

Response criteria in oncology

Overview

Imaging plays a major role in the objective assessment of tumor response to drug therapies in clinical trials. Most methods used to evaluate treatments are based on the measurement of lesion size. Response to treatment is quantitatively evaluated using response criteria. Response criteria are quantitative imaging biomarkers.

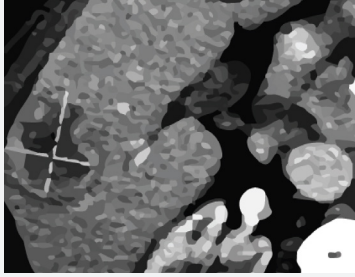
Response criteria in oncology

There are a large number of response criteria for oncology; each one is best-suited for a particular type of tumor or type of therapy.

Response criteria	For use with	Date established	Notes
WHO	Solid tumors	1979	Original response criteria using bidimensional measurements, the framework for standardization of reporting of response for patients with cancer
RECIST	Solid tumors	2000	Response criteria using unidimensional measurements and longest diameter
RECIST1.1	Solid tumors	2009	Gold standard for evaluating response in solid tumors; Revised RECIST guidelines (version1.1) lowered the number of measurable lesions. Longest dimensions are measured except for lymph nodes (short axis dimension)
iRECIST	Immunotherapies	2017	Modified RECIST that account for the delayed response and pseudoprogression. Defines new progression confirmation rules; directly comparable to RECIST1.1
irRC	Immunotherapies	2009	Modified WHO criteria that account for delayed response and pseudoprogression with immunotherapies
irRECIST	Immunotherapies	2013	Modified irRC and RECIST criteria that account for delayed response and pseudoprogression; directly comparable to RECIST1.1
MacDonald	Glioma, astrocytoma	1990	Modified WHO for malignant glioma, later modified to be RANO
RANO	Glioma, astrocytoma	2010	Accounts for irregular growth patterns, the presence of cystic cavities, pseudo-progression; Uses bidimensional measurements with contrast-enhanced MRI
RANO-BM	Parenchymal brain metastasis	2013	Modified RECIST to evaluate brain metastases
mRECIST	Hepatocellular carcinoma	2010	Accounts for tumor necrosis by not including necrotic portion of lesions in measurement
Cheson	Lymphoma (non-Hodgkin's)	1999	Original response criteria for non-Hodgkin's lymphoma using bidimensional measurements
IWG-Cheson	Lymphoma (non-Hodgkin's)	2007	Includes FDG-PET to characterize response
Lugano Classification	Lymphoma (non-Hodgkin's)	2014	FDG-PET is integrated with CT/MRI according to a 5 point scale to characterize response
NCI-WG	Chronic lymphocytic leukemia	1996	Defines role of imaging in clinical trials and research
IWCLL	Chronic lymphocytic leukemia	2008	Updates the 1996 NCI-WG criteria
PERCIST	Solid tumors	2009	Criteria for assessing metabolic tumor response using FDG-PET
Choi	GIST	2007	Incorporates contrast-enhanced CT tumor attenuation measurement to account for tumor necrosis
Byrne	Mesothelioma	2004	Defines measurement criteria of mesothelioma to account for patterns of appearance on cross-sectional imaging

- Response criteria define a set of rules to objectively measure tumor response or disease progression after treatment with an experimental drug.
- Morphological biomarkers: based on measuring changes in tumor size: tumor size increases = disease progression; tumor size decreases = response to therapy.
- Functional biomarkers: based on changes in physiological factors such as glucose metabolism, hypoxia, angiogenesis.
- Response criteria allow for the uniform reporting of imaging data and the comparison of clinical trial results across trials.

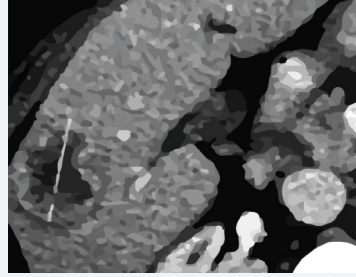
Measuring techniques for various response criteria



Bidimensional

Longest diameter x
Longest perpendicular
diameter

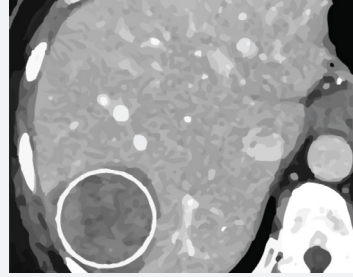
- WHO criteria
- irRC
- MacDonald
- RANO
- Cheson



Unidimensional

Longest diameter

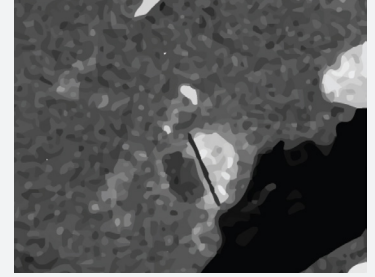
- RECIST 1.0
- RECIST1.1 (short axis for lymph node)
- irRECIST (short axis for lymph node)
- iRECIST (short axis for lymph node)



Region of interest (ROI)

Tumor attenuation

- Choi



Unidimensional, avoiding areas of necrosis

- mRECIST

Reference: Gonzalez-Guindalini FD, Botelho MPF, Harmath CB et al. (2013) RadioGraphics 33, 1781–1800.

Categories of response:

Each set of response criteria has its own definition of disease progression.

Criteria	Definition of progression
RECIST1.1	≥ 20% increase in SoD (short axis axis for lymph node), with an absolute increase of 5mm; new lesions always represent PD
iRECIST	≥ 20% increase in SoD (short axis for lymph node), with an absolute increase of 5mm; First RECIST PD is iUPD confirmed at 4-8 weeks; accounts for flare
irRECIST	≥ 20% increase in TTB, with an absolute increase of 5mm; new lesions are incorporated as part of TTB and do not automatically represent PD; accounts for flare (tumor enlargement prior to stabilization or shrinkage); wait up to 12 weeks post-treatment to confirm PD
irRC	≥ 25% increase in TTB; new lesions are incorporated as part of TTB and do not automatically represent PD; accounts for flare; wait 4 weeks later to confirm PD
Choi	≥ 10% increase in longest diameter and does not meet criteria for PR of ≥ 15% decrease in tumor attenuation (density); appearance of new lesions
mRECIST	≥ 20% increase in SoD of viable (non-necrotic) tissue. Appearance of new viable hepatic lesions ≥ 10mm
RANO	≥ 25% increase product of bidimensional measurements; appearance of new lesions; increase in non-enhancing lesions, definite clinical deterioration

SoD = sum of diameters; PD = progressive disease; TTB = total tumor burden



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