



NEW DOMAINS FOR IG 3.3 FROM REVIEW BATCH 1

RE – RESPIRATORY SYSTEM FINDINGS

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WHAT IS IT?

- **RE Respiratory System Findings**
 - Collects findings related to organs involved in breathing (nose, throat, lungs, etc.)
Example: Spirometry
- **Part of Asthma TAUG 1.0 (as draft domain)**
- **Findings domain => the usual Findings Observation Class variables**
 - Exception: No reference ranges (----NRLO, ----NRHI)
 - New variables on next slide

DOMAIN MODEL: WHAT IS NEW?

- **NEW: REORREF/RESTREFN – Reference result *instead* of reference ranges**

REORREF	Reference Result in Original Units	Char		Variable Qualifier	Reference result for continuous measurements in original units. Should be populated only for continuous results.	Perm
RESTREFN	Reference Result in Standard Units	Num		Variable Qualifier	Reference result for continuous measurements in standard units. Should be populated only for continuous results.	Perm

- **NEW: REIRESFL – Inadequate Results Flag**

REIRESFL	Inadequate Results Flag	Char	(NY)	Record Qualifier	Used to indicate that a result is not considered acceptable/adequate according to the assessment protocol. The value should be Y or null. If additional qualification of the result is collected then this could be recorded in a Supplemental Qualifier variable.	Perm
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- **Codelists RETEST, RETESTCD (SDTM CT since 2014)**

WHAT DOES IT LOOK LIKE?

• Reference Result

- FEV1 best result row includes the predicted value (REORREF)

DOMAIN	USUBJID	SPDEVID	RESEQ	RETESTCD	RETEST	REORRES	REORRESU	REORREF
RE	XYZ-001-001	ABC001	1	FEV1	Forced Expiratory Volume in 1 Second	2.73	L	3.37
RE	XYZ-001-001	ABC001	2	FVC	Forced Vital Capacity	3.91	L	3.80

- Percent Predicted FEV1 result can be determined from FEV1's REORRES and REORREF

DOMAIN	USUBJID	SPDEVID	RESEQ	RETESTCD	RETEST	REORRES	REORRESU	REORREF
RE	XYZ-001-001	ABC001	3	FEV1PP	Percent Predicted FEV1	81	%	
RE	XYZ-001-001	ABC001	4	FVCP	Percent Predicted FVC	101.3	%	
RE	XYZ-001-001	DEF999	5	PEF	Peak Expiratory Flow	6.11	L/s	7.33

- Percent predicted tests do not have reference results

• Inadequate Result Flag

- "Y" indicates that a measurement was done but the result is questionable

DOMAIN	USUBJID	SPDEVID	RESEQ	RETESTCD	RETEST	REORRES	REORRESU	REIRESFL
RE	XYZ-001-001	ABC001	1	FEV1	Forced Expiratory Volume in 1 Second	1.94	L	
RE	XYZ-001-001	ABC001	2	FEV1	Forced Expiratory Volume in 1 Second	1.88	L	
RE	XYZ-001-001	ABC001	3	FEV1	Forced Expiratory Volume in 1 Second	1.88	L	
RE	XYZ-001-001	ABC001	4	FEV1	Forced Expiratory Volume in 1 Second	1.57	L	Y

THANK YOU