NEW DOMAINS FOR IG 3.3 FROM REVIEW BATCH 1

AG – PROCEDURE AGENTS

03-Mar-2015, 20th German CDISC User Network Meeting
Jana Wree, PAREXEL

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Intervention domain: AG - Procedure Agents

- captures the agents administered to the subject as part of a procedure or assessment as opposed to drugs, medications and, therapies administered with therapeutic intent

- allows recording of multiple substance administrations for a single testing procedure

- Included as draft domain in TAUG-Asthma 1.0, TAUG-Alzheimer's 2.0, TAUG-Diabetes 1.0

- Examples:

  - short-acting bronchodilator administered as part of a reversibility assessment

  - glucose given as part of a glucose tolerance test

  - contrast agents and radiolabeled substances used in imaging studies

  - Discussions are ongoing on the handling of radiation (e.g., x-rays or visible light) in SDTM Interventions domains

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Intervention domain: AG - Procedure Agents

- AGTRT captures the name of the agent and it is the required Topic variable.

  - should include only the agent name, and should not include dosage, formulation, or other qualifying information.

    Do not use: "ALBUTEROL 2 PUFF"
    Better use : AGTRT = ALBUTEROL, AGDOSE = 2, AGDOSU = PUFF, and AGDOSFRM = AEROSOL

- --INDC, --DOSTOT, and --DOSRGM will not be used because AG should only contain agents used as part of a procedure or an assessment.

- VISITNUM, VISIT and VISITDY will be used

VISITNUM	Visit Number	Num		Timing	1. Clinical encounter number. 2. Numeric version of VISIT, used for sorting.	Exp
VISIT	Visit Name	Char		Timing	1. Protocol-defined description of clinical encounter. 2. May be used in addition to VISITNUM and/or VISITDY.	Perm
VISITDY	Planned Study Day of Visit	Num		Timing	Planned study day of the visit based upon RFSTDTC in Demographics.	Perm

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WHAT DOES IT LOOK LIKE?

Example

❖ procedure agent (Albuterol) administered as part of a reversibility assessment with the associated spirometer results

ag.xpt

Row	STUDYID	DOMAIN	USUBJID	AGSEQ	AGTRT	AGPRESP	AGOCCUR	AGDOSE	AGDOSU	AGDOSFRM	AGDOSFRQ	AGROUTE	VISIT	AGSTDTC
1	XYZ	AG	XYZ-001-001	1	ALBUTEROL	Y	Y	2	PUFF	AEROSOL	ONCE	ORAL	VISIT 2	2013-06-18T10:05

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1	XYZ	AG	XYZ-001-001	1	ALBUTEROL	Y	Y	2	PUFF	AEROSOL	ONCE	ORAL	VISIT 2	2013-06-18T10:05

- Before testing starts, subject is asked to confirm that they have not used bronchodilators in the previous four hours -> CM domain

cm.xpt

Row	STUDYID	DOMAIN	USUBJID	CMSEQ	CMTRT	CMPRESP	CMOCCUR	CMEVLINT
1	XYZ	CM	XYZ-001-001	1	SHORT-ACTING BRONCHODILATOR	Y	N	-PT4H

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1	XYZ	CM	XYZ-001-001	1	SHORT-ACTING BRONCHODILATOR	Y	N	-PT4H

- Spirometry testing results -> RE domain

re.xpt

Row	STUDYID	DOMAIN	USUBJID	SPDEVID	RESEQ	REGRPID	RETESTCD	RETEST	REORRES	REORRESU	RESTRESC	RESTRESN
1	XYZ	RE	XYZ-001-001	ABC001	1	1	FEV1	Forced Expiratory Volume in 1 Second	2.43	L	2.43	2.43
2	XYZ	RE	XYZ-001-001	ABC001	2	1	FEV1	Forced Expiratory Volume in 1 Second	2.77	L	2.77	2.77
3	XYZ	RE	XYZ-001-001	ABC001	3	1	PCTREV	Percentage Reversibility	13.99	%	13.99	13.99

Row	RESTRESU	VISIT	REDTC	RETPT	RETPTNUM	REELTM	RETPTREF	RERFTDTC
1 (cont)	L	VISIT 2	2013-06-18T10:00	PRE-BRONCHODILATOR ADMINISTRATION	1	-PT5M	BRONCHODILATOR ADMINISTRATION	2013-06-18T10:05
2 (cont)	L	VISIT 2	2013-06-18T10:25	POST-BRONCHODILATOR ADMINISTRATION	2	PT20M	BRONCHODILATOR ADMINISTRATION	2013-06-18T10:05
3 (cont)	%	VISIT 2	2013-06-18T10:25				BRONCHODILATOR ADMINISTRATION	2013-06-18T10:05

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cm.xpt

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re.xpt

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2 (cont)	L	VISIT 2	2013-06-18T10:25	POST-BRONCHODILATOR ADMINISTRATION	2	PT20M	BRONCHODILATOR ADMINISTRATION	2013-06-18T10:05
3 (cont)	%	VISIT 2	2013-06-18T10:25				BRONCHODILATOR ADMINISTRATION	2013-06-18T10:05

- Device type -> DI domain

di.xpt

Row	STUDYID	DOMAIN	SPDEVID	DISEQ	DIPARMCD	DIPARM	DIVAL
1	XYZ	DI	ABC001	1	TYPE	Device Type	SPIROMETER

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THANK YOU

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