

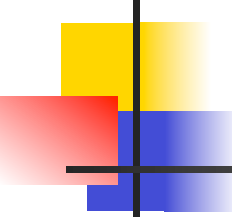
# **How to go from an SDTM Finding Domain to an ADaM-Compliant Basic Data Structure Analysis Dataset: An Example**

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Qian Wang, MSD, Brussels, Belgium

Carl Herremans, MSD, Brussels, Belgium

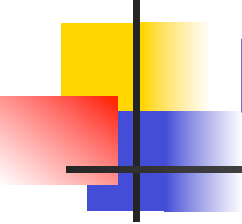
PhUSE 2010, Berlin



# ADaM versus SDTM

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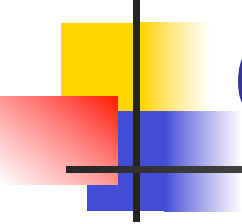
- ADaM datasets do use redundancy for easy analysis – common variables may be found across all analysis datasets (e.g., population flags, subject identifiers, etc.);
- ADaM datasets have a greater number of numeric variables (e.g., SAS formatted dates, numeric representation of a character grouping variable from SDTM);
- ADaM datasets may combine variables from multiple SDTM domains;
- ADaM datasets are named AD<xxxxxx>.



# ADaM-compliant Basic Data Structure (BDS)

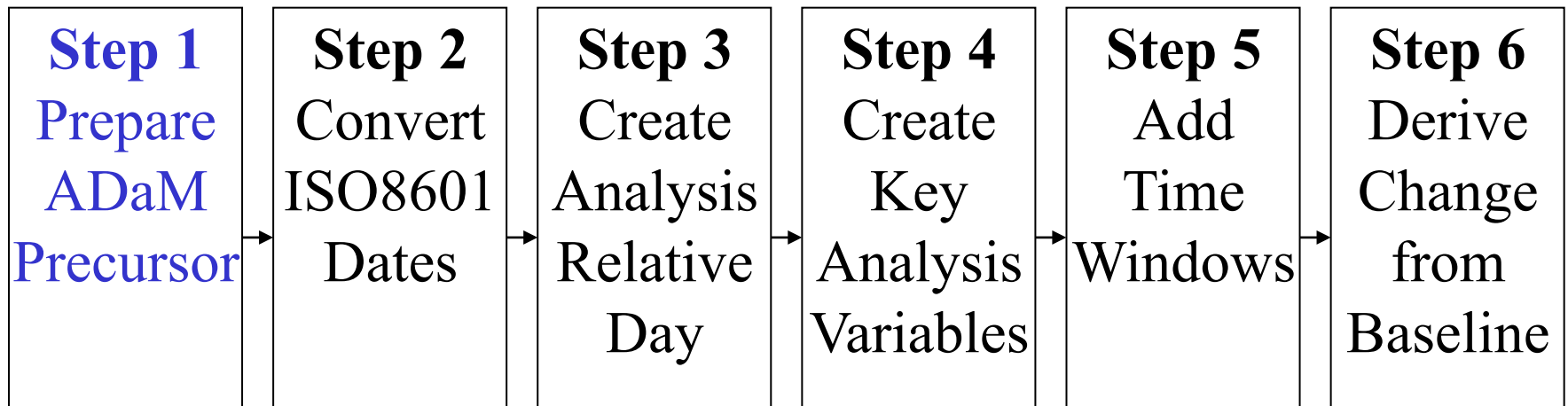
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- A BDS dataset contains one or more records per subject, per analysis parameter and per analysis time point.
- It describes the data being analyzed and also includes variables to support the analysis (e.g. covariates) as well as information to facilitate traceability.

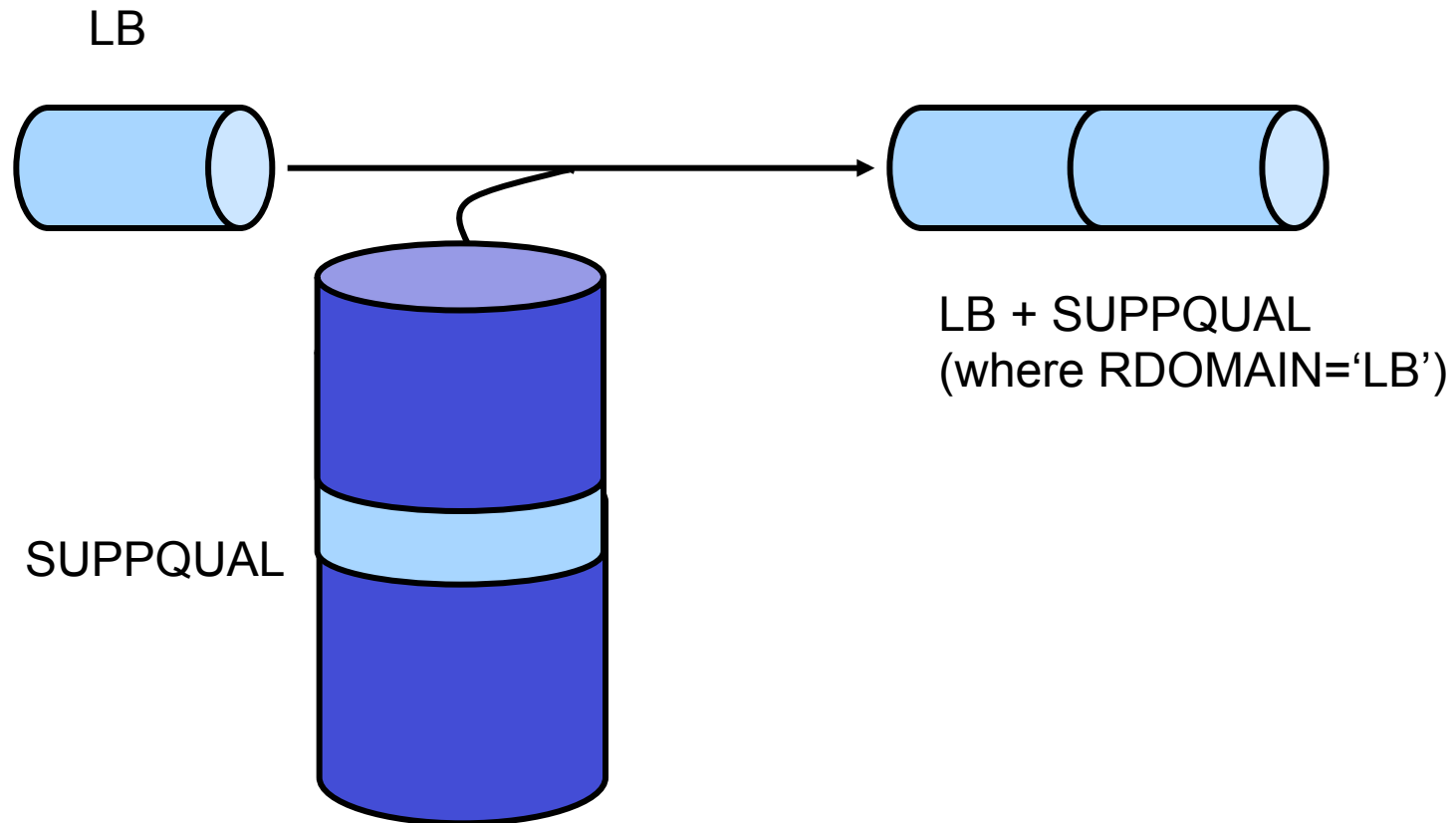


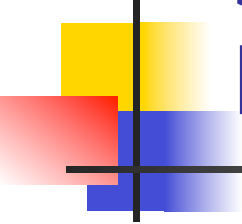
# 6 Basic Steps

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# STEP 1: Preparing for ADAM Precursor by Adding SUPPQUAL to SDTM





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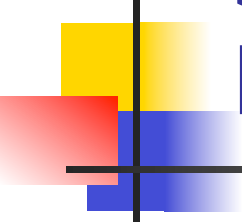
| USUBJID   | SEX | LBSEQ | LBTESTCD | LBORRES |
|-----------|-----|-------|----------|---------|
| 0002_0001 | M   | 1     | NA       | 0.1     |

+

| STUDYID | RDOMAIN | USUBJID   | IDVAR | IDVARVARL | QNAM   | QVAL |
|---------|---------|-----------|-------|-----------|--------|------|
| 0002    | LB      | 0002_0001 | LBSEQ | 1         | LBFAST | Y    |



| USUBJID   | SEX | LBSEQ | LBTESTCD | LBORRES | LBFAST |
|-----------|-----|-------|----------|---------|--------|
| 0002_0001 | M   | 1     | NA       | 0.1     | Y      |

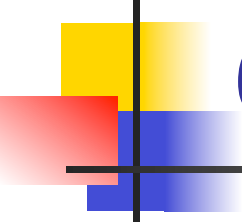


# STEP 1: Preparing for ADAM Precursor by Adding SUPPQUAL to SDTM

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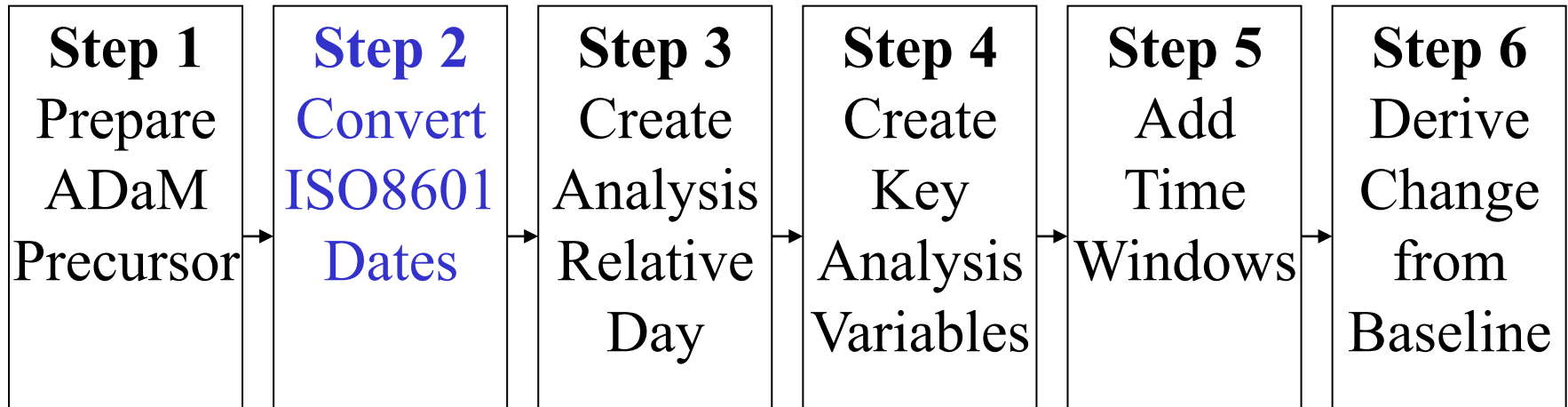
```
proc transpose data=supplb  
    out=supplb2 (rename=(idvarval=lbseq));  
by usubjid idvarval;  
var qval;  
id qnam;  
idlabel qlabel;  
run;
```

```
%addsuppqual(input_library =,  
              input_dataset_suppqual =,  
              input_dataset_define =,  
              output_library =  
              );
```



# 6 Basic Steps

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# STEP 2: Converting ISO8601 Date/Time

--DTC

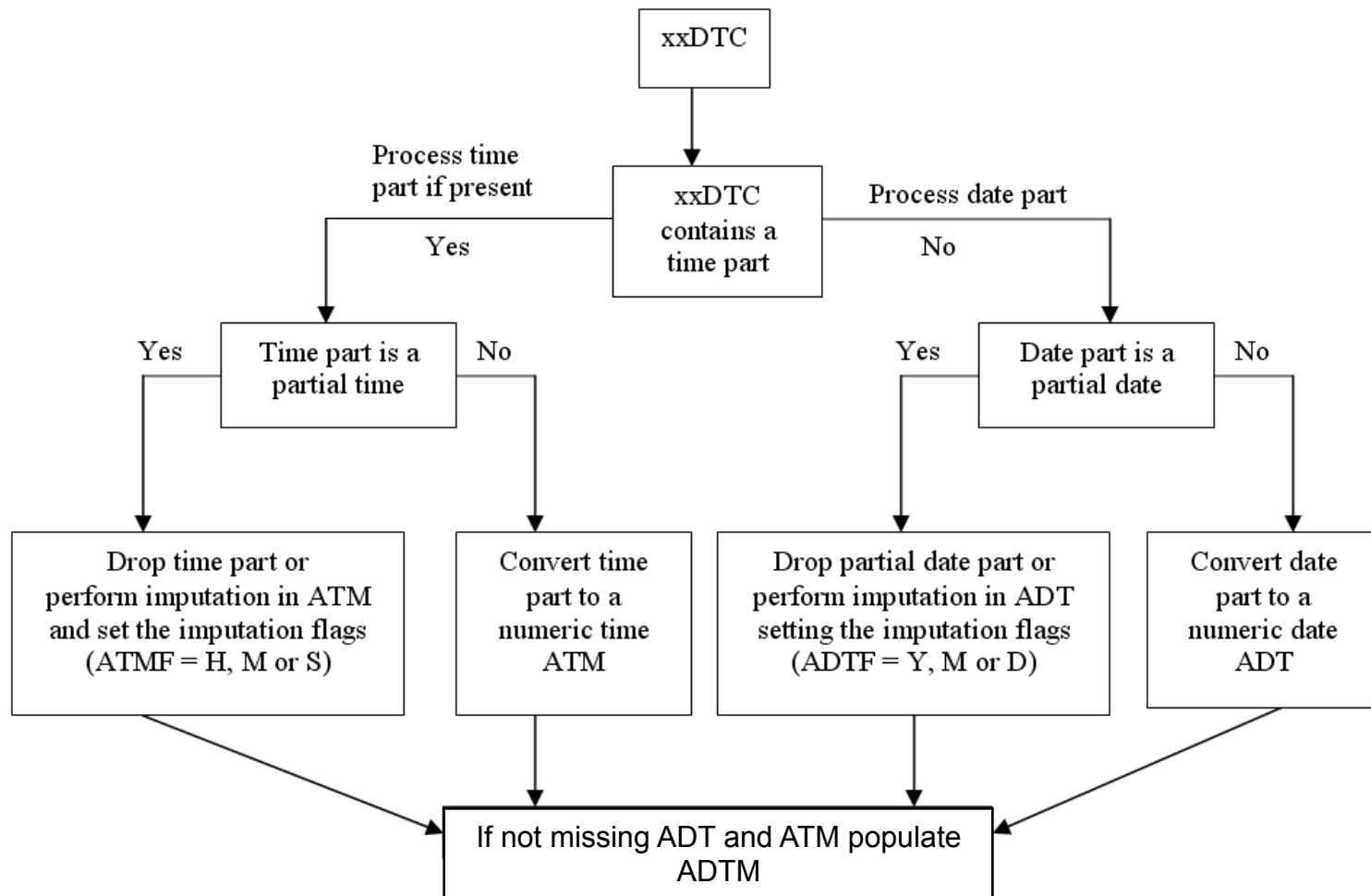
2003-12-15T13:14:17

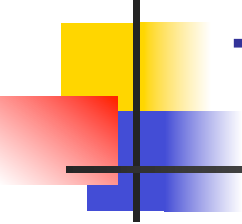


Table 3.2.3.1 Timing Variables for BDS Datasets

| Variable Name | Variable Label     | Type | Codelist / Controlled Terms | Core | CDISC Notes                                                        |
|---------------|--------------------|------|-----------------------------|------|--------------------------------------------------------------------|
| ADT           | Analysis Date      | Num  |                             | Perm | The date associated with AVAL and/or AVALC in numeric format.      |
| ATM           | Analysis Time      | Num  |                             | Perm | The time associated with AVAL and/or AVALC in numeric format.      |
| ADTM          | Analysis Date/Time | Num  |                             | Perm | The date/time associated with AVAL and/or AVALC in numeric format. |

# STEP 2: Converting ISO8601 Date/Time



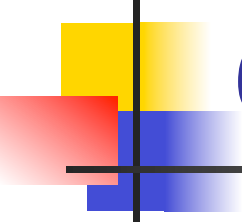


# STEP 2: Converting ISO8601 Date/Time

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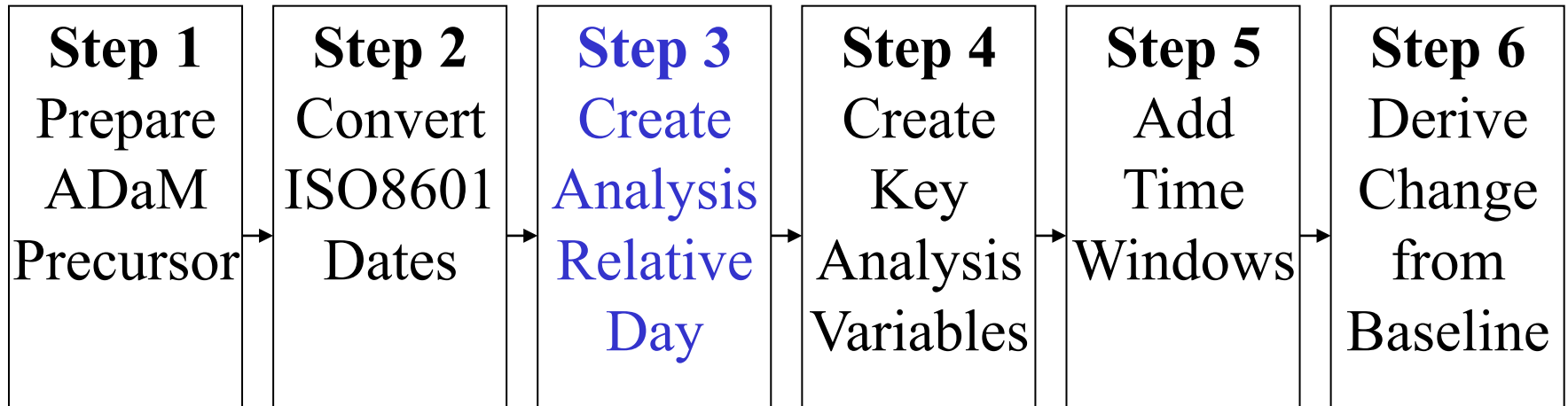
| --DTC               | ADT       | ADTF | ATM      | ATMF | ADTM               |
|---------------------|-----------|------|----------|------|--------------------|
| 2003-12-15T13:14:17 | 15Dec2003 |      | 13:14:17 |      | 15Dec2003:13:14:17 |
| 2003-12-15T13:14    | 15Dec2003 |      | 13:14:00 | S    | 15Dec2003:13:14:00 |
| 2003-12-15T13       | 15Dec2003 |      | 13:00:00 | M    | 15Dec2003:13:00:00 |
| 2003-12-15          | 15Dec2003 |      |          |      |                    |
| 2003-12             | 01Dec2003 | D    |          |      |                    |
| 2003                | 01Jul2003 | M    |          |      |                    |

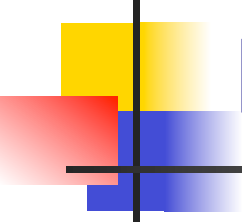
```
%convert2date(input_dataset=,  
               output_dataset=  
               );
```



# 6 Basic Steps

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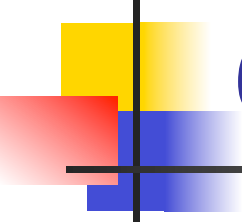




## STEP 3: Creating Analysis Relative Day

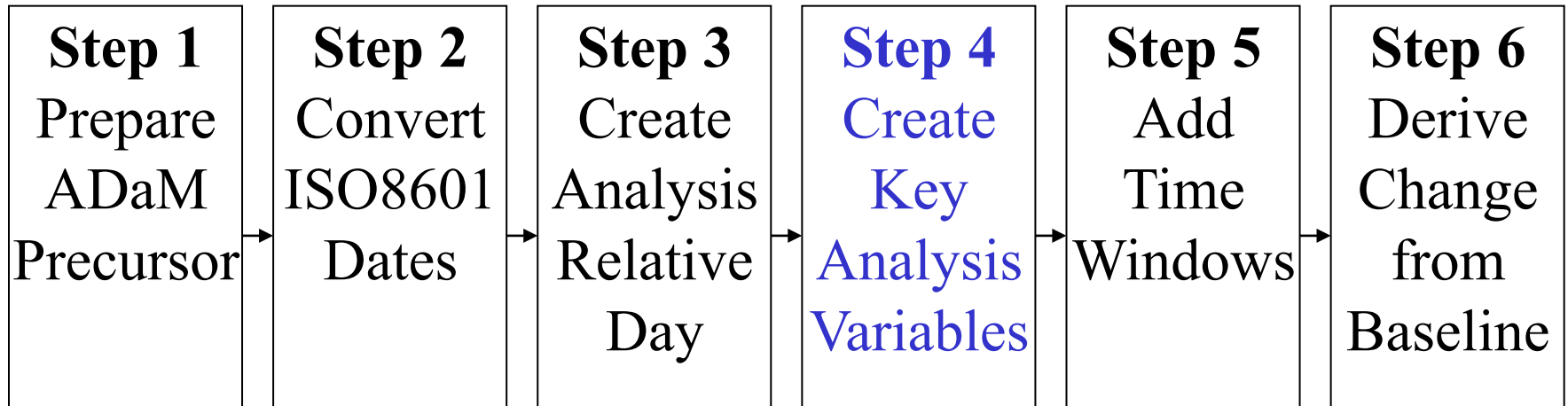
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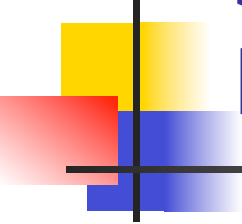
$$\text{ADY} = \text{LBDT} - \text{ADSL.TRTSDT} + \\ (\text{LBDT} > \text{ADSL.TRTSDT})$$



# 6 Basic Steps

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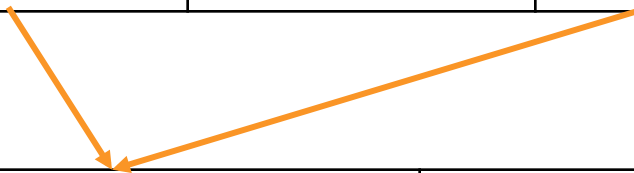


## STEP 4: Creating Key Analysis Parameter Variables PARAM(CD), AVAL

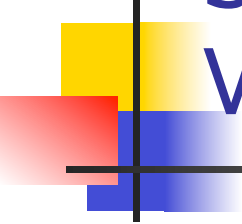
### SDTM LB

| LBTESTCD | LBTEST    | LBSTRESN | LBSTRESU |
|----------|-----------|----------|----------|
| NA       | Sodium    | 139      | mmol/L   |
| K        | Potassium | 3.5      | mmol/L   |

### ADaM ADLB



| PARAMCD | PARAM              | AVAL |
|---------|--------------------|------|
| NA      | Sodium (mmol/L)    | 139  |
| K       | Potassium (mmol/L) | 3.5  |



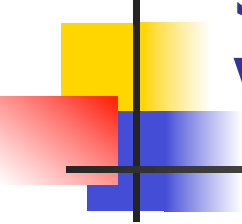
## STEP 4: Creating Key Analysis Parameter Variables PARAM(CD), AVAL

### SDTM LB

| LBDY | LBTESTCD | LBTEST | LBSTRESN | LBSTRESU |
|------|----------|--------|----------|----------|
| 1    | NA       | Sodium | 139      | mmol/L   |
| 1    | NA       | Sodium | 145      | mmol/L   |

### ADaM ADLB

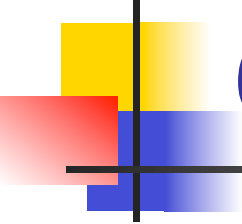
| ADY | PARAMCD | PARAM           | AVAL | DTYPE   | ANL01FL |
|-----|---------|-----------------|------|---------|---------|
| 1   | NA      | Sodium (mmol/L) | 139  |         |         |
| 1   | NA      | Sodium (mmol/L) | 145  |         |         |
| 1   | NA      | Sodium (mmol/L) | 142  | AVERAGE | Y       |



## STEP 4: Creating Key Analysis Parameter Variables PARAM(CD), AVAL

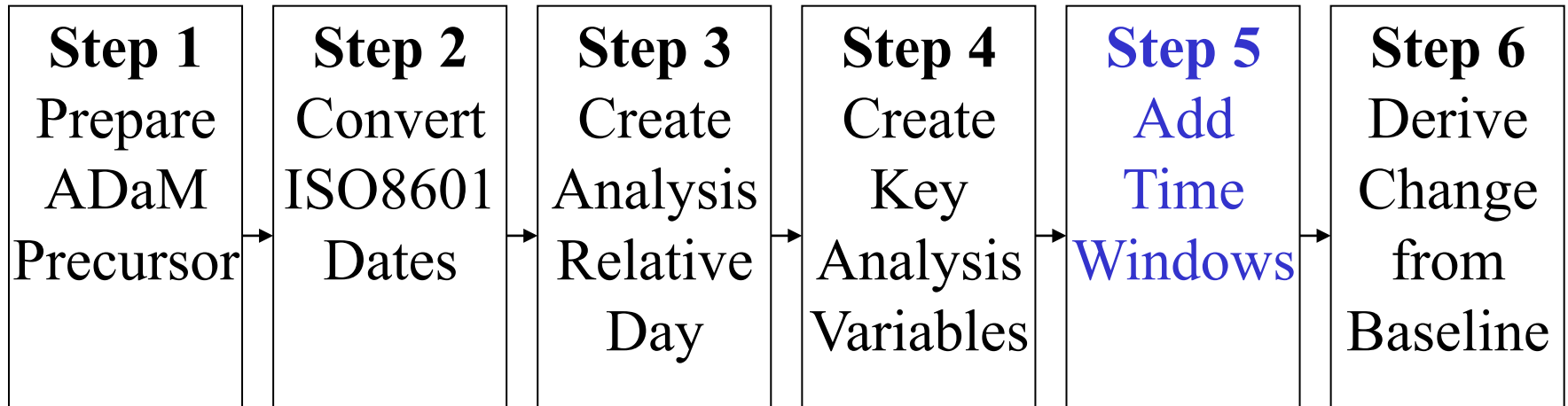
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```
%finding(input_dataset=,  
        domain=,  
        summaryfunction=AVERAGE,  
        output_dataset=  
        );
```



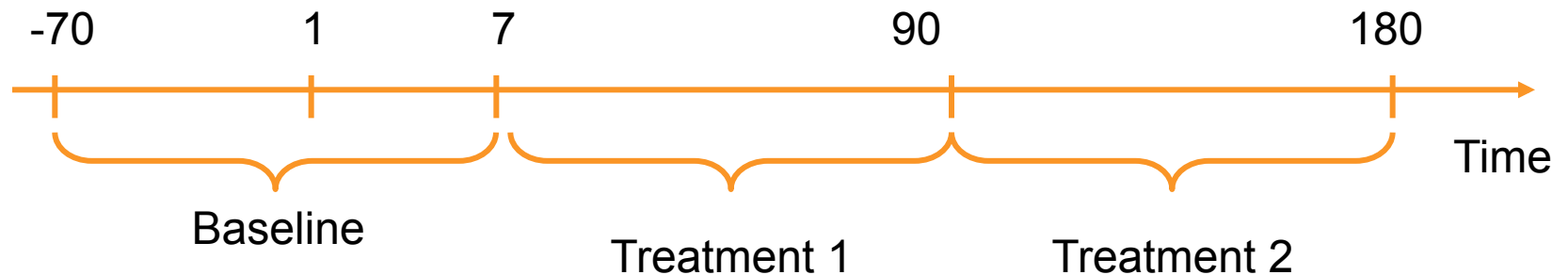
# 6 Basic Steps

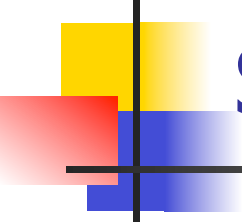
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# STEP 5: ADDING TIME WINDOWS

| Time Point (Target Day) | Time window<br>in Days |
|-------------------------|------------------------|
|                         |                        |
| Baseline (1)            | -70 to 7               |
| Treatment 1 (45)        | 8 to 90                |
| Treatment 2 (135)       | 91 to 180              |

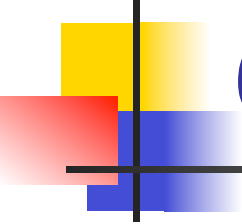




# STEP 5: ADDING TIME WINDOWS

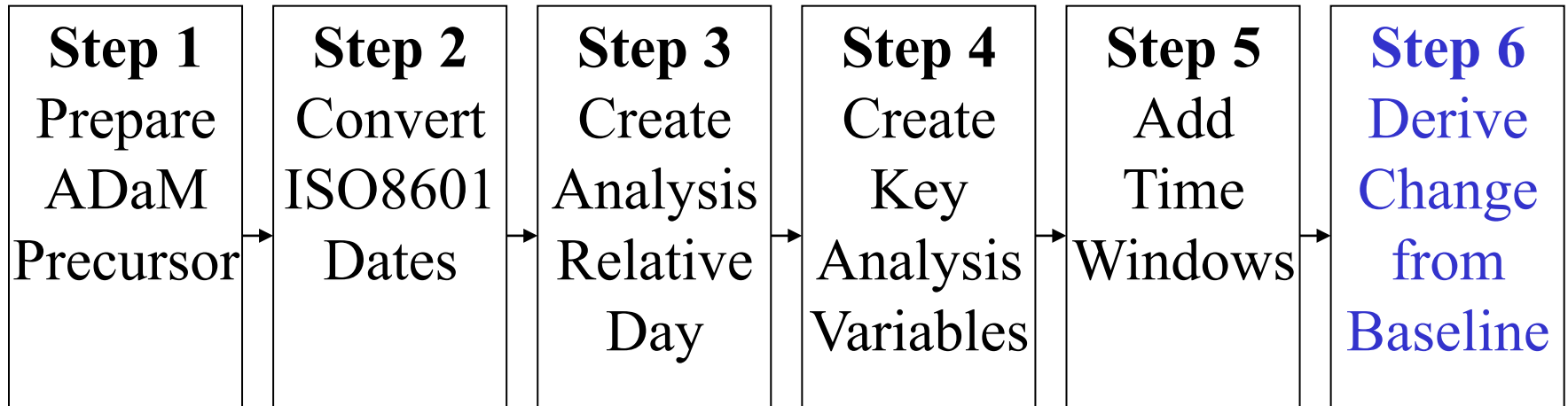
| Start day | Stop day | Target | AVISIT      | AVISITN | Baseline |
|-----------|----------|--------|-------------|---------|----------|
| -70       | 7        | 1      | Baseline    | 0       | Y        |
| 8         | 90       | 45     | Treatment 1 | 1       |          |
| 91        | 180      | 135    | Treatment 2 | 2       |          |

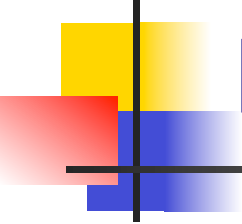
| ADY | PARAMCD | AVAL | AVISIT      | AVISITN | AWTARGET | AWRANGE  | ABLFL | ANL02FL |
|-----|---------|------|-------------|---------|----------|----------|-------|---------|
| -18 | NA      | 141  | Baseline    | 0       | 1        | -70 to 7 |       |         |
| 1   | NA      | 140  | Baseline    | 0       | 1        | -70 to 7 | Y     | Y       |
| 14  | NA      | 145  | Treatment 1 | 1       | 45       | 8 to 90  |       |         |
| 46  | NA      | 149  | Treatment 1 | 1       | 45       | 8 to 90  |       | Y       |



# 6 Basic Steps

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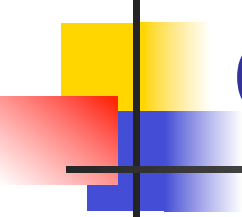


# Step 6: Deriving Change From Baseline

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| ADY | PARAMCD | AVAL | AVISIT      | AVISITN | ABLFL | BASE | CHG |
|-----|---------|------|-------------|---------|-------|------|-----|
| -18 | NA      | 141  | Baseline    | 0       |       | 140  | 1   |
| 1   | NA      | 140  | Baseline    | 0       | Y     | 140  | 0   |
| 14  | NA      | 145  | Treatment 1 | 1       |       | 140  | 5   |
| 46  | NA      | 149  | Treatment 1 | 1       |       | 140  | 9   |

```
%change(input_dataset=,  
        input_timewindow_dataset=,  
        output_dataset=  
        );
```



# Conclusion

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6 Steps have been described to transform a SDTM finding dataset into an ADaM-compliant BDS analysis dataset.

