



Your statistical health consultancy



CHM
staying healthy

CRO
getting healthy

TEMP WORK
team health

The oncology specific domains TU, TR and RS: What to know as a statistical analyst

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Agenda

1. Motivation
2. Exemplary study
 - Oncology specific domains
 - RECIST
3. Summary

Motivation

- Typical oncological endpoints hard to assess
- Standardized criteria essential: RECIST
- Standardized Data Structure (CDISC)
- Tumor package in SDTM: 3 domains
- Goal:

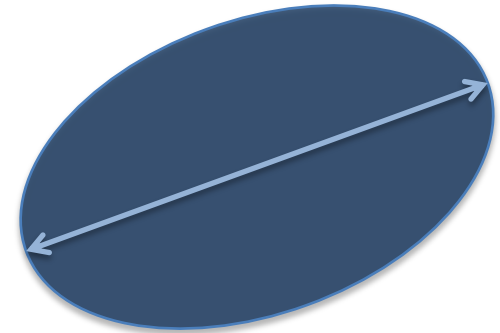


Study setting

- Accompany Steve on his way
- 67 years old / diagnosed with lung cancer
- Participation in phase I study
- Baseline tumor assessment at screening visit
- Additional assessments every 6 weeks

Screening visit

- CT scan of lung: 3 Lesions
- Categorization according to RECIST:
 1. Measurable/non-measurable
 - Longest diameter ≥ 10 mm $\rightarrow$ measurable
 2. Target/non-target
 - Max. of 5 target lesions in total
 - Max. of 2 per organ



Screening visit

TULINKID	TUTEST	TUORRES	TULOC	TUMETHOD	VISIT
T01	Tumor Identification	TARGET	LUNG	CT SCAN	Screening
T02	Tumor Identification	TARGET	LUNG	CT SCAN	Screening
NT01	Tumor Identification	NON-TARGET	LUNG	CT SCAN	Screening

Screening visit

TRLNKID	TRLNKGRP	TRTEST	TORRES	TORRESU	VISIT
T01	A1	Diameter	20	mm	Screening
T02	A1	Diameter	15	mm	Screening
	A1	Sum of Diameter	35	mm	Screening
NT01	A1	Tumor State	PRESENT		Screening

TR Week 6

TRLNKID	TRLNKGRP	TRTEST	TORRES	TORRESU	VISIT
	A1	Sum of Diameter	35	mm	Screening
T01	A2	Diameter	13	mm	Week 6
T02	A2	Diameter	17	mm	Week 6
	A2	Sum of Diameter	30	mm	Week 6
	A2	Percent Change from Baseline in Sum of Diameter	-14	%	Week 6
	A2	Percent Change from Nadir in Sum of Diameter	-14	%	Week 6
NT01	A2	Tumor State	PRESENT		Week 6

Response evaluation in target lesions

- CR: Disappearance of all target lesions
- PR: $\geq 30\%$ decrease in sum of diameter
- SD: no PR, neither PD
- PD:
 - $\geq 20\%$ increase in sum of diameter
 - Absolute increase of 5 mm

Response evaluation in non-target lesions

- CR: Disappearance of all non-target lesions
- Non-CR/Non-PD: Persistence of non-target lesions
- PD: Unequivocal progression

RS Week 6

- Target Lesions: Change from BL / Nadir = -14%
- Non Target Lesions: Present

RSLNKGRP	RSTEST	RSCAT	RSORRES	VISIT
	Target Response	Recist 1.1	SD	Week 6
	Non-Target Response	Recist 1.1	Non-CR/Non-PD	Week 6
A2	Overall Response	Recist 1.1	SD	Week 6

TR Week 12

TRLNKID	TRLNKGRP	TRTEST	TORRES	TORRESU	VISIT
	A1	Sum of Diameter	35	mm	Screening
	A2	Sum of Diameter	30	mm	Week 6
T01	A3	Diameter	18	mm	Week 12
T02	A3	Diameter	22	mm	Week 12
	A3	Sum of Diameter	40	mm	Week 12
	A3	Percent Change from Baseline in Sum of Diameter	14	%	Week 12
	A3	Percent Change from Nadir in Sum of Diameter	33	%	Week 12
NT01	A3	Tumor State	PRESENT		Week 12

RS Week 12

- Target Lesions: Change from BL / Nadir = 14% / 33%
- Non Target Lesions: Present

RSLNKGRP	RSTEST	RSCAT	RSORRES	VISIT
A2	Overall Response	Recist 1.1	SD	Week 6
	Target Response	Recist 1.1	PD	Week 12
	Non-Target Response	Recist 1.1	Non-CR/Non-PD	Week 12
A3	Overall Response	Recist 1.1	PD	Week 12

Summary



Summary

Good programming is essential...

...knowing the medical context is even better

Thank you!

Any questions?

References

- Clinical Data Interchange Consortium (CDISC) Submission Data Standards Team. Study Data Tabulation Model Implementation Guide: Human Clinical Trials. Version 3.2. 2013
- Eben J. Implementation of oncology specific SDTM domains. Paper PP06. Phuse 2014.
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New Response Evaluation Criteria in Solid Tumours: Revised RECIST Guideline (Version 1.1). European Journal of Cancer. Vol 45. 2009;
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