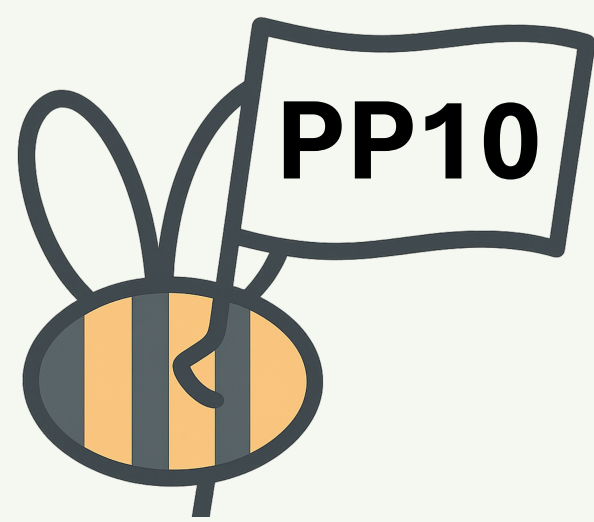




But wait, there's more: When RECIST 1.1 is not enough

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1. What is RECIST?

The **Response Evaluation Criteria in Solid Tumors** (RECIST) is a standardized framework for assessing tumor response to treatment in clinical trials. It provides objective criteria for defining measurable disease and categorizing treatment response as Complete Response (CR), Partial Response (PR), Stable Disease (SD), Progressive Disease (PD), or Not Evaluable (NE).

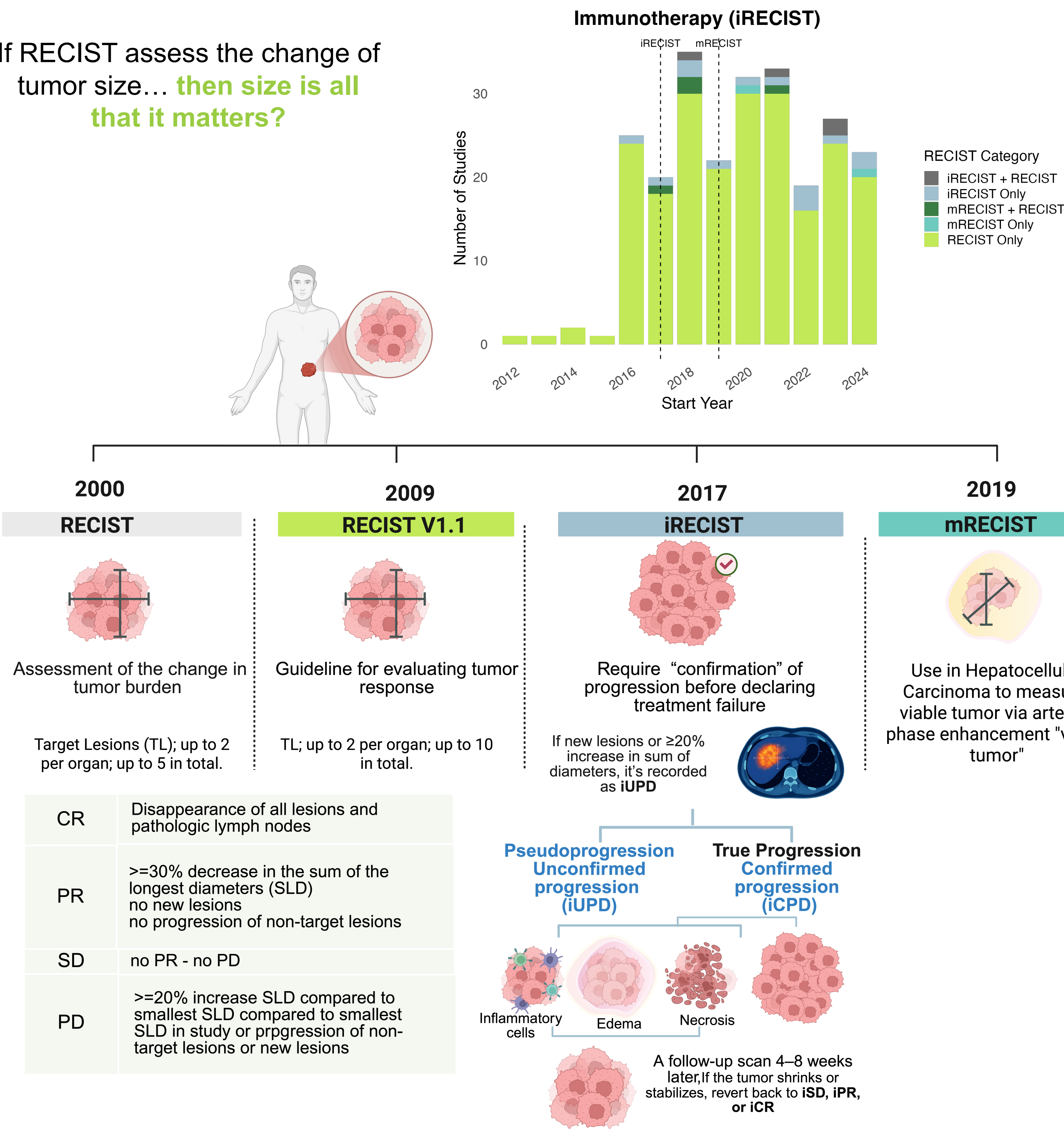
In 2009, the RECIST Working Group published a revised version of the guideline, RECIST version 1.1 (RECIST v1.1). This update introduced several key modifications:

- Reduced the maximum number of target lesions to five in total, with no more than two per organ.
- Revised the measurement criteria for lymph nodes (LNs).
- Refined the definition of PD.
- Updated the guidance for selecting bone lesions and cystic lesions as target lesions.
- Incorporated the use of positron emission tomography (PET) findings to support the assessment of tumor progression.

RECIST v1.1 remains the predominant standard for objective tumor response assessment in oncology clinical trials and is widely applied in both research and regulatory contexts.

2. Evolution of Tumor Response Criteria

If RECIST assess the change of tumor size... then size is all that it matters?



3. In Summary

RECIST V1.1	- Maximum number of target lesions: 5 in total, with no more than 2 per organ. - Measurable lesions: ≥ 10 mm (non-nodal), nodes measurable if ≥ 15 mm short axis and considered normal if < 10 mm. - PR: $\geq 30\%$ decrease vs baseline. - PD: $\geq 20\%$ increase vs nadir and ≥ 5 mm absolute increase. - Non-target or new lesions can define PD if unequivocal progression.
iRECIST	Uses same lesion rules and thresholds as RECIST - initial PD is classified as iUPD (immune-unconfirmed PD). - Requires confirmation at 4–8 weeks; further progression confirms ICPD (immune-confirmed PD).
mRECIST	Focuses on viable tumor only , defined as arterially enhancing portion - Measured as enhancing Sum of Longest Diameters (eSLD). - Applies the same percentage change thresholds as RECIST (e.g., PR $\geq 30\%$ decrease vs baseline; PD $\geq 20\%$ increase vs nadir +5 mm) but restricted to the viable component.

4. Dataset and Pipeline

Inputs

ADSL (subject-level)

Unique Subject ID	Sex	Planned Treatment Arm	Treatment Start	Age
SUBJ001	M	Drug A	05JAN2025	62

ADLB (LDH at Baseline)

Unique Subject ID	Parameter Code	Baseline Flag	Lab Value
SUBJ001	LDH	Y	280

ADTR (Target Lesions / SLD)

Visit	Date	SLD (mm)	Baseline SLD
Baseline	01JAN2025	50	50
Visit 1	05FEB2025	34	50
Visit 2	20MAR2025	43	50
Visit 3	17APR2025	35	50
Visit 4	15MAY2025	46	50

ADTR_VIABLE (eSLD for mRECIST)

Visit	Date	Viable (eSLD, mm)	Baseline Viable
Baseline	01JAN2025	40	40
Visit 1	05FEB2025	20	40
Visit 2	20MAR2025	24	40
Visit 3	17APR2025	0	40
Visit 4	15MAY2025	0	40

ADTU (Tumor Identification)

Visit	Lesion ID	Location	TUSCAT
Baseline	TL01	Liver S5	TARGET
Baseline	TL02	Lung RLL	TARGET
Baseline	NT01	LN Para	NONTARGET
Visit 4	NEW01	Liver S8	NEW

Counts per visit: #Target=2, #Non-target=1; new lesion only at Visit 4.

Key Rules

RECIST v1.1 (nadir +5 mm) PD if $\geq 20\%$ increase from nadir and ≥ 5 mm absolute $\uparrow$; PR if $\leq -30\%$ vs baseline; CR if SLD=0; else SD.
iRECIST (state machine) First PD $\rightarrow$ iUPD Confirm in 4–8 weeks by <u>additional</u> progression from the iUPD reference; otherwise reset to iCR/iPR/iSD.
mRECIST (HCC) Evaluate viable (arterial-enhancing) burden. CR requires eSLD=0 and <u>no new lesions</u> . Any new lesion $\rightarrow$ PD.

Column Lineage (ADRS_ALL)

Variable	Source
usubjid, avisit, adt, aval, base	ADTR
pchg_bl	Derived from ADTR (aval, base)
ldh_cat	Derived from ADLB (aval)
eaval, ebase	ADTR_VIABLE
nt_prog, new_lesion	ADPROG
n_tl, n_ntl, has_new	ADTU aggregated per visit
ovr, iopr, movr + nadir metrics	Derived rules

Visit-derived Features (ADRS_ALL)

Feature	Value
% Δ vs BL (SLD)	V1 $\sim 32\%$, V2 $\sim 14\%$, V3 $\sim 30\%$, V4 $\sim 8\%$
RECIST / iRECIST / mRECIST	See final table
Lesion counts	#Target=2, #Non-target=1 per visit
New lesion	Visit 4 only
LDH category	280 > 250 $\rightarrow$ High

5. I know you cannot RECIST

Hands on...

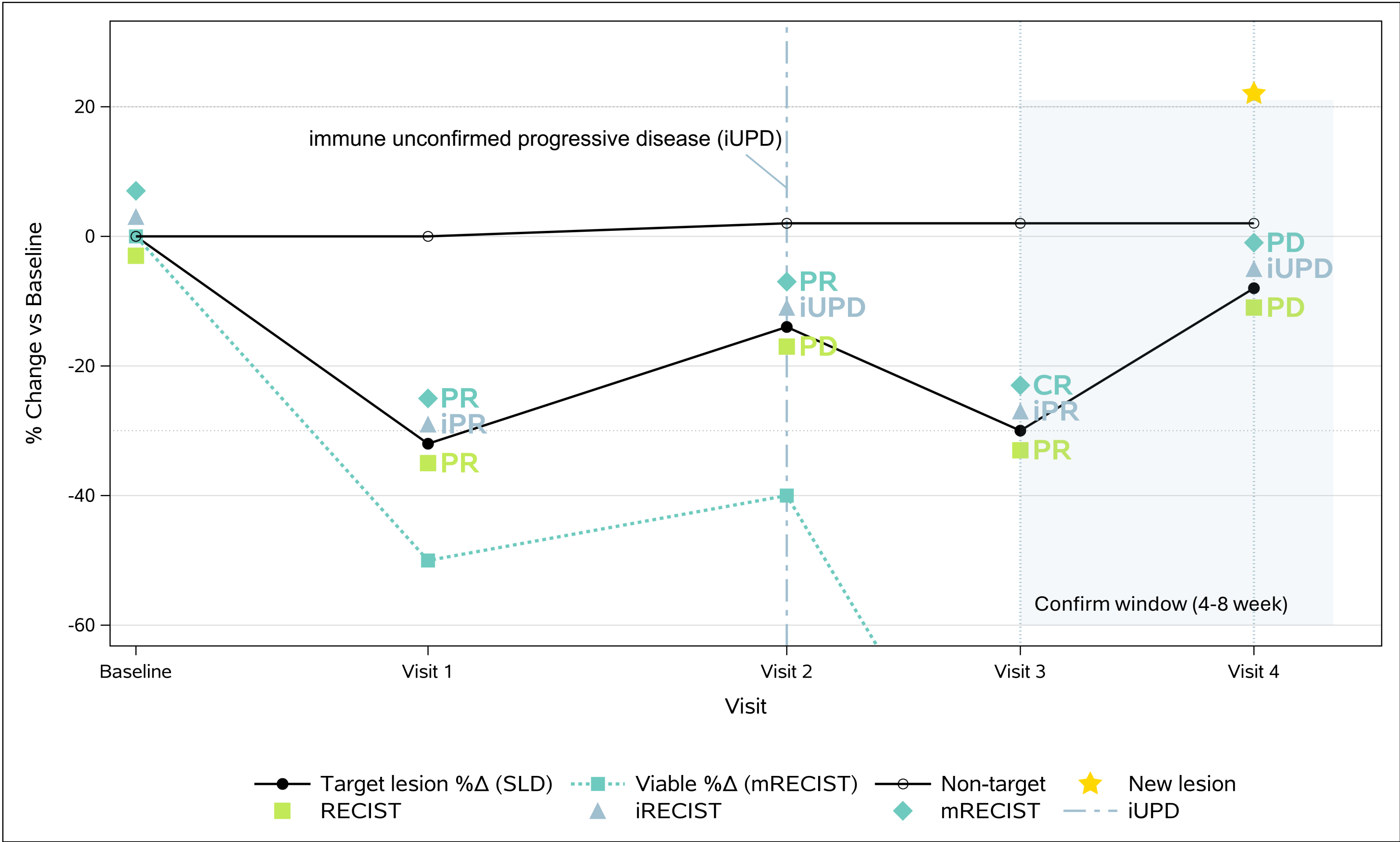
Using the visit-level data provided in the following result table, determine the **Best Overall Response (BOR)** for each response framework.

What to Do

- Examine the table row by row in chronological order.
- Identify baseline, nadir, and progression points.
- Assign a visit-level response for each framework at each visit.
- From those visit-level calls, decide the **Best Overall Response (BOR)** for each framework.

Final visit-level dataset (ADRS_ALL)

Visit	Date	SLD (mm)	% Δ vs BL	New lesion	RECIST v1.1	iRECIST	mRECIST
Baseline	2025-01-01	50	0%	No	NA	NA	NE
Visit 1	2025-02-05	34	-32%	No	PR	iPR	PR
Visit 2	2025-03-20	43	-14%	No	PD	iUPD	PR
Visit 3	2025-04-17	35	-30%	No	PR	iPR	CR
Visit 4	2025-05-15	46	-8%	Yes	PD	iUPD	PD
BOR	NA	NA	NA	NA	PR	iPR	CR



Solution:

Visit (Date)	RECIST v1.1 Assessment	iRECIST Assessment	mRECIST Assessment
Baseline	Target-lesion sum: 50 mm (baseline)	–	Viable tumor sum: 50 mm
Visit 1 (05 Feb 2025)	Target-lesion sum decreased to 34 mm ($\sim 32\%$ from baseline), meeting PR .	Mirrors RECIST: iPR .	Viable tumor sum decreased to 20 mm , meeting PR .
Visit 2 (20 Mar 2025)	Target-lesion sum increased to 43 mm , representing a $\geq 20\%$ increase from nadir (34 mm) and ≥ 5 mm absolute growth, fulfilling PD .	Classified as iUPD because progression requires confirmation on a subsequent scan.	Viable tumor sum remained at 24 mm ($\sim 40\%$ from baseline), maintaining a PR .
Visit 3 (17 Apr 2025)	Target-lesion sum improved to 35 mm ($\sim 30\%$ from baseline), sustaining a PR .	Due to renewed tumor shrinkage, immune assessment resets to iPR .	Viable tumor sum reached 0 mm , indicating CR .
Visit 4 (15 May 2025)	A new lesion was detected and target-lesion sum increased to 46 mm . The appearance of a new lesion defines PD .	Presence of a new lesion is recorded as iUPD , pending confirmation 4–8 weeks later.	The new lesion also defines PD .

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Contact

