RECIST
New CRA Orientation
Alliance

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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

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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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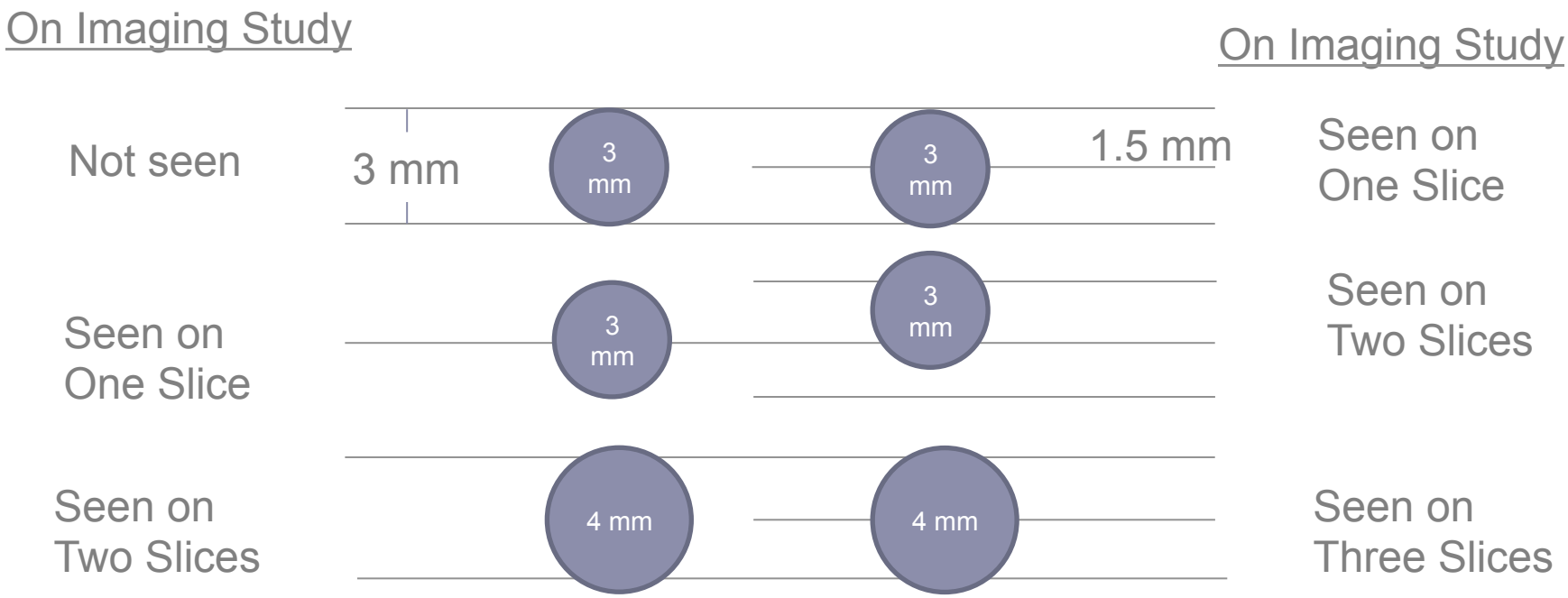
Slice Thickness



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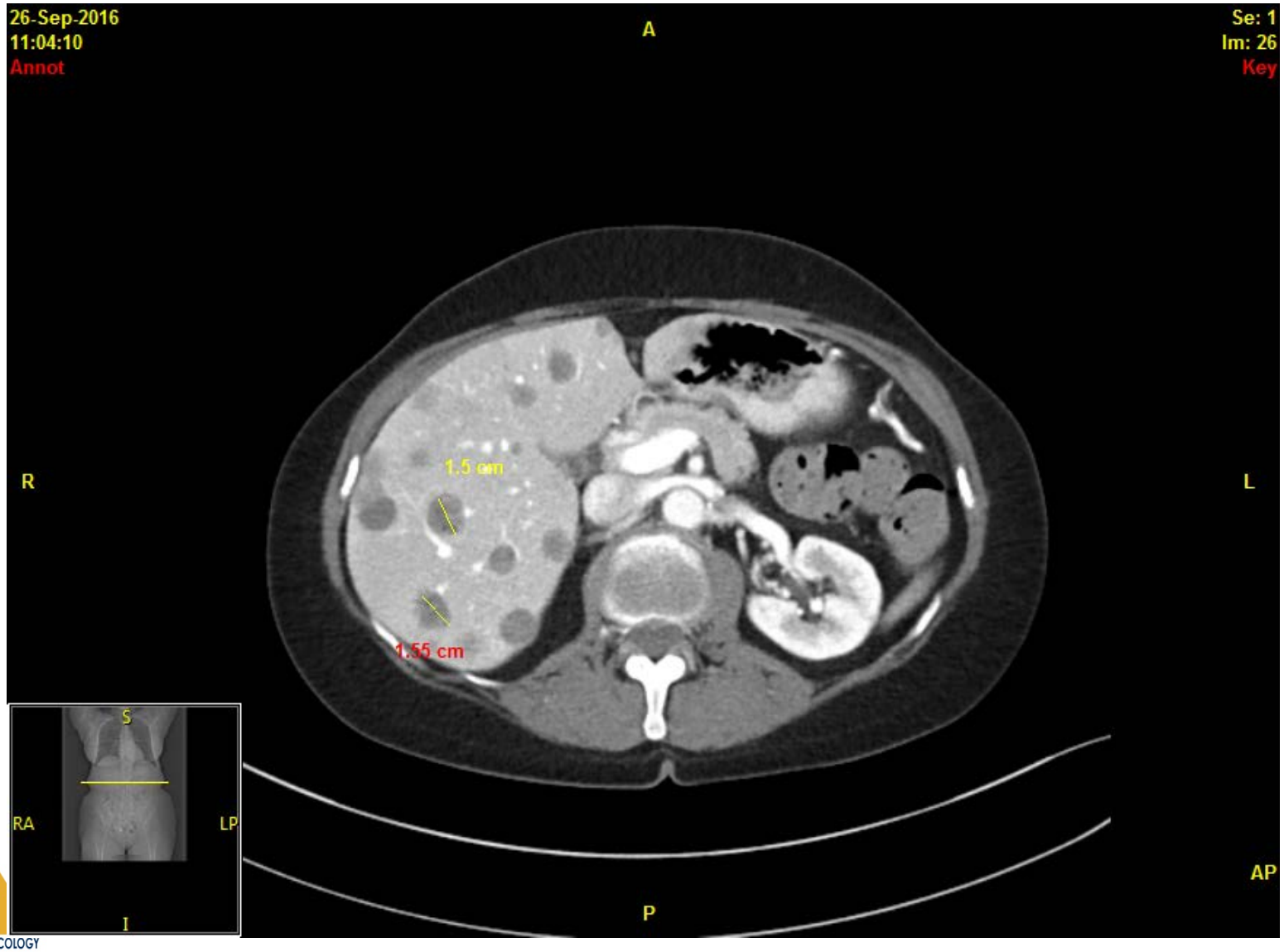
Target Lesion. Need to Mark 2 Lesions
Non-Target: Liver mets



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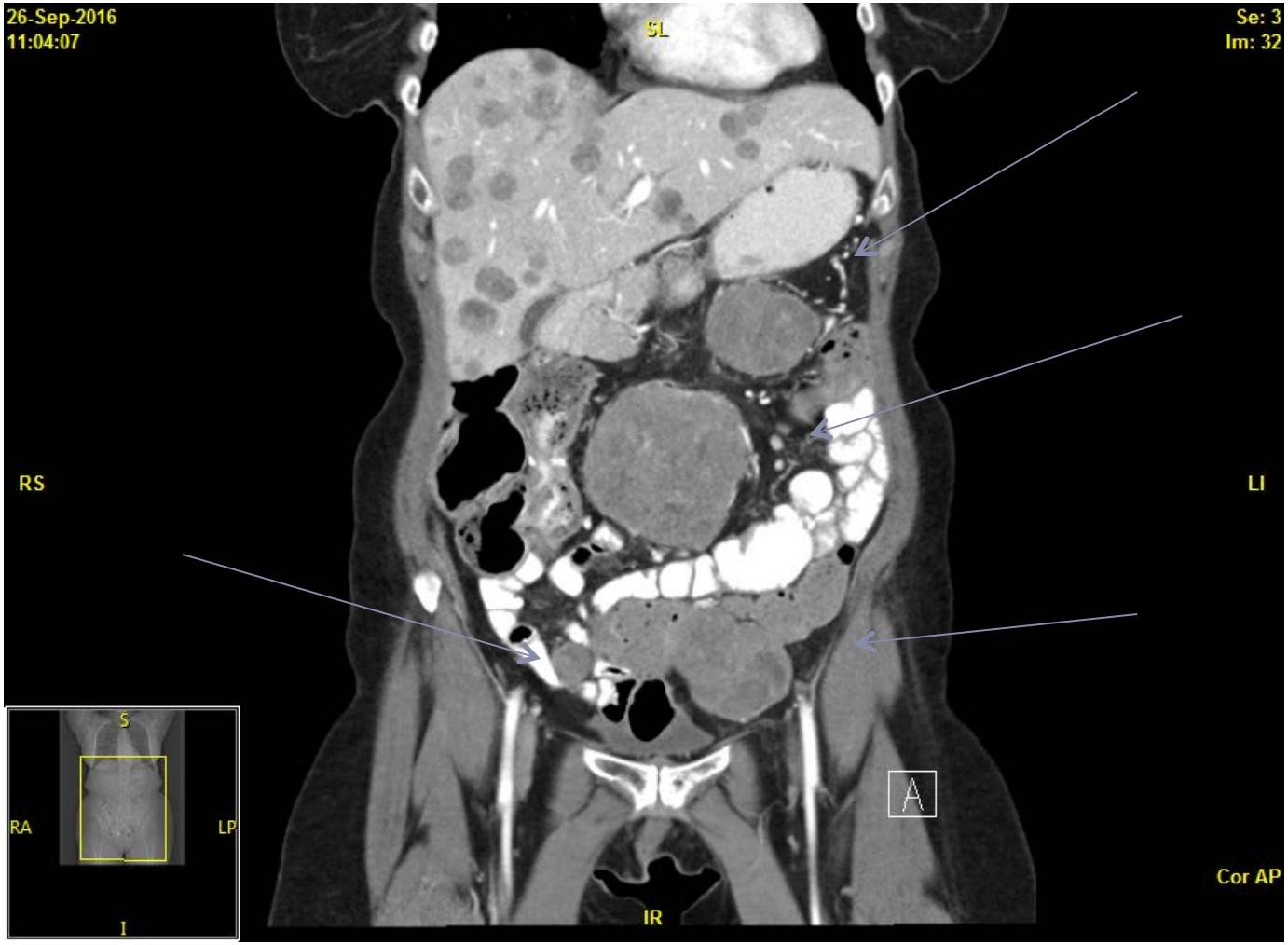
Target Lesion: 2 in Liver and 2 in Peritoneum
Non-Target: Liver and Peritoneum



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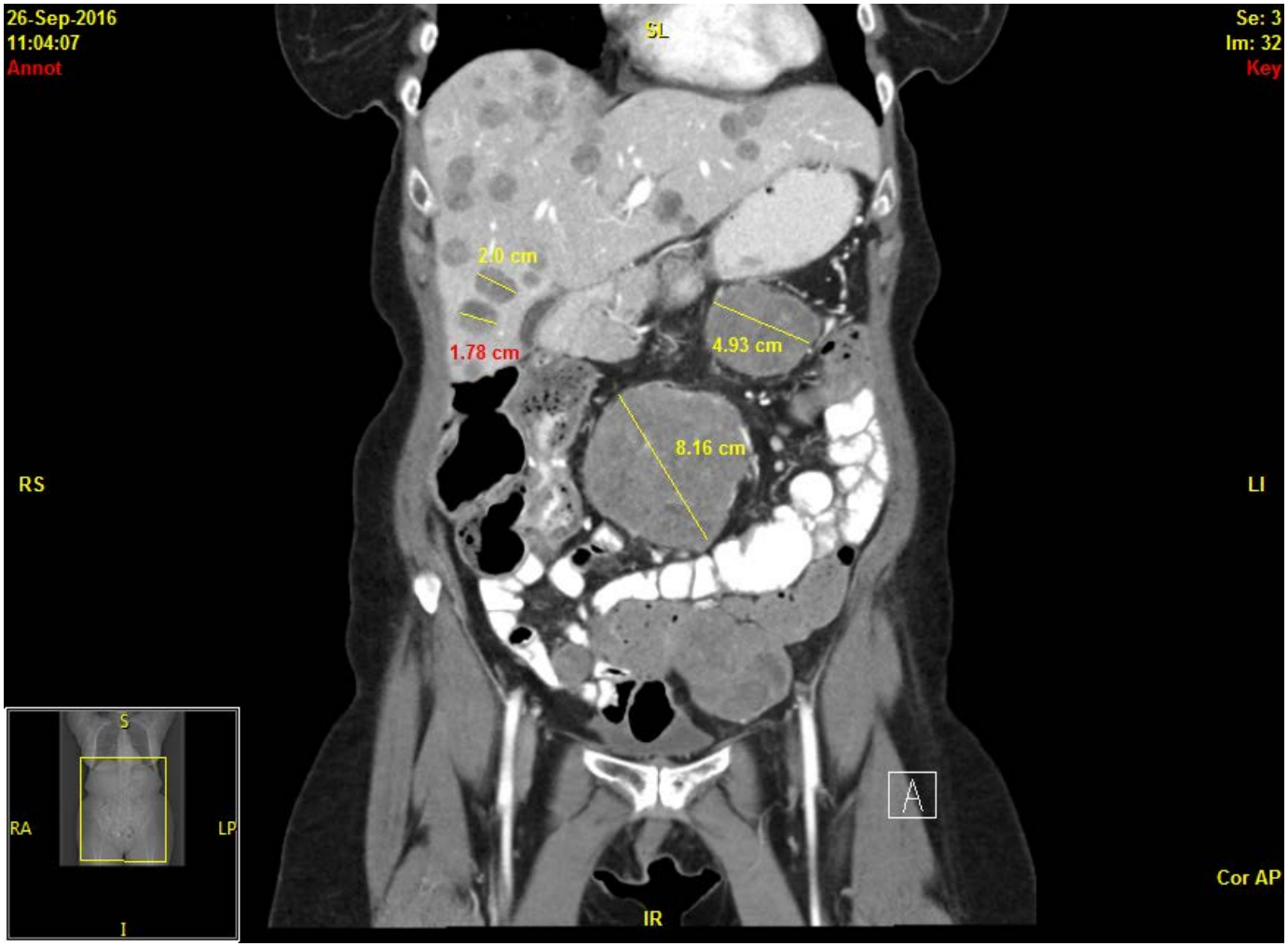
Measurements and Documentation of Slice and Image:



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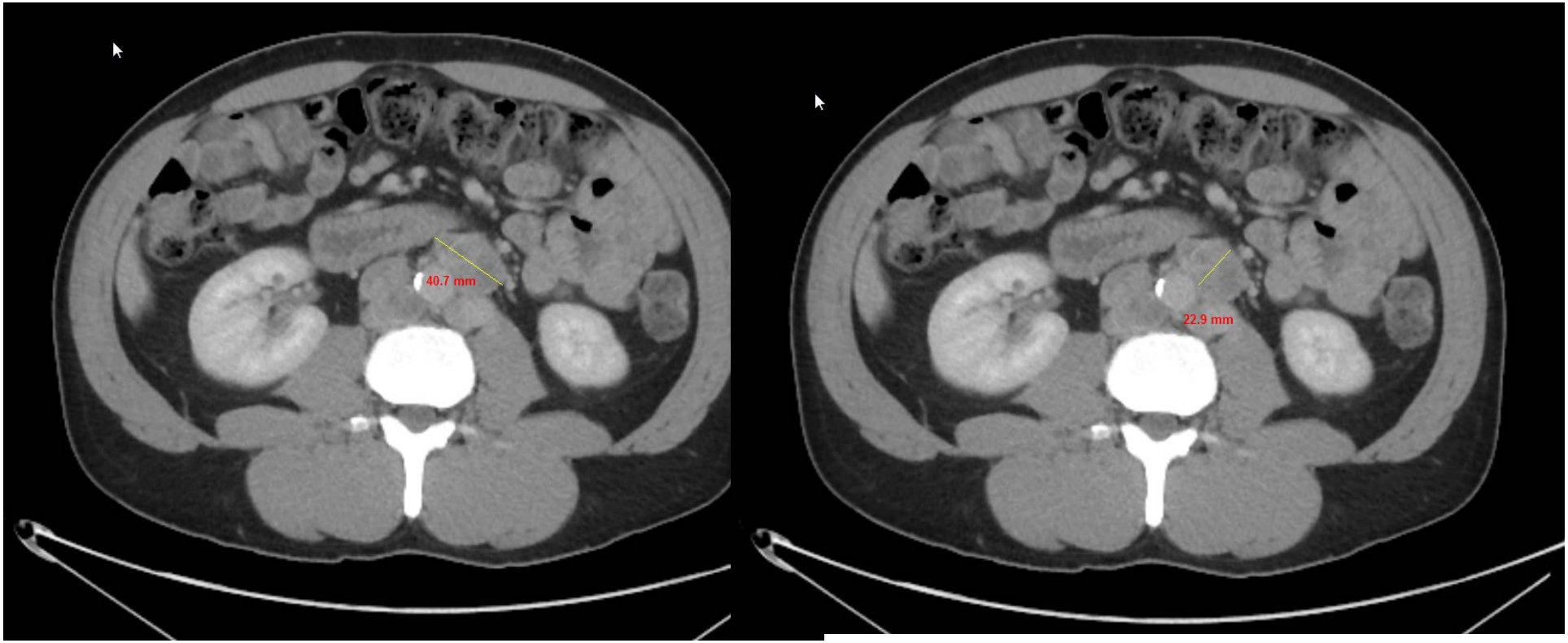
Metastatic Paraganglioma With Retroperitoneal Adenopathy:
Correct Measurement: 40.7 mm or 22.9 mm?*



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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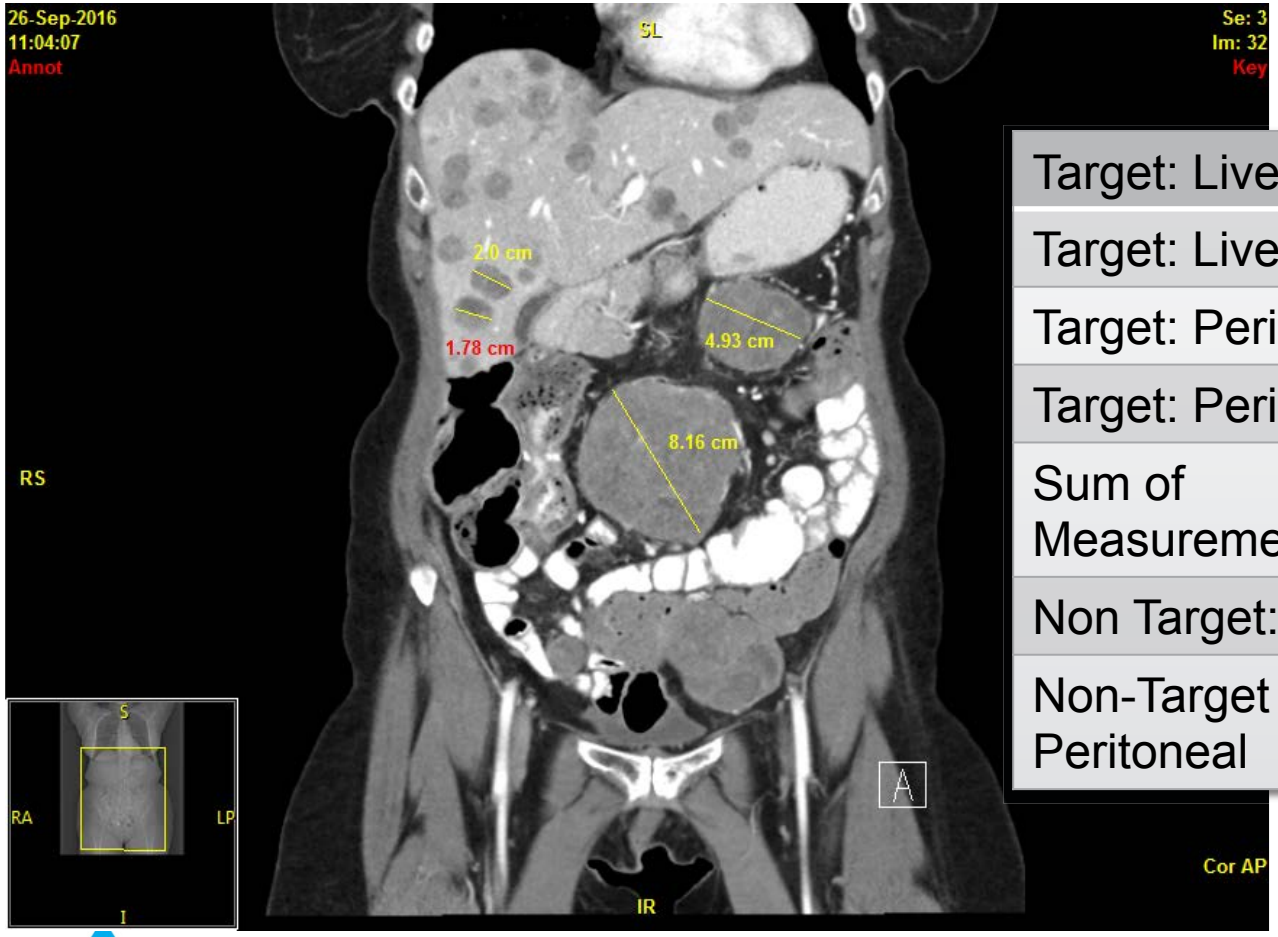
Sum of Measurements



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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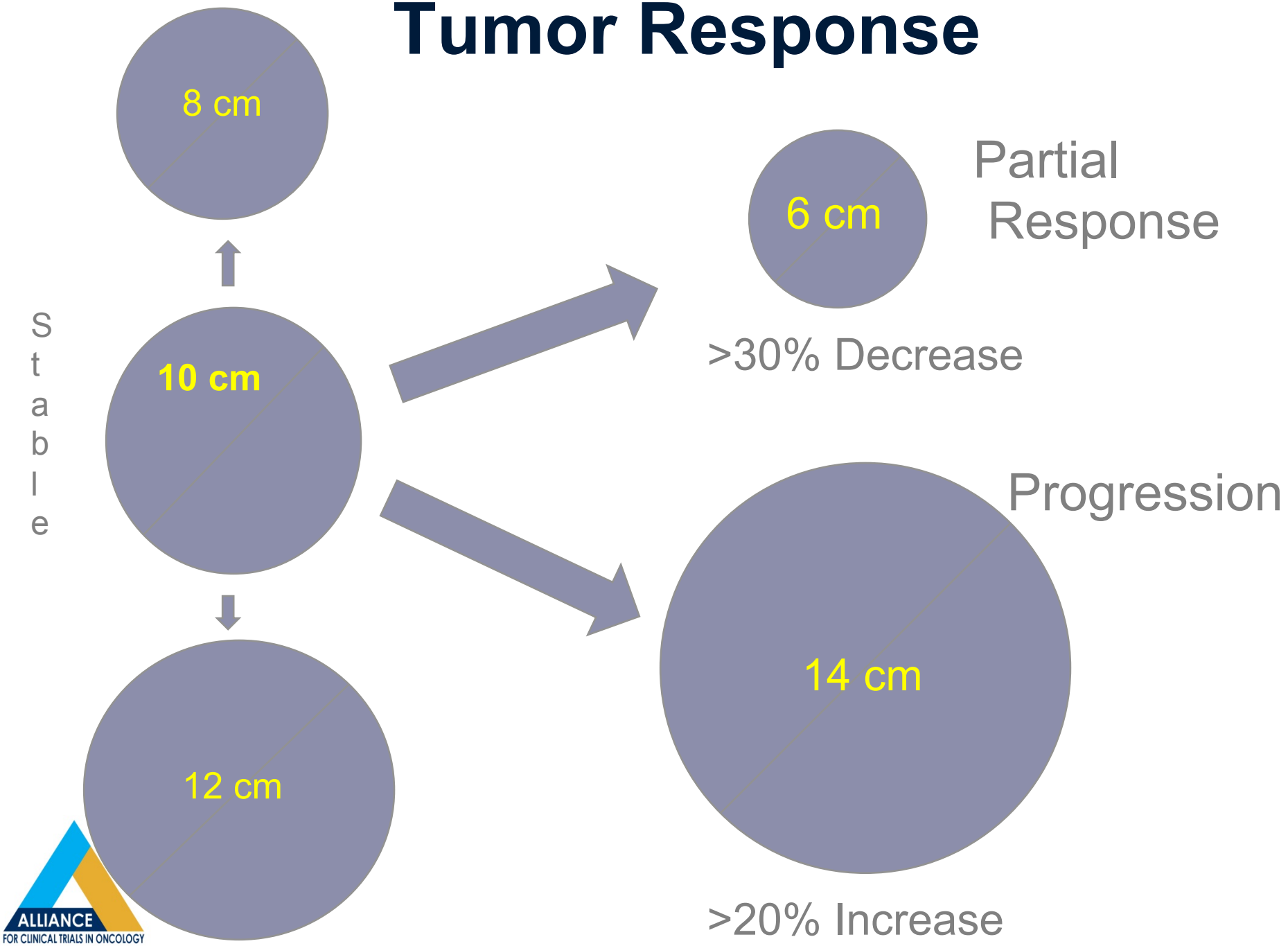
Tumor Response



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

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*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

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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.

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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.

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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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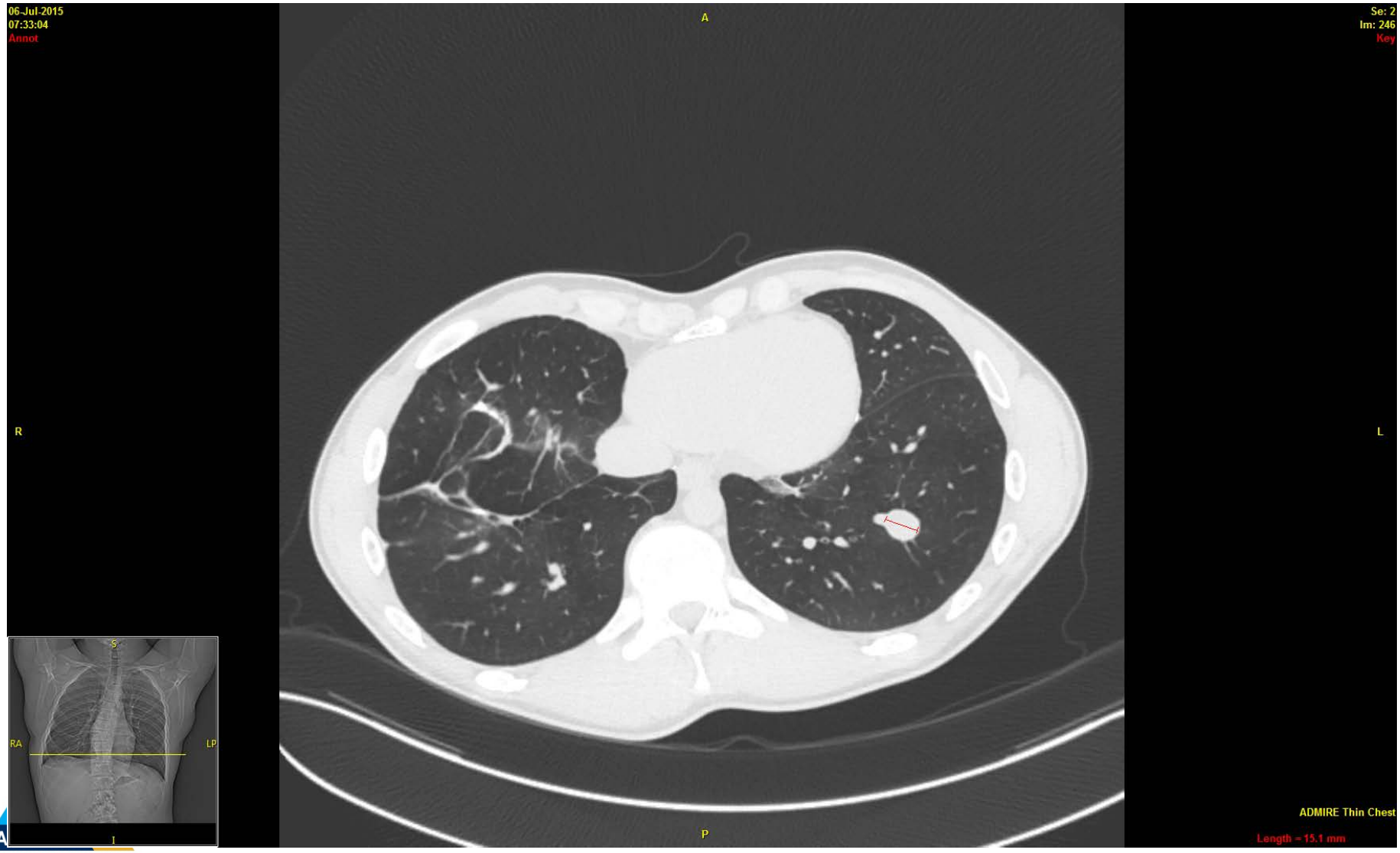
Left Lung Lesion (series 2 image 246)



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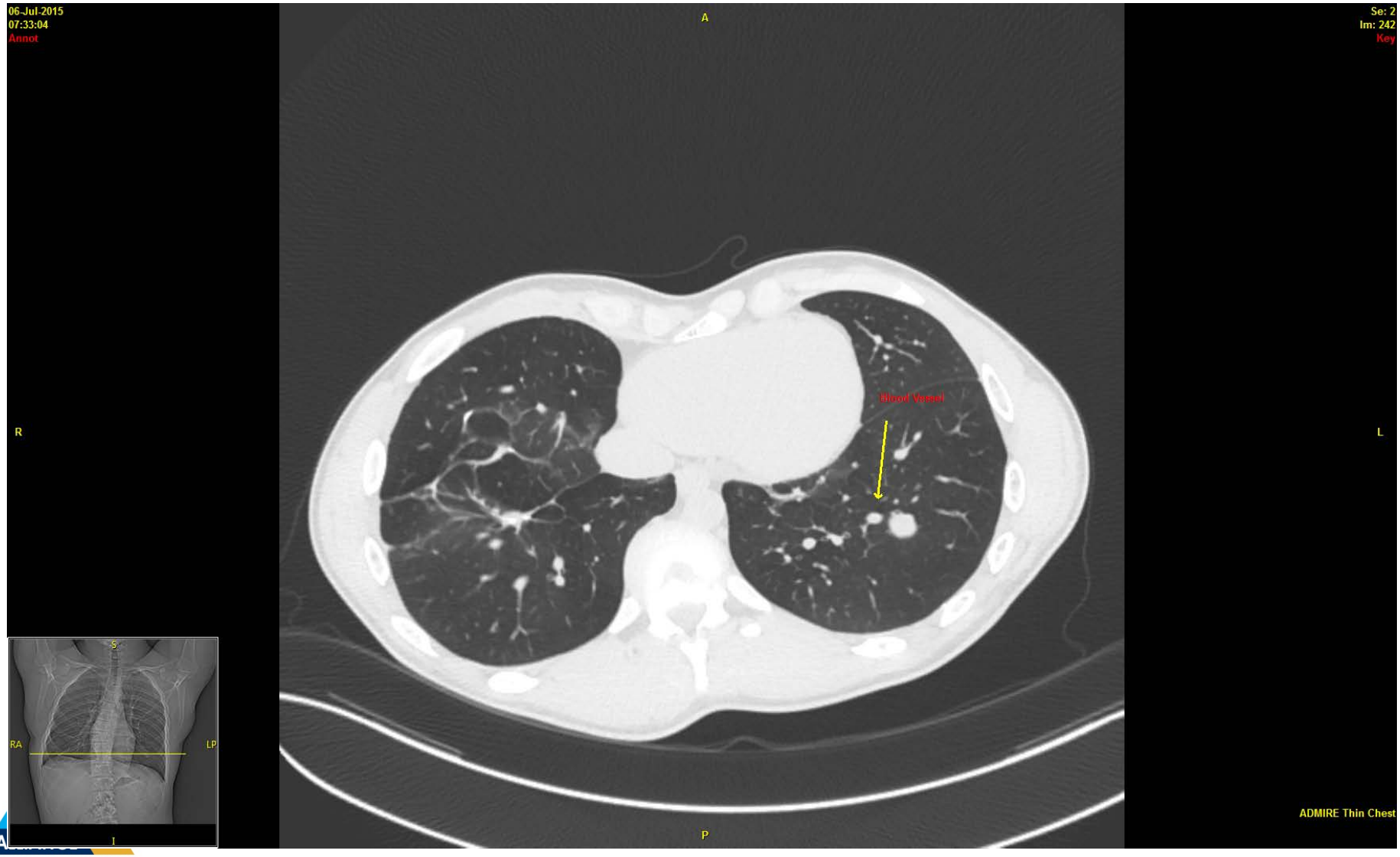
Left Lung Lesion (series 2 image 242)



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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:

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