



Single Day Event

Dante Di Tommaso
Andre Couturier
Sanofi



Path to automation

The Sanofi journey (so far...)

The progress we made in the last 2.5 years, and the road ahead.



Challenges

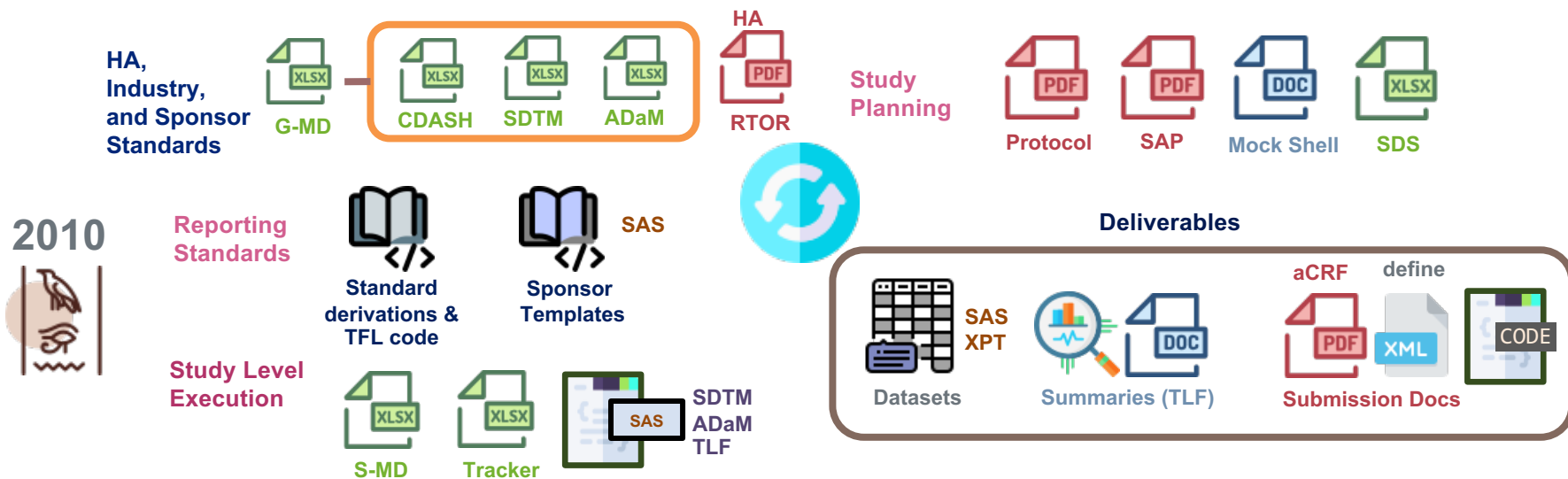
- Alignment: broad, cross-functional alignment
 - Bottom-up consolidation of similar goals & efforts
- Endorsement of vision: automation by design
 - Organizational commitment through to success
- Analyze and Specify: budget both time & resources
 - Break down silos: analyze, align and digitize end-to-end
 - Design, build & fill gaps (content, tools, knowledge)

- Design & deploy: roles & responsibilities
 - IT and business (re-)alignment
 - Acquire technical skills
- Change Management
 - aim for 70% automation, 100% facilitation
 - address concerns early and comprehensively

What is MAP

The old way

Re-think end-to-end workflows: reduce silos, eliminate manual processing



Challenges: Analysis

- Deterministic processing
 - assembling and evaluating sets of rules that UNambiguously lead to specific outcomes.
 - should stress CPUs, not distract people
- Intelligent processing
 - interpreting and assessing assets, resources and scenarios vis-a-vis objectives to complete activities.
 - should be the focus of people



Challenge: Digitize company info





Digitize company information

Metadata

Standards

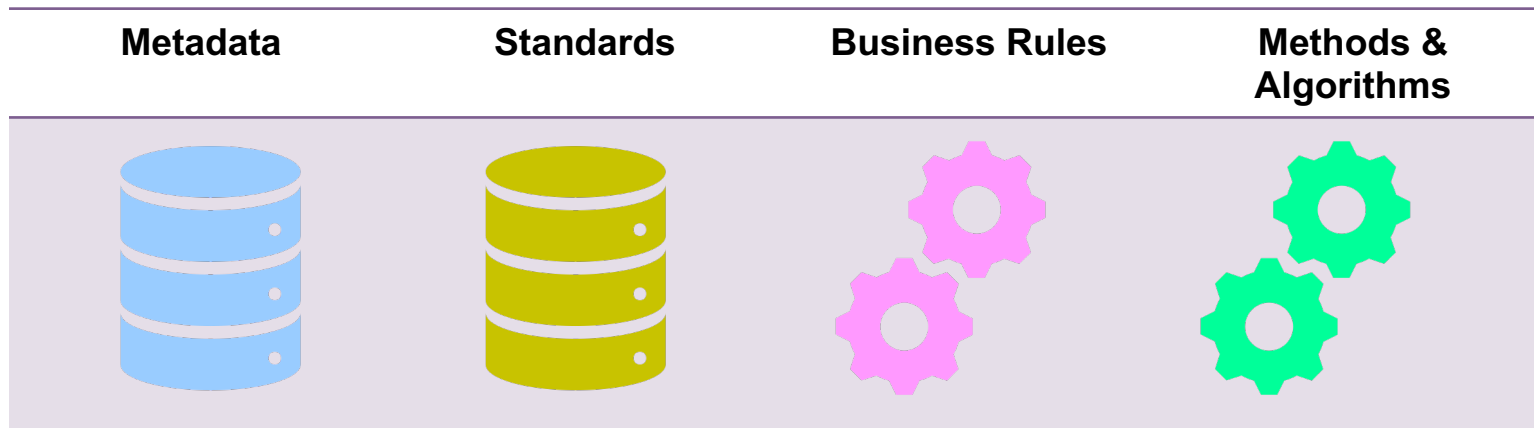
Business
rules

Methods &
Algorithms



Digitize company information

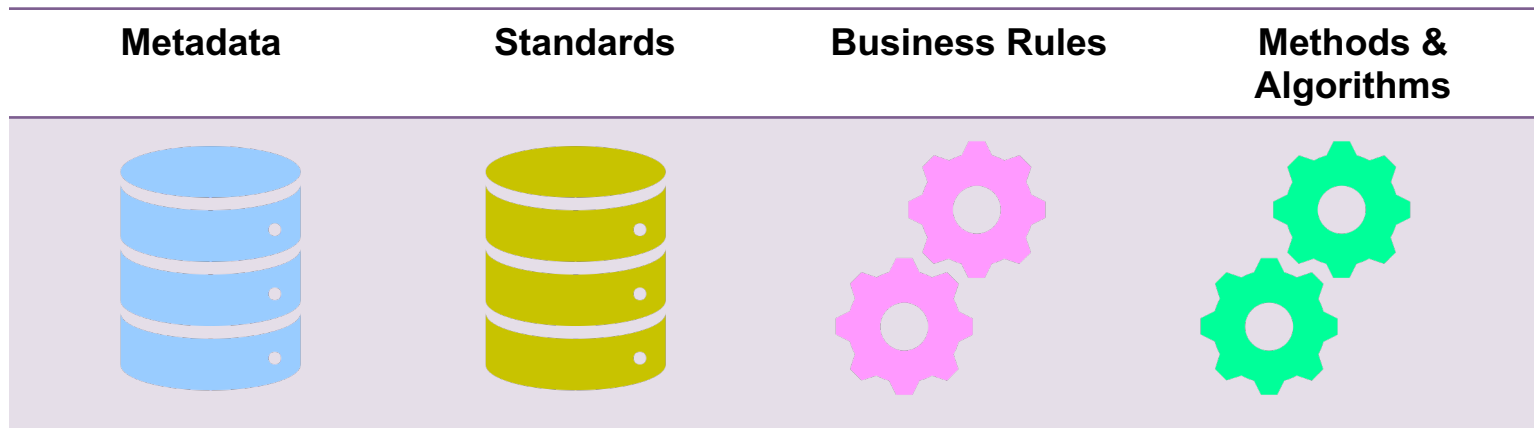
- To digitize corporate information:
analyze, organize, model ... integrated workflows
- Do not underestimate the burden of these efforts



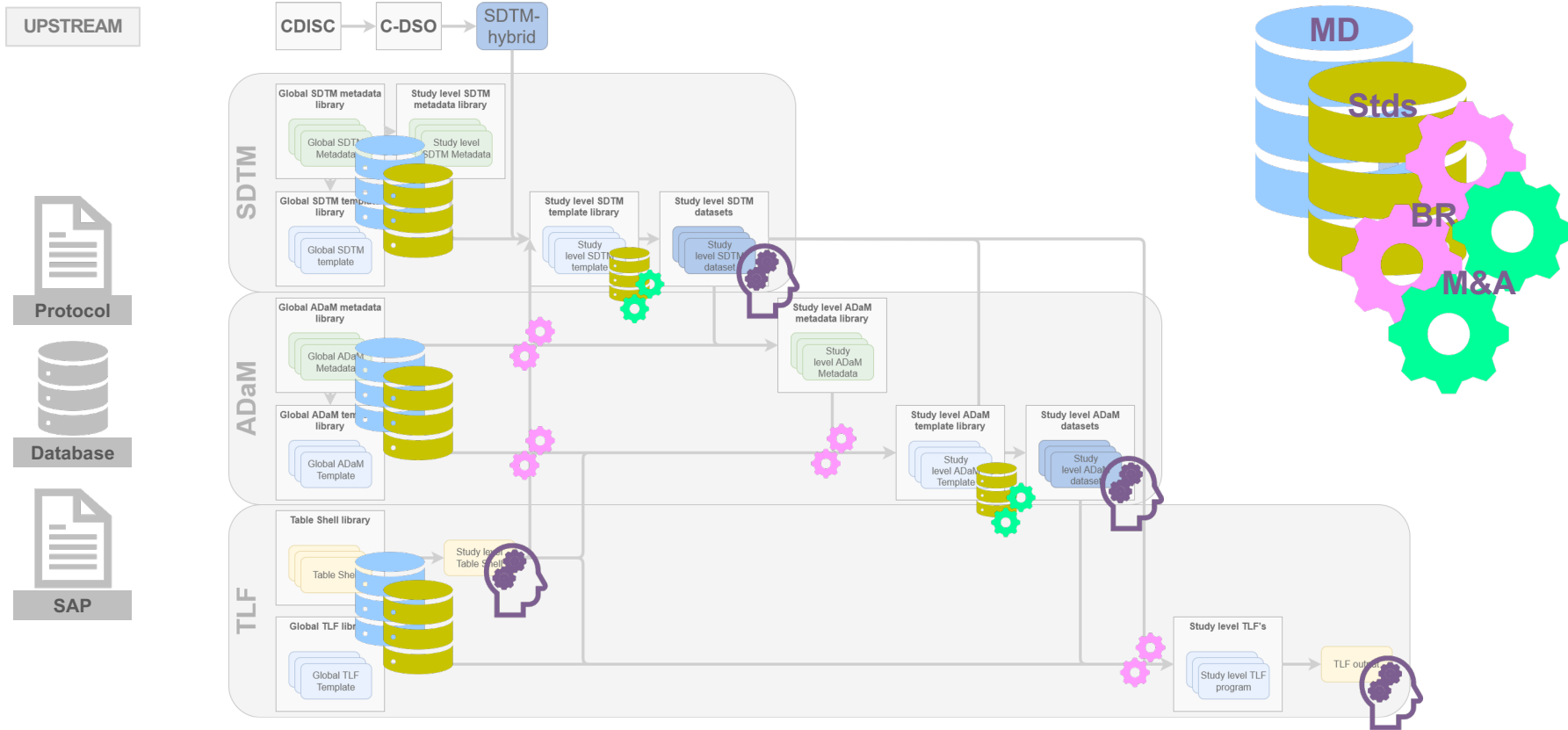


Redesign mindset & workflows

- Accumulate information with intention
- Design to automate, and plan to fill gaps: budget both time & resources to succeed



Data-driven workflows





IT and Business (re-)alignment

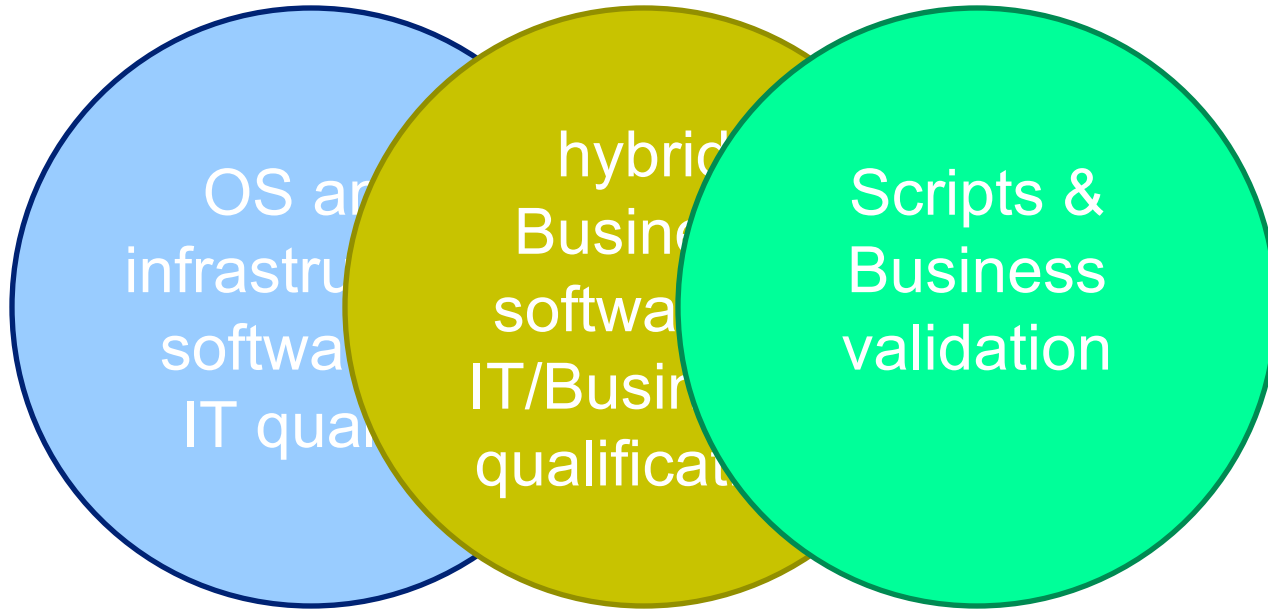
- New roles & responsibilities, new boundaries
- TransCelerate - Modern Statistical Analytics Framework (draft)
 - "Creating the handshake between IT and Business when it comes to implementing and changing the statistical analysis environment. IT traditionally builds and maintains computing environments based upon SOPs and other defined processes that ensures reliability. **Business functions will also build tools and utilities to automate processes or make tasks easier.**" (*emphasis added*)



IT and Business (re-)alignment

Traditional

Modern



- Familiar concepts, new perspective:
 - Automation

<https://www.cdisc.org/events/webinar/cdisc-360-journey-so-far-and-road-ahead>

TITLE			
SUBTITLE			
STUBHEAD LABEL	SPANNER COLUMN LABEL		COLUMN LABEL
	COLUMN LABEL	COLUMN LABEL	
ROW GROUP LABEL			
ROW LABEL	CELL	CELL	CELL
ROW LABEL	CELL	CELL	CELL
SUMMARY LABEL	CELL	CELL	CELL
FOOTNOTES			
SOURCE NOTES			

Table 7.1. Demographic Summary
 <insert population (for example, Safety Population (N = xxx))>
 <insert study ID(s) or description of database utilized>
 Study Phase or phases (if needed)

Demographic Parameter	PL (N=100)	T1 (N=100)	T2 (N=100)
Sex = (N)			
Female	xx (xx.x)	xx (xx.x)	xx (xx.x)
Male	xx (xx.x)	xx (xx.x)	xx (xx.x)
Missing	xx (xx.x)	xx (xx.x)	xx (xx.x)
Age (years)			
Mean	xx.x	xx.x	xx.x
SD	xx.x	xx.x	xx.x
Median	xx.x	xx.x	xx.x
Q1, Q3	xx.x	xx.x	xx.x
Min, Max	xx.x	xx.x	xx.x
Missing	xx (xx.x)	xx (xx.x)	xx (xx.x)
Age Group = (N)			
<18	xx (xx.x)	xx (xx.x)	xx (xx.x)
18 and <25	xx (xx.x)	xx (xx.x)	xx (xx.x)
25 and <35	xx (xx.x)	xx (xx.x)	xx (xx.x)
35 and <45	xx (xx.x)	xx (xx.x)	xx (xx.x)
45 and <55	xx (xx.x)	xx (xx.x)	xx (xx.x)
55 and <65	xx (xx.x)	xx (xx.x)	xx (xx.x)
65 and <75	xx (xx.x)	xx (xx.x)	xx (xx.x)
75 and <85	xx (xx.x)	xx (xx.x)	xx (xx.x)
85 and <95	xx (xx.x)	xx (xx.x)	xx (xx.x)
>=95 years	xx (xx.x)	xx (xx.x)	xx (xx.x)
Missing	xx (xx.x)	xx (xx.x)	xx (xx.x)
Race = (N)			
American Indian or Alaska Native	xx (xx.x)	xx (xx.x)	xx (xx.x)
Asian	xx (xx.x)	xx (xx.x)	xx (xx.x)
Black or African American	xx (xx.x)	xx (xx.x)	xx (xx.x)
Native Hawaiian or Other Pacific Islander	xx (xx.x)	xx (xx.x)	xx (xx.x)
White	xx (xx.x)	xx (xx.x)	xx (xx.x)
Multiple	xx (xx.x)	xx (xx.x)	xx (xx.x)
Missing	xx (xx.x)	xx (xx.x)	xx (xx.x)
Ethnicity = (N)			
Hispanic or Latino	xx (xx.x)	xx (xx.x)	xx (xx.x)
Not Hispanic or Latino	xx (xx.x)	xx (xx.x)	xx (xx.x)
Missing	xx (xx.x)	xx (xx.x)	xx (xx.x)
Weight (kg)			
Mean	xx.x	xx.x	xx.x
SD	xx.x	xx.x	xx.x

Study - CDISC 360

Table 14.1.1.1
 Demographic Characteristics (Safety Population)

Characteristic	TRT001 (N=100)	TRT002 (N=100)
Age (years)		
Mean	xx (xx.x)	xx (xx.x)
SD	xx (xx.x)	xx (xx.x)
Median	xx (xx.x)	xx (xx.x)
Q1, Q3	xx (xx.x)	xx (xx.x)
Min, Max	xx (xx.x)	xx (xx.x)
Missing	xx (xx.x)	xx (xx.x)
Age Group = (N)		
<18	xx (xx.x)	xx (xx.x)
18 and <25	xx (xx.x)	xx (xx.x)
25 and <35	xx (xx.x)	xx (xx.x)
35 and <45	xx (xx.x)	xx (xx.x)
45 and <55	xx (xx.x)	xx (xx.x)
55 and <65	xx (xx.x)	xx (xx.x)
65 and <75	xx (xx.x)	xx (xx.x)
75 and <85	xx (xx.x)	xx (xx.x)
85 and <95	xx (xx.x)	xx (xx.x)
>=95 years	xx (xx.x)	xx (xx.x)
Missing	xx (xx.x)	xx (xx.x)
Gender = (N)		
Male	xx (xx.x)	xx (xx.x)
Female	xx (xx.x)	xx (xx.x)

Max = Maximum, Min = Minimum, N = Number of subjects in treatment group, n = Number of subjects included in analysis, SD = Standard deviation.
 Dataset used = adsl
 Generated by @victor-mo @CDISCITY/360-M

Study	Analysis	Group	Filename	Type	Ord
CDISC	CDISC 360	Safety	demog_saf	rtf	1
CDISC	CDISC 360	Safety	tbl_soc_of_saf	rtf	2
CDISC	CDISC 360	Safety	tblsoc_saf	rtf	2

Output	Display	Style	Results	WhereClause	Tr
DisplayID	DisplayVersion	Population, Dataset	Population, Variable	Population, Comparator	
T14111_SAF_DEMOG	1	adsl	SAFPL	EQ	

Output	Display	Style	Results	WhereClause	Tr
DisplayID	ID	Version			
T14111_SAF_DEMOG	T14111_01_SAF_DEMOG	1			1
T14111_SAF_DEMOG	T14111_01_SAF_DEMOG	1			2
T14111_SAF_DEMOG	T14111_01_SAF_DEMOG	1			3
T14111_SAF_DEMOG	T14111_01_SAF_DEMOG	1			4
T14111_SAF_DEMOG	T14111_01_SAF_DEMOG	1			5

DisplayID	WhereClauseID	Dataset	WhereClause
Table 14.1.1.1	_01_SAF_DEMOG_01	adsl	AGE
Table 14.1.1.1	_02_SAF_DEMOG_02	adsl	AGEGR1
Table 14.1.1.1	_03_SAF_DEMOG_03	adsl	AGEGR1
Table 14.1.1.1	_04_SAF_DEMOG_04	adsl	SEX
Table 14.1.1.1	_05_SAF_DEMOG_05	adsl	SEX

<https://gt.rstudio.com/>

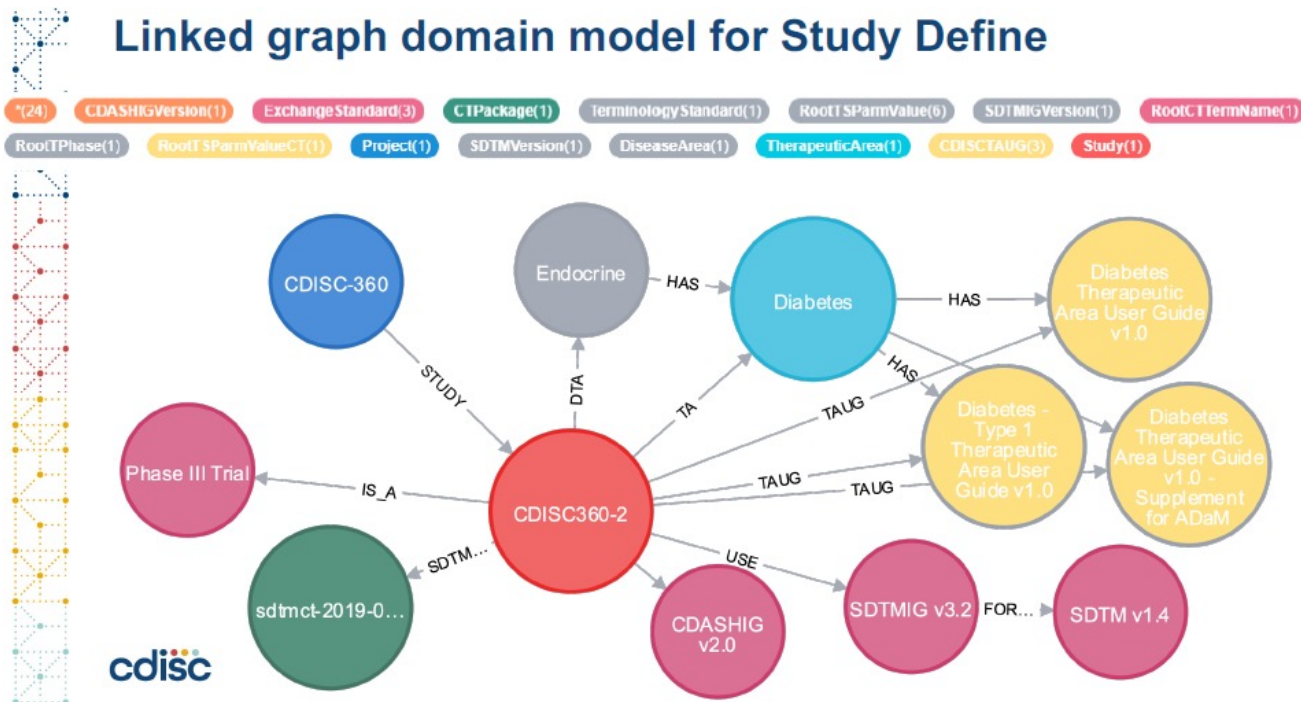
<https://github.com/atorus-research/Tplyr>

Technical solutions - Decompose

Demographics and <participant> characteristics at baseline - Randomized population			
	Analysis group <attributes>	Summary <attributes>	
	Trt A (N=##)	Trt B (N=##)	All (N=##)
Continuous block or data service <attributes>	Age (years)		
	Number	##	##
	Mean (SD)	##.# (##.#)	##.# (##.#)
	Median	##.#	##.#
	Q1 ; Q3	##.# ; ##.#	##.# ; ##.#
	Min ; Max	## ; ##	## ; ##
Categorical block or data service <attributes>	Age group [n (%)]		
	Number	##	##
	Newborns (0-27 days)	## (##.#)	## (##.#)
	Infants and toddlers (28 days - 23 months)	## (##.#)	## (##.#)
	Children (2-11 years)	## (##.#)	## (##.#)
	Adolescents (12-17 years)	## (##.#)	## (##.#)
	From 18 - 64 years	## (##.#)	## (##.#)
	From 65 - 84 years	## (##.#)	## (##.#)
	85 years and over	## (##.#)	## (##.#)

- Methods
- Data handling
- Business Rules
- Data formatting
- Style preference

Database design



Source: M. Traun, N. de Saint Jorre, *Study Design and Configuration using CDISC 360 concept based standards*, CDISC EU Interchange, April 2020

Technical solutions - Engineering

Mapping Specifications: Dimension 2

Metadata definition

Dataset Level

Variable Level

Value Level

Source		Mapping						Target		
Source Sequence	Source Library	Source Dataset	Subset Condition	Pre Processing	Join Type	Join Timing	Join Merge Key	Target Sequence	Target Library	Target Dataset
1	CDASH	VS						5	SDTM	VS
2	SDTM	DM			TARGET	PRE	USUBJID	5	SDTM	VS
3	SDTM	SV			TARGET	PRE	USUBJID, VISITNUM	5	SDTM	VS
4					SORT		USUBJID, VISITNUM, VSDTC	5	SDTM	VS
5					SORT		USUBJID, VSTESTCD, VISITNUM, VSDTC	5	SDTM	VS

Source Sequence	Source Library	Source Dataset	Source Variable	Map Sequence	Origin	Method	Comment	Code List	Target Library	Target Dataset	Target Variable	Target Description	Target Data Type	Target Length	Target Sorting Order
4				3	Assigned	VS.VSTESTCD		VSTESTCD	SDTM	VS	VSTESTCD	Vital Signs Test Short Name	text	6	6
4				4	Derived	VS.VSORRES			SDTM	VS	VSORRES	Result or Finding in Original Units	text	4	9
4				5	Derived	VS.VSORRESU		VSUNIT	SDTM	VS	VSORRESU	Original Units	text	9	10
4				6	Assigned	VS.VSTRESU		VSUNIT	SDTM	VS	VSTRESU	Standard Units	text	9	13
4				7	Derived	VS.VSTRESN			SDTM	VS	VSTRESN	Numeric Result/Finding in Standard Units	float	8	12
4				8	Derived	VS.VSTRESC			SDTM	VS	VSTRESC	Character Result/Finding in Std Format	text	4	11
4				9	Assigned	VS.VSPOS		VSPOS	SDTM	VS	VSPOS	Position	text	7	13

Source Sequence	Source Library	Source Dataset	Source Variable	Source Class	Condition	Output	Map Sequence	Origin	Method	Comment	Code List	Target Library	Target Dataset	Target Variable	Target Data Type	Target Length	Significant Digits
3	WORK	VSORRES	VS.VSTESTCD.EQ.DWBP	DWBP_VSPERF = "Y"	Y	7	Convert				best.	SDTM	VS	VSTESTCD	float	8	0
3	CDASH	VS	DWBP_VSORRES	VS.VSTESTCD.EQ.DWBP	DWBP_VSPERF = "Y"	Y	7	Convert			best.	SDTM	VS	VSTESTCD	float	8	0
3	CDASH	VS	HR_VSORRES	VS.VSTESTCD.EQ.FULGE	HR_VSPERF = "Y"	Y	7	Convert			best.	SDTM	VS	VSTESTCD	float	8	0
3	CDASH	VS	TEMP_VSORRES	VS.VSTESTCD.EQ.TEMP	TEMP_VSPERF = "Y"	Y	7	Convert			best.	SDTM	VS	VSTESTCD	float	8	1
3	CDASH	VS	HEIGHT_VSORRES	VS.VSTESTCD.EQ.HEIGHT	HEIGHT_VSPERF = "Y"	Y	7	Derived	VS.VSTESTCD.items		best.	SDTM	VS	VSTESTCD	float	8	2
3	CDASH	VS	WEIGHT_VSORRES	VS.VSTESTCD.EQ.WEIGHT	WEIGHT_VSPERF = "Y"	Y	7	Convert			best.	SDTM	VS	VSTESTCD	float	8	0

Source: CDISC 360: The Journey So Far and the Road Ahead
 Automation of SDTM Generation & Artifacts using CDISC 360 enriched standards
<https://www.cdisc.org/events/webinar/cdisc-360-journey-so-far-and-road-ahead>



Organizational commitment

- Executive Buy-in:
 - Costs & Return on Investment
 - Commitment to long-term investment
 - Maintain commitment with regular results ("ROI")
- Resourcing: often under-estimated
 - Much work to digitize information, fill gaps
 - and still design and engineer integrated solutions



Organizational commitment

- "Competing" with clinical development and other corporate objectives
 - Future capabilities are *enabling*
 - Can lead to (temporary?) setbacks
 - Design regular progress, deliver regular advances



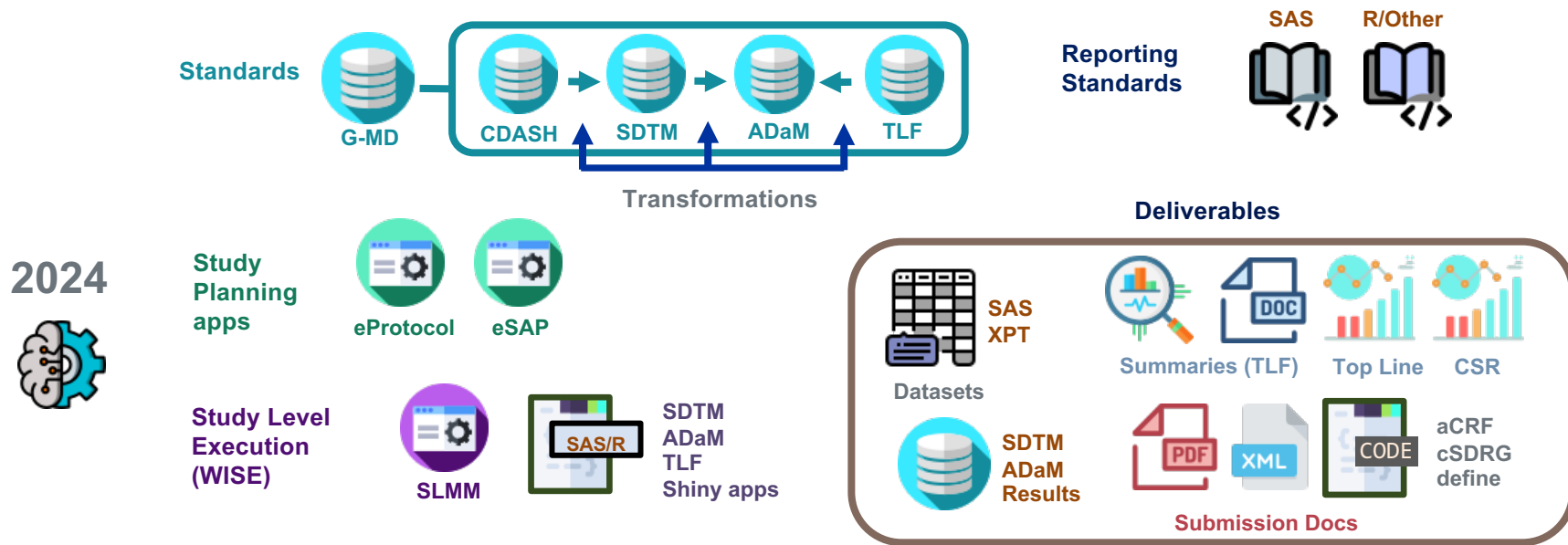
Change Management

- Addressing the refrain "So you want to eliminate all of our jobs?!"
- Overcome the mindset "There is nothing (*more interesting?*) to do besides what I've been doing."
- "Study specific cannot be automated" would have prevented self-driving cars, high-speed interception of asteroids, ...

What is MAP

The new way

To achieve this, it requires us to rethinking how we current work



This is a long transformation process: don't forget to give some quick wins along the way

- Facilitate metadata management
- Machine-readable data derivations
- Model & record table specification
- Model & record graphical specifications
- Prototype & establish building blocks

Discussion

Contact

- **André Couturier**

Group Head Analytics and Reporting Tools

Andre.Couturier@sanofi.com

- **Dante Di Tommaso**

Senior Tools and Applications Leader

Dante.DiTommaso@sanofi.com