

SAS SUPPORT CDISC AND CLINICAL METADATA MANAGEMENT

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Abstract:

SAS's current and future support of CDISC, such as possible integration with CDISC SHARE, and enhanced metadata management in clinical data repository based on customers' use cases and product road maps.

Main Items:

- Industry and CDISC maturing – more than 10 years of CDISC progress
- SAS support of CDISC
- Standards updated frequently – updates without new SAS versions
- Roadmap (recent, next release, next 3 years):



- Industry and CDISC maturing – more than 10 years of CDISC progress
- Much has changed in the last decade –
 - Starting with creation of CDISC itself
 - Soon followed by SDTM and ODM standards
 - Through the CDISC SHARE project and Dataset XML

- SAS provides formal support for many CDISC standards:
- SDTM versions 3.1.1, 3.1.2, 3.1.3 and 3.2
- ADaM 2.1
- SEND 3.0
- define.xml (CRT-DDS 1.0 and Define 2.0)
- ODM 3.1 and 3.1.1
- Supported in SAS Drug Development and SAS Clinical Data Integration via SAS Clinical Standards Toolkit

- Dataset XML, CDASH, and SHARE support coming soon

- Standards updated frequently – updates without new SAS versions
- Loading ODM terms first supported in Clinical Standards Toolkit 1.5
- Download desired terminology list from CDISC/NCI in CDISC ODM format
- Use process defined in Lex Jansen's PharmaSUG 2013 paper [HT06-SAS](#)

- CDISC SHARE will provide data standards structures and other metadata
- Once available, CDISC SHARE extracts will be importable in a similar way
- CDISC SHARE to provide define.xml and ODM formats which can be used now

CLINICAL DEVELOPMENT ROADMAP

RECENT RELEASES, NEXT RELEASE, NEXT 3 YEARS



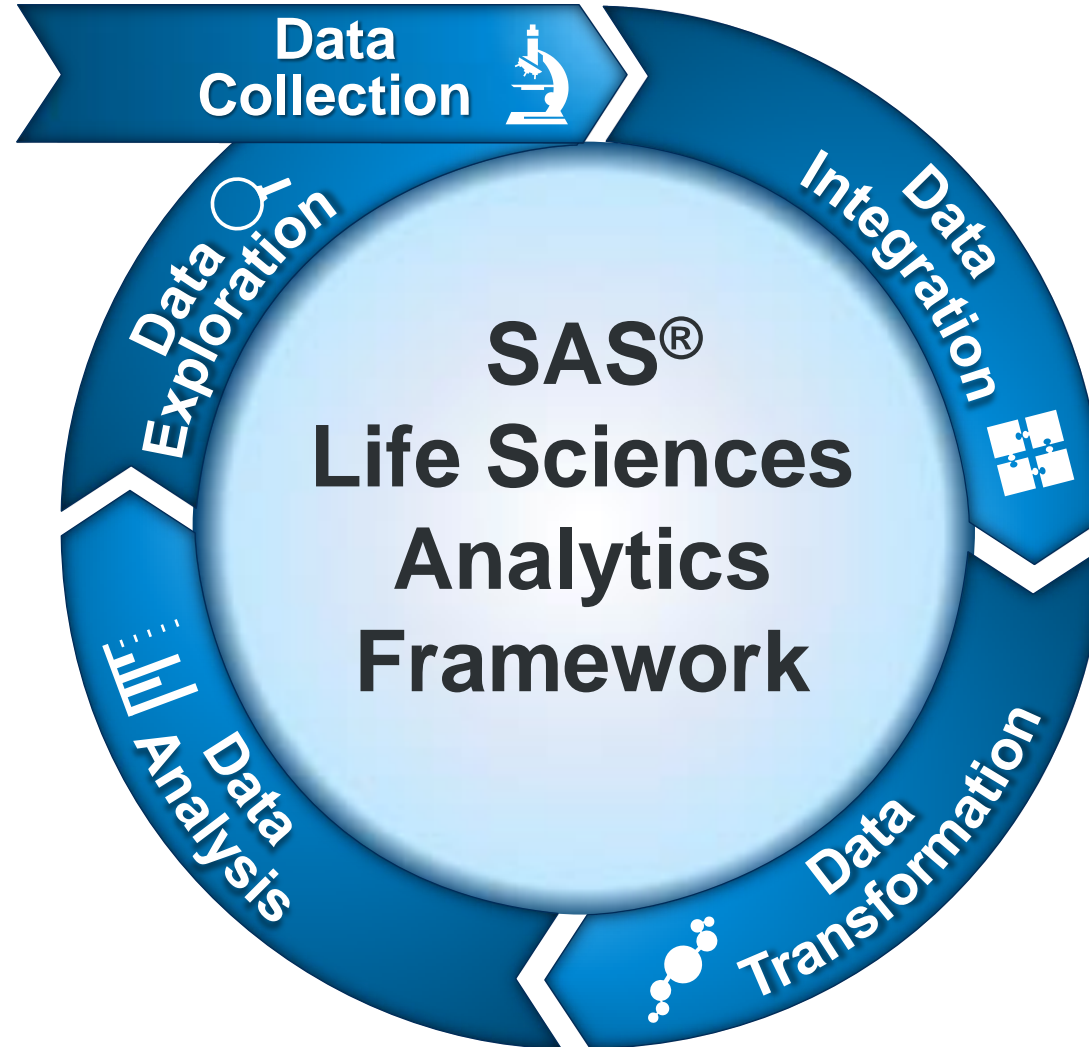
- Clinical Data Integration 2.5 released in March, 2015
- Clinical Standards Toolkit 1.6 released in Feb, 2015
- Key new features
 - SDTM 3.2 Support
 - Define 2.0 Support
 - Version 5 Transport File Handling
 - Creating Metadata from Define-XML Files
 - Incremental Update of Data Standard Metadata from CST

- Clinical Data Integration 2.6 and Clinical Standards Toolkit 1.7
- Planned release 2015 Q1
- Completion of define metadata (1.0 and 2.0)
- Support for CDISC Dataset XML
 - SAS participating in FDA pilot for Dataset XML (replacement for SAS V5 Transport)
- Incorporation of CDISC CDASH data collection standard

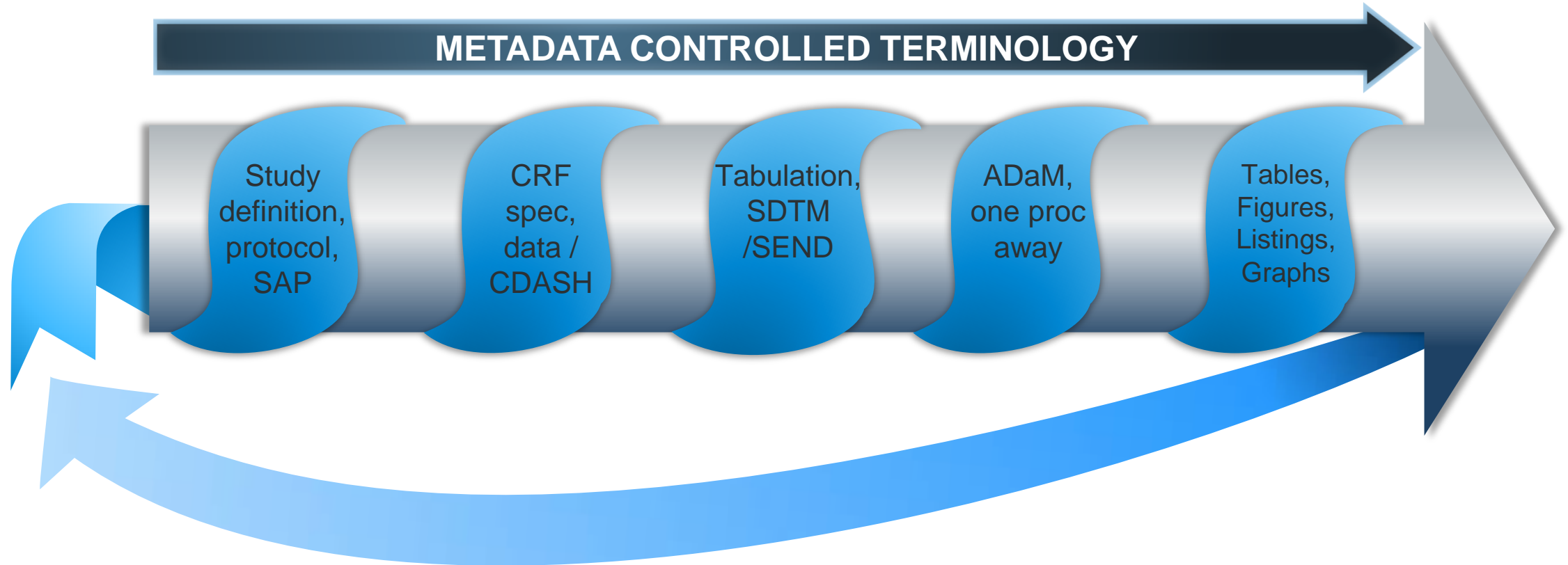
- Releasing new SAS offering 2015, Q2 – Life Science Analytics Framework
- Combined feature set with new metadata management capabilities
 - Switch CDASH-SDTM/SEND-ADaM definitions to SAS dataset
 - Ability to create define.xml (10/2.0) for appropriate standards
 - All versioned and controlled
 - Modifications made via rule-based wizards (like in CDI today)
 - Clear understanding of study-study linkages/portfolio of studies a core concept

SAS, CDISC, AND CLINICAL METADATA

END-TO-END ANALYTICS



EXAMPLE: DATA FLOW AUTOMATED FROM STUDY METADATA



- CDISC maturing – existing standards changing slowly but new ones added
- SAS supports CDISC and customers using their standards
- Update standards without installing new SAS versions
- SAS plans many new capabilities for future software releases

THANK YOU – BILLJ.GIBSON@SAS.COM



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