



**INSTRUCTIONS:**

*Please document the RECIST and iRECIST assessments.*

Methods

Please document the methods used at/for this visit and their respective date.

Disease assessed by

- Clinical exam
- X-ray
- CT-scan
- MRI
- PET
- PET-CT
- Ultrasound
- Bone scan
- SPECT
- Other Please specify in the field below

Please record the dates of the imaging methods in their respective fields below.

Specify other method  #50

Date of clinical exam

Date of X-ray

Date of CT

Date of MRI

Date of PET

Date of ultrasound

Date of bone scan

Date of SPECT

Date of other method

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Baseline Lesions

ID	Site	Description	Method	Target lesion	Measurement	Too small	Response
<input type="text" value="#1"/>	<input type="text" value=""/>	<input type="text" value=""/>	<input type="text" value=""/>	<input type="radio"/> No <input type="radio"/> Yes	<input type="text" value=""/> mm ###	<input type="checkbox"/> Yes	<input type="text" value=""/>

Report Next Baseline Lesion

Sum  mm ###

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RECIST Response of Baseline Lesions

Response of non-target lesions

- Complete response (CR)
- Non-CR/non-PD
- Progressive disease (PD)
- Not evaluable
- Not Done

Response of target lesions

- Complete response (CR)
- Partial response (PR)
- Stable disease (SD)
- Progressive disease (PD)
- Not evaluable
- Not Done

**Please complete & attach all pages up to page 3 of this form**

**(00000) Date:** \_\_/\_\_/\_\_

**Signature :** .....



**INSTRUCTIONS:**

*Please document the RECIST and iRECIST assessments.*

**IRECIST Response of Baseline Lesions**

IRECIST response of non-target lesions

- Complete response (ICR)
- Non-ICR/non-IUPD
- Unconfirmed progression (IUPD)
- Confirmed progression (ICPD)
- Not evaluable

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Not Done

IRECIST response of target lesions

- Complete response (ICR)
- Partial response (IPR)
- Stable disease (ISD)
- Unconfirmed progression (IUPD)
- Confirmed progression (ICPD)
- Not evaluable

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Not Done

**New Lesions**

New lesions observed

- No <sup>?</sup>
- Yes, first new lesion(s)
- Yes, subsequent new lesion(s) <sup>?</sup>

ID	Site	Description	Target lesion	Method	Measurement	Too small	Response
#1							

ID  Please provide an ID - from A to Z - for each lesion.

Site

Description

Target lesion  No  Yes

Method

Measurement  mm  If the default 5mm for lesions too small to be measured would be reported, please tick the below field.

Lesion too small to be measured  Yes  No Tick the box if the 5 mm measurement is default instead of actually measured.

Response

**IRECIST Response of New Lesions**

IRECIST response of non-target lesions

- Complete response (ICR)
- Non-ICR/non-IUPD
- Unconfirmed progression (IUPD)
- Confirmed progression (ICPD)
- Not evaluable

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Not Done

IRECIST response of target lesions

- Complete response (ICR)
- Partial response (IPR)
- Stable disease (ISD)
- Unconfirmed progression (IUPD)
- Confirmed progression (ICPD)
- Not evaluable

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Not Done

**Please complete & attach all pages up to page 3 of this form**

**(00000) Date:** \_\_/\_\_/\_\_

**Signature :** .....



**INSTRUCTIONS:**

*Please document the RECIST and iRECIST assessments.*

RECIST Overall Response

Overall response RECIST

- Assessment after RECIST PD
- Complete response (CR)
- Partial response (PR)
- Stable disease (SD)
- Progressive disease (PD)
- Not evaluable

Specify the overall response assessed  #100

This is an optional field, available to clarify the response as assessed by the investigator.

Date of first radiological evidence of PD  DD-MMM-YYYY

Please report the date of the first imaging that showed progressive disease per RECIST.

iRECIST Overall Response

Overall response iRECIST

- Complete response (iCR)
- Partial response (iPR)
- Stable disease (iSD)
- Unconfirmed progression (iUPD)
- Confirmed progression (iCPD)
- Not evaluable

Date of first evidence of the corresponding PD  DD-MMM-YYYY

Please report the date of the first imaging that showed progression that got confirmed per iRECIST.

iRECIST Discontinuation

If this was the last iRECIST assessment for this subject, and iCPD was not confirmed, please record reason for discontinuation of iRECIST assessment.

Reason for iRECIST assessment discontinuation

- Study treatment discontinuation
- Subject not clinically stable
- iCPD never occurred
- Patient's decision Please specify why patient decided as such, in the field below.
- Other Please specify the reason in the field below

Specify reason  #150

**Please complete & attach all pages up to page 3 of this form**

**(00000) Date:** \_\_/\_\_/\_\_

**Signature :** .....