

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\_V1 |
| **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 | 28Feb2017 | Jennifer Showalter  Robin White | Original version of the document |
|  |  |  |  |

## 2.3 Electronic Storage

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| --- |
| Electronic Report Location |
| JReview,TU/TR,Oncology,ONC\_TU206\_RS009\_RS018\_RS023\_V1 |

## 2.4 Detailed Report Specifications

| Detailed Specifications | |
| --- | --- |
| **Data Source** | TU1001, TU2001, TU3001, RS1001, DS1001 |
| **Variables of Interest**  (Includes derived variables [give formulas]) | **ASSUMPTION**: Studies using the first version of Onc CRF templates will use this report. The first study will be I3Y-MC-JPBZ.  See attached excel document.    Dervied 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. * 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 a 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 or trstresc = not measured then response = NE or Not All Evaluated * 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 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. |