PhUSE SDE Basel

Data integration automation

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Novartis Campus Basel
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The data integration paradigm

Fragmented

Cumulative

Iterative

Labor intensive

Increasing volume of data

More variety in demands

Narrower time window

How to defragment realizations, promote reusability and improve efficiency ?

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Introducing the Data Integration Factory

Flexible

can address many types of data integration request

Scalable

centralization promotes reusability

Portable

standards independant I/O, for any programmer

Cost efficient

less rework, faster delivery, facilitate validation

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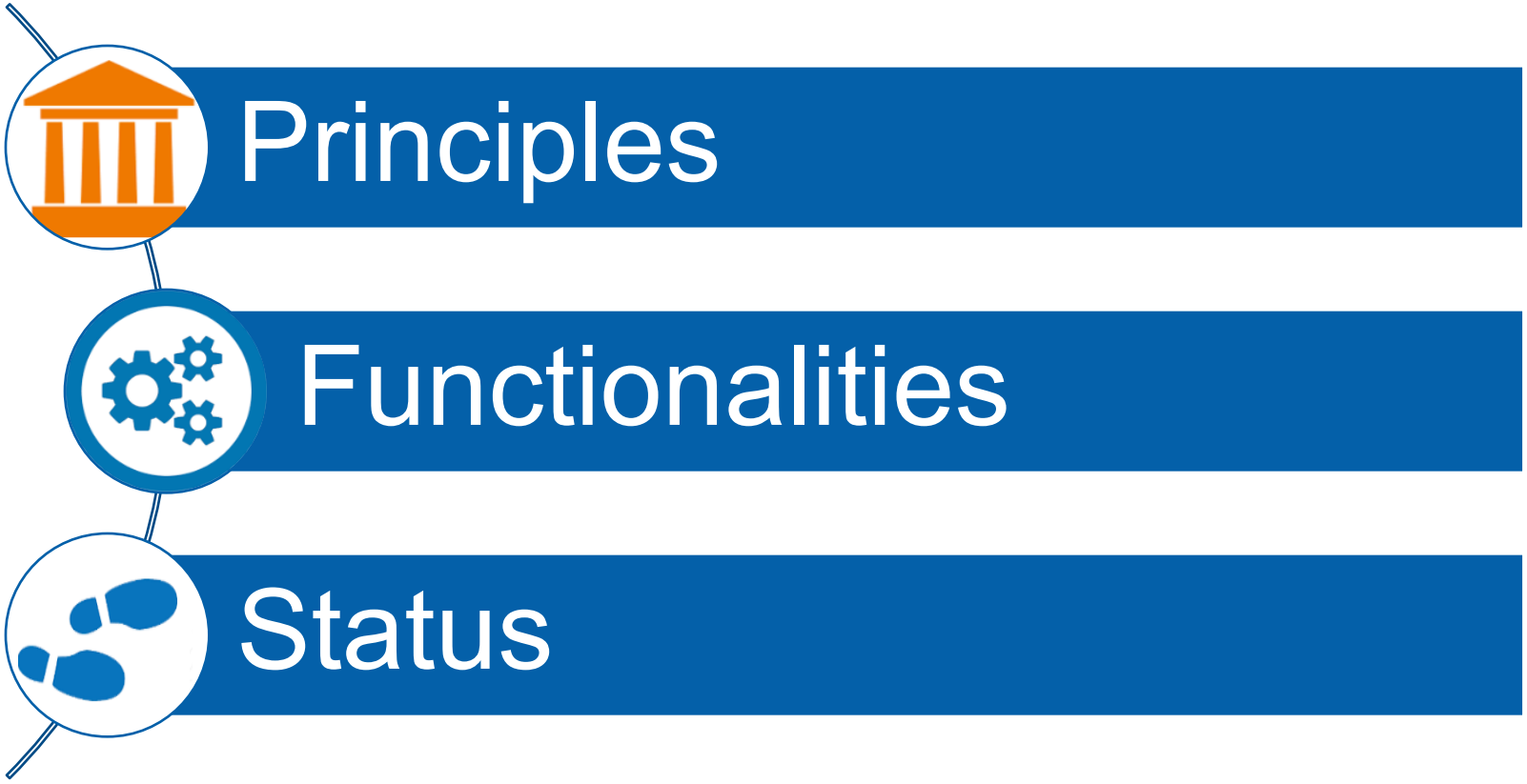
The Data Integration Factory



DIF Principles

Data Integration Factory = end to end framework

Extraction

Transformation

Loading

1- Harmonization

Possible pre or post conformance

Re-usability

Temporary Generic Structure

2- Preparation

Analysis specific

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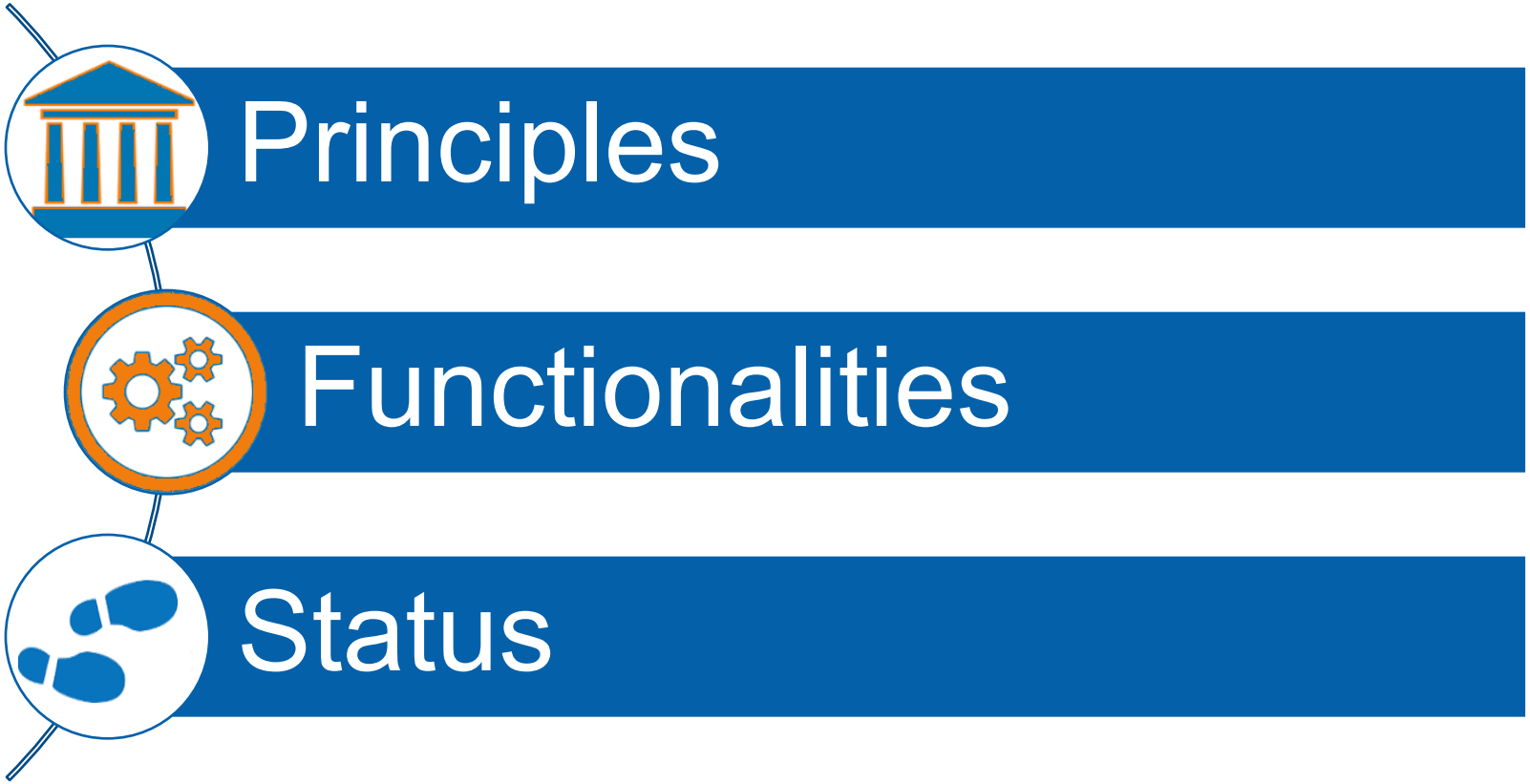
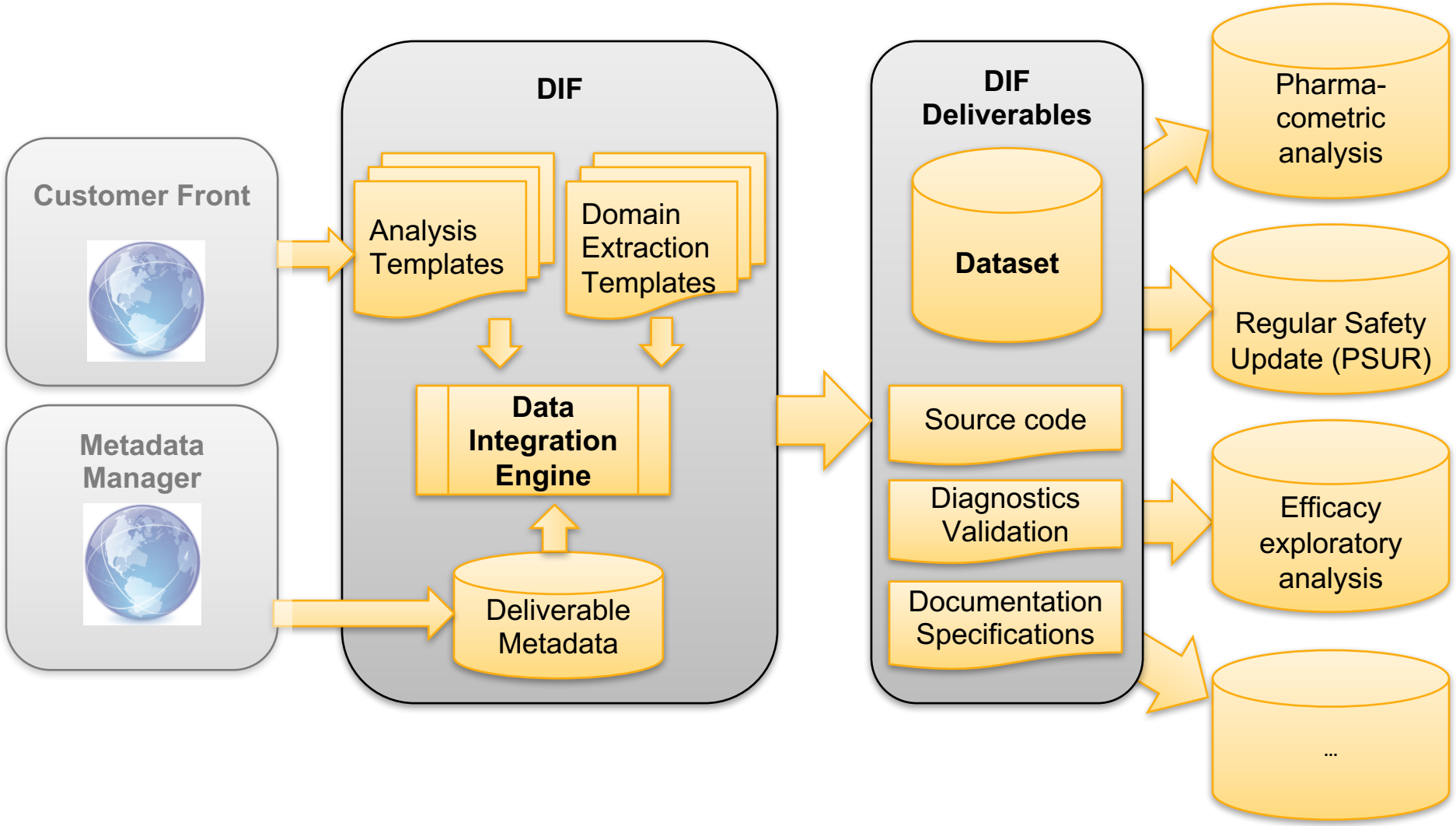
The Data Integration Factory



DIF Functionalities 1/5



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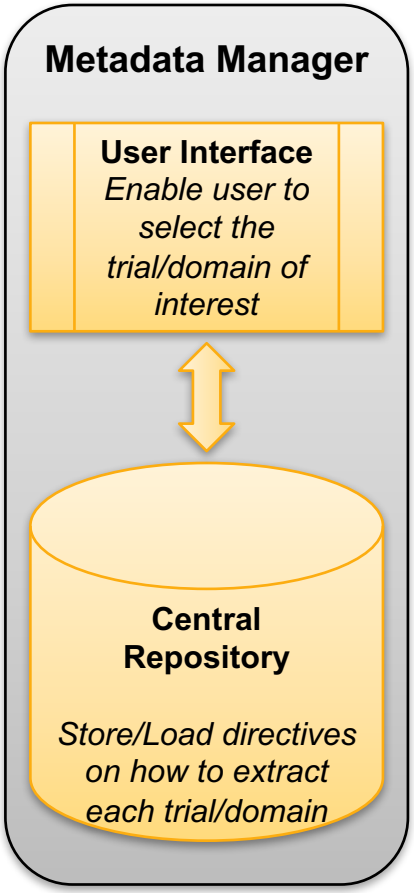
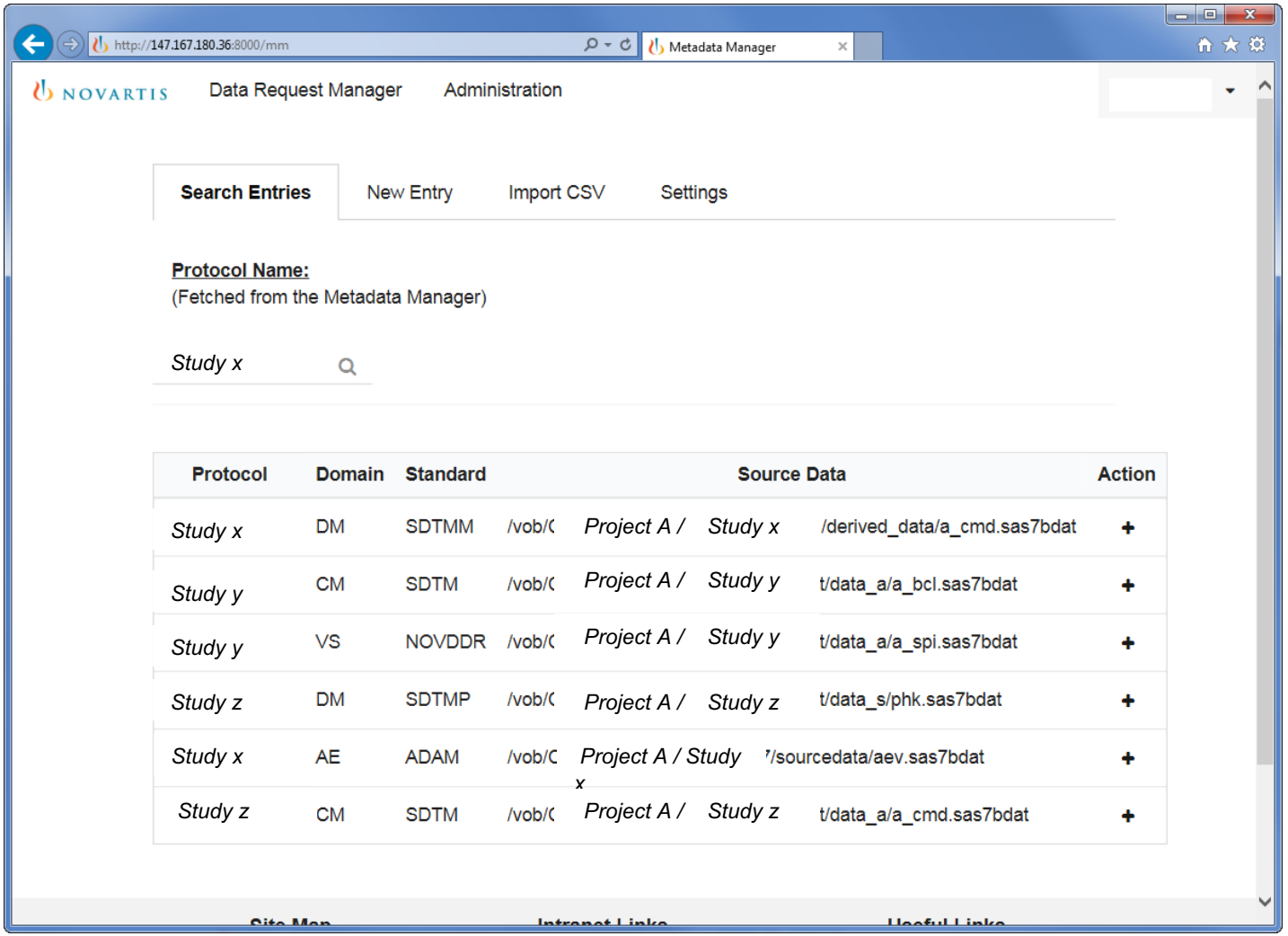
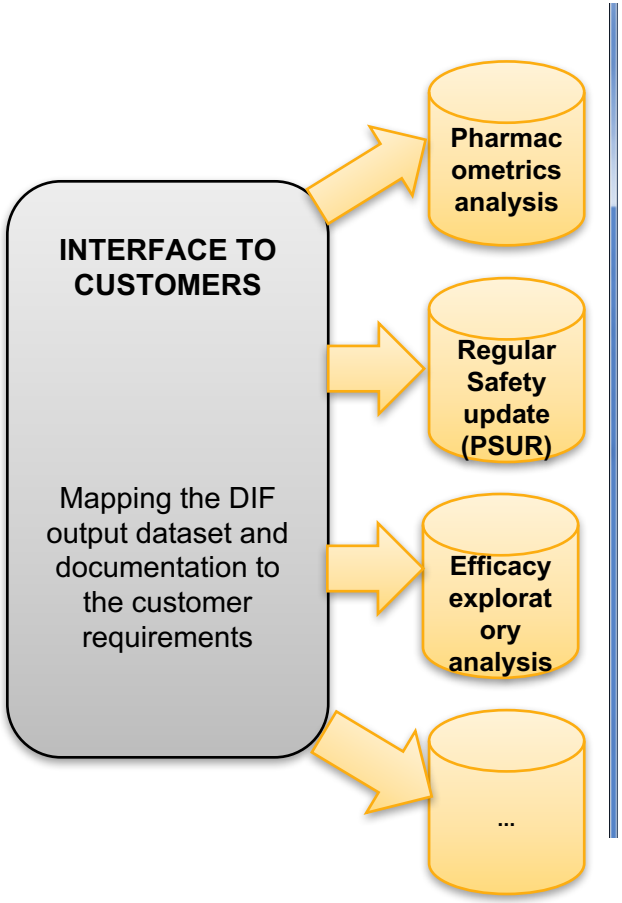
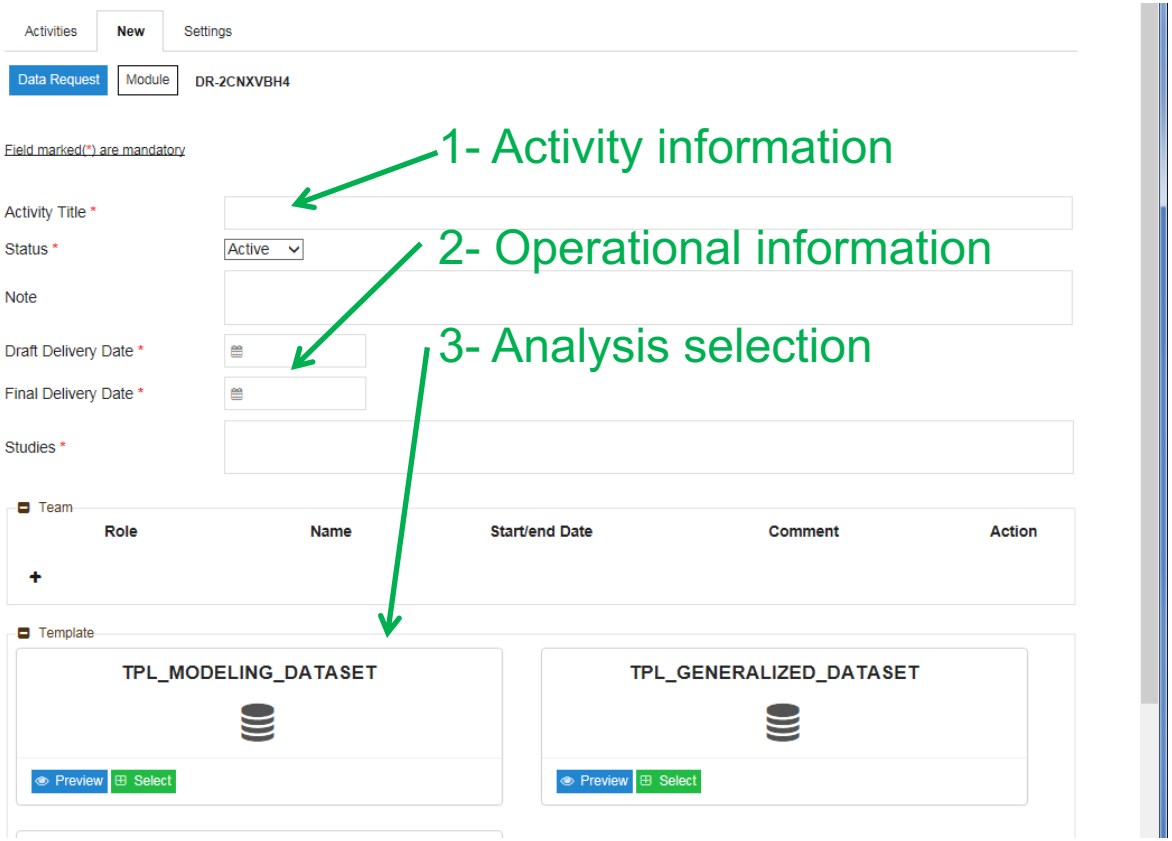
DIF Functionalities 2/5
Metadata manager (user front)



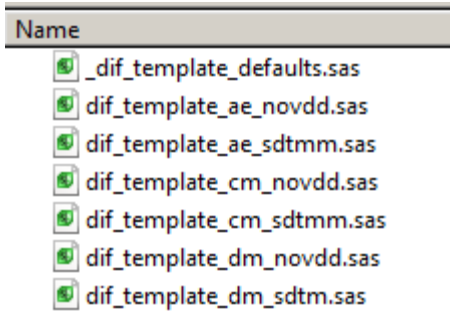


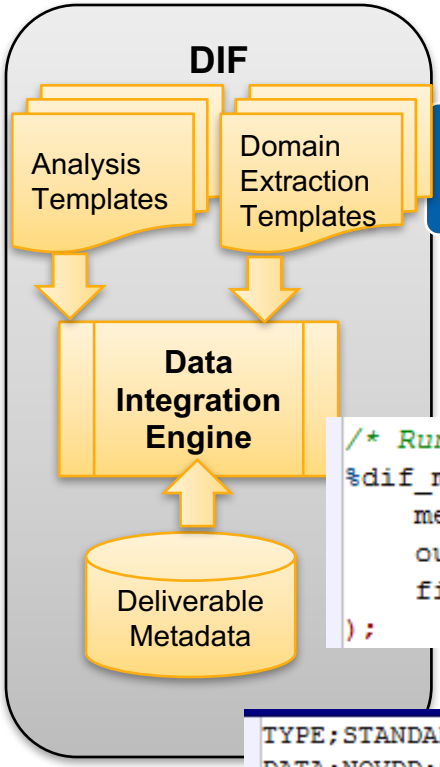
DIF Functionalities 3/5
Customer front

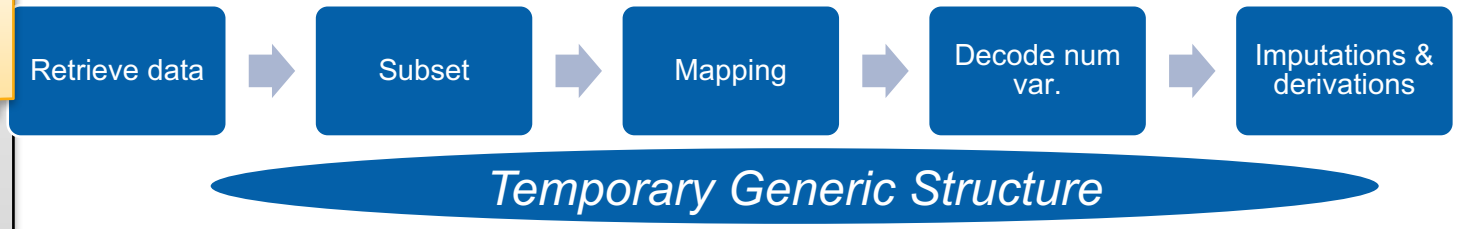




DIF Functionalities 4/5
The core



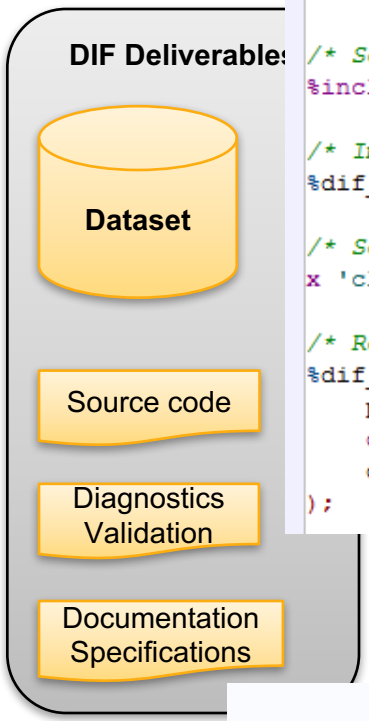





```
/* Run DIF */
%dif_main(
    metadataFile=/vob/CMNSGEN/PMXPA/util/dif_dev/_examples/Example01/mt92395_md.csv,
    outDir= /vob/CMNSGEN/PMXPA/util/dif_dev/_examples/Example01,
    filePrefix= mt92395
);
```

```
TYPE;STANDARD;PROTOCOL;DOMAIN;SOURCEDATA;SUBSET;VARIABLES
DATA;NOVDD;Study_x;DM;/vob/Project_A/Study_x/report/data_s/dmg.sas7bdat;;
DATA;NOVDD;Study_x;EX;_PRE_;;
DATA;NOVDD;Study_x;LB;_PRE_;PARNAM1C in ('HGB' 'ABSLYM');
DATA;SDTMM;study_y;DM;/vob/Project_A/Study_y/report/data_s/dm.sas7bdat;;
DATA;SDTMM;study_y;EX;/vob/Project_A/Study_y/report/data_s/zq.sas7bdat;;
DATA;SDTMM;study_y;LB;/vob/Project_A/Study_y/report/data_s/lb.sas7bdat;LPARM in ('HGB' 'LYM');
```

DIF Functionalities 5/5
Deliverables




```
/* Start timer */
%let dif_start= %sysfunc(datetime());

/* Setup DIF environment */
%include '/vob/CMNSGEN/PMXPA/util/dif/system/dif_setup.sas';

/* Import metadata */
%dif_import metadata(inFile=/vob/CINC280X/pool/pool 003/report/pgm a/inc aepool L R1 md.csv, order=  );

/* Set us
x 'cleart

/* Retrie
%dif_extr
    proto
    data=
    domai
);
```

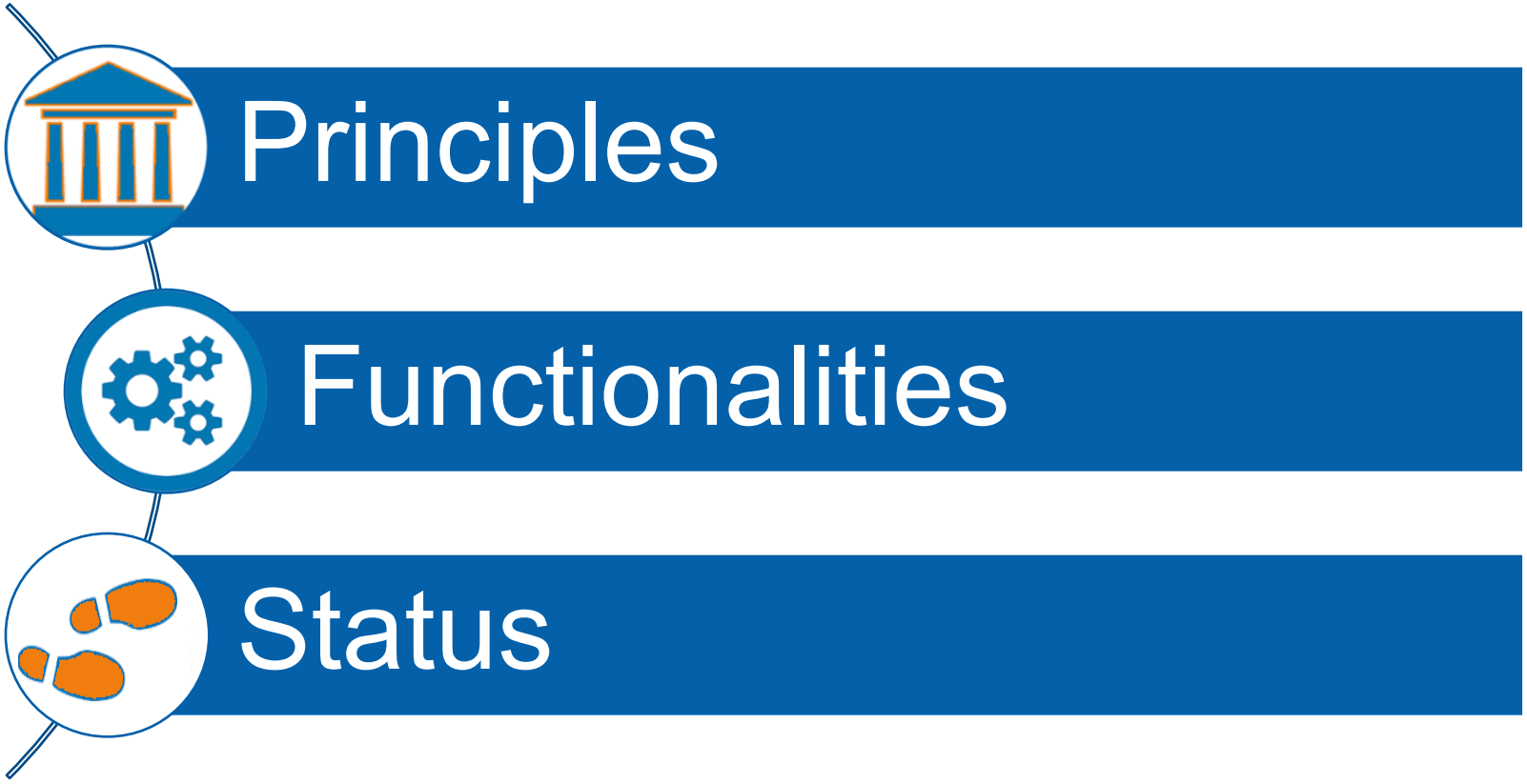
Overall summary of numerical variables

		N	NMiss	Min	P25	Median	P75	Max
Age	Study Identifier							
	Study_x	60	0	23.00	36.00	42.50	48.50	65.00
	Study_y	0	480	0	0	0	0	0
Visit Report Number	Study Identifier							
	Study_x	60	0	1.00	1.00	1.00	1.00	1.00
	Study_y	480	0	1.00	1.00	1.00	1.00	1.00

Subjects with several records by USUBJID, PARAM, SDAT_N, STIM_N, VALUE, UNIT, DAYPART

Unique Study Identifier	Parameter name	Start date (numeric)	Start time (numeric)	Parameter value	Parameter unit	Day part	Count
Study_x/Patient_1	Lab_1	2012-10-29	12:00:00	1	mL		2
Study_x/Patient_1	Lab_1	2012-11-26	11:05:00	1	mL		2

The Data Integration Factory



Status

DIF Status

- Approaching 1st Release

Promising first experiences

- on pharmacometric analysis (popPK data composed of demog, PK, lab, vital signs, exposure)
- on adverse events target reporting in few different compounds for exploratory and potential safety update

Benefits of the Data Integration Factory

Flexible

can address many types of data integration request

Scalable

centralization promotes reusability

Portable

standards independant I/O

Cost efficient

less rework, faster delivery, facilitate validation

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Thank you!

Acknowledgements

- **Novartis Pharmacometrics Programming team et al**

Questions & Open discussion

- Any different challenges for clinical data integration?
- Any different approaches / programming solutions ?

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Thank you

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