EDGE User Guide for JRMO Staff

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Introduction

As of 2nd January 2019, the Joint Research Management Office have transitioned from using Research Database Application (ReDA) to EDGE as their Local Portfolio Management System. As EDGE remains unable to complete all tasks needed by the Joint Research Management Office (JRMO) as sponsor for Medicines and Healthcare Products Regulatory Agency (MHRA) regulated studies and some functions of all studies teams will also use ReDA to enable full sponsor oversight, namely monitoring, automated reminders and Pharmacovigilance activities.

ReDA is still accessed in a read only format but the JRMO office but limited to write access only to: - Governance Operations Manager, Research Information Lead, Governance Team Leader, Good Clinical Practice (GCP) and Compliance team members and the Office Manager. ReDA remains under that care of the Research Information Lead.

EDGE currently consists of Global/Green level and Site/Red level where the JRMO staff complete the relevant tasks throughout the life cycle of the study: from study set up to study closure. These tasks can be found in the Appendix 1, 2 and 3.

Scope and purpose

This user guide intends to demonstrate the ease of navigation of the system (EDGE) and what the JRMO are to complete when using the system.

The aim of this user guide is for instructional purpose only to be followed by the JRMO staff.

Topics that are not covered in this user guide can be found in the support section of EDGE where you can access a wide range of online guides covering how to use EDGE or submit a support ticket for issues.

Definitions and clarification

AAC	Assess, Arrange, Confirm	IRAS	Integrated Research Application System
AE	Adverse Event	IRT	Interactive Response Technology
AESI	Adverse Event of Special Interest	JRMO	Joint Research Management Office
APR	Annual Progress Report	MHRA	Medicines and Healthcare products Regulatory Agency
Barts Health	Barts Health NHS Trust	MREC	Multi-centre Research Ethics Committees
C&C	Capacity and Capability	NCC	National Coordinating Centre
CAG	Confidentiality Advisory Group	NCRN	National Cancer Research Network
CAPA	Corrective Action Preventative Action	NIHR	National Institute for Health Research
CE Mark	Conformité Européene Mark	PI	Principal Investigator
CI	Chief Investigator	PIC	Participant Identification Centres
COV	Close Out Visit	PV	Pharmacovigilance
CRDG	Clinical Research Delivery Group	QA Manager	Quality Assurance Manager
CRF	Case report Form	Queen Mary	Queen Mary University of London
CRN	Clinical research Network	R&D	Research and Development
CSR	Clinical Study Report	REC	Research Ethics Committee
CSS	Clinical Support Service	ReDA	Research Database Application
CTIMP	Clinical Trials of Investigational Medicinal Products	RIL	Research Information Lead
CTU	Clinical Trials Unit	RMGO	Research Management Governance Officer
DSUR	Development Safety Update Report	RSI	Reference Safety Information
EMA	European Medicines Agency	RTT	Referral to Treatment
EOT	End of Trial	SAE	Serious Adverse Event
ETC	Excess Treatment Costs	SIV	Site Initiation Visit
EUDRA CT	European Union Drug Regulating Authorities Clinical Trials Database	SOG	Sponsor Oversight Group
GCP	Good Clinical Practice	SOP	Standard Operating Procedure
GDPR	General Data Protection Regulation	SUSAR	Suspected Unexpected Serious Adverse Reaction
HRA	Health Research Authority	TMF	Trial Master File
ICR	Institute of Cancer Research	UKCRN	UK Clinical Research Network
IMP	Investigational Medicinal Product		

JRMO EDGE Local administrators:
Zabed Ahmed (Research Information Lead) – zabed.ahmed@qmul.ac.uk
Shafa Ullah (Governance Team Leader) – shafa.ullah@qmul.ac.uk

EDGE Projects work at 2 levels:

Green= Global Project Level
Red= Site Project Level

Workflows and attributes apply at each project level depending on activities undertaken. For example, sponsorship would go on Green/Global level whereas local capacity and capability would go on Red/Site level.

Staff Responsibilities for EDGE completion:

Appendices 1, 2 and 3 lists staff roles and responsibilities with workflows and attributes contents to ensure all required sections on EDGE are completed.

1. Users, access, and accounts

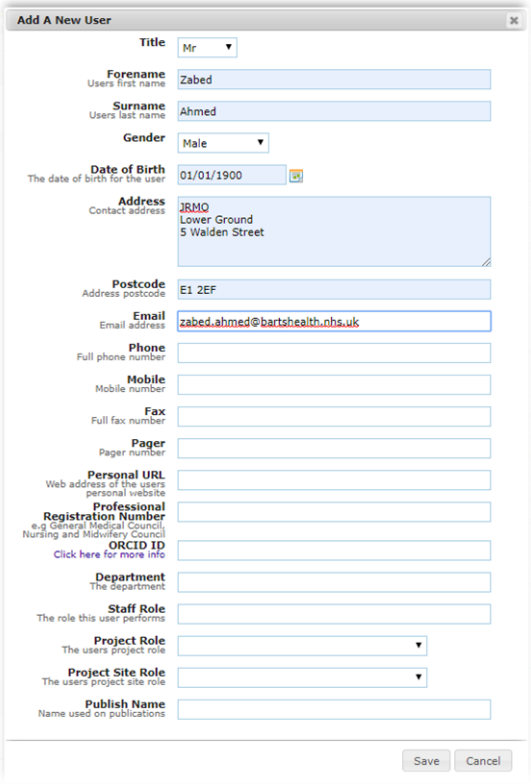
1.1 Adding a new user account to EDGE

Responsible staff	Research Information Lead

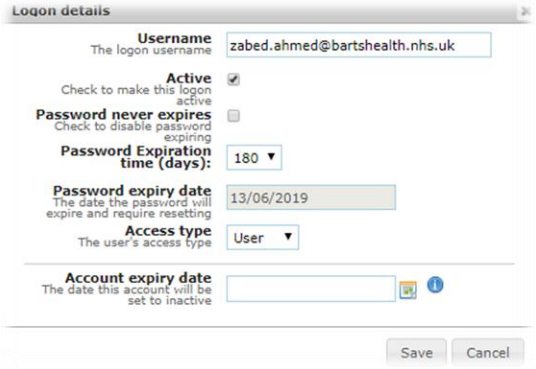
All staff who intend to use EDGE will need to contact their Local Administrator to request an account is created for them. For Barts Health or Queen Mary this is someone within the Performance Team so you can contact the Research Information Lead (RIL) on research.governance@qmul.ac.uk.

In order to create an account for a new user the following information is required – Please email (research.governance@qmul.ac.uk) with the new users details: title, forename, surname, address, telephone number and email address.

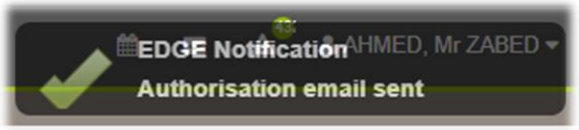
Step 1: Go to HOME > MANAGEMENT > USERS > ADD > Add User Details
Complete the new user details with their details and email address and click save.



Step 2: Click the LOGON DETAILS tab and click ADD LOGON from the right-hand side. A logon details box will be displayed. Select their logon as ACTIVE and change the Access type accordingly and click on Save



Once saved an authentication email will automatically be sent out to the new user to authenticate their account



1.2 Creating and adding a team to EDGE

Responsible staff	Research Information Lead/ Performance Team

In order to create a team in EDGE a request needs to be submitted to the Research Information Lead /Performance team which will then be discussed in the performance team and if approved it will be created for the respected requested party

1.2.1 Creating a team on EDGE

Step 1: Go into management tab

Step 2: Click on teams

Step 3: Click on add

Step 4: Create a name for the team

Step 5: Click on the team name you have just created

Step 6: Right hand side of the page add a team leader if you wish by clicking add and then type in person's name

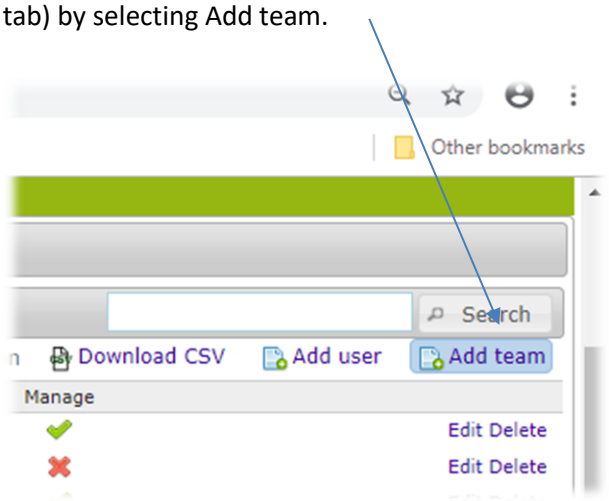
Step 7: Under team leader box you also have team members add team members here by clicking add and then type in the people you want to add to team

Step 8: Team created now you go into your project/projects and click on staff tab and click on add team right hand side of the page

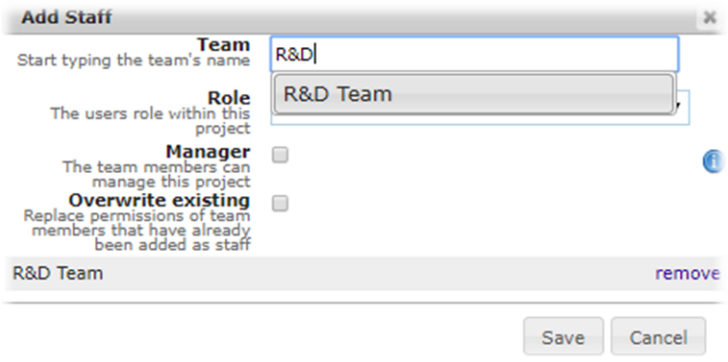
Step 9: Type in the team's name you have created and then add

1.2.2 Adding a team on EDGE

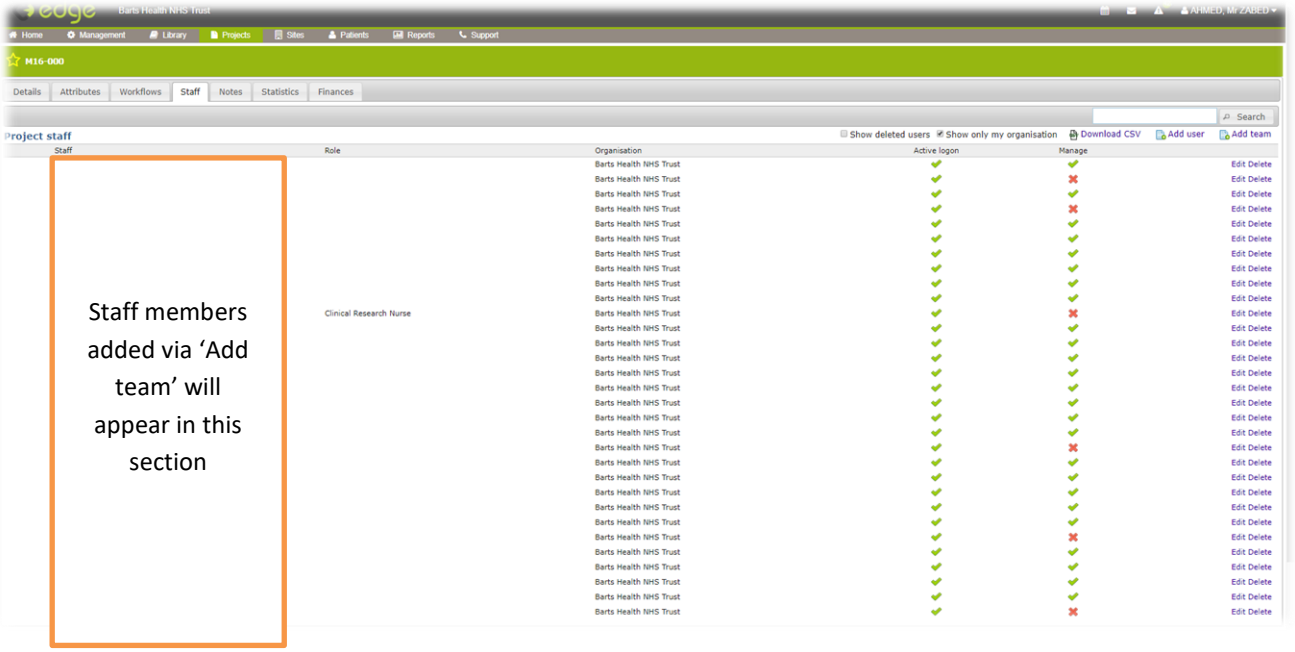
Once teams are created you can assign teams to projects on either level (for Green level go to green level staff tab & for Red level go to red level staff tab) by selecting Add team.



Below pop up box appears search for team and chose appropriate access level and click on save.



Once saved the staff members will be added to the projects with appropriate access level. See below.



Staff members added via 'Add team' will appear in this section

1.3 Process for approval of new admin users

Responsible staff	Research Information Lead / Performance Team

Type of access level on EDGE:

EDGE Admin access	EDGE User access
Can create any reports through reporting tab	Can run pre-defined project report built in by EDGE (using type, status, disease area, site)
Can share any reports with users by assigning users	Can view/run any reports admin gives access for
Can create new attribute and workflows via library	Can add attributes and workflows already available/created
Can add themselves to any study and with any access rights (Manage, Clinical)	Can add themselves to site level once they're given manage access by admin

- *To request an EDGE admin user, this must be emailed to RIL via research.governance@qmul.ac.uk*

Step 1: Receive new EDGE user account request: **Admin** or **User**

- If Admin, follow step 2
- If User, follow step 3

Step 2: Check if user account exists on EDGE

- If Admin Access requested review at Performance team meeting and if approved follow step 3 and 5
- If User Access only requested and it does not exist on EDGE, follow step 3.

Step 3: Create user account, refer to section 1.1

Step 4: If requested from external stakeholders - Check with Governance team (Research Management Governance Officer (RMGO)) - Request research passport/ honorary contract/ email confirmation from Barts Health or Queen Mary staff to inform us that the staff is taking part in research at Barts Health/Queen Mary.

Step 5: Provide EDGE training

1.4 Confidentiality agreement if permission is given to grant admin user access outside the JRMO

Responsible staff	Research Information Lead / Performance Team

An agreement needs to be signed by any research member of staff (external user to JRMO) to access the EDGE system.

Local Admin Access to Administrator Rights: Process

1 – Send request to JRMO via research.governance@qmul.ac.uk justifying the reasons why admin user access is required.

2 – JRMO will discuss all the admin user access requests internally at the bi-monthly Research Performance meetings.

3 – Requestor will receive an email about the outcome of the request.

Condition(s) for approval (the employee requesting administrator rights must meet at least one

of the following):

1 – Admin user request is necessary for the requestor's job performance.

2 – If no admin access is already in place for that specific department.

3 - The requestor uses EDGE reporting / attributes functionality regularly

EDGE Admin User Agreement & EDGE Local Admin Role Agreement can be found in Appendix 5

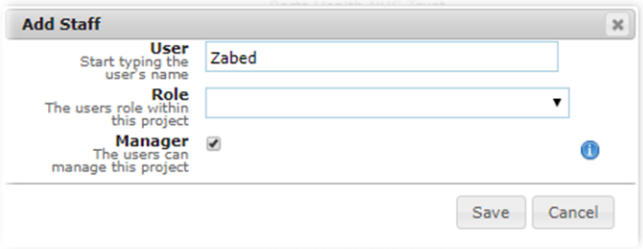
1.5 Assigning a user or team to a Project on EDGE

Responsible staff	All JRMO staff

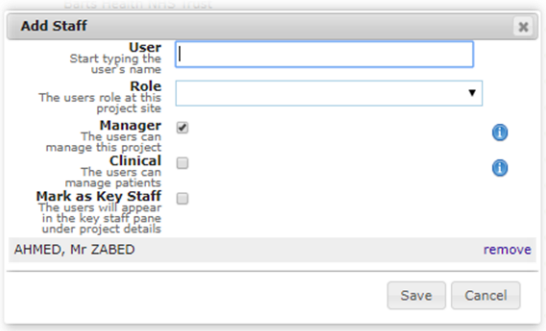
Steps in assigning a user or team to a Project:

a) Locate the project (see section 4.1)
b) Go to project level Staff Tab. To enable access to the Red/Site level, you must add the user to the Green/Project level first in the staff tab.
c) Search for user (if user does not exit then create user account as per 1.1). To add JRMO team type 'Research and Development (R&D)' (see example in section 1.5).
d) Give user the appropriate access level (manager/clinical & mark as key staff) (for JRMO staff 'manager 'is the appropriate level).
e) Click on save

Green level:



Red level:



2. Adding and using Attributes, Workflows, and documents

2.1 Adding and using Attributes

Responsible staff	All JRMO staff

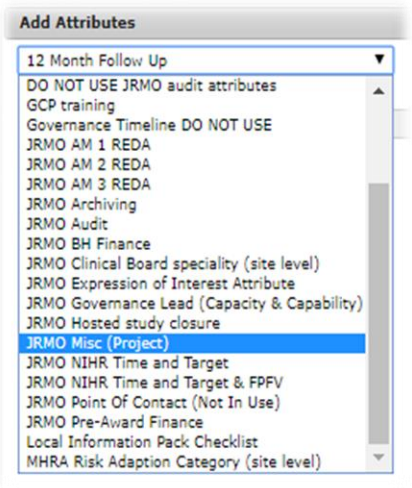
This guide outlines step by step the process for applying Attributes to a Project. When you have created template attribute sets, these can be applied to a project currently being approved. In order to apply these attributes at a site/green level you **MUST** be assigned as a manager for the project. If you wish to create a new attribute/amend attribute, then contact the Research Information Lead for support using research.governance@qmul.ac.uk.

2.1.1 Adding an attribute to a project

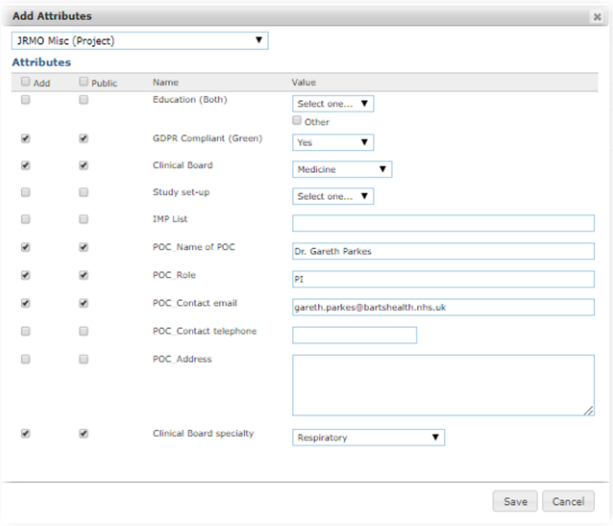
HOME > PROJECTS > ASSIGNED PROJECT > (Select Applicable Project) > ATTRIBUTES

Choose the applicable project and project level and select the **ATTRIBUTES** tab along the top. Click **ADD** to apply your template and select the applicable template from the drop-down list (see Appendix 2 for list of JRMO attributes).

Go to project > site level > attribute > Add> Select applicable Project attribute (see screen shot below)

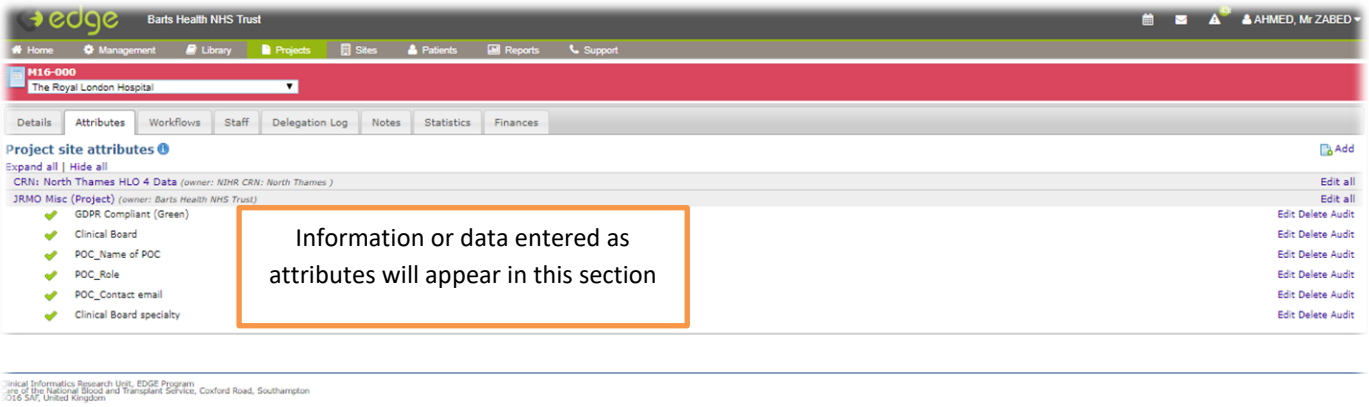


The attributes (fields) will now be displayed within the Add Project Attributes window. You can choose to either **ADD ALL** or **ADD** individual attributes by selecting the tick boxes. Enter the information in the **VALUE** column as well as selecting to make the attribute "Public" or "Private".



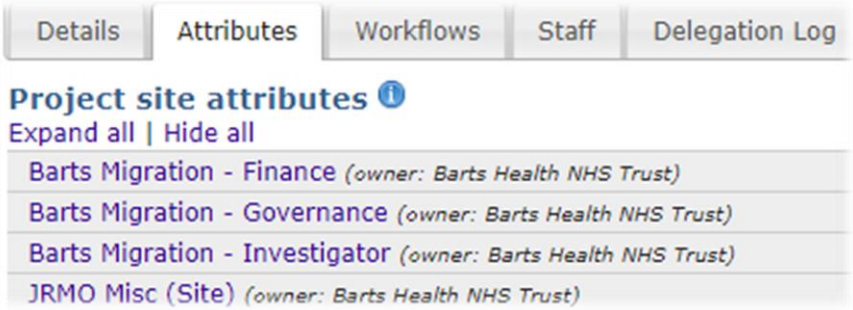
Complete all the applicable attributes and click **SAVE.** Attributes do not need to be completed all at once or in the order which they have been listed on the template, but it is advisable to do so to ensure data accuracy and completion. To share this information with other organisations you have to set up collaborations on the project, click the public

tick box next to the applicable attribute before clicking **SAVE**. Once applied, any attribute can be edited or updated by clicking the highlighted **EDIT** icon.

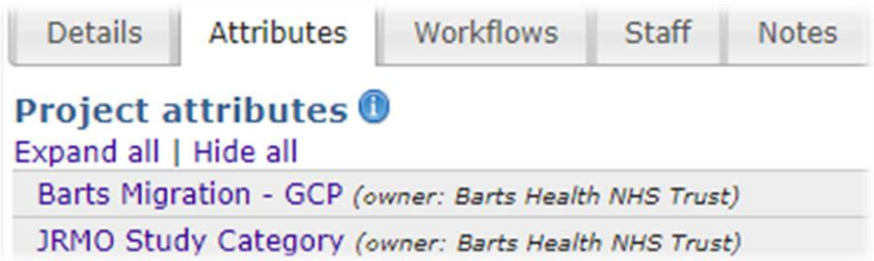


The information input against the project attributes section can now be reported on in the **PROJECT ATTRIBUTES REPORTING** function of EDGE (for reporting liaise with the Research Information Lead).

ReDA migrated data – these have been migrated into Red/Site Level and Green/Project Level EDGE attributes on the EDGE attributes Red/Site Level:



EDGE attributes Green/Project Level:



For a full list of all Attribute set contents please see Appendix 2.1

2.2 Adding and completing workflows

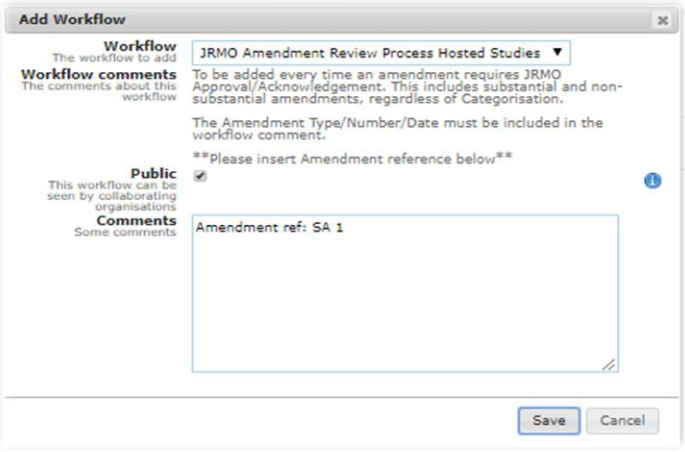
Responsible staff	All JRMO staff

This guide outlines the step by step process for adding and using Workflows to a Project Site. When you have created template workflows for all of your governance processes or departmental working processes, these can be applied to a project currently being approved. In order to apply these workflows at a site/green level you **MUST** be assigned as a manager for the project. If you wish to create a new workflow/amend workflow, then contact the Research Information Lead for support using research.governance@qmul.ac.uk.

2.2.1 Adding the appropriate workflow to EDGE

HOME > PROJECTS > (Select applicable Project) > (Select applicable Site) > WORKFLOWS

From the high-level project **DETAILS** overview click the **SITES** tab and select the site you wish to apply the workflow too then click the **WORKFLOWS** tab. To add a workflow to the project click **ADD** within the workflows tab and select the relevant workflow from the drop-down box (see appendix 3 for list of all JRMO workflows). Only workflows with the type set to Project Site can be applied at Project Site level.



Once you have selected your required workflow you can add comments to the front page (e.g. who is assigned to this workflow or delay notes) as well as selecting to make the workflow "Public" or "Private" (see Matrix below). To complete click **SAVE** to apply it to the Project. The allocated member of staff will now be able to complete the steps of the workflow according the processes defined during its development (see section 7.2 below).

Public Workflow	Private Workflow
By marking a workflow as public within the Project record the workflow will be visible and editable to organisations which you have chosen to collaborate with. If you have not set any collaboration the workflow will not be visible to any other organisation.	Workflows which do not have the public box checked will remain private. No organisations will be able to view this workflow even if collaborations have been set.

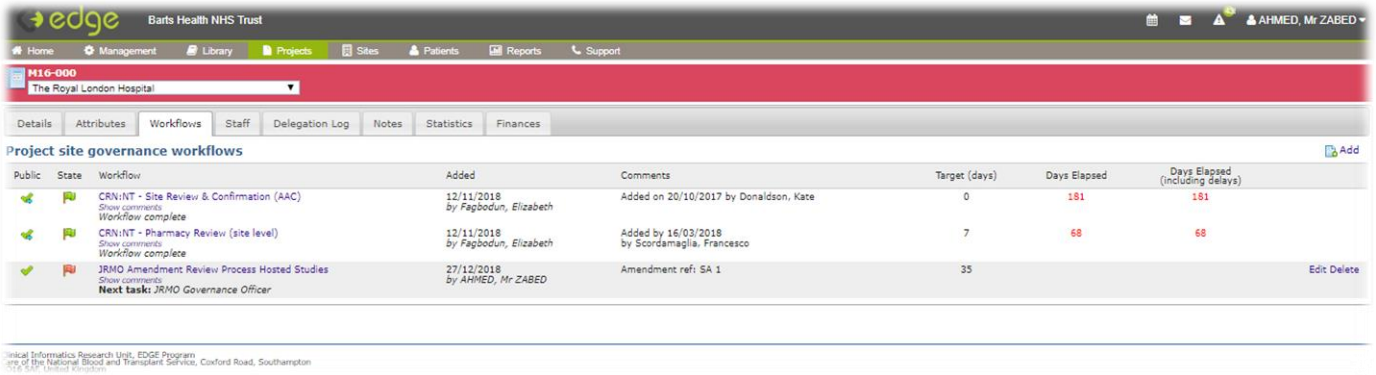
2.3 Using workflows

Responsible staff	All JRMO staff

Go to project > site level > workflows > Add> Select applicable Project workflow (see screen shot below)

Ensure ***'public'*** is ticked.

'Public' - users from your Organisation and any Organisations that you are collaborating with can see this document



Multiple workflows can be applied and completed at one time and multiple users can complete multiple workflows. The progress of each workflow is shown by the coloured flag on the left side of the screen.

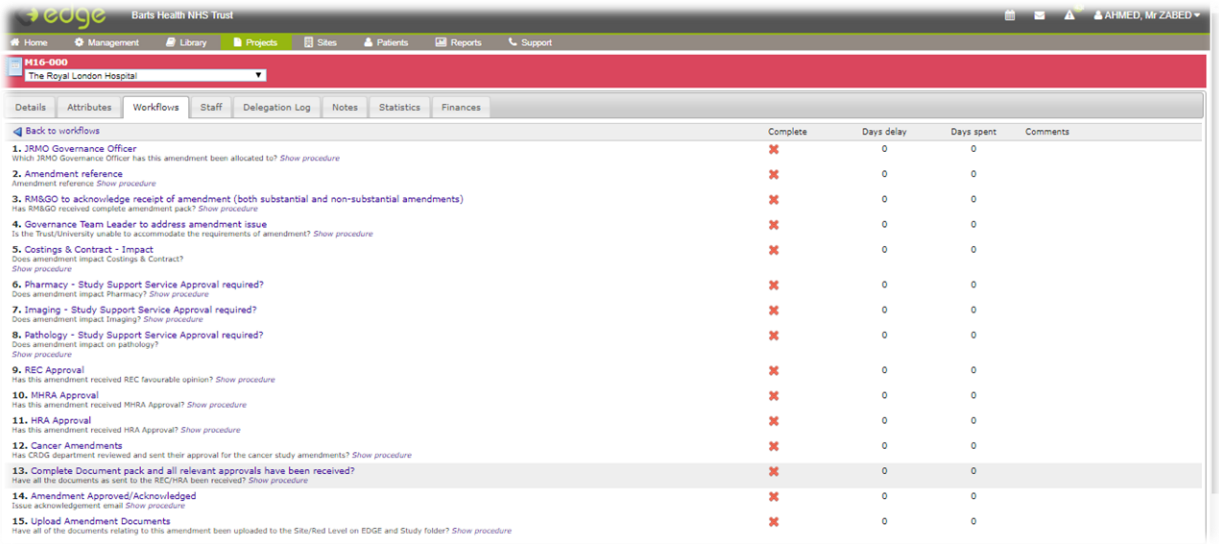
- **Red:** Applied to the project site but no stages of the workflow have been started
- **Orange:** The workflow is in progress and stages have been started
- **Green:** Completed

The workflow's title is shown with the next task in the process due to be completed, the date it was added and by which team member, as well as the target days it will take to complete alongside the actual number of days it has taken. To edit a workflow, click the highlighted workflow title or the **EDIT** function.

Within the workflow each step will be numbered sequentially
When each step is completed, select the applicable step of the workflow, and check the **COMPLETED** box alongside the completion date, the number of days delay and any comments associated with this step. Then click **SAVE**.

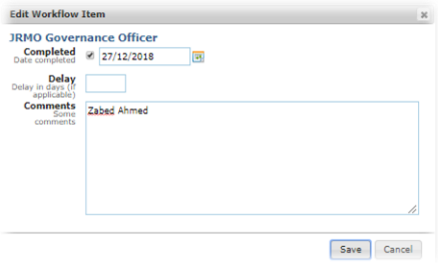
The rest of the workflow can now continue to be completed, the days delay and comments will accumulate and be displayed on the front page of the workflow.
Once you have selected the applicable project the below workflow will be added to the project site level.

Open the workflow by clicking on the hyperlink and the below workflow will appear then open each step and complete it with relevant information.



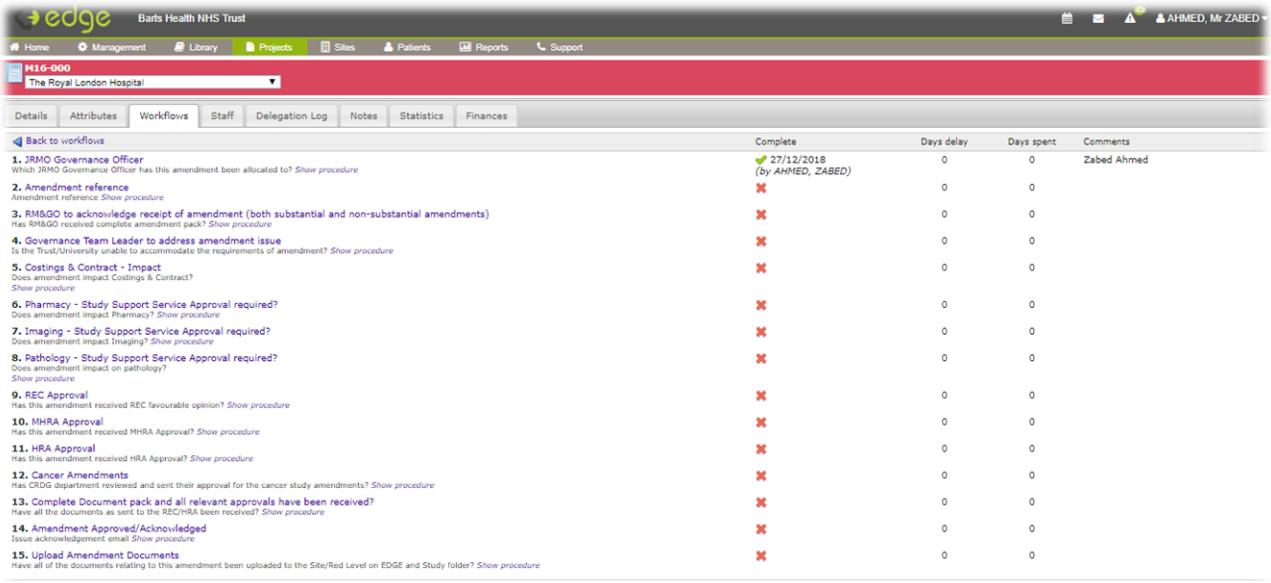
2.3.3 Steps to take to complete a workflow – example:

Adding 'JRMO Amendment Review Process Hosted Studies' workflow

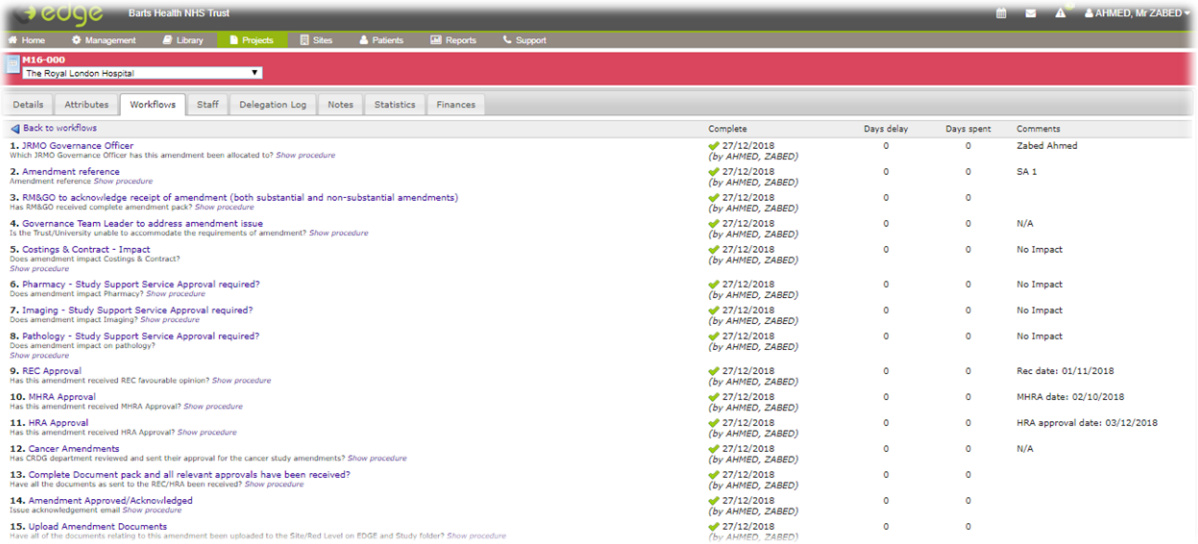


Open each step and complete it accordingly.

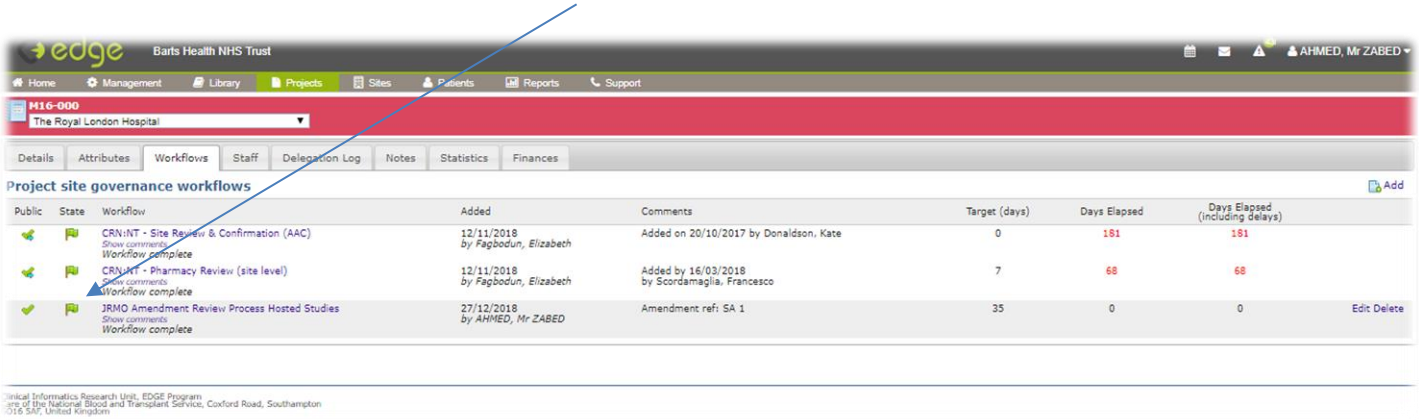
The date stamp is the day you are completing the workflow. Any relevant dates should go in the comments section and state what it is e.g. Health Research Authority (HRA) approval date: 20/03/2018. A tick will appear beside the steps once saved. See below screenshot.



Once all steps have been completed it should appear as below. If support departments are impacted please ensure to insert date received confirmation of approval from department. If steps are not relevant to the study please leave a comment e.g No impact or N/A.



Once workflow is completed it should show a tick and a green flag to state that it is complete.



Once all steps have been completed you can move onto the next process.

For a full list of all <u>Workflow contents</u> please visit Appendix 3.1

2.4 Document/file upload management

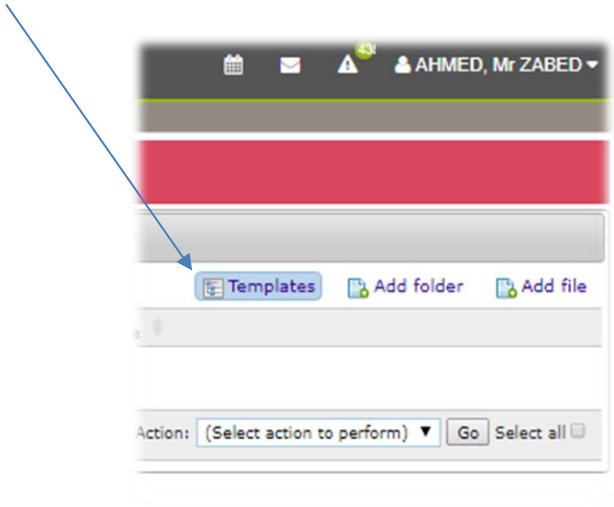
Responsible staff	All JRMO staff

Only EDGE users with Manage rights can use the upload file function. Standard Users can download and view this information. The below steps are a guide to uploading document/file on the HOSTED (Red/Site level), this also applies to SPONSORSHIP (Green/Project level) documents/file upload. For details of which document should be uploaded and at which time point please refer to *SOP 27 (JRMO FILING) - TBC.*

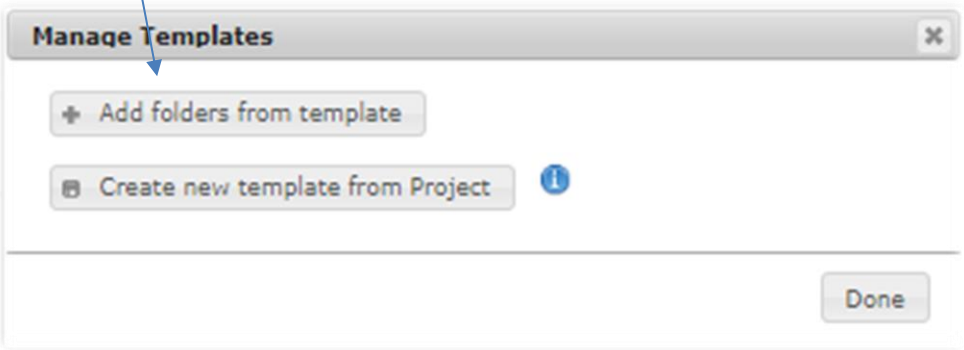
2.4.1 Selecting template folder structure

PROJECTS > ASSIGNED PROJECTS > (Select Applicable Project**) > FILES**

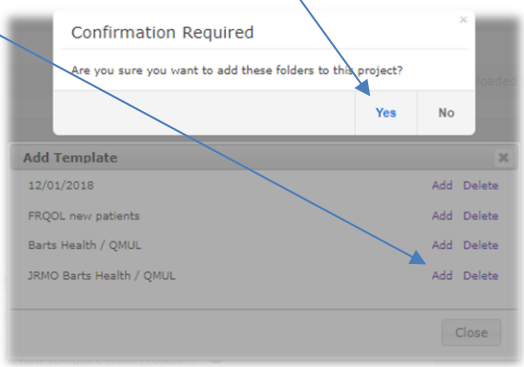
Step 1: Click on Template



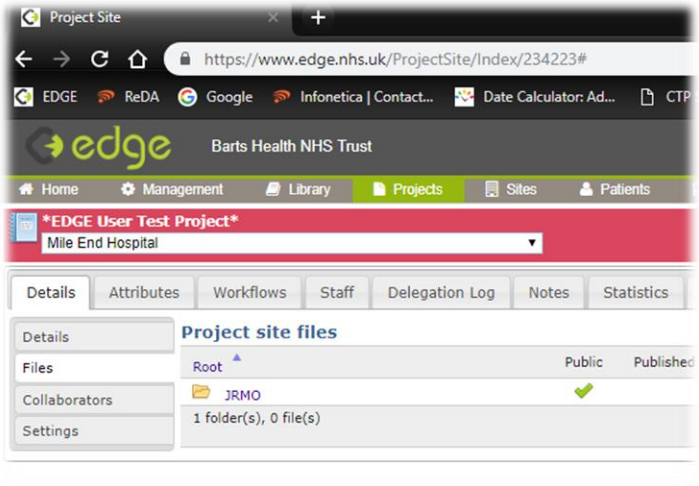
Step 2: Click on 'Add folders from template'



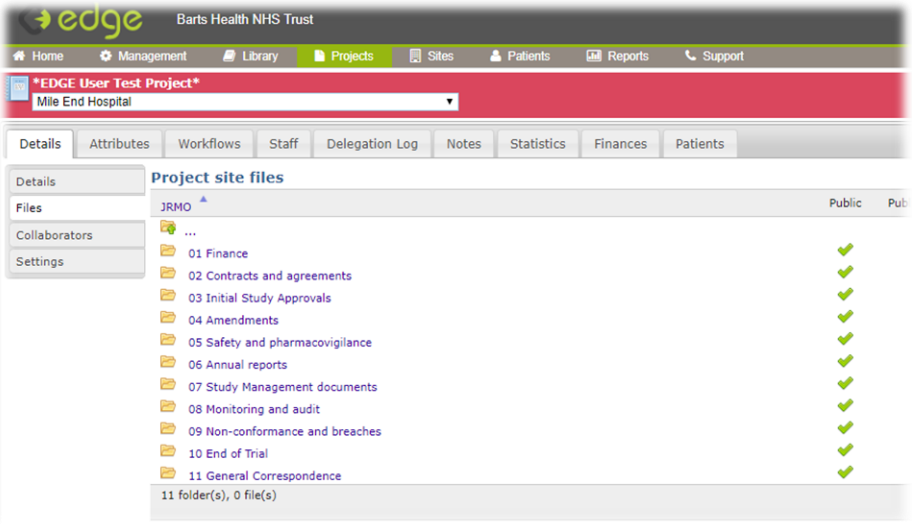
Step 3: Add JRMO Barts Health / Queen Mary and click Yes



Once template selected the below folder structure will be displayed.

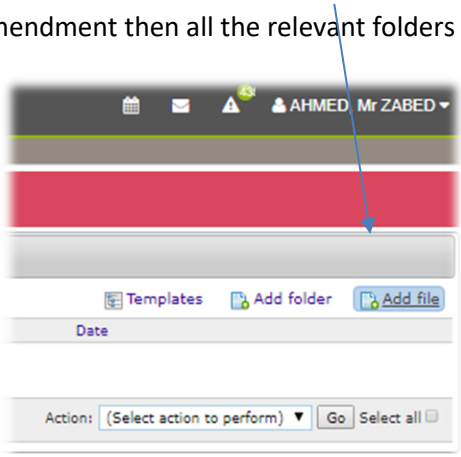


A folder is created – JRMO (see above) and within that folder further folders are displayed (see below)

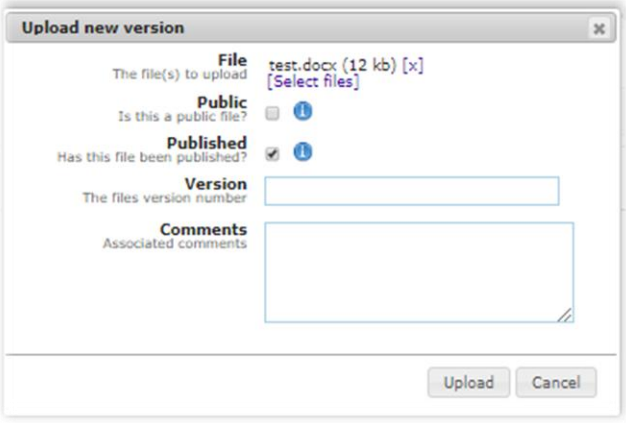


2.4.2 Adding files on EDGE

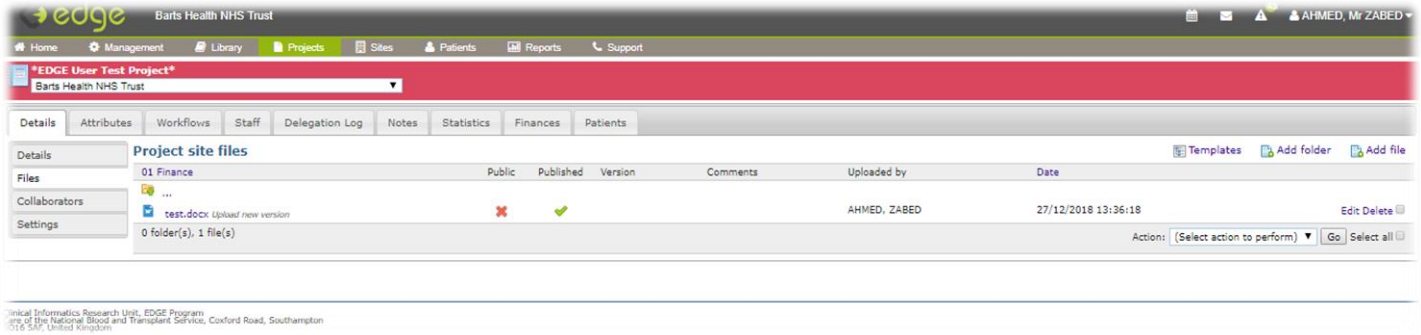
To add files to relevant folders, open folder and click on Add files. Please note only finalised documents are to be uploaded to EDGE, when there is an amendment then all the relevant folders must be updated.



Choose FILE to upload a file from your computer or shared drive. This works in a similar way to attaching a document to an email. You can then apply version and privacy controls as well as comments to the file. Depending on the file size and your network speed this can take up to 30 seconds to upload. The file size limit is 100Mb.



Once file uploaded it will be displayed as below:



The above instructions (section 2.4) apply at Red / Site level (Hosted studies) document upload. The same instructions apply for sponsorship study documents at the Green / project level.

ReDA document and files have been migrated into EDGE in 'The Royal London Hospital' site under JRMO ReDA import folder structure.

2.4.3 Version Controlling files uploaded to EDGE

To upload a new version of a file in EDGE click the **UPLOAD NEW VERSION** icon to the right of the file name. A light box will open to select the new file, a version number and comments can be uploaded to this file. To complete the upload, click **UPLOAD**.

To view all versions of a single document click the clock next to the **EDIT / DELETE** icon for the file, this will open a light box with the document history.

2.5 Documents to be uploaded to EDGE

Responsible staff	**All JRMO staff**

List of documents that should be uploaded to EDGE at **SPONSORSHIP** level and **HOSTED** level and the type of restriction it should be set to.

A file can be marked as public or private:

Public – users from your Organisation and any Organisations that you are collaborating with can see this document

Private – only users in your Organisation can see this document.

Published Files are visible to all staff within this organisation and **Unpublished Files** are visible to Admins and Users with manage access to the project/project site.

Documents to upload on **SPONSORSHIP**: Green/Project Level at a minimum:
Note – finalised versions of documents only, when there are amendments then the main study folders must be updated as well.

Public	**Private**
Approved document set	Correspondence
Regulatory approvals	Any documents containing financial award directly to the investigator
Local sign offs and approvals (all supporting department)	Monitoring and audit reports and correspondence
Study management documents and device specifications	Annual progress reports and contacts
Investigatory product documents i.e. IB brochure	Costings and contracts
All Amendments	Committee minutes – where stated
Sponsorship letter and email	Commercially sensitive data or details
Capacity and Capability (C&C) email	
Public database registration confirmation (if applicable)	

Documents to upload on **HOSTED**: Red/Site Level at a minimum:

Public	**Private**
Approved document set	Correspondence
Costings & contracts (per patient cost is fine) Any documents containing financial awards directly to the investigator	Safety and pharmacovigilance
C&C email and email from sponsor confirming sponsorship	Monitoring and audit
Costings and contracts	Annual progress reports
Study management documents	
Investigatory product documents i.e. IB brochure	
Amendments	
Local sign off and approval (all supporting departments)	
Public database registration confirmation if applicable)	

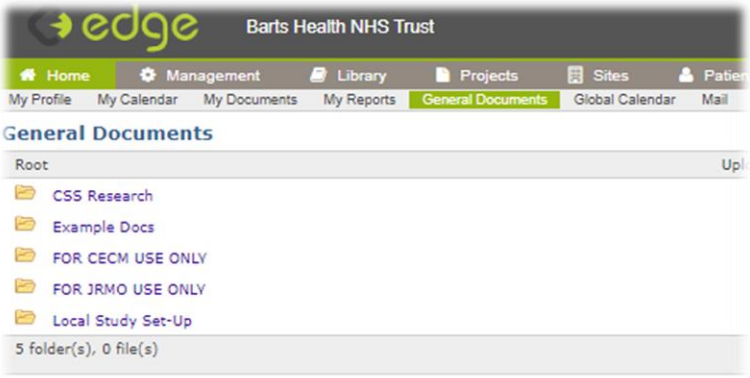
3. Standard Operating Procedures (SOP) documents on EDGE

3.1 SOP files on EDGE

Responsible staff	Quality Assurance Manager

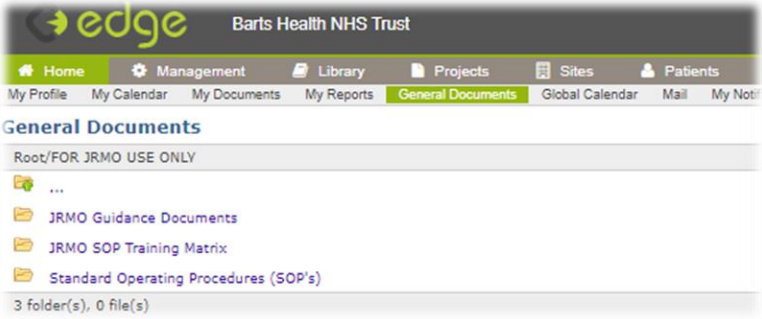
The SOP documents and files are located in General Documents tab

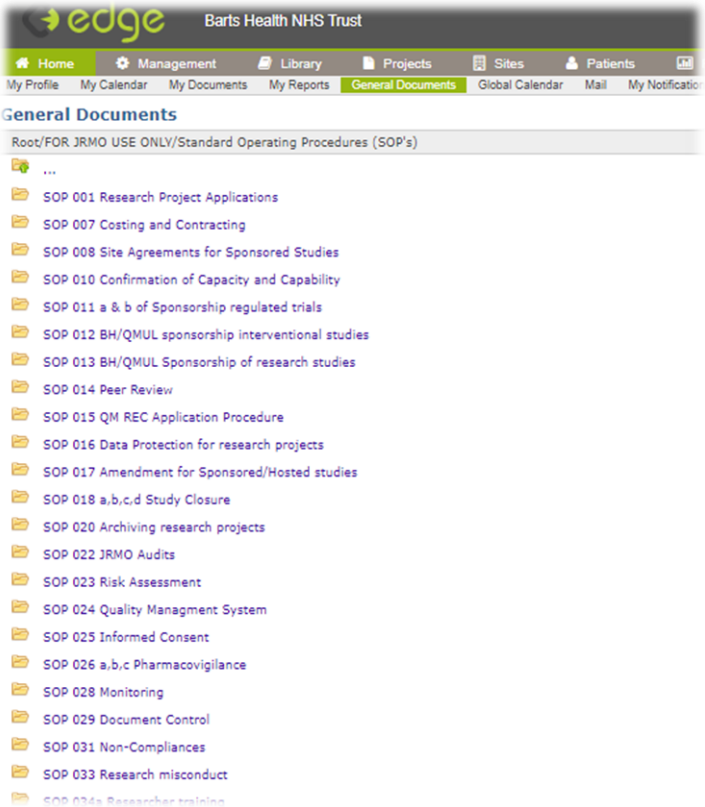
Go to Home > General Documents > FOR JRMO USE ONLY > Standard Operating procedures (SOP's)



Click on 'FOR JRMO USE ONLY' then the below is displayed

Open 'Standard Operating Procedures (SOP's)' folder, then the below will be displayed





Within each folder the documents are read/view only and are version controlled. It is managed and maintained by the QA Manager, for any documents that needs updating or editing please contact the JRMO QA Manager via research.governace@qmul.ac.uk

4. Setting up a study on EDGE

4.1 Locating a project and requesting involvement in a project

Responsible staff	All JRMO staff

4.1.1 Project level

Within the EDGE search page there are 3 levels of Projects:
>Assigned Projects– These are projects which you are currently involved in as an individual. These could be at an administrative level, project management level or user level.

>Organisation Project– This tab denotes the project which your organisation is currently involved in, either as a site or sponsor for the study.

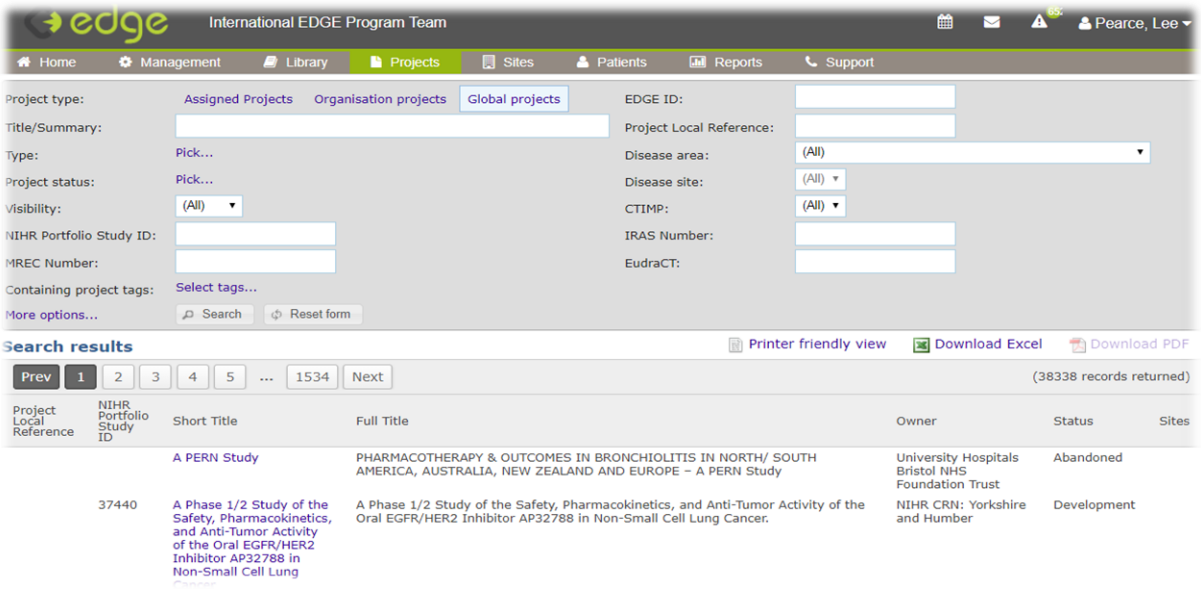
>Global Projects– The last tab is a global list of all studies being managed within the EDGE programme both inside and outside your organisation.

4.1.2 Searching for Projects

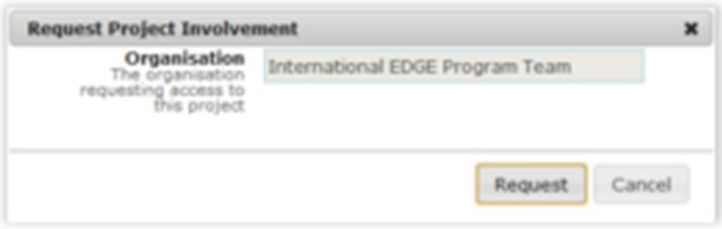
a) To assign a project to your organisation from the **GLOBAL PROJECTS** you will need to first find the project. Within **GLOBAL PROJECTS.** Enter your search criteria into the applicable fields and click **SEARCH**. You can search by:

Title / Description	**Acronym / Title / Description, or part of any**
Type	Whether the Project has commercial involvement or portfolio badging
Project Status	The current status of the project e.g. feasibility, in set up, open, closed – in follow –up
Visibility	(Public / Private) Public Studies are visible to all users nationally of the EDGE system. Private Studies are only visible to the organisation locally which has created them
NIHR Portfolio Study ID	National Institute for Health Research (NIHR) Assigned Unique Identifier (i.e. – UK Clinical Research Network (UKCRN) ID)
MREC Number	Multi-Centre Research Ethics Committees (MREC) Unique identifier for the Project
Chief Investigator (CI)	The investigator with overall responsibility for the research. In a multi-site study, the CI has co-ordinating responsibility for research at all sites. The CI is usually based within the Sponsor Organisation
Owner	Organisation assigned to maintain, update, and amend the record within the EDGE application
Project Phase	Which stage of drug approvals process is the project. E.g. phase 1, 2, 3, or 4
Funder	Project Funding Organisation
Sponsor	Project Sponsoring Organisation
Project Local Reference	The Local Project Identifier as denoted by each organisation locally
Disease Area	Classification of Disease Area e.g. Cancer
Disease Site	Classification of specific site within disease area e.g. Breast
IRAS Number	Integrated Research Application System (IRAS) Ethics approval systems generated number
Principal Investigator (PI)	Local Lead investigator for each site or NHS Trust
Project Site Status	The current status of the project e.g. feasibility, in set up, open, closed – in follow –up

b) Click the name of the study (hyper-linked blue) and it will open high project details page.



c) From there select the **ORGANISATIONS** tab. In the top right corner click the **REQUEST INVOLVEMENT** button. A box will appear with your organisation's requesting details greyed out, if the details are correct, click **REQUEST.**



This will automatically initiate a notification to the host organisation/project owner for them to approve your request for involvement and access to all the project details. When this notification for involvement has been approved by the project owner the project will be listed in your **ORGANISATIONS PROJECTS** tab. Please be aware that this can take up to 24 hours. A message to confirm this approval will be displayed in your **NOTIFICATIONS AREA** on the **HOME SCREEN** and you will receive an automated email. You will now be able to assign yourself as a member of staff to the study as well as your recruiting sites.

Notes and Tips:

- If after 24 hours the Host Organisation or Project Owner has not approved your request for involvement, please contact the Project Owner directly. It is worth noting that ownership of a record always lies with the sponsor, as it is Sponsor's responsibility to keep all the records up to date.

  Once approval has been granted from the project owner, clicking on the **STAFF TAB** will enable you to see all users at other sites working on this project. You are then able to edit/delete information for your users at your own organisation.

- All NIHR, (National Cancer Research Network) NCRN and CRN portfolio adopted projects are already stored in the EDGE **GLOBAL PROJECTS** library. Variations in title, description and acronym can, on occasion, may hinder you locating your project. Please ensure you are searching using the project title or NIHR Portfolio Study ID from the NIHR Portfolio Portal and **not** the title which the project may be referred to locally. http://public.ukcrn.org.uk/Search/Portfolio.aspx

- **Do not** add NIHR Portfolio adopted projects manually as this will create a project duplication within EDGE. If you are unable to find your portfolio adopted projects, please contact the EDGE team via the support tab with the project information including the NIHR Portfolio Study ID

4.2 Adding a new project to EDGE

Responsible staff	**All JRMO Staff**

This guide outlines step by step process for adding a Project manually.

4.2.1 Searching for existing project

When adding any project whether it be Portfolio, Non-Portfolio, Sponsored or Hosted, you should first search (using Research Ethics Committee (REC) ref, IRAS ID, Short title etc.) GLOBAL PROJECTS to ensure it has not already been added by another organisation (for how to search please see Section 2.2).

The EDGE team receive a data cut from the NIHR of all portfolio projects every two weeks which is subsequently uploaded onto EDGE. Therefore, any organisation requiring involvement in a portfolio project is likely to find the record on the GLOBAL PROJECTS list already. If the project is not available on the Global Projects list add the record manually but ensure that you add the NIHR Portfolio ID so that the EDGE team can identify duplicate records during the next portfolio import and merge them. To add the NIHR Portfolio/CPMS ID go to the PROJECT RECORD > ATTRIBUTES > ADD >NIHR PORTFOLIO DATASET > NIHR PORTFOLIO STUDY ID.

4.2.2 Adding a new project

HOME > MANAGEMENT > ADD A NEW PROJECT

When adding a new project, you will be prompted to complete the core details of the study, please see below. At a minimum you would be required to add the following, see below.

Data fields
Short title
Full title
Summary
IRAS Number
Status – Change to Open once sponsorship with condition provided
Phase
Project type
Clinical Trials of Investigational Medicinal Products (CTIMP)
Device
CI
Planned Start Date
Planned End Date
Disease area
Randomisation
Patient Scope
Funder – If funder doesn't exist then you need to contact the local EDGE admin to add the new funder
Sponsor – If sponsor doesn't exist then you need to contact the local EDGE admin to add the new sponsor

4.3 Adding a new site to a project on EDGE

Responsible staff	All JRMO Staff

This guide outlines step by step the process for adding a site to a Project. This guide is for all users of EDGE with management permissions at a project level. If you need to obtain management permissions to use this function, please contact your Local Administrator, See below for contact details: research.governance@qmul.ac.uk.

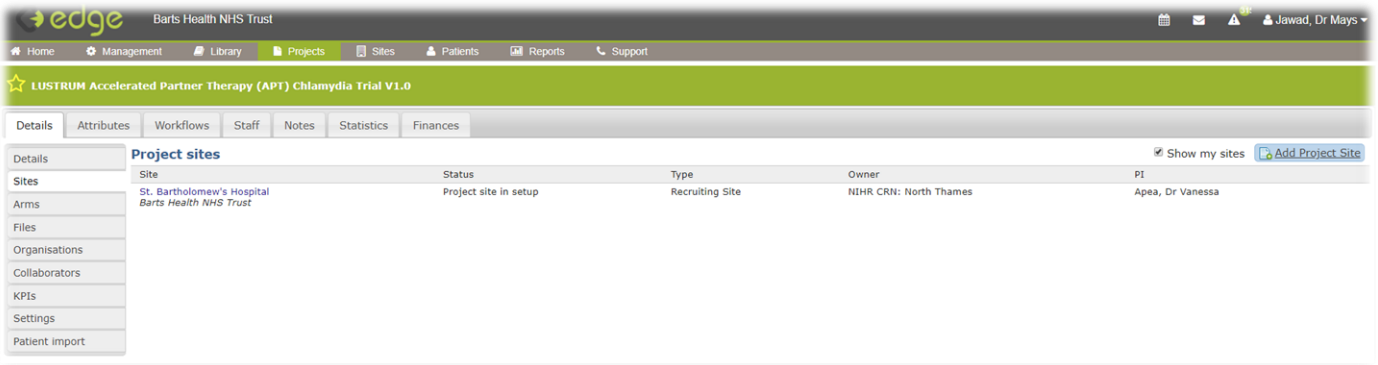
4.3.1 Find the project at the global level

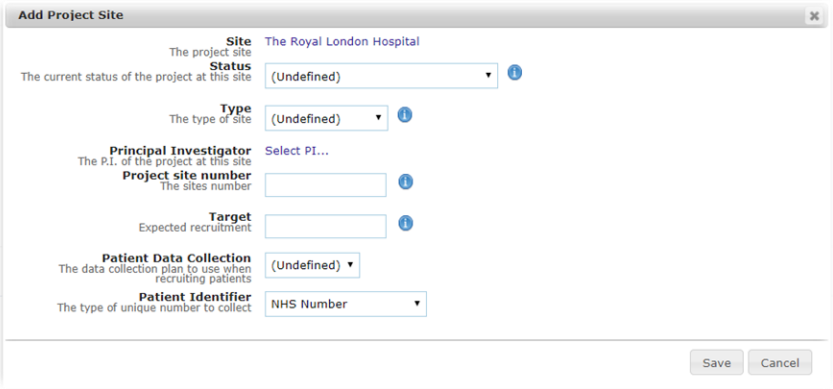
Once you have requested involvement in a project from the GLOBAL REGISTER (see section 2) or uploaded your project manually (see section 5) and assigned yourself as a staff member to the project (see section 3), you will be able to add the sites within your organisation which will be holding the local site data and recruiting patients. Select the applicable project from your ASSIGNED PROJECTS tab.

4.3.2 Adding local site

HOME > PROJECTS > ASSIGNED PROJECTS > (Select Project Name) > SITES

From the green level project details select the SITES tab from the left side and click ADD in the top right corner. The EDGE screen will grey out and display an ADD PROJECT SITE light box which needs to be completed with the site approval information. If you are running this project at multiple sites within your organisation you will need to repeat this process for each site making you sure you add the exact site name (example below is St Bartholomew's but you can also add the Royal London etc.).





Note. If the site that you are looking for does not appear in the drop-down list, then check that it has not been assigned to the project already.

For Portfolio projects being set up by North Thames CRN: email CRN Study support service (sss.crnnorththames@nihr.ac.uk) to add the site on EDGE.

4.4 Sponsorship – Governance Team

Responsible staff	Governance Team

When creating a new project/study on EDGE the following data fields need to be completed for all sponsored studies.

Please make sure that the below fields are completed on EDGE before requesting Trust Authorisation (C&C) from the Governance Operations Manager or Governance Team Leader. If a field is not relevant to the study/process, please move on to next step.

For sponsored studies data entry, attributes and workflows must be completed on the Green/Project level

Data entry fields:

Data fields	Project Level	Responsible staff
Short title	Green/Project Level	RMGO
Full title	Green/Project Level	RMGO
Summary	Green/Project Level	RMGO
IRAS Number	Green/Project Level	RMGO
Status – Change to Open once sponsorship with condition provided	Green/Project Level	RMGO
Phase	Green/Project Level	RMGO
Project type	Green/Project Level	RMGO
CTIMP	Green/Project Level	RMGO
Device	Green/Project Level	RMGO
CI	Green/Project Level	RMGO
Planned Start Date	Green/Project Level	RMGO
Planned End Date	Green/Project Level	RMGO
Disease area	Green/Project Level	RMGO
Randomisation	Green/Project Level	RMGO
Patient Scope	Green/Project Level	RMGO
Funder – If funder doesn't exist then you need to contact the local EDGE admin to add the new funder	Green/Project Level	RMGO
Sponsor – If sponsor doesn't exist then you need to contact the local EDGE admin to add the new sponsor	Green/Project Level	RMGO

List of **Attributes** to be completed by the responsible staff when a study is going through the SPONSORSHIP route:

Attributes	Project Level	Responsible Staff
JRMO Annual Progress Report (APR)	Green/Project Level	Research Administrator
JRMO Confidentiality Advisory Group (CAG) APR	Green/Project Level	RMGO
JRMO Interventional Studies Submission Checklist	Green/Project Level	RMGO
JRMO QMREC	Green/Project Level	RMGO
JRMO Governance Lead (Sponsorship)	Green/Project Level	RMGO
JRMO Regulatory Approval Dates (Sponsorship)	Green/Project Level	RMGO
JRMO Risk Assessment Score	Green/Project Level	RMGO
JRMO Study Category	Green/Project Level	RMGO
JRMO Supporting Department (Sponsor)	Green/Project Level	RMGO

List of **Workflows** to be completed by the responsible staff when a study is going through the SPONSORSHIP route:

Workflows	Project Level	Responsible staff
JRMO Amendment Review Process Sponsored Studies	Green/Project Level	RMGO
JRMO Closure – Sponsor Non-Regulated	Green/Project Level	RMGO/ Research Administrator
JRMO Sponsor APR- Non-Regulated	Green/Project Level	RMGO
JRMO Sponsor CAG APR- Non-Regulated	Green/Project Level	RMGO
JRMO Sponsorship Review- Interventional Studies	Green/Project Level	RMGO
JRMO Sponsorship Review- Regulated Studies	Green/Project Level	RMGO
JRMO Sponsorship Review- Research Studies	Green/Project Level	RMGO

Reminder – Remember to use the notes section for any problems with the set up / delays.

If Confirmation of Capacity and Capability is required to be issued, then please follow section 4.7 Confirmation of Capacity and Capability

Please upload relevant documents and files in the appropriate folders in the Green/Project level, refer to section 2.4 Document/file upload management in EDGE.

For a full list of all Attribute set contents please visit Appendix 2.1
For a full list of all Workflow contents please visit Appendix 3.1

4.5 Sponsorship – GCP and Compliance Team

Responsible staff	GCP and Compliance Team

The GCP and compliance team are involved in all internally sponsored MHRA regulated studies which are undertaken at Barts Health or Queen Mary. They are responsible for completing the following attribute sets and workflows at Green/Project Level.

Attributes and workflows completed when a study is going through the SPONSORSHIP route:

Attributes	Project Level	Responsible Staff
JRMO GCP Dataset	Green/Project Level	GCP Manager or Clinical Trials Monitor
JRMO GCP Lead (sponsorship)	Green/Project Level	GCP Manager or Clinical Trials Monitor
JRMO MHRA Risk Assessment Score	Green/Project Level	GCP Manager/ RMGO
JRMO MHRA Sponsor Dossier Attribute set (Project)	Green/Project Level	GCP and compliance team

Workflows	Project Level	Responsible staff member
JRMO Closure – Sponsor Regulated	Green/Project Level	GCP Manager
JRMO GCP Manager Checklist Part 1	Green/Project Level	GCP Manager
JRMO GCP Manager Checklist Part 2	Green/Project Level	GCP Manager
JRMO GCP Manager's Review of Amendments	Green/Project Level	GCP Manager
JRMO Sponsor CAG APR- Non-Regulated	Green/Project Level	RMGO/ Governance Team Leader
JRMO Sponsor APR- Regulated studies	Green/Project Level	GCP Manager
JRMO Summary Monitoring Report	Green/Project Level	Clinical Trials Monitor
JRMO Development Safety Update Report (DSUR)	Green/Project Level	GCP Manager

Attributes completed when a study is going through the HOSTED route:

Attributes	Project Level	Responsible Staff
JRMO MHRA Hosted Dossier Attribute set (Site)	Red/Site Level	Governance Team

For a full list of all Attribute set contents please visit Appendix 2.1
For a full list of all Workflow contents please visit Appendix 3.1

4.6 GCP and Compliance Team process completed on ReDA

Responsible staff	**GCP and Compliance Team**

The GCP team are currently using ReDA to capture items EDGE cannot.

New Study Set up CTIMP studies.
The GCP manager or delegate will set up a study at any point after funding confirmed before Sponsorship is given.
The minimal data set for a new study on **ReDA** are the following (not limited to the below).

- Short Title
- Full Title
- IRAS ID
- ReDA No
- REC no
- European Union Drug Regulating Authorities Clinical Trials Database (EUDRA-CT)
- Study Status
- EDGE ID
- CI
- Sponsor

Completed on ReDA:

	-		
Monitoring visits	**ReDA:** - Finance tab – monitoring visits		GCP Clinical Trials Monitors
Pharmacovigilance & Pregnancy reports	**ReDA:** - Post Approval tab		GCP Clinical Trials Monitors
End of Trial (EOT) and Clinical Study Report (CSR) reminders	- **ReDA:** Governance tab		GCP Clinical Trials Monitors
DSUR and APR reminders	**ReDA:** - Governance tab		GCP Clinical Trials Monitors

4.7 Confirmation of Capacity and Capability (C&C)

Responsible staff	**RMGO**

A C&C is issued if Barts Health has the capacity and capability to deliver all study activities for a study

For HOSTED studies please complete the hosted Site/Red level data entry fields and the relevant attributes and workflows below.

C&C **data fields** to be completed by the responsible staff:

Data fields	Project Level	Responsible staff
Principle investigator - If PI doesn't exist then you need to request a PI account from your Local EDGE administrator	Red/Site Level	RMGO
Site Target	Red/Site Level	RMGO
Status - *RMGO completes this at hosted level*	Red/Site Level	RMGO
Approval process – Select appropriate process from dropdown list	Red/Site Level	RMGO
Capacity and Capability	Red/Site Level	RMGO
Date site invited	Red/Site Level	RMGO
Date site selected	Red/Site Level	RMGO
Date site confirmed by sponsor – *to be completed once CC is issued*	Red/Site Level	RMGO
Date site confirmed - *to be completed once C&C is issued*	Red/Site Level	RMGO
Non conformation status - *to be completed once C&C is issued*	Red/Site Level	RMGO
Date of non-conformation – *to be completed once C&C is issued*	Red/Site Level	RMGO
Recruitment end date (Planned)	Red/Site Level	RMGO
Recruitment end date (Actual)	Red/Site Level	RMGO
Key staff - can be selected from the staff tab	Red/Site Level	RMGO

Attributes to be complete for hosted studies:

Attributes	Project Level	Responsible Staff
JRMO Archiving	Red/Site Level	TBC
JRMO MHRA Hosted Dossier Attribute set (Site)	Red/Site Level	RMGO/ Governance Team Leader
JRMO Hosted Non-Commercial CTIMP	Red/Site Level	Governance Team
JRMO Governance Lead (Capacity & Capability)	Red/Site Level	RMGO
JRMO Misc (Site) *	Red/Site Level	RMGO
JRMO Regulatory Approval Dates (Hosted)	Red/Site Level	RMGO
JRMO Supporting Department (Hosted)	Red/Site Level	RMGO
JRMO Trust Authorisation	Red/Site Level	Governance Team Leader or R&D Governance Operations manager

*This is applicable to JRMO staff who complete the work. For NIHR portfolio studies study set up (capacity and capability) is completed by the JRMO Governance section and in such cases the Trust authoriser (Governance Team Leader or R&D Governance Operations manager) will ensure that these are captured.

Workflows to complete for hosted studies:

Workflows	Project Level	Responsible staff member
JRMO Site Capacity and Capability Review	Red/Site Level	RMGO
JRMO Amendment Review Process Hosted Studies	Red/Site Level	RMGO

Please upload finalised documents and files in the appropriate folders in the site level, refer to section 2. For a breakdown of all required files that needs to be uploaded refer to 2.4.

For a full list of all Attribute set contents please visit Appendix 2.1
For a full list of all Workflow contents please visit Appendix 3.1

4.8 Trust Authorisation Checklist

Responsible staff	Governance Operations Manager/Governance Team Leader

Governance Operations Manager/Governance Team Leader- please make sure that the below data fields, attributes, and workflows are completed on EDGE before providing Trust Authorisation. If a field is not relevant to the study/process, please move on to next step.

- For sponsored studies – data fields, attributes and workflows must be completed on the Green/Project level
- For hosted studies data entry, attributes and workflows must be completed on the Red/Site level

All Trust Authorisation requests can vary, but in all cases the following documents need to be available or completed: Assess, Arrange, Confirm (ACC) form, details about funding, supporting departments, Pharmacy Greenlight, timelines and delay notes (especially pharmacy, imaging, delay from date site selected etc.), protocol, HLO9 notes (added by CRN North Thames – Study Support Services), JRMO Misc attribute as well as JRMO Trust authorisation attribute. "Clarification required" under the Trust authorisation attribute should be kept live with comments. Comments always starts with initials and the clarification / update i.e. "SU – Pharmacy greenlight not approved"

If certain sections are incomplete, please liaise with the relevant colleagues to complete their required sections or data entry fields.

What to quality check at the different scenarios presented below, for a list of data fields to be completed please refer to 4.6

Scenario 1:

- Barts Health as sponsor and Barts Health as a site or Queen Mary as the sponsor and Barts Health as a site.

  Please check if sponsorship level and hosted level data fields are completed, files uploaded, attribute and workflows exist and are completed. Notes about any delays added.

Scenario 2:

- If Barts Health and Queen Mary do not sponsor a study the Governance Operations Manager/Governance Team Leader do not need to quality check the Green/Project level in detail as we are hosting the study but host the study then they need to quality check Red/Site level see section 4.6 Confirmation of Capacity and Capability for data fields, files uploaded, attributes and workflows list. Notes about any delays added.

Scenario 3:

- Barts Health and Queen Mary acting as a Participating Identification Centre (PIC) site.
  Please check if sponsorship level and hosted level data fields are completed, files uploaded, attribute and workflows exist and are completed Notes about any delays added.

The Trust authoriser to check if relevant staff members have completed the correct data fields in order to proceed to the next stage i.e. provide C&C

List of data fields to check if completed or not: SPONSORSHIP route

Data fields on Green/Project Level
Short Title
Full title
Summary
IRAS Number
Status – *RMGO completes this at sponsorship level*
Phase
Project type
CTIMP
Device
CI
Planned Start Date
Planned End Date
Disease area
Randomisation
Patient Scope
Funder
Sponsor

Attributes and **Workflows** to be checked by the Operations Manager/Governance Team Leader before providing trust authorisation for a Barts Health or Queen Mary site when a study goes through the SPONSORSHIP route.

Attributes	**Project Level**	**Responsible Staff**
JRMO GCP Lead (sponsorship)	Green/Project Level	GCP Manager or Clinical Trials Monitor (completed if CTIMP)
JRMO MHRA Risk Assessment Score	Green/Project Level	GCP Manager (completed if CTIMP)
JRMO MHRA Sponsor Dossier Attribute set (Project)	Green/Project Level	GCP Manager (completed if CTIMP)
JRMO Interventional Studies Submission Checklist	Green/Project Level	Governance Team
JRMO QMREC	Green/Project Level	RMGO
JRMO Governance Lead (Sponsorship)	Green/Project Level	RMGO
JRMO Regulatory Approval Dates (Sponsorship)	Green/Project Level	RMGO
JRMO Risk Assessment Score	Green/Project Level	RMGO
JRMO Study Category	Green/Project Level	RMGO
JRMO Supporting Department (Sponsored)	Green/Project Level	RMGO

Workflows	Project Level	Responsible staff member
JRMO Amendment Review Process Sponsored Studies	Green/Project Level	RMGO
JRMO GCP Manager Checklist Part 1	Green/Project Level	GCP Manager
JRMO GCP Manager Checklist Part 2	Green/Project Level	GCP Manager
JRMO Sponsorship Review- Interventional Studies	Green/Project Level	RMGO
JRMO Sponsorship Review- Regulated Studies	Green/Project Level	RMGO
JRMO Sponsorship Review- Research Studies	Green/Project Level	RMGO

List of **data fields** to check if completed or not: HOSTED route

Data fields Site/Red level
Principle investigator - If PI doesn't exist then you need to request a PI account from your Local EDGE administrator
Site Target
Site – *study site name e.g. The Royal London Hospital*
Patient data collection plan
Status – *RMGO completes this at hosted level*
Approval process – *Select appropriate process from dropdown list*
Capacity & Capability assessment required?
Date site invited
Date site selected
Date site confirmed by sponsor – *to be completed once C&C is issued*
Date site confirmed - *to be completed once C&C is issued*
Site Initiation Visit (SIV) Date – *if available*
Open to recruitment date – *if available*
Recruitment end date (Planned)
Recruitment end date (Actual)
Key staff - can be selected from the staff tab

Attributes and workflows to be checked by Governance Operations Manager or Governance Team Leader before authorising trust authorisation when a study goes through the **HOSTED** route.

Attributes	Project Level	Responsible Staff
JRMO MHRA Hosted Dossier Attribute set (Site)	Red/Site Level	Governance Team
JRMO Hosted Non-Commercial CTIMP	Red/Site Level	GCP Team / RMGO
JRMO Governance Lead (Capacity & Capability)	Red/Site Level	RMGO
JRMO Misc (Site) *	Red/Site Level	RMGO
JRMO Regulatory Approval Dates (Hosted)	Red/Site Level	RMGO
JRMO Supporting Department (Hosted)	Red/Site Level	RMGO
JRMO Pre-Trust Authorisation	Red/Site Level	Governance Team Leader or R&D Governance Operations Manager

Workflows	Project Level	Responsible staff member
JRMO Site Capacity and Capability Review	Red/Site Level	RMGO
JRMO Amendment Review Process Hosted Studies	Red/Site Level	RMGO

For a full list of all Attribute set contents please visit Appendix 2.1
For a full list of all Workflow contents please visit Appendix 3.1

5. Barts Health Finance/Costings Teams

5.1 Announcements – Pre-Award Costings and Contracts Team

Responsible staff	**Barts Health Pre-Award Costings & Contracts Team**

This is completed after the C&C is issued by the JRMO Governance Team or CRN study support services for a study.

- When processing announcements please complete the following attribute set on EDGE.
- Files and documents should be uploaded to EDGE in the relevant folders, refer to section 2.4

Attribute	Project Level	Responsible Staff
JRMO Pre-Award Finance	Red/Site Level	Pre-Award Costings & Contracts Team

For a full list of all Attribute set contents please visit Appendix 2.1

5.2 Financial management – Barts Health Post-Award Finance Team

Responsible staff	**Barts Health Post-Award Finance Team**

This is completed once an announcement is created by the Barts Health Pre-Award Team.

- When raising a budget code or invoicing for a research activity please complete the following attribute set on EDGE.
- Files and documents should be uploaded to EDGE in the relevant folders, refer to section 2.4

Attribute	Project Level	Responsible Staff
JRMO Post-Award Finance	Red/Site Level	Post-Award Finance Team

For a full list of all Attribute set contents please visit Appendix 2.1

6. Study Progress on EDGE

6.1 Amendments

Responsible staff	RMGO

For all SPONSORED studies and HOSTED studies amendment related activities (including regulated studies) please follow *SOP 017a Sponsored studies – JRMO staff* and *SOP 017b Hosted studies,* which can be found on EDGE- refer to section *2. Or* Go to Home > General Documents > FOR JRMO USE ONLY > Standard Operating Procedures (SOP's)

Amendment Workflows:

If an amendment results to a change please update relevant data fields on EDGE accordingly depending on the amendment i.e. change of PI or CI, change of recruitment target, change of study closure date etc.

Workflows to be completed by the responsible staff when a study is going through the SPONSORSHIP route.

Workflows	Project Level	Responsible staff member
JRMO Amendment Review Process Sponsored Studies	Green/Project Level	RMGO
JRMO GCP Manager's Review of Amendments	Green/Project Level	GCP Manager

Workflows to be completed by the responsible staff when a study is going through the HOSTED route.

Workflows	Project Level	Responsible staff member
JRMO Site Capacity and Capability Review	Red/Site Level	RMGO
JRMO Amendment Review Process Hosted Studies	Red/Site Level	RMGO

Once an amendment has been approved please upload relevant amendment related files into the correct level:

- SPONSORED amendment files uploaded to Green/Project level
- HOSTED amendment files uploaded to Red/Site level

NOTE: No attributes for amendment activities on EDGE

For a full list of all Workflow contents please visit Appendix 3.1

6.2 Audit Section

Responsible staff	Clinical Research Auditor

The Clinical Research Auditor is responsible to update the **attribute** set on the Green/Project level.

Attribute	Project Level	Responsible Staff
JRMO Audit	Green/Project Level	Clinical Research Auditor

All files related to Audit can be uploaded to EDGE on the relevant level.

NOTE: No workflows for audit activities on EDGE

For a full list of all Attribute set contents please visit Appendix 2.1

6.3 Progress Reports- APRs, DSURs, CAGs

Responsible staff	RMGO / Research Administrator / GCP Manager

Attributes to be completed on SPONSORSHIP level

Attributes	Project Level	Responsible Staff
JRMO APR	Green/Project Level	Research Administrator
JRMO CAG APR	Green/Project Level	RMGO

Workflows to be completed on SPONSORSHIP level

Workflows	Project Level	Responsible staff member
JRMO Sponsor APR- Non-Regulated	Green/Project Level	RMGO
JRMO Sponsor CAG APR- Non-Regulated	Green/Project Level	RMGO
JRMO Sponsor APR- Regulated studies	Green/Project Level	GCP Manager
JRMO DSUR	Green/Project Level	GCP Manager

All files related to Progress Reports- APRs, DSURs, CAGs can be uploaded to EDGE on the relevant level.

For a full list of all Attribute set contents please visit Appendix 2.1
For a full list of all Workflow contents please visit Appendix 3.1

6.4 Summary Monitoring Reports

Responsible staff	Clinical Trials Monitor or Delegate

Workflows	Project Level	Responsible staff member
JRMO Summary Monitoring Report	Green/Project Level	GCP Manager or Clinical Trials Monitor

NOTE: No attributes for quality monitoring report activities on EDGE

For a full list of all Workflow contents please visit Appendix 3.1

6.5 MHRA Dossier (Sponsored)

Responsible staff	GCP Manager

Attributes to be completed when a study is going through the SPONSORSHIP route

Attributes	Project Level	Responsible Staff
JRMO MHRA Risk Assessment Score	Green/Project Level	GCP Manager
JRMO MHRA Sponsor Dossier Attribute set (Project)	Green/Project Level	GCP Manager

6.6 MHRA Dossier (Hosted)

Responsible staff	RMGO/ Governance Team Leader

Attributes to be completed when a study is going through the HOSTED route

Attributes	Project Level	Responsible Staff
JRMO MHRA Hosted Dossier Attribute set (Site)	Red/Site Level	RIL/ RMGO/ Research Administrator/ Governance Team Lead

NOTE: No workflows for MHRA activities on EDGE

For a full list of all Attribute set contents please visit Appendix 2.1

7. End of Study Activities

7.1 Study Closure – Process for JRMO staff

Responsible staff	RMGO / Research Administrator / GCP Manager

Once end of study submission from the CI or delegate received then update EDGE status to "Closed" and enter end of trial date on EDGE as the date on the end of study form.

If no EDGE record is available for the study, a record needs to be created for the study. Refer to section 4.2

Once the final report acknowledgement has been received, complete the relevant closure workflow on EDGE.

Workflows to be completed on the Green/Project Level.

Workflows	Project Level	Responsible staff member
JRMO Closure – Sponsor Non-Regulated	Green/Project Level	RMGO/ Research Administrator
JRMO Closure – Sponsor Regulated	Green/Project Level	GCP Manager

NOTE: No attributes for MHRA activities on EDGE

For a full list of all Workflow contents please visit Appendix 3.1

7.2 Archiving

Responsible staff	TBC

We need to make sure that EDGE is updated when SPONSORED studies have finished.

To archive a study on EDGE please complete the below attribute set and upload all related documents and files to EDGE in the relevant project level, refer to section 2.4

Attribute to be completed:

Attribute	Project Level	Responsible Staff
JRMO Archiving	Green/Project Level	Office Manager

NOTE: No workflows for archiving activities on EDGE

For a full list of all Attribute set contents please visit Appendix 2.1

Appendix 1 – Roles and Responsibilities

Roles	Responsible staff
Users, access, and accounts	
1.1 Adding a new user account to EDGE	Research Information Lead/ Performance Team
1.2 Process for approval of new admin users	Research Information Lead/ Performance Team
1.3 Assigning a user or team to EDGE	Research Information Lead/ Performance Team
1.4 Confidentiality agreement if permission is given to grant admin user access outside the JRMO	Research Information Lead/ Performance Team
1.5 Creating and adding a team on EDGE	All JRMO staff
Adding and using Attributes, Workflows, and documents	
2.1 Adding and using Attributes	All JRMO staff
2.2 Adding and using Workflows	All JRMO staff
2.3 Document/file upload management in EDGE	All JRMO staff
2.4 Documents to be uploaded to EDGE	All JRMO staff
2.5 Documents to be uploaded to EDGE	All JRMO staff
Standard Operating Procedures (SOP) documents on EDGE	
3.1 SOP files on EDGE	Quality Assurance (QA) Manager
Setting up a study on EDGE	
4.1 Locating a project and requesting involvement in a project	All JRMO staff
4.2 Adding a new project to EDGE	All JRMO staff
4.3 Adding a new site to a project on EDGE	All JRMO staff
4.4 Sponsorship – Governance Team	Governance Team
4.5 Sponsorship – GCP and Compliance Team	GCP and Compliance Team
4.6 Confirmation of Capacity and Capability	RMGO
4.7 Trust Authorisation check list	Governance Operations Manager/ Governance Team Leader
Barts Health Pre-Award Costings and Contract Team / Barts Health Post-Award Finance Team	
5.1 Announcements	Barts Health Pre-Award Costings and Contract Team
5.2 Financial management	Barts Health Post-Award Finance Team
Study Progress on EDGE	
6.1 Amendments	RMGO
6.2 Audit section	Clinical Research Auditor
6.3 Progress Reports- APRs, DSURs, CAGs	RMGO / Research Administrator / GCP Manager
6.4 Quarterly Monitoring Reports	Clinical Trials Monitor or Delegate
6.5 MHRA Dossier (Sponsored)	GCP Manager
6.6 MHRA Dossier (Hosted)	RIL/ RMGO/ Research Administrator/ Governance Team Lead
End of study Activities	
7.1 Study Closure	RMGO / Research Administrator / GCP Manager
7.2 Archiving	Office Manager

Appendix 2: Attributes table

Attributes to be completed when a study is going through the SPONSORSHIP route

Attributes	Project Level	Responsible Staff
1- **JRMO APR**	Green/Project Level	Research Administrator
2- **JRMO CAG APR**	Green/Project Level	RMGO
3- **JRMO Audit**	Green/Project Level	Clinical Research Auditor
4- **JRMO GCP Dataset**	Green/Project Level	GCP Manager or Clinical Trials Monitor
5- **JRMO GCP Lead (sponsorship)**	Green/Project Level	GCP Manager or Clinical Trials Monitor
6- **JRMO MHRA Risk Assessment Score**	Green/Project Level	GCP Manager
7- **JRMO MHRA Sponsor Dossier Attribute set (Project)**	Green/Project Level	GCP Manager
8- **JRMO Interventional Studies Submission Checklist**	Green/Project Level	Governance team
9- **JRMO QMREC**	Green/Project Level	RMGO
10- **JRMO Governance Lead (Sponsorship)**	Green/Project Level	RMGO
11- **JRMO Regulatory Approval Dates (Sponsorship)**	Green/Project Level	RMGO
12- **JRMO Risk Assessment Score**	Green/Project Level	RMGO
13- **JRMO Study Category**	Green/Project Level	RMGO
14- **JRMO Supporting Department (Sponsored)**	Green/Project Level	RMGO
15- **JRMO Archiving**	Green/Project Level	Governance section / Post-Award Finance Team / Archivist

Attributes to be completed when a study is going through the HOSTED route

Attributes	Project Level	Responsible Staff
16- **JRMO MHRA Hosted Dossier Attribute set (Site)**	Red/Site Level	RMGO/ Governance Team Leader
17- **JRMO Hosted Non-Commercial CTIMP**	Red/Site Level	Governance team
18- **JRMO Governance Lead (Capacity & Capability)**	Red/Site Level	RMGO
19- **JRMO Misc (Site) ***	Red/Site Level	RMGO
20- **JRMO Regulatory Approval Dates (Hosted)**	Red/Site Level	RMGO
21- **JRMO Supporting Department (Hosted)**	Red/Site Level	RMGO
22- **JRMO Trust Authorisation**	Red/Site Level	Governance Team Leader or R&D Governance Operations manager

*This is applicable to JRMO staff who complete the work. For most NIHR portfolio studies study set up (capacity and capability) is completed by the North Thames CRN and in such cases the Trust authoriser (Governance Team Leader or R&D Governance Operations manager) will ensure that most of these are captured.

Attributes to be completed by the Research Information Lead/ Performance team

Attributes	Project Level	Responsible Staff
23- **JRMO NIHR PID**	Red/Site Level	Research Information Lead/ Performance team

Attributes to be completed by the Post-Award Finance team & Pre-Award Finance team

Attributes	Project Level	Responsible Staff
24- **JRMO Post-Award Finance**	Red/Site Level	Post-Award Finance Officer
25- **JRMO Pre-Award Finance**	Red/Site Level	Pre-Award Costings & Contracts Officer

Attributes to be completed by the Governance section on Red/Site Level and Green/Project Level

Attributes	Project Level	Responsible Staff
26- **JRMO COVID-19 Study status (Hosted)**	Red/Site Level	Governance section
27- **JRMO COVID-19 Study status (Sponsored)**	Green/Project Level	Governance section

ReDA to EDGE migration attribute set - The migration attributes exist for migration purposes only; they are strictly not to be used.

Attributes	Project Level	Responsible Staff
28- **Barts Migration – Governance**	Red/Site Level	N/A
29- **Barts Migration – GCP**	Green/Project Level	N/A
30- **Barts Migration – Finance**	Red/Site Level	N/A
31- **Barts Migration – Investigator**	Red/Site Level	N/A

1- JRMO APR
Responsible staff: Research Administrator
Green/Project Level

APR 1 - Date requested	Date
APR 1 - Date received	Date
APR 2 - Date requested	Date
APR 2 - Date received	Date
APR 3 - Date requested	Date
APR 3 - Date received	Date

2- JRMO CAG APR
Responsible staff: RMGO
Green/Project Level

CAG APR 1 - Date requested	Date
CAG APR 1 - Date received	Date
CAG APR 2 - Date requested	Date
CAG APR 2 - Date received	Date
CAG APR 3 - Date requested	Date
CAG APR 3 - Date received	Date

3- JRMO Audit
Responsible staff: Auditor
Green/Project Level

Audit reference	Text
Audit date	Date
Audit note	Memo
Audit certificate issued	Date

4- JRMO GCP Dataset
Responsible staff: GCP Manager or Clinical Trials Monitor
Green/Project Level

Is Primary End Point Lab Based? : YES/NO/Not Set	Lookup	Dropdown	Yes
			No
			Not set
Lab for Primary End Point (drop down):	Lookup	Dropdown	- External
			- Queen Mary
			- Barts Health Cellular Pathology
			- Barts Health Clinical Biochemistry
			- Barts Health Cytogenetics
			- Barts Health Haematology
			- Barts Health Immunology
			- Barts Health Microbiology
			- Barts Health Virology
			- Barts Health (Not Specified)

			- Institute of Cancer Research (ICR) Laboratories
			- Other (enter details in Comments)
Number of Primary sample per patient:	Memo		
Primary End Points – additional comments:	Memo		
Is Secondary End Point Lab Based? : YES/NO/Not Set	Lookup	Dropdown	Yes
			No
			Not set
Lab for Secondary End Point (drop down):	Lookup	Dropdown	- External
			- Queen Mary
			- Barts Health Cellular Pathology
			- Barts Health Clinical Biochemistry
			- Barts Health Cytogenetics
			- Barts Health Haematology
			- Barts Health Immunology
			- Barts Health Microbiology
			- Barts Health Virology
			- Barts Health (Not Specified)
			- ICR Laboratories
			- Other (enter details in Comments)
Number of Secondary sample per patient:	Memo		
Secondary End Points – additional comments	Memo		
Other Labs in use	Memo		
Recruitment No: Total:	Numeric		
Recruitment No: UK:	Numeric		
Recruitment No: Barts Health:	Numeric		
Safety: No. of Serious Adverse Event (SAE):	Numeric		
Safety: No. of Suspected Unexpected Serious Adverse Reaction (SUSAR):	Numeric		
Number of sites: Total Open:	Numeric		
Number of sites: UK Open:	Numeric		
Number of sites: Total Closed:	Numeric		
Vendor name 1	Memo		
Vendor service 1	Memo		
Vendor status 1	Lookup	Dropdown	- Known Supplier
			- Unknown Supplier
			- Preferred Supplier
			- Unfavoured Supplier
Vendor name 2	Memo		
Vendor service 2	Memo		
Vendor status 2	Lookup	Dropdown	- Known Supplier
			- Unknown Supplier

			- Preferred Supplier
			- Unfavoured Supplier
Vendor name 3	Memo		
Vendor service 3	Memo		
Vendor status 3	Lookup	Dropdown	- Known Supplier
			- Unknown Supplier
			- Preferred Supplier
			- Unfavoured Supplier
Current Reference Safety Information (RSI)	Memo		

5- JRMO GCP Lead (sponsorship)
Responsible staff: GCP Manager or Clinical Trials Monitor
Green/Project level

GCP Manager	Lookup	Dropdown	Marie-Claire Good
			Robert Hughes
GCP Monitor	Lookup	Dropdown	Adam Mold

6- JRMO MHRA Risk Assessment Score
Responsible staff: GCP Manager
Green/Project level

MHRA Risk Assessment Score	Text		
MHRA Risk classification	Lookup	Dropdown	Less than 5 = Low Risk
			5 to 9 = Moderate Risk
			10 to 14 = High Risk
			15 or More = Unacceptable
MHRA Comments (Team Leader/GCP Manager)	Memo		

7- JRMO MHRA Sponsor Dossier Attribute set (Project)
Responsible staff: GCP Manager
Green/Project level

Risk Adaption Category	Lookup	Dropdown	A
			B
			C
Investigational Medicinal Product (IMP) Names	Memo		
IMP Status in the UK (answer for each IMP)	Lookup	Dropdown	Unlicensed (anywhere)
			UK Unlicensed (not licensed in the UK, but is licensed elsewhere)
			Unlicensed Use (UK Licence, but used in new indication)
			Licensed Use
Is IMP assembled under exception 37	Lookup	Dropdown	Yes
			No
If under exemption 37, is the IMP sterile?	Lookup	Dropdown	Yes
			No
			N/A
Number of Subjects Recruited total	Numeric		

Number of Subjects Recruited (UK)	Numeric		
Number of sites Total	Numeric		
Number of Sites (UK)	Numeric		
Trial Status (UK)	Lookup	Dropdown	Planning - Funded
			Planning - Submitted to JRMO
			Planning - Sponsorship issued
			Live - to requirement
			Live - In follow up
			Completed - EOT submitted
			Early termination -EOT submitted
			Reported- CSR submitted
Trial Start Date (UK)	Date		
Actual Trial End Date (UK)	Date		
Actual Trial End Date (Global)	Date		
Date of Clinical Study Report (if applicable)	Date		
Reason for Termination/Temporary Halt	Memo		
Number of SAEs (UK)	Numeric		
Number of SUSARs (UK)	Numeric		
Therapeutic area	Memo		
Who manages the Trial? - Sponsor Only	Memo		
Sponsor Tasks Delegated to others	Memo		
Trial for regulatory MA submission?	Lookup	Dropdown	Yes
			No
Is this trial in relation to an RMP?	Lookup	Dropdown	Yes
			No
MA Submission Reference Number (if applicable)	Memo		
Trial Master File (TMF) type	Lookup	Dropdown	Paper
			Electronic
			Hybrid
Location of TMF	Memo		
Name of eTMF system (if applicable)	Memo		
Case Report Form (CRF)/diaries systems (names and versions)	Memo		
Interactive Response Technology (IRT) (Name and version)	Memo		
Pharmacovigilance (PV) system used (Name and version of database)	Memo		
Primary or secondary endpoint Lab based?	Lookup	Dropdown	Yes
			No
Lab for secondary endpoint	Memo		
Lab stopping criteria	Memo		
Type of monitoring	Lookup	Dropdown	On site
			Central only
			Both

8- JRMO Interventional Studies Submission Checklist
Responsible staff: RMGO
Green/Project site level

Will Barts Health NHS Trust be a site?	Lookup	Dropdown	

Specify site locations	Lookup	Dropdown	Royal London Hospital
			St Bartholomew's Hospital
			Mile End Hospital
			Newham University Hospital
			Whipps Cross University Hospital
			Queen Mary University of London
Have you discussed with Governance team?	Lookup	Dropdown	Yes
			No
External vendors or collaborators (Please specify)	Memo		
Costings officer	Memo		
On NIHR Portfolio?	Lookup	Dropdown	Yes/No
IRAS form	Lookup	Dropdown	Yes/No
Cover letter to REC	Lookup	Dropdown	Yes/No
Conditions of Sponsorship	Lookup	Dropdown	Yes/No
Research Protocol	Lookup	Dropdown	Yes/No
Participant Information Sheet(s)	Lookup	Dropdown	Yes/No
Consent form(s)	Lookup	Dropdown	Yes/No
Scientific peer review	Lookup	Dropdown	Yes/No
Departmental Authorisation	Lookup	Dropdown	Yes/No
Letter from a Statistician	Lookup	Dropdown	Yes/No
JRMO-completed costings	Lookup	Dropdown	Yes/No
Funding / Award letter	Lookup	Dropdown	Yes/No
Curriculum Vitae of CI	Lookup	Dropdown	Yes/No
Evidence of training for CI	Lookup	Dropdown	Yes/No
HRA Statement of Activities	Lookup	Dropdown	Yes/No
HRA Schedule of Events	Lookup	Dropdown	Yes/No
Validated questionnaire	Lookup	Dropdown	Yes/No

9- JRMO QMREC
Responsible staff: RMGO
Green/Project level

Does this study require QMREC Dual review?	Lookup	Dropdown	QMREC Dual Review – Yes
			Other *(comment)*

10- JRMO Governance Lead (Sponsorship)
Responsible staff: RMGO
Green/Project level

Governance Lead	Lookup	Dropdown	Shafa Ullah
			Lilima Begum
			Sandra Burke
			Safia Ornelas
			Raheemah Akhtar
			Marria Khan
			Nadia Rahman
			Philip Diamond
	Lookup	Dropdown	Yes

General Data Protection Regulation (GDPR) Compliant			No
			N/A
Is this project registered prior to sponsorship?	Lookup	Dropdown	Yes
			No
Publication Database	Lookup	Dropdown	ClinicalTrial.gov
			EudraCT
			ISRCTN
			N/A
Registration date	Date		
Registration ID	Text		
Date become Live/Public	Date		

11- JRMO Regulatory Approval Dates (Sponsorship)
Responsible staff: RMGO
Green/Project level

HRA Approval Date	Date		
REC Approval Date	Date		
MHRA Approval Date	Date		
CAG Approval Date	Date		
Student Project	Lookup	Dropdown	Yes
			No
Classification	Lookup	Dropdown	Interventional Studies
			MHRA Regulated Studies
			Research Studies
Division	Lookup	Dropdown	1
			2
			3
			4
			5
			6
Speciality	Lookup	Dropdown	Cancer
			Generic Health Relevance
			Cardiovascular
			Oral and Gastrointestinal
			Reproductive Health and Childbirth
			Inflammatory and Immune System
			Injuries and Accidents
			Infection
			Neurological Disorders
			Metabolic and Endocrine
			Dementia's and Neurodegenerative Diseases
			Renal and Urogenital
			Mental Health
			Blood
			Surgery
			Musculoskeletal

			Paediatrics
			Pain
			Diabetes
			Congenital Disorders
			Respiratory
			Perioperative Medicine
			Gastroenterology
			Gynaecology
			Dental
			Hepatology
Date of Submission by Researcher	Date		
Submission Received by Governance Officer	Date		
Valid Submission	Date		
Initial Feedback Sent (Researcher)	Date		
First CI/PI Response	Date		
Last Response from CI/PI	Date		
Sponsorship with Conditions	Date		
HRA Approved Documents Received	Date		
CTIMP ONLY - Governance agreement to proceed	Date		
Confirmation of Sponsorship	Date		
Research delay comments (please provide details)	Memo		

12- JRMO Risk Assessment Score
Responsible staff: RMGO
Green/Project level

Risk Assessment Score	Text		
Risk Classification – Research Studies	Lookup	Dropdown	Unacceptable risk above 70
			High risk above 60
			Moderate risk between 45-60
			Low risk below 45
Risk Classification - Intervention studies	Lookup	Dropdown	Unacceptable risk above 70
			High risk above 50
			Moderate risk between 45-50
			Low risk below 42
Comments	Memo		
If MODERATE - TL comment or confirmation of review	Memo		
If HIGH-TL&GCP, comment or confirmation of review	Memo		

13- JRMO IRAS Category
Responsible staff: RMGO

Green/Project level

JRMO Study Category	Lookup	Dropdown	Clinical trial of an investigational medicinal product
			Clinical investigation or other study of a medical device
			Combined trial of an investigational medicinal product and an investigational medical device
			Other clinical trial to study a novel intervention or randomised clinical trial to compare interventions in clinical practice
			Basic science study involving procedures with human participants
			Study administering questionnaires/interviews for quantitative analysis, or using mixed quantitative/qualitative methodology
			Study involving qualitative methods only
			Study limited to working with human tissue samples (or other human biological samples) and data (specific project only)
			Study limited to working with data (specific project only)
			Research tissue bank
			Research database
			Other study
			QMREC
			Not Set on ReDA

14- JRMO Supporting Department (Sponsored)
Responsible staff: RMGO
Green/Project level

Peer Review requested	Date
Peer Review reviewed	Date
Peer Review comments	Memo
Departmental authorisation requested	Date
Departmental authorisation reviewed	Date

Departmental authorisation comments	Memo
Pre-award team contacted	Date
Pre-award team responded	Date
Pre-award team delay comments	Memo
Pharmacy requested	Date
Pharmacy reviewed	Date
Pharmacy comments	Memo
Imaging requested	Date
Imaging reviewed	Date
Imaging comments	Memo
Pathology requested	Date
Pathology reviewed	Date
Pathology comments	Memo
Medical / Clinical Physics requested	Date
Medical / Clinical Physics reviewed	Date
Medical / Clinical Physics comments	Memo
GCP Team requested by Gov team	Date
GCP Team reviewed by Gov team	Date
GCP Team comments by Gov team	Memo
Lung Function requested	Date
Lung Function reviewed	Date
Lung Function comments	Memo
Tissue Bank/Tissue storage approval requested	Date
Tissue Bank/Tissue storage approval reviewed	Date
Tissue Bank/Tissue storage approval comments	Memo
Information Governance requested	Date
Information Governance reviewed	Date
Information Governance comments	Memo
Other	Memo
GCP Team Initial review requested	Date
GCP Team Initial feedback received	Date
GCP Team review:1-response to feedback requested	Date
GCP Team review:2-response to feedback requested	Date
GCP Team:1-response to feedback received	Memo
GCP Team:2-response to feedback received	Date
GCP Team comments	Memo

15- JRMO Archiving
Responsible staff: Governance section / Post-Award Finance Team / Archivist
Green/Project level

Date Governance file closed	Date
Date Finance file closed	Date
Study fully closed in archive	Date

16- JRMO MHRA Hosted Dossier Attribute set (Site)
Responsible staff: RMGO / Governance Team Leader
Red/Site level

Risk Adaption Category	Lookup	Dropdown	A
			B

			C
Number of SAEs (UK)	Numeric		
Number of SUSARs (UK)	Numeric		
Sponsor Tasks Delegated to others	Memo		
Is the primary endpoint lab based?	Lookup	Dropdown	Yes
			No
Lab for primary endpoint	Memo		
Number of primary endpoint samples per patient	Numeric		
Is the secondary endpoint lab based?	Lookup	Dropdown	Yes
			No
Lab for secondary endpoint	Memo		
Number of secondary endpoint samples per patient	Numeric		

17- JRMO Hosted Non-Commercial CTIMP
Responsible staff: Gov Team
Red/Project site level

Risk Adaption Category	Lookup	Dropdown	A
			B
			C
Trial Status (UK)	Lookup	Dropdown	Live
			Completed
			Early termination
Trial End Date, early termination/temporary halt	Date		
Reason for Termination/Temporary Halt	Memo		
Number of SAEs at your site	Numeric		
Number of SUSARs at your site	Numeric		

18- JRMO Governance Lead (Capacity & Capability)
Responsible staff: RMGO
Red/Project site level

Governance Lead	Lookup	Dropdown	Shafa Ullah
			Lilima Begum
			Sandra Burke
			Safia Ornelas
			Raheemah Akhtar
			Marria Khan
			Nadia Rahman
			Philip Diamond

19- JRMO Misc (Sit
Responsible staff: RMGO
Red/Project site level

Education	Lookup	Dropdown	BA/BSc
			MD
			MSc
			MPhil
			PhD
GDPR Compliant	Lookup	Dropdown	Yes
			No
			N/A

Study set-up	Lookup	Dropdown	CRF (Jo Morgan's Unit – RLH & WHX) Clinical Trials Unit (CTU) – Pragmatic (Sandra Eldridge's team) CTU – Other (Preventive – Chris' team) CVCTU (Cardio studies) BCI-Set up team (Cancer studies) WHRC Wingate (Auzra / Aziz)
Is study led by Nursing, Midwifery or AHPs?	Lookup	Dropdown	
IMP List	Text		
POC_Name of POC	Text		
POC_Role	Text		
POC_Contact email	Text		
POC_Contact telephone	Numeric		
POC_Address	Memo		
Clinical Board	Lookup	Dropdown	Cancer Cardiovascular Children's health GCS (Group Clinical Services) Emergency care Medicine Surgery Women's health No clinical board
Clinical Board speciality	Lookup	Dropdown	Cancer Cardiovascular Children's Health Emergency Care Trauma Acute medicine Dermatology Diabetes Endoscopy/ Gastroenterology Haematology Hepatology Infectious Diseases Neurosciences Older People's Services Renal Respiratory Rheumatology Sexual Health & HIV Stroke Breast surgery Colorectal Critical Care Dental / OMFS ENT

			General Surgery
			Gynae-Oncology
			Hepatobiliary
			Ophthalmology
			Orthopaedics
			Pain
			Perioperative
			Plastics
			Upper GI
			Urology
			Vascular
			Gynaecology
			Perinatal
			Metabolic and Endocrine
			Musculoskeletal
			Echocardiography
			No clinical speciality
Excess Treatment Costs (ETC)	Lookup	Dropdown	Yes
			No
ETC amount per patient (£)	Numeric		
Cost Saving	Lookup	Dropdown	Yes
			No
Cost savings per patient (£)	Numeric		
No cost form	Lookup	Dropdown	Yes
			No

20- JRMO Regulatory Approval Dates (Hosted)
Responsible staff: RMGO
Red/Project site level

HRA Approval Date	Date
REC Approval Date	Date
MHRA Date	Date
Submission Received by Governance Officer	Date
Initial feedback (Researcher)	Date
PI Response	Date
Hosted Research comments	Text

21- JRMO Supporting Department (Hosted)
Responsible staff: RMGO
Red/Project site level

Clinical director authorisation requested	Date
Clinical director authorisation reviewed	Date
Clinical director authorisation comments	Memo
Pre-award team contacted	Date
Pre-award team responded	Date
Pre-award team comments	Memo
Pharmacy requested	Date
Pharmacy reviewed	Date
Pharmacy comments	Memo
Imaging requested	Date
Imaging reviewed	Date
Imaging comments	Memo

Pathology requested	Date
Pathology reviewed	Date
Pathology comments	Memo
Medical / Clinical Physics requested	Date
Medical / Clinical Physics reviewed	Date
Medical / Clinical Physics comments	Memo
Lung Function requested	Date
Lung Function reviewed	Date
Lung Function comments	Memo
Tissue Bank/Tissue storage approval requested	Date
Tissue Bank/Tissue storage approval reviewed	Date
Tissue Bank/Tissue storage approval comments	Memo
Information Governance requested	Date
Information Governance reviewed	Date
Information Governance comments	Memo
Other	Memo

22- JRMO Trust Authorisation
Responsible staff: Governance Team Leader or R&D Governance Operations manager
Red/Project site level

Trust Authorisation Requested	Date
Clarification requested	Memo
Trust Authorisation Issued	Date

23- JRMO NIHR PID
Responsible staff: Research Information Lead/ Performance team
Red/Project site level

PI - Reason for delay in recruiting	Lookup	Checkbox List	a) Permissions Delayed / Denied
			b) Suspended by Sponsor
			c) Closed by Sponsor
			d) Sponsor Delays
			e) Staff Availability Issues
			f) No Patients Seen
			g) No Patients Consented
			h) Contracting Delays
			i) Rare Diseases
			j) Other
PI - Source of delay in recruiting	Lookup	Radio	NHS (host site)
			Sponsor (including NHS Sponsor)
			Both NHS and Sponsor
			Neither NHS (host site) nor Sponsor
PI - Delay Comment	Memo		
PD – Referral to Treatment (RTT) Met?	Lookup	Dropdown	Yes
			No
PD - Recruitment to Time and Target Comment	Memo		

Principle Investigator Declined	Lookup	Dropdown	Yes No
Status (PID)	Lookup	Dropdown	Withdrawn - PI Declined

24- JRMO Post-Award Finance
Responsible staff: Post-Award Finance Team
Red/Project site level

Does this study require invoicing?	Lookup	Dropdown	Yes No
Finance Lead	Lookup	Dropdown	Peng Lim Halima Master Mohammed Suman Yasmin Uddin Maria Fearon Adele Sofolabo Edward Santos Samuel Fabo Audrey Mitchell
Budget Code Arm 1	Text		
Budget Code Arm 2	Text		
Budget Code Arm 3	Text		
Budget Code Arm 4	Text		
Budget Code Arm 5	Text		
Arm 1 Cost	Numeric		
Arm 2 Cost	Numeric		
Arm 3 Cost	Numeric		
Arm 4 Cost	Numeric		
Arm 5 Cost	Numeric		
Total study budget	Numeric		
Notes	Memo		
Finance extension	Lookup	Dropdown	Yes No
Finance extension date	Date		

25- JRMO Pre-Award Finance
Responsible staff: Pre-Award Costings & Contracts Team
Red/Project site level

Costings and Contracts Officer	Lookup	Dropdown	Gerry Collins Julie Lester Laura Kennard Jason Terranova Anam Hoque Simon Hindley
Portfolio	Lookup	Dropdown	Commercial Non-Commercial
Work Tribe Number	Text		
Is there a Contract?	Lookup	Dropdown	
Funding required?	Lookup	Dropdown	
Notes	Memo		
Number of Patients	Numeric		
Cost Per Patient	Numeric		
Budget Total	Numeric		Yes
Announcement created?	Lookup	Dropdown	No

			Yes
Amendment - change of costs	Lookup	Dropdown	No
Latest amendment number	Numeric		
Online costing tool	Lookup	Dropdown	Yes
			No
Date completed by Pre-Award team	Date		

26- JRMO COVID-19 Study status (Hosted)

COVID-19 study (Hosted)	Lookup	Dropdown	Yes
Status (COVID-19) (Hosted)	Lookup	Dropdown	Recruitment on Hold – COVID-19
			Project site setup
			suspended - COVID-19
			Follow up on hold - COVID-19
			Suspended
			Re-Opened
Status (COVID-19) effective from date (Hosted)	Date		
Brief reason (Hosted)	Memo		
CMO Badged	Lookup	Dropdown	Yes
			No
			TBC

27- JRMO COVID-19 Study status (Sponsored)

COVID-19 study (Hosted)	Lookup	Dropdown	Yes
Status (COVID-19) (Hosted)	Lookup	Dropdown	Recruitment on Hold – COVID-19
			Follow up on hold - COVID-19
			Suspended
			Closed - COVID-19
			Re-Opened
Status (COVID-19) effective from date (Hosted)	Date		
Brief reason (Hosted)	Memo		
CMO Badged	Lookup	Dropdown	Yes
			No
			TBC

28- Barts Migration – Governance
Red/Project site level

JRMO Governance Lead	Memo
GDPR Compliant	Text
Education	Text
UKCRC Health Category	Text
NIHR Sub Specialties	Text
Care Group	Text
H1 R&D Initial Feedback date	Text
H2 Await Completed Submission date	Text
(H3/S5) Rcvd Complete Submission date	Text
H4 Final R&D Approval date	Text

H5 First patient consented date	Text
H6 Selected for JRMO Over-sight Audit date	Text
S1 R&D Initial Feedback date	Text
S2 Await Provisional Submission date	Text
S3 Rcvd Prov Submission date	Text
S4 Sponsorship with conditions Given/ Await Reg Approval	Text
S6 Final R&D Approval date	Text
S7 First Patient Consented date	Text
First Participant Recruited date	Text
APR date	Text
APR-Draft Received date	Text
APR-REC Acknowledgement received date	Text
APR Reviewed-Permission to submit date	Text
End of trial/study notification date	Text
Archiving Date	Text
File location	Text
Risk Adaption Category	Text
Risk Assessment score	Text
Local Recruitment Target	Text

29- Barts Migration – GCP
Red/Project site level

DSUR - Draft Received date	Text
DSUR- MHRA acknowledgment received date	Text
DSUR- reviewed and permission to submit date	Text
Is Primary End Point Lab Based?	Text
Is Secondary End Point Lab Based?	Text
Lab for Primary End Point	Text
Number of Primary sample per patient	Text
Lab for Secondary End Point	Text
Number of Secondary sample per patient	Text
Primary End Points – additional comments	Memo
Secondary End Points – additional comments	Memo
Other Labs in use	Text
Recruitment No: Total	Text
Recruitment No: UK	Text
Recruitment No: Barts Health	Text
Safety: No. of SAE	Text
Safety: No. of SUSAR	Text
Number of sites: Total Open	Text
Number of sites: UK Open	Text
Number of sites: Total Closed	Text
Vendor name 1	Text
Vendor service 1	Text
Vendor status 1	Text
Vendor name 2	Text
Vendor service 2	Text
Vendor status 2	Text
Vendor name 3	Text

Vendor service 3	Text
Vendor status 3	Text
IMP Names	Text

30- Barts Migration – Finance
Red/Project site level

Finance Lead	Text
Funding Category	Text
Budget Code	Text
Finance Start Date	Text
Finance End Date	Text
Primary Funder Name	Text
Primary Funder Total	Text
Secondary Funder Name	Text
Secondary Funder Total	Text
Tertiary Funder Name	Text
Tertiary Funder Total	Text

31- Barts Migration – Investigator
Red/Project site level

CI Name	Text
CI Email	Text
PI Name	Text
PI Email	Text
PoC Name	Text

Appendix 3: Workflows table

Workflow table

List of Workflows to be completed by the responsible staff when a study is going through the SPONSORSHIP route:

	Workflows	Project Level	Responsible staff member
1-	**JRMO Amendment Review Process Sponsored Studies**	Green/Project Level	RMGO
2-	**JRMO Closure - Sponsor Non-Regulated**	Green/Project Level	RMGO/ Research Administrator
3-	**JRMO Closure - Sponsor Regulated**	Green/Project Level	GCP Manager
4-	**JRMO GCP Manager Checklist Part 1**	Green/Project Level	GCP Manager
5-	**JRMO GCP Manager Checklist Part 2**	Green/Project Level	GCP Manager
6-	**JRMO GCP Manager's Review of Amendments**	Green/Project Level	GCP Manager
7-	**JRMO Sponsor APR- Non-Regulated**	Green/Project Level	RMGO
8-	**JRMO Sponsor CAG APR- Non-Regulated**	Green/Project Level	RMGO
9-	**JRMO Sponsor APR- Regulated studies**	Green/Project Level	GCP Manager
10-	**JRMO Sponsorship Review- Interventional Studies**	Green/Project Level	RMGO
11-	**JRMO Sponsorship Review- Regulated Studies**	Green/Project Level	RMGO
12-	**JRMO Sponsorship Review- Research Studies**	Green/Project Level	RMGO
13-	**JRMO Summary Monitoring Report**	Green/Project Level	Clinical Trials Monitor
14-	**JRMO DSUR**	Green/Project Level	GCP Manager

Workflows to be completed by the responsible staff when a study is going through the HOSTED route

	Workflows	Project Level	Responsible staff member
15-	**JRMO Site Capacity and Capability Review**	Red/Site Level	RMGO
16-	**JRMO Amendment Review Process Hosted Studies**	Red/Site Level	RMGO

1- JRMO Amendment Review Process Sponsored Studies

Green/Project level

To be added every time an amendment requires JRMO Approval/Acknowledgement. This includes substantial and non-substantial amendments, regardless of Categorisation.

Use this workflow for Barts Health/Queen Mary sponsored studies.

1 Notification of the amendment for sponsor review	
Q:	Has the JRMO been notified of an amendment with all necessary documents?
P:	Has the JRMO been notified of an amendment with all necessary documents?
2 Receipt of valid amendment application for sponsor review	
Q:	Has a Valid application been received?
P:	If an invalid application is received the allocated Research Management & Governance Officer (RMGO) should request the appropriate amendment documents from the CI/ delegate(s) on notification of the amendment.
	If a valid application is received move to Step 3.
3 Classify and assess the implication of amendment	
Q:	Has the amendment been classified as substantial or non-substantial, and assess the implications of the amendment?
P:	The allocated RMGO will classify/confirm the amendment as substantial or non-substantial and assess the implications of the amendment.
4 Impacted departments to confirm approval	
Q:	Has the RMGO liaised with the appropriate service/delivery support departments and finance team?
P:	RMGO to email service/delivery/Support teams, for approval.
	The RMGO should record in the comments section on EDGE which service/delivery support departments the amendment has been sent to the support team for approval.
5 Costings & Contract - Impact	
Q:	Does amendment impact Costings & Contract?
P:	If impact then email relevant costing contract officer and copy in researcher to initiate that review.
	Please use comment box for Costings & Contract comments.
6 Pharmacy - Study Support Service Approval required?	
Q:	Does amendment impact Pharmacy?
P:	Please use comment box for Pharmacy approval and any other comments.
	Record the date when JRMO initially contacted Pharmacy and any subsequent follow-up.
	rlhpharmacyct.bartshealth@nhs.net
7 Imaging - Study Support Service Approval required?	
Q:	Does amendment impact Imaging?
P:	Please use comment box for Imaging approval and any other comments.
	Record the date when JRMO initially contacted Imaging and any subsequent follow-up.
	(Imaging Generic E-mail / CSS / Claudio Melchiorri
8 Pathology - Study Support Service Approval required?	
Q:	Does amendment impact pathology?
P:	Please use comment box for pathology approval and any other comments.
	Record the date when JRMO initially contacted pathology and any subsequent follow-up.
	sarah.mahmood5@nhs.net
9 REGULATED STUDIES ONLY - Dual Review of Sponsorship amendment	
Q:	Has a GCP manager reviewed and approved the amendment?
P:	RMGO will obtain GCP Manager approval for the amendment in the form of an email.
	If the JRMO object the amendment, then the R&D Operational Manager & GCP Manager will arrange a meeting with the CI to discuss further.
10 Amendment tool locked by Sponsor	
Q:	Has the RMGO signed and locked the amendment tool?
P:	Once RMGO has signed and locked the amendment tool, the RMGO will issue an acknowledgment email and send the locked pdf amendment tool to proceed with submission to regulatory bodies.
11 REC Approval	

Q:	Has this amendment received REC favourable opinion?
P:	Record when REC issued approval on EDGE.
	This is only applicable to substantial amendments.
12 MHRA Approval	
Q:	Has this amendment received MHRA Approval?
P:	Record when MHRA issued approval on EDGE.
	This is only applicable to REGULATED studies where the amendment has been submitted to the MHRA.
13 HRA Approval date / Add HRA approved Documents received	
Q:	Has this amendment received HRA Approval?
P:	Record when HRA issued approval on EDGE
14 Final amendment approval from sponsor to implement	
Q:	Have all relevant regulatory approvals been received?
P:	CI/ delegate to forward all regulatory approvals to RMGO.
	RMGO to check all regulatory approved documents (check version numbers and dates) have been received.
	RMGO to issue sponsored amendment approval letter (regulated studies only) attached in an email.
	If non-regulated studies approval via email will suffice.
15 Upload Amendment Documents	
Q:	Have all of the documents relating to this amendment been uploaded to the Global/Green Level on EDGE and Study folder?
P:	All documents relating to this amendment (including the JRMO Approval e-mail) must be uploaded to the relevant amendment folder on the Site/Red Level on EDGE and Study folder.
	For regulated studies RGMO to print approval email and amendment approval letter only and file it in the relevant GCP monitors study box.

2- JRMO Closure - Sponsor Non-Regulated
Green/Project level

1 Received draft EOT from researcher	
Q:	Enter the date received
P:	Enter the date received
2 Approve EOT submission	
Q:	Approve EOT submission
P:	"The following must be considered:
	• Plans for analysis of the data.
	• Have all serious breaches been reported to the sponsor and all corrective action preventative actions (CAPAs) been followed up to resolution?
	• Have all the data queries from monitoring and auditing visits been resolved? Has a monitoring close out visit (COV) been performed/scheduled?
	• Has the data lock taken place and, if so, has this been documented?
	• Has all completed and withdrawn participant data been accounted for before analysis and has this been documented?
	• Was an interim publication written? If so, are there any participants who are still on the trial or in follow-up who might be affected by the publication of trial results? For example, if treatment has been proven effective, the trial participants may wish to be un-blinded. Consider the ethical implications of informing the participants; input from the trial REC may be needed.
	• Have arrangements been made with pharmacy for the destruction or return of all remaining investigational medicinal product (IMP)?
	• Have all unused trial supplies been returned or destroyed according to trial requirements?
	• Have arrangements been made for the destruction or ongoing storage of retained biological samples and diagnostic material?
	• Update the research database application (ReDA) with minutes of trial committee meetings, annual progress reports (APRs), development safety update reports (DSURs), recruitment numbers, adverse events (AEs) (according to the GCP Checklist), and request other documents and information as necessary."
3 Evidence of EOT submission received_REC	

Q:	Enter date that evidence is received
P:	Enter date that evidence is received
4 Agreed Final Study Report submission date	
Q:	Enter date - this is one year following Date of end of trial on EOT form.
P:	Enter date - this is one year following Date of end of trial on EOT form.
5 Final Study Report received by JRMO	
Q:	Enter date
P:	Enter date
6 Final Study Report acknowledgement received	
Q:	Have the REC/ HRA acknowledged receipt of the final report?
P:	Enter date that acknowledgement is issued

3- JRMO Closure - Sponsor Regulated
Green/Project level

1 Received draft EOT from researcher	
Q:	Enter the date received
P:	Enter the date received
2 Approve EOT submission	
Q:	Approve EOT submission
P:	"The following must be considered:
	• Plans for analysis of the data.
	• Have all serious breaches been reported to the sponsor and all corrective and preventative actions (CAPAs) been followed up to resolution?
	• Have all the data queries from monitoring and auditing visits been resolved? Has a monitoring close out visit (COV) been performed/scheduled?
	• Has the data lock taken place and, if so, has this been documented?
	• Has all completed and withdrawn participant data been accounted for before analysis and has this been documented?
	• Was an interim publication written? If so, are there any participants who are still on the trial or in follow-up who might be affected by the publication of trial results? For example, if treatment has been proven effective, the trial participants may wish to be un-blinded. Consider the ethical implications of informing the participants; input from the trial REC may be needed.
	• Have arrangements been made with pharmacy for the destruction or return of all remaining investigational medicinal product (IMP)?
	• Have all unused trial supplies been returned or destroyed according to trial requirements?
	• Have arrangements been made for the destruction or ongoing storage of retained biological samples and diagnostic material?
	• Update the research database application (ReDA) with minutes of trial committee meetings, annual progress reports (APRs), development safety update reports (DSURs), recruitment numbers, adverse events (AEs) (according to the GCP Checklist), and request other documents and information as necessary."
3 Evidence of EOT submission received_REC	
Q:	Enter date that evidence is received
P:	Enter date that evidence is received
4 Evidence of EOT submission received_MHRA	
Q:	Enter date that evidence is received
P:	Enter date that evidence is received
5 Agreed CSR submission date	
Q:	Enter date - this is one year following Date of end of trial on EOT form.
P:	Enter date - this is one year following Date of end of trial on EOT form.
6 Study requested from European Medicines Agency (EMA)	
Q:	Study requested from EMA
P:	Study requested from EMA
7 Study visible in JRMO EUDRACT	
Q:	Study visible in JRMO EUDRACT

P:	Study visible in JRMO EUDRACT
8 Study team member allocated and given access	
Q:	Study team member allocated and given access
P:	Study team member allocated and given access
9 CSR approved	
Q:	CSR approved
P:	Enter date
10 EUDRACT submission	
Q:	EUDRACT submission
P:	Enter date
11 CSR published on EUDRACT	
Q:	Enter date
P:	Enter date

4- JRMO GCP Manager Checklist Part 1

Green/Project level

Workflow to be completed by JRMO GCP Manager only

1 CI confirmed as suitable (training and experience)	
Q:	Is the CI suitably qualified and experienced?
P:	Review CV, qualifications and past experience running clinical trials.
	Consider:
	- Does the CI have the correct qualifications for the trial type?
	- Have they acted as a CI before?
	- Have they acted as a host site PI before?
	- Have they managed multi-centre trials before?
	- Have they run CTIMPs or Clinical Investigations before?
	- What risk categorisation did their previous projects have?
	- Are they supported by a CTU, research group or mentor?
2 CI Training completed	
Q:	Has CI completed training?
P:	CI must have completed JRMO GCP training within the last two years.
3 Conditions of sponsorship and delegation discussed and signed	
Q:	Has the sponsorship agreement been signed?
P:	Sign sponsorship agreement and obtain signature from CI (and CTU if required).
4 Appropriate statistician identified	
Q:	Is there are appropriate statistician?
P:	The CI may not be the statistician for regulated trials.
5 Protocol	
Q:	Is the protocol compliant with requirements?
P:	Ensure that the protocol is on the JRMO template or an appropriate alternative.
	Ensure that the protocol has not deviated from standard wording.
	Ensure that all template text has been answered and removed.
6 Review of documentation complete and reviewer satisfied	
Q:	Is the full document set present, compliant and of high quality?
P:	Check that all required documents are present (per JRMO SOPs and review body requirements.)
	Review the documents for quality and compliance to applicable regulations. Raise any queries with the CI.
	Confirm that CI has answered all queries satisfactorily.
7 Coordination Resource Agreed	
Q:	Are appropriate trial coordination arrangements in place?

P:	Consider how the trial will be managed and which responsibilities will be delegated to which individuals or organisations. Pay careful attention to lone Investigator studies or small or inexperienced research teams.
8 Monitoring plan agreed in principle	
Q:	What are the monitoring arrangements for this trial and are they appropriate?
P:	Discuss the monitoring arrangements for the trial - who will conduct monitoring visits/ central monitoring and how frequent the visits will be.
	The monitoring plan does not need to be written at this stage, but general arrangements must be agreed in principle.
9 Pharmacovigilance arrangements agreed	
Q:	Are appropriate pharmacovigilance processes in place?
P:	Consider:
	-AE recording and reporting.
	-SAE reporting to sponsor.
	-SAE assessments.
	-SUSAR reporting to MHRA.
	-Adverse Event of Special Interests (AESI)
	-Reporting exemptions.
	-DSURs
10 Confirm insurance cover?	
Q:	Are all activities insured?
P:	Confirm whether NHS Indemnity/ Queen Mary will cover all activities.
	International sites may require additional insurance cover.
	If external organisations are involved in the trial they will be required to insure their own activities.
11 Funding contract fully executed	
Q:	Has the primary funding agreement been fully executed?
P:	Confirm with costings and contracts team that the primary funding agreement has been fully executed.
12 IMP Supplier agreed in principle	
Q:	Is the proposed IMP supplier suitable?
P:	Contract should normally be put in place at this stage and the suitability of the supplier should be assessed via vendor assessment.
13 Database and CRF agreed	
Q:	Are the data management arrangements suitable?
P:	Database / CRFs do not need to be designed at this stage, but the planned arrangements should be agreed. If an external provider are to be used then a vendor assessment should take place.
14 All vendors identified and vendor assessment complete	
Q:	Are all vendors suitable?
P:	Confirm the full list of vendors to be used for the trial. Check whether the vendors are known to the sponsor or preferred suppliers. For any unknown vendors, complete a vendor assessment. Make sure that the contact team are aware of the vendor so that they can put a contract in place.
15 Risk assessment performed	
Q:	Has the sponsor risk assessment been completed?
P:	Complete risk assessment and obtain CI signature.
16 Provisional pharmacy agreement received	
Q:	Has provisional pharmacy agreement been issued?
P:	Receive approval from pharmacy.
17 Equipment and devices under review with clinical physics	
Q:	Have all equipment and devices to be used in the trial been approved by clinical physics, or are currently undergoing review?
P:	All trial specific equipment and devices must be under review by clinical physics if they have not yet obtained approval.

18 Kick-off meeting held	
Q:	Has the kick-off meeting taken place? Were all of the below topics discussed?
P:	Discuss following topics at kick-off meeting:
	-TMF setup
	-Version Control
	-CI training completed / due
	-CI capacity to run trial
	-Trial unit / group specific SOPs and their relation to the JRMO QMS (provide name of CTU / group)
	-Site activation process
	-Monitoring plan
	-Pharmacovigilance arrangements
	-Recruitment and participant population discussed, including feasibility of targets
19 Contract checklist updated following kick-off meeting and saved	
Q:	Has the contract checklist been updated following the kick-off meeting?
P:	Obtain confirmation form the contract officer that the contract checklist has been updated following the kick-off meeting.
20 Confirmation of GCP and regulatory compliance	
Q:	Does the trial comply with GCP and regulations?
P:	Consider compliance with:
	-ICH GCP
	-UK Policy Framework
	-The Medicines for Human Use (Clinical Trials) Regulations and amendments
	-The Medical Devices Regulations and amendments
	-Human Tissue Act
	-Data Protection Act
	-Mental Capacity Act
	List is not exhaustive.
21 Agreement in writing to governance team to proceed	
Q:	-
P:	Once all above steps have been completed, instruct governance lead to issue sponsorship with conditions of the trial. Please document here the name, number and version of the Sponsorship SOP that was followed for this stage or the approval

5- JRMO GCP Manager Checklist Part 2
Green/Project level
Workflow to be completed by JRMO GCP Manager only

1 Final governance meeting held and documented as per meeting report	
Q:	Has the final governance meeting been held and documented?
P:	Organise the final governance meeting. Minute the meeting using the final governance meeting report and send actions to all attendees.
2 Final version of protocol signed by CI and statistician	
Q:	Has the version of the protocol approved by the regulatory bodies been signed by the CI and statistician?
P:	Check the final document and request signatures if required.
3 Database build in progress and on target	
Q:	Is the database build in progress?
P:	Confirm with trial team.
4 Monitoring plan in place	
Q:	Is the monitoring plan in place?
P:	Obtain fully signed monitoring plan.

5 All contracts agreed and fully executed	
Q:	Is the contract checklist complete?
P:	Obtain signed contract checklist from the contract officer.
6 Final pharmacy agreement received	
Q:	Has the sponsor pharmacist approved the trial
P:	Obtain final sponsor pharmacist approval email.
7 Agreement in writing received from governance team to proceed	
Q:	Has the appropriate governance officer confirmed that they have received everything that they require for Confirmation of sponsorship?
P:	Obtain email confirmation from relevant governance officer.
8 Coordination delegation log signed	
Q:	Has the coordination delegation log been signed?
P:	Obtain a copy of the signed delegation log.
9 HRA Approval & conditions met	
Q:	Has HRA Approval been issued
P:	Obtain HRA Approval letter.
10 MHRA approval received & conditions met	
Q:	Has MHRA approval been issued
P:	Obtain a copy of the Clinical Trial Authorisation.
11 REC approval received & conditions met	
Q:	Has REC approval been issued?
P:	Obtain a copy of the favourable opinion letter.
12 CI has capacity to begin trial	
Q:	Does the CI have capacity to run the trial?
P:	Obtain confirmation from CI that they have capacity to commence the trial at the present time.
13 Reminder sent to Clinical Trial Monitors to ensure that ReDA and sponsor file are up to date	
Q:	Have the monitors been reminded to update ReDA and the sponsor files?
P:	Remind the monitors to update ReDA and the sponsor files?
14 All final governance meeting actions completed?	
Q:	Have all of the actions from the final governance meeting been completed?
P:	Document that all actions from the final governance meeting have been completed.
15 Confirmation of sponsorship email sent to CI and team	
Q:	Have all required actions for confirmation of sponsorship been completed?
P:	Once all required actions are complete, send confirmation of sponsorship email to CI and team. Please document here the name, number and version of the Sponsorship SOP that was followed for this stage or the approval

6- JRMO GCP Manager's Review of Amendments

Green/Project level

GCP manager's review of amendments for regulated studies

1 Amendment categorisation	
Q:	-
P:	Confirm that the amendment categorisation is correct and that the amendment will be submitted to the correct review bodies.
2 Change in RSI	
Q:	-
P:	Check whether the Reference Safety Information section of the Investigator Brochure or Summary of Product Characteristics has changed. If it has, notify the JRMO Clinical Trial Monitor.
3 Impact on study resources and management	
Q:	-
P:	Check whether the amendment will have an impact on support departments (e.g. pharmacy, radiology, pathology…). If it will, flag this to the Research Governance and Management Officer to obtain approval.

	Consider whether the changes are likely to affect IMP management (e.g. changes to IMP supply process, pharmacy manual or IMP label). If they will then obtain approval from the sponsor pharmacist.
	Check whether the amendment involves an extension to the study.
	Ensure that a confirmation of costs form has been completed, signed and is accurate with any resource implications correctly documented.
4 Impact on scientific integrity	
Q:	-
P:	Consider whether the changes are likely to affect the statistical analysis of the study (e.g. changes to the sample size, endpoints or randomisation procedure…). If they will, ensure that the statistician has approved the amendment or obtain approval from the trial statistician.
	Determine whether the peer review should be updated based on the information in the amendment and the outcome of the risk assessment. If a new peer review is required, request this from the CI or trial coordinator.
5 Impact on participants	
Q:	-
P:	Consider whether the changes will place addition risks or burdens on the participants. If they will, consider whether the risks have been suitably mitigated and whether the participant information and re-consent arrangements are appropriate.
6 Compliance with regulations and standards	
Q:	-
P:	Confirm that the amendment complies with applicable regulatory guidelines and sponsor policies and SOPs
7 Addition of sites, countries or vendors	
Q:	-
P:	Check whether the amendment will change the number of sites. If so, does the risk assessment and monitoring plan need to be updated? Confirm that the financial arrangements are documented on the confirmation of costs form.
	Check whether the amendment will add new countries. If so, assess the suitability of the country and complete a vendor assessment for the proposed National Coordinating Centre (NCC).
	Check whether the amendment will require the use of any other new vendors. If so, complete a vendor assessment.
8 Risk assessment and monitoring	
Q:	-
P:	Perform a preliminary risk assessment of the amendment and determine whether the overall sponsor risk assessment must be adjusted. If so, document the changes and obtain signatures from the relevant parties.
	Consider whether the changes could pose reputation risks for the sponsor organisation. If they will, consider whether these risks have been suitably mitigated and whether the amendment should be escalated within the organisation.
	Determine whether the monitoring plan should be updated based on the information in the amendment and the outcome of the risk assessment. If it does need to be updated, do so and obtain signatures from the relevant parties
9 Confirm approval of amendment	
Q:	-
P:	Notify the Research Governance and Management Officer that the amendment can be authorised.

7- JRMO Sponsor APR- Non-Regulated
Green/Project level

1 Received draft APR from researcher	
Q:	Received draft APR from researcher
P:	Received draft APR from researcher
2 JRMO review of APR completed	
Q:	JRMO review of APR completed
P:	JRMO review of APR completed
3 Approve APR submission to REC	

Q:	Approve APR submission to REC
P:	Approve APR submission to REC
4 APR acknowledgement by REC received	
Q:	APR acknowledgement by REC received
P:	APR acknowledgement by REC received

8- JRMO Sponsor CAG APR- Non-Regulated
Green/Project level

1 Received draft CAG APR from researcher	
Q:	Received draft CAG APR from researcher
P:	Received draft CAG APR from researcher
2 JRMO review of CAG APR completed	
Q:	JRMO review of CAG APR completed
P:	JRMO review of CAG APR completed
3 Approve CAG APR submission to REC	
Q:	Approve CAG APR submission to REC
P:	Approve CAG APR submission to REC
4 CAG APR acknowledgement by REC received	
Q:	CAG APR acknowledgement by REC received
P:	CAG APR acknowledgement by REC received

9- JRMO Sponsor APR- Regulated studies
Green/Project level

1 APR period	
Q:	APR period
P:	Enter date period
2 APR number	
Q:	APR number
P:	Enter number (i.e. how many years has this study been open)
3 REC Anniversary date	
Q:	REC Anniversary date
P:	Enter a date - the REC Anniversary date must be exactly one year after the start of the APR period
4 APR due date	
Q:	APR due date
P:	Enter a date - this is the REC anniversary date + 30 days
5 Draft received by JRMO	
Q:	Draft received by JRMO
P:	Enter a date
6 Draft approved	
Q:	Draft approved
P:	Enter a date
7 Final version received	
Q:	Final version received
P:	Enter a date
8 Evidence of submission received	
Q:	Evidence of submission received
P:	Enter a date

10- JRMO Sponsorship Review- Interventional Studies
Green/Project level

1 Sponsorship request received	
Q:	Have all necessary documents as per checklist received? If not inform researcher regarding missing documents.
P:	Check received documents against necessary checklist as per study type.
	If no document received send appropriate checklist.
2 Valid application received	
Q:	Have all the mandatory documents received as per checklist?
P:	Check documents received against checklist.
	If mandatory documents missing inform researcher
3 Confirmation of valid application	
Q:	In accordance with SOP 12b send a confirmation email to the CI and relevant member of the team
P:	Notify the CI delegate to confirm valid application and assigned reviewer (Governance officer introductory email)
4 Undertake sponsorship review	
Q:	Undertake sponsorship review
P:	Undertake sponsorship review
5 If applicable confirm Costings and requirement of Contract	
Q:	Has been appropriately costed by JRMO?
	Does it have a WorkTribe number?
	Check contract requirement in case of Tissue, Data, Funds transfer.
P:	Evidence of funding provided? is it sufficient to cover the cost of the whole study?
	Has declaration of No cost been provided?
	-Check arrangement for Tissue, Data, Funds transfer from sponsor to site.
	-Check if external labs will be used.
	-Check any role being delegated to external organisation.
	If above is true inform Costings & Contract team.
6 Support department/s involved?	
Q:	Is Pharmacy, Imaging and Pathology involved?
	Is approval / support provided with application?
P:	Check involvement of Pharmacy, Imaging and Pathology.
	If no approval has been provided, direct study team to Clinical Support Service (CSS) contact.
7 Initiate risk assessment	
Q:	Undertake risk assessment
P:	Undertake risk assessment
8 Meeting arranged with CI	
Q:	Has meeting been arranged with the CI/team
P:	If the study is:
	- Multi-centre
	- Using CTIMPs
	- Using NON Conformité Européene Mark (CE) Marked Device/s
	- Complex
	- Poor application
	- In the event of Governance query
	Then a meeting must be arranged to discuss the application and sponsor review. The CI is expected to attend along with the study team.

	Where a meeting is not required, simply put N/A in the comments.
9 Initial Feedback sent	
Q:	Has the initial review been sent to the CI and the team
P:	Once the initial review has been undertaken, the response must be sent to the CI and the team dealing any queries or points of clarification and amendments that are required.
10 CI Feedback response received	
Q:	Has a response to the initial review been received?
P:	A response to the initial review has been received. Check that all items within the review have been addressed and that revised documentation with revised version numbers and dates have been submitted as evidence of the revisions.
11 Responses checked and accepted	
Q:	Are responses adequate and accepted?
P:	If all responses have been submitted and documents revised and provided as evidence of the revisions, and all responses have been accepted, then this workflow item can be completed.
	Where queries remain notes must be made in the comment section.
12 Check all applicable authorisations/ approvals/ support/ sign off received?	
Q:	Check all applicable authorisations/ approvals/ support/ sign off received?
P:	Check all applicable authorisations/ approvals/ support/ sign off received?
13 Check applicable contract/s signed and dated? Are JRMO contract colleague happy to proceed?	
Q:	Check applicable contract/s signed and dated? Are JRMO contract colleague happy to proceed?
P:	Check applicable contract/s signed and dated? Are JRMO contract colleague happy to proceed?
14 Complete Risk Assessment and Sponsorship Review	
Q:	Complete Risk Assessment and Sponsorship Review
P:	Complete Risk Assessment and Sponsorship Review
15 Issue sponsorship with conditions	
Q:	Issue sponsorship with conditions
P:	Issue sponsorship with conditions using standard email template and attach insurance indemnity document (if required)
16 Authorise IRAS form	
Q:	Authorise IRAS form
P:	Authorise IRAS form
17 Necessary regulatory approvals received	
Q:	Make sure all regulatory approvals (HRA, REC etc.) received
P:	Make sure all regulatory approvals (HRA, REC etc.) received
18 Cross-check document version and date match with approvals	
Q:	Cross-check document version and date match with approvals
P:	Cross-check document version and date match with approvals
	If any discrepancies or missing documents liaise with the CI/ CI delegate.
19 Confirmation of Sponsorship	
Q:	Confirmation of Sponsorship
P:	Please document here the name, number and version of the Sponsorship SOP that was followed for this stage or the approval

11- JRMO Sponsorship Review- Regulated Studies
Green/Project level

1 Early Engagement (Optional)	
Q:	Has investigator contacted Costings & Contracts team and GCP managers?
	Has Costings & Contracts officer flagged any CTIMPS MHRA-regulated trials to GCP & governance manager?

P:	Check with Costings & Contracts officer and GCP managers.
2 Regulatory categorisation & International trial	
Q:	Check with GCP & Governance Manager if study is assessed with regards to regulatory categorisation acting as legal representative and inclusion of any international sites.
P:	Check with GCP & Governance Manager if study is assessed with regards to regulatory categorisation acting as legal representative and inclusion of any international sites.
3 Assessing the CI assignment	
Q:	Has the GCP & Governance Manager assessed the CI's assignment?
P:	If the CI has not previously worked as a CI on a Barts Health or Queen Mary sponsored MHRA-regulated trial, it may be necessary to discuss their proposal to be the CI with the Sponsors Oversight Group. For trials sponsored by Queen Mary or Barts Health, the CI must have a substantive contract with the sponsor (Barts Health or Queen Mary accordingly). In order for the sponsor to delegate to the CI the role of pharmacovigilance medical assessor, CI's must be medically qualified in the therapeutic area and be able to prescribe the IMP of this trial. Where necessary, the GCP & Governance Manager may liaise with the Sponsor Oversight Group (SOG) to make this decision.
4 Appropriate Costings	
Q:	Check with JRMO Costings team have costed appropriately, if not sure, liaise with GCP Manager & Pre-award Manager
P:	Check with JRMO Costings team have costed appropriately, if not sure, liaise with GCP Manager & Pre-award Manager
5 Evidence of funding received?	
Q:	Evidence of funding received?
P:	Evidence of funding received- liaise with JRMO Costings team to check funds are appropriate in-order to cover the cost of the project
6 Early Engagement Meeting	
Q:	Early Engagement Meeting if funding is secured - consult with GCP & Governance Manager
P:	Upon receipt of funding, consider an Early Engagement Meeting.
7 Sponsorship request received	
Q:	Have all necessary documents as per checklist received? If not inform researcher regarding missing documents.
P:	Check received documents against necessary checklist as per study type.
	If no document received send appropriate checklist.
8 Valid application received	
Q:	Have all the mandatory documents received as per checklist?
P:	Check documents received against checklist.
	If mandatory documents missing inform researcher
9 Confirmation of valid application & organise Kick-off meeting	
Q:	In accordance with SOP 12b send a confirmation email to the CI and relevant member of the team
P:	Notify the CI / CI delegate to confirm valid application and assigned reviewer (Governance officer introductory email)
10 Undertake joint sponsorship review with GCP Manager	
Q:	Undertake joint sponsorship review with GCP Manager
P:	Undertake joint sponsorship review with GCP Manager
	Governance officer & GCP Manager to review study and provide single feedback (via Governance officer).
11 GCP Manager to conduct Risk Assessment as per SOP	
Q:	GCP Manager to conduct Risk Assessment as per SOP
P:	GCP Manager to conduct Risk Assessment as per SOP.
	Use relevant workflow on EDGE (insert name of workflow)
12 Initial Feedback sent	

Q:	Has the initial review been sent to the CI and the team
P:	Once the initial review has been undertaken, the response must be sent to the CI and the team dealing any queries or points of clarification and amendments that are required.
13 Kick-off meeting	
Q:	Kick-off meeting arranged?
P:	Organise and Host the kick-off meeting.
	The purpose of the kick-off meeting is to ensure that the key stakeholders from the JRMO and the CI's team are aware of the:
	• the key information about the study.
	• the requirements for sponsorship with conditions to be issued.
	• the contracts and agreements that need to be put in place.
	• the actions that must be completed once the study has been submitted for regulatory approval.
	It is mandatory for the CI to attend the kick-off meeting, and it is recommended that the study coordinator or manager attends as well.
	From the JRMO, the GCP & Governance Manager, Costings and Contracts Officer and Clinical Trial Pharmacist must be present. The Governance Officer and the Clinical Trial Monitor assigned to the study must should attend the meeting where possible.
14 Receipt of confirmation from JRMO Costings & Contract that requirements are met	
Q:	Has been appropriately costed by JRMO?
	Does it have a WorkTribe number?
	Check JRMO Costings & Contract team regarding requirement Contract for Tissue, Data, Funds transfer & any labs.
P:	Evidence of funding provided? is it sufficient to cover the cost of the whole study?
	Has declaration of No cost been provided?
	-Check arrangement for Tissue, Data, and Funds transfer from sponsor to site.
	-Check if external labs will be used.
	-Check any role being delegated to external organisation.
	If above is true inform Costings & Contract team.
15 Support department/s involved?	
Q:	Is Pharmacy, Imaging and Pathology involved?
	Is approval / support provided with application?
P:	Check involvement of Pharmacy, Imaging and Pathology.
	If no approval has been provided, direct study team to Clinical Support Service (CSS) contact.
16 GCP checklist (link to GCP Manager Checklist)	
Q:	Check with GCP Manager whether GCP checklist has been completed.
P:	Check with GCP Manager whether GCP checklist has been completed.
17 CI Feedback response received	
Q:	Has a response to the initial review been received?
P:	A response to the initial review has been received. Check that all items within the review have been addressed and that revised documentation with revised version numbers and dates have been submitted as evidence of the revisions.
18 Responses checked and accepted	
Q:	Are responses adequate and accepted?
P:	If all responses have been submitted and documents revised and provided as evidence of the revisions, and all responses have been accepted, then this workflow item can be completed.
	Where queries remain notes must be made in the comment section.
19 Check all applicable authorisations/ approvals/ support/ sign off received?	
Q:	Check all applicable authorisations/ approvals/ support/ sign off received?
P:	Check all applicable authorisations/ approvals/ support/ sign off received?

20 Check applicable funding agreement signed and dated? Are JRMO contract colleague happy to proceed?	
Q:	Check applicable funding agreement signed and dated? Are JRMO contract colleague happy to proceed?
P:	Check applicable funding agreement signed and dated? Are JRMO contract colleague happy to proceed?
21 Check all Sponsorship with conditions actions complete	
Q:	Check all Sponsorship with conditions actions complete
P:	Check all Sponsorship with conditions actions complete
22 QC Cross-Check	
Q:	Request a quality control check of the documentation and approvals using 'Governance QC Countercheck'.
P:	Request a quality control check of the documentation and approvals using 'Governance QC Countercheck' (JRMO Associated Document 10). Once satisfied sign the QC Countercheck document as evidence of the sponsor's QC check. This must be performed by someone other than the RM and Governance Officer who undertook the sponsorship review, to ensure that a 'fresh pair of eyes' reviews before confirmation of sponsorship.
23 Issue sponsorship with conditions	
Q:	Issue sponsorship with conditions
P:	Issue sponsorship with conditions using standard email template and attach insurance indemnity document (if required)
24 Authorise IRAS form	
Q:	Authorise IRAS form
P:	Authorise IRAS form
25 Necessary regulatory approvals received	
Q:	Make sure all regulatory approvals (HRA, REC, MHRA etc.) received
P:	Make sure all regulatory approvals (HRA, REC, MHRA etc.) received
26 Cross-check document version and date match with approvals	
Q:	Cross-check document version and date match with approvals
P:	Cross-check document version and date match with approvals
	If any discrepancies or missing documents liaise with the CI/ CI delegate.
27 Final Governance meeting with the JRMO	
Q:	Final Governance meeting with the JRMO
P:	When REC and MHRA approvals have been sent to the JRMO, the GCP & (CI) and Governance Manager will schedule the 'Final Governance meeting'. The Research team purpose of the 'Final Governance meeting' is for the sponsor to identify all items outstanding before the GCP & Governance Manager can issue the sponsorship with conditions and permit activation of sites. This meeting can occur before or after HRA approval but must be after the REC and MHRA have approved the study.
	The CI must be present for the meeting to take place. Other members of the JRMO or trial team are welcome to join the meeting e.g. Costing & Contracts Manager, research nurse, data manager, and statistician as part of trial specific training, CTU (if applicable) and clinical physics expert (if a Clinical Investigation). Attendance will be recorded.
	The 'final governance meeting report' (Associated Document 2) should be used as an agenda. Following the meeting the Final Governance meeting report must be completed by the GCP & Governance Manager and distributed to the study team. Any actions or items outstanding identified in the meeting should be emailed to the CI and followed up to resolution.
	The CI should be able to demonstrate that they have existing TMF and SOPs/systems in place (see SOP 45 Essential documentation and trial master file (TMF)). If needed a JRMO monitor will review the TMF prior to sponsorship with conditions.
	The 'CI-Sponsor agreement' will be discussed and ideally re-signed during this meeting.
28 Confirmation of Sponsorship	
Q:	Confirmation of Sponsorship

P:	Please document here the name, number and version of the Sponsorship SOP that was followed for this stage or the approval

12- JRMO Sponsorship Review- Research Studies
Green/Project level

1 Sponsorship request received	
Q:	Have all necessary documents as per checklist received? If not inform researcher regarding missing documents.
P:	Check received documents against necessary checklist as per study type.
	If no document received send appropriate checklist.
2 Valid application received	
Q:	Have all the mandatory documents received as per checklist?
P:	Check documents received against checklist.
	If mandatory documents missing inform researcher
3 Confirmation of valid application	
Q:	In accordance with SOP 12b send a confirmation email to the CI and relevant member of the team
P:	Notify the CI delegate to confirm valid application and assigned reviewer (Governance officer Introductory email)
4 Undertake sponsorship review	
Q:	Undertake sponsorship review
P:	Undertake sponsorship review
5 If applicable confirm Costings and requirement of Contract	
Q:	Has been appropriately costed by JRMO?
	Does it have a WorkTribe number?
	Check contract requirement in case of Tissue, Data, Funds transfer.
P:	Evidence of funding provided? is it sufficient to cover the cost of the whole study?
	Has declaration of No cost been provided?
	-Check arrangement for Tissue, Data, Funds transfer from sponsor to site.
	-Check if external labs will be used.
	-Check any role being delegated to external organisation.
	If above is true inform Costings & Contract team.
6 Support department/s involved?	
Q:	Is Pharmacy, Imaging and Pathology involved?
	Is approval / support provided with application?
P:	Check involvement of Pharmacy, Imaging and Pathology.
	If no approval has been provided, direct study team to Clinical Support Service (CSS) contact.
7 Initiate risk assessment	
Q:	Undertake risk assessment
P:	Undertake risk assessment
8 Meeting arranged with CI	
Q:	Has meeting been arranged with the CI/team
P:	If the study is:
	- Multi-centre
	- Using CTIMPs
	- Using NON-CE Marked Device/s
	- Complex
	- Poor application
	- In the event of Governance query

	Then a meeting must be arranged to discuss the application and sponsor review. The CI is expected to attend along with the study team.
	Where a meeting is not required, simply put N/A in the comments.
9 Initial Feedback sent	
Q:	Has the initial review been sent to the CI and the team
P:	Once the initial review has been undertaken, the response must be sent to the CI and the team dealing any queries or points of clarification and amendments that are required.
10 CI Feedback response received	
Q:	Has a response to the initial review been received?
P:	A response to the initial review has been received. Check that all items within the review have been addressed and that revised documentation with revised version numbers and dates have been submitted as evidence of the revisions.
11 Responses checked and accepted	
Q:	Are responses adequate and accepted?
P:	If all responses have been submitted and documents revised and provided as evidence of the revisions, and all responses have been accepted, then this workflow item can be completed.
	Where queries remain notes must be made in the comment section.
12 Check all applicable authorisations/ approvals/ support/ sign off received?	
Q:	Check all applicable authorisations/ approvals/ support/ sign off received?
P:	Check all applicable authorisations/ approvals/ support/ sign off received?
Edit 13Check applicable contract/s signed and dated? Are JRMO contract colleague happy to proceed?	
Q:	Check applicable contract/s signed and dated? Are JRMO contract colleague happy to proceed?
P:	Check applicable contract/s signed and dated? Are JRMO contract colleague happy to proceed?
14 Complete Risk Assessment and Sponsorship Review	
Q:	Complete Risk Assessment and Sponsorship Review
P:	Complete Risk Assessment and Sponsorship Review
15 Issue sponsorship with conditions	
Q:	Issue sponsorship with conditions
P:	Issue sponsorship with conditions using standard email template and attach insurance indemnity document (if required)
16 Authorise IRAS form	
Q:	Authorise IRAS form
P:	Authorise IRAS form
17 Necessary regulatory approvals received	
Q:	Make sure all regulatory approvals (HRA, REC, CAG etc.) received
P:	Make sure all regulatory approvals (HRA, REC, CAG etc.) received
18 Cross-check document version and date match with approvals	
Q:	Cross-check document version and date match with approvals
P:	Cross-check document version and date match with approvals
	If any discrepancies or missing documents liaise with the CI/ CI delegate.
19 Confirmation of Sponsorship	
Q:	Confirmation of Sponsorship
P:	Please document here the name, number and version of the Sponsorship SOP that was followed for this stage or the approval

13- JRMO Summary Monitoring Report
Green/Project level

1 Period Covered	
Q:	-

P:	Confirm the period and dates covered by the summary monitoring report - (e.g. Q1 2020 – 01/01/2020-31/03/2020)
2 Save all documents.	
Q:	-
P:	All Documents should be saved within Indemnity. All embedded documents should be saved separately. Document should be saved in BOTH monitoring and the appropriate specific locations e.g. trial committee papers should be saved within the trial committee folder in Section 7 – Study Management Documents.
3 Confirm protocol version.	
Q:	-
P:	Check that the protocol version and date listed on the summary monitoring report matches the most recent protocol in JRMO records. Query any discrepancies.
4 Confirm reference safety information version.	
Q:	-
P:	Check that the reference safety information version(s) and date(s) listed on the summary monitoring report matches the most recent version(s) on file and the version listed in the most recent DSUR. Query any discrepancies.
5 Confirm safety report numbers	
Q:	-
P:	Check that the number of SAEs and SUSARs given on the summary monitoring report matches the number recorded on ReDA. Query any discrepancies.
6 Confirm amendment numbers	
Q:	-
P:	Check that the number of amendments listed on the summary monitoring report matches the number in JRMO records. Query any discrepancies.
7 Confirm trial committee dates	
Q:	-
P:	Confirm that the frequency of all trial committee meetings matches the committee charters. Check that all minutes are filed in Indemnity. Request any that are not.
8 Update EDGE with sites and recruitment	
Q:	-
P:	Update the site and recruitment figures in the GCP MHRA attribute on EDGE.
9 Verify ReDA reminders	
Q:	-
P:	Check that ReDA reminders are in place for the APR, DSUR and CSR as required and that the dates are accurate.
10 Review non-compliances	
Q:	-
P:	Review non-compliance log. Escalate non-compliances which raise concerns to the JRMO QA manager and GCP manager. Query if non-compliance log not present.
11 Review monitoring schedule	
Q:	-
P:	Review the monitoring visits against the study monitoring plan. Escalate significant deviations to the GCP manager.
12 Record monitoring visits.	
Q:	-
P:	Add each monitoring visit to the monitor tab of ReDA. Escalate significant findings to the GCP manager.
13 Review Trial Steering Committee minutes.	
Q:	-
P:	Escalate significant concerns to the GCP manager.
14 Review CI's comments on overall study progress.	

Q:	-
P:	Escalate significant concerns to the GCP manager.

14- JRMO DSUR

Green/Project level

1 DSUR period	
Q:	DSUR period
P:	Enter date period
2 DSUR number	
Q:	DSUR number
P:	Enter number (i.e. how many years has this study been open)
3 MHRA Anniversary date	
Q:	DSUR Anniversary date
P:	Enter a date -this must be exactly one year after the start of the DSUR period
4 DSUR due date	
Q:	DSUR due date
P:	Enter a date -This is the date of MHRA submission plus 60 days
5 Draft received by JRMO	
Q:	Draft received by JRMO
P:	Enter a date
6 Draft approved	
Q:	Draft approved
P:	Enter a date
7 Final version received	
Q:	Final version received
P:	Enter a date
8 Evidence of submission received	
Q:	Evidence of submission received
P:	Enter a date

15- JRMO Site Capacity and Capability Review

Red/Project site level

1 Date sponsor provides HRA validated document set	
Q:	Date sponsor provides HRA validated document set
P:	-Upload documents to EDGE
	-Add Pharmacy, Medical Exposure, Costing & Contracts workflows as applicable
	-Send notification to Divisions and Sites
2 Governance Officer	
Q:	Name of the Governance Officer
P:	Governance Officer
3 Date Introductory/validation email sent out	
Q:	Date Introductory/validation email sent out
P:	-Send email to sponsor/ sponsor contact copying PI/ Local study team
	-Validate documents submitted or request further/missing documents to enable the initiation of the review
4 Initiate capacity and capability review	
Q:	Initiate capacity and capability review
P:	Initiate capacity and capability review
5 Pharmacy - Study Support Service Approval required?	
Q:	Does this study impact Pharmacy?
P:	Please use comment box for Pharmacy approval and any other comments.
	Record the date when JRMO initially contacted Pharmacy and any subsequent follow-up.

6 Imaging - Study Support Service Approval required?	
Q:	Does this study impact Imaging?
P:	Please use comment box for Imaging approval and any other comments.
	Record the date when JRMO initially contacted Imaging and any subsequent follow-up.
7 Labs - Study Support Service Approval required?	
Q:	Does this study impact Labs?
P:	Please use comment box for Labs approval and any other comments.
	Record the date when JRMO initially contacted Labs and any subsequent follow-up.
8 Other support department approval required?	
Q:	What other support department approvals may be required (e.g. IG, Clinical Physics etc.)?
P:	Seek approval as appropriate
9 Has costs been reviewed by JRMO Costings & Contracts team	
Q:	Has costs been reviewed by JRMO Costings/ Contracts team?
P:	Has costs been reviewed by JRMO Costings/ Contracts team?
	If not liaise with JRMO Costings & Contracts team?
10 Has HRA Approval been received?	
Q:	Has HRA Approval been received?
P:	Has HRA Approval been received:
	Add HRA date on attribute
11 Has REC favourable opinion received	
Q:	Has REC favourable opinion received
P:	Has REC favourable opinion received:
	Add REC favourable opinion date on attribute
12 Other Regulatory approvals	
Q:	What other regulatory approvals are required for this project? (E.g. CAG, MHRA etc.)
P:	Ensure approval is in place as appropriate
13 Peer review/Clinical board/CAG/Departmental authorisation received?	
Q:	Peer review/Clinical board/CAG/Departmental authorisation received?
P:	Peer review/Clinical board/CAG/Departmental authorisation received?
	If not received prompt PI to arrange it
14 Complete the capacity and capability review	
Q:	Complete the capacity and capability
P:	Complete the capacity and capability
15 Date contract/SOA signed and confirmation sent to PI, Local study team & Sponsor	
Q:	Date contract/SOA signed and confirmation sent to PI, Local study team & Sponsor
P:	Date contract/SOA signed and confirmation sent to PI, Local study team & Sponsor to confirm site's capacity and capability to participate.

16- JRMO Amendment Review Process Hosted Studies

Red/Project site level

To be added every time an amendment requires JRMO Approval/Acknowledgement. This includes substantial and non-substantial amendments, regardless of Categorisation.

Use this workflow for Barts Health/Queen Mary Hosted studies.

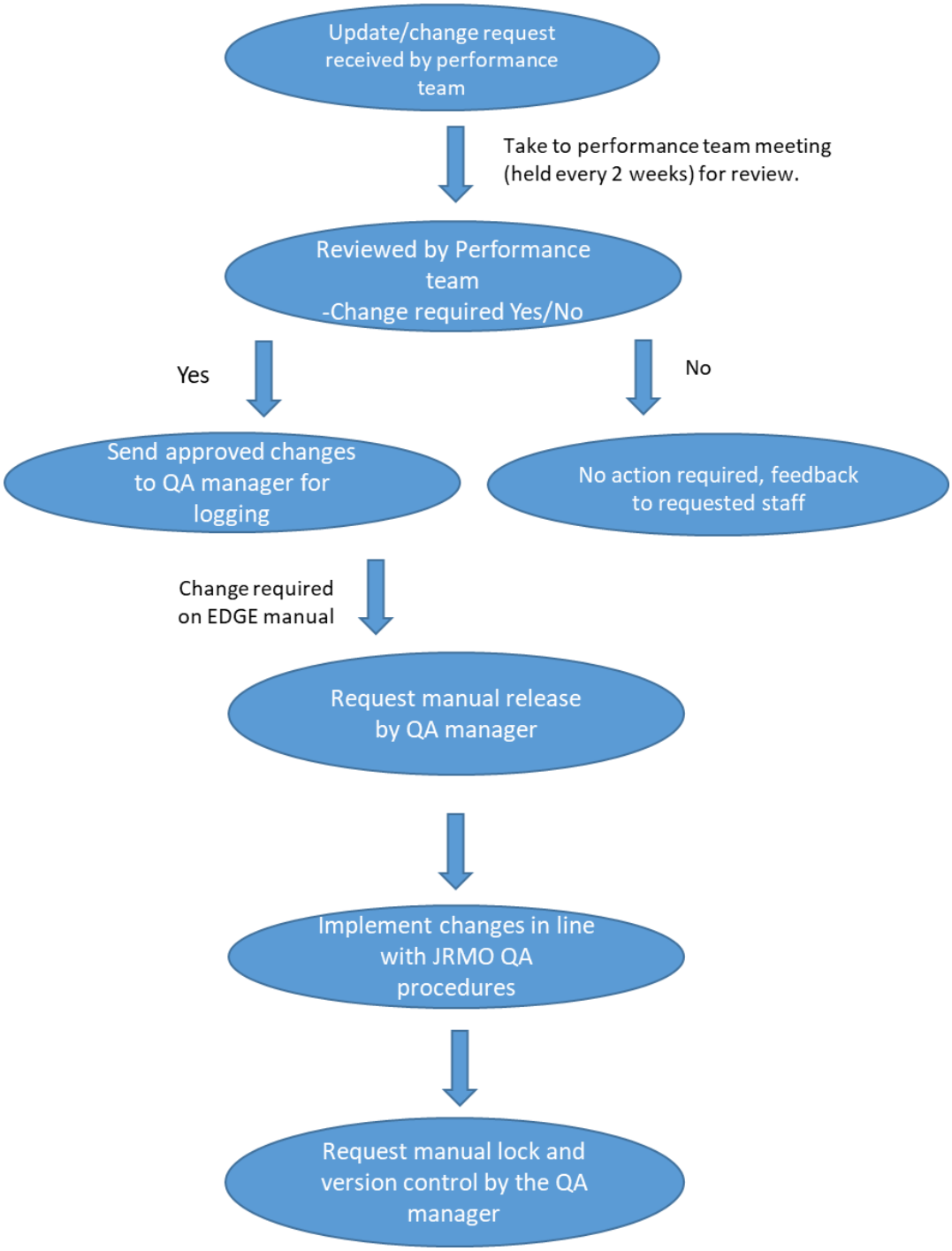
1 JRMO Governance Officer	
Q:	Which JRMO Governance Officer has this amendment been allocated to?
P:	Amendments are allocated to JRMO Governance Officer according to the division.
2 Amendment reference	
Q:	Amendment reference (any other reference not added in the comments)
P:	Amendment reference
3 RM&GO to acknowledge receipt of amendment (both substantial and non-substantial amendments)	
Q:	Has RM&GO received complete amendment pack?

P:	RM&GO to acknowledge amendment received and request if there are any missing documents.
	Also request if there are any impacts to clinical support services and costing and contracts
4 To address amendment issue to relevant Team Leader/GCP Manager	
Q:	Is the Trust/University unable to accommodate the requirements of amendment?
P:	Governance Team Leader to address this with the sponsor/sponsor rep.
5 Costings & Contract - Impact	
Q:	Does amendment impact Costings & Contract?
P:	Check this with sponsor and liaise with JRMO Costings & Contract team if there is an impact.
	Please use comment box for Costings & Contract comments.
	Commercial Sponsor should provide the following if there are impacts to costing/contract:
	1. Draft Costing Spreadsheet
	Ensure you have confirmation from costing/contract team that the contract amendment has been fully executed before acknowledging the amendment.
6 Pharmacy - Study Support Service Approval required?	
Q:	Does amendment impact Pharmacy?
P:	Please use comment box for Pharmacy approval and any other comments.
	Record the date when JRMO initially contacted Pharmacy and any subsequent follow-up.
	rlhpharmacyct.bartshealth@nhs.net
7 Imaging - Study Support Service Approval required?	
Q:	Does amendment impact Imaging?
P:	Please use comment box for Imaging approval and any other comments.
	Record the date when JRMO initially contacted Imaging and any subsequent follow-up.
	imgingrsrchamendment.bartshealth@nhs.net
8 Pathology - Study Support Service Approval required?	
Q:	Does amendment impact on pathology?
P:	Please use comment box for pathology approval and any other comments.
	Record the date when JRMO initially contacted pathology and any subsequent follow-up.
	sarah.mahmood5@nhs.net
9 REC Approval	
Q:	Has this amendment received REC favourable opinion?
P:	Record when the REC favourable opinion was given for this amendment.
	This is only applicable to substantial amendments.
10 MHRA Approval	
Q:	Has this amendment received MHRA Approval?
P:	Record when the MHRA approved the amendment.
	This is only applicable to REGULATED studies where the amendment has been submitted to the MHRA.
11 HRA Approval	
Q:	Has this amendment received HRA Approval?
P:	Record when HRA approval has been issued.
12 Cancer Amendments	
Q:	Has Clinical Research Delivery Group (CRDG) department reviewed and sent their approval for the cancer study amendments?
P:	Has the amendment been forwarded to CRDG for their review/approval?
	Has CRDG department sent their approval for the cancer amendment?
	CRDGAmendments.bartshealth@nhs.net
	CECM will not review and approve amendments for paediatric cancer studies; these will be reviewed and approved by Deanna Gibbs (deanna.gibbs1@nhs.net) or Stewart James Cleeve (stewartjames.cleeve@nhs.net)
	For cancer trials that include both adults and children 2 approvals will be required:
	- 1 for the adult portion of the study (the CECM will only review the documents applicable to the adult study)
	- 1 for the paediatric portion of the study (documents applicable to the paediatric portion of the study will be reviewed and approved by Deanna or Stewart James).
13 Complete Document pack and all relevant approvals have been received?	

Q:	Have all the documents as sent to the REC/HRA been received?
P:	Record when all the documents for this amendment have been processed by JRMO.
	For substantial amendments, these documents should be as listed in the REC favourable opinion letter.
	For non-substantial amendments, these should be as sent to the HRA.
	Make a note in the comments box.
14 Amendment Approved/Acknowledged	
Q:	Issue acknowledgement email
P:	RG&MO to send acknowledgement email to PI and copy in sponsor and any key contact from the study team.
	If it is cancer amendment then send acknowledgment email back to CRDG only, acknowledging receipt and that amendment will be saved on file.
15 Upload Amendment Documents	
Q:	Have all of the documents relating to this amendment been uploaded to the Site/Red Level on EDGE and Study folder?
P:	All documents relating to this amendment (including the JRMO Approval e-mail) must be uploaded to the relevant amendment folder on the Site/Red Level on EDGE and Study folder.
16 Update details on EDGE	
Q:	Update relevant fields accordingly depending on the amendment i.e. change of PI, change of recruitment target, change of study closure date etc…
P:	Update relevant fields accordingly depending on the amendment i.e. change of PI, change of recruitment target, change of study closure date etc…

Appendix 4: Process for making updates to EDGE Manual

Requested changes will go to QA Manager, who will keep a log and then the agreed changes are implemented quarterly. RIL would be logging the requests and then when requesting the document from the QA Manager, present all the changes requested and then the document is released for an update then the agreed changes are implemented quarterly.



All the requested changes will be made during the review period *only*

- *1st January*
- *1st April*
- *1st July*
- *1st October*

Appendix 5: EDGE Local Admin Role Agreement & EDGE Admin User Agreement

EDGE Local Admin Role Agreement

Preface

This document explains JRMO Guidelines on providing "Local Admin Role Agreement" permissions and the "Local Administrator User Agreement." It addresses various things such as information security risks, Barts Health / Queen Mary best practices. All Barts Health/Queen Mary employees who wants or requires administrator permissions is required to sign the Local Administrator User Agreement below.

Local Admin Access to Administrator Rights: Process

1 – Send request to JRMO via research.governance@qmul.ac.uk justifying the reasons why admin user access is required.

2 – JRMO will discuss all the admin user access requests internally at the bi-monthly Research Performance meetings.

3 – Requestor will receive an email about the outcome of the request.

Condition(s) for approval (the employee requesting administrator rights must meet at least one

of the following):

1 – Admin user request is necessary for the requestor's job performance.

2 – If no admin access is already in place for that specific department.

3 - The requestor uses EDGE reporting / attributes functionality regularly.

EDGE Admin User Agreement

I understand that by accepting role of Administrator within the Barts Health / Queen Mary EDGE instance I am confirming that:

- I hold a current substantive employment contract with either Barts Health or Queen Mary, and a letter of access or honorary contract with the other organisation.
- I have been delegated the role of EDGE administrator by my clinical lead and by my line manager's approval.
- I am at an expert level of EDGE; therefore, I can do the following without any support:
    - Pull reports from existing criteria as well as create new reports using new criteria
    - Share any reports with users
    - Create new attributes via "Entities"
    - Create new workflows via "Entities"
    - Create study teams
    - Add themselves / study teams to any study with the required access rights (manage, clinical etc…)
- I agree to only preform the above activities within my department /assigned area.
- I agree to follow Data policies in place by Barts Health / Queen Mary / EDGE.
- I agree to provide JRMO Governance performance team a list of users I have created quarterly without fail.
- I take full responsibility for deactivation of users in my department that leave or change their role as well as keeping other user details updated.
- I agree to act as the EDGE key contact within my department.
- I will only access data and reports that are relevant to my team, department, and scope; if a Trust wide report is needed, I will ask the JRMO admin team for permission first.
- I agree not to tamper with any data, which doesn't relate to my department.
- I agree not to request any changes directly from the EDGE team.
- I agree to notify JRMO Governance performance team (via research.governance@qmul.ac.uk with subject "EDGE Admin User – Changes") of any changes regardless of how minor they maybe.
- I agree to report any deviations to *EDGE manual* and any confidentiality breaches to the JRMO Governance performance team immediately or within 1 working day of becoming aware without fail (via research.governance@qmul.ac.uk with subject "EDGE Admin User – Breach").

Above guidelines and restrictions, do not supersede compliance with any local and national law(s).

_____Employee Signature _____ Date

_____ Name (Please Print)

_____Line Manager Signature _____ Date

_____ Name (Please Print)

EDGE local admin role agreement, version 1.0, dated 08/04/2020 – S.Ullah
Associated document for EDGE manual version XX, dated xx/xx/xxxx