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Item groups - Study **CES** - MetaData Version **CES_MDV_V1**

Name	OID	Repeating ?	Reference Data ?	SAS Dataset Name	Domain	Origin	Role	Purpose	Comment
Common	IG_COMMON	No		COMMON	DM				
Demographics	IG_DM	No		DEMOG	DM				
Smoking History	IG_SH	No		SMOKE	SU				
Drinking History	IG_DH	No		DRINK	SU				
Physical Exam	IG_PE_BASE	No		PHYEXBAS	VS				
XRay	IG_XRAY	No							
Physical Exam	IG_PE_WEEK	No		PHYEX	VS				
Patient Diary	IG_PD	Yes		DIARY	QS				
Adverse Events Occurred	IG_AE_OCCURRED	No		AEOCCUR	AE				
Adverse Event	IG_AE	Yes		AEEVENT	AE				
Non-study Medications Taken	IG_CM_TAKEN	No		NSMEDTK	CM				
Prior or Concomitant Medications	IG_CM	Yes		CONMED	CM				
Hematology	IG_LB_HEMATOLOGY	No		LAB	LB				
Complaints due to smoking	IG_SMOKING_COMPLAINTS	No							

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Item Group: Common

Item Group Description:

Language	Translated Text
en	Common
fr	General
de	Algemein

Items:

Item Name	Item OID	Order Number	Mandatory ?	Key Sequence	Imputation Method (deprecated)	Method	Collection Exception Condition OID	Role	Role Code List
Site Number	I_SITE	1	Yes						
Subject ID	I_SUBJECTID	2	Yes						
Visit Date	I_VISIT	3	Yes						
Visit Time	I_VISITTIME	4	Yes						

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Item Group: Demographics

Item Group Description:

Language	Translated Text
en	Demographics
fr	Demographie

de	Demografie
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Items:

Item Name	Item OID	Order Number	Mandatory ?	Key Sequence	Imputation Method (deprecated)	Method	Collection Exception Condition OID	Role	Role Code List
Date of Birth	I_BRTHDT	1	Yes						
DM - Sex	I_SEX	2	Yes						
DM - Race	I_RACE	3	No						

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Item Group: Smoking History

Item Group Description:

Language	Translated Text
en	Smoking History
fr	Histoire consommation du tabac
de	Vergangenheit i.B.a. Rauchen

Items:

Item Name	Item OID	Order Number	Mandatory ?	Key Sequence	Imputation Method (deprecated)	Method	Collection Exception Condition OID	Role	Role Code List
Smoking	I_SMOKING	1	Yes						
Number of cigarettes per day	I_NR_CIGARETTES	2	No				COND.SMOKING		

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Item Group: Drinking History

Item Group Description:

Language	Translated Text
en	Drinking history
fr	Histoire consommation de l'alcool
de	Vergangenheit i.B.a. Alkoholverbrauch

Items:

Item Name	Item OID	Order Number	Mandatory ?	Key Sequence	Imputation Method (deprecated)	Method	Collection Exception Condition OID	Role	Role Code List
Drinking	I_DRINKING	1	Yes						

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Item Group: Physical Exam

Item Group Description:

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Language	Translated Text
en	Physical examination: Base
fr	Examination du corps: Base
de	Körperuntersuchung: Basis

Items:

Item Name	Item OID	Order Number	Mandatory ?	Key Sequence	Imputation Method (deprecated)	Method	Collection Exception Condition OID	Role	Role Code List
Height	I_HEIGHT	1	Yes						
Weight	I_WEIGHT	2	Yes						
Systolic BP	I_SYSBP	3	No						
Diastolic BP	I_DIABP	4	Yes						
Dizziness at low DBP	I_DIZZY	5	Yes				COND.DBP.DIZZY		

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Item Group: XRay

Item Group Description:

Language	Translated Text
en	X-Ray
fr	Rayons X
de	Röntgenbild

Items:

Item Name	Item OID	Order Number	Mandatory ?	Key Sequence	Imputation Method (deprecated)	Method	Collection Exception Condition OID	Role	Role Code List
Link to XRay	I_XRAY	1	Yes						

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Item Group: Physical Exam

Item Group Description:

Language	Translated Text
en	Physical Examination: Week
fr	Examination du corps: Semaine
	Körperuntersuchung: Woche

Items:

Item Name	Item OID	Order Number	Mandatory ?	Key Sequence	Imputation Method (deprecated)	Method	Collection Exception Condition OID	Role	Role Code List
Weight	I_WEIGHT	1	Yes						
Systolic BP	I_SYSBP	2	Yes						
Diastolic BP	I_DIABP	3	Yes						

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Item Group: Patient Diary

Item Group Description:

Language	Translated Text
en	Patient diary
fr	Journal du patient
de	Patient Tagesbuch

Items:

Item Name	Item OID	Order Number	Mandatory ?	Key Sequence	Imputation Method (deprecated)	Method	Collection Exception Condition OID	Role	Role Code List
Diary Day	I_DAY	1	Yes						
Diary Date	I_DATE	2	Yes						
Scale	I_DIARY	3	Yes						

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Item Group: Adverse Events Occurred

Item Group Description:

Language	Translated Text
en	Adverse events
fr	Événements défavorables
de	Unerwünschte Vorfälle

Items:

Item Name	Item OID	Order Number	Mandatory ?	Key Sequence	Imputation Method (deprecated)	Method	Collection Exception Condition OID	Role	Role Code List
Adverse Event Experienced	I_AE_OCCURRED	1	Yes						

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Item Group: Adverse Event

Item Group Description:

Language	Translated Text
en	Adverse events
de	Unerwünschte Vorfälle
fr	Événement défavorables

Items:

Item Name	Item OID	Order Number	Mandatory ?	Key Sequence	Imputation Method (deprecated)	Method	Collection Exception Condition OID	Role	Role Code List
Adverse Event Number	I_AE_EVENT	1	Yes						

Medication Dose Frequency	I_CM_DOSEFREQ	5	Yes						
Medication Start Date	I_CM_START	6	Yes						
Medication Continues	I_CM_CONTINUES	7	Yes						
Medication Stop Date	I_CM_STOP	8	Yes				COND.CMSTOP.STOP_DATE		
Pre-existing Illness	I_CM_IEXISTING	9	Yes						
Adverse Event	I_CM_IAE	10	Yes						
Prophylaxis	I_CM_IPROP	11	Yes						
Prophylaxis Description	I_CM_IPROPDESC	12	Yes				COND.PROHYLAXIS		

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Item Group: Hematology

Item Group Description:

Language	Translated Text
en	Hematology Lab
fr	Hématologie Laboratoire
de	Hematologie Laboratorium

Items:

Item Name	Item OID	Order Number	Mandatory ?	Key Sequence	Imputation Method (deprecated)	Method	Collection Exception Condition OID	Role	Role Code List
Laboratory Name	I_LB_NAME	1	Yes						
Laboratory ID	I_LB_ID	2	Yes						
Accession Number	I_LB_ACCESSION	3	Yes						
RBC Done	I_LB_RBC_NOTDONE	4	Yes						
RBC	I_LB_RBC	5	Yes				COND.LB_RBC		
RBC Normal Range Lo	I_LB_RBC_LO	6	Yes				COND.LB_RBC		
RBC Normal Range Hi	I_LB_RBC_HI	7	Yes				COND.LB_RBC		
WBC Done	I_LB_WBC_NOTDONE	8	Yes						
WBC	I_LB_WBC	9	Yes				COND.LB_WBC		
WBC Normal Range Lo	I_LB_WBC_LO	10	Yes				COND.LB_WBC		
WBC Normal Range Hi	I_LB_WBC_HI	11	Yes				COND.LB_WBC		

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Item Group: Complaints due to smoking

Item Group Description:

Language	Translated Text
en	Complaints related to smoking
fr	Plaintes en relation avec la consommation de tabac
de	Klagen in beziehung zum Rauchen

Items:

Item Name	Item OID	Order Number	Mandatory ?	Key Sequence	Imputation Method (deprecated)	Method	Collection Exception Condition OID	Role	Role Code List
Breath complaints	I_BREATHING	1	No						
Coughing problems	I_COUGHING	2	No						
Hart complaints	I_HEART_COMPLAINTS	3	No						
No. of illness days last year	I_ILNESS_DAYS_LAST_YEAR	4	No						
No. of bronchitis illnesses	I_BRONCHITS	5	No						
No. of pneumonia illnesses	I_PNEUMONIA	6	No						

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