

TRACK III: Fair Market Value Update

Implementing Fair Market Value

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THE TWELFTH ANNUAL **Pharmaceutical Regulatory and Compliance Congress and Best Practices Forum**

TRANSFORMATIONAL LEARNING –
EFFECTIVE KNOWLEDGE EXCHANGE

Important

- *The content and opinions expressed in this presentation are my own, and not necessarily those of my employer.*
- *This is not advice.*

Agenda

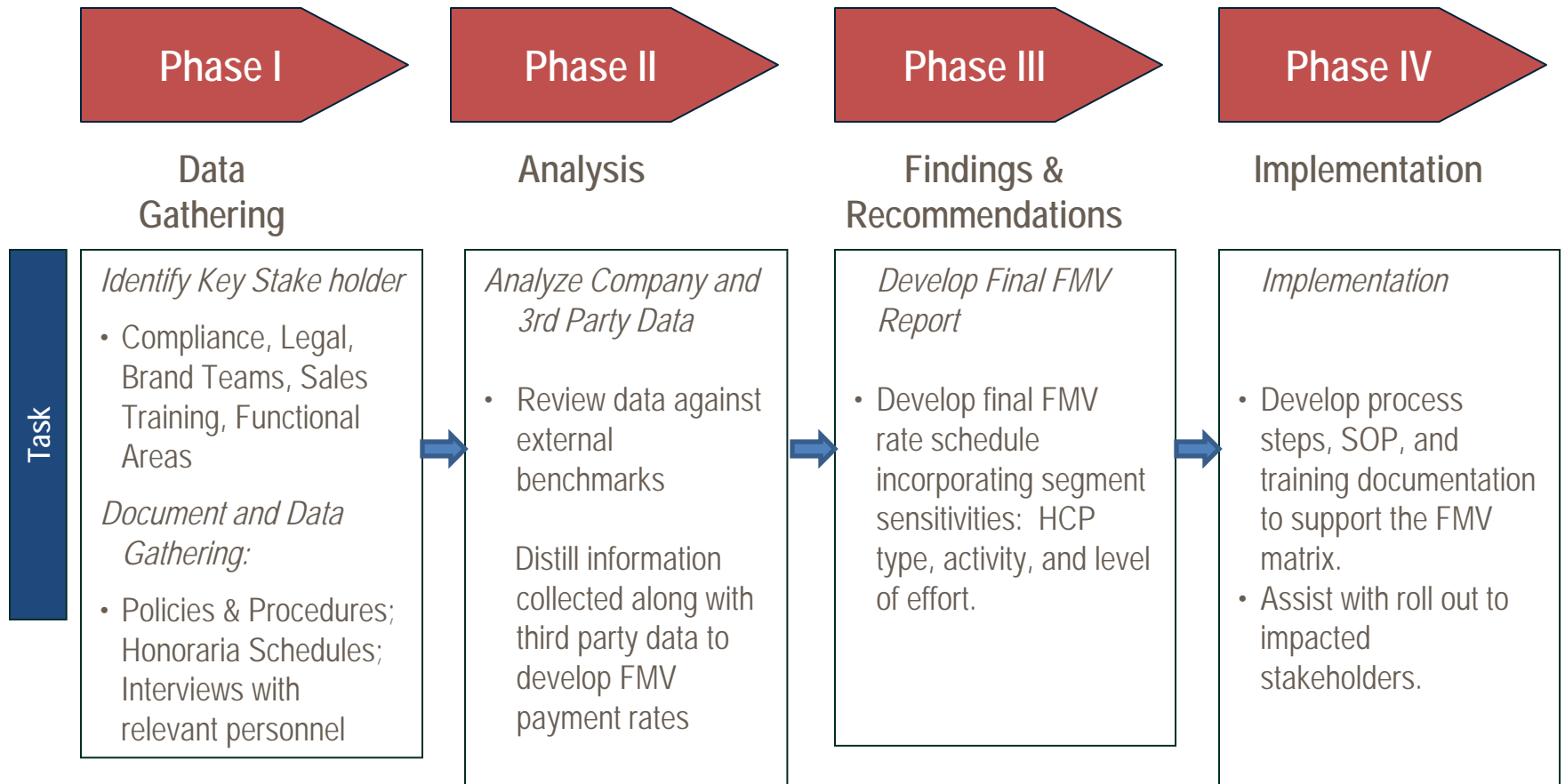
I. Introduction

II. The Four Key Phases to a successful FMV implementation

III. Challenges and FAQs

IV. Q & A

Four Key Phases



Question/Challenge: “Who owns FMV?”

- FMV is being owned by the business. E&C, Legal can help to facilitate implementation of methodology but don't own the process
- Business is responsible and liable for accuracy of FMV calculations

Question/Challenge: “Why do we have FMV?”

- Because it is the law.

Question/Challenge:
“What is the right FMV?”

- Do not spend time on this – the right number doesn't exist!

Question/Challenge: "Rate Ranges or Fixed Rates?"

- While ranges offer more flexibility, they may lead to operational challenges
- Fixed rates support consistency
- Fixed rates are easier to operationalize

Questions/Challenge:

“Dr. X said he gets paid more by our competitors and will not work for us for the offered FMV rate”

- We do not know our competitor's FMV methodology

Challenge: Travel Compensation

- Backed into the hourly rates or additional compensation?

Challenge: Exception Process

- Be careful how you communicate internally
- No all requests are true exception requests
- Define KOL (KOL's don't have to be exceptions)
- Exceptions and Deviations (one time, not permanent vs. permanent)
- Criteria:
 - offer the regular honorarium and have HCP decline
 - Business justification, incl. rareness/uniqueness
 - Support from Senior Mgt. Member

Challenge:

Who does the Leveling of HCPs?

- In-House
- External Party
- Use consistent leveling criteria
- Preference is to use third party

Question:

"Can I pay below FMV Rates?"

- If you do, be aware of the risk
- If you do, have documented as to why

Question:

“FMV Calculator vs. Spreadsheets?”

Question:

“The HCP wants to forgo his honorarium – is that okay?”

Question:

“Can we pay the institution instead of the HCP directly?”

Take Aways:

1. Choose your stakeholders and influencers wisely
2. Don't waste time on finding the right number
3. Offer a calculator and think about synergies
4. Document, document, document!

Questions?

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