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<h2>Vendor Assessment</h2>	
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1. PURPOSE

The purpose of this SOP is to aid with the selection, approval and maintaining oversight of all external vendors who will take part in the functions related to the conduct of any clinical trial/research conducted with Imperial College.

2. INTRODUCTION

Within the duration of a study, it is expected that certain functions, services or products will not be handled by the Research Governance and Integrity Team (pl). In these cases external support will be required to ensure compliance and delivery of the study and depending on the status of the study the RGIT can work to engage a potential vendor. Where necessary, the RGIT will involve the Chief Investigator (CI) and the relevant CTU to ensure the correct vendor is being selected to complete the services required. The CI will also work closely with the procurement and contracts team to ensure that the procurement regulations are being followed and the complete execution of the contract.

A vendor can be identified as a person, organisation or agency external to Imperial College or Imperial College Healthcare NHS Trust that provides functions, services or products that are related to the conduct of studies which are sponsored by the RGIT – Imperial College/ICHT

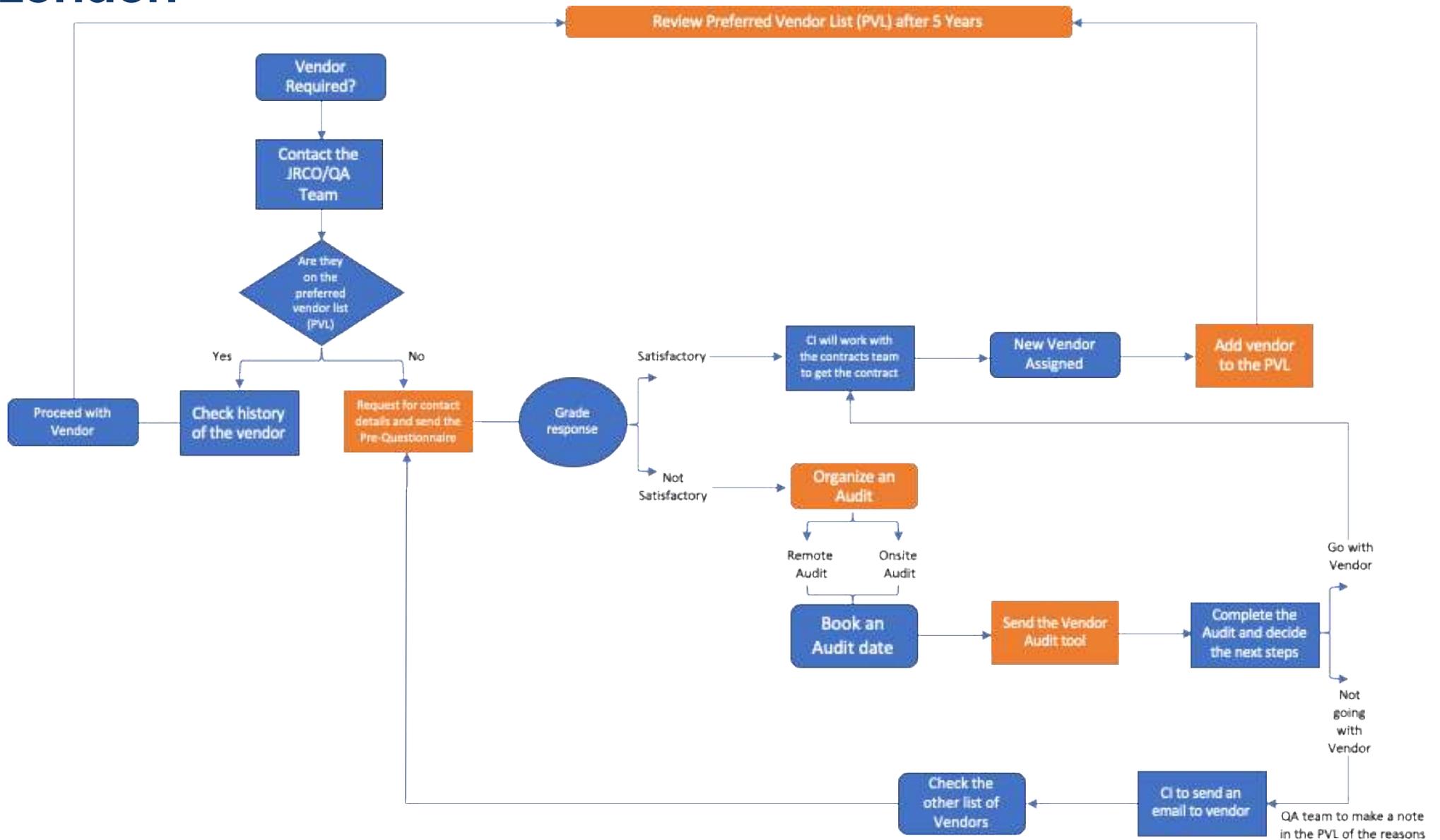
3. RESPONSIBILITIES

The Vendor assessment will be conducted by RGIT for CTIMP studies therefore the procedure of this SOP applies for RGIT sponsored CTIMP studies only. For Non-CTIMP studies and COVID-19 studies, the CI will remain responsible to ensure the vendor used are adequate and have checked they are suitable to conduct the activities and functions as required. The Sponsor will ensure collaboration alongside the CI; to assess the level of risk associated with the tasks/functions which are delegated to the vendor whilst the Sponsor will assess that the method demonstrated by the vendor will be suitable.

Once the vendor has been selected to take on the delegated tasks the reason for selection and the final decision agreed upon between the Vendor and the JRO contracts team will be documented within the contract.

4. PROCEDURE

In order to assess the suitability of a vendor there are a number of steps which will need to be followed to aid the selection process of the vendor. The selection process will be broken up to assess the reason for selecting the vendor, the level of oversight the vendor/sponsor will maintain and all/any risks identified. The steps have been displayed below in the flowchart:



The summary of the flowchart above is as follows:

1. CI approach RGIT team for a proposed vendor or the vendor is identified during the early stage of study/project i.e. during the risk assessment stage.
2. CTIMP Manager will conduct the risk assessment (possibly at the sponsorship stage), for more information on this please refer to RGIT_SOP_009 – Sponsorship and Insurance Approval.
3. QA team to check against RGIT Preferred Vendor List (PVL) and check if vendor is on the list of preferred vendors. If on the list, double check the vendor is conducting the same task/activity and no past issues.
4. If the vendor is not on the list, send the Vendor Pre-Questionnaire to the Vendor contact (this will cover info such as company QMS, delegated tasks (e.g. if external lab are they analysing primary or secondary endpoint data, history of audits/inspections etc).
5. Upon receipt of this, QA team to assess if onsite/remote audit required based on.
6. If onsite/remote audit necessary, plan, organise and execute audit. If audit is performed and satisfactory and vendor successfully selected and then added to Preferred Vendor List (PVL).
7. If vendor is not selected an email is sent out by the CI informing the vendor and the original vendor list is revisited and the process begins again.
8. Upon selection of the vendor, CI and the contracts team will work together to get the contract finalised.

1.4.1. Evaluation Methods

i. Vendor Pre-Questionnaire

In order to access the capability of a new or existing vendor, the Vendor Pre-Questionnaire will be sent out to the vendor contact before any decisions are made. The questionnaire can be sent to more than one vendor at once in order to evaluate and measure the best vendor for the service desired to be fulfilled. The pre-questionnaire covers different sections for the vendor to provide information about their company and their quality management system (QMS). The first 4 sections cover: company overview, team competency, study conduct/communication and quality management system. The other sections are only applicable for the vendor in questioned. If the vendor is completing any laboratory activities, the “Laboratory GCP Questionnaire for CTIMPs” RGIT_TEMP_061 template will be sent to be completed.

Each vendor will be given 1 month to complete the questionnaire. The Vendor Pre-Questionnaire is created to gather initial information about the vendor. Following the completion of the pre-questionnaire, the Vendor selection team will review the response given and grade the response as either being satisfactory or not satisfactory.

If the vendor is not chosen an email will be sent by the CI explaining the outcome of the questionnaire and another vendor can either be chosen based on their response or an audit is scheduled to investigate further. The QA team will make a note in the Preferred Vendor List (PVL) in order to keep a log of reasons a vendor is not chosen, If the vendor is selected the CI will send out the email confirming the next stages to the chosen vendor.

All documentations received from each vendor will be managed and filed by the QA team.

1.4.2. Preferred Vendor List (PVL)

The Preferred Vendor List (PVL), will hold all the current and new vendors being used by Imperial College for studies and research conducted.

The PVL will be managed by the QA team to ensure that all information is accurate and cannot be changed. The PVL will apply for new vendors only and RGIT will not go back retrospectively on all current vendors to assess for suitability unless concerns are raised. Provided that there are no issues with the current vendors being utilised, they will be added to the list, however if any concerns are raised e.g. serious breach related to the vendor; then the vendor is to be reviewed and assessed to ensure the vendors suitability for the project. If the CI or the RGIT team have experienced medium-high alert issues with the vendor in the past, an assessment will be conducted to ensure the vendor may remain being utilised.

1.4.3. Selecting Clinical Trial Unit (CTU)

Some clinical trials or studies conducted with Imperial may be managed or coordinated by delegated Clinical Trial Units (CTU). There are 2 categories that the CTU's can fall under: either Internal or External. The procedure to assess the suitability of their SOPs are described in the RGIT_SOP_011 – SOP Writing and Review. For selecting CTU's as vendors, the RGIT_SOP_011 – SOP Writing and Review and this SOP should be used.

5. REFERENCES

6. APPENDICES

The following Appendices list the following Templates associated to this SOP which can be found on the [SOP, Associated Documents & Templates page](#).

Appendix 1: Vendor Pre-Questionnaire – RGIT_TEMP_055

Appendix 2: RGIT Preferred Vendor List

Appendix 3: Laboratory GCP Questionnaire for CTIMPs – RGIT_TEMP_061