



cdisc® 2026 Europe Interchange

THE FUTURE IS CONNECTED: STANDARDS AND AI POWERING DIGITAL TRANSFORMATION



MILAN, ITALY | MAIN CONFERENCE: 20-21 MAY | TRAININGS & WORKSHOPS: 18, 19, & 22 MAY

Deterministic Automation Meets Generative AI: ADaM Programming with the Mighty Framework Gives the Best of Both Worlds

Matthew Phelps, Clinical Data Scientist Specialist, Novo Nordisk

Speakers



Building tools that make producing regulatory deliverables for clinical trials faster, more reliable, and less painful

Matthew Phelps

Clinical Data Scientist Specialist

Novo Nordisk

**Views and opinions expressed are those of
the speakers and not necessarily those of
Novo Nordisk**

Code is cheap.

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Validation is hard

how many R's are in the word strawberry

I count 1 R in the word strawberry

“Jagged edge of AI” definition

Dell'Acqua, Fabrizio and McFowland III, Edward and Mollick, Ethan R. and Lifshitz-Assaf, Hila and Kellogg, Katherine and Rajendran, Saran and Kray, Lisa and Candelon, François and Lakhani, Karim R., Navigating the Jagged Technological Frontier: Field Experimental Evidence of the Effects of Artificial Intelligence on Knowledge Worker Productivity and Quality (September 15, 2023). Harvard Business School Technology & Operations Mgt. Unit Working Paper No. 24-013, The Wharton School Research Paper, Organization Science, Forthcoming, Available at SSRN: <https://ssrn.com/abstract=4573321> or <http://dx.doi.org/10.2139/ssrn.4573321>

how many R's are in the word strawberry

I count 1 R in the word strawberry

how many R's are in the word strawberry

There are exactly 3 R's in the word strawberry.
Here is how I verified it:

```
word = 'strawberry'  
print(word.lower().count('r'))  
>>> 3
```



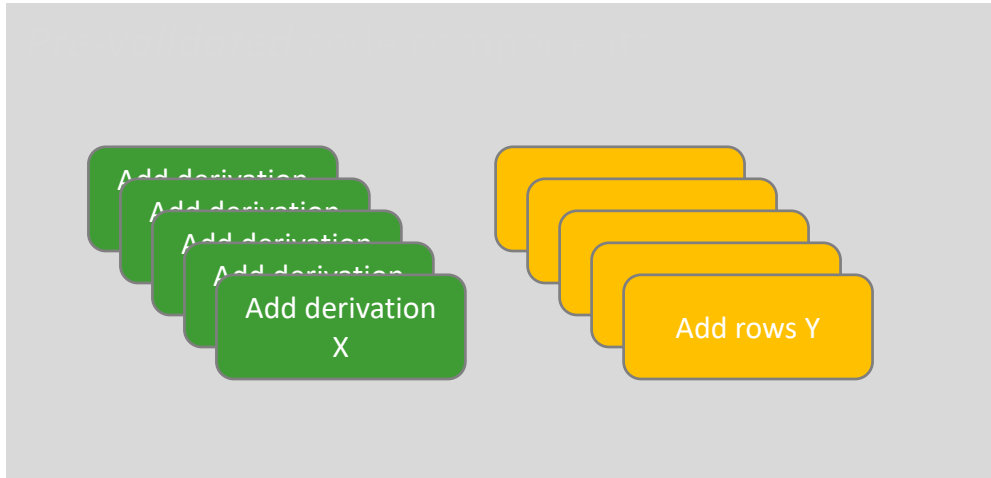
AI
solutions

Management





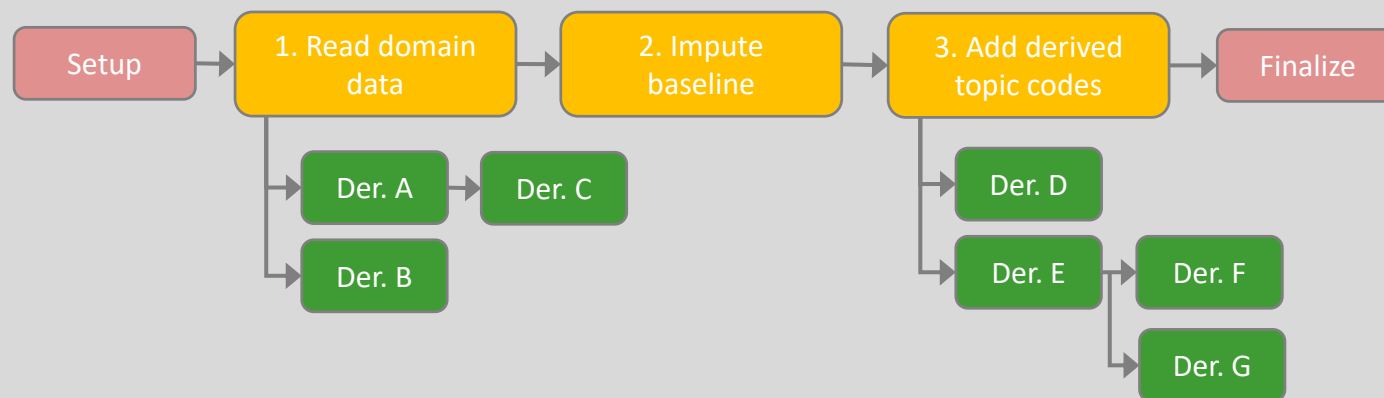
Deterministic Automation Meets Generative AI



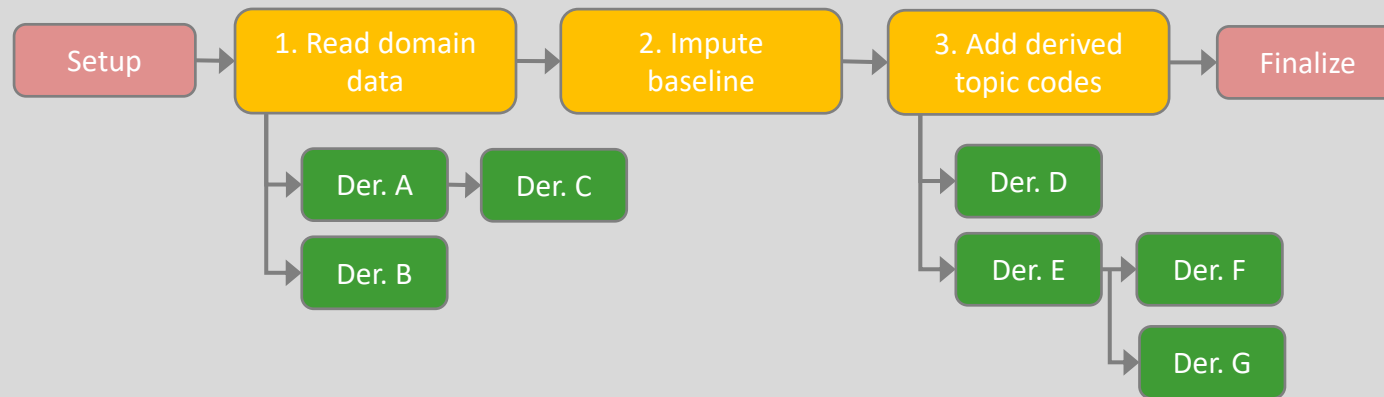
code components



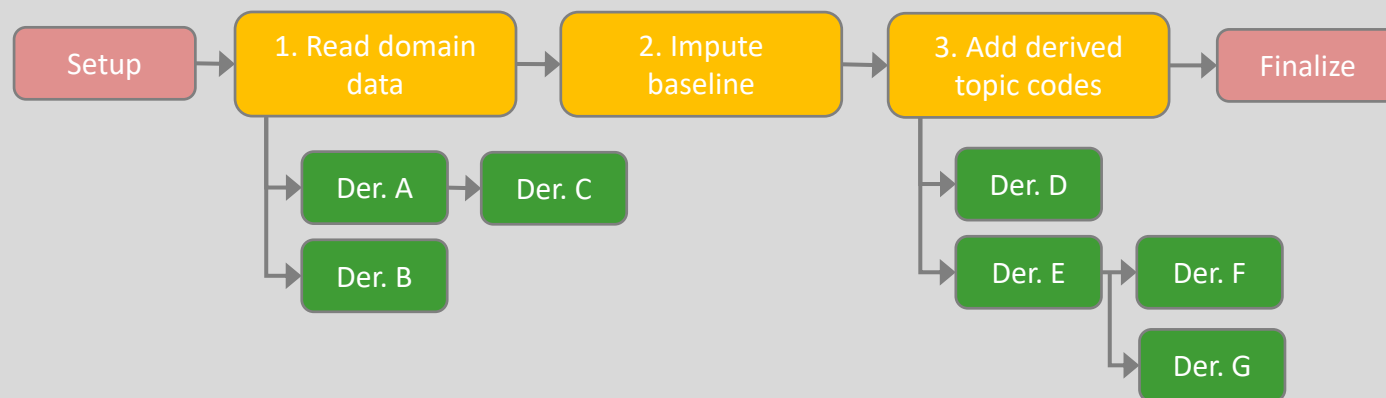
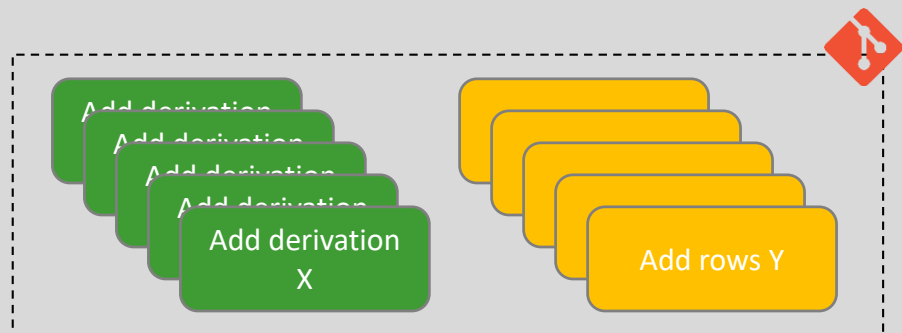
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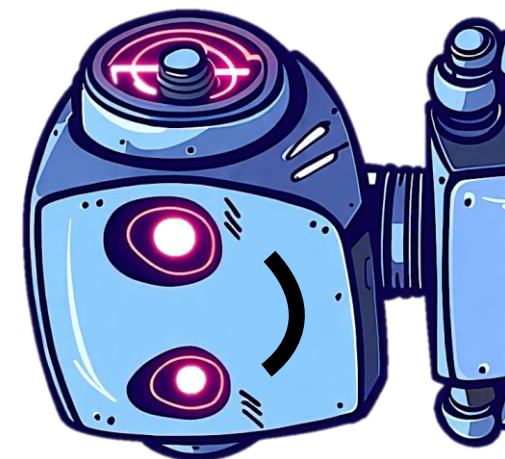
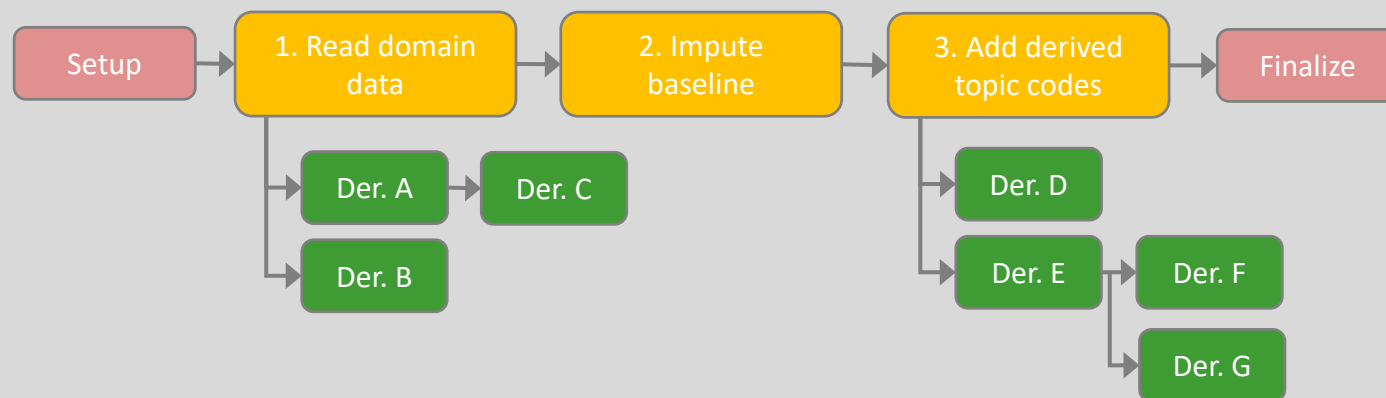
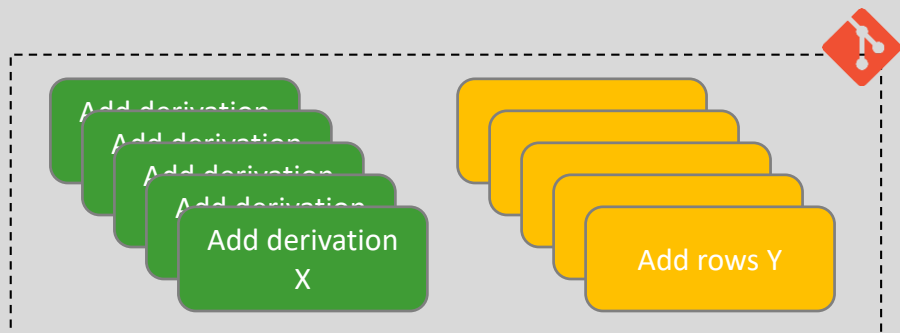
code components



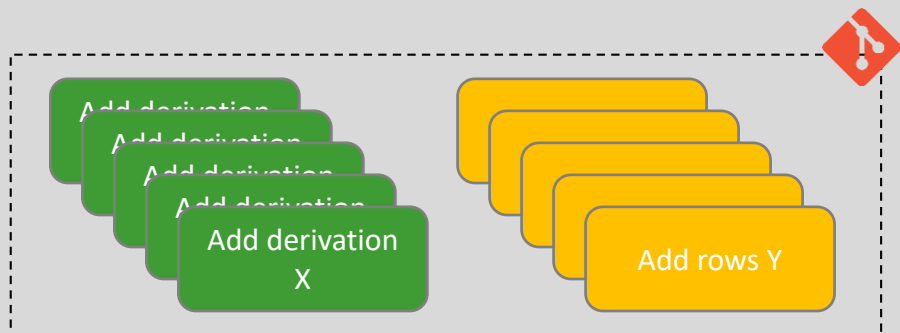
Pre-validated code components



Pre-validated code components

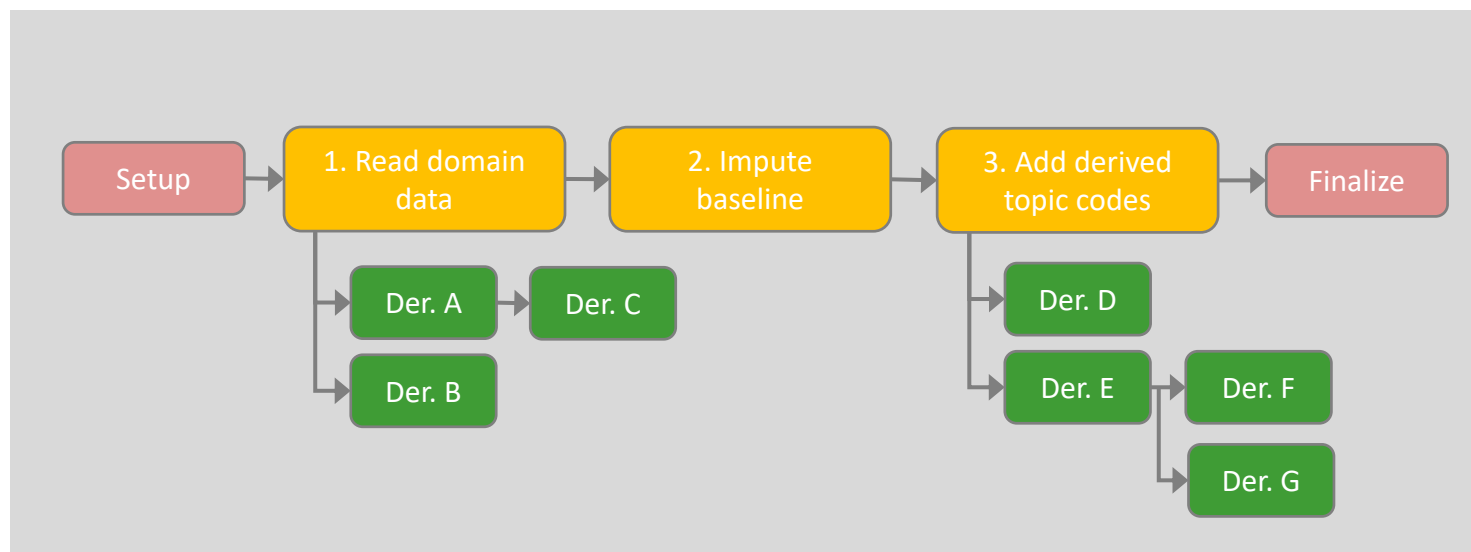


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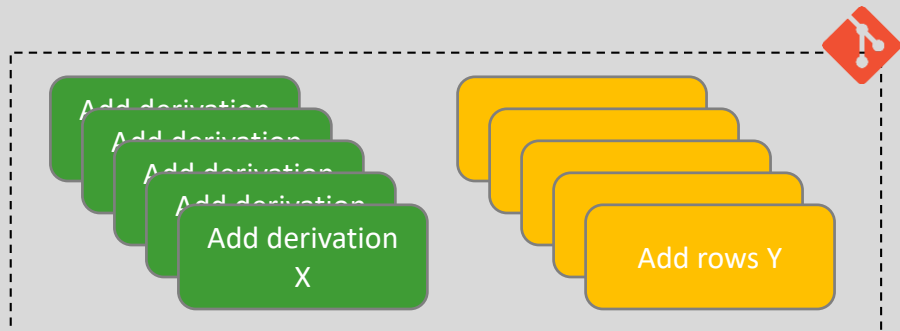


ADaM specifications

- ✓ Predecessors
- ✓ Derivations
- ✓ Imputations
- ✓ Derived parameters
- ✓ ...

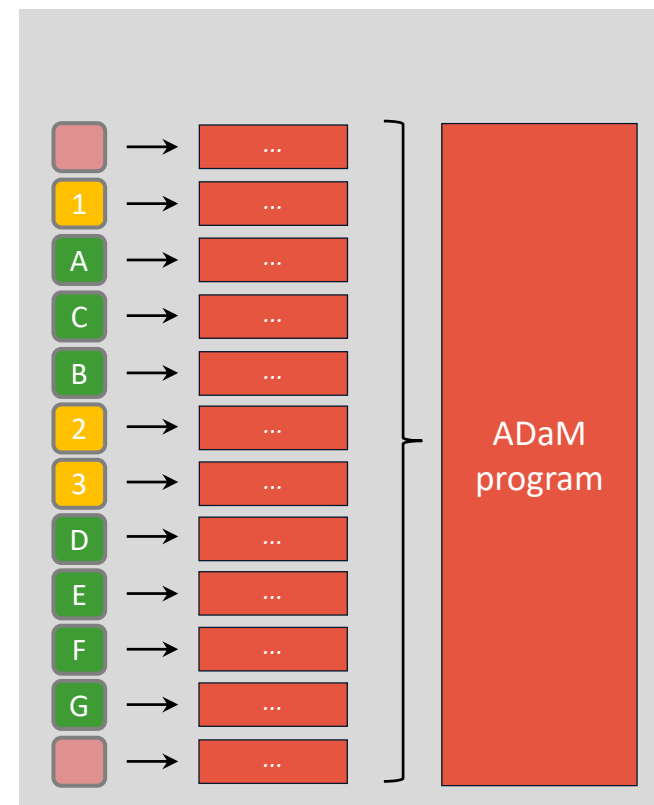
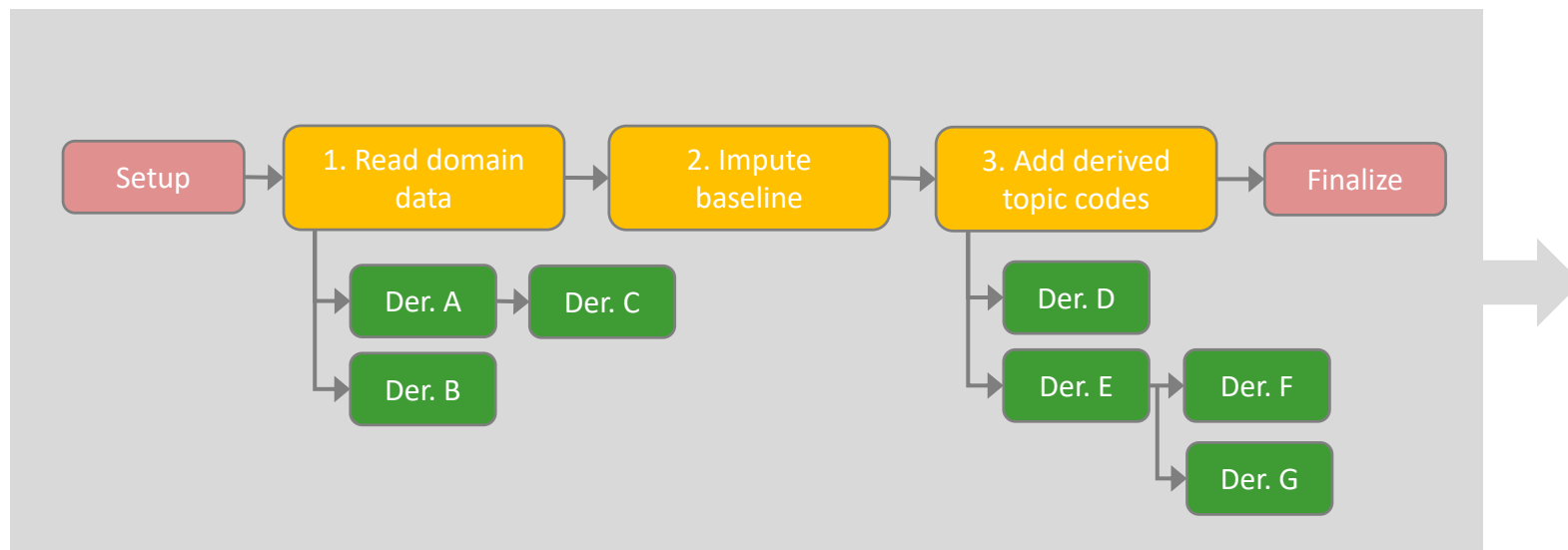


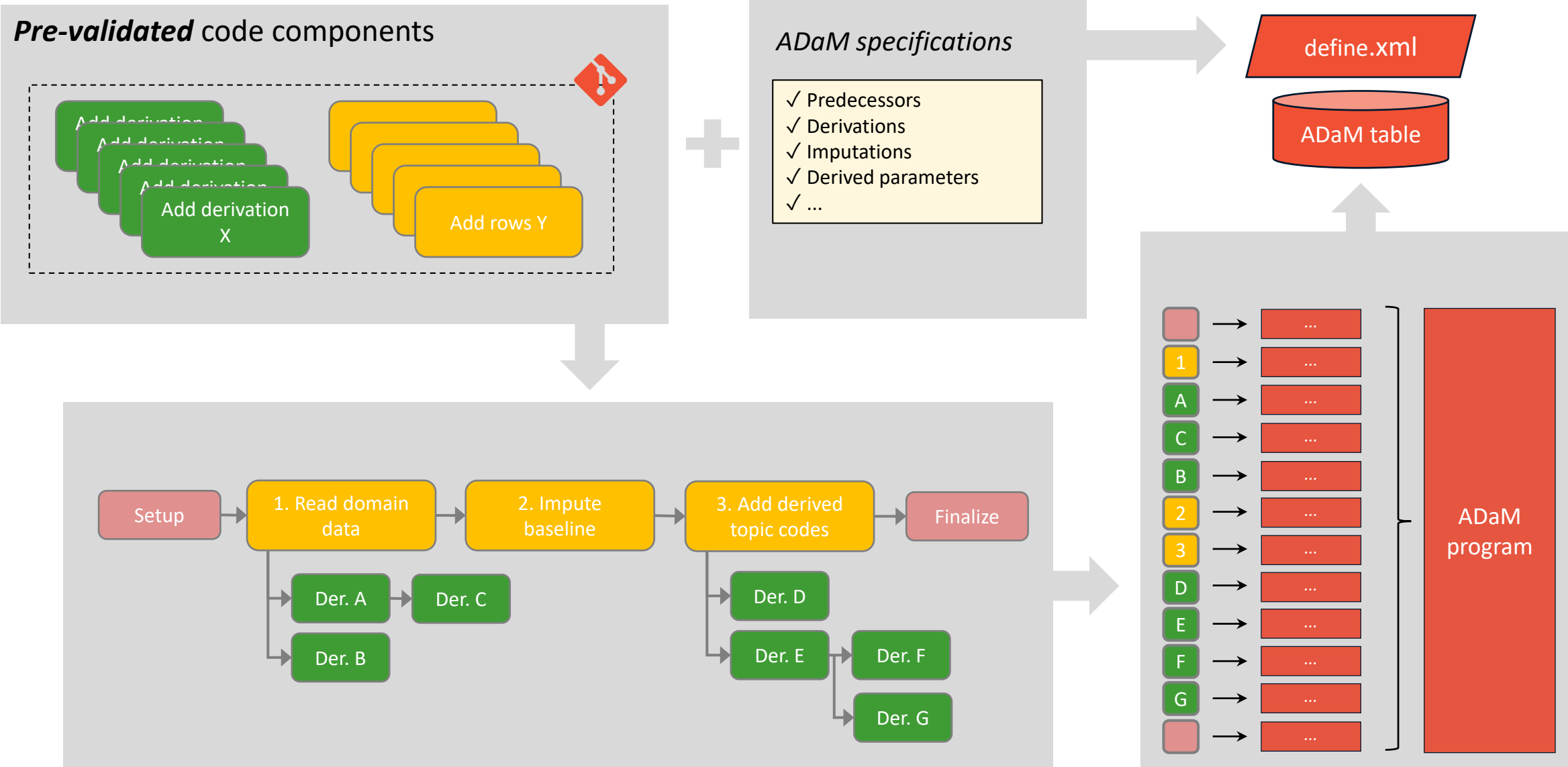
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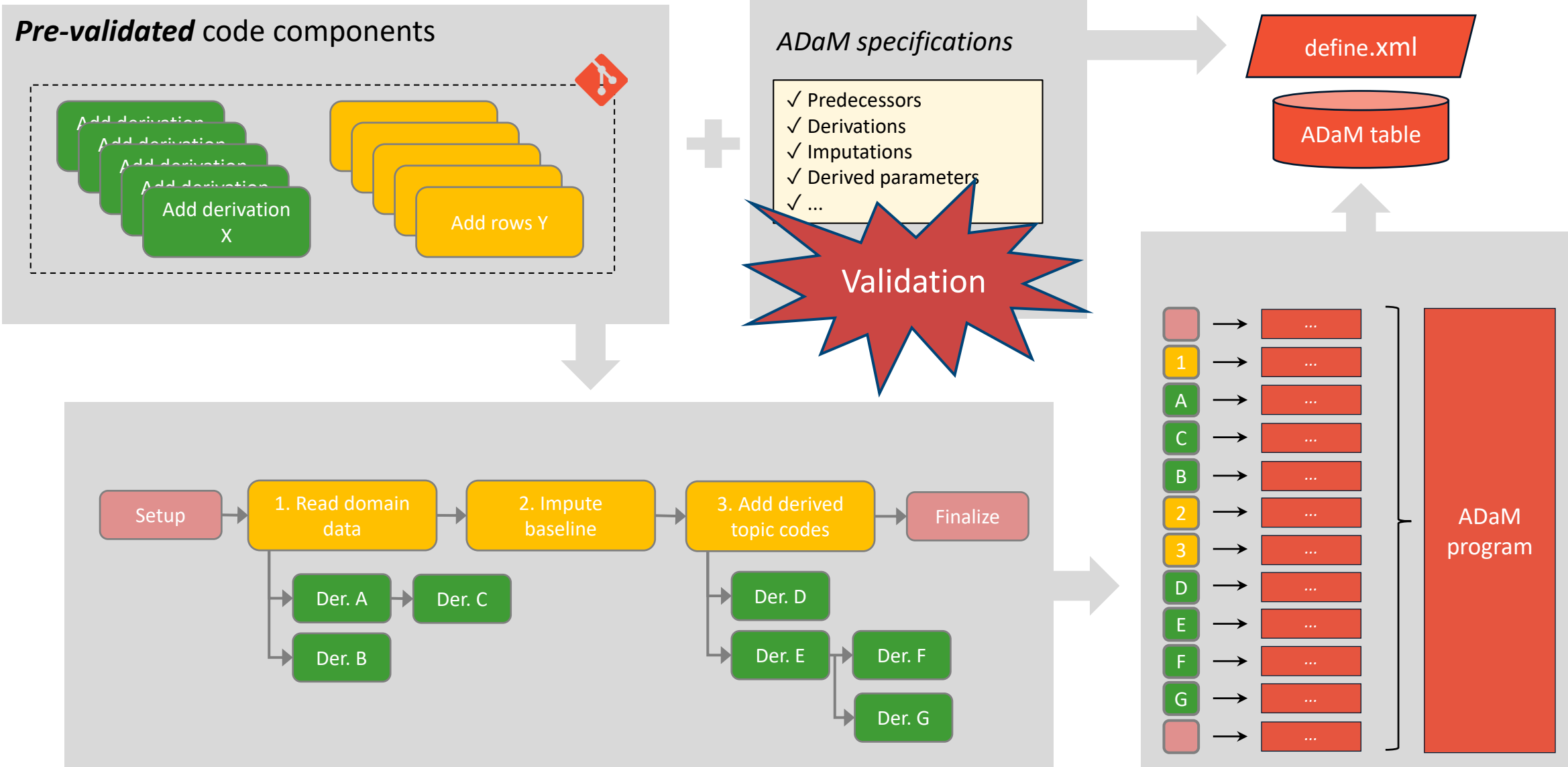


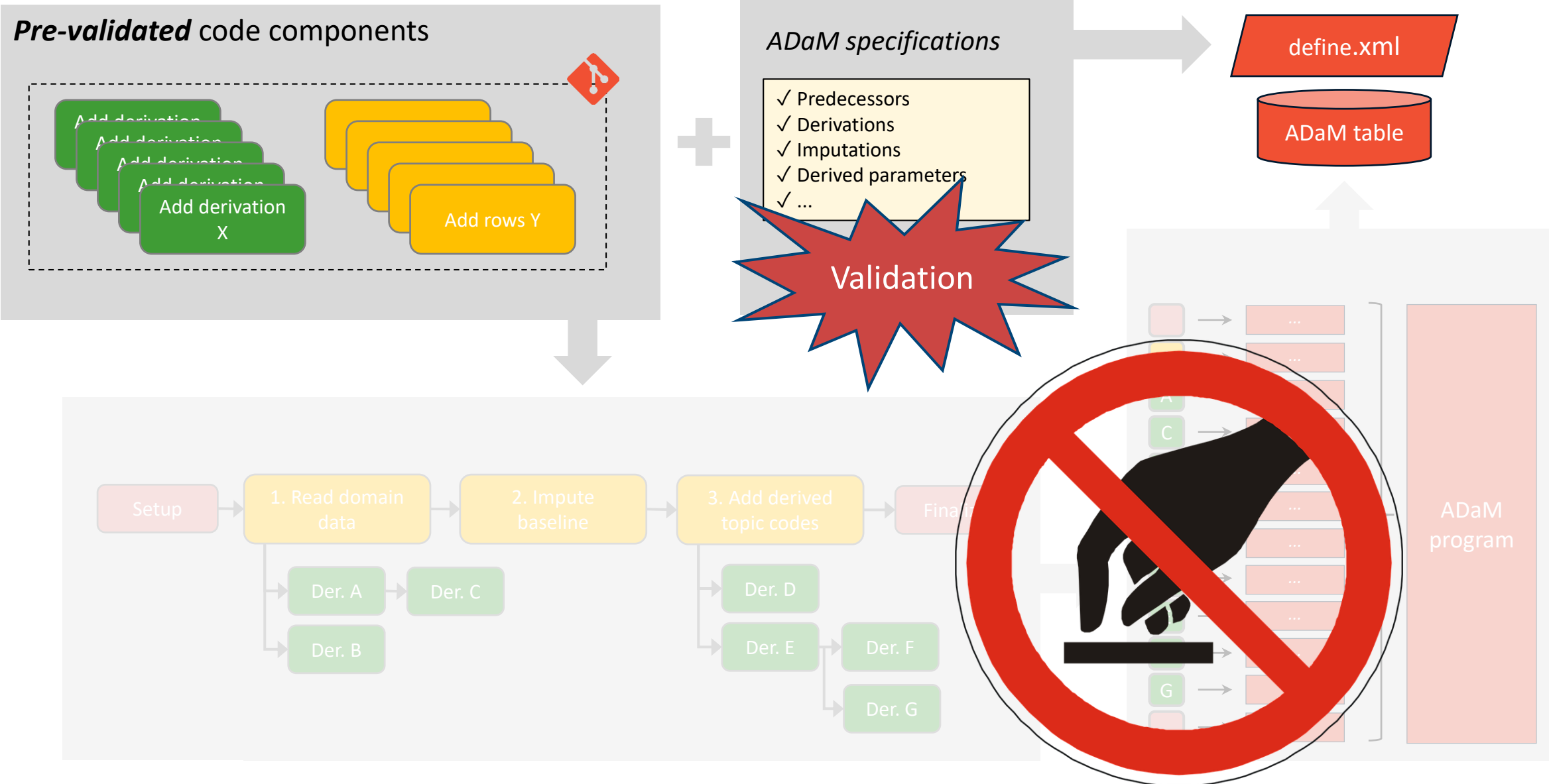
ADaM specifications

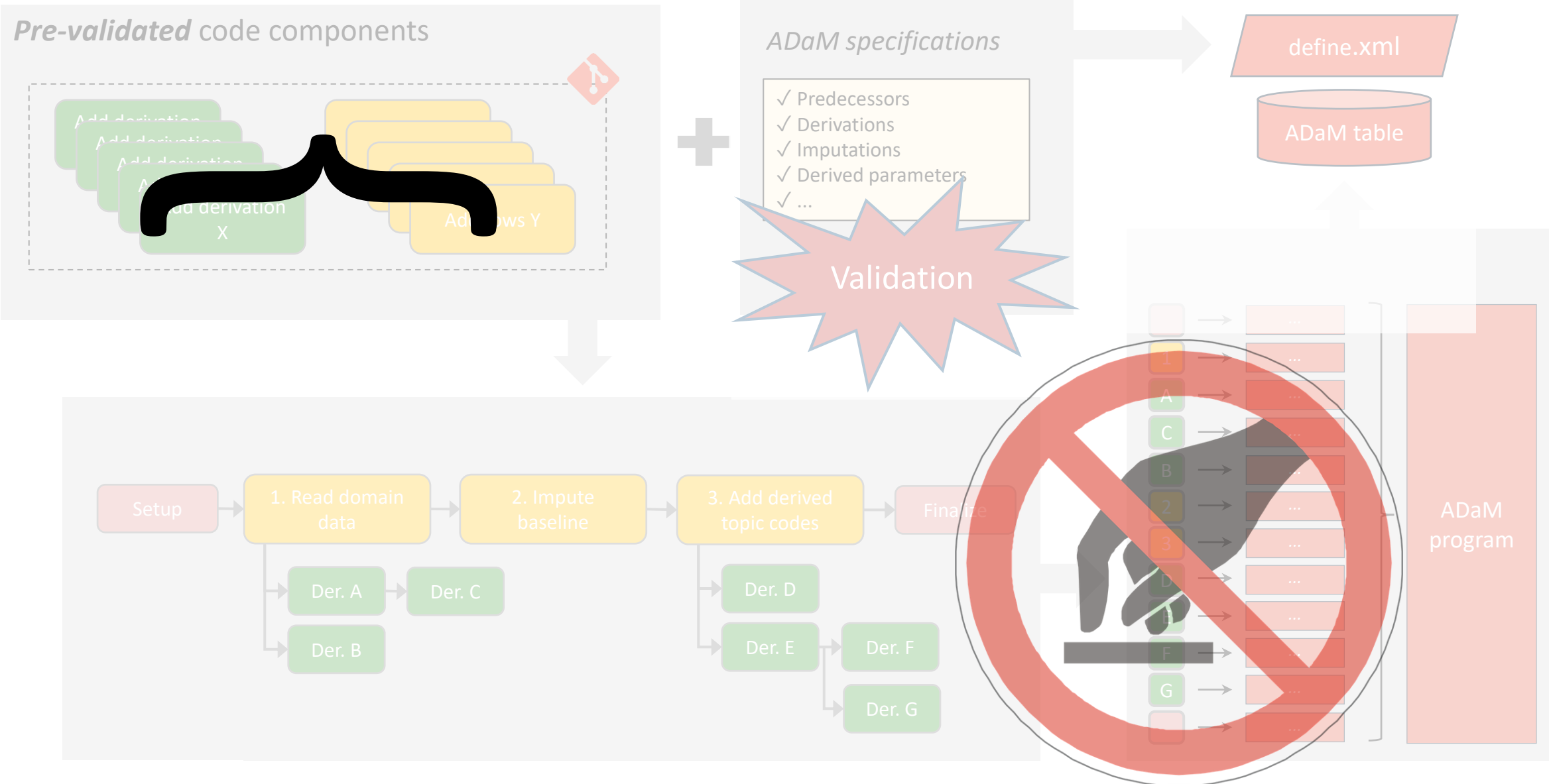
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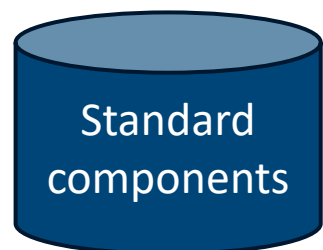
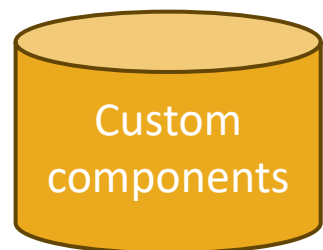


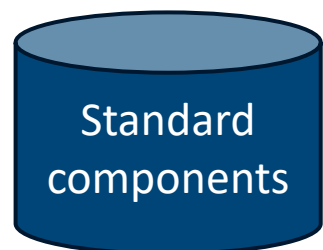
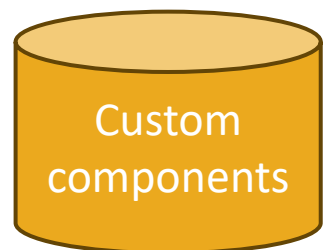
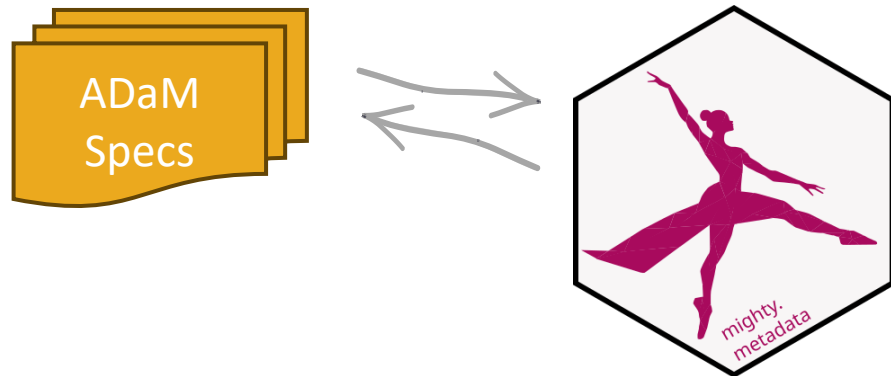


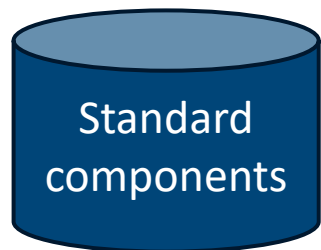
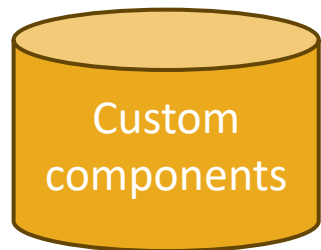
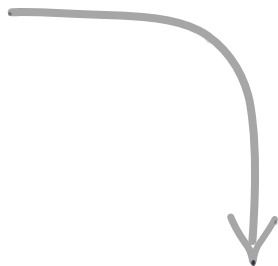
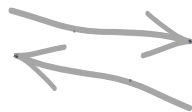


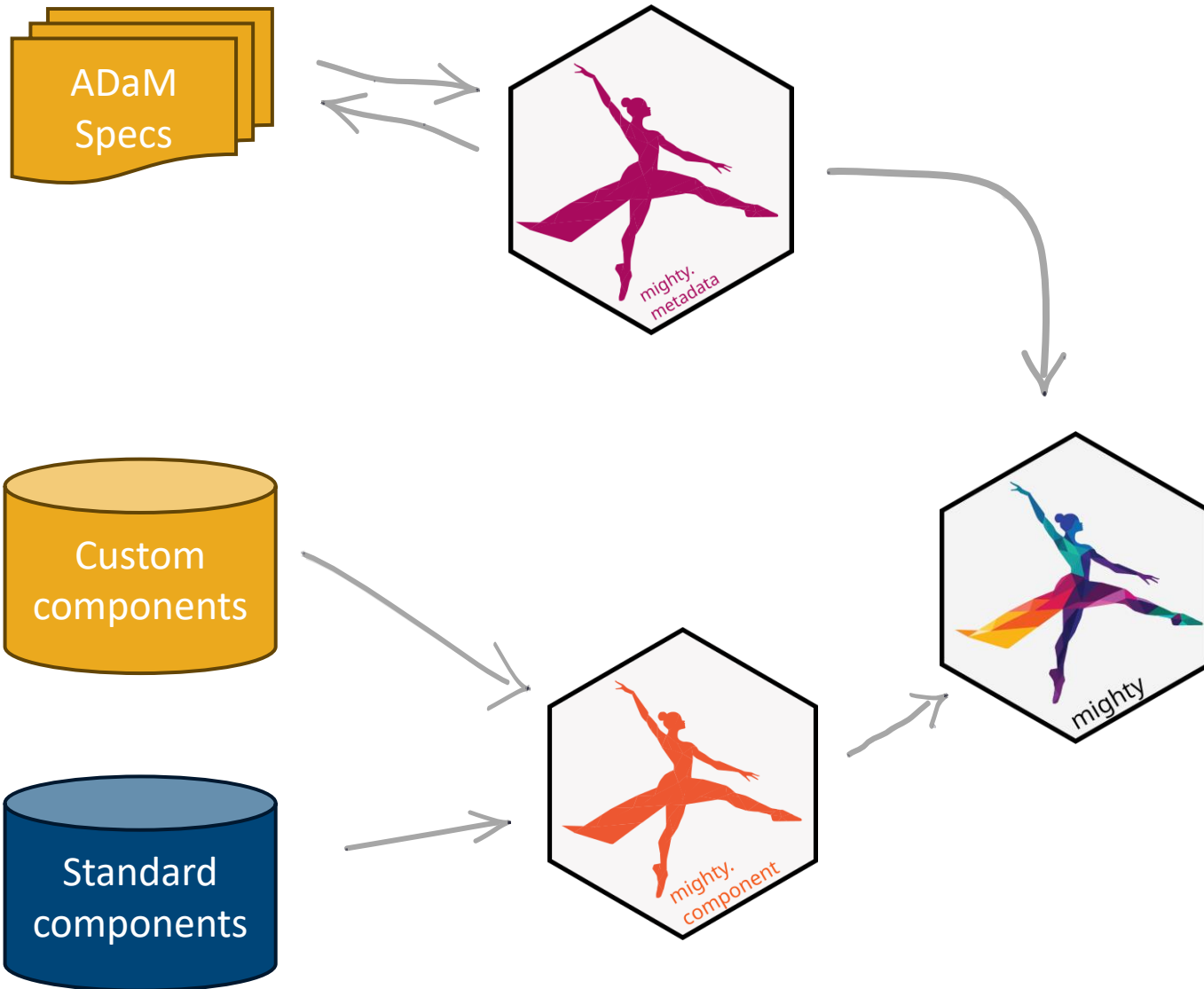


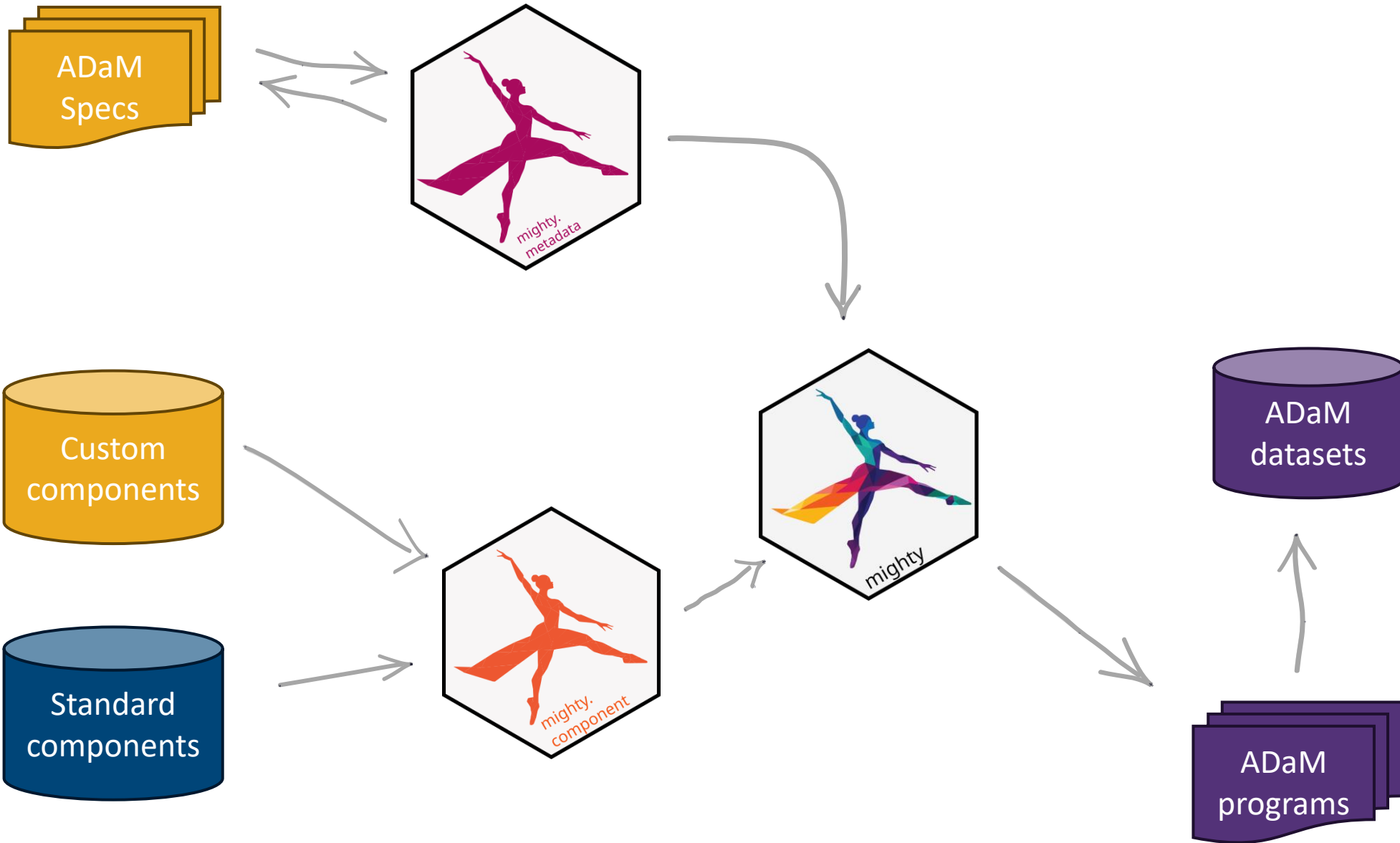


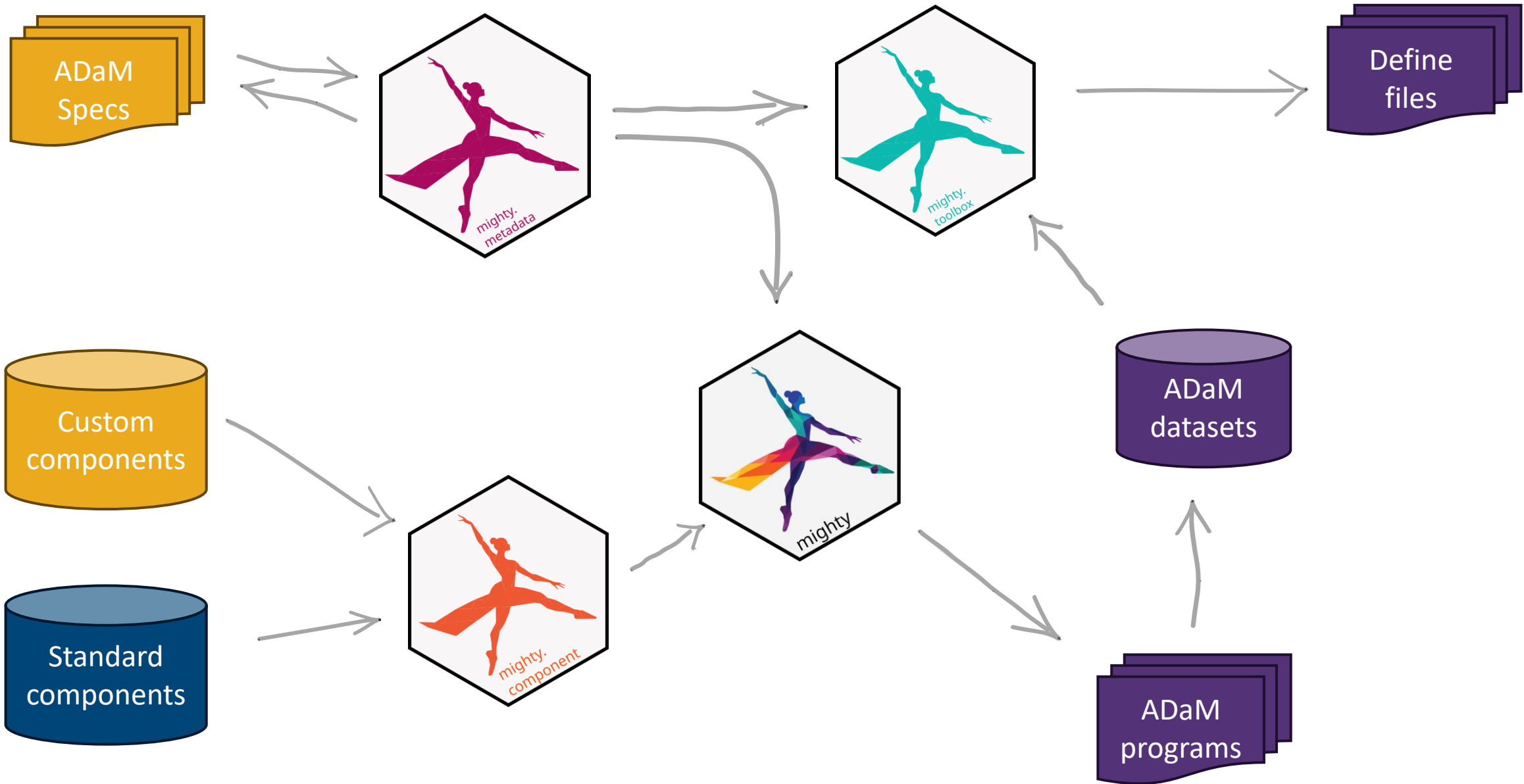


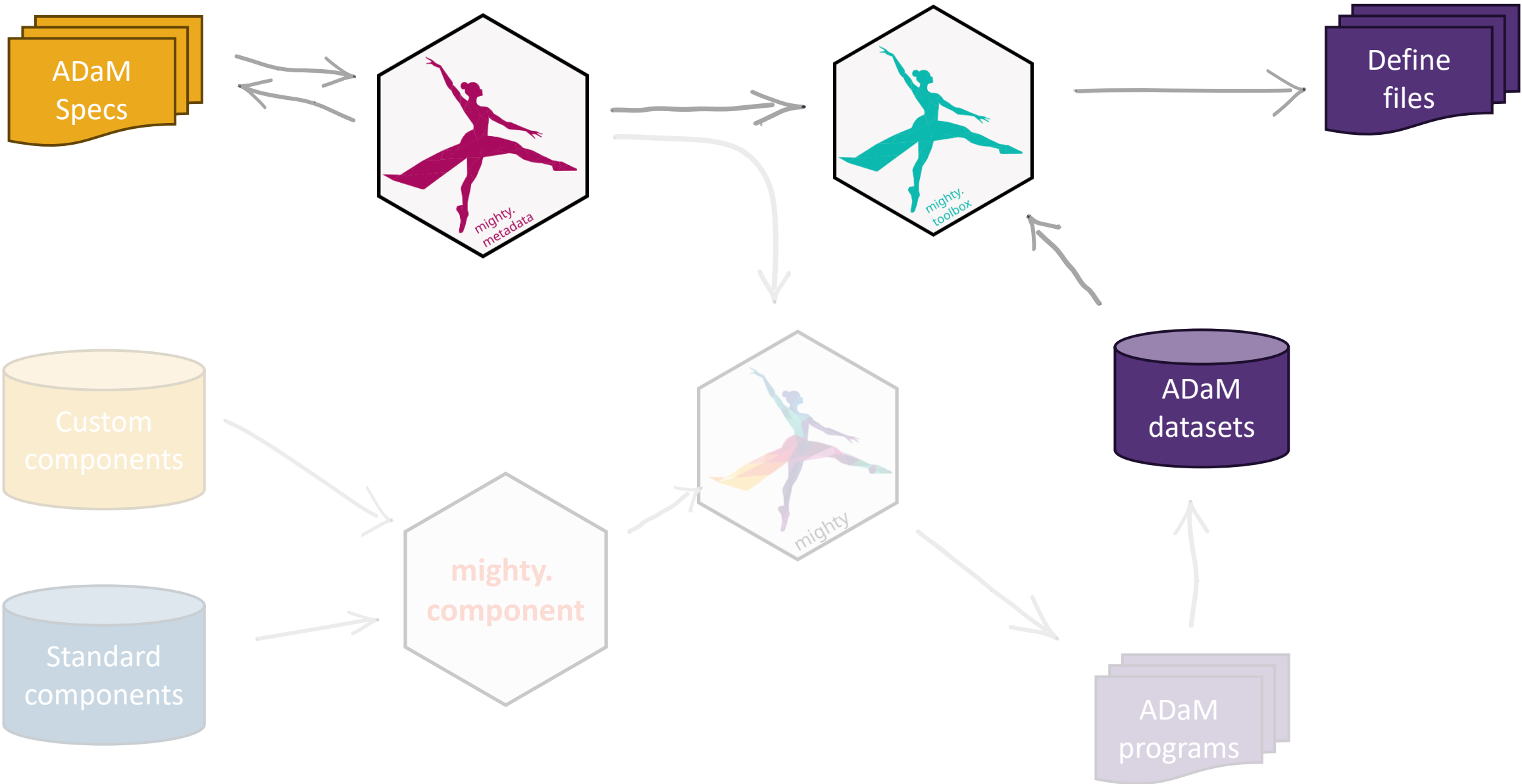


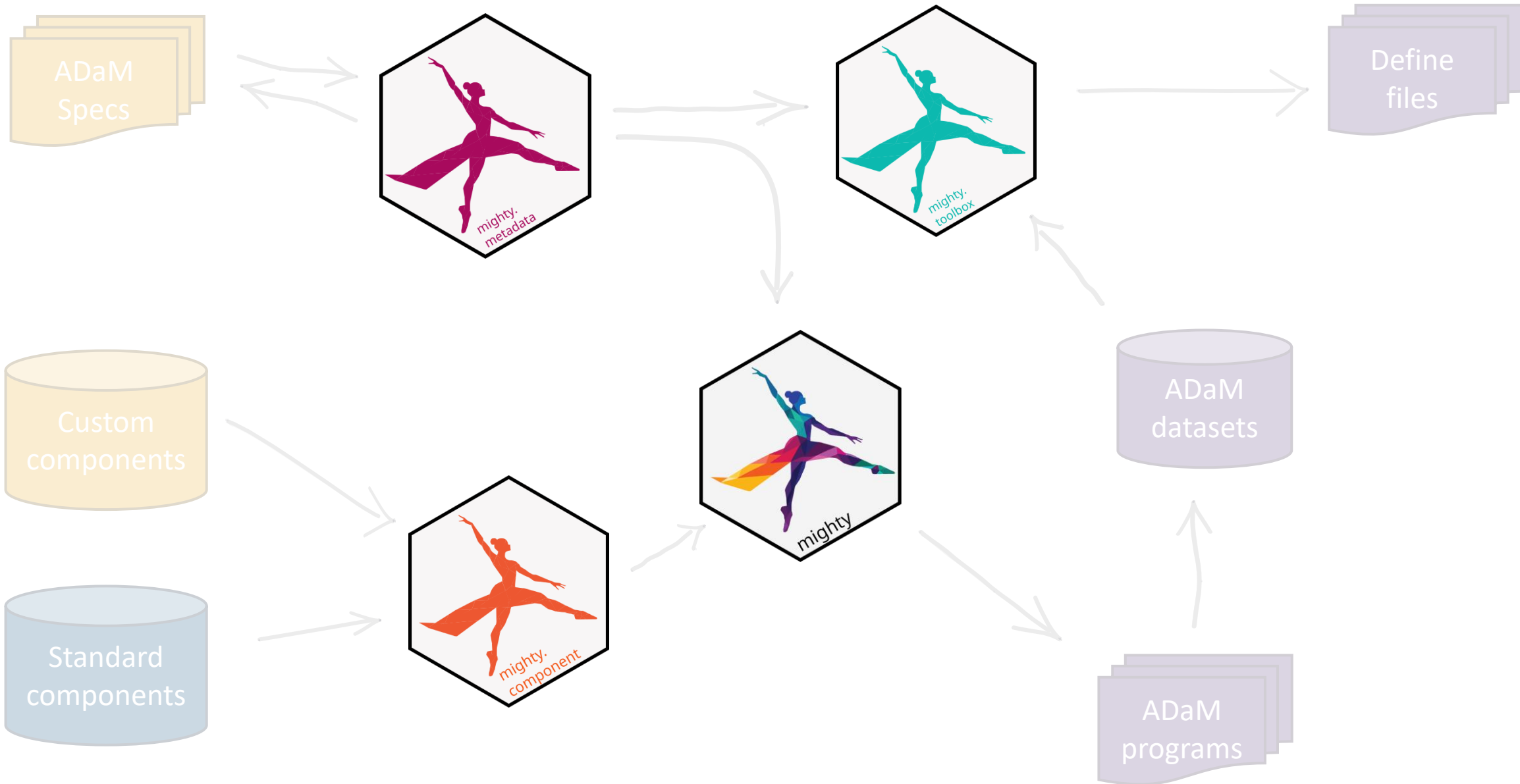














Deterministic Automation Meets **Generative AI**

Mock TFL

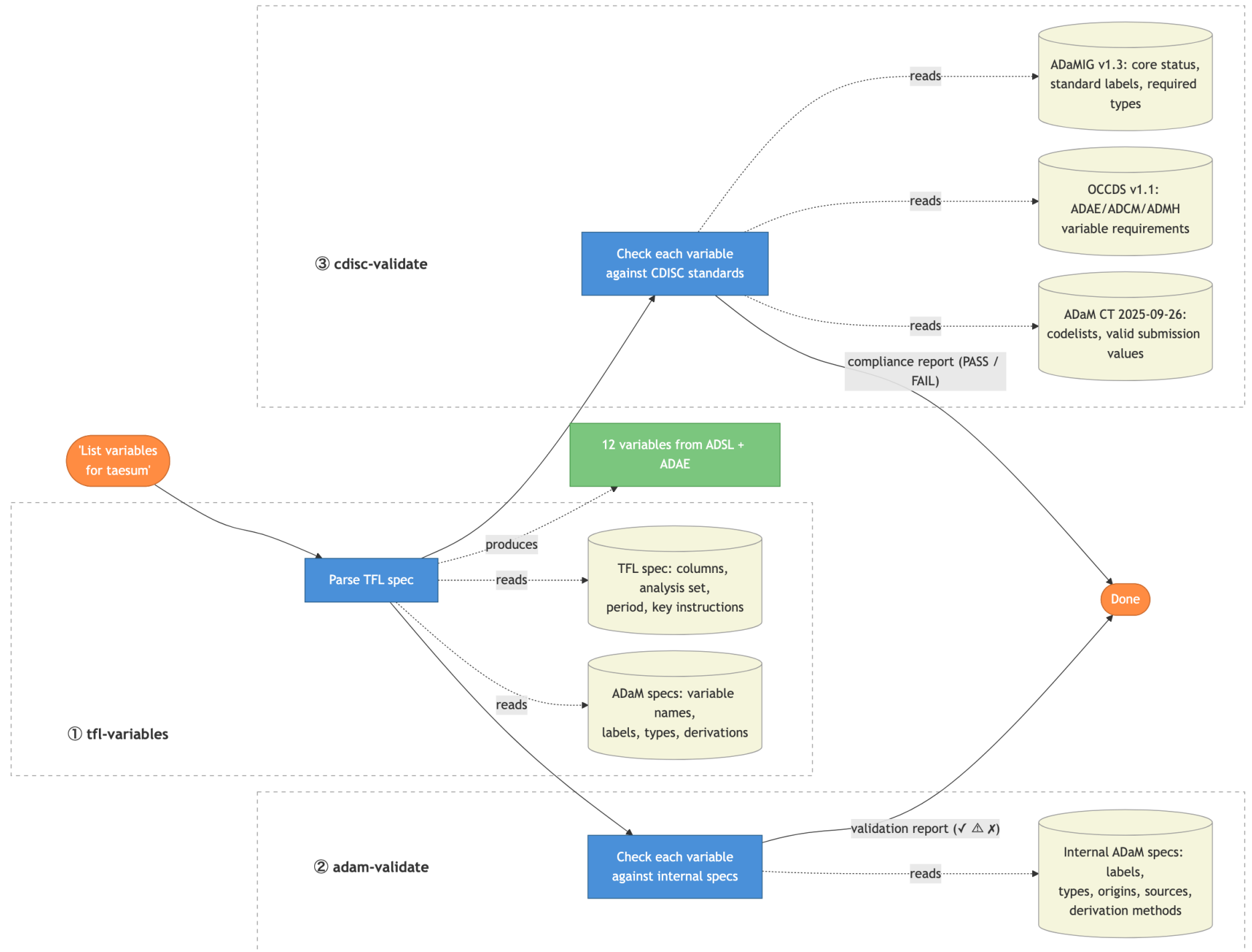


mighty
components

Mock TFL



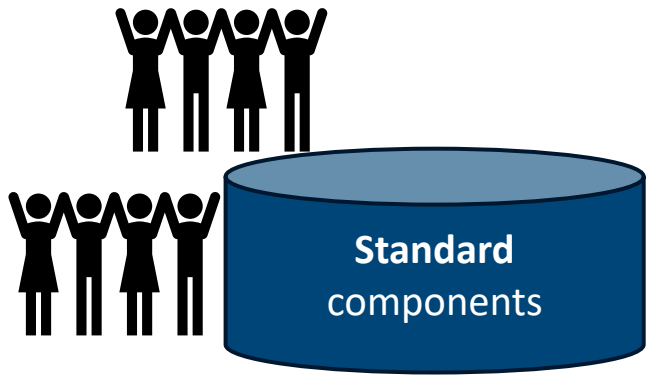
Unvalidated mighty
components



Mock TFL



Unvalidated mighty
components

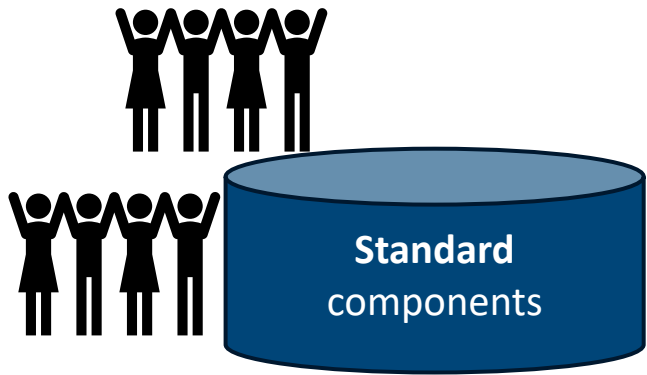


Business SME



Technical SME



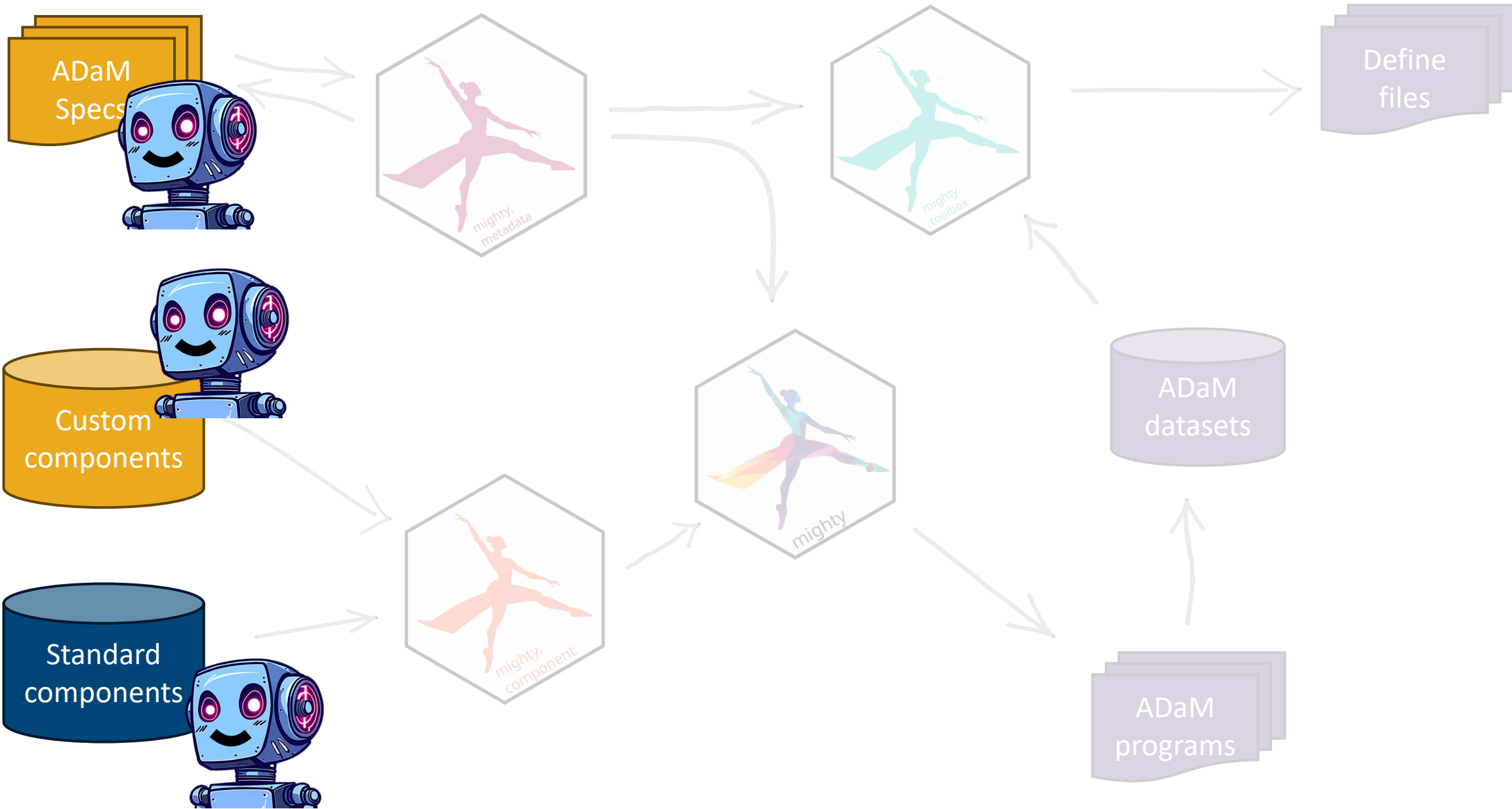


Business SME



Technical SME







Where are we in the mighty journey?

- Used as double programming
- Flagship project as main programming approach
- Standards coming “after summer”
- Open-source



[NovoNordisk-OpenSource/mighty](#)



[NovoNordisk-OpenSource/mighty.metadata](#)



[NovoNordisk-OpenSource/mighty.component](#)