AS 16- Statistical Programming Methods for Evaluating the Impact of Immunogenicity on Safety and Efficacy Outcomes

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Better Health, Brighter Future

Agenda

- Introduction
- Immunogenicity Data Sources and Structure
- Flow of the Immunogenicity Data
- ADaM framework for Immunogenicity
- Immunogenicity Impact on Safety, PK and Efficacy analysis
- Example TLFs
- Conclusion

Introduction

Immunogenicity is the immune system’s response to biologic therapies. This response may result in ADA and NAb

ADA and NAb may impact

Safety

Pharmacokinetics

Efficacy

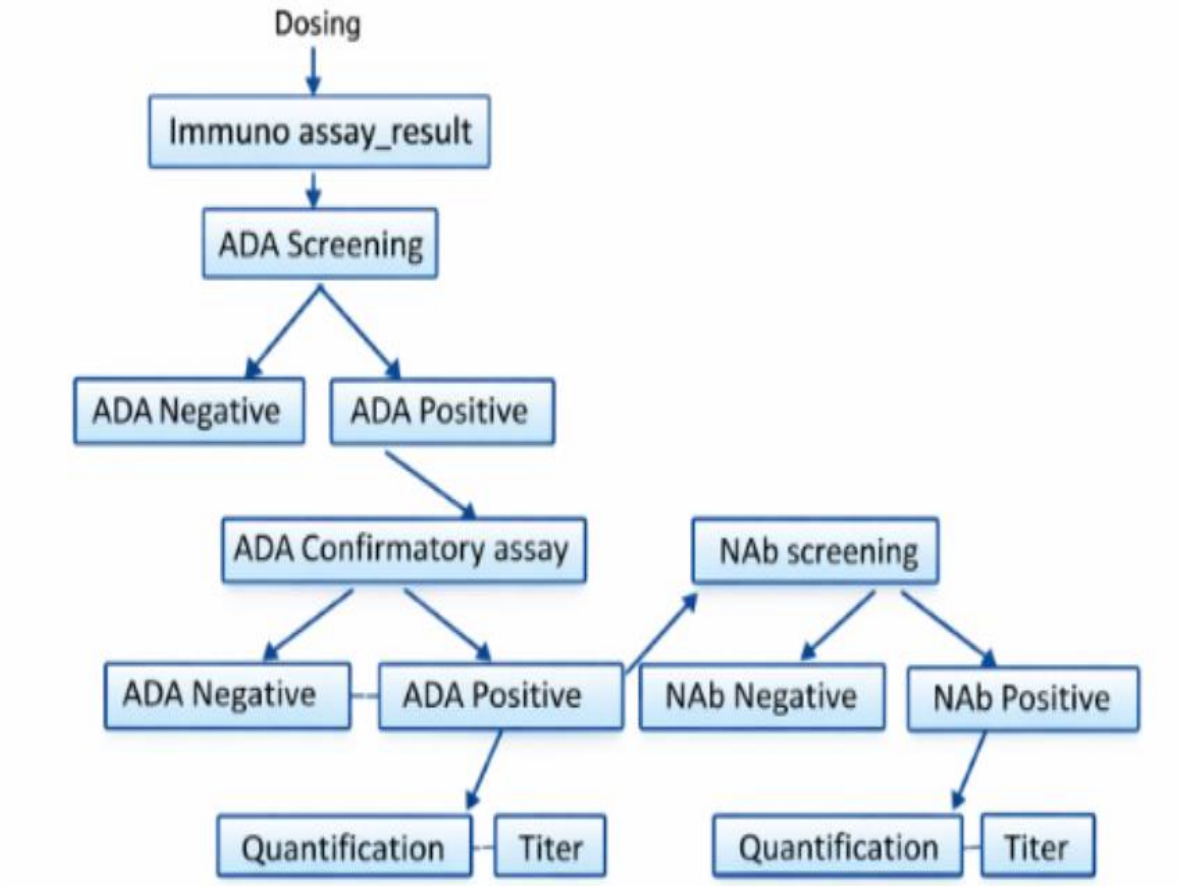
Anti-drug antibodies (ADA) are the antibodies produced against the drug; these antibodies can interfere with the drug's effectiveness by reducing its efficacy or causing adverse reactions.

Neutralizing antibodies (NAb)- The produced ADAs which can directly bind to a target and potentially impacting the pharmacologic activity of the drug.

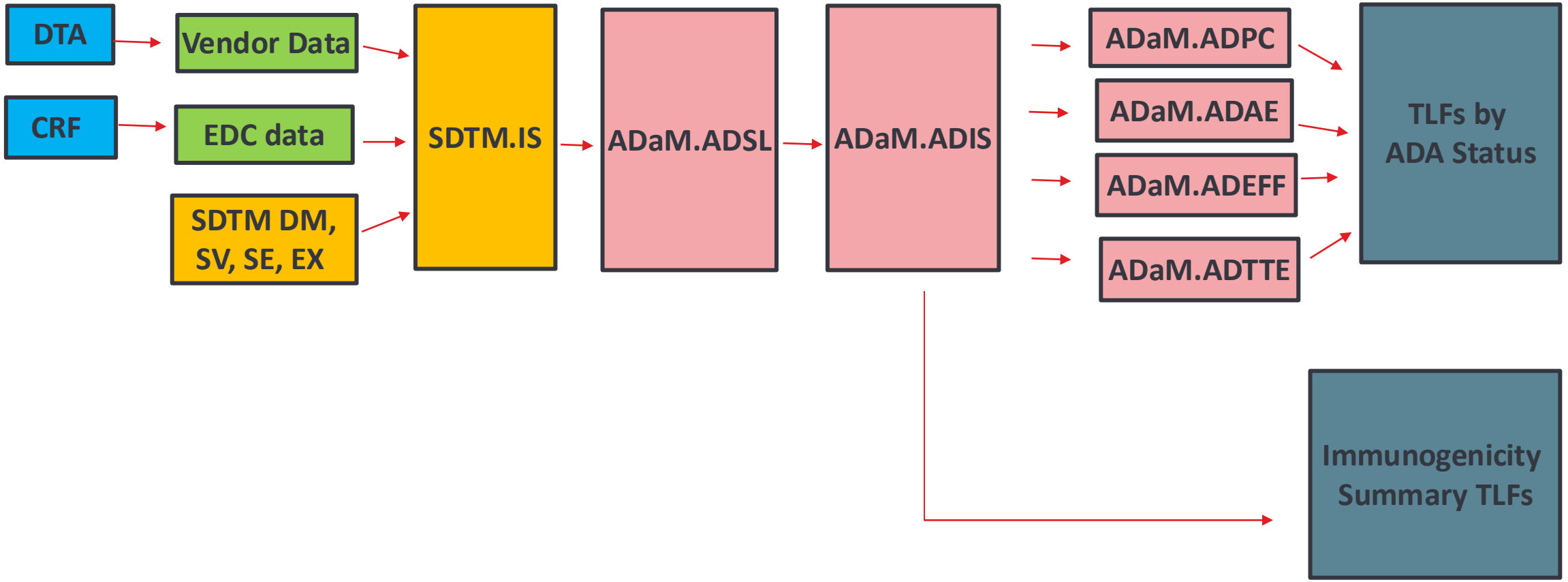
Regulatory guidance recommends systematic assessment of immunogenicity and its potential clinical impact without assuming causality.

Immunogenicity Data Sources and Structure

- Immunogenicity data results are typically generated from bioanalytical assays.
- These assays commonly include a multi-tiered testing strategy consisting of screening assays to identify potential anti-drug antibody (ADA) responses, confirmatory assays to verify specificity, titer and neutralizing antibody (NAb) assays for the ADA positive samples.
- Immunogenicity data from EDC and central laboratory vendor sources were integrated and mapped to the SDTM IS dataset.
- EDC data serves as the primary source for subject identifiers, specimen collection details, visit name and number, collection date/time.
- Vendor laboratory data provides analytical results from anti-drug antibody (ADA) and neutralizing antibody (NAb) assays, including screening, confirmatory, titer, and quantitative assessments.



The Flow of the Immunogenicity data



ADaM Framework

ADSL

- The Subject-Level Analysis Dataset (ADSL) serves as the foundational dataset for ADaM analyses.

- For immunogenicity assessments, ADSL is extended to include derived population flags that identify subjects with evaluable anti-drug antibody (ADA) and neutralizing antibody (NAb) data which can be used across downstream ADaM datasets.

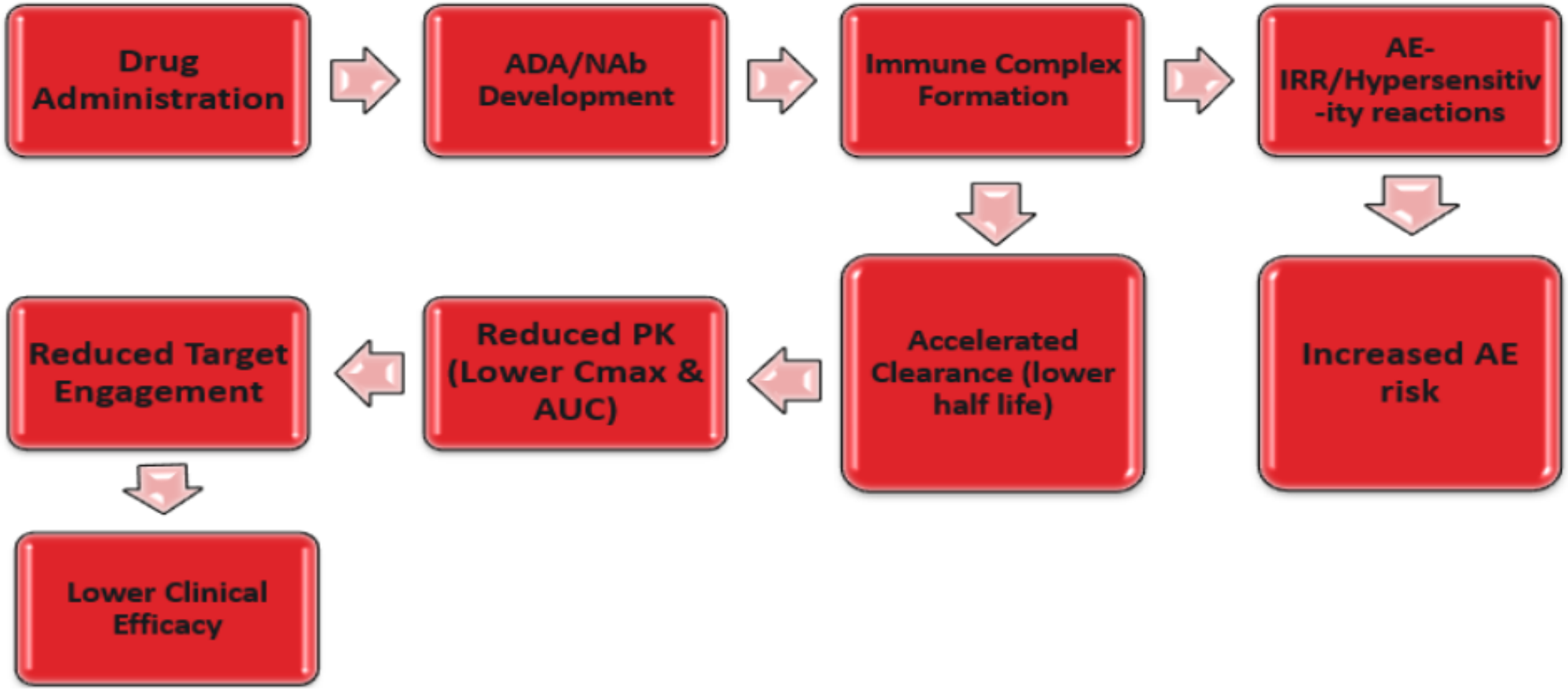
- Several immunogenicity-specific population flags are derived in ADSL to ensure consistent subject inclusion across downstream ADaM datasets
  - The Immunogenicity population flag: defined as the subjects who received at least one dose of the study drug and have at least one post-baseline Immunogenicity assessment.
  - Immunogenicity PK-Evaluable population flag: derived as subjects who received at least one dose of the study drug and have at least one post-baseline Immunogenicity assessment and sufficient PK data to reliably report 1 or more PK parameters.
  - Immunogenicity Efficacy population flag: derived as subjects who received at least one dose of the study drug and have at least one post-baseline Immunogenicity assessment and post-baseline efficacy assessment.

Analysis Dataset for Immunogenicity (ADIS)

- ADIS is an ADaM Basic Data Structure (BDS) dataset with one record per subject per parameter per analysis time point structure.
- Supports longitudinal analysis of immunogenicity endpoints, including ADA and NAb responses.
- Uses a PARAM/PARAMCD-driven structure to represent derived immunogenicity parameters such as overall ADA status, treatment-emergent ADA status.
- The dataset is designed to support descriptive summaries of immunogenicity incidence and prevalence, time-based evaluations of antibody development, and integration with safety, pharmacokinetic, and efficacy analyses.

PARAMCD	PARAM	Derivation Logic
ADASTAT	ADA Status	Subject level ADA Status, Derived as 'Negative' for subjects with pre-existing ADA or subjects with Negative results at baseline and post-baseline. Derived as 'Positive' for subjects with Treatment Emergent or Treatment Boosted ADA.
NEUTSTAT	Neutralizing Status	Subject level NAb Status, Derived as 'Negative' for subjects with Negative results at baseline and post-baseline. Derived as 'Positive' for subjects with at least 1 Positive results at post-baseline.
ADAPRE	Pre-Existing ADA	Subjects with ADA positive at baseline and all the post-baseline positive sample titer values are <= x-fold increase from baseline titer values.
ADATRTEM	Treatment emergent ADA	Subjects with ADA negative at baseline and with at least one post-baseline positive ADA
ADATRTBS	Treatment-boosted ADA	Subjects with ADA positive at baseline and any of the post-baseline positive sample titer values are > y-fold increase from baseline titer values.
ADAPRST	Persistent ADA	Treatment emergent ADA subjects with at least 2 consecutive positive post-baseline samples separated by at least a y-week period with no ADA negative results in between
ADAINDT	Indeterminate ADA	Treatment-induced ADA subjects with positive result at last post-baseline visit only
ADATRNS	Transient ADA	Treatment-induced ADA subjects who do not satisfy the conditions for Persistent or Indeterminate ADA
ADATONS	Time to onset of 1st ADA	The time between 1st dose date and first instance of treatment-induced ADA
ADAPDUR	Duration of Positive ADA	The time between 2 positive post-baseline ADA samples with no ADA negative results in between.
ADAMXTIT	Maximum Titer	Maximum Titer value observed for the post-baseline Positive ADA Samples
ADAMXTIC	Maximum Titer Categories	Categories are based on the maximum post baseline titer value 0-<1000 1000-<=10000 >10000

Analysis of Impact



ADA Impact on Safety

- Immunogenicity has the potential to influence the safety profile of biologic therapies through immune-mediated mechanisms or indirect effects on drug exposure.

- While the presence of ADA does not imply increased safety risk, certain antibody characteristics such as treatment-emergent status, high titers, or neutralizing capacity may need further evaluation.

Immunogenicity impact on Adverse Events

- Guidance from the FDA and EMA notes that the development of ADA may be associated with immune-mediated adverse events, including hypersensitivity reactions, infusion-related reactions, and other immune-related safety signals.

- To meet these regulatory expectations, there is a need for the integration of the Immunogenicity with AE data.

- Analyses typically compare incidence, severity, and seriousness of treatment-emergent adverse events between ADA-positive and ADA-negative subjects.

- Explore whether adverse events occur predominantly before or after confirmed ADA positivity.

- Ensure traceability from raw data through SDTM and ADaM to final safety outputs.

ADA Impact on Safety (Contd.,)

- Subjects can have multiple confirmed ADA-positive assessments over time as well as multiple adverse events
- To Integrate, the traditional DATA step merge may not be appropriate due to many-to-many relationships
- Integration must be implemented as a controlled Cartesian join using PROC SQL, with explicit join conditions based on subject identifiers and timing variables to ensure correct record pairing and traceability.

Below is the table summarizing the additional variables that can be derived in ADAE in the context of immunogenicity.

Variable Name	Variable Label	Type	Derivation
IRRFL	Infusion Related Reaction Flag	Char	Derived from SuppAE.QVAL where QNAM=IRRFL
HYPSFL	Hypersensitivity Reaction Flag	Char	Derived from SuppAE.QVAL where QNAM=IRRFL
ADASTAT	ADA Status	Char	Derived from ADIS.AVALC when ADIS.PARAMCD=ADASTAT
ADAMXTIT	ADA Maximum Titer Value	Integer	Derived from ADIS.AVALC when ADIS.PARAMCD=ADAMXTIT
NABSTAT	NAb Status	Char	Derived from ADIS.AVALC when ADIS.PARAMCD=NABSTAT
NABMXTIT	NAb Maximum Titer Value	Integer	Derived from ADIS.AVALC when ADIS.PARAMCD=NABMXTIT
ADATRTEM	Treatment-Emergent ADA Flag	Char	Derived from ADIS.AVALC when ADIS.PARAMCD=ADATRTEM
ADATONS	Time to onset of 1st ADA	Integer	Derived from ADIS.AVALC when ADIS.PARAMCD=ADATONS
AETIMREL	AE Timing Relative to ADA	Char	If analysis is based on the first confirmed ADA-positive date: if ASTDT >= ADATONS then AETIMREL = POST-ADA'; else If ASTDT < ADATONS then AETIMREL=PRE-ADA. If analysis is based on aligning each AE relative to each ADA Positive sample then use PROC SQL join.

ADA Impact on AE: TLF Examples

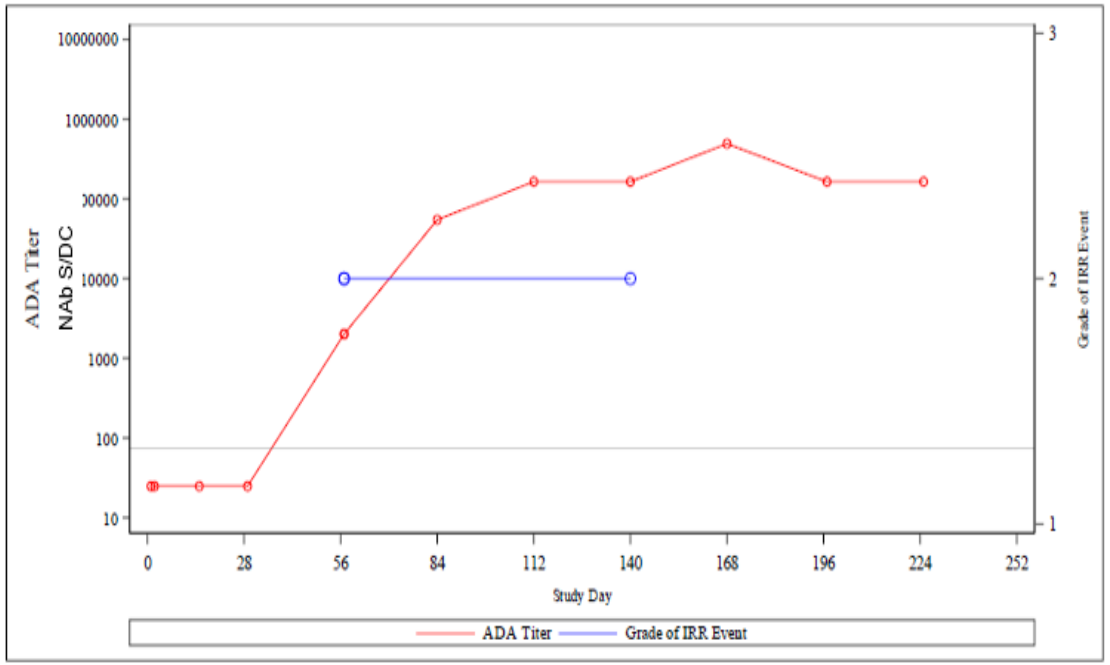


Figure to evaluate individual IRR event grades vs Titer for each patient

(ADA/NAb Status)/ Adverse Events Grade	Treatment 1 (N=XX)	Treatment 2 (N=XX)	Total (N=XX)
All Safety patients	xx	xx	xx
IRR Events	xx (xx.x)	xx (xx.x)	xx (xx.x)
Grade 1	xx (xx.x)	xx (xx.x)	xx (xx.x)
Grade 2	xx (xx.x)	xx (xx.x)	xx (xx.x)
Grade 3	xx (xx.x)	xx (xx.x)	xx (xx.x)
…			
Immunogenicity-Evaluable Patients	xx	xx	xx
IRR Events	xx (xx.x)	xx (xx.x)	xx (xx.x)
Grade 1	xx (xx.x)	xx (xx.x)	xx (xx.x)
Grade 2	xx (xx.x)	xx (xx.x)	xx (xx.x)
Grade 3	xx (xx.x)	xx (xx.x)	xx (xx.x)
…			
ADA Negative (Immunogenicity-Evaluable Patients)	xx	xx	xx
IRR Events	xx (xx.x)	xx (xx.x)	xx (xx.x)
Grade 1	xx (xx.x)	xx (xx.x)	xx (xx.x)
Grade 2	xx (xx.x)	xx (xx.x)	xx (xx.x)
Grade 3	xx (xx.x)	xx (xx.x)	xx (xx.x)
…			
ADA Positive (Immunogenicity-Evaluable Patients)	xx	xx	xx
IRR Events	xx (xx.x)	xx (xx.x)	xx (xx.x)
Grade 1	xx (xx.x)	xx (xx.x)	xx (xx.x)
Grade 2	xx (xx.x)	xx (xx.x)	xx (xx.x)
Grade 3	xx (xx.x)	xx (xx.x)	xx (xx.x)
…			
NAb Negative (Immunogenicity-Evaluable Patients)	xx	xx	xx
IRR Events	xx (xx.x)	xx (xx.x)	xx (xx.x)
Grade 1	xx (xx.x)	xx (xx.x)	xx (xx.x)
Grade 2	xx (xx.x)	xx (xx.x)	xx (xx.x)
Grade 3	xx (xx.x)	xx (xx.x)	xx (xx.x)
…			
NAb Positive (Immunogenicity-Evaluable Patients)	xx	xx	xx
IRR Events	xx (xx.x)	xx (xx.x)	xx (xx.x)
Grade 1	xx (xx.x)	xx (xx.x)	xx (xx.x)
Grade 2	xx (xx.x)	xx (xx.x)	xx (xx.x)
Grade 3	xx (xx.x)	xx (xx.x)	xx (xx.x)

Summary table of IRR events summarized by ADA/NAb Status

ADA Impact on AE: Additional TLF Examples

Output Type	Title	Description
Table	Incidence of Treatment-Emergent Adverse Events by ADA Status	Summarizes subject-level incidence of treatment-emergent adverse events stratified by ADA status.
Table	Timing of Treatment-Emergent Adverse Events Relative to ADA Detection	Summarizes treatment-emergent adverse events classified as occurring before or after first confirmed ADA positivity
Table	Severity and Seriousness by ADA Status	Displays incidence of Grade ≥3 adverse events, serious adverse events, and adverse events leading to discontinuation, stratified by ADA status.
Table	Kaplan–Meier Plot of Cumulative Incidence —Time to First TEAE by ADA Status	Illustrates cumulative incidence of first treatment-emergent adverse event stratified by ADA status, enabling exploratory evaluation of event timing.
Listing	Listing of Subjects with Treatment-Emergent ADA and Related AEs	Provides subject-level details for treatment-emergent ADA-positive subjects, including ADA timing, AE onset, severity, seriousness, and relationship to treatment.
Figure	Bar Chart of AE Incidence by ADA Group	Displays percentage of subjects with at least one TEAE by ADA subgroup, providing a high-level visual comparison of safety incidence.

ADA Impact on PK

- Immunogenicity may influence pharmacokinetic (PK) behavior of biologic therapies by altering drug disposition, clearance, or bioavailability.
- The development of anti-drug antibodies (ADA), particularly neutralizing antibodies (NAb), has the potential to reduce circulating drug concentrations through immune complex formation, enhanced clearance, or direct neutralization of pharmacologic activity.
- Guidance from the FDA and EMA recommend evaluating PK exposure in relation to immunogenicity to understand whether antibody development is associated with clinically meaningful changes in drug concentrations.
- Analyses typically evaluate PK concentrations and derived PK parameters (e.g., Cmax, AUC, trough concentrations) stratified by ADA or NAb status.
- In addition, PK samples are often categorized as occurring before or after confirmed ADA positivity.

ADA Impact on PK (Contd.,)

- Subjects can have multiple confirmed ADA-positive assessments over time as well as multiple PK samples collected over time.
- To Integrate, the traditional DATA step merge may not be appropriate due to many-to-many relationships
- Integration must be implemented as a controlled Cartesian join using PROC SQL, with explicit join conditions based on subject identifiers and timing variables to ensure correct record pairing and traceability.

Below is the table summarizing the additional variables that can be derived in ADPC/ADPP to evaluate PK concentrations and PKParameters in the context of immunogenicity.

Variable Name	Variable Label	Type	Derivation
IRRFL	Infusion Related Reaction Flag	Char	Derived from SuppAE.QVAL where QNAM=IRRFL
HYPSFL	Hypersensitivity Reaction Flag	Char	Derived from SuppAE.QVAL where QNAM=IRRFL
ADASTAT	ADA Status	Char	Derived from ADIS.AVALC when ADIS.PARAMCD=ADASTAT
ADAMXTIT	ADA Maximum Titer Value	Integer	Derived from ADIS.AVALC when ADIS.PARAMCD=ADAMXTIT
NABSTAT	NAb Status	Char	Derived from ADIS.AVALC when ADIS.PARAMCD=NABSTAT
NABMXTIT	NAb Maximum Titer Value	Integer	Derived from ADIS.AVALC when ADIS.PARAMCD=NABMXTIT
ADATRTEM	Treatment-Emergent ADA Flag	Char	Derived from ADIS.AVALC when ADIS.PARAMCD=ADATRTEM
ADATONS	Time to onset of 1st ADA	Integer	Derived from ADIS.AVALC when ADIS.PARAMCD=ADATONS
AETIMREL	AE Timing Relative to ADA	Char	If the analysis is based on the first confirmed ADA-positive date: if ASTDT >= ADATONS then AETIMREL = POST-ADA'; else If ASTDT < ADATONS then AETIMREL=PRE-ADA. If analysis is based on aligning each AE relative to each ADA Positive sample then use PROC SQL join.

ADA Impact on PK: TLF Examples

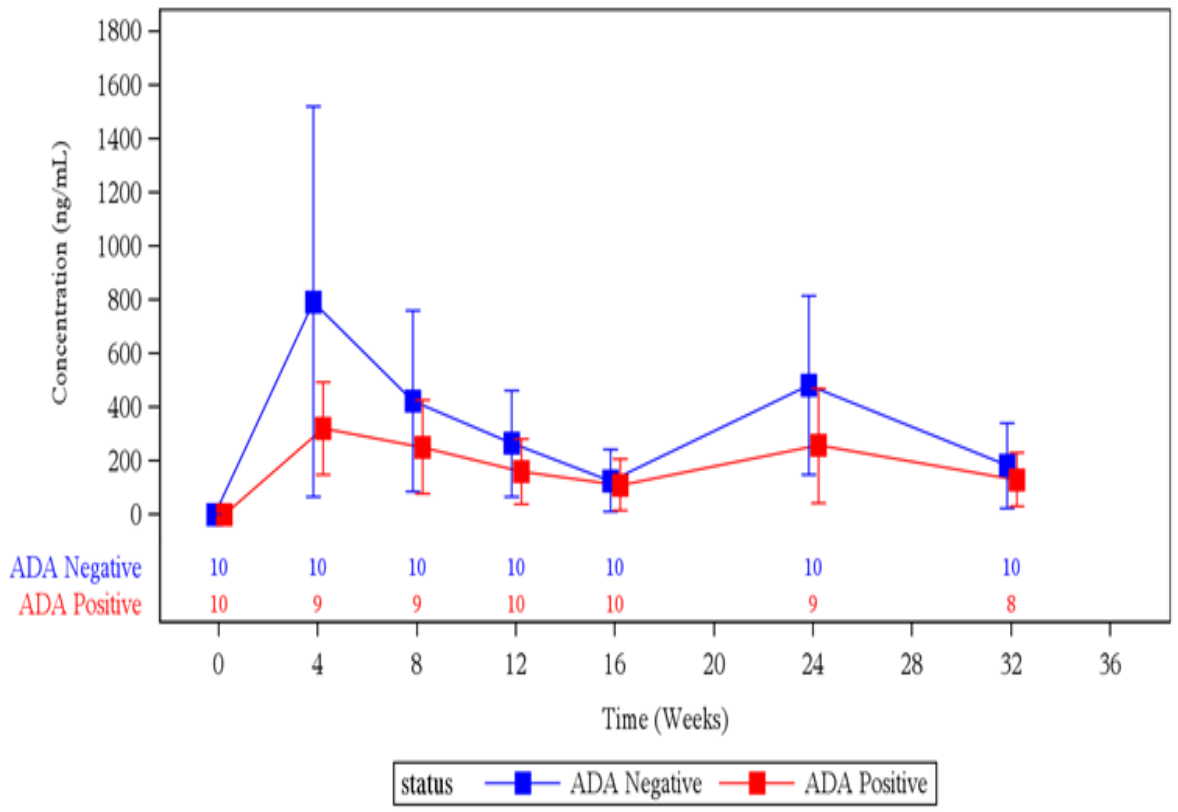


Figure to evaluate mean PK Concentrations by ADA Status

Visit	ADA/NAb Status	Summary statistics	Scheduled Timepoint: D1 Predose	D1 End of Infusion	D1 2-4 Hours	D2 Visit	D8 Visit	D15 Visit	% Change in EOI vs C1D1 EOI
Cx	ADA-	n	xx	xx	xx	xx	xx	xx	xx
		Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	
		SD	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	
		%CV	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	
		Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	
		Minimum	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	
		Maximum	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	
		Geometric mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	
		Geometric CV%	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	
	ADA+/NAb-	n	xx	xx	xx	xx	xx	xx	xx
		Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	
		SD	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	
		%CV	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	
		Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	
		Minimum	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	
		Maximum	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	
		Geometric mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	
		Geometric CV%	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	
	ADA+/NAb+	n	xx (xx)	xx (xx)	xx (xx)	xx (xx)	xx (xx)	xx (xx)	xx
		Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	
		SD	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	
		%CV	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	
		Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	
		Minimum	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	
		Maximum	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	
		Geometric mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	

Summary table of PK Concentrations summarized by ADA/NAb Status

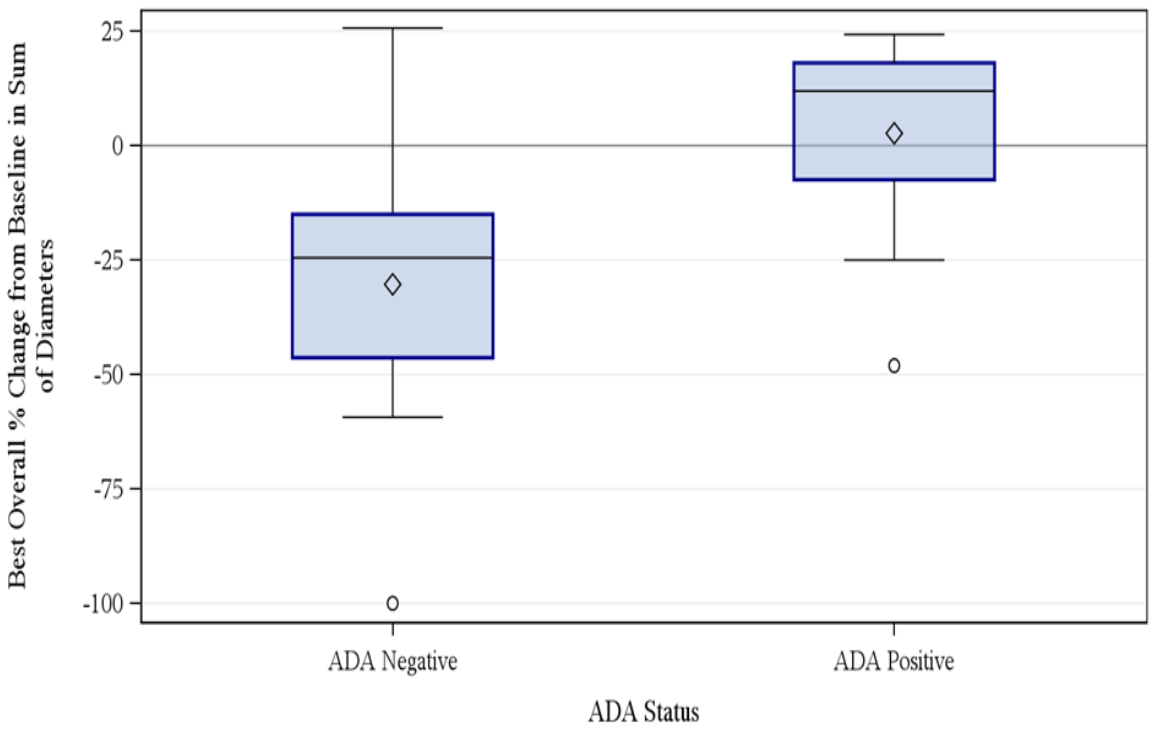
ADA Impact on PK: Additional TLF Examples

Output Type	Title	Description
Table	Summary of PK Exposure Parameters by ADA Status	Summarizes geometric mean of PK exposure parameters (e.g., Cmax, AUC, trough, CL) stratified by ADA and NAb status using the immunogenicity PK-evaluable population
Table	PK Exposure by ADA and NAb Titer Quartiles	Presents PK exposure parameters across increasing ADA and NAb titer categories
Table	PK Concentrations Before and After ADA Development	Summarizes PK concentrations classified as pre-ADA or post-ADA based on time alignment to the first confirmed ADA-positive assessment
Figure	Individual PK Concentrations Relative to ADA Timing	Scatter plot Showing the distribution of individual PK concentrations before and after ADA development among ADA-positive subjects
Figure	Scatter or Box Plots of PK Exposure vs ADA/NAb Titer	Illustrates the relationship between PK exposure parameters and ADA or NAb titers, providing a visual assessment of potential exposure–titer associations

ADA Impact on Efficacy

- Immunogenicity may influence the clinical efficacy of biologic therapies through both direct and indirect mechanisms.
- The development of ADA, particularly Nab's, has the potential to reduce therapeutic effectiveness by neutralizing the drug's pharmacologic activity or by altering drug exposure through increased clearance.
- Regulatory guidance from the FDA and EMA recommend evaluating efficacy outcomes in the context of immunogenicity to assess whether treatment response differs between ADA-positive and ADA-negative subjects.
- Assessment of the relationship between immunogenicity and efficacy requires integration of immunogenicity data with efficacy endpoints at both the subject and visit level.
- Analyses typically compare response rates, change-from-baseline measures, or time-to-event endpoints across immunogenicity subgroups and explore the timing of efficacy assessments relative to ADA development.

ADA Impact on Efficacy: TLF Examples



Best Overall %Change from Baseline in Sum of Diameters by ADA Status

(ADA/NAb Status)/ Efficacy Assessment	Treatment 1 (N=XX)	Treatment 2 (N=XX)	Total (N=XX)
All patients	xx	xx	xx
ORR, n(%) [b]	xx (xx.x)	xx (xx.x)	xx (xx.x)
PFS, median (min, max)	xx.x, (xx.x, xx.x)	xx.x, (xx.x, xx.x*)	xx.x, (xx.x*, xx.x)
OS, median (min, max)	xx.x, (xx.x, xx.x)	xx.x, (xx.x, xx.x)	xx.x, (xx.x, xx.x)
DOR, median (min, max)	xx.x, (xx.x, xx.x)	xx.x, (xx.x, xx.x)	xx.x, (xx.x, xx.x)
TTR, median (min, max)	xx.x, (xx.x, xx.x)	xx.x, (xx.x, xx.x)	xx.x, (xx.x, xx.x)
DOT, median (min, max)	xx.x, (xx.x, xx.x)	xx.x, (xx.x, xx.x)	xx.x, (xx.x, xx.x)
Immunogenicity-Evaluable Patients	xx	xx	xx
ORR, n(%) [b]	xx (xx.x)	xx (xx.x)	xx (xx.x)
PFS, median (min, max)	xx.x, (xx.x, xx.x)	xx.x, (xx.x, xx.x)	xx.x, (xx.x, xx.x)
OS, median (min, max)	xx.x, (xx.x, xx.x)	xx.x, (xx.x, xx.x)	xx.x, (xx.x, xx.x)
DOR, median (min, max)	xx.x, (xx.x, xx.x)	xx.x, (xx.x, xx.x)	xx.x, (xx.x, xx.x)
TTR, median (min, max)	xx.x, (xx.x, xx.x)	xx.x, (xx.x, xx.x)	xx.x, (xx.x, xx.x)
DOT, median (min, max)	xx.x, (xx.x, xx.x)	xx.x, (xx.x, xx.x)	xx.x, (xx.x, xx.x)
ADA Negative (Immunogenicity-Evaluable Patients)	xx	xx	xx
ORR, n(%) [b]	xx (xx.x)	xx (xx.x)	xx (xx.x)
PFS, median (min, max)	xx.x, (xx.x, xx.x)	xx.x, (xx.x, xx.x)	xx.x, (xx.x, xx.x)
OS, median (min, max)	xx.x, (xx.x, xx.x)	xx.x, (xx.x, xx.x)	xx.x, (xx.x, xx.x)
DOR, median (min, max)	xx.x, (xx.x, xx.x)	xx.x, (xx.x, xx.x)	xx.x, (xx.x, xx.x)
TTR, median (min, max)	xx.x, (xx.x, xx.x)	xx.x, (xx.x, xx.x)	xx.x, (xx.x, xx.x)
DOT, median (min, max)	xx.x, (xx.x, xx.x)	xx.x, (xx.x, xx.x)	xx.x, (xx.x, xx.x)
ADA Positive (Immunogenicity-Evaluable Patients)	xx	xx	xx
ORR, n(%) [b]	xx (xx.x)	xx (xx.x)	xx (xx.x)
PFS, median (min, max)	xx.x, (xx.x, xx.x)	xx.x, (xx.x, xx.x)	xx.x, (xx.x, xx.x)
OS, median (min, max)	xx.x, (xx.x, xx.x)	xx.x, (xx.x, xx.x)	xx.x, (xx.x, xx.x)
DOR, median (min, max)	xx.x, (xx.x, xx.x)	xx.x, (xx.x, xx.x)	xx.x, (xx.x, xx.x)
TTR, median (min, max)	xx.x, (xx.x, xx.x)	xx.x, (xx.x, xx.x)	xx.x, (xx.x, xx.x)
DOT, median (min, max)	xx.x, (xx.x, xx.x)	xx.x, (xx.x, xx.x)	xx.x, (xx.x, xx.x)

Summary of Efficacy Assessments by ADA/NAb Status

ADA Impact on Efficacy: Additional TLF Examples

Output Type	Title	Description
Table	Change from Baseline in Efficacy Endpoints by ADA Status	Summarizes change-from-baseline efficacy measures stratified by ADA and NAb status using the immunogenicity efficacy population
Table	Efficacy Outcomes Before and After ADA Positive	Presents efficacy assessments classified as occurring before or after confirmed ADA positivity, supporting time-aligned evaluation of treatment response
Table	Tumor Response Categories by ADA Status	Displays distribution of response categories (e.g., CR, PR, SD, PD) stratified by ADA status for descriptive comparison
Figure	Spider Plot of Efficacy Changes Across Time Points by ADA Status	Provides a visual summary of change-from-baseline efficacy measures comparing ADA-positive and ADA-negative subjects
Figure	Kaplan–Meier Plots for Time-to-Event Efficacy Endpoints by ADA Status	Displays percentage of subjects with at least one TEAE by ADA subgroup, providing a high-level visual comparison of safety incidence.

Conclusion

- Immunogenicity remains a critical consideration in the clinical development of biologic therapies due to its potential impact on safety, pharmacokinetics, and efficacy.
- Immunogenicity analyses are complex but manageable with a structured programming approach.
- Standardized ADaM framework supports efficient TLF generation and enables traceable and reproducible evaluation of immunogenicity data.

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THANK YOU!!

Q & A