

Baseline Tumor Assessment (BTA) form: Disease Assessment

(please also refer to [SWOG CRA Manual for Oncology Research Professionals: General Forms and Guidelines, Chapter 16](#) and [Response Assessment, Chapter 11](#))

Subject: 900100
Page: Baseline Tumor: Assessment - Disease Assessment (1)

RECIST 1.1
Instructions: Record the requested information for all target lesions and all sites of other disease. Please refer to Section 10.0 of the protocol for definitions. Choose all measurable lesions, up to a maximum of two lesions per organ and **five lesions** to follow as target lesions. **Record any remaining measurable lesions** (including size in cm) and all non-measurable disease **as non-target disease**. Use the **Comments** section for any needed explanations. **The same test procedures used for target disease assessment must be used for all required subsequent disease assessments.**

Does the patient have target lesions? Yes

Does the patient have non-target disease and/or more than 5 measurable lesions? Yes

Lesions assessment and/or measurements provided by Radiologist

Was FDG-PET imaging used to evaluate patient for malignancy? No

If Yes, date

List all **negative** diagnostic tests/studies used to evaluate patient for malignancy

#	Tests/Studies	Assessment date
1	Brain scan	14 Feb 2017

Add a new Log line - Inactivate

Comments

If you're not done completing this form, but want to save your work for later, check the box below and click Save button. Note that edit checks will still fire.

Save this form, but don't submit to SWOG yet.

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Save

Only negative scans should be listed here.
If an entry is made, the redacted reports
should be uploaded.

Baseline Tumor Assessment (BTA) form: Target Disease Assessment

(please also refer to [SWOG CRA Manual for Oncology Research Professionals: General Forms and Guidelines, Chapter 16](#) and [Response Assessment, Chapter 11](#))

Subject: 900100
Page: Baseline Tumor: Target Lesions - Disease Assessment (1)

RECIST 1.1
Instructions: Record the requested information for all target lesions and all sites of other disease. Please refer to Section 10.0 of the protocol for definitions. Choose all measurable lesions, up to a maximum of two lesions per organ site, as target lesions. Record any remaining measurable lesions and all non-measurable disease as non-target disease. Use the **Comments** section for any needed explanations. **The same test procedures used for baseline must be used for all required subsequent disease assessments.**

#	Target lesion location	Lesion size [?]	Assessment type	Lymph node?	Assessment date	
1	liver	2.3 cm (xx.x)	CT scan	No	10 Feb 2017	
2	RU lung	2.7 cm (xx.x)	CT scan	Yes	10 Feb 2017	

Sum of lesion sizes (derived upon Save) 5.0 cm (xxxx.x)

Remember that the RECIST criteria listed at baseline will remain mbl lesions, even if they eventually disappear.

Follow-up Tumor Assessments: Please insure that the lesion size is reported in cm, not mm.

Assessment type used at baseline must meet eligibility requirements and be repeated at each follow-up scan.

If you save this form, but don't submit to SWOG yet, check the box below and click the Save button. Note that edit checks will still fire.

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A few things to note (also highlighted in above form):

- Measurable lesions (per RECIST criteria) that are listed at baseline will remain measurable lesions, even if they eventually disappear.
- Lesion size must be reported in **cm**.
- Assessment type used at baseline must meet eligibility requirements and be repeated at each follow-up scan.

Baseline Tumor Assessment (BTA) form: Non-Target Disease Assessment

(please also refer to [SWOG CRA Manual for Oncology Research Professionals: General Forms and Guidelines, Chapter 16](#) and [Response Assessment, Chapter 11](#))

Subject: 900100
Page: Baseline Tumor: Non-target Disease - Disease Assessment (1)

RECIST 1.1
Instructions: Record the requested information for all non-target lesions. Please refer to Section 10.0 of the protocol for definitions. You may record multiple non-target lesions involving the organ on a single line under "Non-Target Disease Assessment (N-TDA)". Use the **Comments** section for any needed explanations. **The same test procedures used for baseline disease assessment must be used for all required subsequent disease assessments.**

#	Non-target disease location	Lesion Size?	Check here if non-measurable	Extent	Assessment type	Lymph Node?	Assessment date
1	RL lung	cm (xx.x)	<input checked="" type="checkbox"/>	multiple small lesions	CT scan	No	10 Feb 2017

Rave will prefill this patient's Follow-up Tumor Assessment (FUTA) form with the lesion labels listed above. Note that any modifications to these labels after saving this form must be manually modified on the FUTA forms to match. Please uncheck this box if you would rather that Rave not prefill the values.

Comments
If you're not done completing this form, but want to save it, click the box below and save. This will save the form, but not submit it to SWOG yet.

Only one of these boxes should be filled in. Lesion size is NOT required if non-measurable box is checked.

Free text field. An entry as simple as 'present' is acceptable. Use as much or as little detail as you wish.

Assessment type used at baseline must meet eligibility criteria and be repeated at each follow-up scan.

A few things to note (also highlighted in above form):

- Lesion size is NOT required if non-measurable “box” is checked.
- “Extent” is a free text entry field. An entry as simple as ‘present’ is acceptable.
- Assessment type used at baseline must meet eligibility requirements and be repeated at each follow-up scan.