



Single Day Event

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**Automate TLF Mock Shell Generation
using AI Techniques (ML/NLP)**



The Problem

Statistical Analysis Plan:-

It is a document details Statistical analysis needed as per the protocol explaining Safety & Efficacy analysis. It describes statistical techniques to be employed in order to address the objectives (Primary & Secondary) of the clinical trial.

- SAP has two parts : SAP & Mock shell for Tables/Listing/Figure (TLF)
- We are trying to automate creating mock Shell. The TLF mock shell is a guide to generate Statistical reports in a specified in shell.
- TLF Mock Shell is created by Bio-Statistician manually.
- Most of the Non-efficacy TLF shells are repetitive from study to study
- No automotive way to handle Errors and multiple iterations



TYPE Of Tables

1. CONTINUOS VARIABLES

- Both by visits (Central Tendency and Change from Baseline)

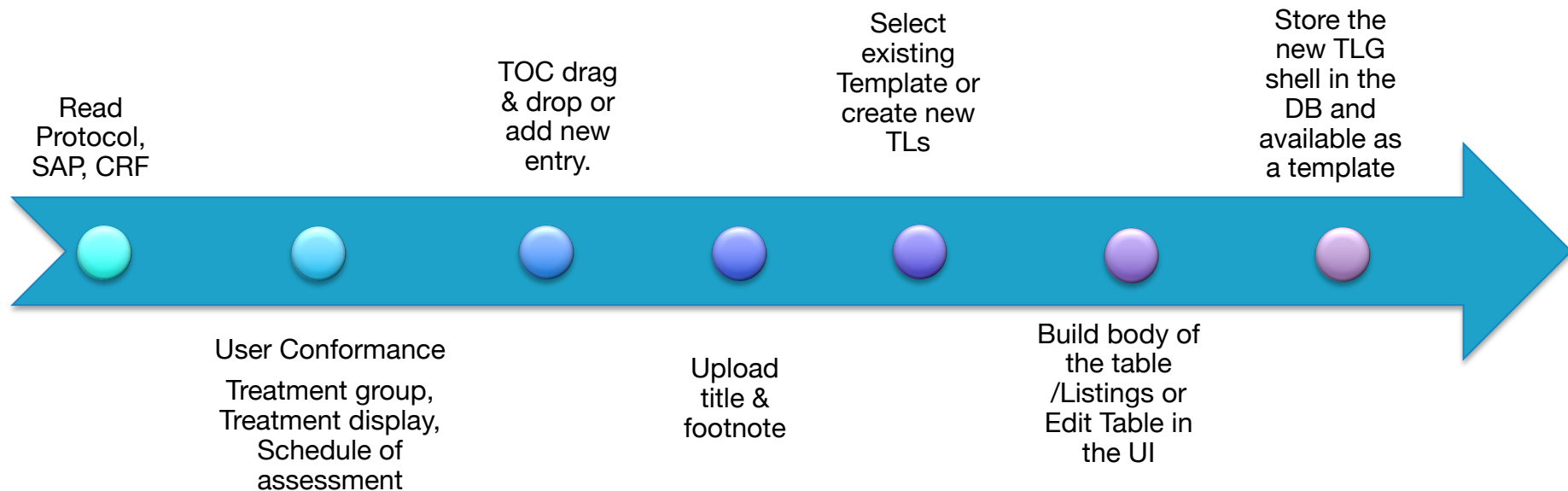
2. CATEGORICAL VARIABLES

- Frequency Table (n (%))
- Shift Table (shift from baseline to post baseline)

3. BOTH CONTINUOS & CATEGORICAL

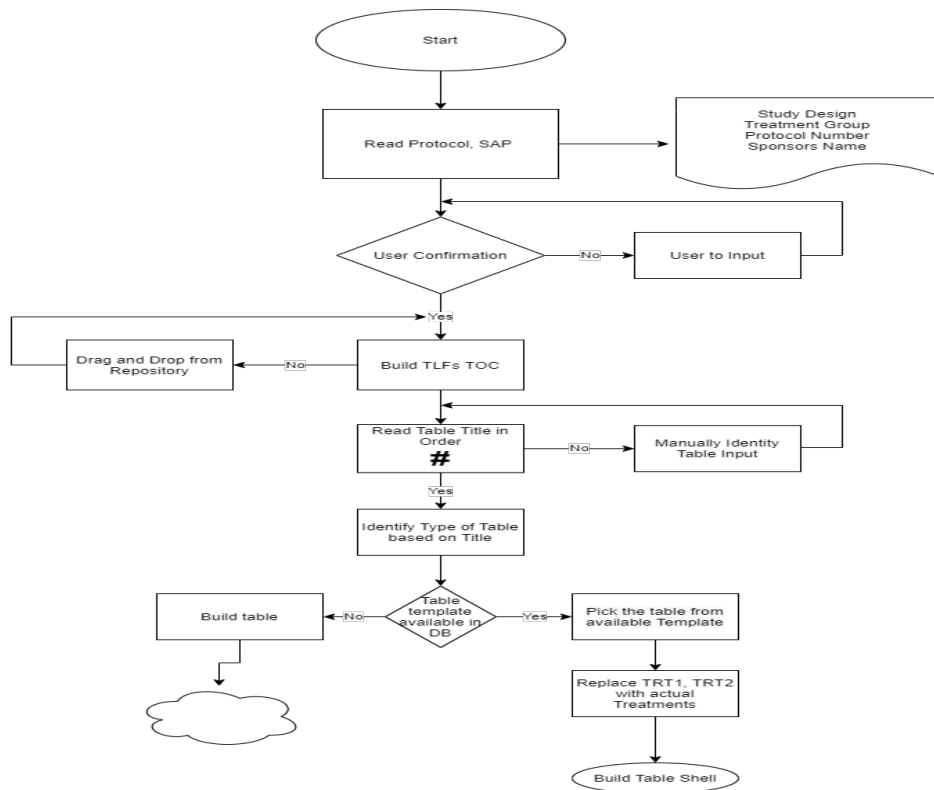


Steps



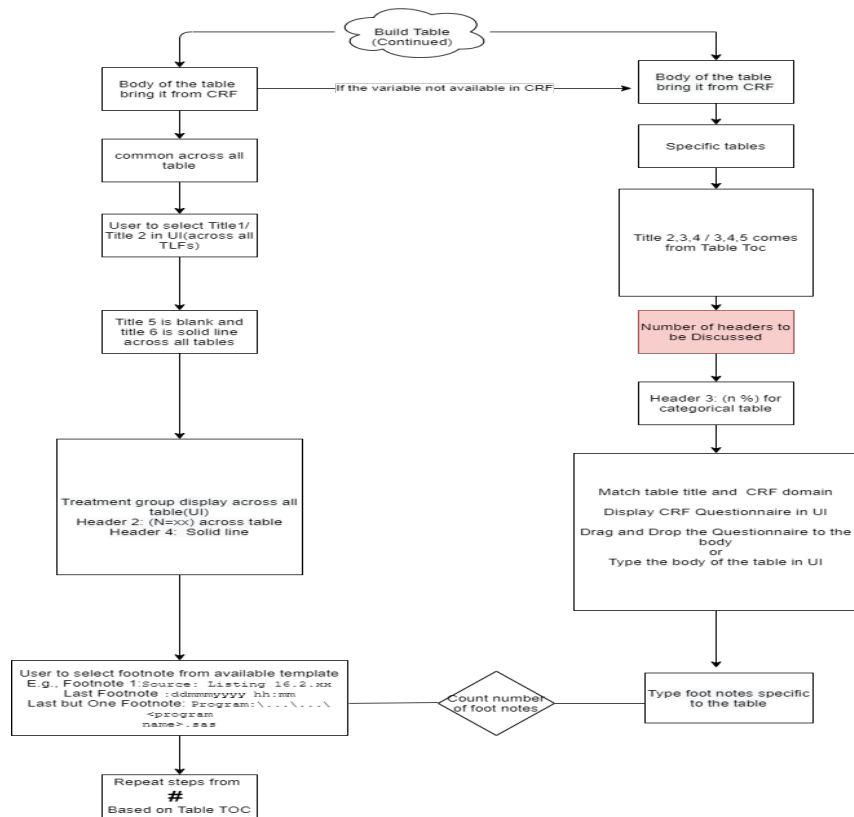


Process Flow





Process Flow- Listings





Process – Detailed description

1. Read protocol, SAP & CRF

2. User to confirm the following

Treatment group in the study

Treatment group display in table header

3. Build TLF TOC

- Build TOC from the available DB or add new entry. DB will have title, number, population, type of table for table only
- TLF templates also will be stored in the DB. For most tables there will be 5 or 6 templates and it will appear on the screen for the user to choose one and edit on screen.
- Finalize table and move on to next
- System automatically changes the treatment group in the header based on user input stored previously
- If no template is available for a table , then build table process will be enabled
 - ❖ Based on the table title, system will pick the column 1 of the table and body of the table will be built.

Header 1: treatment display Single line or two or three

Header 2: treatment display in two or based on the type of table from table toc in DB, it should be (N=xx)

Header 3: treatment display in three or based on the type of table from table toc in DB, it should be n (%) or

no header 3

Header 4: if treatment group displayed in 3 headers, then 4th header is (N=XX)

Header 5: if treatment group displayed in 3 headers, then 5th header is n (%) based on table TOC in DB

4. Table formatting

The N, Mean, Median , Min, Max , % format is based on one time user input.



Process- description (Continued)

5. User to input the following

Title 1- Sponsor's name, protocol number, Right justified page number.

Title 1-sponsors name, right justified page number.

Title 2- is from table TOC

Title 3- Protocol No Should be concatenated with table title with TOC

Title 1/ Title 2 should be selected from the UI

Create listings mock shell

1. UI will have the following

Do you need headers? - Y/N

If yes, Header 1 → User Entry.... Header 10

Patient identifier! - Y/N

If yes, patient identifier columns- 1/2/3?

Column1/2/3 → User to enter.

2. Body of the listing

System should read the uploaded CRF

ML/NLP should match the CRF forms based on Listing Title, if applicable.

UI should display the uploaded CRF on the left side of the screen

User should be able to drag and drop the questioner in the CRF to the right side of screen to build the body of listing.

User should be able to edit the dragged questions from the right side of the screen

Once all the questions are copied from CRF for a listing, user should be able to add/modify the columns



File upload


Files


TOC


Setting



Type	Name	Actions
Protocol	Select File	
SAP	Select File	
CRF	Select File	

Upload



TLF shell toc (Drag & drop)


Files


TOC


Setting



Search Title

14.1.1 Subject Disposition and Primary/Other Reason for Discontinuation from Study

14.1.3 Demographics and Baseline Characteristics

14.1.4.1 Medical History by System Organ Class and Preferred Term

14.1.5.1 Prior Medications

14.1.5.2 Concomitant Medication

14.3.2.1 Overview of Treatment-Emergent Adverse Events

14.3.2.2 Treatment-Emergent Adverse Events by System Organ Class and Preferred Term

14.3.2.3 Treatment-Emergent Adverse Events by System Organ

Add New Title

T.No	NAME	TYPE	POPULATION	ACTIONS
14.1.1	Subject Disposition and Primary/Other Reason for Discontinuation from Study	Categorical	All Randomized Subjects	 
14.1.4.1	Medical History by System Organ Class and Preferred Term	Categorical	Safety Analysis set	
14.1.5.1	Prior Medications	Categorical	Full Analysis set	



TLF shell toc – Create new TLF entry

Search Title

Add New Title

Table Of Content

Table Number *

14.5.2

Title *

Concomitant Medications

Type *

Categorical

Population *

All Randomized Subjects

Save Close

POPULATION	ACTIONS
All Randomized Subjects	 
Safety Analysis set	
Full Analysis set	

Files

TOC

Setting

14.1.1 Subject Disposition and Primary Discontinuation from Study

14.1.3 Demographics and Baseline Characteristics

14.1.4.1 Medical History by System Organ Class and Preferred Term

14.1.5.1 Prior Medications

14.1.5.2 Concomitant Medication

14.3.2.1 Overview of Treatment-Emergent Adverse Events by System Organ Class and Preferred Term

14.3.2.2 Treatment-Emergent Adverse Events by System Organ Class and Preferred Term

14.3.2.3 Treatment-Emergent Adverse Events by System Organ Class and Preferred Term



Use/edit existing TLF template

Files

TOC

Setting

< Back to TOC

14.1.1 Subject Disposition and Primary/Other Reason for Discontinuation from Study

< Previous

Next >

1

2

3

4

5

6

7

8

Create Table

Select this Template

Table 14.1.1
Subject Disposition and Primary/Other Reason for Discontinuation from Study
All Randomized Subjects

Page 1 of X

	(N=xx) n (%)
Number of Subjects Randomized	xx (xx.x)
Number of Subjects Completed the Study	xx (xx.x)
Number of Subjects Discontinued Prematurely	xx (xx.x)
Primary Reason for Premature Discontinuation	xx (xx.x)
Adverse Event	xx (xx.x)
Clinical status did not improve or deteriorated	xx (xx.x)
Formal withdrawal of consent by the subject	xx (xx.x)
Treatment with other PAH therapeutic agents	xx (xx.x)
Positive pregnancy test	xx (xx.x)
Non-compliance to any of the protocol procedures	xx (xx.x)
Discretion of Investigator	xx (xx.x)
Discretion of Myogen	xx (xx.x)

Page 1 of 1

100%



Build new table

Files

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14.1.4.1 Medical History by System Organ Class and Preferred Term

< Previous

Next >

Edit Header

Edit Body

Header

Treatment Group Display

☒ N=(xx) ☒ n(%)

Header One

MedDRA System Organ Class
Preferred Term

Save

Close

MedDRA System Organ Class	Preferred Term
Eye disorders	Eye irritation
Myopia	xx (xx.x)
Gastrointestinal disorders	xx (xx.x)
Abdominal pain upper	xx (xx.x)
Diarrhoea NOS	xx (xx.x)

Page 1 of X



Select variables from CRF for listing (drag & drop)

TLF

Files

TOC

Setting

Subject Disposition at End of Screening

1 of 10 Automatic Zoom

DOMAIN=DS where DS=CRF PROTOCOL FILESTONE

DSTERM, DSDECD = INFORMED CONSENT OBTAINED

DSSTDT, DSCT, DM, RFLCDTC

DSTERM=SUBJECT WILL CONTINUE TO PARTICIPATE IN THE STUDY where DSDECD=COMPLETED

DSSTDT, DSCT

DSSCAT=PRIMARY REASON

DSTERM where DSDECD = SCREEN FAILURE

DSTERM where DSDECD= WITHDRAWAL BY SUBJECT

DSTERM where DSDECD = PREGNANCY

DSTERM where DSDECD= OTHER

DSTERM where DSDECD = ADVERSE EVENT

SUPPDS QVAL where QNAM=AEDSCOD

DSTERM where DSDECD = LOST TO FOLLOW-UP

DSTERM where DSDECD= PREGNANCY

DSTERM where DSDECD= OTHER

Study Object Descriptions: Screening Disposition

Type	RefName	Description
DSSTDT, DSCT	Date Informed Consent signed by Subject	Date Informed Consent signed by Subject
DSSTDT, DSCT	Date Informed Consent signed by Subject	Date Informed Consent signed by Subject

CodeList Values Tables: Screening Disposition

CodeList RefName	CodeList Data Type	Label	Code	CodeList Item RefName	Data Variable RefName
DSSTDT, DSCT	Integer	Yes	49688	DSSTDT, DSCT	DSSTDT, DSCT
DSSTDT, DSCT	Integer	No	49687	DSSTDT, DSCT	DSSTDT, DSCT
DSSTDT, DSCT	Integer	Did not meet inclusion/exclusion criteria	49628	DSSTDT, DSCT	DSSTDT, DSCT
DSSTDT, DSCT	Integer	Adverse event(s)	49629	DSSTDT, DSCT	DSSTDT, DSCT
DSSTDT, DSCT	Integer	Lost to follow up	49627	DSSTDT, DSCT	DSSTDT, DSCT
DSSTDT, DSCT	Integer	Withdrawal of consent	49634	DSSTDT, DSCT	DSSTDT, DSCT
DSSTDT, DSCT	Integer	Pregnancy	49635	DSSTDT, DSCT	DSSTDT, DSCT
DSSTDT, DSCT	Integer	Other - Please Specify	17649	DSSTDT, DSCT	DSSTDT, DSCT

Show All Listing domain pa

record. To the best of my kn

V3.000 PROD SLF 22NOV2019

Subject Case Report Forms

Signature Prompt: I have rev

record. To the best of my kn

the source documents.

Project Name: 5051-103

Form: Enrollment

V3.000 PROD SLF 22NOV2019

Thank You!!



**The Global Healthcare
Data Science Community**

Contact Channels

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