Disease Assessment in Solid Tumors

Rose Ermete RN, BSN, OCN, CRN-BC, CCRP

Senior Quality Assurance Nurse Auditor

Disclosures:

- This activity has been approved by the Maryland Nurses Association for approval to award contact hours. Maryland Nurses Association is accredited as an approver of nursing continuing professional development by the American Nurses Credentialing Center's Commission on Accreditation.
- To receive 1 CEU contact hour via webinar attendance, participant must:
  - Login with CTEP credentials and "Enroll" to the SWOG ExertusOne Course via the following link: QA webinar- Disease Assessment in Solid Tumors prior to the start of the webinar. We recommend enrolling by December 5, 2024. After enrolling, participants will receive a system-generated calendar invite with a link to the course.
  - On 12/6/24: Individually log into the webinar via the join link in the SWOG ExpertusOne Course. Verify that your name is appearing correctly in the Webex.
- Attend the entire educational activity and then complete and submit the self-evaluation form via Survey Monkey.
  - The link to the post-activity evaluation will be provided via Webex chat message at the conclusion of the webinar.
- CEU certificates will be batch-issued to all attendees who complete the post-activity evaluation within approximately one week after the webinar.
- Note: Participants who are not able to participate in the entire webinar due to any reason will be able to subsequently review the content and meeting recording online via a separate course link (to be published after the webinar) and complete the post-activity evaluation to obtain 1 CEU contact hour via completion of the online course.
- No one with the ability to control content of this activity has relevant financial relationship with an ineligible company.
- The expiration of this activity is December 6, 2026.

What is your current role?

A. Data manager
B. Research Nurse
C. Regulatory
D. Administration
E. Quality Assurance
F. Other

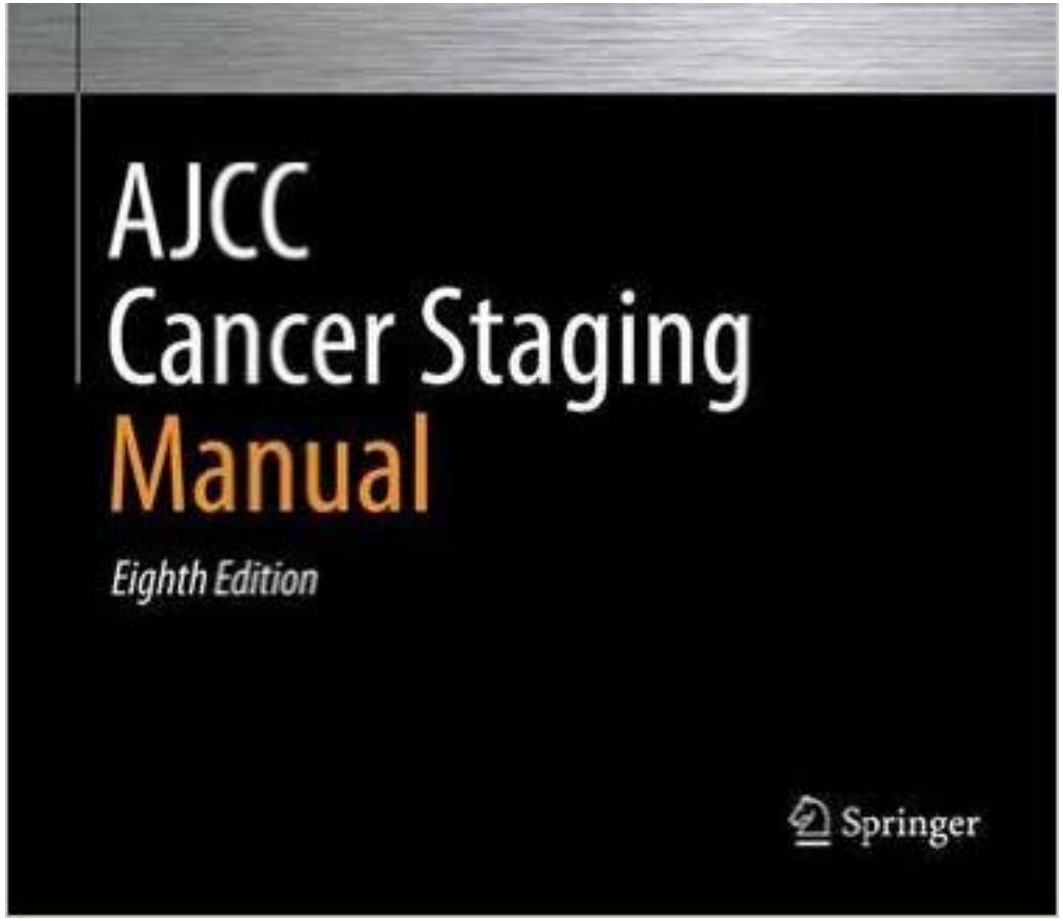
Do you participate in the review or reporting of the cancer stage or disease assessment?

A. Never
B. Sometimes
C. Frequently
D. Not sure

Overview

- Staging of Cancer
- Response Assessment
  - RECIST
  - iRECIST
  - Lugano

Cancer Staging

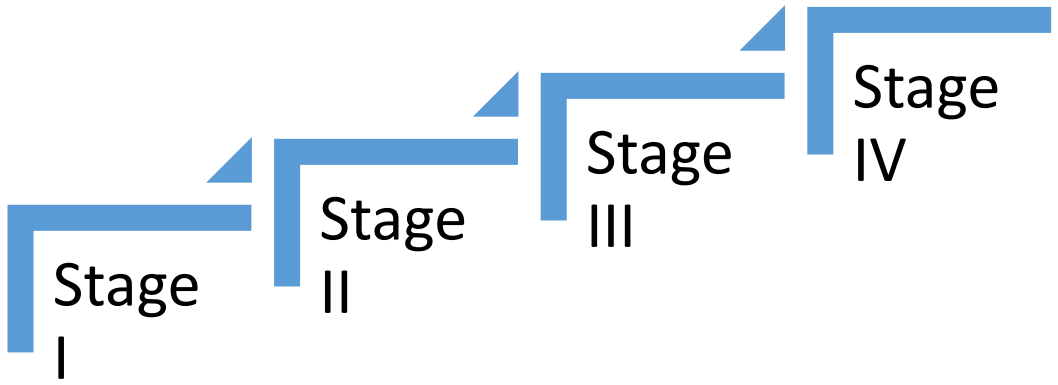


- Purpose
  - Study objectives
  - Patient Protection
  - Common language

- Staging Systems

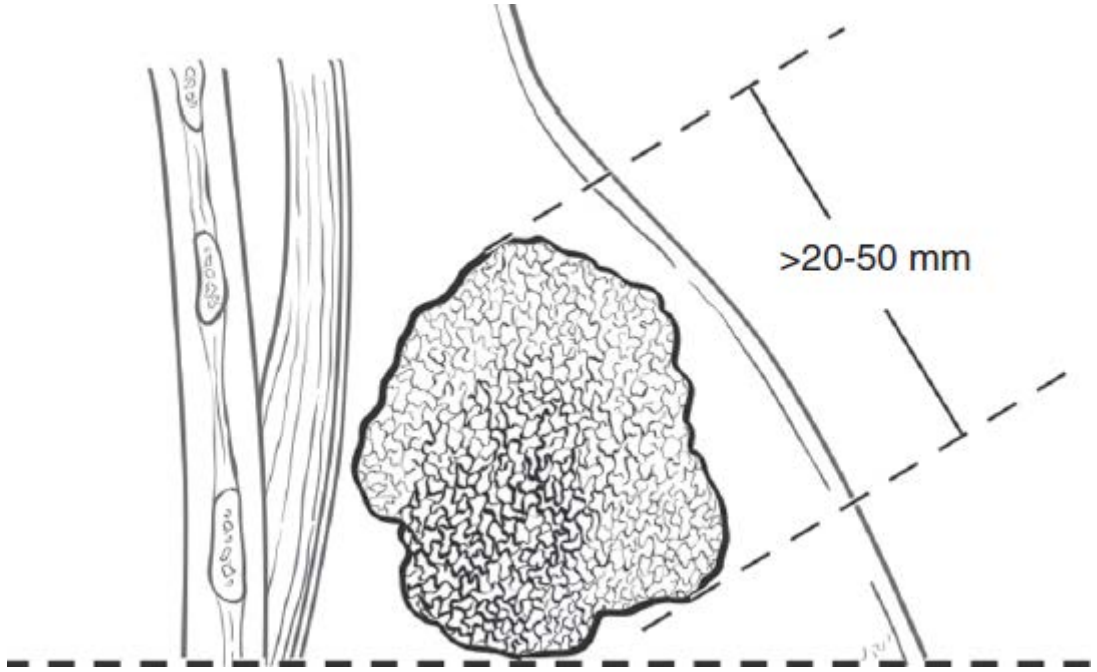
TNM Staging System

Category	Defined by:
T	TX: Primary tumor cannot be measured. T0: Primary tumor cannot be found. Tis: Carcinoma in situ (in the same place, not spread to nearby tissue) T1, T2, T3, T4: The size &/or extent of the primary tumor. The higher the number after the T, the larger the tumor or the more it has grown into nearby tissue.
N	NX: Cancer in nearby lymph nodes cannot be measured. N0: There is no cancer in regional lymph nodes. N1, N2, N3: Refers to the number and location of lymph nodes that contain cancer. The higher the number after the N, the more lymph nodes that contain cancer.
M	M0: No evidence of spreading to other parts of the body. M1: Cancer has spread to other parts of the body. (There is no MX designation in the 8th ed. The absence of any clinical history or physical findings suggestive of metastases is sufficient to assign the clinical M0 category)[2]



Breast Cancer

76-year-old woman with a 3 cm biopsy proven tumor in the right breast.

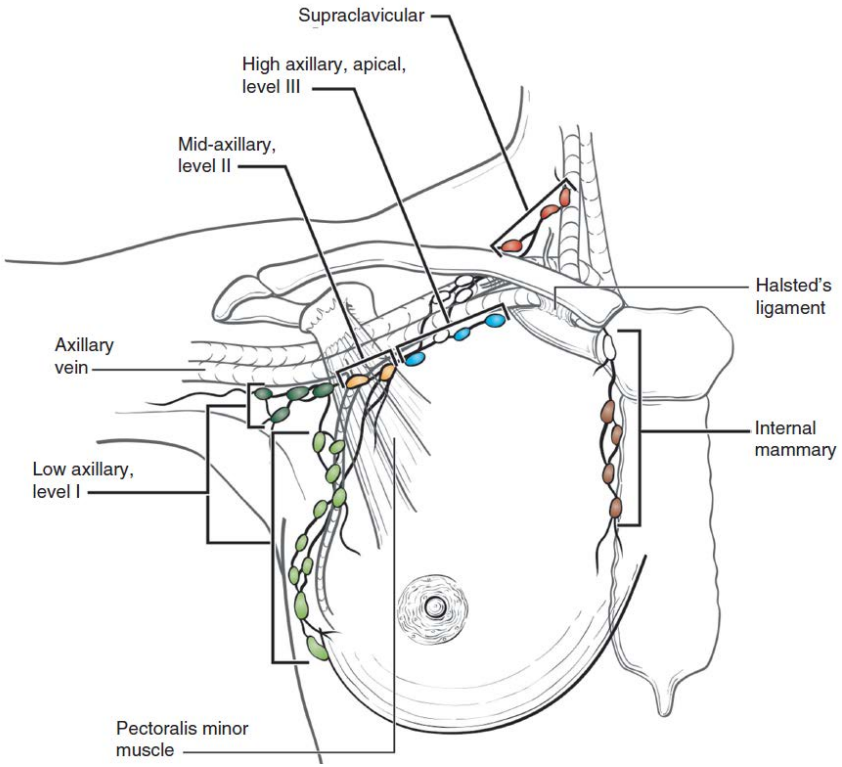


T Category	T Criteria
TX	Primary tumor cannot be assessed
T0	No evidence of primary tumor
Tis (DCIS)*	Ductal carcinoma *in situ*
Tis (Paget)	Paget disease of the nipple NOT associated with invasive carcinoma and/or carcinoma *in situ* (DCIS) in the underlying breast parenchyma. Carcinomas in the breast parenchyma associated with Paget disease are categorized based on the size and characteristics of the parenchymal disease, although the presence of Paget disease should still be noted.
T1	Tumor ≤20 mm in greatest dimension
T1mi	Tumor ≤1 mm in greatest dimension
T1a	Tumor >1 mm but ≤5 mm in greatest dimension (round any measurement >1.0–1.9 mm to 2 mm).
T1b	Tumor >5 mm but ≤10 mm in greatest dimension
T1c	Tumor >10 mm but ≤20 mm in greatest dimension
T2	Tumor >20 mm but ≤50 mm in greatest dimension
T3	Tumor >50 mm in greatest dimension
T4	Tumor of any size with direct extension to the chest wall and/or to the skin (ulceration or macroscopic nodules); invasion of the dermis alone does not qualify as T4
T4a	Extension to the chest wall; invasion or adherence to pectoralis muscle in the absence of invasion of chest wall structures does not qualify as T4
T4b	Ulceration and/or ipsilateral macroscopic satellite nodules and/or edema (including peau d'orange) of the skin that does not meet the criteria for inflammatory carcinoma
T4c	Both T4a and T4b are present
T4d	Inflammatory carcinoma (see section "Rules for Classification")

AJCC Cancer Staging Manual 8th ed., 2018

Breast Cancer

Metastasis to 2/10 Lymph nodes, largest met: 4.0mm in 1 right axillary node. 1 + right internal mammary node, no isolated tumor clusters.



pN Category	pN Criteria
pNX	Regional lymph nodes cannot be assessed (e.g., not removed for pathological study or previously removed)
pN0	No regional lymph node metastasis identified or ITCs only
pN0(i+)	ITCs only (malignant cell clusters no larger than 0.2 mm) in regional lymph node(s)
pN0(mol+)	Positive molecular findings by reverse transcriptase polymerase chain reaction (RT-PCR); no ITCs detected
pN1	Micrometastases; or metastases in 1–3 axillary lymph nodes; and/or clinically negative internal mammary nodes with micrometastases or macrometastases by sentinel lymph node biopsy
pN1mi	Micrometastases (approximately 200 cells, larger than 0.2 mm, but none larger than 2.0 mm)
pN1a	Metastases in 1–3 axillary lymph nodes, at least one metastasis larger than 2.0 mm
pN1b	Metastases in ipsilateral internal mammary sentinel nodes, excluding ITCs
pN1c	pN1a and pN1b combined
pN2	Metastases in 4–9 axillary lymph nodes; or positive ipsilateral internal mammary lymph nodes by imaging in the absence of axillary lymph node metastases
pN2a	Metastases in 4–9 axillary lymph nodes (at least one tumor deposit larger than 2.0 mm)
pN2b	Metastases in clinically detected internal mammary lymph nodes with or without microscopic confirmation; with pathologically negative axillary nodes
pN3	Metastases in 10 or more axillary lymph nodes;
	or in infraclavicular (Level III axillary) lymph nodes;
	or positive ipsilateral internal mammary lymph nodes by imaging in the presence of one or more positive Level I, II axillary lymph nodes;
	or in more than three axillary lymph nodes and micrometastases or macrometastases by sentinel lymph node biopsy in clinically negative ipsilateral internal mammary lymph nodes;
	or in ipsilateral supraclavicular lymph nodes
pN3a	Metastases in 10 or more axillary lymph nodes (at least one tumor deposit larger than 2.0 mm);
	or metastases to the infraclavicular (Level III axillary lymph) nodes
pN3b	pN1a or pN2a in the presence of cN2b (positive internal mammary nodes by imaging);
	or pN2a in the presence of pN1b
pN3c	Metastases in ipsilateral supraclavicular lymph nodes

Breast Cancer

Bone scan is negative for metastatic disease.

CT scan of the chest, abdomen & pelvis are negative for metastatic disease.

M Category	M Criteria
M0	No clinical or radiographic evidence of distant metastases*
cM0(i+)	No clinical or radiographic evidence of distant metastases in the presence of tumor cells or deposits no larger than 0.2 mm detected microscopically or by molecular techniques in circulating blood, bone marrow, or other nonregional nodal tissue in a patient without symptoms or signs of metastases
cM1	Distant metastases detected by clinical and radiographic means
pM1	Any histologically proven metastases in distant organs; or if in non-regional nodes, metastases greater than 0.2 mm

Stage of Disease

What stage would the patient be?

A. Stage IB
B. Stage IIA
C. Stage IIB
D. Stage IIIA

When T is…	And N is…	And M is…	Then the stage group is…
Tis	N0	M0	0
T1	N0	M0	IA
T0	N1mi	M0	IB
T1	N1mi	M0	IB
T0	N1	M0	IIA
T1	N1	M0	IIA
T2	N0	M0	IIA
T2	N1	M0	IIB
T3	N0	M0	IIB
T0	N2	M0	IIIA
T1	N2	M0	IIIA
T2	N2	M0	IIIA
T3	N1	M0	IIIA
T3	N2	M0	IIIA
T4	N0	M0	IIIB
T4	N1	M0	IIIB
T4	N2	M0	IIIB
Any T	N3	M0	IIIC
Any T	Any N	M1	IV

Terminology

Term	Definition
Ipsilateral	Occurring on the same side
Occult	Cancer in which the site of the primary tumor cannot be found.
Tumor Grade	The description of tumor cells based on how abnormal (differentiated) they look compared to the tissue of origin. (G1 – 4)
Mitotic rate:	The assessment of how many dividing cells are present.
Nuclear grade	An evaluation of the size and shape of the nucleus
Synoptic Report	A list of specific data elements in a specific format contained in a pathology report.
Synchronous	Cancers in the same organ identified with a diagnosis date < 4 months apart.
Metachronous	Cancers occurring in the same organ system identified with diagnosis dates > 4 months apart.

Melanoma

Staging terms

- Breslow Thickness
- Ulceration
- Clark Level
- Microsatellite
- Satellite lesion
- In-Transit Metastasis

T Category	Thickness	Ulceration status
TX: primary tumor thickness cannot be assessed (e.g., diagnosis by curettage)	Not applicable	Not applicable
T0: no evidence of primary tumor (e.g., unknown primary or completely regressed melanoma)	Not applicable	Not applicable
Tis (melanoma *in situ*)	Not applicable	Not applicable
T1	≤1.0 mm	Unknown or unspecified
T1a	<0.8 mm	Without ulceration
T1b	<0.8 mm 0.8–1.0 mm	With ulceration With or without ulceration
T2	>1.0–2.0 mm	Unknown or unspecified
T2a	>1.0–2.0 mm	Without ulceration
T2b	>1.0–2.0 mm	With ulceration
T3	>2.0-4.0 mm	Unknown or unspecified
T3a	>2.0–4.0 mm	Without ulceration
T3b	>2.0–4.0 mm	With ulceration
T4	>4.0 mm	Unknown or unspecified
T4a	>4.0 mm	Without ulceration
T4b	>4.0 mm	With ulceration

N Category	Number of tumor-involved regional lymph node	Presence of in-transit, satellite, and/or microsatellite metastases
NX	Regional nodes not assessed (e.g., SLN biopsy not performed, regional nodes previously removed for another reason)	No
	Exception: When there are no clinically detected regional metastases in a pT1 cM0 melanoma, assign cN0 instead of pNX	
N0	No regional metastases detected	No
N1	One tumor-involved node or in-transit, satellite, and/or microsatellite metastases with no tumor-involved nodes	
N1a	One clinically occult (i.e., detected by SLN biopsy)	No
N1b	One clinically detected	No
N1c	No regional lymph node disease	Yes

A 47-year-old female is diagnosed with rectal cancer. She received treatment with chemotherapy and radiation followed by surgical resection. The surgical report states the tumor invades the submucosa, but not the muscularis, there are three positive regional LN, and all scans are negative for metastasis. What would be the most likely TNM category for this patient?

A. T2N1M0
B. cT1N1M0
C. pT1N1M0
D. ypT1N1M0

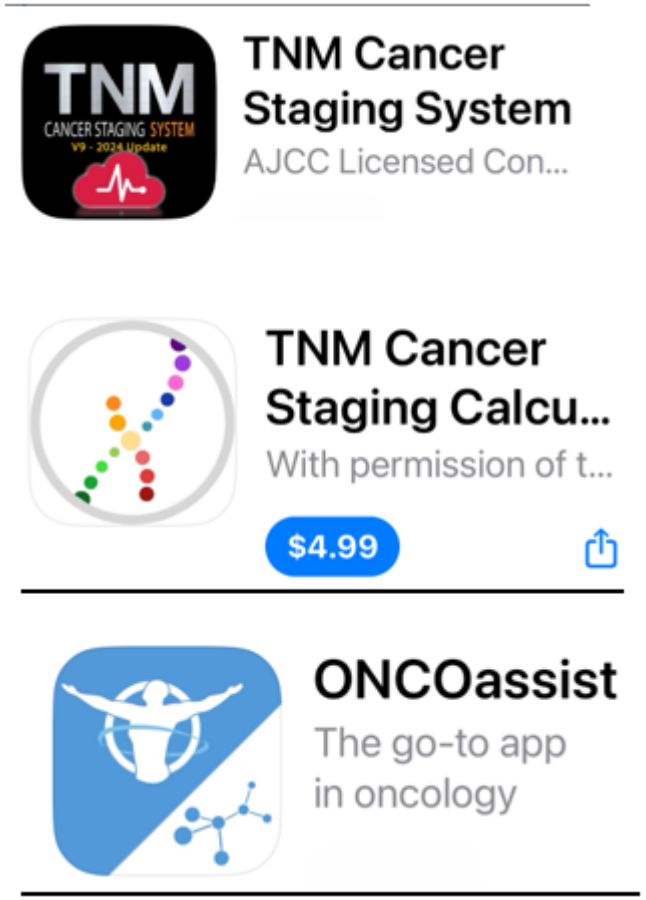
T Category	T Criteria
TX	Primary tumor cannot be assessed
T0	No evidence of primary tumor
Tis	Carcinoma *in situ*, intramucosal carcinoma (involvement of lamina propria with no extension through muscularis mucosae)
T1	Tumor invades the submucosa (through the muscularis mucosa but not into the muscularis propria)
T2	Tumor invades the muscularis propria
T3	Tumor invades through the muscularis propria into pericolorectal tissues
T4	Tumor invades* the visceral peritoneum or invades or adheres** to adjacent organ or structure

Is it possible to have an “N” category without any lymph node involvement?

A. Yes
B. No
C. I’m not sure

Staging Resources

- AJCC Staging Manual, 8th edition
- Section 4 of the protocol
- APPs

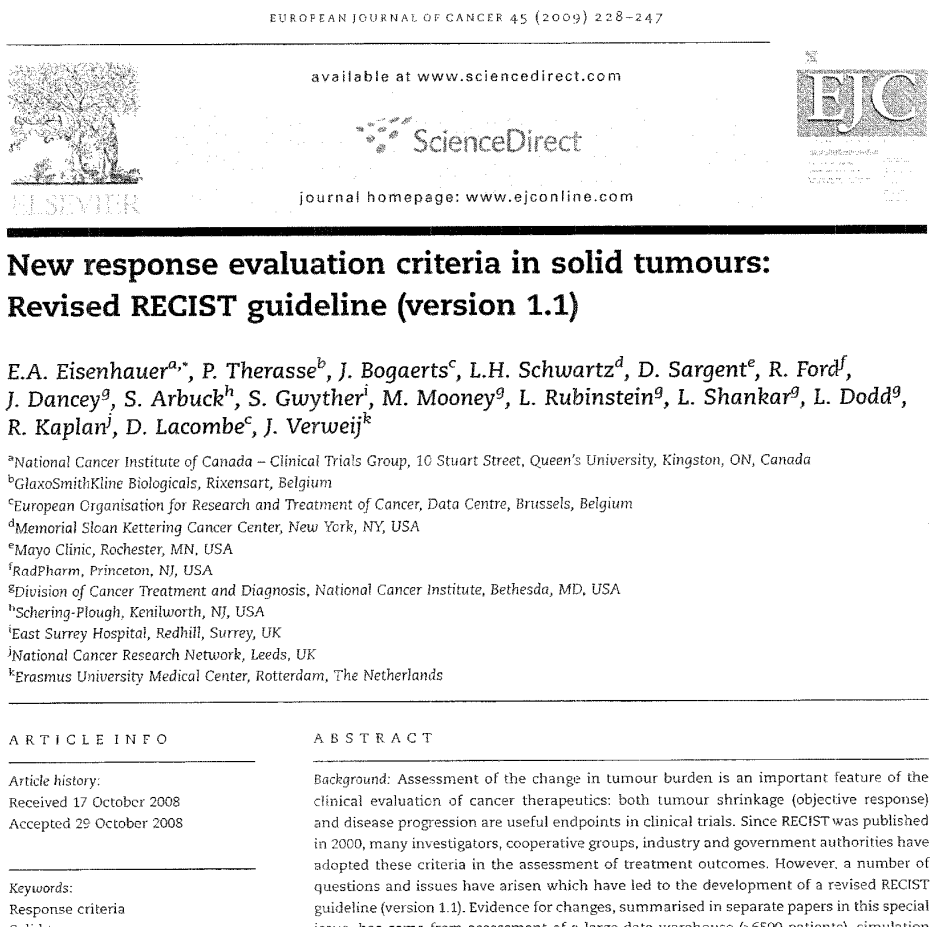


Disease Response Assessment

- Important to evaluate the disease response to determine the efficacy of the treatment
  - Prospective end point in early clinical trials
  - Prospective end point in more definitive clinical trials
- Section 10 of the protocol will define how disease is to be measured.
  - How disease will be measured (e.g., CT scan, bone marrow biopsy);
  - When the measurements are to be conducted (e.g., every other cycle); and
  - What standard criteria will be used to define the response (i.e., what constitutes complete response, partial response, and progressive disease)
- Established standard response criteria by international consensus for solid tumors and hematologic malignancies.

RECIST version 1.1

- **Re**sponse **C**riteria **I**n **S**olid **T**umors
- WHO: 1979
- RECIST:2000
- RECIST 1.1: 2009



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

E.A. Eisenhauer[a,], P. Therasse[b], J. Bogaerts[c], L.H. Schwartz[d], D. Sargent[e], R. Ford[f], J. Dancey[g], S. Arbuck[h], S. Gwyther[i], M. Mooney[g], L. Rubinstein[g], L. Shankar[g], L. Dodd[g], R. Kaplan[j], D. Lacombe[c], J. Verweij[k]*

[a]National Cancer Institute of Canada – Clinical Trials Group, 10 Stuart Street, Queen's University, Kingston, ON, Canada
[b]GlaxoSmithKline Biologicals, Rixensart, Belgium
[c]European Organisation for Research and Treatment of Cancer, Data Centre, Brussels, Belgium
[d]Memorial Sloan Kettering Cancer Center, New York, NY, USA
[e]Mayo Clinic, Rochester, MN, USA
[f]RadPharm, Princeton, NJ, USA
[g]Division of Cancer Treatment and Diagnosis, National Cancer Institute, Bethesda, MD, USA
[h]Schering-Plough, Kenilworth, NJ, USA
[i]East Surrey Hospital, Redhill, Surrey, UK
[j]National Cancer Research Network, Leeds, UK
[k]Erasmus University Medical Center, Rotterdam, The Netherlands

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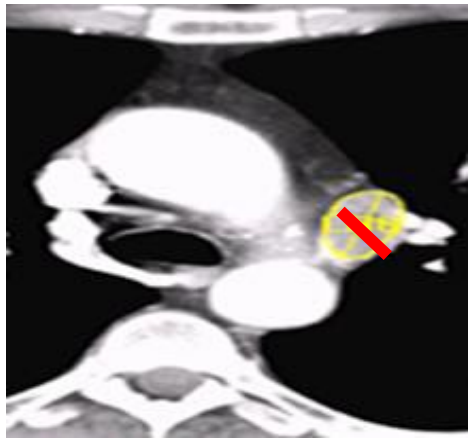
ABSTRACT

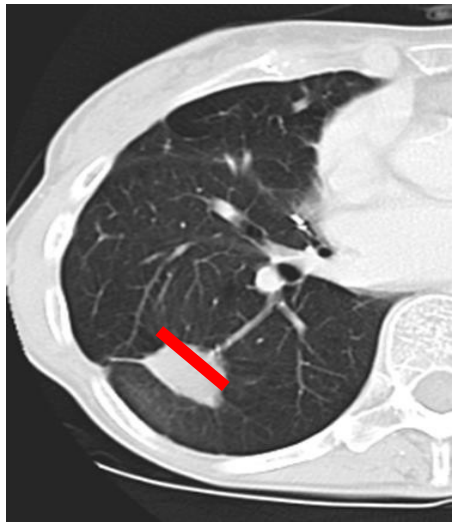
Background: Assessment of the change in tumour burden is an important feature of the clinical evaluation of cancer therapeutics: both tumour shrinkage (objective response) and disease progression are useful endpoints in clinical trials. Since RECIST was published in 2000, many investigators, cooperative groups, industry and government authorities have adopted these criteria in the assessment of treatment outcomes. However, a number of questions and issues have arisen which have led to the development of a revised RECIST guideline (version 1.1). Evidence for changes, summarised in separate papers in this special

Measurability

- Measurable disease (Target)
  - Lesions you can follow
  - Baseline timepoint
  - Tumor lesions measured in LONGEST diameter
  - Lymph nodes measured in short axis



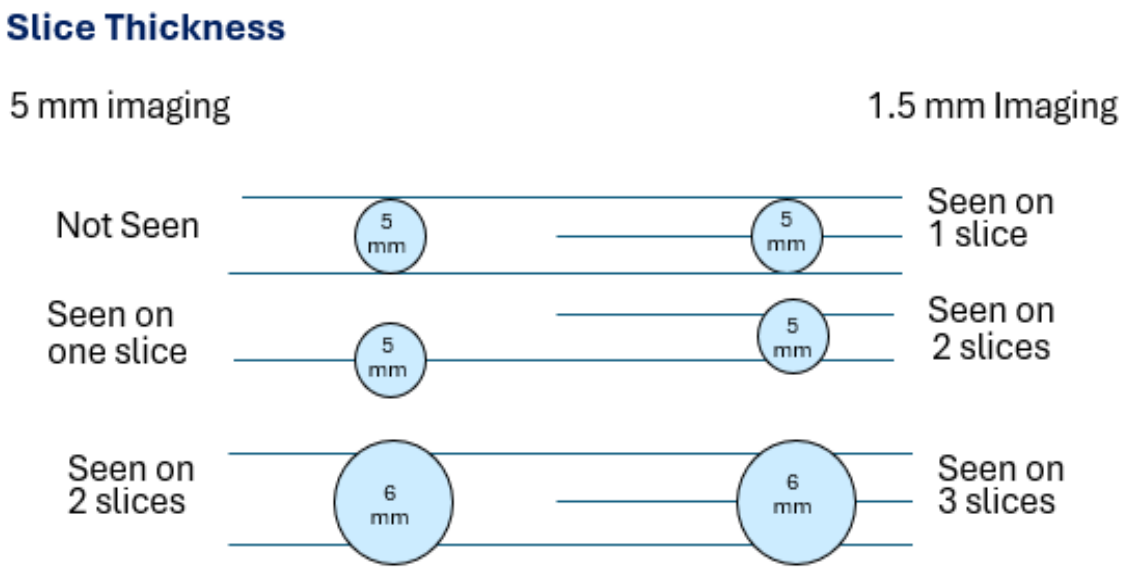
- Non-measurable disease (Non-Target)
  - All other lesions that do not meet the criteria to be measurable
    - Bone lesions
    - Leptomeningeal disease
    - Pleural/Pericardial effusions
    - Cysts



Schwartz et al., 2009; Ganeshalingam et al. 2009

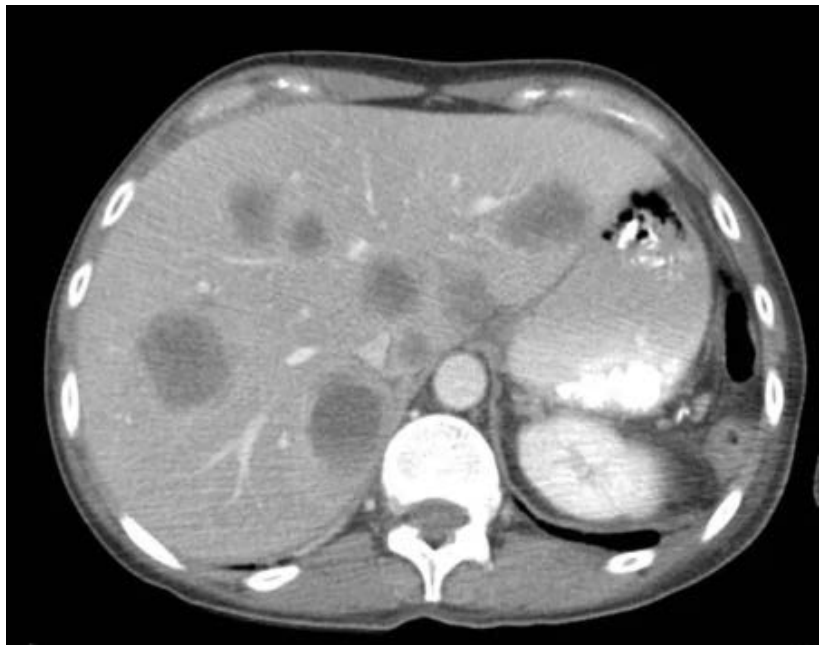
Measurable – Target Lesion

- Minimum size of measurable non-nodal lesions
  - CT scan 5 mm slice: ≥10 mm
  - CT scan > 5 mm slice: 2x slice thickness
  - Calibers (clinical exam): ≥10 mm
  - Chest x-ray: ≥ 20 mm
  - Lymph node ≥ 15 mm
- Nodal Lesions
  - ≥ 1.5 cm



Choosing Lesions

- Always use the same technique for assessment
- Representative of the over all tumor burden.
  - All measurable lesions up to 5 total (max of 2/organ)
  - Sum of diameters (Quantitative)
- Once deemed a target lesion, always a target lesion.
- Non-Target: Qualitative
  - Measurement not required, either present or absent
  - Can record multiple non-target lesions in same organ as single item on CRF



64 y.o. female is being considered for a clinical trial with second line treatment for stage IV lung cancer. The current staging CT scan demonstrates:

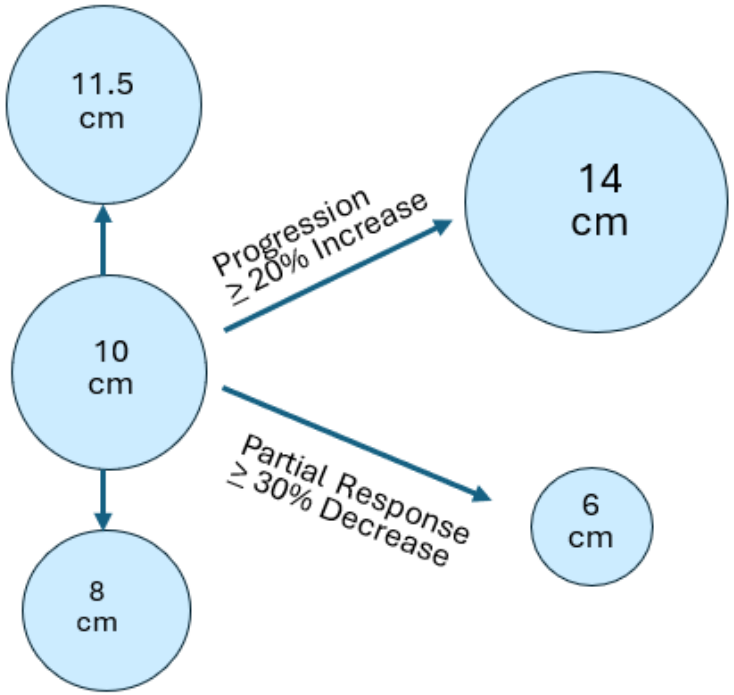
a. 2.2 cm lesion in the temporal region of the brain.
b. 1.4 cm Para-aortic lymph node
c. 6.9 cm mass in the RUL
d. 1.5 cm nodule in the RUL
e. Right sided pleural effusion, known to be malignant
f. 2 cm blastic lytic lesion in the right 7th rib

Which lesions could be used as target lesions?

1. c only
2. b, c & d
3. a, c & d
4. c & d

RESPONSE ASSESSMENT – TARGET

- **Complete Response (CR)**
  - Disappearance of all target lesions
  - Any pathological lymph nodes (whether target or non-target) must have reduction in short axis to <10 mm
- **Partial Response (PR)**
  - At least a 30% decrease in the sum of the diameters of target lesions, taking as reference the baseline sum diameters
- **Progressive Disease (PD)**
  - At least a 20% increase in the sum of the diameters of target lesions, taking as reference the smallest sum on study (this includes the baseline sum if that is the smallest on study).
  - In addition to the relative increase of 20%, sum must also demonstrate an absolute increase of at least 5 mm. (Note: the appearance of one or more new lesions is also considered progressions).
- **Stable Disease (SD)**
  - Neither sufficient shrinkage to qualify for PR nor sufficient increase to qualify for PD, taking as reference the smallest sum diameters while on study



Longest Target Lesion Diameter

Lesion	BL	#1
Rt.Lung #1	3	2
Rt.Lung #2	2.5	2
Lt liver lobe	6	5
Rt Liver lobe	2.5	2
Total Length	14	11
% Change		-21%
Disease Status		SD

- 11/14 = 0.79
- 0.79 - 1 = (-0.21)
- (-0.21) x 100% = -21%

Not 30% decrease = SD

Longest Target Lesion Diameter: BL, #1, #2

Lesion	BL	#1	#2
Rt.Lung #1	3	2	2
Rt.Lung #2	2.5	2	2
Lt liver lobe	6	5	3
Rt Liver lobe	2.5	2	2
Total Length	14	11	9
% Change		-21%	-36%
Disease Status		SD	PR

- 9/14 = 0.64
- 0.64 - 1 = (-0.35)
- (-0.355) x 100% = -36%

PR = > 30% decrease

Longest Target Lesion Diameter

Lesion	BL	#1	#2	#3	#4
Rt.Lung #1	3	2	2	2	3
Rt.Lung #2	2.5	2	2	2	3
Lt liver lobe	6	5	3	3	5
Rt Liver lobe	2.5	2	2	2	2
Total Length	14	11	9	9	13
% Change		-21%	-36%	-36%	+44% *
Disease Status		SD	PR	PR	PD
* Change from nadir					

- 13/9 = 1.44
- 1.44 - 1 = (0.44)
- (0.44) x100% = 44%

PD = > 20% increase from nadir

Best Response = PR

RESPONSE ASSESSMENT Non-TARGET

- **Complete 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)
  - Note: If tumor markers are initially above the upper normal limit, they must normalize for a patient to be considered in complete clinical response.
- **Stable Disease**
  - Persistence of one or more non-target lesion(s) and/or maintenance of tumor marker level above the normal limits
- **Progressive Disease (PD)**
  - Appearance of one or more new lesions and/or *unequivocal progression* of existing non-target lesions.
  - *Unequivocal progression* should not normally trump target lesion status.
  - It must be representative of overall disease status change, not a single lesion increase.

New Lesions

- Must be unequivocal and not attributed to different scanning technique or non-tumor.
- When in doubt, continue to treat and repeat
- If scan showing new lesions is of an anatomical region which wasn’t included in baseline, it is still Progressive Disease

Overall Response

Target Lesions	Non-Target Lesions	New Lesions	Overall Response	Best Overall Response when Confirmation is Required*
CR	CR	No	CR	≥4 wks. Confirmation**
CR	Non-CR/Non-PD	No	PR	≥4 wks. Confirmation**
CR	Not evaluated	No	PR	
PR	Non-CR/Non-PD/not evaluated	No	PR	
SD	Non-CR/Non-PD/not evaluated	No	SD	documented at least once ≥4 wks. from baseline**
PD	Any	Yes or No	PD	no prior SD, PR or CR
Any	PD***	Yes or No	PD	
Any	Any	Yes	PD	

* See RECIST 1.1 manuscript for further details on what is evidence of a new lesion.

** Only for non-randomized trials with response as primary endpoint.

*** In exceptional circumstances, unequivocal progression in non-target lesions may be accepted as disease progression.

Note: Patients with a global deterioration of health status requiring discontinuation of treatment without objective evidence of disease progression at that time should be reported as "symptomatic deterioration." Every effort should be made to document the objective progression even after discontinuation of treatment.

What is the response?

Lesion	BL (mm)	#1	#2
Liver lesion	82	40	78
Lung RUL	49	20	48
R Paratracheal LN	18	10	18
R adrenal	20	10	18
Mult liver lesions	Present	Stable	Stable
SUM	169	80	162
% change			
Disease Status			

What is the response at time point #1

a. Stable disease
b. Partial Response
c. Complete Response
d. Progressive Disease

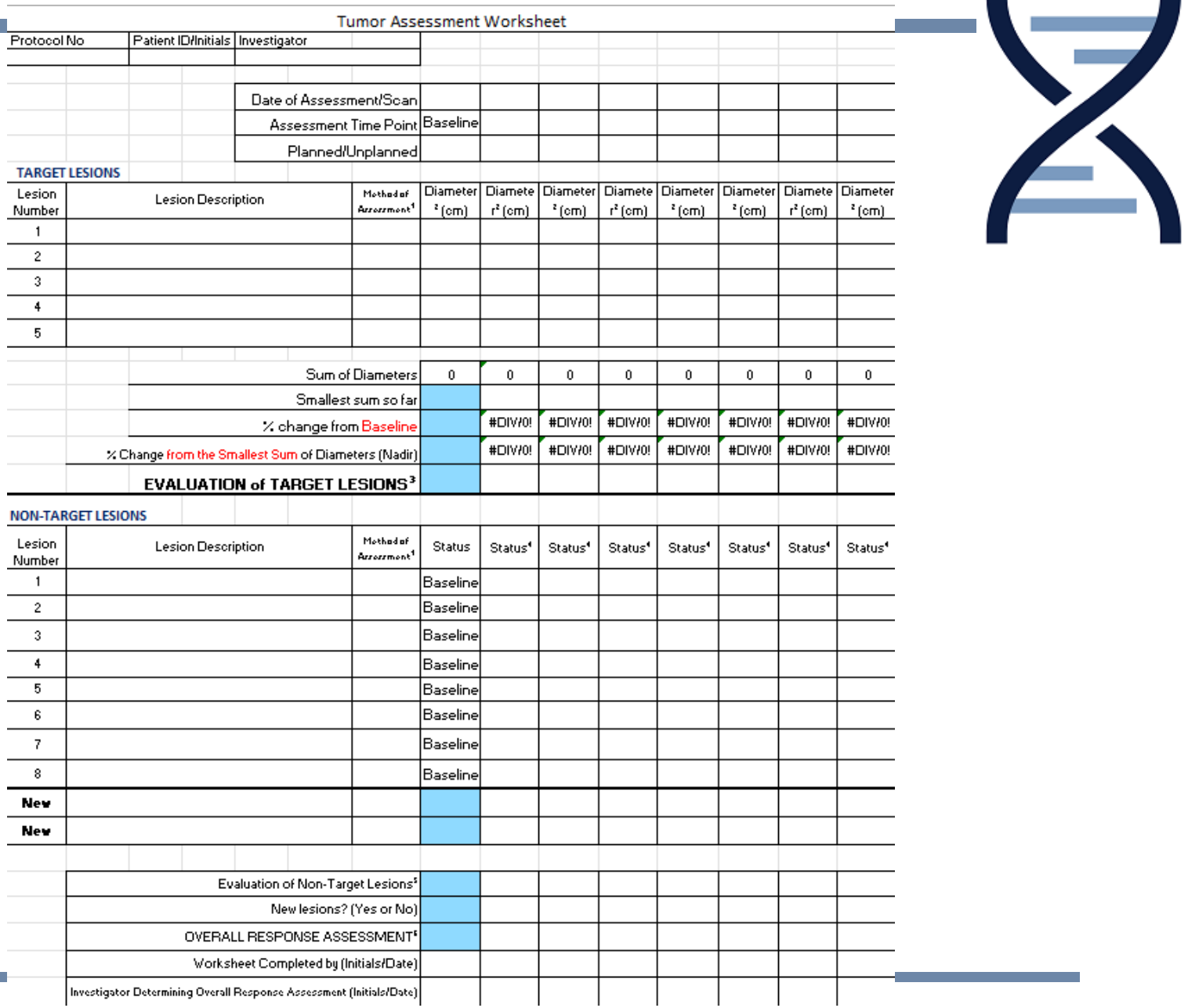
What is the response?

Lesion	BL (mm)	#1	#2
Liver lesion	82	40	78
Lung RUL	49	20	48
R Paratracheal LN	18	10	18
R adrenal	20	10	18
Mult liver lesions	Present	Stable	Stable
SUM	169	80	162
% change		53	
Disease Status		PR	

What is the response at time point #2

a. Stable disease
b. Partial Response
c. Complete Response
d. Progressive Disease

RECIST Documentation



Tumor Assessment Worksheet

Protocol No	Patient ID/Initials	Investigator

Date of Assessment/Scan								
Assessment Time Point	Baseline							
Planned/Unplanned								

TARGET LESIONS

Lesion Number	Lesion Description	Method of Assessment[1]	Diameter[2] (cm)	Diameter[2] (cm)	Diameter[2] (cm)	Diameter[2] (cm)	Diameter[2] (cm)	Diameter[2] (cm)	Diameter[2] (cm)	Diameter[2] (cm)
1										
2										
3										
4										
5										

Sum of Diameters	0	0	0	0	0	0	0	0
Smallest sum so far								
% change from Baseline		#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!
% Change from the Smallest Sum of Diameters (Nadir)		#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!
EVALUATION of TARGET LESIONS[3]								

NON-TARGET LESIONS

Lesion Number	Lesion Description	Method of Assessment[1]	Status	Status[4]	Status[4]	Status[4]	Status[4]	Status[4]	Status[4]	Status[4]
1			Baseline							
2			Baseline							
3			Baseline							
4			Baseline							
5			Baseline							
6			Baseline							
7			Baseline							
8			Baseline							
New										
New										

Evaluation of Non-Target Lesions[5]								
New lesions? (Yes or No)								
OVERALL RESPONSE ASSESSMENT[6]								
Worksheet Completed by (Initials/Date)								
Investigator Determining Overall Response Assessment (Initials/Date)								

iRECIST

- iRECIST is based on RECIST 1.1
- Immunotherapy
  - Frequently leads to responses that resemble a tumor flair.
  - Disease meeting the criteria for PD per RECIST, were noted to have responses later that were, deep and durable.
- Early discontinuation of an effective drug is not desirable, but continued long-term treatment with a non-effective drug may delay the initiation of potentially effective therapy.

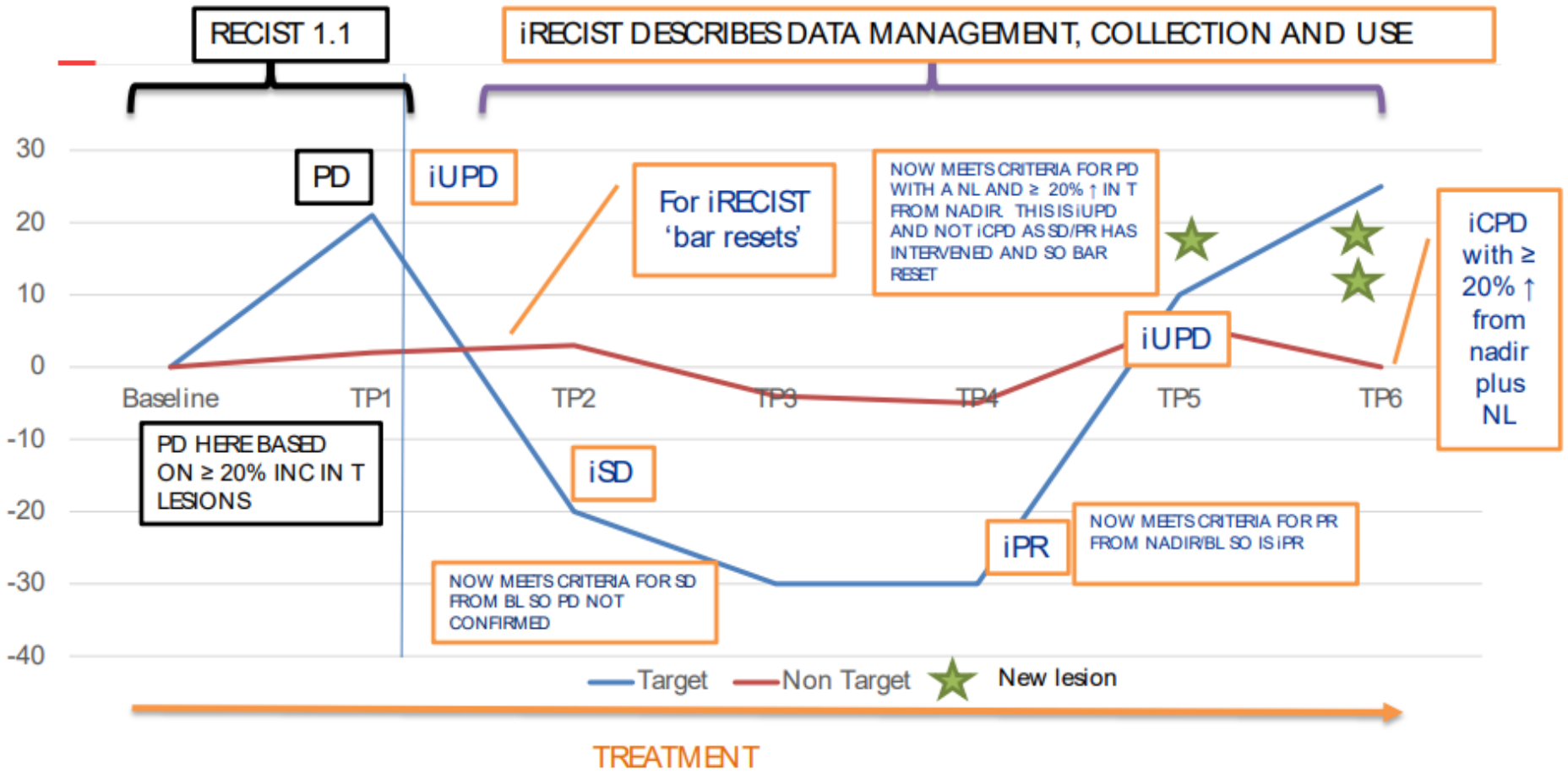
Terminology

- Pseudoprogression:
  - An increase in the size of lesions, or the visualization of new lesions, followed by a response, which might be durable.

iRECIST is based on RECIST 1.1

	iRECIST
Definitions of measurable, non-measurable disease	SAME
Definitions of target & non-target lesions	SAME
Measurement & management of nodal disease	SAME
Calculation of the sum of measurement	SAME
Definition of CR, PR, SD	SAME
Management of new lesions	DIFFERENT
Confirmation of progression required	DIFFERENT
Collection of reason why progression cannot be confirmed	New
Inclusion & recording of clinical status	New

Confirming Progression (iCPD)



Treating past progression

- No worsening of performance status
- No clinically relevant increase in disease related symptoms
- No requirement for intensified management of disease related symptoms (radiation, palliative care)

REFER TO YOU PROTOCOL

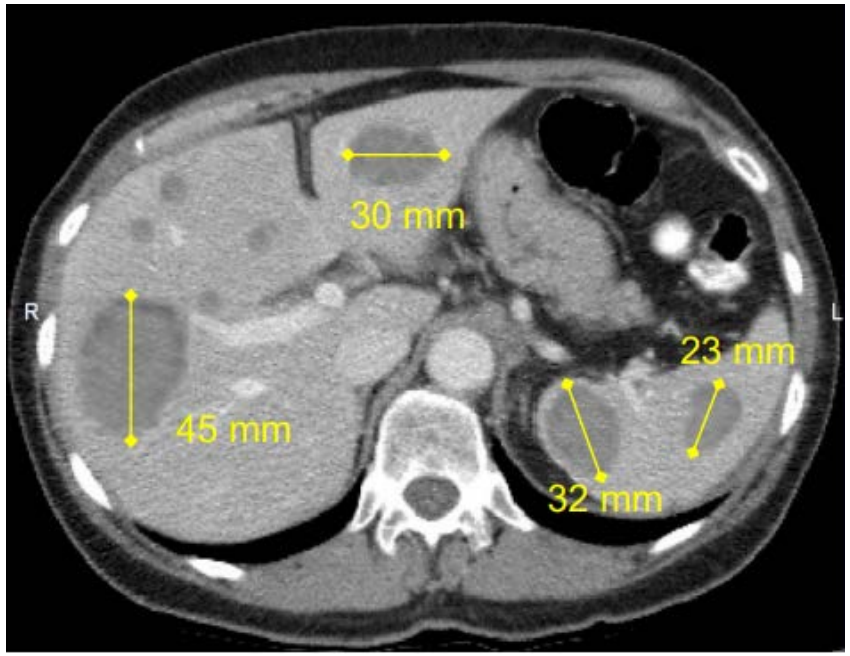
Frequency of tumor assessments

- Follow-up every 6 – 12 weeks, depending on the frequency of treatment visits.
- Protocol should specify which locations are assessed at baseline & Follow-up.
- Assessments should be on a calendar schedule & not be affected by delays in therapy.
- Confirmation scans should be done 4 – 8 weeks after iUPD.
- If progression is not confirmed, reassessment should continue as originally planned.

76 y.o male with stage IV lung cancer is receiving second line Pembrolizumab. The baseline sum of the target lesions = 100 mm. At the 6 - week scan, the sum of the target lesions = 130 mm, no new lesions, and non-target lesions are stable.

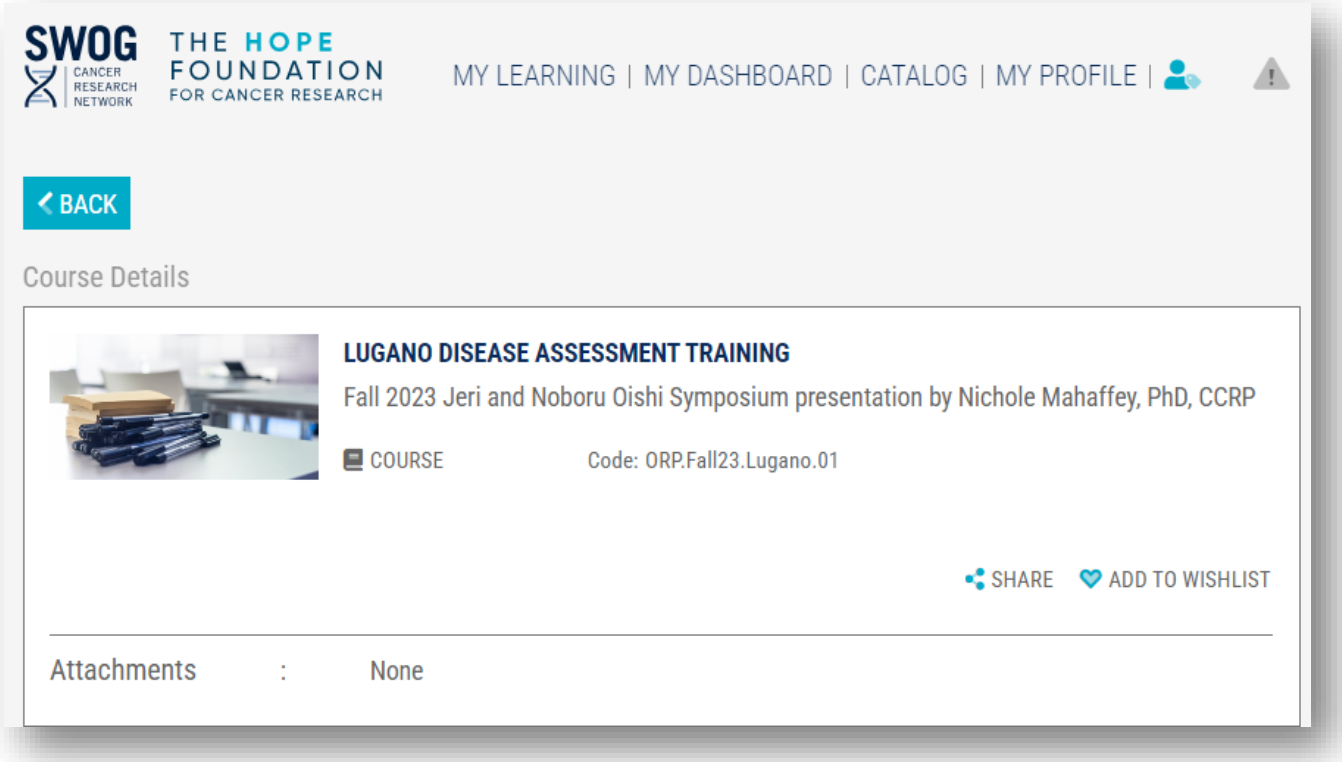
What are the most likely next steps, assuming protocol Section 10 follows iRECIST:

a. Stop Protocol therapy, the patient has PD
b. Continue protocol therapy until next required disease assessment
c. Continue treatment, re-assess in 4 – 6 wks



Lugano

- FDG-PET/CT
- Use with Lymphoma
- Lugano vs Deauville



Ricard et al., 2023; Ragheb et al., 2020; You, K.H., 2022

Choosing Lesions

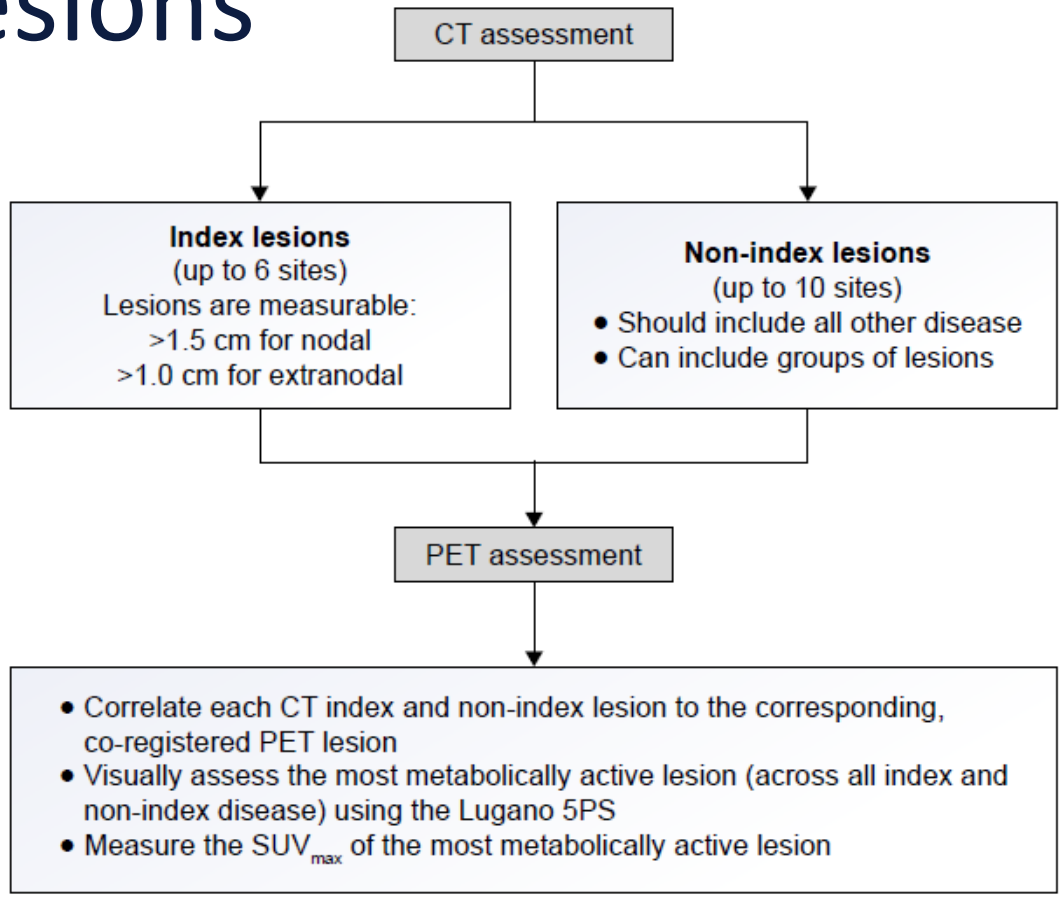


Figure 1 Proposed baseline assessment workflow.
Abbreviations: CT, computed tomography; PET, positron emission tomography; 5PS, 5-point scale; SUV_{max}, maximum standardized uptake value.

Van Hertum et al., 2017; Ricard et al., 2023

RESPONSE Assessment

PET 5-Point Scale / Deauville score:

- 1, no FDG uptake above background;
- 2, FDG uptake ≤ mediastinum;
- 3, FDG uptake > mediastinum but ≤ liver;
- 4, FDG uptake moderately >liver;
- 5, FDG uptake markedly higher than liver and/or new lesions;
- X, new areas of uptake unlikely to be related to lymphoma.

S1826: Section 10 & 18.7

LYRIC criteria: Section 18.1

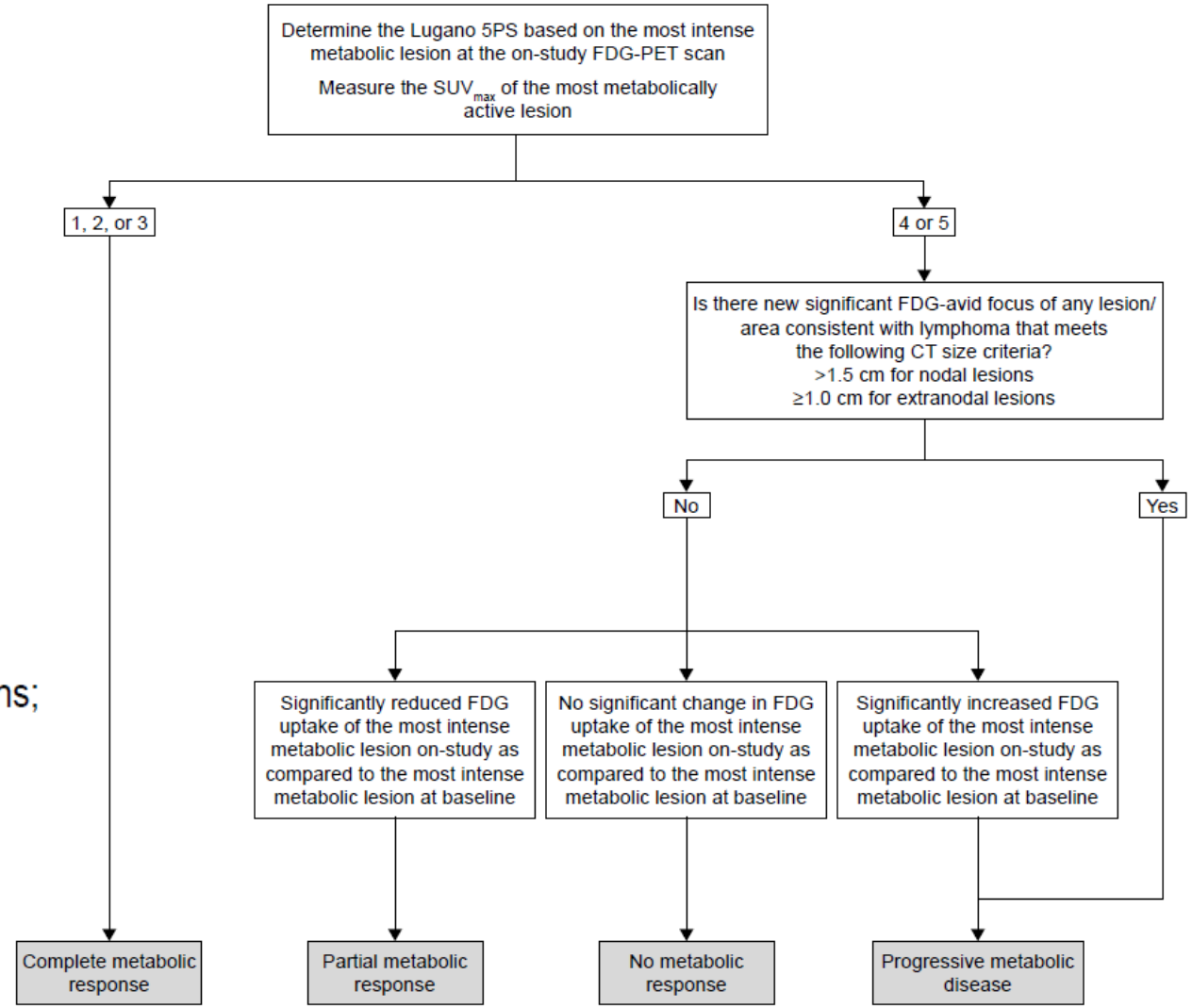
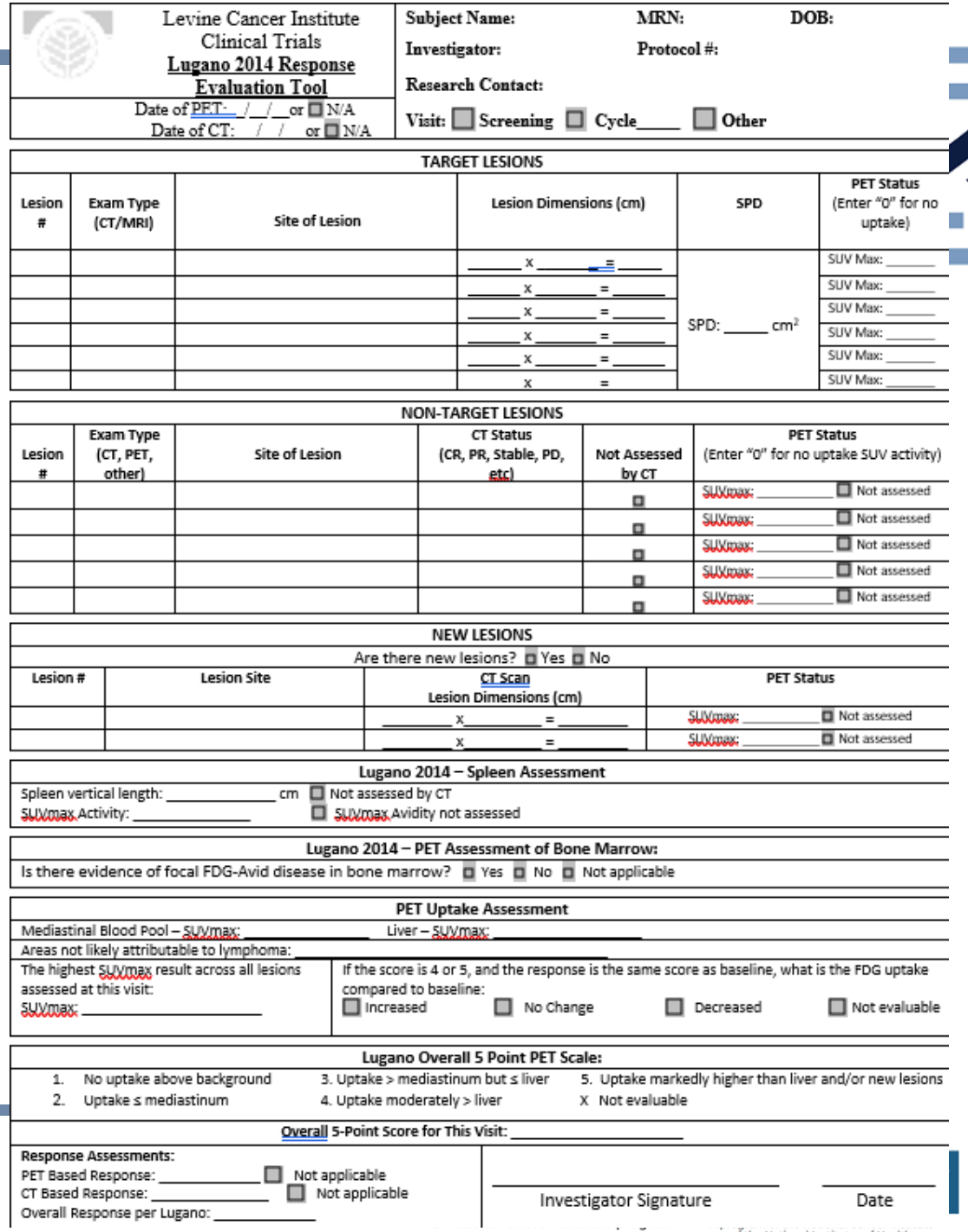


Figure 2 On-study PET response workflow.
Abbreviations: PET, positron emission tomography; 5PS, 5-point scale; FDG, [^{18}F] fluorodeoxyglucose; SUV_{max}, maximum standardized uptake value; CT, computed tomography.

Ricard et al., 2023; Van Hertum et al., 2017

Documentation

- Consistent documentation
- Communication with radiology
  - Any required missing information needs to be obtained.
  - When a size or SUV is not given for a lesion, it should not be assumed that it is 0.



Levine Cancer Institute
Clinical Trials
Lugano 2014 Response Evaluation Tool

Date of PET: __/__/__ or ☐ N/A
Date of CT: __/__/__ or ☐ N/A

Subject Name: **MRN:** **DOB:**
Investigator: **Protocol #:**
Research Contact:
Visit: ☐ Screening ☐ Cycle____ ☐ Other

TARGET LESIONS

Lesion #	Exam Type (CT/MRI)	Site of Lesion	Lesion Dimensions (cm)	SPD	PET Status (Enter "0" for no uptake)
			____ x ____ = ____	SPD: ____ cm^2	SUV Max: ____
			____ x ____ = ____		SUV Max: ____
			____ x ____ = ____		SUV Max: ____
			____ x ____ = ____		SUV Max: ____
			____ x ____ = ____		SUV Max: ____
			x =		SUV Max: ____

NON-TARGET LESIONS

Lesion #	Exam Type (CT, PET, other)	Site of Lesion	CT Status (CR, PR, Stable, PD, etc)	Not Assessed by CT	PET Status (Enter "0" for no uptake SUV activity)
				☐	SUVmax: ____ ☐ Not assessed
				☐	SUVmax: ____ ☐ Not assessed
				☐	SUVmax: ____ ☐ Not assessed
				☐	SUVmax: ____ ☐ Not assessed
				☐	SUVmax: ____ ☐ Not assessed

NEW LESIONS

Are there new lesions? ☐ Yes ☐ No

Lesion #	Lesion Site	CT Scan Lesion Dimensions (cm)	PET Status
		____ x ____ = ____	SUVmax: ____ ☐ Not assessed
		____ x ____ = ____	SUVmax: ____ ☐ Not assessed

Lugano 2014 – Spleen Assessment

Spleen vertical length: ____ cm ☐ Not assessed by CT
SUVmax Activity: ____ ☐ SUVmax Avidity not assessed

Lugano 2014 – PET Assessment of Bone Marrow:

Is there evidence of focal FDG-Avid disease in bone marrow? ☐ Yes ☐ No ☐ Not applicable

PET Uptake Assessment

Mediastinal Blood Pool – SUVmax: ____ Liver – SUVmax: ____
Areas not likely attributable to lymphoma: ____

The highest SUVmax result across all lesions assessed at this visit:
SUVmax: ____

If the score is 4 or 5, and the response is the same score as baseline, what is the FDG uptake compared to baseline:
☐ Increased ☐ No Change ☐ Decreased ☐ Not evaluable

Lugano Overall 5 Point PET Scale:

1. No uptake above background
2. Uptake ≤ mediastinum
3. Uptake > mediastinum but ≤ liver
4. Uptake moderately > liver
5. Uptake markedly higher than liver and/or new lesions
X Not evaluable

Overall 5-Point Score for This Visit: ____

Response Assessments:
PET Based Response: ____ ☐ Not applicable
CT Based Response: ____ ☐ Not applicable
Overall Response per Lugano: ____

Investigator Signature ____ Date

You are collecting data for the EOT assessment to complete the CRF for a patient on S1826. When reviewing the report, you notice that only one measurement is given for one of the target lesions, and the SUV is not in the report. What do you do?

A. Report the missing information as 0 on the CRF.
B. Leave the information blank on the CRF and add a comment that it was not evaluated.
C. Report the lesion as not evaluated.
D. Meet with the radiologist to obtain the missing information.

Tips for Accuracy

- ALWAYS refer to your protocol for measurement criteria & Timing
- Review scans with radiology/investigator
- Try to have a few radiologists or PI to measure disease
- Utilize a measurement form that clearly delineates the lesions being followed.

Prior QA Webinars Accessible for Review

Links to Previous Webinars and Upcoming Webinar Announcements are posted at: **SWOG Quality Assurance Live Webinar Series | SWOG**

CEU Courses in ExpertusOne:

- **Research Protocol Deviations vs Deficiencies** (1 contact hour)
- **Best Practices for Informed Consent** (1 contact hour)
- **Workload Prioritization in Clinical Trials** (1.5 contact hours)

Non-CEU Courses now in CLASS:

- **Adverse Event Reporting**
- **Serious Adverse Event Reporting**
- **SWOG Audits: Preparing for Success and Audit Process**
- **How to Develop a CAPA Plan**