RECIST
New CRA Orientation
Alliance

Scott Okuno, MD
Medical Oncology
Mayo Clinic

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RECIST 1.1 Definition

- Assessing Change of Tumor Burdon
- **RE**sponse **C**riteria **I**n **S**olid **T**umor version 1.1
- Other response criteria
  - Prostate
  - Leukemia
  - Lymphoma

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EUROPEAN JOURNAL OF CANCER 4 5 (2 0 0 9) 2 2 8 –2 4 7

RECIST 1.1

- Why do we need RECIST?
  - Physical exam
  - Slice-thickness of scans
  - Pseudo-progression
- Research vs Clinical response

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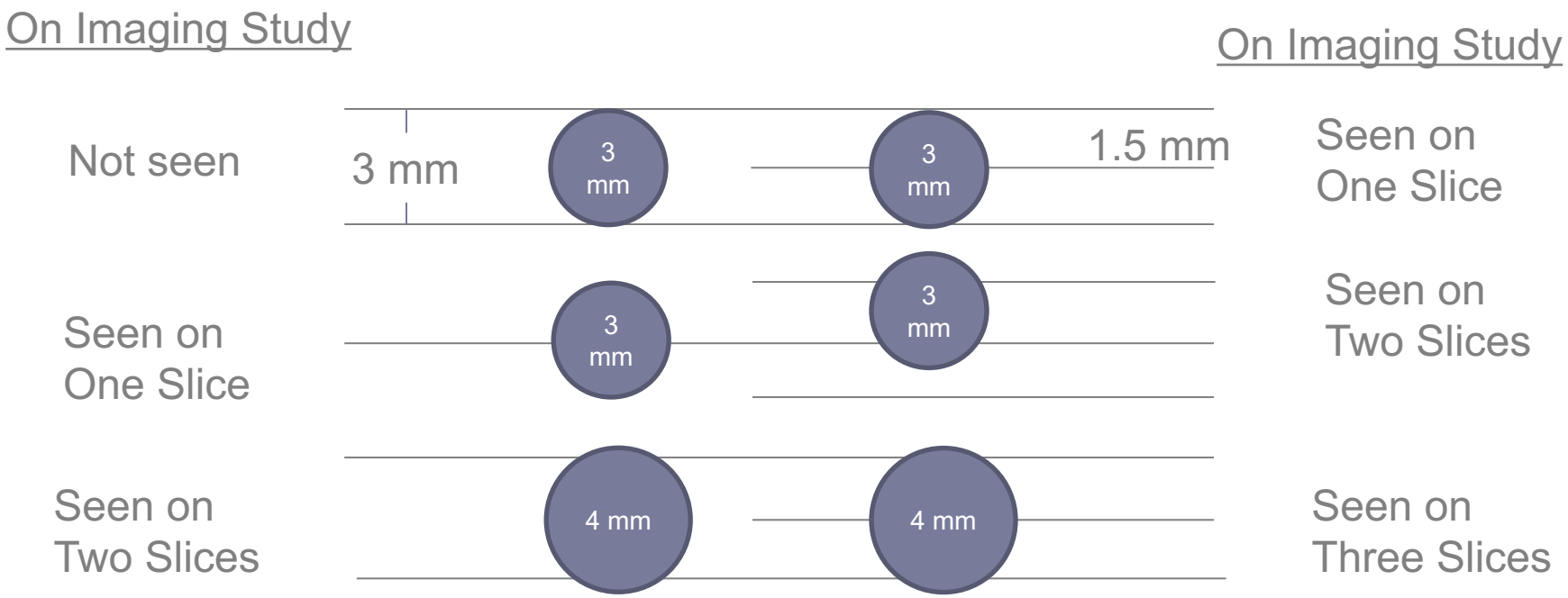
Slice Thickness



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Measurable 3.1.1

- Tumour lesions:
  - Must be accurately measured in at least on dimension (longest diameter in the plane of measurement is to be recorded)
  - Minimum size of:
    - 10 mm by CT scan (CT scan slice thickness no greater than 5 mm
    - 10 mm caliper measurement by clinical exam (lesions which cannot be accurately measured with calipers should be recorded as non-measurable)
    - 20 mm by chest X-ray

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How to Measure

- Mass/Lesion/Lump
  - Uni-dimension long axis
- Lymph node
  - Uni-dimension short axis
- Minimal size
  - 10 mm

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Non-measurable 3.1.2

- All other lesions, including small lesions (longest diameter <10 mm or pathological lymph nodes with ≥10 to <15 mm short axis) as well as truly non-measurable lesions.
- Lesions considered truly non-measurable include:
  - Leptomeningeal disease
  - Ascites, pleural or pericardial effusion, inflammatory breast disease, lymphangitic involvement of skin or lung
  - Abdominal masses/abdominal organomegaly identified by physical exam that is not measurable by reproducible imaging techniques

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Method of Assessment 3.2.2

- The same method of assessment and the same technique should be used to characterize each identified and reported lesion at baseline and during follow-up
- If use CT, stay with CT
- If use MRI, stay with MRI

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Target Lesion

- When more than one measurable lesion is present at baseline all lesions up to a maximum of five lesions total (and a maximum of two lesions per organ) representative of all involved organs should be identified as target lesions and will be recorded and measured at baseline
- Max of 5 lesions
- Max of 2 per organ

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Non-Target

- All other lesions (or sites of disease) including pathological lymph nodes should be identified as non-target lesions and should also be recorded at baseline

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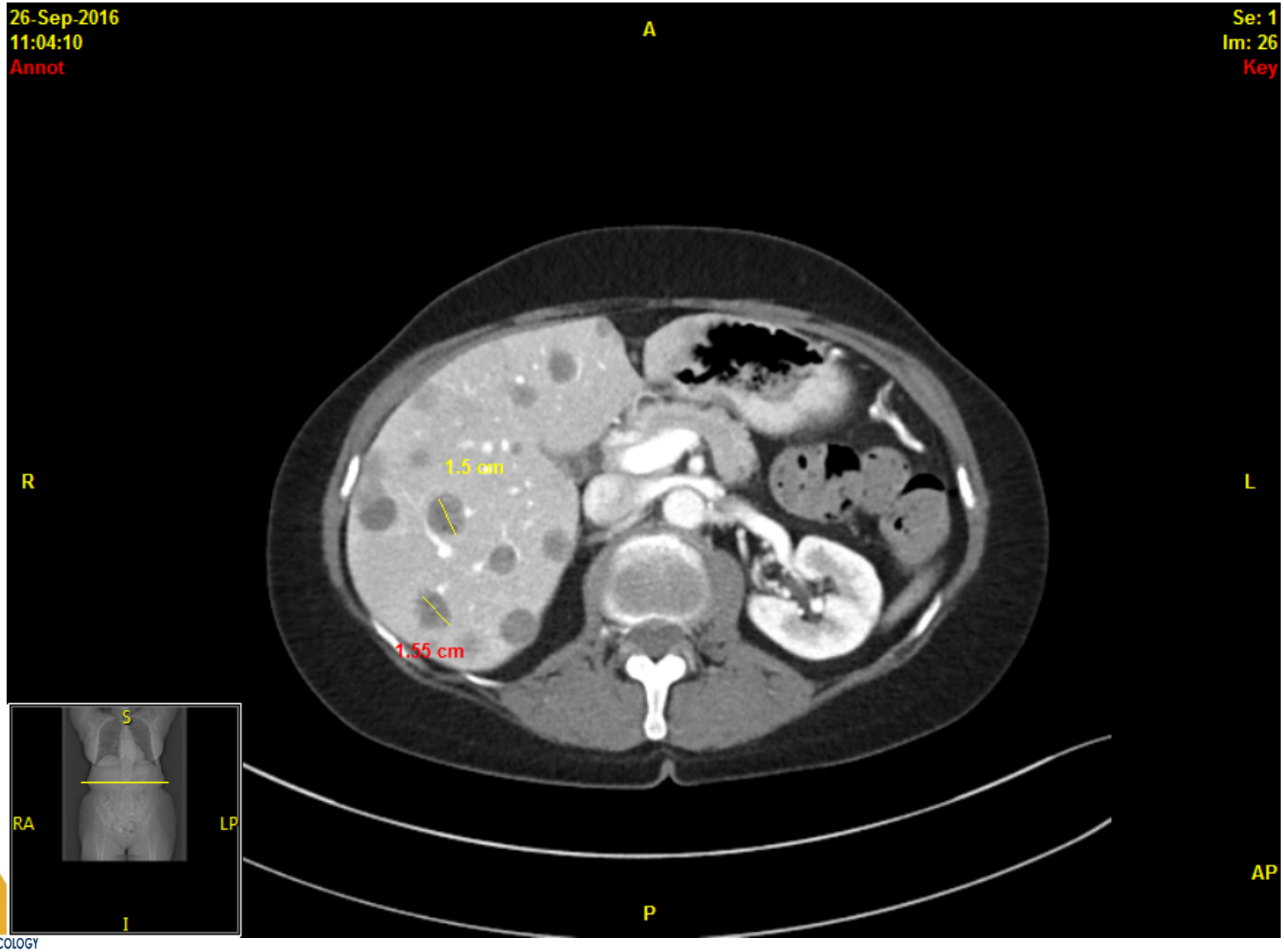
Target Lesion. Need to Mark 2 Lesions
Non-Target: Liver mets



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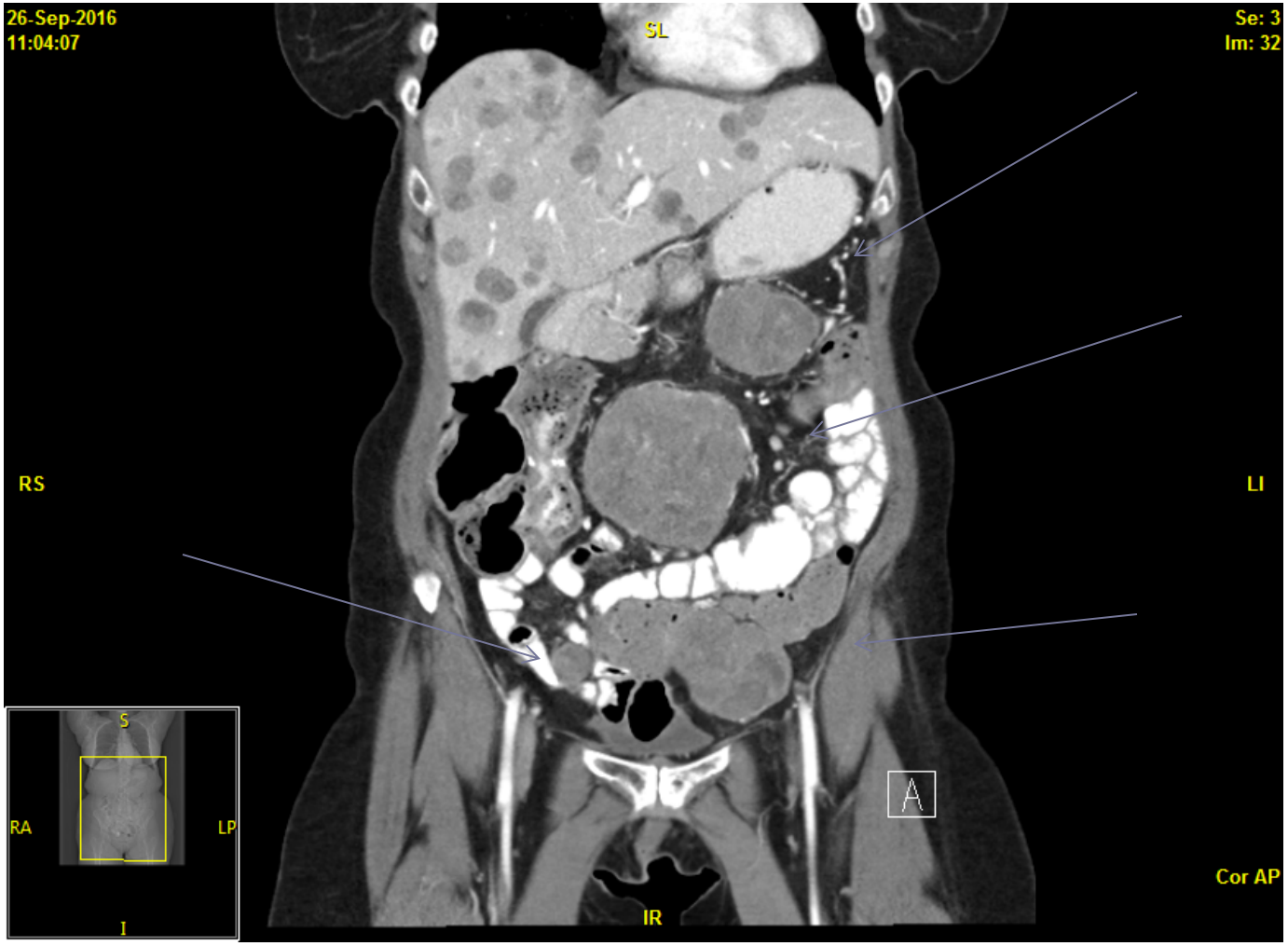
Target Lesion: 2 in Liver and 2 in Peritoneum
Non-Target: Liver and Peritoneum



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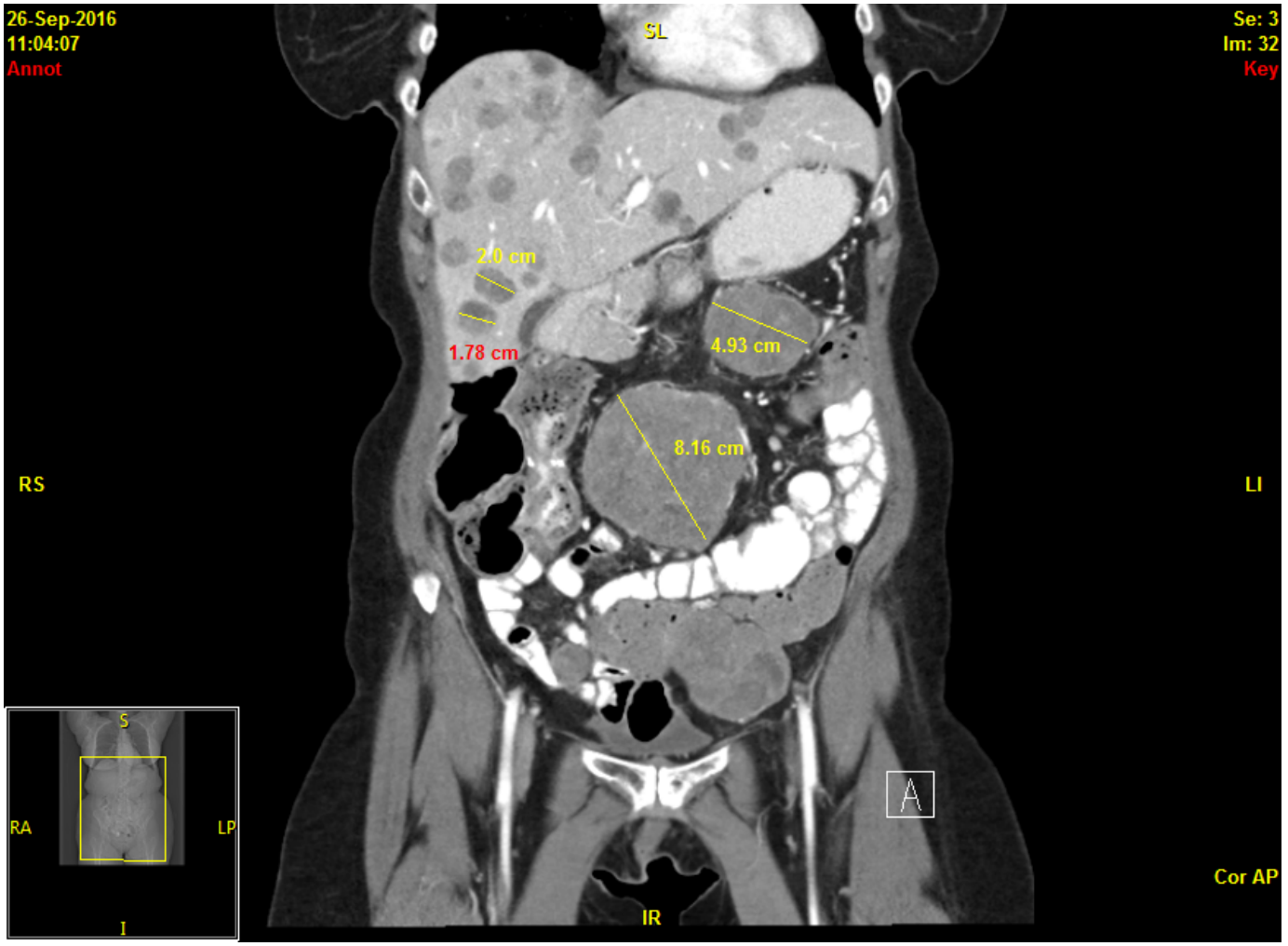
Measurements and Documentation of Slice and Image:



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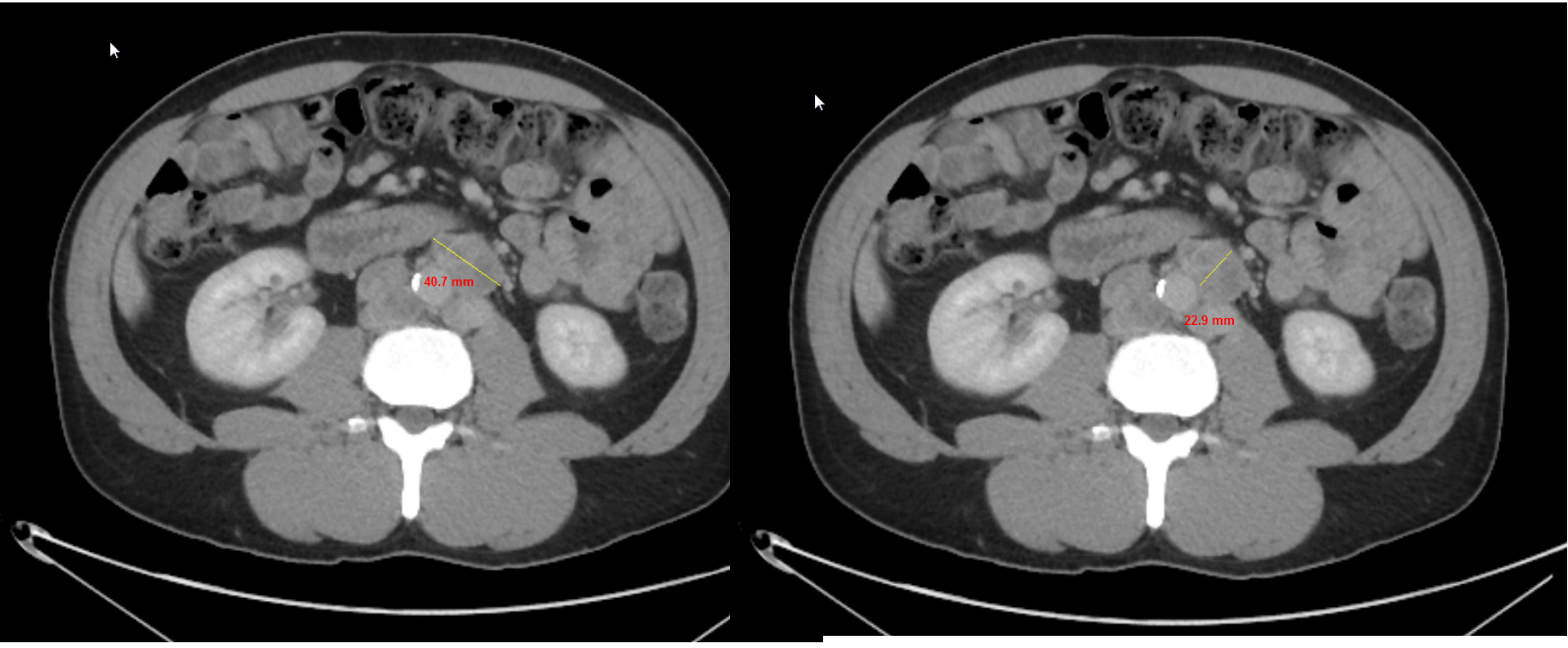
Metastatic Paraganglioma With Retroperitoneal Adenopathy: Correct Measurement: 40.7 mm or 22.9 mm?*



Lymph Node: 40.7 mm

Lymph Node: 22.9 mm

*Hint: Lymph Nodes are measured on the short axis

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Sum of Diameters of Target Lesions

- A sum of the diameters (longest for non-nodal lesions, short axis for nodal lesions) for all target lesions will be calculated and reported as the baseline sum diameters

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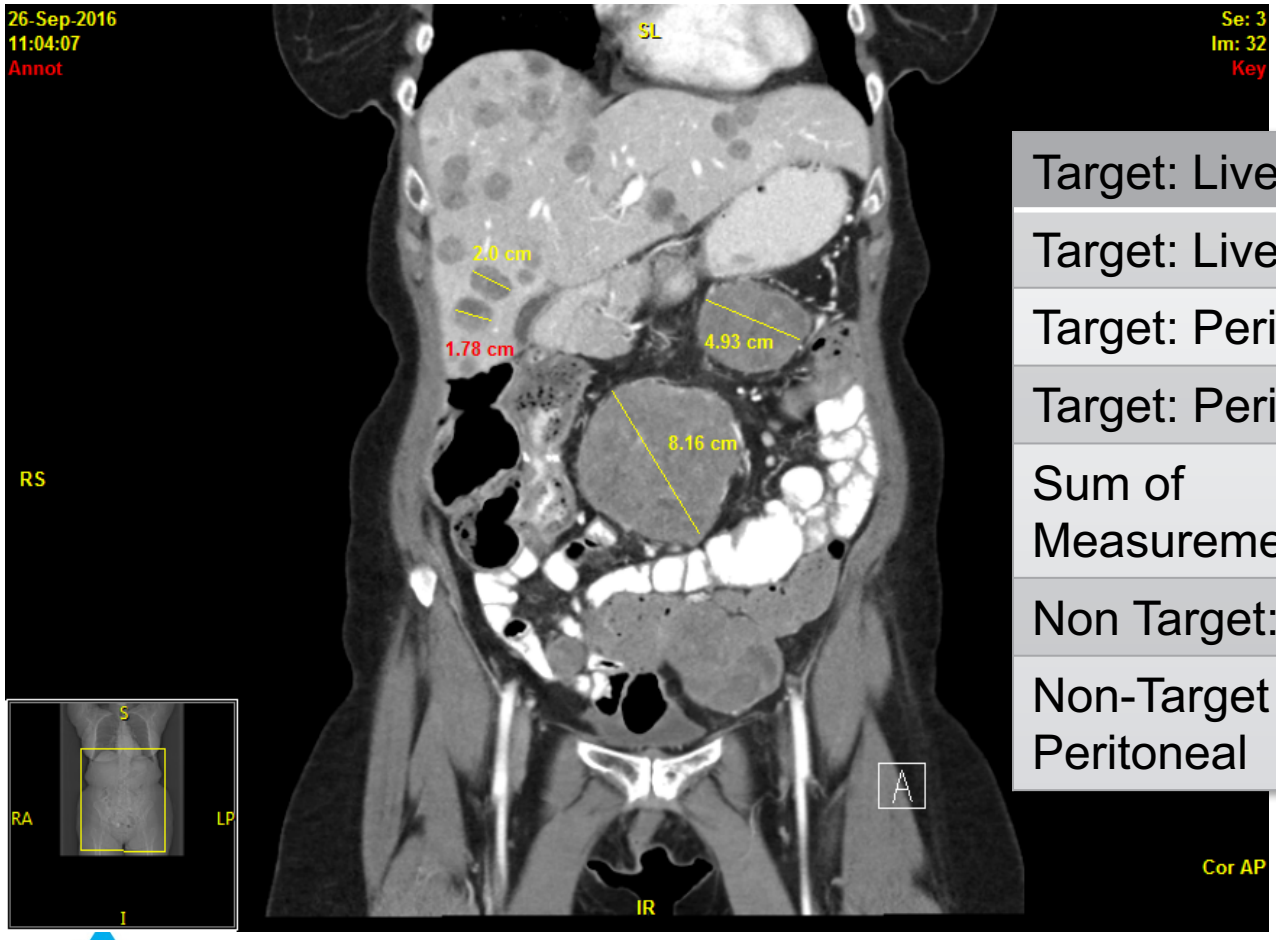
Sum of Measurements



Target: Liver	20 mm
Target: Liver	17.8 mm
Target: Peritoneal	49.3 mm
Target: Peritoneal	81.6 mm
Sum of Measurements	168.7 mm
Non Target: Liver	present
Non-Target Peritoneal	present

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Evaluations of Target Lesions

- 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 diameters of target lesions, taking as reference the baseline sum diameters

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Evaluations of Target Lesions

- Progressive Disease (PD): At least a 20% increase in the sum of 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%, the sum must also demonstrate
  - An absolute increase of at least 5 mm. (Note: The appearance of one or more new lesions is also considered progression)

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Evaluation of Target Lesion

- 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

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Evaluation of Non-Target Lesions

- Complete Response (CR): Disappearance of all non-target lesions and normalization of tumour marker level. All lymph nodes must be non-pathological in size (<10mm short axis).
- Non-CR/Non-PD: Persistence of one or more non-target lesion(s) and/or maintenance of tumour marker level above the normal limits.
- Progressive Disease (PD): Unequivocal progression (see comments below) of existing non-target lesions. (Note: The appearance of one or more new lesions is also considered progression)

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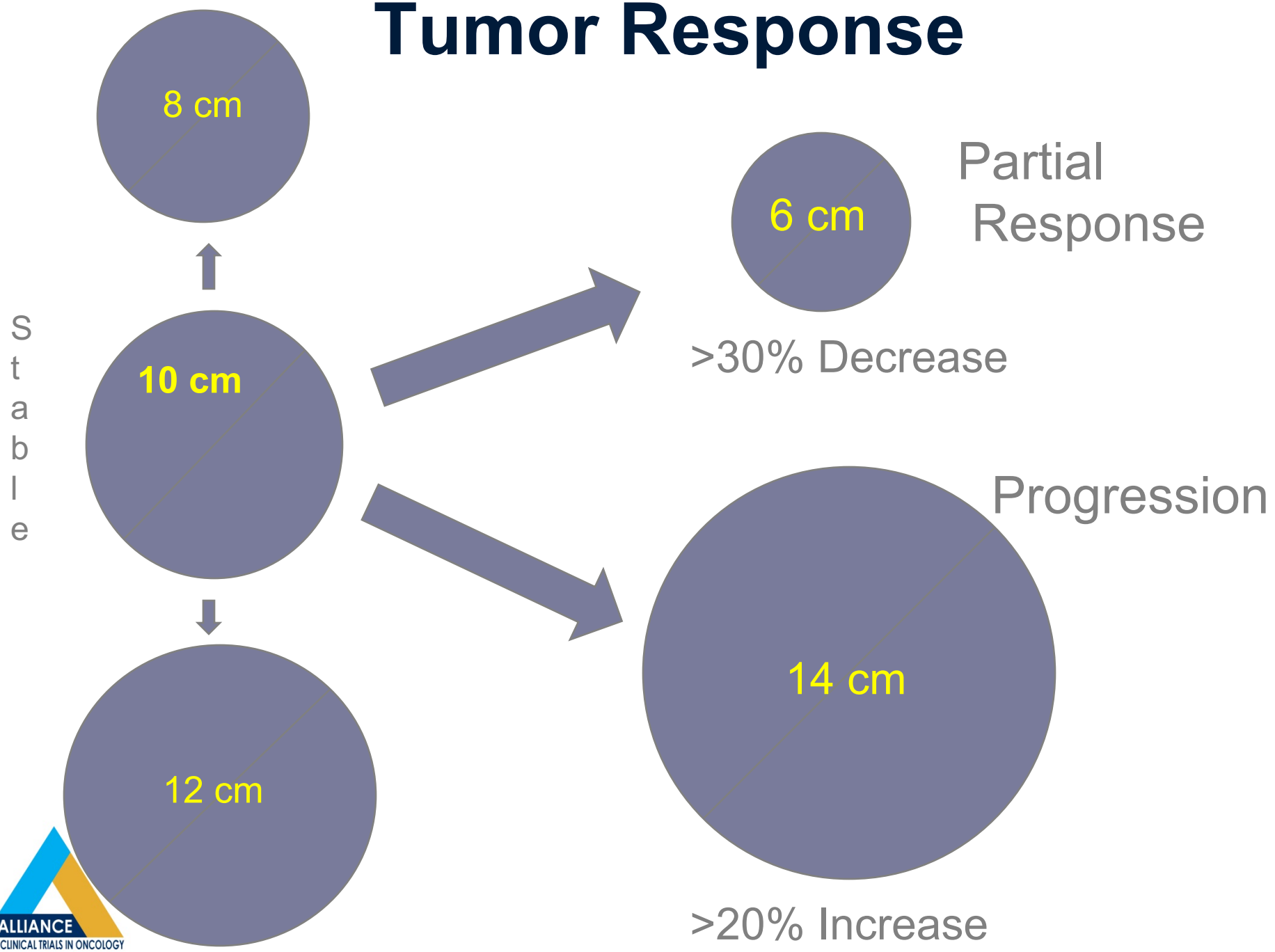
Tumor Response



Protocol: _____ **Site:** _____ **Subject ID:** _____ **Sheet:** ____ **of** ____

Lesion #	Lesion Site	Description of Lesion	Method of Imaging: CE, CT, MRI, Other	Cycle #: _____ ____/____/_____		Cycle #: _____ ____/____/_____		Cycle #: _____ ____/____/_____		Cycle #: _____ ____/____/_____	
Target Lesion		**Lesions assessment completed?**		**Yes**	**No**	**Yes**	**No**	**Yes**	**No**	**Yes**	**No**
TL01					mm		mm		mm		mm
TL02					mm		mm		mm		mm
TL03					mm		mm		mm		mm
TL04					mm		mm		mm		mm
TL05					mm		mm		mm		mm
Non-Target Lesion		**Lesion assessment completed?**		**Yes**	**No**	**No**	**Yes**	**Yes**	**No**	**Yes**	**No**
				Please circle one: Present (P) or Absent (A)							
NT01				**P**	**A**	**P**	**A**	**P**	**A**	**P**	**A**
NT02				**P**	**A**	**P**	**A**	**P**	**A**	**P**	**A**
NT03				**P**	**A**	**P**	**A**	**P**	**A**	**P**	**A**
NT04				**P**	**A**	**P**	**A**	**P**	**A**	**P**	**A**
NT05				**P**	**A**	**P**	**A**	**P**	**A**	**P**	**A**
NT06				**P**	**A**	**P**	**A**	**P**	**A**	**P**	**A**
NT07				**P**	**A**	**P**	**A**	**P**	**A**	**P**	**A**
New Lesion		**Any new lesions?**		**Yes**	**No**	**Yes**	**No**	**Yes**	**No**	**Yes**	**No**
COMMENTS/CLARIFICATIONS:											

Sum of Longest Diameters (mm):				
Percent Change:				
CR = Complete Response, PR = Partial Response, PD = Progressive Disease, SD = Stable Disease, NE = Not Evaluated, NA = Not Applicable, NCR = Non-Complete Response/Non-Progressive				
Target Lesion Response:				
Non-Target Lesion Response:				
Total Overall Tumor Response:				
If Treatment Ended, Best Overall Response:				
Signature of Investigator and date:				

SARC
collaborating to cure sarcoma

Evaluation of Response

Lesions	1/2/2016 Baseline mm	3/2/2016 C2 mm	5/2/2016 C4 mm
Target: Liver	20	18	35
Target: Liver	18	18	20
Target: Peritoneal	49	52	60
Target Peritoneal	82	90	120
Non-Target: Liver	Present	Stable	Stable
Non-Target Peritoneal	Present	Growth*	Stable
Sum of Measurements	169	178	235
Best Response		Stable	Progression

*Non-Target: Report said growth, the PI said not unequivocal growth

Evaluation of Response

Lesions	1/2/2016 Baseline mm	3/2/2016 C2 mm	5/2/2016 C4 mm
Target: Liver	20	10	18
Target: Liver	18	10	18
Target: Peritoneal	49	20	48
Target Peritoneal	82	40	78
Non-Target: Liver	Present	Stable	Stable
Non-Target Peritoneal	Present	Stable	Stable
Sum of Measurements	169	80	162
Best Response		Partial Regression	Progression

Table 1 – Time point response: patients with target (+/– non-target) disease.

Target lesions	Non-target lesions	New lesions	Overall response
CR	CR	No	CR
CR	Non-CR/non-PD	No	PR
CR	Not evaluated	No	PR
PR	Non-PD or not all evaluated	No	PR
SD	Non-PD or not all evaluated	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, and NE = inevaluable.

Table 2 – Time point response: patients with non-target disease only.

Non-target lesions	New lesions	Overall response
CR	No	CR
Non-CR/non-PD	No	Non-CR/non-PD[a]
Not all evaluated	No	NE
Unequivocal PD	Yes or No	PD
Any	Yes	PD

CR = complete response, PD = progressive disease, and NE = inevaluable.

a 'Non-CR/non-PD' is preferred over 'stable disease' for non-target disease since SD is increasingly used as endpoint for assessment of efficacy in some trials so to assign this category when no lesions can be measured is not advised.

Best Overall Response

- The best overall response is determined once all the data for the patient is known
  - First evaluation Stable Disease (SD)
  - Second evaluation Partial Response (PR)
  - Third evaluation Progression (PROG)

  - Best Overall Response is PR

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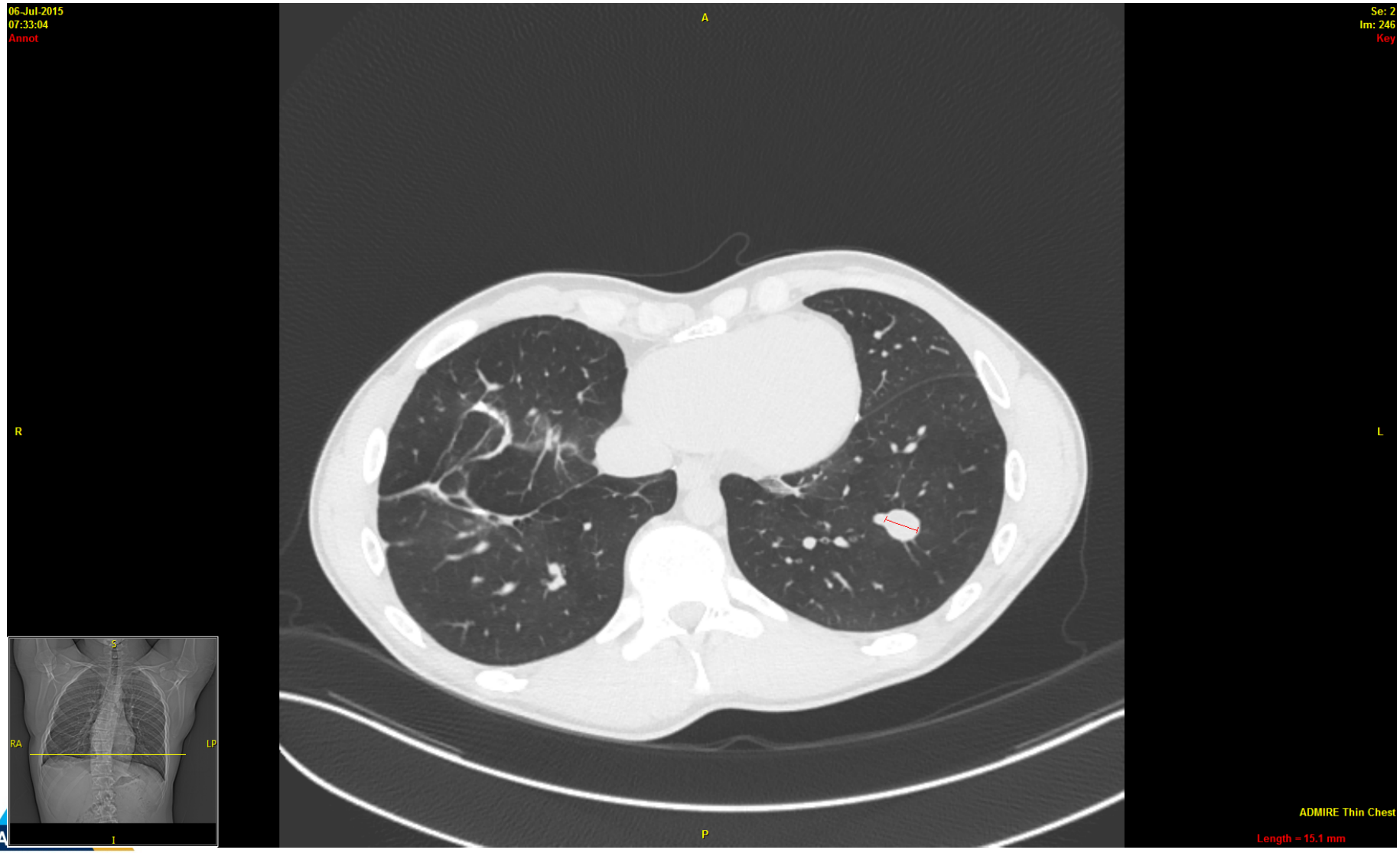
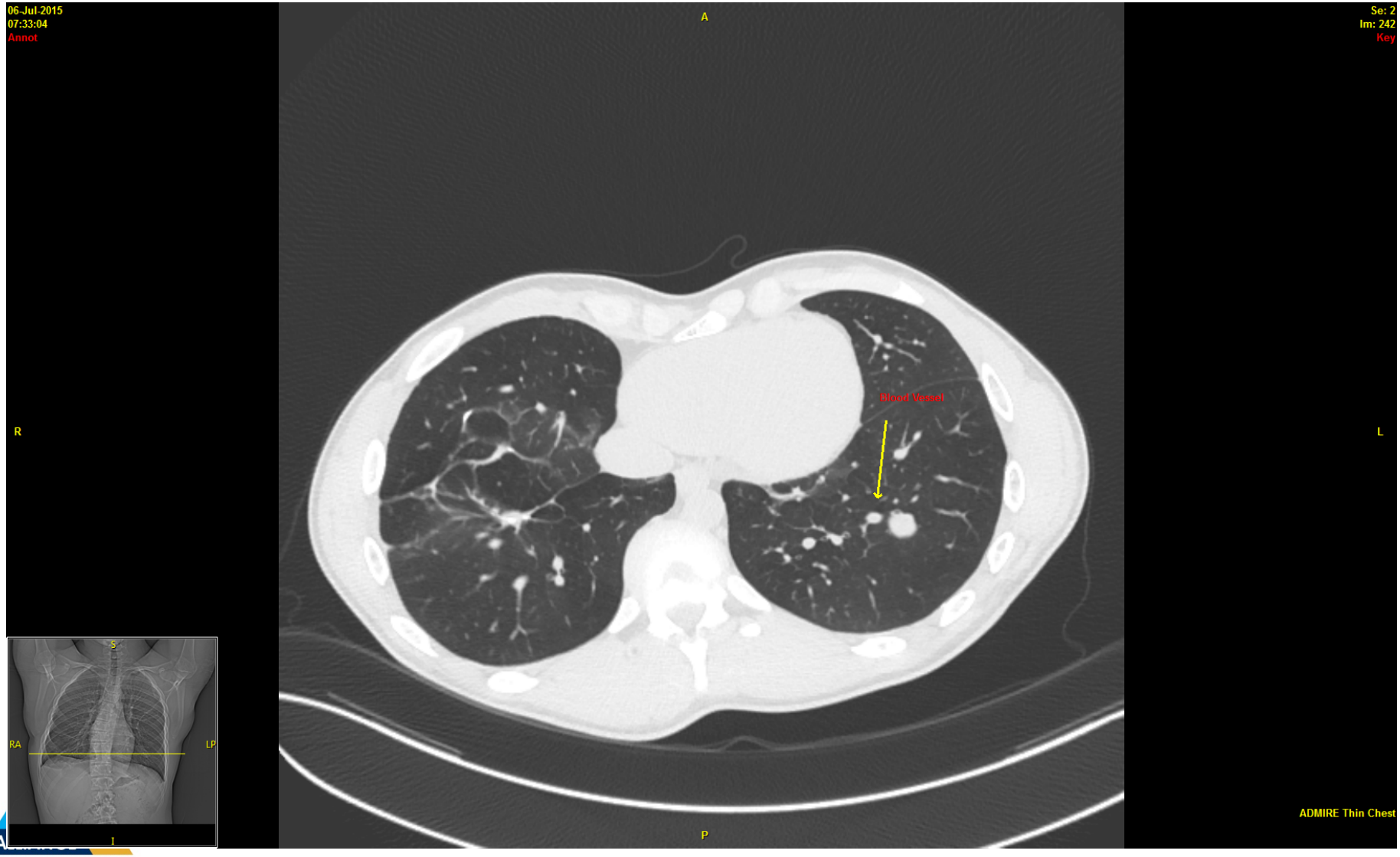
Left Lung Lesion (series 2 image 246)



Left Lung Lesion (series 2 image 242)



Pitfalls

- No change since prior scan
- New lesion
- Growth of Non-target lesion
- Growth after response
- Best Response
- Timing of imaging

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Interpretation of Radiology Reports

- 1/2016 Baseline: Metastatic disease in liver and peritoneal
- 3/2016 First Assessment: No significant change in liver and peritoneal lesions
- 5/2016 Second Assessment: No significant change in liver and peritoneal lesion since prior exam
- 7/2016 Third Assessment: No significant change in liver and peritoneal lesion since prior exam
- 9/2016 Fourth Assessment: No significant change in liver and peritoneal lesion since prior exam

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Interpretation of No Significant Change Since Prior Scan

Lesions	1/2/2016 Baseline mm	3/2/2016 C2 mm	5/2/2016 C4 mm	7/2/2016 C6 mm	9/2/2016 C8 mm
Target: Liver	20	22	24	26	28
Target: Liver	18	20	22	24	26
Target: Peritoneal	49	51	53	55	57
Target Peritoneal	50	52	54	56	58
Non-Target: Liver	Present	Stable	Stable		
Non-Target Peritoneal	Present	Stable	Stable		
Sum of Measurements	137	145	153	161	169
Best Response		Stab	Stab	Stab	PROG

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Timing of Imaging

- Baseline then prior to odd cycles of chemo
  - C3, C5, C7, etc…
- Baseline then every 21 days
  - Not necessarily based on cycles of chemotherapy if delays

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Summary: RECIST 1.1

- RECIST 1.1: Know better than PI or Radiologist
- Measurement (Measureable, Non-Measureable, Target, Non-Target, and LN)
- # of lesions and # per organ (5/2)
- Work with Radiologist and PI to accurately document which lesion is being followed and from baseline or best response
- When is patient SD, PR, PROG

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QUESTIONS:

OKUNO.SCOTT@MAYO.EDU

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