

Digitization and Modernization Impact on Statistical Programming



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Novartis

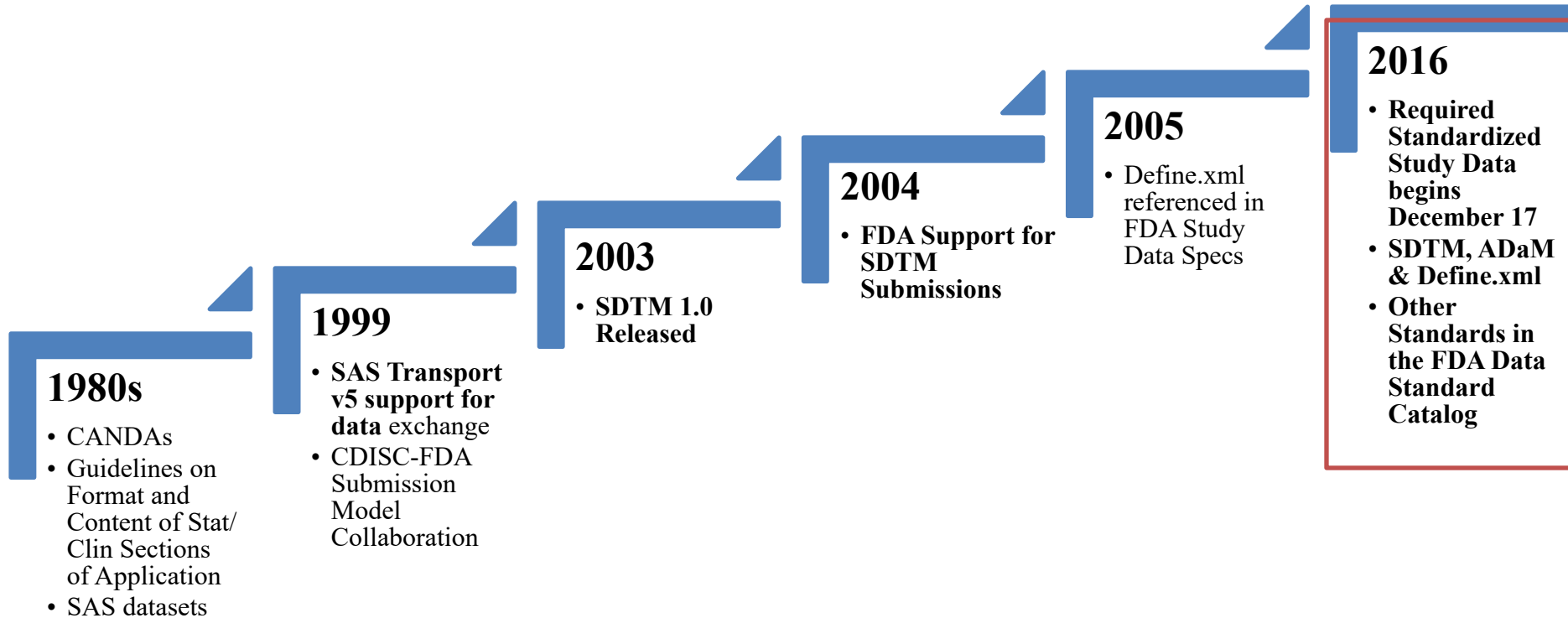


Agenda

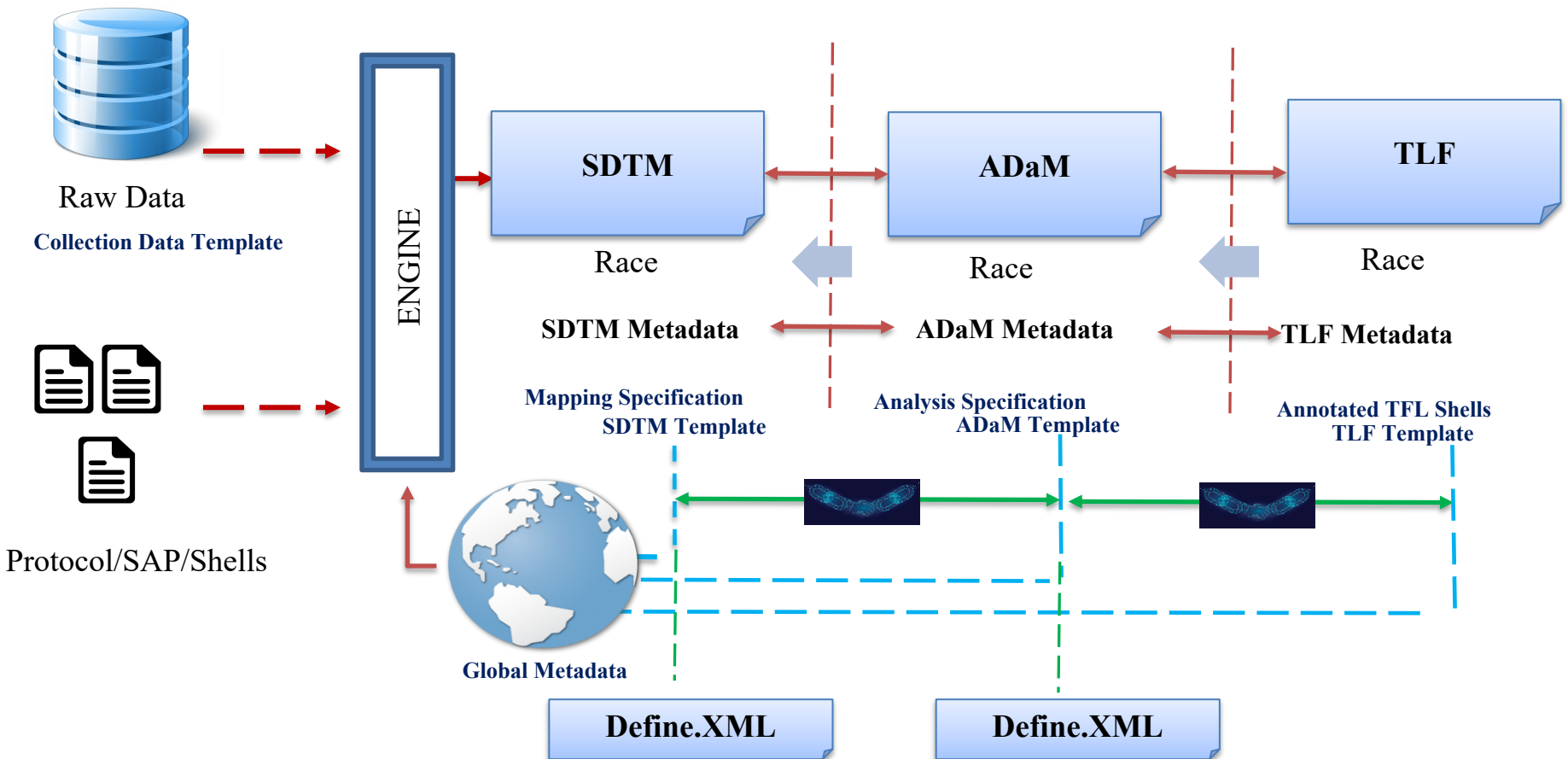
- Introduction
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- Standardization at what level?
- Programming Capabilities Type – Past/Present/Future
- Statistical deliverables – Past /Present/Future
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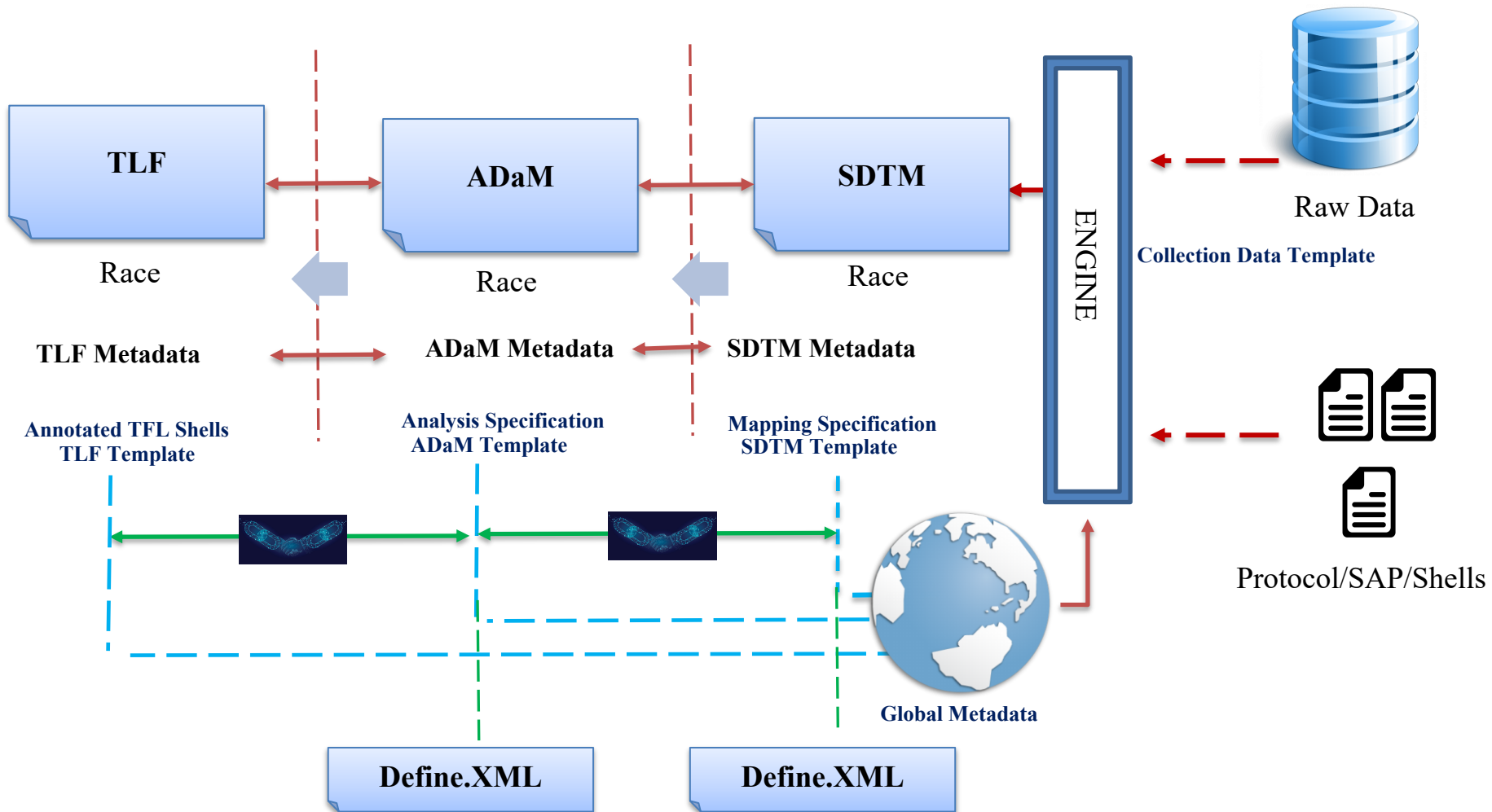
Progress towards required Standardized Study Data



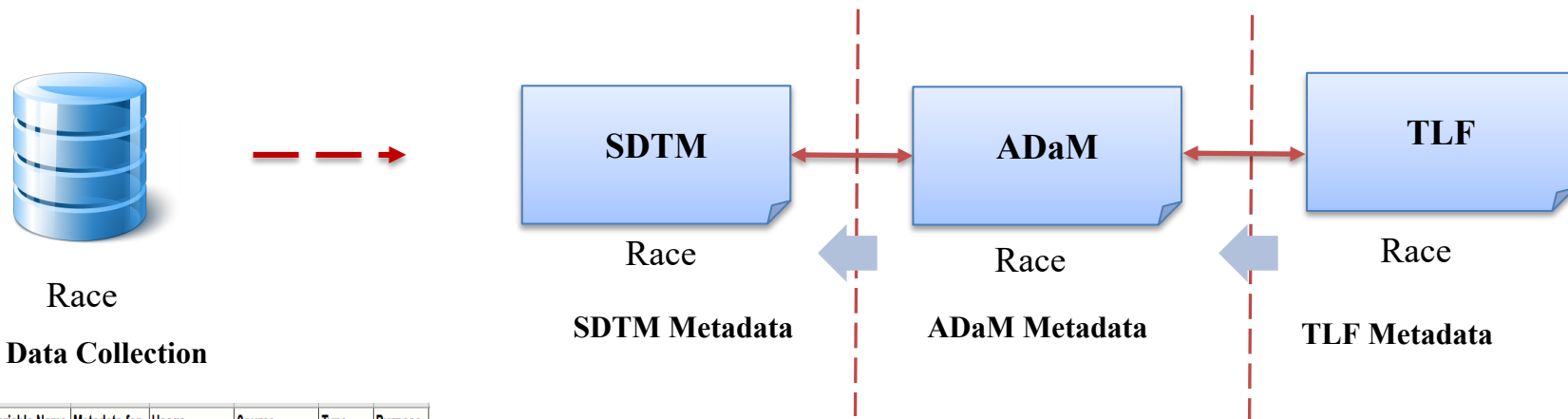
Metadata Driven Workflow



Reverse Metadata Workflow



Metadata Driven Workflow Contd..



Variable Name	Metadata for	Usage	Source	Type	Purpose
RACE	RAW	DM01.RACE	Site Entry	Char	

Variable Name	Metadata for	Usage	Source	Type	Purpose
RACE	RAW	DM01.RACE	Site Entry	Char	
RACE	SDTM	DM.RACE	DM01.RACE	Char	

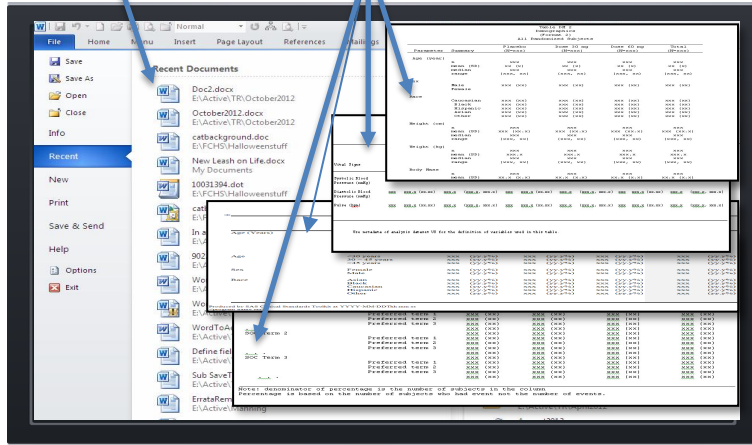
Variable Name	Metadata for	Usage	Source	Type	Purpose
RACE	RAW	DM01.RACE	Site Entry	Char	
RACE	SDTM	DM.RACE	DM01.RACE	Char	
RACE	ADaM	ADSL.RACE	SDTM.RACE	Char	
RACE	ADaM	ADSL.RACEN	SDTM.RACE	Num	

Variable Name	Metadata for	Usage	Source	Type	Purpose
RACE	RAW	DM01.RACE	Site Entry	Char	
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RACE	ADaM	ADSL.RACE	SDTM.RACE	Char	
RACE	ADaM	ADSL.RACEN	SDTM.RACE	Num	
RACE	Listings	L1601	ADSL.RACE	Char	Display
RACE	Tables	T1401	ADSL.RACE	Char	Display
RACE	Tables	T1401	ADSL.RACEN	Num	Sorting

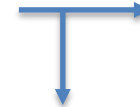
Metadata Driven Workflow Contd..

TFL Shells Repository

Pop-up of the TFL Shell by just mouse drag



SAS Macro Processing



SDTM & ADaM datasets

SAS Programmer -

CODE LOG RESULTS

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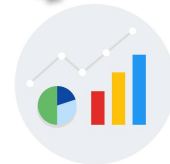
Obs	Make	Model	Type	Origin	DriveTrain	MSRP	Invoice	Engine Size	Cylinders	Horsepower	MPG_City	MPG_Highway	Weight
1	Acura	MDX	SUV	Asia	All	\$36,945	\$35,337	3.5	6	265	17	23	4451
2	Acura	RSX Type S	Sedan	Asia	Front	\$23,820	\$21,761	2.0	4	200	24	31	2778
3	Acura	TL 4dr	Sedan	Asia	Front	\$26,060	\$24,647	2.4	4	200	22	28	3230
4	Acura	TL 4dr	Sedan	Asia	Front	\$33,165	\$30,290	3.2	6	270	20	28	3676
5	Acura	3.5 RL 4dr	Sedan	Asia	Front	\$43,755	\$39,014	3.5	6	225	18	24	3880
6	Acura	3.5 RL w/Navigation 4dr	Sedan	Asia	Front	\$46,100	\$41,100	3.5	6	225	18	24	3893
7	Acura	NSX coupe 2dr manual S	Sports	Asia	Rear	\$69,765	\$70,976	3.2	6	280	17	24	3153
8	Audi	A4 1.8T 4dr	Sedan	Europe	Front	\$25,940	\$23,508	1.8	4	170	22	31	3282
9	Audi	A4 1.8T quattro 2dr	Sedan	Europe	Front	\$35,940	\$32,506	1.8	4	170	23	30	3638
10	Audi	A4 3.0 4dr	Sedan	Europe	Front	\$31,840	\$28,948	3.0	6	220	20	28	3482
11	Audi	A4 3.0 quattro 4dr manual	Sedan	Europe	All	\$33,430	\$30,388	3.0	6	220	17	28	3563
12	Audi	A4 3.0	Sedan	Europe	All	\$34,480	\$31,388	3.0	6	220	18	25	3527

Table 1 Example demographic table

Variables	Treatment (N=628)	Control (N=372)	P value
Age			<0.0001
N (Nmiss)	628 (0)	372 (0)	
Mean ± SD	41.8±7.6	48.8±7.4	
Min-Max	29.0-59.0	29.0-61.0	
Median (IQR)	40.5 (35.5-48.0)	50.0 (44.5-55.0)	
Gender (%)			<0.0001
Female	414 (65.9)	173 (46.5)	
Male	214 (34.1)	199 (53.5)	
Weight			<0.0001
N (Nmiss)	628 (0)	370 (0)	
Mean ± SD	149.5±26.4	157.3±26.3	
Min-Max	87.0-243.0	71.0-250.0	
Median (IQR)	146.0 (129.5-165.0)	155.0 (137.0-175.0)	

N, number of non-missing values; Nmiss, number of missing values; SD, standard deviation; IQR, interquartile range.

Final RTF output



Figures



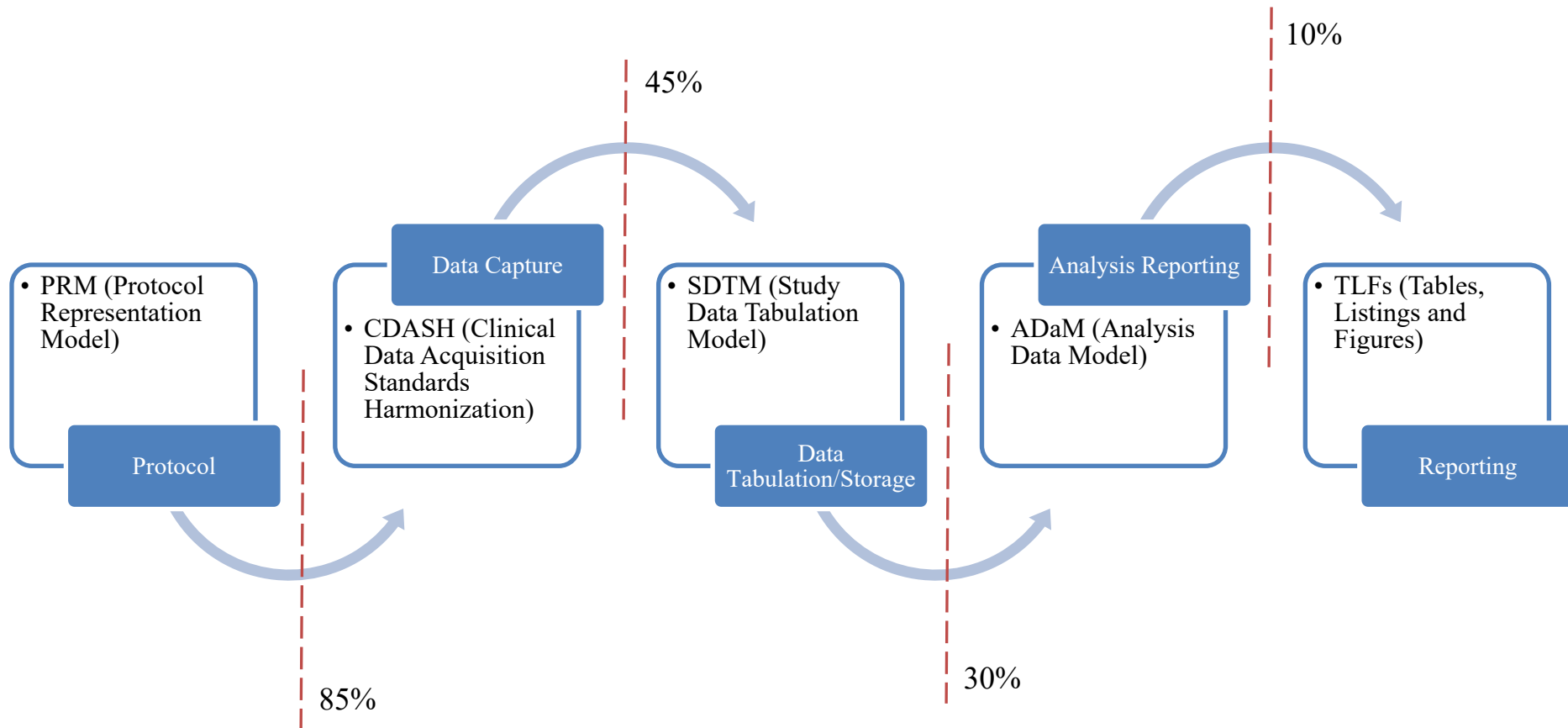
SAS programs



SAS datasets



Standardization at what level ?



Programming Capabilities Type – Past/Present/Future

>15 Years

<5-15 Years

Present

Future



Standards



Standards



Automatic Data Reporting



Statistical deliverables – Past /Present/Future

Deliverables	>15 Years Ago	Present	Future
Analysis/ADaM dataset	-	✓	✓
Spec for (Analysis/ADaM dataset)	-	✓	✓
define.pdf	✓		
Annotated CRF	-		✓*
SDTM dataset	-	✓	✓
define.xml	-	✓	✓
Reviewers Guide	-	✓	✓**

* Automated

** Electronically Automated



Skill set – Past/Present/Future

Skill Set	>15 Years Ago	Present	Future
Management skills for Lead Programmers	-	↑	↑ ↑
Communication	-	↑ ↑	
CDISC Knowledge	-	↑	↑ ↑
Statistics knowledge	↑	↑ ↑	↑ ↑
Clinical understanding	↑	↑ ↑	↑ ↑
Writing specifications	-	↑	↑ ↑
FDA Guidance	-	↑	
Data Modeling and Scripting	-	↑	↑ ↑

PAST

PRESENT

FUTURE

Submission and Take away



Sponsors

Paper Based Submissions



Health Authorities



Electronic Submissions

Sponsors

Health Authorities



Health Authorities supervising and generating reports real time

FOCUS





Thank you

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