

Supporting A Data Review and Visualization Application with SDTM

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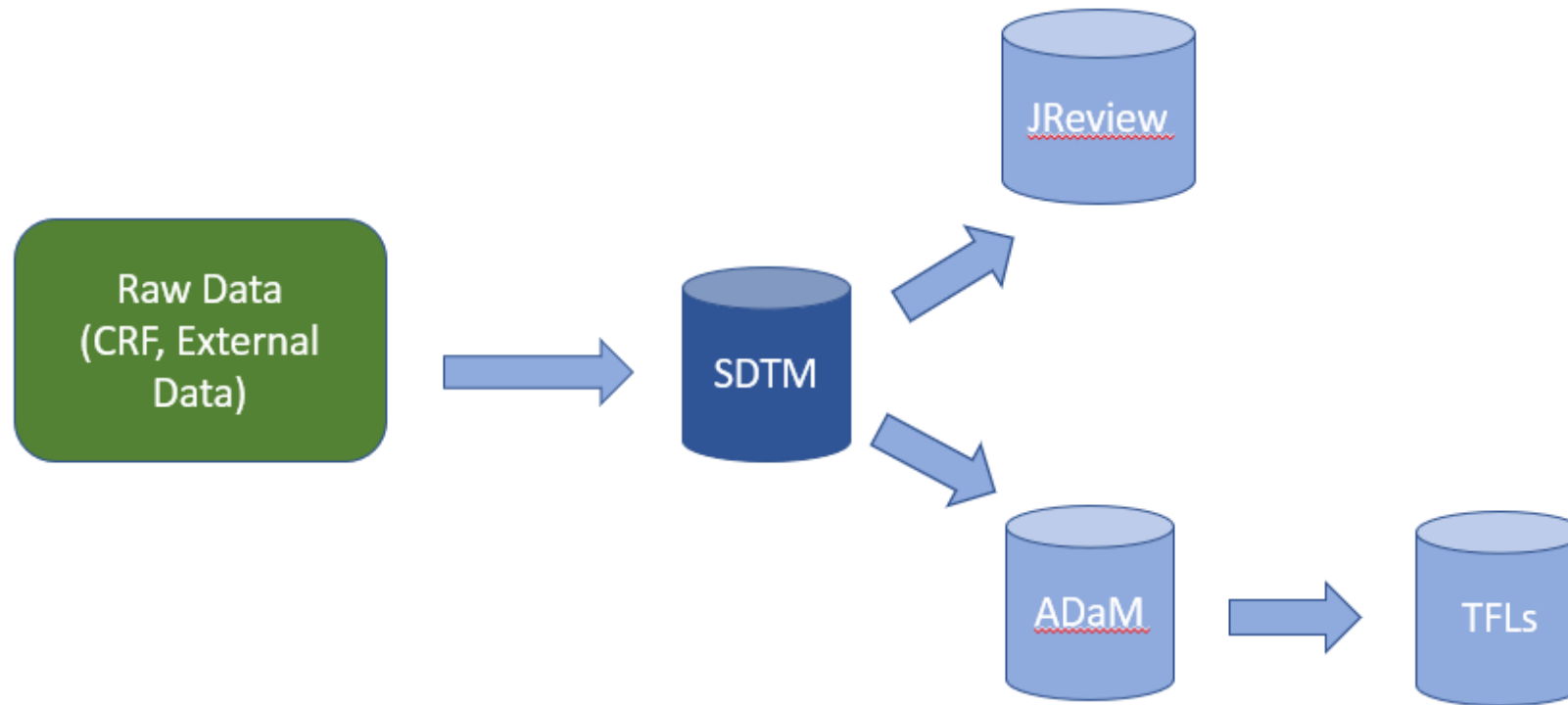
Roadmap

- ▶ Introduction to JReview and our Clinical Data Stream
- ▶ Why leveraging CDISC SDTM was the best choice
- ▶ Designing a clinical data stream that supports both review and analysis
- ▶ Supporting consistent SDTM mapping with a sponsor implementation guide
- ▶ Ensuring that available data content supports all consumer needs
- ▶ Building a refresh and review process that makes accurate data available as needed
- ▶ Examples of how the application supported efficient use and review of study data

JReview Introduction

- ▶ JReview is the tool we use to perform:
 - ▶ data visualization
 - ▶ reporting
 - ▶ exploration
- ▶ Monitor data quality and patient safety, as well as visually explore data to identify trends
- ▶ Used at Medimmune to review raw clinical study data received from EDC and external study data sources, i.e., lab, pk, etc.
- ▶ Automated daily extracts on raw data are performed, converted to SDTM and loaded to JReview
- ▶ JReview reports are generated for internal use only, primarily for data review, and will not be used for any official or regulatory purpose

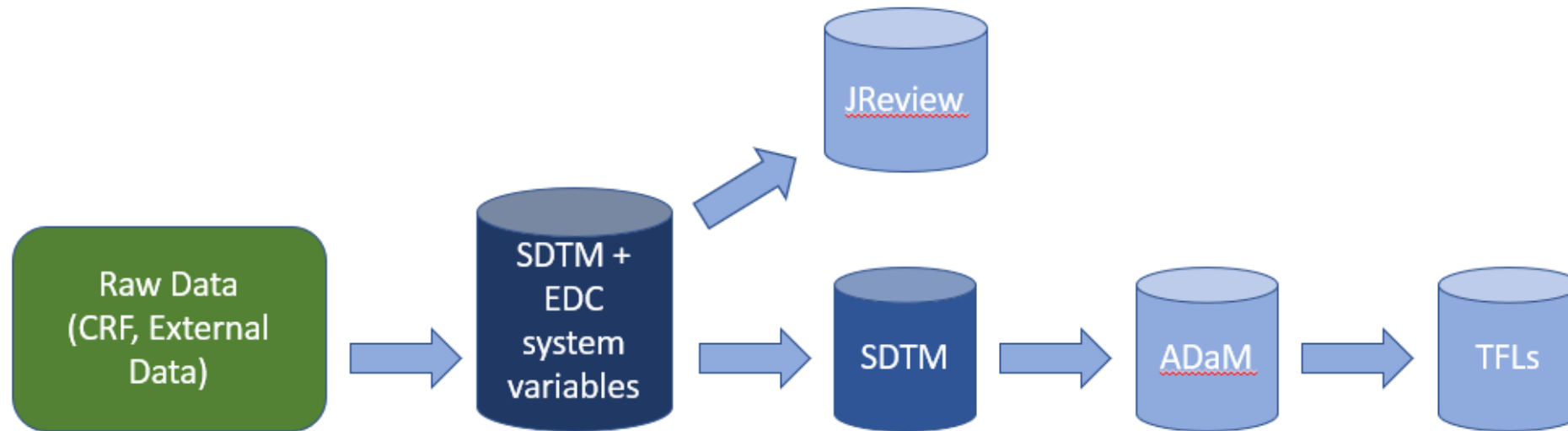
Clinical Data Stream Introduction



Why Leveraging CDISC SDTM Best Choice?

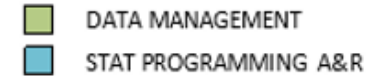
- ▶ Single source of standardized data
- ▶ If raw data is used for data visualization, then the reports and visualization schema would have to be rebuilt and revalidated for each study.
- ▶ The same data will be reviewed by statistical teams and used for analysis and submission.
- ▶ This will reduce the effort from having multiple groups reviewing the same data in multiple formats.

Clinical Data Stream as Applied: SDTM + EDC System Variables for JReview

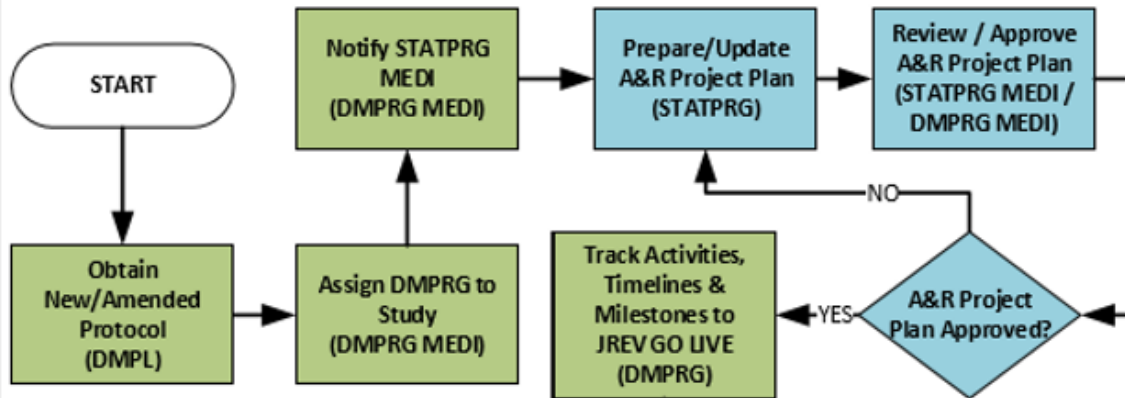


J-Review Study Setup & Maintenance

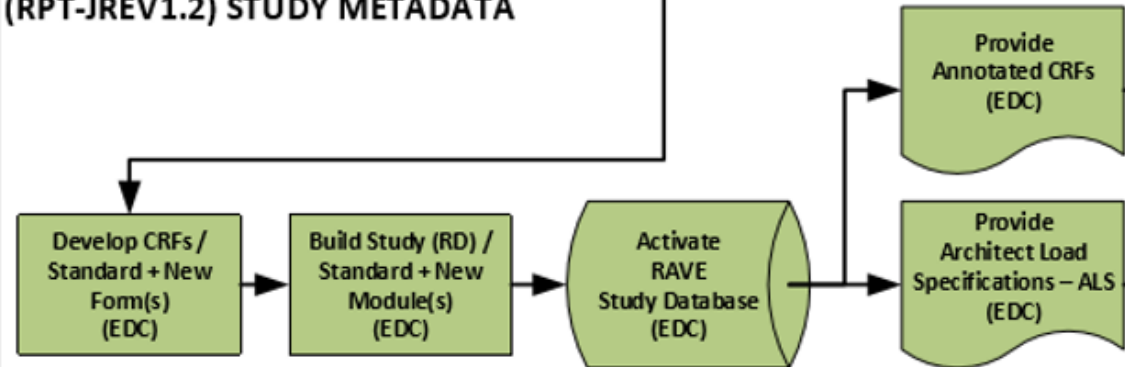
(RPT-JREV1.0) J-REVIEW STUDY SETUP & MAINTENANCE USING SDTM DATA



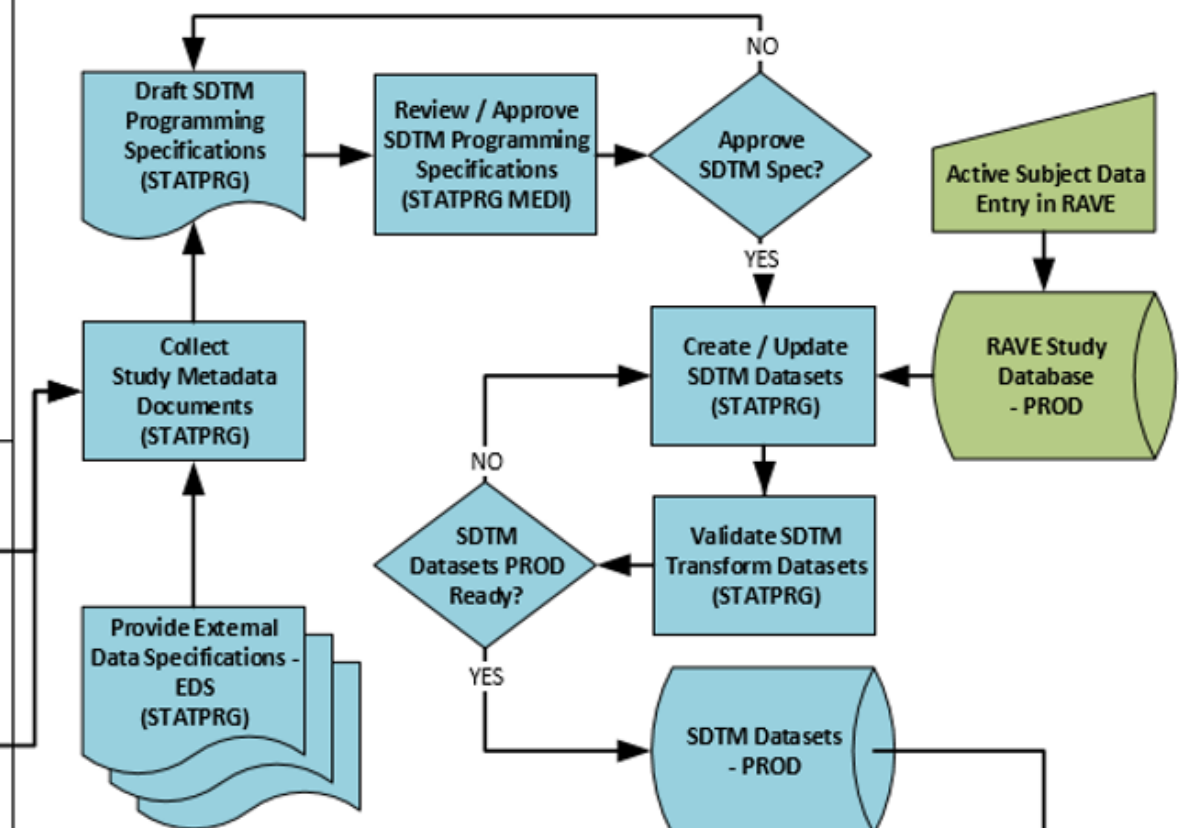
(RPT-JREV1.1) SDTM PROJECT PLAN & JREV TRACKING



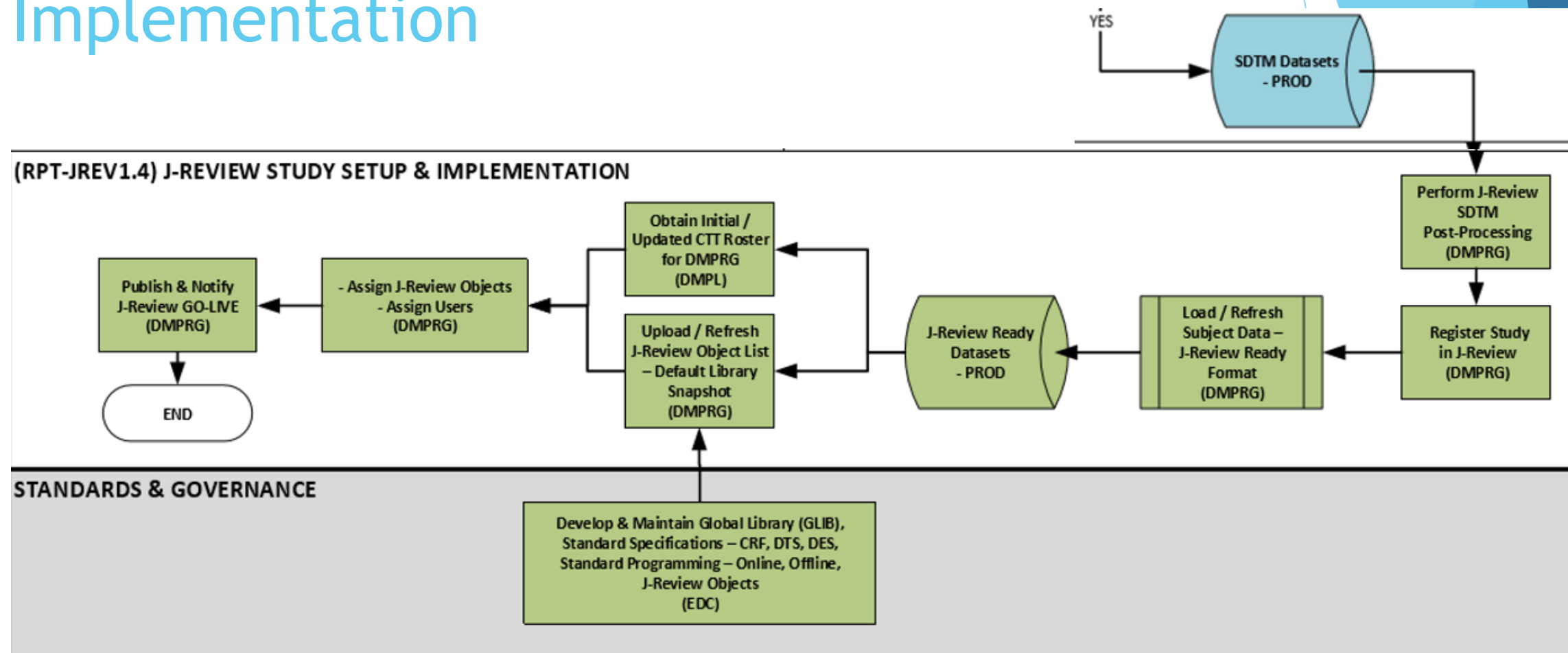
(RPT-JREV1.2) STUDY METADATA



(RPT-JREV1.3) SDTM DATA PROVISIONING



J-Review Study Setup & Implementation



Medi SDTM IG

- ▶ To ensure consistent mapping, Medimmune has developed an SDTM Interpretation Guide.
- ▶ The Medi SDTM IG consists of all the mapping standards based on the SDTM IG and Medimmune specific implementation rules.
- ▶ The Medi SDTM IG includes standard mapping for all supported domains and includes several tabs:
 - ▶ SDTM Planning
 - ▶ Raw Dataset-Domains Chart
 - ▶ Domains tab
 - ▶ Individual domain tabs

SDTM Planning Tab

- ▶ Completed as part of the SDTM planning meeting held prior to the start of mapping.
- ▶ Contains key information about the applicable SDTM standard and Pinnacle 21 version.
- ▶ Includes an overview of the study protocol, basic timing (first subject dose, database lock, etc.) and information about SDTM the delivery schedule for each end user group (such as JReview and analysis).

Raw Dataset-Domains Chart Tab

- ▶ Provides an overview of how raw datasets and CRF forms relate to SDTM domains.
- ▶ Highlights key mapping decisions that would benefit from discussion.
- ▶ Helps ensure that all the raw datasets and unique CRF forms are mapped to SDTM.

CRF Form	CRF Pages	Raw DS	SDTM domain	Notes
Subject	1-2	SUBJECT	Not applicable	
Inform Consent	3-4	IC	DM, DS	
Entry/Randomization	5-6	ENTRAND	DM, DS	
Screen Failure	7-8	SF	DM, DS	
Screen Failure Eligibility	9-11	SFIE	IE	
Screen Failure Demographics	12-15	SFDM	DM, VS	
Screen Failure Adverse Event	16-20	SFAE	AE	

Domains Tab

- ▶ Contains the domain level information required for the define.xml.
- ▶ Includes domain names and labels (including supplemental domains) in alphabetical order.
- ▶ Key variables used to define a unique record are listed.
- ▶ Domain structure and class information is also available.

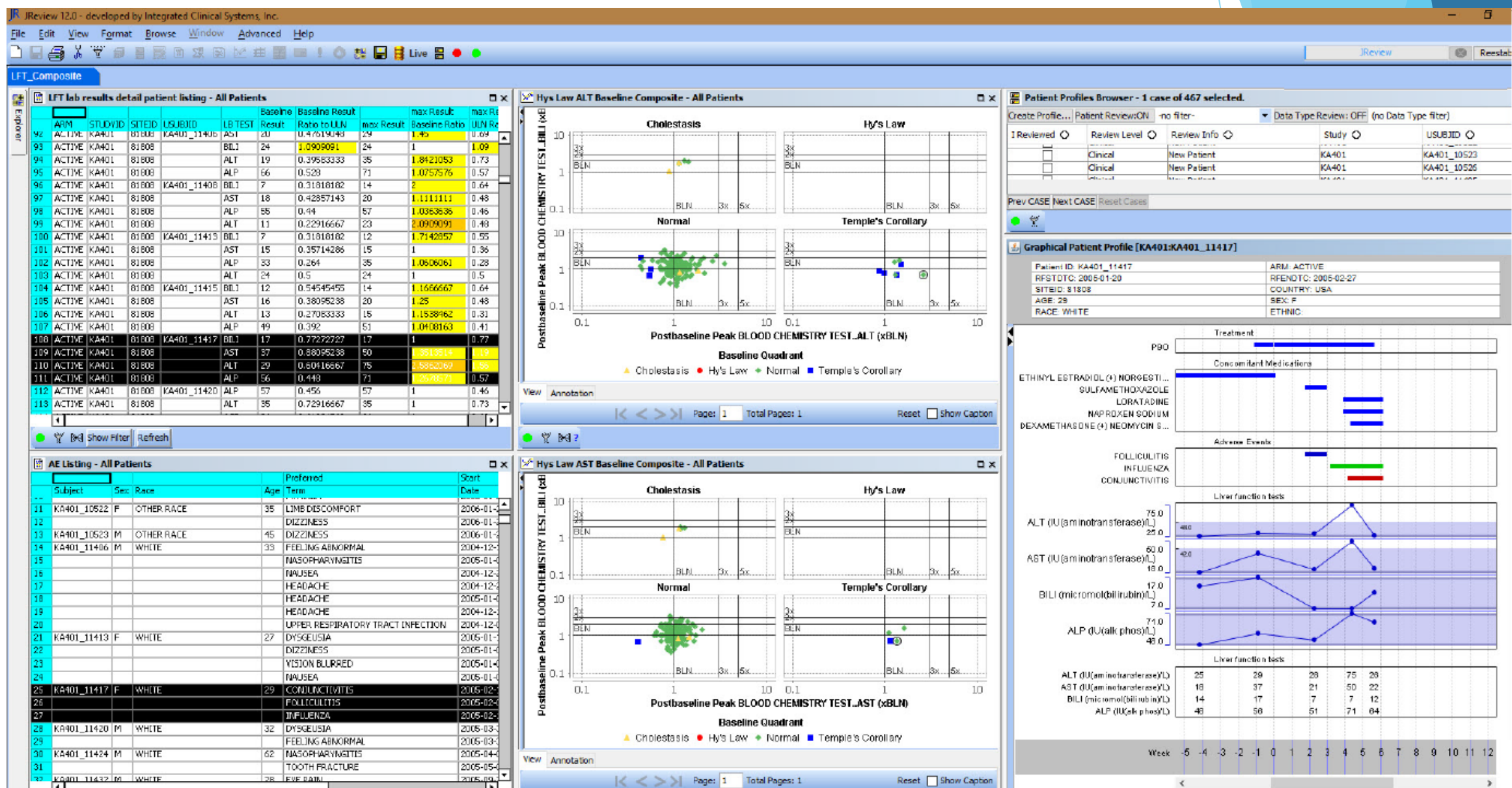
Domain	Description	KeyVariables	Structure	Purpose	Class
AE	Adverse Events	STUDYID, USUBJID, AEDECOD, AETERM, AESTDTC	One record per adverse event per subject	Tabulation	Events
AG	Procedure Agents	STUDYID, USUBJID, VISITNUM, AGSTDTC, AGTRT	One record per constant dosing interval per subject	Tabulation	Interventions
CE	Clinical Events	STUDYID, USUBJID, CETERM, CESTDTC	One record per event per subject	Tabulation	Events
CM	Concomitant Medications	STUDYID, USUBJID, CMTRT, CMSTDTC	One record per recorded medication occurrence or constant-dosing interval per subject	Tabulation	Interventions
DA	Drug Accountability	STUDYID, USUBJID, DATESTCD, VISITNUM	One record per drug accountability finding per subject	Tabulation	Findings
DD	Death Details	STUDYID, USUBJID, DDTESTCD	One record per finding per subject	Tabulation	Findings
DM	Demographics	STUDYID, USUBJID	One record per subject	Tabulation	Special Purpose Domains

Individual Domain Tabs

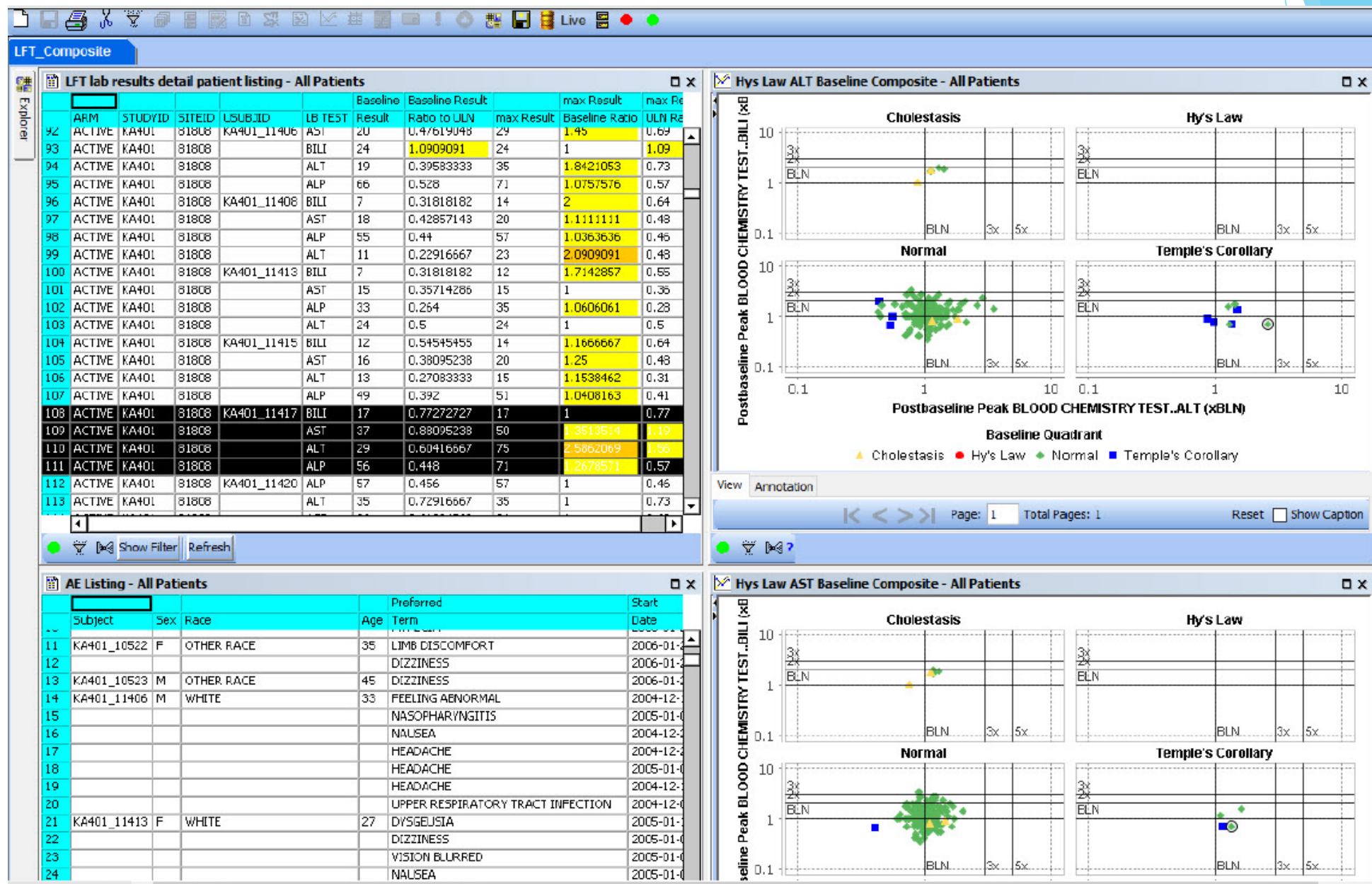
- ▶ Consist of all the variable level details required for programming and define generation.
- ▶ All the mapping instructions (based on raw data and study documents) are provided in the programming notes column.
- ▶ Medimmune specific guidelines for mapping are provided for each variable.

DOMA	ORDER	KEEP_VAR	VARIABLE	LABEL	MEDI_GUIDANCE	PROG_NOTES	SOURCE	DEFINE_COMMENT
AE	1	Y	STUDYID	Study Identifier	Must match SDTM DM.studyid	Set to STUDYID from SDTM DM		Set to STUDYID from SDTM DM.
AE	2	Y	DOMAIN	Domain Abbreviation	Set to AE	Set to AE		Set to AE.
AE	3	Y	USUBJID	Unique Subject Identifier	Must match SDTM DM.usubjid	Set to USUBJID from SDTM DM		Set to USUBJID from SDTM DM.
AE	4	Y	AESEQ	Sequence Number	Based on "keys" variables in the domains tab; should define unique records within a subject	Sort by key variables, assign sequential integer by USUBJID.		Sort by key variables and assign sequential integer within each USUBJID.
AE	5	N	AEGRPID	Group ID	Typically not needed/populated. Can be used to associate related AEs for a subject. This is for categories that vary across subjects.	<drop>		
AE	6	Y	AEREFID	Reference ID	Typically used for references that are not on the CRF; use for the variable value that is used as a key reference for linking AE records and associated coding records.	Set to AE.recordid, SFAE.recordid, AECD.recordid, SFAECD.recordid (this is a key merge variable between AE, and AECD, SFAE and SFAECD)	AE.recordid SFAE.recordid AECD.recordid SFAECD.recordid	

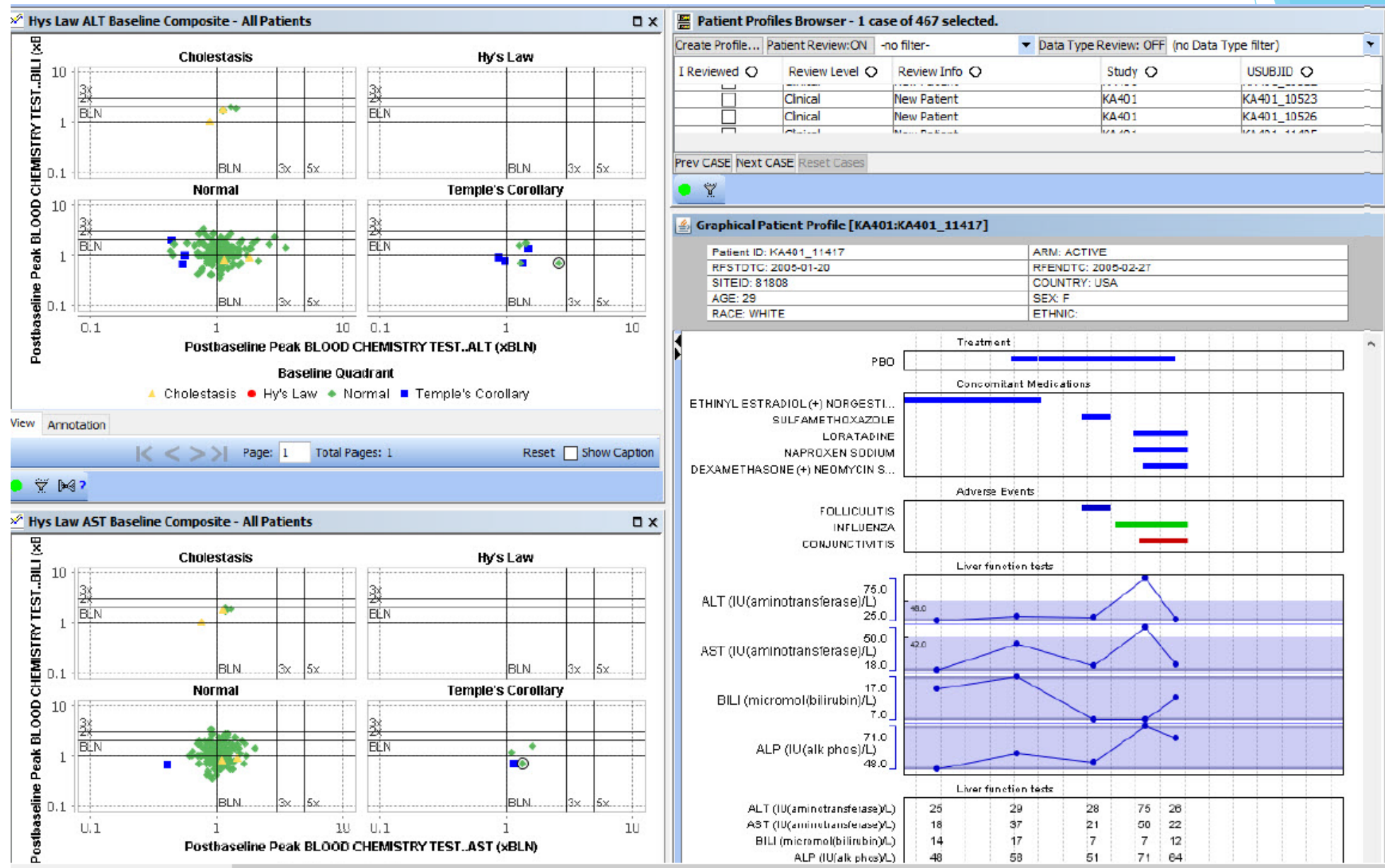
Data Visualization Example - Hy's Law Dashboard



Composite Hy's Law with Patient Data



Composite Hy's Law with Patient Profile



Conclusion

- ▶ Our single SDTM data stream supports all consumer requirements and facilitates efficient use.
- ▶ Consistent standardization across studies allows us to consolidate data and visualize vast amounts of information.
- ▶ Using an API allows us to automate the process and review live study data in near real time.
- ▶ Data visualization tool provides a platform for clinical review teams to review data in a timely manner



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Back-up Example

