

An Automatic SDTM Platform: Create Your SDTM Since Case Report Form is Ready!

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ABSTRACT

The industry trend towards integrated platforms for standardized SAS deliveries, including SDTM, TFL, and ADaM, has prompted the development of an innovative SDTM Platform at BeiGene. This platform leverages a Python-powered backend and a JavaScript-driven frontend to provide SAS programmers with a streamlined method to generate SDTM datasets. Upon uploading Case Report Forms (CRFs) and their corresponding Architect Loader Specification (ALS) files, the platform automates the SDTM process efficiently, regardless of whether actual raw data is present.

Initially, the platform generates an annotated CRF (aCRF) and specifications tailored for SDTM programming and Trial Design Model (TDM). These outputs are presented through an intuitive, user-friendly interface, leveraging study-specific ALS files and global accumulated SDTM annotation library. Additionally, the platform offers study self-adaptive derived variables for SDTM, simplifying the process for users.

Programmer can easily trigger backend SAS macros via an interface button to generate SDTM individual programs and datasets. After reviewing the TDM, aCRF, and study self-adaptive SDTM derived rules, programmers can make necessary adjustments. Subsequently, the final SDTM datasets are generated and updated seamlessly.

INTRODUCTION

In the clinical programming industry, the generation of SDTM datasets traditionally involves SAS programmers manually creating annotated CRFs (aCRF) and SDTM programming specifications, followed by developing individual SAS programs for each domain based on these documents. While there are existing automated methods that enhance efficiency in certain steps, such as automating aCRF generation, this paper introduces an intelligent platform that revolutionizes the SDTM creation process.

This platform offers SAS programmers a comprehensive approach to SDTM generation, encompassing the creation of aCRF, Trial Design Model (TDM), individual programs, and SDTM datasets. By significantly reducing manual and repetitive programming work, the platform eliminates the need for programmers to write code for each domain from scratch.

The simplified workflow involves:

1. Uploading study CRFs, ALS files, and Study Edit Check Specifications to the platform, which manages these files in the backend database.
2. Reviewing generated content such as TDM, a preview of the aCRF (referred to as aCRF hereafter), SDTM specifications (used for annotation and SDTM-like data conversion, referred to as SDTM minus specification or minus spec hereafter), and study-specific SDTM derived specifications.
3. Making necessary adjustments through the platform's interface to tailor these configurations.
4. Clicking a button on the platform to automatically generate SDTM programs and datasets in a predefined location. Programmers can then update individual programs as needed for specific study requirements.

This intelligent platform marks a great advancement, offering a streamlined, user-friendly solution for SDTM creation.

SDTM PLATFORM FLOWCHART

The SDTM Platform operates by handling uploaded files within a backend database using Python. Upon upload, the Study Blank CRF and ALS files are merged with the company's comprehensive SDTM

annotation library to generate an aCRF and Minus Spec. Additionally, the Study Edit Check Specification, containing protocol inclusion/exclusion criteria, is merged with ALS to initialize the Trial Design Model (TDM). All backend-generated files are formatted in JSON data.

Subsequently, the backend transfers this JSON data to the platform interface via an Application Programming Interface (API). The platform interface, powered by JavaScript, receives, and displays the JSON data in a user-friendly manner. Moreover, the interface also utilizes JavaScript to facilitate the creation and execution of SAS programs in a predefined path.

This functionality allows users to interact with the platform interface, where they can click buttons to utilize the JSON data as source data. Users can then execute the company's global SDTM macros, which generate SDTM-Like datasets from raw data, Study Derive Specification, SDTM programs, and SDTM datasets. A detailed flowchart illustrating this process is depicted in Figure 1.

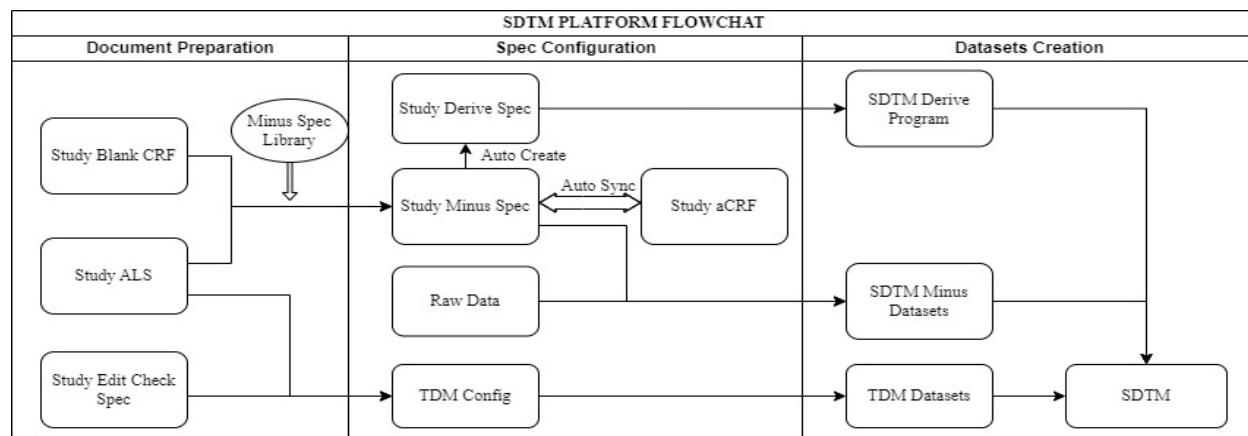


Figure 1. SDTM Platform Flowchart

INITIAL SETUP AND UPLOAD FILES TO DATABASE

To begin setting up a clinical study on the platform, programmers can define a corresponding working folder where the produced products will be exported. This ensures organization and accessibility throughout the study lifecycle.

HOME PANEL

Upon logging into the platform, users are directed to the "Home" panel, illustrated in Figure 2. This panel is one of six panels available, each serving distinct functions detailed further in the accompanying diagram.

The "Home" panel provides an overview of all CRF versions associated with the selected study. Different CRF IDs are linked to various CRF versions or owners. By selecting Button 7, users can seamlessly proceed to the subsequent processes outlined within the platform.

Home
Setting
TDM
Minus
aCRF
Derive
Current CRF ID: BGB_..._V1

1
2
3
4
5
6



Welcome to the SDTM Intelligent Robot!

This is your SDTM working station, a smart console for SDTM creation, including TDM, SDTM minus (edc data in SDTM-like format), aCRF, SDTM derived variables, and DEFINE package.

[User Manual](#)

Working folder: bgb_... - bgb_... - test_sdtm_platform

Create a new version

CRF ID	CRF Version	Comments	Created by	Created at	Action
BGB_..._V1	V2.0 CC1 01NOV2023 2009		Wei Wang	June 5, 2024 9:44 PM	7 ☐ ☐ ☐
BGB_..._V2			Wei Wang	June 6, 2024 2:36 PM	☐ ☐ ☐

Panel Descriptions

- ① Home: create/display personal CRF ID entries
- ② Setting: config setup.
- ③ TDM: create TDM datasets
- ④ Minus: spec to create minis datasets
- ⑤ aCRF: virtual rendering of aCRF
- ⑥ Derive: create derived spec/programs and run final SDTM datasets

Figure 2. Platform Home Panel

SETTING PANEL

In the Setting panel, users can upload necessary documents to initialize all SDTM metadata. This includes specifying the default annotation reference order to merge annotations from all historical libraries. For instance, if a CRF undergoes a new migration, the platform automatically sets the latest version of the CRF annotation as the highest priority in the annotation reference order. The default rule covers most of the practical need. User can specify priority reference order overriding the default setting as needed.

Home
Setting
TDM
Minus
aCRF
Derive
Define
Current CRF ID: BGB_..._V1

SDTM setting for BGB_..._V1

Analysis Address: Z:\bgcrh\build\bgb_...\bgb_...test_sdtm_platform [Open](#)

CRF: No file chosen
1
Browse
Upload
Refresh

ALS: No file chosen
2
Browse
Upload
Refresh

Reference CRF ID for TDM:
3
Edit
4
Get TDM from Refs

Reference Study for Annotation:
5
Edit
6
Get Annotations from Refs

SDTM Macros:
7
Edit

Comments: Edit

Figure 3. Platform Setting Panel

General settings for SDTM macros can be configured as shown in Figure 4. It includes macro package versions and macro parameters. And it also defines default paths such as raw data, sdtm datasets and programs and so on.

SDTM Macros Parameters Setting: Z:\bgcrh\build\bgb_20240617\test_sdtm_platform

SDTM Macro Package Version

☐ Legacy
☒ Standard

dev

Z:\bgcrh\build\zzz_tools\sdtm\uat_02\tools

☐ Custom Folder

SDTM IG Version

☒ 3.3

Raw Data and Cut-off

Rawdata Address

Z:\bgcrh\build\bgb_20240617\test_sdtm_platform\dev\crts\rawdata

Open

Change

☐ Apply Cut-off on raw data
☐ Apply Filter on Rawdata
☐ Fix the Lab Test issue

Input/Output Address

SDTM Datasets Address

Z:\bgcrh\build\bgb_20240617\test_sdtm_platform\dev\crts\sdtm

Open

Change

SDTM Snippet Codes Address

Z:\bgcrh\build\bgb_20240617\test_sdtm_platform\tools\sdtm_local

Open

Change

SDTM Data Export Address

Z:\bgcrh\build\bgb_20240617\test_sdtm_platform\dev\pam\sdtm

Open

Change

Figure 4. SDTM Macro Setting

REVIEW AND UPDATE SDTM FILES IN PLATFORM

TDM PANEL

Once the initial setup and file uploads are complete, programmers proceed to review, check, and update the SDTM-related files displayed in the platform interface. The TDM panel plays a crucial role in this phase. Here, the uploaded ALS and Edit Check Spec files initialize the Trial Design Model (TDM) with accuracy and efficiency. The panel features components like "TDM Setting" and "TDM Preview," which are further detailed below.

TDM Setting

The "TDM Setting" component allows users to review and update default values retrieved from the database, automatically refreshing the final TDM datasets (see Figure 5). For instance:

- In the "Visit" tab, the "Foldername" value is imported entirely from the ALS file. The "Visit_Type" categorizes visit types into three options: "Image" for scheduled image scan visits (e.g., Response Assessment Week 52), "Non-Image" for general scheduled visits (e.g., Screening, Cycle 2 Day 5), and "N/A" for others (e.g., Adverse Event, Unscheduled Visit). Users can modify these values as needed, adjusting the visit type can exclude certain visits ("N/A") from the final TV dataset. The database includes built-in algorithms for default VISIT/VISITNUM mappings based on common foldername values in TV, which users can also customize.
- In the "Trial Element" tab, values are initially populated from the database but can be updated according to the study protocol. Icons in the "Action" column facilitate operations such as row deletion, insertion, copying, and pasting. The "EPOCH" column value automatically transposes to corresponding columns in the "Trial Arm and Visit" tab for seamless data management.

This interactive functionality enhances user control and accuracy in configuring the TDM, ensuring alignment with study-specific requirements and protocols.

1

Home Setting **TDM** Minus aCRF Derive Define Current CRF ID: B0821447_101_V2

TDM Setting TDM Preview Export TDM SAS Dataset Export TDM Program

Restore Save

Visit Trial Element Trial Arm and Visit

☐	Foldername	Visit_Type	VISITNUM	VISIT
☐	Screening	Non-Image	10000	SCREENING
☐	Day -3	Non-Image	10997	DAY -3

Visit Trial Element Trial Arm and Visit

☐	ETCD	ELEMENT	TESTRL	TEENRL	EPOCH	TEDUR	Action
☐	SCRN	Screen	Informed consent obtained	First dose of treatment	SCREENING	P28D	
☐	TRT1	Treatment 1	First dose of treatment 1	End of treatment 1	TREATMENT		
☐	TRT2	Treatment 2	First dose of treatment 2	End of treatment 2	TREATMENT		
☐	FU	Follow-up	End of treatment	End of study	FOLLOW-UP		

Visit Trial Element Trial Arm and Visit

☐	ARMCD	ARM	VISIT	SCREENING	TREATMENT	FOLLOW-UP	Action
☐	A	Arm A	All Visits	SCRN	TRT1	FU	
☐	B	Arm B	All Visits	SCRN	TRT2	FU	

TRT1
TRT2

Figure 5. TDM Setting Panel

In the "Trial Arm and Visit" tab shown in Figure 5, users can set arms, visits, and epoch mappings. For each arm, the values in the SCREENING, TREATMENT, and FOLLOW-UP columns automatically synchronize with the "ETCD" of the corresponding epoch in the "Trial Element" tab. Users need to select the appropriate values from the "ETCD" list. For some studies, different arms may experience different visits, and users can select the specified visits for each arm, as illustrated in Figure 6.

Select the Visits for ARM: Arm A

Unselected 0/97

Enter keyword

☐ DAY -3

☐ DAY -2

☐ DAY -1

☐ RAMP-UP WEE...

☐ RAMP-UP WEE...

Selected 0/3

Enter keyword

☐ SCREENING

☐ RAMP-UP DAY 1

☐ RAMP-UP DAY 2

Reset Cancel Save

Figure 6. ARM Visits Selection Interface

TDM Preview

Once everything in the "TDM Setting" is configured, click the "TDM Preview" button to review the final TDM files, as shown in Figure 7. The values in the TA/TE/TV tabs automatically synchronize with the "TDM Setting" and are uneditable. Users can update the "TDM Setting" to resolve any issues found while reviewing these tabs.

For the "TI" tab, users need to obtain the Study Edit Check Specification and upload this file through the "Upload" button. The platform will then locate the related contents in this specification and export the inclusion/exclusion criteria, as illustrated in Figure 7. If the length of IETEST exceeds 200 characters, a notification will prompt the user to rewrite the criteria.

After reviewing all the tabs, users can export TDM SAS datasets by clicking the "Export TDM SAS Dataset" button. The backend will silently download TDM files to a default location, and the interface will create and autorun a SAS program to convert TDM files into SAS datasets in a predefined path. Additionally, the backend includes a checklist to identify any issues in the TDM files that could cause the export to fail. If any issues are found, a pop-up window will appear, as shown in Figure 8. Users can also click the "Export TDM Program" button to export the TDM SAS program to a specified location.

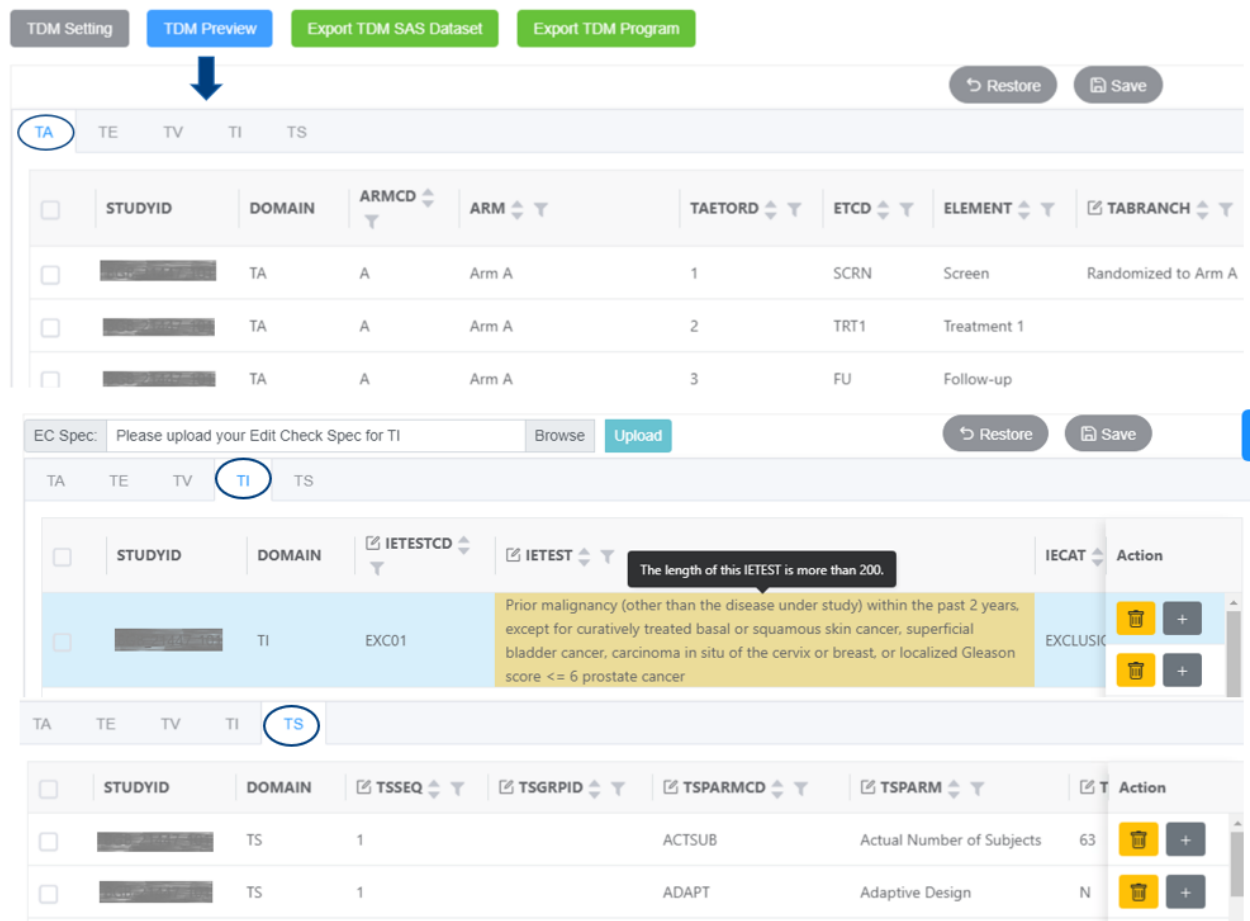


Figure 7. TDM Preview Panel

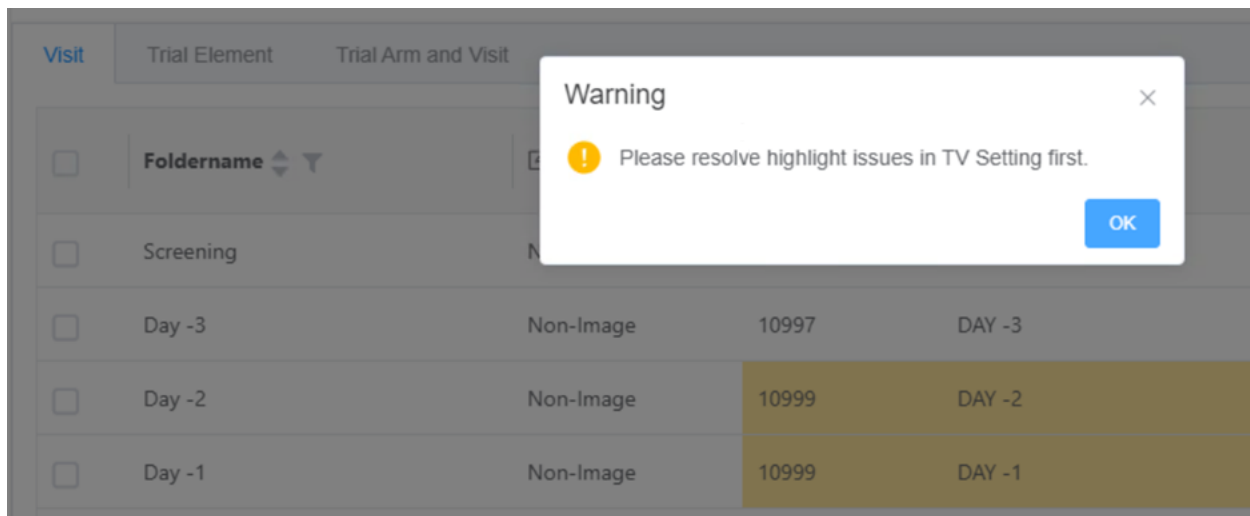


Figure 8. TDM Export Warning

MINUS PANEL

When the blank CRF and ALS are successfully uploaded in the "Setting" panel, the minus specification and aCRF are automatically created in the database. By clicking the "Minus" panel, users can review and update the minus spec, as shown in Figure 9. The minus spec can be interpreted as aCRF equivalent data in Excel format, containing information such as Form, Field, Field Value, reference source, annotation position coordinates, and corresponding SDTM variable mappings (e.g., domain, variable, label, and variable value). Most importantly, it includes the algorithm to process this field for SDTM conversion. It serves as SDTM metadata tailored for minus dataset conversion during SDTM programming. The minus dataset is an SDTM-like dataset, almost directly converted from the EDC raw data per the defined algorithm. By clicking the "Create Minus Datasets" button, the interface will use the minus spec and predefined raw data as source data to run the company's SAS macro and generate minus datasets.

On the left side of the "Minus" tab, users can click the bookmark to activate the corresponding CRF form in red color. There is a built-in data checklist indicating which annotations require further confirmation, with an exclamation mark icon next to the bookmark reminding users to pay attention to highlighted annotation comments. This allows users to easily identify which field's annotations need careful review.

Figure 9. Minus Panel

To edit the current annotation, users can double-click the “Ref Triggered Annotation” column to trigger a pop-up window, as shown in Figure 10. The annotation is decomposed into multiple boxes, allowing users to easily update the annotation in the corresponding box. A list of input suggestions will appear for users to choose from, helping to avoid common input mistakes. The values in the "SDTM Domain/Variable" table will be automatically updated according to the changes made to the annotation boxes mentioned above. The “Algorithm” value explains the derivation method for the current annotation and will be used in the SAS macro to generate minus datasets.

Annotation

Field/Value

Field Name:Form

Field Label:Enrollment

Field Control:

Value:

Annotation/Algorithm

Pattern:VariableAssigned (e.g., BEOCCUR = Y)

Algorithm:Assigned

EPOCH

=

SCREENING

Annotation:EPOCH = SCREENING

SDTM Domain/Variable

Domain	Domain Label	Dataset	Variable Name	Variable Label	Variable Type	Variable Value
DS	Disposition	DS	EPOCH	Epoch	Char	SCREENING

Save

Figure 10. Annotation Pop-up Window

The platform can also analyze the potential annotation patterns for a field based on the input data type of the current field and the annotation level (form level, field value, or value level). The pattern dropdown list in Figure 11 displays all allowed annotation types for the field, and users can select one to fill in the annotation boxes. These features help prevent users from using improper annotations.

Pattern:DatetimeCopy (e.g., AESTDTC)

Algorithm:DT2DTC

Annotation:

DatetimeCopy (e.g., AESTDTC)

DatetimeQNAMCopy (e.g., SUPPSS.QVAL where QNAM = LSALVDTC)

NotSubmitted (e.g., NOT SUBMITTED)

QNAMAssigned (e.g., SUPPDM.QVAL = ASIAN where QNAM = RACEA)

VariableAssigned (e.g., BEOCCUR = Y)

WhereAssign (e.g., TUORRES = TARGET where TUTESTCD = TUMIDENT)

WhereDatetimeCopy (e.g., DSSTDTC where DSDECOD = INFORMED CONSENT OBTAINED)

Domain/Variable

Domain	Variable Name	Variable Label	Variable Type	Variable Value

Figure 11. Example of Annotation Pattern

ACRF PANEL

The "aCRF" panel provides users with a real-time, bilaterally synchronized aCRF renderer, as shown in Figure 12. The aCRF renderer and minus spec are essentially the same data in different formats. Updates in either one will synchronize with its counterpart simultaneously. For newly created annotation entries in the minus spec, the box automatically fits the size of the text content, colors the background, and places itself in the blank area of the aCRF renderer.

The screenshot displays the aCRF Renderer Panel. On the left is a bookmark menu with categories like Subject, Date of Visit, COVID-19 Impact Form, Informed Consent, Demographics, Enrollment, Study Eligibility, Prior History Summary, Medical History, Prior Systemic Therapy, Prior Radiation Therapy, Prior Cell Therapy, Disease History, Unscheduled Assessments, Vital Signs, Vital Signs 1, Vital Signs 2, B Symptoms, Physical Examination, Targeted Physical Exam, ECOG Performance Status, ECG Local Read, ECG Local - Triplicate, ECG Central Assessment, Cardiovascular Assessments, Hematology - Local, and Hematology - Local (Predose). The main area shows a form with fields like 'Was the subject enrolled in the study?', 'Date of enrollment', 'Reason for screen failure', 'Inclusion/Exclusion criteria', 'Adverse event', 'Withdrawal by subject', 'Other', 'Was this subject screened previously?', 'Previous screening number', 'Cohort', 'Ramp-up Schedule', and 'Target Dose Level'. A red rectangular box highlights a dashed annotation box around the 'Ramp-up Schedule' field. On the right, a list of fields is shown, including Form, ENRYN, ENR_DSSTDAT, DSTERM_ENRREAS, DSTERM_OTHSP, and ENRPSCR, each with its control type and format.

Figure 12. aCRF Renderer Panel

The "aCRF" panel consists of three parts. On the left side, the bookmark can be used to select a CRF form and indicate further review reminders, similar to the "Minus" panel. On the right side, a list of all fields in the current form is provided. Users can drag a relevant field to the middle section, and an annotation pop-up window, like in Figure 10, will appear once the drag is complete. Users can add a new annotation in the pop-up window and click save to see an annotation box with automatic size adjustment and background coloring at the drop position.

The middle section is the main body of the aCRF renderer(or called preview). Users can double-click the box to edit the annotation in a pop-up window like in Figure 10. They can also smoothly move and adjust the size of the annotation box within the aCRF renderer.

The aCRF renderer includes several features to enhance the user experience and streamline operations. If further confirmation and review of an annotation are required, dashed lines will appear around the box, as shown in the red rectangular box in Figure 12. When users click the dashed annotation box, a reminder box with a detailed review checklist will pop up. Additionally, there may be duplicate annotations for repeat fields within one form across multiple pages, such as annotations for the form header area or for the same fields at multiple time points (e.g., VSTPT). In traditional aCRF annotation processes, programmers need to manually add these repeat annotations. However, the platform synchronizes these repeat annotations with the first occurrence origin, so users only need to edit or move the first origin annotation. For convenience, the repeat annotations will be half-transparent and unable to be edited or moved, as shown in Figure 13.

aCRF Derive Define Current CRF ID: 72 / 287 Download aCRF

VS = Vital Signs
V1.0 21APR2023 1528: PDF
Project Name: BGB-21447-101
Form: Vital Signs 1
Generated On: 27 Apr 2023 03:34:23

VSTPT
Time point Predose 4h

VSTESTCD = VSALL VSTEST = Vital Signs VSSTAT = NOT DONE
Not done

VSDTC
Date and time of vital signs

VSTEST = Temperature VSORRES where VSTESTCD = TEMP VSORRESU = C
Temperature Fixed Unit: C

VSTEST = Systolic Blood Pressure VSORRESU = mmHg VSORRES where VSTESTCD = SYSBP
Systolic blood pressure Fixed Unit: mmHg

Figure 13. Duplicate Annotations Format in aCRF Renderer

The aCRF is ready to download when users have completed the review and updates of minus spec or aCRF renderer. The downloadable aCRF is totally identical to aCRF renderer. Therefore, the movement and updates in minus spec or aCRF renderer will be automatically reflected in the downloaded aCRF. Additionally, it's very easy to export aCRF by clicking the button "Downloading aCRF" in "aCRF" panel or "Minus" panel, and it only takes less than 15 seconds to download one complete aCRF in pdf format to predefined path.

OBTAIN SDTM DATASETS AND PROGRAMS

DERIVE PANEL

Once all the previous panels are prepared, the final step to generate individual SDTM programs and datasets is to add SDTM-derived variables to the minus datasets and convert them to the final SDTM datasets. This can be accomplished in the "Derive" panel, as illustrated in Figure 14.

Clicking on the "Derive" panel triggers the interface to dynamically generate a programming specification (also called derive spec) containing the derived rules for SDTM-derived variables, such as VISIT, xxSEQ, xxDY, xxBLFL, and so on. We call it 'dynamically' because only the required and expected derived variables will be added not as long as they are not present in SDTM minus. The derive spec will be displayed in the interface under two tabs: "Domain" and "Variables." Users can click the arrow button at the end of each row in the "Domain" tab to go to the "Variable" tab to review derive rules for the corresponding domain.

The "Variable" tab lists detailed programming methods, macros used for the variable, and macro algorithm descriptions. Users can review and update the macro parameters as needed for the study and generate all SDTM programs by clicking the "Create All Dev SDTM pgms" button, using the updated derive spec as source data. Users can then batch run all SDTM programs to generate SDTM datasets. Additionally, if users only want to update the program for a certain domain, they can update the derive rules in the "Variable" tab and return to the "Domain" tab to click the "Dev" or "QC" button to re-generate the corresponding SDTM program for development or validation.

The screenshot displays the 'Derive' panel of the SDTM platform, divided into two tabs: 'Domain' and 'Variable'.

Domain Tab:

Domain	Description	Order	Pre Process	Post Process	Action
DC	Demographics as Collected	10			Dev, QC, IT, +, -
DM	Demographics	20			Dev, QC, IT, +, -
SV	Subject Visits	30			Dev, QC, IT, +, -
SE	Subject Elements	40			Dev, QC, IT, +, -
EC	Exposure as Collected	50			Dev, QC, IT, +, -
EX	Exposure	60	Copy data from EC minus where ECMOOD='PERFORMED' and		Dev, QC, IT, +, -
AE	Adverse Events	70			Dev, QC, IT, +, -

Variable Tab:

Domain	Variable	Variable Label	Algorithm Label	Algorithm Description	Origin	Comment	Method	Action
EC	VISITNUM	Visit Number	%m_sdtm_visit(exclude=BE_BM S PR_PC PR_POS PR_POSR)	Merge with SV by USUBID and VISIT to get VISITNUM	Assigned			+
EC	EPOCH	Epoch	%m_sdtm_epoch	Derived from SE domain based on ECSTDT, SESESTDT and SESEENDT.	Assigned	Derived from SE domain based on ECSTDT, SESESTDT and SESEENDT.		+
EC	ECSEQ	Sequence Number	%m_sdtm_seq(keyvar=STUDYID USUBID ECSTDT ECTRT ECMOOD)	1. Sort by key variables 2. Assigned as 1 for the first record of the subject 3. Incremented by 1 for each subsequent record (Initial sorting keys may need to be adjusted to be unique for each record)	Derived	ECSEQ is computed as: Within all records with the same USUBID, assigned as 1 for the first record and incremented by 1 for each subsequent record (Applied to dataset sorted by key variables). Reset to 1 for each new USUBID.		+
EC	ECENDY	Study Day of End of Treatment	%m_sdtm_studyday	ECENDT-RFSTDT<+ (ECENDT>=RFSTDT)	Derived	ECENDY is computed as: ECENDT - RFSTDT + 1 if ECENDT is on or after RFSTDT, ECENDT - RFSTDT if ECENDT precedes RFSTDT.		+

Figure 14. Domain and Variable Tab in Derive Panel

CONCLUSION

This SDTM platform provides programmers with an intelligent, more convenient, and time-saving method to generate SDTM datasets, in terms of saving on tedious and repetitive coding so as to put more focus on reviewing and refining annotation rules to ensure quality. The platform facilitates the SDTM process with the following advantages:

1. Reduced coding requirements.
2. Easy-to-use, straightforward, and self-explanatory UI buttons.
3. Convenient sharing and referencing of study metadata.

Additionally, the functionalities for creating the SDTM submission package are handled in "Define" panel, which is not covered in this paper.

Platformization and innovation are popular trends in the clinical industry. This platform design allows for flexible addition of smart functions in the future such as embed AI application at designated points. Furthermore, it can define input patterns and data checks to guide users in filling data more conveniently with minimized mistakes. This brings use a great of convenience and efficiency gain.

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