AstraZeneca Standard Output Library (AZSOL): Driving Excellence in Standardization and Automation for Tables, Figures, and Listings (TFLs)

Birgit Weinkauf, AstraZeneca
Magdalena Soin, AstraZeneca

Meet the Speakers

Birgit Weinkauf

Title: Director, Statistics

Organization: Standards, Automation and Specialist Programming, Clinical Operations, R&D, AstraZeneca, Cambridge, UK

Birgit Weinkauf holds a degree in Statistics from the Dortmund Technical University and has over 25 years of experience in the pharmaceutical industry, specifically in phase II to IV clinical studies within oncology, transplantation medicine, and central nervous system areas. Her background includes roles as both, study and program statistician, and intense involvement in submissions to regulatory agencies such as the EMA, FDA, PMDA, and sFDA. Since joining AstraZeneca in 2018, she has contributed to the AZ Corporate Endpoint Library, supported standardization of clinical study documents, including the Statistical Analysis Plan, and initiated and led the AstraZeneca Standard Output Library (AZSOL). She plays a key role in maintaining and governing standards in AstraZeneca and has contributed to various automation initiatives.

Magdalena Soin

Title: Associate Director, Standards Developer

Organization: Standards, Automation and Specialist Programming, Clinical Operations, R&D, AstraZeneca, Warsaw, Poland

Magdalena holds a degree in Chemical Technology from the Warsaw University of Technology and has over 10 years of experience in clinical trials. Since joining AstraZeneca in 2016, she has progressed from a specialist role, supporting the Clinical Data Standards team, to her current position, where she is responsible for the maintenance, implementation, and improvements in clinical data standards and related processes. Magdalena has extensive experience in CDASH implementation in AstraZeneca's Data Collection Standards. In the past three years, she has also strongly contributed to AstraZeneca Standard Output Library (AZSOL) development. Additionally, she plays an important role in end-to-end enhancements of clinical data standards in AstraZeneca by supporting standards governance and automation initiatives.

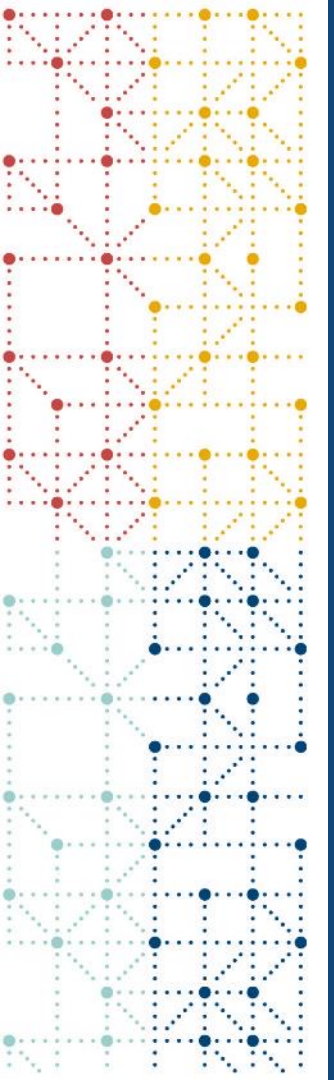
Disclaimer and Disclosures

- *The views and opinions expressed in this presentation are those of the author(s) and do not necessarily reflect the official policy or position of CDISC.*

- *The author(s) have no real or apparent conflicts of interest to report.*

Agenda

1. AZSOL Framework and Benefits
2. AZSOL Journey
3. Using AZSOL in MOSAIC Biometrics
4. E2E Mindset is a Key to Standardization
5. Future Directions



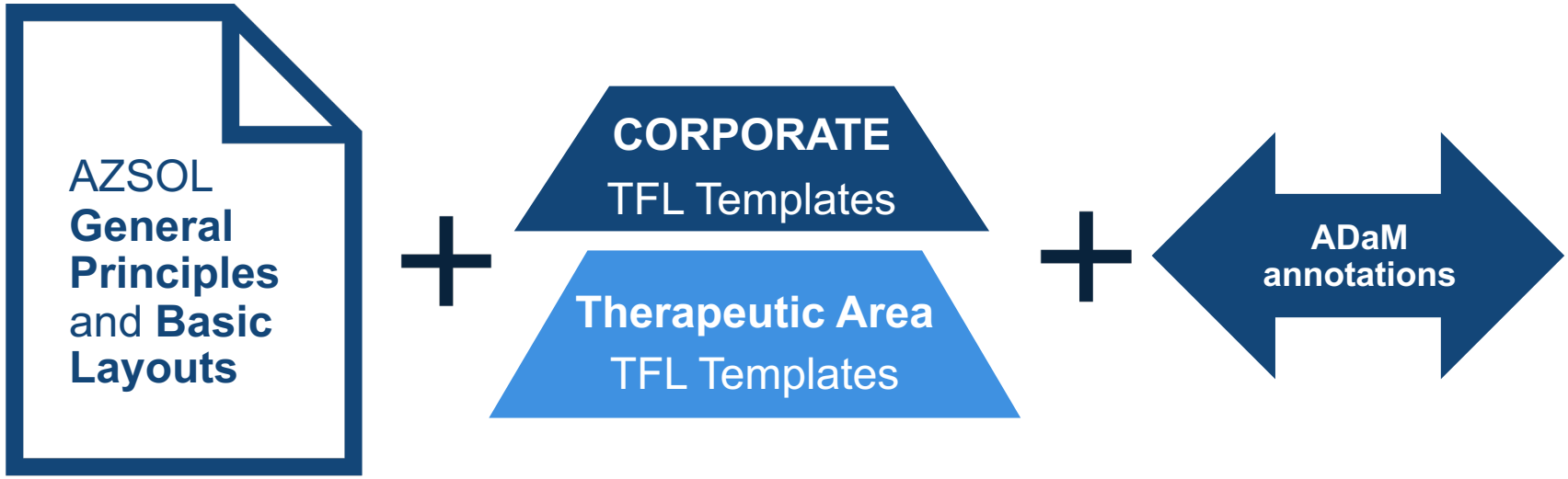
AZSOL Framework and Benefits

Introduction

AZ Standard Output Library (AZSOL) is the AstraZeneca standard for Tables, Figures, and Listings (TFLs).

- AZSOL provides a unified framework for creation of TFLs across Therapeutic Areas.
- AZSOL templates, paired with General Principles and Basic Layouts, ensure a consistent design, structure, and terminology, enhancing efficiency in producing outputs as well as clarity and interpretability of study results, leading to faster submissions to regulatory agencies.
- By integrating AZSOL with automation tools like MOSAIC Biometrics, it allows automatic, instant monitoring of standard adherence at study level through traffic light functionality.

AZSOL Framework



AZSOL General Principles

If an output for a particular data summary is not available in AZSOL library, it is created following a set of predefined **General Principles** and **Basic Layouts.**

Example of AZSOL General Principles

inciple					AZ Standard Output Library	
Principle ID	Library scope	Category	Subcategory	Short description	General principle	Rationale
026	All output	Style	Treatment groups	Order of treatment groups (example available)	Columns in tables are ordered as follows (using the protocol specific labelling for a particular study): AZ Low AZ Medium AZ High AZ Total, if applicable Active Comparator Placebo Overall Total, if applicable For key subject information tables and listings, the page by variable is used to present treatment groups and the same ordering is used. Refer to the notes underneath each listing template for full details.	Nomenclature stresses that order of active treatment groups should be from low dose to high, however, it is still generic enough to account for alternative designs such as crossover.
038	Table	Style	Presentation and alignment of statistics	Order of statistics	If Q1 and Q3 are not presented: n Mean SD Min Median Max. If Q1 and Q3 are presented: n Mean SD Min Q1 Median Q3 Max. Lognormal variable statistics: If Q1 and Q3 are not presented: n GeoMean CV (%) Min Median Max. If Q1 and Q3 are presented: n GeoMean CV (%) Min Q1 Median Q3 Max.	Improves readability. Follows the order that would be seen on a distribution graph.
078	Table	Format	Presentation and alignment of statistics	Presenting CIs	• Without brackets, in a separate column to the estimate. • With a comma to separate values (eg, "xx.x,xx.x"). • Same precision as estimate (see general principle with short description "Precision of estimate").	Consistent approach across AZ projects.

AZSOL Basic Layouts

If an output for a particular data summary is not available in AZSOL library, it is created following a set of predefined **General Principles** and **Basic Layouts.**

007	All output	Library	Customisation	Creating a shell that is not covered by an existing AZ Standard Output Library template	• Only if required as per study/project need or per regulatory requirement. • General principles are to be followed. • Use a basic layout to start (see category='Layout' and subcategory='Basic layouts'). • Please submit a CRYSTAL CR for your prototype based on this basic layout.	For consistency. To align with the technical options in MOSAIC Biometrics.

Table of contents - Basic Layouts

ID	Version	Type	Type of variable	Type of presentation
AZTBL01b	1.0	Categorical variable(s) at 1 timepoint	categorical	1 timepoint
AZTBL01c	1.0	Categorical variable(s) at 1 post-baseline timepoint	categorical	1 post-baseline timepoint
AZTBL01d	1.0	Categorical variable(s) over time	categorical	>1 timepoint
AZTBL02a	1.0	Categorical and continuous variables at 1 timepoint	categorical, continuous	1 timepoint
AZTBL03a	1.0	Continuous variable(s) at 1 timepoint	continuous	1 timepoint
AZTBL03b	1.0	Continuous variable(s) over time	continuous	>1 timepoint
AZTBL03c	1.0	Continuous variable(s) over time	continuous	>1 timepoint
AZTBL04a	1.0	Shift table	categorical	Change from baseline; 1 timepoint
AZTBL04b	1.0	Shift table	categorical	Change from baseline; >1 timpeoint
AZTBL05b	1.0	Cross table	categorical	2 variables; 1 timepoint
AZTBL06a	1.0	Subgroup presentation	categorical	1 timepoint
AZTBL06b	1.0	Subgroup presentation	categorical	1 timepoint

List of Basic Layouts

AZSOL Basic Layouts

Example: AZSOL Basic Layout for Categorical variable(s) over time.

Table 14.x.x.x
<<Table title>> (<<Analysis set>>)

<<Page by values *See note.*>>

		AZD1 <<low dose>> N=xxx n/Nobs (%)	AZD2 <<high dose>> N=xxx n/Nobs (%)	AZ Total N=xxx n/Nobs (%)	Control N=xxx n/Nobs (%)	Total N=xxx n/Nobs (%)
<<Timepoint 1>>						
	<<Category 1>>	x/xxx (x.x)	x/xxx (x.x)	x/xxx (x.x)	xx/xxx (xx.x)	x/xxx (x.x)
	<<Category 2>>	xxx/xxx (xx.x)	xxx/xxx (xx.x)	xxx/xxx (xx.x)	xxx/xxx (xx.x)	xxx/xxx (xx.x)
	<<Category 3>>	0/xxx	0/xxx	0/xxx	0/xxx	0/xxx
<<Timepoint 2>>						
	<<Category 1>>	x/xxx (x.x)	x/xxx (x.x)	x/xxx (x.x)	0/xxx	x/xxx (x.x)
	<<Category 2>>	xxx/xxx (xx.x)	xxx/xxx (xx.x)	xxx/xxx (xx.x)	xxx/xxx (xx.x)	xxx/xxx (xx.x)
	<<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)	xx/xxx (xx.x)	xx/xxx (xx.x)	xx/xxx (xx.x)

<<Footnote.>>
<<Footnote.>>

Note:
<<Any instruction or guidance for this templates can be provided here.>>
Parameter/grouping variable is used as a page-by variable. If applicable, present the AZ preferred reporting unit next to the parameter name in brackets.
The 'Total' column is compulsory if more than 1 treatment group is used for Study population.

AZSOL Templates

AZSOL Templates provide Corporate and Therapeutic Area level layouts for commonly presented analyses.

009	All output	Library	Requiredness of output	Required or optional output	Templates in the library are classified as follows: • Required: Information contained in these outputs is expected based on ICH E3 guidelines (1996). Content has been adapted to reflect current standards and key stakeholder requirements. The accountability for the decision to not include this output is with the study statistician. • Conditional: Reflects a dependency. If the dependency is met, the output should be treated as required (described above). Details related to the dependency are included in the table notes. • Optional: As per study/project/agency requirement. Information about requiredness is presented: • Excel: in the table of contents tab of each domain, next to template title, • MOSAIC Biometrics: in the 'Additional information' field in template properties area (this is being updated on an ongoing basis).	• Ensures a core set of output that has not to be customised. • Establishes an AZ approach.

AZSOL Templates

AZSOL Templates provide Corporate and Therapeutic Area level layouts for commonly presented analyses.

Table 14.3.2.x
Overall summary of adverse events - subject count <<- Period>> (Safety set)

<<Page by values>>

	AZD1 <<low dose>> N=xxx n (%)	AZD2 <<high dose>> N=xxx n (%)	AZ Total N=xxx n (%)	Control N=xxx n (%)
Any AE	xxx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Any SAE	x (x.x)	xx (xx.x)	x (x.x)	x (x.x)
Any SAE with outcome death	x (x.x)	xx (xx.x)	x (x.x)	x (x.x)
Any AE leading to discontinuation of IP	x (x.x)	0	x (x.x)	x (x.x)
Any possibly related AE [a]	x (x.x)	x (x.x)	x (x.x)	x (x.x)
Any possibly related SAE [a]	x (x.x)	x (x.x)	x (x.x)	x (x.x)
Any AE leading to IP dose reduction	x (x.x)	x (x.x)	x (x.x)	x (x.x)

[a] Possibly related is defined as reasonable possibility that the AE was caused by investigational product, as assessed by investigator. Conditional footnote.
<<Period: >>The table includes adverse events with an onset date on or after the date of first dose of IP up to and including << xx days following>> the date of last IP dose.
If period is not used in the title, remove <<Period:>> but keep the footnote to explain what is covered in this table. If period is used, please refer to the options for period.
Subjects with multiple occurrences in the same category are counted once per category regardless of the number of occurrences.
IP Investigational product; n Number of subjects per category; N Number of subjects per treatment group.

ADaM Dataset:
ADAE where SAFFL = 'Y' { and TRTEMFL = 'Y' and APERIODC }
ADSL - { TRTxxA/TRTxxAN } for calculation of N

{ ADSL.TRTxxA }

AAE001FL = 'Y'
AAE003FL = 'Y'
AAE003FL = 'Y' and AAE004FL = 'Y'
AAE005FL = 'Y'
AAE016FL = 'Y'
AAE016FL = 'Y' and AAE003FL='Y'
AAE014FL = 'Y'

Note:
If any of optional categories is presented, a respective table is required that shows the AE type by SOC and PT. Templates are provided in this document.

Annotation note:
All variables from ADAE unless anything else is stated
This table may be repeated per treatment period or other page by variable
Treatment group to be defined as in SAP, normally actual treatment for safety tables
APERIODC may be replaced by other time period variables per study needs, TRTxxA may be replaced by e.g. ACTARM, TRTEMFL may be replaced by TREMzzFL per treatment period
AOCCFL must be set such that it flags all categories in the table, i.e. there will be multiple observations where AOCCFL="Y"

ADaM Annotations

ADaM Annotations provide E2E traceability of standards and support for programmers.

Table 14.3.2.x
Overall summary of adverse events – subject count <<- Period>> (Safety set)

<<Page by values>>

	AZD1 <<low dose>> N=xxx		AZD2 <<high dose>> N=xxx		AZ Total N=xxx		Control N=xxx	
	n	(%)	n	(%)	n	(%)	n	(%)
Any AE	xxx	(xx.x)	xx	(xx.x)	xx	(xx.x)	xx	(xx.x)
Any SAE	x	(x.x)	xx	(xx.x)	x	(x.x)	x	(x.x)
Any SAE with outcome death	x	(x.x)	xx	(xx.x)	x	(x.x)	x	(x.x)
Any AE leading to discontinuation of IP	x	(x.x)	0		x	(x.x)	x	(x.x)
Any possibly related AE [a]	x	(x.x)	x	(x.x)	x	(x.x)	x	(x.x)
Any possibly related SAE [a]	x	(x.x)	x	(x.x)	x	(x.x)	x	(x.x)
Any AE leading to IP dose reduction	x	(x.x)	x	(x.x)	x	(x.x)	x	(x.x)

[a] Possibly related is defined as reasonable possibility that the AE was caused by investigational product, as assessed by investigator. Conditional footnote.
<<Period: >>The table includes adverse events with an onset date on or after the date of first dose of IP up to and including << xx days following>> the date of last IP dose.
If period is not used in the title, remove <<Period:>> but keep the footnote to explain what is covered in this table. If period is used, please refer to the options for period.
Subjects with multiple occurrences in the same category are counted once per category regardless of the number of occurrences.
IP Investigational product; n Number of subjects per category; N Number of subjects per treatment group.

ADaM Dataset:
ADAE where SAFFL = 'Y' { and TRTEMFL = 'Y' and APERIODC }
ADSL - { TRTxxA/TRTxxAN } for calculation of N

{ ADSL.TRTxxA }

AAE001FL = 'Y'
AAE003FL = 'Y'
AAE003FL = 'Y' and AAE004FL = 'Y'
AAE005FL = 'Y'
AAE016FL = 'Y'
AAE016FL = 'Y' and AAE003FL='Y'
AAE014FL = 'Y'

Note:
If any of optional categories is presented, a respective table is required that shows the AE type by SOC and PT. Templates are provided in this document.

Annotation note:
All variables from ADAE unless anything else is stated
This table may be repeated per treatment period or other page by variable
Treatment group to be defined as in SAP, normally actual treatment for safety tables
APERIODC may be replaced by other time period variables per study needs, TRTxxA may be replaced by e.g. ACTARM, TRTEMFL may be replaced by TREMzzFL per treatment period
AOCCFL must be set such that it flags all categories in the table, i.e. there will be multiple observations where AOCCFL="Y"

Example of AZSOL template – Demographics

Table 14.1.x
Demographics (Full analysis set)
Subjects with confirmed or suspected COVID-19 *Subtitle for Oncology use, only if applicable.*
<<Page by values>>

	Statistic	AZD1 <<low dose>> N=xxx	AZD2 <<high dose>> N=xxx	AZ Total N=xxx	Control N=xxx	Total N=xxx	ADaM Dataset: ADSL where FASFL = "Y"
							CSCOVFL='Y'
Age (<<unit>>)							{ AAGE (AAGEU) }
	n	xxx	xxx	xxx	xxx	xxx	
	Mean	xx.x	xx.x	xx.x	xx.x	xx.x	
	SD	xx.x	xx.x	xx.x	xx.x	xx.x	
	Min	xx	xx	xx	xx	xx	
	Q1 *See note.*	x.x	x.x	x.x	x.x	x.x	
	Median	xx.x	xx.x	xx.x	xx.x	xx.x	
	Q3 *See note.*	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x	
	Max	xxx	xxx	xxx	xxx	xxx	
Age group (<<unit>>)							
<<Category1>>	n (%)	xxx (xx.x)	0	xx (xx.x)	xxx (xx.x)	xxx (xx.x)	AGEGRy/AGEGRyN (AGEU)
<<Category2>>	n (%)	x (x.x)	xxx (100)	xxx (xx.x)	x (x.x)	x (x.x)	
<<Category3>>	n (%)	x (x.x)	0	xxx (xx.x)	x (x.x)	x (x.x)	
<<…>>	n (%)	x (x.x)	0	xxx (xx.x)	x (x.x)	x (x.x)	
Missing	n (%)	x (x.x)	0	x (x.x)	x (x.x)	x (x.x)	
Age group 2 (<<unit>>)							
<<Category1>>	n (%)	xxx (xx.x)	0	xx (xx.x)	xxx (xx.x)	xxx (xx.x)	AGEGRy/AGEGRyN (AGEU)
<<Category2>>	n (%)	x (x.x)	xxx (100)	xxx (xx.x)	x (x.x)	x (x.x)	
<<Category3>>	n (%)	x (x.x)	0	xxx (xx.x)	x (x.x)	x (x.x)	
<<…>>	n (%)	x (x.x)	0	xxx (xx.x)	x (x.x)	x (x.x)	
Missing	n (%)	x (x.x)	0	x (x.x)	x (x.x)	x (x.x)	
Sex							
Female	n (%)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	{ ASEX/ASEXN }
Male	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	
Missing	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	
Ethnicity							
Hispanic or Latino	n (%)	xxx (xx.x)	0	xx (xx.x)	xxx (xx.x)	xxx (xx.x)	{ AETHNIC/AETHNICN }
Not Hispanic or Latino	n (%)	x (x.x)	xxx (100)	xxx (xx.x)	x (x.x)	x (x.x)	
Missing	n (%)	x (x.x)	0	x (x.x)	x (x.x)	x (x.x)	
Race							
American Indian or Alaska Native	n (%)	xxx (xx.x)	xxx (xx.x)	xx (xx.x)	xxx (xx.x)	xxx (xx.x)	{ ARACE }
Asian	n (%)	x (x.x)	xx (x.x)	xxx (xx.x)	x (x.x)	x (x.x)	

Key subj info (guidance) | Anti-drug Antibody | Anti-drug Antibody (guidance) | Basic Layouts | AZTSP01 | AZTSP02 | AZTSP03 | AZTSP04 | AZTSP05 | AZTSP06 | AZTSP07 | AZTSP08

Example of AZSOL template – Baseline characteristics

Table 14.1.x

Baseline characteristics (Full analysis set)

Subjects with confirmed or suspected COVID-19 *Subtitle for Oncology use, only if applicable.*

<<Page by values>>

	Statistic	AZD1 <<low dose>> N=xxx	AZD2 <<high dose>> N=xxx	AZ Total N=xxx	Control N=xxx	Total N=xxx
Height (cm)						
	n	xxx	xxx	xxx	xxx	xxx
	Mean	xx.x	xx.x	xx.x	xx.x	xx.x
	SD	x.x	x.x	x.x	x.x	x.x
	Min	x.x	x.x	x.x	x.x	x.x
	Median	xx.x	xx.x	xx.x	xx.x	xx.x
	Max	xxx	xxx	xxx	xxx	xxx
Weight (kg)						
	n	xxx	xxx	xxx	xxx	xxx
	Mean	xx.x	xx.x	xx.x	xx.x	xx.x
	SD	x.x	x.x	x.x	x.x	x.x
	Min	x.x	x.x	x.x	x.x	x.x
	Median	xx.x	xx.x	xx.x	xx.x	xx.x
	Max	xxx	xxx	xxx	xxx	xxx
Weight group (kg)						
<<Category1>>	n (%)	xxx (xx.x)	0	xx (xx.x)	xx (xx.x)	xx (xx.x)
<<Category2>>	n (%)	x (x.x)	xxx (100)	xxx (100)	xxx (xx.x)	xxx (100)
<<Category3>>	n (%)	x (x.x)	xxx (100)	xxx (100)	xxx (xx.x)	xxx (100)
<<…>>	n (%)	x (x.x)	x (x.x)	x (x.x)	x (x.x)	x (x.x)
Missing	n (%)	x (x.x)	0	x (x.x)	x (x.x)	x (x.x)
BMI (kg/m2)						
	n	xxx	xxx	xxx	xxx	xxx
	Mean	xx.x	xx.x	xx.x	xx.x	xx.x
	SD	x.x	x.x	x.x	x.x	x.x
	Min	x.x	x.x	x.x	x.x	x.x

ADaM Dataset:
ADSL where FASFL = "Y"

CSCOVFL='Y'

{ TRTxxP/TRTxxPN }

HEIGHTBL

WEIGHTBL

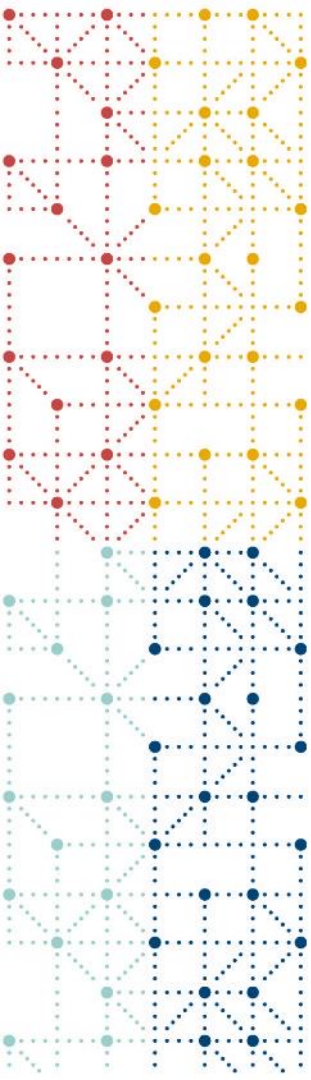
WGHTBLGy/WGHBLGyN

BMIBL

Key subj info (guidance) | Anti-drug Antibody | Anti-drug Antibody (guidance) | Basic Layouts | AZTSP01 | AZTSP02 | AZTSP03 | AZTSP04 | AZTSP05 | AZTSP06 | AZTSP07 | AZTSP08 | AZTSP09

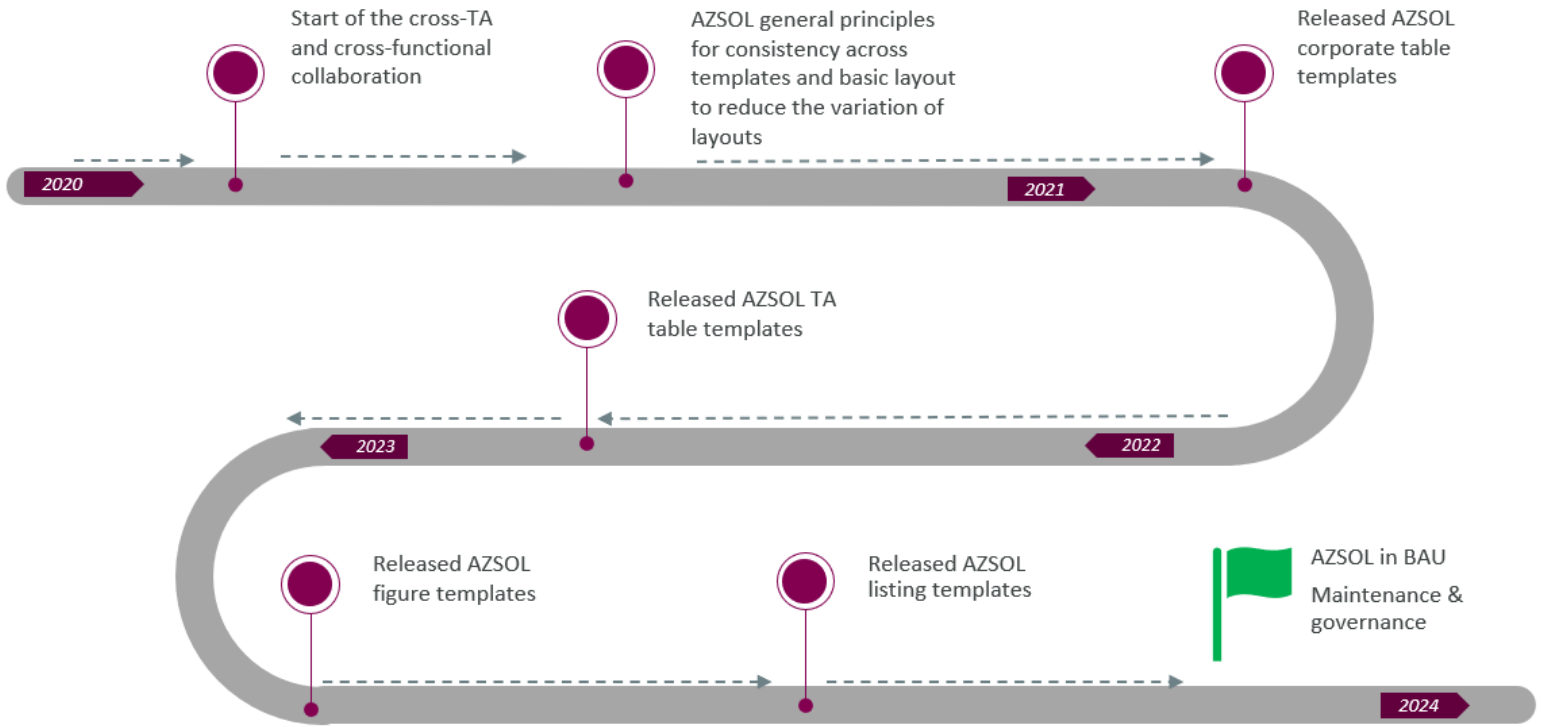
Benefits of AZSOL

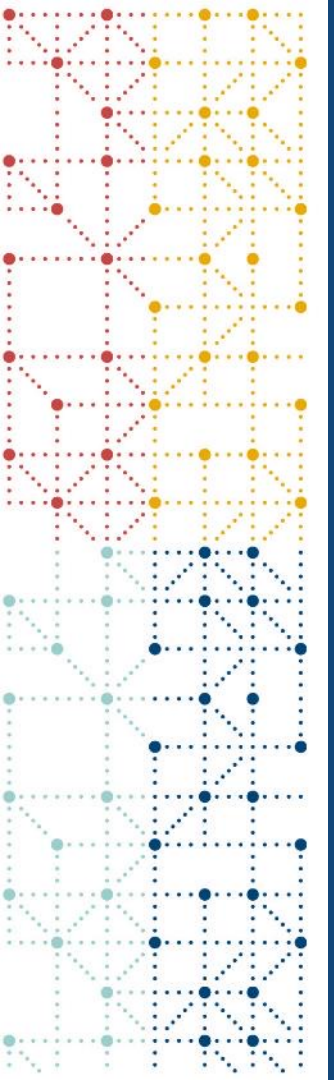
- ✓Reduction of layout variation
- ✓Enhanced data analysis and interpretation
- ✓Streamlined preparation of regulatory submissions
- ✓Efficient data review
- ✓Seamless integration of automation tools
- ✓E2E traceability



AZSOL Journey

AZSOL Journey





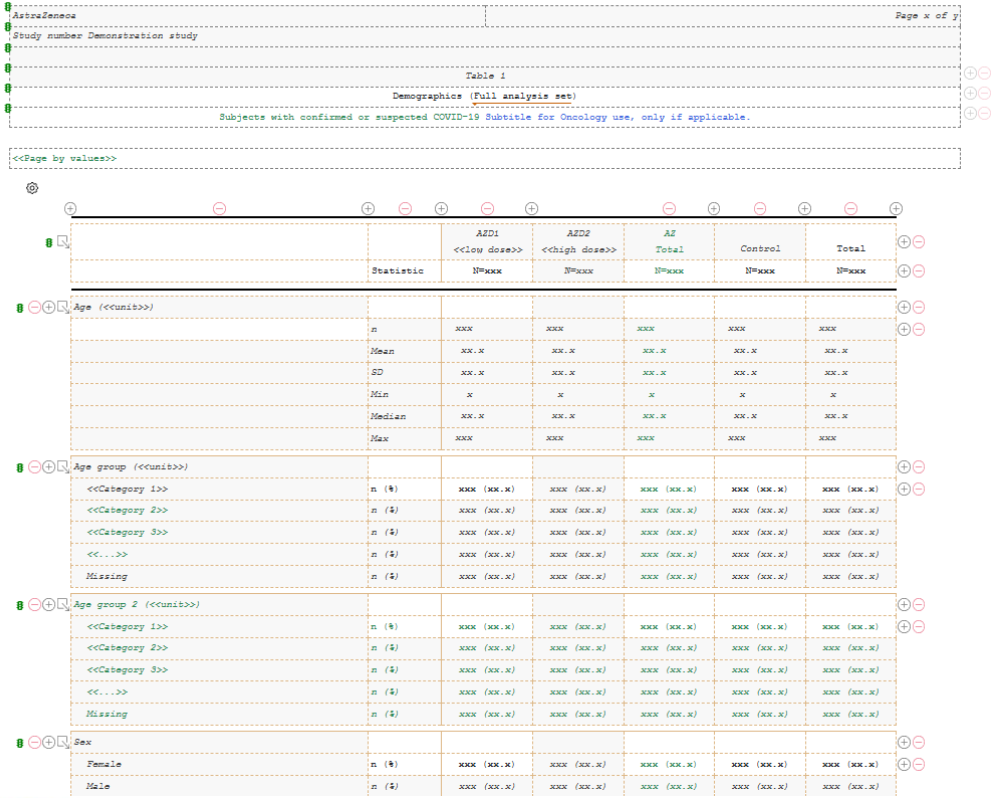
Using AZSOL in MOSAIC Biometrics

Using AZSOL in MOSAIC Biometrics

AZSOL Templates and AZSOL Basic Layouts are maintained and utilized within an automation tool developed by AstraZeneca (MOSAIC Biometrics).

- Efficient TFL shell creation based on AZSOL templates
- Facilitating automation
- Improving consistency with AZ standards
- Continuous implementation of new MOSAIC Biometrics functionalities
- Audit trail and Power BI dashboards for metrics
- Monitoring of standard adherence on study level

Using AZSOL in MOSAIC Biometrics



AstraZeneca — Page x of y

Study number Demonstration study

Table 1

Demographics (Full analysis set)

Subjects with confirmed or suspected COVID-19 Subtitle for Oncology use, only if applicable.

<<Page by values>>

	Statistic	AZD1 <<low dose>> N=xxx	AZD2 <<high dose>> N=xxx	AZ Total N=xxx	Control N=xxx	Total N=xxx
Age (<<unit>>)						
	n	xxx	xxx	xxx	xxx	xxx
	Mean	xx.x	xx.x	xx.x	xx.x	xx.x
	SD	xx.x	xx.x	xx.x	xx.x	xx.x
	Min	x	x	x	x	x
	Median	xx.x	xx.x	xx.x	xx.x	xx.x
	Max	xxx	xxx	xxx	xxx	xxx
Age group (<<unit>>)						
<<Category 1>>	n (%)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
<<Category 2>>	n (%)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
<<Category 3>>	n (%)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
<<...>>	n (%)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
Missing	n (%)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
Age group 2 (<<unit>>)						
<<Category 1>>	n (%)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
<<Category 2>>	n (%)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
<<Category 3>>	n (%)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
<<...>>	n (%)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
Missing	n (%)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
Sex						
Female	n (%)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
Male	n (%)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)

Example of AZSOL Template in MOSAIC Biometrics

Using AZSOL in MOSAIC Biometrics

Monitoring of standard adherence on study level:

- Source Traffic Light

Blue – TLF shell created basing on existing AZSOL template

Magenta – TLF shell created basing on existing AZSOL basic layout (change request is required)

Purple – TLF shell created from scratch (change request is required)

- Standards Adherence Traffic Light

Green – TLF shell created basing on AZSOL template is compliant with AZSOL template and/or AZSOL General Principles

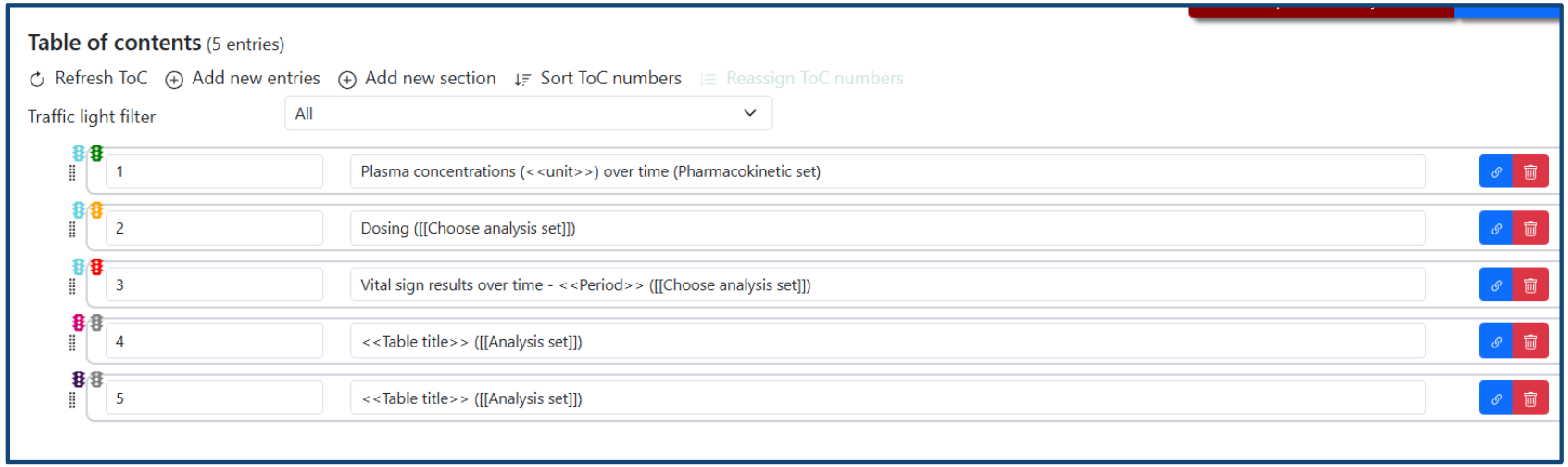
Red – TLF shell created basing on AZSOL template deviates from AZSOL template and/or AZSOL General Principles (change request is required)

Orange – an action is required (choose option from drop down list)

Using AZSOL in MOSAIC Biometrics

Monitoring of standard adherence on study level:

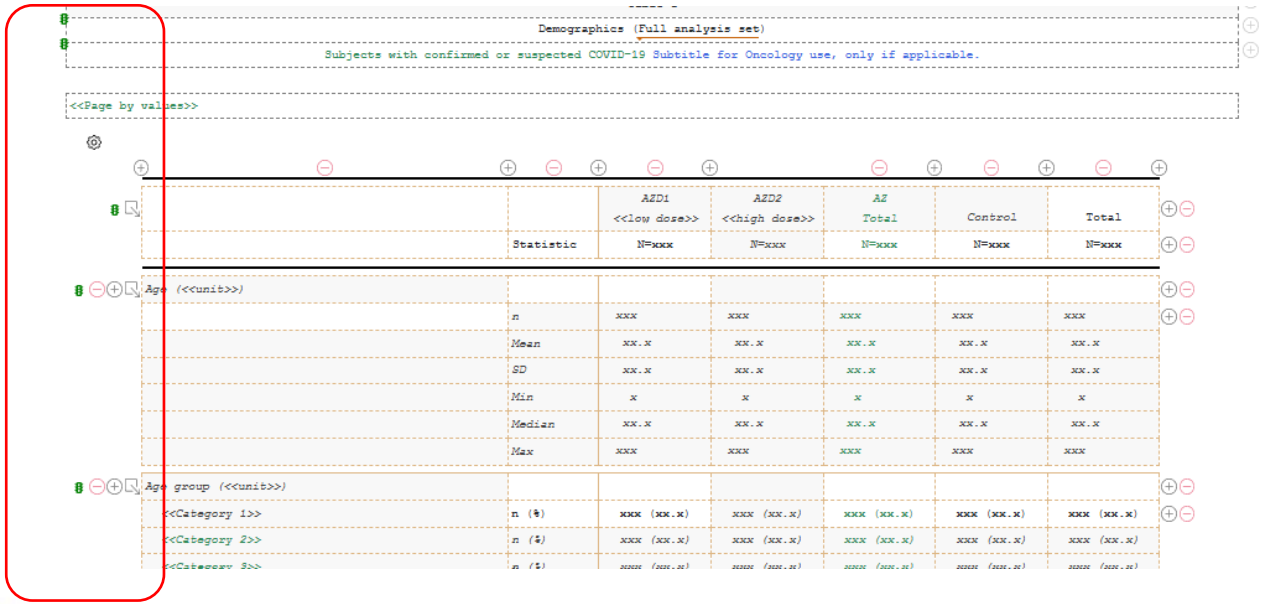
Example:



Using AZSOL in MOSAIC Biometrics

Monitoring of standard adherence on study level:

Individual traffic lights in the TLF shell:

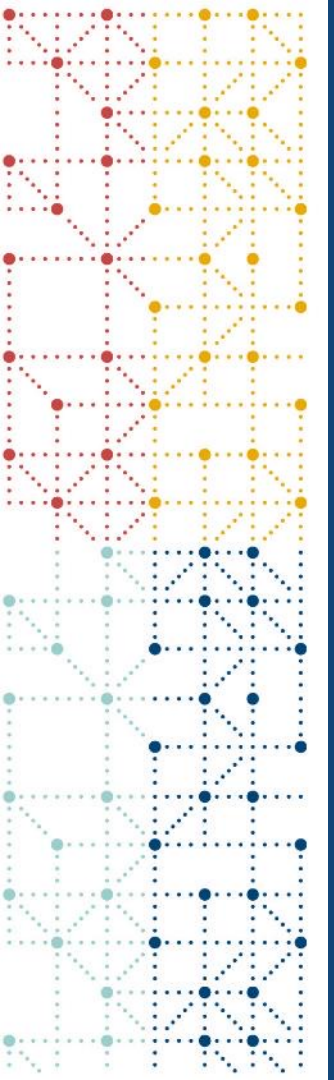


Demographics (Full analysis set)

Subjects with confirmed or suspected COVID-19 Subtitle for Oncology use, only if applicable.

<<Page by values>>

		AZD1 <<low dose>>	AZD2 <<high dose>>	AZ Total	Control	Total
	Statistic	N=xxx	N=xxx	N=xxx	N=xxx	N=xxx
Age (<<unit>>)						
	n	xxx	xxx	xxx	xxx	xxx
	Mean	xx.x	xx.x	xx.x	xx.x	xx.x
	SD	xx.x	xx.x	xx.x	xx.x	xx.x
	Min	x	x	x	x	x
	Median	xx.x	xx.x	xx.x	xx.x	xx.x
	Max	xxx	xxx	xxx	xxx	xxx
Age group (<<unit>>)						
<<Category 1>>	n (%)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
<<Category 2>>	n (%)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
<<Category 3>>	n (%)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)



E2E Mindset is a Key to Standardization

End-to-End Standardization

AZSOL team is part of Clinical Data Standards (CDS) group at AstraZeneca that is also responsible for Data Collection Standards, SDTM and ADaM standards.

- Supporting an end-to-end data flow standardization across the organization and an interconnected approach to data standards
- Easier standards governance process, end-to-end impact review for each update in any component of Clinical Data Standards
- ADaM annotations in AZSOL library are developed and maintained by ADaM experts within CDS group

End-to-End Standardization

Example: With each update in Data Collection Standards the E2E impact is assessed (impact on AZSOL, SDTM, ADaM).

Table 14.1.x
Important protocol deviations (<<Analysis set>>)

<<Page by values>>

	AZD1 <<low dose>> N=xxx		AZD2 <<high dose>> N=xxx		AZ Total N=xxx		Control N=xxx		Total N=xxx	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Subjects with at least one important protocol deviation	xx	(xx.x)	xx	(xx.x)	xx	(xx.x)	xx	(xx.x)	xx	(xx.x)
Inclusion criteria	xx	(xx.x)	xx	(xx.x)	x	(x.x)	x	(x.x)	x	(x.x)
Exclusion criteria		0		0	x	(x.x)	x	(x.x)	x	(x.x)
Discontinuation criteria for study product met but subject not withdrawn from study treatment	xx	(xx.x)	xx	(xx.x)	x	(x.x)	x	(x.x)	x	(x.x)
Discontinuation criteria for overall study withdrawal met but subject not withdrawn from study	xx	(xx.x)	xx	(xx.x)	x	(x.x)	x	(x.x)	x	(x.x)
Investigational product deviation	xx	(xx.x)	xx	(xx.x)	x	(x.x)	x	(x.x)	x	(x.x)
Excluded medication taken	xx	(xx.x)	xx	(xx.x)	x	(x.x)	x	(x.x)	x	(x.x)
Deviations related to study procedure	xx	(xx.x)	xx	(xx.x)	x	(x.x)	x	(x.x)	x	(x.x)
Other important protocol deviations	xx	(xx.x)	xx	(xx.x)	x	(x.x)	x	(x.x)	x	(x.x)

ADaM Dataset:
ADPRODEV where IPDFL = "Y" and { ENRLFL = "Y" }

{ TRTxxP/TRTxxPN }

IPDFL = "Y"

{ ACAT1/ACAT1N }

End-to-End Standardization

Example: With each update in Data Collection Standards the E2E impact is assessed (impact on AZSOL, SDTM, ADaM).

Subcategories are described in Data Collection Standards instructions

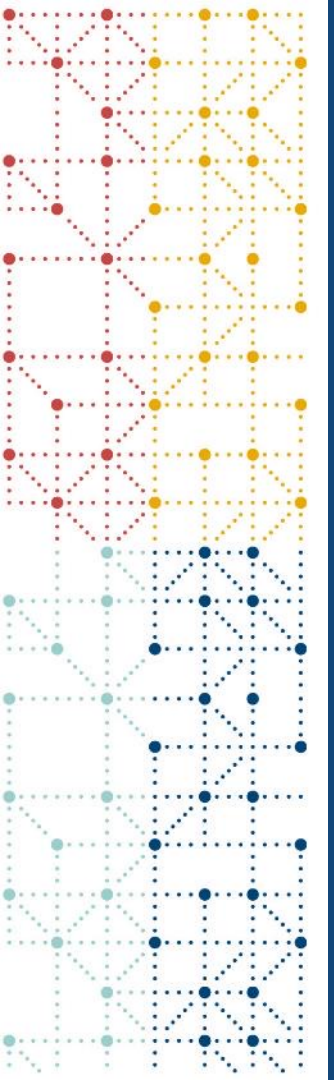
Table 14.1.x
ortant protocol deviations (<<Analysis set>>)

A									
<low									
N=									
n									
xx									
Subjects with at least one important protocol deviation	xx	(xx.x)	xx	(xx.x)	x	(x.x)	x	(x.x)	x	(x.x)
Inclusion criteria		0		0	x	(x.x)	x	(x.x)	x	(x.x)
Exclusion criteria	xx	(xx.x)	xx	(xx.x)	x	(x.x)	x	(x.x)	x	(x.x)
Discontinuation criteria for study product met but subject not withdrawn from study treatment	xx	(xx.x)	xx	(xx.x)	x	(x.x)	x	(x.x)	x	(x.x)
Discontinuation criteria for overall study withdrawal met but subject not withdrawn from study	xx	(xx.x)	xx	(xx.x)	x	(x.x)	x	(x.x)	x	(x.x)
Investigational product deviation	xx	(xx.x)	xx	(xx.x)	x	(x.x)	x	(x.x)	x	(x.x)
Excluded medication taken	xx	(xx.x)	xx	(xx.x)	x	(x.x)	x	(x.x)	x	(x.x)
Deviations related to study procedure	xx	(xx.x)	xx	(xx.x)	x	(x.x)	x	(x.x)	x	(x.x)
Other important protocol deviations	xx	(xx.x)	xx	(xx.x)	x	(x.x)	x	(x.x)	x	(x.x)

DVSCAT ***Subcategory for Protocol Deviation***	For Important Protocol Deviations (DVCAT=Important) possible valid values for sub-categories are following: Inclusion criteria deviations, Exclusion criteria deviations, Discontinuation Criteria for study product met but patient not withdrawn from study treatment, Discontinuation Criteria for overall study withdrawal met but patient not withdrawn from study, Investigational Product Deviation, Excluded medications taken, Deviations related to study procedure, Other Important Protocol Deviations

ADaM Dataset:
ADPRODEV where IPDFL = "Y" and { ENRLFL = "Y" }

{ ACAT1/ACAT1N }



Future Directions

Future Directions

AZSOL and MOSAIC Biometrics enables future end-to-end automations for the TFL delivery within Analysis and Reporting, utilizing the TFL shells, ADaM annotations and machine-readable metadata to create code aligned with standardized templates and generate ADaM specifications.

Thank You!