

Customer Oriented CDISC Implementation

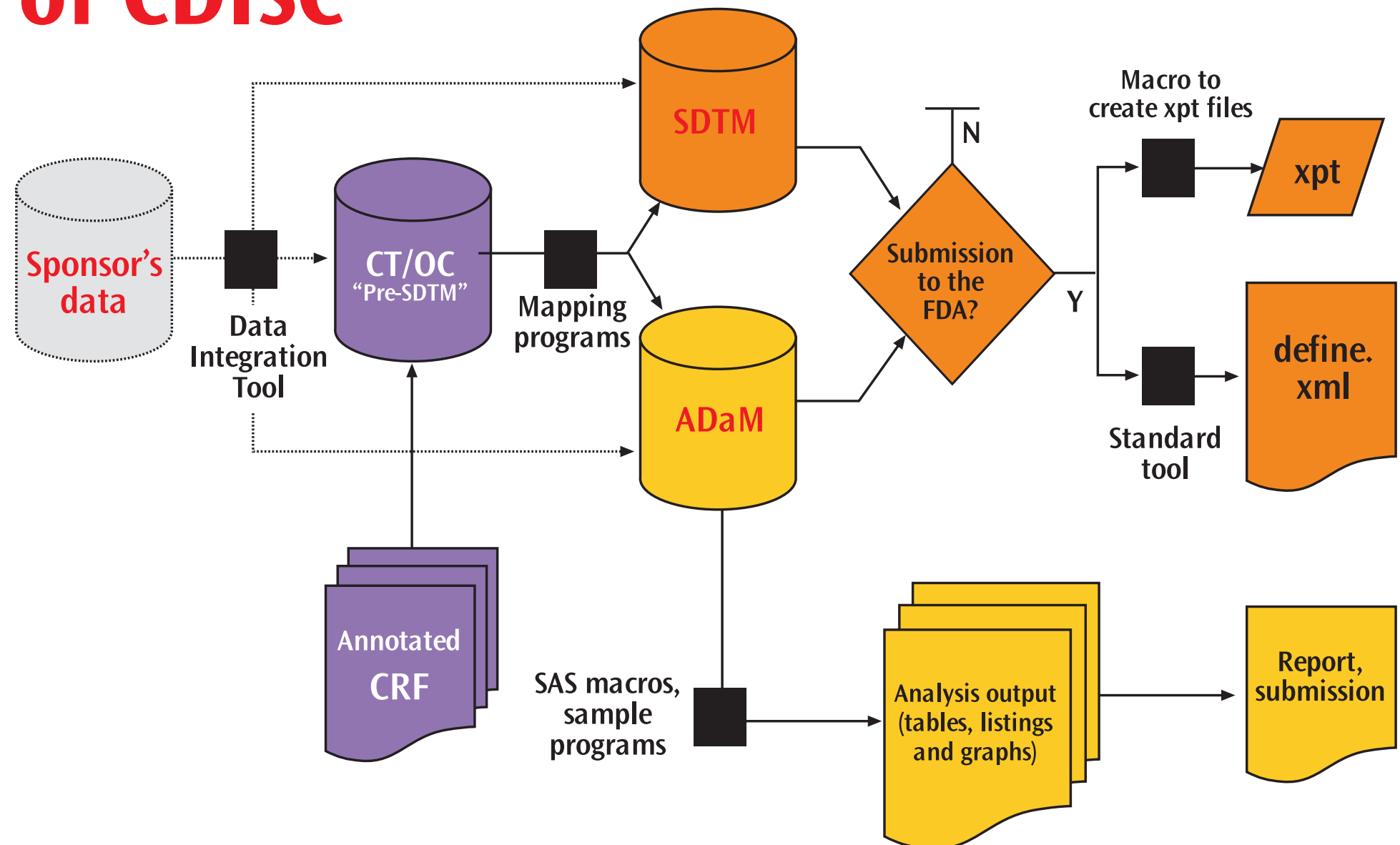
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Introduction

Companies might go for different strategies with regard to implementation of CDISC SDTM and ADaM models due to differences in internal systems and processes. However, at ACCOVION the consideration of the following cornerstones has been helpful in selection of the appropriate strategy:

- ✓ **FDA expectations:**
 - ✓ CDISC compliant SDTM and ADaM datasets
 - ✓ Documentation (define.xml and links to supplemental documents)
- ✓ **Accovion's inventory**
 - ✓ Software: Clintrial / Oracle Clinical
SAS 8.2 and 9.1.3
 - ✓ Core functions: Database and Statistical Programmers
- ✓ **Sponsor's requirements**

ACCOVION's workflow in the light of CDISC



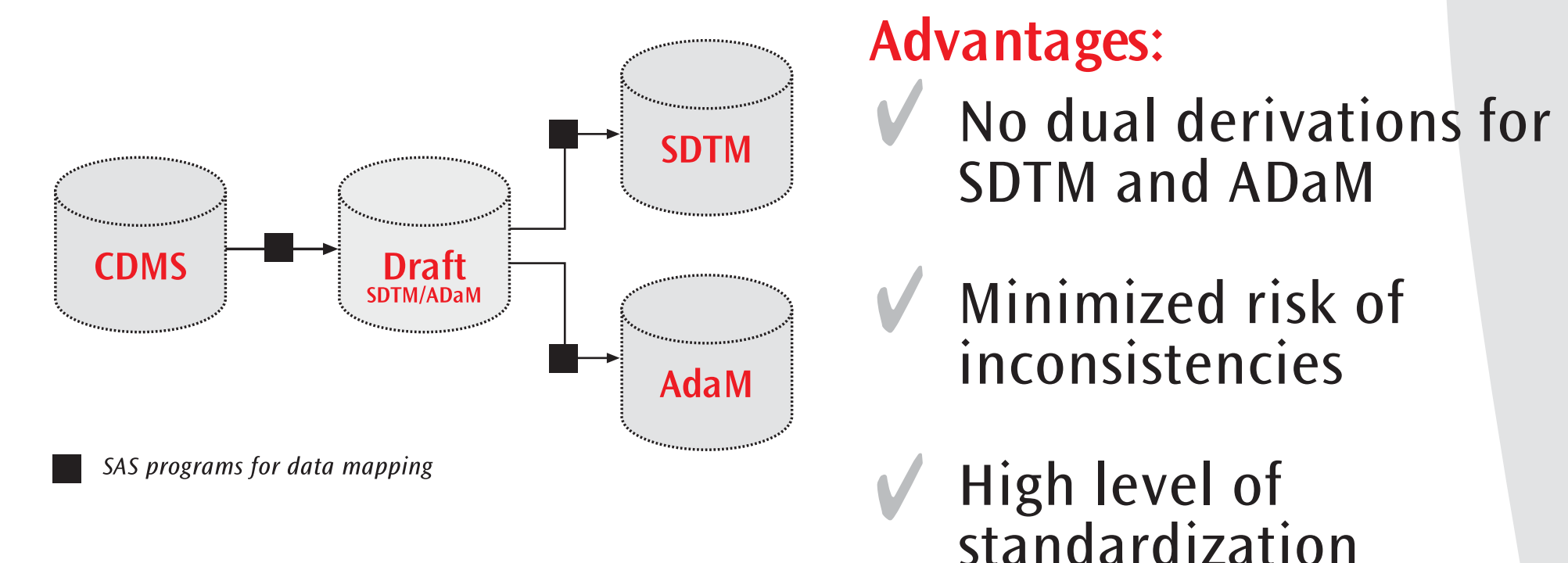
Database set-up

- ✓ **Use global libraries including:**
 - ✓ SDTM pure:
SDTM variables and metadata
 - ✓ SDTM comfort:
Additional variables for analysis
- ✓ **Copy metadata from global libraries and adapt on study level:**
 - ✓ Clinical data management system (CDMS) builds a “Pre-SDTM” – 100% finalization of SDTM is performed in SAS

Advantages: Numeric variables available in the CDMS and useful for analysis do not have to be determined again for ADaM. Flexibility of SAS can be used for more complex tasks.

SDTM and ADaM implementation

SDTM: Only few additional steps have to be made from “Pre-SDTM” in CDMS to final SDTM.
ADaM: The current CDISC guidance leaves some freedom for the set-up of the ADaM structure. Accovion uses standards across projects on top of ADaM to increase the efficiency.



- Advantages:**
- ✓ No dual derivations for SDTM and ADaM
 - ✓ Minimized risk of inconsistencies
 - ✓ High level of standardization



Tool for SDTM and ADaM implementation: A SAS program generator based on Excel sheets is used for mapping.

Example for a mapping table:

	ADaM variable metadata information						Source information			Mapping information			
Studyid	Domain	Variable	Label	Type	Length	Format	SAS library	Dataset name	Variable name	Task	Transform (SAS code)	Comments	Exec. order
1234	ADSL	SEX	Sex	Char	1		SDTM	DM	SEX	no change			
1234	ADSL	TRTAN	Actual Treatment Group Number	Num			SDTM	EX	EXTRT	macro	%trta (indata, outdata	...	2

Documentation: ACCOVION will extract the information from the mapping tables to automate the generation of define.xml (standardized format plus hyperlinks between datasets and documentation) as much as possible.

Data Integration: Non-compliant data structures (legacy studies) can be mapped with our standard tool to either the CDISC SDTM and ADaM structures or ACCOVION “Pre-SDTM” structure with subsequent use of our standards.

Analysis output

- ✓ Programming is based on the analysis datasets in ADaM format.
- ✓ Requirements for analysis outputs are driving the ADaM setup (backward planning).
- ✓ A set of 20 standard tables was developed covering most tables.
- ✓ ACCOVION has standard analysis tools which benefit from ADaM standards.

Conclusion

The modular approach of ACCOVION benefits from standards by keeping the flexibility for study and customer specific needs.

More Info

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