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ADaM Datasets: Balancing Automated & Manual Conformance Checks

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Meet the Speaker

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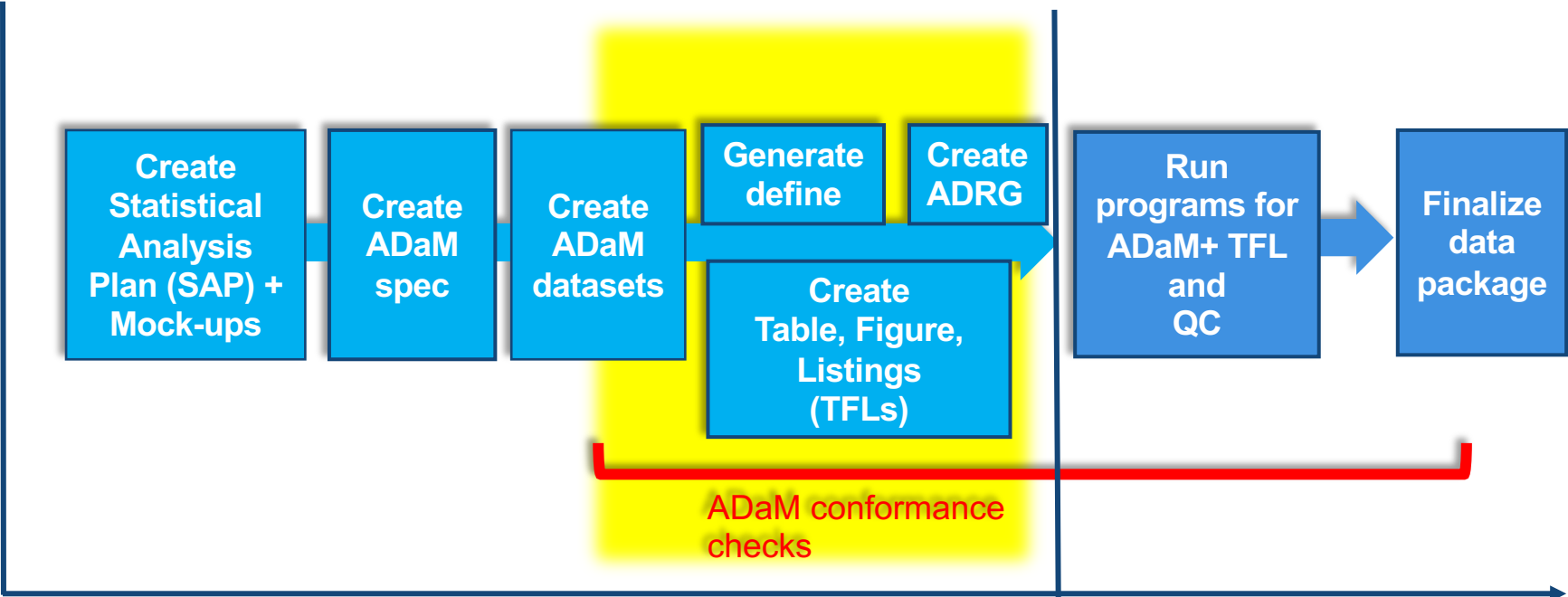
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Agenda

1. General Stat Process Flow
2. Conformance check
3. Automated checks are useful
4. Manual check examples

General Stat Process Flow



Protocol created

Database Lock (DBL)



Conformance check

ADaM Conformance rules

A	B	C	D	E	F	G
Check Number	IG Version	Variable Group	Logical Seq	ADaM Structure Group	Machine-Testable Failure Criteria	Message Type
1	1.0	ADSL	1	ADSL	ADSL dataset does not exist	Error
1	1.1	ADSL	1	ADSL	ADSL dataset does not exist	Error
1	1.2	ADSL	1	ADSL	ADSL dataset does not exist	Error
2	1.0	label	127.04	ALL:SDTM	A variable is present in ADaM with the same name as a variable present in SDTM but the variables do not have identical labels	Error
2	1.1	label	127.04	ALL:SDTM	A variable is present in ADaM with the same name as a variable present in SDTM but the variables do not have identical labels	Error
2	1.2	label	127.04	ALL:SDTM	A variable is present in ADaM with the same name as a variable present in SDTM but the variables do not have identical labels	Error
5	1.0	FL	65.03	ALL	A variable with a suffix of FL has a value that is not Y, N or null	Warning
5	1.1	FL	65.04	ALL	A variable with a suffix of FL has a value that is not Y, N or null	Error
5	1.2	FL	65.04	ALL	A variable with a suffix of FL has a value that is not Y, N or null	Error
6	1.0	FL	65.05	ALL	A variable with a suffix of FL is present and a variable with the same root and a suffix of FN has a value that is not 0, 1 or null	Warning
6	1.1	FL	65.05	ALL	A variable with a suffix of FL is present and a variable with the same root and a suffix of FN has a value that is not 0, 1 or null	Warning
6	1.2	FL	65.05	ALL	A variable with a suffix of FL is present and a variable with the same root and a suffix of FN has a value that is not 0, 1 or null	Warning
7	1.0	FL	65.02	ALL	A variable with a suffix of FN is present but a variable with the same root and a suffix of FL is not present	Warning
7	1.1	FL	65.02	ALL	A variable with a suffix of FN is present but a variable with the same root and a suffix of FL is not present	Warning
7	1.2	FL	65.02	ALL	A variable with a suffix of FN is present but a variable with the same root and a suffix of FL is not present	Warning
10	1.0	FL	65.06	ALL	A variable with a suffix of FL is equal to Y and a variable with the same root and a suffix of FN is not equal to 1	Error
10	1.1	FL	65.06	ALL	A variable with a suffix of FL is equal to Y and a variable with the same root and a suffix of FN is not equal to 1	Error
10	1.2	FL	65.06	ALL	A variable with a suffix of FL is equal to Y and a variable with the same root and a suffix of FN is not equal to 1	Error
11	1.0	FL	65.07	ALL	A variable with a suffix of FL is equal to N and a variable with the same root and a suffix of FN is not equal to 0	Error
11	1.1	FL	65.07	ALL	A variable with a suffix of FL is equal to N and a variable with the same root and a suffix of FN is not equal to 0	Error
11	1.2	FL	65.07	ALL	A variable with a suffix of FL is equal to N and a variable with the same root and a suffix of FN is not equal to 0	Error
12	1.0	FL	65.08	ALL	A variable with a suffix of FL is equal to null and a variable with the same root and a suffix of FN is not equal to null	Error
12	1.1	FL	65.08	ALL	A variable with a suffix of FL is equal to null and a variable with the same root and a suffix of FN is not equal to null	Error
12	1.2	FL	65.08	ALL	A variable with a suffix of FL is equal to null and a variable with the same root and a suffix of FN is not equal to null	Error
13	1.0	length	127.08	ALL	The length of a variable name exceeds 8 characters	Error
13	1.1	length	127.08	ALL	The length of a variable name exceeds 8 characters	Error
13	1.2	length	127.08	ALL	The length of a variable name exceeds 8 characters	Error
14	1.0	naming	125.01	ALL	A variable name does not start with a letter (A-Z)	Error
14	1.1	naming	125.01	ALL	A variable name does not start with a letter (A-Z)	Error
14	1.2	naming	125.01	ALL	A variable name does not start with a letter (A-Z)	Error
15	1.0	naming	125.02	ALL	A variable name contains a character other than letters (A-Z), underscores (_), or numerals (0-9)	Error
15	1.1	naming	125.02	ALL	A variable name contains a character other than letters (A-Z), underscores (_), or numerals (0-9)	Error
15	1.2	naming	125.02	ALL	A variable name contains a character other than letters (A-Z), underscores (_), or numerals (0-9)	Error

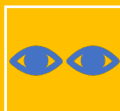
Automated checks are useful



Impossible to check all datasets manually



Quick



Check rules hard to find by eyes (ex., misspelled label, inappropriate letters)



Developed tools can support validation checks for submitting to regulatory agencies

Is it enough?

Creation of ADaM

Run automated checks

No issue found

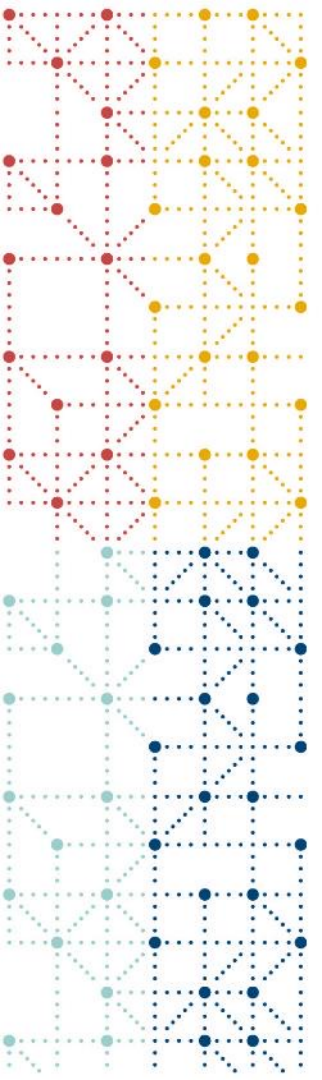
I'm finished with ADaM
conformance check!



Manual checks are necessary too!!



- Automated checks can't check everything for you.



Manual Check Examples

Population Flags in SAP vs ADaM

Did you create analysis population flags needed for analyses in your ADaM datasets?

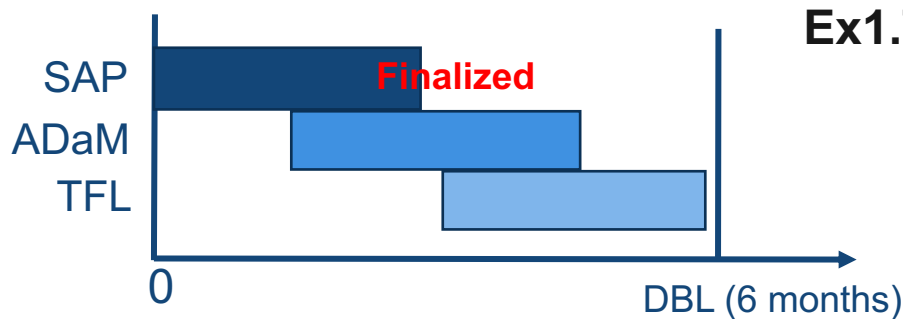
ADSL

USUBJID	FASFL	SAFFL	MITTFL
01-01-0000	Y	Y	Y
01-01-0001	Y	Y	Y
01-01-0002	Y	Y	Y
01-01-0003	Y	Y	Y
01-01-0004	N	Y	N

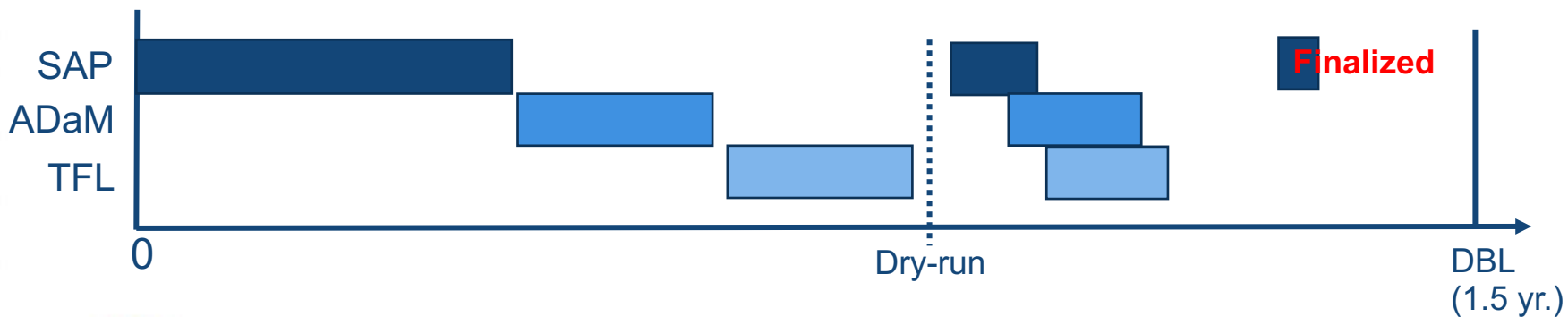
Population indicator checks

Publisher ID	Machine-Testable Failure Criteria	Message Type
5	A variable with a suffix of FL has a value that is not Y, N or null	Error
6	A variable with a suffix of FL is present and a variable with the same root and a suffix of FN has a value that is not 0, 1 or null	Warning
7	A variable with a suffix of FN is present but a variable with the same root and a suffix of FL is not present	Warning
10	A variable with a suffix of FL is equal to Y and a variable with the same root and a suffix of FN is not equal to 1	Error
11	A variable with a suffix of FL is equal to N and a variable with the same root and a suffix of FN is not equal to 0	Error
12	A variable with a suffix of FL is equal to null and a variable with the same root and a suffix of FN is not equal to null	Error
19,20,21,22,23,24, 25	COMPLFL/ FASFL/ ITTFL/ PPROTFL/ SAFFL/ RANDFL /ENRFL is present and has a value that is not Y or N	Error
48	A variable with a suffix of FL is not present in ADSL	Error
366	RANDDT is not present when RANDFL is equal to Y for at least one record.	Error

Timing of ADaM creation varies



Ex2. Study is years long



Population Flags in SAP vs ADaM

SAP

4. Analysis Sets

4.1 Full Analysis set

Full analysis set is defined as all subjects who received at least one dose of XXX.....

4.2 Safety Analysis set

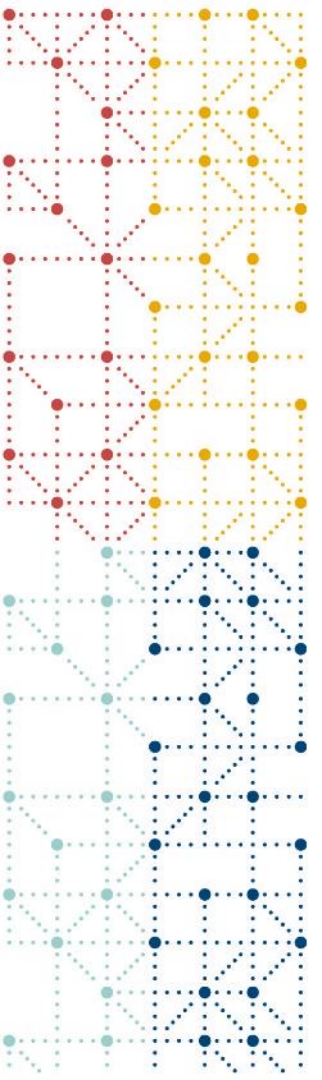
Safety analysis set is defined as

5.

ADSL

USUBJID	FASFL	SAFFL	XYZFL
01-01-0000	Y	Y	Y
01-01-0001	Y	Y	Y
01-01-0002	Y	Y	Y
01-01-0003	Y	N	Y
01-01-0004	N	N	Y

??



Manual Check Examples

When date/time imputations are done

When date/time imputations are done



x.1 Missing Data Handling

In general, missing data will not be imputed except missing/partial missing event adverse event (AE) start date



ADAE

USUBJID	AESEQ	AEDECOD	AESTDTC	ASTDT	TRTSDT	TRTEMFL
01-01-0000	1	Eye Swelling	2020-02	2020-02-01	2020-03-01	
01-01-0000	2	Nausea	2020-03-04	2020-03-04	2020-03-01	Y
01-01-0000	3	Cough	2020	2020-01-01	2020-03-01	

Date/time imputation checks

ADaM Conformance Rule:

Publisher ID	Machine-Testable Failure Criteria	Message Type
507, 508	A variable ending in DTF/TMF must contain "Date/Time Imputation Flag" in the label	Error
513, 514	A variable ending in SDTF/STMF must contain "Start Date/Time Imputation Flag" in the label	Error
519, 520	A variable ending in EDTF/ETMF must contain "End Date/Time Imputation Flag" in the label	Error


P21 Community Result:

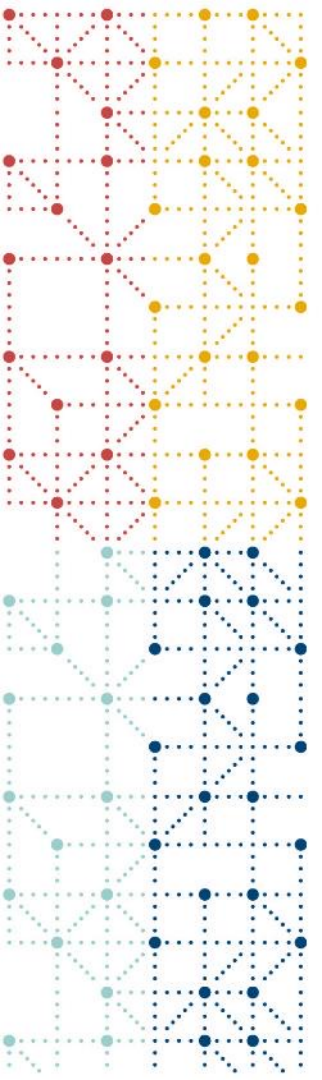
D	E	F	G
Variables	Values	Pinnacle 21 ID	Message
VARIABLE, LABEL	ASTDTF, Analysis Start Date Imputation Flag	AD0018	Variable label mismatch between dataset and ADaM standard
ASTDTF	Z	CT2001	ASTDTF value not found in 'Date Imputation Flag' non-extensible codelist

When date/time imputation is done

USUBJID	AESEQ	AEDECOD	AESTDTC	ASTDT	ASTDTF	TRTSDT	TRTEML
01-01-0000	1	Eye Swelling	2020-02	2020-02-01	D	2020-03-01	
01-01-0000	2	Nausea	2020-03-04	2020-03-04		2020-03-01	Y
01-01-0000	3	Cough	2020	2020-01-01	M	2020-03-01	

 Don't forget to add imputation flags

 Automated checks can check the values of imputation flags (Y/M/D) or (H/T/S) but not if you create imputation flags based on SAP!



Manual Check Examples

AVAL & AVALC 1:1 relationship

AVAL & AVALC 1:1 relationship

AVAL	AVALC
1	None
2	Some
3	Marked

1:1

Row	USUBJID	PARAM	PARAMCD	AVISIT	AVAL	AVALC
1	01-01-0000	Test Improvement	IMPROV	AVISIT1	1	None
2	01-01-0000	Test Improvement	IMPROV	AVISIT2	1	None
3	01-01-0000	Test Improvement	IMPROV	AVIIST3	1	NE
4	01-01-0000	Test Improvement	IMPROV	AVIIST4	2	Some
5	01-01-0000	Test Improvement	IMPROV	AVIIST5	3	Marked
6	01-01-0001	Test Improvement	IMPROV	AVISIT1	2	Some
7	01-01-0001	Test Improvement	IMPROV	AVISIT2	22	Some

AVAL & AVALC 1:1 relationship

ADaM Conformance Rule:

Publisher ID	Machine-Testable Failure Criteria	Message Type
149	Within a given value of PARAMCD, there is more than one value of AVALC for a given value of AVAL, considering only those rows on which both variables are populated	Error
150	Within a given value of PARAMCD, there is more than one value of AVAL for a given value of AVALC, considering only those rows on which both variables are populated	Error

P21 Community Result:

D	E	F	G
Variables	Values	Pinnacle 21 ID	Message
STUDYID, PARAMCD, AVAL, AVALC	01-01-0000, IMPROV, 1, NE	AD0149B	Inconsistent value for AVALC
STUDYID, PARAMCD, AVAL, AVALC	01-01-0001, IMPROV, 22, Some	AD0150	Inconsistent value for AVAL

AVAL & AVALC 1:1 relationship

✘ 1:1

USUBJID	PARAM	PARAMCD	AVISIT	AVAL	AVALC
01-01-0000	Body Mass Index(kg/m ²)	BMI	AVISIT1	17.80008088888	17.80008088
01-01-0000	Body Mass Index(kg/m ²)	BMI	AVISIT2	17.80008088832	17.80008088
01-01-0000	Body Mass Index(kg/m ²)	BMI	AVIIST3	18.26288298777	18.26288299

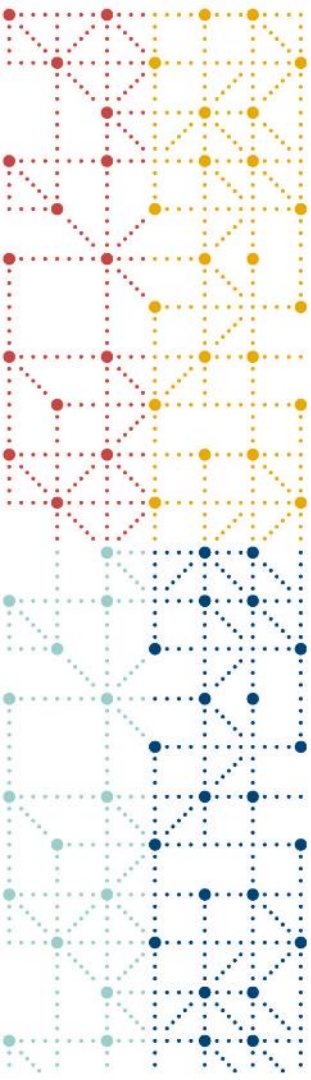


- P21 Community rounds and allows up to 7 places after the decimal
- AVALC is not a character representation of AVAL
- Better to keep original SDTM variables or use AVAL in listing programs



Conclusion

- Automated checks do most of the work for you to help find conformance issues.
- Understand the value and coverage from these automated checks.
- Important to supplement them with certain manual checks that those automated checks can't check.
- Most importantly, your datasets cover everything that you need for your analyses and in compliance with ADaM rules.



Thank You!

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