

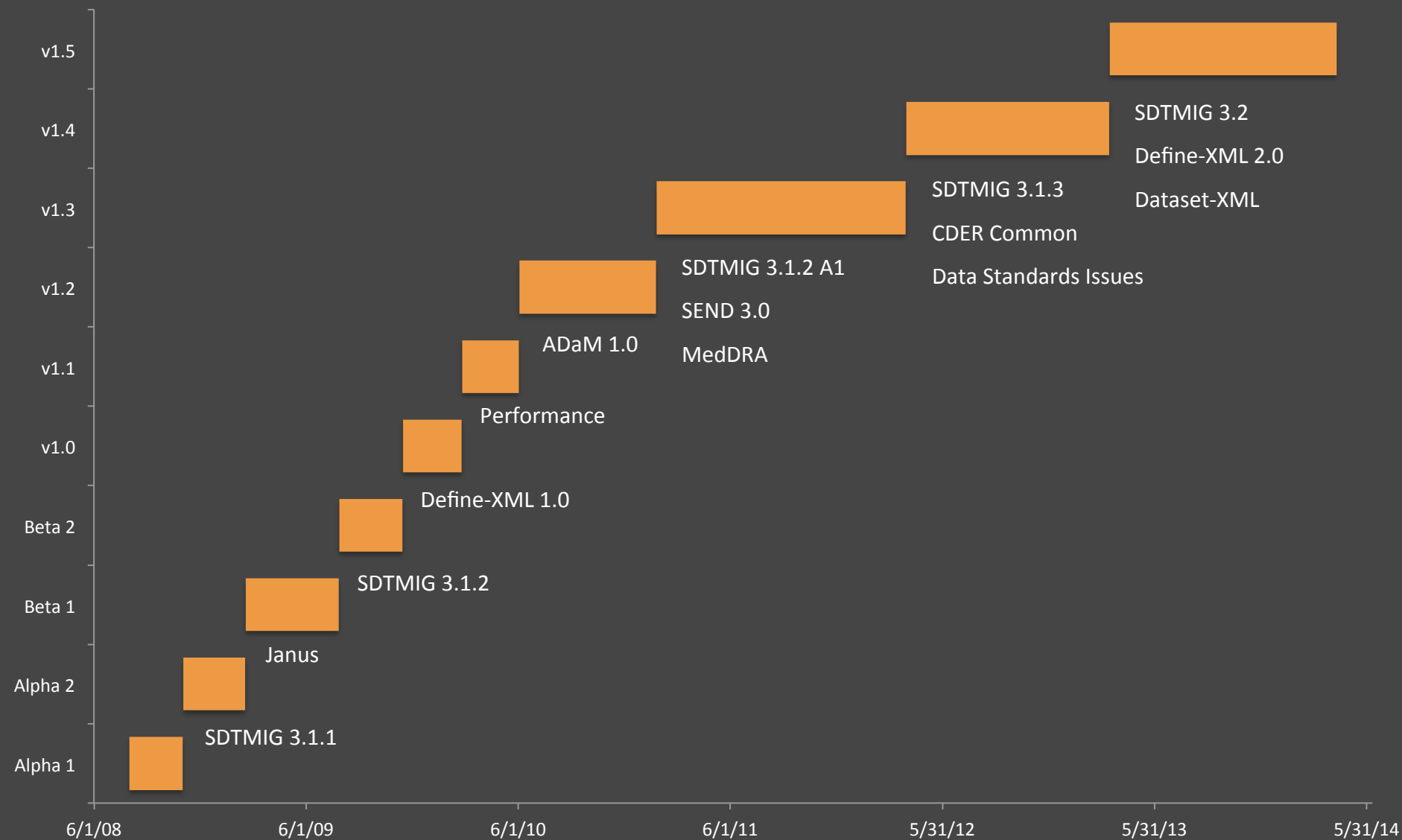
OpenCDISC Community v2.0

What's new in the upcoming release

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OpenCDISC Release History



“What are OpenCDISC’s main challenges?”

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- › More standards
- › More controlled terminology
- › More validation rules

OpenCDISC is no longer alone

- › CDISC Validation Initiatives
 - › SDS Validation Subgroup
 - › ADaM Validation Subgroup
 - › Define.xml Validation Subgroup
- › FDA Validation Initiatives
 - › Data Fitness (data quality + analysis reqs)
 - › Published as addendum to FDA Study Data Technical Conformance Guide

OpenCDISC can now focus on

- › Implementing new rules
- › Releasing rule updates more frequently
- › Building more tools

OpenCDISC Community v2.0

- › Movement to metadata driven validation
- › 3 new tools
 - › Define.xml Designer
 - › Data Converter
 - › ClinicalTrials.gov Miner
- › New interface
- › Automatic updates

Define.xml Designer Editions

	Community	Enterprise
Client Interface	Desktop	Web Hosted
Create fully compliant Define.xml 2.0 for following standards	SDTM, SEND, ADaM	SDTM, SEND, ADaM and company custom
Convert Define.xml 1.0 to 2.0	✓	✓
Extract metadata from SAS datasets	✓	✓
Extract origin page numbers from annotated CRFs		✓
Merge metadata from external specifications		✓
Generate Define.pdf		✓
Validate Define.xml content in real-time		✓
Compare metadata with standards and other studies		✓
Create and manage multiple versions		✓
Track changes between versions		✓

Data Converter

- › Converts data between
 - › SAS XPORT
 - › Dataset-XML
 - › Excel
 - › CSV

ClinicalTrials.gov Miner

- › Aggregate Clinical Outcome Measures/Endpoints across trials and Therapeutic areas for a specified criteria (e.g. all endpoints for immunosuppressant therapy for patient population X and compound Y)
- › Provide a list of clinical trial site information (PI name, phone number, addresses, other Contacts, etc..)
- › All reports are tabulated as either CSV or Excel

OpenCDISC Events

- › OpenCDISC Live
- › Webinars
- › Training

Questions

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