

SDTM-ADaM HYBRID:

SUPERMODEL or FRANKENSTEIN?

**PhUSE Annual Conference 2017
DH11**

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11 October, 2017







DISCLAIMER:

Operational Model

.....not *a submission model*

WHAT WILL BE COVERED TODAY ABOUT THE SDTM-ADaM HYBRID?

BACKGROUND

What has brought us to this premise?

EXPLORATION

What factors might determine how this hybrid would look?

BENEFITS

What might be the potential gains?

CHALLENGES

What obstacles might need to be overcome?



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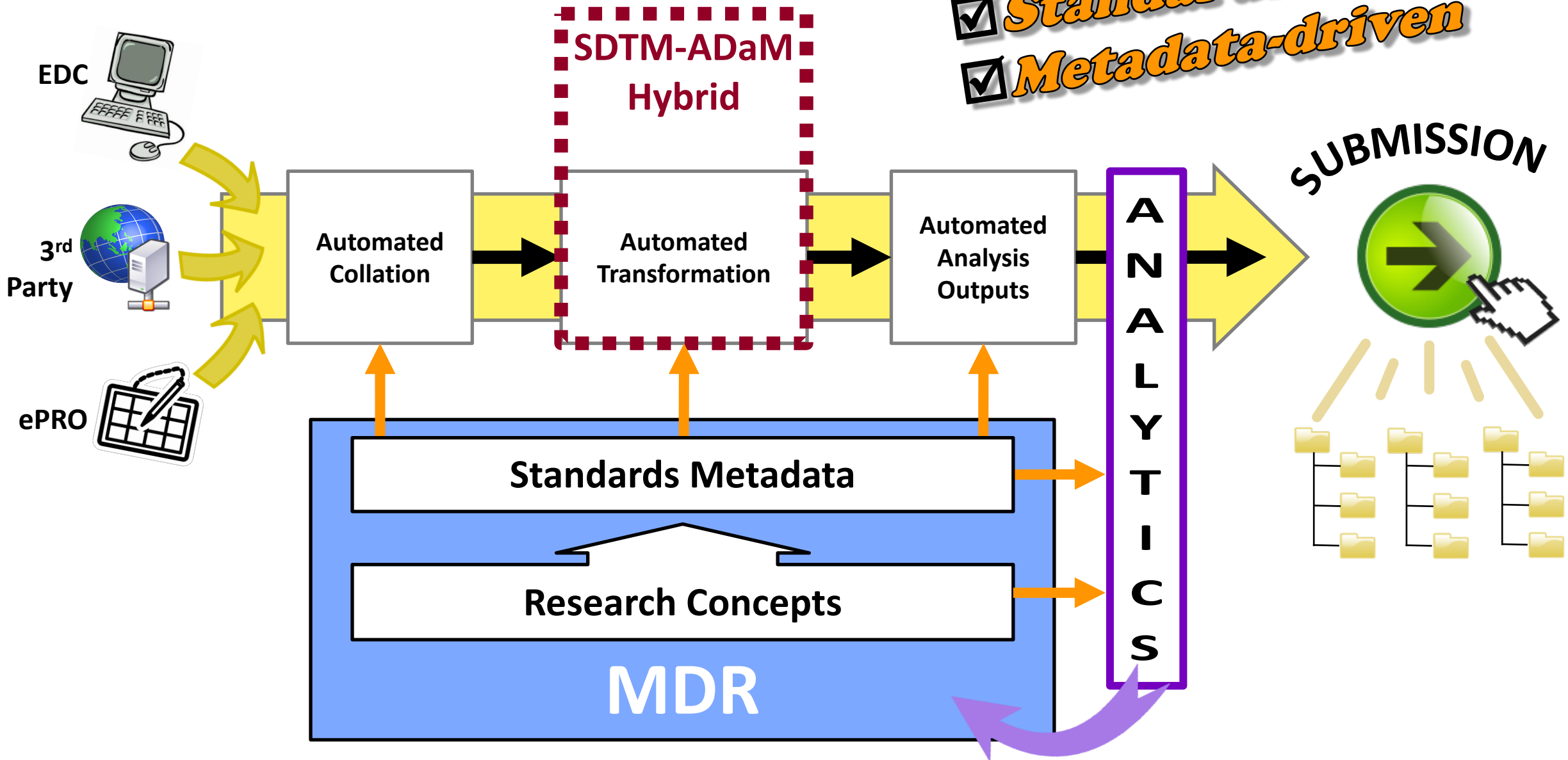
PERSPECTIVE ON
CHARTING NEW
DIRECTIONS IN CLINICAL
RESEARCH

“If we knew what it was we were doing, it would not be called **research, would it?”**

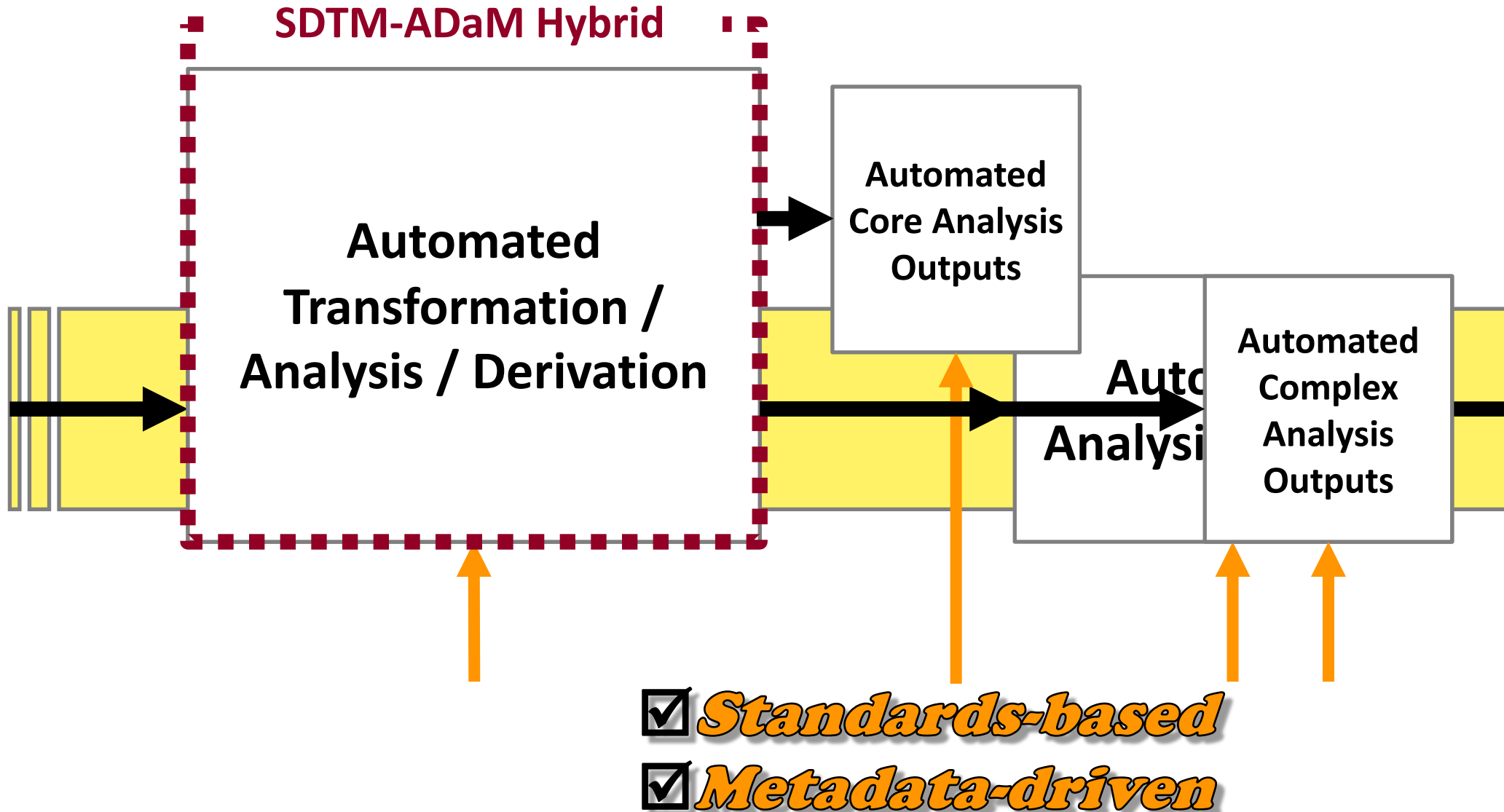
“Only two things are infinite, the universe and human stupidity, and I'm not sure about the former.”

- Albert Einstein

INTELLIGENT DATA FLOW



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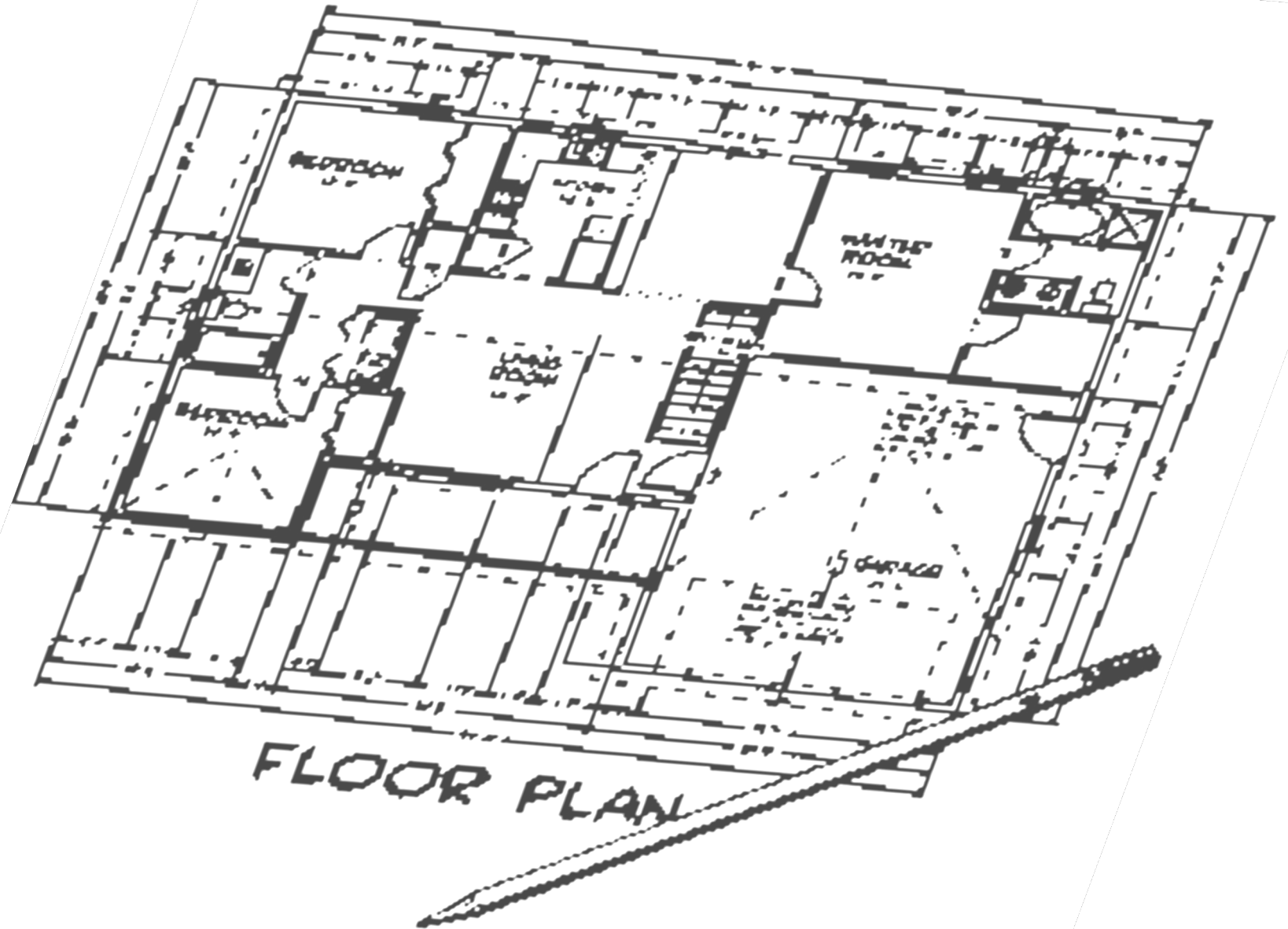
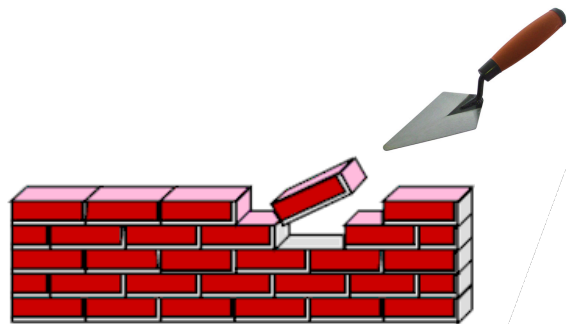
BENEFITS

What might be the potential gains?

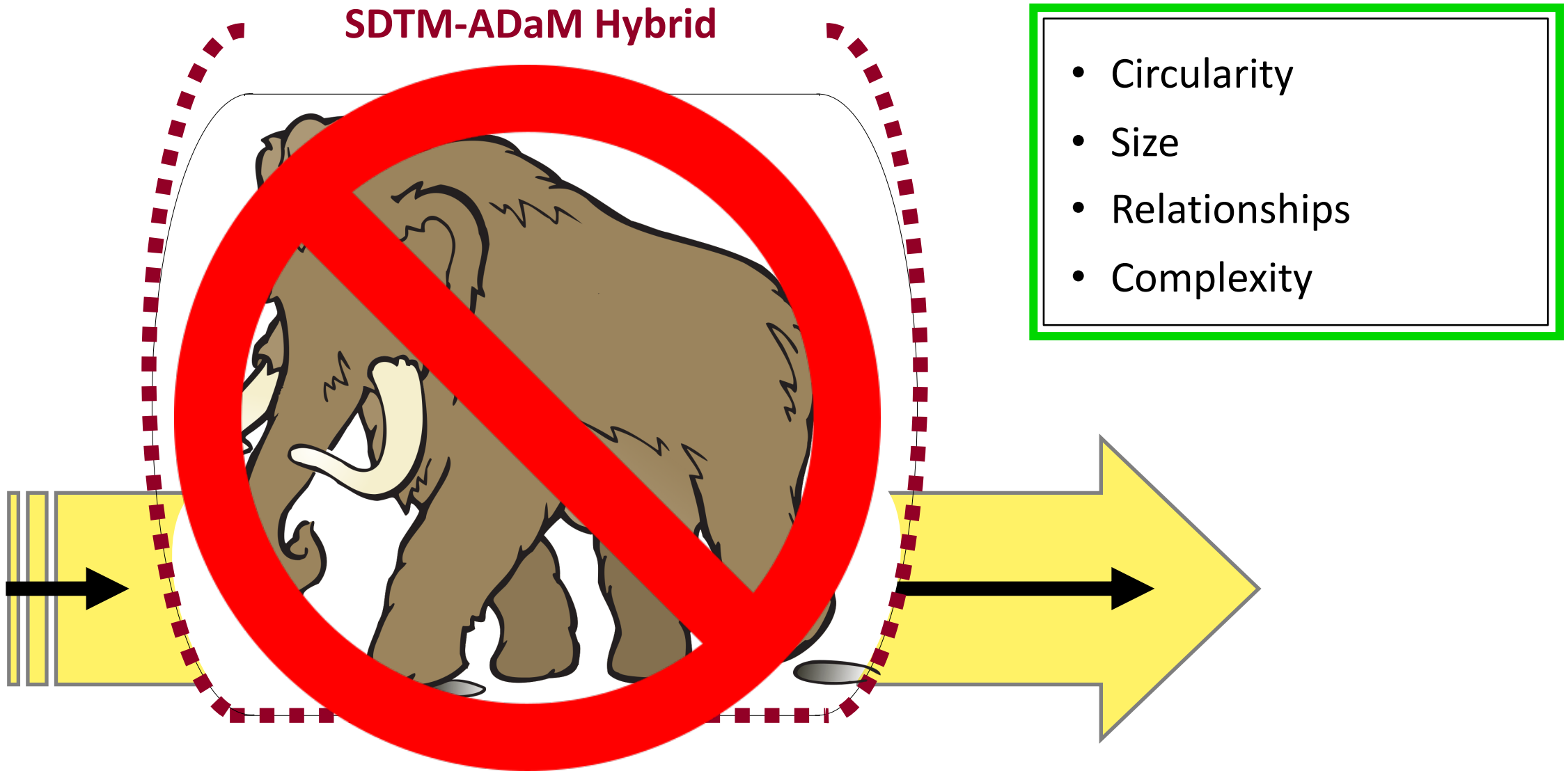
CHALLENGES

What obstacles might need to be overcome?

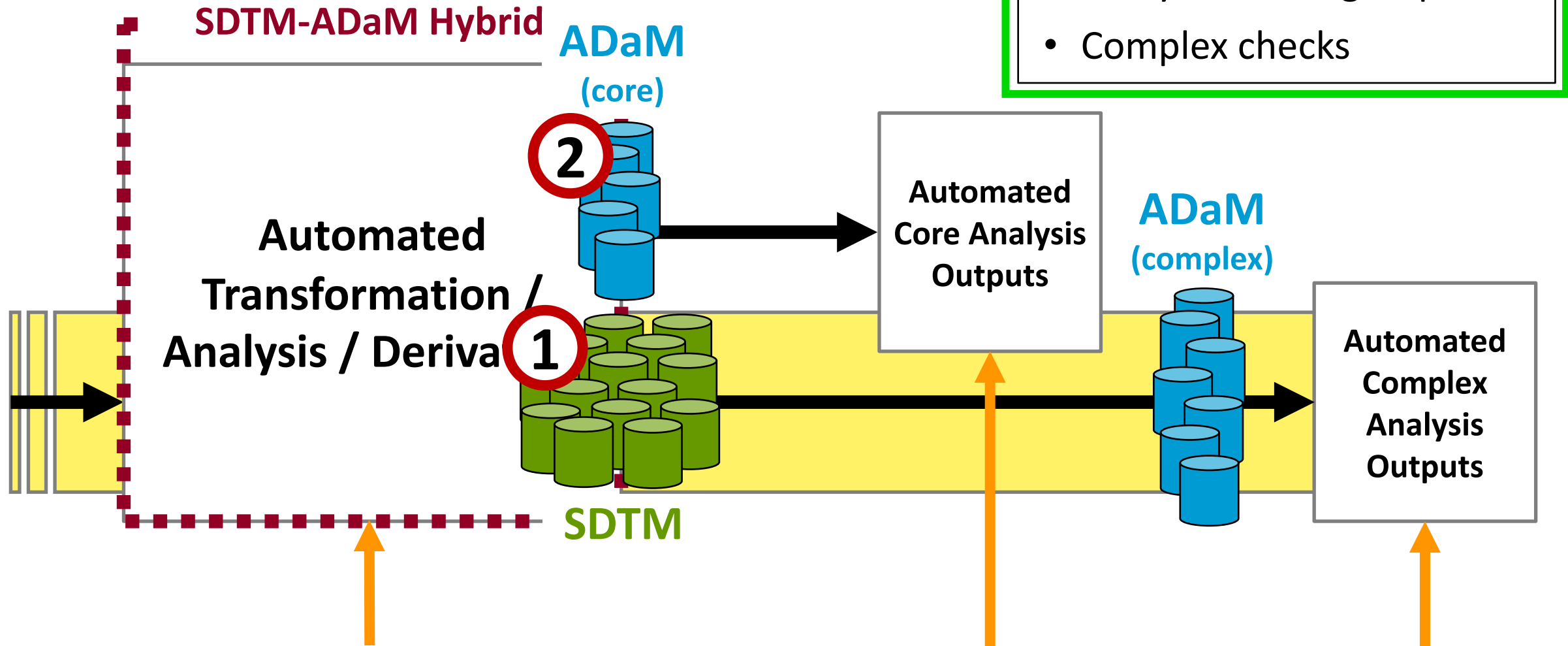
WHERE TO START?



A MASSIVE SUPERSET?



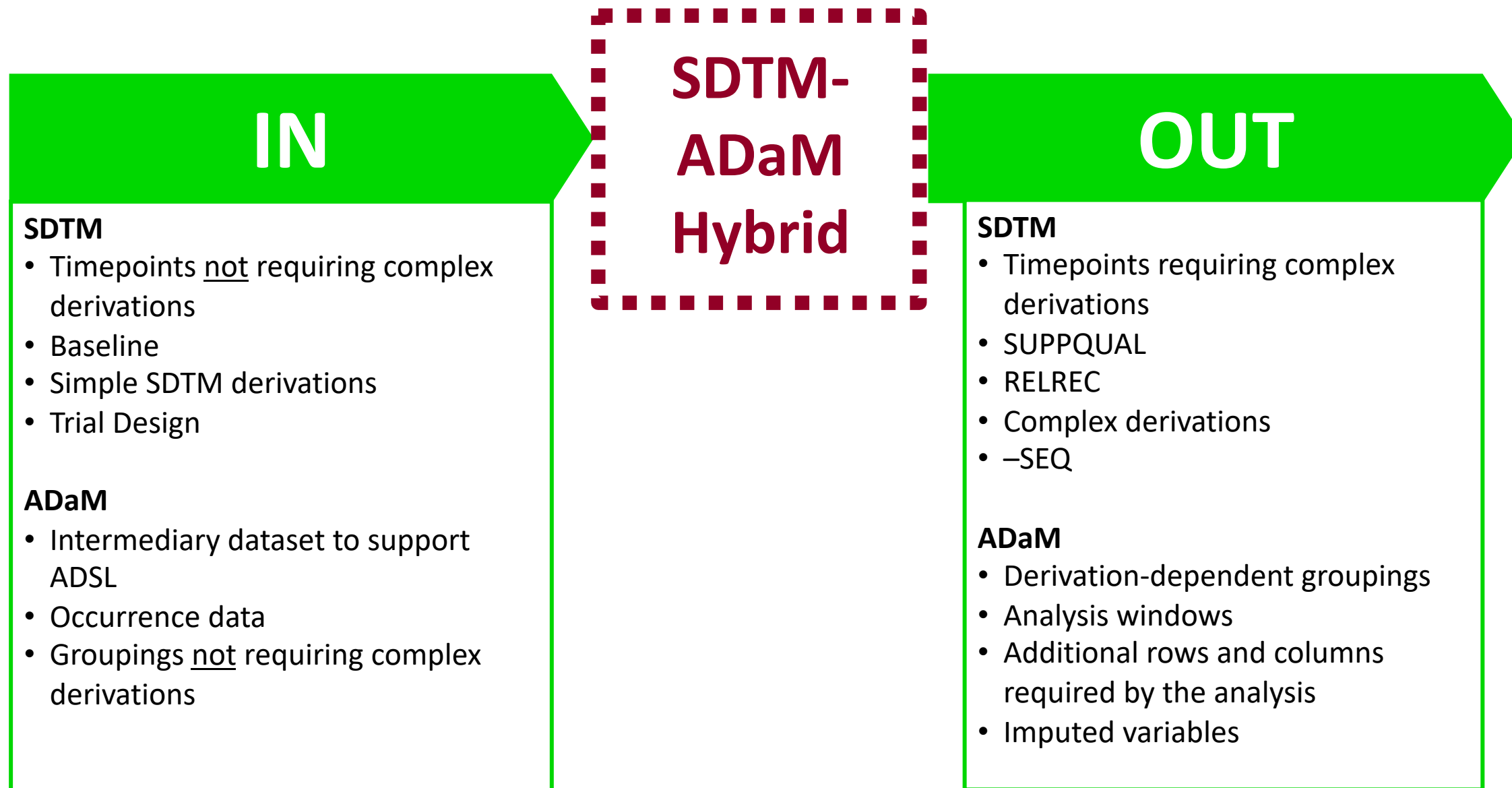
A BETTER WAY FORWARD?



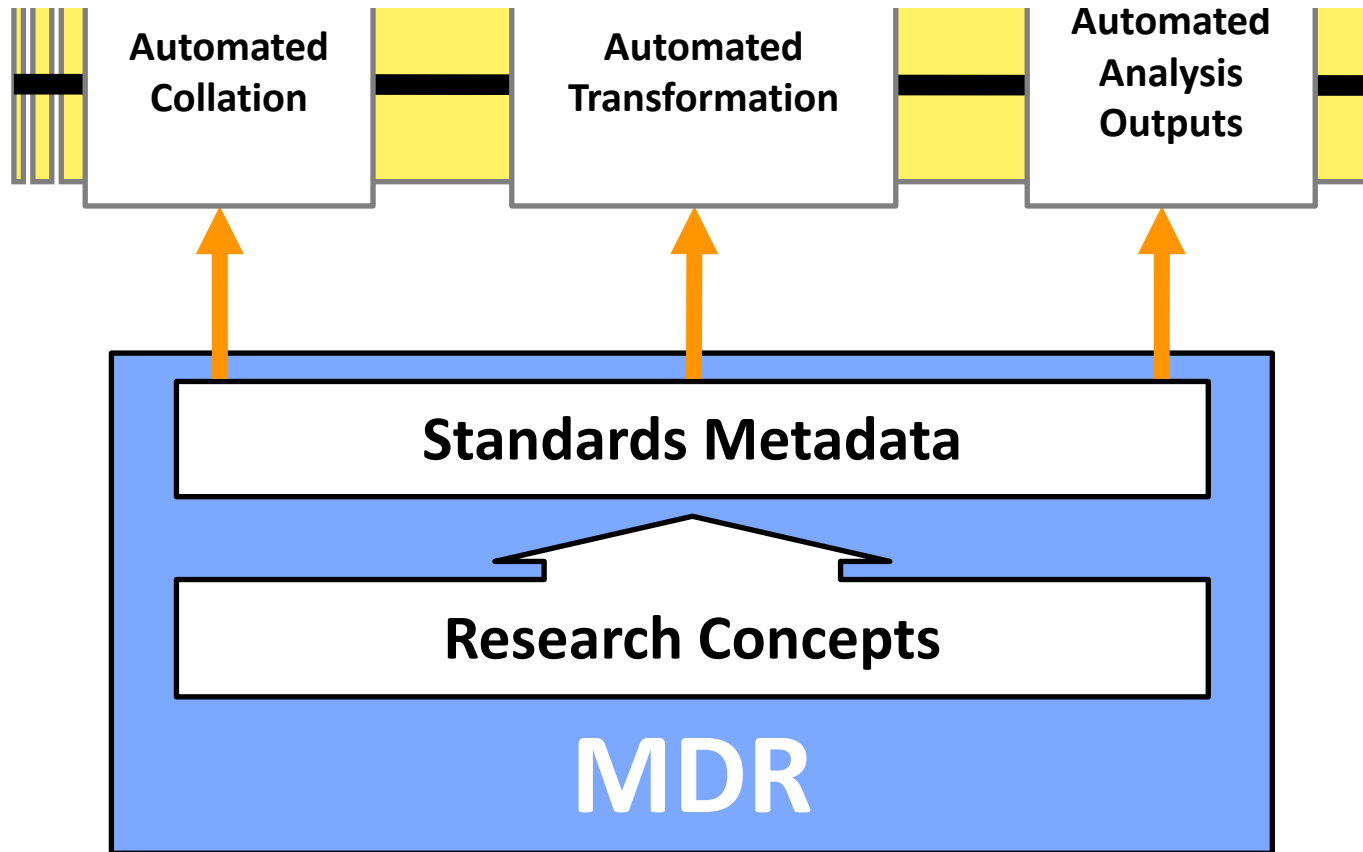
EXPLORING THE DIFFERENCES IN ADAM

Structure	Example	Evaluation
Subject-Level Analysis	ADSL	• There would be a need for the use of an intermediary dataset in the hybrid that would contain the necessary SDTM data behind derived flags, factors, and groupings • Some variables would be highly study-specific
Basic Data Structure (BDS)	Vital Signs, Laboratory Results	• Hybrid is probably suitable only for simple analysis structures where minimal additional columns and rows are necessary • Any SDTM qualifiers that are incorporated into PARAM are good candidates for the hybrid structure • Imputed variables would likely need to be computed after the hybrid just before the creation of the ADaM dataset
Occurrence Data Structure (OCCDS)	Adverse Events, Concomitant Medications	• Best candidate for the hybrid model, as it is already most like SDTM+ structures • Occurrence counts are manageable in the hybrid • Not only for Events and Interventions, but also for Findings results such as Labs where the result can be converted to a text-based event and analyzed as an Event
Time-to-Event (TTE)	Time to Death	• TTE computations are likely too complex to facilitate use within a hybrid model, whether they consist of single or composite endpoints

CALCULATIONS AND DERIVATIONS



MAGNITUDE OF METADATA ROLE



- Standards definition
- Process definition
- Centrally-managed
- Knowledgeable governance
- Interfaces between MDR and clinical systems
- High % standards usage
- Timeliness
 - Up-to-date
 - During study set-up



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BENEFITS



Early subset of core analysis output

Demog

Conmed

AEs

Vitals

Med Hx

Labs



Early complex data checks



Reviewer sees more SDTM data next to the analysis data



Earlier decision-making



Reduction in the amount of siloed processing



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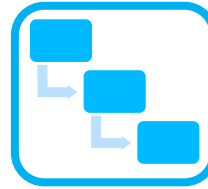
CHALLENGES



Snapshot process / audit trail



ADSL is highly study-specific



Sequence of derivations



Re-defined interfaces between functional areas

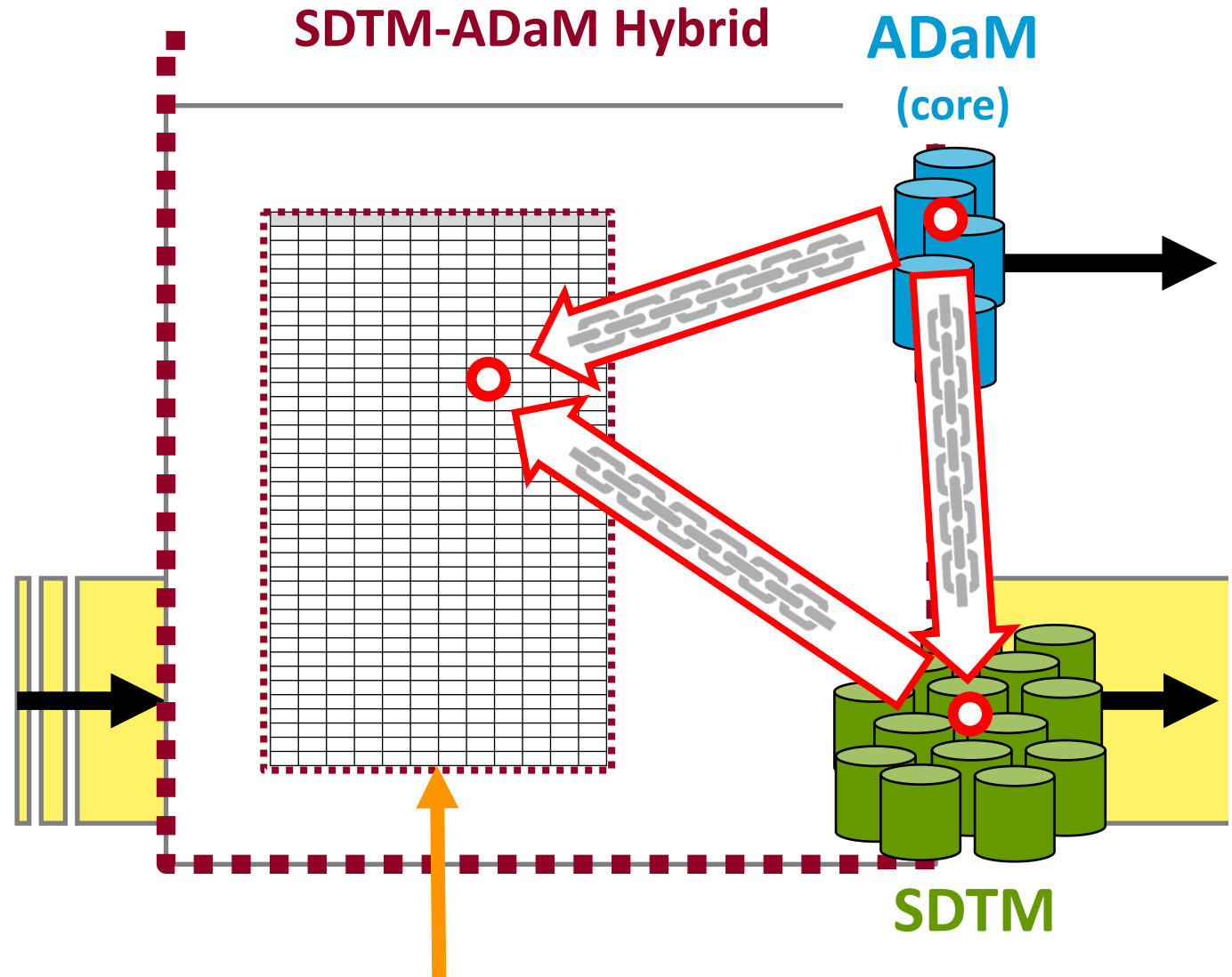


Traceability

TRACEABILITY

“Traceability is built by clearly establishing the path between an element and its immediate predecessor.”

- Analysis Data Model
Implementation Guide, Version
1.1



CONTACT INFORMATION

Ken Stoltzfus

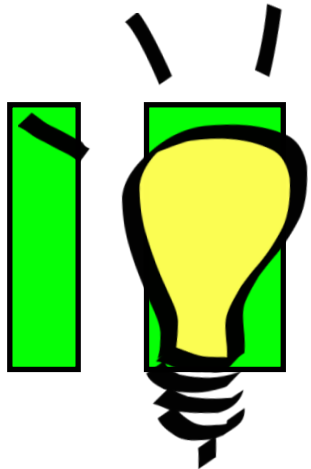
Clinical Data Strategies

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*Feel free to visit the Accenture booth for
more information on Accenture's solutions*

Q & A

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