SANOFI
Clinical Data Integration Solution as Part of SDTM Generation

PHUSE 2014
TS05

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Currently….

Is the SDTM generation the best added value for Statistical programmer???
EXECUTIVE SUMMARY

1. SCALA : Innovation and Integration for better performance

2. SAS® CDI solution : SDTM generation with industrialization approach

3. SCALA in production : optimized CDI processes, users profiles and support services

4. Conclusion : new challenge, new team !
SCALA

Innovation and Integration for better performance

UNIFY Program

MAESTRO Program

SCALA

*SCE Application for Linear Data model

✓ Innovative way of operating clinical development
✓ Integration of clinical data from diverse sources
✓ Sanofi, Sanofi Pasteur and Genzyme entities
✓ Flexibility to produce standard and study-specific SDTM
✓ Standard library of jobs
✓ Efficient organization and process

Clinical Data Integration Solution as Part of SDTM Generation
SCALA
Clinical Data Integration with metadata driven approach

SCALA Project: SDTM generation

EXT Data Provider

Integration Service

ODS*
Clinical data

Extract, transform & milestones
Study Metadata file

SDTM mart

STDM & ADaM datasets for submission & analysis

SCE*:
Statistical Computing Environments

CDASH Metadata
EXT Metadata
Study SDTM Metadata
ADaM Metadata
CDMS* : Clinical Data Management System
ODS* : Operating Data System
SCE* : Statistical Computing Environments

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SAS® CDI Solution aligned with SCALA needs

**Approach**
- Metadata driven

**User Friendly**
- Programming with pre-defined objects
- No need of advanced SAS programming knowledge

**Flexible**
- Integration of SANOFI custom developments

**Role Based**
- SCALA Administrator
- SCALA Programmer
2 SCALA Production Platform & Global Process

**DEVOPS**
- Study SDTM jobs programming
- CDI job execution
  - SAS® CDI
- Study SDTM SAS datasets for validation
  - Study compliance checks reports

**PRODOPS**
- Study SDTM SAS programs
- SAS programs execution by using a scheduler
  - CDI jobs deployment
- Study SDTM SAS datasets
  - Study compliance checks reports

**SHARED AREA**
- Study Clinical Raw Data (test and production data)

**ODS Clinical Data**
- Raw Data Extraction

**SCE**
- SAS datasets copy
- SANOFI

**SCALA Administrator**
- SCALA Programmer
Study SDTM Programming in SAS® CDI

1. Register Study SDTM Metadata using SAS® Clinical Standards Toolkit

2. Create Study Source Metadata

3. Register Study Source Metadata

4. Import Study SDTM Domain Metadata

5. Program Mappings and Derivations & Program Compliance Checks

6. Deploy CDI Jobs and create Study SDTM

SDTM Hybrid mart

SANOFI DATA STANDARD

SCALA STANDARD LIBRARY

Clinical Data Integration Solution as Part of SDTM Generation
# SCALA Development

## Clinical Data Integration Solution as Part of SDTM Generation

<table>
<thead>
<tr>
<th>Purpose</th>
<th>Custom Efforts</th>
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<tbody>
<tr>
<td><strong>Study Clinical Data Extraction</strong></td>
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<tr>
<td>• Extract Clinical raw data in SAS datasets format from ODS to SCALA</td>
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<tr>
<td><strong>SANOFI Data Standard Registration</strong></td>
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<tr>
<td>• Register SANOFI Standard SDTM &amp; Study SDTM metadata-based Data Standard in SAS® CDI using SAS® Clinical Standards Toolkit</td>
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<td><strong>SCALA Standard Library</strong></td>
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<tr>
<td>• Develop a library of SANOFI SDTM job templates</td>
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<td>• Develop a library of compliance checks</td>
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<tr>
<td>• Develop macros and transformations</td>
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SCALA IN PRODUCTION

optimized CDI processes, users profiles and support services

SECURED USER PROFILES

SCALA Administrator
SCALA developers
Scheduler

SPECIFIC PROCESSES

SANOFI custom data standards
Source data for study milestones
Job Versioning & Deployment
Scheduling refresh of output SAS datasets

SUPPORT SERVICES

5 resources / 100 studies
Interaction with other stakeholders
Service level agreements
Data managers
Study biostatisticians & programmers
Technical teams
3 to 6 weeks per study SDTM generation
Quality and Efficiency

SANOFI

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CONCLUSION / Lessons learned

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QUESTIONS ? ?

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