**SOLID TUMOR MEASUREMENT FORM (RECIST v 1.1)**

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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Patient Identifier: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | | | | Study Identifier: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | | | |
|  | | | | | |  | | | | | |
| **Date of Exam:**  **(mm/dd/yy)** | // | | // | | | // | | // | | |
| **Method:** |  | |  | | |  | |  | | |
| **Target Lesions** | | | | | | | | | | | |
| **lesion(s) description and location** |  | |  |  | |  |  |  |  | |
|  | \_\_\_\_ mm | series # \_\_\_ image # \_\_\_ | \_\_\_\_ mm | series # \_\_\_  image # \_\_\_ | | \_\_\_\_ mm | series # \_\_\_ image # \_\_\_ | \_\_\_\_ mm | series # \_\_\_ image # \_\_\_ | |
|  | \_\_\_\_ mm | series # \_\_\_ image # \_\_\_ | \_\_\_\_ mm | series # \_\_\_ image # \_\_\_ | | \_\_\_\_ mm | series # \_\_\_ image # \_\_\_ | \_\_\_\_ mm | series # \_\_\_ image # \_\_\_ | |
|  | \_\_\_\_ mm | series # \_\_\_ image # \_\_\_ | \_\_\_\_ mm | series # \_\_\_ image # \_\_\_ | | \_\_\_\_ mm | series # \_\_\_ image # \_\_\_ | \_\_\_\_ mm | series # \_\_\_ image # \_\_\_ | |
|  | \_\_\_\_ mm | series # \_\_\_ image # \_\_\_ | \_\_\_\_ mm | series # \_\_\_ image # \_\_\_ | | \_\_\_\_ mm | series # \_\_\_ image # \_\_\_ | \_\_\_\_ mm | series # \_\_\_ image # \_\_\_ | |
|  | \_\_\_\_ mm | series # \_\_\_ image # \_\_\_ | \_\_\_\_ mm | series # \_\_\_ image # \_\_\_ | | \_\_\_\_ mm | series # \_\_\_ image # \_\_\_ | \_\_\_\_ mm | series # \_\_\_ image # \_\_\_ | |
| total/% change from screening/nadir | \_\_\_\_ mm | \_\_\_\_ % | \_\_\_\_ mm | \_\_\_\_ % | | \_\_\_\_ mm | \_\_\_\_ % | \_\_\_\_ mm | \_\_\_\_ % | |
| **Response** (targeted lesions) | **CR PR SD PD** | | **CR PR SD PD** | | | **CR PR SD PD** | | **CR PR SD PD** | | |
| **Non - Target Lesions** | | | | | | | | | | | |
| **lesion(s) / node description/location** | **present, absent, or progression** | | **present, absent, or progression** | | | **present, absent, or progression** | | **present, absent, or progression** | | | |
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| **Response** (non-targeted lesions) | **CR non-CR/non-PD PD** | | **CR non-CR/non-PD PD** | | | **CR non-CR/non-PD PD** | | **CR non-CR/non-PD PD** | | | |
| **New Lesion(s)**  - yes  - no | | | - yes | - no | | - yes | - no | - yes | | - no | |
| **Overall Response** | **CR PR SD PD NE** | | **CR PR SD PD NE** | | | **CR PR SD PD NE** | | **CR PR SD PD NE** | | | |
| **physician signature**  **date (mm/dd/yy)** |  | |  | |  | | |  | | | |
|  | |  | |  | | |  | | | |

**THESE MEASUREMENTS SUPERCEDE ANY OTHER SOURCE PERTAINING TO LESION MEASUREMENTS FOR THE DATES ABOVE. Version date: Jul 3, 2013**

NOTES

Free smart phone app for RECIST by downloading MDMToolKit from the app store

Quick reference for CTCAE v 1.1. at ctep.cancer.gov/protocolDevelopment/docs/quickrcst.doc

Source article: <http://www.eortc.be/recist/documents/RECISTGuidelines.pdf>

**MEASUREMENT/ASSESSMENT:**

**Target Lesions:**

Record longest dimension, maximum of 5 target lesions with no more than 2 per organ.

Additional requirements for lymph nodes (LN) - to be a target lesion a LN must meet the minimum criterion of a short axis of 15 mm by CT scan, and in the case of LN s record the shortest dimension. LN ≥10 mm, but < 15 mm may be used as a non-target lesion

**Non - Target Lesions:**

All other lesions (or sites of disease)- record at baseline -measurements are not required - these lesions should be followed as **‘present’, ‘absent’,** or in rare cases **‘unequivocal progression’**; multiple non-target lesions involving the same organ should be recorded as a single item on the case record form (e.g. ‘multiple enlarged pelvic lymph nodes’ or ‘multiple liver metastases’)

**New Lesion(s)**:

If a new lesion is equivocal, for example because of its small size, in the absence of disease progression involving the target lesions, therapy may continue and a f/u exam performed to clarify if truly represents new disease.

**RESPONSE ASSESSMENT:**

**Target Lesions Response** (LD = longest dimension)

* **CR -**  Disappearance of all target lesions - any pathological lymph nodes (whether target or non-target) must have reduction in short axis to <10 mm
* **PR -** At least a 30% decrease in the sum of the LD of target lesions, taking as reference the baseline sum LD
* **SD -** neither PR or PD
* **PD**  **-** At least a 20% increase in the sum of the LD of target lesions, taking as reference the smallest sum LD recorded since the treatment started or the appearance of one or more new lesions

**Non-Target Lesions 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)
* **Non CR/Non PD** persistence of 1 or more non target lesions
* **PD** Unequivocal progression of existing non-target lesions (there must be an overall level of substantial worsening in non-target disease such that, even in presence of SD or PR in target disease, the overall tumor burden has increased sufficiently to merit discontinuation of therapy or appearance of one or more new lesions

**Overall Response**

|  |  |  |  |
| --- | --- | --- | --- |
| **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 evaluated | no | PR |
| SD | non-PD or not evaluated | no | SD |
| not evaluated | non-PD | no | NE (not evaluable) |
| PD | any | yes or no | PD |
| Any | PD | yes or no | PD |
| Any | Any | yes | PD |