

Common Errors in RECIST v1.1 Reporting

Even with sufficient staff training, mistakes in documentation and reporting are frequent findings during an audit. The table below outlines some of the more common errors in RECIST documentation and the corresponding RECIST 1.1 guideline that should be followed.

Documentation Error	RECIST 1.1 Guideline
Selection of non-nodal target lesions and non-target lesions	- No more than 5 target lesions (up to 2 per organ) measuring $\geq 10\text{mm}$ in longest diameter can be chosen. - There is no cap on the number of non-target lesions, however they must measure $< 10\text{mm}$ in longest diameter.
Recording of lymph nodes	- Lymph nodes are considered one organ and must be recorded using the smallest diameter of the node (short axis). - Lymph nodes $\geq 15\text{mm}$ in short axis may be target lesions. - Lymph nodes $10\text{-}14\text{mm}$ in short axis are considered non-target lesions. - Lymph nodes $< 10\text{mm}$ are considered non-pathological and should not be recorded.
Assessment of target lesion response	- Complete Response (CR): Disappearance of all target lesions. Lymph nodes must have a reduction in short axis to $< 10\text{mm}$. - Partial Response (PR): At least a 30% decrease in the sum of target lesions compared to the baseline sum. - Progressive Disease (PD): At least a 20% increase in the sum compared to the smallest sum of previous measurements. In addition, the sum must also demonstrate an absolute increase of $\geq 5\text{mm}$. - Stable Disease (SD): Neither sufficient decrease to qualify for PR nor sufficient increase to qualify for PD compared to the smallest sum of previous measurements. Note: If a target lesion is believed to be present but is too small to be measured, it should be recorded as 5mm.
Assessment of non-target lesion response	- Complete Response (CR): Disappearance of all non-target lesions and normalization of tumor markers (if applicable). All lymph nodes must be $< 10\text{mm}$ in short axis. - Non-CR/Non-PD: Persistence of one or more non-target lesions and/or maintenance of tumor marker level above normal limits. - Progressive Disease (PD): Unequivocal progression of existing non-target lesions.
Identification of a new lesion	The appearance of one or more new lesions of any size is considered progression. New lesions should be unequivocal and not attributable to differences in scanning technique or findings which may not be tumor.

	• A lesion identified on a follow-up study in a location that was not previously scanned is considered a new lesion and indicative of disease progression. • If a new lesion is equivocal, therapy should be continued until the next scan assessment. If the repeat scan confirms a definite new lesion, progression should be reported using the date the new lesion was first seen.
Selection of bone and cystic lesions	• Lytic or mixed lytic-blastic bone lesions <i>with identifiable soft tissue components</i> are measurable target lesions if their size is $\geq 10\text{mm}$ in longest diameter. • Blastic bone lesions and bone lesions with soft tissue components measuring $< 10\text{mm}$ are considered non-measurable disease. • Cystic lesions thought to represent metastases are considered target lesions if they measure $\geq 10\text{mm}$ in longest diameter. However, if the patient has other non-cystic lesions, these should be selected as target lesions over cystic lesions.
Selection of lesions with prior treatment	• Tumor lesions located in a previously irradiated area, or in an area treated with other loco-regional therapy, are usually not considered measurable unless there has been demonstrated progression in the lesion. Refer to the study protocol for details in which such lesions would be considered measurable.