



DH01 - EFFECTIVE USE OF A METADATA REPOSITORY ACROSS DATA OPERATIONS: THE NEED FOR A MACHINE READABLE FORM OF (PART OF) THE PROTOCOL

PhUSE Annual
Barcelona, 11th October 2016

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- **Overview of Clinical MDR as part of E2E Data Standard**
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- **Conclusion**

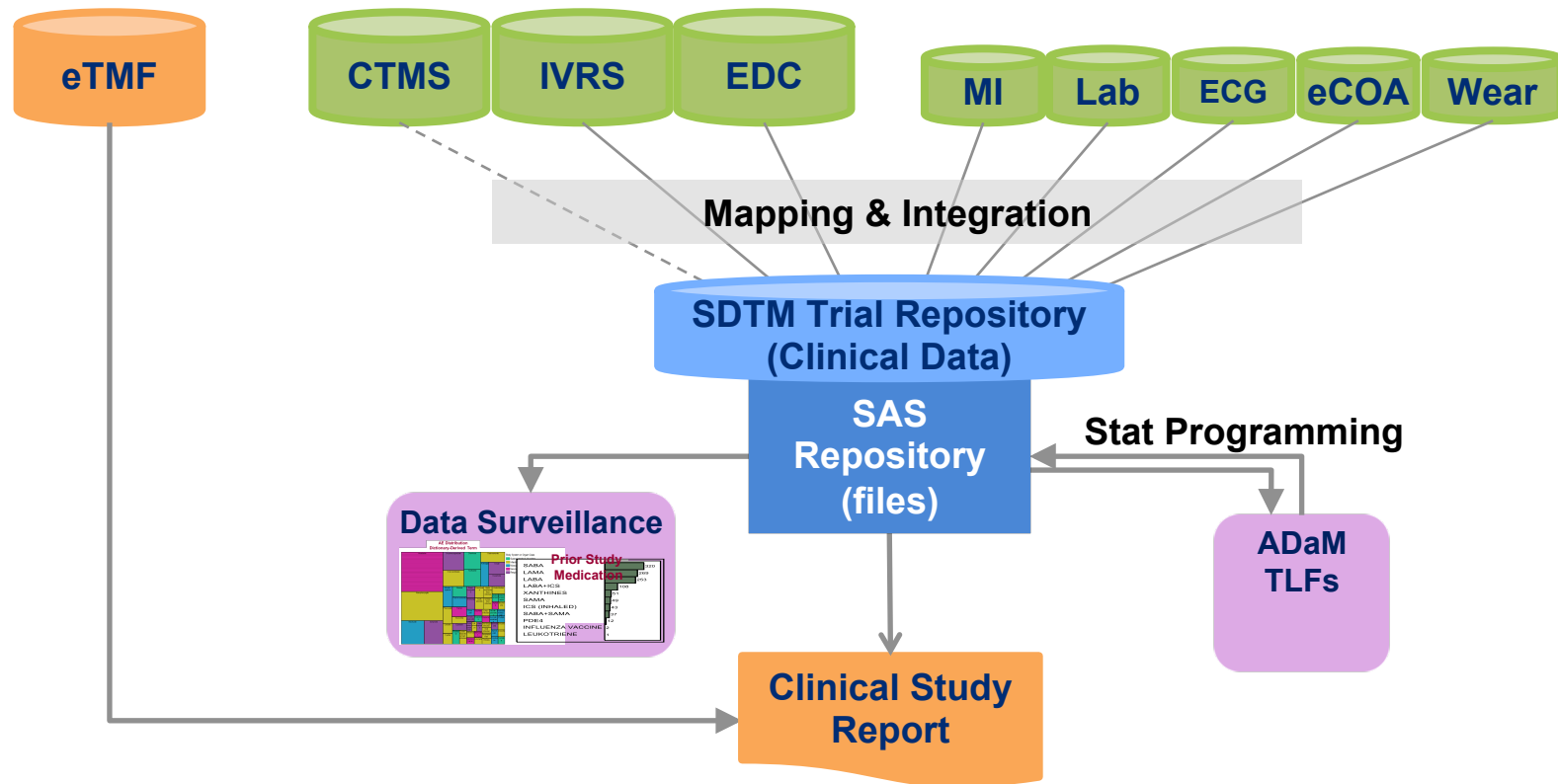
INTRODUCTION TO METADATA REPOSITORY

- **A MDR is an application that manages data standards in compliance with sponsor and regulatory requirements**
- **Opportunities**
 - Compliance to regulatory requirements (e.g. CDISC SDTM mandated by FDA as of 17 December 2016)
 - Re-usability, increased efficiency and quality
- **Challenges**
 - Governance of different - but related, standards (e.g. submission, reporting) in an effective and consistent manner
 - Operationalization of standards i.e. actual use within data and trial execution ACROSS ALL DCI

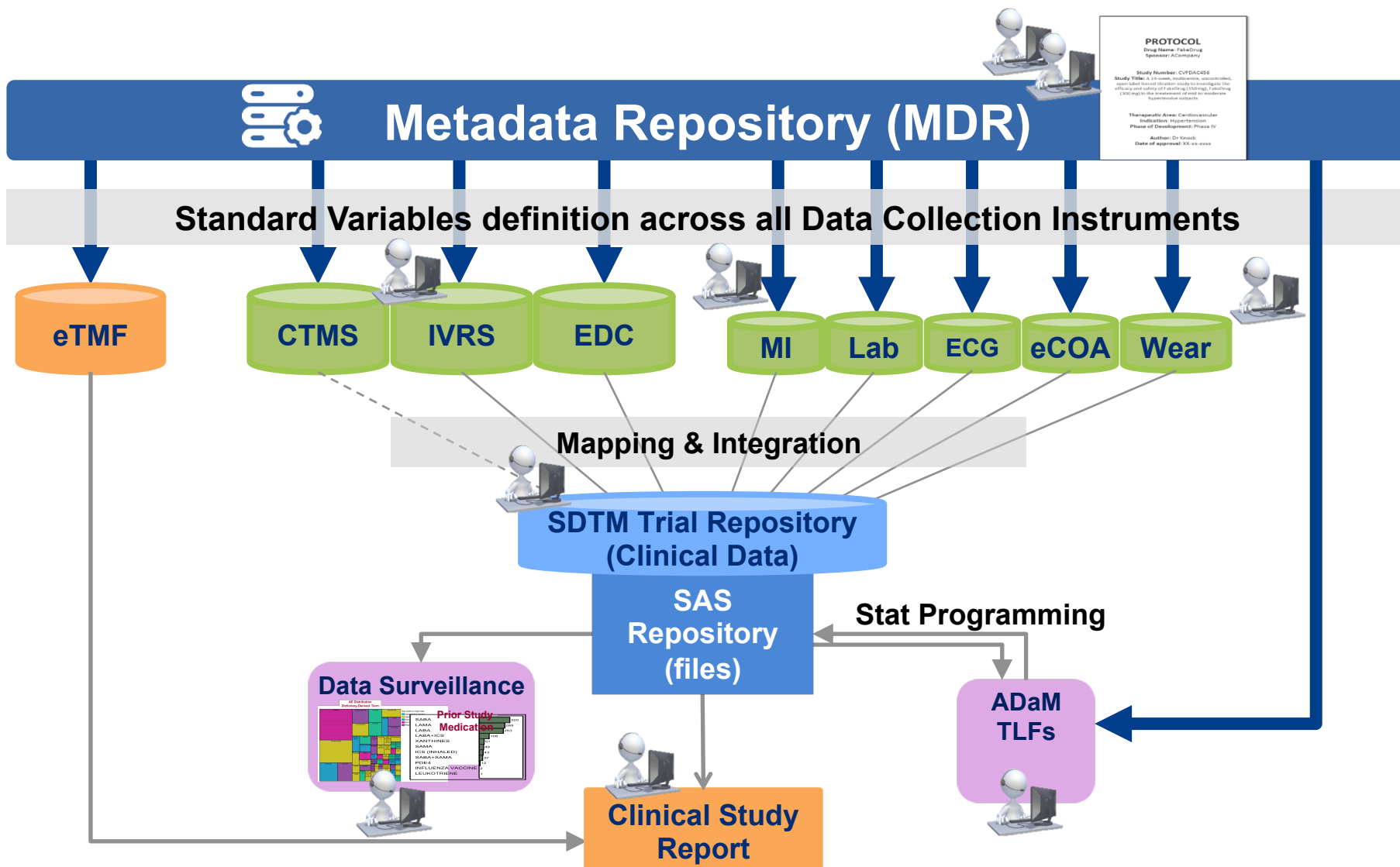
Cfr session on PAREXEL® Clinical MDR in CDISC stream

Focus of this session

OPPORTUNITY: TRIAL SET-UP WITH A MDR



OPPORTUNITY: TRIAL SET-UP WITH A MDR

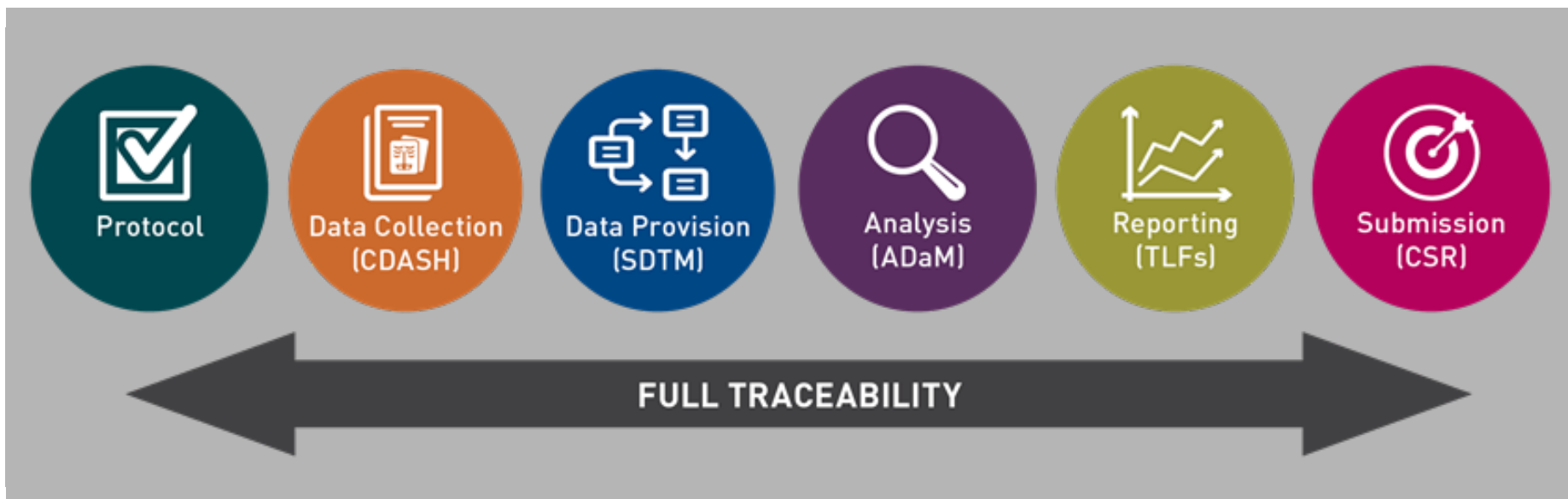


- One single interpretation of protocol
- Increased consistency and data quality
- Reduced time for integration and secondary data use

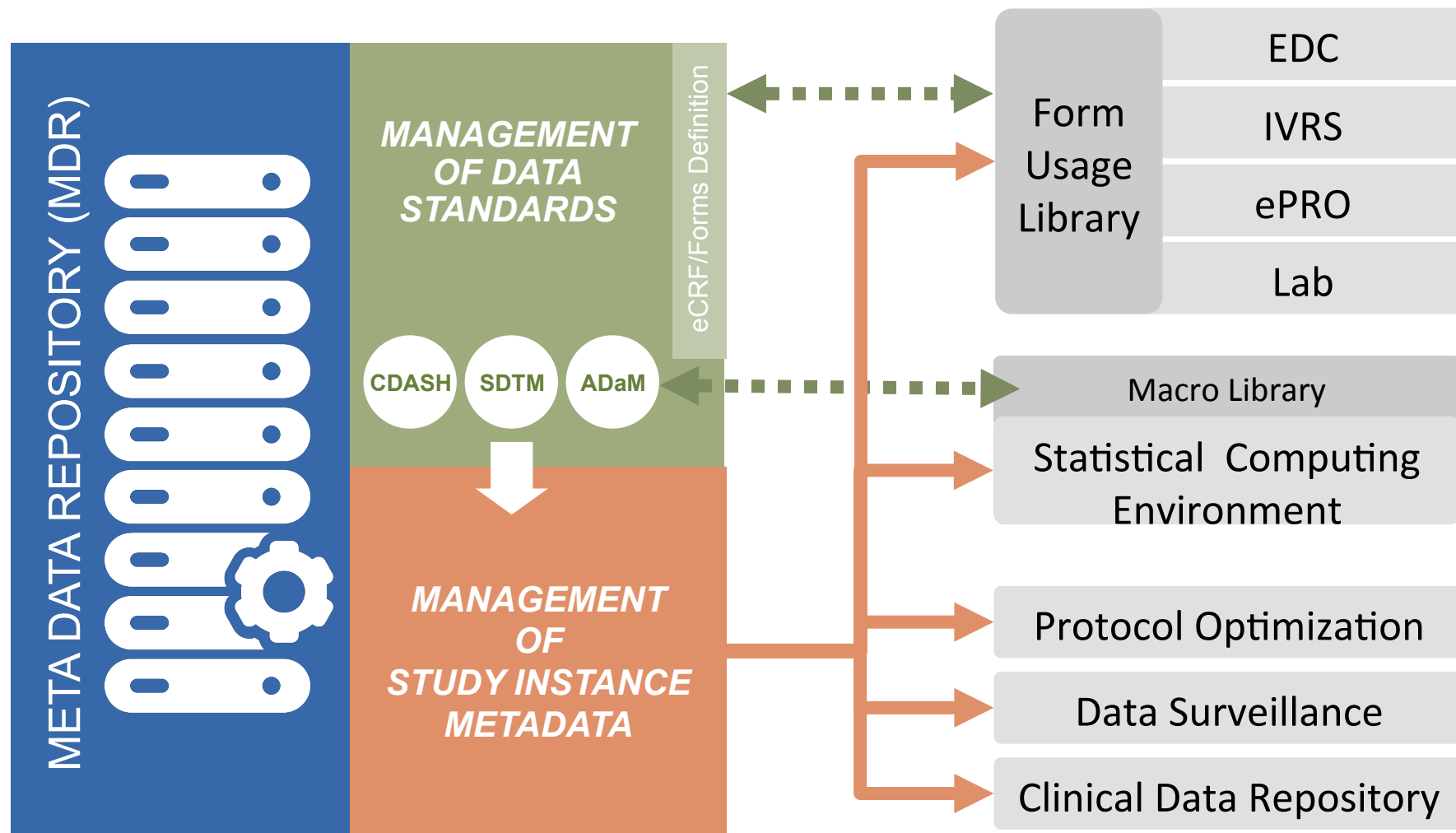
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ENHANCING GLOBAL DATA OPERATIONS THROUGH E2E DATA STANDARDS



MDR OVERVIEW



MANAGEMENT OF DATA STANDARDS

HUB AND SPOKE APPROACH SUPPORTED BY PATTERNS

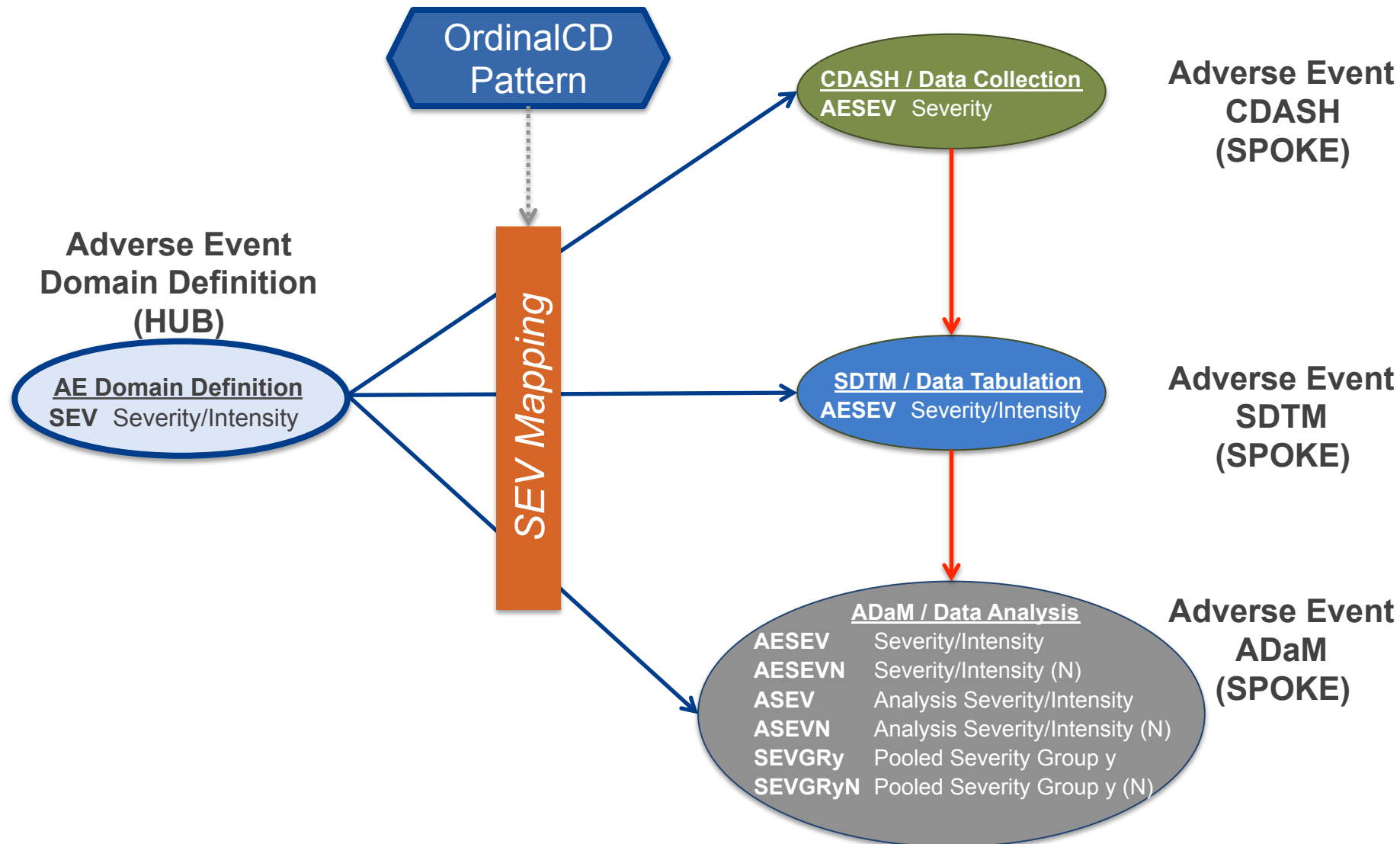
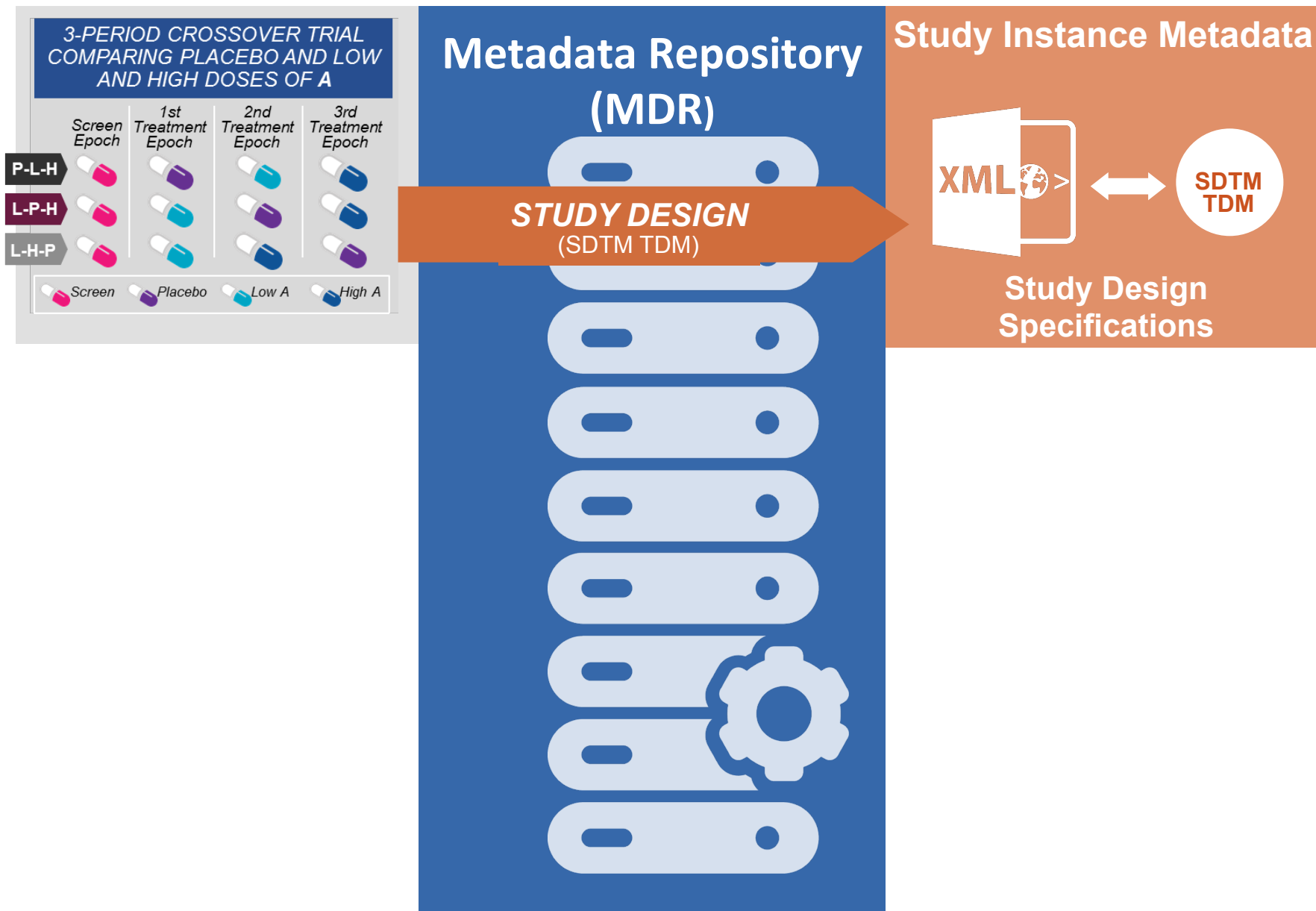


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STUDY DESIGN



VISIT SCHEDULE

Period	Screening	Study treatment period														Follow-up
Week	-2	0	1	2	3	4	5	6	8	10	12	16	20	24	Within week 25	
Visit	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	
Type of contact	Visit	Visit	phone call	Visit	phone call	phone call	phone call	Visit	phone call	phone call	Visit	visit	phone call	visit	phone call	

Inclusion and Clinical evaluation:

Patient Demography	X														
Vital Signs and Body Weight	X	X													
Previous and Current Medication	X	X		X	X	X	X								
Inclusion and Exclusion Criteria	X	X													
Randomization		X													
Central Laboratory Testing:															
HbA1c		X*													
Lipid Profile ¹ (in fasting state)		X*													
Biochemistry ²		X*													
Serum Pregnancy Test															
Treatment:															
Dispensation of insulin glargine and corresponding training															
Dispensation of insulin glargine if needed (see section 9.1.3) and corresponding training															
Accountability of Investigational Products		X		X											
Plasma Glucose Self-Monitoring:															
Dispensation of plasma glucose meter	X														
Training of the patient (PG meter, diary)	X	X													
in the week before the visit				X											
7-point plasma glucose profile of 3 consecut															
Insulin Efficacy				X	X	X	X	X							
Treatment															
Hypoglycemia															
AE / SAE															

Specification for Wearable

Specification for Mobile

EDC: Annotated eCRF for Patient Demography

Visit: VIS1N Date of visit: VIS1D

Demography

Date of birth: DOB1D Age (years): AGEDRV1N

Sex: SEX1C

Predominant race: RCESC

Ethnicity: ETH2C Specify: ETHSPY1A

Source of subject referral: SRCREF1C Specify: SRCREF1A

If the subject is a screen failure, Click here

If you need to correct the Subject's Initials, please enter correct initials and Click on the push button below:

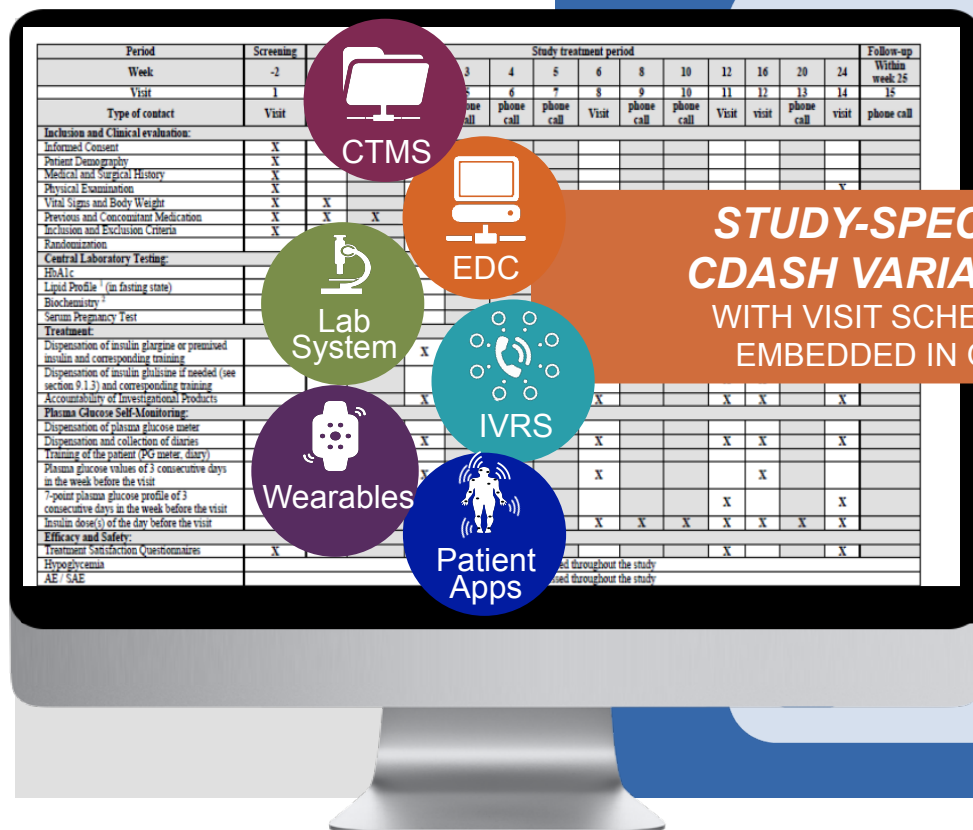
Correct Subject Initials: Click here to correct initials

The subject's data are considered clean: ISRINTA1C

To be assessed throughout the study

VISIT SCHEDULE

Metadata Repository (MDR)



Period	Screening	Study treatment period														Follow-up
Week	-2	3	4	5	6	8	10	12	16	20	24	Within week 25				
Visit	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	
Type of contact	Visit	phone call	phone call	phone call	Visit	phone call	phone call	Visit	visit	phone call	visit	phone call	visit	phone call		
Inclusion and Clinical evaluation:																
Informed Consent	X															
Patient Demography	X															
Medical and Surgical History	X															
Physical Examination	X															
Vital Signs and Body Weight	X	X														
Previous and Concomitant Medication	X	X	X													
Inclusion and Exclusion Criteria	X															
Randomization	X															
Central Laboratory Testing:																
HbA1c																
Lipid Profile (in fasting state)																
Biochemistry																
Serum Pregnancy Test																
Treatment:																
Dispensation of insulin glargine or premixed insulin and corresponding training		X														
Dispensation of insulin glargine if needed (see section 9.1.3) and corresponding training		X														
Accountability of Investigator's Products		X														
Plasma Glucose Self-Monitoring:																
Dispensation of plasma glucose meter		X														
Dispensation and collection of diaries		X														
Training of the patient (PG meter, diary)		X														
Plasma glucose values of 3 consecutive days in the week before the visit		X														
7-point plasma glucose profile of 3 consecutive days in the week before the visit		X														
Insulin dose(s) of the day before the visit		X	X	X	X	X	X	X	X	X	X	X	X	X	X	
Efficacy and Safety:																
Treatment Satisfaction Questionnaires	X															
Hypoglycemia																
AE / SAE																



CTMS



EDC



Lab System



IVRS



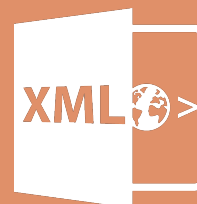
Wearables



Patient Apps

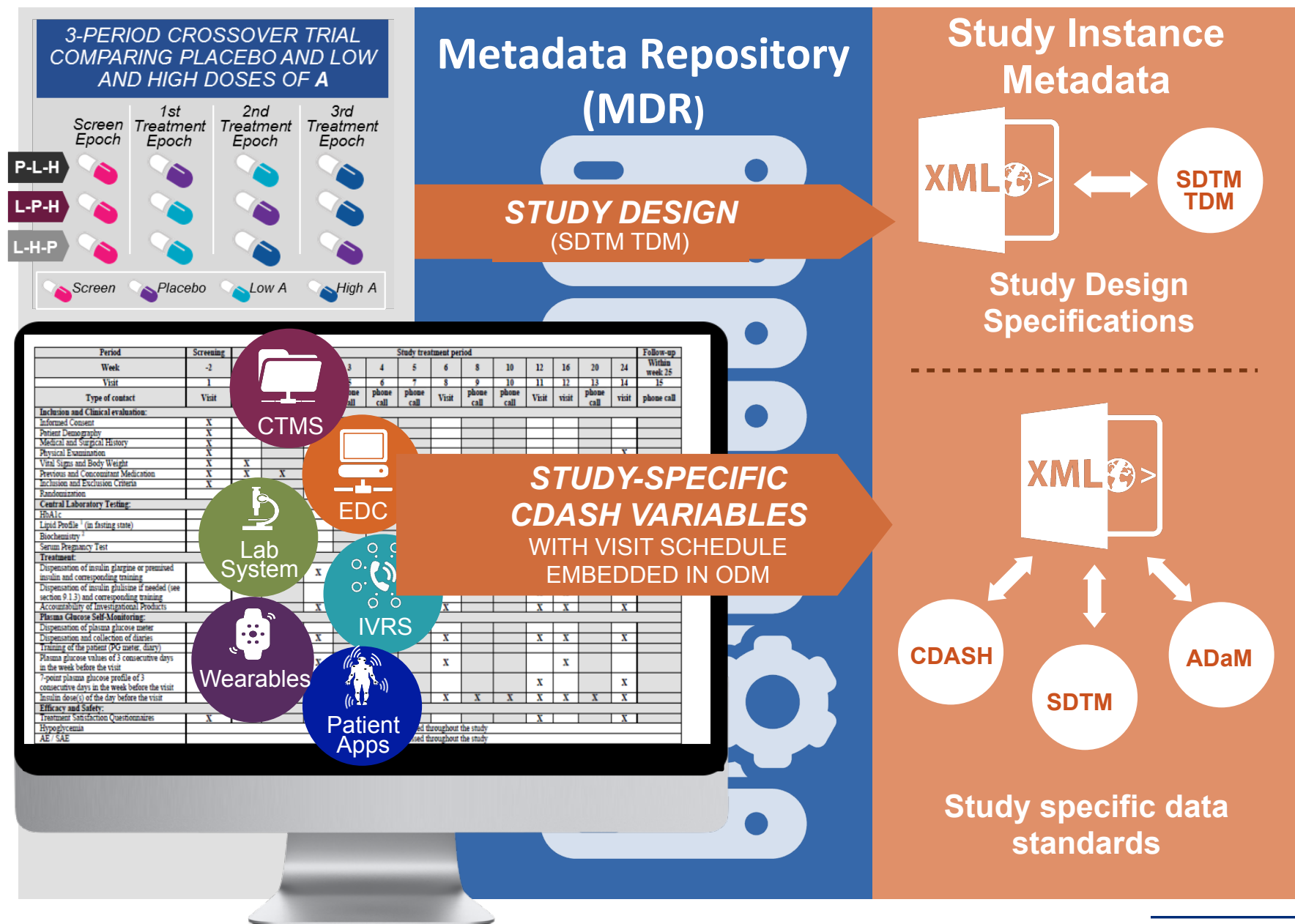
STUDY-SPECIFIC CDASH VARIABLES WITH VISIT SCHEDULE EMBEDDED IN C

**STUDY-SPECIFIC
CDASH VARIABLES
WITH VISIT SCHEDULE
EMBEDDED IN ODM**

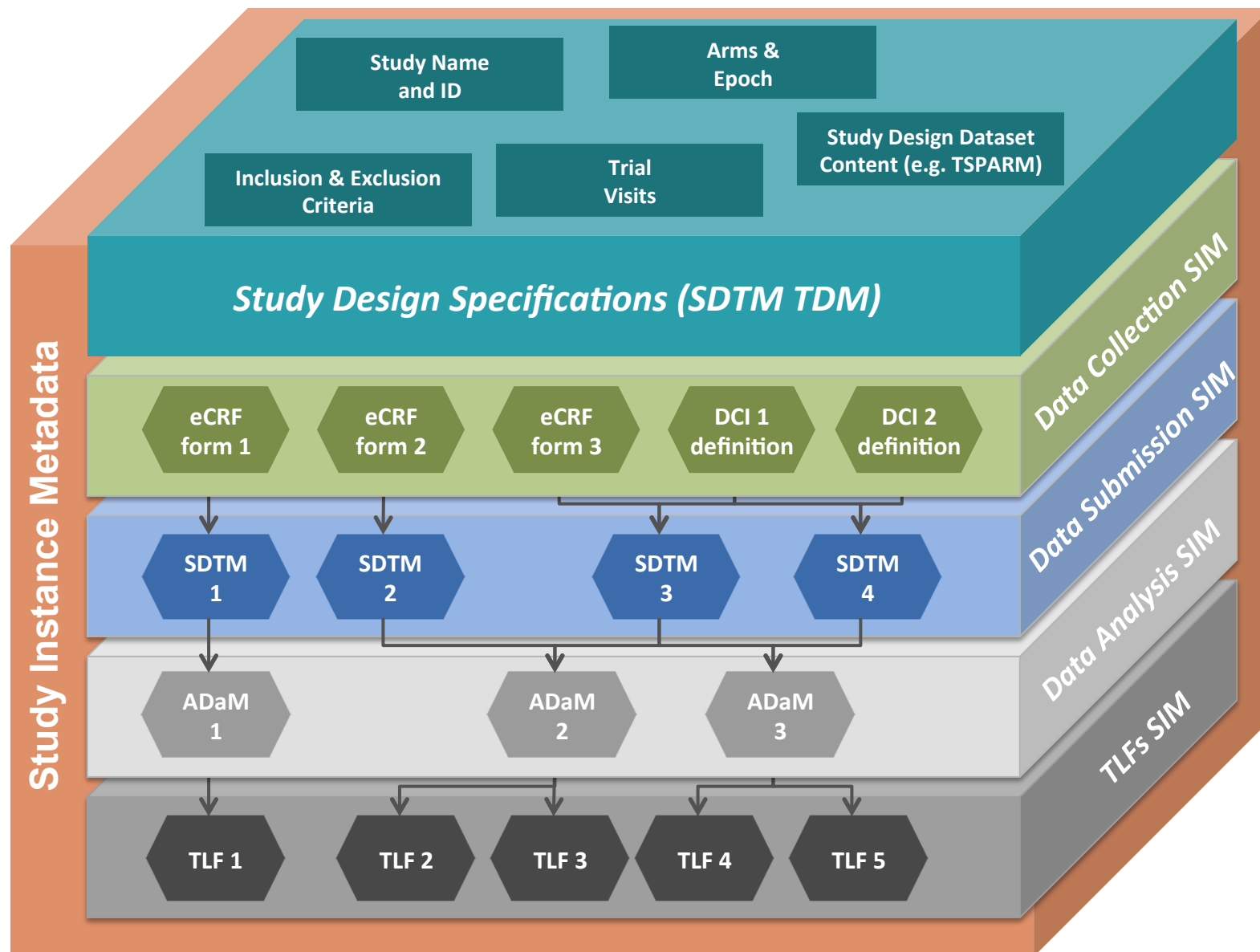


**Study specific data
standards**

SIM = MACHINE READABLE FORM OF (PART OF) THE PROTOCOL



SIM CONTENT



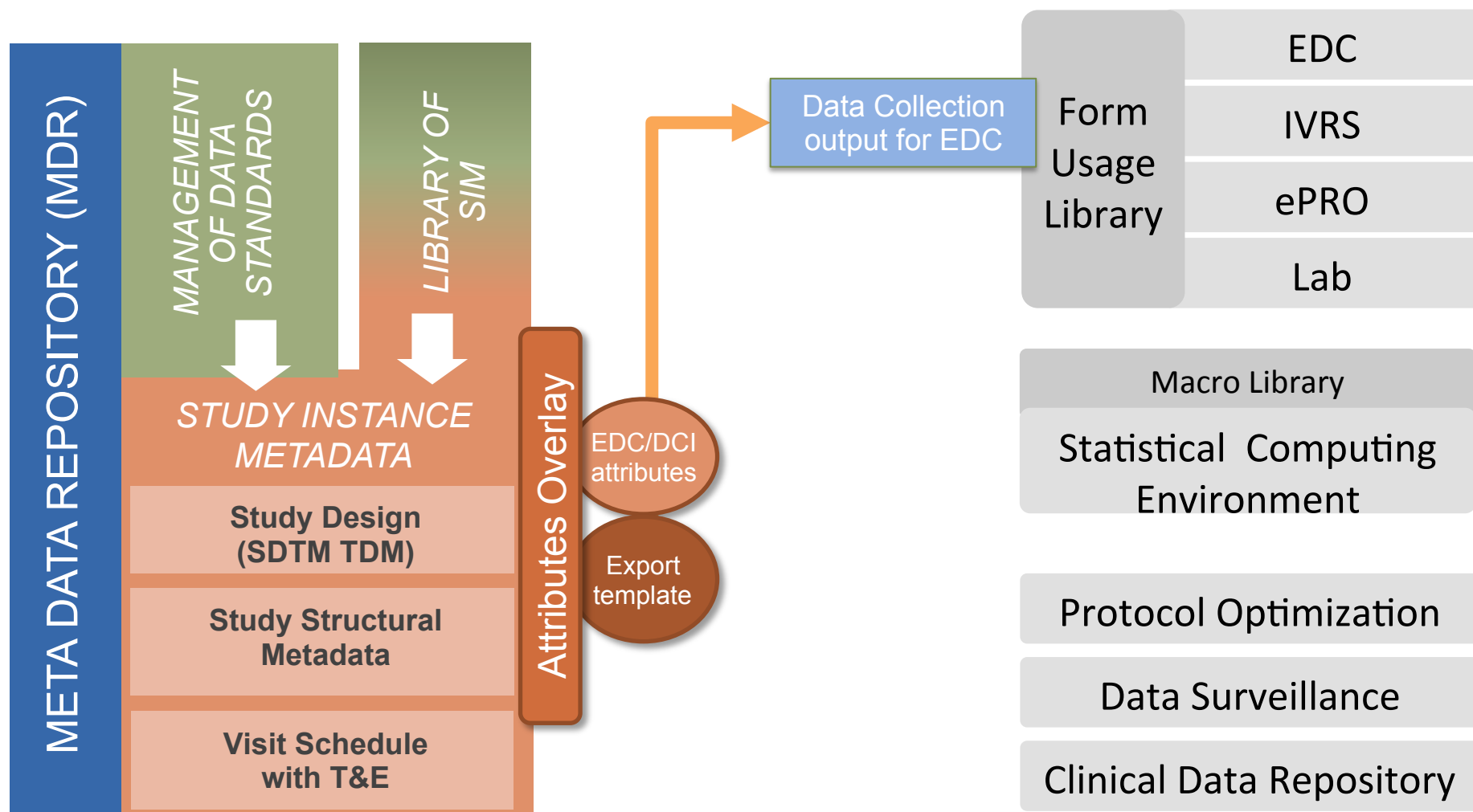
KEY FEATURES

- **After “bulk” import, maintenance of MDR content is done as needed in studies, when defining the SIM, with strict governance**
- **Possibility to have**
 - SIM versioning related to protocol amendment
 - DIFF between different versions of a SIM
 - DIFF between the SIM content and eCRF library (assuming it is synchronized with MDR content)
- **SIM library enables re-use possible across studies**
- **Data lineage from data collection onwards, with draft specification of SDTM and ADaM**
- **Attributes overlay for different uses**

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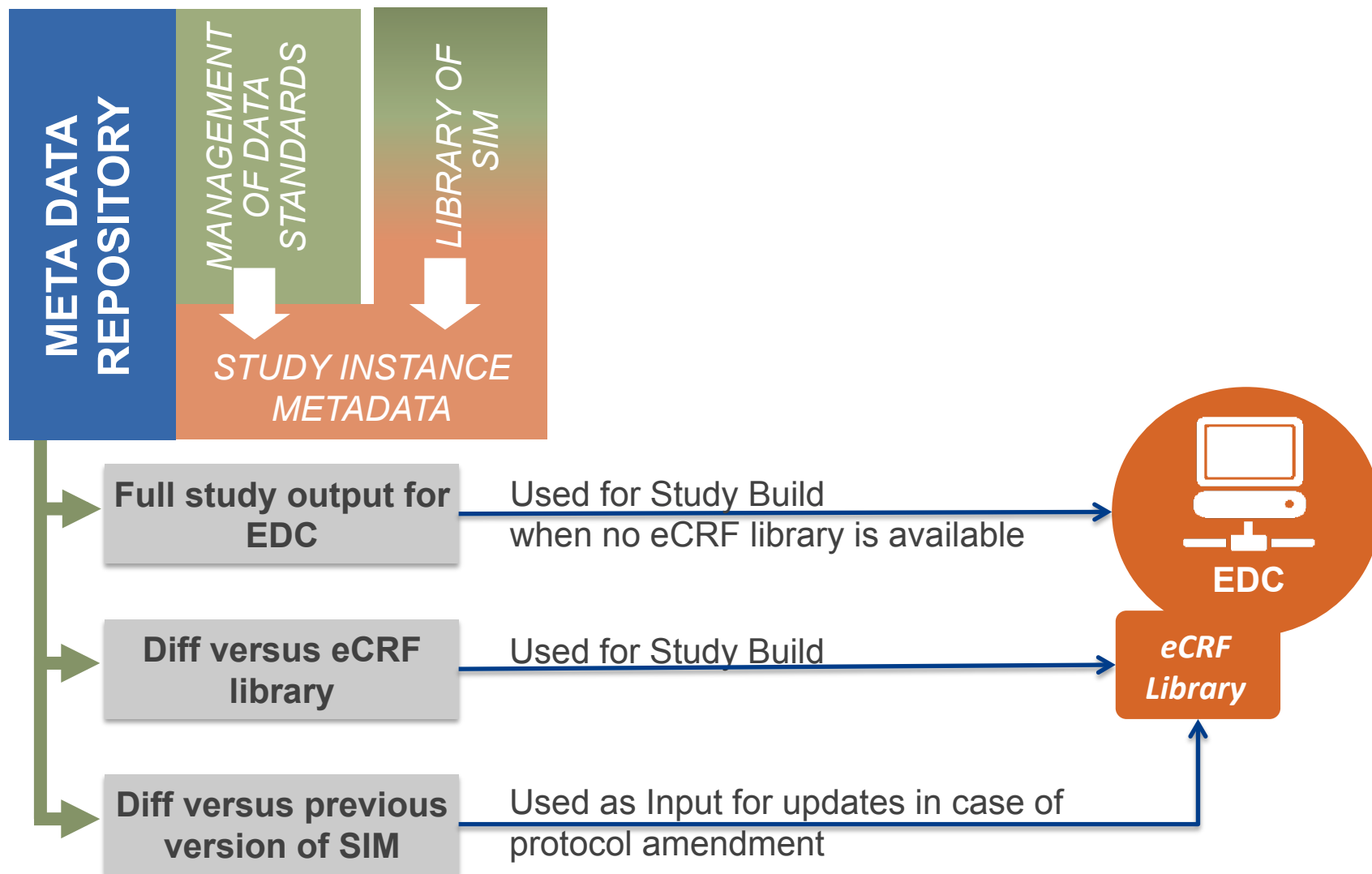
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USING THE SIM (TODAY)

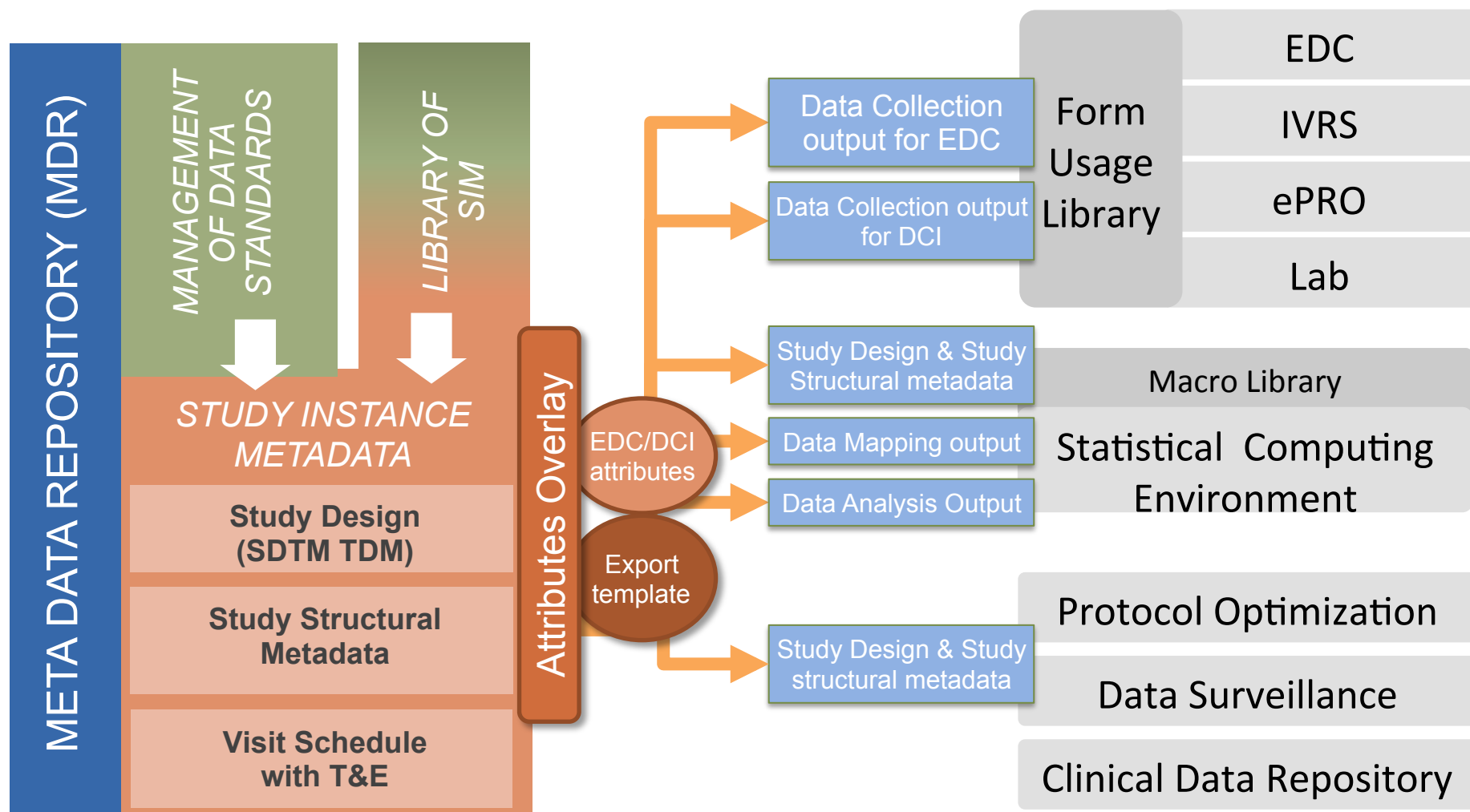


USING THE SIM (TODAY)

STUDY SET-UP OF EDC



USING THE SIM (FUTURE)



BENEFITS OF USING A SIM

- **Comparison of design of new studies enables study design optimization & decreasing protocol amendments**
- **Faster design of a study by using previous study from the SIM library**
- **Faster & consistent study set-up across all data collection instruments (EDC, wearables, MI, ..)**
- **Availability of the SDTM and ADaM specification, with data lineage**
- **Consistent standards across studies enabling secondary data use**

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CONCLUSION

- **While developing the PAREXEL® Clinical MDR one key concern was proper integration within data operations**
- MDR should not be limited to usage by Data Standards experts
- The SIM – *as a machine readable form of (part of the) protocol-* is core to usage (and enforcement) of data standards within operations for study set-up and to support many downstream activities
- **Clinical trials data are a critical business asset that can be better re-used through the SIM**
- As an industry, we are spending Billions in collecting data - yet we do not use enough these data outside of their primary use, because of the cost of mapping & transformation
- The SIM – *as a metadata layer of the study data* – should be stored in data lakes to support just in time transformation of the data

Why not come and learn more about the PAREXEL Clinical MDR at our booth and see SIM in action!

The PAREXEL MDR went in pilot use
in September 2016

THANK YOU

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