



Quanticate

The Clinical Data Experts

Clinical Documents

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What are Clinical Documents?

Before the Trial

- Clinical Trial Protocol
- Case Report Form



Planning Stage

- Statistical Analysis Plan
- Data Mapping Specification



During the Trial

- SDTM and ADaM Implementation Guides
- Standard ADAM and SDTM Templates



After the Trial

- Data Definition Document
- SDTM and ADaM Reviewers Guides

Before the Trial

Clinical Trial Protocol (CTP)

- Background, research plan and research methods.
- Basis for the SAP.
- Generally contains:
 - Background
 - Research question and objectives
 - Research methods and limitations
 - Study procedures
 - Assessments
 - Data analysis and statistical methods
 - Plans for study results
 - Quality control and assurance

Before the Trial

Case Report Form (CRF)

- Records all the protocol required information.
- eCRF (electronic) / aCRF (annotated).
- Generally contains:

- Inclusion/exclusion criteria
- Annotations
- Demographic data
- Lab results
- Adverse events
- Medical history



PE=Physical Examination		Assessment Date: PEDTC			
PHYSICAL EXAM					
		PEORRES	PESTAT	PEORRES	
PHYSICAL EXAM		Normal	Abnormal	Not Done	Comment only if abnormal
PETEST					
1. Appearance/Skin	PEORRES where PETESTCD="PE01"	☐	☐	☐	
2. Head/Neck (Including Thyroid)	PEORRES where PETESTCD="PE02"	☐	☐	☐	
3. Eyes-Ears-Nose-Throat	PEORRES where PETESTCD="PE03"	☐	☐	☐	
4. Cardiovascular	PEORRES where PETESTCD="PE04"	☐	☐	☐	
5. Pulmonary	PEORRES where PETESTCD="PE05"	☐	☐	☐	
6. Abdomen	PEORRES where PETESTCD="PE06"	☐	☐	☐	
7. Neurological	PEORRES where PETESTCD="PE07"	☐	☐	☐	
8. Musculoskeletal	PEORRES where PETESTCD="PE08"	☐	☐	☐	
9. Other	PEORRES where PETESTCD="PE09"	☐	☐	☐	

Note: If result is abnormal then PEORRES = Comment

Planning Stage

Statistical Analysis Plan (SAP)

- Describes the planned statistical analysis.
- Generally contains:
 - Planned analyses
 - Analyses populations
 - Data handling conventions
 - List of data displays (TFLs) to be generated
 - Example mock shells

	XXX	PLACEBO	OVERALL
AGE (YEARS)			
MEAN	xx.x	xx.x	xx.x
S.D.	xx.xx	xx.xx	xx.xx
MEDIAN	xx.x	xx.x	xx.x
MINIMUM	xx	xx	xx
MAXIMUM	xx	xx	xx
N	xx	xx	xx
SEX			
MALE	xx (xx%)	xx (xx%)	xx (xx%)
FEMALE	xx (xx%)	xx (xx%)	xx (xx%)
TOTAL	xx (xx%)	xx (xx%)	xx (xx%)
RACE			
CAUCASIAN	xx (xx%)	xx (xx%)	xx (xx%)
BLACK	xx (xx%)	xx (xx%)	xx (xx%)
ASIAN	xx (xx%)	xx (xx%)	xx (xx%)
ORIENTAL	xx (xx%)	xx (xx%)	xx (xx%)
OTHER	xx (xx%)	xx (xx%)	xx (xx%)
TOTAL	xx (xx%)	xx (xx%)	xx (xx%)

Planning Stage

Data Mapping Specification

- Definition of what will be included in data sets.
- Generally contains:
 - Variable name
 - Variable label
 - Type
 - Length
 - Format
 - Origin
 - Comments
 - Instructions and derivations
 - Codelist

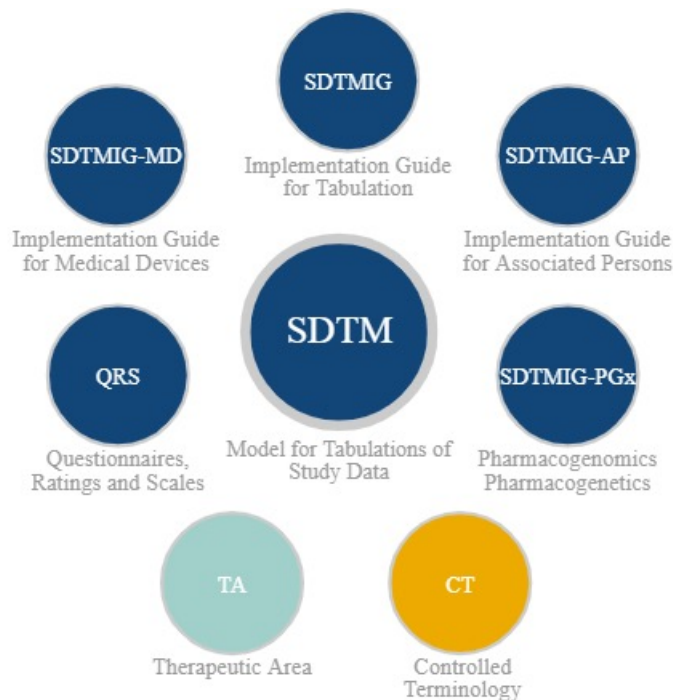
Include	Variable Name	Variable Label	Type	Length	Format	Origin	Comments
Yes	STUDYID	Study ID	Char	10		Derived	STUDYID = 12345678
Yes	REGIONCD	Region Code	Num	8		Derived	
Yes	REGION	Region	Char	40		Derived	

During the Trial

Other Documents

Implementation Guide (IG)

- SDTMIG.
- ADAMIG.
- Sub IGs e.g.
- Therapeutic area specific guides.



During the Trial

Other Documents

Standard ADAM and SDTM Templates

- Company/CDISC standard templates for creating specifications.

Protocol/CRF Amendments

- Any document revisions which take effect during the trial.

After the Trial

Other Documents That Are Finalised

Data Definition Document (define.xml)

- Metadata for datasets.
- Analysis Results Metadata (ARM).

Reviewers Guides

- SDTM reviewers guide (cSDRG).
- ADaM reviewers guide (ADRG).

Key Points

Clinical Trial Protocol

- Research plan, background and objectives.

Case Report Form

- Provides information on how data is collected.

Statistical Analysis Plan

- Describes the planned statistical analysis.

Data Mapping Specification

- Describes what will be included in datasets.