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Metadata becomes alive via a web service between MDR and SAS

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Agenda

- Introduction of Metadata
- Introduction of MDR
- A Web Service and its method (SOAP and REST)
- Data Exchange between MDR and SAS
- SOAP XML request and response file
- Conversion to SAS data set
- Metadata driven clinical artefacts development

Introduction of Metadata

- Definition
  - Data about other data
- Examples of metadata

Variable Name	Variable Label	Type	CT	Role	Core
STUDYID	Study Identifier	Char		Identifier	Req
DOMAIN	Domain Abbreviation	Char	DM	Identifier	Req
USUBJID	Unique Subject Identifier	Char		Identifier	Req

Types of Metadata

- Structural metadata

Variable Name	Variable Label	Type	CT	Role	Core
USUBJID	Unique Subject Identifier	Char		Identifier	Req
Age	Age	Num		Identifier	Req

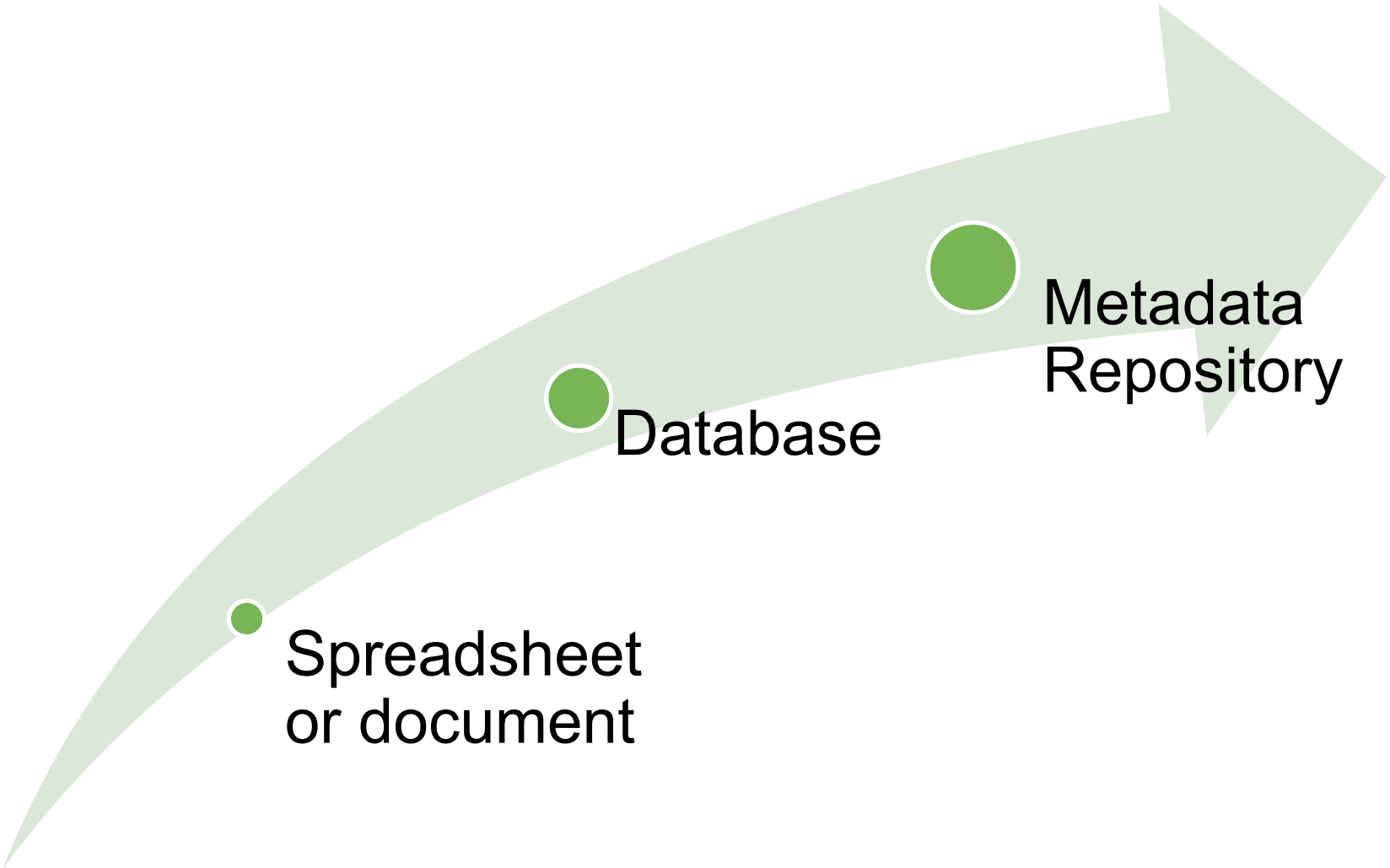
- System agnostic transformation metadata

Target dataset	Target variable	Business Rule	Source dataset	Source variable
DM	USUBJID	is equal to	DEMO	USUBJID
DM	AGE	Age from birth date to study start date		

- System dependable transformation metadata

Target dataset	Target variable	Machine readable derivation	Source dataset	Source variable
DM	USUBJID	=	DEMO	USUBJID
DM	AGE	%AGE(DM.RFSTDTC – BRTHDTC)		

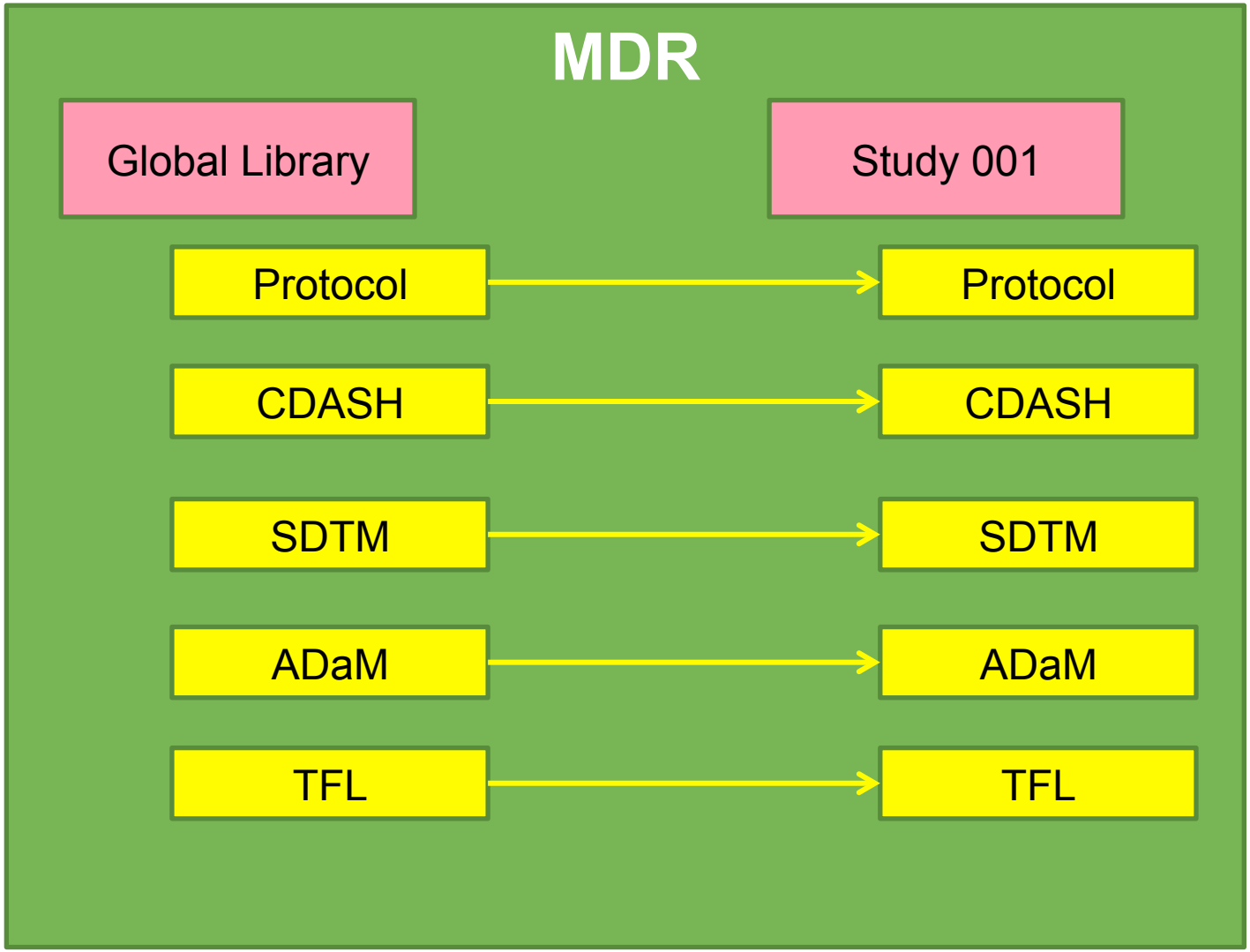
Evolution of metadata technology



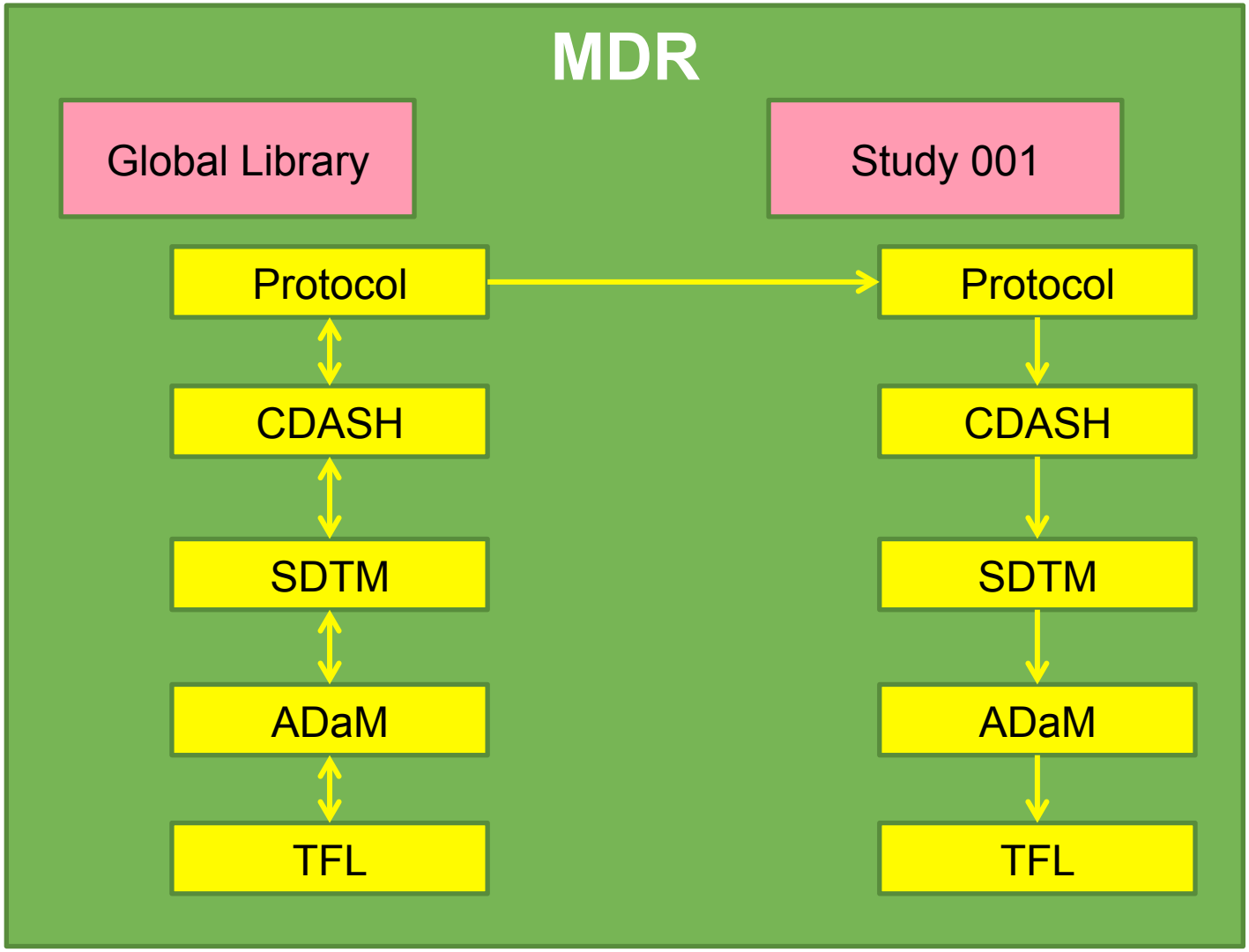
Metadata Repository (MDR)

- General definition: an application for database created to store metadata.
- Its function in healthcare:
  - Develop and maintain Standards metadata(e.g., CDISC Standards and sponsors-specific Standards)
  - Govern Standards metadata(e.g., workflow, people)
  - Control Standards versions
  - Store the history of all the activities(e.g., request, development, approval and retirement)
  - Provide taxonomy/level of Standards and their library
    - Industry/Dictionary
    - Global, Therapeutic, Compound, Study

Study level metadata definition development in MDR

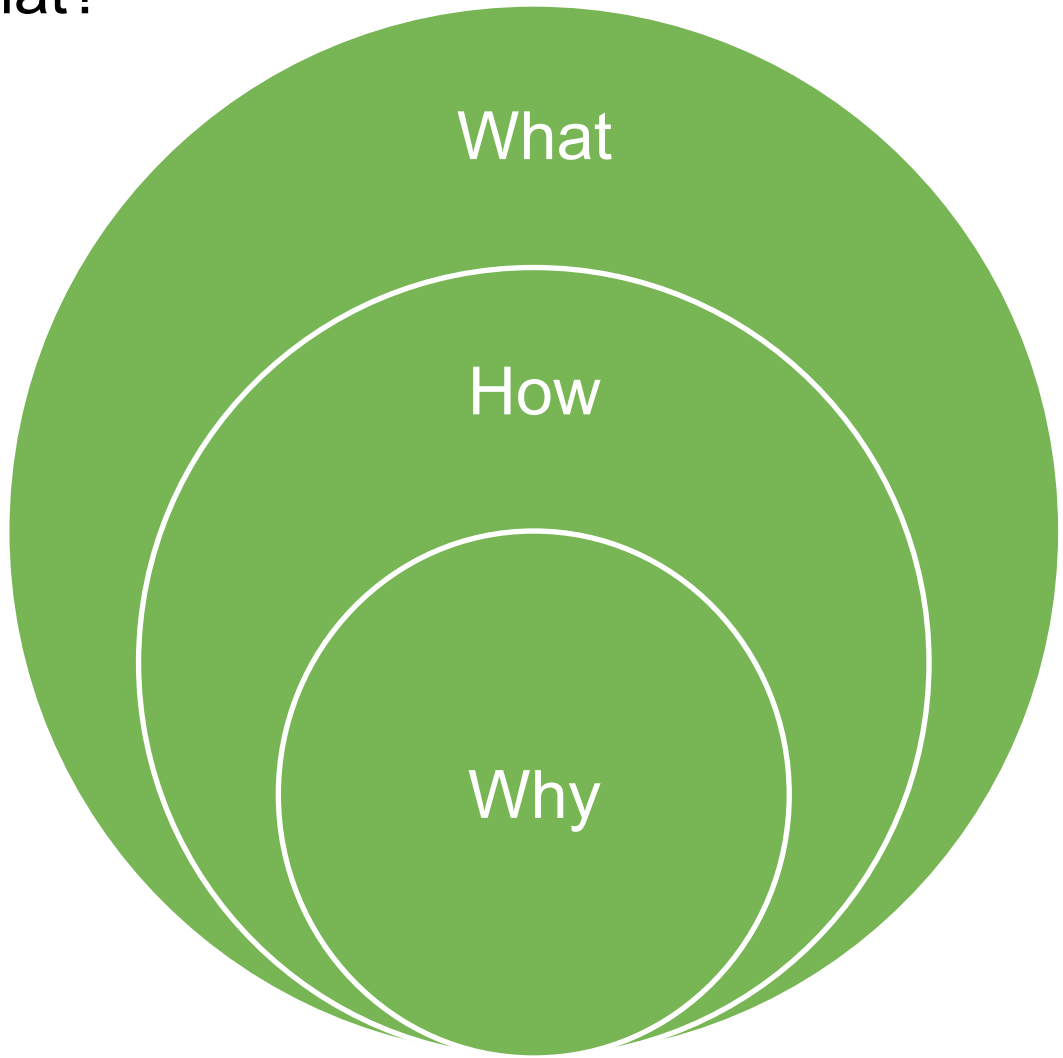


Study level metadata definition development in MDR (2)

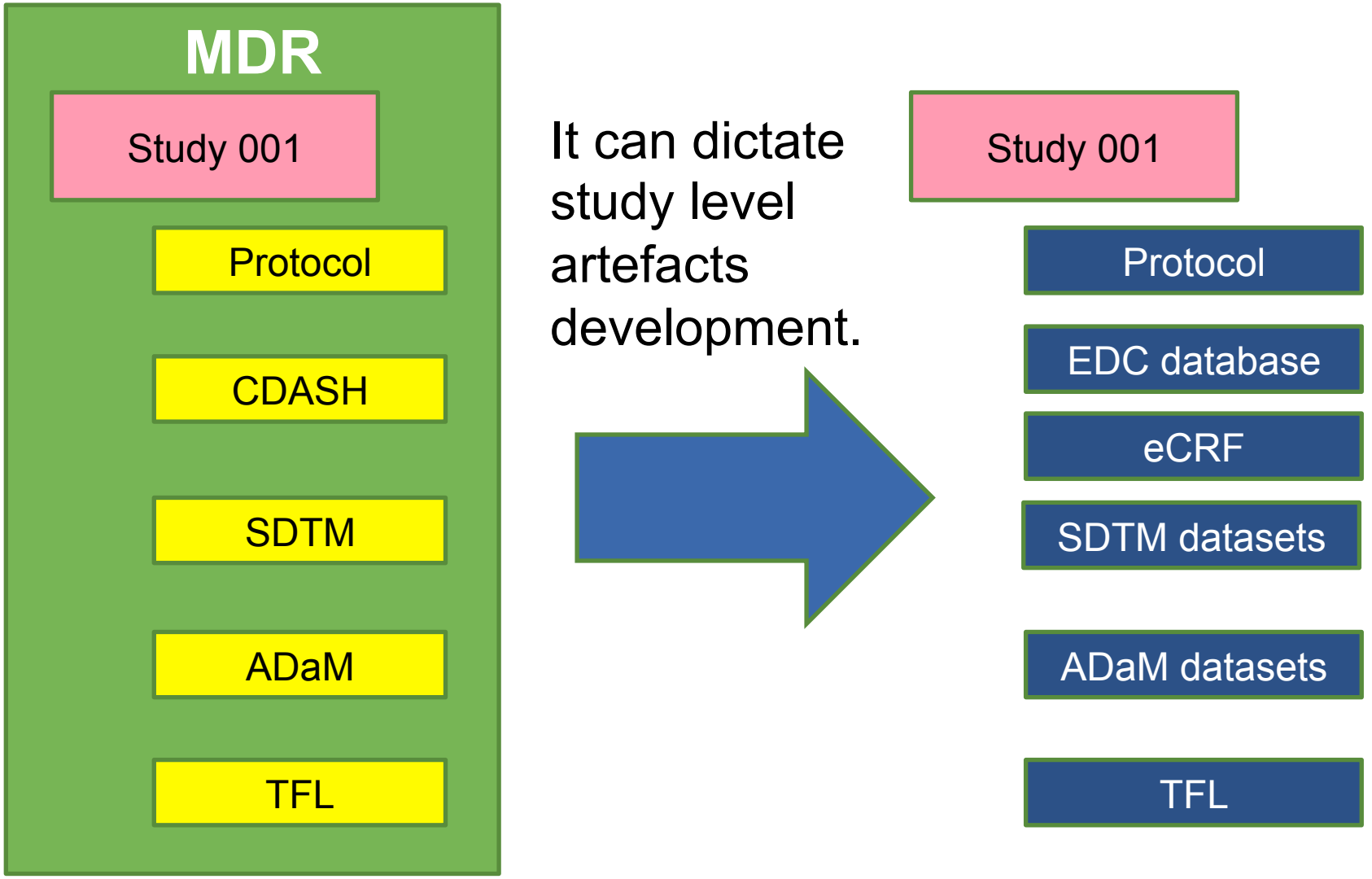


Question

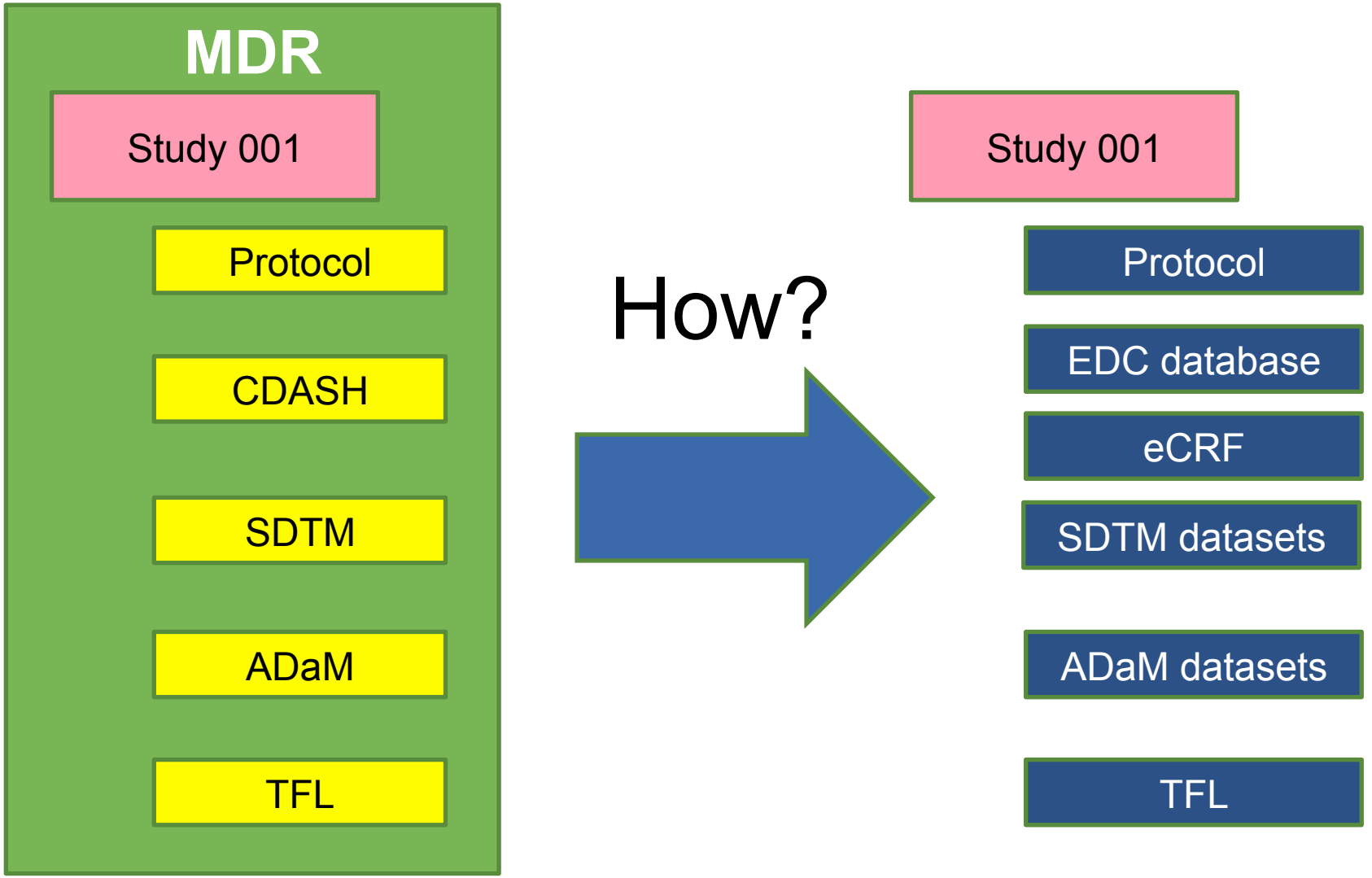
- Now, we built all the study level metadata in MDR, but then what?



Why is Study Level metadata definition in MDR important?

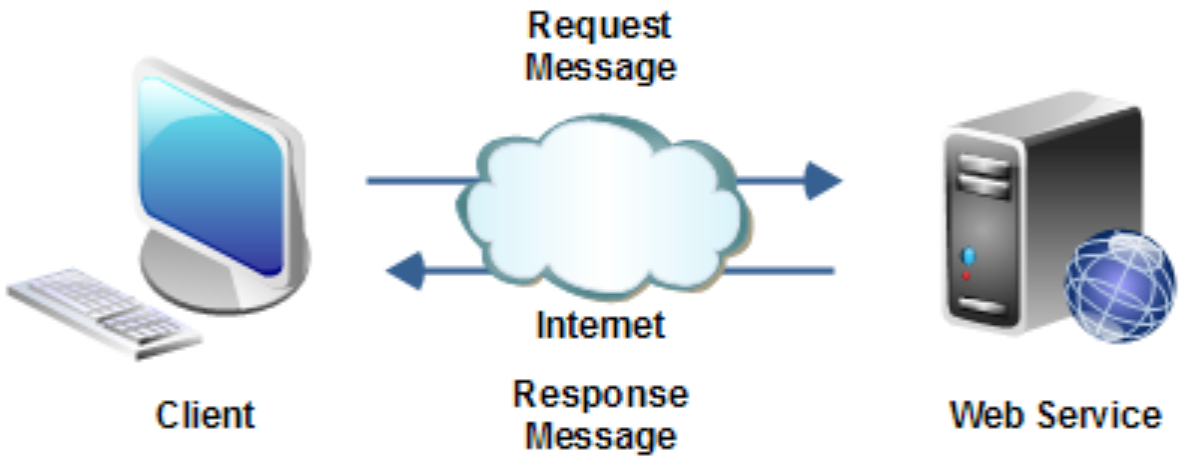


How can study level metadata in MDR be used to create artefacts?



Data(e.g., metadata) exchange over internet

Introduction of a web service



A web service is a method of communication that allows two software systems to exchange the data over the internet. Two primary architectures for web services are SOAP and REST.

Introduction of Simple Object Access protocol (SOAP)

Simple Object Access protocol (SOAP) is a protocol specification for data exchange in web services.

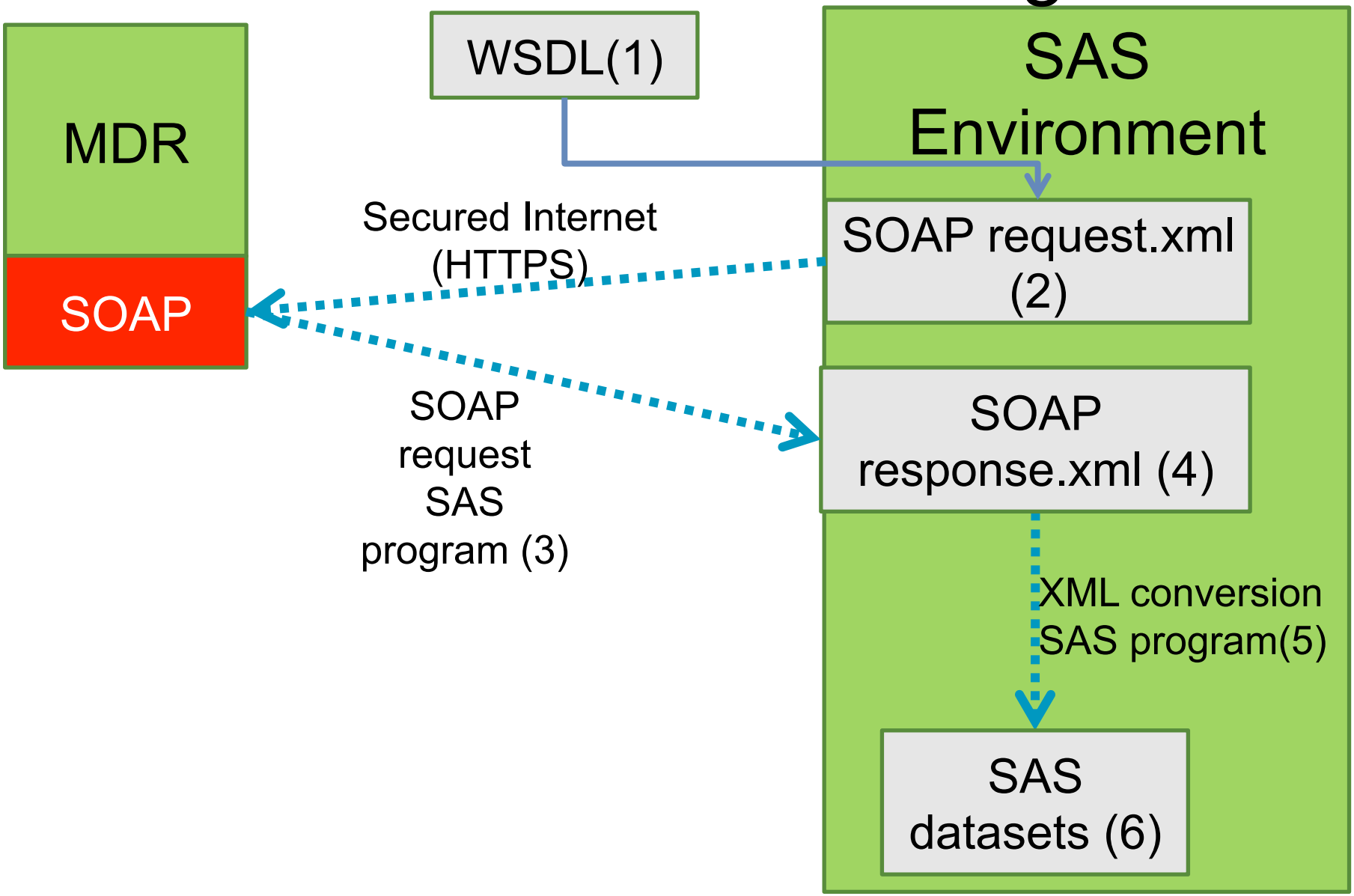
- It is platform, system and language independent and communicates through the internet.
- It uses XML format and Hypertext Transfer Protocol (HTTP).
- It sends request files in XML and receives response file in XML.
- Structures: SOAP envelope, head and body.

Introduction of Representational state transfer (REST)

Representational state transfer (REST) is a simpler data exchange format than SOAP data exchange.

- It is also platform, system and language independent and communicates through the internet.
- It also uses HTTP, but unlike SOAP, response files come ready to be used, not wrapped in SOAP envelope. So, REST does not need to use XML format to send and receive data through web services.
- It could include HTTP Get parameters in the URL

Example of Metadata Flow Diagram between MDR and SAS using SOAP



1. Example of WSDL

- Web Service Description Language (WSDL), which is an XML-based interface definition language that is used for describing the functionality offered by a web service of MDR.
- With WSDL and SOAPUI, SOAP XML request file can be created.
- Example:

```
<wsdl:definitons xmlns:wsdl="http://schemas.xmlsoap.org/wsdl"
xmlns:s="http://www.w3.org/2001/XMLschema" >
   <wsdl:types>
         <s:element name="GetMetadata"> <s:sequence>
            <s:element name="Study"/> <s:element name="Standards"/>
         </s:sequence> </s:element">
        ….
   </wsdl:types>
…..
```

2. Example of SOAP XML request file to MDR

```
<soapenv:Envelope  xmlns:soapenv="http://
schemas.xmlsoap.org/soap/envelope/" xmlns:ns="http://
www.accenture.adrs.com/quantum/client1">
   <soapenv:Header/>
   <soapenv:Body>
      <ns:GetMetadata>
         <ns:Study>study001</ns:Study>
         <ns:Standards>SDTM</ns:Standards>
      </ns:GetMetadata>
   </soapenv:Body>
</soapenv:Envelope>
```

3. Example of SAS program for SOAP request

```
FILENAME request 'T:\study001\Request.xml' ;
FILENAME response 'T:\study001\Response.xml';

DATA _NULL_;
** URL is from SOAP Header in POST;
        url="http://www.accenture.adrs.com/quantum/client1";
** SOAPACTION is from SOAP Header in POST;
        SOAPACTION='GetMetadata';
        rc=SOAPWEB("request",url,"response",soapaction,,,,,,,);
RUN;
```

4. Example of SOAP XML response file from MDR

```
<?xml version="1.0" encoding="UTF-8"?>
    <GetMetadataResponse >
      <GetMetadataResult  xmlns="http://www.cdisc.org/ns/sdtm/v3.2" >
          <domain label="Demographics" name="DM">
              <variable>
                    <name>USUBJID</name>
                    <label>Unique subject Identifier</label>
                    <type>Char</type>
                    <source>DEMO.USUBJID</source>
                    <deriviation>=</deriviation>
              </variable>
              <variable>
                    <name>AGE</name>
                    <label>Age</label>
                    <type>Num</type>
                    <source>DM.RFSTDTC DM.BRTHDTC</source>
                    <deriviation>%AGE(DM.RFSTDTC, DM.BRTHDTC)</deriviation>
               </variable>
          </domain>
      </GetMetadataResult>
    </GetMetadataResponse>
```

5. Example of SAS program to convert XML files to SAS datasets

```
** SOAP response xml files;
filename  myresp "T:\study001\Response.xml";

**** Create response xml map file;
filename  respmap " T:\study001\response.map";
libname myresp xmlv2 xmlmap=respmap automap=replace;

**** Convert SOAP response xml files to SAS temporary dataset
in work area;
proc copy in=myresp out=work;
run;

Data
```

6. Example of SAS datasets from SOAP request file

domain SAS dataset

GetMetadataResult_ORDINAL	domain_ORDINAL	domain_name	domain_label
1	1	DM	Demographics

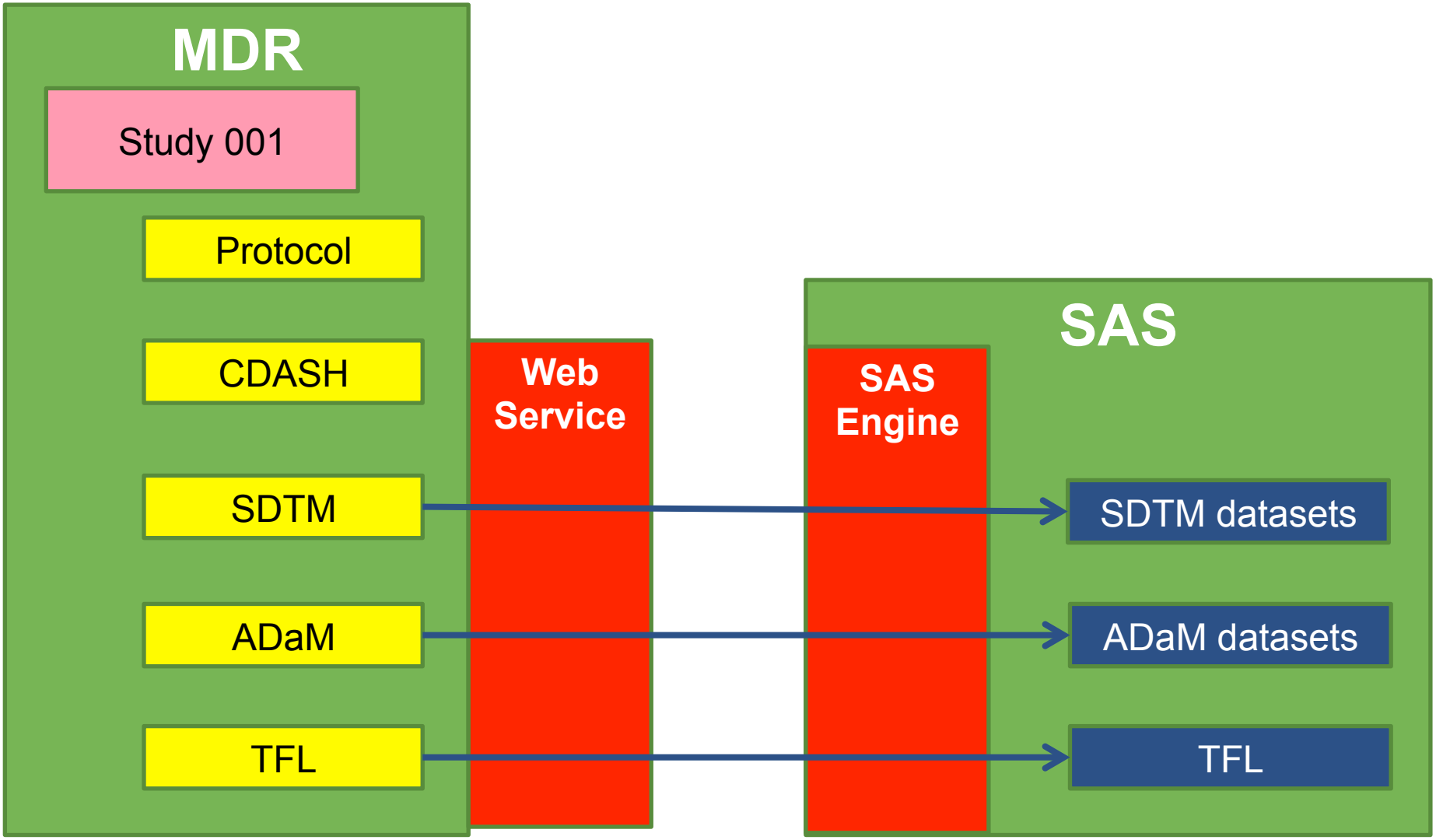
variable SAS dataset

domain_ORDINAL	variable_ORDINAL	name	label	type	source	derivation
1	1	USUBJID	Unique subject identifier	Char	DEMO.USUBJID	=
1	2	AGE	Age	Num	DM.RFSTDTC DM.BRTHDTC	%AGE(DM.RFSTDTC, DM.BRTHDTC)

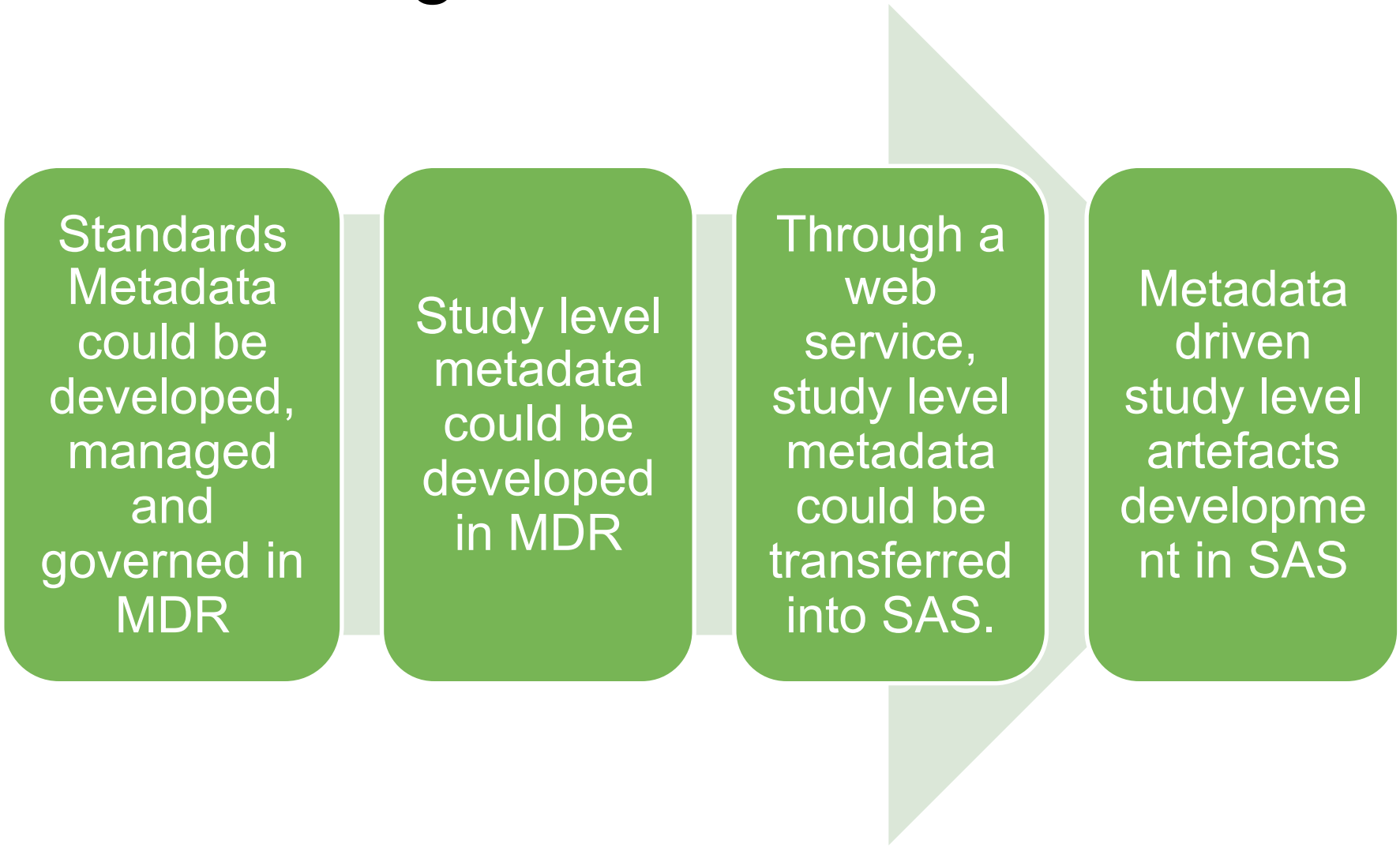
What can we do with metadata from MDR in SAS environment?

- Compliance checks on clinical study artefacts with metadata
- Metadata driven clinical study artefacts development
- Automated clinical study artefacts development driven by metadata.

Metadata driven clinical study artefact development in SAS



Final Thought



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