**Software Development Request**

# Change History

| **Version** | **Written by** | **Role** | **Date** | **Significant Changes** |
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# request

Requested by : Duncan Appelbe

Date requested : 23Feb2020

Senior stakeholder :

Additional stakeholders :

# Needs Analysis

## Briefly outline the general requirement for a computer system

Many clinical studies collect diagnostic images as part of their source data. Some studies will just require a simple repository that holds the uploaded files along with some basic metadata (e.g. Randomisation Number and Study visit) whilst other studies require the ability to view these images as pat of a review by a clinical adjudication panel. In the later case, any application needs to record the answers to specific questions relating to the image and allocate images to members of the adjudication panel for review.

## Are there any existing 3rd party or University applications that meet, or could be modified to meet, the above requirement?

No

## Why is bespoke software required?

There currently does NOT exist a system that can meet these requirements.

# Requirement specification

## Outline in as much detail as possible the requirement for a computer system, how this is to be used and how this may impact on the integrity and quality of clinical data.

See the attached User requirements specification.

## Is it a bespoke system, only suitable for single study, or can it be used more generally over multiple studies?

This application could be used for multiple studies.

## What data are to be stored and how much (how many patients, studies, sites, etc.)?

* The data to be stored are diagnostic images in the form of jpeg/png/gif/dicom.
* The following meta-data are to be recorded

| **Meta data** | **Description** |
| --- | --- |
| Randomisation Number | This is the unique study number for the participant |
| Study Site | This is the site that the participant is associated with, e.g. John Radcliffe Hospital (this should be pulled from the study data collection system when needed to save multiple data entry) |
| Visit | The visit that the images are associated with, e.g. Baseline |
| Date of upload | The date & time that the images were uploaded |
| Uploaded by | The name of the person uploading the images |
| Date of download | The date and times that these images were downloaded (there may be multiple downloads) |
| Downloaded by | The name of the person downloading the data (this should be taken from the user logged into the system) |
| Reviewed by | The name of the reviewer(s) |
| Review date | The date & time of any review(s) |
| Review questions | The answers to any questions that reviewers need to complete (these questions should be configurable from study to study) |

* The system should be capable of handling many thousands of patients split across multiple sites and studies.

## What are the system access requirements (public internet, closed desktop system, 24/7/365, etc.)?

The application should be web based, accessed from anywhere world-wide, 24/7 365 days a year.

## Will the system need to interface with any other systems?

The application should interface with the primary data collection system for the study (e.g. REDCap) in order to report on expected/missing data.

## Are there any risks to consider (such as security considerations for collecting personally identifiable data)?

Where possible images will be anonymised, the system should consider the probability that an image has not been anonymised.

The system should encrypt data at rest.

The system should require two factor authentications when logging in.

## What system roles will be required (Administrator, Restricted Access, Read Only, Editor, etc.)?

| **Role** | **Description** |
| --- | --- |
| Administrator | A role given to IT staff, this role can see all data in the application and can undertake any action within the system. |
| Manager | A similar role to the Administrator, but actions are limited to a specific study only. |
| Supervisor | Can see all images in the system and the responses from all reviewers |
| Reviewer | A role that can only view images through the web interface and complete any review questions configured. |
| User | Either an uploader or downloader of data. The user should be assigned to one or more sites. |

## Are multiple systems required (e.g. demo and live instances)?

Yes, live & test

## Is there a hardware need?

Existing hardware should suffice.

## Any other information or comments?

See the attached user requirements specification

# Timeline

## Please provide as much timeline information as possible. Can there be phased releases or will the complete system need to be delivered by a given date? When would there be suitable times for testing or demonstrating the system prior to release etc.? When must the system be ready by?

Complete system to be delivered as soon as is possible.