

# New Oncology domains in SDTM

Jozef Aerts  
XML4Pharma

# Status

- 3 Oncology domains published for public review
- Review period ends 29 April 2011
- TU: tumor identification
- TR: tumor results
- RS: tumor response

# Basics

- developed with RECIST Criteria in mind
- RECIST = "Response Evaluation Criteria in Solid Tumor"
- see: <http://www.eortc.be/recist/>

# New variables (!!!)

- **--LINKID**
  - to link records between TU and TR
  - as GRPID, REFID and SPID are already needed
- **--ACPTFL**
  - acceptance flag (independent assessor)
- **--EVALID**
  - evaluator ID
  - to be used in combination with --EVAL

# New variables

- **--LAT**
  - qualifier for anatomical location detailing laterality
  - e.g. "LEFT", "RIGHT", "BILATERAL"
- **--DIR**
  - qualifier for anatomical location further detailing directionality
  - e.g. "UPPER", "ANTERIOR", "DORSAL", "PROXIMAL"
- **-- DSTRBN**
  - qualifier for anatomical location or specimen further detailing the distribution
  - e.g. "ENTIRE", "SINGLE", "SEGMENT", "MANY"

# TU: Tumor Identification

- data that uniquely identifies tumors
- TUORRES has CT depending on TUTESTCD
  - so no TUORRESU
- TUGRPID, TUREFID, TUSPID (perm.)
- TULINKID (exp.)
- TULOC (exp.)
- TULAT, TUDIR, TUDSTRBN (perm.)

# TR: Tumor Results

- TRLINKID (exp.)
- TRORES: no CT
- TRORESU (exp.)
  
- TRMETHOD (exp.)

# TRETSTCD - TRTEST

<b>TRTESTCD</b>	<b>TRTEST</b>
AREA	Area
DIAMETER	Diameter
LDIAM	Longest Diameter
LPERP	Longest Perpendicular
PCHGBL	Percent Change From Baseline
PCHGNAD	Percent Change From Nadir
SUMAREA	Sum of Area
SUMDIAM	Sum of Diameter
SUMLDIAM	Sum of Longest Diameter
SUMLPERP	Sum of Longest Perpendicular
SUMVDIAM	Sum of Viable Diameter
SUMVOL	Sum of Volume
VDIAM	Viable Diameter
VOLUME	Volume
TUMSTATE	Tumor State



# RS: Response

- RSLINKID (**perm.**)
- Examples of RSTESTCD - RSTEST:

RSTESTCD	RSTEST	Definition
TRGRESP	Target Response	An assessment of the response of a target tumor(s) to the therapy.
NTRGRESP	Non-target Response	An assessment of the response of a non-target tumor(s) to the therapy.
OVRLRESP	Overall Response	An assessment of the overall response of the disease to the therapy.
BESTRESP	Best Overall Response	An assessment of the most clinically favorable overall response of the disease to the therapy.
NRADPROG	Non-Radiological Progression	A non-radiological determination of disease progression based on symptoms or other findings.

RSTESTCD	RSTEST	RSCAT	RSORRES	RSSTRESC
SYMPTPD	Symptomatic Deterioration	RECIST 1.0	Increased Pleural Effusion	PD

Review period ends  
29 April 2011