

Tumor Assessment Using RECIST 1.1 Criteria

Definitions

Tumor burden is composed of the sum of diameters of target lesions.

Target Lesion / Non Target Lesion

- Target Lesion is measured in only one dimension
- The longest diameter of a target lesion must be $\geq 10\text{mm}$
- Any lesion $< 10\text{mm}$ is called non target
- Other lesions that are non Target =
 - Bone lesion (except if there's a soft tissue component)
 - Ascites
 - Leptomeningeal disease
 - Pleural / Pericardial
 - Lymphangitic carcinomatosis
 - Prior irradiated lesion (except if progression is documented)

Specific Cases: Lymph Nodes

- Measure the shortest axis
- Lymph node is NON pathological if its short axis is $< 10\text{mm}$
- Lymph node is NON TARGET lesion if its short axis is between 10 and 15 mm ($10\text{mm} \leq \text{axis} < 15\text{mm}$)
- Lymph node can be Target Lesion if its short axis is $\geq 15\text{mm}$

Notes

- Lymph Node considered “non pathological” if short axis is $< 10\text{mm}$. Therefore, CR can be observed with a sum of diameters $\neq 0$

Tumor Assessment

Assessment of Target Lesions

- Identify and follow a maximum of 5 lesions (max 2 per organ)
- Identify and follow a maximum of 2 Target nodes
- Calculate the total sum of target lesions
- Assess Target Lesion Response

Categories of Target Lesion response:

Complete response (CR): all target lesions disappeared. CR can be observed with $\text{sod} \neq 0$. Nodal lesion can exist, but $< 10\text{mm}$.

Partial Response (PR): at least 30% reduction of sum compared to baseline.

Progressive Disease (PD): increase of disease of at least 20% compared to the smallest sum recorded (nadir) + increase of at least 5mm in absolute value.

Stable disease (SD): no PR, no PD.

Assessment of Non Target lesions

- Identify and follow-up (absence/presence)
- Determine non target lesions response

Categories of Non Target Lesion response:

CR: Disappearance of all non-target lesions and normalization of tumor marker level. All lymph nodes must be non-pathological in size ($< 10\text{mm}$ short axis).

Non CR / Non PD: Presence of at least one non target lesion.

PD: Unequivocal progression of existing non-target lesions.

New lesions:

The appearance of one or more new lesions is considered progression.

Assessing Global Response

Category 1: With target Lesions at baseline assessment

Target Lesion	Non Target Lesion	New Lesion	Global Response
CR	CR	No	CR
CR	Non CR / Non PD	No	PR
CR	NE	No	PR
PR	Non PD or NE	No	PR
SD	Non PD or NE	No	SD
NE	Non PD	No	NE
PD	CR, PD, Non CR/ Non PD, or NE	Yes or No	PD
CR, PR, SD, PD, or NE	Unequivocal PD	Yes or No	PD
CR, PR, SD, PD, or NE	CR, PD, Non CR/ Non PD, or NE	Yes	PD

Category 2: Only Non Target Lesions at baseline assessment

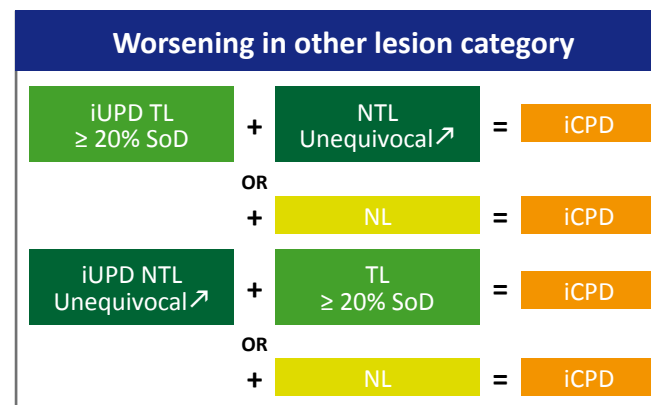
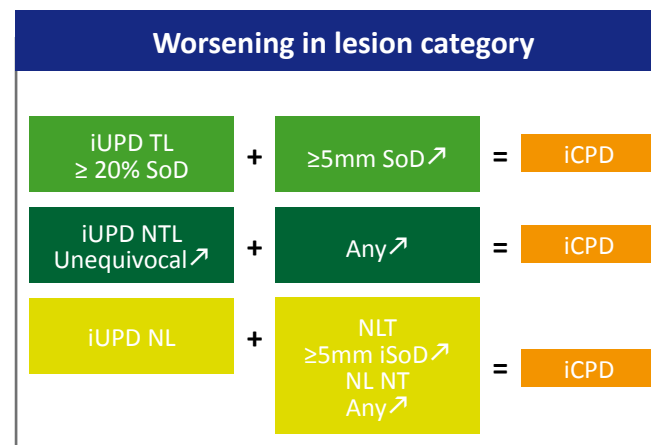
Non Target Lesion	New Lesion	Global Response
CR	No	CR
Non CR / Non PD	No	Non CR/ Non PD
NE	No	NE
Unequivocal PD	Yes or No	PD
CR, PD, Non CR/ Non PD, or NE	Yes	PD

Tumor Assessment Using Alternative Criteria for Immuno-oncology Trials

	irRC	irRECIST	iRECIST
Lesion Measurement	Bidimensional	Unidimensional	Unidimensional
Baseline Lesion Size	5 mm x 5 mm	≥ 10 mm	≥ 10 mm
Baseline Lesion Number	10 lesions total, 5 per organ	5 lesions total, 2 per organ	5 lesions total, 2 per organ
Appearance of New Lesions	Incorporated into TTB	Incorporated into TTB	iUPD
Response	CR = disappearance of all lesions	CR = disappearance of all lesions	CR = disappearance of all lesions
	PR ≥ 50% decrease from baseline TTB	PR ≥ 30% decrease from baseline TTB	PR ≥ 30% decrease from baseline TTB
	SD = when neither PR nor PD can be established	SD = when neither PR nor PD can be established	SD = when neither PR nor PD can be established
	PD ≥ 25% increase in the nadir of TTB	PD ≥ 20% increase in the nadir of TTB (minimum 5 mm)	PD ≥ 20% increase in the nadir of TTB (minimum 5 mm)
Confirmation after first assessment	Yes	Yes, wait up to 12 weeks to confirm PD to account for flare	Yes 4-8 weeks

iRECIST New Progression Confirmation Rules

iCPD: immune confirmed progressive disease



- TL** = Target lesion
- SoD** = Sum of diameters for all target lesions
- iSoD** = Immune sum of diameters for new lesion target
- iUPD** = Immune unconfirmed progressive disease
- iCPD** = Immune confirmed progressive disease
- NLT** = Non target lesion
- NL** = New lesion
- NLT** = New lesion target
- NL NT** = New lesion non target