THE WORLD UPSIDE DOWN

The impact of SDTM datasets on the build of your eCRF

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WHEN YOU NEED TO BE SURE

SGS

One of the most important end to end links is the link between the (e)CRF build and the mapping of the collected data into SDTM datasets.

THE SMALLER HURDLES

Due to technical limitations, and lack of knowledge and experience

NON-COMPLIANT TERMINOLOGY

Demographic Information

Birth Date: *BRTHDTC*
Sex: *SEX*
Race: *RACE*
Ethnicity: *ETHNIC*

Note:
When option 'BLACK' is chosen for RACE, it will be coded as 'BLACK OR AFRICAN AMERICAN'
When option 'AMERICAN INDIAN OR ALASKAN NATIVE' is chosen for RACE, it will be coded as 'AMERICAN INDIAN OR ALASKA NATIVE'
When option 'UNKNOWN' is chosen for RACE, a record will be created in the CO domain with
RDOMAIN = DM, COREF = RACE and COVAL = UNKNOWN

Race	AMERICAN INDIAN OR ALASKA NATIVE
Race	BLACK OR AFRICAN AMERICAN
Race	NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER
Race	WHITE
Race	ASIAN

NON-COMPLIANT DATA STRUCTURE

Vital signs supine

Test	Result	Unit	Ref Range	Clin. Sign.	Comment
Blood pressure	*VSORRES when VSTESTCD = SYSBP*	mmHg	*100-160|60-9*		
	VSORRES when VSTESTCD = DIABP		*0*		
Heart Rate	*VSORRES when VSTESTCD = HR*	bpm	*60-100*		

‘NOT DONE’ CONFIRMATION

Physical Exam

☐ Intentionally left blank.

Physical exam was performed on:

☐☐ / ☐☐☐ / ☐☐☐☐  at: ☐☐ : ☐☐ 

If abnormal, specify clinically significant (cs) or not clinically significant (ncs) and record findings.

Head, Ears, Eyes, Nose, and Throat
Specify findings: ☐ Normal ☐ Abnormal ☐ Not Done
Findings: ☐ cs ☐ ncs

PERIOD 1

Blood PK / Blood PK

Timepoint: **Day 1 5h**

Sample date - time: __/___/____ __ : __

--TPT = 5H

--TPTNUM = 300

❑ Missed

AMBIGUITY

An unclear CRF makes it difficult to create a correct SDTM database

AMBIGUITY

	Spirometry parameters			
	Date performed	XPDTC	Same date as visit date ☐	
		[NOT SUBMITTED]	Other date ☐	
	If 'Other date', please specify (dd MMM yyyy)	XPDTC		
	Time performed (24h time clock)	XPDTC		
XPGRPID = 1	First FEV_1 measurement	XPORRES when XPTESTCD = FEV1	Fixed Unit: L	XPORRESU
XPGRPID = 2	Second FEV_1 measurement	XPORRES when XPTESTCD = FEV1	Fixed Unit: L	
XPGRPID = 3	Third FEV_1 measurement	XPORRES when XPTESTCD = FEV1	Fixed Unit: L	

AMBIGUITY

Spirometry parameters	
Date performed	Same date as visit date
If 'Other date', please specify (dd MMM yyyy)	
Time performed (24h time clock)	17:33
First FEV_1 measurement	12 L
Second FEV_1 measurement	11 L
Third FEV_1 measurement	10 L

AMBIGUITY

- Assign the baseline flag
- Indicate the best measurement for analysis

AMBIGUITY

USUBJID	XP SEQ	XP GRPID	XP TESTCD	XP ORRES	XP ORRESU	XP BLFL	VISITNUM	VISIT	XP DTC
Xxxxx-xxxxx1	10	1	FEV1	12.00	L	Y	2000	DAY0	2015-02-06T17:33
Xxxxx-xxxxx1	11	2	FEV1	11.00	L	Y	2000	DAY0	2015-02-06T17:33
Xxxxx-xxxxx1	12	3	FEV1	10.00	L	Y	2000	DAY0	2015-02-06T17:33

LEGACY CONVERSION

Processing a CRF created without SDTM in mind

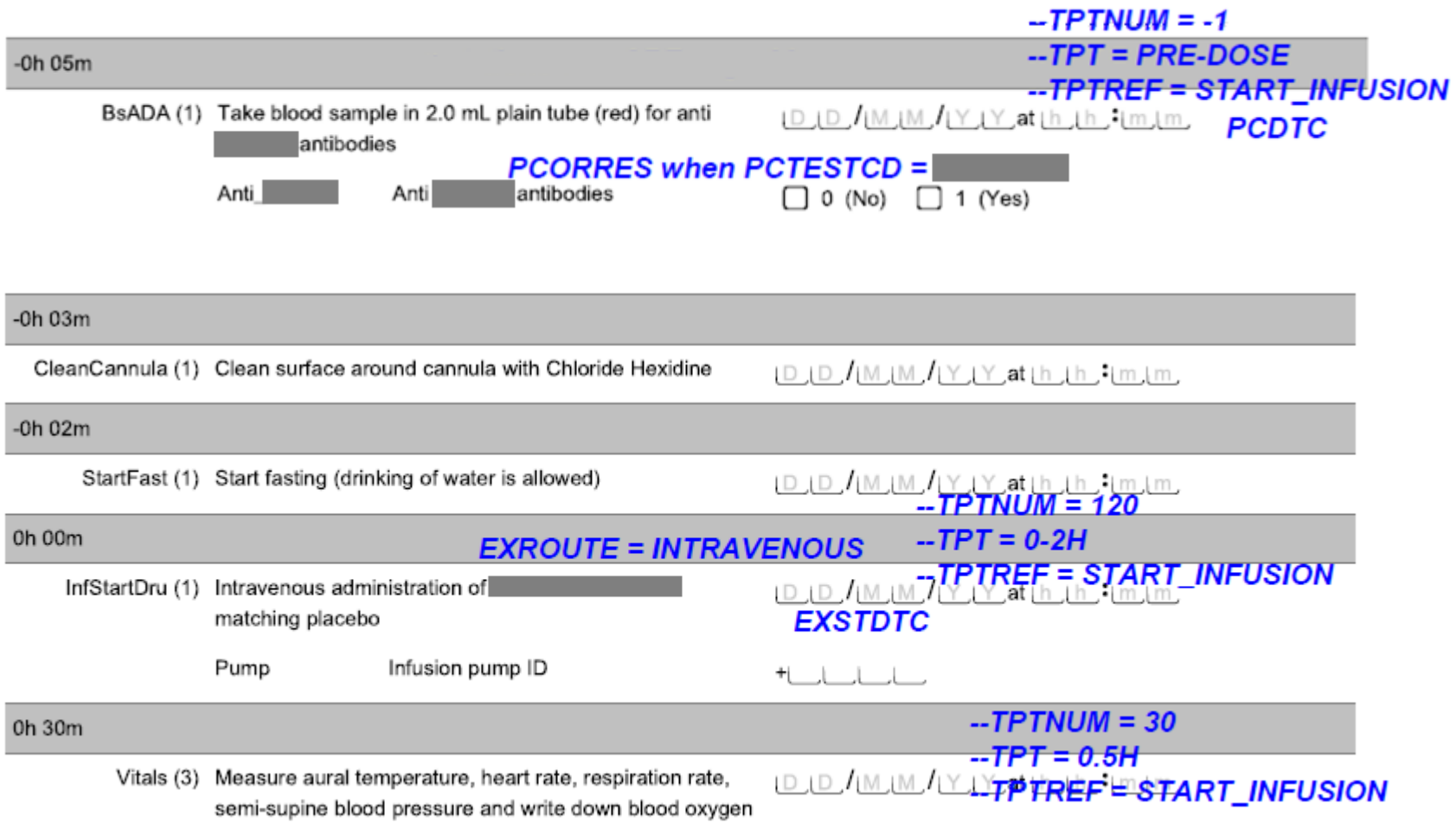
LEGACY CONVERSION

Assessments	Screening (21 days)7	SD-1	1.1.1.1. NI-0101 Treatment - Study Days (SDs)							Follow Up SDs 3-7			Follow Up Wks 2-8 & EOS					Additional PK Visits if necessary10	Withdrawal Visit (WD)	Unscheduled Visit (UV)
			0					1	2	3	4	7	2	3	4	6	8/EOS9			
			Pre-infusion	2hrs post start of infusion	4hrs post start of infusion	6hrs post start of infusion	12hrs post start of infusion													

LEGACY CONVERSION

-11h 00m			
	Sleep (1)	Subject can sleep	_D_D_/_M_M_/_Y_Y_at_h_h_:_m_m_
-3h 00m			
	Wake (1)	Wake up subject	_D_D_/_M_M_/_Y_Y_at_h_h_:_m_m_ --DTC
-2h 00m			
	Breakfast (1)	Serve breakfast	_D_D_/_M_M_/_Y_Y_at_h_h_:_m_m_

LEGACY CONVERSION



LEGACY CONVERSION

PERIOD 1

Blood PK / Blood PK

Timepoint: **Day 1 5h**

Sample date - time: __/___/____ __ : __

--TPT = 5H
--TPTNUM = 300

❑ Missed

Blood PK / Blood PK

Timepoint: **Day 1 6h**

Sample date - time: __/___/____ __ : __

--TPT = 6H
--TPTNUM = 360

❑ Missed

ECG

--TPT = 8H
--TPTNUM = 480

Timepoint: **Day 1 8h**

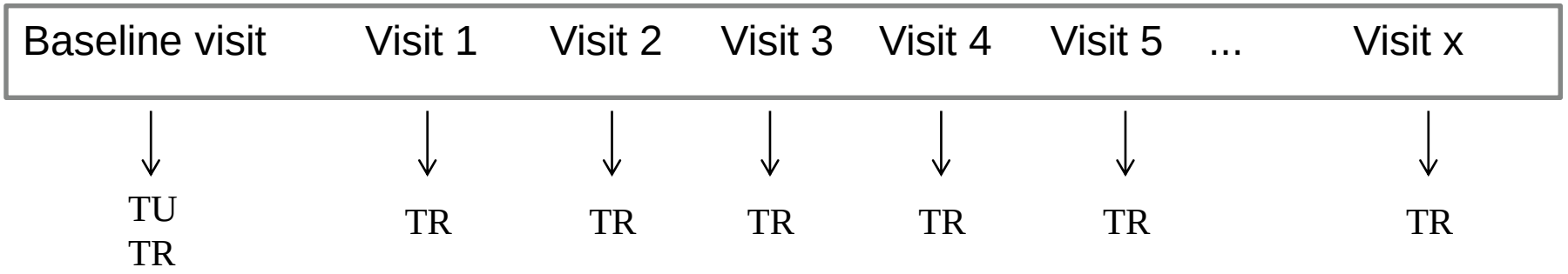
Sample date - time: __/___/____ __ : __

❑ Missed

LINKING DATA

Loss of linking between the tumor datasets TU and TR

COLLECTION OF TU AND TR



- TU: represents data that uniquely identifies tumors (i.e. malignant tumors and other sites of disease, e.g. lymph nodes).
- TR: represents quantitative measurements and/or qualitative assessments of the tumors i.e. malignant tumors and other sites of disease, e.g. lymph nodes) identified in the TU domain.

LINK BETWEEN TU AND TR

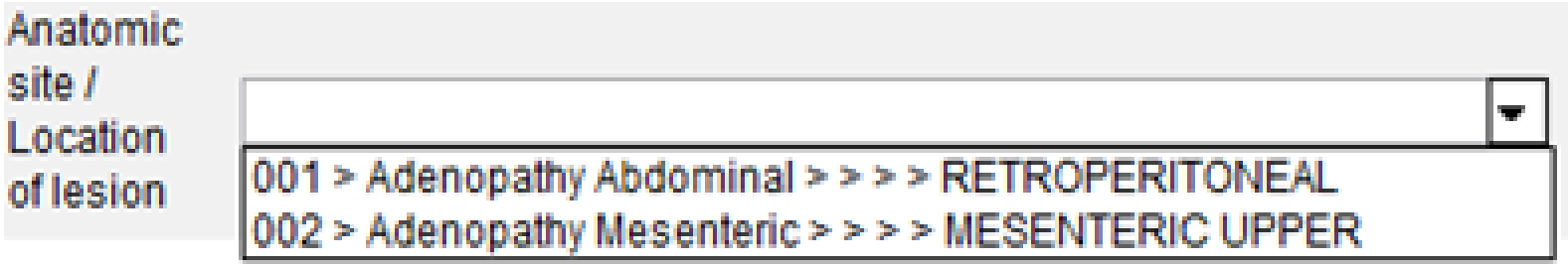
TULNKID	TUTESTCD	TUTEST	TUORRES	TULOC	TUMETHOD	VISIT	TUDTC
	TUMIDENT	Tumor Identification	ASSESSABLE TUMOR LESION	ADENOPATHY CERVICAL	SPIRAL CT	SCREENING	2012-11-01
	TUMIDENT	Tumor Identification	MEASURABLE TUMOR LESION	ADENOPATHY INGUINAL	SPIRAL CT	SCREENING	2012-11-01
	TUMIDENT	Tumor Identification	MEASURABLE TUMOR LESION	ADENOPATHY PARATRACHEAL	SPIRAL CT	SCREENING	2012-11-01

Which tumor results are linked to each identification information?

TRLNKID	TRTESTCD	TRTEST	TRORRES	TRORRESU	TRMETHOD	VISIT	TRDTC
	LONGAXIS	Long Axis	55.0	mm	SPIRAL CT	SCREENING	2012-10-11
	SHRTAXIS	Short Axis	27.0	mm	SPIRAL CT	SCREENING	2012-10-11
	LONGAXIS	Long Axis	53.0	mm	SPIRAL CT	VISIT 1	2013-01-16
	SHRTAXIS	Short Axis	24.0	mm	SPIRAL CT	VISIT 1	
	LONGAXIS	Long Axis	30.0	mm	SPIRAL CT	VISIT 1	2013-04-15
	SHRTAXIS	Short Axis	7.0	mm	SPIRAL CT	VISIT 1	2013-04-15
	LONGAXIS	Long Axis	12.0	mm	SPIRAL CT	VISIT 2	2013-05-20
	SHRTAXIS	Short Axis	6.0	mm	SPIRAL CT	VISIT 2	2013-05-20

Same Tumor ?

LINK BETWEEN TU AND TR



LINK BETWEEN TU AND TR

TUGRPID	TULNKID	TUTESTCD	TUTEST	TUORRES	TULOC	TUMETHOD	VISIT	TUDTC
M2	M2	TUMIDENT	Tumor Identification	MEASURABLE TUMOR LESION	ADENOPATHY PARATRACHEAL	SPIRAL CT	SCREENING	2012-11-01

TRLNKID	TRTESTCD	TRTEST	TRORRES	TRORRESU	TRMETHOD	VISIT	TRDTC
M2	LONGAXIS	Long Axis	55.0	mm	SPIRAL CT	SCREENING	2012-10-11
M2	SHRTAXIS	Short Axis	27.0	mm	SPIRAL CT	SCREENING	2012-10-11
M2	LONGAXIS	Long Axis	53.0	mm	SPIRAL CT	VISIT 1	2013-01-16
M2	SHRTAXIS	Short Axis	24.0	mm	SPIRAL CT	VISIT 1	2013-01-16

SPLIT LESIONS

TUGRPID	TULNKID	TUTESTCD	TUTEST	TUORRES	TULOC	TUMETHOD	VISIT	TUDTC
M2	M2	TUMIDENT	Tumor Identification	MEASURABLE TUMOR LESION	ADENOPATHY PARATRACHEAL	SPIRAL CT	SCREENING	2012-11-01
M2	M2.1	TUMIDENT	Tumor Identification	MEASURABLE TUMOR LESION	ADENOPATHY PARATRACHEAL	SPIRAL CT	VISIT 2	2013-04-15
M2	M2.2	TUMIDENT	Tumor Identification	MEASURABLE TUMOR LESION	ADENOPATHY PARATRACHEAL	SPIRAL CT	VISIT 2	2013-04-15

SPLIT LESIONS

Did this lesion split up?	*[Not submitted]*	Yes ☐ No ☐
If 'Yes', please specify the sequence number	*SUPPTR.QVAL when QNAM = TRSEQNO and IDVAR = TRGRPID*	

Note: In case of a split lesion at this time point, TUCAT, TULOC will be populated with the values of the corresponding original lesion, identified at screening. Linking will be done on TULNKID.

TAKE AWAY

Think

CRF review

Experience

Lessons Learned

Questions and discussion