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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 oversight maintaining of all relevant 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 (RGIT). In these cases external support will be required to ensure that the compliance and delivery of the study, and depending on the status of the study RGIT can work to engage a potential vendor. Where necessary, the RGIT will involve the Chief Investigator (CI) and the relevant Clinical Trials Unit (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 London 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 London/Imperial College Healthcare NHS Trust (ICHT).

3. RESPONSIBILITIES

The vendor assessment will be conducted by the RGIT for CTIMP studies, therefore the procedure in this SOP applies for RGIT sponsored CTIMP studies only. For challenge studies, this will be reviewed on a case-by-case basis depending on the risk of the study. Delegates who work closely with the RGIT can also conduct the vendor assessment. Any delegated duties between sponsor, CI, CTU should include the duties for vendor assessment. The RGIT can, however, utilise the assessed vendor list created by Imperial Clinical Trials Unit (ICTU); as ICTU's processes are compliant with RGIT SOPs, please refer to RGIT_SOP_011 SOP on writing and review; this meaning that the RGIT do not need to re-assess the vendor provided the vendor is performing the same activities as what was previously assessed. For Non-CTIMP studies, the CI will remain responsible to ensure the vendors used are adequate and check they are suitable to conduct the activities and functions as required. The CI will maintain continuous oversight of these vendors throughout the study.

Once the vendor has been selected to take on the delegated tasks the reason for the selection and 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.

1. The CI will approach the RGIT team for a proposed vendor at the sponsorship review stage, or the vendor is identified during the early stage of CTIMP study/project, i.e., during the risk assessment stage.
2. The 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. The QA team will check against the RGIT assessed vendor list (AVL) and check if the vendor is on the list of assessed vendors. If it is on the list, the QA team will double check the vendor is conducting the same task/activity and there are no past issues.
4. If the vendor is not on the list, the QA team will send the RGIT_TEMP_055 (vendor pre-questionnaire) to the vendor contact (this will cover info, such as company QMS, delegated tasks, e.g., if external labs are analysing primary or secondary endpoint data, any history of audits/inspections, etc).
5. Upon receipt of this, the QA team will assess the response and any requested evidence provided are satisfactory. If required, an onsite/remote audit may be requested.
6. If an onsite/remote audit is deemed necessary, the QA team will plan, organise and execute audit. If the audit has been performed, its outcome is satisfactory, and the vendor successfully selected, then the vendor will be added to the AVL.
7. If the vendor is not selected, an email is sent out by the CI informing the vendor, the original vendor list is revisited, and the process begins again.
8. Upon selection of the vendor, the CI and the contracts team will work together to finalise the contract. The vendor will be added to the AVL and will remain there for 5 years. After 5 years of approval of this vendor, if this vendor is being selected for another CTIMP study, then the vendor assessment should be conducted again and the AVL updated as necessary.
9. Throughout the study, the RGIT CTIMP team will maintain an ongoing oversight of the study including the vendor and the activities performed by them. This includes but not limited to regular communication, meetings, progress reports, oversight of issues/concerns that have been escalated to sponsor etc. The level of oversight will vary depending on the risk of the study.

4.1 Vendor Pre-Questionnaire

In order to access the capability of a new or existing vendor, the RGIT_TEMP_055 (vendor pre-questionnaire) will be sent out to the vendor contact before any decisions are made. The questionnaire can be sent out to more than one vendor at once in order to evaluate and measure the best vendor for the desired service 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 may not be applicable for all the vendors. If the vendor is completing any laboratory activities, the RGIT_TEMP_061 (laboratory GCP questionnaire for CTIMPS) will be sent out 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 responses given and grade the responses (and evidence provided) as either being satisfactory or not satisfactory.

If the vendor is not chosen, an email explaining the outcome of the assessment will be sent out to the CI, and another vendor can either be chosen based on their response or an audit is scheduled to investigate it further. The QA team will make a note of this in the AVL in order to keep a log of the reasons why a vendor is not chosen. If the vendor is selected, the AVL will be updated, and the CI and vendor will be notified that the vendor assessment is complete. All documentation received from each vendor will be managed and filed by the QA team.

4.2 Assessed Vendor List (AVL)

The AVL will hold all the current and new vendors being used by Imperial College for studies and research conducted.

The AVL will be managed by the RGIT QA team to ensure that all information is accurate and cannot be changed. The AVL will apply for new vendors only (that is, from October 2020 onwards) and for all vendors (that had been selected before this date), RGIT will not retrospectively assess these for suitability unless concerns are raised. For vendors that were used for CTIMP studies before October 2020, if any concerns are raised which may impact on the suitability of the vendor being used (e.g., a serious breach related to the vendor); then the vendor may be reviewed and assessed to ensure the vendors suitability for the project. If the CI or the RGIT team have experienced high alert issues with the vendor in the past, an assessment may be conducted to ensure the vendor may still be utilised.

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 which the CTUs 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). The RGIT_SOP_011 SOP should be used to select CTUs as vendors unless there are concerns raised for the CTU following review then this SOP may be followed.

5. REFERENCES

ICTU Vendor Selection and Oversight SOP No. CR034

RGIT_SOP_011 SOP on writing and review

RGIT_SOP_009 SOP sponsorship and insurance approval

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 Assessed Vendor List

Appendix 3: Laboratory GCP Questionnaire for CTIMPs – RGIT_TEMP_061