conversations earlier?
- How can we make dossiers more useful for their intended audience?

Thanks for your time and engagement!