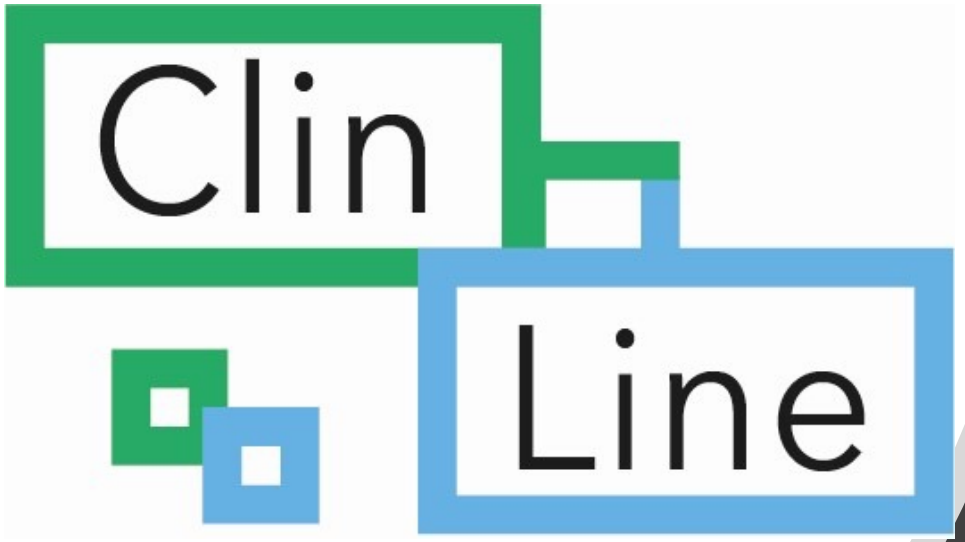
EMEA SDE 2021



How to Scale Up Productivity and Minimise Efforts in Clinical Programming

04 May 2021

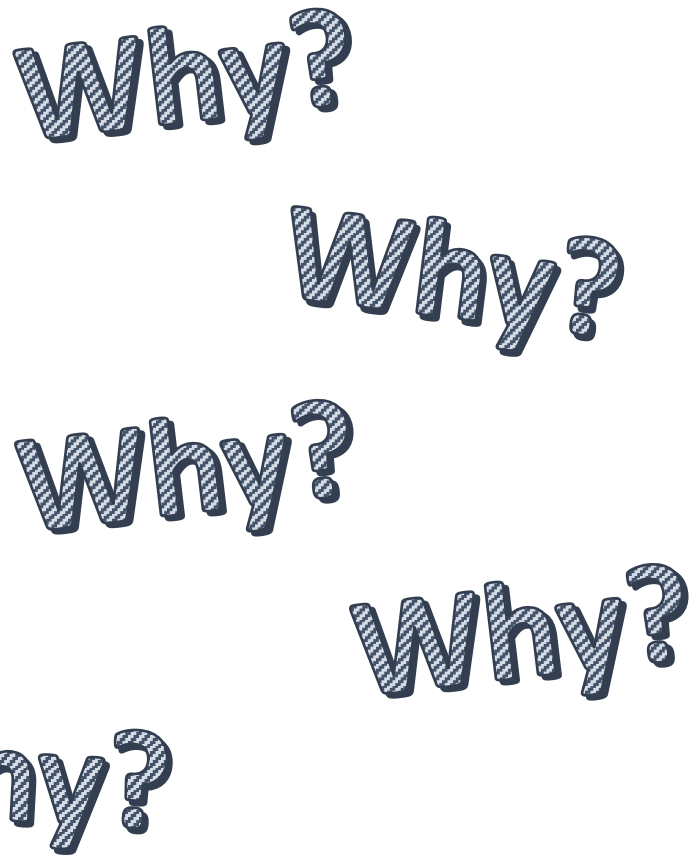

Clin
Line
Improving and optimizing the clinical trial process
- Processes
- Procedures
- KPIs
- ICT
- Data
- Trial
- RWD
- People
- Management Drives
- Appreciative Leadership

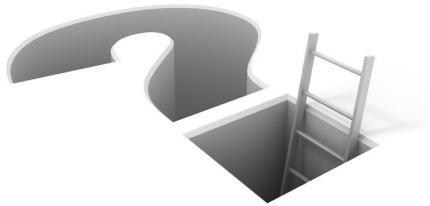

Hé Rotterdammert
Je weet toch, we missen jullie!
NOG EFFE VOLHOUWE!
#SAMENTEGENCORONA #STAYHOME

Resistance

The problem: Reporting inefficiency

- Why is it inefficient ?
  - Repeats of (parts of) the same work
    - Copying introduces errors
    - Reviewing and validation less and less accurate
  - Labour intensive and time consuming
    - Manual programming
    - Repeats of review process
  - Programming of workarounds





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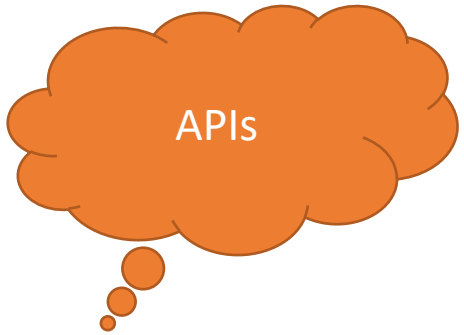
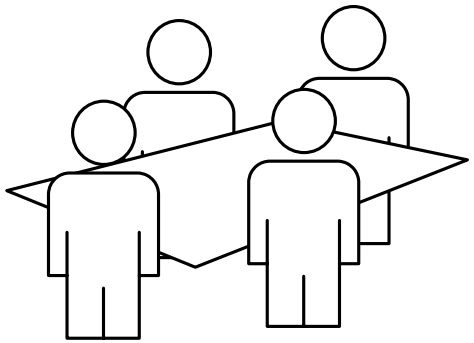
The solution: A reporting engine

- Automated reports
- Flexible
- Interoperable
- Validating
- Interactive ?

- Validated !!





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User Requirement Specifications

- Content
- Examples
- Exceptions
- Errors
- Time delays
- Additional requests

User requirements grouping

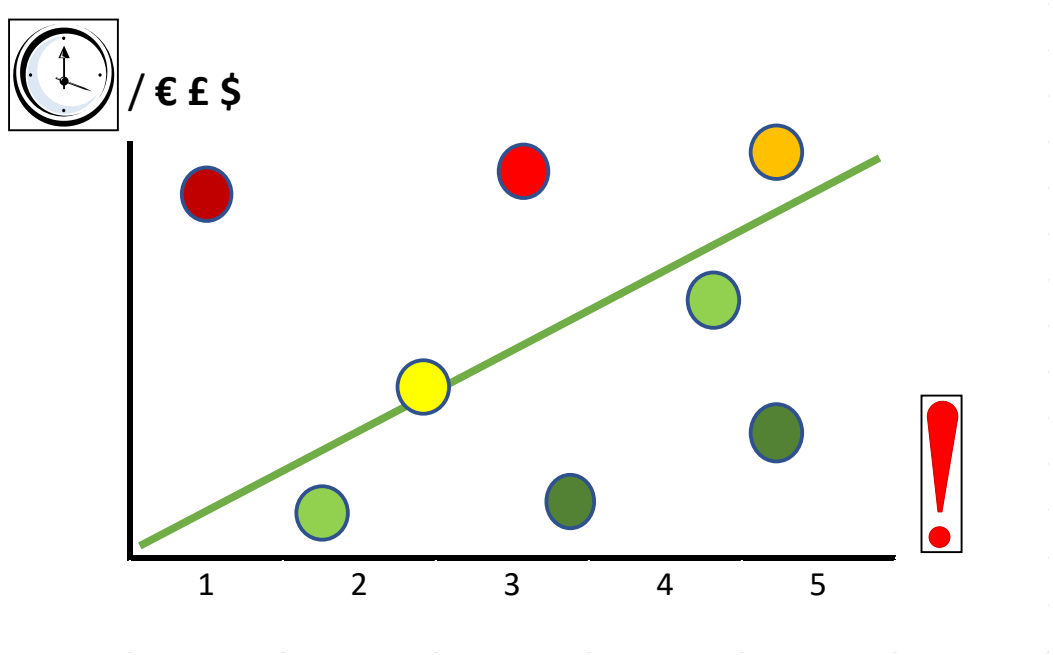
- History and events
- Demographics and safety
- Efficacy
- Derivations

	Treatment	
	A	B
n		
Mean		
SD		
Min-Max		
95% CI		

Treatment		Parameter		
		X	Y	Z
A	n			
	Mean			
	SD			
	Min-Max			
	95% CI			
B	n			
	Mean			
	SD			
	Min-Max			
	95% CI			

	Parameter	n	Mean (SD)	Min-Max	95% CI
A	Q				
	R				
	S				
	T				
	U				
	V				
	W				
	X				
	Y				
	Z				
B	Q				
	R				
	S				
	T				
	U				
	V				
	W				
	X				
	Y				
	Z				

URS iterations



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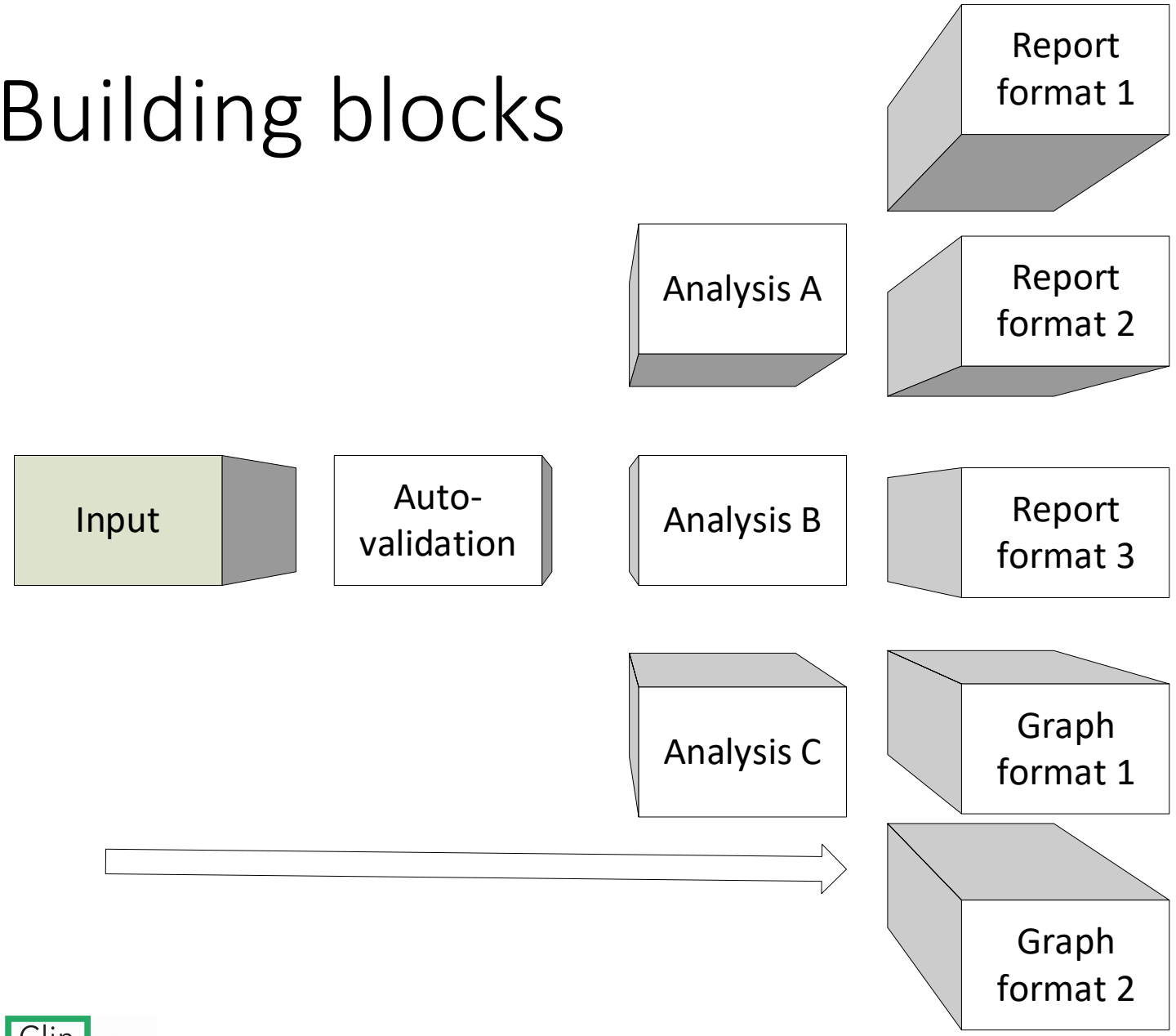
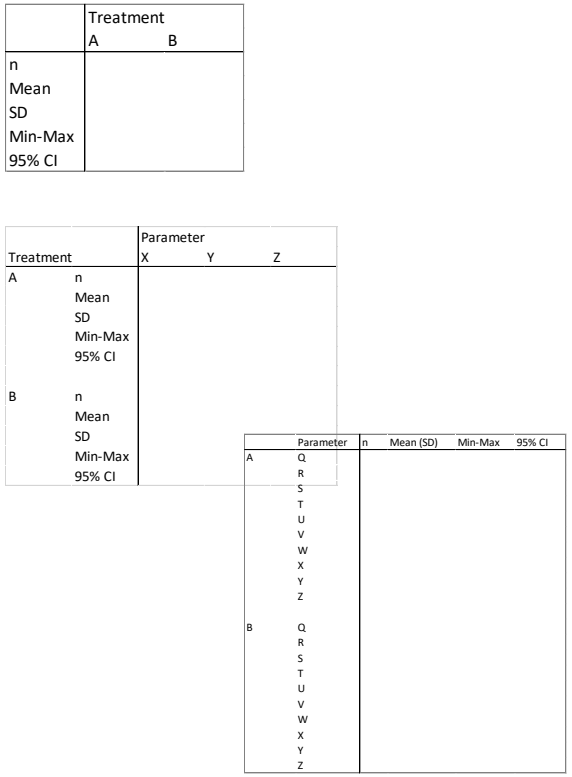
Building blocks

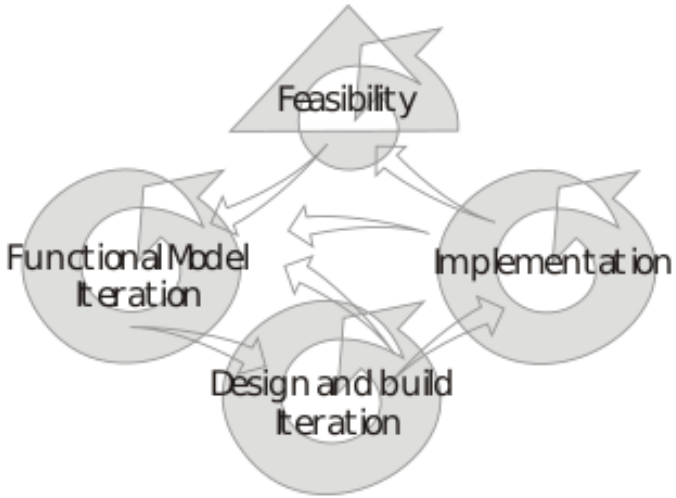


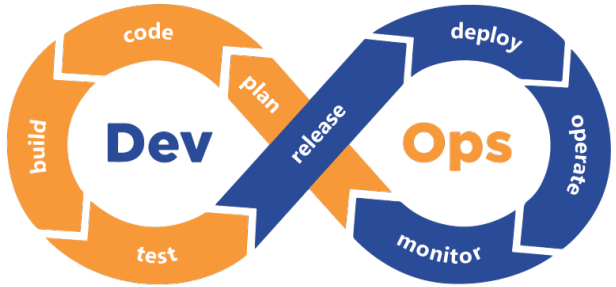


Functional Design Specifications

- By building block
  - Input / output
  - Process
  - Validation
- Dynamic !
- Basis for validation

DSDM





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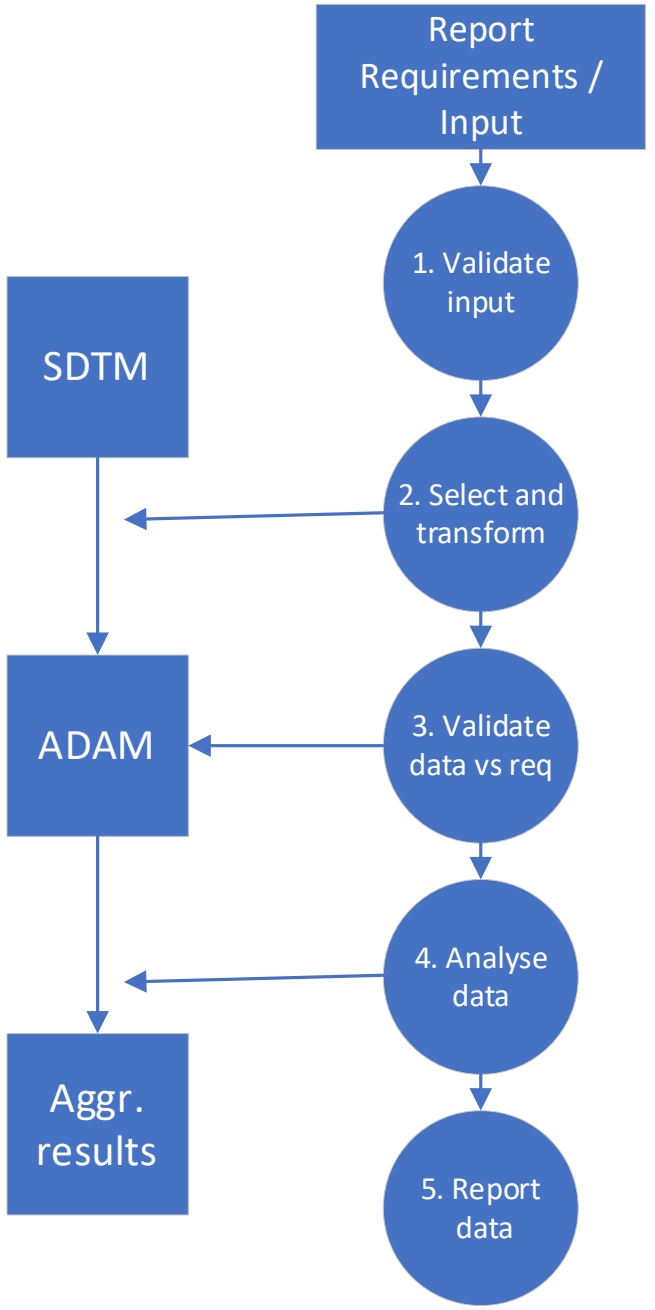
Implementation - Change management

- Technical transition
- Test phase
- Support base
- Communication

Example – SDTM data

Input:
- Data source
- Required report formats
- Required graphs
- Required statistics
- Analyis variable(s)
- Rounding option
- By option
- Population
- Output location and name
- Output dataset name



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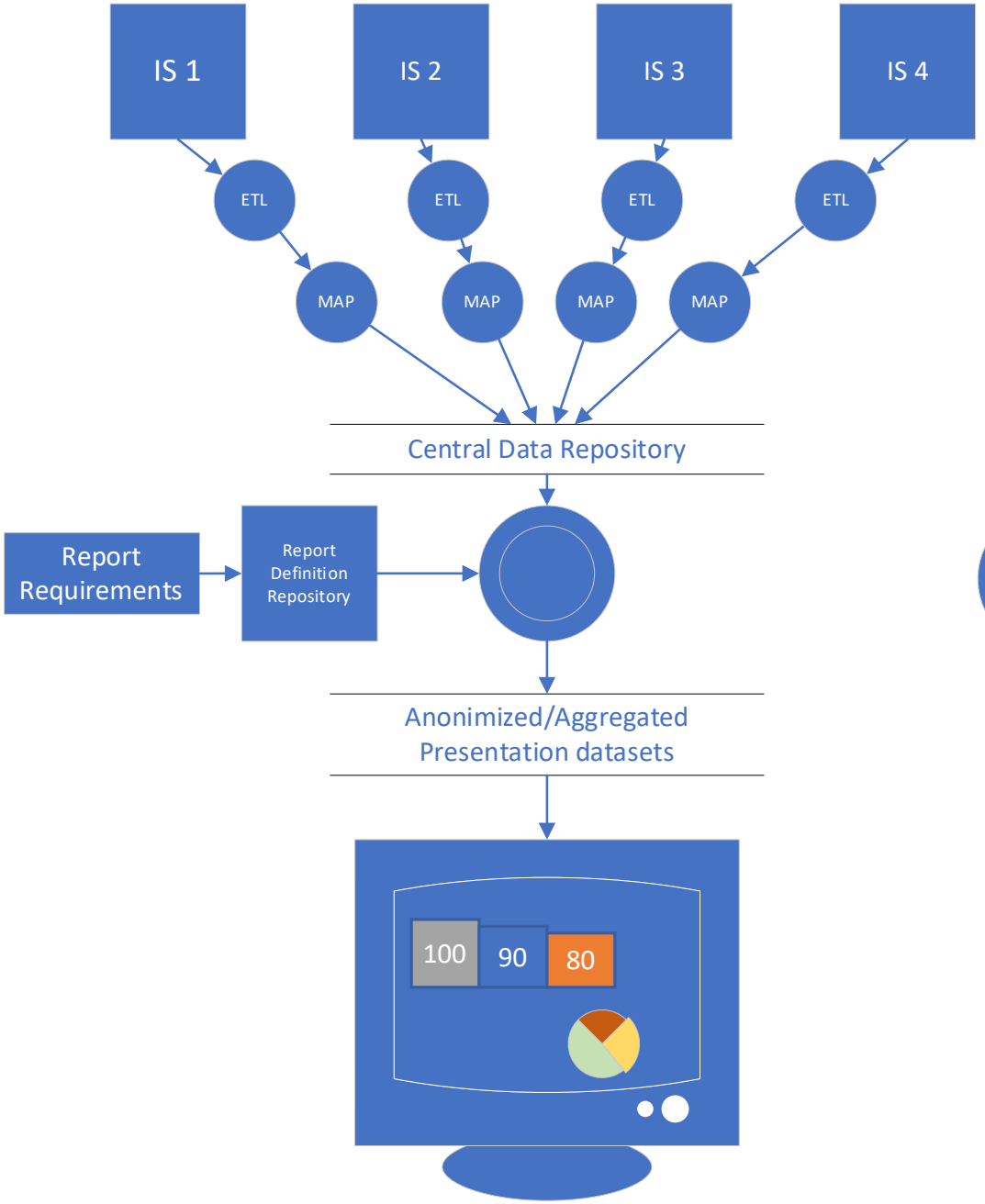
Example - RWD



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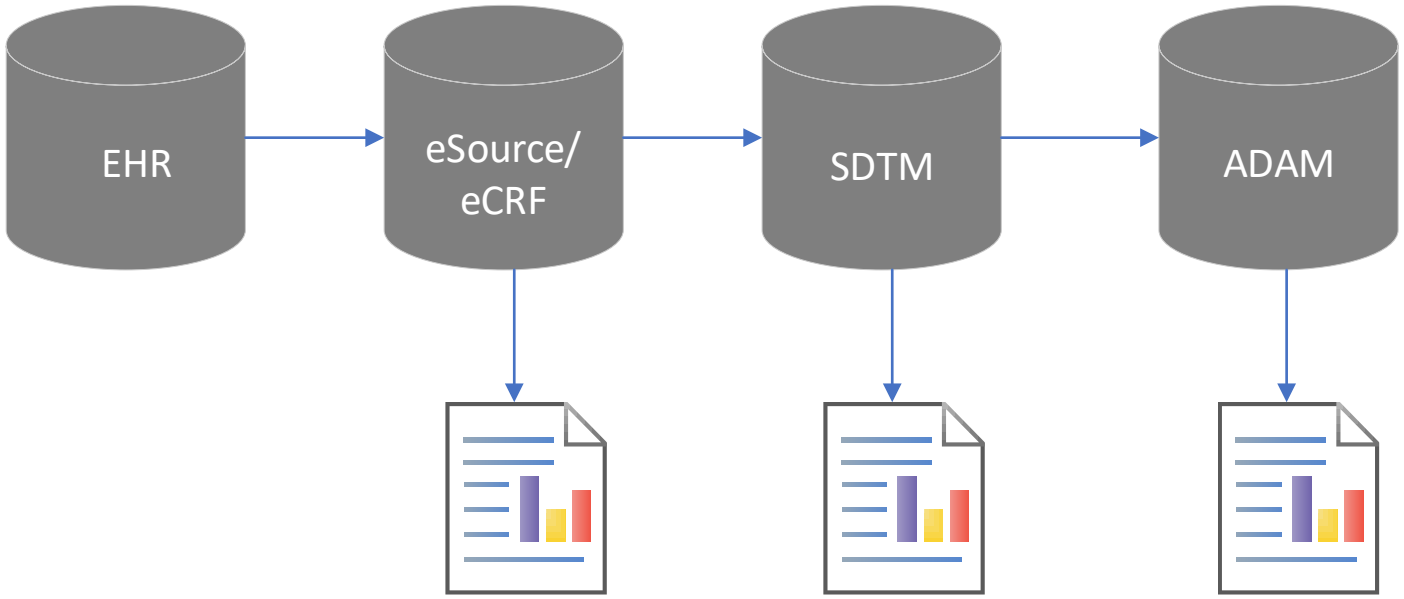
Example – feasibility check

- Check feasibility based on mapped input criteria
  - Mapping flexible input file
- Validate mapping
- Validate input data
- Evaluate eligibility per domain
- Analyse
- Present and export

OMOP	FHIR	CDISC
Basic		
INPUT AND TRANSFORM REAL WORLD DATA		
INPUT AND VALIDATE CRITERIA		
VALIDATE REAL WORLD DATA		
EVALUATE CRITERIA PER DOMAIN		
DEMO	DRUG	COND
SCORE	LAB	OTHER
COMBINE EVALUATIONS PER PATIENT		
ANALYSE, PRESENT AND EXPORT		

End to end automation

- Efficiency gain
- Preliminary insights
- Auto validation
- Interoperability
- Data protection



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Clinline online workshops in 2021
Improving efficiency in clinical research

- 13 May: End to end automation in Clinical research
- 17 June: Digitalized clinical trials: Planning and design
- 02 Sep: Improving clinical trial efficiency by using Real World Data
- 16 Sep: Improving procedures using Lean
- 06 Oct: Managing remote teams using MD and AL

www.clinline.org/workshops

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Questions?

For more information / questions and requests:

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