



RECIST

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Overview

- **History/Background**
- **RECIST Criteria Overview**
- **Comparisons – WHO vs. RECIST**
- **Conclusions**
- **Example/Case Study**

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History of Tumor Evaluation

1950's Definition of a (+) Response

- ↓ tumor mass
- no lesions ↑ size
- ∅ new lesions

- OR -

- Physician quorum voting in favor of interpreted clinical benefit to patient

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RECIST

Response Evaluation Criteria In Solid Tumors

Cooperative Group and NCI Initiative

- Goal is for consistent evaluation criteria
- Enables comparison of regimens within a single trial and regimens between different trials
- Useful nationally and internationally

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Measurability of Tumor Lesions at Baseline

Measurable

Lesions that can be accurately measured in at least one dimension (longest diameter to be recorded) as ≥ 2.0 cm with conventional techniques or as ≥ 1.0 cm with spiral CT scan.

Non-measurable

All other lesions, including small lesions [longest diameter < 2.0 cm with conventional techniques or < 1.0 cm with spiral CT scan] and truly non-measurable lesions.

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Truly Non-Measurable Lesions

- Bone Lesions
- Leptomeningeal Lesions
- Ascities
- Pleural / Pericardial Effusion
- Inflammatory Breast Disease
- Lymphangitis cutis / pulmonis
- Abdominal Masses that are not confirmed and followed by imaging techniques
- Cystic Lesions

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Specifications by Methods of Measurement

- Clinical Exam
- Chest X-Ray
- CT & MRI
- Ultrasound
- Endoscopy & Laparoscopy
- Tumor Markers
- Cytology & Histology

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Tumor Response Evaluation - Baseline

Target Lesions

All measurable lesions up to a maximum of 5 lesions per organ and 10 lesions in total, representative of all involved organs.

Target lesions should be selected on the basis of their size (those with the longest diameters) and their suitability for accurate repeated measurements.

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Tumor Response Evaluation - Baseline

Non-Target Lesions

All other lesions (or sites of disease) should be identified as non-target lesions and should be recorded at baseline.

Measurements of these lesions are not required, but the presence or absence of each should be noted throughout follow-up.

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Response Criteria – Target Lesions

- Complete Response (CR)
- Partial Response (PR)
- Stable Disease (SD)
- Progressive Disease (PD)
- Early Death from Malignant Disease
- Early Death from Toxicity
- Early Death from Other Cause
- Unknown (not assessable, insufficient data)

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Complete Response (CR)

The disappearance of all target lesions.

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Partial Response (PR)

At least a 30% decrease in the sum of the longest diameters of target lesions, *taking as reference the baseline sum longest diameter.*

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Progressive Disease (PD)

At least a 20% increase in the sum of the longest diameter of target lesions, *taking as reference the smallest sum longest diameter recorded since the treatment started or the appearance of new lesion (s).*

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Stable Disease (SD)

Neither sufficient shrinkage to qualify for partial response nor sufficient increase to qualify for progressive disease, *taking as reference the smallest sum longest diameter since the treatment started.*

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Response Criteria – Non-Target Lesions

Complete Response (CR)

The disappearance of all non-target lesions and normalization of tumor marker levels, if applicable.

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Response Criteria – Non-Target Lesions

Incomplete Response/Stable disease (SD)

The persistence of one or more non-target lesion(s) and/or the maintenance of tumor marker level above the normal limits.

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Response Criteria – Non-Target Lesions

Progressive disease (PD)

The appearance of one or more new lesion(s) and/or unequivocal progression of existing non-target lesions.