

- --BLFL Derivation of baseline flags for SDTM
- EPOCH in SE and beyond
- Drug Stop Date / Time
- Empty Variables
- SDTM IG 3.2 – Wrong labels
- Handling of ATC Codes

**Problem:** Scope of baseline flags?  
How should derivation rules look like?

**Solution:** For clinical review only, not for clinical trial report  
Rules should be simple and generic (independent of individual studies)  
Last available value matching timepoint comparison

# Mapping Cases

## --BLFL Derivation of baseline flags for SDTM



Reference DTC	Compare DTC	--BLFL
<b>Only date values available</b>		
2014-08-10	2014-08-10	blank
2014-08-11	2014-08-10	Y
2014-08-10	2014-08-11	blank
<b>Only one end has a time value available</b>		
2014-08-10T12:00	2014-08-10	blank
2014-08-10	2014-08-10T12:00	blank
2014-08-11T12:00	2014-08-10	Y
2014-08-11	2014-08-10T12:00	Y
2014-08-10T12:00	2014-08-11	blank
2014-08-10	2014-08-11T12:00	blank
<b>Date / Time available at both ends</b>		
2014-08-10T12:00	2014-08-10-11:00	Y
2014-08-10T11:00	2014-08-10-12:00	blank
<b>Handling of partial, missing --DTC values? Subject to ADS Creation</b>		
		blank

# Mapping Cases

## EPOCH in SE and beyond

Problem: NCI Code list available but not sufficient  
Need to distinguish multiple treatment / washout periods  
More codes needed, eg „RESIDUAL EFFECT PERIOD“

Solution: Add numbers, such as TREATMENT 1 etc according to IG

Question: Do numbers have a meaning besides the order?  
Eg actual versus planned (TAETORD)  
What if a planned treatment period is skipped?

EPOCH assignment in other domains: -- DTC comparisons?

## Crossover trial: treatment sequence ABCD

USUBJID	SESEQ	ETCD	TAETORD	EPOCH
1000	1	SCRN	1	SCREENING
1000	2	A	2	TREATMENT 1
1000	3	B	3	TREATMENT 2
1000	4	C	4	TREATMENT 3
1000	5	D	5	TREATMENT 4
1000	6	FOLLOWUP	6	FOLLOW-UP
2000	1	SCRN	1	SCREENING
2000	2	A	2	TREATMENT 1
2000	3	C	4	TREATMENT ?
2000	4	D	5	TREATMENT ?
2000	5	FOLLOWUP	6	FOLLOW-UP

# Mapping Cases

## Drug Stop Date / Time

Problem: Drug stop date / time could not or only partially be obtained  
Any imputation acceptable, eg according to TSAP?

If not

Implications for DM, RFENDTC, RFXENDTC?

Implications for SE?

Implications for EX?

Solution: ?

- Problems:
1. Permissible variable, collected on CRF, alle records empty
  2. Y/N question on CRF, mapped to --STAT, --REASND, all answers Y, ie -- STAT, -- REASND empty

- Solution:
1. Drop from SDTM domain
  2. ?

# Mapping Cases

## SDTM IG 3.2 – Wrong labels

**Problem:** Labels detected in IG 3.2 exceeding length of 40  
How to best report back to CDISC?

**Solution:** Compare with same variable type in other domains  
Follow the same pattern if available



# Mapping Cases

## Handling of ATC Codes

**Problem:** Is there any experience utilizing ATC codes in CM?  
Submit actually used ATC codes, or all codes?

**Solution:** Consider suggestion of UMC via CMCLAS, CMCLASCD and SUPPCM, providing all levels

# Mapping Cases Handling of ATC Codes

## CM and SUPPCM as SAS datasets

VIEWTABLE: Work.Cm

	STUDYID	DOMAIN	USUBJID	CMSEQ	CMTRT	CMMODIFY	CMDECOD	CMCLAS	CMCLASCD
1	YYY	CM	ZZZ	1	IBUPROFEN	IBUPROFEN	IBUPROFEN	MULTIPLE	MULTIPLE
2	YYY	CM	ZZZ	2	DUOCET	DUOCET	PARACETAMOL W/TRAMADOL HYDROCHLORIDE	OTHER OPIOIDS	NO2AX

VIEWTABLE: Work.Suppcm

	STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	GNAM	QLABEL	QVAL	GORIG
1	YYY	CM	ZZZ	CMSEQ	1	CMCDSYS	DRUG CODE CODING SYSTEM	WHODDEMARP2014B	DERIVED
2	YYY	CM	ZZZ	CMSEQ	1	CMCD	DRUG CODE	00109201001	DERIVED
3	YYY	CM	ZZZ	CMSEQ	1	CMCLASYS	MEDICATION CLASS CODING SYSTEM	ATC4	DERIVED
4	YYY	CM	ZZZ	CMSEQ	1	CMCLAS1	Medication Class 1	OTHER CARDIAC PREPARATIONS	DERIVED
5	YYY	CM	ZZZ	CMSEQ	1	CMCLAS2	Medication Class 2	ANTIINFLAMMATORY PRODUCTS FOR VAGINAL ADMINISTRATION	DERIVED
6	YYY	CM	ZZZ	CMSEQ	1	CMCLAS3	Medication Class 3	PROPIONIC ACID DERIVATES	DERIVED
7	YYY	CM	ZZZ	CMSEQ	1	CMCLAS4	Medication Class 4	ANTIINFLAMMATORY PREPARATIONS, NON-STEROIDS FOR TOPICAL USE	DERIVED
8	YYY	CM	ZZZ	CMSEQ	1	CMCLASCD1	Medication Class Code 1	C01EB	DERIVED
9	YYY	CM	ZZZ	CMSEQ	1	CMCLASCD2	Medication Class Code 2	G02CC	DERIVED
10	YYY	CM	ZZZ	CMSEQ	1	CMCLASCD3	Medication Class Code 3	M01AE	DERIVED
11	YYY	CM	ZZZ	CMSEQ	1	CMCLASCD4	Medication Class Code 4	M02AA	DERIVED
12	YYY	CM	ZZZ	CMSEQ	2	CMCDSYS	DRUG CODE CODING SYSTEM	WHODDEMARP2014B	DERIVED
13	YYY	CM	ZZZ	CMSEQ	2	CMCD	DRUG CODE	01573601042	DERIVED
14	YYY	CM	ZZZ	CMSEQ	2	CMCLASYS	MEDICATION CLASS CODING SYSTEM	ATC4	DERIVED

