ARS in Action:
An implementation in R

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Introduction

What if I told you…

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Table 14.3.1.1
Overall Summary of Treatment-Emergent Adverse Events
Safety Population

Categories, n (%)	Placebo (N=XX)	Xanomeline Low Dose (N=XX)	Xanomeline High Dose (N=XX)
Number of subjects with at least one event			
TEAE	XX (XX.X)	XX (XX.X)	XX (XX.X)
Related TEAE	XX (XX.X)	XX (XX.X)	XX (XX.X)
Serious TEAE	XX (XX.X)	XX (XX.X)	XX (XX.X)
Related Serious TEAE	XX (XX.X)	XX (XX.X)	XX (XX.X)
TEAE Leading to Death	XX (XX.X)	XX (XX.X)	XX (XX.X)
Related TEAE Leading to Death	XX (XX.X)	XX (XX.X)	XX (XX.X)
TEAE Leading to Dose Modification [a]	XX (XX.X)	XX (XX.X)	XX (XX.X)
TEAE Leading to Treatment Discontinuation	XX (XX.X)	XX (XX.X)	XX (XX.X)

each result

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Table 14.3.1.1
Summary of TEAE by System Organ Class and Preferred Term
Safety Population

System Organ Class Preferred Term [a], n (%)	Placebo (N=XX)	Xanomeline Low Dose (N=XX)	Xanomeline High Dose (N=XX)	Fisher's Exact p-values [b] Placebo vs. Low Dose	 Placebo vs. High Dose
Number of subjects with at least one event	XX (XX.X)	XX (XX.X)	XX (XX.X)	X.XXX	X.XXX
<SOC 1>	XX (XX.X)	XX (XX.X)	XX (XX.X)	X.XXX	X.XXX
<Preferred Term 1>	XX (XX.X)	XX (XX.X)	XX (XX.X)	X.XXX	X.XXX
...	XX (XX.X)	XX (XX.X)	XX (XX.X)	X.XXX	X.XXX
<Preferred Term n>	XX (XX.X)	XX (XX.X)	XX (XX.X)	X.XXX	X.XXX
<SOC 2>	XX (XX.X)	XX (XX.X)	XX (XX.X)	X.XXX	X.XXX
<Preferred Term 1>	XX (XX.X)	XX (XX.X)	XX (XX.X)	X.XXX	X.XXX
...	XX (XX.X)	XX (XX.X)	XX (XX.X)	X.XXX	X.XXX
<Preferred Term n>	XX (XX.X)	XX (XX.X)	XX (XX.X)	X.XXX	X.XXX

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Table 14.3.3.1a
Summary of Observed and Change from Baseline by Scheduled Visits – Vital Signs
Safety Population

Parameter (Units) Visit	Placebo (N=XX) Observed	Placebo (N=XX) Change from Baseline	Xanomeline Low Dose (N=XX) Observed	Xanomeline Low Dose (N=XX) Change from Baseline	Xanomeline High Dose (N=XX) Observed	Xanomeline High Dose (N=XX) Change from Baseline
<Parameter 1> (<unit>)						
Baseline						
n	XX		XX		XX	
Mean (SD)	XX.X (XX.XX)		XX.X (XX.XX)		XX.X (XX.XX)	
Median	XX.X		XX.X		XX.X	
Q1, Q3	XX.X, XX.X		XX.X, XX.X		XX.X, XX.X	
Min, Max	XX, XX		XX, XX		XX, XX	
...						
<Visit n>						
n	XX	XX	XX	XX	XX	XX
Mean (SD)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)
Median	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X
Q1, Q3	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X
Min, Max	XX, XX	XX, XX	XX, XX	XX, XX	XX, XX	XX, XX
<Parameter n> (<unit>)						
...						

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Table 14.3.3.1b
Summary of Observed and Change from Baseline by Scheduled Visits - Vital Signs <Vertical Layout>
Safety Population

Parameter (Units) Visit	Placebo (N=XX)	Xanomeline Low Dose (N=XX)	Xanomeline High Dose (N=XX)
<Parameter 1> (<unit>)			
Baseline			
n	XX	XX	XX
Mean (SD)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)
Median	XX.X	XX.X	XX.X
Q1, Q3	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X
Min, Max	XX, XX	XX, XX	XX, XX
< Visit n >			
n	XX	XX	XX
Mean (SD)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)
Median	XX.X	XX.X	XX.X
Q1, Q3	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X
Min, Max	XX, XX	XX, XX	XX, XX
< Visit n Change from Baseline >			
n	XX	XX	XX
Mean (SD)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)
Median	XX.X	XX.X	XX.X
Q1, Q3	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X
Min, Max	XX, XX	XX, XX	XX, XX
<Parameter n> (<unit>) ...			

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Table 14.1.1
Summary of Demographics
Safety Population

Characteristics	Placebo (N=XX)	Xanomeline Low Dose (N=XX)	Xanomeline High Dose (N=XX)	p-value [1]
Age (years)				
n	XX	XX	XX	X.XXXX
Mean (SD)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	
Median	XX.X	XX.X	XX.X	
Q1, Q3	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X	
Min, Max	XX, XX	XX, XX	XX, XX	
Age Group, n (%)				
< 65 years	XX (XX.X)	XX (XX.X)	XX (XX.X)	X.XXXX
≥ 65 years	XX (XX.X)	XX (XX.X)	XX (XX.X)	
Gender, n (%)				
Male	XX (XX.X)	XX (XX.X)	XX (XX.X)	X.XXXX
Female	XX (XX.X)	XX (XX.X)	XX (XX.X)	
Ethnicity, n (%)				
Hispanic or Latino	XX (XX.X)	XX (XX.X)	XX (XX.X)	X.XXXX
Not Hispanic or Latino	XX (XX.X)	XX (XX.X)	XX (XX.X)	

What if I told you…

each result
for all outputs in a study

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Safety Population

Categories, n (%)	Placebo (N=XX)	Xanomeline Low Dose (N=XX)	Xanomeline High Dose (N=XX)
Number of subjects with at least one event			
TEAE	XX (XX.X)	XX (XX.X)	XX (XX.X)
Related TEAE	XX (XX.X)	XX (XX.X)	XX (XX.X)
Serious TEAE	XX (XX.X)	XX (XX.X)	XX (XX.X)
Related Serious TEAE	XX (XX.X)	XX (XX.X)	XX (XX.X)
TEAE Leading to Death	XX (XX.X)	XX (XX.X)	XX (XX.X)
Related TEAE Leading to Death	XX (XX.X)	XX (XX.X)	XX (XX.X)
TEAE Leading to Dose Modification [a]	XX (XX.X)	XX (XX.X)	XX (XX.X)
TEAE Leading to Treatment Discontinuation	XX (XX.X)	XX (XX.X)	XX (XX.X)

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Safety Population

System Organ Class Preferred Term [a], n (%)	Placebo (N=XX)	Xanomeline Low Dose (N=XX)	Xanomeline High Dose (N=XX)	Fisher's Exact p-values [b] Placebo vs. Low Dose	 Placebo vs. High Dose
Number of subjects with at least one event	XX (XX.X)	XX (XX.X)	XX (XX.X)	X.XXX	X.XXX
<SOC 1>	XX (XX.X)	XX (XX.X)	XX (XX.X)	X.XXX	X.XXX
<Preferred Term 1>	XX (XX.X)	XX (XX.X)	XX (XX.X)	X.XXX	X.XXX
...	XX (XX.X)	XX (XX.X)	XX (XX.X)	X.XXX	X.XXX
<Preferred Term n>	XX (XX.X)	XX (XX.X)	XX (XX.X)	X.XXX	X.XXX
<SOC 2>	XX (XX.X)	XX (XX.X)	XX (XX.X)	X.XXX	X.XXX
<Preferred Term 1>	XX (XX.X)	XX (XX.X)	XX (XX.X)	X.XXX	X.XXX
...	XX (XX.X)	XX (XX.X)	XX (XX.X)	X.XXX	X.XXX
<Preferred Term n>	XX (XX.X)	XX (XX.X)	XX (XX.X)	X.XXX	X.XXX

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Table 14.3.3.1a
Summary of Observed and Change from Baseline by Scheduled Visits – Vital Signs
Safety Population

	Placebo (N=XX)		Xanomeline Low Dose (N=XX)		Xanomeline High Dose (N=XX)	
Parameter (Units) Visit	Observed	Change from Baseline	Observed	Change from Baseline	Observed	Change from Baseline
<Parameter 1> (<unit>)						
Baseline						
n	XX		XX		XX	
Mean (SD)	XX.X (XX.XX)		XX.X (XX.XX)		XX.X (XX.XX)	
Median	XX.X		XX.X		XX.X	
Q1, Q3	XX.X, XX.X		XX.X, XX.X		XX.X, XX.X	
Min, Max	XX, XX		XX, XX		XX, XX	
...						
<Visit n>						
n	XX	XX	XX	XX	XX	XX
Mean (SD)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)
Median	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X
Q1, Q3	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X
Min, Max	XX, XX	XX, XX	XX, XX	XX, XX	XX, XX	XX, XX
<Parameter n> (<unit>)						
...						

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Table 14.3.3.1b
Summary of Observed and Change from Baseline by Scheduled Visits - Vital Signs <Vertical Layout>
Safety Population

Parameter (Units) Visit	Placebo (N=XX)	Xanomeline Low Dose (N=XX)	Xanomeline High Dose (N=XX)
<Parameter 1> (<unit>)			
Baseline			
n	XX	XX	XX
Mean (SD)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)
Median	XX.X	XX.X	XX.X
Q1, Q3	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X
Min, Max	XX, XX	XX, XX	XX, XX
< Visit n >			
n	XX	XX	XX
Mean (SD)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)
Median	XX.X	XX.X	XX.X
Q1, Q3	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X
Min, Max	XX, XX	XX, XX	XX, XX
< Visit n Change from Baseline >			
n	XX	XX	XX
Mean (SD)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)
Median	XX.X	XX.X	XX.X
Q1, Q3	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X
Min, Max	XX, XX	XX, XX	XX, XX
<Parameter n> (<unit>) ...			

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Table 14.1.1
Summary of Demographics
Safety Population

Characteristics	Placebo (N=XX)	Xanomeline Low Dose (N=XX)	Xanomeline High Dose (N=XX)	p-value [1]
Age (years)				
n	XX	XX	XX	X.XXXX
Mean (SD)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	
Median	XX.X	XX.X	XX.X	
Q1, Q3	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X	
Min, Max	XX, XX	XX, XX	XX, XX	
Age Group, n (%)				
< 65 years	XX (XX.X)	XX (XX.X)	XX (XX.X)	X.XXXX
≥ 65 years	XX (XX.X)	XX (XX.X)	XX (XX.X)	
Gender, n (%)				
Male	XX (XX.X)	XX (XX.X)	XX (XX.X)	X.XXXX
Female	XX (XX.X)	XX (XX.X)	XX (XX.X)	
Ethnicity, n (%)				
Hispanic or Latino	XX (XX.X)	XX (XX.X)	XX (XX.X)	X.XXXX
Not Hispanic or Latino	XX (XX.X)	XX (XX.X)	XX (XX.X)	

What if I told you…

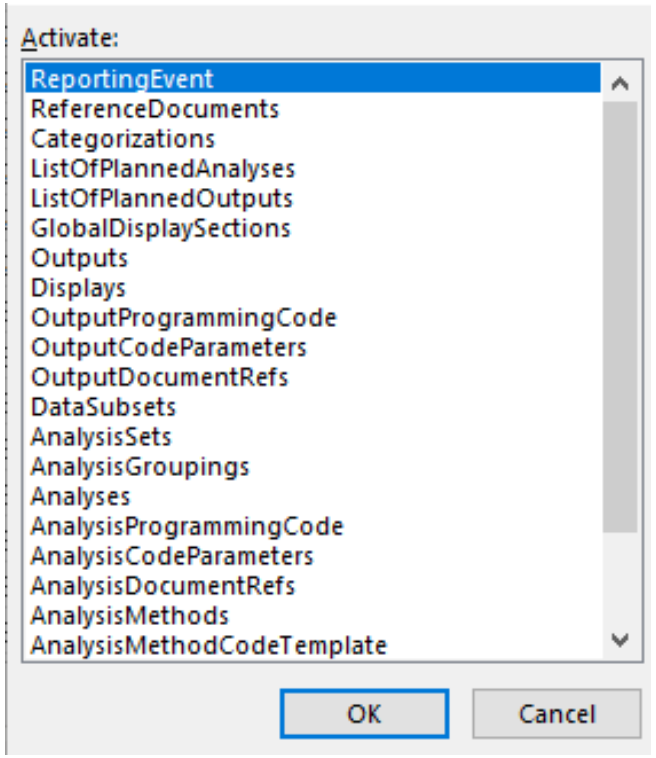
each result
for all outputs in a study
Can be calculated…

What if I told you…

each result
for all outputs in a study
Can be calculated…

- with **one click**

What if I told you…



each result
for all outputs in a study
Can be calculated…

- with **one click**
- referencing **only metadata**

What if I told you…

each result
for all outputs in a study
Can be calculated…

- with **one click**
- referencing **only metadata**
- using **open-source** technology

What if I told you…

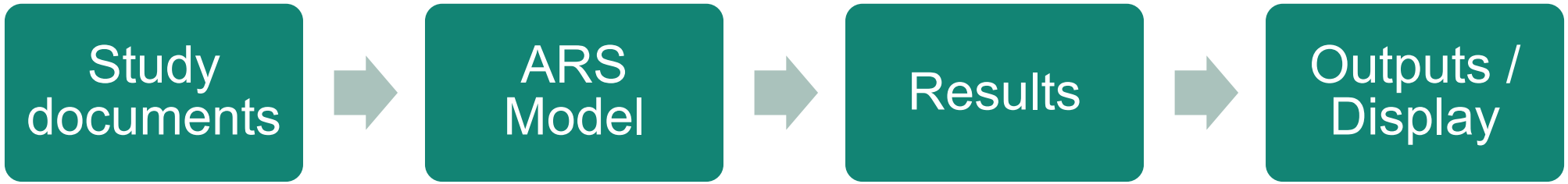
each result
for all outputs in a study
Can be calculated…

- with **one click**
- referencing **only metadata**
- using **open-source** technology

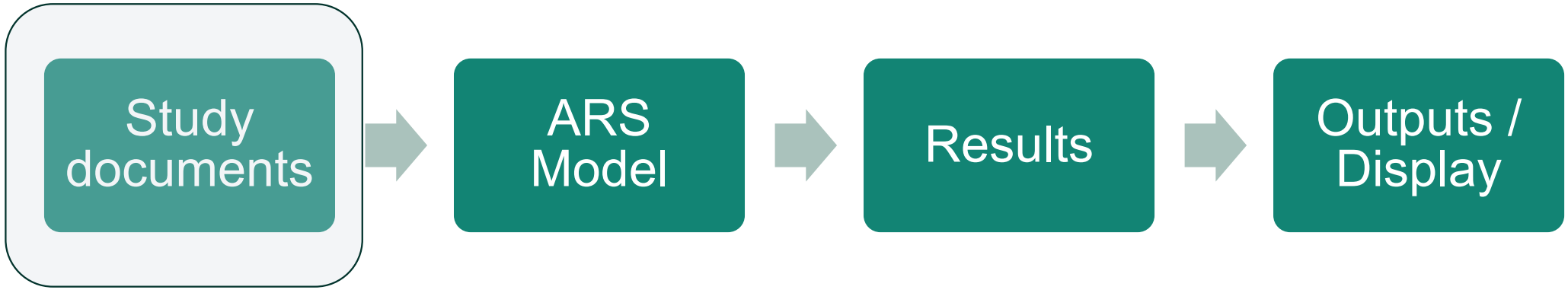
Now, it’s possible!

Process overview

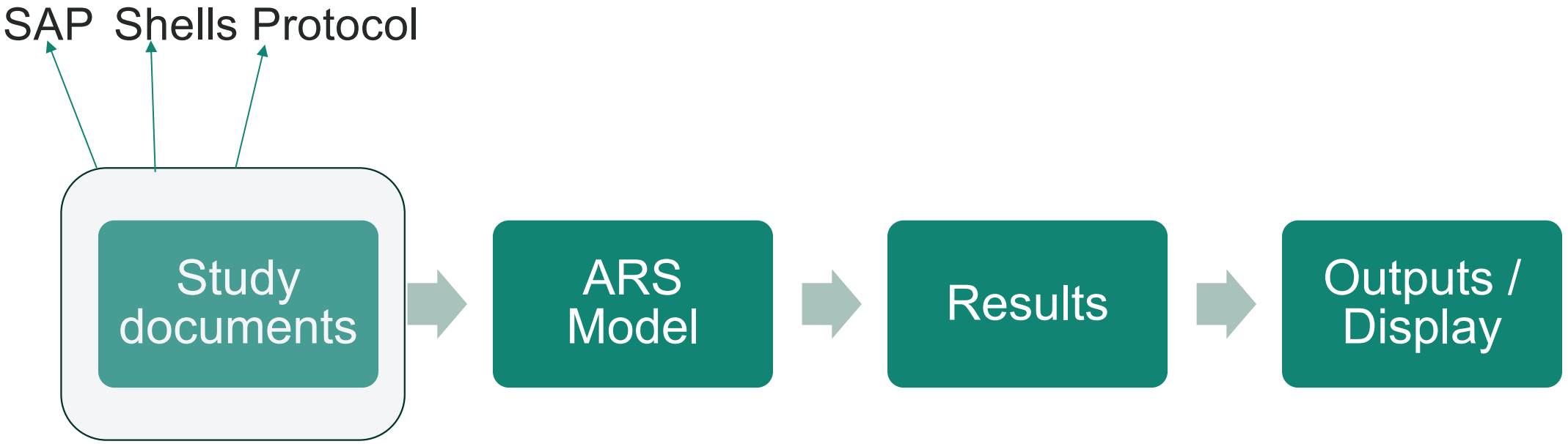
Process overview



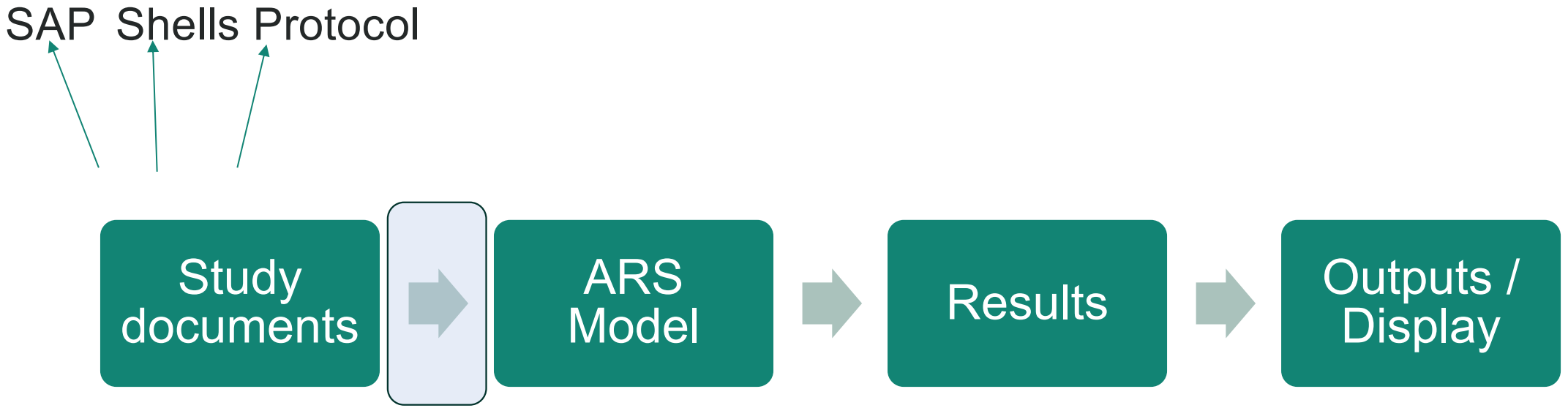
Process overview



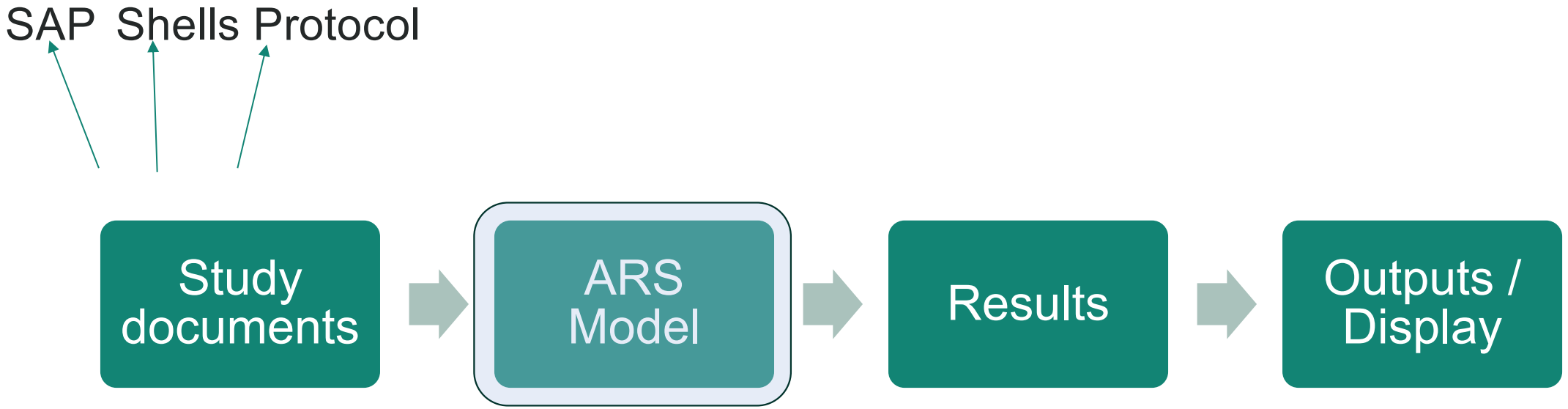
Process overview



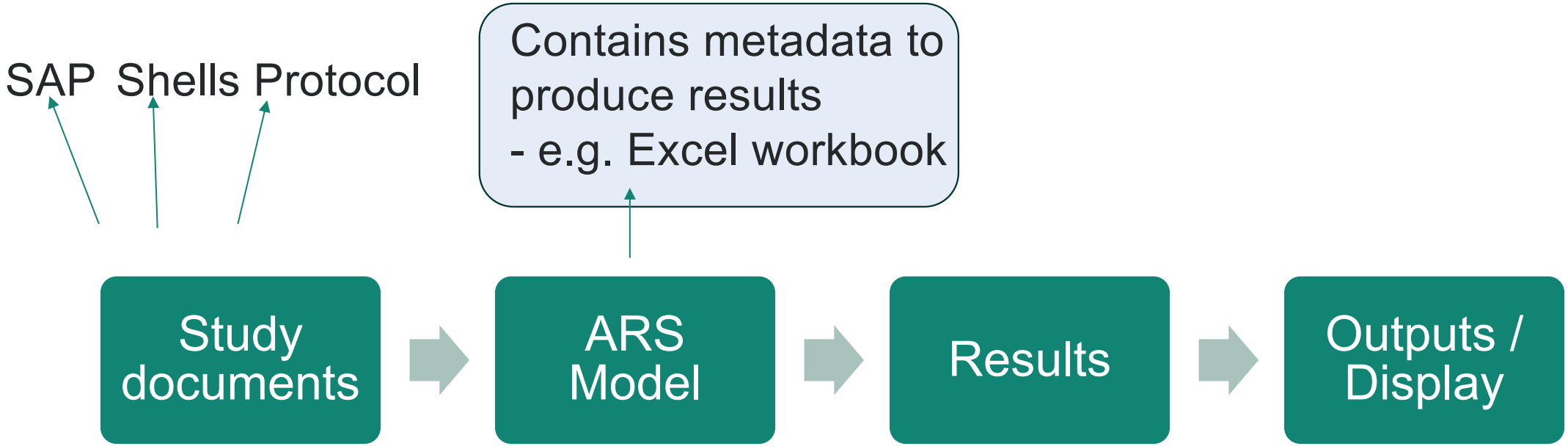
Process overview



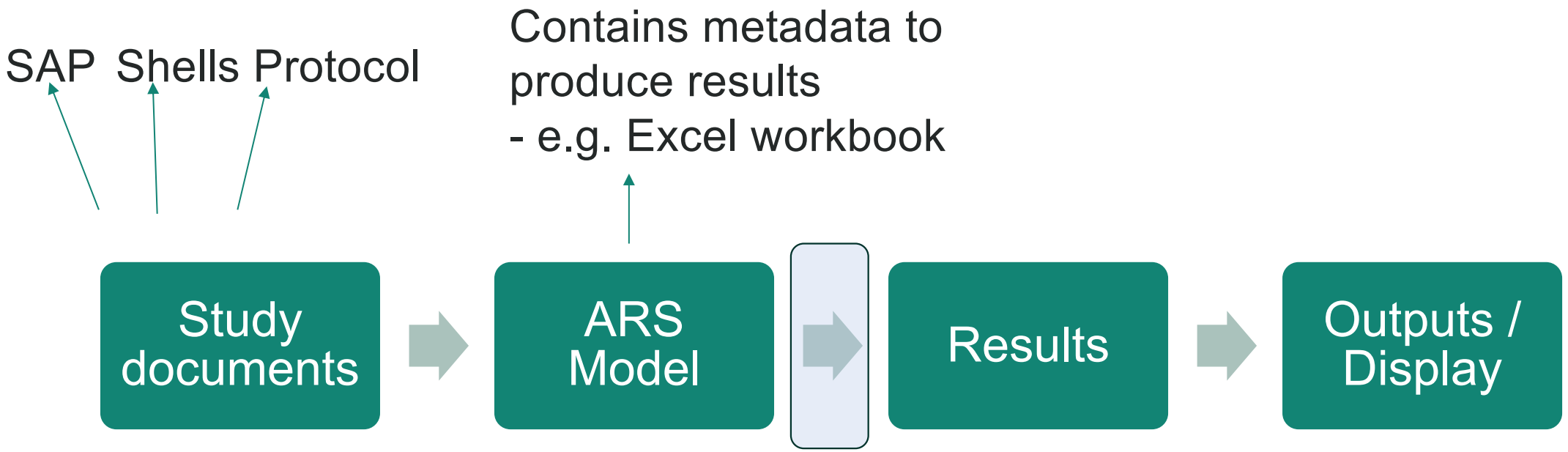
Process overview



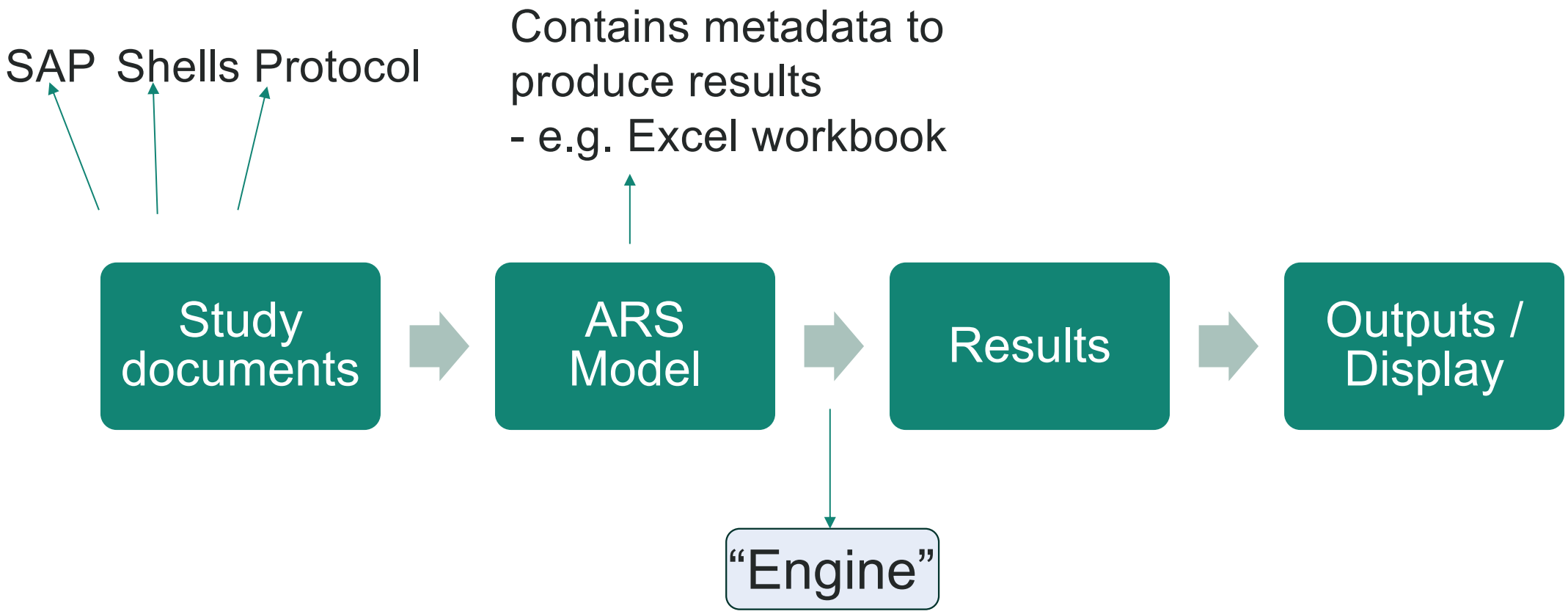
Process overview



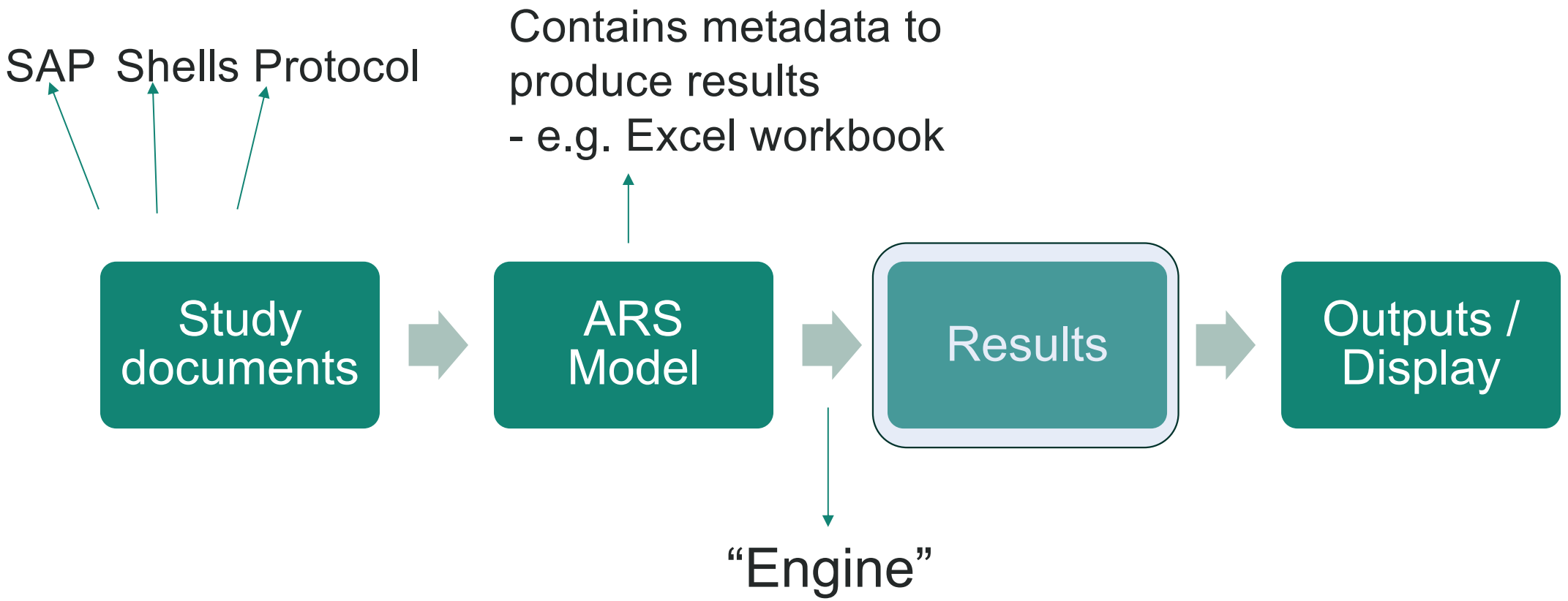
Process overview



Process overview



Process overview



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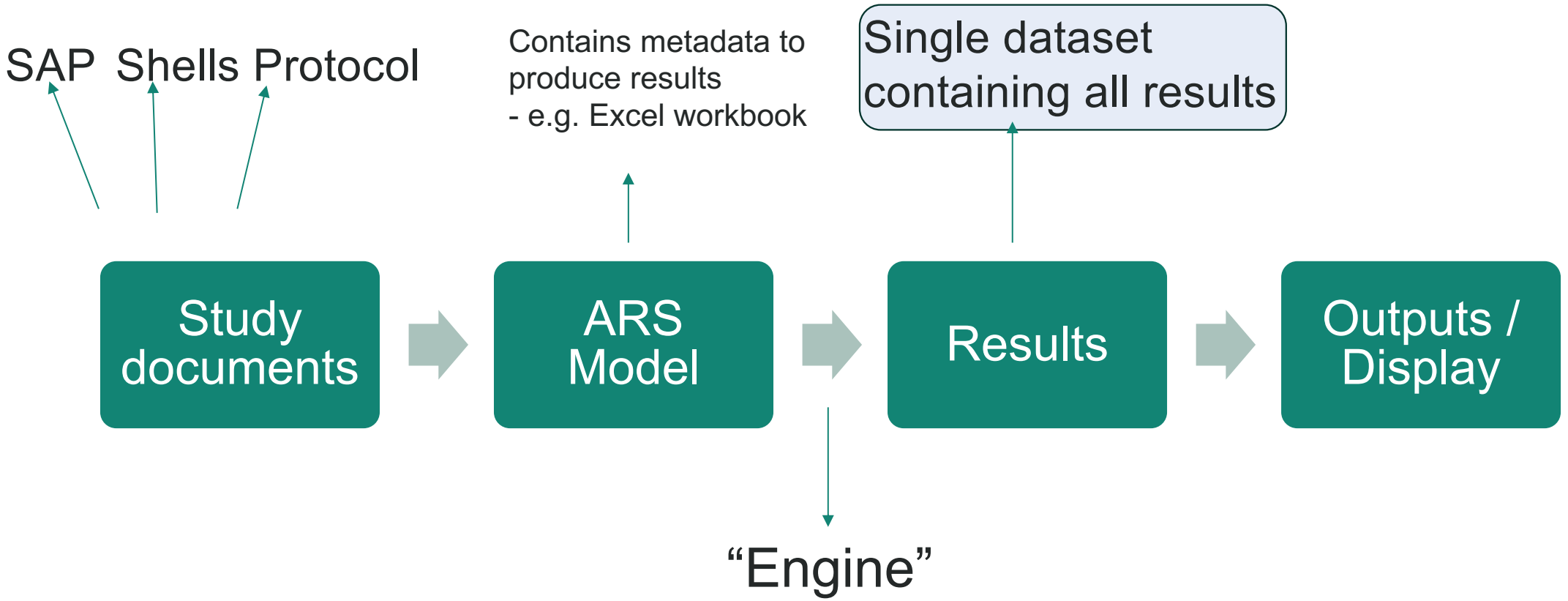

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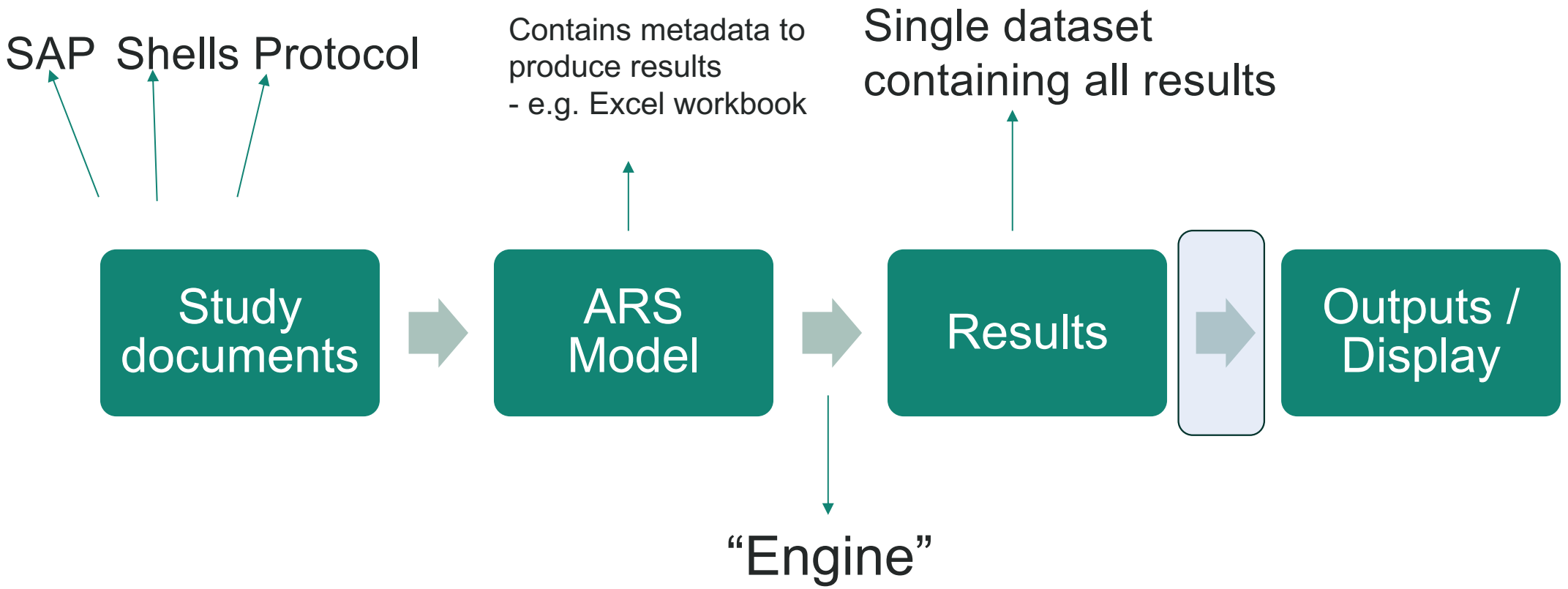
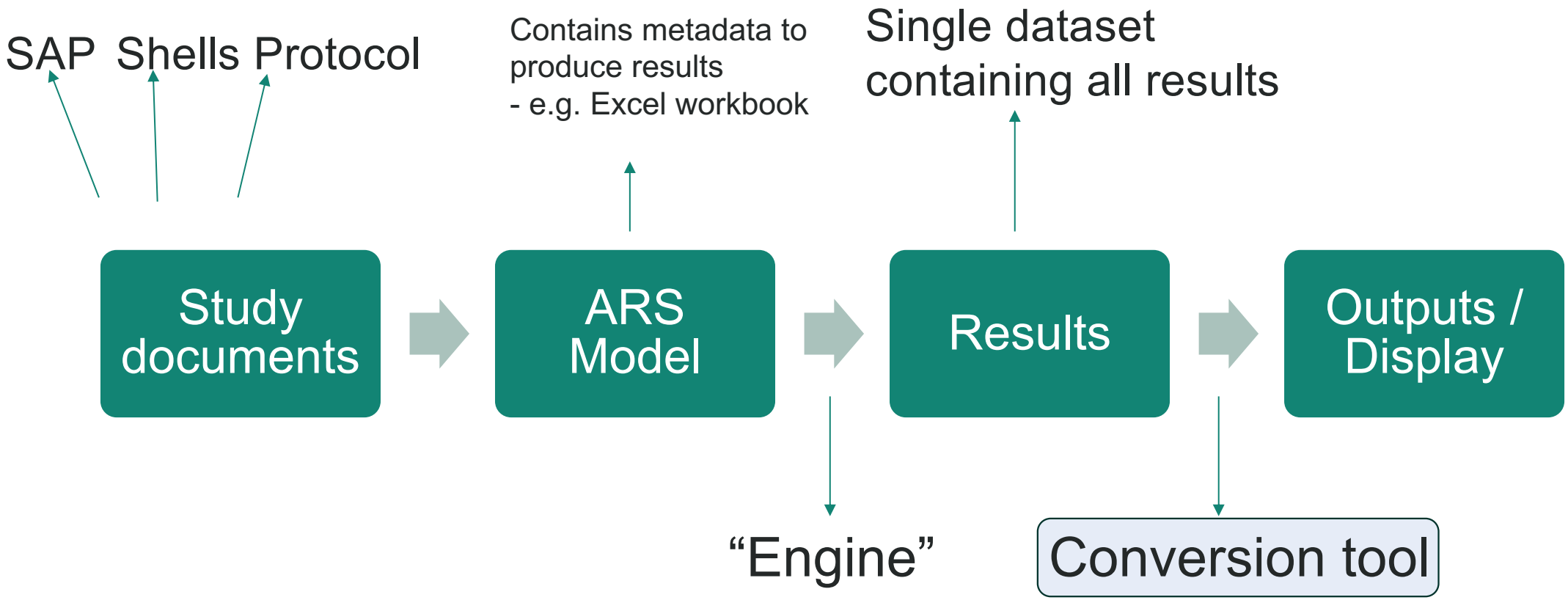


Process overview



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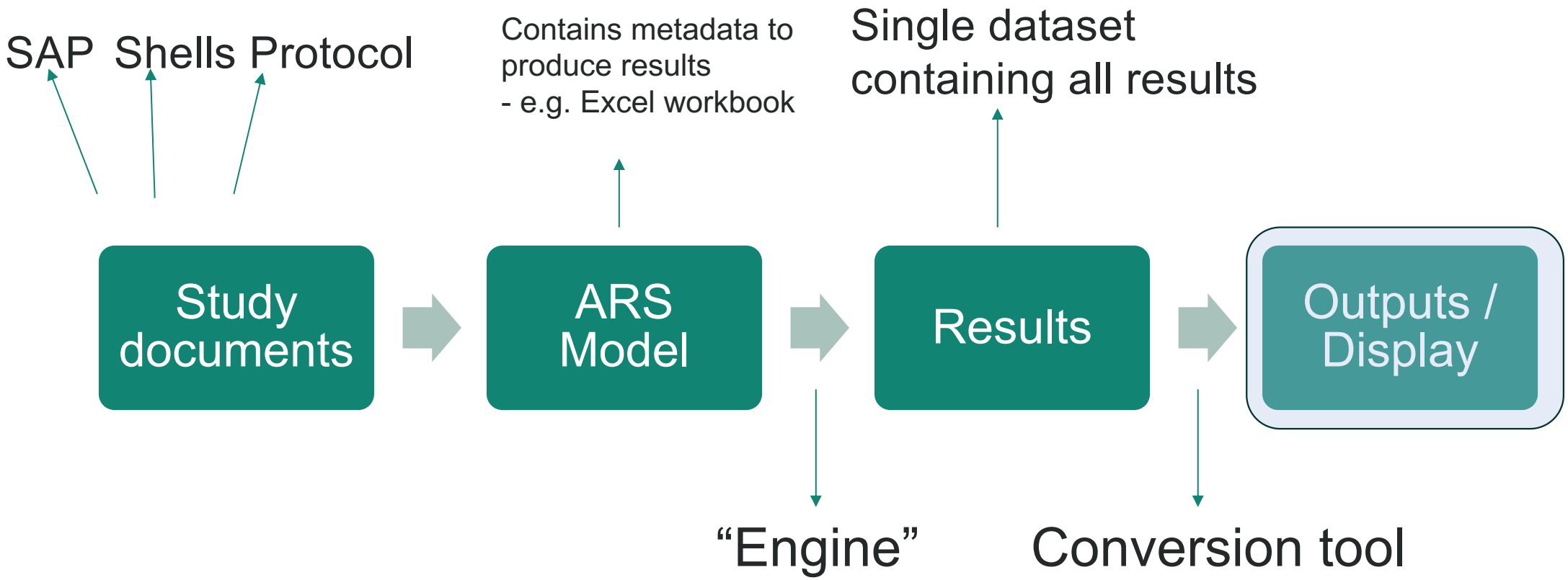
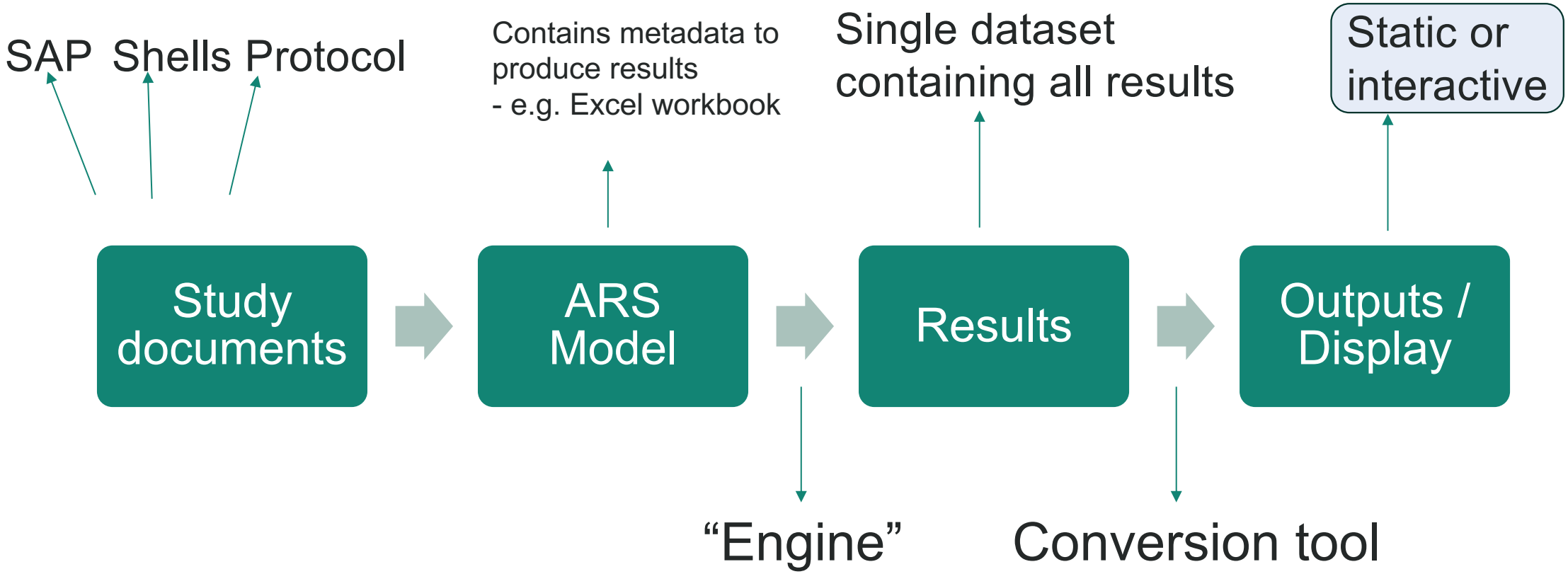
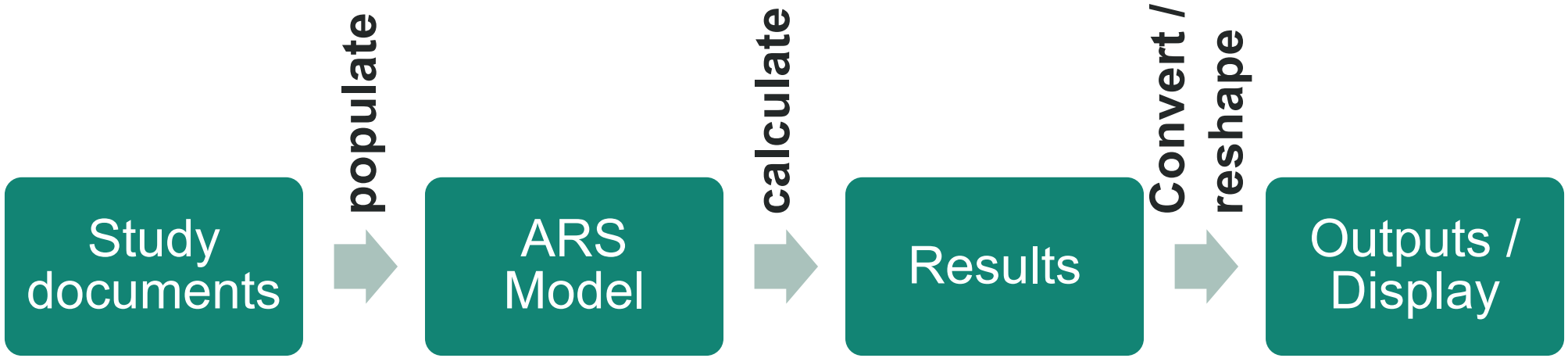


Process overview

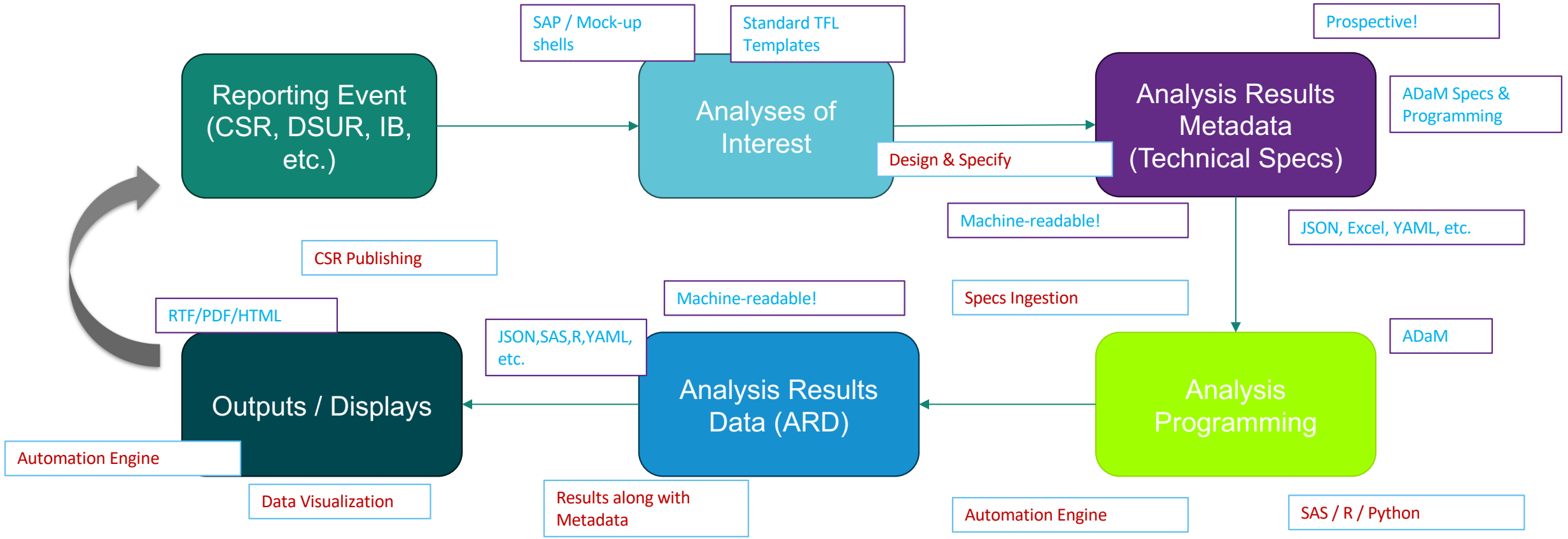


Process overview

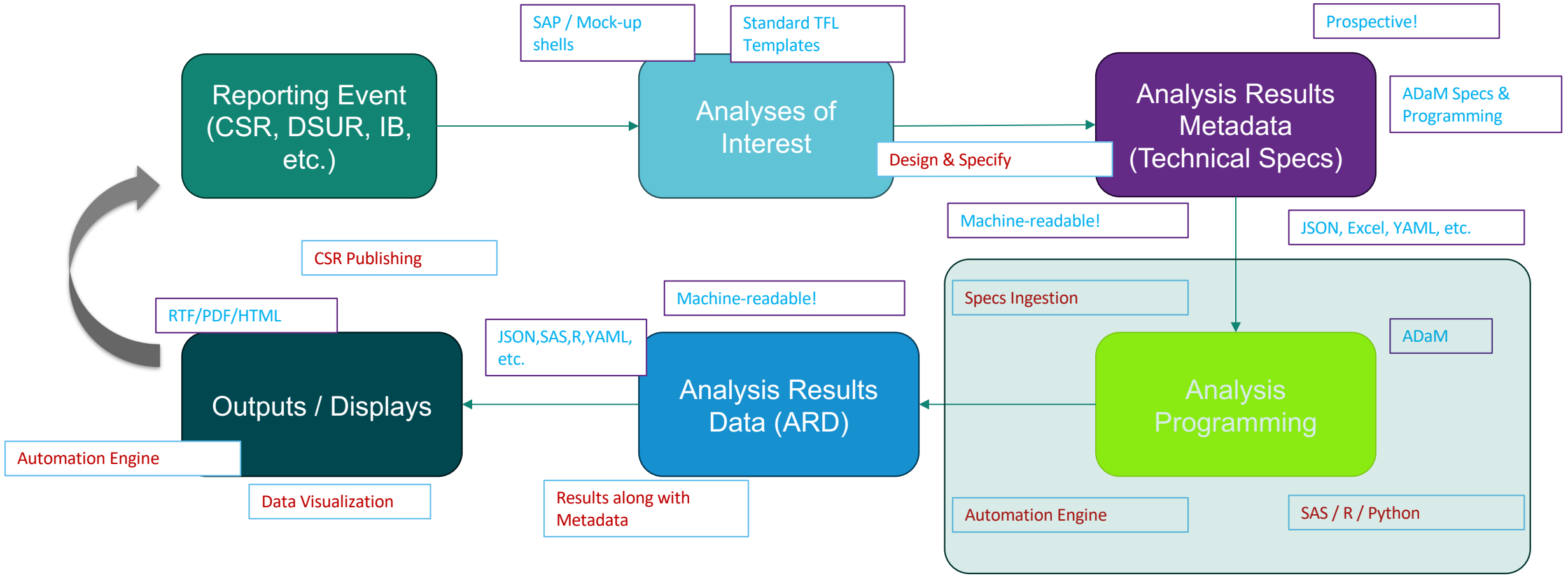


Hackathon project:
ARS in action

Hackathon project

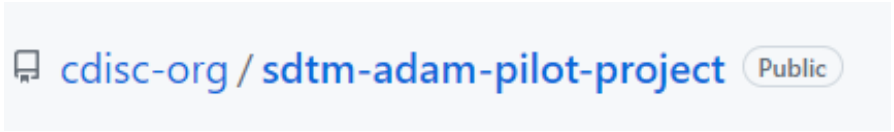


Hackathon project



Hackathon project

Example study:



Hackathon project

Example study: cdisc-org / sdtm-adam-pilot-project Public

Objective: Calculate all results (formatted) required for the safety outputs

Hackathon project

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1. Demographics table

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Table 14.1.1
Summary of Demographics
Safety Population

Characteristics	Placebo (N=XX)	Xanomeline Low Dose (N=XX)	Xanomeline High Dose (N=XX)	p-value [1]
Age (years)				
n	XX	XX	XX	X.XXXX
Mean (SD)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	
Median	XX.X	XX.X	XX.X	
Q1, Q3	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X	
Min, Max	XX, XX	XX, XX	XX, XX	
Age Group, n (%)				
< 65 years	XX (XX.X)	XX (XX.X)	XX (XX.X)	X.XXXX
≥ 65 years	XX (XX.X)	XX (XX.X)	XX (XX.X)	
Gender, n (%)				
Male	XX (XX.X)	XX (XX.X)	XX (XX.X)	X.XXXX
Female	XX (XX.X)	XX (XX.X)	XX (XX.X)	
Ethnicity, n (%)				
Hispanic or Latino	XX (XX.X)	XX (XX.X)	XX (XX.X)	X.XXXX
Not Hispanic or Latino	XX (XX.X)	XX (XX.X)	XX (XX.X)	

Hackathon project

Example study: cdisc-org / sdtm-adam-pilot-project Public

Objective: Calculate all results (formatted) required for the safety outputs

2. Summary of Treatment-Emergent Adverse Events

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Table 14.3.1.1
Overall Summary of Treatment-Emergent Adverse Events
Safety Population

Categories, n (%)	Placebo (N=XX)	Xanomeline Low Dose (N=XX)	Xanomeline High Dose (N=XX)
Number of subjects with at least one event			
TEAE	XX (XX.X)	XX (XX.X)	XX (XX.X)
Related TEAE	XX (XX.X)	XX (XX.X)	XX (XX.X)
Serious TEAE	XX (XX.X)	XX (XX.X)	XX (XX.X)
Related Serious TEAE	XX (XX.X)	XX (XX.X)	XX (XX.X)
TEAE Leading to Death	XX (XX.X)	XX (XX.X)	XX (XX.X)
Related TEAE Leading to Death	XX (XX.X)	XX (XX.X)	XX (XX.X)
TEAE Leading to Dose Modification [a]	XX (XX.X)	XX (XX.X)	XX (XX.X)
TEAE Leading to Treatment Discontinuation	XX (XX.X)	XX (XX.X)	XX (XX.X)

Hackathon project

Example study: cdisc-org / sdtm-adam-pilot-project Public

Objective: Calculate all results (formatted) required for the safety outputs

3. Summary of TEAE by System Organ Class and Preferred Term

Study – CDISC 360 Page x of y

Table 14.3.1.1
Summary of TEAE by System Organ Class and Preferred Term
Safety Population

System Organ Class Preferred Term [a], n (%)	Placebo (N=XX)	Xanomeline Low Dose (N=XX)	Xanomeline High Dose (N=XX)	Fisher's Exact p-values [b]	
				Placebo vs. Low Dose	Placebo vs. High Dose
Number of subjects with at least one event	XX (XX.X)	XX (XX.X)	XX (XX.X)	X.XXX	X.XXX
<SOC 1>	XX (XX.X)	XX (XX.X)	XX (XX.X)	X.XXX	X.XXX
<Preferred Term 1>	XX (XX.X)	XX (XX.X)	XX (XX.X)	X.XXX	X.XXX
...	XX (XX.X)	XX (XX.X)	XX (XX.X)	X.XXX	X.XXX
<Preferred Term n>	XX (XX.X)	XX (XX.X)	XX (XX.X)	X.XXX	X.XXX
<SOC 2>	XX (XX.X)	XX (XX.X)	XX (XX.X)	X.XXX	X.XXX
<Preferred Term 1>	XX (XX.X)	XX (XX.X)	XX (XX.X)	X.XXX	X.XXX
...	XX (XX.X)	XX (XX.X)	XX (XX.X)	X.XXX	X.XXX
<Preferred Term n>	XX (XX.X)	XX (XX.X)	XX (XX.X)	X.XXX	X.XXX

Hackathon project

Example study: cdisc-org / sdtm-adam-pilot-project Public

Objective: Calculate all results (formatted) required for the safety outputs

4. Summary of Observed and Change from Baseline by Scheduled Visits – Vital Signs

Study - CDISC 360 Page x of y

Table 14.3.3.1a
Summary of Observed and Change from Baseline by Scheduled Visits - Vital Signs
Safety Population

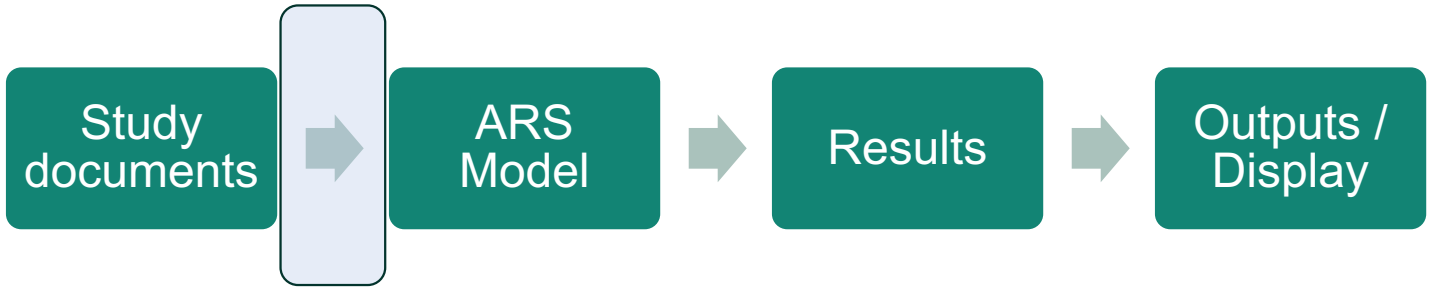
	Placebo (N=XX)		Xanomeline Low Dose (N=XX)		Xanomeline High Dose (N=XX)	
Parameter (Units) **Visit**	**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**	**Observed**	**Change from Baseline**
<Parameter 1> (<unit>)						
Baseline						
n	XX		XX		XX	
Mean (SD)	XX.X (XX.XX)		XX.X (XX.XX)		XX.X (XX.XX)	
Median	XX.X		XX.X		XX.X	
Q1, Q3	XX.X, XX.X		XX.X, XX.X		XX.X, XX.X	
Min, Max	XX, XX		XX, XX		XX, XX	
...						
<Visit n>						
n	XX	XX	XX	XX	XX	XX
Mean (SD)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)
Median	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X
Q1, Q3	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X
Min, Max	XX, XX	XX, XX	XX, XX	XX, XX	XX, XX	XX, XX
<Parameter n> (<unit>)						
...						

Study - CDISC 360 Page x of y

Table 14.3.3.1b
Summary of Observed and Change from Baseline by Scheduled Visits - Vital Signs <Vertical Layout>
Safety Population

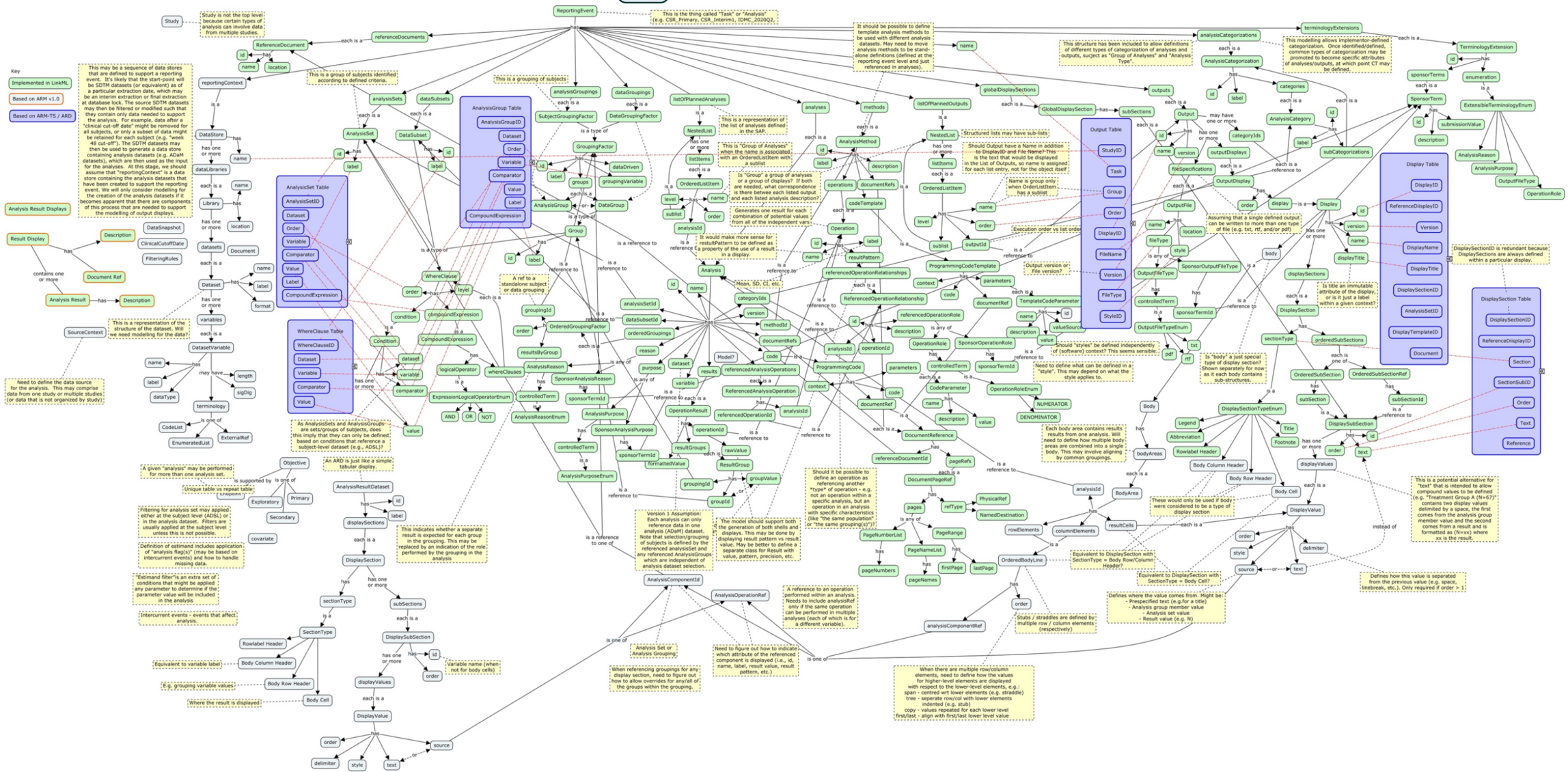
Parameter (Units) **Visit**	Placebo (N=XX)	Xanomeline Low Dose (N=XX)	Xanomeline High Dose (N=XX)
<Parameter 1> (<unit>)			
Baseline			
n	XX	XX	XX
Mean (SD)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)
Median	XX.X	XX.X	XX.X
Q1, Q3	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X
Min, Max	XX, XX	XX, XX	XX, XX
< Visit n >			
n	XX	XX	XX
Mean (SD)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)
Median	XX.X	XX.X	XX.X
Q1, Q3	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X
Min, Max	XX, XX	XX, XX	XX, XX
< Visit n Change from Baseline >			
n	XX	XX	XX
Mean (SD)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)
Median	XX.X	XX.X	XX.X
Q1, Q3	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X
Min, Max	XX, XX	XX, XX	XX, XX
<Parameter n> (<unit>) ...			

Documents -> Model



Documents -> Model

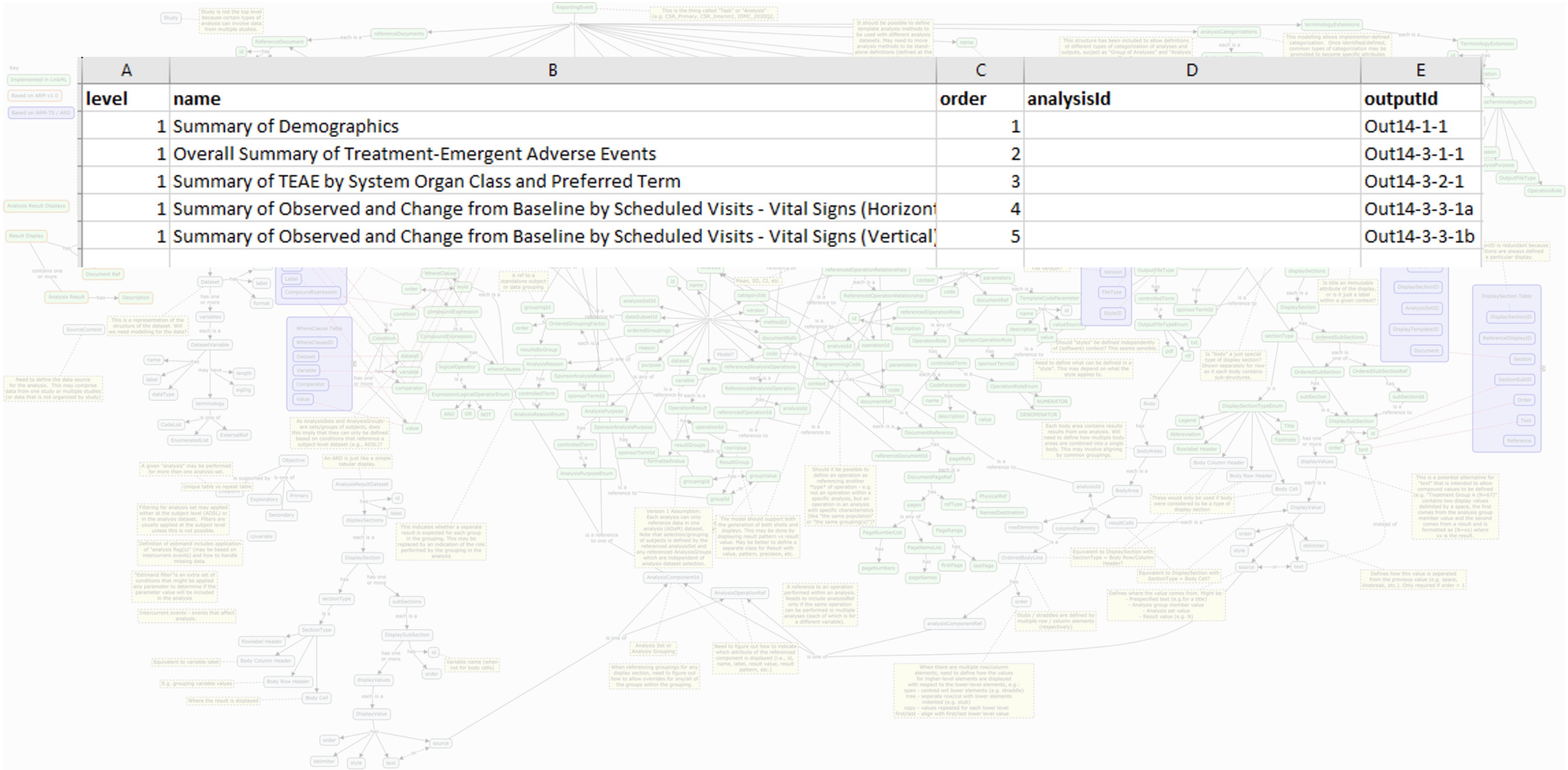
Study documents → ARS Model → Results → Outputs / Display



Documents -> Model

Study documents → ARS Model → Results → Outputs / Display

A	B	C	D	E
level	**name**	**order**	**analysisId**	**outputId**
1	Summary of Demographics	1		Out14-1-1
1	Overall Summary of Treatment-Emergent Adverse Events	2		Out14-3-1-1
1	Summary of TEAE by System Organ Class and Preferred Term	3		Out14-3-2-1
1	Summary of Observed and Change from Baseline by Scheduled Visits - Vital Signs (Horizont	4		Out14-3-3-1a
1	Summary of Observed and Change from Baseline by Scheduled Visits - Vital Signs (Vertical)	5		Out14-3-3-1b



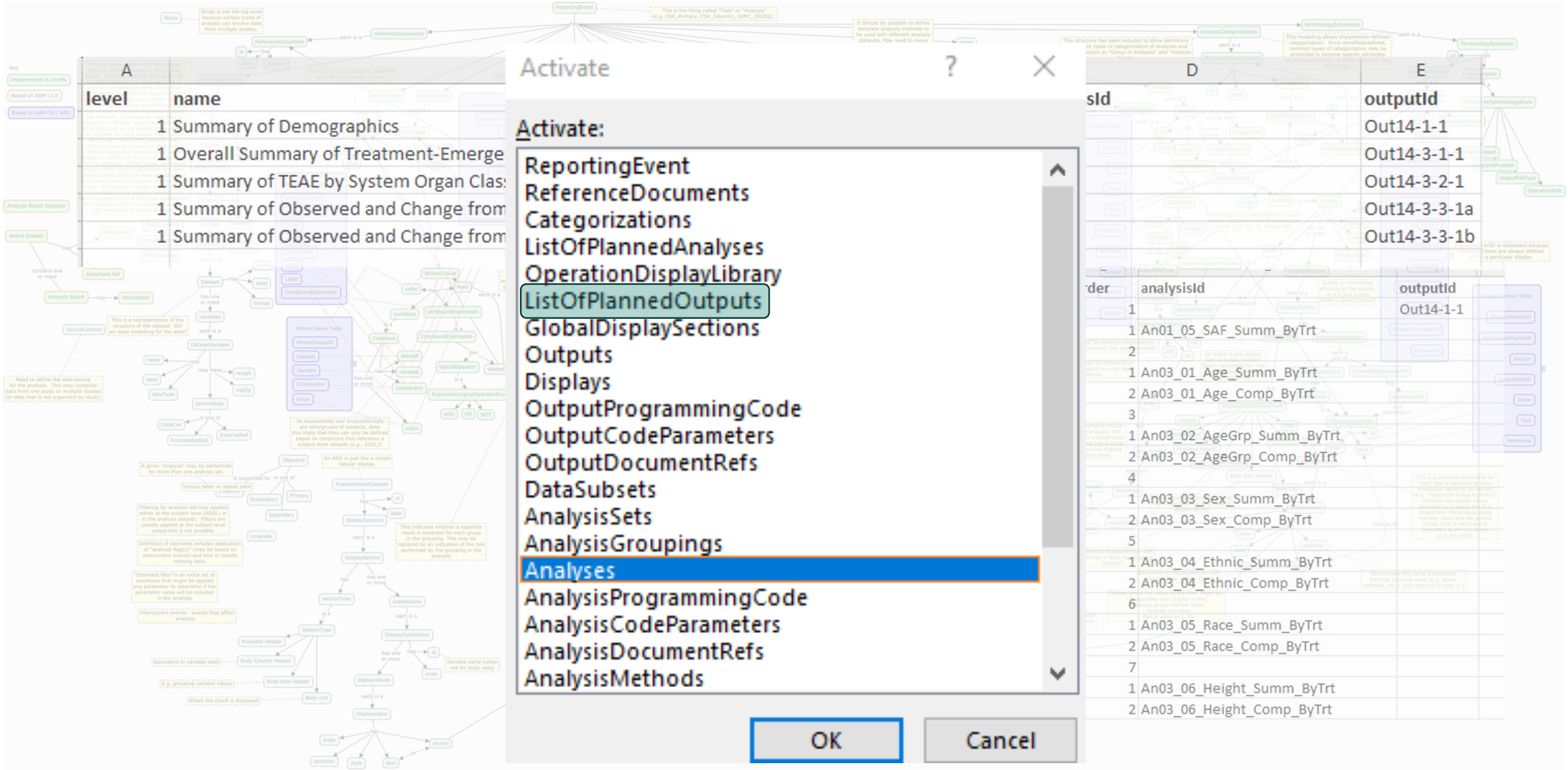
Documents -> Model

Study documents → ARS Model → Results → Outputs / Display

level	name	order	analysisId	outputId
1	Summary of Demographics	1		Out14-1-1
2	Summary of Subjects by Treatment	1	An01_05_SAF_Summ_ByTrt	
2	Age	2		
3	Summary by Treatment	1	An03_01_Age_Summ_ByTrt	
3	Comparison by Treatment	2	An03_01_Age_Comp_ByTrt	
2	Age Group	3		
3	Summary of Subjects by Treatment	1	An03_02_AgeGrp_Summ_ByTrt	
3	Comparison of Subjects by Treatment	2	An03_02_AgeGrp_Comp_ByTrt	
2	Sex	4		
3	Summary of Subjects by Treatment	1	An03_03_Sex_Summ_ByTrt	
3	Comparison of Subjects by Treatment	2	An03_03_Sex_Comp_ByTrt	
2	Ethnicity	5		
3	Summary of Subjects by Treatment	1	An03_04_Ethnic_Summ_ByTrt	
3	Comparison of Subjects by Treatment	2	An03_04_Ethnic_Comp_ByTrt	
2	Race	6		
3	Summary of Subjects by Treatment	1	An03_05_Race_Summ_ByTrt	
3	Comparison of Subjects by Treatment	2	An03_05_Race_Comp_ByTrt	
2	Height	7		
3	Summary by Treatment	1	An03_06_Height_Summ_ByTrt	
3	Comparison by Treatment	2	An03_06_Height_Comp_ByTrt	

Documents -> Model

Study documents → ARS Model → Results → Outputs / Display



A	
level	name
1	Summary of Demographics
1	Overall Summary of Treatment-Emerge
1	Summary of TEAE by System Organ Clas
1	Summary of Observed and Change from
1	Summary of Observed and Change from

Activate

Activate:

- ReportingEvent
- ReferenceDocuments
- Categorizations
- ListOfPlannedAnalyses
- OperationDisplayLibrary
- ListOfPlannedOutputs
- GlobalDisplaySections
- Outputs
- Displays
- OutputProgrammingCode
- OutputCodeParameters
- OutputDocumentRefs
- DataSubsets
- AnalysisSets
- AnalysisGroupings
- Analyses
- AnalysisProgrammingCode
- AnalysisCodeParameters
- AnalysisDocumentRefs
- AnalysisMethods

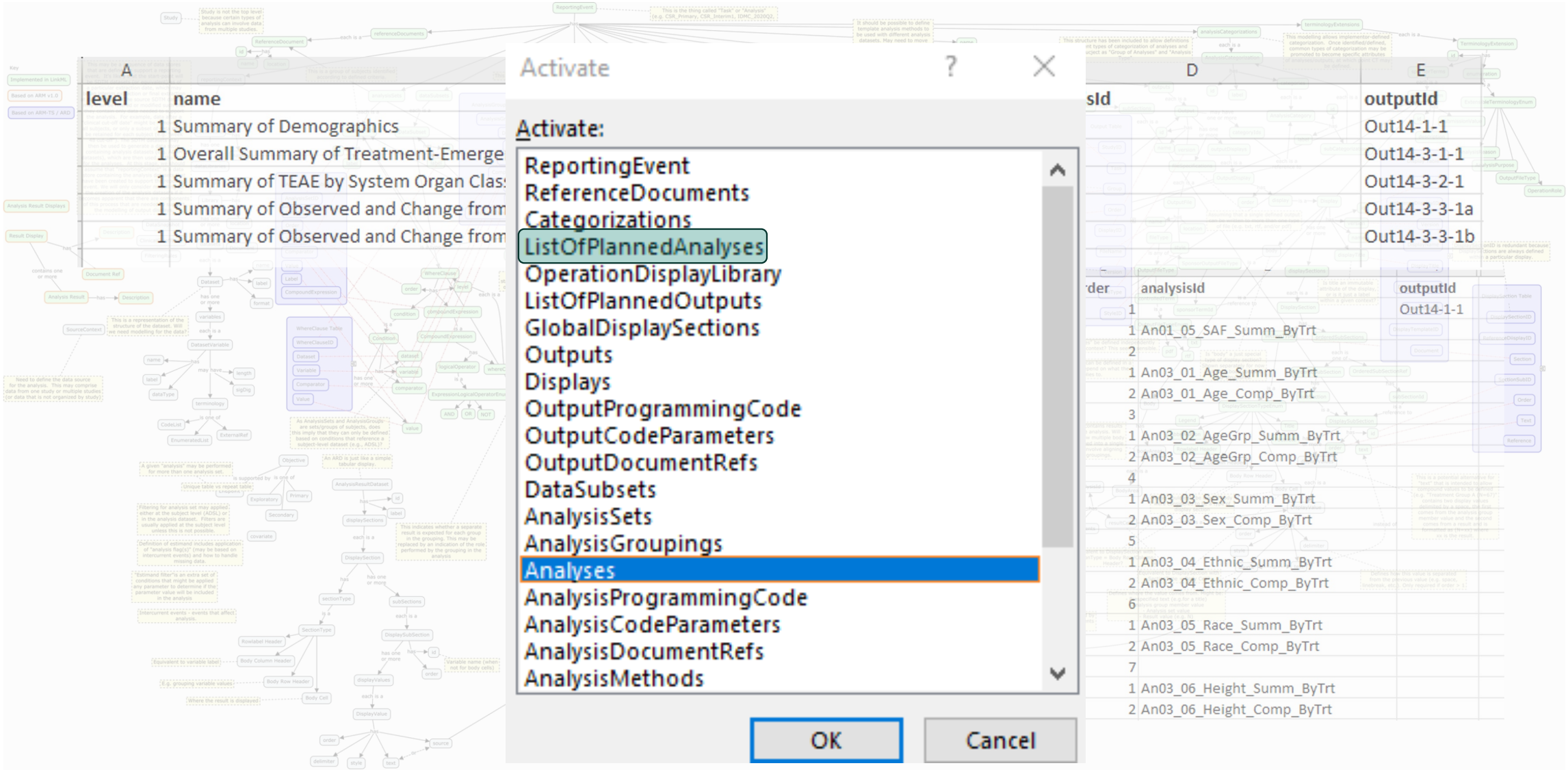
OK Cancel

D	E
sId	outputId
	Out14-1-1
	Out14-3-1-1
	Out14-3-2-1
	Out14-3-3-1a
	Out14-3-3-1b

der	analysisId	outputId
1		Out14-1-1
1	An01_05_SAF_Summ_ByTrt	
2		
1	An03_01_Age_Summ_ByTrt	
2	An03_01_Age_Comp_ByTrt	
3		
1	An03_02_AgeGrp_Summ_ByTrt	
2	An03_02_AgeGrp_Comp_ByTrt	
4		
1	An03_03_Sex_Summ_ByTrt	
2	An03_03_Sex_Comp_ByTrt	
5		
1	An03_04_Ethnic_Summ_ByTrt	
2	An03_04_Ethnic_Comp_ByTrt	
6		
1	An03_05_Race_Summ_ByTrt	
2	An03_05_Race_Comp_ByTrt	
7		
1	An03_06_Height_Summ_ByTrt	
2	An03_06_Height_Comp_ByTrt	

Documents -> Model

Study documents → ARS Model → Results → Outputs / Display



A	
level	name
1	Summary of Demographics
1	Overall Summary of Treatment-Emerge
1	Summary of TEAE by System Organ Clas
1	Summary of Observed and Change from
1	Summary of Observed and Change from

Activate

Activate:

- ReportingEvent
- ReferenceDocuments
- Categorizations
- ListOfPlannedAnalyses
- OperationDisplayLibrary
- ListOfPlannedOutputs
- GlobalDisplaySections
- Outputs
- Displays
- OutputProgrammingCode
- OutputCodeParameters
- OutputDocumentRefs
- DataSubsets
- AnalysisSets
- AnalysisGroupings
- Analyses
- AnalysisProgrammingCode
- AnalysisCodeParameters
- AnalysisDocumentRefs
- AnalysisMethods

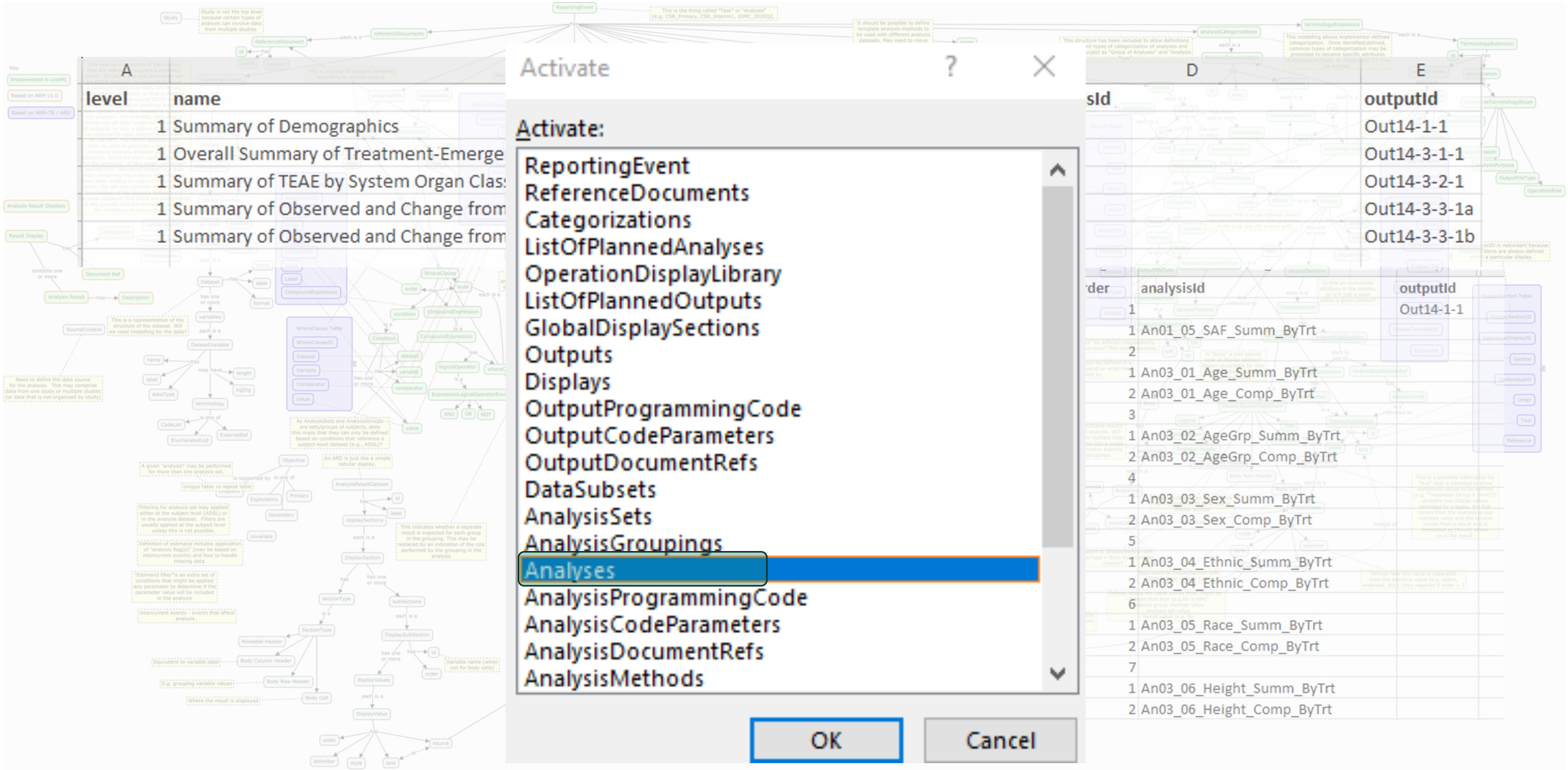
OK Cancel

D	E
sId	outputId
	Out14-1-1
	Out14-3-1-1
	Out14-3-2-1
	Out14-3-3-1a
	Out14-3-3-1b

der	analysisId	outputId
1		Out14-1-1
1	An01_05_SAF_Summ_ByTrt	
2		
1	An03_01_Age_Summ_ByTrt	
2	An03_01_Age_Comp_ByTrt	
3		
1	An03_02_AgeGrp_Summ_ByTrt	
2	An03_02_AgeGrp_Comp_ByTrt	
4		
1	An03_03_Sex_Summ_ByTrt	
2	An03_03_Sex_Comp_ByTrt	
5		
1	An03_04_Ethnic_Summ_ByTrt	
2	An03_04_Ethnic_Comp_ByTrt	
6		
1	An03_05_Race_Summ_ByTrt	
2	An03_05_Race_Comp_ByTrt	
7		
1	An03_06_Height_Summ_ByTrt	
2	An03_06_Height_Comp_ByTrt	

Documents -> Model

Study documents → ARS Model → Results → Outputs / Display



level	name
1	Summary of Demographics
1	Overall Summary of Treatment-Emerge
1	Summary of TEAE by System Organ Clas
1	Summary of Observed and Change from
1	Summary of Observed and Change from

Activate

Activate:

- ReportingEvent
- ReferenceDocuments
- Categorizations
- ListOfPlannedAnalyses
- OperationDisplayLibrary
- ListOfPlannedOutputs
- GlobalDisplaySections
- Outputs
- Displays
- OutputProgrammingCode
- OutputCodeParameters
- OutputDocumentRefs
- DataSubsets
- AnalysisSets
- AnalysisGroupings
- **Analyses**
- AnalysisProgrammingCode
- AnalysisCodeParameters
- AnalysisDocumentRefs
- AnalysisMethods

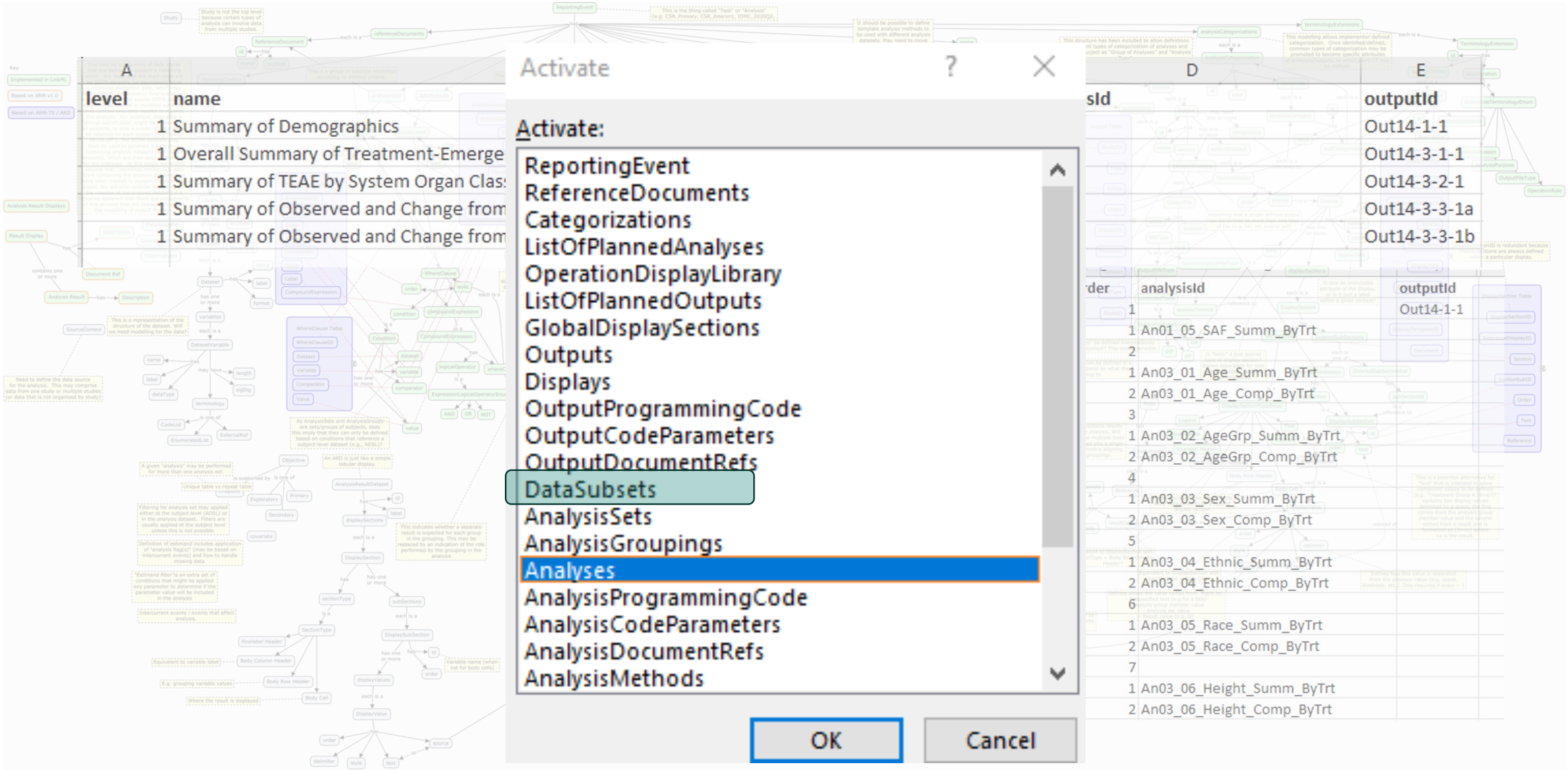
OK Cancel

sId	outputId
	Out14-1-1
	Out14-3-1-1
	Out14-3-2-1
	Out14-3-3-1a
	Out14-3-3-1b

der	analysisId	outputId
1		Out14-1-1
1	An01_05_SAF_Summ_ByTrt	
2		
1	An03_01_Age_Summ_ByTrt	
2	An03_01_Age_Comp_ByTrt	
3		
1	An03_02_AgeGrp_Summ_ByTrt	
2	An03_02_AgeGrp_Comp_ByTrt	
4		
1	An03_03_Sex_Summ_ByTrt	
2	An03_03_Sex_Comp_ByTrt	
5		
1	An03_04_Ethnic_Summ_ByTrt	
2	An03_04_Ethnic_Comp_ByTrt	
6		
1	An03_05_Race_Summ_ByTrt	
2	An03_05_Race_Comp_ByTrt	
7		
1	An03_06_Height_Summ_ByTrt	
2	An03_06_Height_Comp_ByTrt	

Documents -> Model

Study documents → ARS Model → Results → Outputs / Display



A	
level	name
1	Summary of Demographics
1	Overall Summary of Treatment-Emerge
1	Summary of TEAE by System Organ Clas
1	Summary of Observed and Change from
1	Summary of Observed and Change from

Activate

Activate:

- ReportingEvent
- ReferenceDocuments
- Categorizations
- ListOfPlannedAnalyses
- OperationDisplayLibrary
- ListOfPlannedOutputs
- GlobalDisplaySections
- Outputs
- Displays
- OutputProgrammingCode
- OutputCodeParameters
- OutputDocumentRefs
- DataSubsets
- AnalysisSets
- AnalysisGroupings
- Analyses
- AnalysisProgrammingCode
- AnalysisCodeParameters
- AnalysisDocumentRefs
- AnalysisMethods

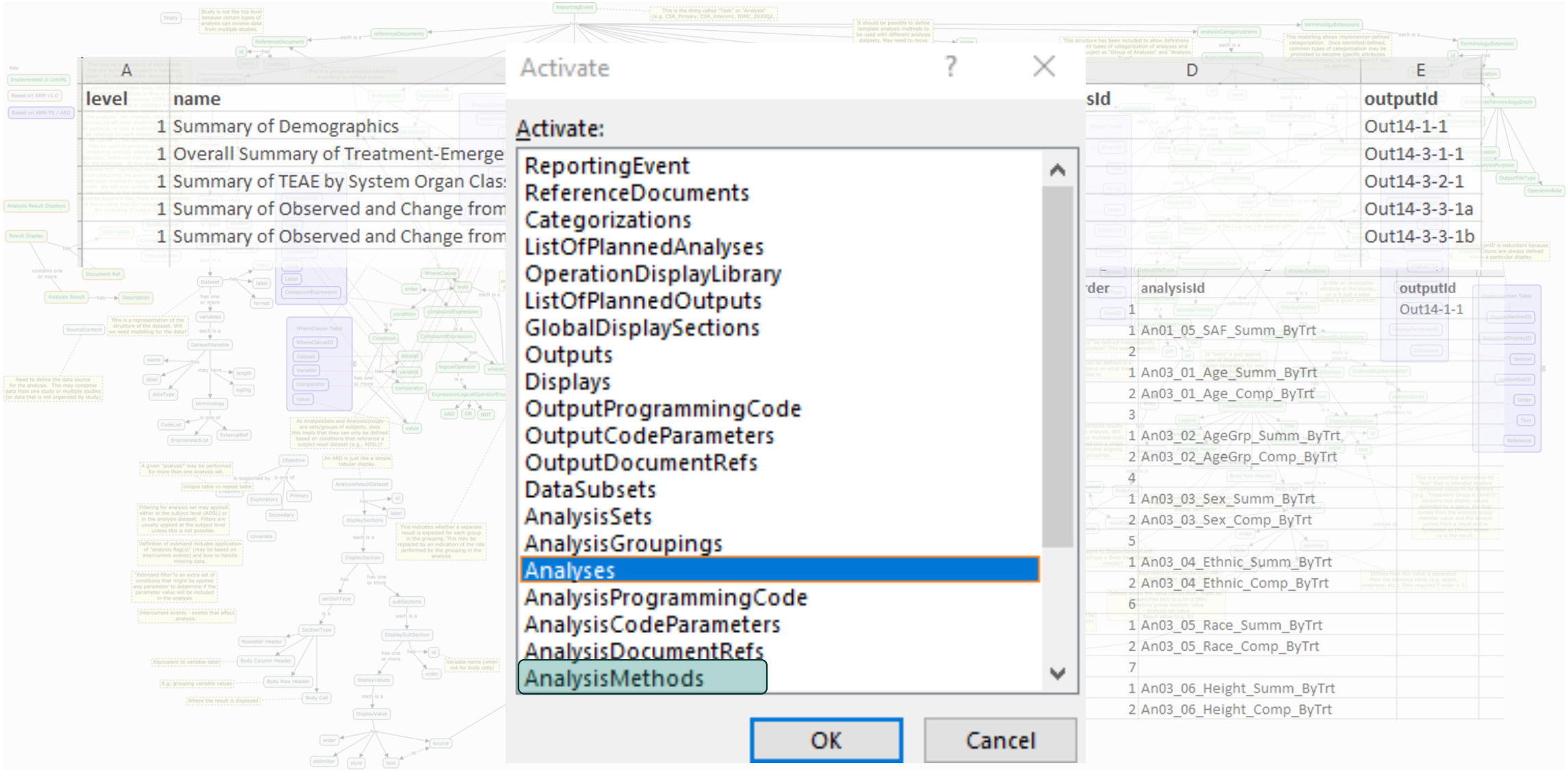
OK Cancel

D	E
sId	outputId
	Out14-1-1
	Out14-3-1-1
	Out14-3-2-1
	Out14-3-3-1a
	Out14-3-3-1b

der	analysisId	outputId
1		Out14-1-1
1	An01_05_SAF_Summ_ByTrt	
2		
1	An03_01_Age_Summ_ByTrt	
2	An03_01_Age_Comp_ByTrt	
3		
1	An03_02_AgeGrp_Summ_ByTrt	
2	An03_02_AgeGrp_Comp_ByTrt	
4		
1	An03_03_Sex_Summ_ByTrt	
2	An03_03_Sex_Comp_ByTrt	
5		
1	An03_04_Ethnic_Summ_ByTrt	
2	An03_04_Ethnic_Comp_ByTrt	
6		
1	An03_05_Race_Summ_ByTrt	
2	An03_05_Race_Comp_ByTrt	
7		
1	An03_06_Height_Summ_ByTrt	
2	An03_06_Height_Comp_ByTrt	

Documents -> Model

Study documents → ARS Model → Results → Outputs / Display



A	
level	name
1	Summary of Demographics
1	Overall Summary of Treatment-Emerge
1	Summary of TEAE by System Organ Clas
1	Summary of Observed and Change from
1	Summary of Observed and Change from

Activate

Activate:

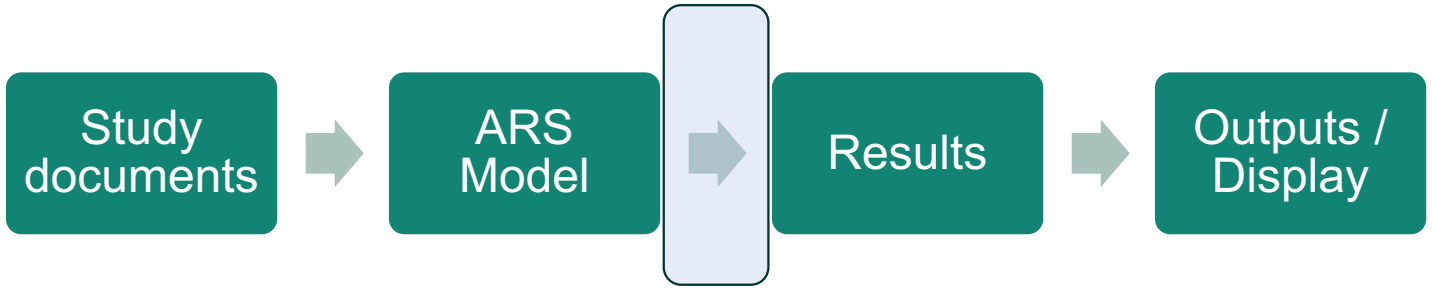
- ReportingEvent
- ReferenceDocuments
- Categorizations
- ListOfPlannedAnalyses
- OperationDisplayLibrary
- ListOfPlannedOutputs
- GlobalDisplaySections
- Outputs
- Displays
- OutputProgrammingCode
- OutputCodeParameters
- OutputDocumentRefs
- DataSubsets
- AnalysisSets
- AnalysisGroupings
- **Analyses**
- AnalysisProgrammingCode
- AnalysisCodeParameters
- AnalysisDocumentRefs
- AnalysisMethods

OK Cancel

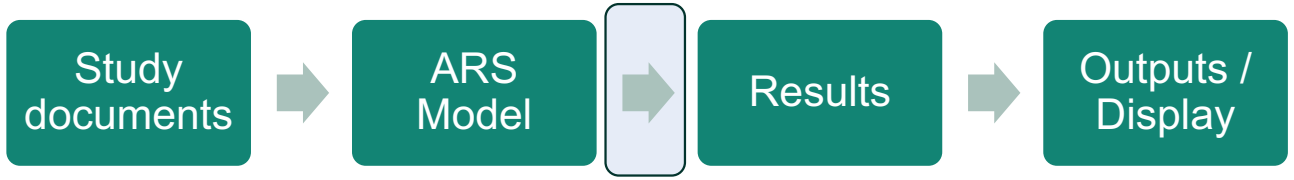
D	E
sId	outputId
	Out14-1-1
	Out14-3-1-1
	Out14-3-2-1
	Out14-3-3-1a
	Out14-3-3-1b

der	analysisId	outputId
1		Out14-1-1
1	An01_05_SAF_Summ_ByTrt	
2		
1	An03_01_Age_Summ_ByTrt	
2	An03_01_Age_Comp_ByTrt	
3		
1	An03_02_AgeGrp_Summ_ByTrt	
2	An03_02_AgeGrp_Comp_ByTrt	
4		
1	An03_03_Sex_Summ_ByTrt	
2	An03_03_Sex_Comp_ByTrt	
5		
1	An03_04_Ethnic_Summ_ByTrt	
2	An03_04_Ethnic_Comp_ByTrt	
6		
1	An03_05_Race_Summ_ByTrt	
2	An03_05_Race_Comp_ByTrt	
7		
1	An03_06_Height_Summ_ByTrt	
2	An03_06_Height_Comp_ByTrt	

Model -> Results

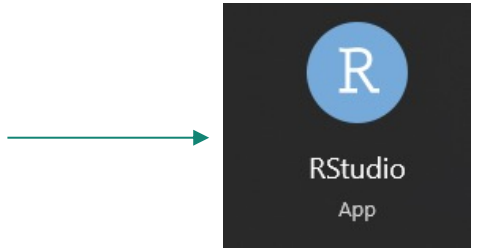


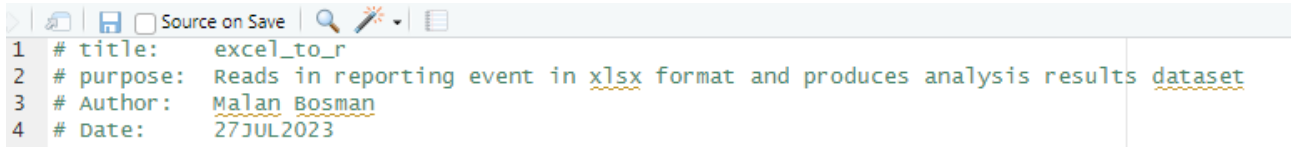
Model -> Results



Method used:

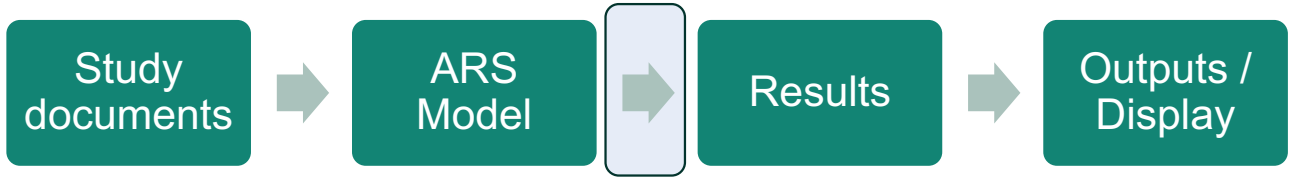
	A	B	C
1	**id**	**version**	**name**
2	CSD	1	Common Safety Displays
3			





"Common Safety displays.xlsx"

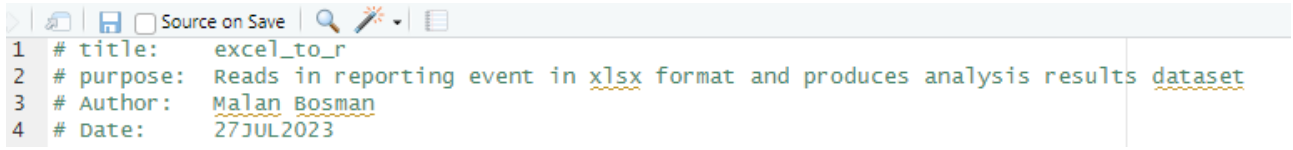
Model -> Results



Method used:

	A	B	C
1	**id**	**version**	**name**
2	CSD	1	Common Safety Displays
3			

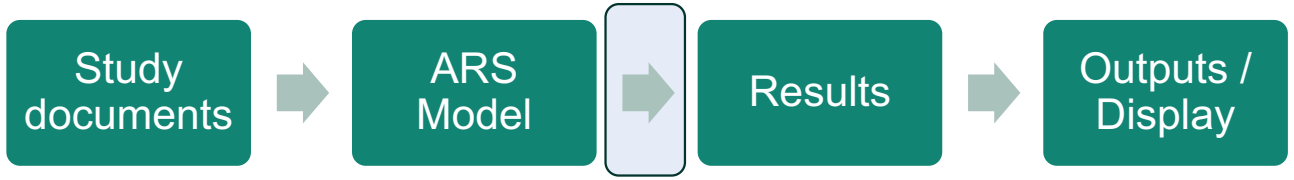
“Common Safety displays.xlsx”



Group1	res	method	operation	output	label	pattern	Group2	Group3	analysis	dec	rnd	disp
Placebo	86.0000000	Mth01_CatVar_Count_ByGrp	Mth01_CatVar_Count_ByGrp_1_n	Out14-1-1	n	(N=XX)			An01_05_SAF_Summ_ByTrt	0	86.0000	(N=86)
Xanomeline High Dose	84.0000000	Mth01_CatVar_Count_ByGrp	Mth01_CatVar_Count_ByGrp_1_n	Out14-1-1	n	(N=XX)			An01_05_SAF_Summ_ByTrt	0	84.0000	(N=84)
Xanomeline Low Dose	84.0000000	Mth01_CatVar_Count_ByGrp	Mth01_CatVar_Count_ByGrp_1_n	Out14-1-1	n	(N=XX)			An01_05_SAF_Summ_ByTrt	0	84.0000	(N=84)
Placebo	86.0000000	Mth02_ContVar_Summ_ByGrp	Mth02_ContVar_Summ_ByGrp_1_n	Out14-1-1	n	XX			An03_01_Age_Summ_ByTrt	0	86.0000	86
Xanomeline High Dose	84.0000000	Mth02_ContVar_Summ_ByGrp	Mth02_ContVar_Summ_ByGrp_1_n	Out14-1-1	n	XX			An03_01_Age_Summ_ByTrt	0	84.0000	84
Xanomeline Low Dose	84.0000000	Mth02_ContVar_Summ_ByGrp	Mth02_ContVar_Summ_ByGrp_1_n	Out14-1-1	n	XX			An03_01_Age_Summ_ByTrt	0	84.0000	84
Placebo	75.2093023	Mth02_ContVar_Summ_ByGrp	Mth02_ContVar_Summ_ByGrp_2_Mean	Out14-1-1	Mean	XX.X			An03_01_Age_Summ_ByTrt	1	75.2000	75.2
Xanomeline High Dose	74.3809524	Mth02_ContVar_Summ_ByGrp	Mth02_ContVar_Summ_ByGrp_2_Mean	Out14-1-1	Mean	XX.X			An03_01_Age_Summ_ByTrt	1	74.4000	74.4
Xanomeline Low Dose	75.6666667	Mth02_ContVar_Summ_ByGrp	Mth02_ContVar_Summ_ByGrp_2_Mean	Out14-1-1	Mean	XX.X			An03_01_Age_Summ_ByTrt	1	75.7000	75.7
Placebo	8.5901671	Mth02_ContVar_Summ_ByGrp	Mth02_ContVar_Summ_ByGrp_3_SD	Out14-1-1	SD	(XX.XX)			An03_01_Age_Summ_ByTrt	2	8.5900	(8.59)

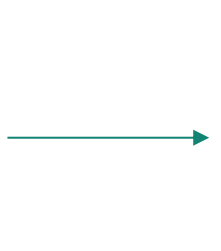
Results dataset

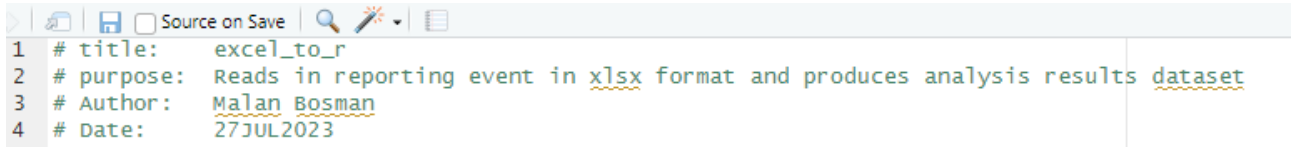
Model -> Results



Method used:

	A	B	C
1	**id**	**version**	**name**
2	CSD	1	Common Safety Displays
3			



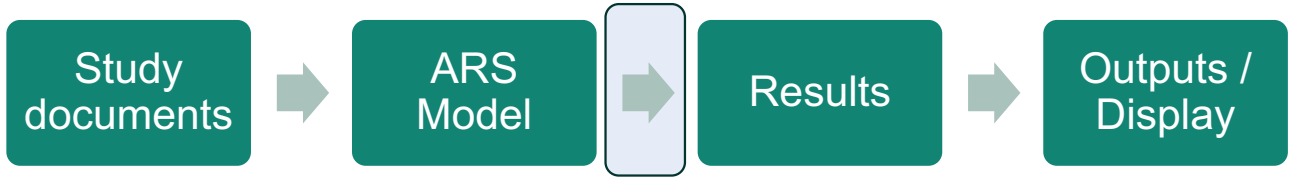


"Common Safety displays.xlsx"

Group1	res	method	operation	output	label	pattern	Group2	Group3	analysis	dec	rnd	disp
Placebo	86.0000000	Mth01_CatVar_Count_ByGrp	Mth01_CatVar_Count_ByGrp_1_n	Out14-1-1	n	(N=XX)			An01_05_SAF_Summ_ByTrt	0	86.0000	(N=86)
Xanomeline High Dose	84.0000000	Mth01_CatVar_Count_ByGrp	Mth01_CatVar_Count_ByGrp_1_n	Out14-1-1	n	(N=XX)			An01_05_SAF_Summ_ByTrt	0	84.0000	(N=84)
Xanomeline Low Dose	84.0000000	Mth01_CatVar_Count_ByGrp	Mth01_CatVar_Count_ByGrp_1_n	Out14-1-1	n	(N=XX)			An01_05_SAF_Summ_ByTrt	0	84.0000	(N=84)
Placebo	86.0000000	Mth02_ContVar_Summ_ByGrp	Mth02_ContVar_Summ_ByGrp_1_n	Out14-1-1	n	XX			An03_01_Age_Summ_ByTrt	0	86.0000	86
Xanomeline High Dose	84.0000000	Mth02_ContVar_Summ_ByGrp	Mth02_ContVar_Summ_ByGrp_1_n	Out14-1-1	n	XX			An03_01_Age_Summ_ByTrt	0	84.0000	84
Xanomeline Low Dose	84.0000000	Mth02_ContVar_Summ_ByGrp	Mth02_ContVar_Summ_ByGrp_1_n	Out14-1-1	n	XX			An03_01_Age_Summ_ByTrt	0	84.0000	84
Placebo	75.2093023	Mth02_ContVar_Summ_ByGrp	Mth02_ContVar_Summ_ByGrp_2_Mean	Out14-1-1	Mean	XX.X			An03_01_Age_Summ_ByTrt	1	75.2000	75.2
Xanomeline High Dose	74.3809524	Mth02_ContVar_Summ_ByGrp	Mth02_ContVar_Summ_ByGrp_2_Mean	Out14-1-1	Mean	XX.X			An03_01_Age_Summ_ByTrt	1	74.4000	74.4
Xanomeline Low Dose	75.6666667	Mth02_ContVar_Summ_ByGrp	Mth02_ContVar_Summ_ByGrp_2_Mean	Out14-1-1	Mean	XX.X			An03_01_Age_Summ_ByTrt	1	75.7000	75.7
Placebo	8.5901671	Mth02_ContVar_Summ_ByGrp	Mth02_ContVar_Summ_ByGrp_3_SD	Out14-1-1	SD	(XX.XX)			An03_01_Age_Summ_ByTrt	2	8.5900	(8.59)

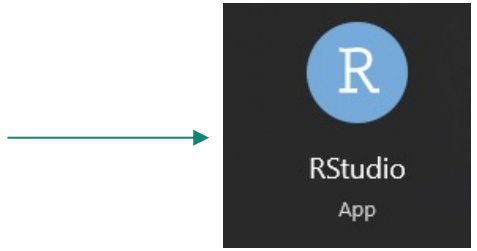
Results dataset

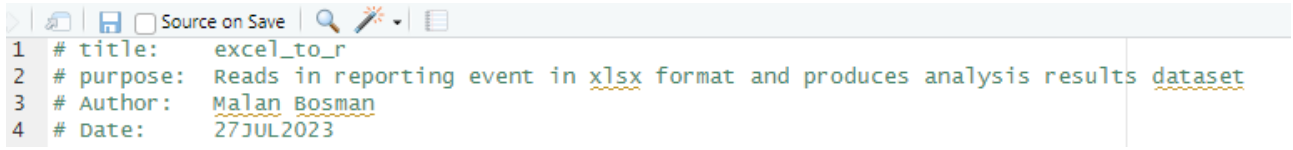
Model -> Results



Method used:

	A	B	C
1	**id**	**version**	**name**
2	CSD	1	Common Safety Displays
3			



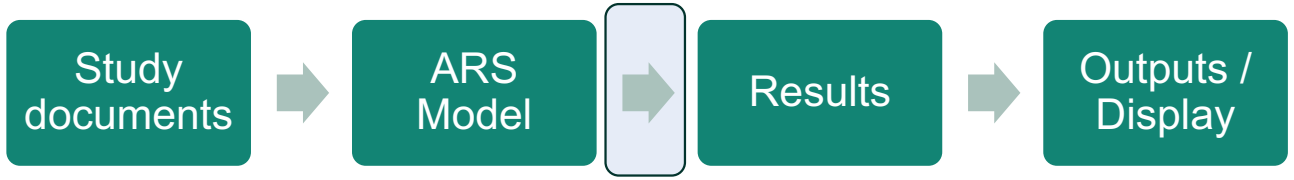


"Common Safety displays.xlsx"

Group1	res	method	operation	output	label	pattern	Group2	Group3	analysis	dec	rnd	disp
Placebo	86.0000000	Mth01_CatVar_Count_ByGrp	Mth01_CatVar_Count_ByGrp_1_n	Out14-1-1	n	(N=XX)			An01_05_SAF_Summ_ByTrt	0	86.0000	(N=86)
Xanomeline High Dose	84.0000000	Mth01_CatVar_Count_ByGrp	Mth01_CatVar_Count_ByGrp_1_n	Out14-1-1	n	(N=XX)			An01_05_SAF_Summ_ByTrt	0	84.0000	(N=84)
Xanomeline Low Dose	84.0000000	Mth01_CatVar_Count_ByGrp	Mth01_CatVar_Count_ByGrp_1_n	Out14-1-1	n	(N=XX)			An01_05_SAF_Summ_ByTrt	0	84.0000	(N=84)
Placebo	86.0000000	Mth02_ContVar_Summ_ByGrp	Mth02_ContVar_Summ_ByGrp_1_n	Out14-1-1	n	XX			An03_01_Age_Summ_ByTrt	0	86.0000	86
Xanomeline High Dose	84.0000000	Mth02_ContVar_Summ_ByGrp	Mth02_ContVar_Summ_ByGrp_1_n	Out14-1-1	n	XX			An03_01_Age_Summ_ByTrt	0	84.0000	84
Xanomeline Low Dose	84.0000000	Mth02_ContVar_Summ_ByGrp	Mth02_ContVar_Summ_ByGrp_1_n	Out14-1-1	n	XX			An03_01_Age_Summ_ByTrt	0	84.0000	84
Placebo	75.2093023	Mth02_ContVar_Summ_ByGrp	Mth02_ContVar_Summ_ByGrp_2_Mean	Out14-1-1	Mean	XX.X			An03_01_Age_Summ_ByTrt	1	75.2000	75.2
Xanomeline High Dose	74.3809524	Mth02_ContVar_Summ_ByGrp	Mth02_ContVar_Summ_ByGrp_2_Mean	Out14-1-1	Mean	XX.X			An03_01_Age_Summ_ByTrt	1	74.4000	74.4
Xanomeline Low Dose	75.6666667	Mth02_ContVar_Summ_ByGrp	Mth02_ContVar_Summ_ByGrp_2_Mean	Out14-1-1	Mean	XX.X			An03_01_Age_Summ_ByTrt	1	75.7000	75.7
Placebo	8.5901671	Mth02_ContVar_Summ_ByGrp	Mth02_ContVar_Summ_ByGrp_3_SD	Out14-1-1	SD	(XX.XX)			An03_01_Age_Summ_ByTrt	2	8.5900	(8.59)

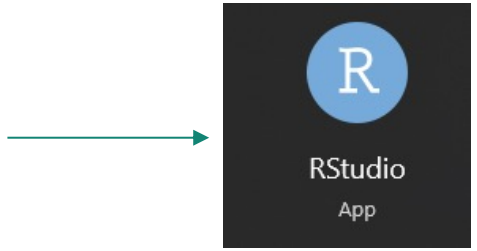
Results dataset

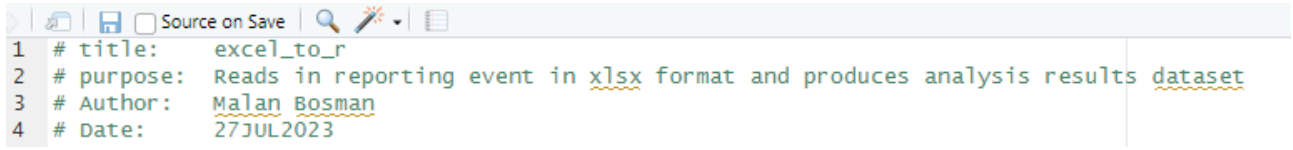
Model -> Results



Method used:

	A	B	C
1	**id**	**version**	**name**
2	CSD	1	Common Safety Displays
3			



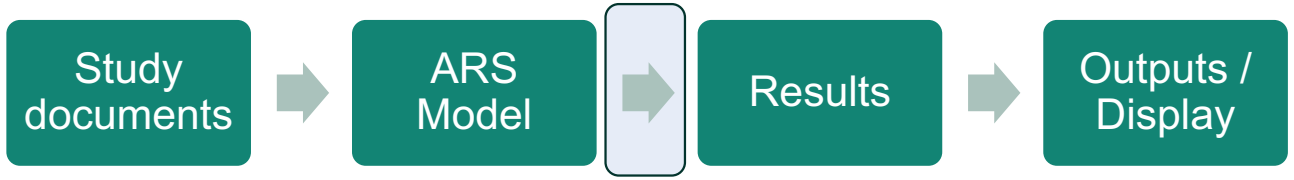


"Common Safety displays.xlsx"

Group1	res	method	operation	output	label	pattern	Group2	Group3	analysis	dec	rnd	disp
Placebo	86.0000000	Mth01_CatVar_Count_ByGrp	Mth01_CatVar_Count_ByGrp_1_n	Out14-1-1	n	(N=XX)			An01_05_SAF_Summ_ByTrt	0	86.0000	(N=86)
Xanomeline High Dose	84.0000000	Mth01_CatVar_Count_ByGrp	Mth01_CatVar_Count_ByGrp_1_n	Out14-1-1	n	(N=XX)			An01_05_SAF_Summ_ByTrt	0	84.0000	(N=84)
Xanomeline Low Dose	84.0000000	Mth01_CatVar_Count_ByGrp	Mth01_CatVar_Count_ByGrp_1_n	Out14-1-1	n	(N=XX)			An01_05_SAF_Summ_ByTrt	0	84.0000	(N=84)
Placebo	86.0000000	Mth02_ContVar_Summ_ByGrp	Mth02_ContVar_Summ_ByGrp_1_n	Out14-1-1	n	XX			An03_01_Age_Summ_ByTrt	0	86.0000	86
Xanomeline High Dose	84.0000000	Mth02_ContVar_Summ_ByGrp	Mth02_ContVar_Summ_ByGrp_1_n	Out14-1-1	n	XX			An03_01_Age_Summ_ByTrt	0	84.0000	84
Xanomeline Low Dose	84.0000000	Mth02_ContVar_Summ_ByGrp	Mth02_ContVar_Summ_ByGrp_1_n	Out14-1-1	n	XX			An03_01_Age_Summ_ByTrt	0	84.0000	84
Placebo	75.2093023	Mth02_ContVar_Summ_ByGrp	Mth02_ContVar_Summ_ByGrp_2_Mean	Out14-1-1	Mean	XX.X			An03_01_Age_Summ_ByTrt	1	75.2000	75.2
Xanomeline High Dose	74.3809524	Mth02_ContVar_Summ_ByGrp	Mth02_ContVar_Summ_ByGrp_2_Mean	Out14-1-1	Mean	XX.X			An03_01_Age_Summ_ByTrt	1	74.4000	74.4
Xanomeline Low Dose	75.6666667	Mth02_ContVar_Summ_ByGrp	Mth02_ContVar_Summ_ByGrp_2_Mean	Out14-1-1	Mean	XX.X			An03_01_Age_Summ_ByTrt	1	75.7000	75.7
Placebo	8.5901671	Mth02_ContVar_Summ_ByGrp	Mth02_ContVar_Summ_ByGrp_3_SD	Out14-1-1	SD	(XX.XX)			An03_01_Age_Summ_ByTrt	2	8.5900	(8.59)

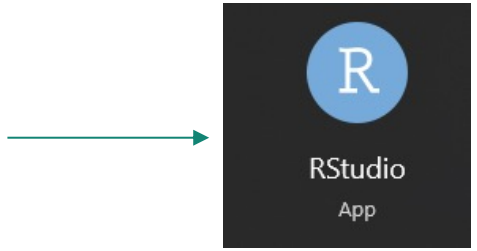
Results dataset

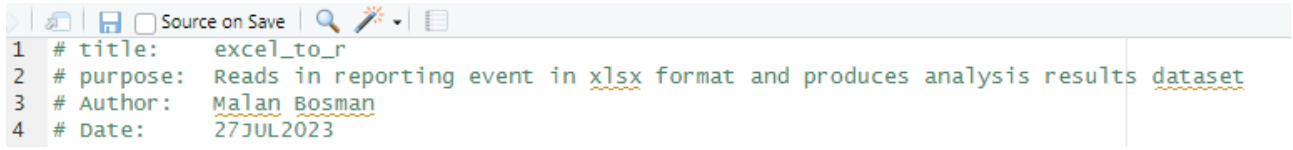
Model -> Results



Method used:

	A	B	C
1	**id**	**version**	**name**
2	CSD	1	Common Safety Displays
3			



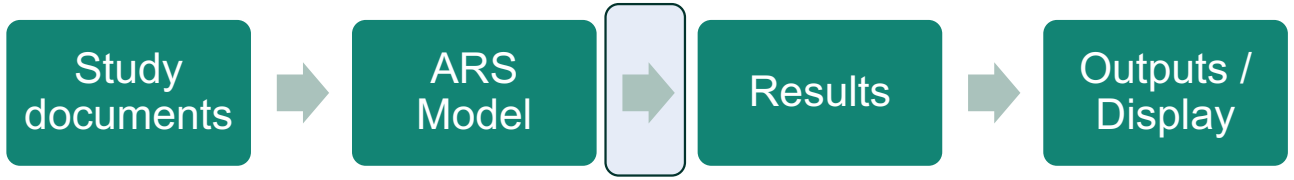


"Common Safety displays.xlsx"

Group1	res	method	operation	output	label	pattern	Group2	Group3	analysis	dec	rnd	disp
Placebo	86.0000000	Mth01_CatVar_Count_ByGrp	Mth01_CatVar_Count_ByGrp_1_n	Out14-1-1	n	(N=XX)			An01_05_SAF_Summ_ByTrt	0	86.0000	(N=86)
Xanomeline High Dose	84.0000000	Mth01_CatVar_Count_ByGrp	Mth01_CatVar_Count_ByGrp_1_n	Out14-1-1	n	(N=XX)			An01_05_SAF_Summ_ByTrt	0	84.0000	(N=84)
Xanomeline Low Dose	84.0000000	Mth01_CatVar_Count_ByGrp	Mth01_CatVar_Count_ByGrp_1_n	Out14-1-1	n	(N=XX)			An01_05_SAF_Summ_ByTrt	0	84.0000	(N=84)
Placebo	86.0000000	Mth02_ContVar_Summ_ByGrp	Mth02_ContVar_Summ_ByGrp_1_n	Out14-1-1	n	XX			An03_01_Age_Summ_ByTrt	0	86.0000	86
Xanomeline High Dose	84.0000000	Mth02_ContVar_Summ_ByGrp	Mth02_ContVar_Summ_ByGrp_1_n	Out14-1-1	n	XX			An03_01_Age_Summ_ByTrt	0	84.0000	84
Xanomeline Low Dose	84.0000000	Mth02_ContVar_Summ_ByGrp	Mth02_ContVar_Summ_ByGrp_1_n	Out14-1-1	n	XX			An03_01_Age_Summ_ByTrt	0	84.0000	84
Placebo	75.2093023	Mth02_ContVar_Summ_ByGrp	Mth02_ContVar_Summ_ByGrp_2_Mean	Out14-1-1	Mean	XX.X			An03_01_Age_Summ_ByTrt	1	75.2000	75.2
Xanomeline High Dose	74.3809524	Mth02_ContVar_Summ_ByGrp	Mth02_ContVar_Summ_ByGrp_2_Mean	Out14-1-1	Mean	XX.X			An03_01_Age_Summ_ByTrt	1	74.4000	74.4
Xanomeline Low Dose	75.6666667	Mth02_ContVar_Summ_ByGrp	Mth02_ContVar_Summ_ByGrp_2_Mean	Out14-1-1	Mean	XX.X			An03_01_Age_Summ_ByTrt	1	75.7000	75.7
Placebo	8.5901671	Mth02_ContVar_Summ_ByGrp	Mth02_ContVar_Summ_ByGrp_3_SD	Out14-1-1	SD	(XX.XX)			An03_01_Age_Summ_ByTrt	2	8.5900	(8.59)

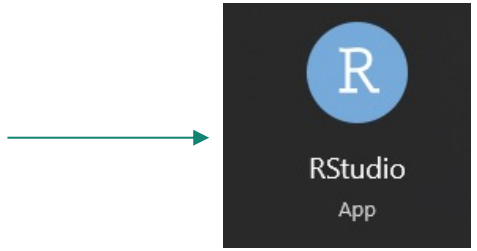
Results dataset

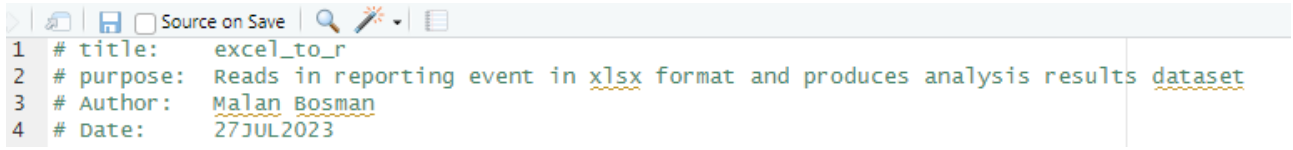
Model -> Results



Method used:

	A	B	C
1	**id**	**version**	**name**
2	CSD	1	Common Safety Displays
3			



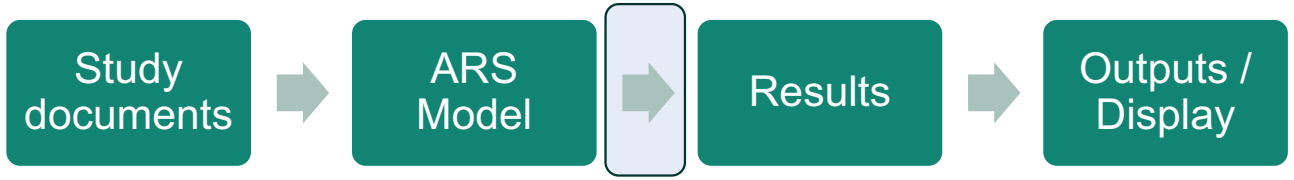


"Common Safety displays.xlsx"

Group1	res	method	operation	output	label	pattern	Group2	Group3	analysis	dec	rnd	disp
Placebo	86.0000000	Mth01_CatVar_Count_ByGrp	Mth01_CatVar_Count_ByGrp_1_n	Out14-1-1	n	(N=XX)			An01_05_SAF_Summ_ByTrt	0	86.0000	(N=86)
Xanomeline High Dose	84.0000000	Mth01_CatVar_Count_ByGrp	Mth01_CatVar_Count_ByGrp_1_n	Out14-1-1	n	(N=XX)			An01_05_SAF_Summ_ByTrt	0	84.0000	(N=84)
Xanomeline Low Dose	84.0000000	Mth01_CatVar_Count_ByGrp	Mth01_CatVar_Count_ByGrp_1_n	Out14-1-1	n	(N=XX)			An01_05_SAF_Summ_ByTrt	0	84.0000	(N=84)
Placebo	86.0000000	Mth02_ContVar_Summ_ByGrp	Mth02_ContVar_Summ_ByGrp_1_n	Out14-1-1	n	XX			An03_01_Age_Summ_ByTrt	0	86.0000	86
Xanomeline High Dose	84.0000000	Mth02_ContVar_Summ_ByGrp	Mth02_ContVar_Summ_ByGrp_1_n	Out14-1-1	n	XX			An03_01_Age_Summ_ByTrt	0	84.0000	84
Xanomeline Low Dose	84.0000000	Mth02_ContVar_Summ_ByGrp	Mth02_ContVar_Summ_ByGrp_1_n	Out14-1-1	n	XX			An03_01_Age_Summ_ByTrt	0	84.0000	84
Placebo	75.2093023	Mth02_ContVar_Summ_ByGrp	Mth02_ContVar_Summ_ByGrp_2_Mean	Out14-1-1	Mean	XX.X			An03_01_Age_Summ_ByTrt	1	75.2000	75.2
Xanomeline High Dose	74.3809524	Mth02_ContVar_Summ_ByGrp	Mth02_ContVar_Summ_ByGrp_2_Mean	Out14-1-1	Mean	XX.X			An03_01_Age_Summ_ByTrt	1	74.4000	74.4
Xanomeline Low Dose	75.6666667	Mth02_ContVar_Summ_ByGrp	Mth02_ContVar_Summ_ByGrp_2_Mean	Out14-1-1	Mean	XX.X			An03_01_Age_Summ_ByTrt	1	75.7000	75.7
Placebo	8.5901671	Mth02_ContVar_Summ_ByGrp	Mth02_ContVar_Summ_ByGrp_3_SD	Out14-1-1	SD	(XX.XX)			An03_01_Age_Summ_ByTrt	2	8.5900	(8.59)

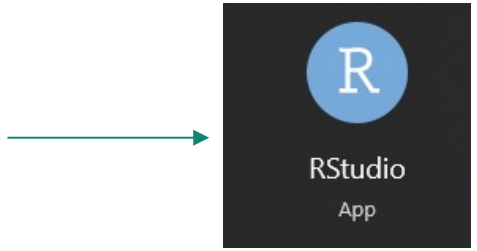
Results dataset

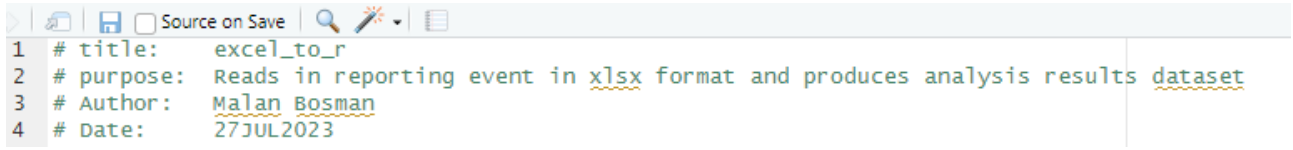
Model -> Results



Method used:

	A	B	C
1	**id**	**version**	**name**
2	CSD	1	Common Safety Displays
3			



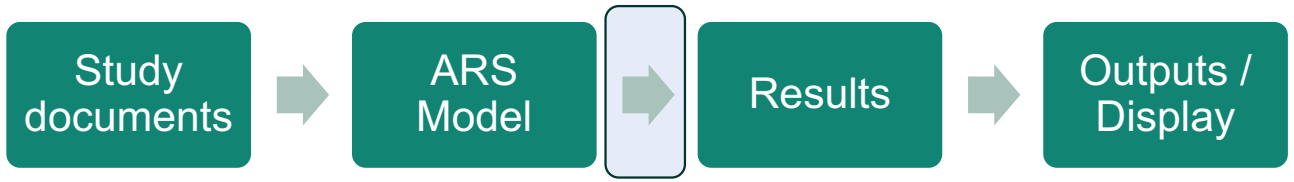


"Common Safety displays.xlsx"

Group1	res	method	operation	output	label	pattern	Group2	Group3	analysis	dec	rnd	disp
Placebo	86.0000000	Mth01_CatVar_Count_ByGrp	Mth01_CatVar_Count_ByGrp_1_n	Out14-1-1	n	(N=XX)			An01_05_SAF_Summ_ByTrt	0	86.0000	(N=86)
Xanomeline High Dose	84.0000000	Mth01_CatVar_Count_ByGrp	Mth01_CatVar_Count_ByGrp_1_n	Out14-1-1	n	(N=XX)			An01_05_SAF_Summ_ByTrt	0	84.0000	(N=84)
Xanomeline Low Dose	84.0000000	Mth01_CatVar_Count_ByGrp	Mth01_CatVar_Count_ByGrp_1_n	Out14-1-1	n	(N=XX)			An01_05_SAF_Summ_ByTrt	0	84.0000	(N=84)
Placebo	86.0000000	Mth02_ContVar_Summ_ByGrp	Mth02_ContVar_Summ_ByGrp_1_n	Out14-1-1	n	XX			An03_01_Age_Summ_ByTrt	0	86.0000	86
Xanomeline High Dose	84.0000000	Mth02_ContVar_Summ_ByGrp	Mth02_ContVar_Summ_ByGrp_1_n	Out14-1-1	n	XX			An03_01_Age_Summ_ByTrt	0	84.0000	84
Xanomeline Low Dose	84.0000000	Mth02_ContVar_Summ_ByGrp	Mth02_ContVar_Summ_ByGrp_1_n	Out14-1-1	n	XX			An03_01_Age_Summ_ByTrt	0	84.0000	84
Placebo	75.2093023	Mth02_ContVar_Summ_ByGrp	Mth02_ContVar_Summ_ByGrp_2_Mean	Out14-1-1	Mean	XX.X			An03_01_Age_Summ_ByTrt	1	75.2000	75.2
Xanomeline High Dose	74.3809524	Mth02_ContVar_Summ_ByGrp	Mth02_ContVar_Summ_ByGrp_2_Mean	Out14-1-1	Mean	XX.X			An03_01_Age_Summ_ByTrt	1	74.4000	74.4
Xanomeline Low Dose	75.6666667	Mth02_ContVar_Summ_ByGrp	Mth02_ContVar_Summ_ByGrp_2_Mean	Out14-1-1	Mean	XX.X			An03_01_Age_Summ_ByTrt	1	75.7000	75.7
Placebo	8.5901671	Mth02_ContVar_Summ_ByGrp	Mth02_ContVar_Summ_ByGrp_3_SD	Out14-1-1	SD	(XX.XX)			An03_01_Age_Summ_ByTrt	2	8.5900	(8.59)

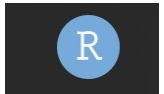
Results dataset

Model -> Results



Method used:

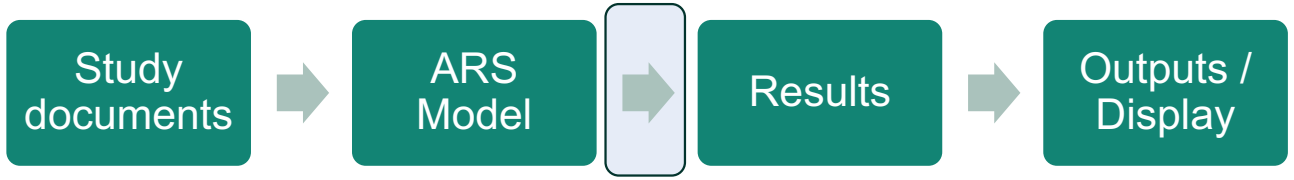
	A	B	C
1	id	version	name
2	CSD	1	Common Safety Displays
3			



Group1	res	method	operation	output	label	pattern	Group2	Group3	analysis	dec	rnd	disp
Placebo	86.0000000	Mth01_CatVar_Count_ByGrp	Mth01_CatVar_Count_ByGrp_1_n	Out14-1-1	n	(N=XX)			An01_05_SAF_Summ_ByTrt	0	86.0000	(N=86)
Xanomeline High Dose	84.0000000	Mth01_CatVar_Count_ByGrp	Mth01_CatVar_Count_ByGrp_1_n	Out14-1-1	n	(N=XX)			An01_05_SAF_Summ_ByTrt	0	84.0000	(N=84)
Xanomeline Low Dose	84.0000000	Mth01_CatVar_Count_ByGrp	Mth01_CatVar_Count_ByGrp_1_n	Out14-1-1	n	(N=XX)			An01_05_SAF_Summ_ByTrt	0	84.0000	(N=84)
Placebo	86.0000000	Mth02_ContVar_Summ_ByGrp	Mth02_ContVar_Summ_ByGrp_1_n	Out14-1-1	n	XX			An03_01_Age_Summ_ByTrt	0	86.0000	86
Xanomeline High Dose	84.0000000	Mth02_ContVar_Summ_ByGrp	Mth02_ContVar_Summ_ByGrp_1_n	Out14-1-1	n	XX			An03_01_Age_Summ_ByTrt	0	84.0000	84
Xanomeline Low Dose	84.0000000	Mth02_ContVar_Summ_ByGrp	Mth02_ContVar_Summ_ByGrp_1_n	Out14-1-1	n	XX			An03_01_Age_Summ_ByTrt	0	84.0000	84
Placebo	75.2093023	Mth02_ContVar_Summ_ByGrp	Mth02_ContVar_Summ_ByGrp_2_Mean	Out14-1-1	Mean	XX.X			An03_01_Age_Summ_ByTrt	1	75.2000	75.2
Xanomeline High Dose	74.3809524	Mth02_ContVar_Summ_ByGrp	Mth02_ContVar_Summ_ByGrp_2_Mean	Out14-1-1	Mean	XX.X			An03_01_Age_Summ_ByTrt	1	74.4000	74.4
Xanomeline Low Dose	75.6666667	Mth02_ContVar_Summ_ByGrp	Mth02_ContVar_Summ_ByGrp_2_Mean	Out14-1-1	Mean	XX.X			An03_01_Age_Summ_ByTrt	1	75.7000	75.7
Placebo	8.5901671	Mth02_ContVar_Summ_ByGrp	Mth02_ContVar_Summ_ByGrp_3_SD	Out14-1-1	SD	(XX.XX)			An03_01_Age_Summ_ByTrt	2	8.5900	(8.59)

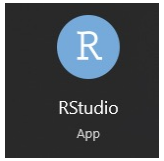
Highlights:

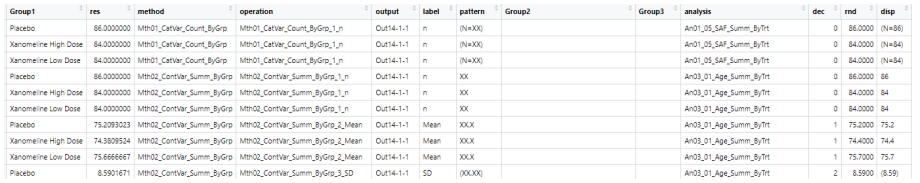
Model -> Results



Method used:

	A	B	C
1	id	version	name
2	CSD	1	Common Safety Displays
3			



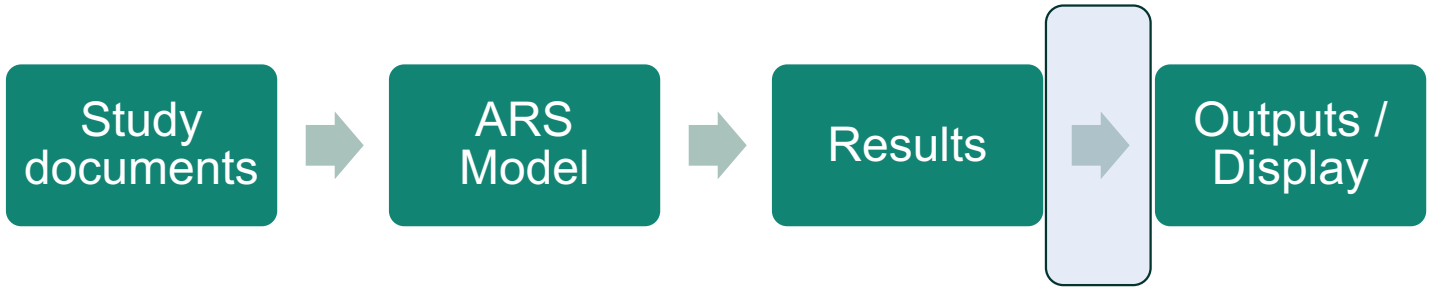


Group1	res	method	operation	output	label	pattern	Group2	Group3	analysis	dec	rnd	disp
Placebo	86.0000000	Mth01_CatVar_Count_ByGrp	Mth01_CatVar_Count_ByGrp_1_n	Out14-1-1	n	(N=XX)			An01_05_SAF_Summ_ByTrt	0	86.0000	(N=86)
Xanomeline High Dose	84.0000000	Mth01_CatVar_Count_ByGrp	Mth01_CatVar_Count_ByGrp_1_n	Out14-1-1	n	(N=XX)			An01_05_SAF_Summ_ByTrt	0	84.0000	(N=84)
Xanomeline Low Dose	84.0000000	Mth01_CatVar_Count_ByGrp	Mth01_CatVar_Count_ByGrp_1_n	Out14-1-1	n	(N=XX)			An01_05_SAF_Summ_ByTrt	0	84.0000	(N=84)
Placebo	86.0000000	Mth02_ContVar_Summ_ByGrp	Mth02_ContVar_Summ_ByGrp_1_n	Out14-1-1	n	XX			An03_01_Age_Summ_ByTrt	0	86.0000	86
Xanomeline High Dose	84.0000000	Mth02_ContVar_Summ_ByGrp	Mth02_ContVar_Summ_ByGrp_1_n	Out14-1-1	n	XX			An03_01_Age_Summ_ByTrt	0	84.0000	84
Xanomeline Low Dose	84.0000000	Mth02_ContVar_Summ_ByGrp	Mth02_ContVar_Summ_ByGrp_1_n	Out14-1-1	n	XX			An03_01_Age_Summ_ByTrt	0	84.0000	84
Placebo	75.2093023	Mth02_ContVar_Summ_ByGrp	Mth02_ContVar_Summ_ByGrp_2_Mean	Out14-1-1	Mean	XX.X			An03_01_Age_Summ_ByTrt	1	75.2000	75.2
Xanomeline High Dose	74.3809524	Mth02_ContVar_Summ_ByGrp	Mth02_ContVar_Summ_ByGrp_2_Mean	Out14-1-1	Mean	XX.X			An03_01_Age_Summ_ByTrt	1	74.4000	74.4
Xanomeline Low Dose	75.6666667	Mth02_ContVar_Summ_ByGrp	Mth02_ContVar_Summ_ByGrp_2_Mean	Out14-1-1	Mean	XX.X			An03_01_Age_Summ_ByTrt	1	75.7000	75.7
Placebo	8.5901671	Mth02_ContVar_Summ_ByGrp	Mth02_ContVar_Summ_ByGrp_3_SD	Out14-1-1	SD	(XX.XX)			An03_01_Age_Summ_ByTrt	2	8.5900	(8.59)

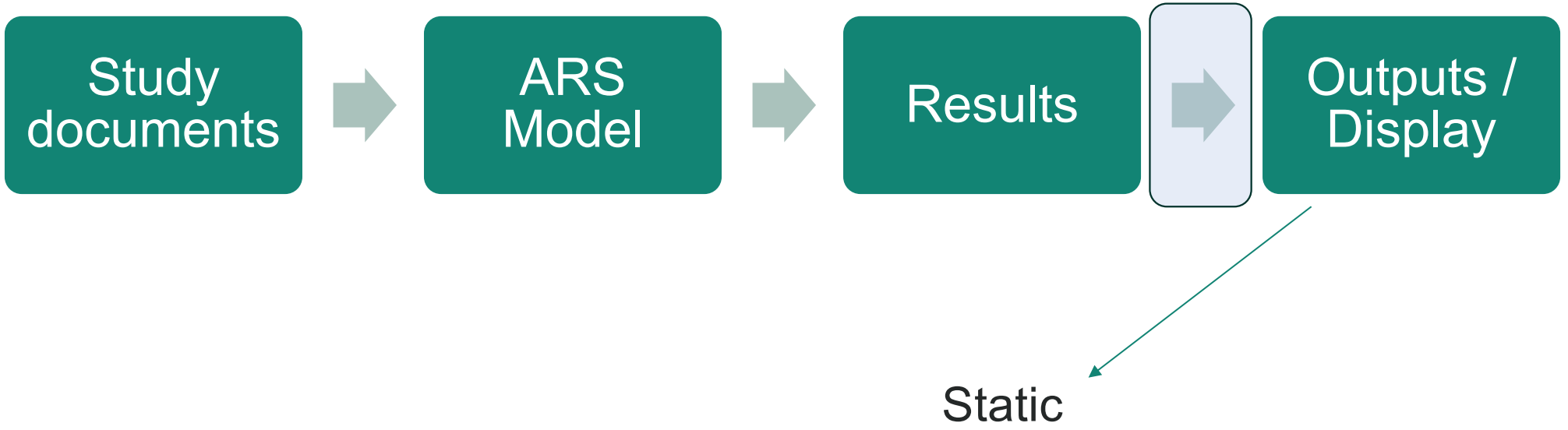
Highlights:

- Performs groupings
- Subsets data
- Basic method: Nested loops through “ListOfPlannedAnalyses”,
  then each Operation linked to the AnalysisMethod (linked to each Analysis)
- Chunk of code performing each operation appends rows after each operation to create Analysis Results dataset
- Applies correct pattern / format to result

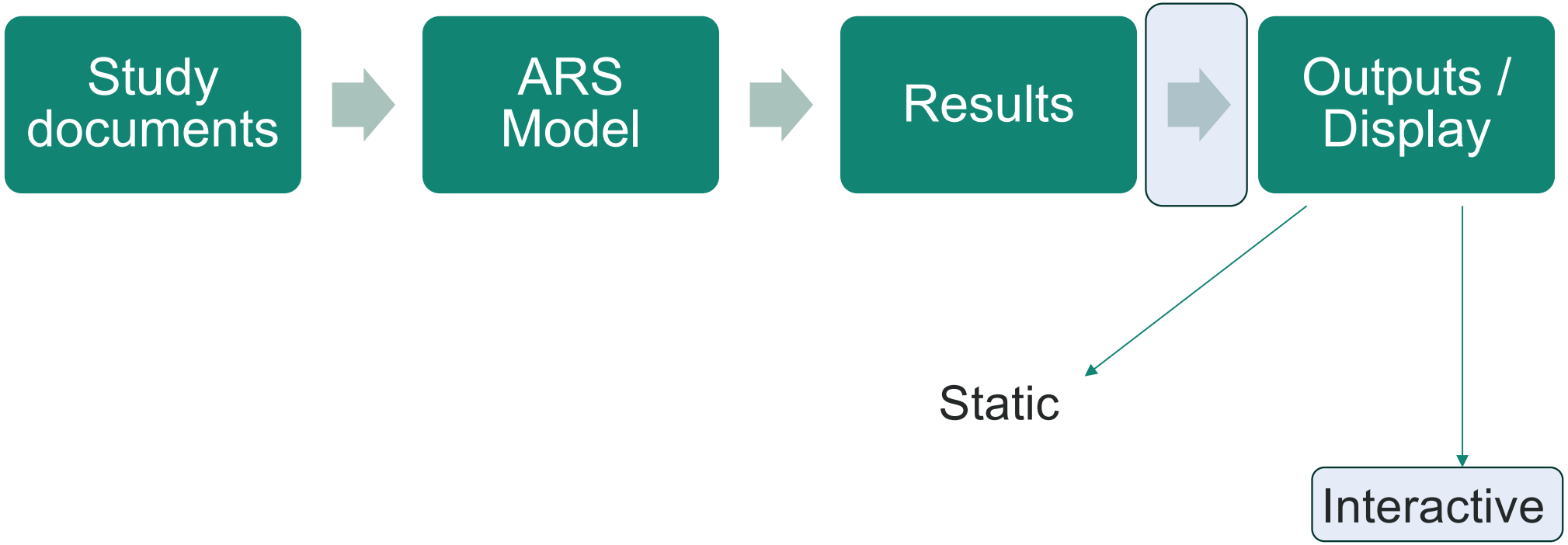
Results -> Outputs / display



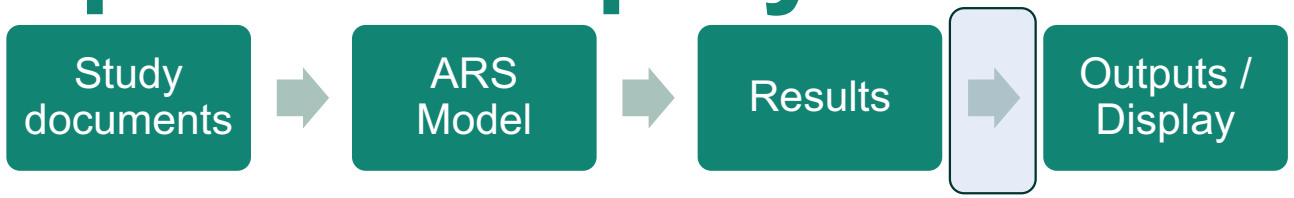
Results -> Outputs / Display



Results -> Outputs / Display



Results -> Outputs / Display



Basic R-Shiny

Common Safety Displays

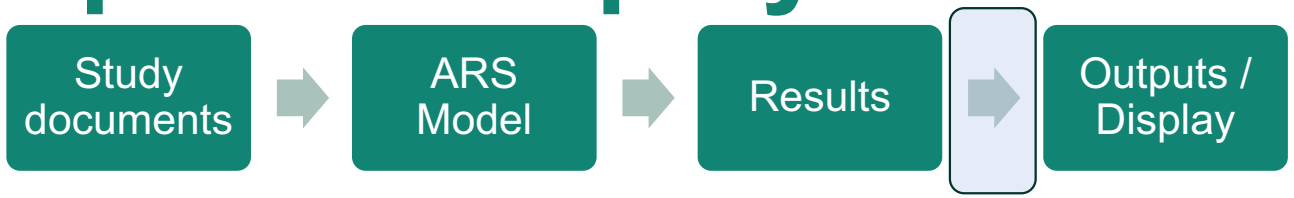
Select output:

Out14-1-1

Show 100 entries

Analysis	Characteristic	Placebo	Xanomeline High Dose	Xanomeline Low Dose	p-value
		(N=86)	(N=84)	(N=84)	
Age (Years) - p-value					0.59340000000000004
Age (Years)	n	86	84	84	
Age (Years)	Mean	75.2	74.4	75.7	
Age (Years)	SD	(8.59)	(7.89)	(8.29)	
Age (Years)	Median	76.0	76.0	77.5	
Age (Years)	Q1	69.0	70.0	71.0	
Age (Years)	Q3	82.0	80.0	82.0	
Age (Years)	Min	52	56	51	
Age (Years)	Max	89	88	88	

Results -> Outputs / Display



Shell:

Study – CDISC 360 Page x of y

Table 14.1.1
Summary of Demographics
Safety Population

Characteristics	Placebo (N=XX)	Xanomeline Low Dose (N=XX)	Xanomeline High Dose (N=XX)	p-value [1]
Age (years)				
n	XX	XX	XX	X.XXXX
Mean (SD)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	
Median	XX.X	XX.X	XX.X	
Q1, Q3	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X	
Min, Max	XX, XX	XX, XX	XX, XX	
Age Group, n (%)				
< 65 years	XX (XX.X)	XX (XX.X)	XX (XX.X)	X.XXXX
≥ 65 years	XX (XX.X)	XX (XX.X)	XX (XX.X)	
Gender, n (%)				
Male	XX (XX.X)	XX (XX.X)	XX (XX.X)	X.XXXX
Female	XX (XX.X)	XX (XX.X)	XX (XX.X)	
Ethnicity, n (%)				
Hispanic or Latino	XX (XX.X)	XX (XX.X)	XX (XX.X)	X.XXXX
Not Hispanic or Latino	XX (XX.X)	XX (XX.X)	XX (XX.X)	

Basic R-Shiny app:

Show 100 entries

Analysis	Characteristic	Placebo	Xanomeline High Dose	Xanomeline Low Dose	p-value
		(N=86)	(N=84)	(N=84)	
Age (Years) - p-value					0.59340000000000004
Age (Years)	n	86	84	84	
Age (Years)	Mean	75.2	74.4	75.7	
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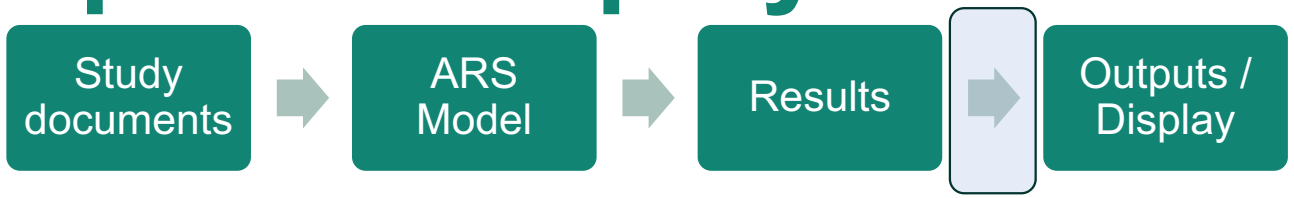
Age (Years)	Min	52	56	51	
Age (Years)	Max	89	88	88	

Results -> Outputs / Display



Shell:

Study – CDISC 360 Page x of y

Table 14.1.1
Summary of Demographics
Safety Population

Characteristics	Placebo (N=XX)	Xanomeline Low Dose (N=XX)	Xanomeline High Dose (N=XX)	p-value [1]
Age (years)				
n	XX	XX	XX	X.XXXX
Mean (SD)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	
Median	XX.X	XX.X	XX.X	
Q1, Q3	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X	
Min, Max	XX, XX	XX, XX	XX, XX	
Age Group, n (%)				
< 65 years	XX (XX.X)	XX (XX.X)	XX (XX.X)	X.XXXX
≥ 65 years	XX (XX.X)	XX (XX.X)	XX (XX.X)	
Gender, n (%)				
Male	XX (XX.X)	XX (XX.X)	XX (XX.X)	X.XXXX
Female	XX (XX.X)	XX (XX.X)	XX (XX.X)	
Ethnicity, n (%)				
Hispanic or Latino	XX (XX.X)	XX (XX.X)	XX (XX.X)	X.XXXX
Not Hispanic or Latino	XX (XX.X)	XX (XX.X)	XX (XX.X)	

Basic R-Shiny app:

Show 100 entries

Analysis	Characteristic	Placebo	Xanomeline High Dose	Xanomeline Low Dose	p-value
		(N=86)	(N=84)	(N=84)	
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Age (Years)	Min	52	56	51	
Age (Years)	Max	89	88	88	

Concluding thoughts

Concluding thoughts

Automation	• Aim for automation • Across industry
Open-source	• Quicker adoption • Easier collaboration
User Experience	• Make it a priority • Part of design

Next steps:

Common Safety Displays

Select output:

Out14-1-1

Show 100 entries

Analysis	Characteristic	Placebo	Xanomeline High Dose	Xanomeline Low Dose	p-value
		(N=86)	(N=84)	(N=84)	
Age (Years) - p-value					0.59340000000000004
Age (Years)	n	86	84	84	
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Age (Years)	SD	(8.59)	(7.89)	(8.29)	
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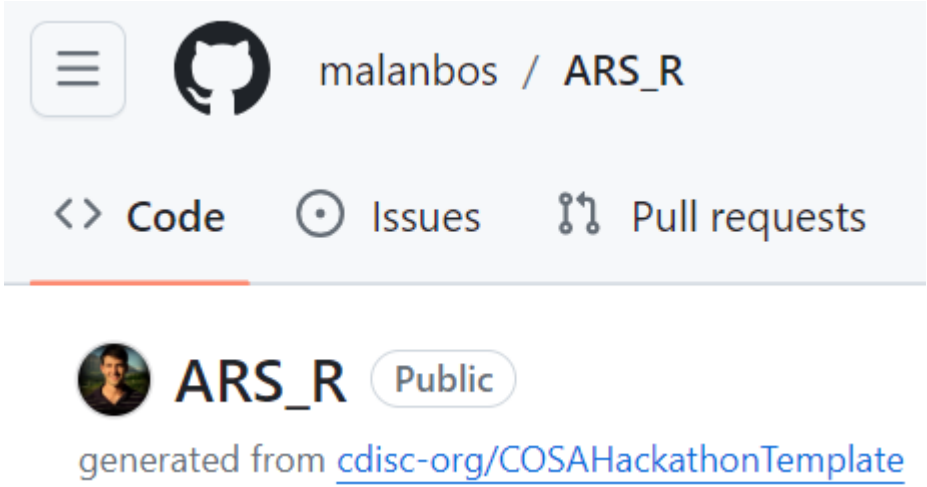
Age (Years)	Min	52	56	51	
Age (Years)	Max	89	88	88	

Github repo:



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