median
The Imaging Phenomics Company®

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 ≥10mm
- Any lesion <10mm 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 <10mm
- Lymph node is NON TARGET lesion if its short axis is between 10 and 15 mm (10mm≤ axis <15mm)
- Lymph node can be Target Lesion if its short axis is ≥15mm

Notes
- Lymph Node considered "non pathological" if short axis is <10mm. Therefore, CR can be observed with a sum of diameters ≠ 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 sod not equal to 0. Nodal lesion can exist, but <10mm.

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 mm short axis).

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

PD: Unequivocal progression of existing non-target lesions.

Assessment of 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

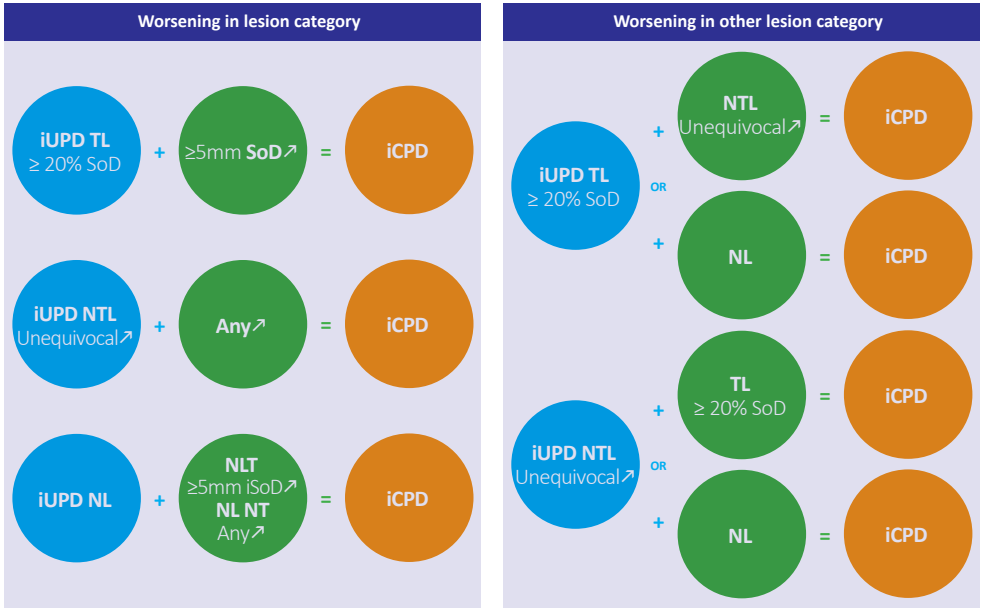
Non Target Lesion	New Lesion	Global Response
CR	No	CR
Non CR/Non PD	No	Non CR/Non PD
NE	No	NE
Unequivocal PD	Yes or No	PD
CR, PD, Non CR/ Non PD, or NE	Yes	PD

Tumor Assessment
Using Alternative Criteria for Immuno-oncology Trials

At a Glance Comparison
irRC vs irRECIST vs iRECIST

	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



About Us

As an imaging CRO, Median Technologies has unmatched clinical, technological and operational experience and expertise in oncology trials. With our offices based in the US, Europe and China, we operate globally to deliver best-in-class end-to-end imaging services for your Phase I to III oncology trials. We have a unique knowledge of the various standard imaging criteria used in clinical trials covering all solid tumor cancer indications, and we also provide innovative imaging biomarkers to ease Go/NoGo decisions in early phase studies. Median Technologies works with large pharma and biotech companies as well as global CROs, has a recognized track record with Phase III studies and has successfully passed FDA and China NMPA audits. We nicely complement the experience of global CROs we partner with by bringing our unique expertise in oncology imaging. We excel in all areas of managing oncologic images in clinical trials. There are many excellent reasons for selecting Median Technologies as your imaging CRO. Contact us to learn more!

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Scan to find out more:

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
NTL	Non target lesion
NL	New lesion
NLT	New lesion target
NL NT	New lesion non target

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