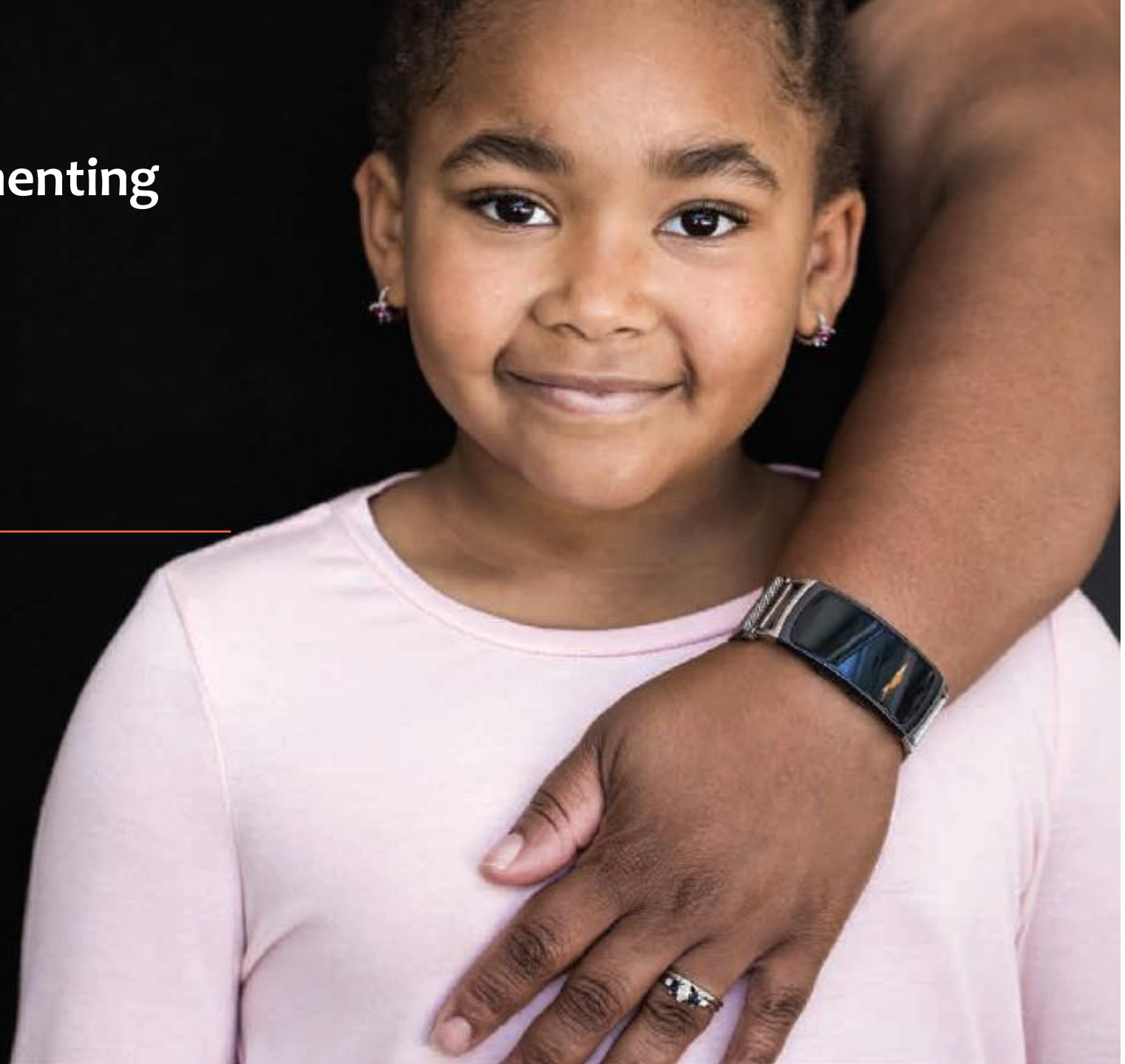


Overview of the Public Commenting Open Forum Held March 29, 2022

Jessica Simpson, MPH

April 11, 2022



Main theme: stakeholder input



- ▶ Discussed where stakeholder feedback has been received, what was heard, and how it's been implemented thus far
- ▶ Reviewed standard setting process and opportunities for engagement throughout
- ▶ Mural session to gather more feedback and prioritize ideas we've heard
- ▶ Reviewed upcoming comment form and asked for further input
- ▶ USP hears stakeholder feedback and is continuing to act on it

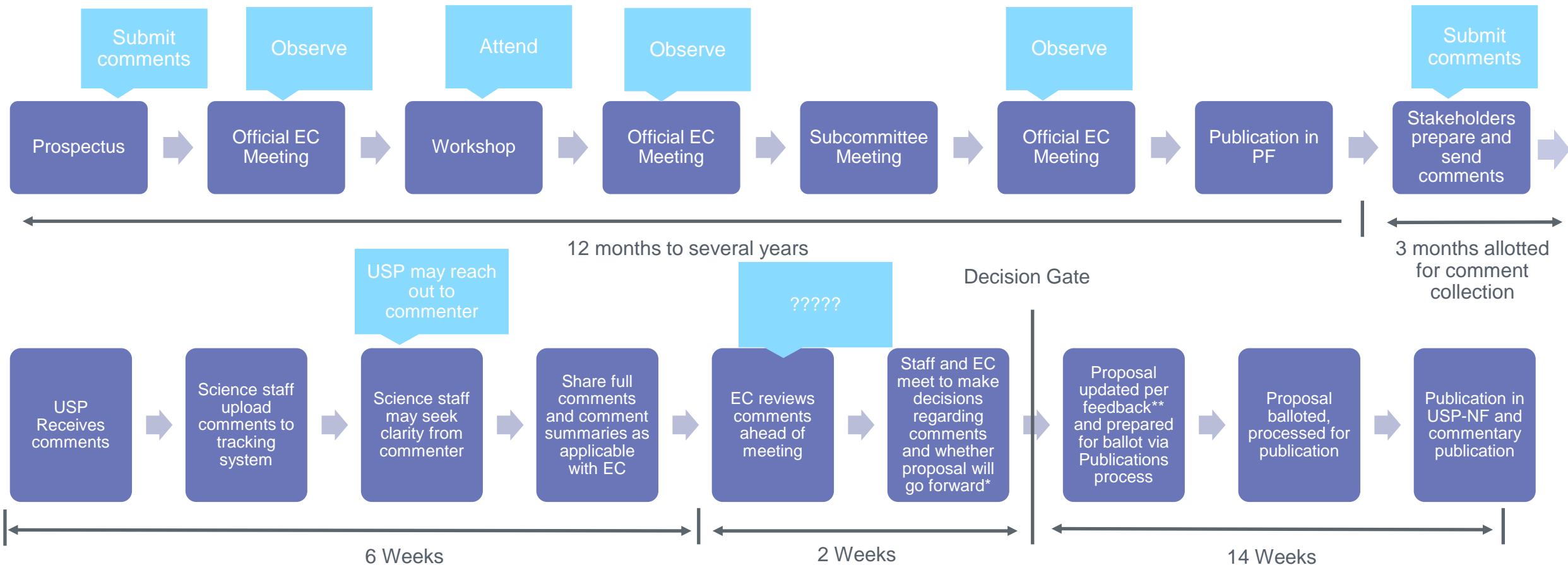


- ▶ Compendial Process Improvement Project Team has provided recommendations to USP throughout its history
- ▶ Multiple surveys
 - USP customers, PNP attendees, PF users, USP-NF users
- ▶ FDA Quarterly meetings
- ▶ Customer Advisory Board
- ▶ Prescription/Non-Prescription Stakeholder Forum
 - Industry presentations
 - Breakouts
- ▶ User interviews

- ▶ How to have an impact on standards—early in the process and during PF
- ▶ Want to know more about commenting
 - How to comment effectively
 - Understand the comment process
 - Dispensation of comments
- ▶ Desire for transparency in the standards-setting process
- ▶ Implement a standardized comment form
- ▶ Incorporate line numbers in PF
- ▶ Want more opportunities to communicate with Expert Committees and more feedback on comments

Comprehensive engagement example and timelines

Example standard goes through one PF publication, moves to ballot, and is approved at ballot



*these decisions are made following Robert's Rules
 **changes must adhere to Rules and Procedures of the CoE

Mural session outcome

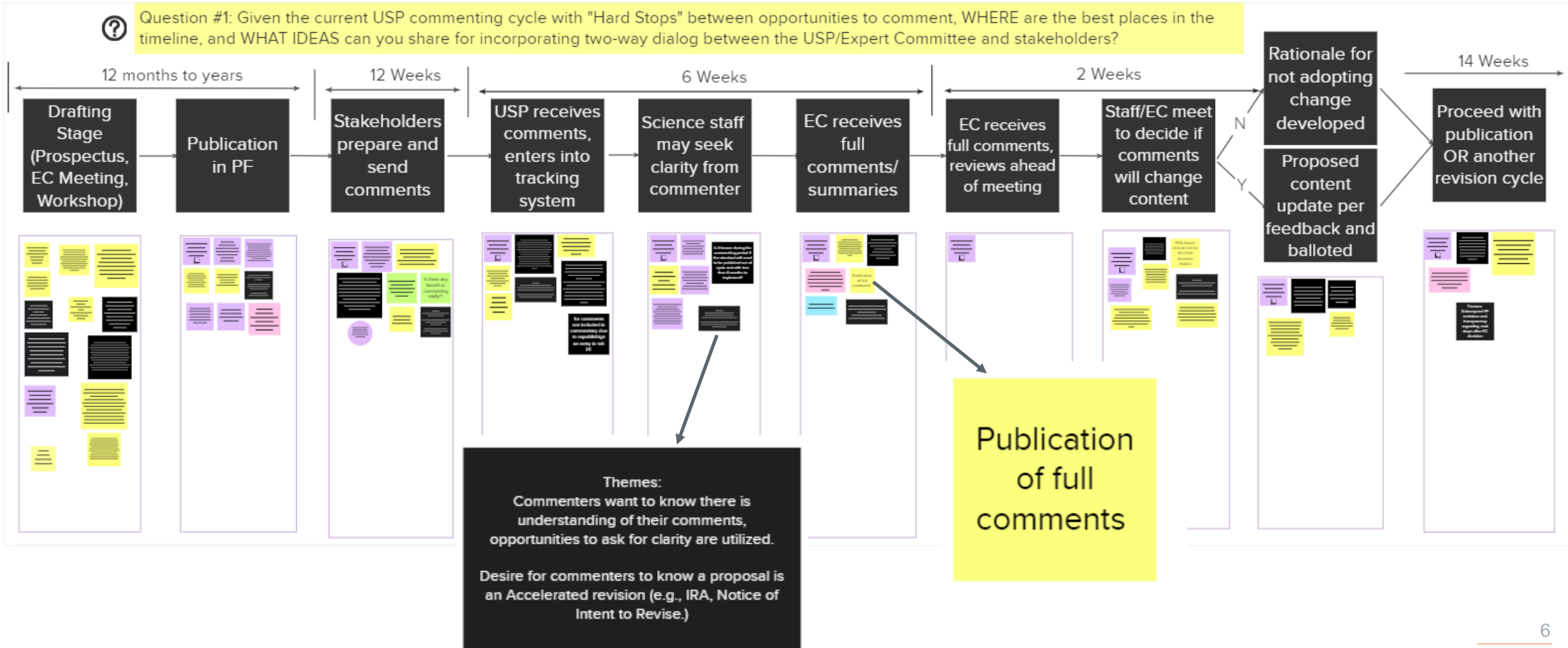


Current/Future of Public Comments Process

Our Goal is to identify best solutions to improving public commenting for both USP and Stakeholders

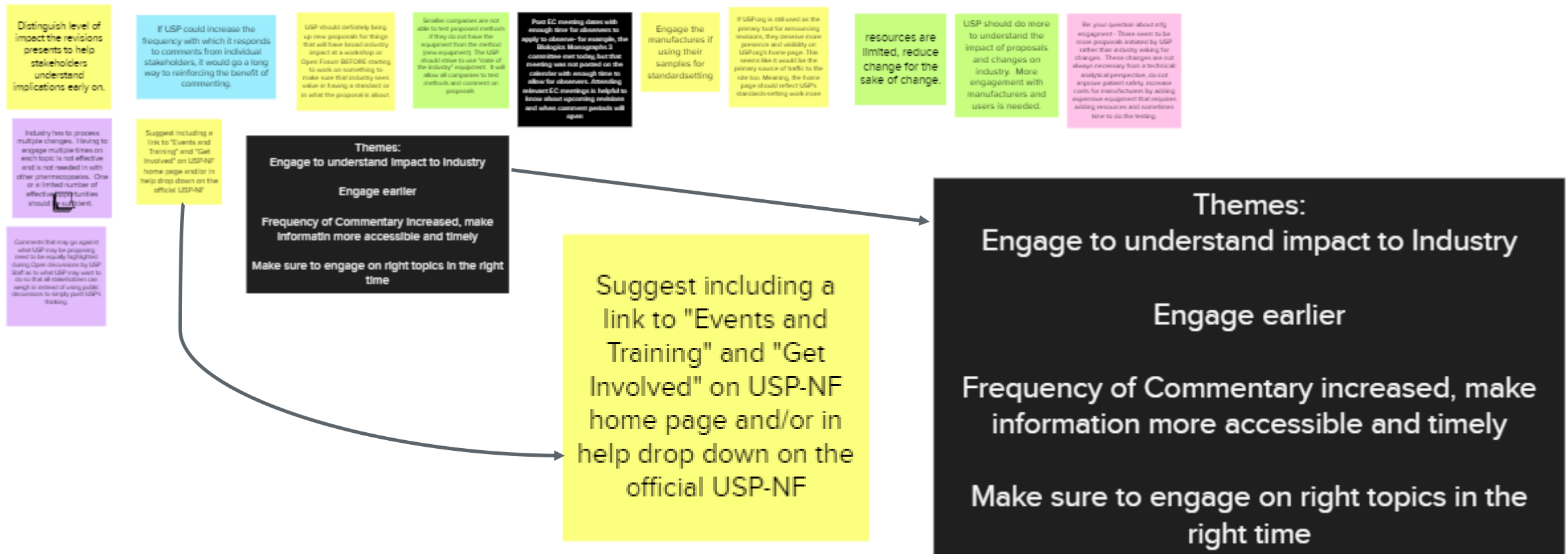


Question #1: Given the current USP commenting cycle with "Hard Stops" between opportunities to comment, WHERE are the best places in the timeline, and WHAT IDEAS can you share for incorporating two-way dialog between the USP/Expert Committee and stakeholders?




Mural session outcome

Question #2: What could the USP do to get Stakeholders to utilize more fully the current opportunities for engagement/comments-sharing regarding standards development?



Mural session outcomes

Voting results

22 votes 

A tracking system for each response/form to enable stakeholders to check on comment status online without going through the liaison each time

Unique voters 21

21 votes

Viewing other commenter's comments publicly, for commenters who agree that their comments may be published

Unique voters 19

5 votes

Implementing a standardized comment form that characterizes comments as critical/other?

Unique voters 4

4 votes

A tool to highlight the exact text you are commenting on that are consistent between online publications and PDF downloads

Unique voters 4

- ▶ Asked stakeholders to use 2 votes to prioritize 4 previously submitted ideas

Comment form updates launching June 2022



Launching June 2022

Draft/Send Comments

Subject:

Who are you submitting these comments on behalf of ? *

Myself

Organization

Organization Type: *

Select

- Select
- Company
- Academic Institution
- Government
- Trade Organization
- Other

Public posting of comments: *

Draft/Send Comments

Subject:

Who are you submitting these comments on behalf of ? *

Myself

Organization

Organization Type: *

Trade Organization

Organization Name:

Saving draft and accessing past comments



Launching June 2022

My Resources

DOCUMENT	COMMENTING STATUS	COMMENTING DATE	PUBLICATION	SUBMISSION STATUS	LAST MODIFIED
Bromelain PF 47(6)	Commenting Open	01-Nov-2021 to 31-Jan-2022	PF 47(6)	Draft	28-Mar-2022
Norflurane PF 47(6)	Commenting Open	01-Nov-2021 to 31-Jan-2022	PF 47(6)	Draft	28-Mar-2022
Bromelain PF 47(6)	Commenting Open	01-Nov-2021 to 31-Jan-2022	PF 47(6)	Draft	28-Mar-2022
Polyethylene Glycol 30 Dipolyhydroxystearate 5 PF 47(6)	Commenting Open	01-Nov-2021 to 31-Jan-2022	PF 47(6)	Submitted	24-Mar-2022
Bromelain PF 47(6)	Commenting Open	01-Nov-2021 to 31-Jan-2022	PF 47(6)	Draft	24-Mar-2022
〈1604〉 Presentation of Aerodynamic Particle Size Distribution (APSD) Measurement Data for Orally Inhaled Drug Products PF 48(1)	Commenting Open	03-Jan-2022 to 31-Mar-2022	PF 48(1)	Draft	01-Mar-2022
〈1604〉 Data					

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- ▶ [Rules and Procedures of the Council of Experts](#)
- ▶ [Request for Revision information and guidelines](#)
 - Stakeholders are welcome to submit information and recommendations for developing new monographs or revising proposed or existing official monographs. Revisions may be to an entire monograph or specific monograph tests, procedures, and/or acceptance criteria. USP also welcomes proposed revisions to general chapters.
- ▶ [Commentary location and schedules](#)
- ▶ [Overview of the USP-NF training webinar](#) (free, 49 minutes)
- ▶ [Accelerated Revision Process and Guideline](#)
 - The Rules and Procedures of USP's Council of Experts specify processes that can be used to make revisions to the USP–NF official more quickly than through USP's standard revision process. These accelerated processes include Errata, Interim Revision Announcements (IRAs), and Revision Bulletins.

Thank You



Empowering a healthy tomorrow