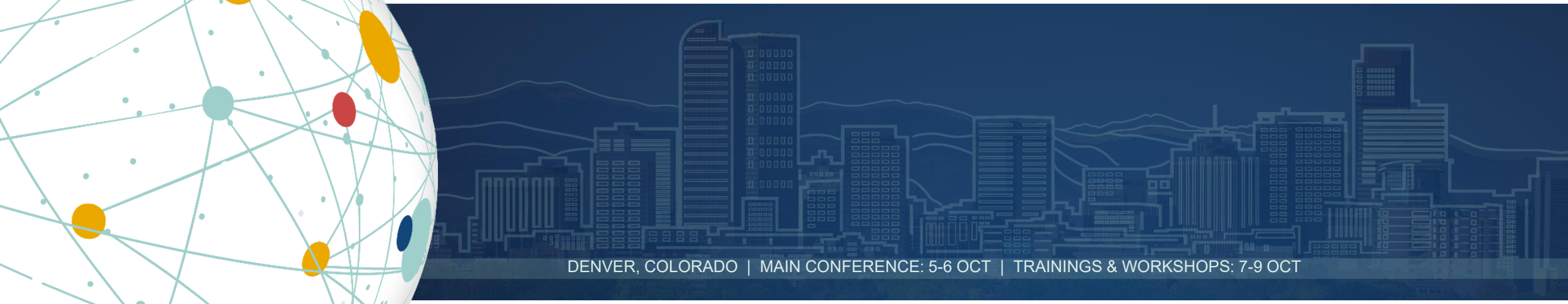


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2026 US Interchange

THE FUTURE IS CONNECTED: STANDARDS AND AI POWERING DIGITAL TRANSFORMATION



What happens when analysis and display are independently produced as Analysis Results DataSets (ARDS) and TFLs?

Andrew Miskell
Advisor Computational Statistician
Eli Lilly and Company

Speaker



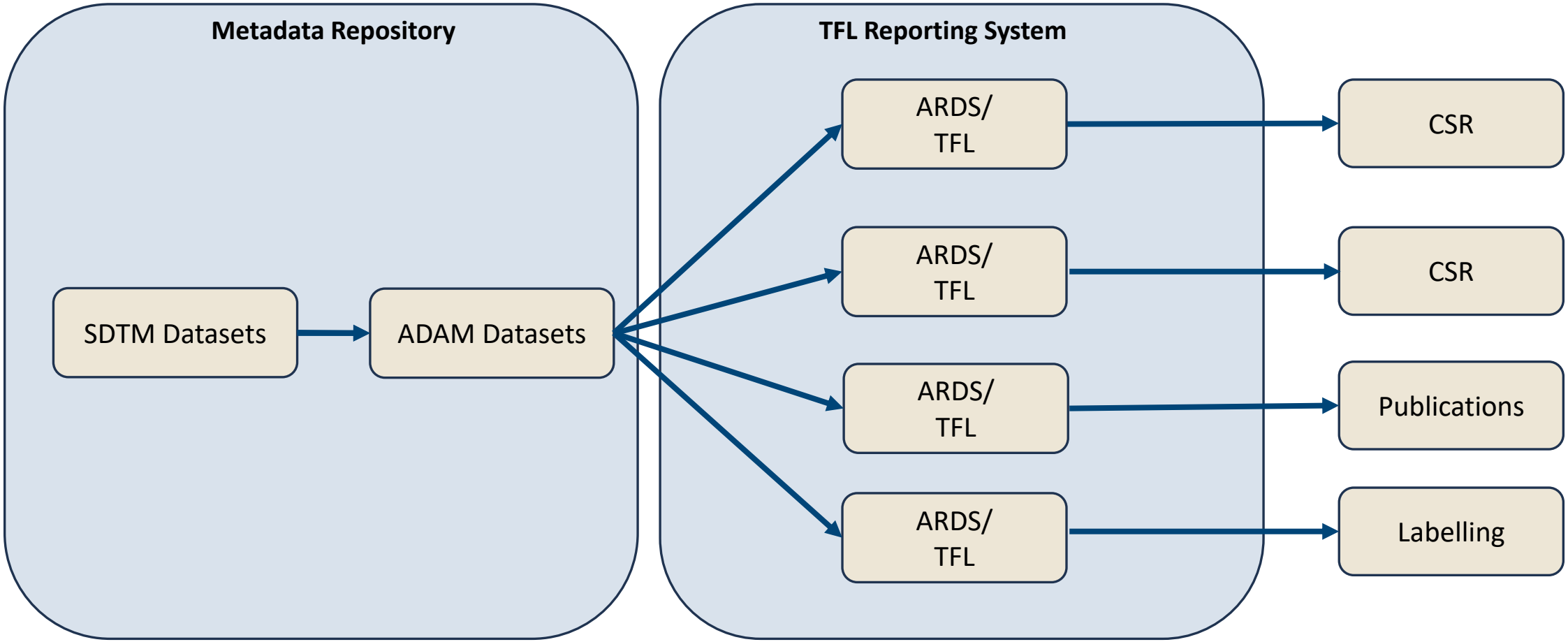
- 11 years at Eli Lilly and Company
- 27 years in industry
- Statistical Programming
- Standards Instantiation
- Automation and Innovation

Andrew Miskell
Advisor Computational Statistician
Eli Lilly and Company

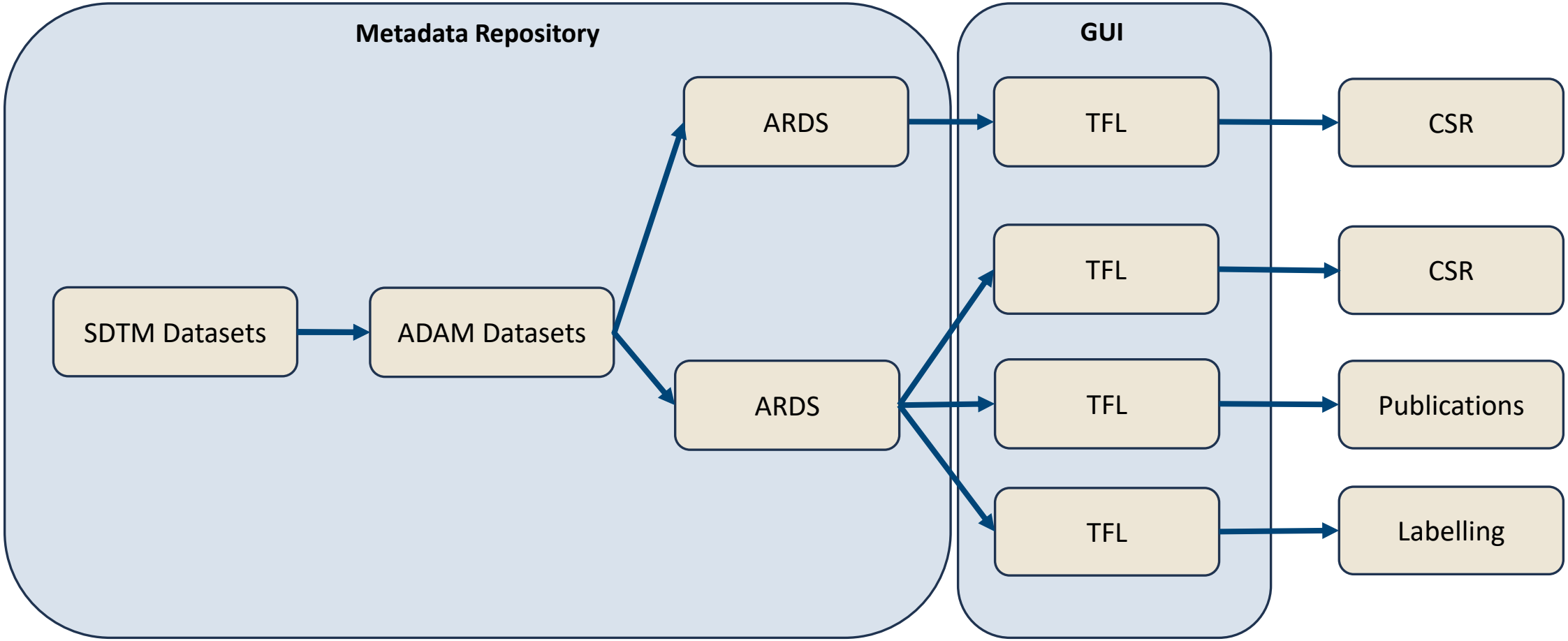
Analysis Results DataSets (ARDS)

- Re-imagine analysis process flow to save out analysis into re-usable files and then make display (TFL) purely a formatting step with no extra analysis performed.
- Include in MDR along with Data Collection, SDTM, and ADAM standards to facilitate dynamic end-to-end transparency of data flow

Clinical Data Flow (Old)



Clinical Data Flow (New)



Robust ARDS Model with vertical structure

- **ARDS structure built out and tested across myriad of standards to ensure robustness**
- Vertical
- Unrounded values
- Any analysis and input structure
- Standard naming conventions and controlled terminology which can be used by downstream tools consuming files
- No display elements such as parentheses, placement, or other formatting

- **Aligned at Lilly and embedded in TFL process starting in 2023**

POPFLAG	POPULATION	CAT1CDVAR	CAT1CD	CAT1VAR	CAT1N	CAT1	CAT2VAR	CAT2N	CAT2	CAT3VAR	CAT3N	CAT3	TRTN	TRT	REFTRTN	REFTRT	ANALYSISTYPE	RESULTTYPE	RESULTTYPE2	RESULTTYPE3	RESULTTYPE4	RESULT
ITTFL	INTENT TO TREAT POPULATION	PARAMCD	XXXXXXX	PARAM	1	xxxxx	AVISIT	1	Baseline				1	Trt A			Baseline	Count	Observed		MMRM	12345
ITTFL	INTENT TO TREAT POPULATION	PARAMCD	XXXXXXX	PARAM	1	xxxxx	AVISIT	1	Baseline				2	Trt B			Baseline	Count	Observed		MMRM	12345
ITTFL	INTENT TO TREAT POPULATION	PARAMCD	XXXXXXX	PARAM	1	xxxxx	AVISIT	1	Baseline				3	Trt C			Baseline	Count	Observed		MMRM	12345
ITTFL	INTENT TO TREAT POPULATION	PARAMCD	XXXXXXX	PARAM	1	xxxxx	AVISIT	1	Baseline				4	Pooled 1			Baseline	Count	Observed		MMRM	12345
ITTFL	INTENT TO TREAT POPULATION	PARAMCD	XXXXXXX	PARAM	1	xxxxx	AVISIT	1	Baseline				5	Pooled 2			Baseline	Count	Observed		MMRM	12345
ITTFL	INTENT TO TREAT POPULATION	PARAMCD	XXXXXXX	PARAM	1	xxxxx	AVISIT	1	Baseline				999	Total			Baseline	Count	Observed		MMRM	12345

ARDS and TFL Instantiation Plan

- Robust ARDS Model with vertical structure
- Modularize specifications in system
- Flexibility and Tailored options for each analysis
- Metadata-driven code produced to create files from requirements allowing for greater standardization
- Dynamic traceability back through ADAM and SDTM to Data Collection
- Separate GUI TFL system focused solely on displaying ARDS output
- Design and development started in 2024

Robust ARDS Model — Standard Macros & Result Sections

Statistics Macros

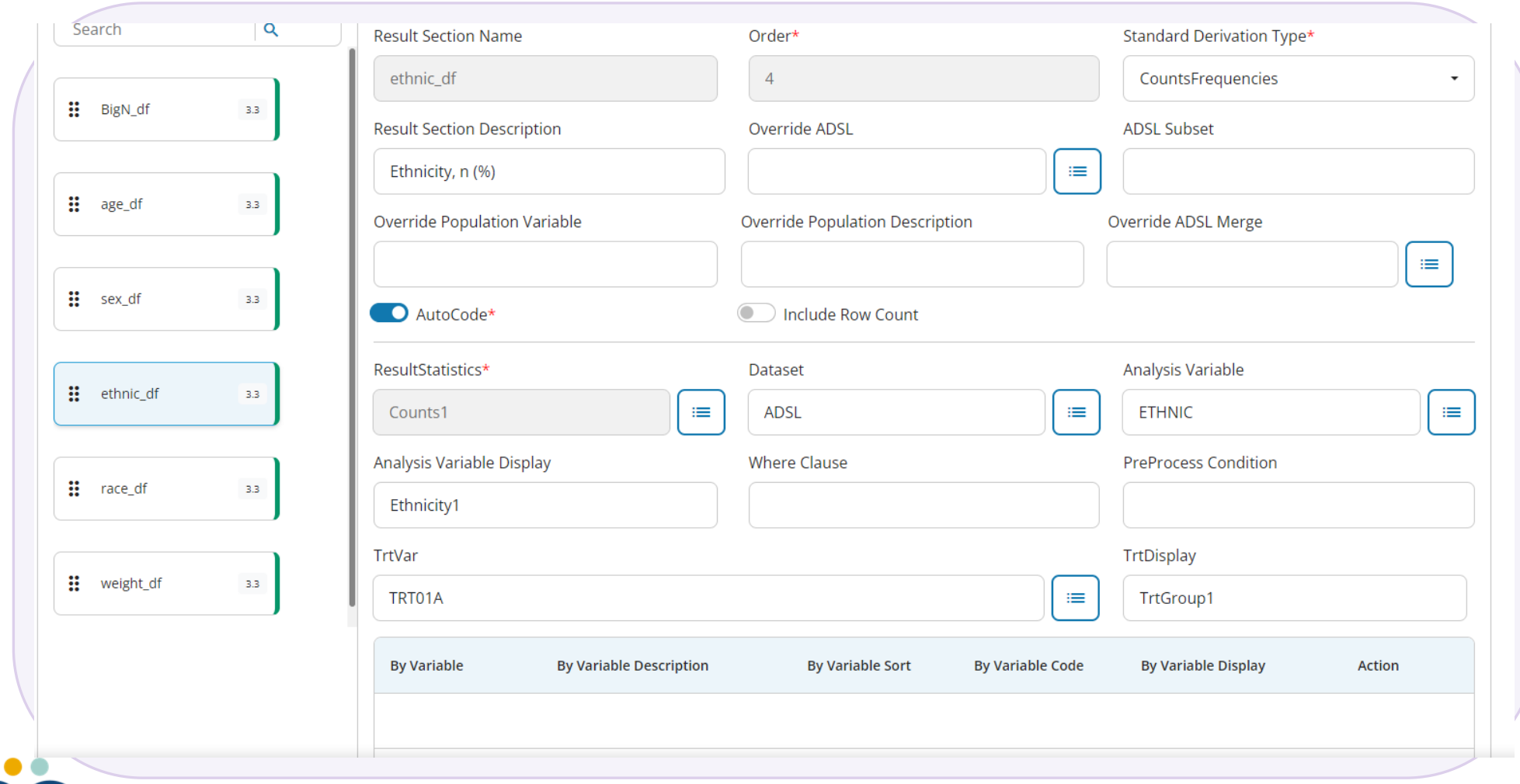
(This list will grow)

- summaryStatistics
- countsFrequencies
- pvalueCategorical
- pvalueContinuous
- oddsRatios
- riskDifference
- incidenceRateEmpirical
- incidenceRateModeling
- linearModelingBinary
- linearModelingCont
- linearRegression
- mmrm
- mmrmCategorical
- survivalFit
- bayesianGLIMMIX
- bayesianMMRM
- adjustedPercentage
- npar1way

Result Section Metadata (example)

Result Section Name	Status	SDTM Version	Standard Derivation	Result Section Description
BigN_df	NoChange	3.3	CountsFrequencies	Big N Treatment Counts
age_df	NoChange	3.3	SummaryStatistics	Age (years)
sex_df	NoChange	3.3	CountsFrequencies	Gender, n (%)
ethnic_df	NoChange	3.3	CountsFrequencies	Ethnicity, n (%)
race_df	NoChange	3.3	CountsFrequencies	Race, n (%)
weight_df	NoChange	3.3	SummaryStatistics	Weight (kg)

Modularize specifications in system



Flexibility and Tailored options for each analysis

Summary Statistics

Requested Statistics (Choose one or many)	
n	Count
mean	Mean
median	Median
q1	Q1
q3	Q3
whisker_low	Low Whisker|Minimum value above lower fence
whisker_high	High Whisker|Maximum value below upper fence
fence_low	Lower Fence|Q1 - 1.5*IQR
fence_high	Upper Fence|Q3 + 1.5*IQR
outlier	Outlier
sd	Std Dev
minimum	Minimum
maximum	Maximum
mean+(2*sd)	Mean+2 Std Dev
mean-(2*sd)	Mean-2 Std Dev

MMRM

Model Parameters:	
Model:	TRT Base*TRT AVISIT
Class Variables	AVISIT
Covariate (dropdown list and can be re-ordered):	UN TOEP ARH(1)
lsmeans	TRT*AVISIT
lsmeans options	diff cl
Random	USUBJID
Degrees of Freedom	Satterthwaite
Confidence Interval Width	95
Repeated	AVISITN/SUBJECT=USUBJID un

Requested Statistics (Choose one or many)	
LS Mean	LS Mean|LS Mean
Std Err	Std Err|LS Mean
CI Low	95% CI Low|LS Mean
CI High	95% CI High|LS Mean
p-value	p-value|LS Mean

Metadata-driven code to create files from requirements

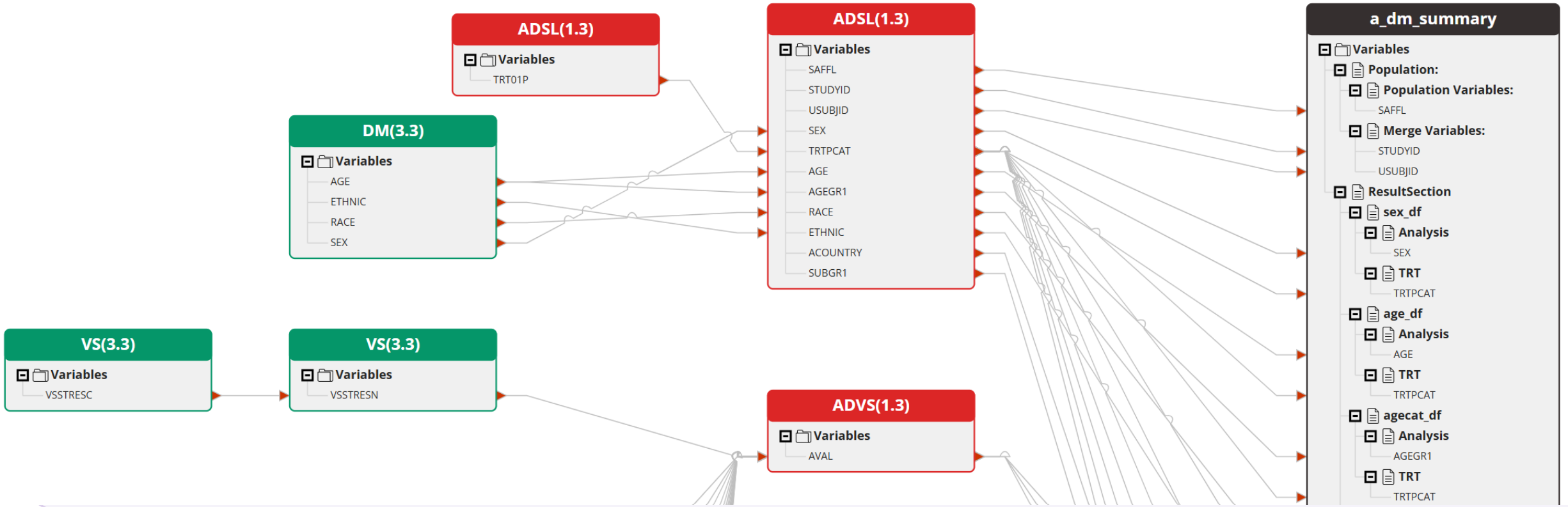
Vertical structure and modular approach enables increase of standardization with code from 70% in current reporting system to anticipated >=90%

FileName	IsAutoCode	IncludeRowCount	Name	Order	DerivationType	TrtVar	TrtDisplay	DataSetTypeName	ResultStatisticsName	OverrideADSLMerge	SDTMVersionName	Description
dm_summary_test1	Yes	No	BigN_df	1	CountsFrequencies	TRT01A	TrtGroup1		BigN		3.3	Big N Treatment Counts
dm_summary_test1	Yes	No	age_df	2	SummaryStatistics	TRT01A	TrtGroup1	ADSL	SummStats1		3.3	Age (years)
dm_summary_test1	Yes	No	sex_df	3	CountsFrequencies	TRT01A	TrtGroup1	ADSL	Counts1		3.3	Gender, n (%)
dm_summary_test1	Yes	No	ethnic_df	4	CountsFrequencies	TRT01A	TrtGroup1	ADSL	Counts1		3.3	Ethnicity, n (%)
dm_summary_test1	Yes	No	race_df	5	CountsFrequencies	TRT01A	TrtGroup1	ADSL	Counts1		3.3	Race, n (%)
dm_summary_test1	Yes	No	weight_df	6	SummaryStatistics	TRT01A	TrtGroup1	VS	SummStats1		3.3	Weight (kg)
dm_summary_test2	Yes	No	BigN_df	1	CountsFrequencies	TRT01A	TrtGroup1		BigN		3.3	Big N Treatment Counts

ARDS Output File

POPFLAG	POPULATION	TRTN	TRT	CAT1VARLABEL	CAT1VAR	CAT1	CAT1N	CAT1LABEL	RESULTTYPE	RESULT
SAFFL	Safety Population	4	Trt D	Age (years)	AGE				n	141
SAFFL	Safety Population	4	Trt D	Age (years)	AGE				Std Dev	10.9300252
SAFFL	Safety Population	999	Total	Age (years)	AGE				Maximum	85
SAFFL	Safety Population	999	Total	Age (years)	AGE				Mean	53.98367347
SAFFL	Safety Population	999	Total	Age (years)	AGE				Median	55
SAFFL	Safety Population	999	Total	Age (years)	AGE				Minimum	18
SAFFL	Safety Population	999	Total	Age (years)	AGE				n	490
SAFFL	Safety Population	999	Total	Age (years)	AGE				Std Dev	11.27549321
SAFFL	Safety Population	2	Trt B	Gender, n (%)	SEX	F	1	Female	Count	59
SAFFL	Safety Population	4	Trt D	Gender, n (%)	SEX	F	1	Female	Count	115
SAFFL	Safety Population	3	Trt C	Gender, n (%)	SEX	F	1	Female	Count	116
SAFFL	Safety Population	1	Trt A	Gender, n (%)	SEX	F	1	Female	Count	114
SAFFL	Safety Population	999	Total	Gender, n (%)	SEX	F	1	Female	Count	404
SAFFL	Safety Population	2	Trt B	Gender, n (%)	SEX	M	2	Male	Count	10
SAFFL	Safety Population	4	Trt D	Gender, n (%)	SEX	M	2	Male	Count	26
SAFFL	Safety Population	3	Trt C	Gender, n (%)	SEX	M	2	Male	Count	25
SAFFL	Safety Population	1	Trt A	Gender, n (%)	SEX	M	2	Male	Count	25
SAFFL	Safety Population	999	Total	Gender, n (%)	SEX	M	2	Male	Count	86
SAFFL	Safety Population	2	Trt B	Gender, n (%)	SEX	F	1	Female	Percentage	85.50724638
SAFFL	Safety Population	4	Trt D	Gender, n (%)	SEX	F	1	Female	Percentage	81.56028369
SAFFL	Safety Population	3	Trt C	Gender, n (%)	SEX	F	1	Female	Percentage	82.26950355
SAFFL	Safety Population	1	Trt A	Gender, n (%)	SEX	F	1	Female	Percentage	82.01438849
SAFFL	Safety Population	999	Total	Gender, n (%)	SEX	F	1	Female	Percentage	82.44897959
SAFFL	Safety Population	2	Trt B	Gender, n (%)	SEX	M	2	Male	Percentage	14.49275362
SAFFL	Safety Population	4	Trt D	Gender, n (%)	SEX	M	2	Male	Percentage	18.43971631
SAFFL	Safety Population	3	Trt C	Gender, n (%)	SEX	M	2	Male	Percentage	17.73049645
SAFFL	Safety Population	1	Trt A	Gender, n (%)	SEX	M	2	Male	Percentage	17.98561151
SAFFL	Safety Population	999	Total	Gender, n (%)	SEX	M	2	Male	Percentage	17.55102041
SAFFL	Safety Population	2	Trt B	Ethnicity, n (%)	ETHNIC	MISSING	9999	Missing	Count	1
SAFFL	Safety Population	3	Trt C	Ethnicity, n (%)	ETHNIC	MISSING	9999	Missing	Count	1
SAFFL	Safety Population	999	Total	Ethnicity, n (%)	ETHNIC	MISSING	9999	Missing	Count	2
SAFFL	Safety Population	2	Trt B	Ethnicity, n (%)	ETHNIC	HISPANIC OR LATINO	1	HISPANIC OR LATINO	Count	32
SAFFL	Safety Population	4	Trt D	Ethnicity, n (%)	ETHNIC	HISPANIC OR LATINO	1	HISPANIC OR LATINO	Count	82
SAFFL	Safety Population	3	Trt C	Ethnicity, n (%)	ETHNIC	HISPANIC OR LATINO	1	HISPANIC OR LATINO	Count	78

Dynamic traceability back through ADAM and SDTM to Data Collection



Pilot Study Results

Apr–Aug 2026

Pilot study timeline

36 TFLs from 26 ARDS files

100% Standard code

*** No bespoke code (DMC deliverable)

*** *For reference, the old system produced 31 standard TFLs and 5 bespoke TFLs.*

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Learnings from Pilot Study

- Almost everything worked as expected with expected inefficiencies to work out

- Biggest Issues:
  - **0 count and missing data handling**
    (example: ADAE having Mild and Severe records and no observations for Moderate but still needed to be displayed on TFL)
  - **Updating configurations in system were manual and it was hard to copy/paste across records**
    (example: study team changed treatment variable halfway through development so every ARDS file needed to be modified)
  - **Connecting updates in ARDS and TFLs**
    (example: Pilot study started with 32 TFLs requested by Statistician before going up to 42 TFLs but then ending with 36 TFLs which affects the ARDS files as well)

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Next Steps

- Resolve issues learned from Pilot study
- Effectively scale out for all new studies and train a large user-base
- Create dynamic Table of Contents with both ARDS and TFLs included
  - Machine-readable to enable AI-facilitation
- Enable and train downstream groups to use ARDS rather than TFLs
- Promote reusability by not creating new ARDS if same results are needed in different output

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Submission-Related Questions

ARDS is a relatively new concept and does not always fit cleanly into traditional submissions. Certain questions need to be answered as ARDS usage expands across the industry.

Agencies and industry should work together to align on common practices. Among questions still to be answered:

Where should ARDS files go in submission package?

- Miscellaneous section
- Program files
- Elsewhere

Upon request, should ARDS code or TFL code be submitted (or both)?

How do we ensure it's easy and transparent for agencies to review ARDS files as intermediary between ADAM and TFLs? Do they necessarily need the TFLs at that point?

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Questions?

