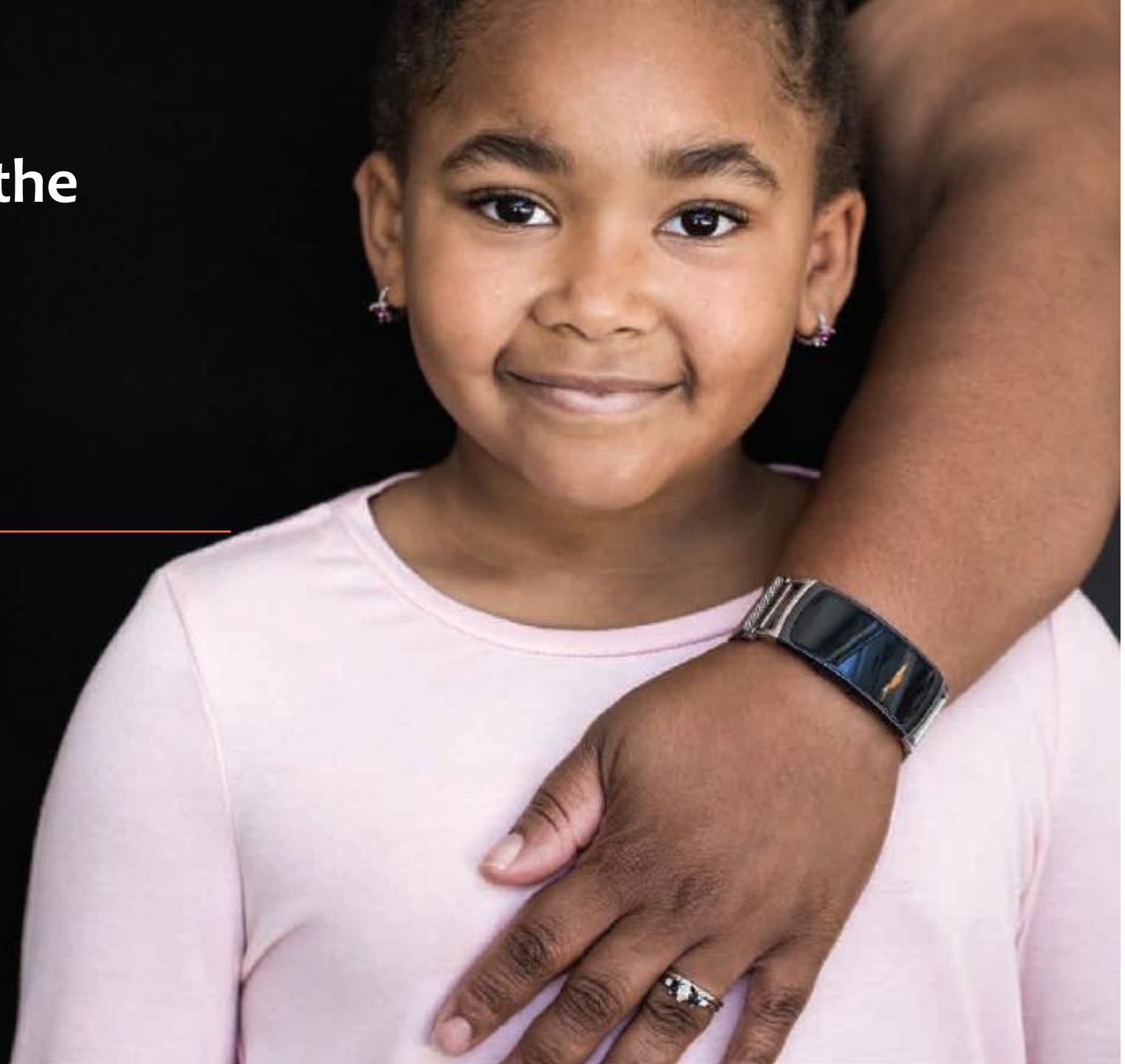


Engagement throughout the Commenting Cycle

Jessica Simpson, M.P.H.

March 29, 2022



1

What we've heard from Stakeholders

- ▶ 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

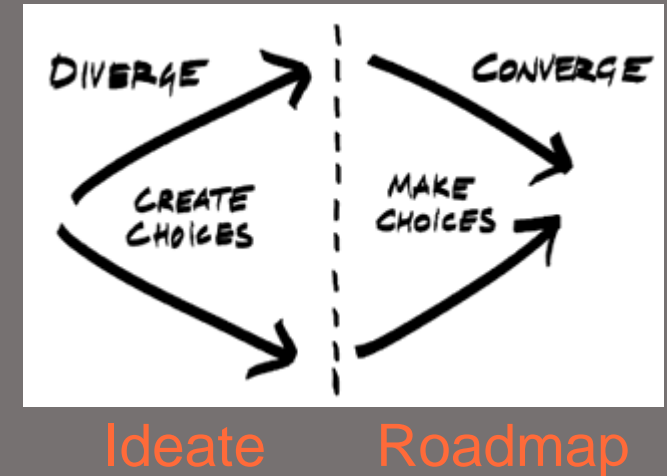
- ▶ How to have an impact on standards—early in the process and during PF
- ▶ Want to know more about commenting
 - How to comment effectively
 - Understand the comment process
 - Dispensation of comments
- ▶ Desire for transparency in the standards-setting process
- ▶ Implement a standardized comment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

Putting the input into design



Understanding user needs

- ▶ USP worked with Designit, an ethnographic research and design thinking firm, to understand user needs throughout the commenting process.
 - Under their previous name, Cooper, they worked with us to redesign USP–NF
- ▶ Compiled all the input received and provided that as foundational information to build off
- ▶ Designit interviewed stakeholders and staff to understand how they interact with the standards-setting process

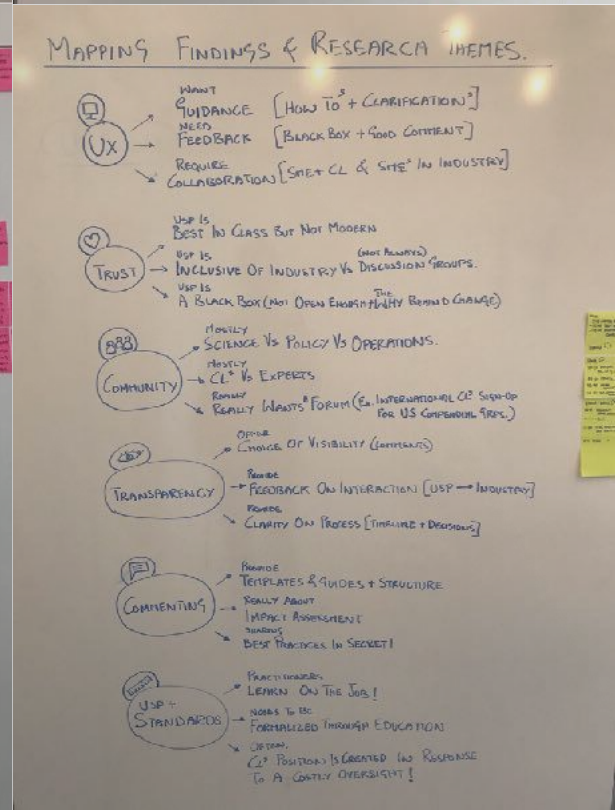
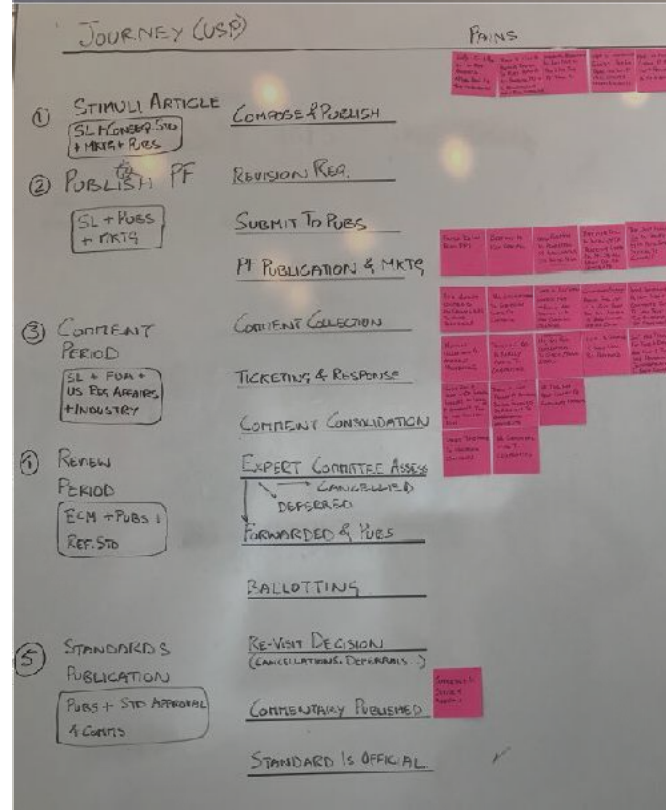


Synthesis

08 iterations

02 weeks

Gathered all the information collected and laid out the data in a "war room." Multiple brainstorming sessions and data re-formatting lead to certain core insights and journey maps for the teams involved.



Awareness and education about USP and the PF greatly determine engagement.



Orchestrating the commenting process takes up most of a compendial liaison's time.



Transparency builds trust in the process and the brand.



Industry comments are prioritized and shaped by assessing both science and operations.



Clarity of communication greatly affects the detail and speed of commenting.



Compendial Liaisons rely on their professional community for context, knowledge sharing, and development.



2

Commenting Process and Timelines

Basic stakeholder engagement

New and regular revisions baseline engagement requirements per the Rules and Procedures of the Council of Experts

*Pharmacopeial
Forum*

Commentary

Comprehensive engagement via the SEM

Stakeholder engagement model pulls engagement forward:

Expert engagement examples:

Expert Committee

Expert Advisor

Working group

Subcomm/joint

Expert Panel

PF

Commentary

Stakeholder engagement examples:

Collect information

Survey

Open Mic

Knowledge Hub

Regulatory outreach

Company trade org outreach

Convene stakeholders

Project Team

Open Forum

Round Table

Stakeholder Forum

Workshop

Formal communications

Prospectus

Compendial Notice

Stimuli Article

Forum Briefing

Journal Article

Informal communications

eNews-letter

Social Media Post

Blog Post

White Paper

Share information

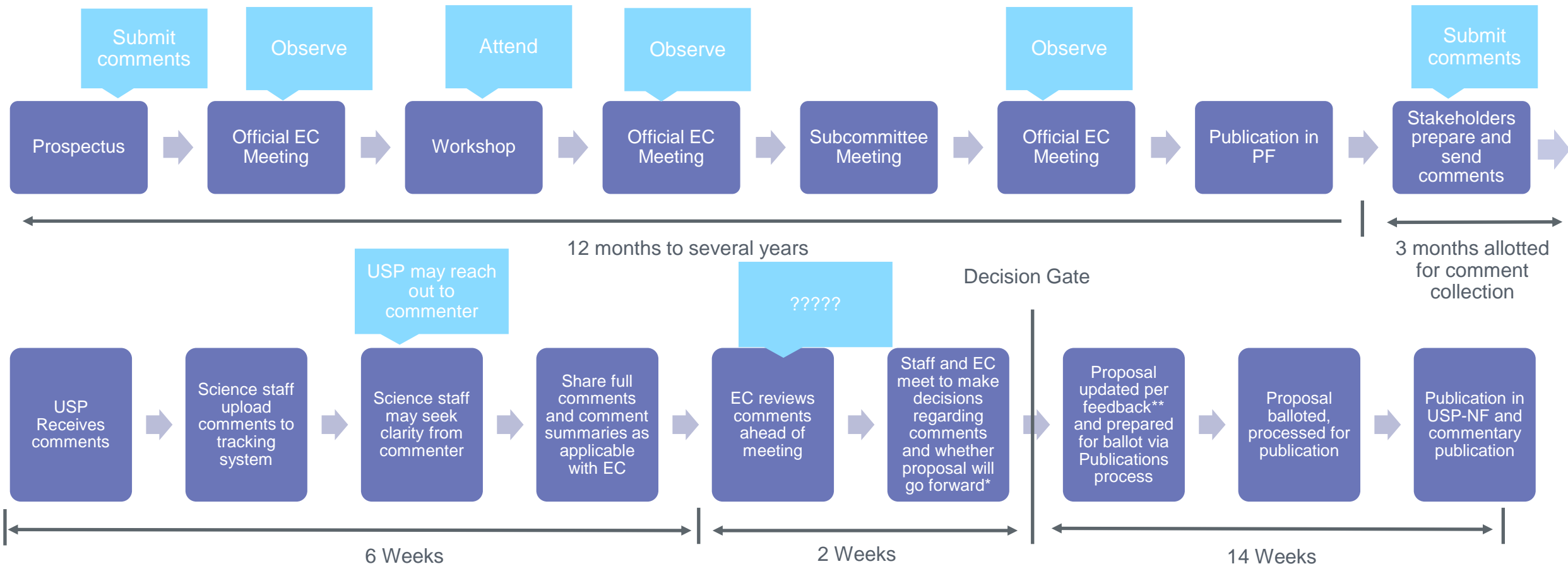
Education course

Open Mic meeting

Meeting Observer

Comprehensive engagement example and timelines

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

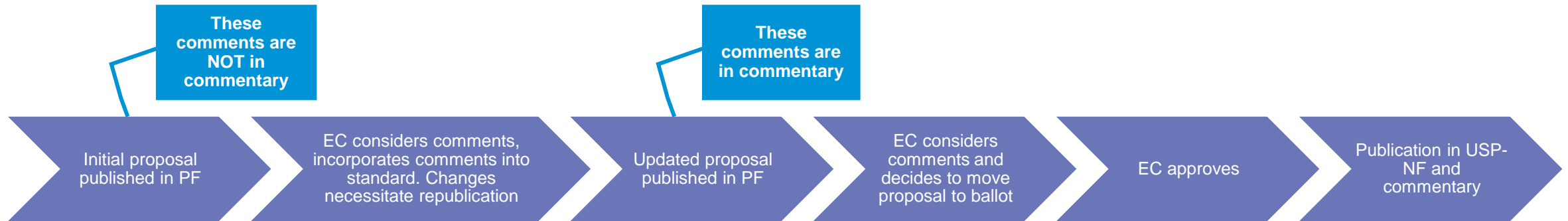


*these decisions are made following Robert's Rules
 **changes must adhere to Rules and Procedures of the CoE

Why aren't my comments in commentary?

There are only two reasons

- ▶ When initial PF publication is followed by another round of PF publication



- ▶ Comment on a section NOT under revision

▶ CoE Rules 9.05(e) Commentary

- Where a proposal appears in the PF and is approved for publication in the USP-NF, a summary or abstract of each significant type of comment received and a succinct response to the comment from the Expert Committee or CoE Chairperson shall be posted on USP's website and called Commentary.
- Comments received on text that are not the subject of a proposed revision generally are not considered for inclusion in the Commentary unless the comments result in a change to the text.

- ▶ Otherwise, your comments are in commentary and are summarized very succinctly

USP-NF: Current State



- ▶ Pharmacopeial Forum (PF):
 - Batched publication 6 times per year
 - 90 day comment collection for all proposals



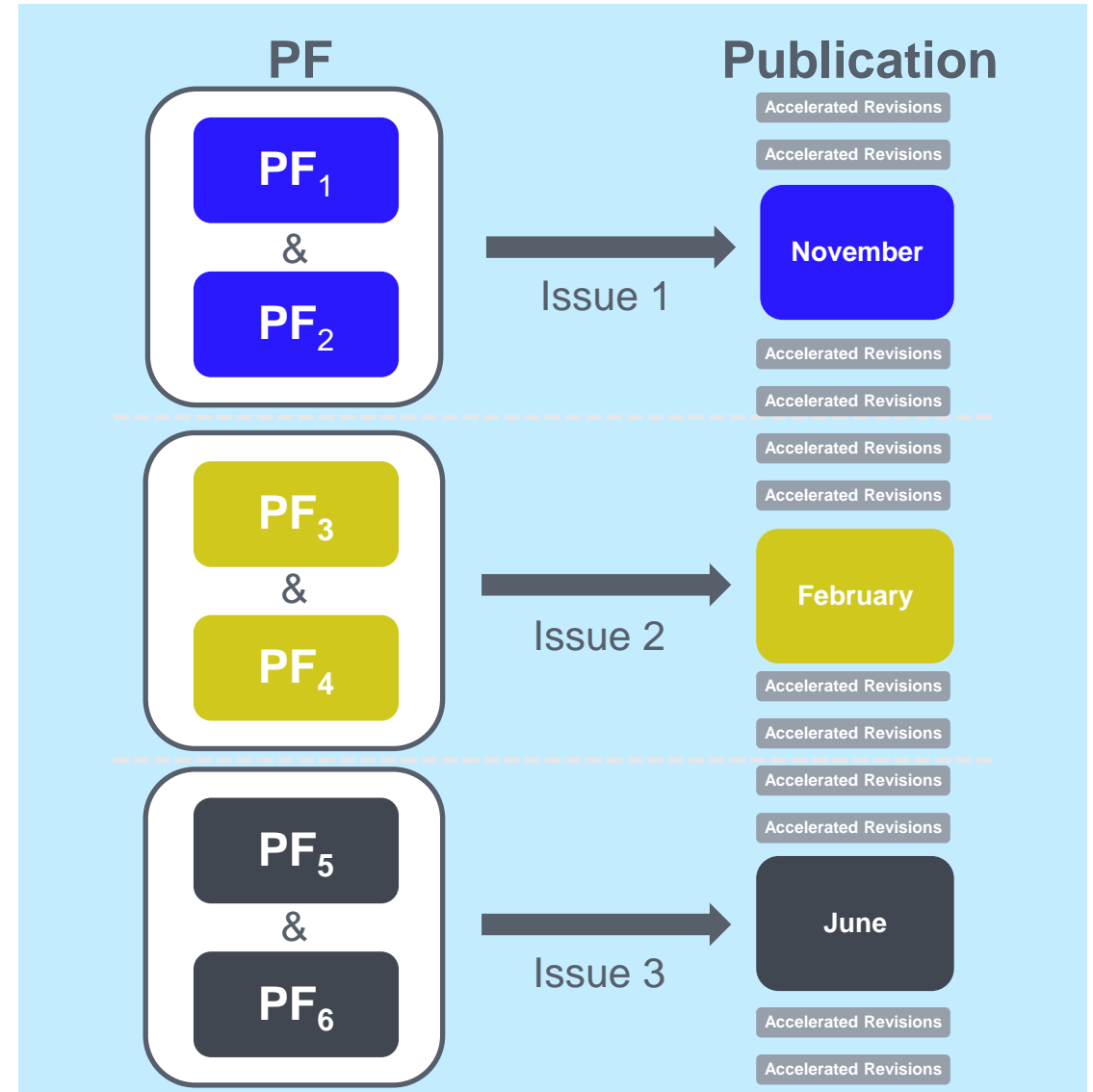
- ▶ PF to Compendial Publication Ratio:
 - Two PFs per Compendial Publication, **2:1**
 - 6 PFs to 3 Compendial Publications per year, **6:3**



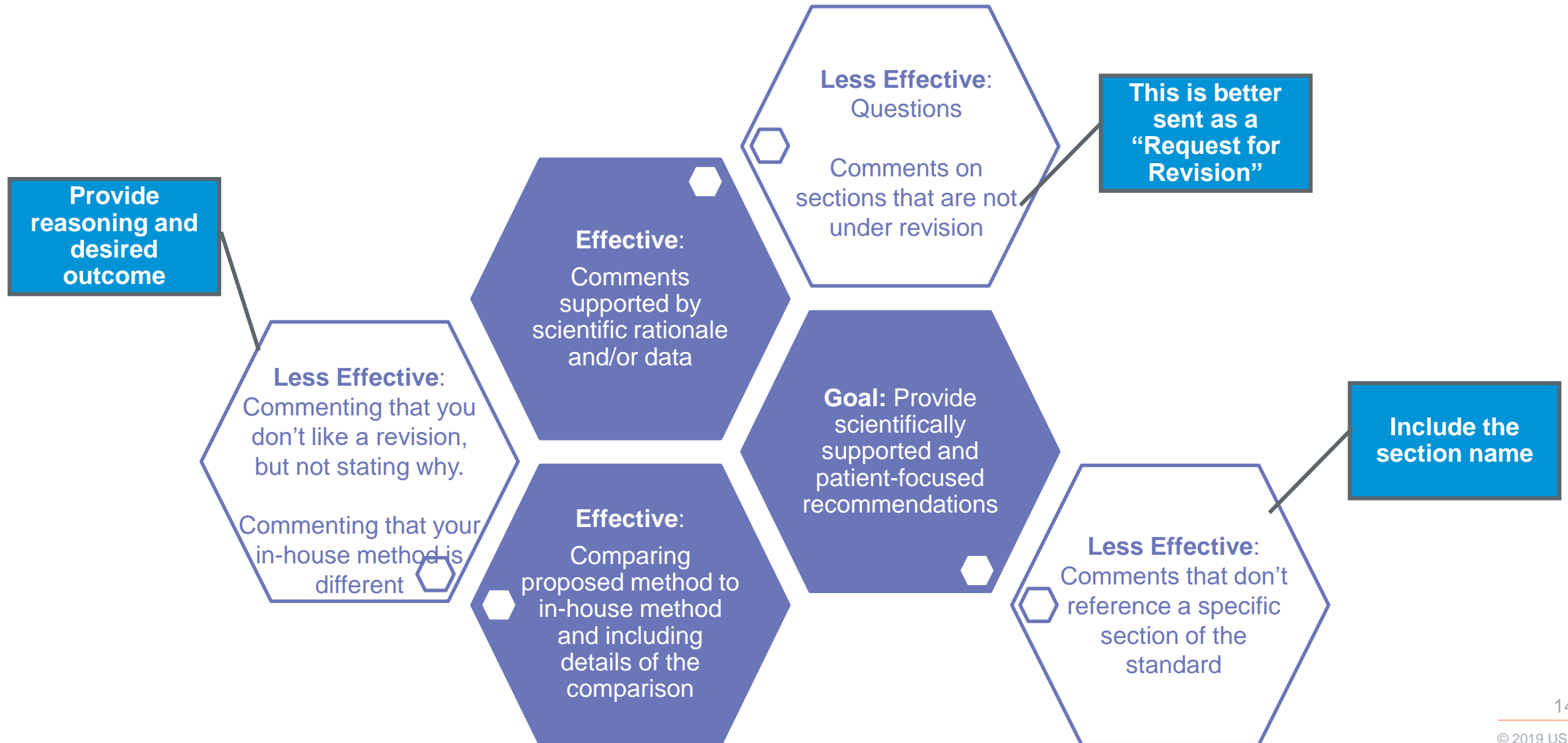
- ▶ Official Publication Schedule:
 - 3 Compendial Publications: November, February, June
 - Uneven spacing between (3, 4, 5 months)
 - 12 Accelerated Revisions: monthly (last Friday of month)



- ▶ Deferrals and Cancelations
 - Based on comments received, some proposals are either
 - Deferred: held from upcoming ballot, still eligible to ballot later
 - Canceled: proposal is withdrawn, no longer eligible for ballot
 - Lists of these are available on uspnf.com



Effective Commenting



- ▶ [Rules and Procedures of the Council of Experts](#)
- ▶ [Request for Revision information and guidelines](#)
- ▶ [Commentary location and schedules](#)
- ▶ [Overview of the USP-NF training webinar](#) (free, 49 minutes)



Thank You



Empowering a healthy tomorrow