

# G-SRS Annual Update



November 16<sup>th</sup>, 2018

## USP Digital Platform and Health IT Activities

Steve Emrick

**Empowering a healthy tomorrow**

# Agenda



## USP Digital Presence & Public Health Role

### Current State and Solutions: Standard translation

- USP Compendial Nomenclature
- Drug Classifications
- Hazardous Drugs
- Drug Allergies and Intolerances

### Future Trajectory

- G-SRS and upstream alignment

### Stay Engaged

- Workshops & Roundtables
- 2020-2025 Convention



# Background: USP & Digital Presence



# A person's metadata (circa 1900)



- ☐ First Name
- ☐ Last Name
- ☐ Date of birth
- ☐ Place of birth
- ☐ Address
- ☐ Sex
- ☐ Height
- ☐ Weight
- ☐ Eye color
- ☐ Hair color
- ☐ Race
- ☐ Mother's Maiden Name
- ☐ Father's Name
- ☐ Occupation
- ☐ Marital Status
- ☐ 28<sup>th</sup> US President!!
- ☒ ~~Social Security Number~~



# A person's metadata today



Picture of your lunch that you posted on Instagram

What you searched on the internet in the last 24 hrs

Most frequently listened to songs on Spotify

All the places you went yesterday



Your connections on LinkedIn

Your friends on Facebook

What you've bought on Amazon in the last year

How quickly you metabolize warfarin



# The GE Digital Twin



Digital twins are software representations of assets and processes that are used to understand, predict, and optimize performance in order to achieve improved business outcomes. Digital twins consist of three components: a data model, a set of analytics or algorithms, and knowledge.

## It's called DigitalMe™.

DigitalMe™ will combine multiple sources of health data to build a virtual you.



**BIOLOGICAL**



**EXPERIENTIAL**



**MEDICAL**



**ENVIRONMENTAL**

Based on your condition, what we're seeing across conditions, and what we're learning from the data - we'll choose from the most advanced scientific resources available today like machine learning to examine your RNA and DNA, your proteins, antibodies, microbiome and metabolites. We're stretching the limits of breakthrough technologies to find answers.

# The importance of digital presence



- **Digitally computable metadata is hugely valuable in every industry**
  - Sports, finance, weather– why?
- **For many organizations, digital absence can be disastrous**
- **For USP, digital absence can hinder our standards ability to deliver positive public health impact**
  - What are USP's 'digital twins'?



# USP & Public Health Role



# About Healthcare Quality & Safety

The quality of medicine and how it's delivered to patients is fundamental to treating illness and maintaining health.

We help build the safety net across the drug industry and healthcare system, establishing standards to help ensure medicine is of the highest **quality from the time it's manufactured until the moment someone takes it.**



# Healthcare Quality & Safety



USP Healthcare Quality and Safety (HQS) supports the development and implementation of **science-based** standards and services to ensure accessibility and the informed, **safe use** of quality medicines for patients and healthcare providers.

- ▶ ↑ Safe Use of Medication & ↓ Medication Errors
  - Unsafe sterile and nonsterile **Compounding Practices**
  - Opioid-related standards
  - Errors caused by **Drug Nomenclature**
- ▶ ↓ Hazardous Drug Exposure to healthcare providers and patients
- ▶ ↑ Patient Health Literacy related to prescription drugs

## Impact

Across distribution channel and across the continuum of care



### Manufacturers

>200 Manufacturers  
>40 new drugs approved/year



### Institutions

5,627 Hospitals  
15,600 SNF  
67,000 Pharmacies



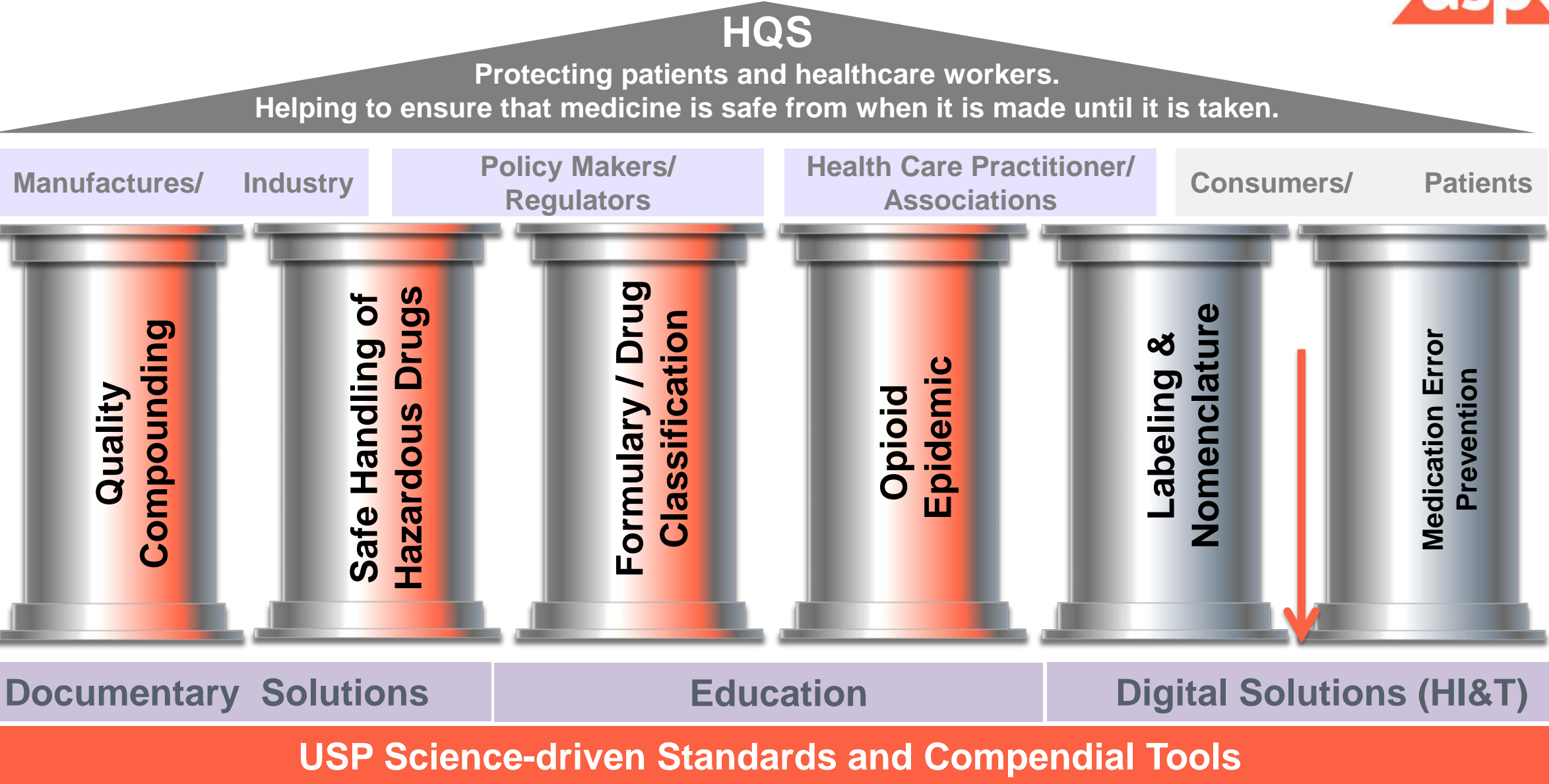
### Healthcare Providers

300K Pharmacists  
380K Pharmacy techs  
2.7M Nurses  
1M MDs

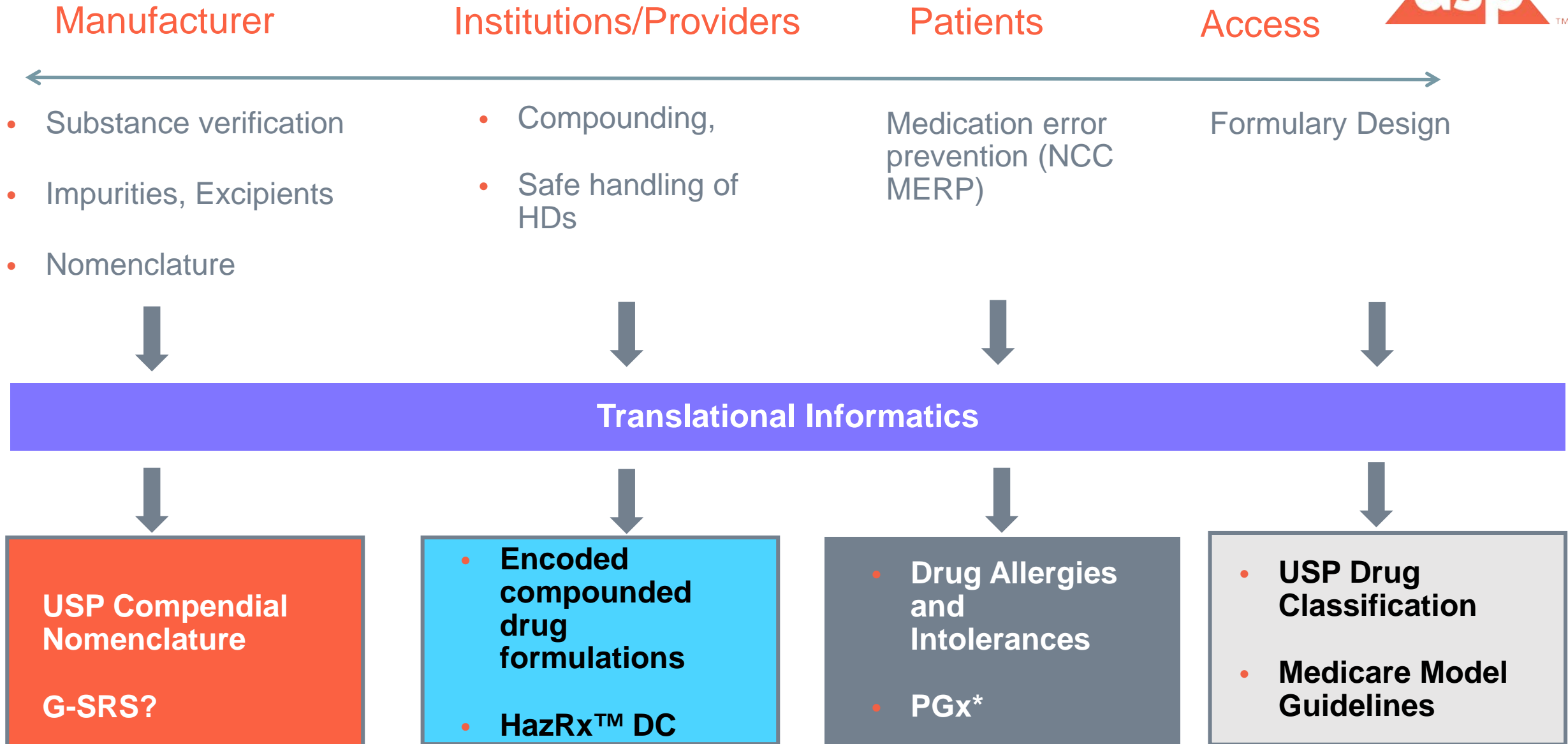


### Patients

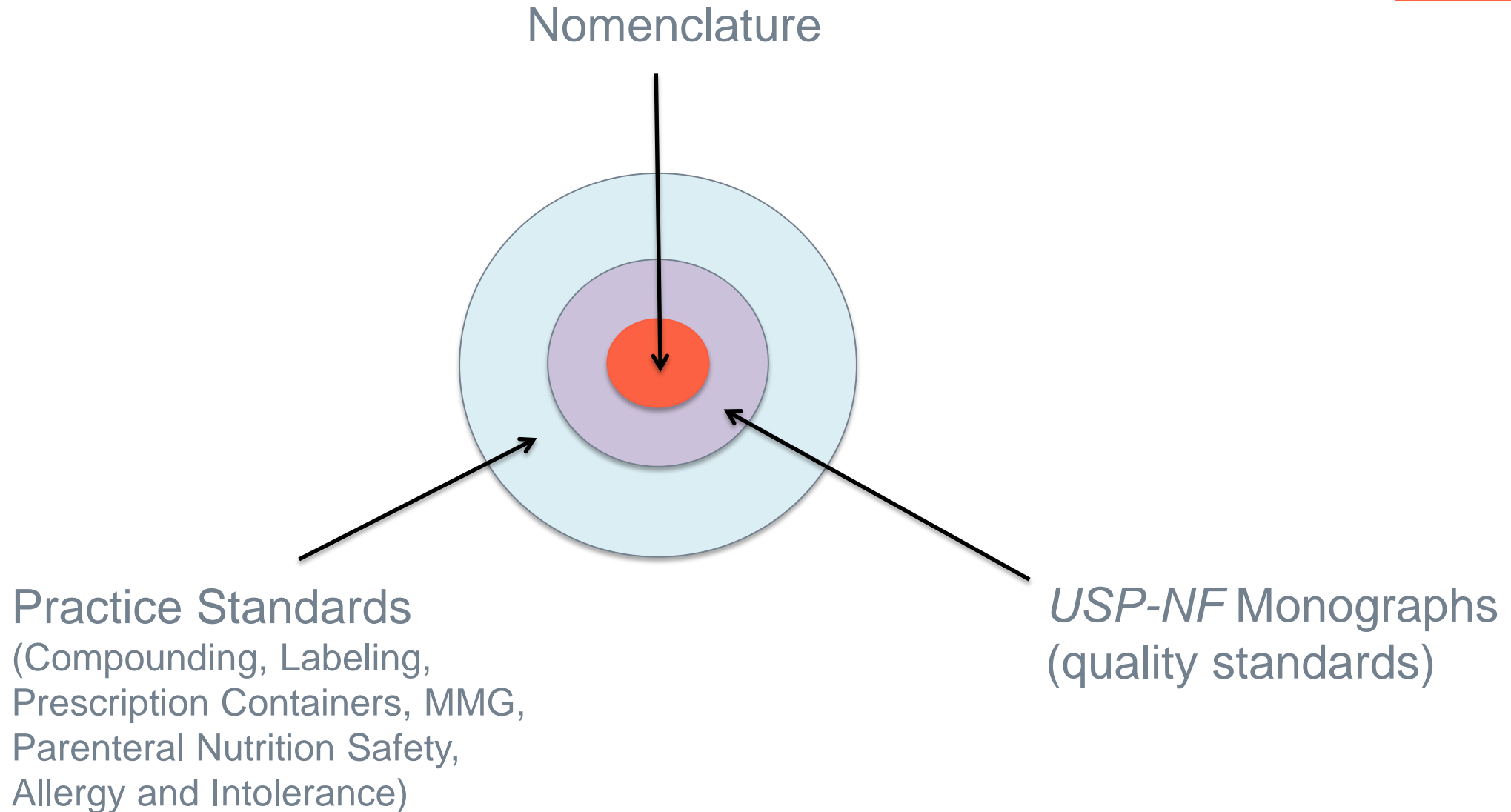
33M hospital admissions  
1.7M patients in SNF  
4B prescriptions



# USP standards impact many points along the drug data chain



# Creation of “USP Core Digital Content”





# Optimal state of core digital content



## “USP Inside”



Mobile Apps

Drug Information  
Systems

Academic  
Research Centers

Lab Information  
Management Systems

Predictive Analytics  
Platforms

# Current State and Solutions

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## Tailoring and Translation of USP Standards



# USP Compendial Nomenclature

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Integration with RxNorm



# What is RxNorm?



- ▶ Drug terminology produced by NLM
  - RxNorm (drugs)
  - SNOMED CT (problem lists)
  - LOINC (lab tests)
- ▶ List of normalized names and unique identifiers for drugs
- ▶ Terminology derived from other drug terminologies

# What is RxNorm?



- FDA Structured Product Labels (DailyMed)
- MeSH
- NDF-RT
- SNOMED CT
- VA National Drug File
- CMS Formulary Reference File
- First DataBank
- Gold Standard
- Medi-Span
- Multum
- Micromedex
- Anatomical Therapeutic Chemical Classification System (ingredients only)
- USP Compendial Nomenclature!!



- ▶ RxNorm is designed for unambiguous, semantically interoperable drug exchange for:
  - ▶ Provider (CPOE) to pharmacy (e-prescribing) transactions
  - ▶ Drugs in patient medication lists (C-EHR Technology, 45 CFR § 170.207)
  - ▶ Drugs listed on formularies



# Why RxNorm?



- ▶ RANITIDINE HYDROCHLORIDE 15 MG ORAL SYRUP
- ▶ RANITIDINE HYDROCHLORIDE 16.8 MG ORAL SYRUP
- ▶ RANITIDINE HYDROCHLORIDE 75 MG/5mL ORAL SOLUTION

RxCUI: 705160

Normalized Name: Ranitidine15 MG/ML Oral Solution

The RxNorm model was built to provide a standard name for drugs as they appear in a provider's medication order, comprised of active ingredient, strength, and dose form.

# Why USP Compendial Nomenclature in RxNorm?

## Digital Presence



- ▶ Allows identification of the USP Compendial drug name in drug databases
  - ▶ Provides source of USP nomenclature within widely used vocabulary standard
  - ▶ Connects nomenclature required for use by drug manufacturers to nomenclature used for prescribing/administration
  - ▶ Can improve data quality of public and private databases
- ▶ Builds upon our strength by expanding our core mission of drug nomenclature into digital environments
- ▶ Programmatically reference our own nomenclature in publications (e.g. USP DC)

# Challenges of integration with RxNorm



- ▶ Data are not uniformly connected (due to salt form names)
- ▶ Different granularities for dosage forms
  - Manufacturer vs dispensing/administration
- ▶ USP will continue to work with NLM over time to uniformly connect concepts will lower implementation barriers for developers of drug information systems

## USP/RxNorm merge

### RxCUI 370579 (m4170)

USP Name	Amoxicillin Tablets
RxNorm Name	Amoxicillin Oral Tablet

## USP/RxNorm split

### RxCUI 83366 (m6340)

USP Name

Atorvastatin  
Calcium Tablets

Relationship

### RxCUI 370621

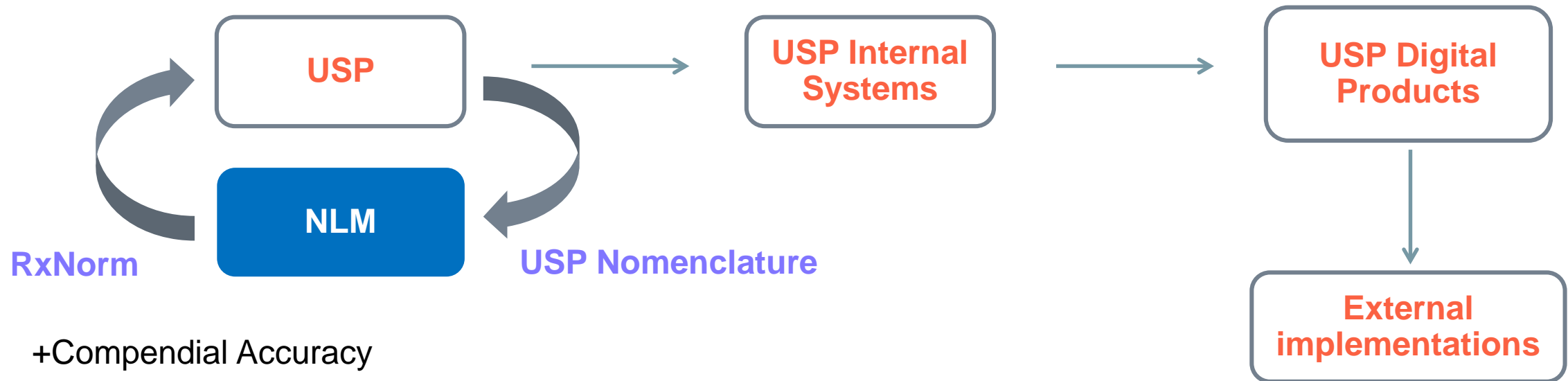
RxNorm Name

Atorvastatin Oral  
Tablet

# USP Compendial Nomenclature and RxNorm – better together!



- Consistent mappings to our monographs
- Single source of truth
- Identify areas for improved content



- +Compendial Accuracy

- Easier implementation of USP standards
- Opportunity to improve drug database content

# Formulary Resources

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## USP Drug Classification



# USP Drug Classification



The USP Drug Classification (USP DC) is an independent drug classification system developed by the USP Healthcare Quality & Safety Expert Committee.

## USP DC Use cases

### Building, Mapping, and Comparing Formularies

- Insurers/PBMs
- Health Institutions
- EHB Compliance

### Reviewing Formularies for a Minimum Baseline of Drugs

- Regulatory Agencies
  - Federal
  - States
- Employer Benefit Managers/ Consultants

### Identifying Drugs Included in a Particular Pharmacological Groupings

- Regulatory Agencies
  - Outlier Analysis
  - Imputing Diagnosis
- Policy Reviewers



# Extended Use of USP Medicare Model Guidelines (Part D)



## **1. Category Class Drug Count Review for EHB Benchmark Plans**

Compares the count of unique chemically distinct drugs in each USP Category and Class for each drug list with the benchmark. Used to compare formulary benefits of different types of plans such as employer plans versus health insurance exchange plans.

## **2. Non Discrimination Formulary Outlier Review**

Identifies and flags as outliers those plans that have unusually large numbers of drugs subject to prior authorization and/or step therapy requirements in 25 USP classes.

## **3. Drug Risk Hybrid Analysis**

The USP classification provides chemical ingredient level identifications to identify and group drugs used for certain diagnoses.

# MMG/USP DC USE

## Comparison of Rx Drug EHB Benchmark Plans – proxy to SDOH?



### California

CATEGORY	CLASS	SESSION COUNT
ANXIOLYTICS	ANXIOLYTICS, OTHER	3
ANXIOLYTICS	SSRIS/SNRIS (SELECTIVE SEROTONIN REUPTAKE INHIBITORS AND NOREPINEPHRINE REUPTAKE INHIBITORS)	3
BIPOLAR AGENTS	BIPOLAR AGENTS, OTHER	5
BIPOLAR AGENTS	MOOD STABILIZERS	5
BLOOD GLUCOSE REGULATORS	ANTIDIABETIC AGENTS	5
BLOOD GLUCOSE REGULATORS	GLYCEMIC AGENTS	1
BLOOD GLUCOSE REGULATORS	INSULINS	6

6 non-insulin  
Blood Glucose  
Regulators

### Alaska

CATEGORY	CLASS	SESSION COUNT
ANXIOLYTICS	ANXIOLYTICS, OTHER	
ANXIOLYTICS	SSRIS/SNRIS (SELECTIVE SEROTONIN REUPTAKE INHIBITORS AND NOREPINEPHRINE REUPTAKE INHIBITORS)	
BIPOLAR AGENTS	BIPOLAR AGENTS, OTHER	6
BIPOLAR AGENTS	MOOD STABILIZERS	5
BLOOD GLUCOSE REGULATORS	ANTIDIABETIC AGENTS	21
BLOOD GLUCOSE REGULATORS	GLYCEMIC AGENTS	2
BLOOD GLUCOSE REGULATORS	INSULINS	10

23 non-insulin  
Blood Glucose  
Regulators

# USP DC 2018 – Downloadable Files



- **USP DC 2018 Spreadsheet**
  - Designed for ‘human readable’ formulary verification/comparison
- **USP DC 2018 Alignment File**
  - Includes placement of RxCUIs (from Feb 2018 Current Prescribable Content) into USP Categories and Classes
  - Available as spreadsheet
    - Encoded identifiers of USP Categories/Classes immediate priority
    - CSV format available upon request, and will be part of standard outputs in the summer

RxCUI	TTY	Name	Dose Form	USP Category	USP Class
1652242	SBD	3 ML INSULIN LISPRO 200 UNT/ML PEN INJECTOR [HUMALOG]	PEN INJECTOR	Blood Glucose Regulators	Insulins
1653198	SBD	3 ML INSULIN, ASPART, HUMAN 100 UNT/ML CARTRIDGE [NOVO CARTRIDGE]	CARTRIDGE	Blood Glucose Regulators	Insulins
1653204	SBD	3 ML INSULIN, ASPART, HUMAN 100 UNT/ML PEN INJECTOR [NOVO PEN INJECTOR]	PEN INJECTOR	Blood Glucose Regulators	Insulins
847261	SBD	3 ML INSULIN, GLULISINE, HUMAN 100 UNT/ML PEN INJECTOR [HUMALOG PEN INJECTOR]	PEN INJECTOR	Blood Glucose Regulators	Insulins
1731317	SBD	3 ML REGULAR INSULIN, HUMAN 500 UNT/ML PEN INJECTOR [HUMALOG PEN INJECTOR]	PEN INJECTOR	Blood Glucose Regulators	Insulins

# Handling Hazardous Drugs

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Mobile App and Drug Classification



# Public Health Challenge

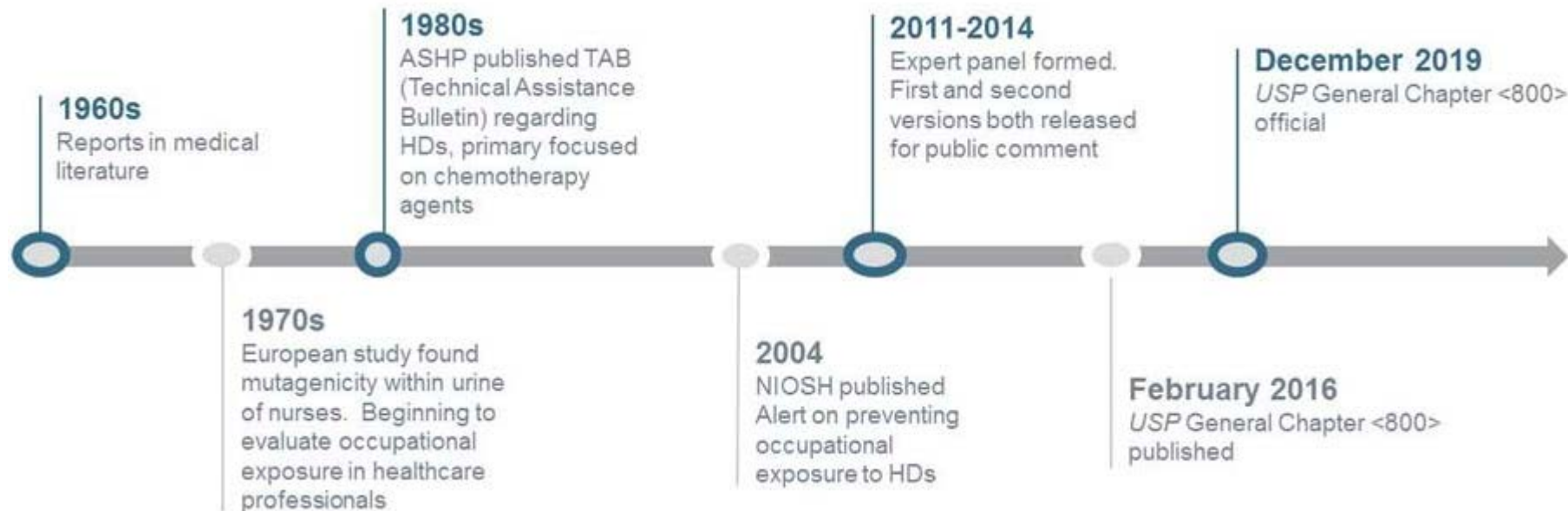


- ▶ 8 million U.S. healthcare workers (HCW) are exposed to hazardous drugs (HDs) such as chemotherapeutics, hormone therapy, antiviral medication, during routine daily activities such as transport, compounding, administration across all healthcare settings
- ▶ Exposure to HDs can lead to acute and chronic illness ranging from rashes, to organ failure and cancer
- ▶ NIOSH list has >200 HD drug listed that translate to more than 1,000 commercially available drugs
- ▶ 12 B doses of HDs are administered yearly in the US, yet less than 10% are labeled as hazardous drugs

# USP Compendial Response: USP GC <800>



- USP General Chapter <800>, Hazardous Drugs—Handling in Healthcare Settings is created for the protection of Healthcare Workers, Patients and the Environment
- Published in February 2016
- Intended official date December 1, 2019 (prior July 2018)





# <800> HazRx™ Mobile App



An innovative app that computes information from three trusted data resources (NIOSH, RxNorm, GC <800>) to help identify HDs at the point of practice and to inform the healthcare worker on what measures to take to help reduce their risk in accordance to established standards.



<800> HazRx™

# <800> HazRx™ Drug Classification Addresses Core Institutional Needs



## Problem

Hazardous drugs are ‘invisible’ in e-prescribing and drug information systems.

Institutions must maintain an updated list of hazardous drugs.

Healthcare providers may not be able to use mobile devices in their work environment.

## HazRx™ DC Value

<800> HazRx™ Drug Classification provides the ability for E-prescribing systems to hook into NIOSH Group, hazardous drug handling activity, and appropriate handling guidance.

Institutions can match products from their inventory against the <800> HazRx™ Drug Classification, and update **each month**.

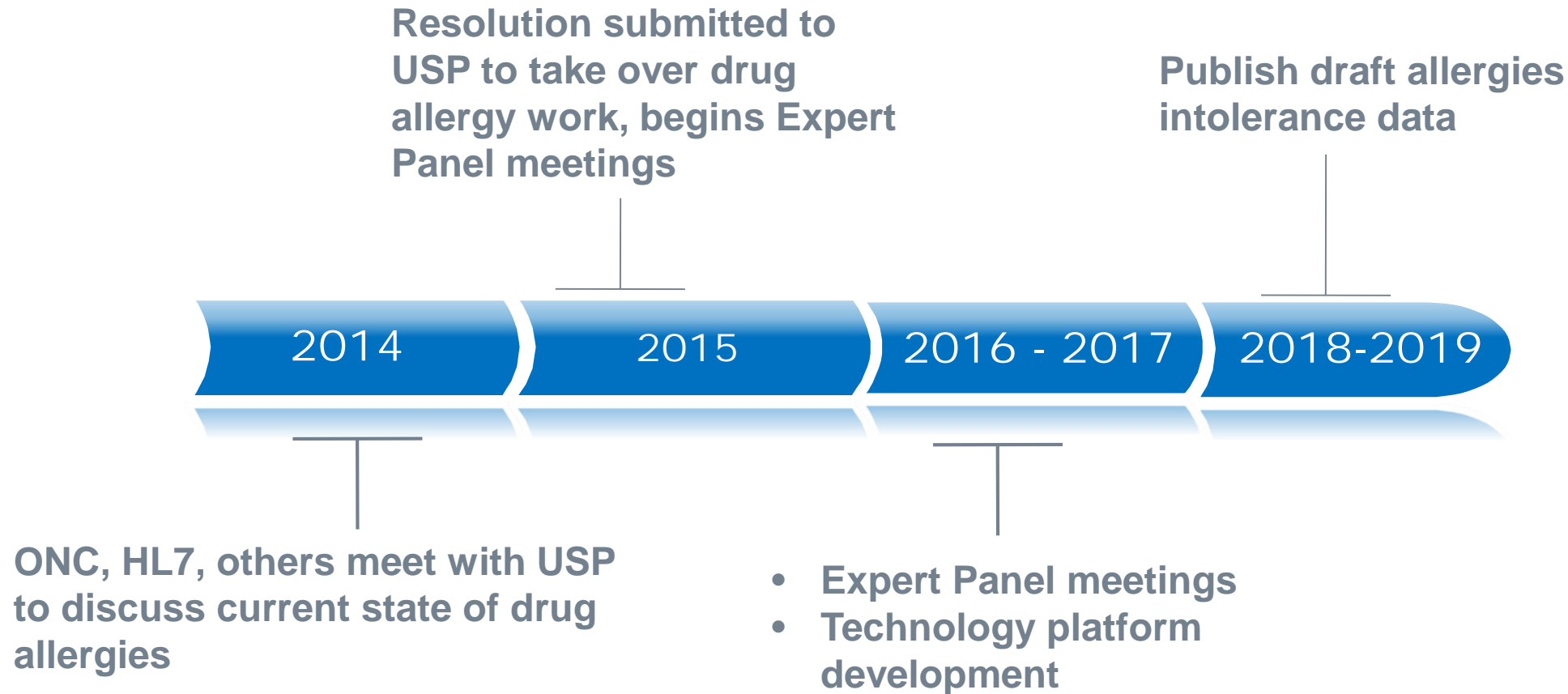
<800> HazRx™ Drug Classification is designed to be integrated into E-prescribing systems and drug information systems where the providers are already working.

# Allergies and Intolerances

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# Allergies/Intolerances Background and Timeline



# Allergies/intolerances – public health problem and background



- The Institute of Medicine, in its report To Err Is Human, estimated 7,000 deaths in the U.S. each year are due to preventable medication errors
- Drug allergies or harmful drug interactions account for 11 percent of preventable medication errors
- Because of the use of disparate systems and proprietary codesets to encode allergies, patient safety issues occur when drug allergy data is incorrectly transferred or omitted in transitions of care settings
- Some of the early allergy value sets encoded information at the drug formulation level rather than ingredient + route (e.g. atorvastatin oral tablet) which is how drug orders are entered and recorded in patient records
- Providers have little insight into probability of cross-sensitivity within a drug class or even outside of a drug class

# USP's goals in developing drug allergy classes



- Improve patient documentation through an encoded starter set of ‘the most frequent’ and ‘the most common’ drug allergy classes, ingredients, and manifestations
  - NSAIDs
  - Antibiotics
  - Cardiovascular Agents (ACEs/ARBs)
  - Opioids
- Allow mapping from C-CDA and FHIR Allergy/Intolerance resource to the USP standard
- Encode at ingredient level, rather than class
- Mitigate problem of alert fatigue within EHR systems/CDS
- Mitigate cross-sensitivity reactions via ‘predictability’

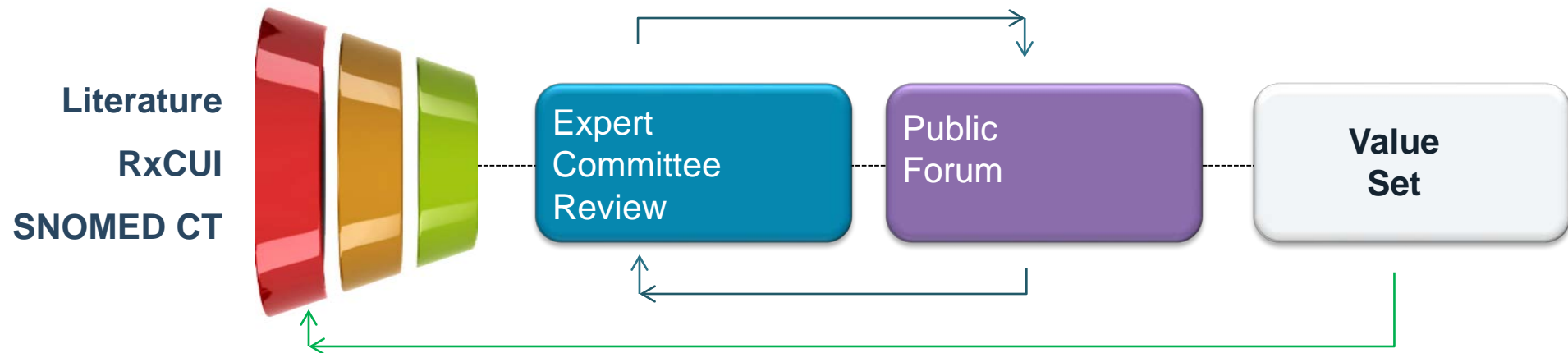
# Science Process



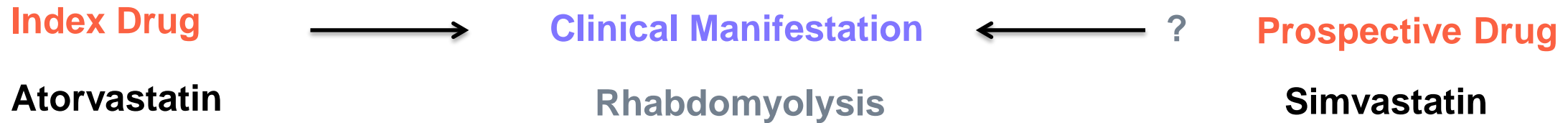
- ▶ Leverages USP process and Expert Committee
- ▶ Relies on existing science and data
- ▶ Data Sources
  - SPL/Daily Med
  - Literature
  - VA/DoD data
  - Other data sources



Designed for interoperability  
(RxNorm, SCT, USP Allergy  
Classes)



# Allergies/Intolerances – standard around cross-sensitivity



What is the likelihood (predictability) that prescribing Simvastatin as an alternative to Atorvastatin will cause rhabdomyolysis?

## Potential Future Activities

- Proactively identify probability of cross reaction
- Application beyond allergies to address clinical manifestation to leverage predictive analytics



# Use Case 1- Provide encoded drug allergy classes to improve interoperability



Improved mapping



## Patient Record

**Substance:** Atorvastatin

**MFST:** Rhabdomyolysis

**Severity:** High

**Criticality:** High

Improved mapping



**C-CDA**  
**Allergies section**

Provide encoded  
drug/manifestation pairs



**USP Drug/Allergy Intolerance**

# Use Case 2- Provide predictability checking for FHIR/C-CDA



**Allergy/Intolerance Resource**

## Patient Record

**Substance:** Atorvastatin

**MFST:** Rhabdomyolysis

**Severity:** High

**Criticality:** High

**C-CDA**

**Allergies section**

Could simvastatin  
cause  
rhabdomyolysis?

Could simvastatin  
cause  
rhabdomyolysis?



**USP Drug/Allergy Intolerance**

**Predictability = High**

# G-SRS (Finally!)

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# Enterprise Informatics Initiative: G-SRS Implementation



## Fits into upstream USP “Digital Twin” Development

- Nomenclature
- Substance Verification
- Impurity Profiles

## Source of truth internally for:

- Molecular Weights
- Chemical Structures
- USP Publications!

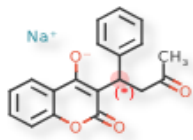
## Links to other standards



- RxNorm (external)
- USP Drug Classification (internal)

### WARFARIN SODIUM

6153CWM0CL

RACEMIC





**Names:** WARFARIN SODIUM [VANDF]  
SODIUM WARFARIN  
WARFARIN SODIUM [ORANGE BOOK]  
COUMADIN  
WARFARIN SODIUM [USP]

**Codes:** CAS: [129-06-6](#)  
EVMPD: [SUB05128MIG](#)  
ChEMBL: [CHEMBL1464](#)  
ECHA (EC/EINECS): [204-929-4](#)

**Relationships:** 6

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**Formula:** C<sub>19</sub>H<sub>15</sub>O<sub>4</sub>.Na

**Mol Weight:** 330.31

# Save the dates!!



## Inaugural Pharmacoinformatics Workshop

- April 3<sup>rd</sup> – 4<sup>th</sup>, 2019

## Coming soon: 2020-2025 Convention

- Have identified need for those with skills in areas such as Pharmacogenomics, vocab and messaging standards, digital therapies, informatics, implantable devices, etc

# Check it out!

<http://www.usp.org/healthcare-quality-safety/digital-solutions>



## USP Digital Solutions

USP standards are being tailored to allow meaningful implementation within modern Health IT Systems. These digital solutions are part of a broader safety net that USP Healthcare Quality and Safety creates related to patient safety, drug nomenclature, access to medicines and healthcare worker safety. These digital solutions aim to help ensure continuity, quality and accuracy of healthcare information in digital environments.

USP is actively working to provide the healthcare milieu with translational products to advance health and healthcare ranging from digital applications to alignment files and core nomenclature alignment. To date USP has several solutions in digital environments and systems that manage drug information, clinical decision support, and formulary design. These solutions are typically derived from our standards-setting activities that are informed by our volunteer Expert Committees and their associated body of works.

Partnerships and collaborations in this space are essential to meeting healthcare needs.

### USP and the National Library of Medicine partner for accuracy in electronic drug nomenclature

USP and the National Library of Medicine (NLM) are pleased to announce that USP Compendial Nomenclature is now integrated into the RxNorm vocabulary. This integration aims to reduce drug nomenclature errors that can occur in electronic environments that may lead to patient safety issues. The inclusion of USP Compendial Nomenclature into RxNorm will help ensure that

### USP Digital Solutions

- **USP Compendial Nomenclature Dataset:** A cumulative data set of all Active Pharmaceutical Ingredients (API).
- **USP<800> HazRx™ Drug Classification:** A data set for institutions and organizations to identify hazardous drugs and provide handling instructions per established standards such as USP <800>.
- **USP <800>HazRx™ Mobile App:** An app for individual healthcare workers to identify hazardous drugs and provide handling instructions per established standards

# Stay connected with us!!



## Healthcare Quality & Safety Updates:

- <http://www.usp.org/hqs-signup-form>

## Twitter

- @USPharmacopeia

## E-mail

- Steven Emrick ([spe@usp.org](mailto:spe@usp.org))

# Thank You



**Empowering a healthy tomorrow**



# Questions



**Empowering a healthy tomorrow**