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RECIST criteria updated version 1.1 use in assessing the efficacy in solid tumors during clinical trials

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Abstract*:*
RECIST CRITERIA Updated Version1.1 In 2009 Came Up With Major Changes In Techniques To Evaluate Solid Tumors, From Classification Of Measurements Based On Target &Non Target Lesions,ShortAxis Diameter (Lymph Nodes) And Assessing Of Lesions Size unidimensional, Objective Of This Literature Is To Focus On Use Of Criteria In Assessment Of Solid Tumors In Clinical Trial where response is primary endpoint,Measuring The Area Of Cancer On A Scan Before And After Treatment, To See How Much It Altered,Evaluation By Complete Response,Partial Response, Progressive Disease And stable Disease In Target & Non Target Lesions. RECIST 1.1 Recommends Measuring Lymph Nodes In Short Axis As Short Axis Measurement More Reproducible &Predictive Of Malignancy.Detection Of New Lesion Appearance Always Marks For A Progressive Disease. Particularly Important When The Patient's Baseline Lesion Assessment Show Partial or Complete Response. The Ruling Of a New Lesion Should Be Unequivocal: I.E. Not Attributable To Differences In Scanning Technique, Focus On Target Lesions &Prevent False Progression Due To Minimal Change In Size .Evaluation DONE By Confirmation &Best Overall Response .It Concludes That ***RECIST*** *1.1Plays Major Role In Identification Disease Progression Hence Recommended For Assessing The Treatment Efficacy In Clinical Trials And Practice.*
Keywords*: Tumor Response, Target Lesion, New Lesion Appearance, Progressive Disease*

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UPDATED VERSION 1.1 RECIST RESPONSE EVALUATION CRITERIA IN SOLID TUMORS

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New response evaluation criteria in solid tumours: Revised RECIST guideline (version 1.1)

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I.INTRODUCTION:

RECIST originally published in 2000,revised in 2009(RECIST 1.1)Is Most widely used set of criteria for assessing response in solid tumors: acceptable for phase II,III,IV clinical trial approval by FDA. There are many ways for researchers to gauge the results of clinical trials. Here are a number of the terms they use We"ve grouped them together into information about: What are end points? Primary & secondary,how long people live (survival)?How well treatment works (response)?RECIST measure the world of cancer on a scan before and after treatment, to ascertain what proportion it has changed.[1]

DEFINITION:

Response evaluation criteria in solid tumors (RECIST) are a set of published regulations that outline when tumors in cancer patients improve ("respond"),stay unchanged ("stabilize"), or worsen ("progress") during treatment Or A standard way to measure how well a cancer patient responds to treatment. It's evaluated whether tumors shrink, stay an equivalent, or get bigger.

RECIST Criteria useful in clinical trials where objective response is primary end point & also describes standard approach in solid tumor measerment, Targeted tumor lesion that is measurable on X-Rays,CTscans,or MRI scans.Types of responses;patient may have Complete Response(CR),PartialResponse(PR),Progressive Disease (PD) and Stable Disease(SD).

- There are other terms that you will hear in cancer research. If you're arrested,it means there are not any signs of cancer on scans or tests.
- A recurrence means the cancer has begun to grow again from its primary location or somewhere else in the body after it had gone away (The highest recurrence rate found in case of Ovarian cancer, nearly 85%) And a relapse means the cancer has began to grow again after it had got smaller or stopped growing.[2]

SOLID TUMORS:

Solid tumors are abnormal solid mass which does not contain cysts or liquid in them. Solid tumor is of two types,Cancerous and Non Cancerous.There are different types of solid tumors.
Examples are Sarcoma, Carcinoma, and Lymphomas [(3).]

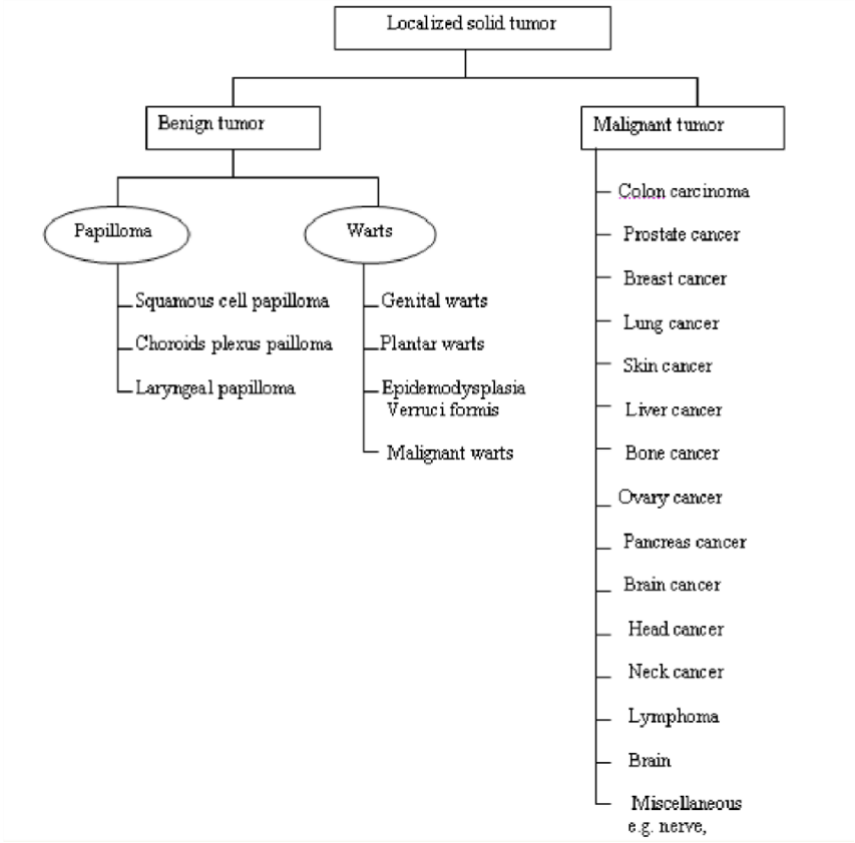


Fig 1. Types of solid tumors

MALIGNANT TUMOR:

Malignant tumors are cancerous. The cells can grow and spread all over the body.

Example here we take as lung cancer

Lung cancer is the term used to describe the expansion of abnormal cells lining the air passages inside the lung tissue. These cells divide and grow sooner than normal cells and mix to make a cluster or tumor.[5]

CLASSIFICATION OF LESIONS:

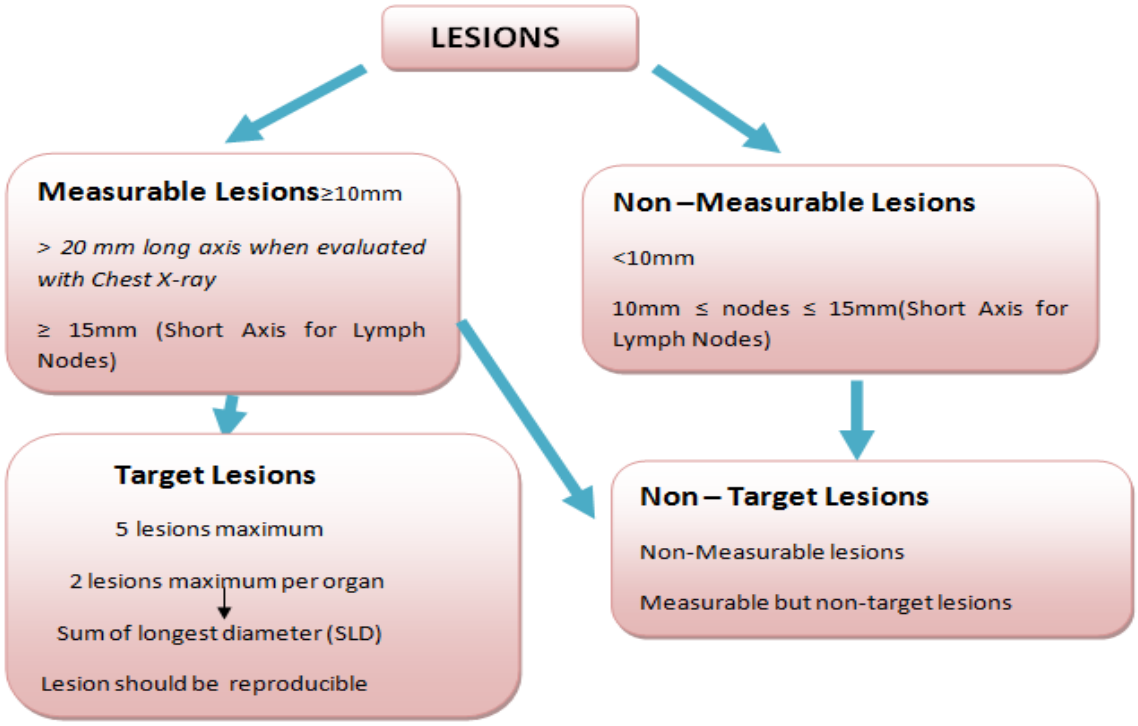


Fig 2.classification of lesion

ACCORDING TO ORIGINAL RECIST 1.1 GUILDLINE:
ELIGIBILITY CRITERIA ARE:

Patients with measurable unwellness at baseline ought to be enclosed in protocols wherever objective neoplasm response is the primary end point.

Measurable disease: The presence of a minimum of two measurable lesion.If the measurable sickness is restricted to a solitary lesion, its growth nature ought to be confirmed by cytology/histology.10 millimetre with spiral CT scan.[3] (it is advisable that CT scan thickness not greater than 5mm).[3]10 mm calliper measurement by clinical examination (If lesion not measurable by calliper then to be considered as non-measurable). 20 millimetre using standard techniques or [3]Measurable lesions - lesions that are accurately measured in a minimum of one dimension with longest diameter(6).Any lesion that is subjected to loco-regional regional therapies (i.e Radiation, ablation)will not be considered as measurable until there is a previous history of progression.

***Malignant lymph nodes*:** To be considered pathologically enlarged *and* measurable, a lymph node must be ≥ 15 mm in *short* axis when assessed by CT scan (CT scan slice thickness recommended to be no greater than 5 mm). At baseline and in follow-up, only the *short* axis will be measured and followed.

Non-measurable lesions - All alternative lesions, including small lesions (longest diameter < 10 mm or pathological lymph nodes with ≥ 10 to < 15 mm short axis) as well as truly non-measurable lesions.The Non measurable lesions considered as; bone lesions, ascites, pleural/pericardial effusion,lymphangitic involvement of skin or lung inflammation breast,rubor cutis/pulmonis, cystic lesions, and additionally abdominal masses/organomegaly identified by physical examination that aren't confirmed and followed by imaging techniques

- In step with RECIST guideline the lesion ought to be measured with calipers or ruler and it should be recorded in metric rotation.
- All techniques and technique of assessment ought to be followed according to pointers solely and it ought to be consistent with assessment at baseline and through follow up.

METHODS OF MEASUREMENT:

- Cytology and microscopic anatomy may be used to differentiate between PR and atomic number 24 in rare cases (e.g., once treatment to differentiate between residual benign lesions and residual malignant lesions in tumour sorts like reproductive cell tumors. ·
- CTscan and MRI square measure best techniques to gauge the lesion, the distinction is 5mm slice thickness in lungs and abdomen.
- Tumor maker square measure alone can't be used for evaluation
- Chest x-ray square measure accustomed known the lesion

BASELINE OF TARGET AND NON-TARGET LESION:
TARGET LESION:

All measurable lesions up to a most of five lesions per organ and ten lesions in total, (maximum of two lesions per organ), representative of all concerned organs should be known as target lesions and recorded and measured at baseline.

- Target lesions ought to be designated on the concept of their size (lesions with the longest diameter) and their suitableness for correct recurrent measurements (either by imaging techniques)
- A total of the longest diameter (LD) for all target lesions goes to be calculated and reported as a result of the baseline sums LD. Measurements of these lesions are not needed, however the presence.

Note: Pathological nodes that are defined as measurable and may be categorized as target lesions if criterion of a short axis of ≥ 15 mm by CT scan is met.

NON-TARGET LESION:

- All other lesions (or sites of disease) should be identified as non-target lesions and can even be recorded at baseline. Measurements of these lesions aren't required, but the presence, absence or in few case unequivocal progression of each should be noted throughout follow-up.

Lesions that split or coalesce on treatment.As noted in Appendix II, when non-nodal lesions,,fragment,the longest diameters of the fragmented portions should be added together to calculate the target lesion sum. Similarly, as lesions coalesce, a plane between them may be maintained that would aid in obtaining maximal diameter measurements of each individual lesion. If the lesions have truly coalesced such that they are no longer separable, the vector of the longest diameter in this instance should be the maximal longest diameter for the "coalesced lesion".

Identifying measurable lesion in short axis for lymph node

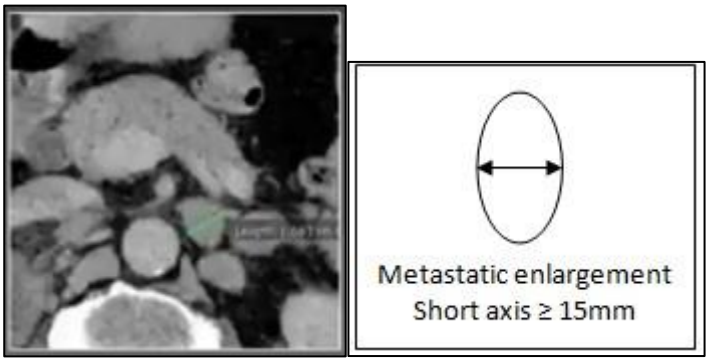


Fig 3 RECIST 1.1 Lymph node short axis

There is a particular rule for Lymph node as per RECIST 1.1 during metastatic enlargement it's always rule to measure short axis diameter enlargement whereas long axis remains same.
Measurement of short axis diameter lymph nodes:
Short axis ≥ 15mm : To Qualify Target Lesion
Short axis ≥ 10mm < 15mm : Non- target Lesion
Short axis <10mm : Non- pathological

METHOD OF MEASURMENT:

1.CT SCAN:
Example:- Malignant solitary fibrous tumor of the pleura in a 69-year-old man with chest pain. Chest computed tomography scan shows a soft tissue mass with coarse boundary [3].

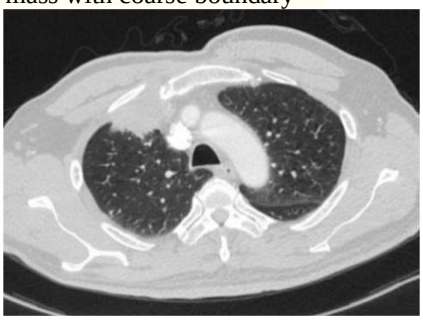


Fig. 4 CT SCAN

2.IMAGE PROCESSING TECHNIQUES:
Lung cancer is the most risky and widespread cancer around the world in step with stage of discovery of the most cancers cells in the lungs, so the procedure of early detection of the disease play an important role.

RESPONSE CRITERIA:
Criteria determine the assessing Tumor Response for target lesions .Measuring the area of cancer on a scan before and after treatment, to see how much it has changed.

EVALUATION OF TARGET LESIONS
They are categorized as:

1. **Complete Response (CR)**
2. **Partial Response(PR)**
3. **Progressive Disease(PD)**
4. **Stable Disease (SD)**

COMPLETE RESPONSE (CR):

- Disappearance of all target lesions.if a lymph node returns back to normal size of 10mm or less, the target response will be considered a complete response.
- There are no signs of cancer on scans or tests.

Example

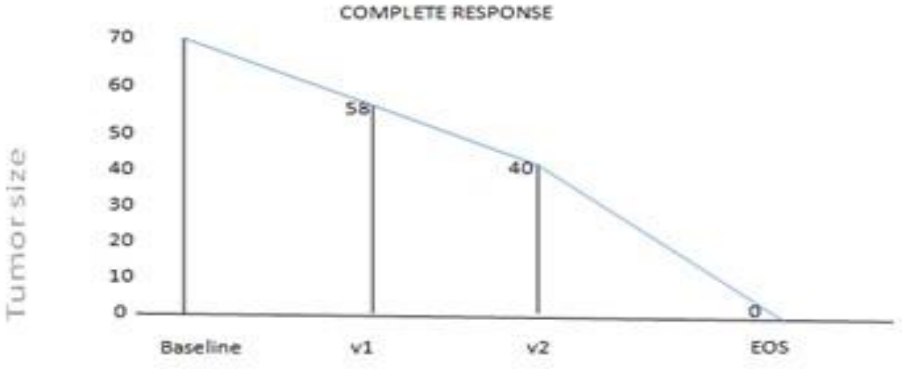


Fig 5. Complete response

Eos = end of study

PARTIAL RESPONSE (PR):

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

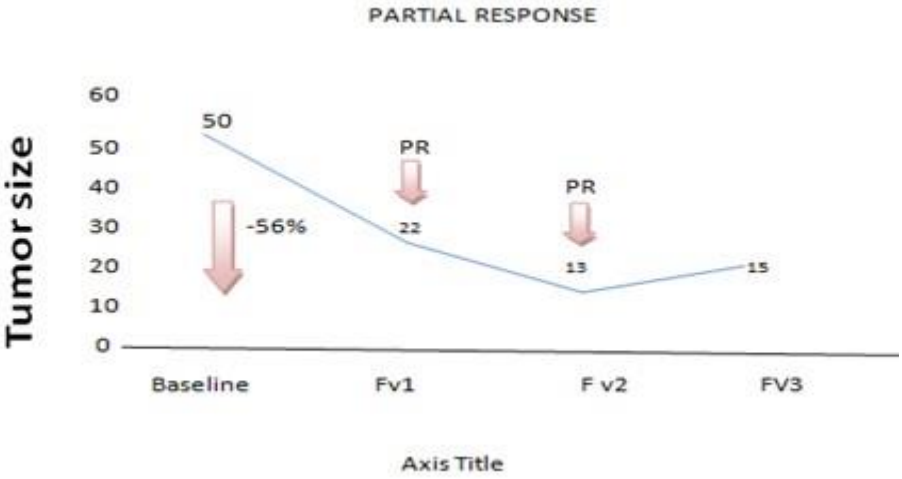


Fig.6 Partial response : FV1= follow up visit

PROGRESSIVE DISEASE (PD):

At least 20% increase in lesions taking reference the smallest (In RECIST, it is called as"**NADIR**".The 'nadir', the smallest lesion diameter during treatment, this is reference for assessment of tumor progression)add of study (this includes the baseline the relative increase of 20%,the add should conjointly demonstrates associate absolute increase of a minimum of 5mm.

[Note: 1 or more of new lesions is additionally thought of progression]

Example

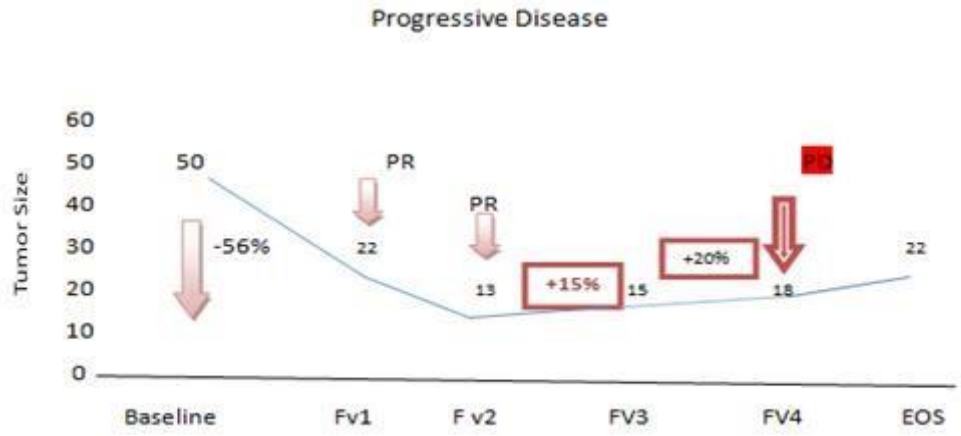


Fig.7 Progressive Disease

Stable Disease (SD): Neither spares shrinkage to qualify for PR nor spare increase to qualify for palladium, taking as reference the littlest. The cancer stayed the same size it hasn‟t got better or worse.

ASSESSMENT NON TARGET LESIONS:

This Criterion is used for determining the tumor response in non-target lesion group. While some non-target lesions may actually be measurable, they should be assessed only qualitatively at the time points outlined in protocol.

Complete response[CR]: Disappearance of all non-target lesions and social control of tumor marker level. All humor nodes should be non-pathological in size(<10mm short axis).

Non-CR/Non-PD: Persistence of 1 or additional non-target lesion(s) and/or maintenance of tumor marker level on top of the conventional limits.

Progressive disease (PD): Unequivocal progression (see comments below) of existing non-target lesions. (Note: the look of 1 or additional new lesions is additionally thought-about progression).

EXAMPLES OF NON TARGET LESIONS ARE :

- Pleural Carcinomatosis
- Peritoneal Carcinomatosis
- Lymphangiosis
- Lymph Node ≥10 < 15mm
- Measurable Diseases :Which Exceeds 5 Target Lesion In Number

All different lesions (or sites of disease) as well as pathological body fluid nodes ought to be known as nontarget lesions and may even be recorded at baseline. modest „increase‟ within the size of 1 or additional nontarget lesions is typically not comfortable to quality for unequivocal progression standing. The designation of overall progression only on the premise of modification in non-target unwellness within the face of Mount Rushmore State or PR of target unwellness can so be very rare[11].

NEW LESION:

The appearance of latest malignant lesions denotes disease progression; therefore, detection of latest lesions are important. There are not any specific criteria for the identification of latest radiographic lesions; however, the finding of a replacement lesion should be unequivocal: i.e. not due to differences in scanning technique, change in imaging modality or findings thought to represent something aside from tumour (for example, some „new‟ bone lesions could also be this is often particularly important when the patient‟s baseline lesions show partial or complete response. for instance , necrosis of a liver lesion could also be reported on a CT scan report as a „new‟ cystic lesion, which it's not.

A lesion identified on a follow-up study in an anatomical location that wasn't scanned at baseline is taken into account a replacement lesion and can indicate disease progression.Significant lesions that completely regress and then reappear are indicative of PD.[8]

An example of this is often the patient who has visceral disease at baseline and while on study features a CT or MRI brain ordered which reveals metastases. The patient‟s brain metastases are considered to be evidence of PD albeit he/she didn't have brain imaging at baseline.

If a replacement lesion is equivocal, for instance due to its small size, continued therapy and follow-up evaluation will clarify if it represents truly new disease. If repeat scans confirm there's definitely a replacement lesion, then progression should be declared using the date of the initial scan. While FDG-PET response assessments need additional study, it's sometimes reasonable to include the utilization of FDG-PET scanning to enrich CT scanning in assessment of progression (particularly possible „new‟ disease).

New lesions on the basis of FDG-PET imagine can be identified according to the following algorithm:

a. Negative FDG-PET at baseline, with a positive FDG-PET at follow-up is PD based on a new lesion. A "positive‟ FDG-PET scan lesion is one which is FDG avid with an uptake greater than twice that of the surrounding tissue on the attenuation corrected image.

b. No FDG-PET at baseline and a positive FDG-PET at follow-up:

If the positive FDG-PET at follow-up corresponds to a new site of disease confirmed by CT,then PD.

If the positive FDG-PET at follow-up is not confirmed as a new site of disease on CT, additional follow-up CT scans are needed to determine if there is truly progression occurring at that time (if so, the date of PD will be the date of the initial abnormal FDG-PET scan).

If the positive FDG-PET at follow-up corresponds to a pre-existing site of disease on CT that is not progressing on the basis of the anatomic images, is not PD.

TIME POINT RESPONSE

It is assumed that at each protocol specified time point, a response assessment occurs.**Table 1** on the next page provides a summary of the overall response status calculation at each time point for patients who have measurable disease at baseline. When patients have non-measurable (therefore non-target) disease only, Table 2 is to be used.

BEST OVERALL RESPONSE

The total number of individuals whose cancer has either gone away (a complete response) or shrunk (a partial response).Best response determination in trials where confirmation of complete or partial response isn't required: Best response in these trials is defined because the best response across all time points (for example, a patient who has SD initially assessment, PR at second assessment, and PD on last assessment features a best overall response of PR).

Table 1

Table 1 – Time point response: patients with target (+/– non-target) disease.

Target lesions	Non-target lesions	New lesions	Overall response
CR	CR	No	CR
CR	Non-CR/non-PD	No	PR
CR	Not evaluated	No	PR
PR	Non-PD or not all evaluated	No	PR
SD	Non-PD or not all evaluated	No	SD
Not all evaluated	Non-PD	No	NE
PD	Any	Yes or No	PD
Any	PD	Yes or No	PD
Any	Any	Yes	PD

CR = complete response, PR = partial response, SD = stable disease, PD = progressive disease, and NE = inevaluable.

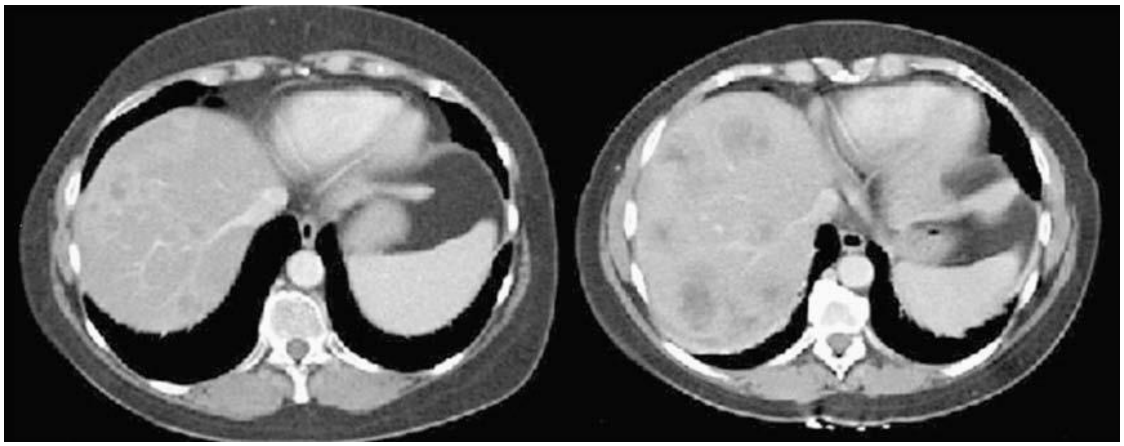
Table 2

Table 2 – Time point response: patients with non-target disease only.

Non-target lesions	New lesions	Overall response
CR	No	CR
Non-CR/non-PD	No	Non-CR/non-PD[a]
Not all evaluated	No	NE
Unequivocal PD	Yes or No	PD
Any	Yes	PD

CR = complete response, PD = progressive disease, and NE = inevaluable.

a 'Non-CR/non-PD' is preferred over 'stable disease' for non-target disease since SD is increasingly used as endpoint for assessment of efficacy in some trials so to assign this category when no lesions can be measured is not advised.



Example of unequivocal progression in non-target lesions in liver[7].

Clinical trial relate to RECIST 1.1 guidelines

- In Clinical trials studies evaluations of response rate of tumors based on RECIST 1.1 criteria were been used for assessing survival rate.
- Clinical Trial records STUDIES carried out of 160 total of which 90 studies are COMPLETE studies by using the RECIST 1.1 criteria.

CONFIRMATION:

In non-randomised trials wherever response is that the primary termination, confirmation of PR and atomic number 24 is needed to confirm responses known aren't the results of measure error. this may conjointly allow applicable interpretation of leads to the context of historical information wherever response has historically needed confirmation in such trials (see the paper by Bogaerts et al(8). In randomized trials (phase II or III) or studies where stable unwellness or progression are the first endpoints, confirmation of response isn't needed since it'll not add price to.

However, elimination of the need for response confirmation could increase the importance of central review to shield against bias, particularly in studies that aren't unsighted. Within the case of Mount Rushmore State, measurements should have met the Mount Rushmore State criteria a minimum of once when study entry at a minimum interval (in general not but 6–8 weeks) that's outlined within the study protocol.

Duration of overall response

The period of overall response is measured from the time measurement criteria are initial met for CR/PR (whichever is initial recorded)untill the primary date that perennial or progressive disease is objectively documented (taking as reference for progressive malady the littlest measurements recorded on study).

The period of overall complete response is measured from the time measure criteria are initially met for till the primary date for complete response.Period of Stable disease is measured from the beginning of the treatment (in irregular trials, from date of randomization) till the standards for progression are met.The clinical connectedness of the period of stable malady varies in several studies and diseases.

Note: The period of response and stable disease and the progression-free survival are influenced by the frequency of follow-up comparing to baseline analysis .it's not within the scope of this guideline to outline a regular follow-up frequency.

The frequency ought to take under consideration several parameters together with disease varieties and stages, treatment regularity and commonplace apply.

However, these limitations of the exactitude of the measured end point ought to be taken under consideration if comparisons between trials are to be created.

When nodal disease is included in the sum of target lesions and the nodes decrease to „normal" size (< 10 mm), they may still have a measurement reported on scans. This measurement should be recorded even though the nodes are normal in order not to overstate progression should it be based on the increase in size of the nodes. this means that patients with CR may not have total sum of „zero".

Patients with a global deterioration of health status requiring discontinuation of treatment without objective evidence of disease progression at that time should be reported as „symptomatic deterioration". Every effort should be made to document objective progression even after discontinuation of treatment. Symptomatic deterioration is *not* a descriptor of an objective response: it is a reason for stopping study therapy. The objective response status of such patients is to be determined by evaluation of target and non-target disease.

Conditions that define „early progression, early death and in evaluability" are trial specific and should be clearly described in each protocol (depending on treatment duration, treatment periodicity).

In some circumstances it may be difficult to distinguish residual disease from normal tissue. When the evaluation of complete response depends upon this determination, it is recommended that the residual lesion be investigated (fine needle aspirate/biopsy) before assigning a status of complete response. FDG-PET may be used to upgrade a response to a CR in a manner similar to biopsy in cases where a residual radiographic abnormality is thought to represent fibrosis or scarring. The use of FDG-PET in this circumstance should be prospectively described in the protocol and supported by disease specific medical literature for the indication. However, it must be acknowledged that both approaches may lead to false positive CR due to limitations of FDG-PET and biopsy resolution/sensitivity.

For equivocal findings of progression (e.g., very small and uncertain new lesions; cystic changes or necrosis in existing lesion), treatment may continue until the next scheduled assessment. If at the next scheduled assessment, progression is confirmed, the date of progression should be the earlier date when progression was suspected.

RECIST 1.1GLANCE:

- Always make sure the progression actually occurred or not as it could also be variability in a CT scan. [9]
- BE careful before the treatment for progression make sure that regime is tolerable.

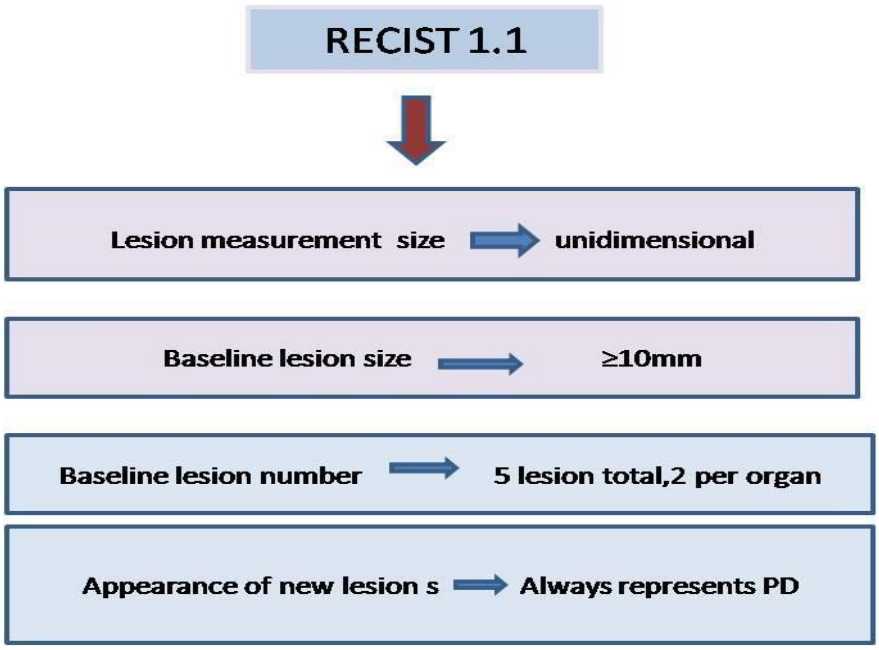


Fig.8.RECIST 1.1 Criteria Brief overview

Appendix I. Summary of major changes RECIST 1.0 to RECIST 1.1

	RECIST 1.0	RECIST 1.1	Rationale	R
Minimum size measurable lesions	CT: 10 mm spiral 20 mm non-spiral	CT 10 mm; delete reference to spiral scan	Most scans used have 5 mm or less slice thickness Clearer to give instruction based on slice interval if it is greater than 5 mm	
	Clinical: 20 mm	Clinical: 10 mm (must be measurable with calipers)	Caliper measurement will make this reliable	
	Lymph node: not mentioned	CT: ⩾15 mm short axis for target ⩾10–<15 mm for non-target <10 mm is non-pathological	Since nodes are normal structure need to define pathological enlargement. Short axis is most sensitive	
Special considerations on lesion measurability	–	Notes included on bone lesions, cystic lesions	Clarify frequently asked questions	
Overall tumour burden	10 lesions (5 per organ)	5 lesions (2 per organ)	Data warehouse analysis shows no loss of information if lesion number reduced from 10 to 5. A maximum of 2 lesions per organ yields sufficient representation per disease site	
Response criteria target disease	CR lymph node not mentioned	CR lymph nodes must be <10 mm short axis	In keeping with normal size of nodes	
	PD 20% increase over smallest sum on study or new lesions	PD 20% increase over smallest sum on study (including baseline if that is smallest) and at least 5 mm increase or new lesions	Clarification that if baseline measurement is smaller than any on study measurement, it is reference against which PD is assessed 5 mm absolute increase to guard against over calling PD when total sum is very small and 20% increase is within measurement error	
Response criteria non-target disease	'unequivocal progression' considered as PD	More detailed description of 'unequivocal progression' to indicate that it should not normally trump target disease status. It must be representative of overall disease status change, not a single lesion increase	Confusion with RECIST 1.0 where some were considering PD if 'increase' in any non-target lesion, even when target disease is stable or responding	
New lesions	–	New section on New lesions	To provide guidance on when a lesion is considered new (and thus PD)	
Overall response	Table integrated target and non-target lesions	Two tables: one integrating target and non-target and the other of non-target only	To account for the fact that RECIST criteria are now being used in trials where PFS is the endpoint and not all patients have measurable (target) disease at baseline	
		Special notes: How to assess and measure lymph nodes CR in face of residual tissue Discussion of 'equivocal' progression	Frequently asked questions on these topics	
Confirmatory measure	For CR and PR: criteria must be met again 4 weeks after initial documentation	Retain this requirement ONLY for non-randomised trials with primary endpoint of response	Data warehouse shows that response rates rise when confirmation is eliminated, but the only circumstance where this is important is in trials where there is no concurrent comparative control and where this measure is the primary endpoint	
Progression-free survival	General comments only	More specific comments on use of PFS (or proportion progression-free) as phase II endpoint Greater detail on PFS assessment in phase III trials	Increasing use of PFS in phase III trials requires guidance on assessment of PD in patients with non-measurable disease	
Reporting of response results	9 categories suggested for reporting phase II results	Divided into phase II and phase III 9 categories collapsed into 5 In phase III, guidance given about reporting response	Simplifies reporting and clarifies how to report phase II and III data consistently	
Response in phase III trials	More relaxed guidelines possible if protocol specified	This section removed and referenced in section above: no need to have different criteria for phase II and III	Simplification of response assessment by reducing number of lesions and eliminating need for confirmation in randomised studies where response is not the primary endpoint makes separate 'rules' unnecessary	
Imaging appendix	Appendix I	Appendix II: updated with detailed guidance on use of MRI, PET/CT Other practical guidance included	Evolving use of newer modalities addressed. Enhanced guidance in response to frequent questions and from radiology review experience	
New appendices		Appendix I: comparison of RECIST 1.0 and 1.1 Appendix III: frequently asked questions		

II.Conclusion:

Response evaluation criteria in solid tumors are Documented in which it explain standard way of conducting trial and its factors.**RECIST** criteria updated version1.1 plays a major role in oncology trial for tumor assessment & recommended for assessing the treatment efficacy during clinical trials and practice.

Reference:

[1]. .https://www.cancerresearchuk.org/find-a-clinical-trial/clinical-trial-results/how-clinical-trial-results-are-used

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