

USP Excipients Stakeholder Forum  
Wednesday, November 13, 2019

# Public Input Lifecycle and Impact Program (PILIP)

Jessica Simpson  
Senior Manager, Compendial-Operations



# Agenda

## What we're talking about today

- ▶ What is PILIP?
  - Goals
  - Scope
  - Benefits
- ▶ How we got here
- ▶ Where we're going
  - The 7 Ideas we're working on now
  - Preview of things to come
- ▶ Breakout Sessions



# What we're not talking about today

- ▶ Design and/or requirements of the future PF
- ▶ Design and/or requirements of future PF tools
- ▶ Implementation timeframes
- ▶ Line numbers (maybe)

# What is PILIP?



## PILIP Goals

- ▶ Improve USP's public input processes, and subsequently USP's standards, through more effective stakeholder outreach and timely engagement that ensures USP standards reflect user needs and constraints, and ultimately are fit for purpose.
- ▶ Develop new, research-based Forum tools and comment mechanisms that integrate the public input processes and systems with transforming standards development processes and systems
  - Conduct both internal and external research
  - Understand the unique needs of stakeholders, especially around communication



# What is PILIP

## PILIP Scope

- ▶ While improving the forum tools is a major component of the project, the scope is much greater
- ▶ PILIP covers the lifecycle of a standard— beginning with development, identification of affected stakeholders, public notice and comment, communication about outcomes
  - Explores stakeholder engagement throughout the process
  - Questions assumptions about policies and processes

Standard

PF

Lifecycle



# Benefits



## ▶ Building Trust

- Bring transparency and enhanced communication across the standards-setting process
  - PILIP is addressing lot of topics touched on today- commentary changes, mechanisms for gathering input, transparency, working together to understand each other's needs and build the right solutions

## ▶ Improving our standards

- Better, more representative engagement leads to improved standards

## ▶ Creating efficiency in the standards-setting process

- Changing the engagement paradigm from active and complex to passive and approachable
- Creating context around proposals, asking the right questions, and creating a clear framework for comments will help users interpret proposals and focus their feedback

## ▶ Demonstrating the value of our process

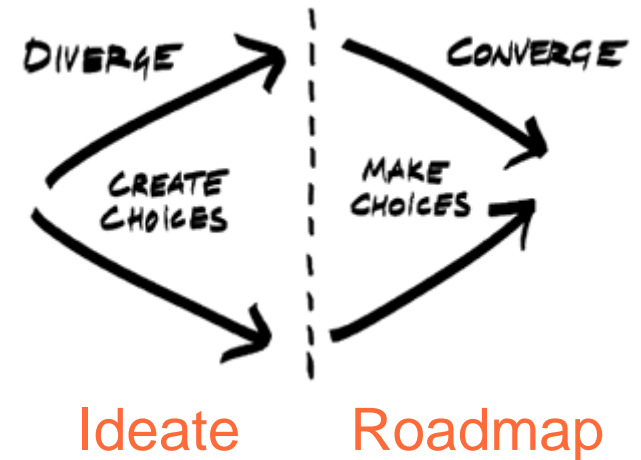
- Enhancements and transparency will make the value of participation more clear, feeding a cycle

# Analysis phase



## Understanding user needs

- ▶ USP worked with Designit, an ethnographic research and design thinking firm, to understand user needs.
  - Under their previous name, Cooper, they worked with us to redesign USP–NF
- ▶ We shared years of feedback (minutes, notes, recommendation letters, and more) from FDA, CPI PT, Stakeholder Forums, staff, survey data
- ▶ Designit interviewed stakeholders and staff to understand how they interact with the standards-setting process
  - Thank you to all who volunteered at the PNP last year!



# Workstreams: 22 ideas from the analysis, categorized



## Collaborative Platform

- Proposal project dashboard
- Internal collaborative workspaces
- User collaborative workspace



## PF User Dashboard

- Historic document views
- Email and dashboard notifications
- Dependencies and suggested subscriptions
- Comment tracker



## Comment Enhancements

- Comment form and visibility
- Consolidated comments
- Inline commenting
- Comment analytics



## PF Engagement Enhancements

- Detailed briefings
- Shareable document previews
- Historic document versions
- Updated editorial guidelines
- Discussion groups
- Impact feedback form
- Education campaigns
- Update badges for USP-NF



## Publication Integration

- Update badges for USP-NF
- Side by side documents
- Integration

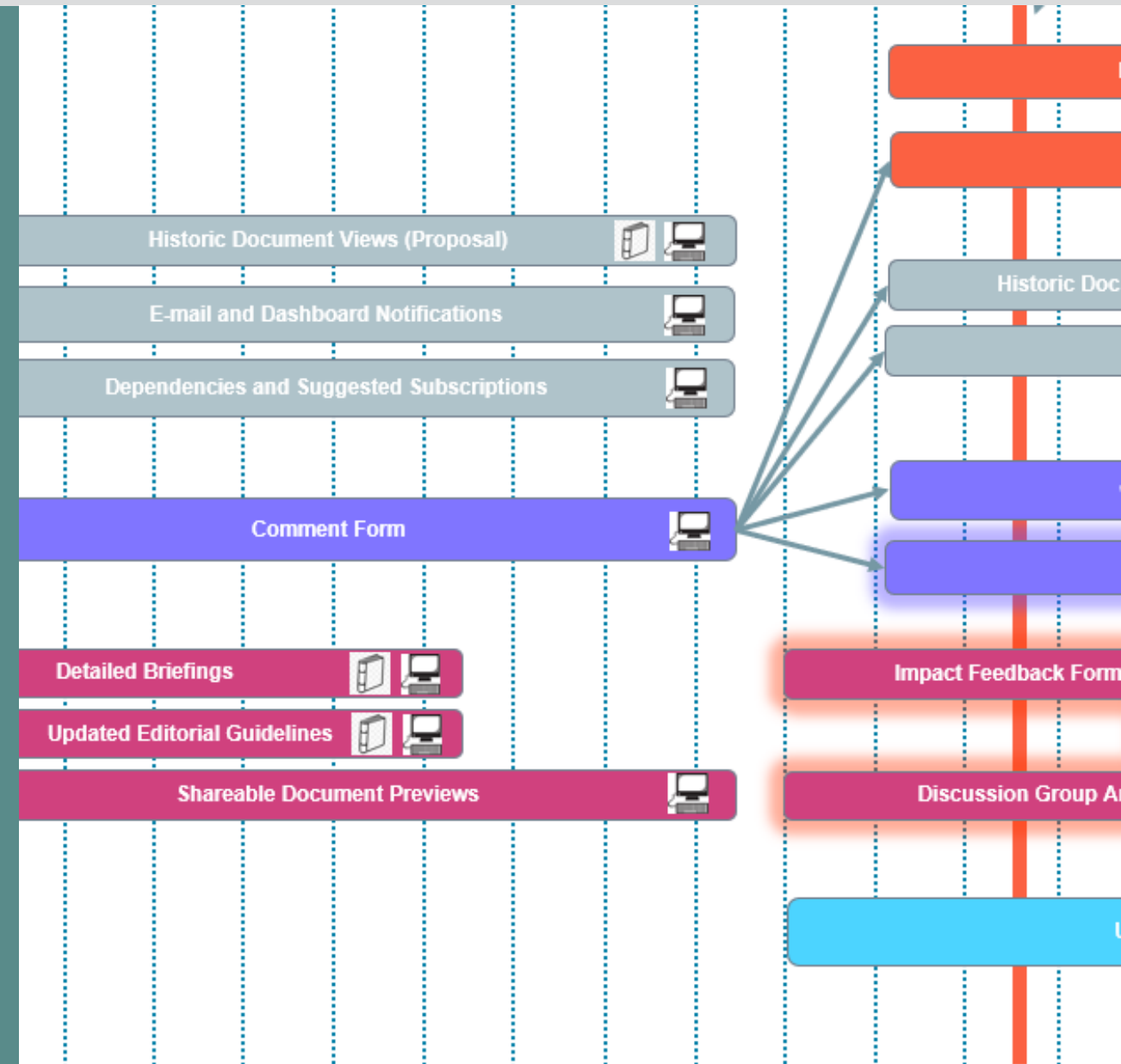
Beyond the 22 ideas: transparency, commentary, “faster PF”, engagement mechanisms, PF as a content hub



# Where we're going

## Release 1

- ▶ PF User Dashboard
  - Historic Document Previews
  - Email and Dashboard Notifications
  - Dependencies and Suggested Subscriptions
- ▶ Comment Enhancements
  - Comment Form
- ▶ PF Engagement Enhancements
  - Detailed Briefings
  - Updated Editorial Guidelines
  - Shareable Document Previews



# 08 Historic document versions

Useful for  
SLs, expert council members, CLs,  
SMEs, lab scientists

Useful during



**Historic versions and comments allows users to explore the context of proposed changes and how their company addressed them in the past.**

CLs manually document all changes and correspondence relevant to their company and products — it helps them respond appropriately to future changes. With all of this information available at a glance, they no longer need to dig up old documents to effectively comment. This could also benefit internal users during the development phase.

### Relevant insights

- Assessment
- Orchestration
- Transparency



# 09 Email and dashboard notifications

Useful for  
SLs, expert council members, CLs,  
SMEs, lab scientists

Useful during



**Individualized notifications and digests of relevant news, proposed changes, or deadlines keeps users engaged at the right times and on the right topics.**

Instead of having to track the timeline of upcoming proposals and sort through the content, users could be alerted of news that is relevant to their company or important tasks in need of their attention.

### Relevant insights

- Awareness
- Community
- Orchestration
- Transparency



# 03 Dependencies and suggested subscriptions

Useful for  
SLs, CLs, SMEs, lab scientists

Useful during



**Showing document dependencies lets users and SLs alike see links and cross-references across the USP-NF.**

A public database of dependencies and cross-references could be useful across the board, helping a user find and 'follow' related documents or showing a scientific liaison how a proposed change might affect other documents.

**Relevant insights**

- Assessment
- Awareness
- Orchestration
- Transparency



# 18 Comment form

A comment submission form structures feedback in a way that supports scientific liaisons and guides compendial liaisons.

Together with the **detailed briefings** and **inline comments**, a submission form for comments can help CLs craft targeted feedback with appropriate validation.

Useful for  
SLs, CLs, SMEs, lab scientists

Useful during



**Relevant insights**

Community  
Orchestration  
Transparency



# 14 Detailed briefings

Useful for  
CLs, SMEs, lab scientists

Useful during

Pre PF   Development   **Commenting**   Review   Standard



**Detailed briefings can give context and specific questions to guide effective commenting.**

An overview of why changes were made as well as prompts for specific feedback would help compendial liaisons assess proposals more quickly and thoroughly. In combination with **historic versions** and **side-by-side documents**, everything they'd need to comment could be viewed at once.

This could also tie directly in to **sharable document previews**.

## Relevant insights

- Assessment
- Clarity
- Orchestration



# 04 Updated editorial guidelines

Useful for  
SLs, CLs, SMEs, lab scientists

Useful during



**Unambiguous language written with end users in mind ensures clarity and fosters better feedback.**

With less time spent interpreting documents, users could spend more time giving useful comments on the content of a proposal rather than the syntax and semantics.

This could also serve users by clearly outlining USP's writing style, mitigating potential confusion.

### Relevant insights

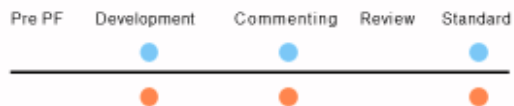
Clarity  
Orchestration



# 11 Sharable document previews

Useful for  
Strategic marketing, CLs

Useful during



**Sharable document previews increase the effectiveness and reach of marketing efforts.**

Without requiring a login and several clicks, previews of proposed changes can be shared with wider audiences. A taste of the platform could also encourage potential users to sign up.

Could tie nicely with **detailed briefings**.

### Relevant insights

- Clarity
- Community
- Transparency





# Further release Ideas to highlight

- ▶ These are not in Release 1
- ▶ We know these are critical components to making PILIP successful
- ▶ Yes, I know you want line numbers
  - I have news for you...

# 16 Inline commenting

Useful for  
SLs, expert council members, CLs,  
SMEs, lab scientists

Useful during



**Inline commenting removes ambiguity and allows for targeted feedback.**

Precision commenting removes much of the burden scientific liaisons face in clarifying the feedback they receive while also giving users the security of knowing they're being understood. Similarly, this could also help collaborators during proposal development and comment review.

### **Relevant insights**

- Clarity
- Orchestration
- Transparency



# 21 Comment tracker

**A visual progress tracker, combined with notifications and conversations with SLs, eliminates the “black hole” and all its frustrations.**

Seeing the progress of their comments and unfolding conversations with SLs could go a long way towards making commenting feel more meaningful and impactful. In the end, commentary could be tracked to individual comments, making it easier to see the final results.

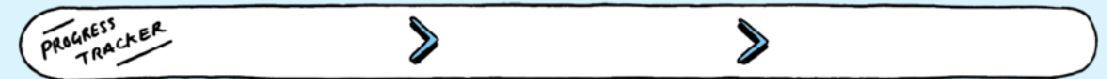
Useful for  
SLs, CLs

Useful during



### Relevant insights

- Community
- Orchestration
- Transparency



# Thank You



**Empowering a healthy tomorrow**