SOLID TUMOR MEASUREMENT

RECIST 1.1

RECIST 1.1 describes a standard approach to solid tumour measurement and definitions for objective assessment of change in tumour size for use in cancer clinical trials. These guidelines for reproducible analysis serve an important purpose in drug discovery. Imaging endpoints assessed per RECIST 1.1 have been used for regulatory approval of new therapeutics by both the FDA and EMA.

ACRONYM KEY

TL = Target Lesion
NTL = Non Target Lesion
NL = New Lesion
CR = Complete Response
PR = Partial Response
PD = Progressive Disease
SD = Stable Disease
NE = Non-Evaluable
SOD = Sum of the Diameters

1 Baseline Assessment

HOW TO SELECT LESIONS

TL
Up to 5 measurable lesions representing tumor burden (2max/organ)

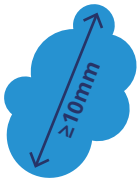
NTL
Other lesions

2 Follow-up Assessment

MONITORING SELECTED LESIONS

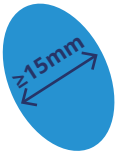
TL
Quantitative Assessment (SOD of all TLs)

NTL
Qualitative Assessment (Absence or Presence)



Tumor Lesions

- Measurable if longest diameter ≥10mm
- Non measurable if longest diameter ≤10mm



Malignant Lymph Node

- Measurable if short axis ≥15mm
- Non measurable if 10mm ≤ Short axis ≤15mm (non pathological if ≤10mm)

Other Lesions

- Bone lesion is considered measurable only if with a soft tissue component that meets definition of measurability, otherwise non measurable
- Non measurable if:
  Blastic bone lesion, ascite, pleural/ pericardial effusion, leptomenigeal disease, lymphangitic involvement of skin or lung, inflammatory breast cancer, abdominal organomegaly that can't be measured by reproducible imaging technique.

Lesion	Response	
TL	CR	All TLs have disappeared or are ≤10mm if lymph node
	PR	30% reduction in SOD compared to baseline
	PD	20% increase in SOD compared to nadir (smallest sum recorded) + 5mm increase in SOD in absolute value
	SD	no PR, no PD
NTL	CR	All NTL have disappeared or are ≤10mm if lymph node
	NON CR / NON PD	Persistance of at least 1 NTL
	PD	Unequivocal progression of existing NTL
NL	The appearance of an unequivocal new lesion will trigger an overall response of PD	

Source: Eisenhauer EA, Therasse P, Bogaerts J, et al. New response evaluation criteria in solid tumours: revised RECIST guideline (version 1.1). Eur J Cancer. 2009;45(2):228–247.

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KEOSYS Medical Imaging

3 Overall Time Point Response
SUBJECTS WITH TARGET LESIONS AND NON TARGET DISEASES

Subjects with Target Lesions

TL	NTL	NL	GLOBAL RESPONSE
CR	CR	No	**CR**
CR	Non CR: Non PD	No	**PR**
CR	NE	No	**PR**
PR	Non PD or NE	No	**PR**
SD	Non PD or NE	No	**SE**
NE	Non PD	No	**NE**
PD	CR, PD, Non CR/ Non PD, NE	Yes or No	**PD**
CR, PR, SD, PD or NE	Unequivocal OD	Yes or No	**PD**
CR, PR, SD, PD or NE	CR, PD, Non CR/ Non PD, NE	Yes	**PD**

Subjects with Non Target Disease Only

NTL	NL	GLOBAL RESPONSE
CR	No	**CR**
Non CR/ Non PD	No	**Non CR / Non PD**
NE	No	**NE**
Unequivoval PD	Yes or No	**PD**
CR, PD, Non CR / Non PD, NE	No	**PD**

4 Top Tips
FOR LIMITING VARIABILITY AND INCREASING ACCURACY OF RESULTS

Select neither too much nor too little TL
All lesions up to a maximum of five lesions total (and a maximum of two lesions per organ) must be identified to represent tumor burden. Don't forget that paired organs count as one!

Don't select TLs in hollow organs
Lesions in hollow organs vary in size depending on the filling status of the organ; measurements are therefore non-reproducible. Watch out for this in gastrointestinal trials!

Declaring PD based on change in NTL is an exceptional case
Only substantial unequivocal progression of NTL can call for PD.

A new unequivocal lesion indicates PD
Even if found in a location that was not scanned at baseline.

Be cautious with temporary inflammatory mechanisms
This can cause a new lesion to be declared by mistake (e.g. bone osteoblastic lesions or pulmonary small nodules).

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