

medical quality system required tool

Code Development Specifications

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| Effective Date: | 01-Aug-2013 |
| Supersedes: | MQS421-013-TL1-v1  MQS460-003-TL5-v1 MQS460-001-TL6-v1 |
| Approved by: | Yolanda Taylor, Director – Global Medical Quality  William S. Clark, Sr. Director – Statistics |
|  | Original approvals are on file. |
| If you are using a printed copy of this document, check that the version number is consistent with the current version number on the Medical Quality System site. | |

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# 2 Code Development Specifications

## 2.1 Specifications

|  |  |
| --- | --- |
| **Title** | ONC\_TU206\_RS009\_RS018\_RS023 |
| **Description, scope, and purpose** | Summary of tumor and response data to ensure that data entered on the CRF aligns with the RECIST 1.1 response criteria. Version 1 of the report aligns with the initial study build template tumor and response forms including the following items: RSDAT, OVRLRESP\_NRP, LDIAM, SAXIS. |
| **Population of Interest** | All subjects in the trial. |

## 2.2 Revision History

|  |  |  |  |
| --- | --- | --- | --- |
| *Version Number* | *Date dd-MMM-yyyy* | *Name* | *Reason for Changes* |
| 1.0 | 22Jun2017 | Jennifer Showalter  Robin White | Original version of the document |
| 2.0 | 29Aug2017 | Robin White | Updated conditions for overall response = PR, SD, and NE for check RS009 in embedded Excel document. |

## 2.3 Electronic Storage

|  |
| --- |
| Electronic Report Location |
| JReview,TU/TR,Oncology,ONC\_TU206\_RS009\_RS018\_RS023 |

## 2.4 Detailed Report Specifications

| Detailed Specifications | |
| --- | --- |
| **Data Source** | TU1001, TU2001, TU3001, RS1001, DS1001 |
| **Variables of Interest**  (Includes derived variables [give formulas]) | See attached excel document.    Derived variables are listed below:   * TULOC\_TEXT: decode the numeric value from TU1001\_TULOC, TU2001\_TULOC, TU3001\_TULOC using the codelist called LOC * SUMDIAM: add all TU2001\_LDIAM and TU2001\_SAXIS values for each assessment number (TRSPID) together for a subject and output in the row for T01. For each tumor per assessment, if TRSTRESC = TOO SMALL TO MEASURE, use 5 as the LDIAM value to calculate SUMDIAM. If TRPERF = N, one or more target tumors has a tumor state = not assessable or trstresc = not measured then do not calculate the SUMDIAM and PCBSD/PCNSD should be left null. * PCBSD: [(New Sum – Baseline Sum)/Baseline Sum] x 100 = % decrease   + Example: [(12 – 15)/15] X 100 = -20% (20% decrease from Baseline Sum) * PCNSD: [(New Sum – Smallest Sum)/Smallest Sum] x 100 = % increase. Use the smallest sum to that point in the data not the smallest sum overall.   + Example: [(15 – 12)/12] X 100 = +25% (25% increase over Smallest Sum) * CALC\_TRGRESP:   + If the sum of diameters of target tumors has a decrease of ≥ 30% from baseline sum then response = PR   + If the sum of the diameters of target tumors has an increase of 20% over the smallest sum and increase in smallest sum has an absolute increase of > or = 5 mm then response = PD   + If the percentage of change does not qualify for PR (decrease of ≥ 30% from baseline sum) nor PD (20% increase over the smallest sum on study) then response = SD   + If one or more target tumors has a tumor state = not assessable, trstresc = not measured or one or more but not all target tumors being followed have TRPERF = N, then response = NE or Not All Evaluated.   + If measurements are not calculated, CALC\_TRGRESP should = NE * NEWTUMOR: set to Y when there is a value in TU1001\_TULNKID for a subject. |
| **Headers** | N/A |
| **Footers** | N/A |
| **Format/Organization of Output** | See attached excel document above in the variables of interest section. Highlight the cell in the output report where the data issue exists.  Output should only contain subjects where an issue (error message) is present. Output all records for a subject if there is any issue (error message) present.  Sort Order should be: SUBJID, TRSPID, TULNKID, TRDAT. For TULNKID, make target tumors always appear first, then non-target tumors, last new tumors.  Response data, derived variables and error message should be applied to the 1st target tumor for each assessment for a subject. If the subject does not have target tumors, apply to the 1st non-target tumor for each assessment for a subject. If there are new tumors reported at an assessment where target and or and not target are not reported, apply to 1st new tumor for the subject. |
| **Output Location** | JReview |

## 2.5 Validation Completion

See Section 5 of the Code Development procedure for the actions required to document the completion of validation.

# Revision History

|  |  |  |
| --- | --- | --- |
| **Version Number** | **Effective Date** | **List of Major Changes** |
| 1 | 01-Aug-2013 | This is the initial release. This required tool replaces the **Data Reports Requirements Document (MQS421-013-TL1-v1)** and **Broad-Use Module Requirements Definition (MQS460-001-TL6-v1)** and **Program Requirements Definition (MQS460-003-TL5-v1)** required tools. |