

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\_TU219\_TU318 |
| **Description, scope, and purpose** | Exceptation based report to know what tumor assessments are missing for the study by subject. |
| **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\_TU219\_TU318 |

## 2.4 Detailed Report Specifications

| Detailed Specifications | | |
| --- | --- | --- |
| **Data Source** | INF\_SITE, TU2001, TU3001, EX1001, DS1001, RS1001 | |
| **Variables of Interest**  (Includes derived variables [give formulas]) | STUDY  INF\_SITE\_sitemnemonic  TU2001\_SUBJID, TU2001\_TUDAT, TU2001\_TRDAT, TU2001\_TRSPID, TU2001\_TULNKID  TU3001\_SUBJID, TU3001\_TUDAT, TU3001\_TRDAT, TU3001\_TRSPID, TU3001\_TULNKID  RS1001\_SUBJID, RS1001\_OVRLRESP, RS1001\_SYMPDET  EX1001\_SUBJID, EX1001\_EXSTDAT  DS1001\_SUBJID, DS1001\_PAGE, DS1001\_DSDECOD, DS1001\_DSSTDAT  Date of Next Scan should be derived by taking the latest TRDAT and calculating the next expected scan date using the 1st study parameter listed in the numbered detailed specifications below. | |
| **Headers** | N/A | |
| **Footers** | N/A | |
| **Format/Organization of Output** | See attached excel document below. | |
| **Output Location** | JReview | |
| **ASSUMPTION**: Studies that will be using this report will be following Onc CRF templates with first study being I3Y-MC-JPBZ   1. A parameter excel (xls) file will be available for the report read in the following study specific parameters:    * Protocol expected scan frequency in weeks (enter the max window between scans)    * Does protocol allow subjects with only non-target disease? 2. Output when there is not a record with TUDAT on or before earliest (Cycle 1) EXSTDAT for a subject.    * Error message: Missing baseline scan. 3. Output when the next assessment is expected (based on parameter) but not present. Include in calculation all projected asssessments not just the 1st missing assessment. a. If a subject is missing multiple projected assessments, create multiple records in the output in date order. b. If RS1001\_OVRLRESP = PD and RS1001\_SYMPDET = N, do not output as an issue. c. If DS1001\_DSDECOD = DEATH or LOST TO FOLLOW-UP and calculated ‘Date of Next Scan’ is greater than or equal to DS1001\_DSSTDAT where DS1001\_DSDECOD = DEATH or LOST TO FOLLOW-UP, do not output as an issue.    * Error message: Missing post baseline scan(s). 4. Output when there are no target tumors identified. a. If there are no target tumors and there is a record for the subject in DS1001\_LF1 then do not output. b. If the answer to the study specific parameter “non-target disease only” = Y, do not output as an issue.    * Error message: No target tumor(s) identified. 5. Output when there are no non-target tumors identified. Only output as an issue when study specific parameter “non-target disease only” = Y and TU3001\_TULNKID does not have a value for a subject.    * Error message: No non-target tumor(s) identified. 6. Output when there is not at least 1 assessment (TRSPID) entered for every TULNKID.    * Error message: No assessment entered for this tumor id. | |

## 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. |