



SA05

Approach of Programming Production Harmonized with Submission

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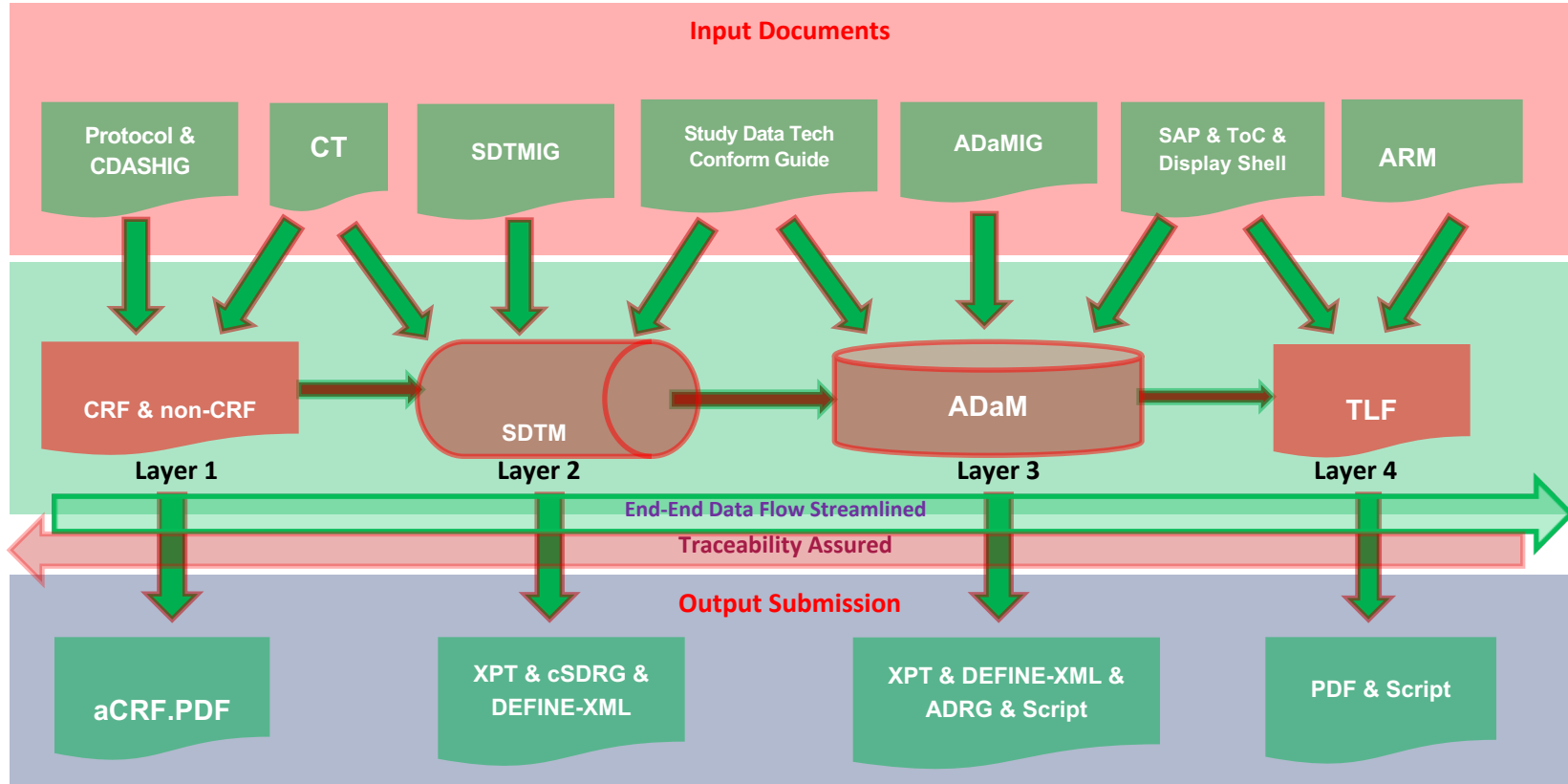
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Agenda

- Introduction
- Programming Documents
- Programming Approach
 - ❖ Typical—Production and Submission Separated
 - ❖ Innovated-- Production and Submission Harmonized
- Conclusion

Introduction

- ❖ End-in-mind Philosophy
- ❖ End-to-end Streamlined Data Processing



CDASHIG=Clinical Data Acquisition Standards Harmonization Implementation Guide; **CT**=Controlled Terminology; **SDTMIG**=Study Data Tabulation Model Implementation Guide; **ADaMIG**=Analysis Data Model Implementation Guide; **SAP**=Statistical Analysis Plan; **ToC**=Table of Content; **ARM**=ADaM Analysis Results Metadata; **aCRF**=Annotated Case Report Form; **TLF**=Table, Listing, and Figure; **XPT**=SAS Transport Version 5 Format File; **cSDRG**=clinical Study Data Reviewer's Guide; **ADRG**=Analysis Data Reviewer's Guide; **PDF**=Portable Document Format; **XML**=eXtensible Markup Language

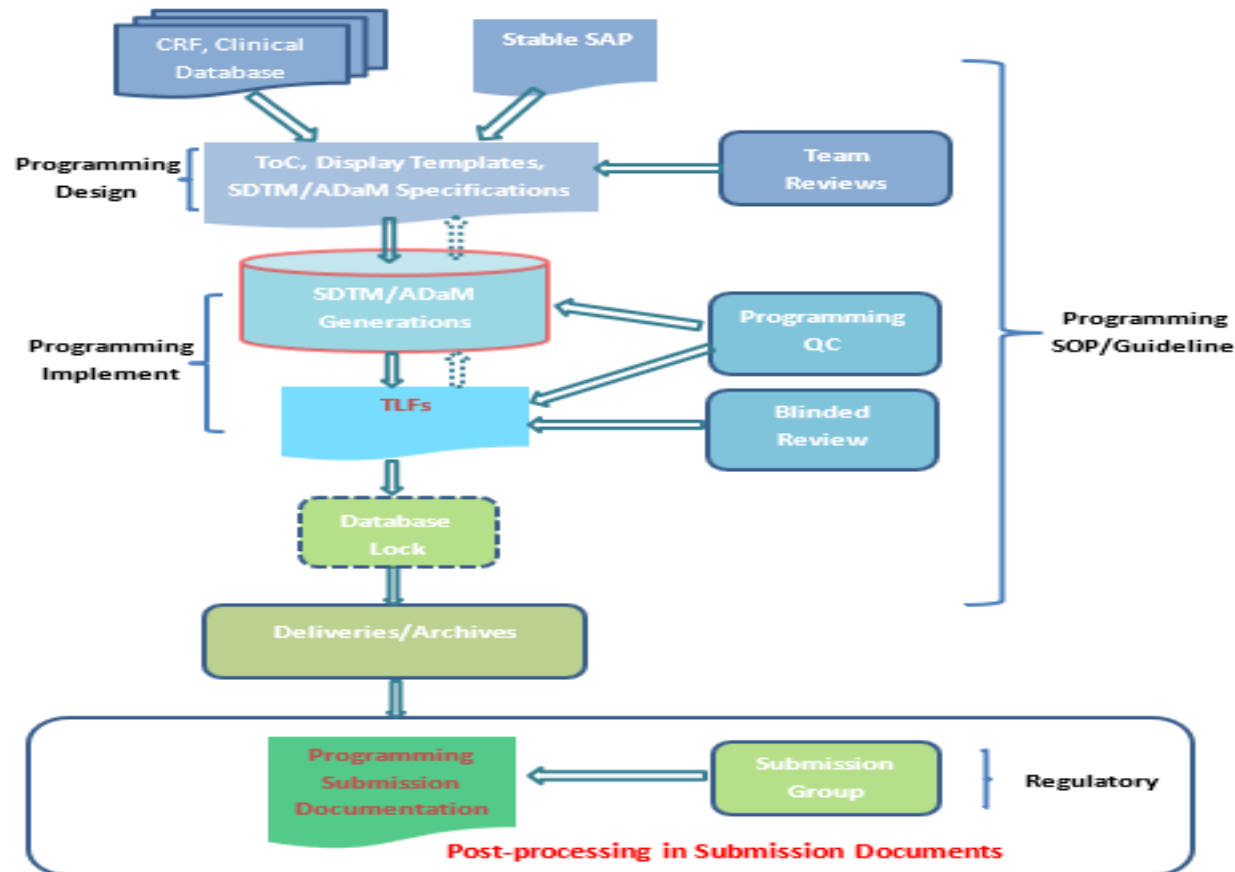
Programming Document

Production	Submission
aCRF, providing instructions to SDTM mapping	aCRF.PDF
SDTM specifications; SDTM datasets as deliveries	SDTM.XPT; DEFINE-XML; cSDRG.PDF
ADaM specifications; ADaM datasets as deliveries	<u>ADaM.XPT</u> ; DEFINE-XML(incl. ARM); ADRG.PDF
ToC; Display Templates; TLFs as deliveries	TLFs.PDF
SAS® Codes incl. Macros	Scripts.TXT with Readability, esp. for Core <u>ADaM</u> or Tables
QC Documents incl. QC codes	NA

Analysis Results Metadata becoming popular in production and submission

Programming Approach

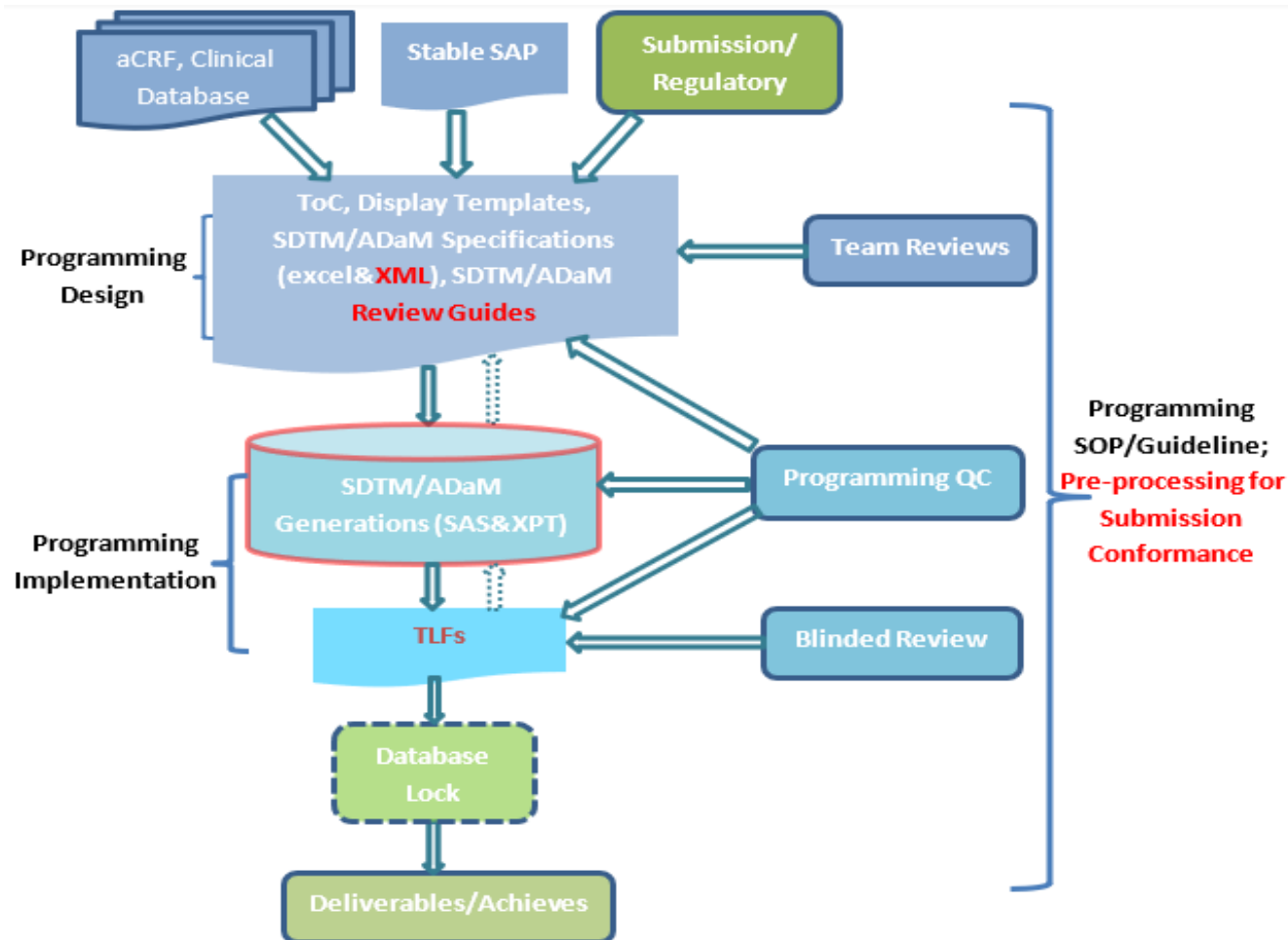
❖ Typical Programming Process-Production/Submission Separated



❖ Challenges During Submission

Programming Approach

❖ Innovated Programming Process-Production/Submission Harmonized



❖ Preferably Production Folders Also Aligned with eCTD.m5.datasets

Conclusion

❖ Programming Process Innovated

Harmonizing Production with Submission

❖ Programming Efficiency Increased

Minimizing Efforts in Submission

❖ Programming Quality Improved

Applying Submission Standards to Production Deliverables

❖ Programming Cost Decreased

Production Cost Similar But Submission Cost Significantly Decreased

It's a New Programming Style Only



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