Data Standards At FDA CDER and CBER

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GInAS 2017 Meeting
October 11, 2017

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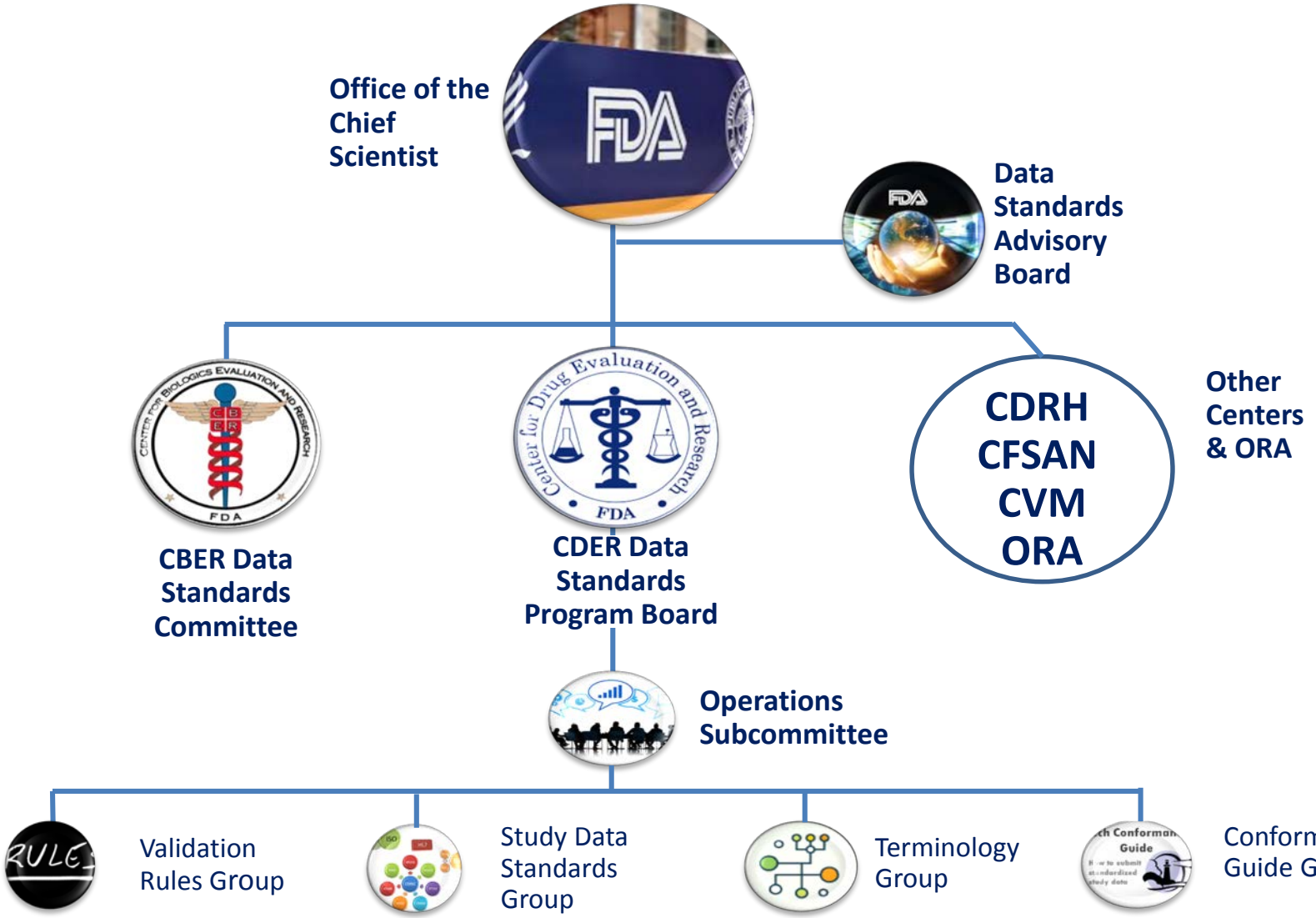
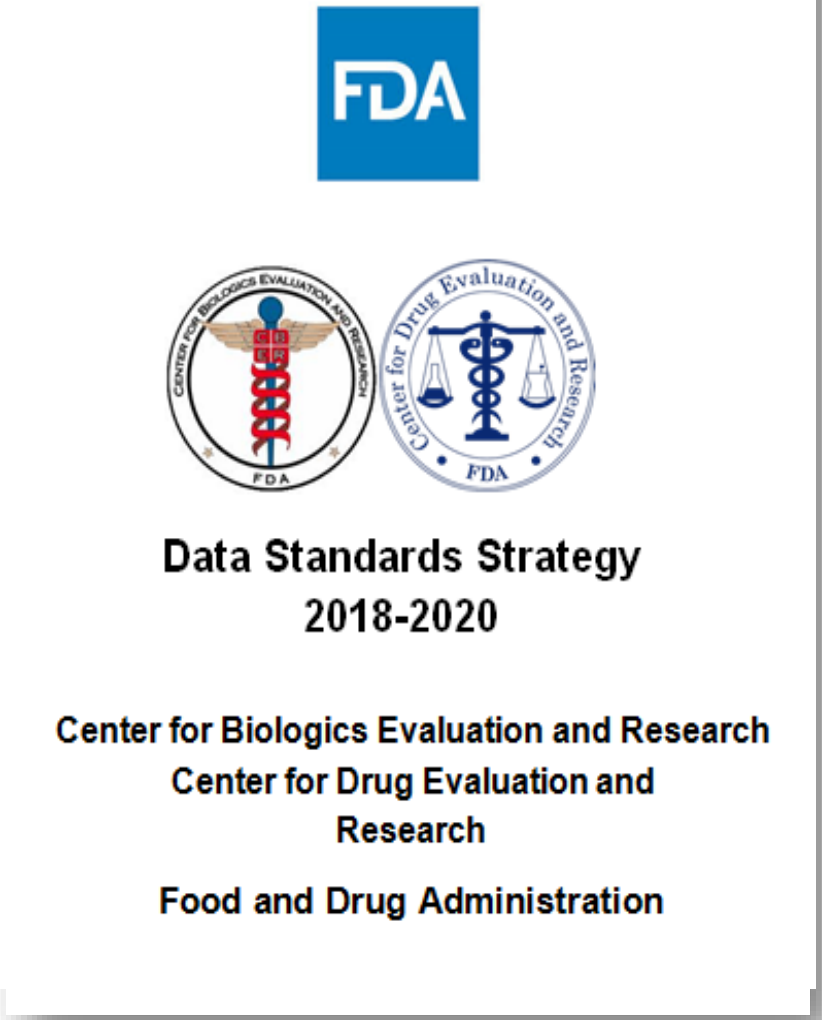
Data Standards Governance at FDA



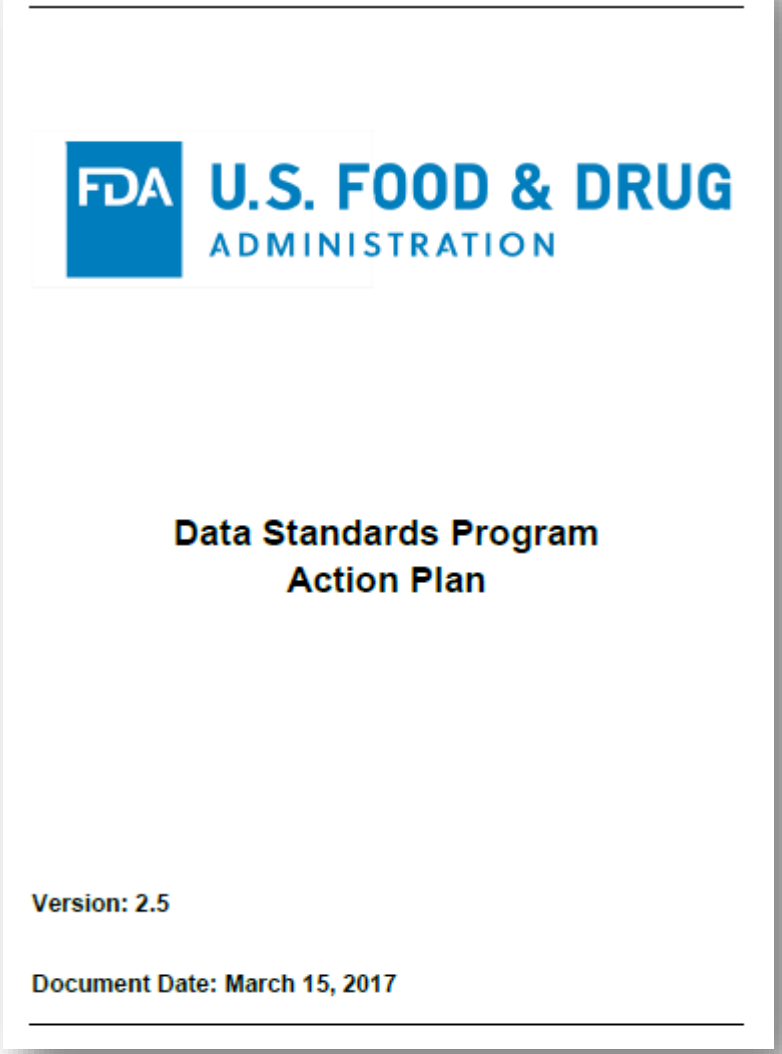
Data Standards Strategy and Action Plan



Data Standards Strategy
2018-2020

Center for Biologics Evaluation and Research
Center for Drug Evaluation and Research

Food and Drug Administration



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Data Standards Program
Action Plan

Version: 2.5

Document Date: March 15, 2017

Coming Soon – CBER-CDER
Data Standards Strategy For 2018-2020

Purpose

To reinforce FDA's ongoing commitment to the development, implementation, and maintenance of a comprehensive data standards program to facilitate the regulatory review process so that safe and effective medical products* are available to patients sooner.

PDUFA VI - Improve the Predictability and Consistency of Electronic Submission Process

- PDUFA VI Section IV Key Commitments
  - Electronic Submission Process Documentation
    - Submission milestones and sponsor notifications from Electronic Submissions Gateway (ESG) through availability by review team
    - Rejection process and validation criteria for electronic submissions
  - Electronic Submission and System Status
    - Publish Targets and Metrics for ESG Overall Availability
    - Publish instructions for sponsors in event of ESG service disruption
    - Involve industry in user acceptance testing of systems that that impact industry's interaction with the system.
  - Enhance Transparency and Accountability of FDA Electronic Submission and Data Standards Activities
    - Hold quarterly meetings with industry, as well as an annual public meeting
    - Post, annually, current metric on ESG performance and standards conformance
    - Publish data standards action plan, quarterly, as well as maintain Data Standards Catalog.

Road to Electronic Submission Standards

2017 *CDER Data Standards Action Plan

Current State:
Submission Metrics for CDER – FY 2017*

- Number (%) NDA submissions ~24,400
  - New / Original ~3,100
- Number (%) BLA submissions ~4,400
  - New / Original 462
- Number (%) ANDA submissions ~52,100
  - New / Original ~7,400
- Number (%) IND submissions ~92,350
  - New / Original ~3,500

- **Total Submissions ~173,234**

*FY2017(As of September 18th)

FDA Data Standards Catalog

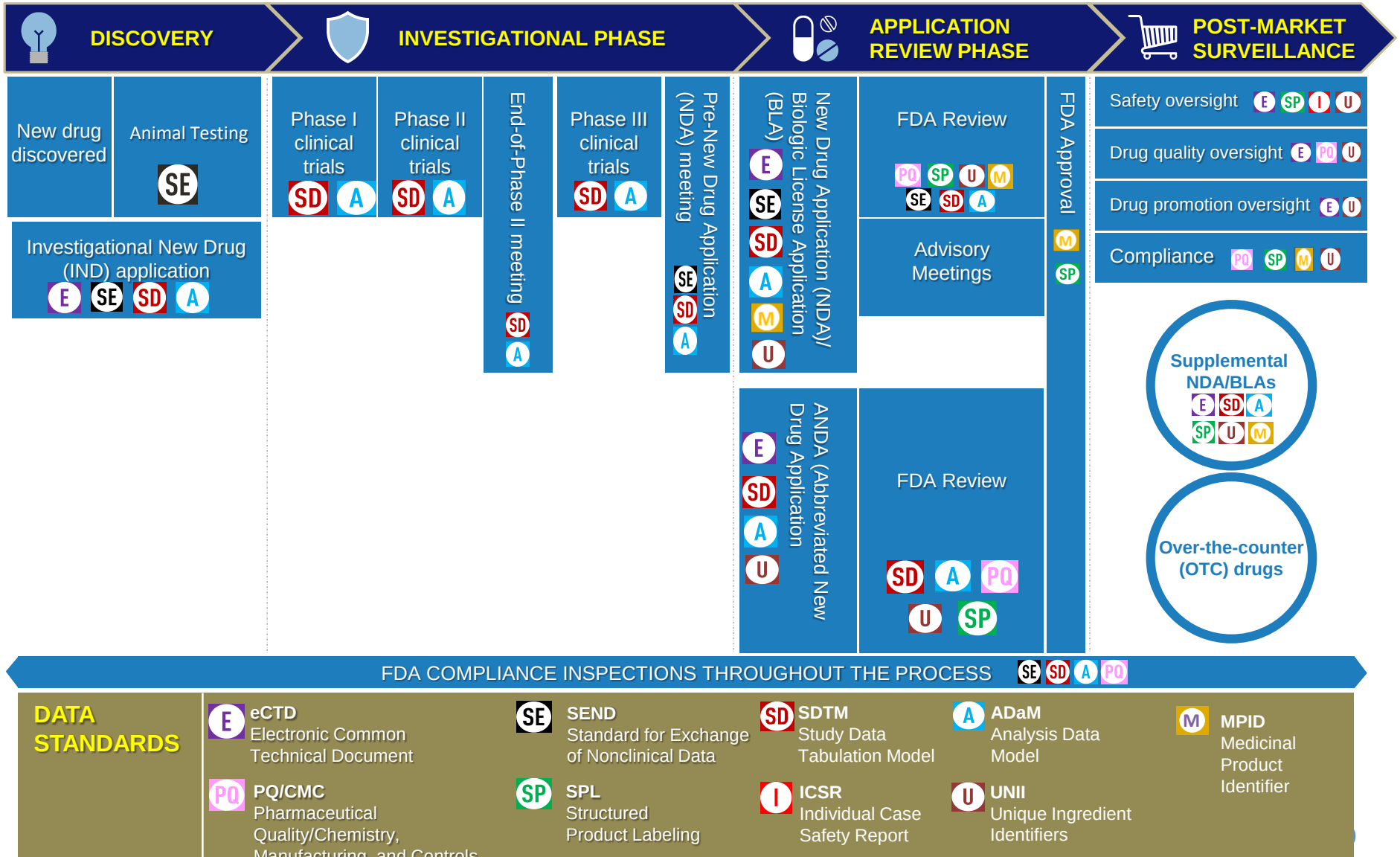
FDA Data Standards Catalog v4.7 (09-01-2017) - Supported and Required Standards

This table contains a listing of the data exchange, file formats and terminology standards supported at FDA. These standards have gone through all the steps necessary to make this part of the regulatory review process, including posting of regulatory guidance documents and associated implementation guidelines and technical specifications. The submission of standardized data using any standard not listed, or to an FDA Center not listed, should be discussed with the Agency in advance. This catalog is incorporated by reference in the guidance to industry, *Providing Regulatory Submissions in Electronic format-Standardized Study Data (http://www.fda.gov/downloads/Drugs/Guidances/UCM292334.pdf).*

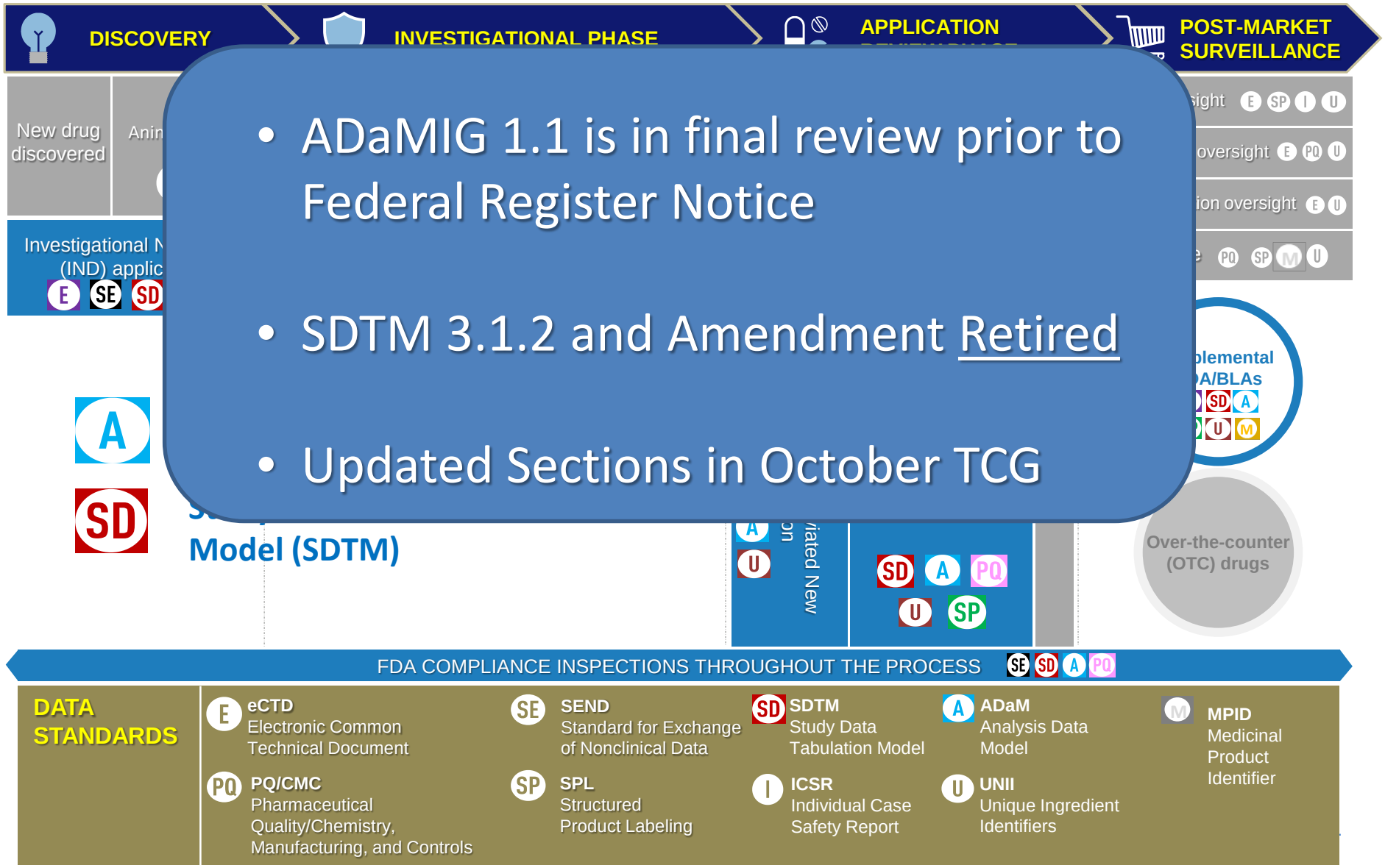
Use	Data Exchange Standard	Exchange Format	Standards Development Organization (SDO)	Supported Version	Implementation Guide Version	FDA Center(s)	Date Support Begins (MM/DD/YYYY)	Date Support Ends (MM/DD/YYYY)	Date Requirement Begins (MM/DD/YYYY)	Date Requirement Ends	Regulatory Reference and Information Sources
Clinical and Non-Clinical study data sets - Transport	SAS Transport (XPORT)	XPT	SAS	5	SAS Technical Support TS-140	CDER, CBER	Ongoing		12/17/2016 [1] 12/17/2017 [2]		For CDER and CBER only: Technical Conformance Guide
Clinical and Non-Clinical study data sets - Transport	SAS XPORT	XPT	SAS	5	SAS Technical Support TS-140	CDRH, CFSAN, CVM	Ongoing				For CDRH only: eCopy Program for Medical Device Submissions
Sharing Structured Information	XML		W3C	1.0		CBER, CDER, CDRH	Ongoing				W3C - XML Technology
Analysis program files	ASCII		ANSI			CBER, CDER, CDRH	Ongoing				www.ansi.org
Clinical study datasets	Study Data Tabulation Model (SDTM)	XPT	Clinical Data Interchange Standards Consortium (CDISC)	1.4	3.2	CDER, CBER	08/17/2015		03/15/2018 [1] 03/15/2019 [2]		CDISC.org - SDTM See Technical Conformance Guide
Clinical study datasets	SDTM	XPT	CDISC	1.3	3.1.3	CDER, CBER	12/01/2012		12/17/2016 [1] 12/17/2017 [2]		CDISC.org - SDTM
Clinical study datasets	SDTM	XPT	CDISC	1.2	Version 3.1.2 Amendment 1	CDER, CBER	08/07/2013	03/15/2019 [1] 03/15/2020 [2]	12/17/2016 [1] 12/17/2017 [2]		CDISC.org - SDTM
Clinical study datasets	SDTM	XPT	CDISC	1.2	3.1.2	CDER, CBER	10/30/2009	03/15/2019 [1] 03/15/2020 [2]	12/17/2016 [1] 12/17/2017 [2]		CDISC.org - SDTM
Clinical study datasets	SDTM	XPT	CDISC	1.1	3.1.1	CDER, CBER	Ongoing	01/28/2015			CDISC.org - SDTM
Clinical study datasets	Analysis Data Model (ADaM)	XPT	CDISC	2.1	1.0	CDER, CBER	Ongoing		12/17/2016 [1] 12/17/2017 [2]		CDISC.org - ADaM
	Standard for										

Instructions | Data Exchange Standards | Terminology Standards | Change History

Update on Data Standards in the Drug Development Lifecycle

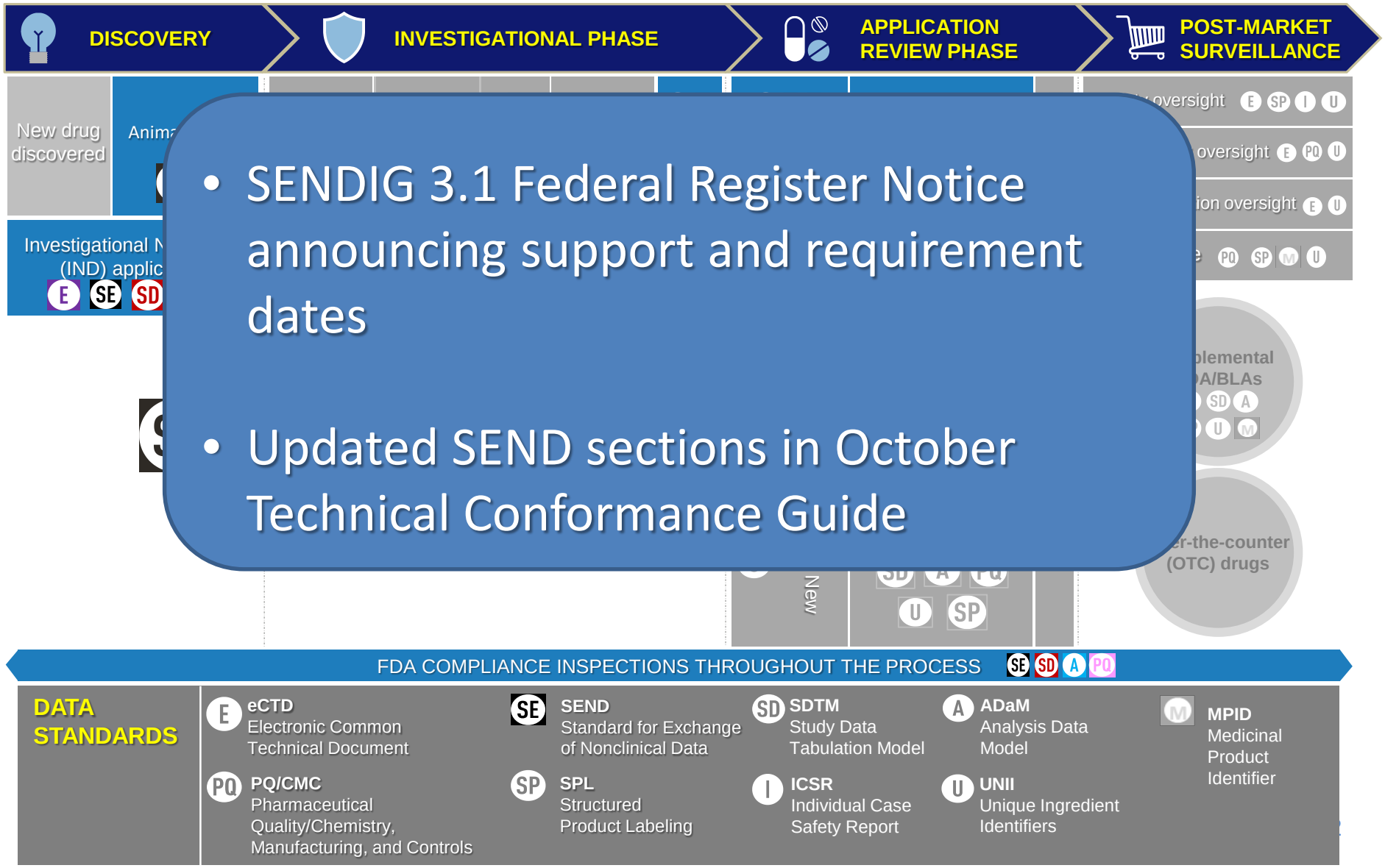


Update on Data Standards in the Drug Development Lifecycle



- ADaMIG 1.1 is in final review prior to Federal Register Notice
- SDTM 3.1.2 and Amendment Retired
- Updated Sections in October TCG

Update on Data Standards in the Drug Development Lifecycle



- SENDIG 3.1 Federal Register Notice announcing support and requirement dates
- Updated SEND sections in October Technical Conformance Guide

FDA's Therapeutic Area Standards Initiative

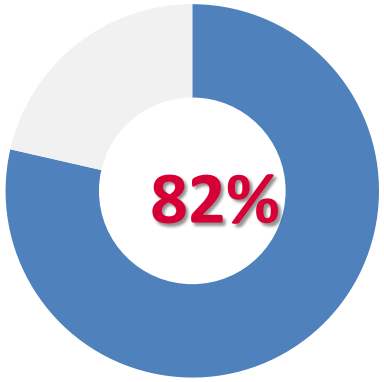
Overview

In 2012, as part of a PDUFA V commitment, CDER compiled a prioritized list of disease and therapeutic areas (TAs) for which standardization was needed.

Approach

Focus is on regulatory review needs

Current Status



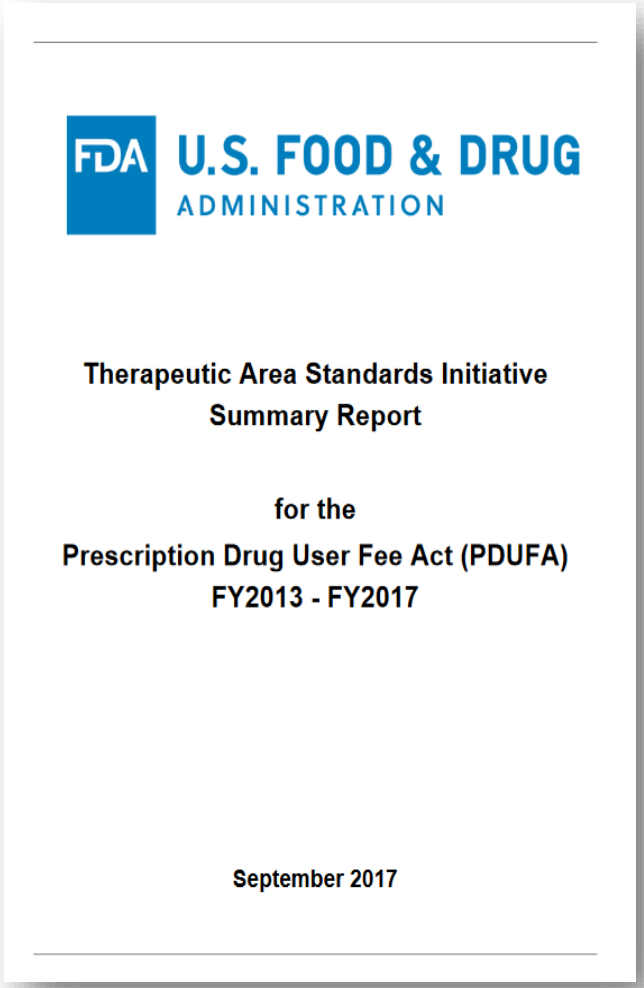
Of the 55 TAs* prioritized, 45 have been initiated as of May 2017

CFAST Key Players

CDISC, C-Path, NIH, FDA, TransCelerate, Duke, HL7 and many other stakeholders

https://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/ElectronicSubmissions/UCM297093.pdf

PDUFA V Therapeutic Area Standards Initiative Summary Report



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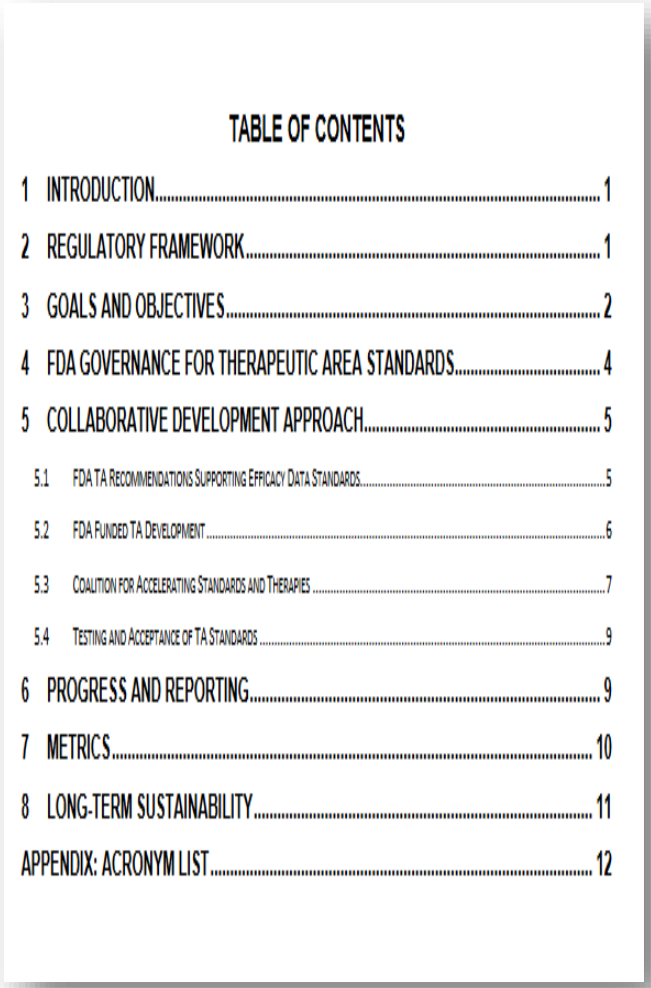
Therapeutic Area Standards Initiative Summary Report

for the

Prescription Drug User Fee Act (PDUFA)
FY2013 - FY2017

September 2017



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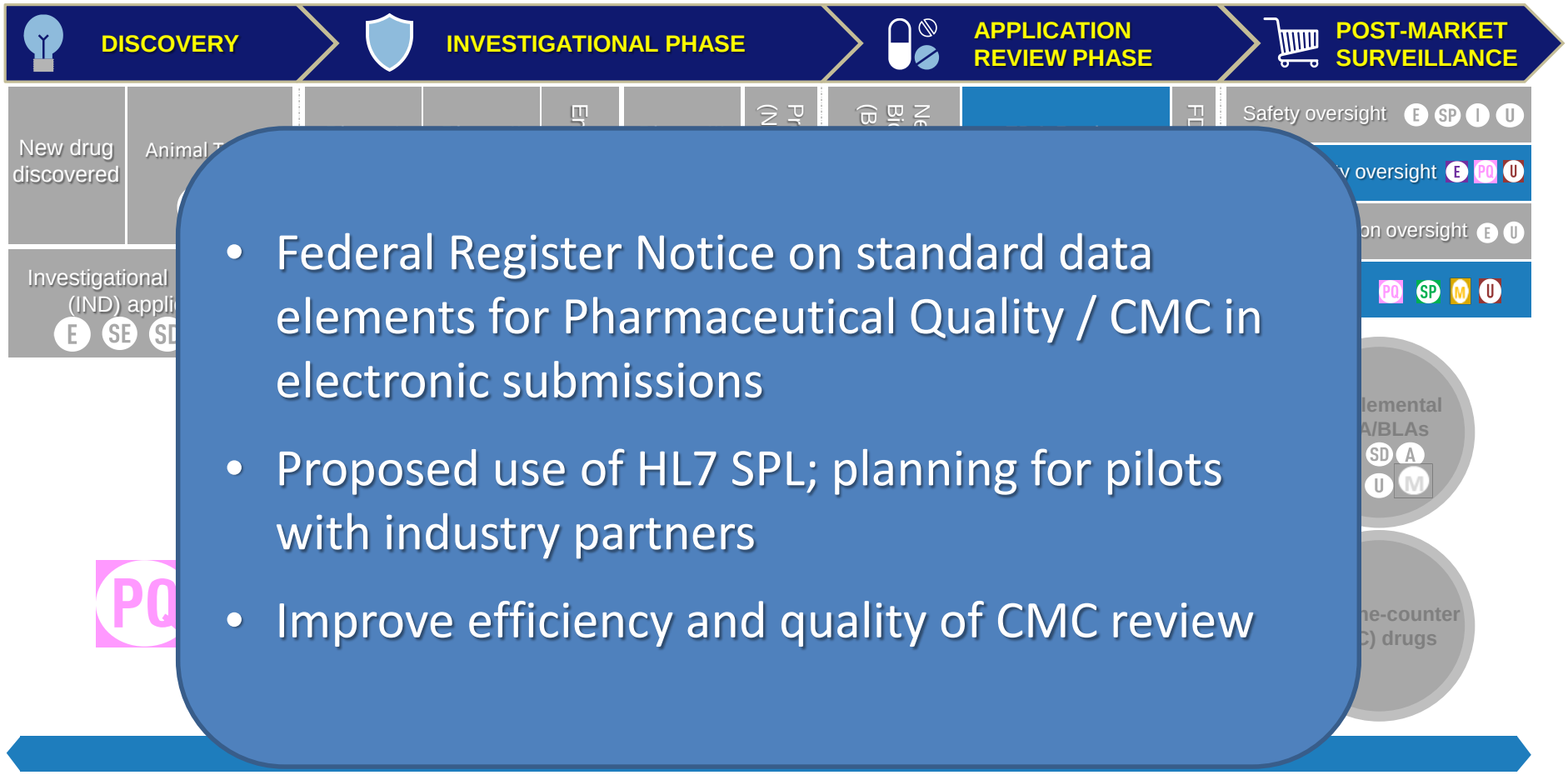


- Federal Register Notice on standard data elements for Pharmaceutical Quality / CMC in electronic submissions
- Proposed use of HL7 SPL; planning for pilots with industry partners
- Improve efficiency and quality of CMC review

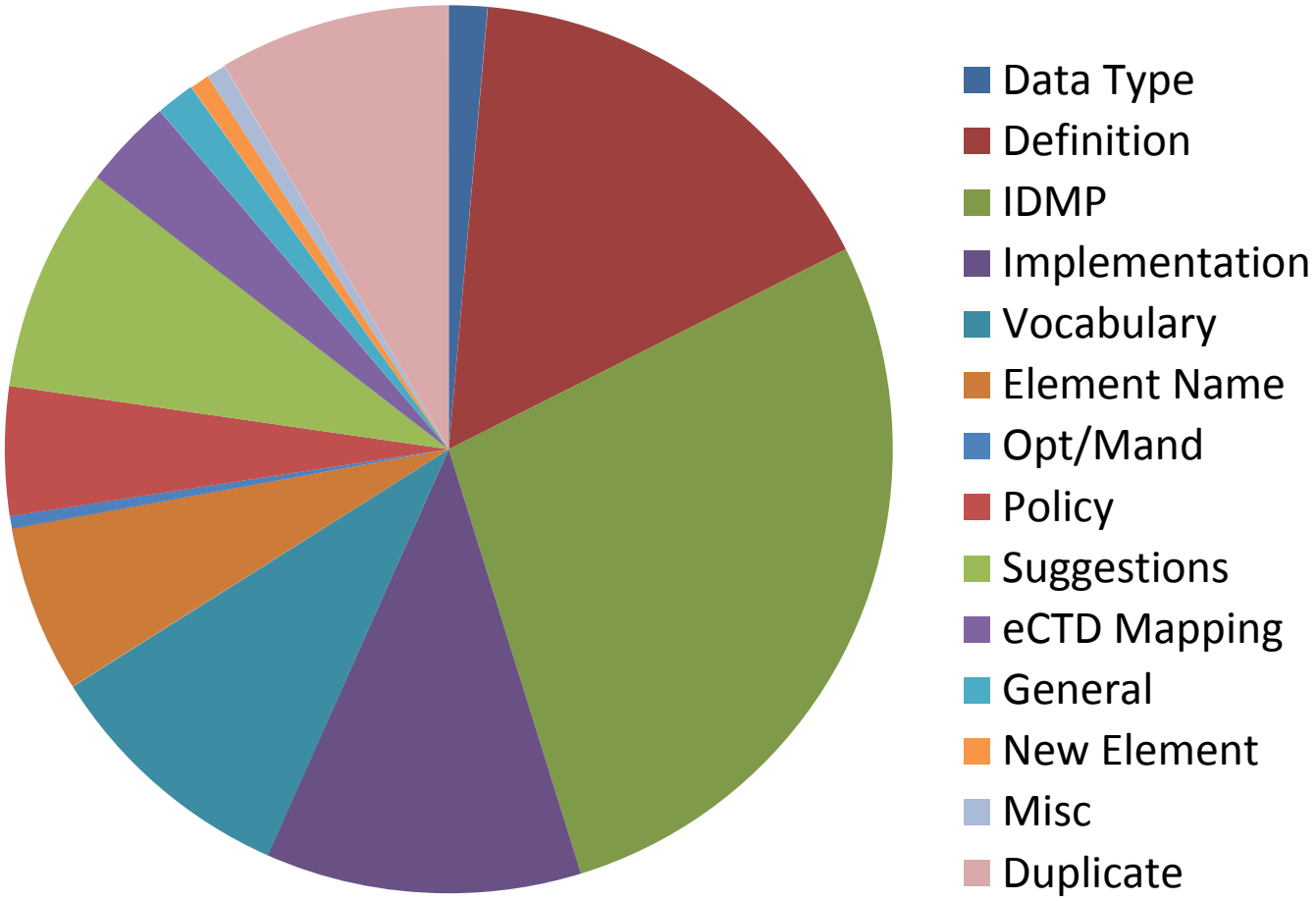
PQ/CMC Federal Register Notice Publication

- FDA published a FRN on July 11th, 2017, and solicited industry comments on the 152 PQ/CMC data elements developed
- Received 450 comments on this docket from 11 distinct organizations
- Comment review is underway

Plans for ISO IDMP Alignment

- FDA is committed to harmonizing with ISO IDMP standard, where applicable
- A subset of PQ/CMC data elements overlap with IDMP 11238 and IDMP 11615 and FDA plans to harmonize PQ/CMC with these IDMP standards
- Project team is currently developing a harmonization plan

PQ/CMC FRN Comment distribution by category



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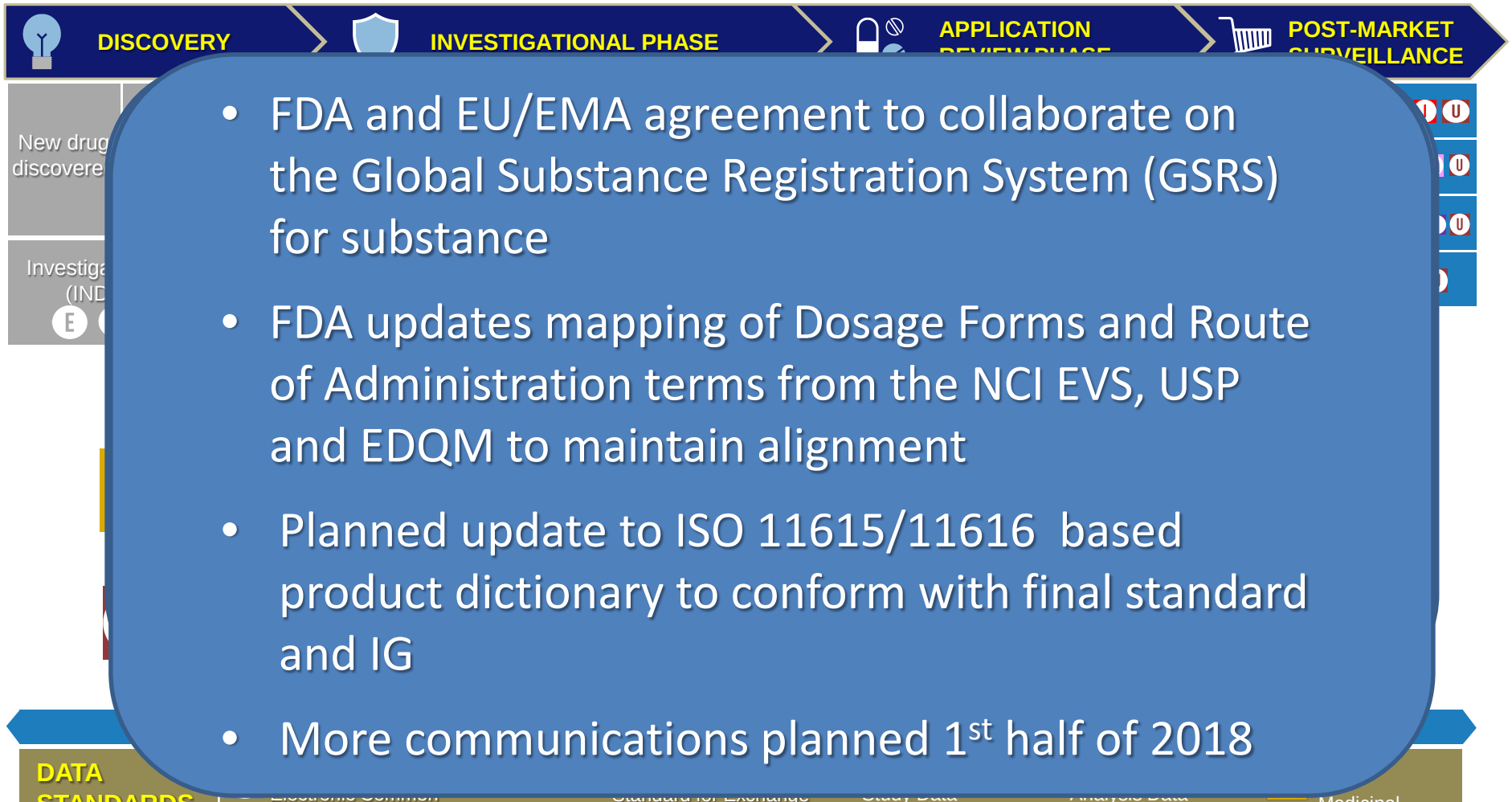

- FDA and EU/EMA agreement to collaborate on the Global Substance Registration System (GSRS) for substance
- FDA updates mapping of Dosage Forms and Route of Administration terms from the NCI EVS, USP and EDQM to maintain alignment
- Planned update to ISO 11615/11616 based product dictionary to conform with final standard and IG
- More communications planned 1st half of 2018

FDA ISO IDMP Implementation

The FDA IDMP Implementation Group (FIIG) oversees IDMP implementation

- FDA cross-organizational participation
- International collaboration and engagement
- Support needed agreements and MoUs
- Champion standards/system/message development
  - ISO IDMP TS development and comments
  - FDA GSRS implementation and integration
  - CDER Integrity Product Domain and Common Vocabulary Domain
  - HL7 FHIR Substance resource pilot and potential pilots of HL7 FHIR product identification resource(s)
- Ensure implementation of relevant governance bodies and processes
- Connect and support alignment of IDMP to other FDA initiatives, e.g., PQ/CMC, DCSCA implementation

Planning for public meeting in 2018

ISO IDMP Implementation

- CDER's Integrity Product Data Domain currently supports ISO/IDMP for MPID and PhPID; will be updated as needed to conform with the final implementations
- Gap analysis to determine needed FDA internal and external usage guidance
- GSRS v1.2 in production; v2.0 in pre-production testing
- Numerous activities underway and in planning to enable IDMP implementation

THANK YOU!

For more information:

CDER Data Standards Web pages:

https://www.fda.gov/drugs/developmentapprovalprocess/formssubmissionrequirements/electronicsubmissions/ucm249979.htm

FDA Data Standards Catalog:

http://www.fda.gov/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/ElectronicSubmissions/ucm153574.htm

General eSUB Questions

eSUB@fda.hhs.gov

Clinical and Nonclinical Data Questions

eDATA@fda.hhs.gov


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