



RECIST 1.0

Criteria Handout



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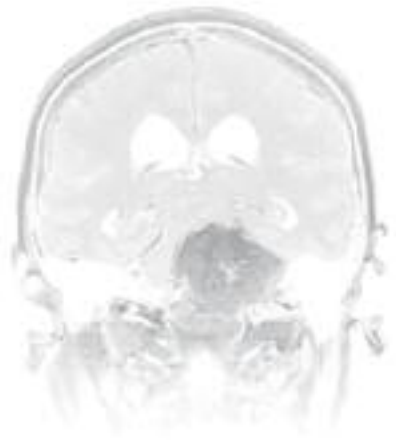
Medical Imaging

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Eligibility

- Measurable disease: Means the presence of at least one measurable lesion.
- Only patients with measurable disease at baseline should be included in protocols where objective tumor response is the primary endpoint.



Imaging Methods

- Spiral CT: slices ≤ 5 mm thick. Oral and IV contrast preferred.
- Conventional (non-spiral) CT: slices ≤ 10 mm thick. Oral and IV contrast preferred.
- MRI: slices ≤ 10 mm thick.
- CXR: PA view, full inspiration, film-tube distance constant between examinations
- Ultrasound: May be an alternative to clinical measurement of superficial palpable nodes, subcutaneous lesions, and thyroid nodules. Caution – often not reproducible.
- Tumor markers alone cannot be used to assess response. If markers are initially above the upper normal limit, they must normalize for a patient to be considered in complete clinical response when all lesions have disappeared.
- Cytology and histology can be used to differentiate between PR and CR in rare cases.

Basic Paradigm

At Baseline:

- Identify all tumor lesions
- Decide which are “measurable”
- Select “target” lesions to follow quantitatively
- Make measurements and calculate sum of longest diameters (SLD)

Follow-Up Evaluations:

- Measure target lesions
- Qualitatively assess non-target lesions
- Look for new ones
- Calculate tumor response

Measurable and Non-Measurable Disease

Measurable Lesions:

- Can be accurately measured in at least one dimension with longest diameter (LD) ≥ 10 mm with spiral CT scan, or ≥ 20 mm with other methods (non-spiral CT, chest X-ray, MRI).

Non-Measurable Lesions:

- All other lesions, including smaller lesions and truly non-measurable lesions (such as lymphangitis, fluid collections, meningeal or peritoneal carcinomatosis, bone lesions, etc.)

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Measurable Lesions: Minimum Size Requirements

- ≥ 10 mm in longest diameter (LD) for spiral CT (nodal and extranodal lesions)
 - If slice thickness > 5 mm, twice the slice thickness
- ≥ 20 mm in LD for non-spiral CT
- ≥ 20 mm in LD for clinical lesions
- ≥ 20 mm in LD for chest x-ray (if clearly defined and surrounded by aerated lung; CT is preferable)

Baseline Documentation of “Target” Lesions

Target Lesions:

- All measurable lesions up to a maximum of five (5) lesions per organ and ten (10) lesions in total, representative of all involved organs.
- Should be selected on the basis of their size (lesions with the longest diameter) and their suitability for accurate repeated measurements.
- The sum of the longest diameters (SLD) for *all target lesions* is recorded at baseline.
- No distinction is made between lymph nodes and non-nodal lesions. Measure longest diameter for ALL target lesions.

Baseline Documentation of “Non-Target” Lesions

Non-Target Lesions:

- All other lesions (or sites of disease) should also be recorded at baseline.
 - Can note multiple lesions in the same organ as a group.
- Assessed qualitatively during follow-up.
- Measurements of these lesions are not required, but the presence or absence of each should be noted throughout follow-up.

Non-malignant lesions should not be selected as either Target or Non-target.

Lesions with Prior Local Treatment

- Lesions in previously irradiated areas should not be selected as target lesions unless there has been documented progression in these lesions. Conditions under which such lesions can be selected as target lesions should be specified in the trial protocol.

Figure 10.10
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Follow-Up Visits

- Measure target lesions
 - Calculate SLD
 - Compare to baseline (for response) and to smallest value seen (for progression)
- Evaluate non-target lesions
 - Absent, present, or showing unequivocal progression
- Search for definite new malignant lesions
- Combine lesion responses into an overall response for the visit using table provided

Evaluation of Target Lesions

Complete Response (CR):	Disappearance of all target lesions
Partial Response (PR):	At least a 30% decrease in the SLD of target lesions, taking as reference the baseline SLD
Progressive Disease (PD):	At least a 20% increase in the SLD of target lesions, taking as reference the smallest SLD recorded since the treatment started
Stable Disease (SD):	Neither sufficient decrease in SLD to qualify for PR nor sufficient increase in SLD to qualify for PD

Evaluation of Non-Target Lesions

Complete Response (CR):	Disappearance of all non-target lesions and normalization of tumor marker level
Incomplete Response/Stable Disease (SD):	Persistence of one or more non-target lesion(s) or/and maintenance of tumor marker level above the normal limits
Progressive Disease (PD):	Unequivocal progression of existing non-target lesions

Assessment of New Lesions

- Search carefully for new malignant lesions. Their appearance indicates progressive disease, regardless of the response of other lesions.
- New lesions should be unequivocal new malignancy, and not attributable to differences in scanning technique or findings which may not be a tumor.
 - Does not have to meet criteria to be “measurable”
- If a new lesion is equivocal, continue to next timepoint. If confirmed then, PD is assessed at the date of the initial scan.

Non-Evaluable Lesions

- If all lesions cannot be evaluated due to missing data or poor image quality the patient is not evaluable at that timepoint.
- If only a subset of lesions can be evaluated at an assessment, the visit is also considered not evaluable, unless a convincing argument can be made that the contribution of the individual missing lesion(s) would not change the assigned timepoint response.

Combining Lesion Responses Into An Overall Response

Target Lesions	Non-Target Lesions	New Lesions	Overall Response
CR	CR	No	CR
CR	Incomplete response/SD	No	PR
PR	Non-PD	No	PR
SD	Non-PD	No	SD
PD	Any	Yes or No	PD
Any	PD	Yes or No	PD
Any	Any	Yes	PD
UE	Any non-PD	No	UE
Any non-PD	UE	No	UE

**CR = Complete Response; PR = Partial Response; SD = Stable Disease
PD = Progressive Disease; UE = Unable to Evaluate**

Best Overall Response

- The best overall response is the best response recorded from the start of the treatment until disease progression/recurrence.
- For PR or CR, response must be confirmed by repeat assessments no less than four (4) weeks after the criteria for response are first met. Longer intervals as determined by the study protocol may also be appropriate.
- The main goal of confirmation of objective response is to avoid overestimating the response rate observed. In cases where confirmation of response is not feasible, it should be made clear when reporting the outcome of such studies that the responses are not confirmed.
- In the case of SD, follow-up measurements must have met the SD criteria at least once after study entry at a minimum interval (in general, not less than 6-8 weeks) defined in the study protocol.

References

Print Version:

“New Guidelines to Evaluate the Response to Treatment in Solid Tumors.”
Journal of the National Cancer Institute, Volume 92, Issue 3 Feb. 2000: 205-214.

Online Version: <http://www.eortc.be/Recist/Default.htm>



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