

THE WORLD UPSIDE DOWN

The impact of SDTM datasets on the
build of your eCRF

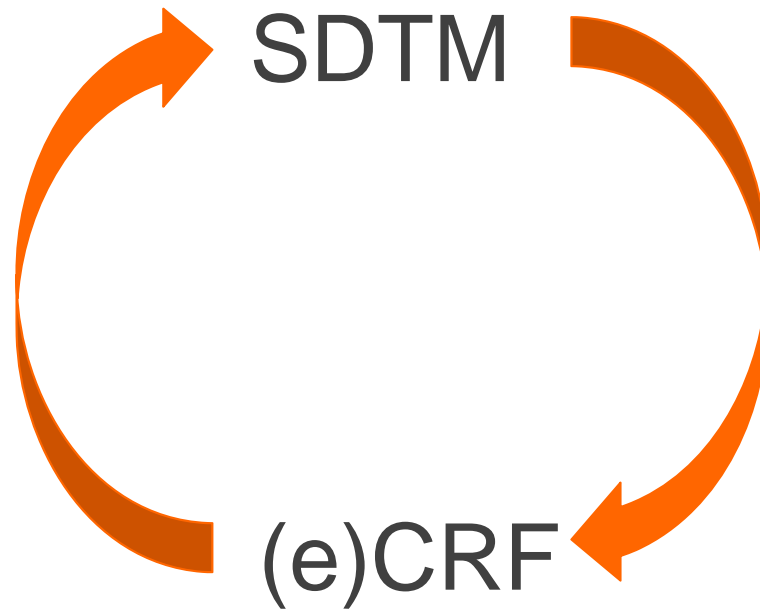
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Clinical Data Manager

Paris, 02/Feb/2016

WHEN YOU NEED TO BE SURE





Introduction

Issues types

- The smaller hurdles
- Ambiguity
- Legacy conversion
- Linking data

Conclusions

THE SMALLER HURDLES

Due to technical limitations, and lack
of knowledge and experience



NON-COMPLIANT TERMINOLOGY

Demographic Information

Birth Date: **BIRTHDTC**
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

Vital signs supine

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

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


AMBIGUITY




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

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 FEV₁ measurement 12 L   

Second FEV₁ measurement 11 L   

Third FEV₁ measurement 10 L   

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 FEV₁ measurement **XPORRES when XPTESTCD = FEV1** Fixed Unit: L **XPORRESU**

XPGRPID = 2 Second FEV₁ measurement **XPORRES when XPTESTCD = FEV1** Fixed Unit: L

XPGRPID = 3 Third FEV₁ measurement **XPORRES when XPTESTCD = FEV1** Fixed Unit: L



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

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







AMBIGUITY

--DRVFL	Derived Flag	Char	Record Qualifier	Used to indicate a derived record (e.g., a record that represents the average of other records such as a computed baseline). Should be Y or null.
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USUBJID	XP TESTCD	XP ORRES	XP ORRESU	XP STRESN	XP STRESU	XP BLFL	XP DRVFL	VISITNUM	VISIT	XP DTC
Xxxxx-xxxxx1	FEV1	12.00	L	12.00	L			2000	DAY0	2015-02-06T17:33
Xxxxx-xxxxx1	FEV1	11.00	L	11.00	L			2000	DAY0	2015-02-06T17:33
Xxxxx-xxxxx1	FEV1	10.00	L	10.00	L			2000	DAY0	2015-02-06T17:33
Xxxxx-xxxxx1	FEV1			12.00	L	Y	Y	2000	DAY0	2015-02-06T17:33

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 FEV₁ measurement~~ 12 L   

~~Second FEV₁ measurement~~ 11 L   




~~Third FEV₁ measurement~~ 10 L   

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 FEV₁ measurement 17:33 17:33 12 L   

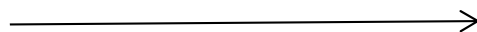
Second FEV₁ measurement 17:34 17:34 11 L   

Third FEV₁ measurement 17:35 17:35 10 L   



















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		2000	DAY0	2015-02-06T17:33
Xxxxx-xxxxx1	11	2	FEV1	11.00	L		2000	DAY0	2015-02-06T17:34
Xxxxx-xxxxx1	12	3	FEV1	10.00	L	Y	2000	DAY0	2015-02-06T17:35

Baseline flag → ok

Best measurement → not ok





















Medically relevant?

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	<input type="checkbox"/> 12 L	  
Second FEV ₁ measurement	<input checked="" type="checkbox"/> 11 L	  
Third FEV ₁ measurement	<input type="checkbox"/> 10 L	  

--ACPTFL	Accepted Record Flag	Char	Record Qualifier	In cases where more than one assessor provides an evaluation of a result or response, this flag identifies the record that is considered, by an independent assessor, to be the accepted evaluation. Expected to be Y or null.
→ not ok				

→ SUPP-- variable

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	  
Indicate Best FEV1 measurement		<ul style="list-style-type: none"> - First - Second - Third

→ SUPP-- variable

USUBJID	XP SEQ	XP GRPID	XP TESTCD	XP ORRES	XP ORRESU	XP BLFL	VISITNUM	VISIT	XP DTC	SUPPXP QNAM	SUPPXP QVAL
Xxxxx-xxxxx1	10	1	FEV1	12.00	L		2000	DAY0	2015-02-06T17:33		
Xxxxx-xxxxx1	11	2	FEV1	11.00	L	Y	2000	DAY0	2015-02-06T17:33	BESTFEV1	Y
Xxxxx-xxxxx1	12	3	FEV1	10.00	L		2000	DAY0	2015-02-06T17:33		

Baseline flag → ok

Best measurement → ok

LEGACY CONVERSION

Processing a CRF created without
SDTM in mind



LEGACY CONVERSION

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 necessary ¹⁰	Withdrawal Visit (WD)	Unscheduled Visit (UV)		
		0					1	2	3	4	7	2	3	4				6	8/EOS ⁹
		Pre- infusion	2hrs post start of infusion	4hrs post start of infusion	6hrs post start of infusion	12hrs post start of infusion													



LEGACY CONVERSION

SD -1

-11h 00m

Sleep (1) Subject can sleep

`{D}{D}/{M}{M}/{Y}{Y} at {h}{h}:{m}{m}`

SD 0

Pre-dose

-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

SD 0

Pre-dose

--TPTNUM = -1

-0h 05m **--TPT = PRE-DOSE**

--TPTREF = START_INFUSION

BsADA (1) Take blood sample in 2.0 mL plain tube (red) for anti at / / at : **PCDTC**

antibodies

Anti- **PCORRES when PCTESTCD =**

Anti- antibodies 0 (No) 1 (Yes)

-0h 03m

CleanCannula (1) Clean surface around cannula with Chloride Hexidine / / at :

-0h 02m

StartFast (1) Start fasting (drinking of water is allowed) / / at :

Dosing

--TPTNUM = 120

0h 00m **--TPT = 0-2H**

--TPTREF = START_INFUSION

InfStartDru (1) Intravenous administration of **EXROUTE = INTRAVENOUS**

matching placebo / / at : **EXSTDTC**

Pump Infusion pump ID +

Post-dose

0h 30m **--TPTNUM = 30**

--TPT = 0.5H

--TPTREF = START_INFUSION

Vitals (3) Measure aural temperature, heart rate, respiration rate, / / at :

semi-supine blood pressure and write down blood oxygen



LEGACY CONVERSION

PERIOD 1

Blood PK / Blood PK

Timepoint: Day 1 5h

--TPT = 5H

Missed

Sample date - time: __/__/__ __: __

--TPTNUM = 300

Blood PK / Blood PK

Timepoint: Day 1 6h

--TPT = 6H

Missed

Sample date - time: __/__/__ __: __

--TPTNUM = 360

ECG

--TPT = 8H

--TPTNUM = 480

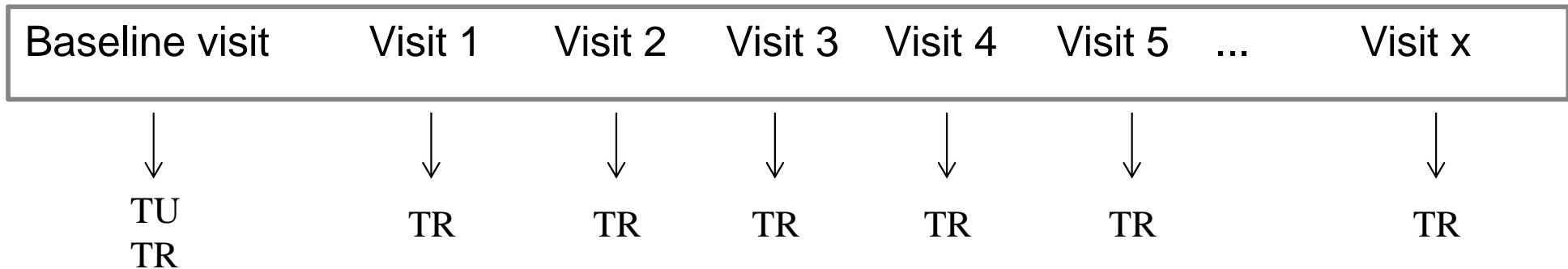
Timepoint: Day 1 8h

Missed

Sample date - time: __/__/__ __: __

LINKING DATA

Loss of linking between the tumor datasets 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	2012-11-01
	SHRTAXIS	Short Axis	27.0	mm	SPIRAL CT	SCREENING	2012-11-01
	LONGAXIS	Long Axis	53.0	mm	SPIRAL CT	VISIT 1	2013-01-16
	SHRTAXIS	Short Axis	24.0	mm	SPIRAL CT	VISIT 1	2013-01-16
	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

Form: Extra Medullary Disease Exam TULNKID

Not Done [NOT SUBMITTED]

Date of Examination (dd MMM yyyy) TUDTC TRDTC

Examination Method TUMETHOD TRMETHOD

Physical Exam
 CT Scan
 MR Scan

Location TULOC

Neck
 Thorax
 Abdomen
 Pelvis
 Other, specify

Other, specify TULOCO in SUPPTU when IDVAR = TUSEQ

Diameter 1 (mm) TRORRESU TRORRES when TRTESTCD = DIAMETE1

Diameter 2 (mm) TRORRESU TRORRES when TRTESTCD = DIAMETE2

Page: Extra Medullary Disease Exam - Visit 10 ?

#	Date of Examination (dd MMM yyyy)	Examination Method	Location	Other, specify	Diameter 1 (mm)	Diameter 2 (mm)
1	11 Mar 2013	Physical Exam	Thorax		100	100
2	11 Mar 2013	Physical Exam	Thorax		-	-
3	11 Mar 2013	Physical Exam	Thorax		-	-

Sub-location
Upper left
Middle
Lower right

Unique TU record

-- LNKID

Page: Measurable tumor lesions (By CT-PET/MRI assessment)(Screening) - Screening[?]

Unique TU record

#	Anatomic site	If 'Adenopathy Other', please specify	Extranodal lesions	If 'Other', please specify	Location of lesion	Measurement 1	Measurement 2	Method	If 'Other', please specify
1	Adenopathy Inguinal	-	-	-	LEFT GROIN	62	30	Spiral CT Pelvic	-
2	Adenopathy Paratracheal	-	-	-	THROAT	55	27	Spiral CT Neck	-

Add a new Log line Inactivate

Dynamic Searchlist

Page: Measurable tumor lesions (By CT-PET/MRI assessment) - Disease evaluation (1)[?]

Currently viewing line 1 of 1.
Click here to return to "Complete View". Apply to Record

Anatomic site / Location of lesion

Bidimensional measurement 1

Bidimensional measurement 2 mm

Method of assessment

If 'Other', please specify

Page: Measurable tumor lesions (By CT-PET/MRI assessment)(Screening) - Screening[?]

#	Anatomic site Adenopathies	If 'Adenopathy Other', please specify	Extranodal lesions	If 'Other', please specify	Location of lesion	Measurement 1	Measurement 2	Method	If 'Other', please specify
1	Adenopathy Inguinal	-	-	-	LEFT GROIN	62	30	Spiral CT Pelvic	-
2	Adenopathy Paratracheal	-	-	-	THROAT	55	27	Spiral CT Neck	-

Add a new Log line Inactivate

Automated process → Copy-through Custom Function

Page: Measurable tumor lesions (By CT-PET/MRI assessment) - Disease Evaluations (1)[?]

#	Anatomic site Adenopathies	If 'Adenopathy Other', please specify	Extranodal lesions	If 'Other', please specify	Location of lesion	Long axis measurement	Short axis measurement	Method	If 'Other', please specify	Did this lesion split up (compared to baseline)?	If 'Yes', please specify the sequence number
1	Adenopathy Inguinal	-	-	-	LEFT GROIN	-	-	-	-	-	-
2	Adenopathy Paratracheal	-	-	-	THROAT	-	-	-	-	-	-

LINK BETWEEN TU AND TR

Page: Tumor Assessment - Target Lesions / T01 / PARATRACHEAL LYMPH NODE / LOWER LEFT - Disease Evaluations [?]

Lesion Identifier	T01												
Is the lesion Soft Tissue, Visceral or a Lymph Node?	Lymph Node												
Anatomical Location	Paratracheal Lymph Node												
If Other, Specify													
Sub-location	LOWER LEFT												
TUMOR ASSESSMENT INFO:													
#	Subject phase	Visit number	Date of Assessment	Method of Assessment	Was contrast agent used?	Longest Diameter [?]	Too small to measure	Short Axis [?]	Too small to measure	Not Evaluable	Reason Not Evaluable	Did the tumor split or coalesce?	Sp Les Ide
1	Screening	_	14 JAN 2016	Spiral CT	IV contrast	-	<input type="checkbox"/>	22 [▲]	<input type="checkbox"/>	<input type="checkbox"/>	-	No	-
2	Treatment	3	25 JAN 2016 [▲]	Spiral CT	IV contrast [▲]	-	<input type="checkbox"/> [▲]	15 [▲]	<input type="checkbox"/> [▲]	<input type="checkbox"/>	-	No [▲]	-
Add a new Log line Inactivate													

Visits





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

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.



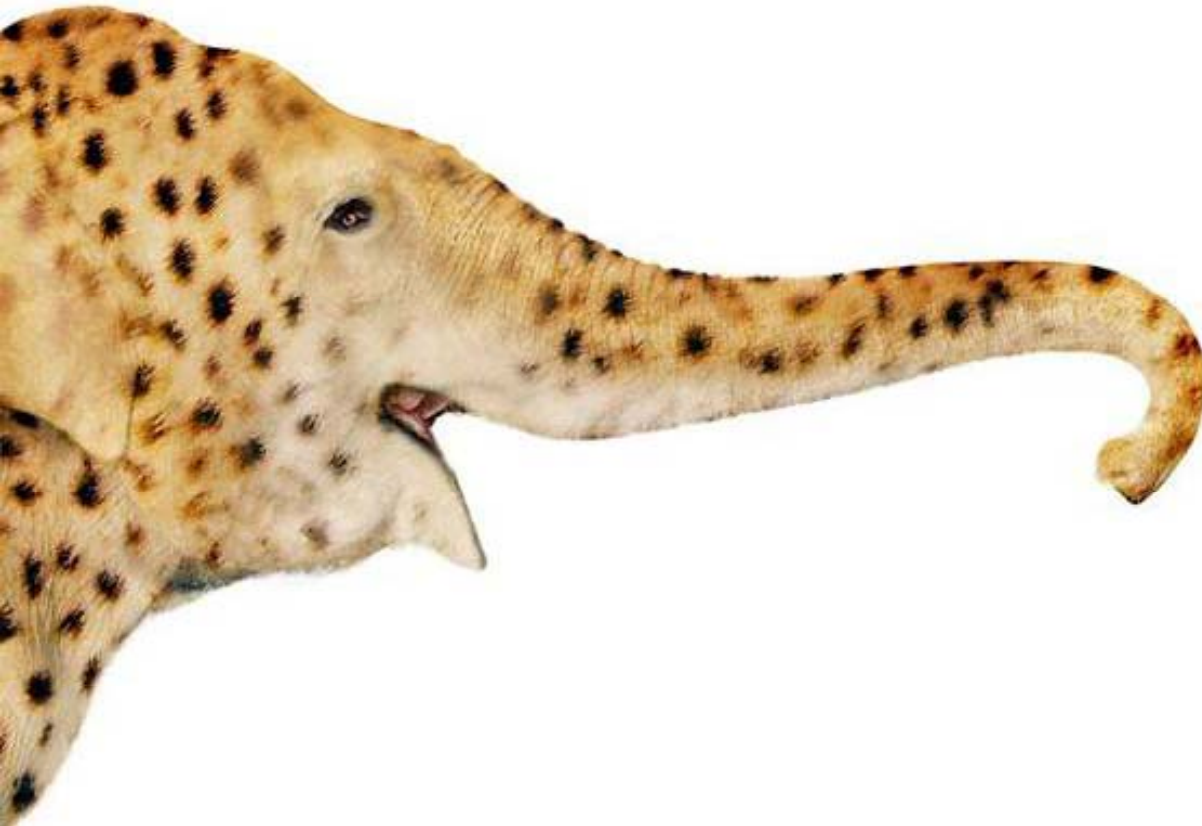
SPLIT LESIONS

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

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.

SGS

THANK YOU FOR YOUR ATTENTION



WHERE MEETS EXPERIENCE SPEED

CONTACT US

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