

Single Day Event

Introduce key initiatives and future
development plan of BeiGene
Programming

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Agenda

1. Introduction
2. Key Initiatives and Achievements
3. Future Development Plan
4. Management Support
5. Q & A



Introduction

- About BeiGene.
- About Global Statistical Programming Department.
- About Global System and Standard Group.



Key initiatives & achievements

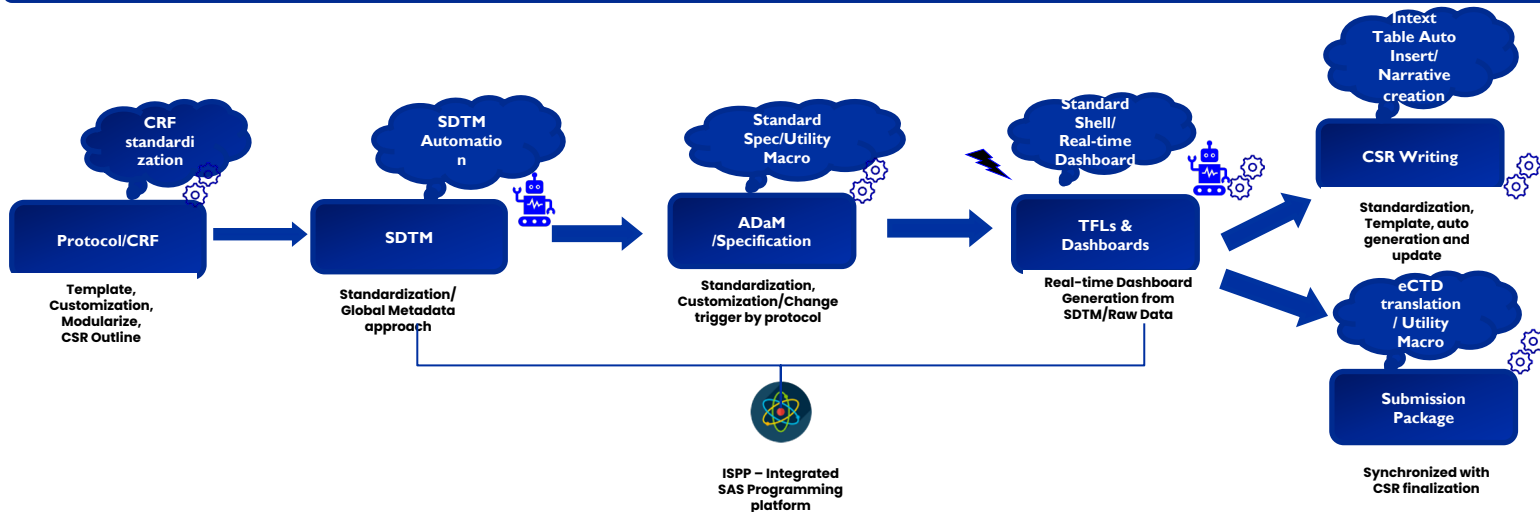
- SDTM automation.
- Global macro library.
- R Shiny applications.
- Chinese eCTD Translation.
- Integrated SAS Programming Platform (ISPP).
- AWS SAS System



LANDSCAPE OF CURRENT CSR DEVELOPMENT & SUPPORT

- Standardization
- Automation
- Integration
- Real-time
- Interaction
- ...

Process Coordination & Task Assignment



BeiGene AWS SAS System


Clinical Data
(via AWS)



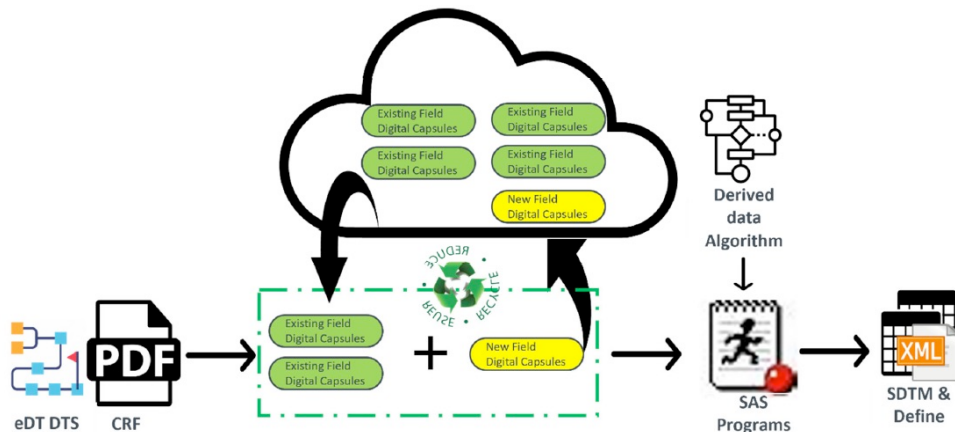
SDTM AUTOMATION

► Overview:

- This tool automates the process of transforming SDTM data. It was designed based on Digitalization & Modularization, Recycling & Integration, and Meta-programming, team could make SDTM transformation specifications and SDTM transformation code ready before First Patient First Visit.

► Key Components:

- Standard CRF
- Centralized annotation CRF
- SDTM DTS (data transfer specification)
- SDTM metadata + CT metadata
- SDTM macro
- SDTM user guideline
- SDTM sas programs
- SDTM & Define





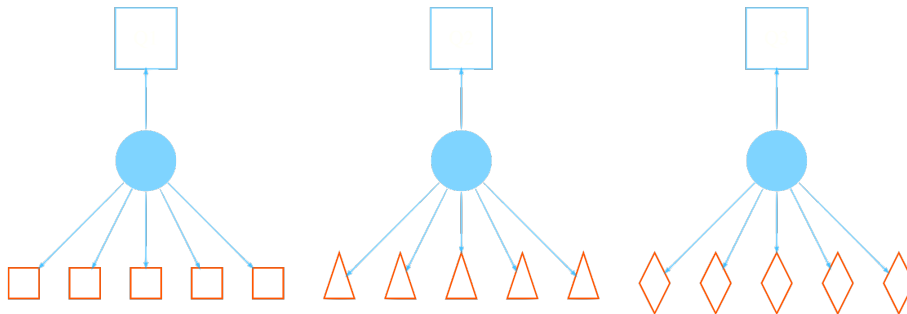
GLOBAL MACRO LIBRARY

► Overview:

- BeiGene has a global macro team who build global macro library to streamline the daily work of programming team. The team maintain macros, provide periodically training, conduct survey, and make improvements of global macros.

► Key Components:

- Source code
- User Manual
- Template Program





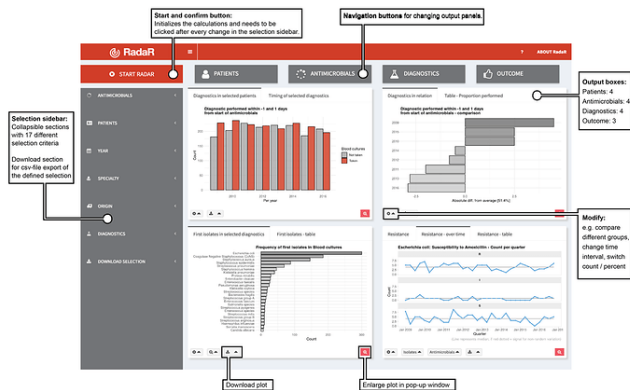
R SHINY APPLICATIONS

► Overview:

- Early Development (ED) Dashboard is a new visualization platform for efficient efficacy profile review. The tool provides real time insights for ED analysis results display including features such as: better view, real-time review, optimize team resource. In addition, BeiGene GSP also established a R Working Group to further develop R package and Shiny App used for CSR generation and display.

► Key Attributes:

- Centralization (*apply for all ED studies*)
- Real-time (*based on RAW data*)
- Interactive & Exploration





CHINESE ECTD TRANSLATION

► Overview:

- GSP generates the tool and define standard process of conduct Chinese translation for submission package deliver to NMPA, the scope includes: aCRF, csdrg, adrg, define file, and datasets(variable labels and coding variables).

► Key functions:

- CRF translation
- ADRG, SDRG translation
- Define file translation (excel -> XML)
- Datasets

V13.0 CO14 21APR2022 1626: Review
Project Name: BGB-3111-212
Form: Subject
Generated On: 25 Apr 2022 06:53:07

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受试者编号 _____ ①

国家 _____ ②

BGB-3111-212 电子信息数据采集表完成指南 _____ ③



INTEGRATED SAS PROGRAMMING PLATFORM (ISPP)

► Overview:

- Integrated SAS Programming Platform (ISPP) currently is a desktop application developed by Scientific programming team in JavaScript language. It runs on user's Amazon Work Station (AWS) and provides many shortcuts to facilitate programmer's daily operations such as batch run SAS jobs, verify SAS logs, combine rtf / pdf outputs, manage SAS programs, etc. These are pretty much all what programmers do every day, and ISPP provides a simple way to do that, which makes the delivery much easier, faster and better.

► Key Features:

- Setup programming environment (i.e. initial.sas)
- Create analysis dashboard
- Batch run (SDTM, ADaM, TFL...)
- Log check
- Create QC tracker
- Output combined PDF
- Soft Lock/Unlock
- Version Control

Analysis Management - Integrated SAS Programming Platform

Home / ISPP / Analysis Management

Analysis Management

Add Analysis Delete Analysis

Filter Type to Search Clear

Filter On ☐ Compound ☐ Study ☐ Analysis
Leave all unchecked to filter on all data

Select	Compound	Study	Analysis	Actions
	bgb_3111	bgb_3111_304	csru	Setting Open SEG Dir Mode Trk Mode Dashboard
	bgb_3111	bgb_3111_304	csru_2020	Setting Open SEG Dir Mode Trk Mode Dashboard
	gmpdev	macros	m_desc	Setting Open SEG Dir Mode Trk Mode Dashboard
	bgb_3111	docs	adam	Setting Open SEG Dir Mode
	zzz_tools	m_arc	v_1_0	Setting Open SEG Dir Mode
	bgb_3111	bgb_3111_304	irc_primary_r3_group1	Setting Open SEG Dir Mode Trk Mode Dashboard
	zzz_tools	m_arc	uat_01	Setting Open SEG Dir Mode

Select all Clear selected



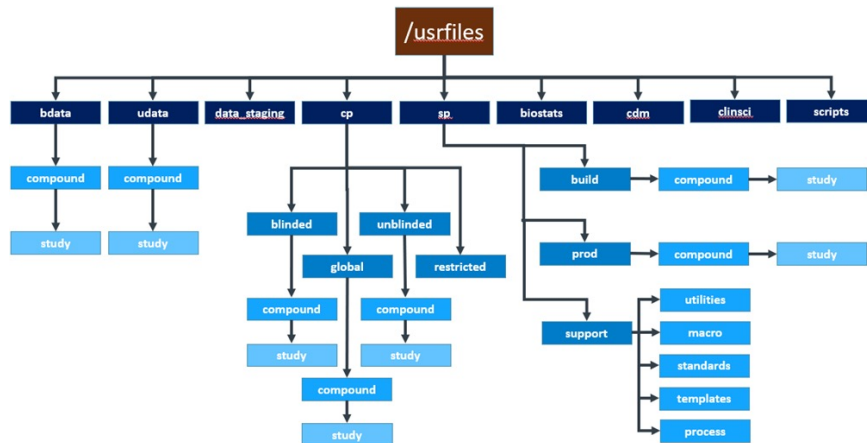
AWS SAS SYSTEM

► Overview:

- The project team is aimed to collect requirements and suggestions from all users, work closely with IT, solve any issues that may exist, perform regular maintenance on both US and CN systems, and apply major upgrades for the system. Overall, to improve our AWS system on its structure, performance, stability that ensure our project work efficiency and secure data access control.

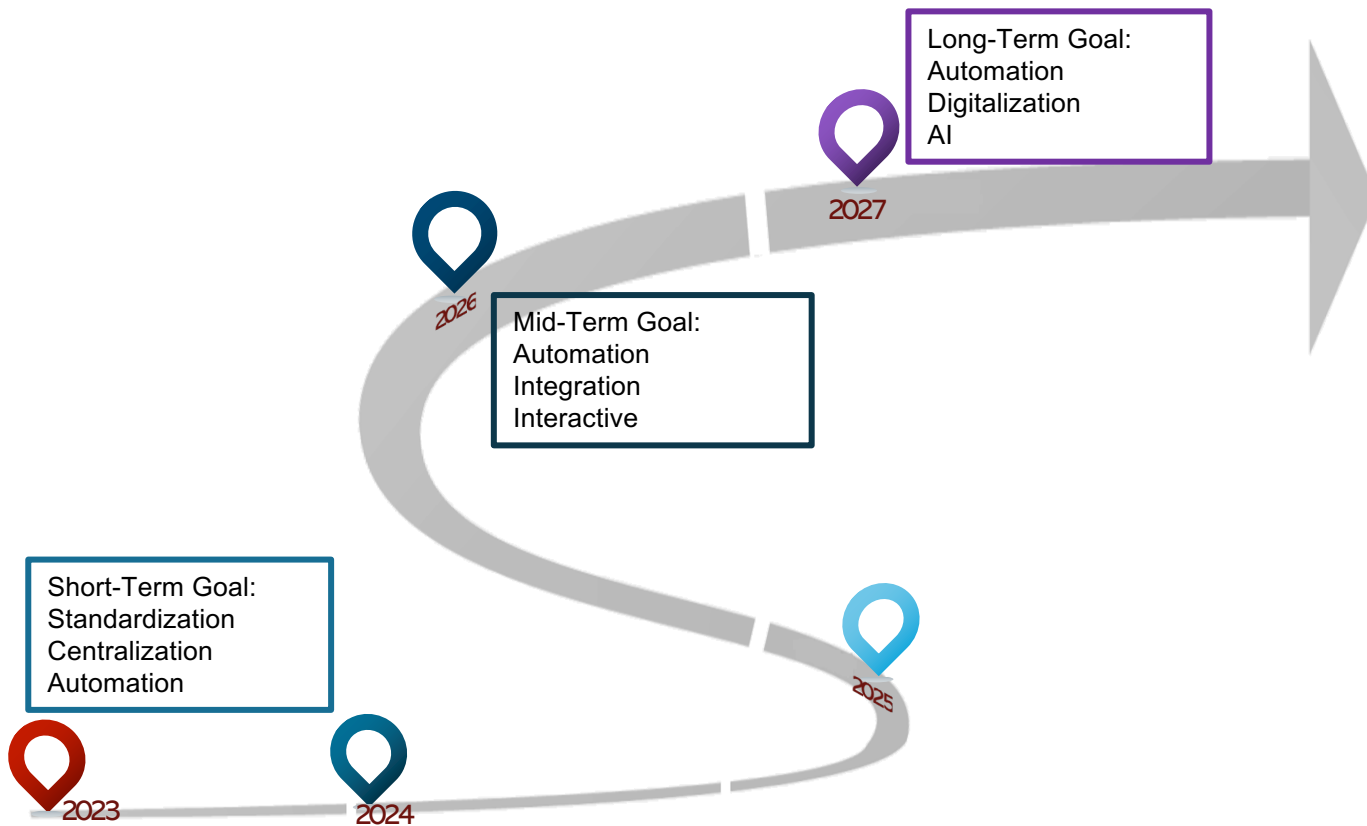
► Key functions:

- Access Control & Review
- Standard File Naming Convention
- Folder Soft Lock/Unlock
- Audit Trail
- Version Control
- Data Storage Optimization
- Data Migration (US to CN)





FUTURE DEVELOPMENT ROAD MAP





GOAL OF IMPROVEMENTS

- ▶ SDTM Automation:
 - Real-time SDTM
 - SDTM Centralization Development Team
- ▶ Global Macro Webpage:
 - All-in-One Place
 - Intelligent UI
- ▶ TFL Automation
 - Standard Template Base
 - Metadata Driven
- ▶ R/R Shiny
 - Extend to CSR
 - Extend to Submission by R



MANAGEMENT SUPPORT

- ▶ Create an effective work model and positive work environment.
 - Non-project Initiative Groups
- ▶ Encourage creativity and innovation.
 - Goal
 - Expectation
 - Reward
- ▶ Provide regular guidance and feedback.
 - Governance team & meeting
 - Centralized Tracker
- ▶ Provide the necessary resources and support.
 - Resources Evaluation tool
 - Training & Learning & Participation Opportunity

***CANCER HAS NO BORDERS,
NEITHER DO WE.***



Q & A

