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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

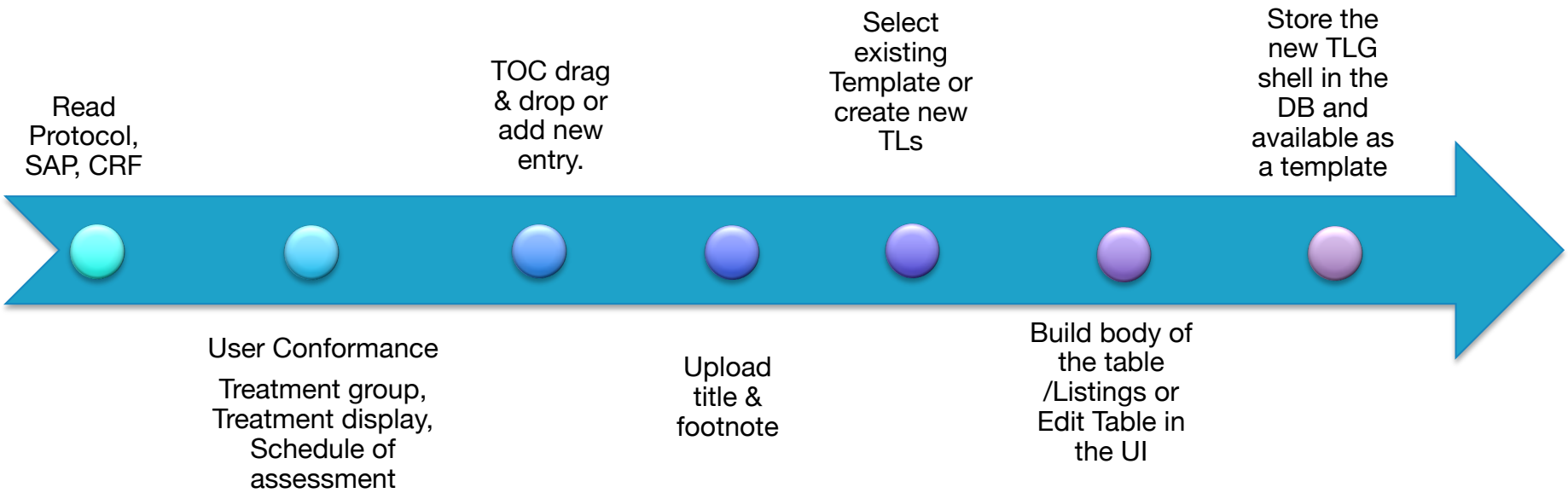
TYPE Of Tables

1. **CONTINUOS VARIABLES**
   - **Both by visits (Central Tendency and Change from Baseline)**

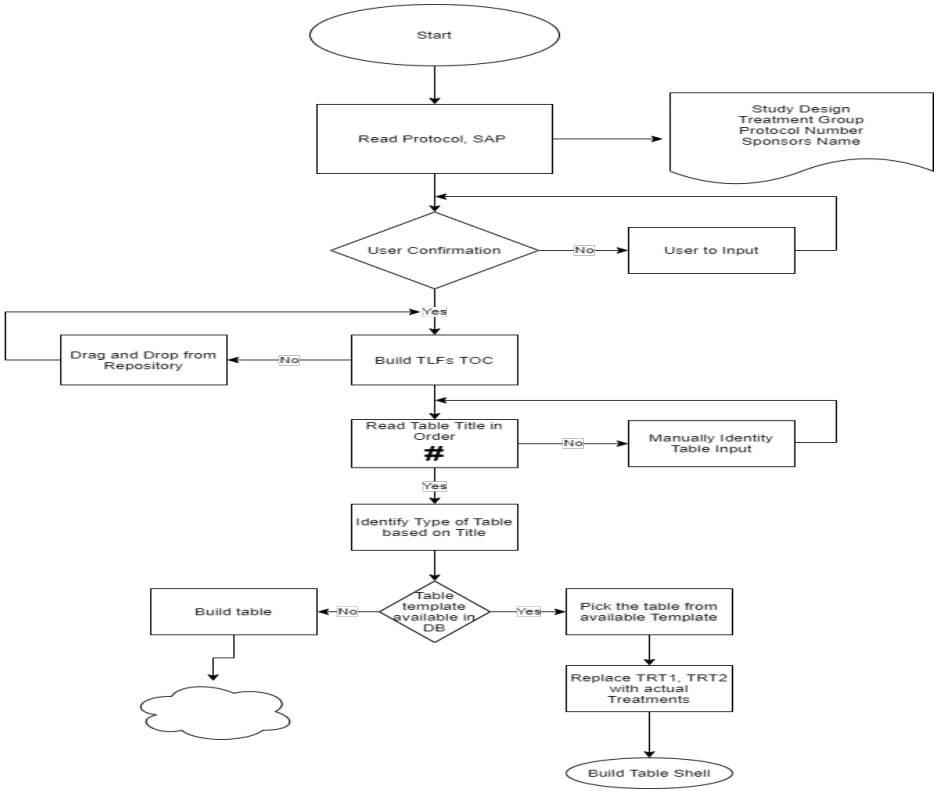
2. **CATEGORICAL VARIABLES**
   - **Frequency Table (n (%))**
   - Shift Table (shift from baseline to post baseline)

3. **BOTH CONTINUOS & CATEGORICAL**

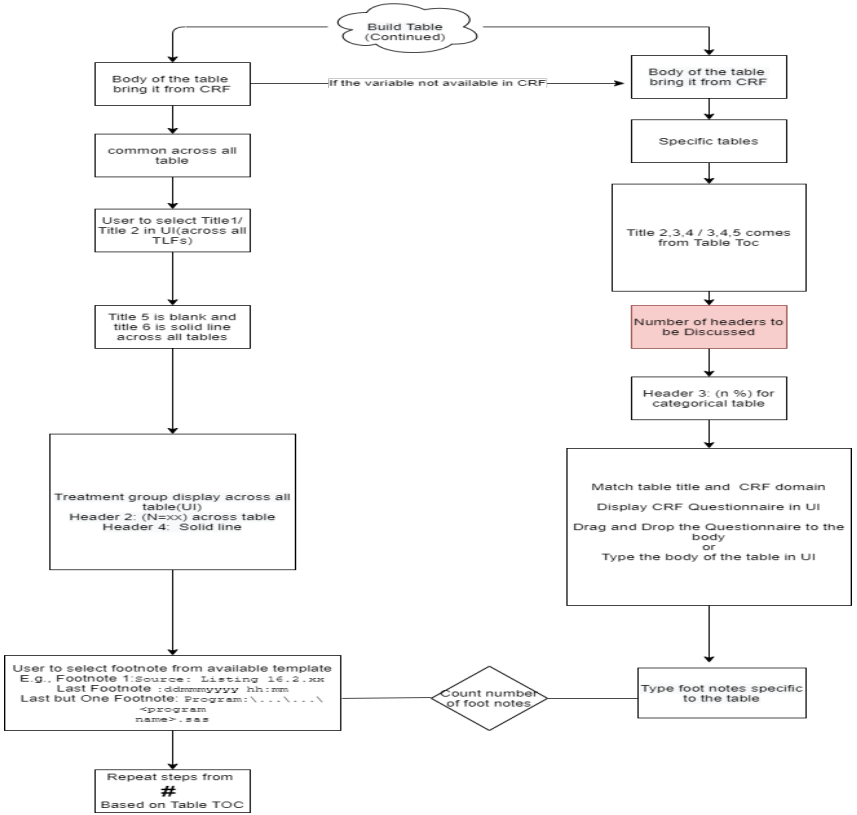
Steps


Read Protocol, SAP, CRF
User Conformance
Treatment group, Treatment display, Schedule of assessment
TOC drag & drop or add new entry.
Upload title & footnote
Select existing Template or create new TLs
Build body of the table /Listings or Edit Table in the UI
Store the new TLG shell in the DB and available as a template

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.

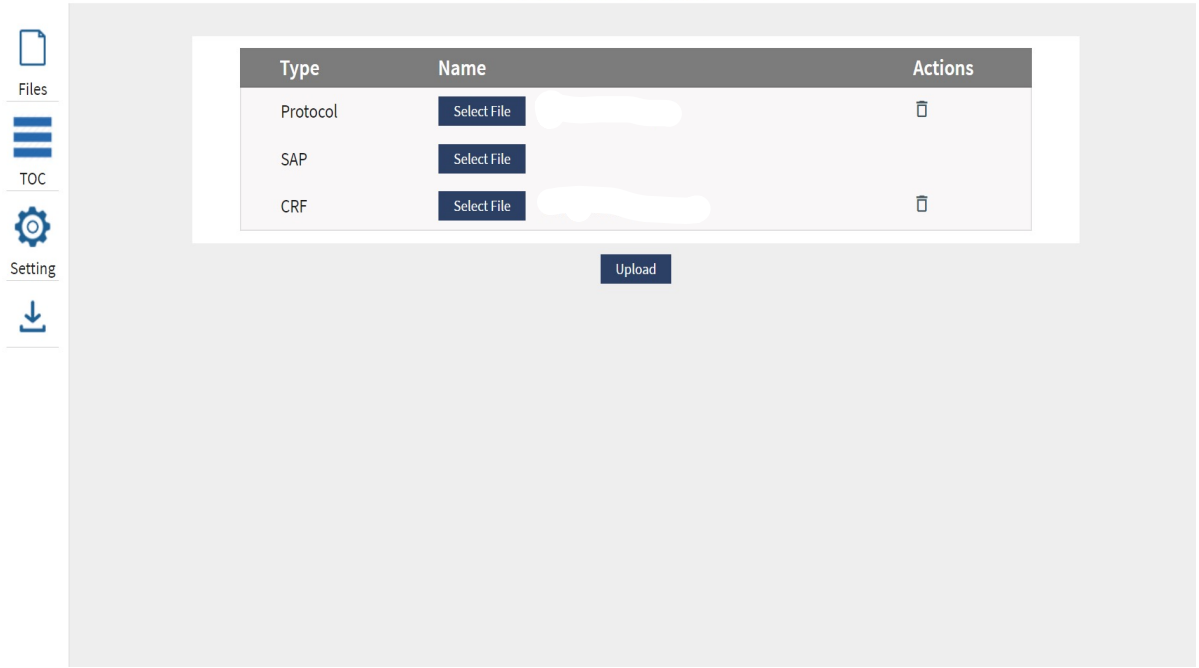
UI should display the uploaded CRF on the left side of the screen

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.

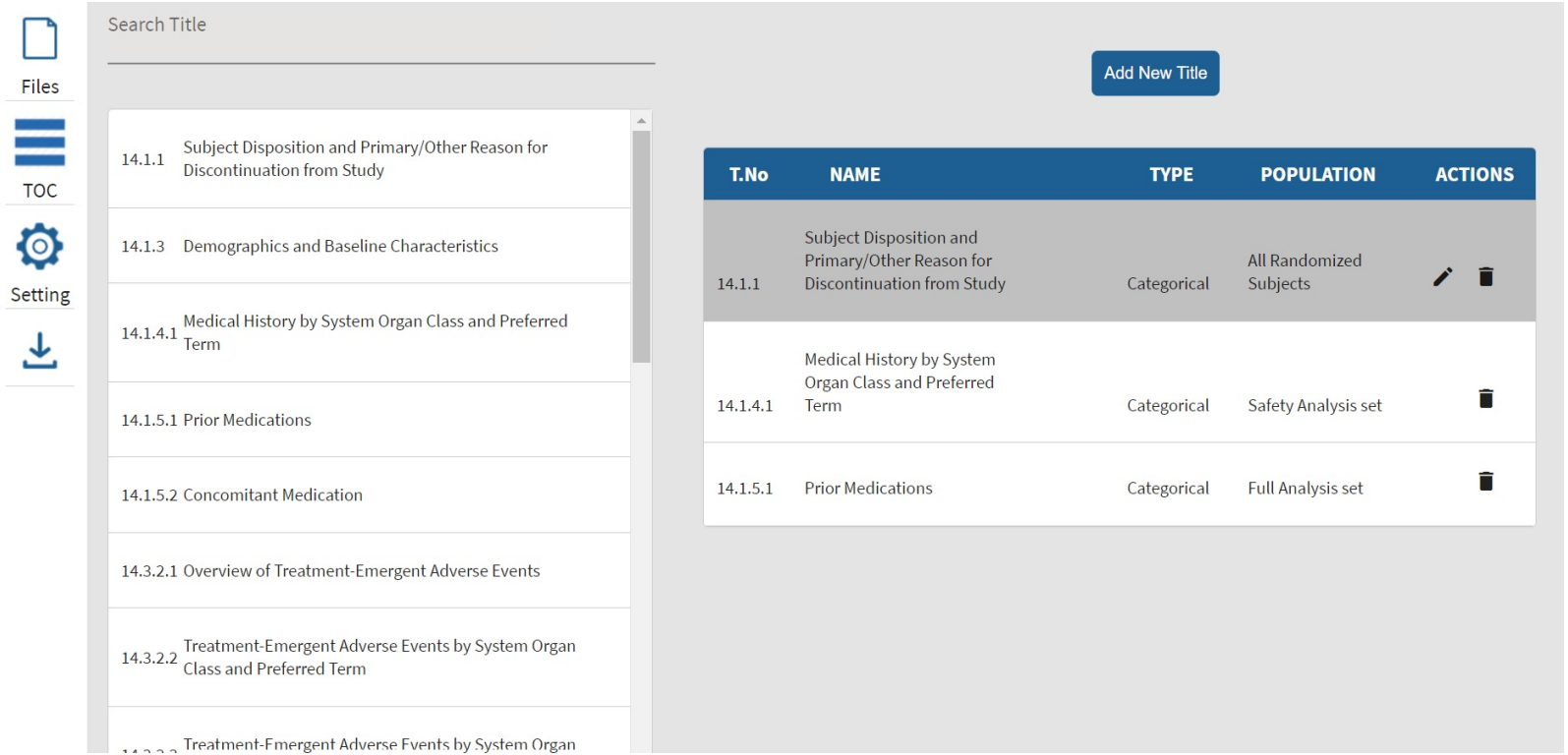
User should be able to edit the dragged questions from the right side of the screen

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

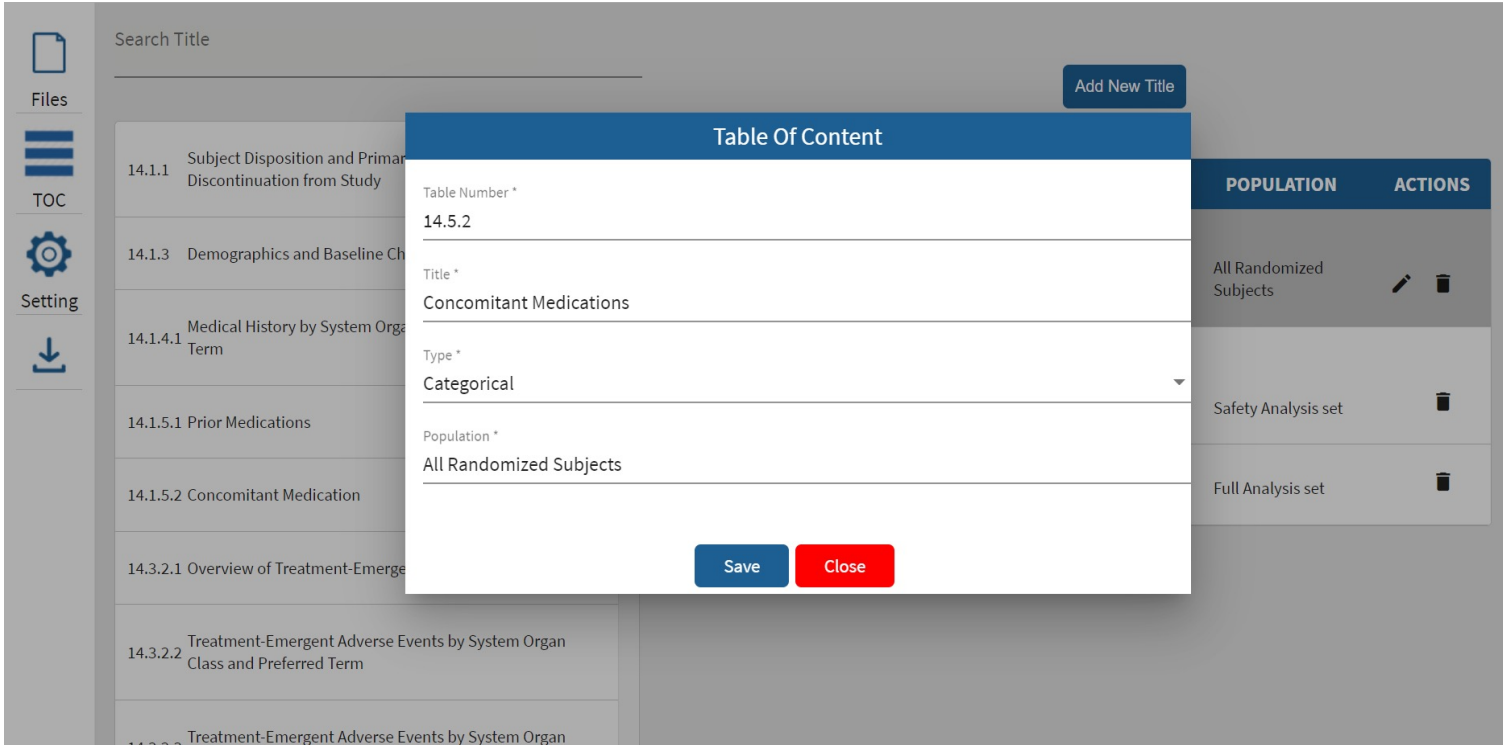
File upload


Files
TOC
Setting
Type
Name
Actions
Protocol
Select File
SAP
Select File
CRF
Select File
Upload

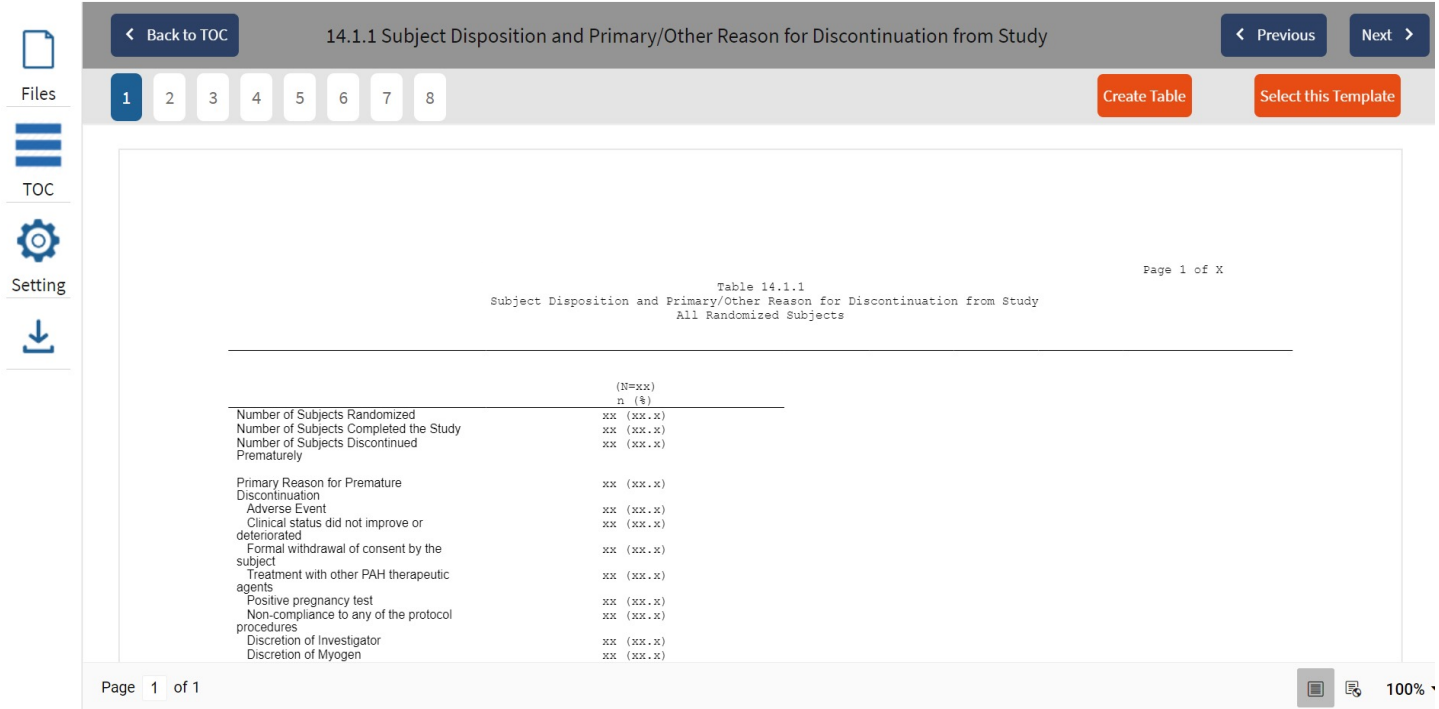
TLF shell toc (Drag &drop)



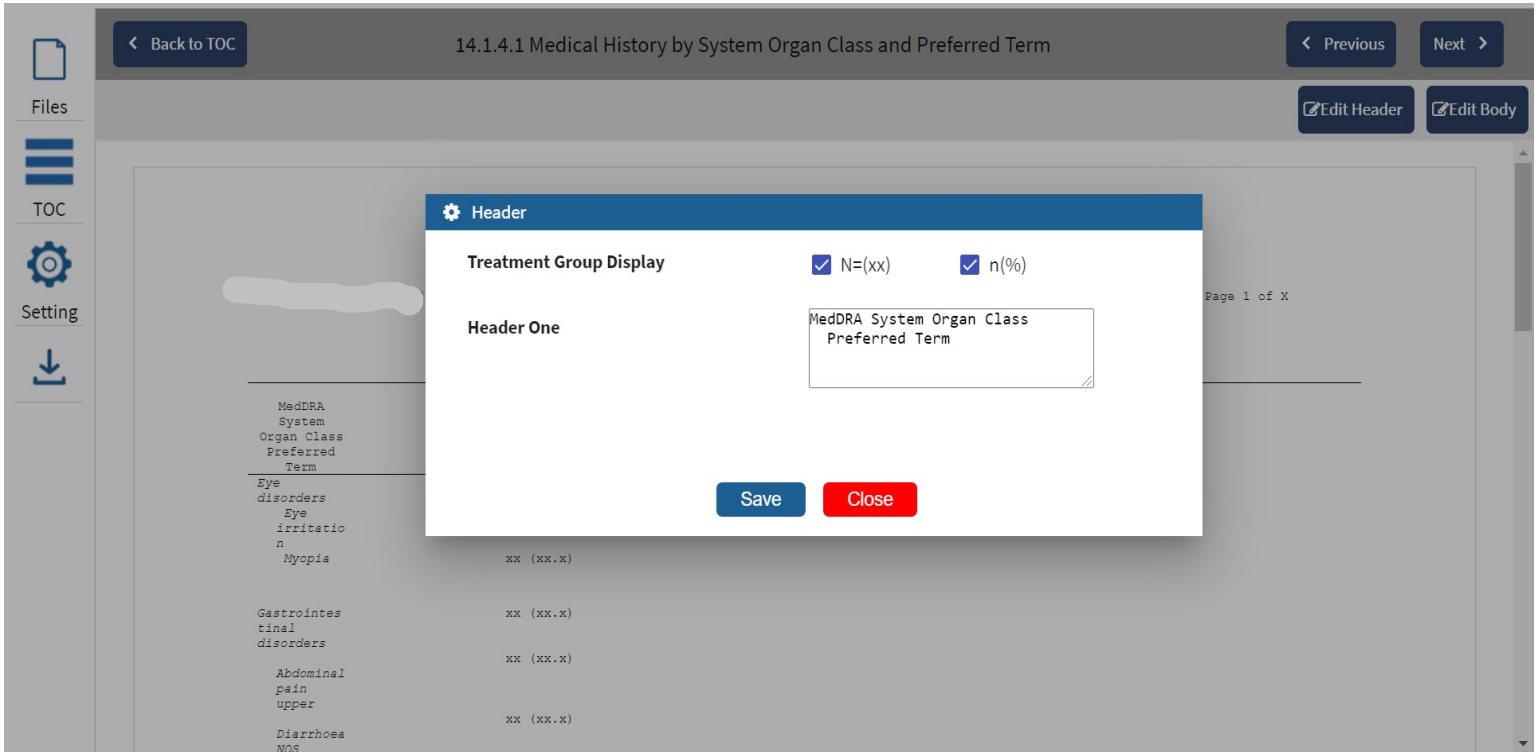
TLF shell toc – Create new TLF entry



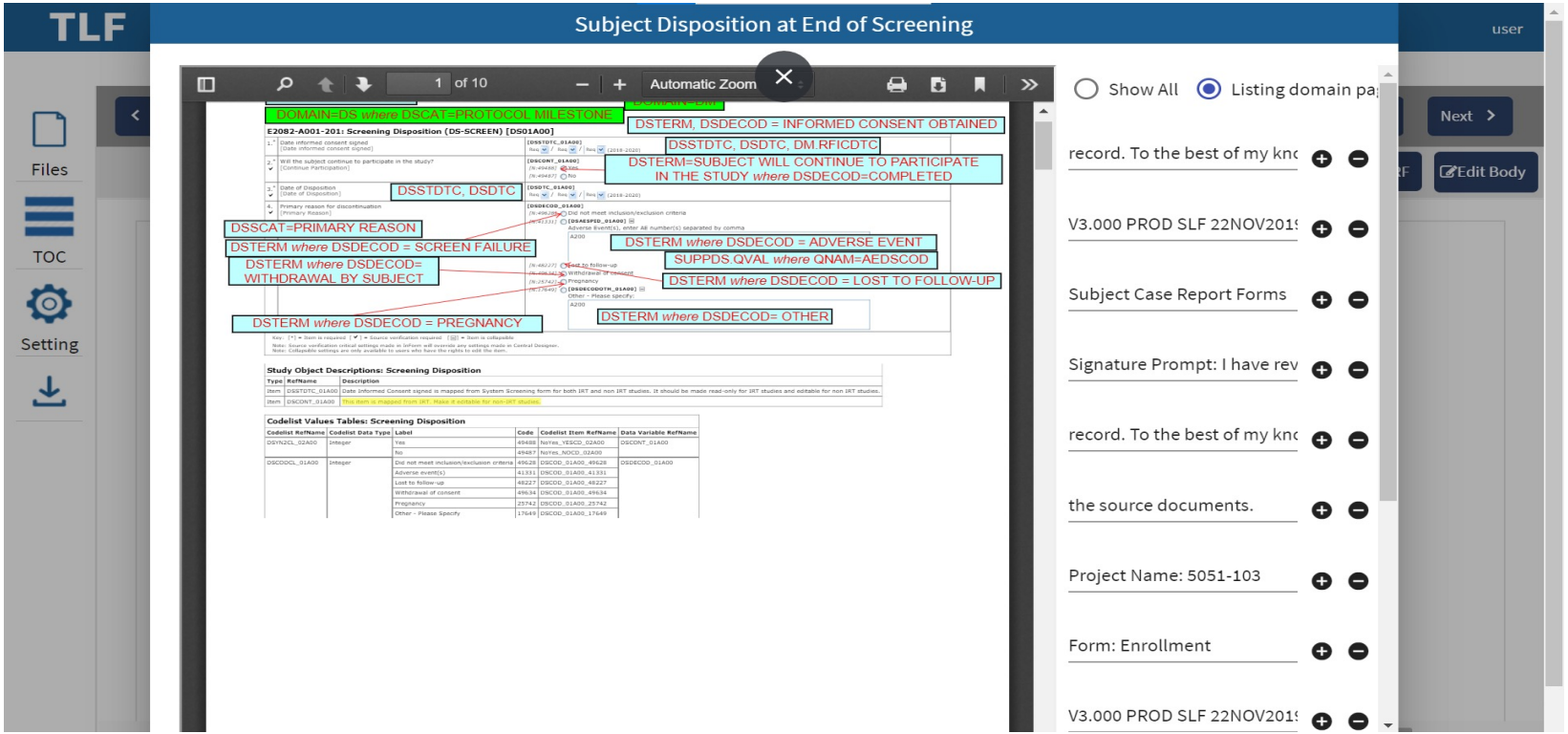
Use/edit existing TLF template



Build new table



Select variables from CRF for listing (drag &drop)



Thank You!!

The Global Healthcare Data Science Community

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