



From BI to AI

A Metadata-Driven Intelligent Ecosystem for Scientific Programming

BI builds the foundation. Metadata connects the workflow. AI accelerates execution.



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Innovation, SPIS | BeOne Medicines

Disclaimer

Presenter Views and Scope

The views, interpretations, and conclusions presented are those of the presenter and do not necessarily represent official positions of BeOne Medicines.

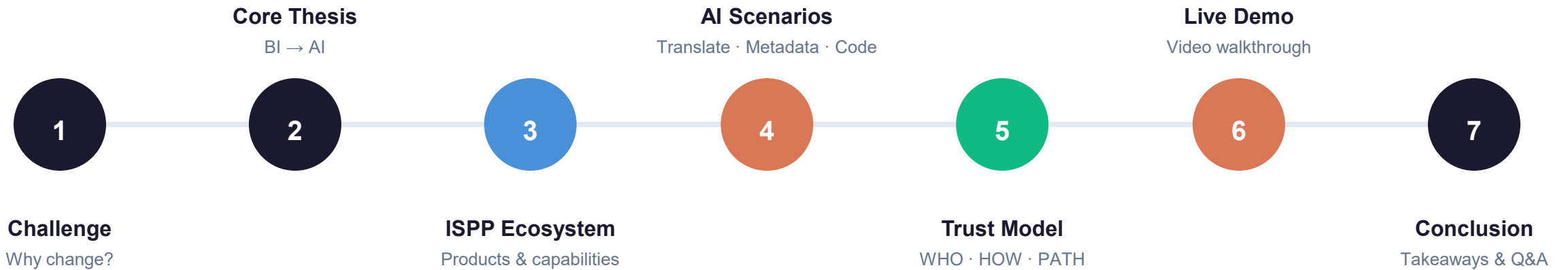
All examples are simplified for presentation purposes. No confidential study data, patient data, or proprietary implementation details are included.

This presentation is intended for knowledge sharing within the PHUSE community and should not be interpreted as regulatory guidance.

Concepts and lessons, not confidential operational detail.

Today's Journey

From operational challenge to trusted AI adoption — a structured path through the ISPP ecosystem.



Structured metadata enables credible AI — products, scenarios, and trust in one narrative.

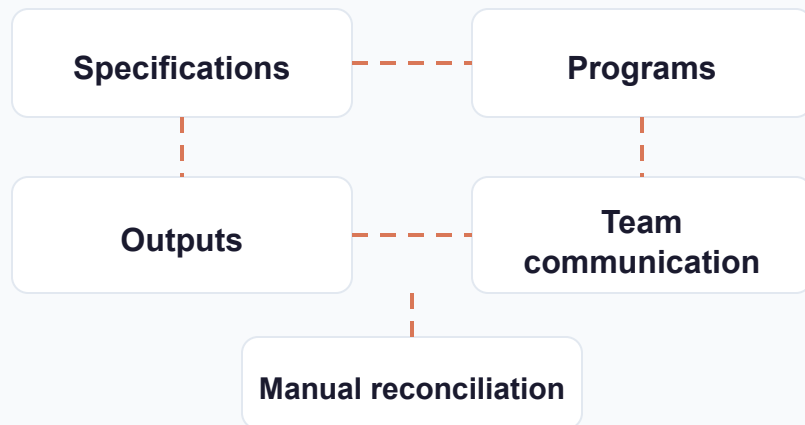
CHALLENGE

Fragmented information flow limits scalable automation and trusted AI

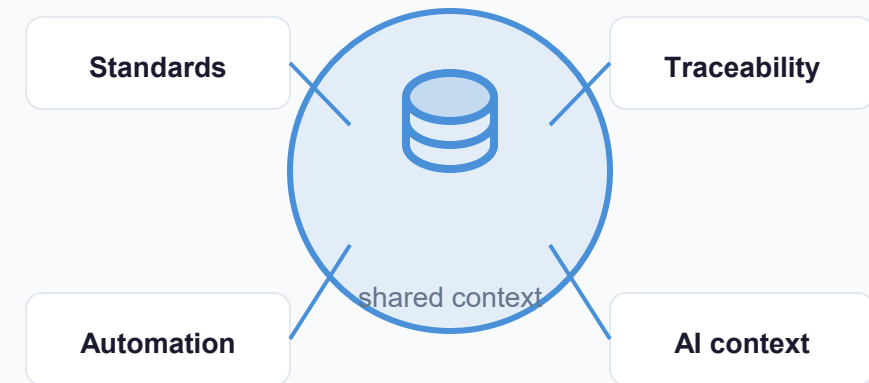
The operating challenge is disconnected context across work, review, and decisions.

Fragmented operating model

Manual handoffs create reconciliation effort and version-control risk.



Connected operating model



Automation and AI need structured context before they become reliable at scale.

AI becomes credible when grounded in metadata and governed by experts



BI foundation

Digitalize assets to create visibility, consistency, and traceability.



Metadata-driven dataflow

Connect metadata across workflow stages so automation works without manual handoffs.



AI acceleration

Draft, generate, translate, and assist faster while staying inside expert-defined context.



Human governance

Define standards, review critical outputs, approve decisions, and own accountability.

metadata spine

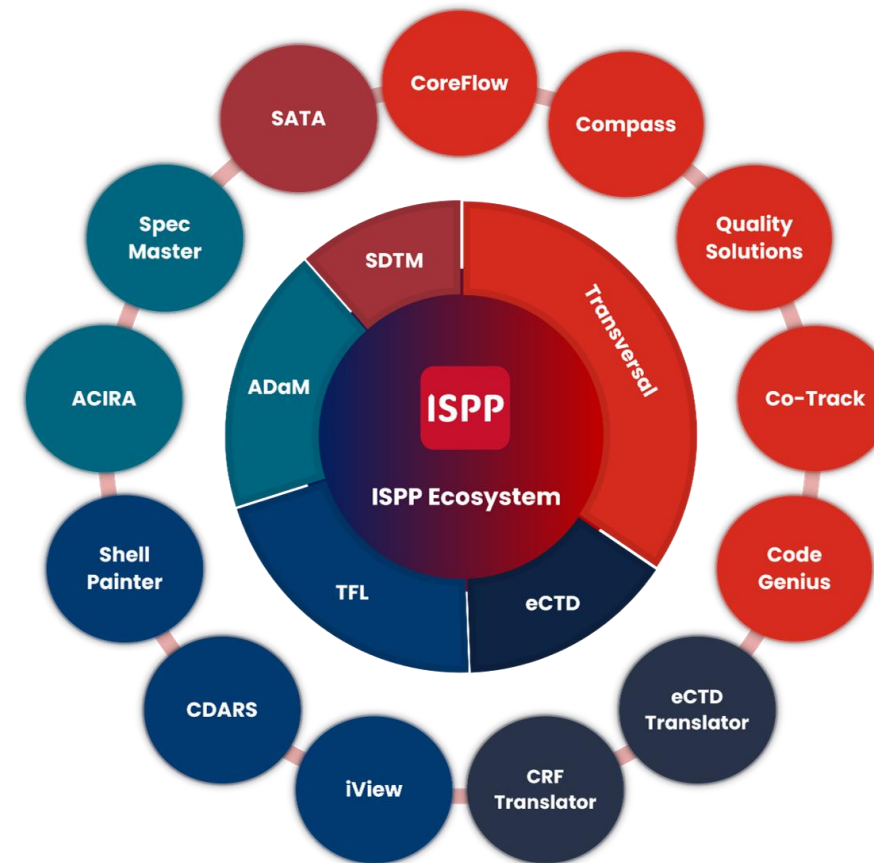
ISPP Product Matrix

A comprehensive ecosystem for scientific programming automation.

Integrated SAS Programming Platform

A cutting-edge ecosystem crafted for scientific programming. It delivers comprehensive, end-to-end solutions engineered to optimize and streamline programming workflows.

ISPP empowers organizations with an extensive suite of tools designed to boost productivity and elevate clinical data analysis.



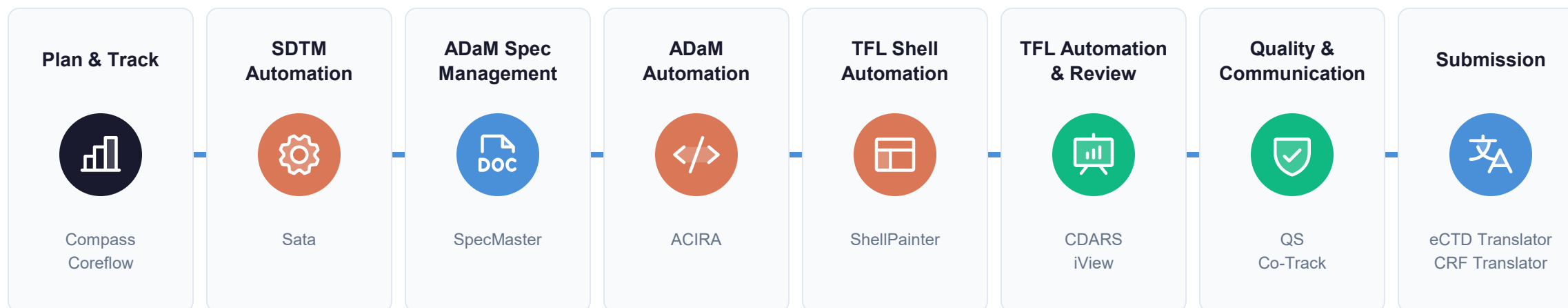
ISPP productizes automation across the programming lifecycle

End-to-end coverage from planning through SDTM, ADaM, TFL, quality review, and submission.



Lifecycle progression

Metadata carries reusable context across every automation stage.



Automation pattern

Governed workflows carry automation from planning and specs through review and submission.

Compass (Developing)

Project management platform for biostatistics, scientific programming, and data management.

Key Capabilities

-  Multi-level management: Project, Study, Analysis
-  Scientific analysis plan and task coordination
-  Resource allocation and workload tracking
-  Progress monitoring and risk control
-  Milestone and deliverable management

COMPASS

MAIN

Dashboard

My Tasks

Resource Managem...

New

Risk Report

PORTFOLIO

Portfolio

Delivery Schedule

STUDY MANAGEMENT

CAS Configuration

New

Delivery Request

New

Progress & Task Allocation

Documents

Programming QC Tracker

ANALYTICS

Metrics

Reports

Workflow Map

Home

Search studies, tasks, documents...

+🌙🔔?

Resource Management

SLP allocation and task claiming for programmers

SLP Assignment

CAS Assignment

CAS Claimed

Role Console

ACIRA

ADaM-Hub

CDARS

LiveTFL

SAC

CDARS

BGB-3111-304

IR

Apr 18, 2026 - Apr 28, 2026

12 unclaimed

ProdQC

Select All

ToSAC

Claim

☒L_tr

☒L_lb

☐L_scr

☐t_lbchg_chem

☐t_cm

☐t_pc

☐L_ex

☐t_ds

☐L_ae

☐t_dm_j

☐t_ex

☐t_bor_irc

BGB-3111-304

sCSR

Apr 24, 2026 - Jun 25, 2026

23 unclaimed

Urgent

ProdQC

Select All

ToSAC

Claim

☐f_bor_irc

☐L_scr

☐t_lbchg_hema_j

☐t_cm

☐L_pc

☐t_dm

☐t_lbchg_hema

☐t_lbchg_chem_j

☐L_cm

☐t_cm_j

☐t_pc

☐t_ds_i

☐t_bor_irc

☐t_ds

☐L_tr

☐L_lb

☐L_pop

☐t_lbchg_chem

☐f_bor_inv

☐L_ae

☐t_ex

☐L_ex

☐t_bor_inv

BGB-3111-304

SMC

Apr 25, 2026 - Apr 8, 2026

19 unclaimed

Urgent

ProdQC

Select All

ToSAC

Claim

Coreflow

Statistical Computing Environment (SCE) for analysis-level operations management.

Key Capabilities

-  Program and output lifecycle management
-  Batch job execution and log monitoring
-  Analysis-level task orchestration
-  Alert status and issue tracking
-  Integration with SAS computing environment

ISPP CoreFlow

[Home](#)

ISPP Copilot

Help Center

Home

Analysis Management 9 total

+ Add Analysis

+ Create Analysis

Search Compound / Study / Analysis

bgb_3111

STUDY bgb_3111_304

ANALYSIS adam

bgb_3111

STUDY bgb_3111_304

ANALYSIS csf

bgb_3111

STUDY bgb_3111_304

ANALYSIS csf_dev

gmpdev

STUDY macros

ANALYSIS m_desc

zzz_tools

STUDY cdars

ANALYSIS uat

zzz_tools

STUDY ispp_uat

ANALYSIS sdtm

zzz_tools

STUDY ispp_uat

ANALYSIS test_create_folder

zzz_tools

STUDY ispp_uat

ANALYSIS uat1

zzz_tools

STUDY ispp_uat

ANALYSIS uat4

Total 9 records << < 1 > >> 10 items/page Go 1 Page

ISPP CoreFlow

[Home](#)

ISPP Copilot

Help Center

Home

Trk ispp_uat - uat1

TFL

Expand Filters

Reset Filters

Select All (All Pages)

Select Page

Run

Check

Details

Issue

Export

Dir Mode

Trk Editor

#	Order	Output	PGM	VPGM	Alert	Issue #	Dtime	Vtime	Log	Vlog	Vist	PDF	Action	RTF
1	0	t_ds	t-ds.sas	v-t-ds.sas	2	0/0	2026-04-01 10:18:18		log				Run Check Details	
2	1	t_ds_cntry_site	t-ds-cntry-site.sas	v-t-ds-cntry-site.sas	4	0/0							Run Check Details	
3	2	t_ds_eot	t-ds-eot.sas	v-t-ds-eot.sas	4	0/0							Run Check Details	
4	3	t_pop	t-pop.sas	v-t-pop.sas	0	0/0	2026-03-27 16:02:43		log				Run Check Details	
5	4	t_dv_imp	t-dv-imp.sas	v-t-dv-imp.sas	4	0/0							Run Check Details	
6	5	t_dv_imp_covid	t-dv-imp.sas	v-t-dv-imp.sas	4	0/0							Run Check Details	
7	6	t_strata	t-strata.sas	v-t-strata.sas	4	0/0							Run Check Details	
8	7	t_covid_miss	t-covid-miss.sas	v-t-covid-miss.sas	4	0/0							Run Check Details	
9	8	t_covid_diag	t-covid-diag.sas	v-t-covid-diag.sas	4	0/0							Run Check Details	
10	9	t_dm	t-dm.sas	v-t-dm.sas	0	0/0	2026-03-27 16:03:46		log			pdf	Run Check Details	

Total 248 records << < 1 2 3 4 5 > >> 10 items/page Go 1 Page

SATA(SDTM Automated Transformation Assistant)

AI-driven SDTM automation — from raw clinical data to standardized datasets.

Key Capabilities

AI-powered mapping and code generation

CDISC standards-driven transformation

Metadata-driven repeatable workflows

SATA

ISPP

CoreFlow

Copilot

Co-Track

iKnow

App Feed Hub

eGuide

Support

Studies > ispp_demo > ISPP_DEMO_V4 > Annotations

Form

Domain

All

Q Search...

1 of 73

All Clear

Patient

Date of Visit

3

COVID - 19 Impact Form

3

1

Informed Consent

8

7

Demographics

Study Eligibility

6

1

Enrollment

10

4

Disease History and Characteristics

49

20

Prior History Summary

4

Medical History

2

Prior Systemic Therapy

6

6

Prior Radiotherapy

6

PD-L1 Test

15

13

Tumor Tissue Sample

1

Vital Signs

57

Vital Signs

57

Physical Examination

2

Pregnancy Test

9

6

ECOG Performance Status

10

Chemistry - Local

20

21

Hematology - Local

7

11

Coagulation - Local

3

Urinalysis - Local

10

7

24 Hour Urine

Thyroid Function - Local

1

Matching Pipeline Done

Complete: 1549 consistent, 92 inconsistent, 207 AI only, 541 RB only

Download

AI-RB Annotation Review (2389)

AI-RB Field Grouping Review

Accepted Mapping Spec Review

Grouping Review - Demographics

35 consistent

22 fields

AI - 1 GROUP

RB - 1 GROUP

DC - group1

DC - group1

BRTHDTC	AGE	AGEU	DOMAIN	ETHNIC	RACE	RACEA	RACEAIAN	RACEBAA	RACENHPI	RACEO
BRTHYY	AGE	AGE	Form	ETHNIC	RACE_AIAN	RACE_ASIAN	RACE_AIAN	RACE_BLACK	RACE_NHPI	RACE_OTH
Year of birth	Age	Age	Demographics	Ethnicity	Race (check all that apply) American Indian or Alaska Native	Asian	Race (check all that apply) American Indian or Alaska Native	Black or African American	Native Hawaiian or other Pacific Islander	Other
		YEARS	DC		INDIAN OR ALASKA NATIVE / ASIAN / ASIAN / BLACK OR AMERICAN / NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER / NOT REPORTED / OTHER / UNKNOWN / WHITE		AMERICAN INDIAN OR ALASKA NATIVE	AFRICAN AMERICAN	NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER	

BRTHDTC	AGE	AGEU	DOMAIN	ETHNIC	RACE	RACEA	RACEAIAN	RACEBAA	RACENHPI	RACEO
BRTHYY	AGE	AGE	Form	ETHNIC	RACE_AIAN	RACE_ASIAN	RACE_AIAN	RACE_BLACK	RACE_NHPI	RACE_OTH
Year of birth	Age	Age	Demographics	Ethnicity	Race (check all that apply) American Indian or Alaska Native	Asian	Race (check all that apply) American Indian or Alaska Native	Black or African American	Native Hawaiian or other Pacific Islander	Other
		YEARS	DC		INDIAN OR ALASKA NATIVE / ASIAN / ASIAN / BLACK OR AMERICAN / NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER / NOT REPORTED / OTHER / UNKNOWN / WHITE		AMERICAN INDIAN OR ALASKA NATIVE	AFRICAN AMERICAN	NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER	

AI - 1 GROUP

RB - 1 GROUP

RP - group1

RP - group1

RPTSTCD	RPTST	RPTSTCD	RPTST
CHILDPOT	CHILDPOT	CHILDPOT	CHILDPOT
Is patient of child-bearing potential?	Is patient of child-bearing potential?	Is patient of child-bearing potential?	Is patient of child-bearing potential?
CHILDPOT	Childbearing Potential	CHILDPOT	Childbearing Potential

RPTSTCD	RPTST	RPTSTCD	RPTST
CHILDPOT	CHILDPOT	CHILDPOT	CHILDPOT
Is patient of child-bearing potential?	Is patient of child-bearing potential?	Is patient of child-bearing potential?	Is patient of child-bearing potential?
CHILDPOT	Childbearing Potential	CHILDPOT	Childbearing Potential

Field Name

Field Label

Variable Value

SpecMaster

Automated ADaM specification generation and management platform.

Key Capabilities

-  Automated ADaM spec drafting from templates
-  Version control and change tracking
-  Consistency validation against standards
-  Cross-study spec reuse and inheritance
-  Collaborative review and approval workflow

ISPPSpecMasterStudyDatasetsVariablesValueLevelCodelistChangeLogCompareCurrent Study: standard Version: 1.3.0HelpReport Question

SearchEditTag Batch EditDeleteClearSaveRefreshQuick CheckBatch ReplaceDisplayAllADSLComment StatusSelect status

	Dataset	Variable	Order	Tag	Label	Type	Length	Fo...	CodeL...	Origin	Comment	Method Type	Method	Programming C	Action
	ADSL	DTHDT	135000	default	Date of Death	num	8			Derived	hover to edit Comment	Computation	Set to Numeric date representation of DM.DTHDTC...	hover to edit Progra	
	ADSL	DTHDT	135000	option	Date of Death	num	8			Derived	hover to edit Comment	Imputation	Set to Numeric date representation of DM.DTHDTC...	The imputation rule	
	ADSL	DTHDTF	136000		Date of Death Imputation Flag	char	1		DATEFL	Assigned	"D" = only day is imputed; "M" = both day and mo...	hover to edit Method		hover to edit Progra	
	ADSL	DTHDY	137000	randomized	Study Day of Death	num	8			Derived	hover to edit Comment	Computation	ADSLDTHDT-ADSLTRTSDT+1. If subject not dosed...	hover to edit Progra	
	ADSL	DTHDY	137000	nonrandomized	Study Day of Death	num	8			Derived	hover to edit Comment	Computation	ADSLDTHDT-ADSLTRTSDT+1. If subject not dosed...	hover to edit Progra	
	ADSL	EDTHDT	137010		Date of Death (Efficacy)	num	8			Derived	Completed death date derived from DM.DTHDTC...	Imputation	Set to Numeric date representation of DM.DTHDTC...	LSTALVDT should be	
	ADSL	DTHCAUS	138000		Cause of Death	char	200			Derived	hover to edit Comment	Computation	DD.DDSTRES where DD.DDTESTCD="PRCDTH"	hover to edit Progra	
	ADSL	DTHCAUSP	139000		Cause Specific of Death	char	200			Derived	hover to edit Comment	Computation	DD.DDORRES where DD.DDTESTCD="PRCDTH" and...	hover to edit Progra	
	ADSL	DTHCAUSS	140000		Cause of Death Sponsor	Char	200			Derived	hover to edit Comment	Computation	<study specific logic>	hover to edit Progra	
	ADSL	NCTXSDT	141000		Start Date of New Anti-Cancer Therapy	num	8			Derived	hover to edit Comment	Imputation	Set to Numeric date representation of Earliest CM...	The imputation log	
	ADSL	NCTXSDT	141000	solid	Start Date of New Anti-Cancer Therapy	num	8			Derived	hover to edit Comment	Imputation	Set to Numeric date representation of Earliest CM...	new FDA required v	
	ADSL	NCTXSDTF	142000		Date 1st Anti-Cancer Therapy Imput. Flag	char	1		DATEFL	Assigned	"D" = only day is imputed; "M" = both day and mo...	hover to edit Method		hover to edit Progra	
	ADSL	TEENDT	143000		Treatment Emergent End Date	num	8			Derived	hover to edit Comment	Computation	Populate for safety population only. If EOTSTT="O...	hover to edit Progra	
	ADSL	LSTALVDT	144000	heme	Date Last Known Alive	num	8			Derived	hover to edit Comment	Computation	Scan all available complete (non-imputed source)...	Search may include	
	ADSL	LSTALVDT	144000	solid	Date Last Known Alive	num	8			Derived	hover to edit Comment	Computation	Scan all available complete (non-imputed source)...	Search may include	
	ADSL	LSTALVDT	144990	default	Date Last Known Alive	num	8			Derived	hover to edit Comment	Computation	1) For subjects who died with complete death date...	Only use complete	
	ADSL	SFUDURD	145000	nonrandomized	Study Follow-up Duration (Days)	num	8			Derived	hover to edit Comment	Computation	If patients discontinued study (EOSSTT="DISCONTI...	hover to edit Progra	
	ADSL	SFUDURD	145000	randomized	Study Follow-up Duration (Days)	num	8			Derived	hover to edit Comment	Computation	If patients discontinued study (EOSSTT="DISCONTI...	hover to edit Progra	
	ADSL	SFUDURM	146000		Study Follow-up Time (Months)	num	8			Derived	hover to edit Comment	Computation	SFUDURD/30.4375	hover to edit Progra	
	ADSL	SFUDURW	147000		Study Follow-up time (Weeks)	num	8			Derived	hover to edit Comment	Computation	SFUDURD/7	hover to edit Progra	
	ADSL	LSURSTAT	148000		Survival Status at Last Contact	char	40			Derived	hover to edit Comment	Computation	last non-missing SS.SSORRES where STESTCD = "...	hover to edit Progra	

Highlighting variable in green indicates that it is an optional variable.

The cells circled in yellow indicate that "SAP" or "SDD" has appeared in this field.

The cells circled in blue indicate that a string with a similar format "<xxx>" has appeared in this field.

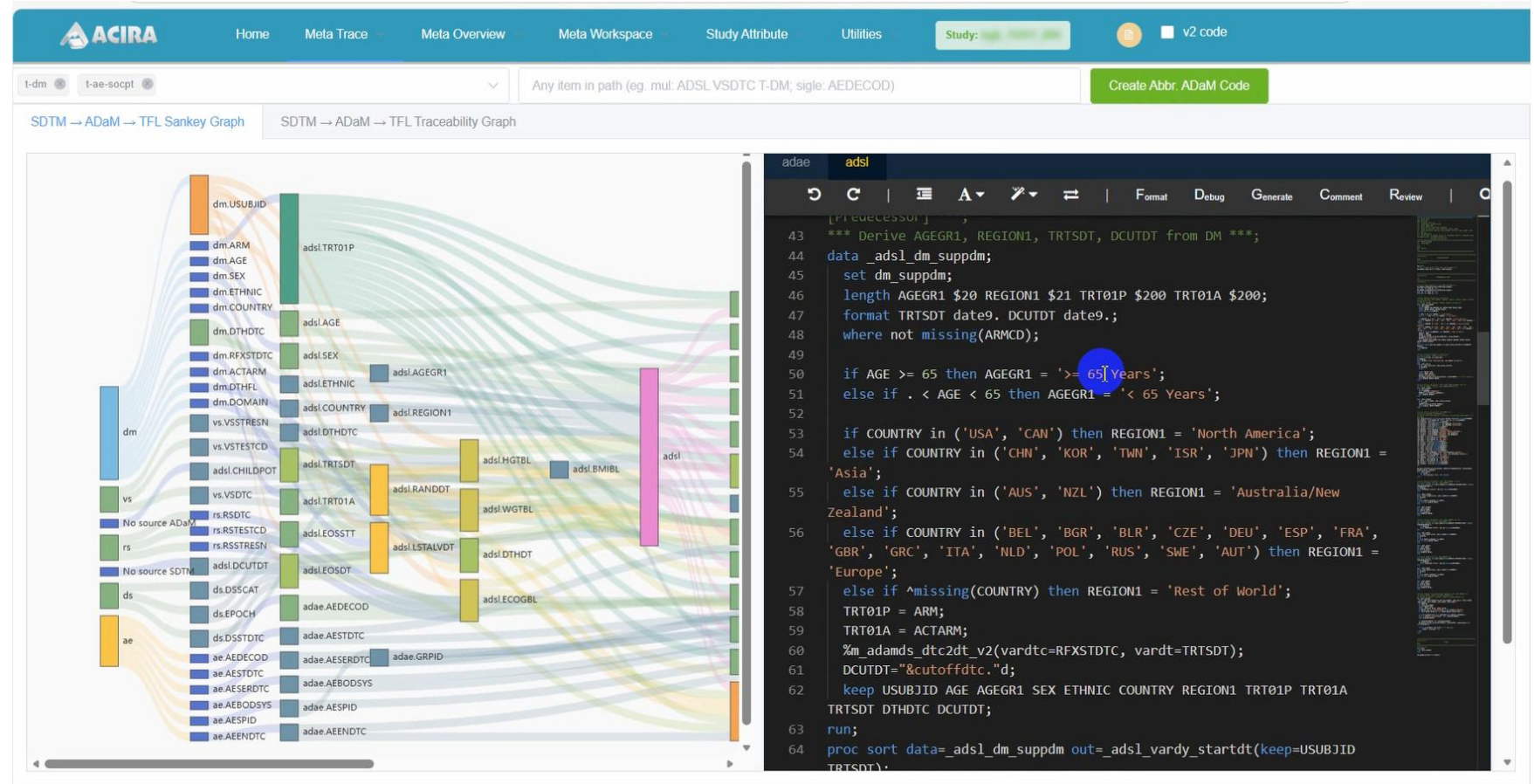
The cells circled in purple indicate that the length of the Label exceeds 40 bytes.

ACIRA (ADaM Code Intelligence for Rapid Analysis)

AI-powered ADaM code and dataset generation for faster clinical data analysis.

Key Capabilities

-  AI-driven ADaM program generation
-  Metadata-driven dataset creation
-  Built-in validation and quality checks
-  Accelerated decision-making workflows
-  Reusable patterns across studies



The screenshot displays the ACIRA web application interface. The top navigation bar includes links for Home, Meta Trace, Meta Overview, Meta Workspace, Study Attribute, and Utilities. A search bar is present with the text "Any item in path (eg. mul: ADSL VSDTC T-DM, sigle: AEDECOD)". A green button labeled "Create Abbr. ADaM Code" is visible.

The main content area is divided into two panels. The left panel, titled "SDTM → ADaM → TFL Sankey Graph", shows a complex Sankey diagram illustrating the flow of data from source datasets (dm, vs, rs, ds, ae) through various intermediate datasets (e.g., dm.USUBJID, dm.ARM, dm.AGE, dm.SEX, dm.ETHNIC, dm.COUNTRY, dm.DTHDTC, dm.RFXSTDTC, dm.ACTARM, dm.DTHFL, dm.DOMAIN, vs.VSSTRESN, vs.VSTESTCD, adsl.CHILDPOT, vs.VSDTC, rs.RSDTC, rs.RSTESTCD, rs.RSSTRESN, adsl.DCUTDT, ds.DSSCAT, ds.EPOCH, ds.DSSTDTC, ae.AEDECOD, ae.AESERDTC, ae.AESTDTC, ae.AEBODSYS, ae.AESPID, ae.AEENDTC) to the final ADaM dataset (adsl). The right panel, titled "SDTM → ADaM → TFL Traceability Graph", displays the generated ADaM code (adsl) in a dark-themed editor. The code includes comments and logic for deriving variables like AGEGR1, REGION1, and TRT01P from the source data.

ShellPainter

Web-based mock shell generator with AI-powered intelligent creation.

Key Capabilities

- Auto-select TOC for shell content
- Auto-adjust analysis content and structure
- AI-driven shell layout Generation (Developing)
- Web-based collaborative interface
- Reusable shell templates and patterns

ISPP

Study Setting Header TOC Central Edit Review Change Log

ISPP_DEMO

CDARS

Reselect Tasks Compare Shell Download Shell

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▼ 14.1.1: Disposition & Protocol Deviations

Table 14.1.1.x Analysis Sets (Intent-to-Treat Analysis Set)

▼ 14.1.2: Demog./Basel./Med.Hist./PriorAnti./Con.Med.

Table 14.1.2.x Demographics and Baseline Characteristics (Intent-to-Treat Analysis Set)

Table 14.1.2.x Disease History and Characteristics (Intent-to-Treat Analysis Set)

Table 14.1.2.x Subsequent Anticancer Therapies (Safety Analysis Set)

Table 14.1.2.x Medical History (Safety Analysis Set)

▼ 14.2: Efficacy Data

Table 14.2.x Analysis of Overall Survival (Intent-to-Treat Analysis Set)

Table 14.2.x Analysis of Progression-Free Survival by Investigator (Intent-to-Treat Analysis Set)

▼ 16.2.1: Discontinued Patients

Listing 16.2.1.x Patient Disposition (Safety Analysis Set)

▼ 16.2.4: Demographic and Baseline Characteristics Data

Listing 16.2.4.x Demographic and Baseline Characteristics Data (Safety Analysis Set)

▼ 16.2.7: Adverse Events

Listing 16.2.7.x Adverse Events (Safety Analysis Set)

▼ 16.2.9: Individual PK/PD Measurements by Patient

Listing 16.2.9.x Listing of Plasma Pharmacokinetic Sample Collection Times and Concentrations (PK Analysis Set)

▼ 14.2: Efficacy Data

Figure 14.2.x Kaplan-Meier Plot for <> by <> (Intent-to-Treat Analysis Set)

Figure 14.2.x Forest Plot for Overall Response Rate by <> (Intent-to-Treat Analysis Set)

Figure 14.2.x Mean Changes From Baseline by Study Visit: <> (Intent-to-Treat Analysis Set)

Listing 16.2.9.x
Listing of Plasma Pharmacokinetic Sample Collection Times and Concentrations
PK Analysis Set

Treatment: XXXXXX

All Columns									
Basic information				Other					
Patient ID	Visit	Actual Study Day	Dosing Datetime	Planned Time (h)	Sample Datetime	Elapse Time (h) *	Plasma Concentration (units)	Comments_add1	Plasma Concentration_add1 (units)
XXXXXX	XXXXXX	XXXXXX	XXXXXX	XXXXXX	XXXXXX	XXXXXX	XXXXXX	XXXXXX	XXXXXX
XXXXXX	XXXXXX	XXXXXX	XXXXXX	XXXXXX	XXXXXX	XXXXXX	XXXXXX	XXXXXX	XXXXXX

Source: ADSL, ADPC. Data extraction: DDMONYYYY. Data cutoff: DDMONYYYY.

Programming notes:
The definitions in footnotes should follow SAP.

Figure 14.2.x
Kaplan-Meier Plot for <<Overall Survival or Progression-Free Survival or Relapse-Free Survival or Duration of Response>> by <<Independent Review Committee or Investigator>>
Intent-to-Treat Analysis Set

Events (%)

Median Hazard Ratio (95% CI) (95% CI) p-Value

<<Arm 1>> 30 (40.5) 10.1 (6.1, 100.7) (0.69, 1.02) 0.0003

<<Arm 2>> 20 (31.1) 8.1 (6.1, 10.2)

<<Endpoints>> Probability

Time (Unit)

<<Arm 1>>

<<Arm 2>>

CDARS

Automated TFL generation for standardized clinical data analysis and reporting.

Key Capabilities

-  Automated TFL output generation
-  Standardized formatting and validation
-  Efficient clinical reporting workflows
-  Reusable output templates
-  Quality-controlled deliverable pipeline

SPSP

CDARS

AnalysisHomeSettingHeaderTFLT-BlockCentral EditProgram MgmtChange Log

CDARS v1.2

Overview of Immune-Mediated Adverse Events by Category and Preferred Term (BGB-A3055 Monotherapy)

Tip

Add/Copy

Remove

Batch Management

Replace

Render

MS Codes

Save

	Act...	T	S...	Drag Row(s)	L...	T	Block Label	Analysis Type	Denominator			Analysis			Action
									Dataset	Filter	Variable	Dataset	Filter	Variable	
☒	☒	1			2		Patients in the Category	CRIT: Criterion Analysis	ADSL	never to add	not suitable for CRIT	ADAE	not missing (cq01nam)	not suitable for CRIT	never to add
☒	☒	2			3		Preferred Term, n/M (%)	CAT: Category Analysis	ADAE	not missing (cq01nam)	not suitable for CAT	ADAE	not missing (cq01nam)	AEDCCO	never to add
☒	☒	3			3		Worst Grade, n/M (%)	CAT: Category Analysis	ADAE	not missing (cq01nam)	not suitable for CAT	ADAE	not missing (cq01nam) and A...	AETONGRN(format=inaegrdn)	never to add
☒	☒	4			2		Patients With Any Immune-Mediated Adverse Event Leading ...	CRIT: Criterion Analysis	ADAE	not missing (cq01nam)	not suitable for CRIT	ADAE	not missing (cq01nam) and A...	not suitable for CRIT	never to add
☒	☒	5			2		Patients With Any Immune-Mediated Adverse Event Leading ...	CRIT: Criterion Analysis	ADAE	not missing (cq01nam)	not suitable for CRIT	ADAE	not missing (cq01nam) and A...	not suitable for CRIT	never to add

Render for Table

Table 14.3.1.19.6
Overview of Immune-Mediated Adverse Events by Category and Preferred Term (BGB-A3055 Monotherapy)
Safety Analysis Set
Pop. where: [ADSL] SAFY="Y" and TR01ag1a=1

	BGB-A3055 60 mg (N = XXX)	BGB-A3055 150 mg (N = XXX)	BGB-A3055 300 mg (N = XXX)	BGB-A3055 600 mg (N = XXX)	BGB-A3055 1200 mg (N = XXX)	BGB-A3055 2400 mg (N = XXX)	Total (N = XXX)
	High: [ADSL] TR01A = "BGB-A3055 60 mg" Column: [ADSL] TR01A = "BGB-A3055 60 mg"	High: [ADSL] TR01A = "BGB-A3055 150 mg" Column: [ADSL] TR01A = "BGB-A3055 150 mg"	High: [ADSL] TR01A = "BGB-A3055 300 mg" Column: [ADSL] TR01A = "BGB-A3055 300 mg"	High: [ADSL] TR01A = "BGB-A3055 600 mg" Column: [ADSL] TR01A = "BGB-A3055 600 mg"	High: [ADSL] TR01A = "BGB-A3055 1200 mg" Column: [ADSL] TR01A = "BGB-A3055 1200 mg"	High: [ADSL] TR01A = "BGB-A3055 2400 mg" Column: [ADSL] TR01A = "BGB-A3055 2400 mg"	High: [ADSL] 10 Column: [ADSL] 10
ImAE Category							
By Variable Category XXX							
By data: [ADAE] [IMAE] where not missing [IMAE]							
Patients in the Category	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Block Annotation for [CRIT]: (Analy. data: [ADAE] where not missing [cq01nam]; Deno. data: [ADSL])							
Preferred Term, n/M (%)							
AEDCCO category 1	xx/xxx (xx.x)	xx/xxx (xx.x)	xx/xxx (xx.x)	xx/xxx (xx.x)	xx/xxx (xx.x)	xx/xxx (xx.x)	xx/xxx (xx.x)
AEDCCO category 2	xx/xxx (xx.x)	xx/xxx (xx.x)	xx/xxx (xx.x)	xx/xxx (xx.x)	xx/xxx (xx.x)	xx/xxx (xx.x)	xx/xxx (xx.x)
AEDCCO category 3	xx/xxx (xx.x)	xx/xxx (xx.x)	xx/xxx (xx.x)	xx/xxx (xx.x)	xx/xxx (xx.x)	xx/xxx (xx.x)	xx/xxx (xx.x)
...							
Block Annotation for [CAT]: (Analy. data: [ADAE] [AEDCCO] where not missing [cq01nam]; Deno. data: [ADAE] where not missing [cq01nam]) Order by descending frequency of column #, 2.							
Worst Grade, n/M (%)							
Grade 3	xx/xxx (xx.x)	xx/xxx (xx.x)	xx/xxx (xx.x)	xx/xxx (xx.x)	xx/xxx (xx.x)	xx/xxx (xx.x)	xx/xxx (xx.x)
Grade 4	xx/xxx (xx.x)	xx/xxx (xx.x)	xx/xxx (xx.x)	xx/xxx (xx.x)	xx/xxx (xx.x)	xx/xxx (xx.x)	xx/xxx (xx.x)
Grade 5	xx/xxx (xx.x)	xx/xxx (xx.x)	xx/xxx (xx.x)	xx/xxx (xx.x)	xx/xxx (xx.x)	xx/xxx (xx.x)	xx/xxx (xx.x)
Block Annotation for [CAT]: (Analy. data: [ADAE] [AETONGRN] where not missing [cq01nam] and AETONGRN=3; Deno. data: [ADAE] where not missing [cq01nam]) Order by format innaegrdn value.							
Patients With Any Immune-Mediate							
d Adverse Event Leading to Discontinuation, n/M (%)							
Block Annotation for [CRIT]: (Analy. data: [ADAE] where not missing [cq01nam] and [AEDSNFL="Y"]; Deno. data: [ADAE] where not missing [cq01nam])							
Patients With Any Immune-Mediate							
d Adverse Event Leading to Treatment Modification of A3055, n/M (%)							
Block Annotation for [CRIT]: (Analy. data: [ADAE] where not missing [cq01nam] and [AEMODNPL="Y"]; Deno. data: [ADAE] where not missing [cq01nam])							
Source: ADSL, ADAE.							
Abbreviations: ImAE, immune-mediated adverse event.							
ImAEs were identified based on (Beigene standard process, as defined in ImAE Identification Charter <xx>xxx>). ImAE Company Custom Queries <xx>xxx>.							
Adverse events were graded for severity using CTCAE v5.0.							
The Categories were presented by a pre-specified order.							
M is the number of patients in the category. Percentages were calculated based on M.							
Treatment modification included dose delay, dose interruption <and infusion rate decreased> for <IQ>.							

Web-based collaborative TFL review platform promoting transparency and team engagement.



iView
User Manual

iView / TFL Review / zzz_tools -- ispp_demo -- csr -- test001 / t-14-1-1-3-ds-mono-c.pdf test001

Table 14.1.1.1.3: Patient Disposition and Reasons for Discontinuation (Dose Expansion, Monothe...)

Q 🔍 ↕ ▾ 1 / 4

– + 自动缩放

Navigate Mode
Rectangle

Protocol ISPP-DEMO

Page 1 of 4

	NSCLC				HNSCC				NSCLC PD-L1 High				Total (N = 88)
	Drug A 400 mg (N = 11)	Drug A 1200 mg (N = 21)	Drug A 2400 mg (N = 22)	Subtotal (N = 54)	Drug A 1200 mg (N = 19)	Drug A 2400 mg (N = 9)	Subtotal (N = 28)	Drug A 2400 mg (N = 19)	Subtotal (N = 7)	Total (N = 88)			
Number of Patients Treated, n (%)	11 (100.0)	21 (100.0)	22 (100.0)	54 (100.0)	10 (100.0)	9 (100.0)	19 (100.0)	19 (100.0)	7 (100.0)	80 (100.0)			
Number of Patients Discontinued From Drug A, n (%)	11 (100.0)	21 (100.0)	22 (100.0)	54 (100.0)	10 (100.0)	9 (100.0)	19 (100.0)	19 (100.0)	7 (100.0)	80 (100.0)			
Reason for Discontinuation													
Symptomatic Deterioration	6 (54.5)	15 (71.4)	14 (63.6)	35 (64.8)	7 (70.0)	8 (88.9)	15 (79.9)	4 (57.1)	54 (87.5)	4 (57.1)			
Physician Decision	4 (36.4)	12 (57.1)	10 (45.5)	26 (48.1)	7 (70.0)	6 (66.7)	13 (68.4)	4 (57.1)	43 (69.4)	4 (57.1)			
Other	0 (0.0)	4 (19.0)	4 (18.2)	8 (14.8)	1 (10.0)	1 (11.1)	2 (10.5)	0 (0.0)	10 (12.5)	0 (0.0)			
Death	2 (18.2)	1 (4.8)	2 (9.1)	5 (9.3)	1 (10.0)	0 (0.0)	1 (5.3)	0 (0.0)	6 (7.5)	1 (12.5)			
Adverse Event	1 (9.1)	1 (4.8)	1 (4.5)	3 (5.6)	1 (10.0)	0 (0.0)	1 (5.3)	1 (14.3)	5 (6.2)	1 (12.5)			
Other	2 (18.2)	0 (0.0)	1 (4.5)	3 (5.6)	0 (0.0)	0 (0.0)	0 (0.0)	2 (28.6)	5 (6.2)	5 (6.2)			

Source: AZML Data cutoff: 21SEP2024 Data extraction: JACOY2024
zzz_tools_ispp_demo_csr_der_page1tfl-t-14-1-1-3-ds-mono-c.rtf

Total: 3 Unresolved: 3 Resolved: 0

Page 1

- Jining Li Test comment 03/26 : @Jiapeng Hej please check this number
- Jining Li please check the whole section! 03/26 :
- Jining Li Test comments 03/26 : @Jiapeng Hej please check

Next Table 14.1.1.1.3: Demographics and Baseline Characteristics (Dose Expansion, Monotherapy) (Safety Analysis Set)

Version A: 002 → Version B: 001

Output: Demographics and Baseline Characteristics by Dose [Compare]

Comparing: 002 → 001

Page Comparison

Page 2

002

Protocol ISPP-DEMO

Page 2 of 4

	NSCLC				HNSCC				NSCLC PD-L1 High				Total (N = 88)
	Drug A 400 mg (N = 11)	Drug A 1200 mg (N = 21)	Drug A 2400 mg (N = 22)	Subtotal (N = 54)	Drug A 1200 mg (N = 19)	Drug A 2400 mg (N = 9)	Subtotal (N = 28)	Drug A 2400 mg (N = 19)	Subtotal (N = 7)	Total (N = 88)			
Race, n (%)	1 (27.3)	20 (95.2)	21 (95.5)	41 (76.1)	1 (10.0)	1 (11.1)	2 (10.5)	1 (14.3)	4 (57.1)	41 (76.1)			
White	4 (36.4)	0 (0.0)	1 (4.5)	5 (9.3)	1 (10.0)	1 (11.1)	2 (10.5)	1 (14.3)	4 (57.1)	10 (12.5)			
Asian	0 (0.0)	1 (4.8)	0 (0.0)	1 (1.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)			
Other	7 (63.6)	1 (4.8)	20 (91.5)	28 (51.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (57.1)	28 (34.6)			

Ethnicity, n (%)

Hispans or Latino

Not Hispanic or Latino

Height (cm)

Mean (SD)

Median

Q1, Q3

Min, Max

Source: AZML Data cutoff: 21SEP2024 Data extraction: JACOY2024
zzz_tools_ispp_demo_csr_der_page1tfl-t-14-1-1-3-ds-mono-c.rtf

001

Protocol ISPP-DEMO

Page 2 of 4

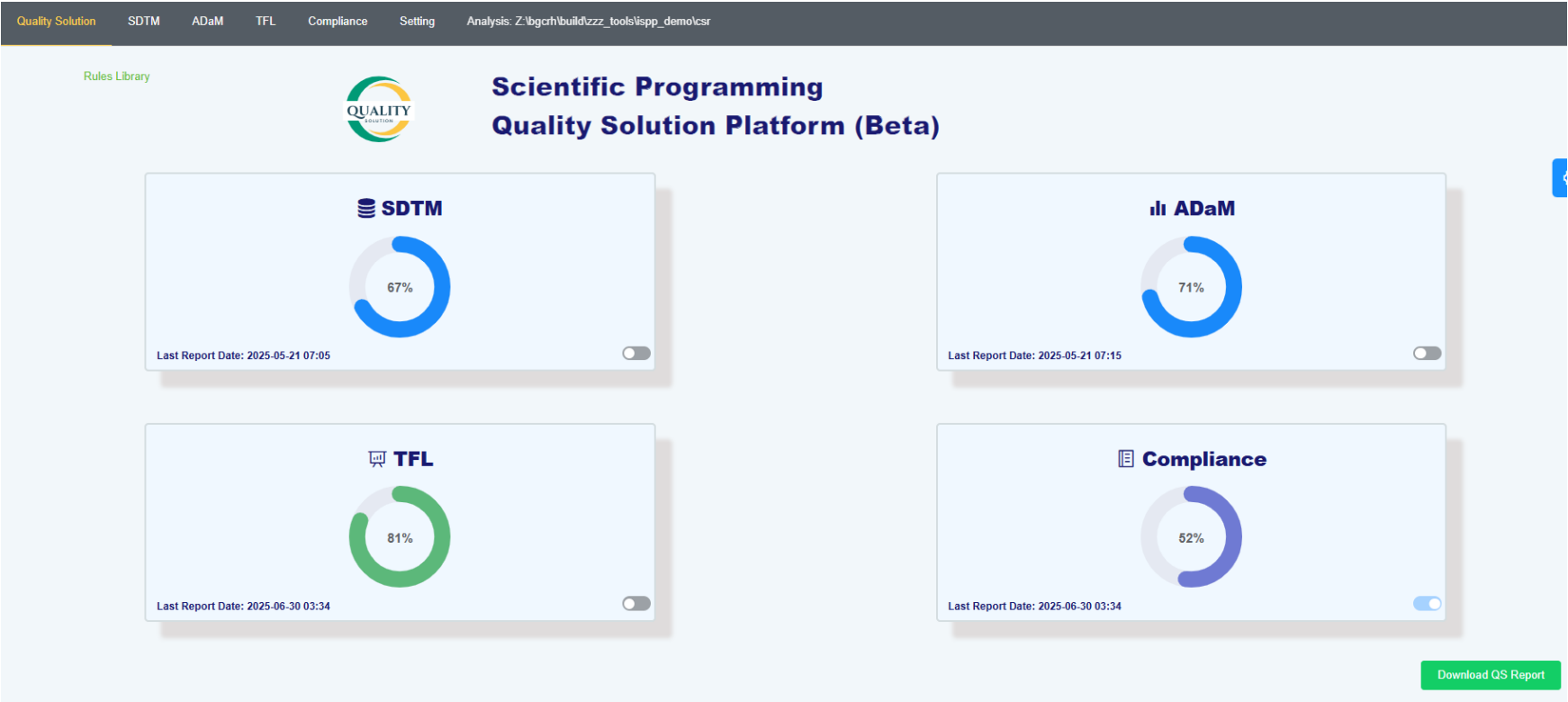
	NSCLC				HNSCC				NSCLC PD-L1 High				Total (N = 88)
	Drug A 400 mg (N = 11)	Drug A 1200 mg (N = 21)	Drug A 2400 mg (N = 22)	Subtotal (N = 54)	Drug A 1200 mg (N = 19)	Drug A 2400 mg (N = 9)	Subtotal (N = 28)	Drug A 2400 mg (N = 19)	Subtotal (N = 7)	Total (N = 88)			
Race, n (%)	1 (27.3)	20 (95.2)	21 (95.5)	41 (76.1)	1 (10.0)	1 (11.1)	2 (10.5)	1 (14.3)	4 (57.1)	41 (76.1)			
White	4 (36.4)	0 (0.0)	1 (4.5)	5 (9.3)	1 (10.0)	1 (11.1)	2 (10.5)	1 (14.3)	4 (57.1)	10 (12.5)			
Asian	0 (0.0)	1 (4.8)	0 (0.0)	1 (1.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)			
Other	7 (63.6)	1 (4.8)	20 (91.5)										

QS

Rigorous quality standards and comprehensive quality checks across programming workflows.

Key Capabilities

-  Comprehensive quality check workflows
-  Standardized quality assessment criteria
-  Issue identification and tracking
-  Quality metrics and trend analysis



Co-Track

Centralized management of analysis outputs, quality comments, and study decisions.

Key Capabilities

-  Quality control comment management
-  Study decision documentation
-  Analysis output tracking and attribution
-  Cross-functional team collaboration
-  Full traceability and audit trail

PRODISPP

HomeCoreFlowCopilotCo-TrackiKnowApp Feed HubAdmin

eGuideSupport

BackCo-Trackzzz_tools-isp-uat-uat1

All Issues

FiltersRefresh

6 row(s)Grid viewManage all posts

☐	Type	Output	Title	Status	Created by	Created at	Assign to	
☐	ADaM	adae	test email with Chinese char in body @0 +	?		2026-01-12 14:20:45		   
☐	ADAM	adae	xxx @0 +	?		2025-12-08 16:39:17		   
☐	ADAM	adae	test @0 +	?		2025-12-08 16:39:05		   
☐	TFL	t_tle_comp	what a good issue. @0 +	?		2025-04-27 19:32:42		   
☐	ADAM	adae	ADaM Issue 1 @2 +	?		2025-02-09 10:16:57		   
☐	TFL	t_ds	xxx @1 +	?		2024-03-26 16:31:59		   

<<<1>>>

20/pageTotal 6 record

eCTD Translator (1/2)

AI-native translation system for Define files, Reviewer's Guides, and aCRF.

Key Capabilities

AI-powered document translation

Define.xml and Reviewer's Guide support

aCRF annotation and translation

Fully integrated web-based interface

Regulatory submission compliance

ISPP / Scientific Programming / CRF Translation

Studies > CRF Translation-bgb_11417_102

HomeCRF TranslationCRF Translation Table

10 / 28410Confirm PageDownload CRFShow SDTM Annotation

Search Forms...

受试者信息

访视日期

日

知情同意书

人口统计

入组

研究资格

疾病史(血液学)

先前的病史总结

病史

既往系统性治疗

既往放射治疗

既往干细胞移植

计划外评估

生命体征

生命体征 - 时间点1

生命体征 - 时间点2

体格检查

有针对性的体格检查

B 症状

疾病相关全身症状

ECOG评分

LVEF评估

12导联心电图当地实验室评估 (三次)

血常规-当地实验室

血常规-当地实验室 (给药前)

血常规-当地实验室 (给药后2小时)

血常规-当地实验室 (给药后4小时)

血常规-当地实验室 (给药后6小时)

血常规-当地实验室 (给药后8小时)

血常规-当地实验室 (给药后12小时)

血常规-当地实验室 (给药后24小时)

血生化-当地实验室

V4.0 CC3 15May2023 0952: ALL FORMS

Project Name: BGB-11417-102

Form: Demographics

Generated On: 15 May 2023 14:54:27

Year of birth

AgeFixed Unit: Years

SexMaleFemale

Is subject of child-bearing potential?YesNo

EthnicityHispanic or LatinoNot Hispanic or LatinoNot reportedUnknown

Race (check all that apply)American Indian or Alaska Native

Asian

Asian Indian

Chinese

Filipino

Japanese

V4.0 CC3 15May2023 0952: 所有表格

项目名称: BGB-11417-102

表格: 人口统计

生成日期: 15 May 2023 14:54:27

出生年份

年龄Fixed Unit: Years

性别MaleFemale

受试者是否有生育能力?YesNo

族群Hispanic or LatinoNot Hispanic or LatinoNot reportedUnknown

种族 (勾选所有适用项) | 美洲印第安人或阿拉斯加原住民

亚洲人

亚洲印度人

中国人

菲律宾人

日本人

eCTD Translator (2/2)

AI-native translation system for Define files, Reviewer's Guides, and aCRF.

Key Capabilities

 AI-powered document translation

 Define.xml and Reviewer's Guide support

 aCRF annotation and translation

 Fully integrated web-based interface

 Regulatory submission compliance

 eCTD Translator(ET) Define-XML Reviewer's Guide

eCTD Translator / Review Guide / Viewer

Search Title...

1. Introduction

1.1 Purpose

1.2 Acronyms

1.3 Study Data Standards and Dictionary Inventory

2.2 Protocol Design

2.3 Trial Design Datasets

2.3.1 TA - Trial Arms

2.3.2 TE - Trial Elements

2.3.3 TV - Trial Visits

2.3.4 TI - Trial Inclusion/Exclusion Criteria

2.3.5 TS - Trial Summary

3. Subject Data Description

3.2 Annotated CRFs

3.2.2 Bookmarks

3.2.3 Annotation Conventions

3.3 Additional Content of Interest

3.3.2 --CAT & --SCAT Standardization

3.3.3 RELREC

3.3.4 EPOCH

3.3.5 Unscheduled Visits

3.3.6 Deaths

3.3.7 Suspected Drug Induced Liver Injury

3.3.8 Adverse Event Operational Fields

3.3.9 Endpoints & SDTM Domains

3.4 SDTM Subject Domains

3.4.1 AE - Adverse Events

3. Subject Data Description

3.1 Overview

Are the submitted data taken from an ongoing study? Yes.

If yes, describe the data cut or database status:
This version is for 9-Month Ad-Hoc analysis, data cutoff date is 05OCT2025, and survival status data use 19OCT2025 as data cut-off date.

Were the SDTM datasets used as source for the analysis datasets? Yes.

Do the submission datasets include screen failures? No.

Were any domains planned, but not submitted because no data were collected? Yes.

If yes, list the domains not submitted: HP, SUPPH, ML, SUPPML, SU, SUPPSU, XO, SUPPXO, SUPPCV, SUPPNV, SUPPRP, SUPPVS.

Are the submitted data a subset of collected data? No.

Is adjudication data present? Yes.

If yes, describe the implementation approach and location of the adjudication data:
Per protocol, scans are submitted to a central imaging core laboratory for archival and response assessment by Blinded Independent Central Review (BICR). RECIST 1.1 BICR assessments are included in the RS, TR and TU domains, and they can be distinguished by the --EVAL equaling "INDEPENDENT ASSESSOR" in the corresponding domain.
As per the independent review charter, trained and approved readers will read subject scans according to a three-reader baseline review, followed by a two-reader in post-baseline time point. Adjudication occurs if there is a discordance in timepoint response between two readers. The adjudicator selects the read that most accurately represents the current timepoint response.
If there is no discordance, the results from the first radiology read are used. If there is discordance, an adjudication is performed. The data for analysis is identified by the variable --ACPTFL equals to "Y" in RS, TR, TU domain

3. 受试者数据说明

3.1 概览

递交的数据是否取自尚在进行中的研究？是的。

如果是的话，请描述所截取的数据或数据库的状态：
此版本用于9个月临时分析，数据截止日期为2025年10月5日，生存状态数据使用2025年10月19日作为数据截止日期。

SDTM数据集是否用作分析数据集的来源？是的。

递交的数据集是否包含筛选失败数据？否。

是否有计划递交，但因未采集到数据而未递交的域？是的。

如果是，请列出未提交的领域：HP, SUPPH, ML, SUPPML, SU, SUPPSU, XO, SUPPXO, SUPPCV, SUPPNV, SUPPRP, SUPPVS.

所递交的数据是否为所有采集数据的一个子集？否。

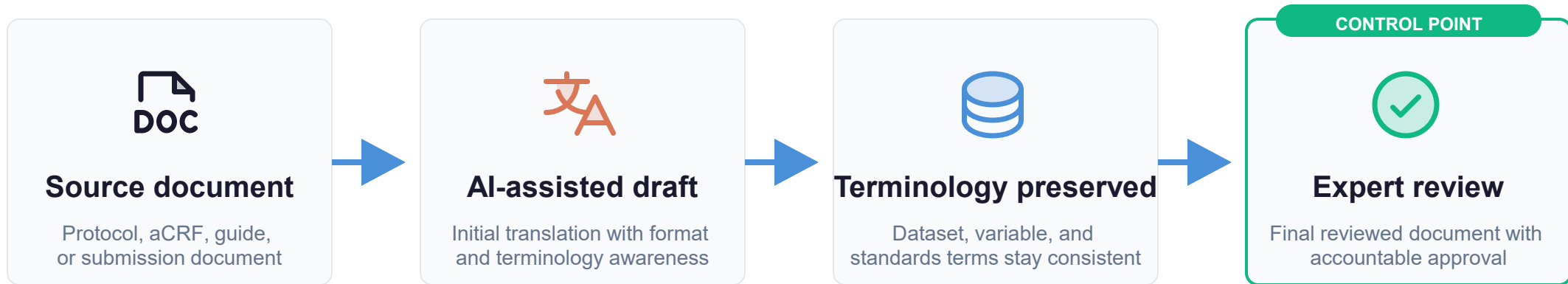
是否存在裁决数据？是的。

如果是，请描述裁定数据的实施方法和位置：
根据方案，扫描提交给中央影像核心实验室进行存档和由盲法独立中央审查（BICR）进行响应评估。RECIST 1.1 BICR评估包含在RS, TR和TU领域中，可以通过相应领域中--EVAL等于"INDEPENDENT ASSESSOR"来区分。
根据独立审查章程，经过培训和批准的读者将根据三读者基线审查读取受试者扫描，然后在基线后时间点进行两读者审查，如果两个读者之间的时间响应存在不一致，则进行裁定，裁定者选择最准确代表当前时间响应的读数。
如果没有不一致，则使用第一次放射学读数的结果。如果存在不一致，则进行裁定。用于分析的数据由变量标识
--ACPTFL在RS, TR, TU领域中等于"Y"。

USE CASE 1

Translation is a practical AI entry point, with expert review as the control point

Value is clear, but scientific meaning still requires expert review.



Where metadata helps

Preserves clinical terminology, keeps dataset and variable terms consistent, and supports document-specific review expectations with traceability of changes.

AI improves drafting speed; humans review meaning and scientific accuracy.

USE CASE 2

Metadata generation converts scientific intent into reusable structure

AI helps improve the foundation itself, not only downstream outputs.

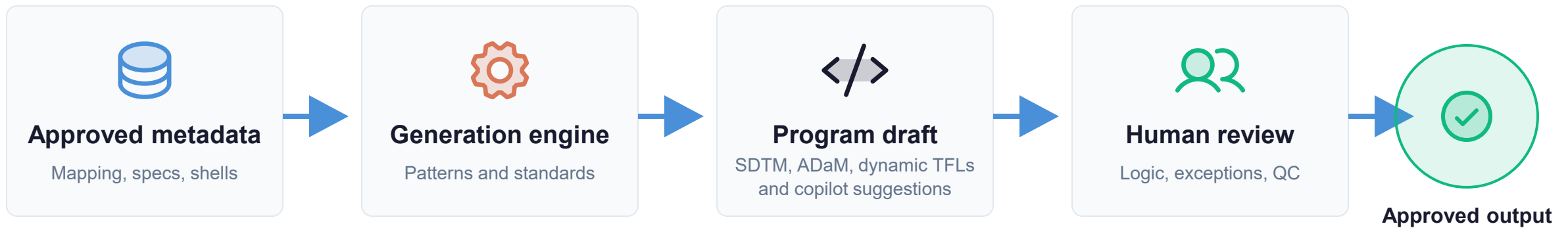


The highest-value AI output may be better metadata, not just faster documents.

USE CASE 3

Code generation is most credible when metadata defines what the code should do

The goal is reducing repetitive drafting, not replacing programmer judgment.



Guardrails

Generate from approved metadata

Keep human review

Retain QC checks

Preserve traceability

Metadata defines the task; programmers govern correctness and exceptions.

Clear responsibility boundaries are what make AI collaboration trustworthy

AI scales execution; humans govern standards, meaning, approval, and accountability.



Human experts

- Define standards and metadata rules
- Review scientific and statistical logic
- Resolve exceptions and study context
- Approve critical outputs
- Own final accountability



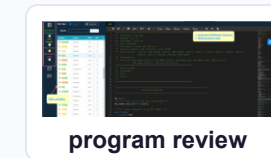
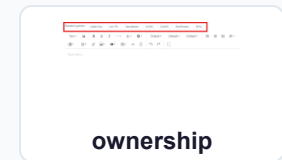
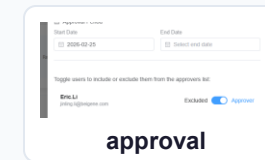
AI assistance

- Draft translations, metadata, and code
- Apply patterns consistently
- Surface suggestions and quality signals
- Reduce repetitive manual effort
- Provide traceable assistance

TRUST BOUNDARY



Governance in practice



Human experts remain accountable for scientific judgment and final approval.

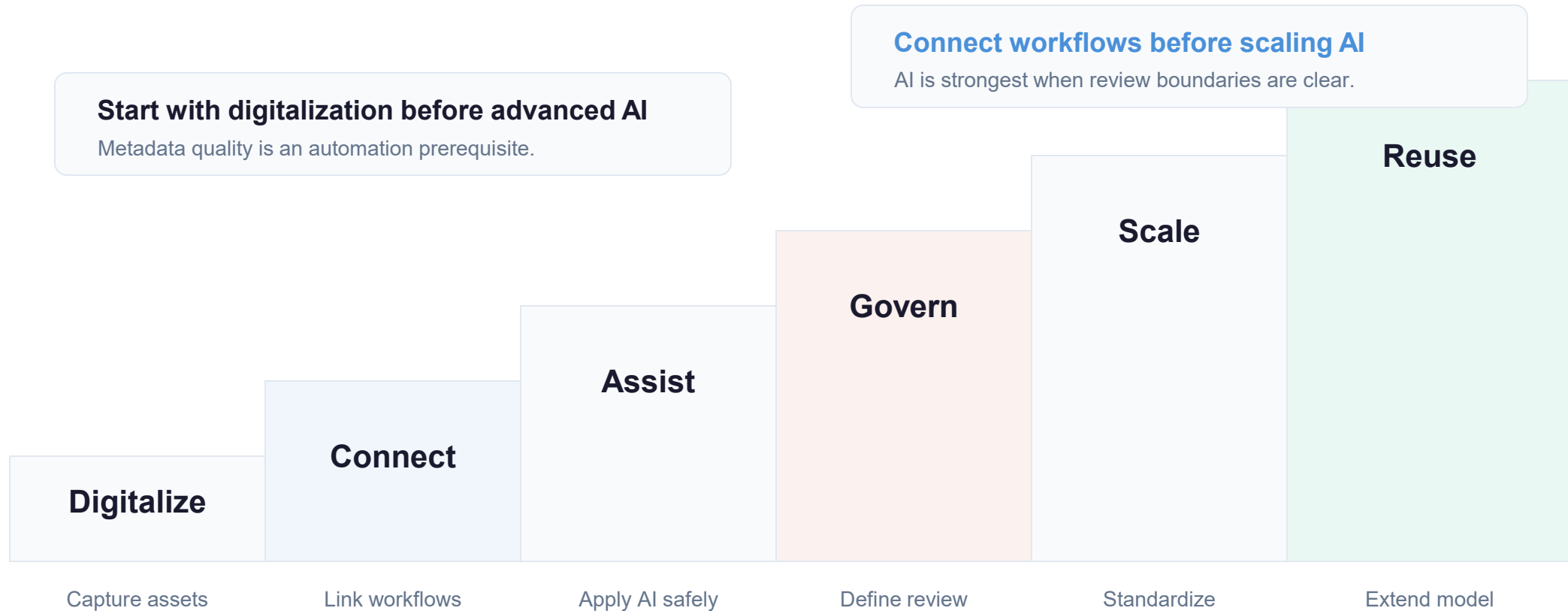
Operational trust comes from metadata, workflow integration, control, and standards



Governed by expert-defined standards: compliance belongs inside quality governance.

The BI-to-AI model is practical, incremental, and reusable

Build maturity in sequence rather than jumping directly to broad AI deployment.



Keep experts accountable for standards, exceptions, and final decisions.

VIDEO DEMONSTRATION

4-Minutes ISPP Workflow Demonstration

Watch how metadata is captured once, reused across workflows, and used to guide assistance.

CONCLUSION

BI and metadata make AI credible in scientific programming

The future is a metadata-driven ecosystem where AI accelerates execution and people govern trust.

The strategic point is not AI alone.

It is a connected operating model where metadata makes automation traceable, reusable, and reviewable.



BI foundation

BI creates the structured foundation AI needs.



Metadata flow

Metadata connects specs, execution, review, and delivery.



Embedded AI

AI is strongest when used inside governed workflows.



Human experts

Experts remain accountable for quality and judgment.

A credible AI strategy starts with digitalized assets, governed metadata, and expert oversight.

Thank You

Questions and Discussion

Thank you to the PhUSE SDE Beijing community
for the opportunity to share this work.

Acknowledgment: ISPP ecosystem contributors across programming, standards,
data management, quality, and platform engineering.



Open discussion

Open for questions on metadata, automation strategy, governance, and adoption.

Jinling (Eric) Li

Innovation, SPIS | BeOne Medicines

PhUSE SDE | 2026-05-15