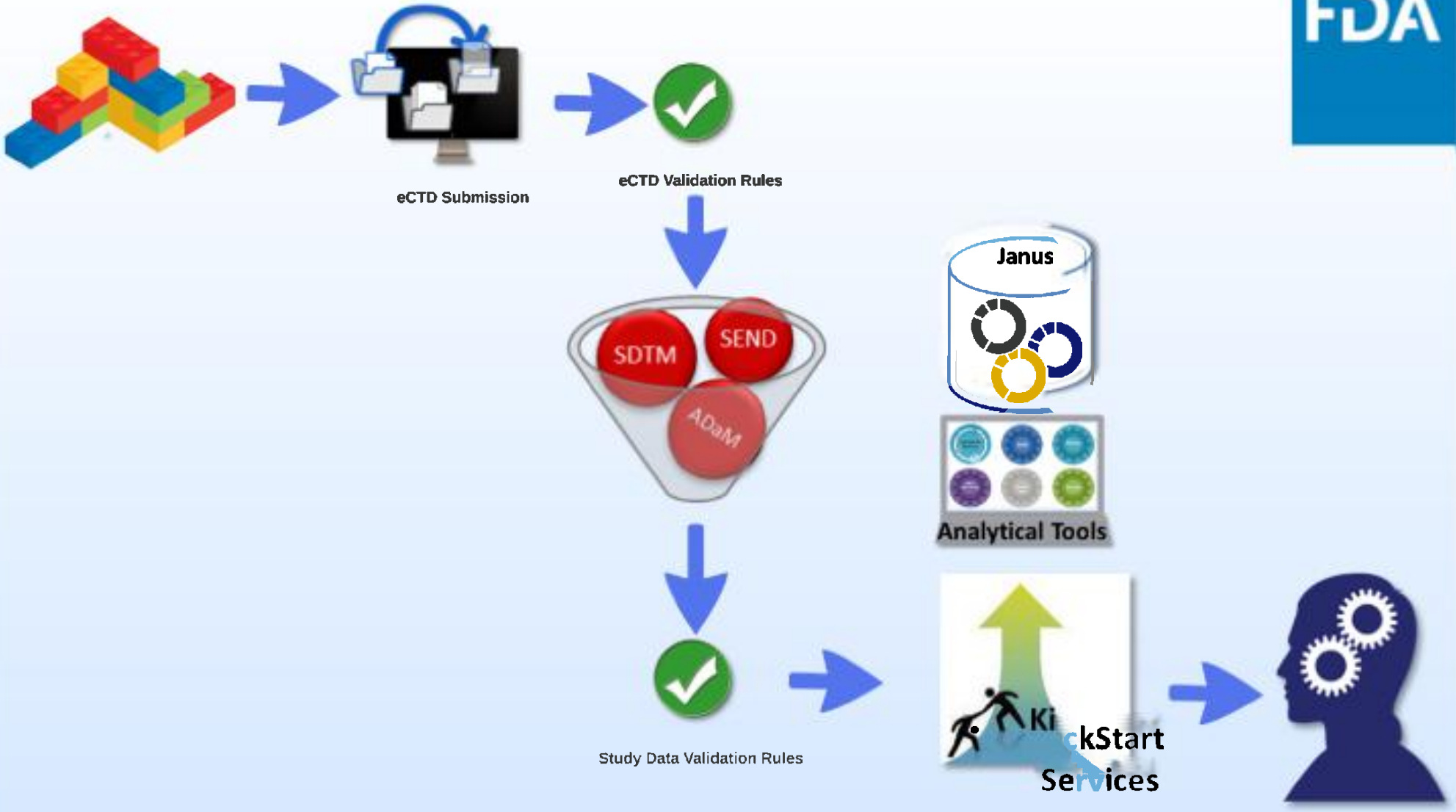
U.S. FOOD & DRUG ADMINISTRATION

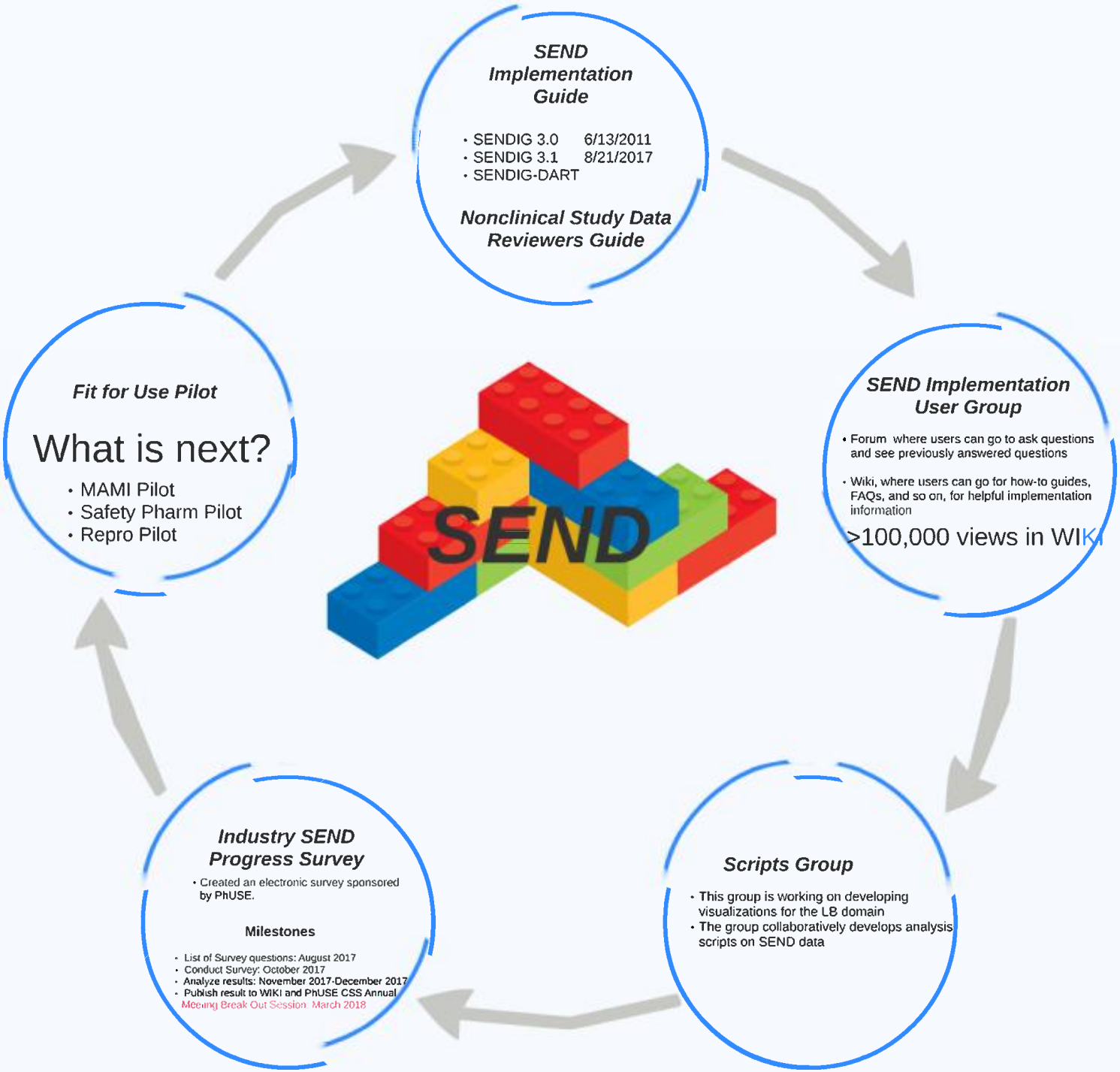
OFFICE OF COMPUTATIONAL SCIENCE

Lilliam Rosario, Ph.D.
Director, Office of Computational Science

Better Data I Better Tools I Better Decisions



Better Data | Better Tools | Better Decisions


SEND Implementation Guide
• SENDIG 3.0 6/13/2011
• SENDIG 3.1 8/21/2017
• SENDIG-DART
Nonclinical Study Data Reviewers Guide
SEND Implementation User Group
• Forum where users can go to ask questions and see previously answered questions
• Wiki, where users can go for how-to guides, FAQs, and so on, for helpful implementation information
>100,000 views in WIKI
Scripts Group
• This group is working on developing visualizations for the LB domain
• The group collaboratively develops analysis scripts on SEND data
Industry SEND Progress Survey
• Created an electronic survey sponsored by PhUSE.
Milestones
• List of Survey questions: August 2017
• Conduct Survey: October 2017
• Analyze results: November 2017-December 2017
• Publish result to WIKI and PhUSE CSS Annual Meeting Break Out Session: March 2018
Fit for Use Pilot
What is next?
• MAMI Pilot
• Safety Pharm Pilot
• Repro Pilot
SEND

SEND Implementation Guide

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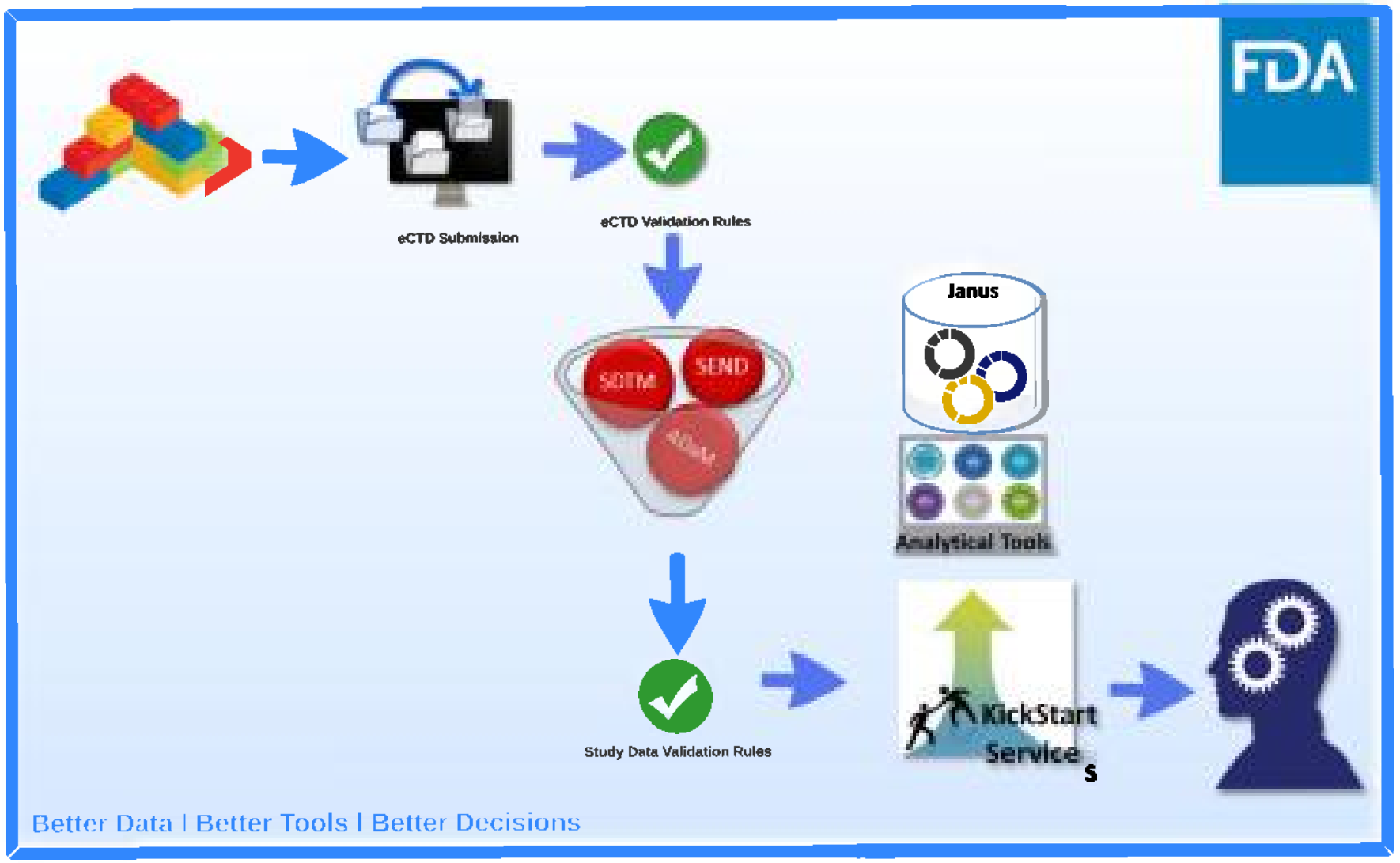
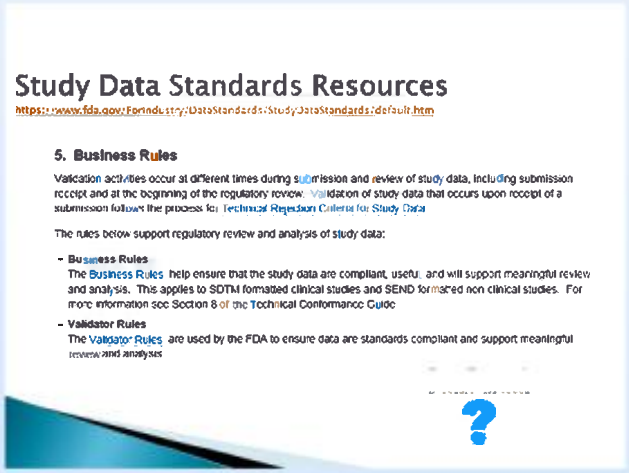

FDA
eCTD Submission
eCTD Validation Rules
SDTM
SEND
ADaM
Janus
Analytical Tools
Study Data Validation Rules
KickStart Service
s
Better Data | Better Tools | Better Decisions

Validation activities occur at different times during submission and review of study data, includin submission receipt and at the beginning of the regulatory review.

eCTD Valid tion Rules

eCTD Study Data Validation Rules and Severity

High	Demographic dataset (DM) and the define.xml must be submitted in Module 4 and the DM dataset Subject level analysis dataset (ADSL) and define.xml must be submitted in Module 5
High	Trial Summary (TS) dataset must be presented for each study in Module 4 or 5
Medium	Correct STF file-tags must be used for all standardized datasets • Data-tabulations-dataset-sdtm • Analysis-dataset-adam
Medium	For each study, no more than one dataset of the same type should be submitted as new



Study Data Standards Resources

https://www.fda.gov/ForIndustry/DataStandards/StudyDataStandards/default.htm

5. Business Rules

Validation activities occur at different times during submission and review of study data, including submission receipt and at the beginning of the regulatory review. Validation of study data that occurs upon receipt of a submission follows the process for Technical Rejection Criteria for Study Data

The rules below support regulatory review and analysis of study data:

- Business Rules
  The Business Rules help ensure that the study data are compliant, useful, and will support meaningful review and analysis. This applies to SDTM formatted clinical studies and SEND formatted non clinical studies. For more information see Section 8 of the Technical Conformance Guide
- Validator Rules
  The Validator Rules are used by the FDA to ensure data are standards compliant and support meaningful review and analyses

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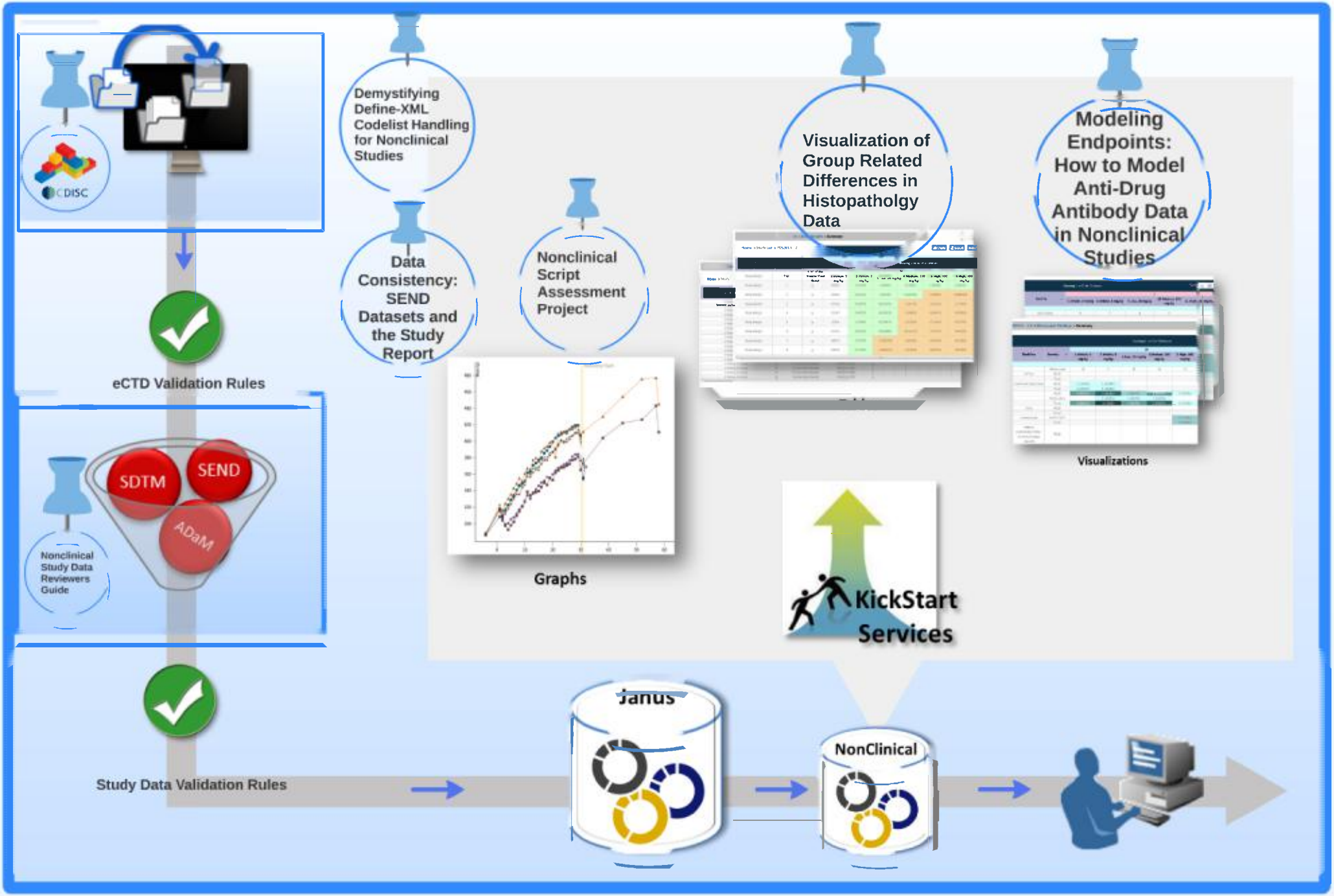
eCTD Validation Rules
SDTM
SEND
ADaM
Study Data Validation Rules
Graphs
Tables
KickStart
Services
SEND
SEND
SEND


CDISC
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Study Data Validation Rules
Demystifying Define-XML Codelist Handling for Nonclinical Studies
Data Consistency: SEND Datasets and the Study Report
Nonclinical Script Assessment Project
Graphs
Visualization of Group Related Differences in Histopatholgy Data
Modeling Endpoints: How to Model Anti-Drug Antibody Data in Nonclinical Studies
Visualizations
KickStart Services
Janus
NonClinical


Implementers
FIT
FOR
USE


SDTM
SEND
ADaM
NonClinical
KickStart
Services