

➡ ***Clinical Study Data Submission Package***

➡ ***aCRF & An Efficient Way To aCRF***

CLINICAL STUDY DATA SUBMISSION PACKAGE

- ☐ **Tabulation Data Submission Package**
- ☐ **Analysis Data Submission Package**

TABULATION DATA SUBMISSION PACKAGE

- ☐ **SDTM domain datasets based on the SDTM IG as SAS transport(XPT) files**
- ☐ **A data definition file in define.xml format**
- ☐ **A blank case report form (CRF) annotated to the tabulation data**
- ☐ **A Study Data Reviewer's Guide**

ANALYSIS DATA SUBMISSION PACKAGE



- ☐ Analysis datasets based on the ADaM IG as SAS transport(XPT) files
- ☐ A data definition file in define.xml format
- ☐ An Analysis Data Reviewer's Guide
- ☐ **Software programs** used to create all the analysis datasets, some tables & figures associated with primary and secondary efficacy analysis

ACRF & AN EFFICIENT WAY TO ACRF

- ☐ What Is ACRF
- ☐ Why ACRF Is Necessary
- ☐ Traditional way to aCRF
- ☐ New way to aCRF
- ☐ CRF & aCRF Standardization
- ☐ Create aCRF automatically
- ☐ Advantage
- ☐ Conclusion

ANNOTATED CASE REPORT FORM (ACRF)



An Annotated Case Report Form (aCRF) is a PDF document that maps the study data collected in CRF fields to the corresponding variables in the SDTM datasets.

WHY ACRF IS NECESSARY

- ❑ **A good way to understand the study and database**
 - ✓ **From the perspective of reviewers, can know the CRF page source of the variables in SDTM when review SDTM define.xml, also can know how the information in every field of CRF map into SDTM database when review aCRF, then get a whole and clear recognition of the study and database quickly.**

NOTE OF ACRF SUBMISSION

- ☐ The aCRF should be provided as a PDF file named “acrf.pdf”
- ☐ The SDTM Metadata Submission Guidelines should be used for aCRF to match with define.xml
- ☐ The aCRF should map each variable on the CRF to the corresponding variables in the SDTM datasets when applicable
- ☐ When data are recorded on the CRF but are not submitted, should annotate with the text "NOT SUBMITTED" in aCRF, and explain in the Study Data Reviewer's Guide

TRADITIONAL WAY TO ACRF

- ❑ Blank CRF - Mapping spec - SDTM datasets**

- ❑ Define.xml and aCRF and RG for submission**
 - ✓ CRF annotation is just a work for submission, don't be involved in our analysis process**

BEGIN WITH END - NEW WAY TO ACRF

❑ Standard CRF – aCRF – SDTM datasets

- ✓ **Standard CRF is the core, which need to be designed based on CDISC standard.**
- ✓ **aCRF can be looked as a mapping spec to develop SDTM directly.**
- ✓ **aCRF can be involved in the analysis process, not just a work for submission**

CRF & ACRF STANDARDIZATION

❑ Standard CRF & aCRF

- ✓ **The standard CRF is designed based on CDISC standard, make sure one page in CRF can display one domain or one category of domain information as much as possible.**

- ❑ In a new study, we can refer the standard CRF to design CRF, extract the proper pages, modify and add some specific pages according to requirement.**

AN EXAMPLE PAGE IN STANDARD ACRF

SDTM Data Set Name = VS VS.DOMAIN = 'VS'
VS.VSCAT = 'PHYSICAL MEASUREMENT'



5.2 (30NOV2015 SG PROD): CRF Spec
Project Name: DATA_STEWARDSHIP
Form: Physical Measurement
Generated On: 30 Nov 2015 13:40:03

Date of Examination		VS.VSDTC
Height	VS.VSTESTCD = 'HEIGHT'	VS.VSORRES
Height Unit	Centimeters ☐	VS.VSORRESU
	Inches ☐	
Height (cm) (Derived)	VS.VSSTRESU	VS.VSSTRESC
Weight	VS.VSTESTCD = 'WEIGHT'	VS.VSORRES
Weight Unit	Kilogram ☐	VS.VSORRESU
	Pound ☐	
Weight (kg) (Derived)	VS.VSSTRESU	VS.VSSTRESC
BMI	VS.VSTESTCD = 'BMI'	VS.VSORRES
BMI Unit (Derived)	Kilogram per square meter ☒	VS.VSORRESU
BMI (kg/m2) (Derived)	VS.VSSTRESU VS.VSDRVFL = 'Y'	VS.VSSTRESC
BSA	VS.VSTESTCD = 'BSA'	VS.VSORRES
BSA Unit (Derived)	Square meter ☒	VS.VSORRESU
BSA (m2) (Derived)	VS.VSSTRESU VS.VSDRVFL = 'Y'	VS.VSSTRESC
Waist Circumference	VS.VSLOC = 'WAIST'	VS.VSTESTCD = 'WSTCIR' VS.VSORRES

CREATE ACRF AUTOMATICALLY

%CRF_annot (infile = The name of the .pdf file containing the CRF Annotations of the initial study,

Outfile = The name of the .pdf file to be created containing the CRF Annotations of the target study,

Reffile = The name of the Excel file containing the corresponding pages from the initial study to the targeted study);

CREATE ACRF AUTOMATICALLY

❑ Reffile = < name of input Excel file >



- ✓ Find all the corresponding relationship between initial study and target study, if the target study don't have pages in the initial study, need to input "delete" in the sheet.

	A	B
1	Initial Study	Target Study
2	3	3
3	4	4
4	5	5
5	6	9
6	7	12
7	8	13
8	9	14
9	10	15
10	11	16
11	12	17
12	13	18
13	14	27
14	15	25
15	16	26
16	17	6
17	19	29
18	23	23
19	24	24
20	25	21
21	26	delete
22	27	delete
23	28	30
24	29	delete
25	30	31
26	33	32
27	34	34
28	35	36
29	36	37

ADVANTAGE



- ❑ **CDISC designed CRF - Automation - Efficient & high quality aCRF**
- ❑ **aCRF can be looking as mapping spec to help to develop SDTM**

☐ Begin with end, get more benefit in the analysis process

- ✓ Study data submission can't be just a work for submission, we should incorporate the requirement into study analysis process to improve our work
- ✓ FDA also recommend to implement the SDTM standard prior to the conduct of the study

THANK YOU