

Pre ADSL-Revolutionize your ADaM workflow

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Data Handling & Data Engineering (DH04)

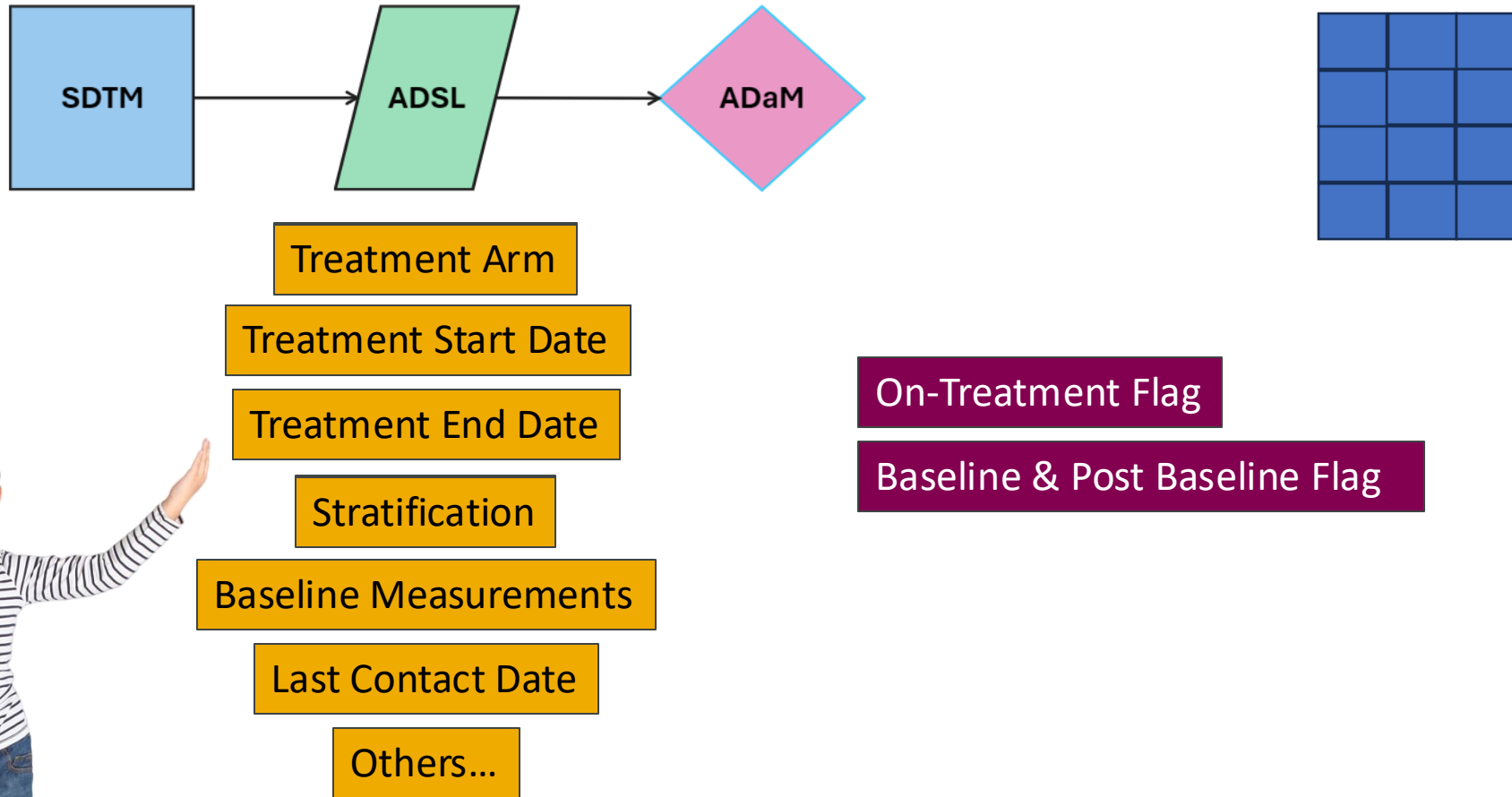
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MADRID2, Strasbourg Convention Centre

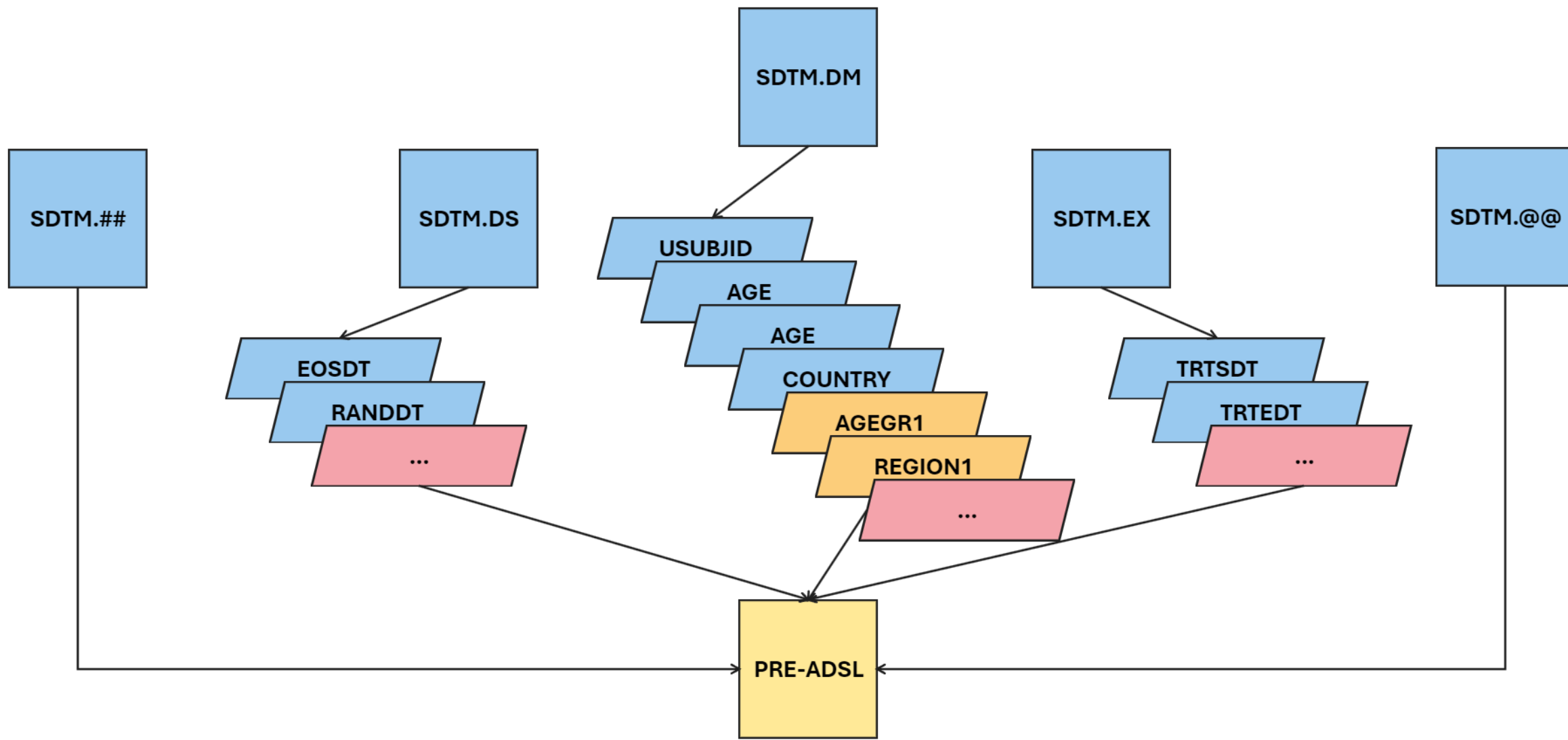
Today's flow

Challenge	Potential Solution	Example(s)	Keep an eye on -	Alternatives
Complex ADaM derivations in multiple Datasets	Consolidating Derived values in Temporary Datasets	• Pre-ADSL for iDMC • Pre-ADaMs & CROSS dataset	• Specifications • eCRT package	• Recursive Workflow • Macros • Other

Typical ADaM Workflow



Consolidation of derivations in PRE-ADSL





PRE-ADSL for Independent Data Monitoring Committee



Actions

- ✓ Create PRE-ADSL code
- Copy PRE-ADSL code to Unblinded area ✓
- ✓ Create Unblinded PRE-ADSL
- Copy PRE-ADSL to Blinded area ✓
- ✓ Create Blinded ADSL
- Create Unblinded ADSL ✓
- ✓ Create Blinded TFLs
- Create Unblinded TFLs ✓
- ✓ Match Total Columns



Blinded
Programmer



Unblinded
Programmer

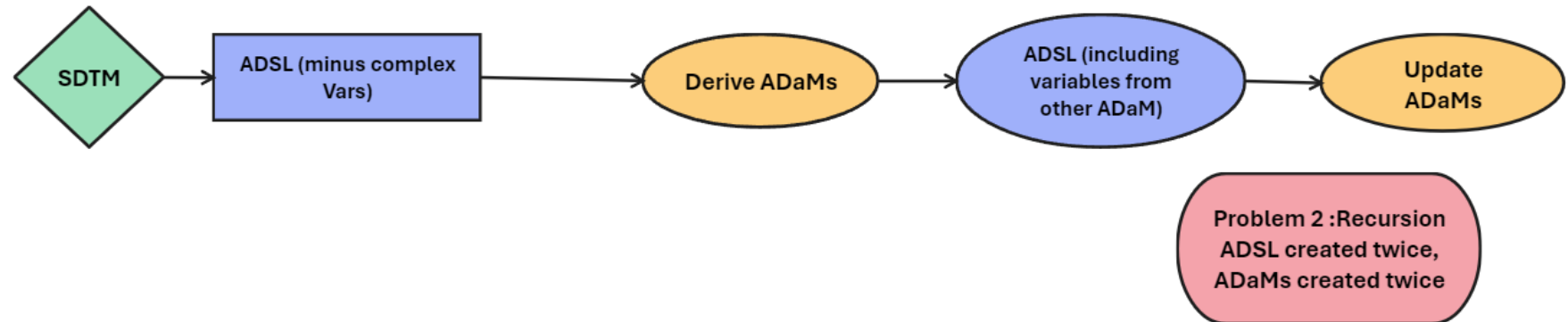
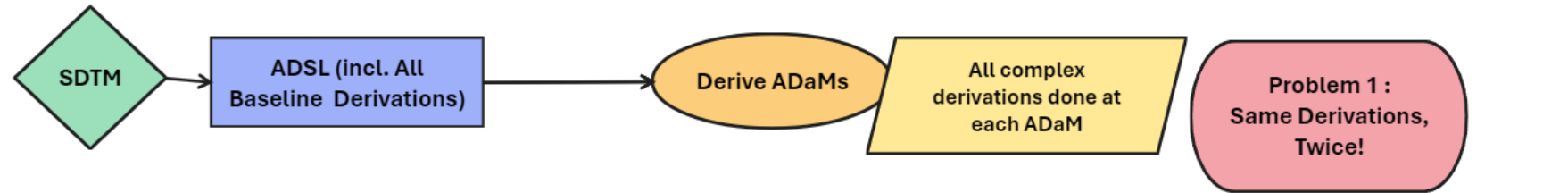
PRE-ADaMs & CROSS Dataset Workflow

PROBLEM:

✓ Deriving Complex Derivation in more than one ADaMs dataset.



Solution 1 : Derive information Twice

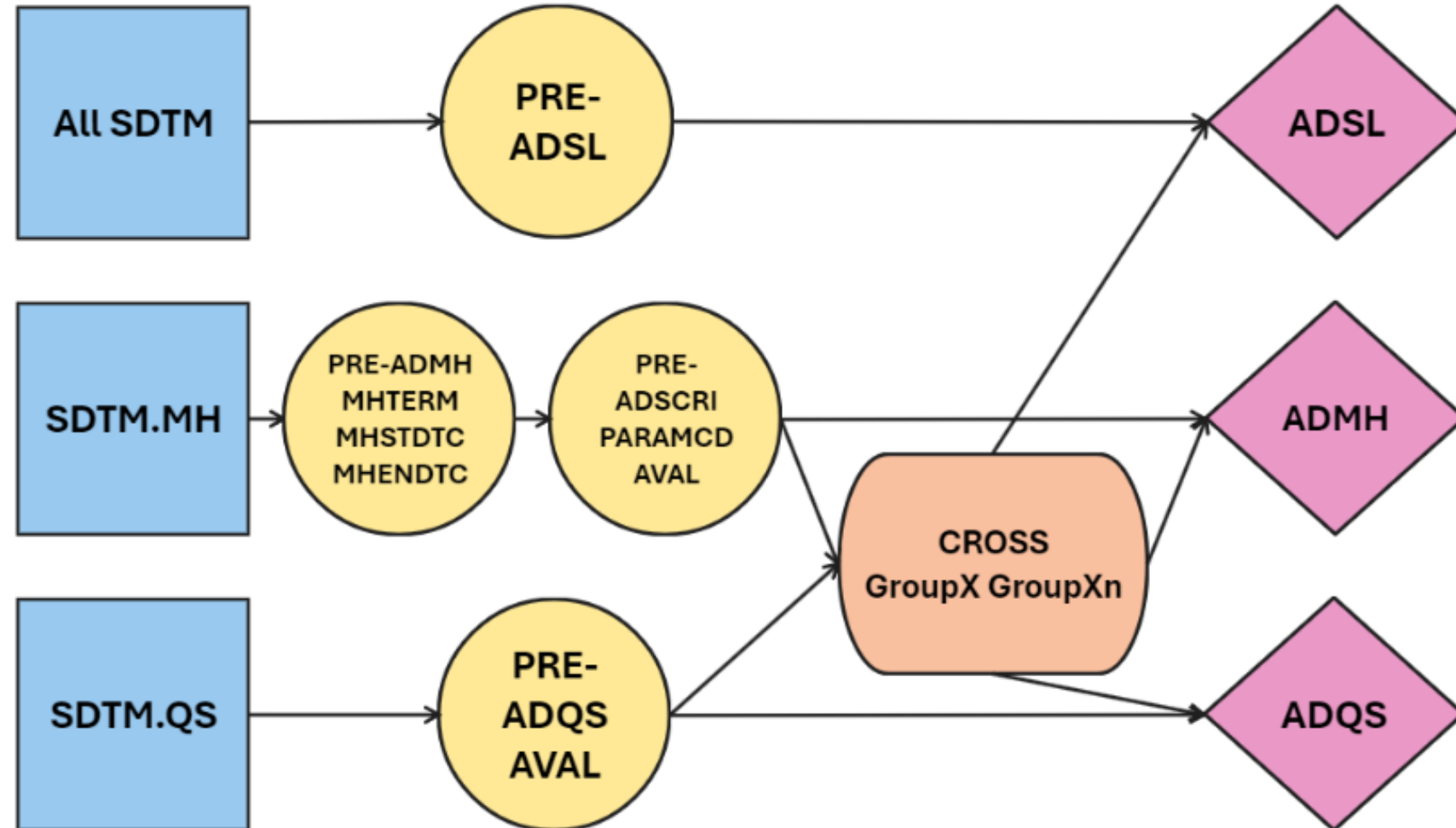


Solution 2 : Deriving in ADaM and incorporating into ADSL

Flowchart of managing repeated variables in ADaM and ADSL

SOLUTION?

- ✓ This might look like that of a typical Recursion, but it is not.
- ✓ Keeping an intermediate Champion dataset – CROSS



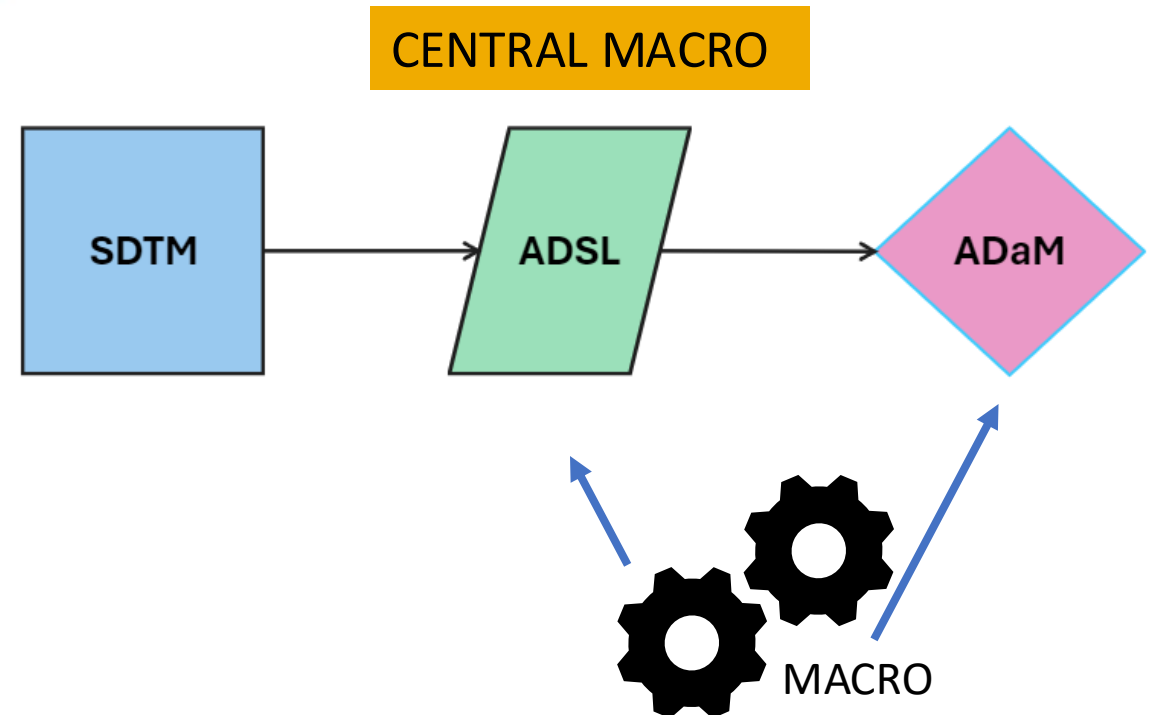
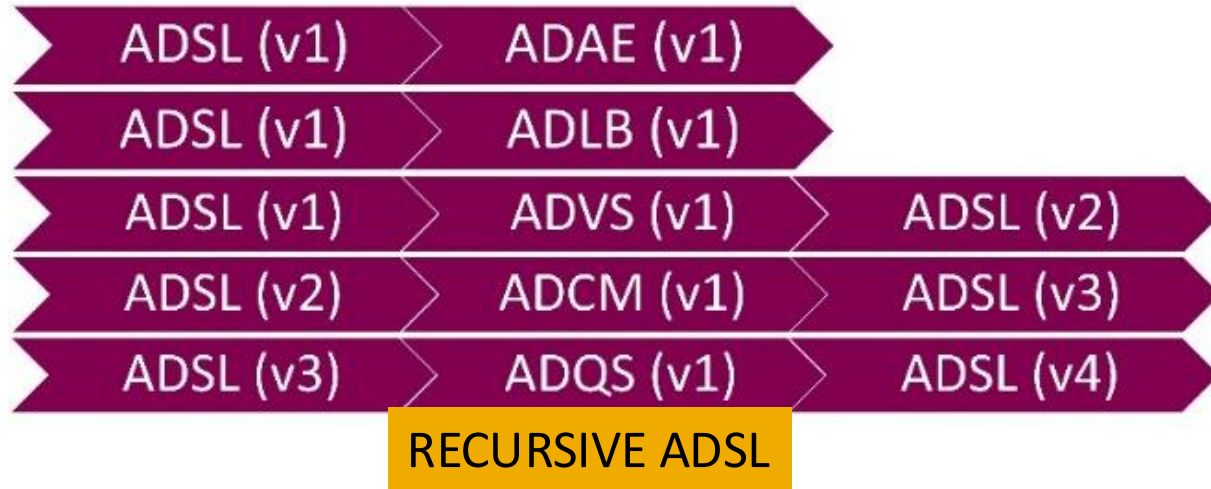
ADaM eCRT



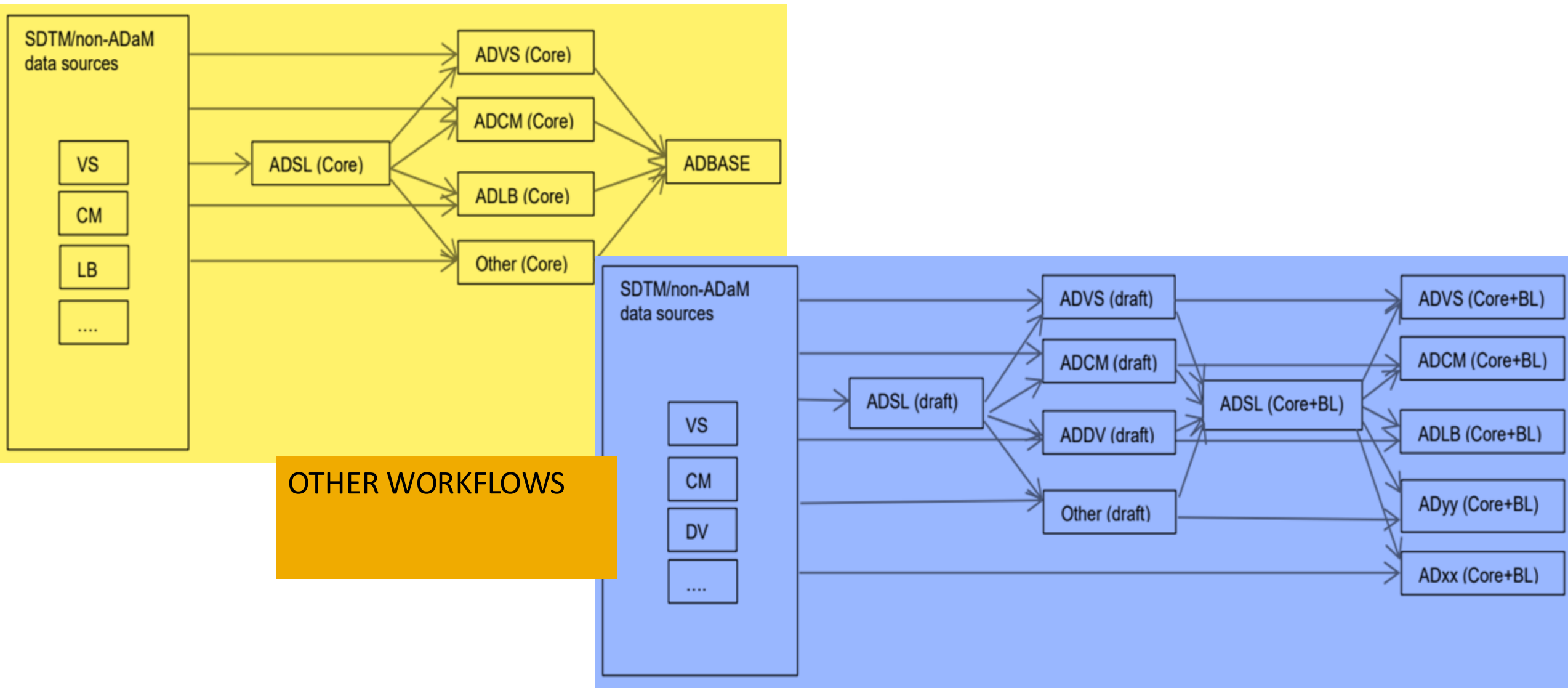
Dataset	Variable	Source	Input Dataset
ADSL	USUBJID	Predecessor	SDTM.DM
ADSL	GROUPIX1	Derived	ADAM.CROSS
ADSL	GROUPIX2	Derived	ADAM.CROSS
ADMH	USUBJID	Predecessor	ADAM.ADSL
ADMH	MHTERM	Derived	SDTM.MH
ADMH	MHSTDTC	Derived	SDTM.MH
ADMH	MHENDTC	Derived	SDTM.MH
ADSCRI	USUBJID	Predecessor	ADAM.ADSL
ADSCRI	PARAMCD	Derived	ADAM.PRE_ADMH
ADSCRI	AVAL	Derived	ADAM.PRE_ADMH
ADQS	USUBJID	Predecessor	ADAM.ADSL
ADQS	PARAMCD	Derived	SDTM.QS
ADQS	AVAL	Derived	SDTM.QS

Example of Dataset Specification highlighting sources for variables

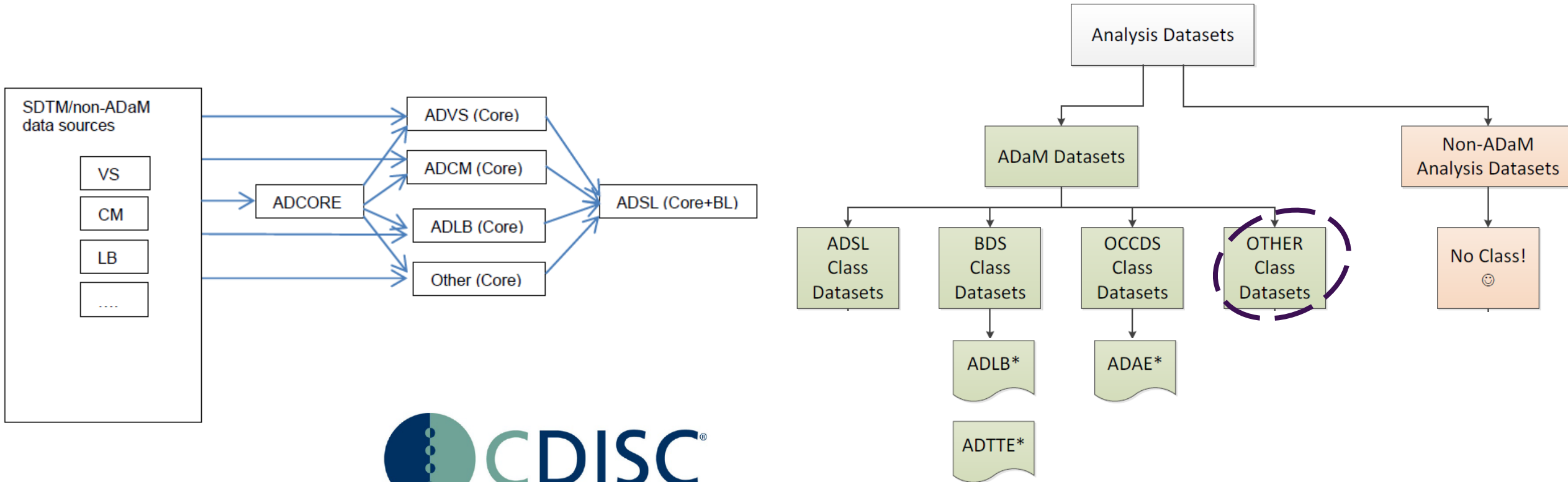
Alternative Approaches



Alternative Approaches



Conclusion



Therapeutic Area User Guide for Prostate
Cancer

Therapeutic Area Data Standards
User Guide for Breast Cancer

ADEVENT

ADDATES

Thanks & References

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- Therapeutic Area User Guide for Prostate Cancer Version 1.0 (Provisional) (2017-07-10).

QUESTIONS?



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