

Developing Drug Monographs for Evidence-Based Formularies (and the P&T Competition)

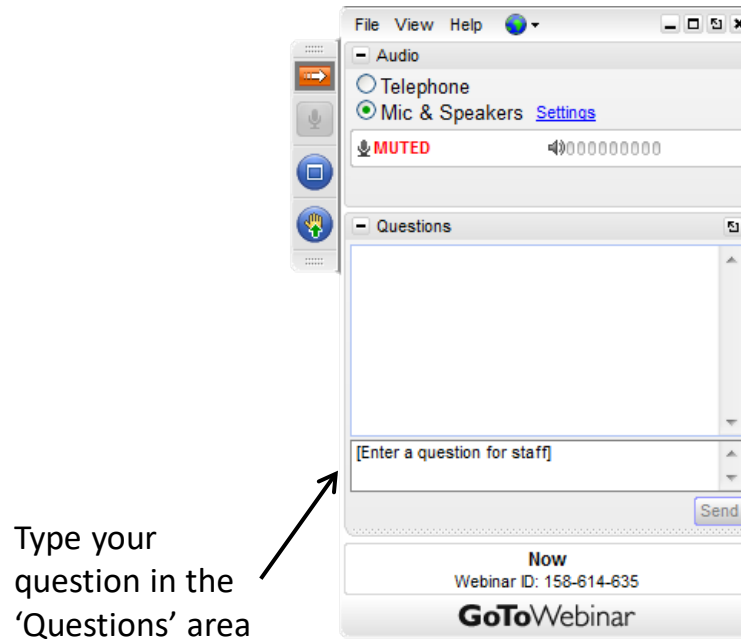
AMCP Student Pharmacist Committee Webinar



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How to Ask a Question



Webinar Agenda

1. Developing Drug Monographs for Evidence-Based Formularies (and the P&T Competition)
2. Monographs Q&A
3. Local Competitions Best Practices and COVID-19 Troubleshooting
4. Adjourn



Moderator:

*Paula J. Eichenbrenner, MBA, CAE
Executive Director, AMCP Foundation*



P&T Competition



Annual National Student Pharmacist
P & T C O M P E T I T I O N



Thank You

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Elizabeth Sampsel, PharmD, MBA, BCPS

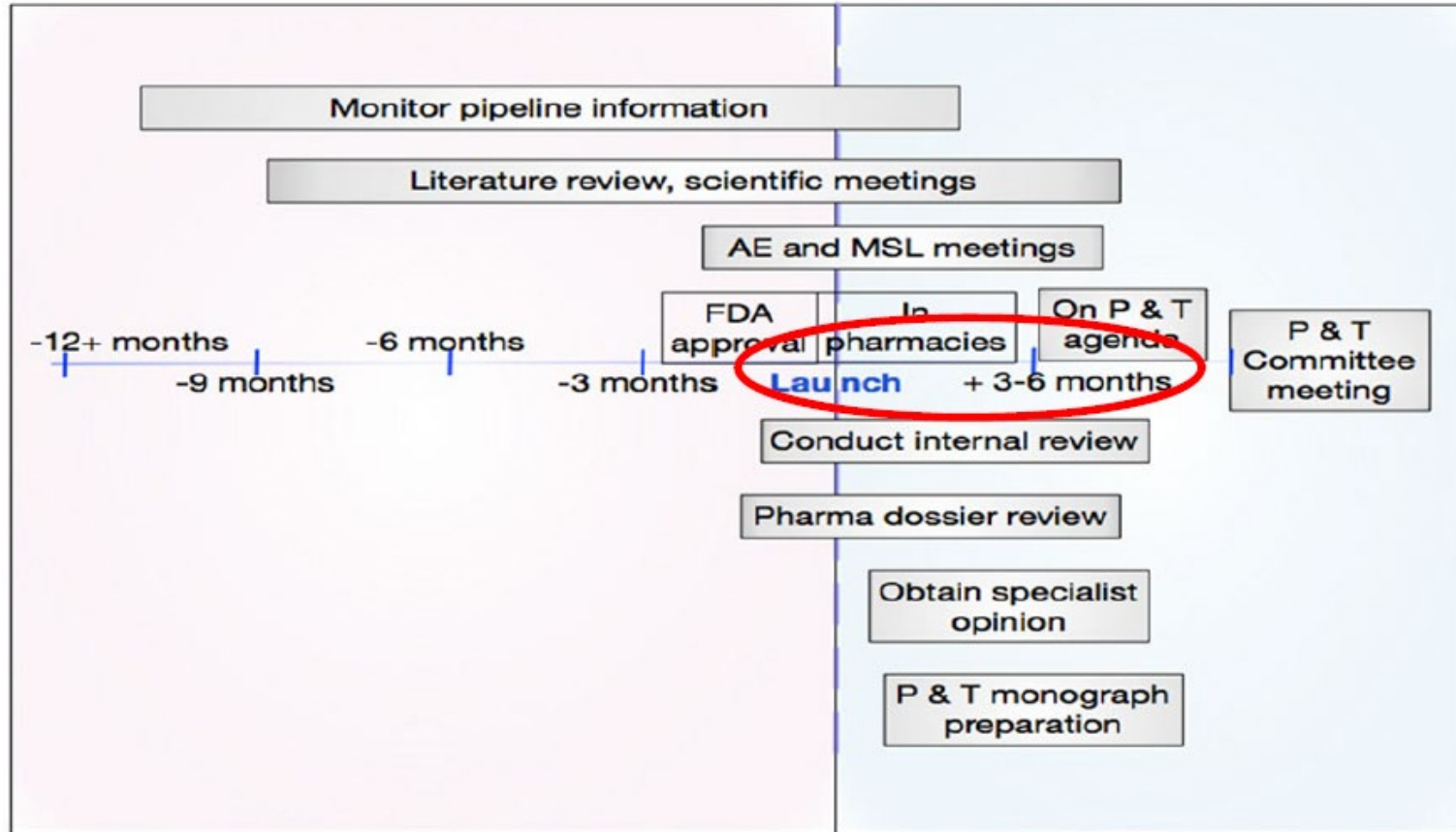
Clinical Program Manager, MedImpact
Healthcare Systems, Inc.

AMCP Diplomat, Xavier University

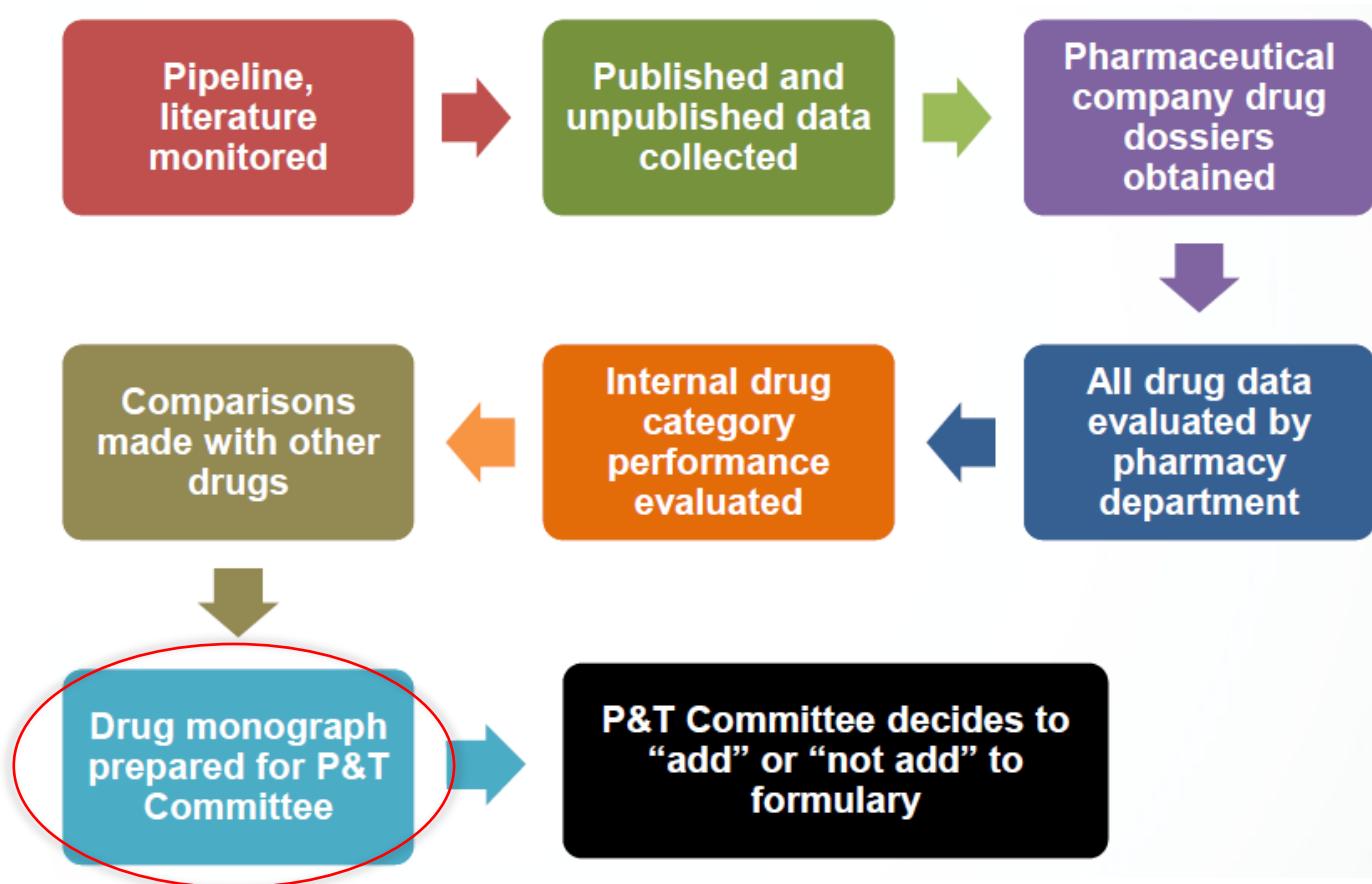
Monographs in Formulary Decision-Making

- Monographs provide an overview/evaluation of drugs, therapeutic classes and disease state therapies, to include efficacy, safety, cost information and recommendations for formulary placement
- Prepared by pharmacists who support P&T Committees
- Sometimes reviewed by specialists prior to P&T Committees

Monographs in Formulary Decision-Making



Preparing for P&T Committee Reviews



P&T Competition Monograph Sections

Executive Summary

Evidence Gaps

Value and Operational Matrix

Recommendations to the Committee

Clinical Evidence Evaluation

- Efficacy
- Safety
- Comparative effectiveness
- Value proposition
- Patient subgroups

Economic Evidence Evaluation

Clinical Evidence Tables

Cost-Effectiveness Evidence Summary

Background

- Disease background
- Treatment alternatives
- Product background

Methodology

References

Discussion of Key Sections

- Executive Summary

Executive Summary

[The Executive Summary should contain everything P&T Committee members need to know in order to reach the conclusion you are recommending. In each section of the Executive Summary, summarize the key points in a brief, succinct paragraph.]

Efficacy in Clinical Trials (Strength of Evidence: [High/Medium/Low])

Text

Reason for evidence grade:

Safety in Clinical Trials (Strength of Evidence: [High/Medium/Low])

Text

Reason for evidence grade

Real World Comparative Effectiveness (Strength of Evidence: [High/Medium/Low])

Discussion of Key Sections

- Evidence Gaps

Evidence Gaps

To help the P&T Committee understand the specific limitations of the existing body of evidence, list the evidence gaps for the following PICOT elements. If none, state “None”

Population

Text [e.g., How well do the subjects in clinical trials correspond to Patients First Health Plan membership demographics?]

Intervention

Text [e.g., Is the intervention clearly described and practical outside of a study setting?]

Comparator

Discussion of Key Sections

- Clinical Evidence Tables

Clinical Evidence Tables

Copy the table below for each study you are including.

Reference:						
Study Design and Evidence Grade	Drug Regimens	N	Time Horizon	Study Population	Endpoints	
					Primary	Secondary
	1. 2.					
Efficacy/Effectiveness					Serious Adverse Events	
					•	
					Weaknesses Impacting Internal/External Validity	

A Good Monograph...

- Is informed by the evidence, but is quite different from a systematic literature review
- Is not unnecessarily long
 - P&T Competition: Most top scoring monographs have fewer than 40 pages
 - In practice: P&T Committee members are very busy!

Before You Submit Your Monograph

- Adequate background is provided, without overwhelming
- Each study is critically assessed
 - Evidence tables demonstrate understanding of study
 - Primary and secondary study endpoints identified
 - Treatment groups adequately identified
 - Specific study limitations are identified
- Total body of evidence is evaluated
- Warnings/precautions are included
- Cost considerations are reasonably explained

Before You Submit Your Monograph

- Conclusion/recommendation
 - Reflects complete and accurate understanding
 - Includes PA criteria in recommendation to committee *(if you have developed PA criteria)*
 - Sufficient documentation, without overwhelming
 - Makes a clear recommendation
- Style
 - Clear, straightforward, concise
 - Use drug name rather than brand name
 - Consistent formatting
 - Correct grammar and spelling
- P&T Competition details
 - Remove any information that could identify your school or team
 - Follow the rules!

Common Errors

- Does not adhere to P&T Competition rules and requirements
- Grammar
- Typographical errors and spelling
- Abbreviations used are not defined when first used

References & Resources

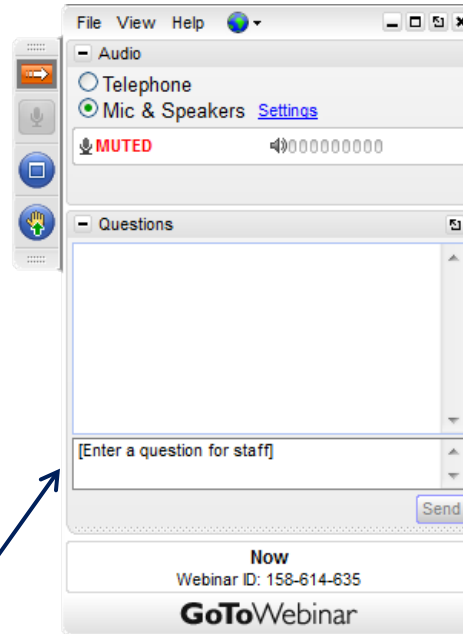
- General resources are publicly available on [2021 P&T Competition page](#) on AMCP Foundation website
- 2021 case study resources are available for secure download by Competition Coordinators and Advisors
- AMCP Foundation/SPC archived session on [Identifying and Evaluating Information for Evidence-Based Drug Formularies](#)
- AMCP [Fundamentals of Managed Care Pharmacy](#) course

Other resources could be helpful but if they were not designed with a managed care focus... Ask your advisor or Diplomat!



Questions?

How to Ask a Question



Type your
question in the
'Questions'
area

Panel on Local Competitions & COVID

Panelists



Karen Nguyen, PharmD Candidate 2022
University of Maryland, School of Pharmacy
AMCP Student Pharmacist Committee Member



Ryan Thailiffdeen, PharmD Candidate 2021, Univ. of California at San Francisco
1st place national team, AMCP Foundation P&T Competition 2020
AMCP Student Pharmacist Committee Member



Emily Tran, PharmD Candidate 2023, University of Illinois at Chicago
UIC Competition Coordinator



Local Competitions & COVID

Faculty Advisor Survey

(Oct. 1, 2020)

- 24 schools represented
- 100% schools were operating with one or more restriction related to COVID-19
- 91% still planned to host a local competition



Learn more about the P&T Competition:
www.amcpfoundation.org/PT

Deadline January 25, 2021!

Register for upcoming AMCP webinars:
www.amcp.org/calendar

Thank You

