

USP Informatics Activities

Allotrope Foundation Meeting
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Steve Emrick
spe@usp.org





Building foundations for a healthier world



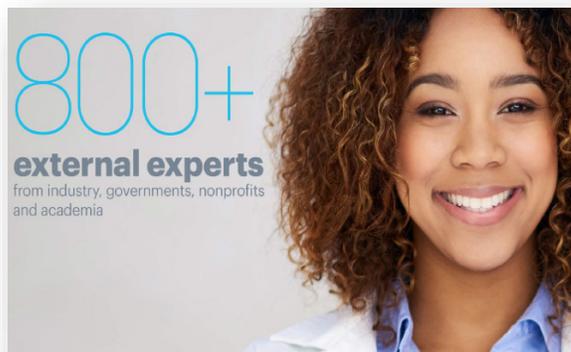


200

**years building quality
foundations for a
healthier world**



Advocating for Quality

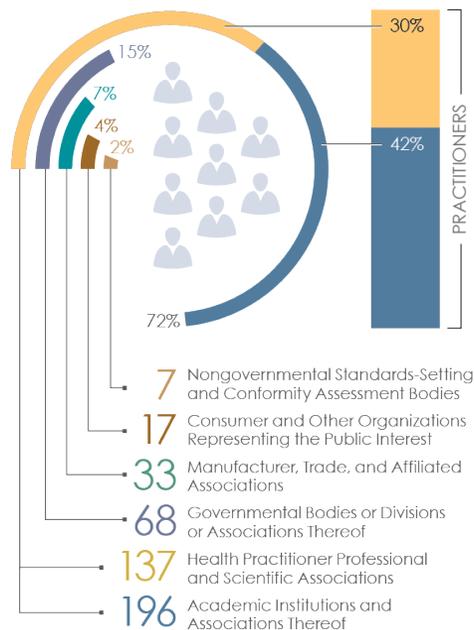


▶ USP-NF is recognized 40+ countries

▶ Diverse and strong partnerships

> 450 Organizations

- Academic Institutions and Associations
- Health Practitioner, Professional, and Scientific Associations
- Manufacturer, Trade, and Affiliated Associations
- Governmental Bodies, Divisions and Associations
- Consumer and Other Organizations Representing the Public Interest
- Non-governmental Standards-setting and Conformity Assessment Bodies



▶ Expert engagement

2020-2025 Strategic Priorities



USP is building informatics capacity and thinking into the standards setting process

- ▶ **Strategy:** Aligning strategic vision with informatics in mind
- ▶ **Science:** Creation of Health IT Expert Committee
- ▶ **Execution/Operation:** Creation of Informatics framework within the organization
 - Proof of concepts and future standards landscape
 - Enhance informatics capabilities
 - Translational Informatics
 - Pharma manufacturing
 - Healthcare Practitioner
- ▶ **Stakeholders:** Expand and strengthen partnerships with key stakeholders in informatics



USP standards impact many points along the value chain



Manufacturer Regulatory Healthcare Practitioners Patients Access



- Substance verification
- Impurities, Excipients

- Compounding,
- Safe handling of HDs

Medication error prevention (NCC MERP)

Formulary Design



Translational Informatics



- **USP Compendial Nomenclature**
- **API/Impurity Data Services***

- **Encoded compounded drug formulations**
- **HazRx®**

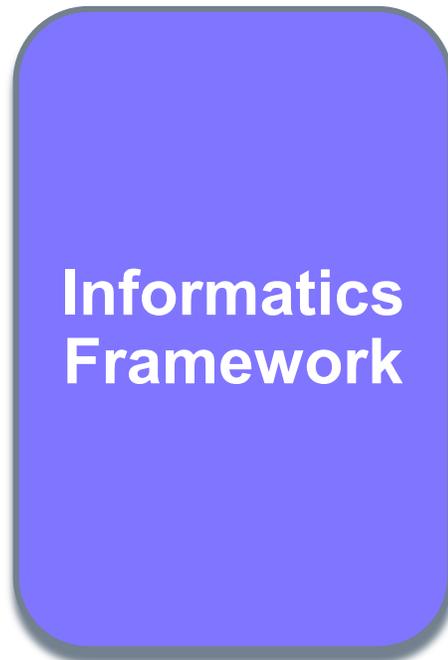
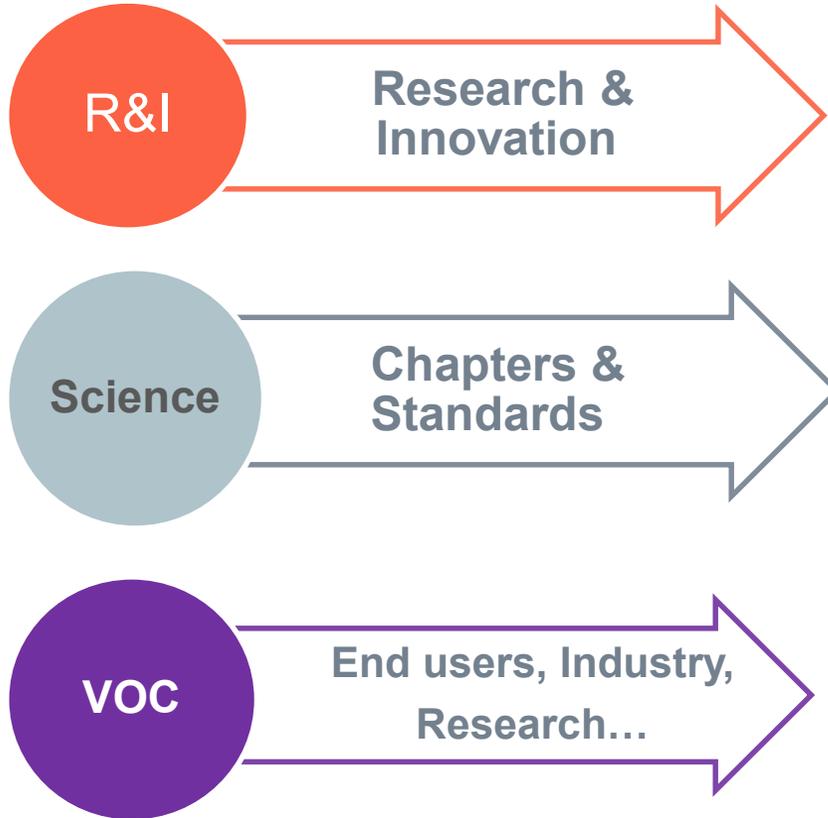
- **Drug Allergies and Intolerances***
- **Pharmacogenomics***

- **USP Drug Classification**
- **Medicare Model Guidelines**

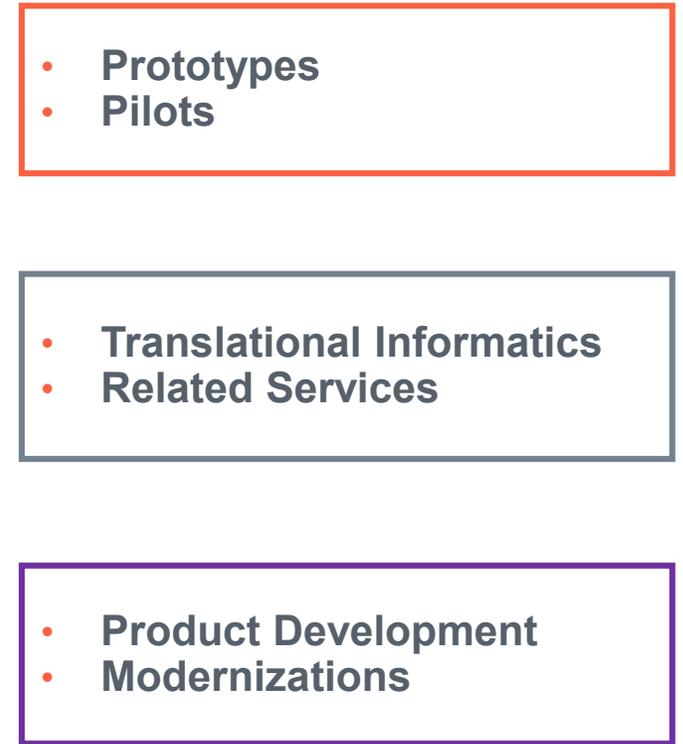
Informatics Framework: Inputs and Outputs



Input Sources



Output types



Possible efficiencies and innovations of USP & Allotrope working together



▶ Monograph use cases

- ▶ Reduce/eliminate manual transcription of content from monographs
- ▶ Fully automate the QC run and validate against the monograph

▶ Data Science and Machine Learning

- ▶ Machine-readable library of compendial content

▶ Regulatory Support

- ▶ Synergy to support PQ/CMC, KASA, other regulatory use cases

The screenshot shows the USP Monographs website interface for Fluoxetine Hydrochloride. At the top, a yellow banner indicates "NOT YET OFFICIAL" with a date of "To be Official on 1-Dec-2019". Below this is a "Document Tools" sidebar with options for "HISTORY", "CONTENTS", and "SUPPORT". The main content area displays the title "Fluoxetine Hydrochloride" and its chemical structure. The structure is a benzene ring with a trifluoromethyl group at the 3-position and a propylamine chain at the 4-position, shown as a hydrochloride salt. The molecular formula is $C_{17}H_{18}F_3NO \cdot HCl$ and the molecular weight is 345.79. The text below the structure provides the full name: "Benzenepropanamine, N-methyl-γ-[4-(trifluoromethyl)phenoxy]; hydrochloride, (±); (±)-N-Methyl-3-phenyl-3-[(α,α,α-trifluoro-p-tolyl)oxy]propylamine, hydrochloride; N-Methyl-3-phenyl-3-[4-(trifluoromethyl)phenoxy]propan-1-amine hydrochloride [56296-78-7]; UNII: I9W7N6B1KJ." The "DEFINITION" section states: "Fluoxetine Hydrochloride contains NLT 98.0% and NMT 102.0% of fluoxetine hydrochloride ($C_{17}H_{18}F_3NO \cdot HCl$), calculated on the anhydrous basis." The "IDENTIFICATION" section lists three tests: A. Infrared Absorption (197K); B. Identification Tests—General (191), Chemical Identification Tests, Chloride; and C. The retention time of the major peak of the Sample solution corresponds to that of the Standard solution, as obtained in the Assay (USP 1-Dec-2019).

Get involved!



- ▶ Call for Candidates
- ▶ Sign up for updates
- ▶ Provide input
- ▶ spe@usp.org

Voices

→ There is more to volunteering at USP than serving as an expert. Hear from our current volunteers what it means to contribute to improving the quality of medicines.

[View videos](#)

The graphic features four portrait photos of diverse individuals arranged in a 2x2 grid. To the right of the portraits is a dark grey box with the word 'Voices' in large white font, a right-pointing arrow icon, and a paragraph of text. Below the text is an orange button with the text 'View videos'.

- ▶ Fill out our brief questionnaire to help us better understand your needs (use the QR code below to access the questionnaire)

