

RECIST 1.1

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New response evaluation criteria in solid tumours: Revised RECIST guideline (version 1.1)

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RECIST

Response Evaluation Criteria in Solid Tumours

- It is a standard measure of how well a cancer patient responds to treatment.
- It is primarily based on whether tumours shrink, remain the same, or get bigger.
- Objective response -> Measurable response.
- Useful in clinical trials where the objective response is the primary endpoint.
- Revised RECIST guideline version 1.1

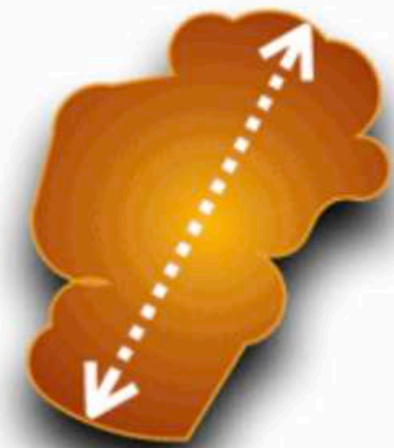
Classification of tumour lesions

Measurable

- Measurable tumour lesions are **tumours** with a **longest diameter ≥ 10 mm**.
- In the case of **lymph nodes**, **short axis ≥ 15 mm**.
- CT scan **slice thickness** should **be no greater than 5mm**.

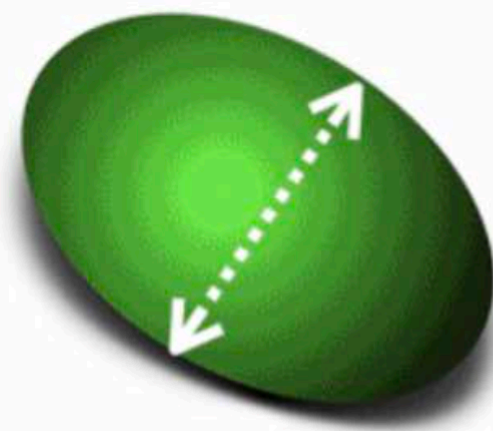
Tumours

CT scan: long axis ≥ 10 mm
Chest X-ray: long axis ≥ 20 mm

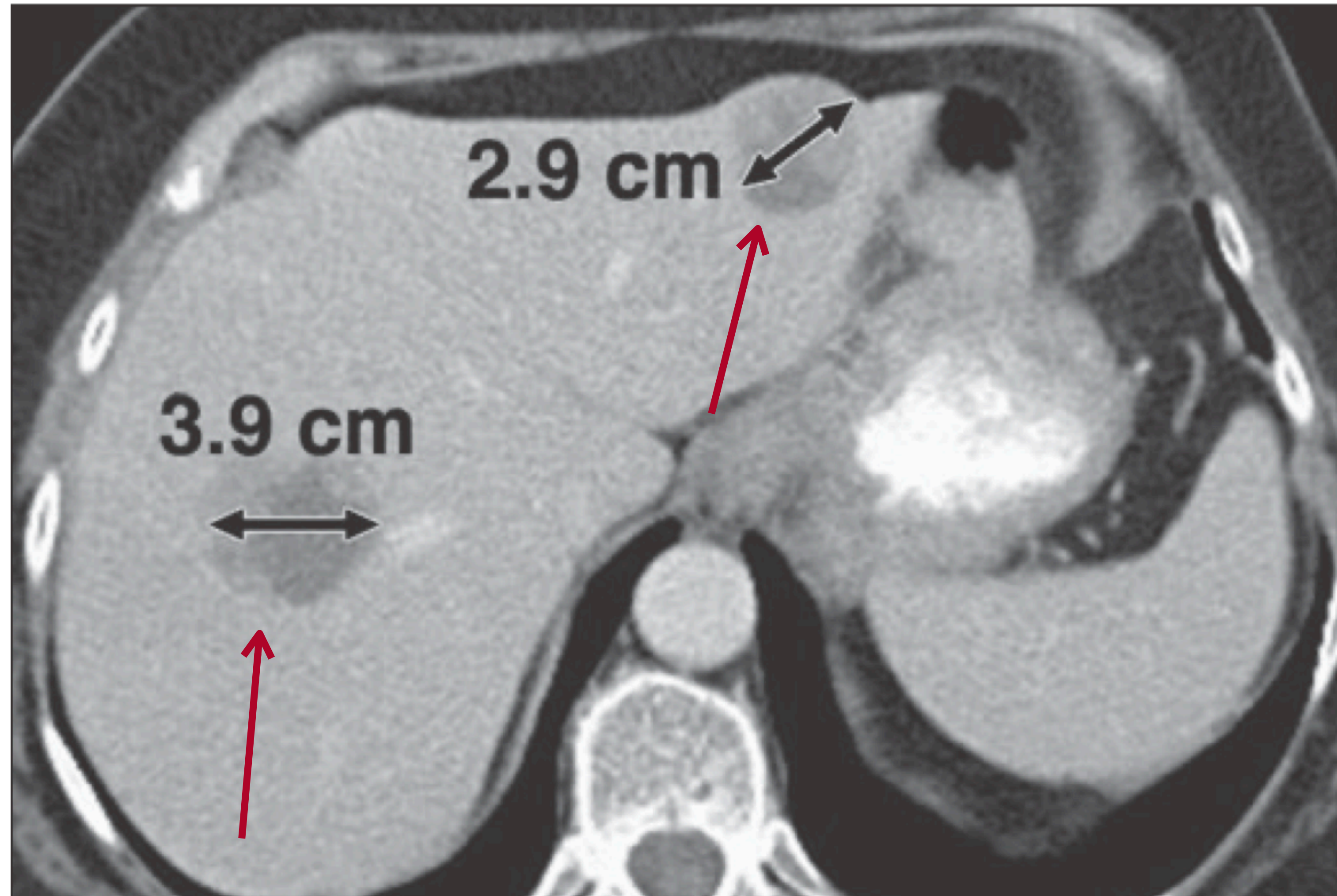


Malignant lymph nodes

Short axis diameter ≥ 15 mm



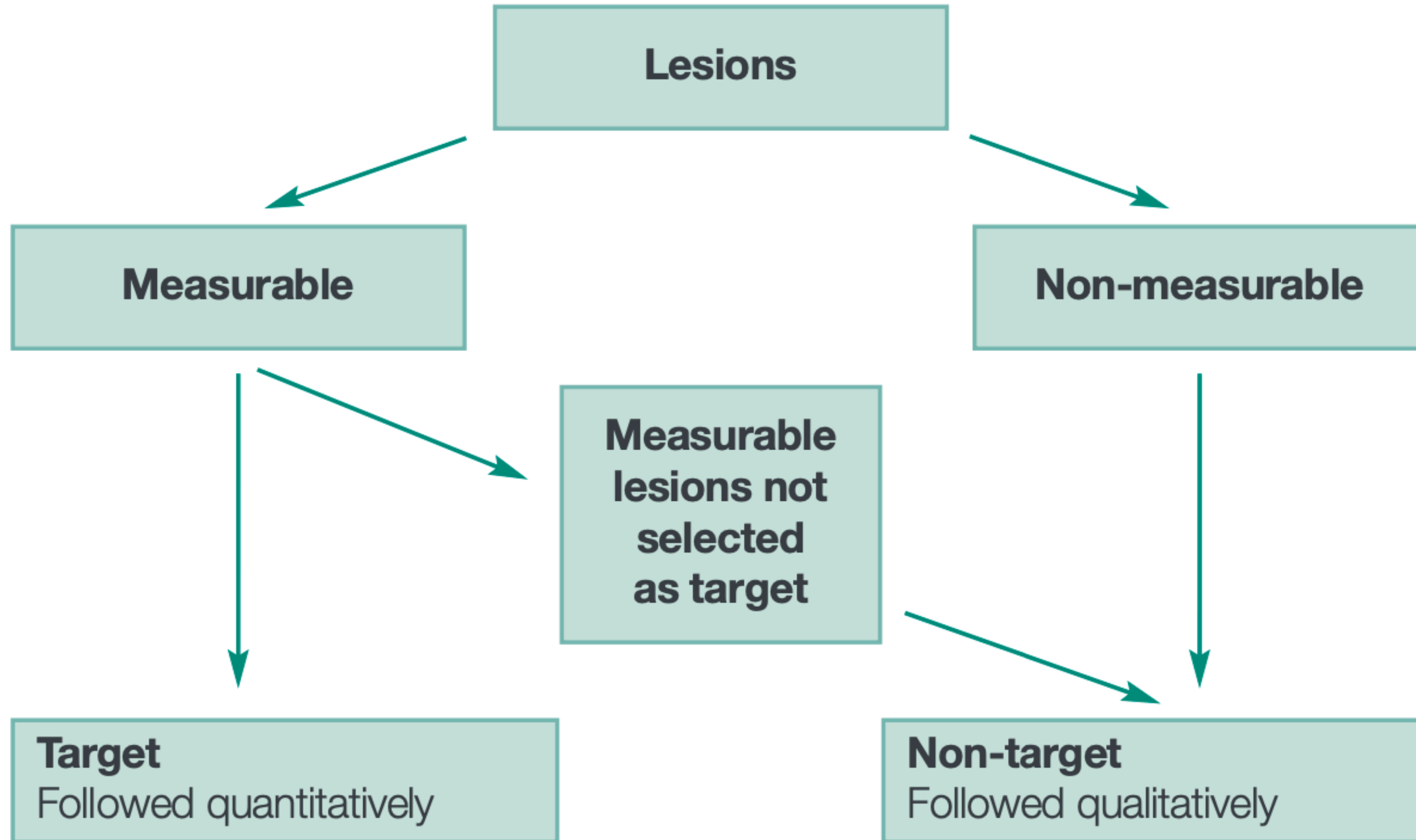
Measurable



Non-measurable

- Non-measurable **tumour** lesions are tumours with a **longest diameter < 10 mm**.
- In the case of **lymph nodes**, the condition is **10 mm ≤ short axis < 15 mm**.
- **Lymph nodes** whose **short axis is < 10 mm** are considered **non-pathological** and should not be recorded or followed.

Baseline Lesion Burden



Target lesion selection

Target lesions:

- Choose up to **5 measurable lesions**.
- Up to **2 per organ**
- **Add up the longest diameters** (LD) of non-nodal lesions (axial plane)
- **Add short-axis diameters** of nodes.
- This is the “**sum of the longest diameters**” (SLD)
- Select the **largest reproducibly measurable** lesions.
- If the largest lesion cannot be measured reproducibly, select the **next largest lesion** which can lead to **reproducible measures**.

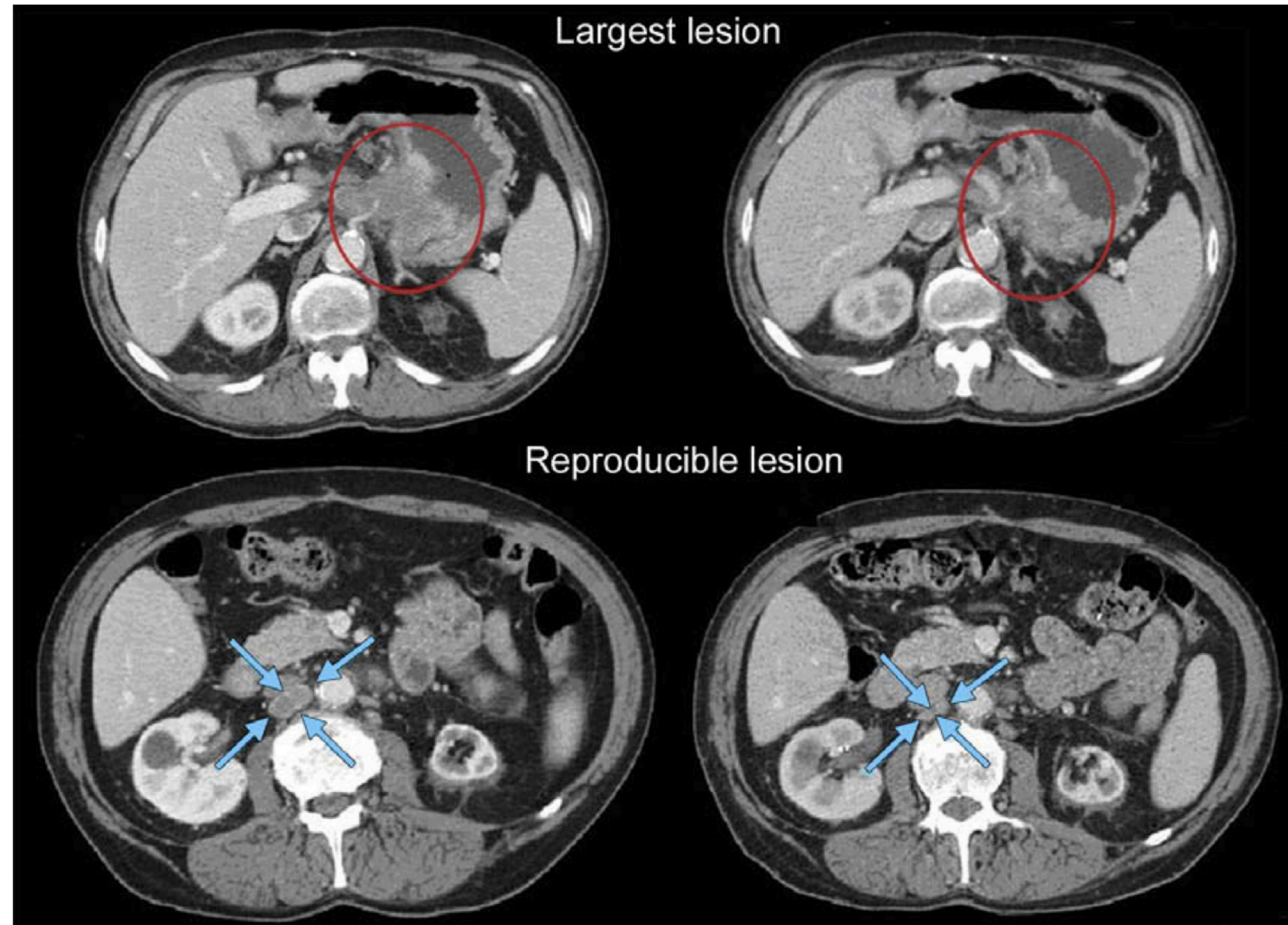


Fig. 3 – Largest lesion may not be most reproducible: most reproducible should be selected as target. In this example, the primary gastric lesion (circled at baseline and at follow-up in the top two images) may be able to be measured with thin section volumetric CT with the same degree of gastric distention at baseline and follow-up. However, this is potentially challenging to reproduce in a multicentre trial and if attempted should be done with careful imaging input and analysis. The most reproducible lesion is a lymph node (circled at baseline and at follow-up in the bottom two images).

Target lesion selection

1. Select **measurable lesions**.

Organ	LD of tumor in (mm)						Total
Liver	5	10	3	10	5	10	
Lung	10	4					
Kidney	8	7	10				
Spleen	10	10	6	4			
Lymph	7	6	5	8	10		

Target lesion selection

2. Select **two Lesions per organ**.

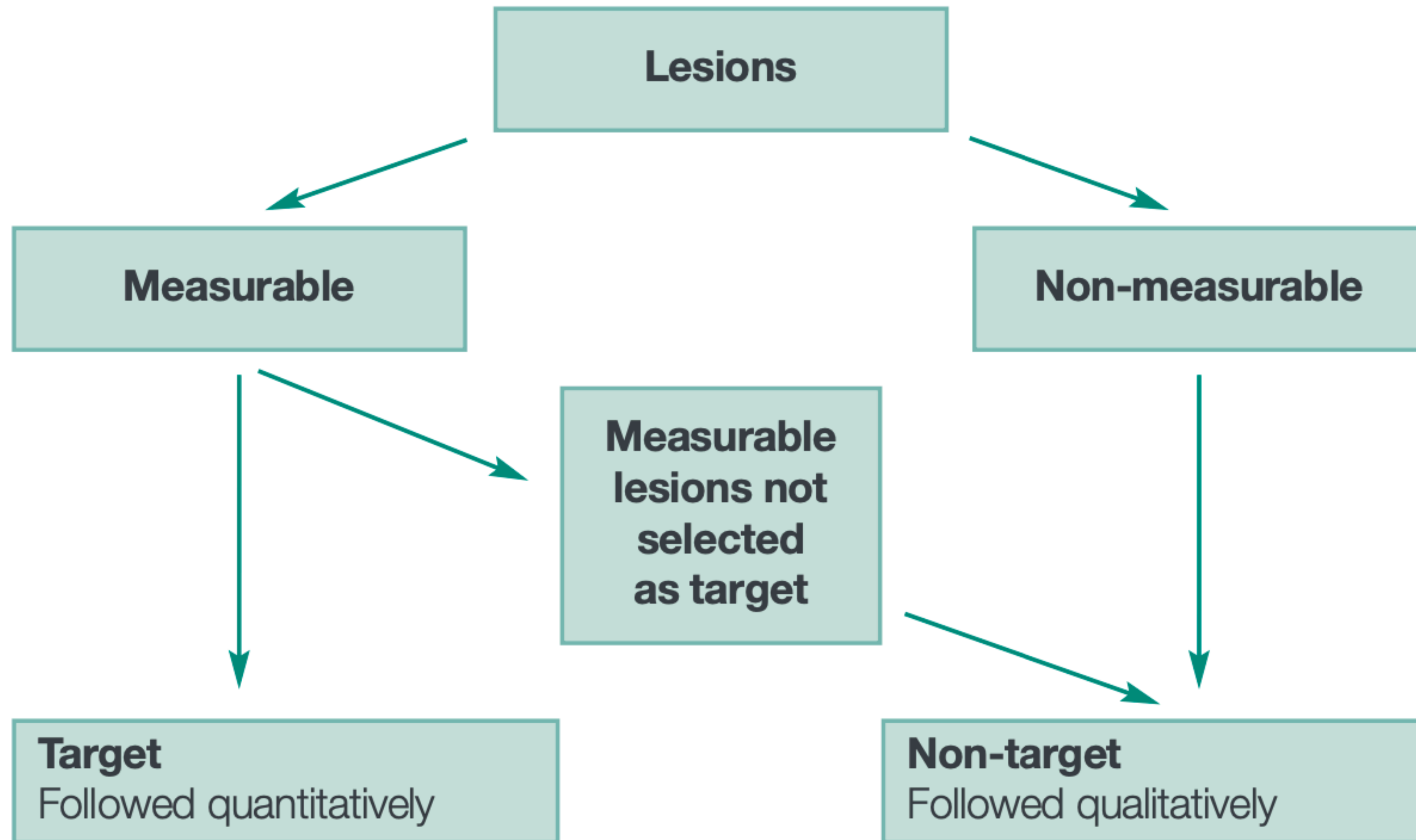
Organ	LD of tumor in (mm)					Total		
Liver	5	10	3	10	5	10		
Lung	10	4						
Kidney	8	7	10					
Spleen	10	10	6	4				
Lymph	7	6	5	8	10			

Target lesion selection

3. Select a total of five Lesions and compute SLD.

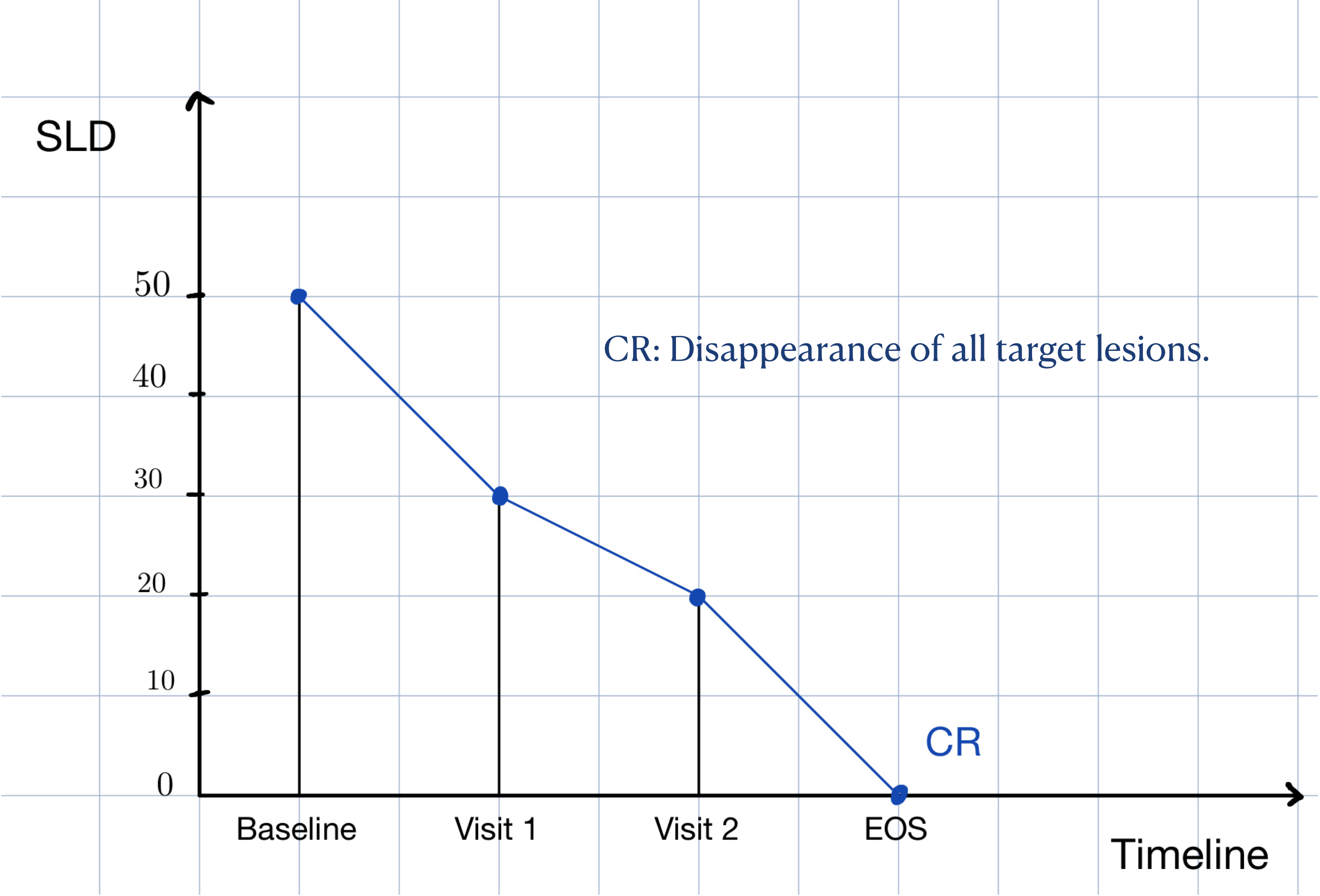
Organ	LD of tumor in (mm)						Total
Liver	5	10	3	10	5	10	20
Lung	10	4					10
Kidney	8	7	10				10
Spleen	10	10	6	4			10
Lymph	7	6	5	8	10		50

Baseline Lesion Burden

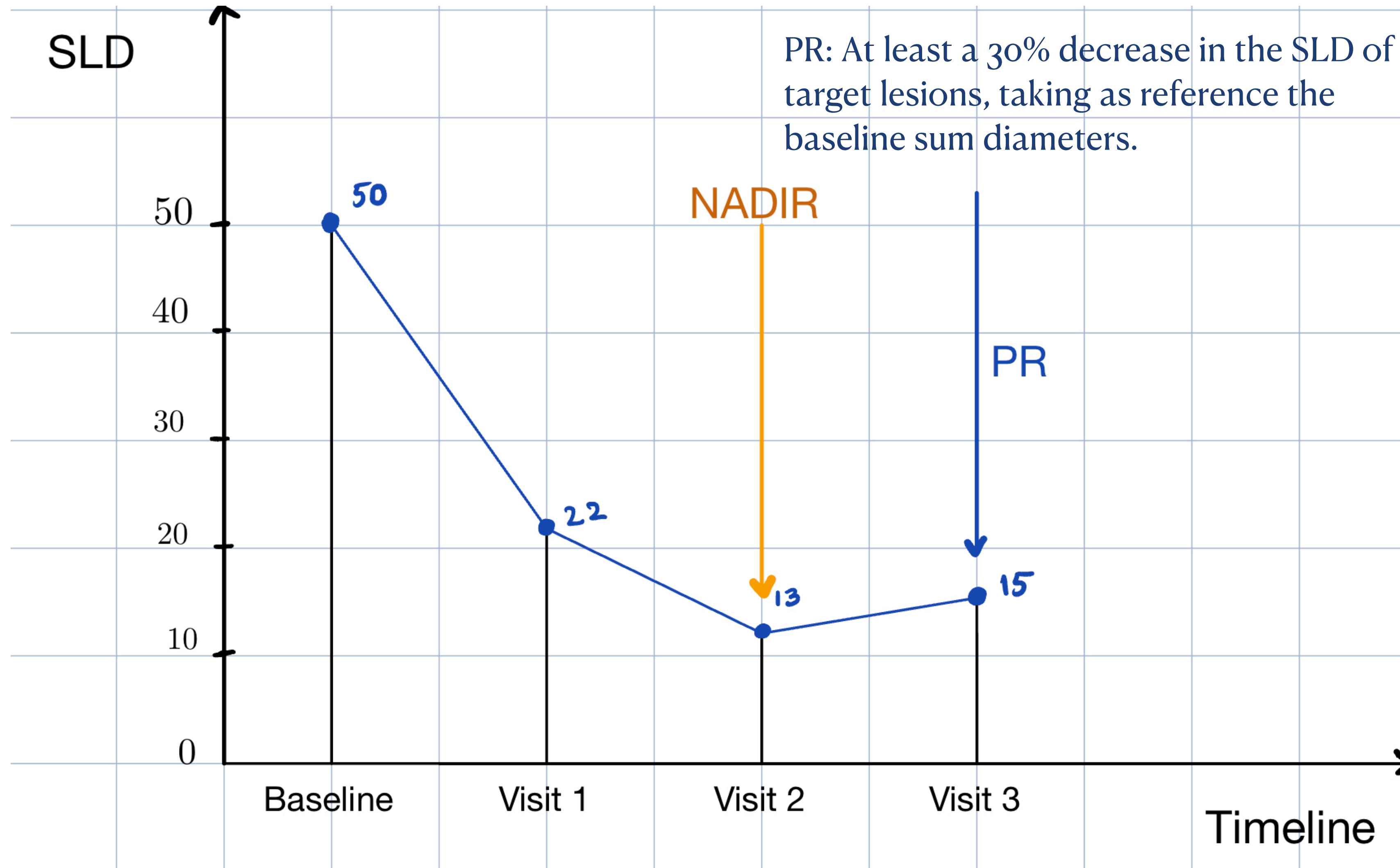


Evaluation of target lesions

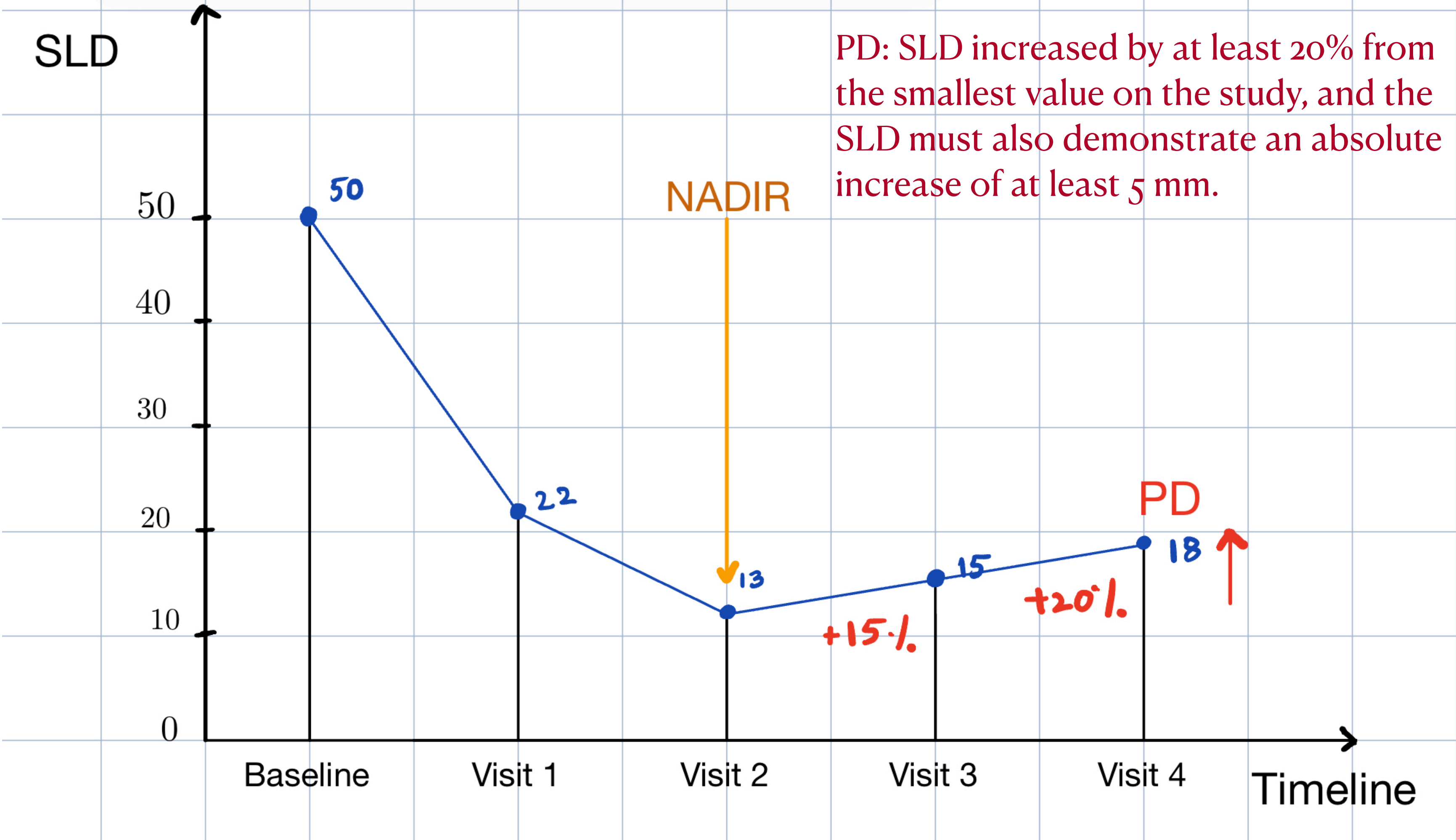
Complete Response



Partial Response



Progressive Disease



Summary

Target Lesion Evaluation

Response	Definition
Complete Response (CR)	Disappearance of all extranodal target lesions. All pathological lymph nodes must have decreased to <10 mm in short axis.
Partial Response (PR)	At least a 30% decrease in the SLD of target lesions, taking as reference the baseline sum diameters
Progressive Disease (PD)	SLD increased by at least 20% from the smallest value on study (including baseline, if that is the smallest) The SLD must also demonstrate an absolute increase of at least 5 mm. (Two lesions increasing from 2 mm to 3 mm, for example, does not qualify)
Stable Disease (SD)	Neither sufficient shrinkage to qualify for PR nor sufficient increase to qualify for PD

Evaluation of non target lesions

Summary

Non-Target Lesion Evaluation

Response	Definition
Complete Response (CR)	<ul style="list-style-type: none">■ Disappearance of all extranodal non-target lesions■ All lymph nodes must be non-pathological in size (<10 mm short axis).■ Normalization of tumor marker level
Non CR/Non PD	Persistence of one or more non-target lesion(s) and/or maintenance of tumor marker level above the normal limits
Progressive Disease (PD)	Unequivocal progression of existing non-target lesions. (Subjective judgement by experienced reader)

* Unequivocal progression: A very large progression of the non-target lesion.

Overall response

Overall Response

Target Lesions	Non-Target Lesions	New Lesions	Overall 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
Not all evaluated	Non-PD	No	NE
PD	Any	Yes or No	PD
Any	PD	Yes or No	PD
Any	Any	Yes	PD

**CR = Complete Response, PR = Partial Response, SD = Stable Disease,
PD = Progressive Disease, NE = Not Evaluable**

“Thank you”