**TRIAGE - OCTRU Research Image Manager**

**User Requirements Specification**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | **NAME** | **ROLE** | **SIGNATURE** | **DATE** |
| Written by: | Duncan Appelbe | Senior Research Information Specialist |  |  |
| **Sign-off by:** |  | *Senior Stakeholder* |  |  |
| **Technical Sign-off:** |  | *Programmer* |  |  |

# Change History

| **Version** | **Date** | **Significant Changes** | **Previous Version** |
| --- | --- | --- | --- |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

# Executive Summary

TRIAGE is a web-based application that can be used as a central repository for images collected as part of a clinical research study.

In it’s most basic form the application stores all of the available images providing reports showing:

* Outstanding images (i.e. images that should have been uploaded at a specific time point, but have not)
* What images have been uploaded and by who
* What images have been downloaded and by who.

The timepoints and expected ranges are configurable, whilst the system will interact with Clinical Data Management systems, such as REDCap to obtain information on the participants that have been randomised or withdrawn.

In a more complex form, the application will allow for the viewing of JPEG, PNG, GIF, DIACOM files and recording meta data about these images (configurable).

Access to the system will be controlled via roles and unique usernames and passwords.

# Requirements

## User Requirements

| **User Requirement Specification ID** | **User Requirement Specification Description** | **User Requirement Specification Risk Severity** | **Comment** |
| --- | --- | --- | --- |
|  | It should be possible to view images relating to the operation for each participant within the study | Medium | This is one of the primary purposes of the application |
|  | It should be possible to answer questions about each participant’s images. | Medium | Used for adjudication |
|  | It should be possible for a “Manager” to specify the questions to be asked about each image type | Medium | Used for adjudication |
|  | It should be possible to upload images associated with each participant to the system | Medium | This is one of the primary purposes of the application |
|  | It should be possible to specify the meta data that is to be associated with each of the uploaded images | Medium | This is one of the primary purposes of the application |
|  | User to confirm that all identifiable data has been removed from the image prior to uploading | High | For information security purposes |
|  | It should be possible to customise the application for a given study | Low | Branding can be important. |
|  | It should be possible to assign a subset of images to each user for review | Medium | To reduce burden |
|  | User home page to list the number of images outstanding for review | Medium | To reduce burden |

## Core Business Requirements

| **User Requirement Specification ID** | **User Requirement Specification Description** | **User Requirement Specification Risk Severity** | **Comment** |
| --- | --- | --- | --- |
|  | Users should have to login to access any reports or pseudo identifiable data | High | For data security purposes |
|  | Each user should be assigned to one of the following roles:   * Administrator (Can access all studies) * Manager (Can only access a specific study) * Supervisor (Can only access a specific study) * Uploader Supervisor (Can only access a specific study) * Reviewer (Can only access a specific study) | High | For data security purposes |
|  | The Reviewer role can   * Access a specific study * Access all images assigned to the user for review * Complete an assessment of the image, based on that defined by the manager | Medium | This is one of the primary purposes of the application |
|  | The Uploader role can:   * Access a specific study * Upload a participant’s images * Associate those images with a randomisation number and study time point * View a list of study participants for a site that are outstanding | Medium | This is one of the primary purposes of the application |
|  | The supervisor can:   * Undertake all activities that can be undertaken by an Uploader and Reviewer * View all results * View outstanding reviews | Medium | This is one of the primary purposes of the application |
|  | The manager can:   * Undertake all activities that can be undertaken by a supervisor * Set up users * Manage users (except for administrators) * Set up sites * Manage sites * Specify review questions | Medium | This is one of the primary purposes of the application |
|  | The administrator can:   * Undertake all activities that can be undertaken by a manager * Configure Studies | Medium | This is one of the primary purposes of the application |
|  | All uploaded images to be collated by study, site and status | Medium | To reduce burden |
|  | Images can only be uploaded as jpg/diacom/png/zip/gif format | Medium | To reduce burden |
|  | All images to be displayed as thumbnails | Medium | To reduce burden |
|  | Images when selected to be displayed in as large a format as possible, with the ability to zoom in | Medium | To reduce burden |
|  | Any changes to data should require a reason for change | High | For data security purposes |
|  | User accounts, when created, send an E-Mail asking the user to set their password. | High | For data security purposes |
|  | User must be able to reset their own password without administrator action | High | For data security purposes |
|  | All users must be able to have their access disabled | High | For data security purposes |
|  | Password rule to be enforced:   * 12-20 Characters * At least one Upper case * At least one lower case * At least one number * At least one special character * No spaces | High | For data security purposes |
|  | 2FA – The administrator can enable two factor authentication, if required.  Once a password has been enter the user will then be sent a code by E-Mail/SMS. | Medium | For data security purposes. |
|  | Contain a page to explain data usage and cookies for the application | High | Regulatory requirements |
|  | All pages displaying any patient data or user data can only be visible if logged in | High | For data security purposes |
|  | If no activity in the last 5 minutes display a pop-up warning that the user will be logged out in 2 minutes time | High | For data security purposes |
|  | Auto log the user out if no activity for 7 minutes | High | For data security purposes |

## Common Technical Requirements for the System

The following sections define requirements that are Common and Technical and that apply to the whole system.

| **User Requirement Specification ID** | **User Requirement Specification Description** | **User Requirement Specification Risk Severity** | **Comment** |
| --- | --- | --- | --- |
|  | All identifiable data to be encrypted at rest | High | For data security purposes |
|  | The application should only be accessible over a secure (https) connection | High | For data security purposes |
|  | The application should be written in PHP v7.1 | Low | PHP 7.1 is supported by all our servers |
|  | The application should use the Laravel 5.8 as the application framework | Low | This is a common framework that should be used where possible. |
|  | Application usable via Chrome version 74.0.3729.157 at a minimum | Low | Common Web browser |
|  | Application usable via Firefox version 67.0 at a minimum | Low | Common Web browser |
|  | Application usable via Internet Explorer version 11.766 at a minimum | Low | Common Web browser |
|  | Application usable via Edge version 42.17134.1.0 at a minimum | Low | Common Web browser |
|  | Application usable via Safari version 1.2 (windows) at a minimum | Low | Common Web browser |
|  | Application should be usable on a tablet with a minimum size of 9.7” | Low | Some users will access the application from a tablet |
|  | Files to be stored in the structure:  Study   * Site * Randomisation Number * Time-Point | Medium | Separation of concerns |

## Reporting Requirements

| **User Requirement Specification ID** | **User Requirement Specification Description** | **User Requirement Specification Risk Severity** | **Comment** |
| --- | --- | --- | --- |
|  | It should be possible for a user to see a list of all their actions within the application | Medium | For auditing purposes |
|  | It should be possible for an administrator to see a list of all users’ actions within the application | Medium | For auditing purposes |
|  | It should be possible to view the review status of all images | Medium | For adjudication purposes |
|  | It should be possible to view a list of reviewed images awaiting resolution of reviewers’ disagreements |  |  |
|  | It should be possible to download the results for all assessments (if undertaken) with the format:  RandomisationNumber, Timepoint, Review1, Review2, Review3, DateOfReview1, DateOfReview2, dateOfReview3 | Medium | For adjudication purposes |
|  | It should be possible to obtain a list of outstanding reviews by reviewer | Medium | For adjudication purposes |
|  | It should be possible to obtain a list of outstanding reviews by randomisation number | Medium | For adjudication purposes |
|  | List of missing but expected images | Medium | To minimise missing data |

# User Stories

# Site Layout

| **Page** | **Screen shot** |
| --- | --- |
| Login Page |  |
| Request Password Reset link Page |  |
| Admin Home Page |  |