

Authors Introduction



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Expectation and Collaboration – Recipe for Successful CDISC Deliverables!

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Expectations



Reality



Expectation: A clear idea of the requirement and what is being expected at the outcome.

Collaboration: Effective correspondence and mutual sharing of ideas to get the expected outcome.

We wanted the datasets in SDTM I.G V3.1 so all our studies are consistent

We used the latest version available

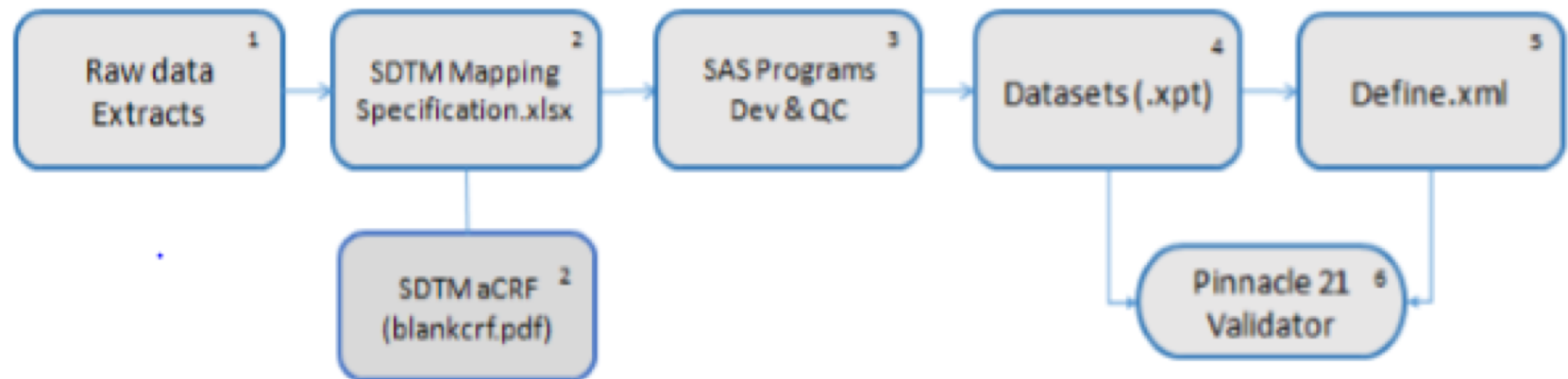


Client

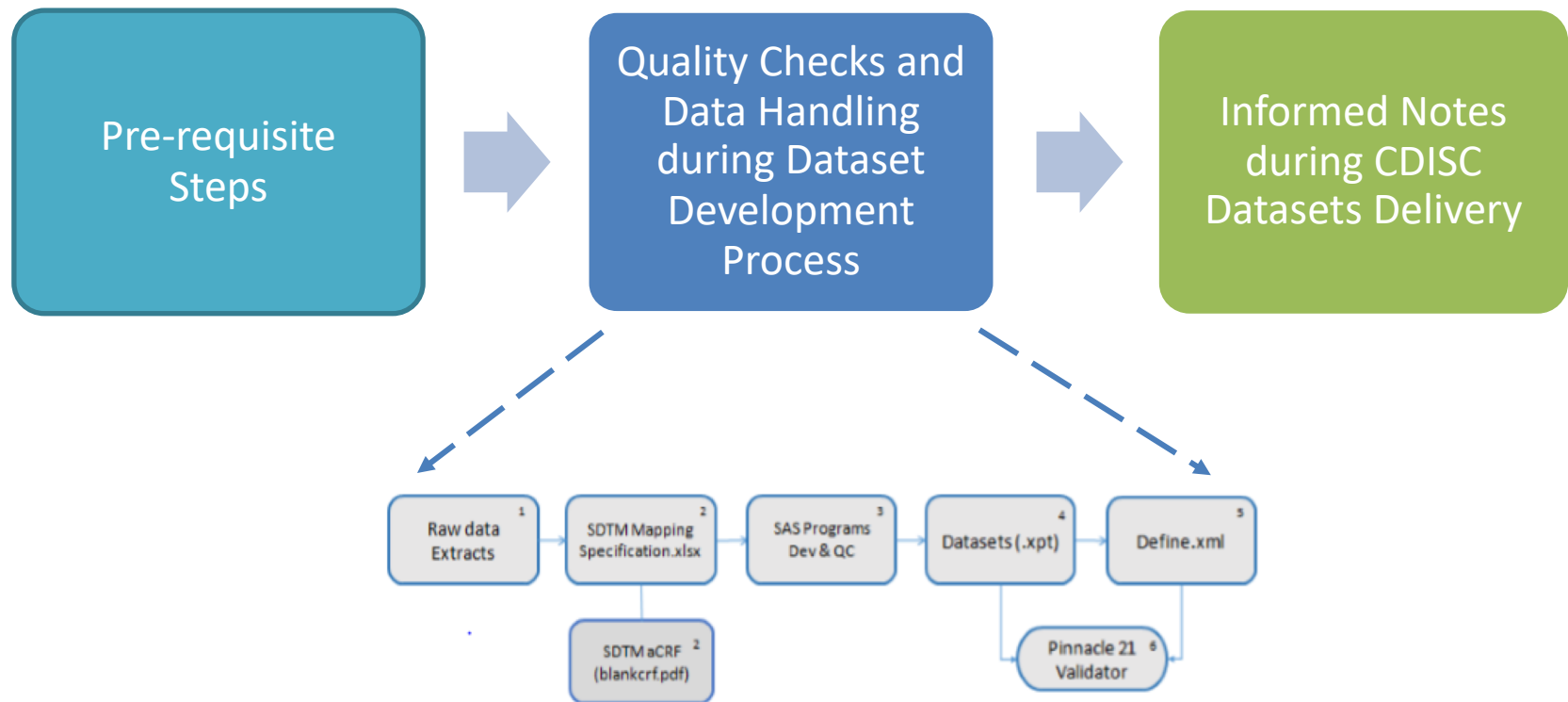


Vendor

SDTM Development Steps



Steps to Successful CDISC Deliverables



1) Pre-requisite Step

Gathering study documents & requirements such as:

- ☐ Protocol
- ☐ Model & IG version
- ☐ CT, Dictionary versions
- ☐ eCRF with raw annotations
- ☐ Source data Analysis
- ☐ External data Specifications
- ☐ Randomization
- ☐ Study Milestones
- ☐ Frequency of Transfer
- ☐ P21/Define versions
- ☐ CRF Annotation

2) Quality Check & Data Handling

During Specifications Development - share a checklist with the Sponsor:

- ☐ ARM/ARMCD used
- ☐ Elements
- ☐ Visit naming conventions
- ☐ Handling of 'Unscheduled Visits'
- ☐ TEST/TESTCD's used
- ☐ Custom dataset mapping information

2) Quality Check & Data Handling

During Programming & Validations Steps – keep an eye on the following:

- ❑ Metadata different b/w different snapshots of raw datasets
- ❑ Generate define.xml
- ❑ Manual check of all the datasets
- ❑ Check for compliance via P21 validator
 - With passing the define.xml

3) Informed Notes During The Delivery Of Datasets

When providing deliverables to the sponsor make sure to provide the following

- ☐ The total number of datasets in the transfer/data cutoff date
- ☐ List of any missing dataset/reason
- ☐ The total number of subjects and breakdown by ARM
- ☐ Any information regarding Specific subjects that the vendor thinks would be helpful for review by the sponsor
- ☐ Data issues logs/Clarification logs
- ☐ Any errors/warnings from P21 that stand out from the normal ones.

Goals Achieved



Expectation



Reality





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