

NthSDM – an SDTM Solution

Nth Analytics

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Services

- Services:
 - Statistical Analyses
 - PK/PD Analysis
 - SAS Programming
 - Standard reports
- Specialties:
 - CDISC Registered Solution Provider
 - SAS BI Server – Enterprise Guide

CDISC Registered Solutions Provider

- Preferred provider listed on the CDISC website - http://www.cdisc.org/sponsors_members/index.html
- CDISC Corporate member
- CDISC Industry Advisory Board IAB member
- Providing Study Data Tabulation Data Model (SDTM) files since 2004
 - SDTM for FDA Submissions and in-house use
 - Reporting systems
 - ADaM (Analysis Data Model)

CDISC SDTM Recent Projects

- SDTM for FDA submission (MannKind - ongoing)
- SDTM with a vaccine table package (Merck)
- SDTM Validation for FDA submission (Kos)
- SDTM+ including an automated mapping process and a generic table package (Merck)
- Legacy SDTM and ADaM midsize Pharmaceutical company (MannKind)
- Legacy SDTM – pharmacovigilance (J&J)
- Custom tool to automate DEFINE.PDF documentation (Merck)
 - Passed Merck validation audit

Legacy Data to SDTM Conversions - Expertise

- We have presented at the last 3 CDISC Legacy Data Workshops
 - CDISC Interchange - September 2006
 - CDISC European Interchange – April 2007
 - CDISC Interchange – October 2007
- Large project for J&J converting concomitant medication and lab data to SDTM for pharmacovigilance

Legacy Data to SDTM Conversions – Systematic Approach

- Legacy data combined with data from current studies are often required for submissions or pharmacovigilance.
- Often there are multiple Legacy systems, disparate from each other
- Problem: design an efficient method for converting legacy data to SDTM
- Need one system to convert both

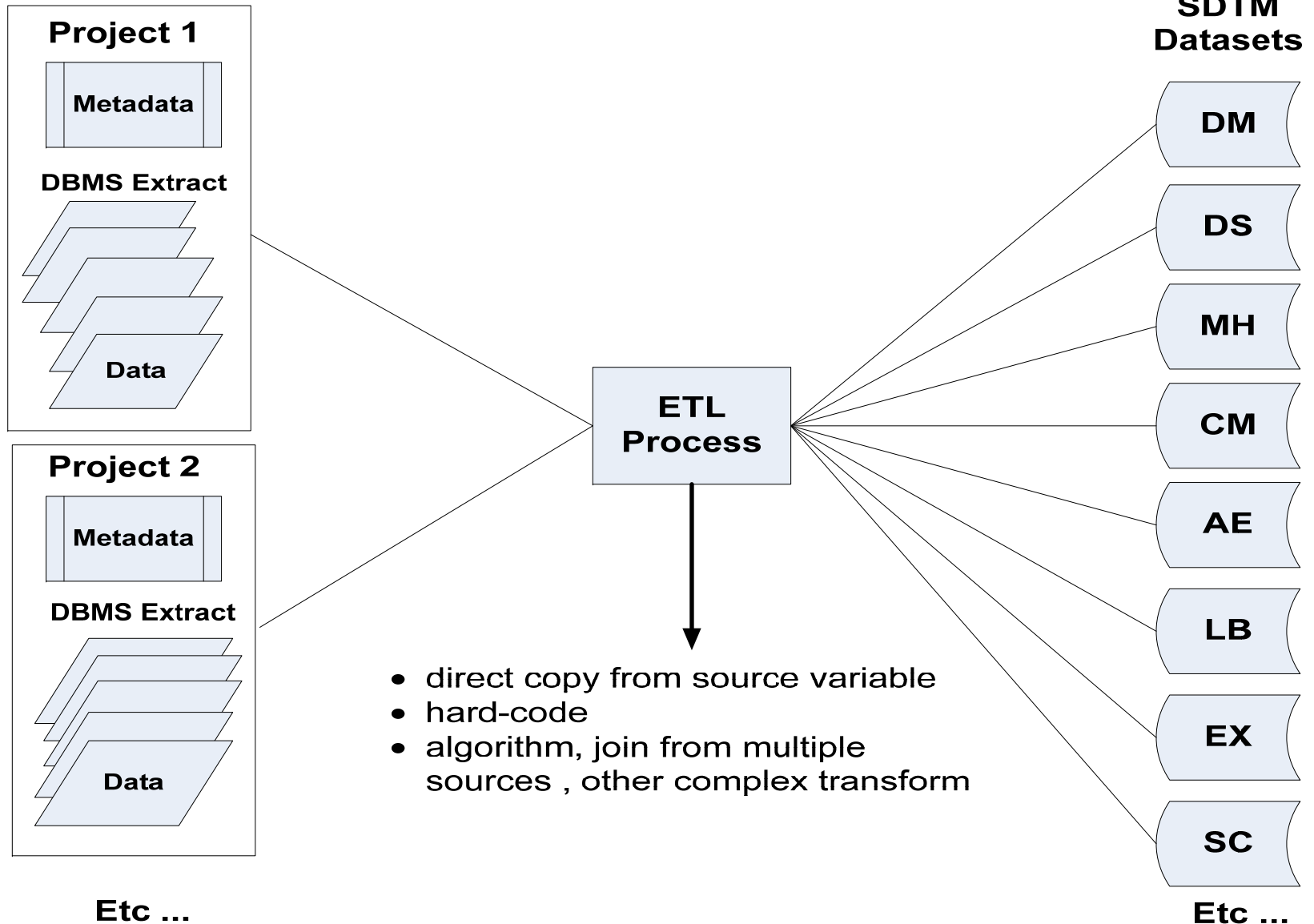
SDTM Conversion Strategy

- No knowledge needed of system that originally produced the legacy data
- Applicable to files from any system
- Implementation is flexible enough to adapt to different study designs
- CDISC conforming
- Minimal programming support required for maintenance
- Reasonable cost

Our Process - NthSDM

- ETL Process – Extract, Transform, Load
- SAS Business Intelligence Server
 - Enterprise Guide tool
- Metadata - EXCEL Mapping Spreadsheet
- SAS Programming – SQL
- Standard checks of SAS log
- Automated Validation checks
- Automated Documentation

NthSDM ETL Process



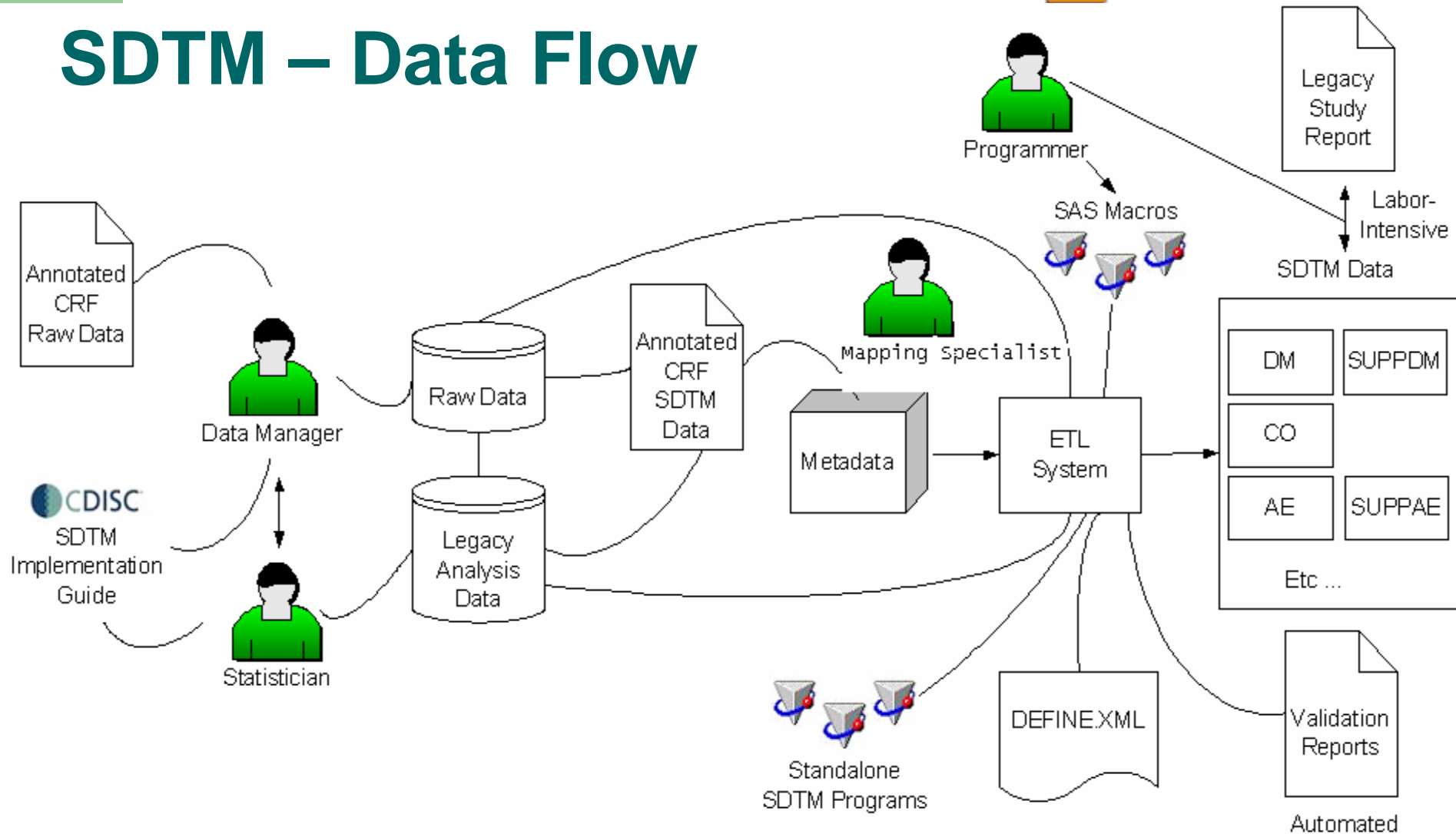
SDTM – Compliance Validation

- SDTM Structure and Format
- Conformance with Implementation Guide rules via 105 WebSDM checks
- Checks SDTM domain structure and format against the domain models in the Implementation Guide
- Keys, topic variables are constructed correctly
- Variable names, labels, type etc. are correct
- All required variables have values, etc.
- All expected variables are present
 - etc. - ensuring that all rules are followed

SDTM – Content Validation

- Ensure source data are mapped correctly
- Verify source data transfer at the domain level
 - Data manager is the source for these checks
 - Automated checks with a manual review process
- Techniques
 - Programmatic checks for each SDTM domain
 - For each source dataset - verify data is converted correctly to SDTM testing key variables, derivations and other domain specific logic
 - Automatically generates the validation evidence in the form of a Test Script

SDTM – Data Flow



NthSDM - Advantages

- Does not require knowledge of any clinical trial system
- It works for both legacy and current data
- Only new study specific situations cause additional coding – usually a change in a derivation
- Changes to CDISC standards are made to the metadata avoiding costly programming revisions
- Self documenting – converts to define.pdf
- Generates submission-ready SAS programs
- Automated: manual steps are minimized