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INTERACTIVE WORKSHOP 1: RESPONSE ASSESSMENT CRITERIA

Thursday 4 October 2012, 11:00–12:30

RECIST rules

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Abstract

Response Evaluation Criteria for Solid Tumours (RECIST) were introduced in 2000 to provide a standardized method for assessing response to treatments. The RECIST Working Group has updated RECIST to Version 1.1.

Keywords: *Response Evaluation Criteria for Solid Tumours; version 1.1.*

Response Evaluation Criteria for Solid Tumours (RECIST) were introduced in 2000 to provide a standardized method for assessing response to treatments[1]. The RECIST Working Group has updated RECIST to Version 1.1[2]. The revised version has maintained assessment of tumour burden using the sum of the diameters and continues to use uni-dimensional measurements. The response categories are still complete response, partial response (30% decrease in sum from baseline), stable disease and progressive disease (20% increase in sum from nadir). The revisions address issues that have arisen related to the use of the criteria in clinical practice. Table 1 outlines the main changes.

Table 1

	RECIST 1.0	RECIST 1.1
Tumour burden	Maximum 10 target lesions in total and up to 5 per organ	Maximum 5 target lesions in total and up to 2 per organ
Measurable lesions	≥10 mm in longest diameter (LD) for spiral CT (nodal and extranodal lesions) ≥20 mm in LD for non-spiral CT ≥20 mm in LD for clinical lesions ≥20 mm in LD for chest radiograph Ultrasound (US) may be an alternative to clinical measurement of superficial nodes or nodules	≥10 mm in LD and 2 time the slice thickness for extra-nodal lesions ≥15 mm in short axis diameter (SAD) for nodal lesions ≥10 mm in LD for clinical lesions ≥20 mm in LD for chest radiograph US cannot be used to measure lesions
Lymph nodes	Nodal lesions not distinguished from extra-nodal lesions	Lymph nodes are considered abnormal enlarged if SAD >10 mm Measurable nodal lesions must be ≥15 mm in SAD Non-measurable nodal lesions SAD >10 mm and <15 mm The sum of the diameters (LD for extra-nodal target lesions and SAD for nodal lesions) is followed through treatment
Complete response (CR)	CR requires disappearance of all lesions	CR requires the disappearance of all extra-nodal lesions and regression of nodal lesions to <10 mm SAD

(continued)

Table 1 Continued

	RECIST 1.0	RECIST 1.1
Progressive disease (PD)	PD occurs if the sum of the longest diameters increases by ≥20% from nadir PD occurs if there is "unequivocal progression" of existing non-target lesions	PD occurs if the sum of the diameters has increased by ≥20% and ≥5 mm from nadir Patients with measurable disease for "unequivocal progression" based on non-target disease, there must be an overall substantial worsening that merits discontinuation of therapy (if target disease is SD/PR) Patients without measurable disease for "unequivocal progression" of non-target disease, the increase in overall tumour burden must be comparable to the increase needed for PD of measurable disease
Confirmation of response	CR and PR require confirmation by a repeat assessment 4 weeks after initial documentation	Confirmation of PR/CR is ONLY required for non-randomized trials where response is the primary end point
New lesion	Not specifically defined	New lesions should be unequivocal and not attributable to differences in scanning technique or findings which may not be tumour. If a new lesion is equivocal then repeat scans are needed to confirm. Lesions identified in anatomic locations not scanned at baseline are considered new. New lesions on US should be confirmed on CT/magnetic resonance imaging (MRI)
Fluorodeoxyglucose (FDG)-positron emission tomography (PET)	No specific recommendations	New lesions can be assessed using FDG/PET PET negative at baseline and positive at follow-up is PD based on a new lesion No PET at baseline and positive PET at follow-up is PD if the new lesion is confirmed on CT No PET at baseline and positive PET at follow-up corresponding to a pre-existing lesion on CT that is not progressing is not PD
Overall response	Overall response table integrates target, non-target and new lesions	One overall response table integrates target, non-target and new lesions Another table integrates non-target and new lesions for the assessment of subjects without measurable disease

Table modified from: http://www.corelabpartners.com/CoreLabPartners/media/Corelab/RECIST-Guide_122011web.pdf

References

[1] Therasse P, Arbuck SG, Eisenhauer EA, et al. New guidelines to evaluate the response to treatment in solid tumors. European Organization for Research and Treatment of Cancer, National Cancer Institute of the United States, National Cancer Institute of Canada. J Natl Cancer Inst 2000; 92: 205–216. doi:10.1093/jnci/92.3.205. PMid:10655437.

[2] 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: 228–472. doi:10.1016/j.ejca.2008.10.026. PMid:19097774.