# READAdmin Configuration Form

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| **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**

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| **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: |  | | | |
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| 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. | | | | | | | | |  | |
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| **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** |  |  |  | |  | |
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| **Comments** | | | | | | |
| Please add any further details regarding the project: | | | | | |  |
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*This form is uncontrolled unless referred to in an approved BRS*