

PRA for Kura KO-TIP-007 (10005043) Efficacy Business Requirements Specification

Bioclinica

**Sponsor**: PRA Health Sciences (PRA) for Kura Oncology, Inc. (Kura)

**Protocol Title:** The AIM-HN and SEQ-HN Study: A 2-Cohort, Non-Comparative, Pivotal Study Evaluating the Efficacy of Tipifarnib in Patients with Head and Neck Squamous Cell Carcinoma (HNSCC) with HRAS Mutations (AIM-HN) and the Impact of HRAS Mutations on Response to First Line Systemic Therapies for HNSCC (SEQ-HN)

**Protocol Number**: KO-TIP-007

**Project Code:** 10005043

**Document Version:** Final Version 1.0

**Date:** 08-Nov-2019

# BRS Signature Page

**Final BRS Version 1.0 Date: 08-Nov-2019**

This Business Requirements Specifications (BRS) document has been created based on the PRA Health Sciences (PRA) for Kura Oncology, Inc. (Kura) KO-TIP-007 Charter. Study- and criteria-specific changes have been discussed with and agreed to between PRA/Kura and Bioclinica during Charter development.

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# Document Revision History

| **Revision Number Revision Date** | **Reason for Revision** | **Reviewed By** | **Prepared By** |
| --- | --- | --- | --- |
| Final Version 1.0  08Nov2019 | Updated to final version, prepared for signatures |  | Pamela Weisberg |
| Version 1.0 Internal Draft v0.1/01Nov2019 | Updated to internal draft 0.2 per review/internal discussion on review of draft 0.0. | Reviewed By:  Alice Wan  Srinidhi Emkay  Zachary LaVoie | Pamela Weisberg |
| Version 1.0 Internal Draft v0.0/28Oct2019 | Initial draft created for Internal review. | Reviewed By:  Alice Wan  Zachary LaVoie  Ross Gaughan  Michelle Kramer  Srinidhi Emkay | Pamela Weisberg |

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# Introduction

## Document Purpose

The purpose of this document is to define the business requirements for the PRA Health Sciences (PRA) for Kura Oncology, Inc. (Kura) KO-TIP-007 efficacy read application. The business requirements contained in this document are the same as the standard RECIST 1.1 template Version 12.0 date 06-Jun-2019, and serve as the foundation for all subsequent design, coding, testing, and user documentation for the read application.

This document contains the following sections that will be updated for review for each application:

1. **File Base Configuration Definition**: table includes configurable requirements in the template, and designated values for the specific project.
2. **Modifications to Validated Requirement**: listed here will be any modifications to standard (non-configurable) requirements, and any additional requirements not included in the template.
3. **READAdmin Configuration Form**: form includes read administration configuration for the specific project, completed by the PM for each application.
4. **Mock Ups**: mock-up of how the eCRF will look for your project (this section will only display additional information not provided in the Standard template).

# Referenced Documents

This Business Requirements Specifications (BRS) document was developed based on the following document(s):

|  |  |
| --- | --- |
| **Document** | **Version/Effective Date** |
| PRA KO-TIP-007 Charter | Version 2.0 30Oct2019 |
| Standard RECIST 1.1 template | Version 12.0 06Jun2019 |

# File Base Configuration Definition

| **Setting Name** | **Description** | **Value in Config File** | **Corresponding Requirement Number** |
| --- | --- | --- | --- |
| **General-RadiologyConfiguration** | | | |
| iuhioj | Enable Eligibility Workflow and displays Eligibility Question: 1= Enable  0= Disable | 0 | **BRS-RA-001**  **BRS-S1QA-001**  **BRS-S1QA-005**  **BRS-S1QA-006** |
| NumEligibilityReaders | Specify the number of Eligibility Readers. Possible values = 1,2 | n/a | **BRS-RA-001** |
| ShowPETImagingParameters | Display PET Imaging parameters 1= Display 0= Do not display | 1 | **BRS-DR-040** |
| ShowMRIContrastSummary | Display MRI Contrast Summary  1= Display  0= Do not display | 1 | **BRS-DR-041** |
| DisplaySequenceDetails | Display Sequence Details  1= Display  0= Do not display | 1 | **BRS-DR-036** |
| DisplayDiseaseIndication | Display Disease Indication:  1= Display from BioPACs  2= Display hardcoded value | 2 | **BRS-DR-055** |
| DiseaseIndicationValue | This will be populated only if we have to hard code Indication, otherwise leave this empty. | < HNSCC > | **BRS-DR-055** |
| ScreeningPopUpMessage | Display pop-up if no target lesions at screening:  1= Display  0= Do not display | 1 | **BRS-S1QA-007** |
| **Modality** | | | |
| AllowBusinessModality | List of Modalities that are allowed or All. | CT, MR, PET, PET-CT, PET-MR, NM, X-Ray | **BRS-IDH-001** |
| BlockBusinessModality | List of Modalities that need to be blocked. | <Empty> | **BRS-IDH-001** |
| ReadOnlyBusinessModality | List of Modalities where ROIs cannot be created. | X-Ray, PET | **BRS-IDH-005** |
| BlockSequenceModality | List of Sequence Modalities that need to be blocked. | <Empty> | **BRS-IDH-005** |
| ReadOnlySequenceModality | List of Sequence Modalities where ROIs cannot be created. | PT | **BRS-IDH-005** |
| ImageDecimalPrecision | Decimal precision on Image Display <n> | 0 | **BRS-IDH-025**  **BRS-OLT-005** |
| **Anatomical** | | | |
| AllowAnatomical | List of Anatomical areas that are allowed or 'ALL'. | ALL | **BRS-IDH-001** |
| BlockAnatomical | List of Anatomical areas that need to be blocked. | <Empty> | **BRS-IDH-001** |
| **Start Date** | | | |
| StartDateRequiredBaseline | Start date is required for reading Screening/Baseline  1= Required  0 = Not required | 1 | **BRS-DR-050** |
| StartDateType | States the type of Start date that needs to be present  1= Dosing  2= Randomization  3= Enrollment. | 1 | **BRS-BR-010**  **BRS-OBR-010** |
| **Lesion Level** | | | |
| LimitTargetLesions | Maximum number of Target lesions allowed  -1 implies unlimited | 5 | **BRS-TLL-005** |
| LimitTargetLesionsPerOrgan | Maximum number of Target lesions per organ  -1 implies unlimited | 2 | **BRS-TLL-010, BRS-TLL-015** |
| LimitNTLesions | Maximum number of Non Target lesions allowed  -1 implies unlimited | 10 | **BRS-NTLL-005** |
| LimitNewLesions | Maximum number of New lesions allowed.  -1 implies unlimited | 10 | **BRS-NLL-010** |
| LimitNewLesionsPerOrgan | Maximum number of New lesions per organ.  -1 implies unlimited | 10 | **BRS-NLL-011**  **BRS-NLL-012** |
| ExtranodalBaselineThreshold | Threshold value for Extranodal lesions at Baseline | 10 | **BRS-MST-001**  **BRS-OMST-001** |
| NodalBaselineThreshold | Threshold value for Nodal lesions at Baseline. | 15 | **BRS-MST-001** |
| NodalNormalLesionThreshold | Threshold for considering Nodal lesions as normal Threshold for New Nodal lesions in follow up timepoints. | 10 | **BRS-MST-001,  BRS-MSNL-001** |
| DefaultTargetThreshold | TSTM value. | 5 | **BRS-TLL-050**  **BRS-OTLL-045** |
| IsReliablyMeasuredTarget | Target lesion reliably measured Question visibility:  1= Display  0= Do not display | 0 | **BRS-TLL-046**  **BRS-TLL-050**  **BRS-MST-001**  **BRS-OTLL-040**  **BRS-OMST-001** |
| NTFluidWithNoPriorResolved | Provide ‘Present with progression’ status in context menu:  1= allow  0= do not allow | <Note: This field will be blank. Refer modification section> | **BRS-NTLL-035** |
| NTFluidWithPriorResolved | Provide ‘Present with progression’ status in context menu:  1= allow  0= do not allow | <Note: This field will be blank. Refer modification section> | **BRS-NTLL-036** |
| FluidLocationsForNewLesions | Allow new extranodal fluid lesion to be labeled:  1 = allow  0 = do not allow | <Note: This field will be blank. Refer modification section> | **BRS-ASC-001** |
| **Criteria Level** | | | |
| ConfirmationRequired | Require confirmation for PR and CR.  1 = Yes  0 = No | 1 | **BRS-BR-030**  **BRS-OBR-030** |
| ConfirmingCRRule | Allow PR between confirming CR.  1 = Yes  0 = No | 0 | **BRS-BR-020**  **BRS-OBR-020** |
| SDRuleDays | Timepoint response of SD that falls < n > days from the start date, will be considered NE. | 35 | **BRS-BR-005**  **BRS-OBR-005** |
| RequiresConfirmationDays | Number of days required between the initial and confirmatory time point for confirming response. | 28 | **BRS-BR-030**  **BRS-OBR-030** |
| AddOneInFormula | Calculate DaysOnStudy = (Time point response date – start date) + n. | 1 | **BRS-BR-015**  **BRS-OBR-015** |
| PercentageChangeNadirPD | % Change from Nadir SOD for calculating Target Response as PD (>= n%). | 20 | **BRS-TRG-015**  **BRS-OTRG-015** |
| PercentageChangeBaselinePR | % Change from Baseline SOD for calculating Target Response as PR (-100 < % Change Baseline SOD <= -n). | -30 | **BRS-TRG-045**  **BRS-OTRG-035** |
| TPRDateForPD | 0 = Earliest exam date  1= Latest exam date  2= Use LesionTypes | 1 | **BRS-S2QA-025**  **BRS-OS2QA-035**  **BRS-OS2QA-030** |
| TPRDateForNonPD | 0 = Earliest exam date  1= Latest exam date | 1 | **BRS-S2QA-025**  **BRS-OS2QA-035**  **BRS-OS2QA-030** |
| TPRNEWhenNTNE | 1= TPR Overrides to NE when Non Target response is NE 0= Do not overwrite | 0 | **BRS-TPR-001**  **BRS-OTPR-001** |
| **Calculation Level** | | | |
| DecimalPlacesForActualvalues | Number of decimal places for rounding Actual values. | 2 | **BRS-LT-001**  **BRS-OLT-001** |
| DecimalPlacesForFinalvalues | Number of decimal places for rounding Final values. | 0 | **BRS-LT-001**  **BRS-LT-005**  **BRS-OLT-001**  **BRS-OLT-005** |
| DecimalPlacesForPercentage | Number of decimal places for rounding Percentages. | 0 | **BRS-LT-001**  **BRS-OLT-001** |
| **Questions Visibility** | | | |
| UnequivocalProgression | Confirm Unequivocal Progression for Non-Target Lesions: 1= Display 0= Do not display | 1 | **BRS-S2QA-010** |
| PseudoProgression | Pseudo Progression Question visibility: 1= Display 0= Do not display | 0 | **BRS-S3RA-010**  **BRS-S4DD-001** |
| DOPAtFollowUp | Display DOP at follow up  1 = Display  0 = Do not Display | 0 | **BRS-S2QA-028** |
| DOFRAtFollowUp | Display DOFR at follow up  1 =Display  0 = Do not display | 0 | **BRS-S2QA-029** |
| BestResponseAtFollowUp | Display Best Time Point Response at follow up  1 = Display  0 =Do not display | 0 | **BRS-S2QA-027** |
| PreviouslyIrradiatedTarget | Previously Irradiated Target lesion Question visibility: 1= Display 0= Do not display | 1 | **BRS-TLL-030**  **BRS-OTLL-020** |
| PreviouslyIrradiatedNonTarget | Previously Irradiated Non Target lesion Question visibility: 1= Display 0= Do not display | 1 | **BRS-NTLL-015**  **BRS-ONTLL-015** |
| **Clinical Document** | | | |
| AllowBCSPAtBaseline | Allow BCSP form at Baseline  1 = Yes  0 = No | 1 | **BRS-DR-030** |
| AllowBCSPAtFollowup | 1= Allow BCSP form at Follow up  1 = Yes  0 = No | 1 | **BRS-DR-030** |
| AllowBCSPAtGlobal | Allow BCSP form at Global 1 = Yes  0 = No | 1 | **BRS-DR-030** |
| AllowBCSPAtAdjudication | Allow BCSP form at Adjudication 1 = Yes  0 = No | 1 | **BRS-DR-030** |
| **Adjudication End Points** | | | |
| EndPointListWithOrder | Specify the list of Adjudication variables along with order like BestResponse, DateProgression, DateFirstResponse | <Note: This field will be blank. Refer modification section> | **BRS-RA-005**  **BRS-S4DD-035** |
| ShowStartDateInAdj | Display Start date in Adjudication session: 1= Display 0= Do not display | 1 | **BRS-S4DD-000** |
| **General-ClinicalConfiguration** | | | |
| IsClinicalPresent | Enable Clinical Assessment Session 5: 1= Yes 0= No | 1 | **BRS-OS5DD-000 thru BRS-OS5DD-030**  **BRS-OS5QA-001 thru BRS-OS5QA-060** |
| AddDaysAfterMaxDateClinical | Select a date within the max date + [value + 1] days to the radiology max date of the previous time point (date after the last radiology exam) + [Value] days after the current radiological time point response date | 14 | **BRS-OS5QA-030**  **BRS-OS5QA-040** |
| **ClinicalDocument** | | | |
| AllowBCSPAtClinical | Allow BCSP at Clinical  1 = Yes  0 = No | 0 | **BRS-OS5DD-000** |
| **General-OncologyConfiguration** | | | |
| IsOncologyPresent | Enable Oncology Workflow Assessment  1= Yes 0= No | 0 | **Section 10.0** |
| AddDaysAfterMaxDateOncology | Select a date within the max date + [value + 1] days to the radiology max date of the previous time point (date after the last radiology exam) + [Value] days after the current radiological time point response date | n/a | **BRS-OF5QA-030** |
| **ClinicalDocument** | | | |
| AllowBCSPAtOncology | Allow BCSP at Clinical  1 = Yes  0 = No | n/a | **BRS-OF5DD-000** |
| **LesionController** | | | |
| IsTargetAllowedOncology | Enable Clinical Target lesions:  1= Yes 0= No | n/a | **BRS-OTLL-001**  **thru**  **BRS-OTLL-050**  **BRS-OMST-001**  **BRS-OTL-005**  **BRS-OTL-015**  **BRS-OS1DD-001**  **BRS-OTRG-001**  **Thru**  **BRS-OTRG-040**  **BRS-OTPR-001**  **BRS-CTPR-010**  **BRS-OTPR-015**  **BRS-OF2DD-001**  **BRS-OF2QA-001**  **BRS-OF2QA-010**  **BRS-OF2QA-030** |
| LimitTargetLesionsOncology | Maximum number of clinical target lesions allowed: | n/a | **BRS-OTLL-010** |
| LimitNTLesionsOncology | Maximum number of clinical non-target lesions allowed: | n/a | **BRS-ONTLL-005** |
| LimitNewLesionsOncology | Maximum number of clinical new lesions allowed: | n/a | **BRS-ONLL-010** |
| LimitTargetLesionsOverall | Maximum number of target lesions overall allowed: | n/a | **BRS-OTLL-005** |
| LimitNTLesionsOverall | Maximum number of non-target lesions overall allowed: | n/a | **BRS-ONTLL-005** |
| LimitNewLesionsOverall | Maximum number of new lesions overall allowed: | n/a | **BRS-ONLL-005** |

# Modifications to Validated Standard Requirements

Standard business requirements have been pre-validated. Any changes or modifications to the standard business requirements, as documented in the Final Charter, will be denoted as follows:

* New requirements: will be in red text and will be inserted before or after the applicable standard BRS, using the next available sequential number
* Modified existing requirements: additions will be in *italicized green text*, deletions will be in ~~strikethrough green text~~.

## General Requirements (Section 2.0 in template)

| **Requirement and Description** | |
| --- | --- |
| **BRS-DR-005** | Display the Protocol number [*KO-TIP-007*] in BioREAD from the Read Project Name field stored in the ReadProject table within the project selection screen. |
| **BRS-DR-015** | Display the client name as *PRA.* |

## Display Requirements (Section 1.1 in template)

| **Requirement and Description** | |
| --- | --- |
| **BRS-DR-020** | Display the time point identifier as following:   * Session 1 = <Screening>   + Pre-Screening scans if available must be READ ONLY loaded in session 1. * Session 2 = Timepoint 2, Timepoint 3, etc. load follow-up time points in sequential order, by exam date * Session 3 = Global Review * Session 4 = Adjudication * Session 5 = Clinical Review |

## Reader Allocation (Section 1.2 in template)

| **Requirement** | **Requirement Description** |
| --- | --- |
| **BRS-RA-001** | The system must:   * Support <three> readers in Session 1 * Support three readers, in Sessions 2, and 3. * Support one adjudicator in Session 4. * Support one clinical reader in Session 5 * Support ‘Reviewer’ reader type in all Sessions |
| **BRS-RA-005** | Session 4: Adjudication is required for all subjects.  ~~A case is selected for adjudication if discrepant between the two primary readers when the answers do not match exactly for the following endpoint(s). Display priority of Adjudication variables as follows:~~   1. ~~Best Response~~ 2. ~~Date of Progression~~ 3. ~~Date of First Response~~ |
| **BRS-RA-010** | Assign 1, 2 or 3 at Screening based on the order in which the Screening time point is read.  Example: Reader who completes Screening first will have PrimaryReadNumber as 1.  PrimaryReadNumber value at Screening will be carried forward to all follow up timepoints and Global session. **Field text:** Primary Read Number at Screening, Follow-up and Global [**Control name:** PrimaryReadNumber] |

## Image Data Handling (Section 1.3 in template)

| **Requirement and Description** | |
| --- | --- |
| **BRS-IDH-006** | In Sessions 4 and 5, Image display must include ‘Photography’ when loaded for the time point(s) in READ ONLY fashion. |

## Technical Adequacy (Section 1.4 in template)

| **Requirement and Description** | | |
| --- | --- | --- |
| **BRS-TAA-005** | The system must ask the following question in Sessions 1 & 2:  **Question text**: Give at least one reason for the images being Readable, but not Optimal, or Not Readable.[**Control name:** ImageAdequacyReason] | |
| **Answer Options**   * Artifact * Inadequate contrast * Inadequate chest * Inadequate abdomen * ~~Inadequate pelvis~~ * Inadequate <*neck*> * Missing chest * Missing abdomen * ~~Missing pelvis~~ * Missing <*neck* * Site drawn ROI or measurement present * Subject motion * Time point missing * Other, specify | | **Logic**   * One answer required, multiple allowed when enabled. * If there are no image files for the time point, the system must auto-populate the answer with ‘Time point missing’ and disable all other options. * If there is at least one image available for the time point, the system must disable the answer option ‘Time point missing’. * Enable a required text comment box if ‘Other, specify’ is selected [**Control name**: OtherSpecify]. |

## Session 1 Questions/answers (Section 3.2 in template)

| **Requirement** | **Requirement Description** |
| --- | --- |
| **BRS-S1QA-007** | Session 1 (Screening/Baseline) upon sign off if no target lesion(s) are identified, display a pop-up message to the reader:   * “Protocol requires measurable disease as determined by the Investigator. Please acknowledge in comments there are no measurable lesions and the subject will be followed based on non-target lesion and/or new disease”.   Reader selects ‘OK’ close the message, require comment allow sign off.  Reader selects ‘Cancel’ close the message and prevent sign off. |

| **Requirement and Description** | | |
| --- | --- | --- |
| **BRS-S1QA-011 Field text:**  Comment on No Measurable Disease:  [**Control name**: CommentNoMeasurableDisease] | | |
| **Rule** | **Answer Option** | **Logic** |
| Enable/display text box when reader acknowledges there is no measurable disease identified at screening/baseline time point (reader clicks ‘OK’ to pop-up message at BRS-S1QA-007). | Text | Required if enabled. |

## Session 4 Adjudication Data Display (Section 7.1 in template)

| **Requirement** | **Requirement Description** |
| --- | --- |
| **~~BRS-S4DD-030~~** | ~~Highlight differences in points of adjudication.~~ |
| **BRS-S4DD-035** | Display the following information for each primary reader:   1. Best Response 2. Date of Progression 3. Date of First Response   Comment from Sessions 3 |
| **BRS-S4DD-040** | Allow toggling of the display of Reader 1’s and Reader 2’s and Reader 3’s lesion ROIs. |
| **BRS-S4DD-037** | The system must display clinical data information (loaded in the baseline/screening time point), via the ClinData field from BioPACS, if available. |

## Session 4 Questions/Answers (Section 7.2 in template)

| **Requirement Description** | | |
| --- | --- | --- |
| **BRS-S4QA-001 Field text:** Select one of the two answers  [**Control name:** Adjudication] | | |
| **Rule** | **Answer Option** | **Logic** |
| Always ask this question. | * I agree with Reader 1’s subject assessment * I agree with Reader 2’s subject assessment * I agree with Reader 3’s subject assessment | One required answer. |

| **Requirement** | **Requirement Description** |
| --- | --- |
| **~~BRS-S4QA-010 Field text:~~** ~~Reason for Discordance~~  ~~[~~**~~Control name:~~** ~~ReasonDiscordance]~~ | |
|  | **~~For internal use only (NOT TO BE EXPORTED)~~**~~: the adjudicator will select one reason for the discordance from the list below:~~   * ~~Justifiable difference in lesion selection~~ * ~~Incorrect lesion selection~~ * ~~Justifiable perception difference in determining new lesions~~ * ~~Incorrect perception difference in determining new lesions~~ * ~~Justifiable perception difference in determining progression on the basis of non-target disease~~ * ~~Incorrect perception difference in determining progression on the basis of non-target disease~~ * ~~Justifiable perception in determining response based on non-target disease~~ * ~~Error in perception in determining response based on non-target disease~~ * ~~Justifiable perception difference in lesion measurements~~ * ~~Incorrect perception difference in lesion measurements~~ * ~~Missing clinical data~~ * ~~None – only quality issues contributed to discordance~~ |
| **~~BRS-S4QA-015 Field text:~~** ~~Comment on discordance~~  ~~[~~**~~Control name:~~** ~~DiscordanceComment]~~ | |
|  | ~~Optional Comment field~~ **~~(NOT TO BE EXPORTED)~~** |

## Session 5 Clinical Assessment Questions/Answers (Section 8.2 in template)

| **Requirement and Description** | | |
| --- | --- | --- |
| **BRS-OS5QA-025 Filed text**: Clinical Data:  **[Control name:** ClinicalDataAnswersDisplay**]** | | |
| **Rule** | **Answer Option** | **Logic** |
| Enable in the selected timepoint row change is made for Response and/or Exam Date. | Physical exam findings/Photography  Pathology/Cytology data confirms PD  Pathology/Cytology data downgrades CR  Pathology/Cytology data confirms CR  On-study surgical procedures  On-study radiation therapy  Other (Comment) | Required in each row a change has been made, (multiple answers allowed). |

| **Requirement and Description** | | |
| --- | --- | --- |
| **BRS-OS5QA-045 Field text:** Overall Radiology + Clinical Date of Progression  **[Control name:** DateProgressionCTClinical**]** | | |
| **Rule** | **Answer Option** | **Logic** |
| This field is read-only. | Date (DD-MMM-YYYY) | Display the date associated with the first Overall Radiology + Clinical TPR of PD, else populate with n/a.   * Utilize the latest date between Radiology max exam date and Clinical Exam Date if differ. |

| **Requirement and Description** | | |
| --- | --- | --- |
| **BRS- OS5QA -050 Field text**: Overall Radiology + Clinical Date of First Response  **[Control name**: DateFirstResponseCTClinical**]** | | |
| **Rule** | **Answer Option** | **Logic** |
| This field is read-only. | Date (DD-MMM-YYYY) | Display the date associated with the first Overall Radiology + Clinical TPR of CR or PR was first met, whichever status is recorded first, for subject whose Overall Radiology + Clinical BR is either a CR or a PR, else populate with n/a.   * Utilize the latest date between Radiology max exam date and Clinical Exam Date if differ. |

## Lesion Locations/Anatomical Site Codes (Section 11.0 in template)

**BRS-ASC-001: Extranodal Lesions**

* ~~Pleural Effusion (Malignant) (non-target and new lesion only)~~
* ~~Pericardial Effusion (Malignant) (non-target and new lesion only)~~
* ~~Ascites (Malignant) (non-target and new lesion only)~~

# READAdmin Configuration Form

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Project Information** | | | | | | |
| **Client Name:** | PRA | | | **Date:** | 30-OCT-2019 | |
| **Read Project Name:** | | Project Code\_RECIST 1.1\_Efficacy | | **ProjectCode:** | | 10005043 |
| **Turnaround time for the study:** | | | Standard | | | |

**Read Ready Rules**

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Prerequisite Rules (Applicable to all projects)**  **Note:** The rules in this section pertain to the Subject Level in BioPACS. If any of the below rules (1-8) are marked as ‘Yes’, and the subject fails, READAdmin will not run the Read Rules, no read units will be created, if read units already exist and rule fail, the Read Rules will not be updated until all issues are resolved*.* | | | | | | | | | | | | | | | |
| **Rule** | | | | | | | | | | | | **Project Setting** | | | |
| 1. **Subject must be active** - Subject is listed as active within the database. | | | | | | | | | | | |  | | | |
| 1. **Subject not screen failed** - Subject must not be marked as Screen Failed in BioPACS. | | | | | | | | | | | |  | | | |
| 1. **Subject must be QC OK** - Subject must have completed all QC tasks required. *(If ‘Yes’ requires a QC check list task at Subject level in BioPACS*) | | | | | | | | | | | |  | | | |
| 1. **Subject must not have open queries** - All queries for the subject selected must be resolved. | | | | | | | | | | | |  | | | |
| 1. **Subject must have Date of Dosing -** Subject must have a value for Date of Dosing in BioPACS. | | | | | | | | | | | |  | | | |
| 1. **Subject must have Randomization Date –** Subject must have a value for Randomization Date in BioPACS. | | | | | | | | | | | |  | | | |
| 1. **Subject must have Enrollment Date–** Subject must have a value for Enrollment Date in BioPACS. | | | | | | | | | | | |  | | | |
| 1. **Subject Custom field rule:**  * If Custom field Name is specified, the system will check for any value in BioPACS for the corresponding custom field name, if ‘Check for Null’ is “No”   + If ‘Check for Null’ is “Yes”, the system will check for Blank value in corresponding custom field name.   **If Yes – Custom Field Name**:       **If Yes - Check for Null**: | | | | | | | | | | | |  | | | |
| **Overall Rules** | | | | | | | | | | | | | | | |
| 1. **Must have the minimum number of read units per question set**.. | | | | | | | | | | | |  | | | |
|  | | 1 a. If Rule 1 is Yes - please indicate the minimum number of read units that must be present: | | | | | | | | | | | | | |
|  | Read Unit Name: | |  | |  | Read Unit Name: |  | | |  | Read Unit Name: | |  | |
|  | Min. Number: | |  | |  | Min. Number: |  | | |  | Min. Number: | |  | |
|  | | | |  | | | |  |  | | | | |

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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Configurable Rules** | | | | | | | | | | |
| **Rule** | | | | | | | | | | **Project Setting** |
| 1. **Time Point Modalities** - The time point must have active and *DataLogged* studies with all the configured modalities listed below: | | | | | | | | | |  |
| Modality 1: | | |  | | | Modality 2: |  | | | |
| Modality 3: | | |  | | | Modality 4: |  | | | |
|  | | | | | | | | | |
| 1. **Time Point QC Check** – The Time Point must have a status of QC OK in the database *(If ‘Yes’ requires a QC check list task at Time Point level in BioPACS*). | | | | | | | | | |  |
| 1. **Studies (Modality) QC Check** - All required studies for a time point, must have a status of QC OK in the database *(If ‘Yes’ requires a QC check list task at Study level in BioPACS*). | | | | | | | | | |  |
| 1. **Time Point Open Queries Check** - All queries for the time point must be resolved (*Not a pre-requisite rule, will not stop read units from being created/updated for the subject*). | | | | | | | | | |  |
| 1. **Prior Time Points must be Read Ready Check** – All prior time points must not have open queries or any failed rules. *(If ‘Yes’ requires # 4 Time Point Open Queries Check to also be ‘Yes’. Not a pre-requisite rule, will not stop read units from being created/updated for the subject*). | | | | | | | | | |  |
| 1. **Discontinuation Date Check –** Time point must not include any scans with exam date that exceed discontinuation date configured for the subject*(If ‘Yes’ time point will not be auto-allocated- not a pre-requisite rule, will not stop read units from being created/updated for the subject )* | | | | | | | | | |  |
| 1. **Baseline must be Read Ready** – Baseline (or Screening) time point must be read ready before future time points can be. | | | | | | | | | |  |
| 1. **Time Point Custom Field** - The system must provide a rule that considers a time point to be read ready if the value of a specified custom field is equal to a specified value.    1. If Yes – Custom Field Name:       Required Field Value: | | | | | | | | | |  |
| 1. **Radiology Active Clinical Data Required – S**elected Clinical Data with respective sessions must be inserted for the subject/timepoint, if not inserted will flag as failed in READAdmin *(not a pre-requisite rule, will not stop read units from being created/updated for the subject)* | | | | | | | | | | |
|  | **Form Type** | | | **Screening/Baseline** | **Follow Up** | | |  | | |
| **BCSP** | | |  |  | | |
| **Clinical Data** | | |  |  | | |
| **Biopsy Report** | | |  |  | | |
| **DTF** | | |  |  | | |
| **CRF** | | |  |  | | |
| **ICQ** | | |  |  | | |
| **Phantom Data** | | |  |  | | |
| **Configurable Read Unit Rules**  **Note:** Points 1 **or** 2 are for a one session Clinical assessment (Session V), whereas point 3 will create read units for the oncologist for each time point Session 1 (SCR), Session 2 (On Study), and Session 3 (Global). | | | | | | | | | | |
| 1. **Clinical read unit** - If a project has a clinical session, the clinical read unit must be available when all the configured subject prerequisite rules are met. | | | | | | | | |  | |
| 1. **Clinical read ready rule** - The clinical read unit must be considered read ready if the **subject** **contains** active clinical data. | | | | | | | | |  | |
| 1. **Oncology workflow** – If a project has an oncology workflow session, opening all time **points** sequentially. (*Select ‘Yes’ if the study is allowing the oncologist to add/track clinical lesions on photography, or clinical finding lesions directly on the eCRF*) | | | | | | | | |  | |
| 1. **Enforce Blind Code Selection** – enforce blind code to be allocated to the same reader in all time points. | | | | | | | | |  | |
| 1. **Enforce Same Adjudicator for Cases** (radiology session)– in cases where adjudication needs to be repeated, enforce blind code be allocate to the same reader. | | | | | | | | |  | |
|  | |
| **Reader Monitoring and Adjudication Rules - Subject level** | | | | | | | | | | |
| 1. **Standard Adjudication** - Allocates to a single adjudicator after completion of the reads by both readers. | | | | | | | | |  | |
| 1. **Multiple Reader Adjudication** – If there are multiple primary readers (3+), create adjudication read unit after 2+ readers finished. | | | | | | | | |  | |
| 1. **Central Vs. Local Read Adjudication** – Determine adjudication based on Subject custom field value and central reader’s answer. | | | | | | | | |  | |
| 1. **Clinical Adjudication** – Allocates to a single clinical/oncologist reader after completion of the reads by both clinical/oncologist readers. | | | | | | | | |  | |
| **Time Point Level Adjudication**  **Note:** Only for projects in which each time point is read in isolation (e.g. the GI video studies, not oncology studies where what happens at TP2 affects TP3, etc. Readers will not have access to prior time points. | | | | | | | | | | |
| 1. **Standard Adjudication –** Allocates to a single adjudicator after completion of a time point by both readers. | | | | | | | | |  | |
| 1. **Central Vs. Local Read Adjudication –** Determine adjudication based on Time Point custom field value and central reader’s answer. | | | | | | | | |  | |
| **Project Specific Rules** | | | | | | | | | | |
| 1. **Eligibility plus Efficacy Combined -** eligibility and efficacy will be assessed in a single application    1. If Yes – number of Eligibility Readers: | | | | | | | | |  | |

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| --- | --- | --- | --- | --- | --- | --- |
| **Workflow Rules** | | | | | | |
| Please indicate which workflows steps you wish to use for this project: | | | | | |  |
| **Read Unit** | **Not Ready** | **Pending Client Approval** | **Pending PM Approval** | | **Approved for Allocation** | |
| **Screening** |  |  |  | |  | |
| **Follow-up** |  |  |  | |  | |
| **Global** |  |  |  | |  | |
| **Adjudication** |  |  |  | |  | |
| **Clinical** |  |  |  | |  | |
| **Read Unit 6 Name** |  |  |  | |  | |
|  |  |  |  | |  | |
| **Comments** | | | | | | |
| Please add any further details regarding the project: | | | | | |  |
|  | | | |  | | |

*This form is uncontrolled unless referred to in an approved BRS*

# Appendix – Mock Ups

This appendix is for general layout of content only. Final layout will be dependent upon population information and programming.

Session 1, 2, 3 and 5: please refer to Mock-ups in the Standard BRS template.

**Session 4 Adjudication**

