



Resolution

Year 1 Resolution Update: Digital Transformation of Standards

Resolution

USP will create interoperable core digital solutions that leverage USP data and standards to improve public health through global access to quality medicines.

Alignment with USP's Mission

Enhanced commitment to the rapidly evolving and increasingly meaningful digital realm is an essential step for USP. Transforming standards into interoperable digital components of the healthcare ecosystem is critical to delivering quality medicine and patient safety. USP must 1) ensure that the standards-setting process can accommodate the rapidly evolving world of computational informatics and 2) develop or otherwise support data services that meet stakeholder needs across USP nomenclature as well as pharmaceutical and healthcare informatics platforms that align with and complement USP standards.

Year 1 Update

Key progress areas over the past fiscal year include:

Transition to Modern Platforms – USP launched the Digital & Innovation Division to accelerate and amplify our digitally enabled

public health initiatives and digital fluency for long-term public health impact and to help make more of USP's content available through digital processes. As part of this work, USP has started the transition to a more modern set of platforms to create, manage, and disseminate clinical, chemical, and laboratory informatics content. To date, two technology platforms are being leveraged to fundamentally change the way USP curates and disseminates scientific content as machine-readable structured data.

- ▶ Clinical Architecture's Symedical platform provides a robust and scalable solution for USP to efficiently curate and publish standards and solutions as structured data directly into health IT systems used in healthcare delivery. The software also has simplified editorial interfaces that are being used today by USP Expert Volunteers, including for creation of the USP Drug Classification, which is published each year as a standard to build, map, and evaluate outpatient formularies.
- ▶ The Global Substance Registration System (G-SRS) has been implemented at USP for curation and dissemination of high-quality sources of record for substance information. To date, the platform contains records for USP Reference Standards and is used as the content source for the USP dictionary of drug names. A USP-



branded version of the G-SRS software will serve as the newly redesigned USP dictionary product for the upcoming publication in early 2022. The platform is also being used as the foundation to exchange structured data with FDA as part of a Collaborative Research and Development Agreement between FDA and USP.

Transition to Structured Content – USP is establishing key pilots and partnerships to advance our transition from unstructured to structured standards content, building on USP’s previous licensing of the HazRx Drug Classification data asset. To date, this solution has been deployed to major retail pharmacies, pharmacy benefit managers, and distributors to increase the impact of USP standards through embedded content at the fingertips of healthcare providers. In addition, a project is underway to create a data model for our documentary standards content. This will give USP the blueprint and, eventually, the turnkey tooling and processes to publish our documentary standards content directly into Laboratory Information Management System (LIMS) vendors’ software platforms, which are used in research and development and quality assurance/quality control labs. A pilot with a major LIMS vendor scheduled for early 2022

focuses on the distribution and execution of machine-readable analytical methods found in USP monographs.

Medicine Supply Map – USP is creating the Medicine Supply Map to identify, characterize, and quantify vulnerabilities in the upstream medicine supply chain. The map will help strengthen the supply chain through data and insights that can guide risk mitigation and investment in supply chain resilience.

Planned for Year 2

- ▶ USP will continue to advance understanding of stakeholder needs in digital spaces through customer outreach, including through focus groups and surveys.
- ▶ USP will develop direct and indirect distribution capabilities for USP content to external customers.
- ▶ USP will continue to monitor and prioritize upstream advances in science where USP standards-setting and solution development may advance public health in digital implementations.

Contact

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