USP Open Forum | Excipients

USP Standards Engagement Model and what it means for stakeholders

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The standard of trust

For quality standards to be impactful, they must be…

Aligned with
Public health and patient safety priorities

Developed by
Independent experts

Adapted & Improved
For technology and evolution of healthcare

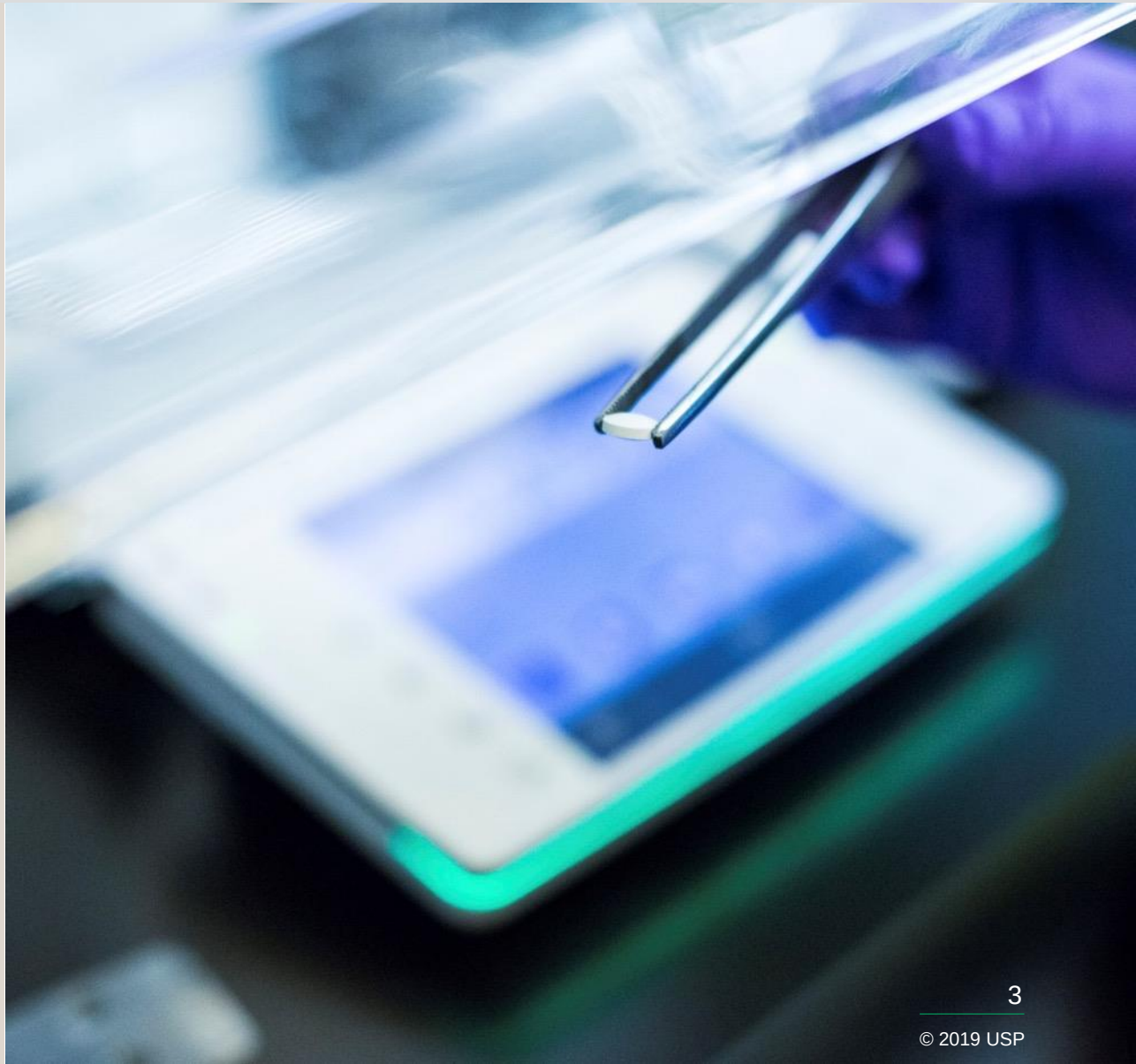
Practical for
- Users of the standard
- Enforcers of the standard

Measured by
Public health impact indicators

Informed by
Real world implications for patients and practitioners

New engagement model focuses on efficiently addressing priority problems

- Smaller core committees with leaner workplan focused on highest priority problems
- Convene the right experts for targeted discussions
- Realize progressive impact and iterate as necessary
- Agility to redeploy efforts as new problems arise
- Engage additional expertise from pool of flexible volunteers (Expert Advisors)



What does this mean for stakeholders?

Enhanced engagement

- Highly impactful standards have been utilizing the full engagement toolkit
- SEM promotes stakeholder engagement as part of *every* problem-solving plan
- Engaging stakeholders early is an important component of ensuring fit-for-purpose standards

Basic stakeholder engagement

New and regular revisions minimum engagement requirements

Pharmacopeial Forum or *Food Chemicals Codex Forum*

Commentary

Comprehensive engagement via the SEM

Evolving engagement toolkit covers the standards lifecycle

Expert engagement examples:

- Expert Committee
- Expert Advisor
- Working group
- Subcomm/ joint
- Expert Panel

PF or *FCCF*

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

Engagement projects in development

What is PILIP?

PILIP Goals

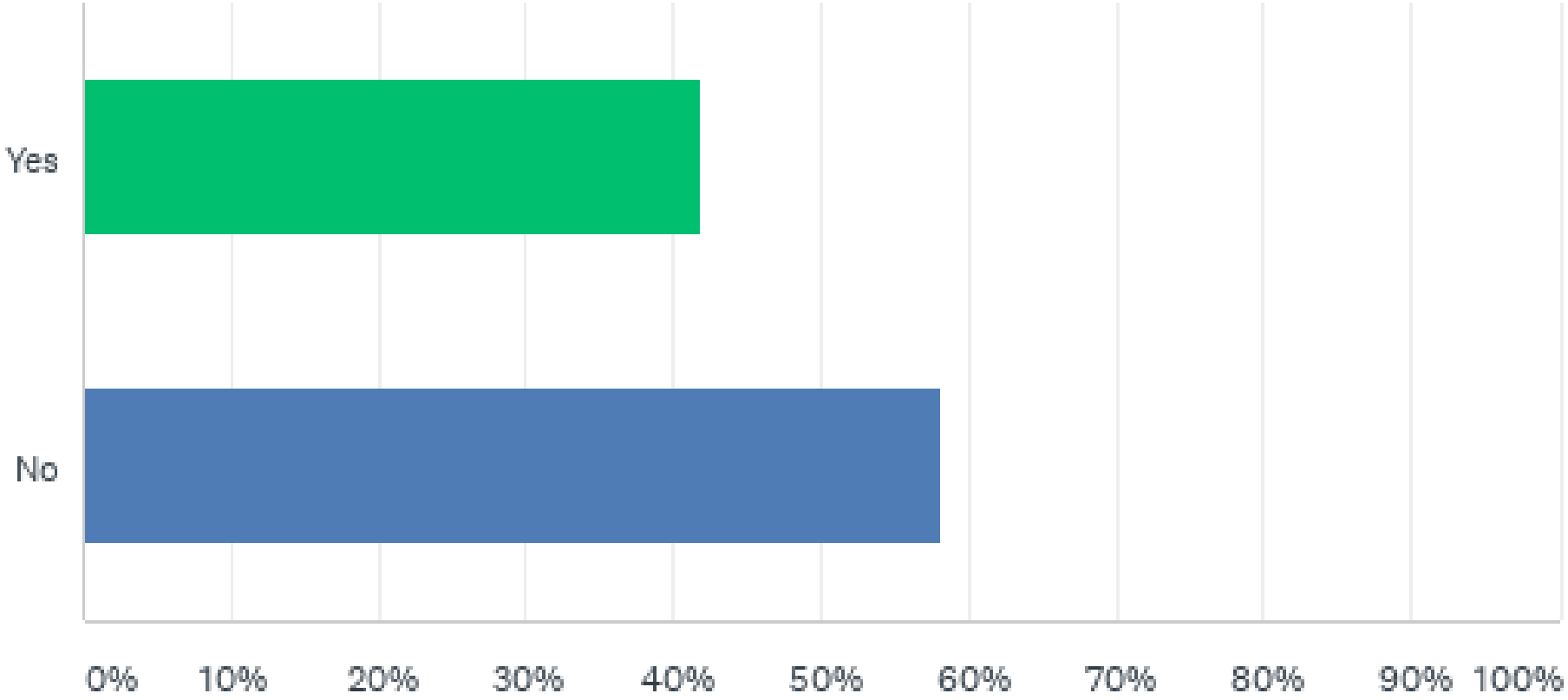
- Improve USP's public input processes, and subsequently USP's standards, through more effective stakeholder outreach and timely engagement that ensures USP standards reflect user needs and constraints, and ultimately are fit for purpose.
- Develop new, research-based Forum tools and comment mechanisms that integrate the public input processes and systems with transforming standards development processes and systems

Stakeholder engagement in PILIP thus far

- Assembled all PNP, Compendial Process Improvement Project Team, and relevant stakeholder feedback to share as foundational information with Designit (fka Cooper)
- Designit interviewed, in depth, stakeholders specifically to understand their comment journey
  - Built on information they learned throughout the USP-NF redesign process and added to it by interviewing domestic and international PF commenters
- PILIP ideas have been designed with this knowledge as the foundation
  - Insights from stakeholder interviews and background combined with “how might we” statements taken from stakeholders were the guide for development
- PNP breakouts in 2019 gave 2 lists of prioritized items which were reviewed by the USP PILIP team and integrated into idea planning. Breakouts in 2020 added more.
- As USP implements the Standards Engagement Model, USP staff who work closely with stakeholders work to represent the research and perspectives

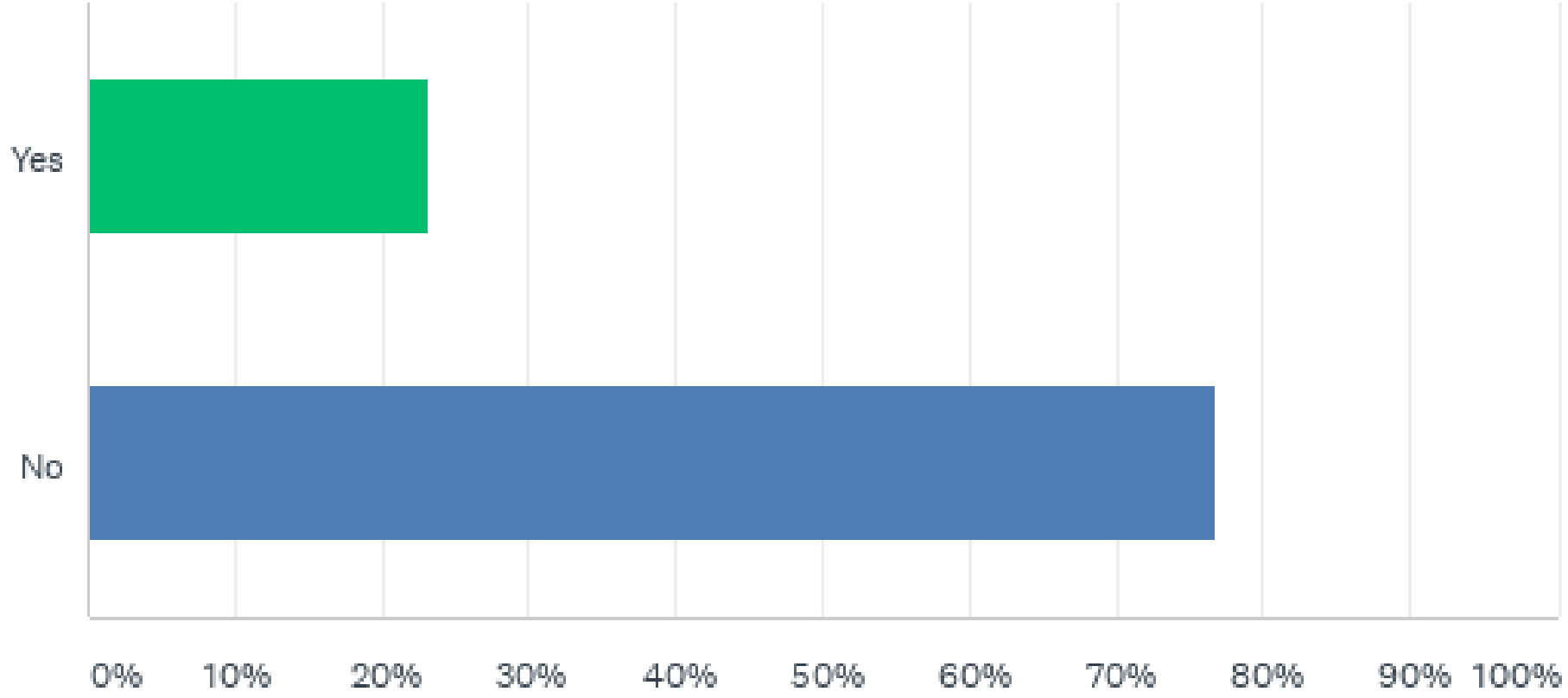
Q2: Do you use the PF comments feature to provide your comments?

- Answered: 43 Skipped: 0



Q4: Have you ever commented on Compendial Notices posted at uspnf.com/notices?

- Answered: 43 Skipped: 0



Where do the tools fit in the SEM?

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Form core EC

Identify problems
EC evaluates potential impact, applicability, and resources, and prioritizes into focused workplan

Identify Experts
Bring together the right people for a prioritized task with clear scope and timing

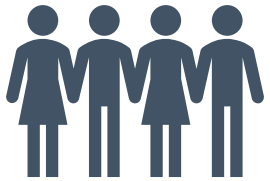
Convene Experts
Focused meetings, shared workspace, leverage virtual tech, engage the public

Share Outputs
Stimuli; proposed standard: manuscript; workshop; early feedback; etc.

Iterate
Realize impact and reconsider for further work

Transparent Comments

Chair/Vice Chair



Core Members

Co

Others (eg, industry rep)

P_1

P_2

P_3

P_4

P_n

Subcommittee
Formed from EC plus GLs, others as needed

Expert Panel
Broader experts join EC reps

Problems to be

PILIP

Pool of Experts

Independent experts

Govt Liaisons

Impacted experts

Global experts from all sectors who are engaged by the EC ad hoc to help solve particular problems

Thank You