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Statistical Reporting Metadata Manager

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Vision



MAPS vision & product mission

MAPS: navigate the world of metadata and streamline clinical programming – all in one interface



Vision statement

MAPS is an application assisting study programmers and biostatisticians to save time for manual, error-prone work.

It empowers them to **focus on their key expertise** by **simplifying, streamlining and centralizing study metadata preparation and data transformation programming**.

Thereby, MAPS **accelerates the analysis and reporting of clinical data**.

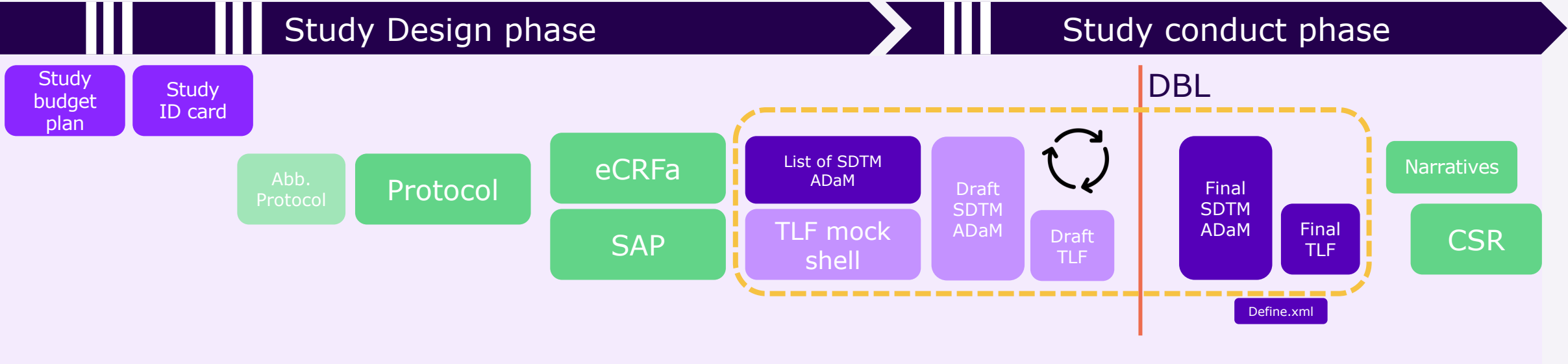


Mission statement

(how we reach the vision by MAPS and per Delivery)

- **MAPS product:** Support B&P statistical programming teams to generate high quality draft SAS / R programs for non-efficacy related SDTM, ADaM, and TLF deliverables

MAPS in the Clinical Trial Value Chain



- Study initiation
- intermediary
- Submission documents
- Submission data & analysis

Metadata Assisted Programming Services

MAPS facilitates standardized data preparation, leveraging standards references and automation of draft programmes to generate the data.

MAPS assistance (B&P programming activities)

Metadata Assisted Programming Services (MAPS)



Capabilities

- Streamline study-level metadata preparation for SDTM and ADaM data creation
- Leverage the use of SDTM & ADaM standards (global level and study level) and versioning
- Automate SAS/R scripts creation (generate a draft)
- Facilitate design and generation of TLF (Tables, Listings and Figures)

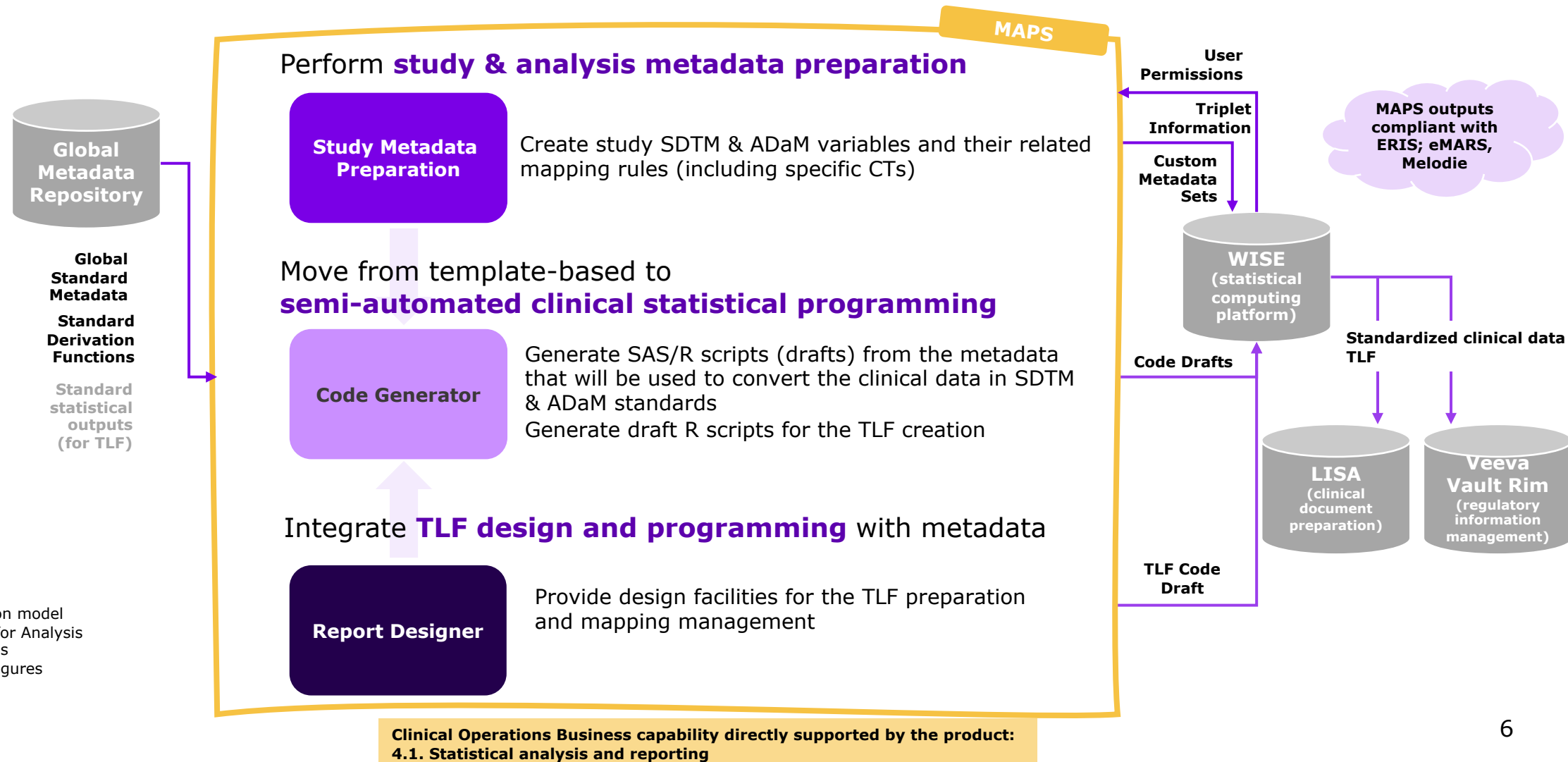


Project Main Objectives

- Support B&P statistical programming teams to generate high quality draft SAS programs for non-efficacy related SDTM, ADaM and TLF deliverables

MAPS product scope

MAPS (Metadata Assisted Programming Services) offers a **unique opportunity to transform clinical statistical programming & gain efficiency** by simplifying and automating the existing manual process



SDTM study data tabulation model
ADaM Derived data used for Analysis
CT Controlled Terminologies
TLF Tables, Listings and Figures

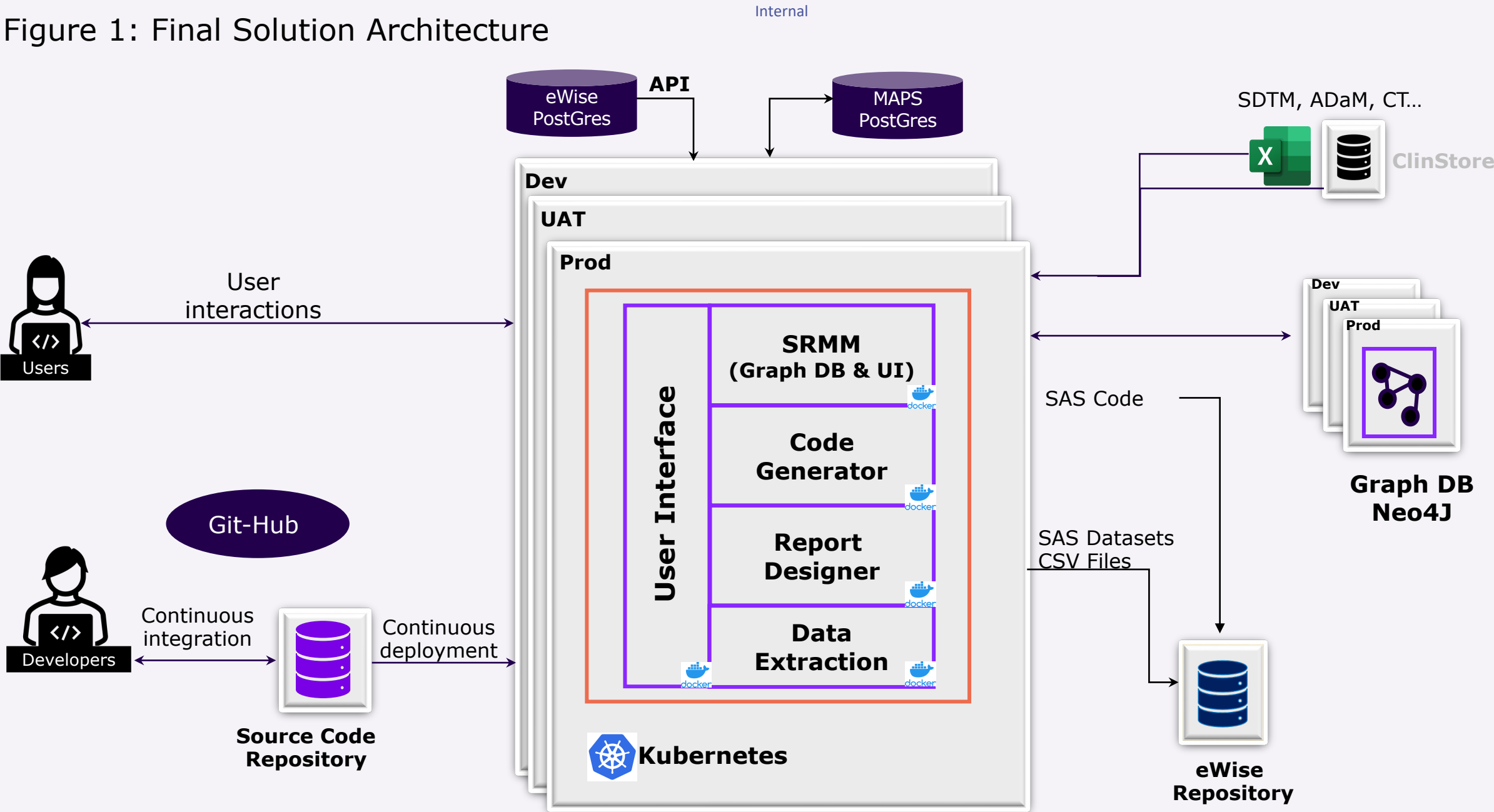
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Workflow



Figure 1: Final Solution Architecture



The study ADaM metadata behind the ADaM variable

ADAE.BDSYORD



	A	B	C	D	J	K	L	M	N	O	P	Q	R	S	
	Dataset Name	Relative Order	Variable Name	Variable Label	Controlled Terminology	Origin	Derivation Type	Source	Derivation	Assigned	Pseudo Code	Pseudocode combination	Comment for generated program	Core	Instructions for Programmers
1350	ADAE	1220	AEBODSYS	Body System or Organ Class	MEDDRA	[Predecessor or Assigned]		[AE.AEBODSYS]		[Assigned from MedDRA dictionary]	std_function	complete		Req	Can contain Primary SOC or Secondary SOC comprised of the primary SOC records and as to the dictionary name and version should be Internationally agreed upon order of MedDRA ADaM Implementation Guide section on MedDRA Used for reporting
1362	ADAE	134	BDSYORD	Body System or Organ Class MedDRA Order		Derived	Computation		[See Note xx]		std_function	complete		Perm	

Metadata Mapping type:
call an eris function
(pseudo code =
std_Function)



```
/* Adding variable(s): */
/* BDSYORD */
/*****
%eris_ae_socord(data_in_ae = adae17
, data_out_ae = adae18
, data_in_soc = eris_app.socord_ref
, aesoccd_name = aebdsycd
, socord_name = bdsyord
, debug_flag = N
);
```

Compound/Study configuration

Compound/Study/Analysis Configurations are Global parameters that describe important attributes.

These are also used to derive one/multiple variables. Examples of such parameters are:

- Number of periods in the study (Used to Derive TRTxxP, TRTxxA, etc.)
- Standardized MedDRA Queries (SMQ) (Used to Derive SMQzzNAM SMQzzCD SMQzzSC SMQzzSCN)
- Number of Analysis Phases in the study (APHASEw, PHwSDT, PHwSDTM, PHwEDT, etc.)

B&P standardization team have compiled list of all possible global parameters and categorized them by Compound/Study/Analysis.

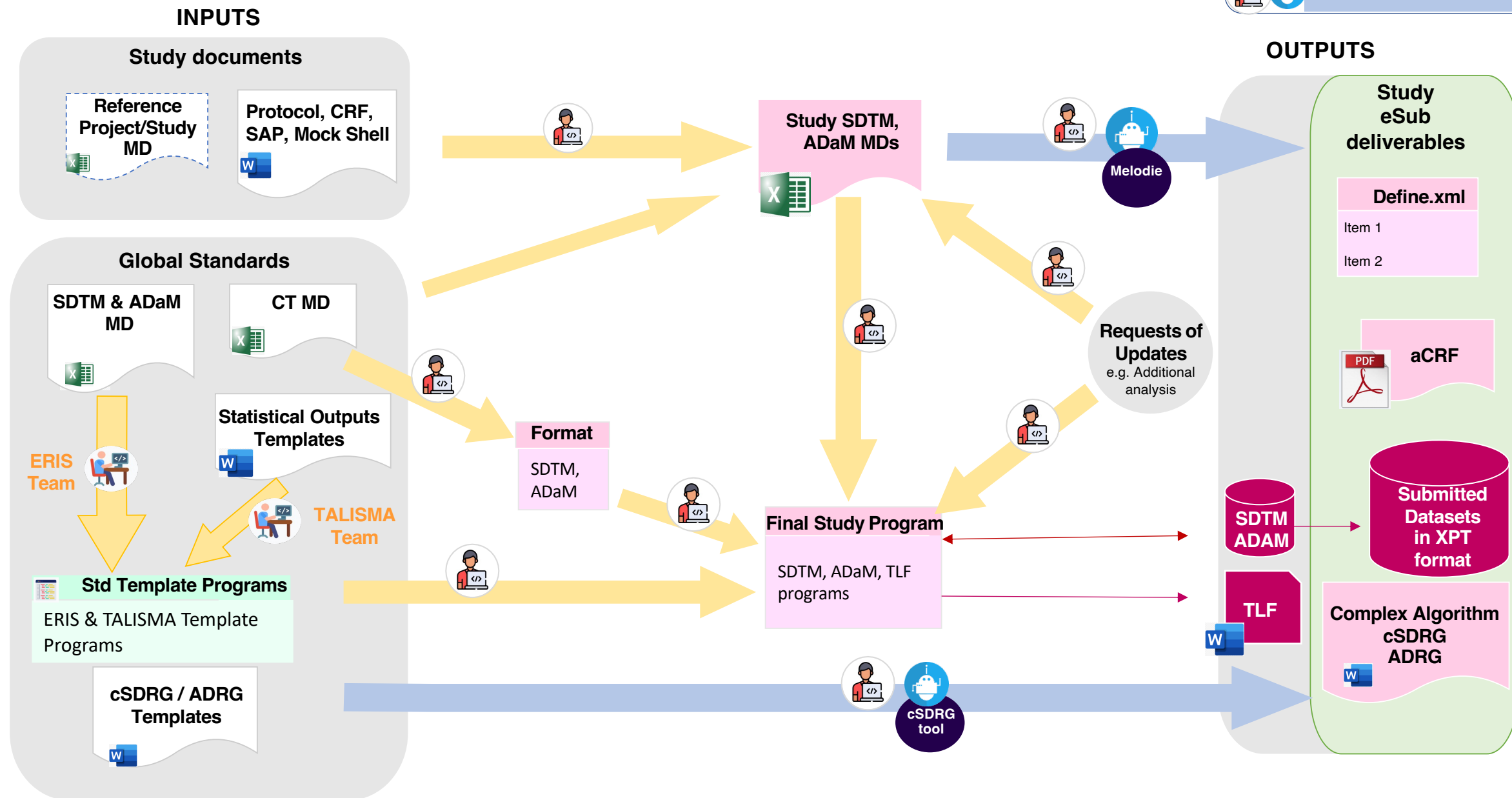
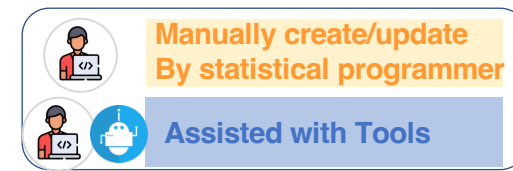
AS-IS PROCESS:

- These are inferred directly from Protocol or SAP
- Programmers manually assign these values to variables at study/analysis level

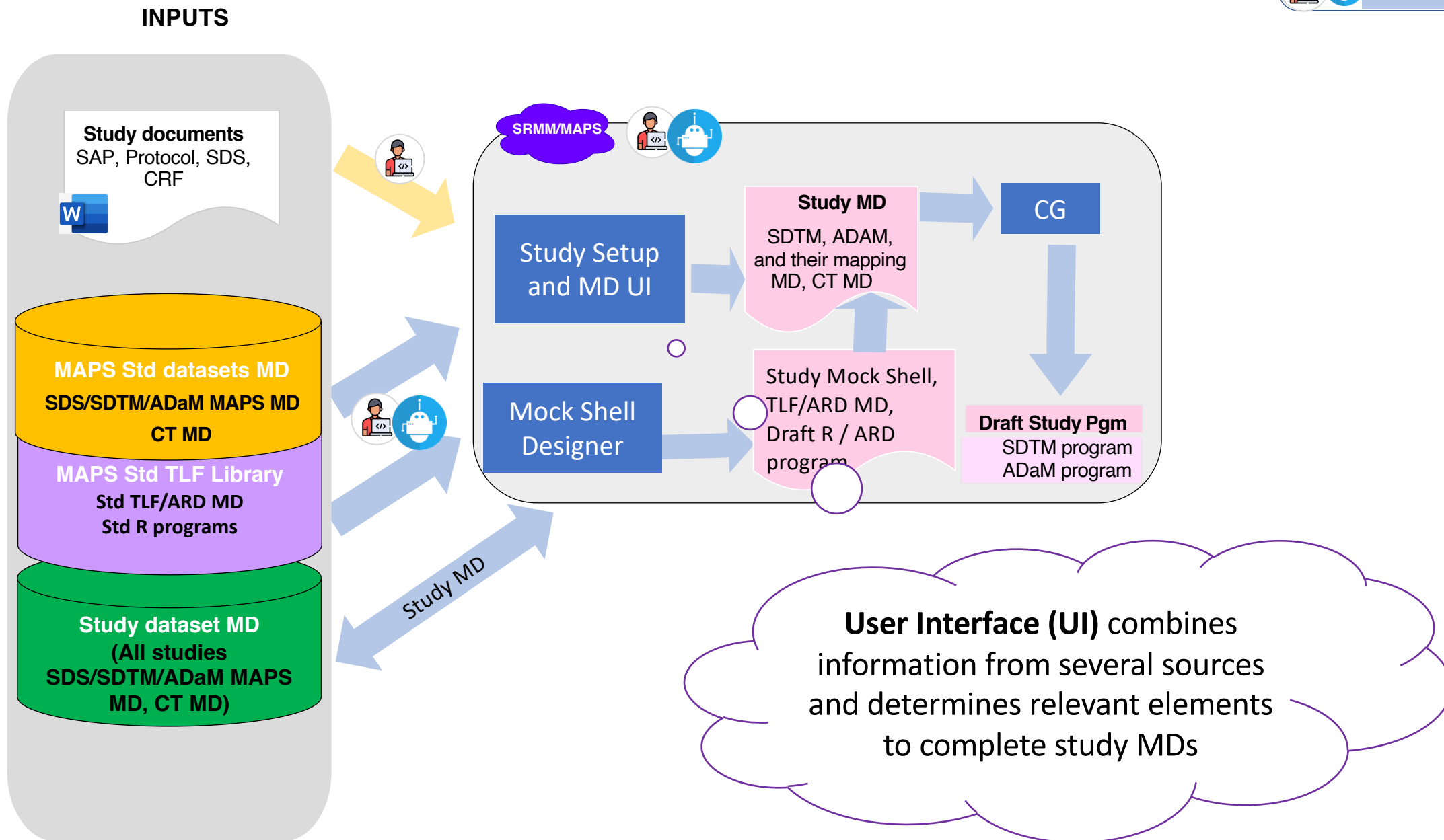
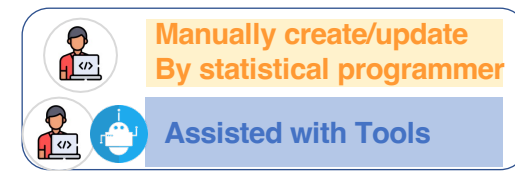
MAPS Process:

- C/S/A Configuration parameters are captured at appropriate levels and can get inherited
 - Example: an Analysis will inherit all study configuration
- The configuration automatically drives creation of variables
- Possibility to connect to digitized Protocol/SAP solutions and pull this information automatically

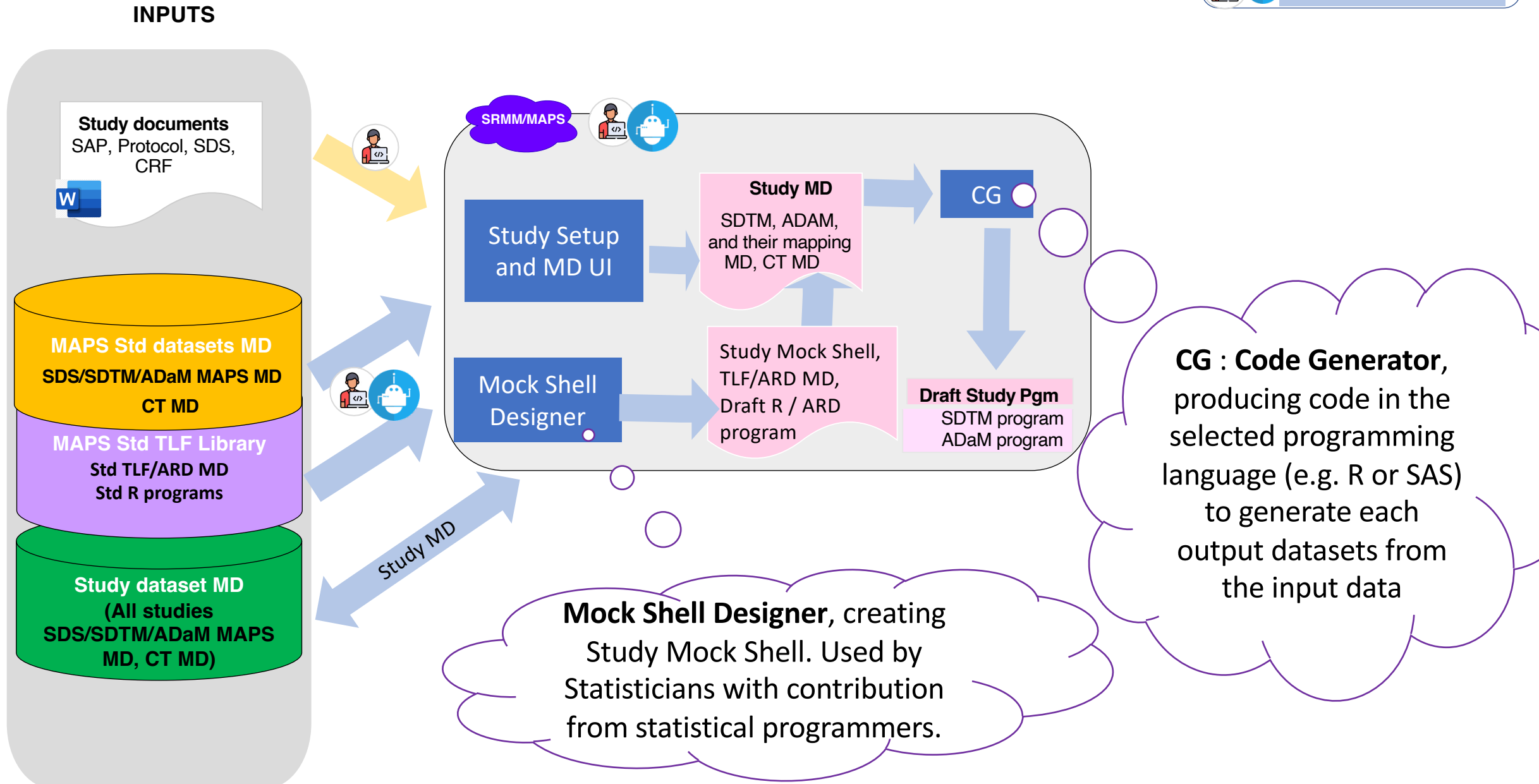
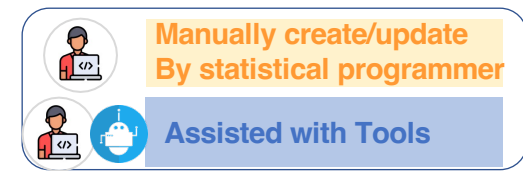
Current End-to-End Workflow



Future End-to-End Workflow



Future End-to-End Workflow



Future End-to-End Workflow



Manually create/update
By statistical programmer



Assisted with Tools

INPUTS

Study documents
SAP, Protocol, SDS,
CRF



MAPS Std datasets MD
SDS/SDTM/ADaM MAPS MD
CT MD

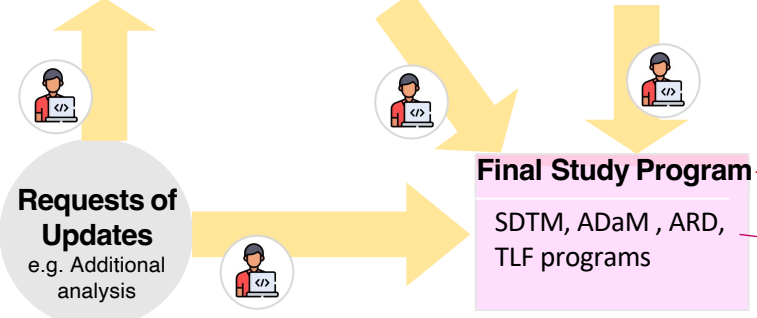
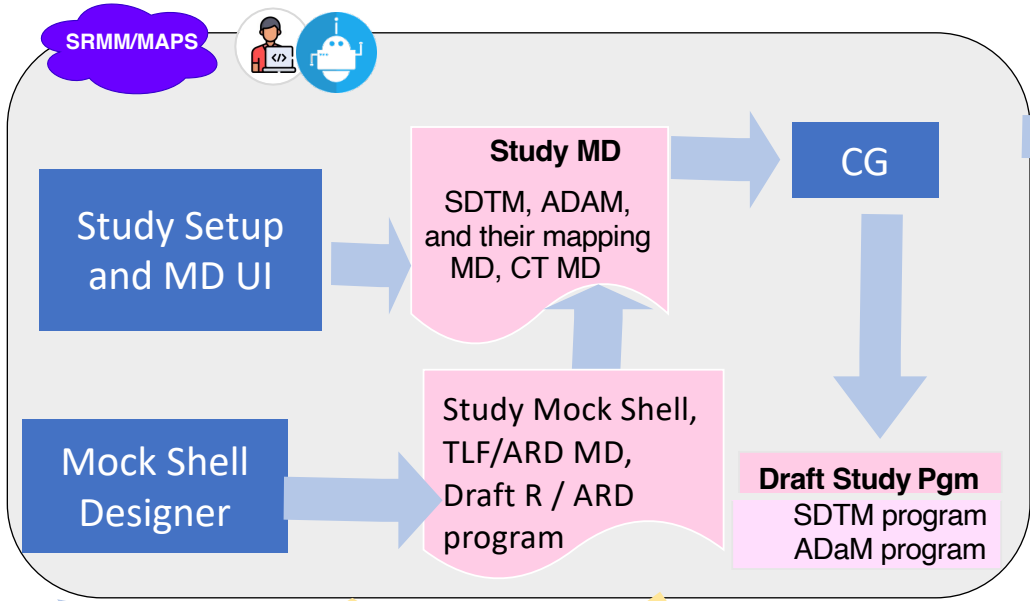
MAPS Std TLF Library
Std TLF/ARD MD
Std R programs

Study dataset MD
(All studies
SDS/SDTM/ADaM MAPS
MD, CT MD)

Study MD

cSDRG / ADRG
Templates





OUTPUTS

Study eSub
deliverables

Define.xml
ARM

aCRF

SDTM
ADAM
ARD

Submitted
Datasets
in XPT
format

TLF

Complex Algorithm
cSDRG
ADRG

cSDRG
tool

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Workflow



MAPS

Benefits for users



More efficient way
working with MD

Better access to the
existing
mapping & derivation

Avoid repetitive work &
retrieve information
automatically

Accelerate data
preparation

MAPS

Benefits for users



MORE EFFICIENT WAY WORKING WITH MD

- **Streamline & Semi-Automate** Study Level MD creation/preparation (e.g. in Study ADaM MD, automatically retrieve study SDTM related elements)
- **Gain efficiency** working with Web Interface & Database instead of Excel. In future, add user-friendly checks.

MAPS

Benefits for users



BETTER ACCESS TO THE EXISTING MAPPING & DERIVATION

- Benefit from historical/ongoing studies (e.g. all Study metadata accessible in read mode)
- **Leverage use of SDTM & ADaM Std :**
 - Promote most commonly used study-level derivations to Global
 - End user has instant access to newly added standard rules

MAPS

Benefits for users



AVOID REPETITIVE WORK & RETRIEVE INFORMATION AUTOMATICALLY

- **One source of truth**
(e.g. an update is impacted automatically throughout the chain)
- **Enter information only once**
(e.g. set up MD to get key information & re-use it automatically)

MAPS

Benefits for users



ACCELERATE DATA PREPARATION

- **Automate** SAS / R generation of draft program, taking into account study specifics
- Use of program MD to standardize coding format & order

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Demo



THANK YOU



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