SOP number	**51.015**	Version	**5.0**
Title	**Assessment of Vendors**		

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SOP category	NHS GG&C Sponsor R&I
Staff category	

Staff Category	**R**	**A**	**C**	**I**
R&I Research Governance Manager		X		
R&I QA Manager	X			
Senior Quality Co-Ordinator	X			
R&I Sponsor Pharmacy Team	X			
Innovation Contract Manager			X	
R&I Sponsor Co-Ordinator			X	
Project Managers			X	

1. Scope

This procedure applies to NHS Greater Glasgow and Clyde (NHSGGC) R&I Department, covering Sponsored, Co-Sponsored Clinical Trials of an Investigational Medicinal Product (CTIMP) and CIMDs. In certain circumstances the need may arise to Vendor Assess an organisation that provides services for Sponsored Non-CTIMPs or Hosted activity although this will not be the default position and conducted only as required.

2. Purpose

The purpose of this SOP is to describe the method of assessing the suitability of an external vendor providing a service.

Under the principles of Good Clinical Practice, the Sponsor is responsible for ensuring that a clinical trial is conducted in accordance with GCP and all other applicable regulations. Whilst the sponsor may transfer trial related duties and functions to other organisations, the ultimate responsibility for quality and integrity of the clinical trial lies with the Sponsor. The Vendor Assessment process is a risk assessment which aids in ensuring that required quality standards are met. The vendor assessment process is not an ongoing overview of the quality of the work delivered by the Vendor and is limited to an initial assessment of the likelihood of the Vendor to provide a quality output for the services being requested of them.

3. Procedures

3.1. Identification of an external vendor

A vendor can be identified at several points within the set-up of a trial and the aim should be to do so at the earliest opportunity, a vendor may provide a number of different services and as such a range of Risk Assessment Forms are in place to cover a variety of circumstances, this list may be updated as the need for further services is identified going forward.

A critical role within the selection of an appropriate vendor is the Chief Investigator, they may at any time ask for a list of approved vendors to select a pre-approved vendor or give advanced notification of a preferred vendor to the Vendor Assessment team (RAndDVendorAssessment@ggc.scot.nhs.uk) who can distribute details on the vendor assessment process, a list of approved vendors and offer assistance in preparation.
It is the responsibility of the Sponsor organisation to ensure that any vendors directly contracted meet the necessary requirements and regulations to undertake the requested activity for the specific clinical trial. If a contracted vendor makes use of a sub-contractor it will be the responsibility of the vendor to assure they meet the required standards. This will be included in the contract. The Sponsor will be responsible for ensuring the vendor has their own process in place to assess the sub-contractor and maintain oversight but it is not required for the Sponsor to vendor assess the sub-contracted organisation. In this circumstance, it is only required to assess the main vendor if they are directly supplying goods or services.

A vendor assessment will only be undertaken if there is an intention to move forward with a contract with the service provider. As such, the timeline of initiating this process may vary from trial to trial. It is advised that a vendor assessment is initiated at such a time there is a clear outcome the trial and the use of the vendor is likely to proceed to avoid unnecessary expenditure of resource.

When a potential vendor is identified during the lifecycle of a trial, for example during the Study Initiation Group (SIG), the appropriate member of staff (R&I Sponsor Co-Ordinator, Project Manager or R&I Pharmacist) may request the approval status from the vendor assessment team (detailed in section 3.1.1) if not already known, for example the Pharmacy Team hold the approval status for IMP related activities already, this can be achieved by contacting the vendor assessment Mailbox (RAndDVendorAssessment@ggc.scot.nhs.uk).

This will highlight if the vendor is pre-approved for the service required or if an assessment is needed. All appropriate vendors must be approved or exempted, as discussed in 3.1.3, through this process as part of their conditions for use. Ideally this activity will be conducted before agreements are made with the vendor, however in some circumstances this activity may be conducted following agreements. This will be decided on the basis of assessing the associated risks, in the example of vendor assessing an IMP Manufacturer the risk profile is significantly lower as they will generally be a highly accredited and assessed organisation. In this instance, agreements may be in place prior to the vendor assessment being carried out.

In order to assist with the identification of potential vendors, the University of Glasgow will supply the grant costings to the Co-Ordinators to help identify any potential vendors from the co applicants in this instances in which this is applicable. Once funding has been approved, the vendor assessment process can commence. If similar costings are available from other Co-Applicants this may be requested to assist.

3.1.1. Vendor Assessment Team

Vendor assessments are carried out by 2 main groups within R&I, for non IMP related vendors the assessments are carried out by either the R&I QA Manager or the Senior Quality Co-Ordinator. For IMP suppliers, the assessment process is carried out by nominated members of the R&I Sponsor Pharmacy Team. The individual carrying out the assessment from these groups will be referred to as the Assessor.

A central mail box is in place (RAndDVendorAssessment@ggc.scot.nhs.uk), which can be accessed by all members of the vendor assessment team and actioned as required.

3.1.2. Adding a New Vendor to Q-Pulse

In the event a new vendor is identified which does not have a record in Q-Pulse they must be added by the assigned Assessor or a relevant Q-Pulse administrator. Certain details will need to be provided such as the Vendor Name, Address, Contact Details, Association with Sponsor/Co-Sponsor, Impact on Primary or Secondary Endpoints etc. Any further details which are required will be requested by the Assessor.

3.1.3. Exemption from Vendor Assessment

Provision is made within the Co-Sponsorship agreement with Glasgow University and NHSGGC that Co-Sponsored trials which make use of Glasgow University Labs which will then be considered as part of the Sponsor organisation. As such they do not require a vendor assessment. However, if an NHSGGC sole sponsored trial is using a University of Glasgow lab a vendor assessment may be required. It is possible to exempt a Glasgow University Lab from undergoing the vendor assessment process on a sole sponsored trial, under these circumstances an exemption request can be made by the Assessor by sending Form 51.015I to the Glasgow University Head of Research Regulation & Compliance to confirm the lab does not require assessment. If a trial with a Co-Applicant makes use of their own facilities to deliver activity in the trial, this exemption process may be used.

3.1.4. Identification of New Vendor Service

It is possible that a new form of service may be required from a vendor which is not currently catered for within the vendor assessment process. In the event that this is identified during the pre-assessment process it may be possible for an existing pre-assessment questionnaire to be used, however some additions or alterations may be required. At this point, appropriate Subject Matter Experts should be identified and a detailed list of questions compiled for the vendor assessment. As this process by its nature concerns content which is unknown, the timescales for this may vary. Every effort will be made to produce the required assessment and undertake the assessment process in a timely manner. In the event the potential for a new service is identified work will begin to create the required risk assessment form in advance of the decision to move forward with the trial or vendor as this will result in a more robust and complete vendor assessment process being available.

3.1.5. Applicability of Vendor Assessment

A vendor assessment is required when a service is utilised from a vendor which impacts on the primary or secondary endpoint of a Sponsored/Co-Sponsored CTIMP/CIMD or provides a service for an activity that is usually the responsibility of the Sponsor. However, if a service is utilised in relation to an exploratory endpoint an assessment may not be required if it in no way impacts the primary or secondary endpoints and has no impact on the safety or welfare of patients. In this instance, it must be detailed within the Risk Assessment (Form 51.004A) that this decision has been taken and justify that it is not believed the provided services will impact the main objectives of the trial or the welfare of patients. In addition, on some occasions it may be required to assess the services of a vendor in relation to a non-CTIMP trial Sponsored by NHSGGC or when NHSGGC are acting as host of a study. In these instance it will be by exception and associated to the individual circumstances or perceived risks. For hosted activity, the Sponsor of the trial must always be made aware of the use of a vendor as they may wish to assess them or be made aware of details of any assessment carried out by NHSGGC.

3.2. Assessment of Vendor

The Sponsor Co-Ordinator/Project Manager will give notification to the Vendor Assessment team via the designated E-Mail address (RAndDVendorAssessment@ggc.scot.nhs.uk) or through direct E-Mail that an assessment is required.

It is important to note that a sufficient period of time is given to complete this process as it may interfere with the timeline of a trial due to the turnaround time of completion. The full lifecycle of a Vendor Assessment allows for 30 working days, not including any delays in responses or incomplete forms. This includes 5 working days to issue the Assessment, 20 working days for the Vendor to complete and 5 working days to be reviewed. The escalation process for non-responses from potential vendors can further extend this. In certain circumstances this timeline can be reduced if agreed upon in advance but will still be subject to the timeliness of responses from potential Vendors. Progress of Vendor Assessments can be tracked through Q-Pulse by all interested parties at any time, the process for this is detailed within Guideline 51.015B. Every effort will be made to ensure the assessment and subsequent decision on the suitability of the vendor is made prior to issuing the Regulatory Green Light for Sponsored or Co-Sponsored CTIMPs/CIMDs.

A documentation assessment, or on-site audit will be conducted, as appropriate, for vendors identified to provide a service for specific Sponsored or Co-Sponsored CTIMP/CIMDs prior to contract negotiation where possible or following this if contracts must be in place to allow access.

For documentation review, an appropriate member of R&I Staff (member of the Vendor Assessment Team), will assess vendors by requesting information using the appropriate vendor assessment form for the vendor, e.g. Laboratory, IMP Manufacturer Assessment. In the event an IMP Manufacturer Assessment is required, this will be undertaken in conjunction with IMP Manufacturer Vendor Assessment Guideline 51.015A.

Completed forms and any supporting evidence or documentation will then be reviewed by a member of the Vendor Assessment Team, with the intention of approving their contents. The aim of this review is to establish if the questions have been answered completely to a sufficient level to determine the suitability of the vendor.

3.2.1. Recording Assessment in Q-Pulse

When conducting a vendor assessment, a record will be created in Q-Pulse in the Audit Module by the Assessor. This will record the progress and output of the vendor assessment and link to any issues identified to be addressed. The process to record and update vendor assessments in Q-Pulse is detailed in Guideline 51.015B.

Any additional requests for information, queries or clarifications will be recorded as a finding linked to the vendor assessment record, the responses to the above will also be recorded to show the complete record. This will be managed by the Assessor and progress will be tracked to completion through Q-Pulse. At this time, other members of the trial team will be consulted as required to assist in addressing the actions needed to deem a vendor approved.

Progress can be tracked at any time directly through Q-Pulse and reports.
In the event of no response from the vendor after prompting (i.e. 3 times within 2 weeks), the issue(s) will be escalated to the R&I QA Manager/Research Governance Manager/ and/or R&I Lead Pharmacist, as appropriate, for review and further action(s). The reminders and escalations will be sent to the Vendor from the Assessor, with the requestor copied in.

Timeline for escalation:

1 Week Notice	1st reminder
Due Date	2nd reminder
1 week	3rd reminder
2 week	Escalation 1
3 week	Escalation 2
4 week	Escalation 3

If the vendor response to give an update on progress and establish a new timeline for completion this process will restart based on the updated timeline if it is deemed to be an acceptable timeline.

The Assessment record in Q-Pulse will act as the repository for all evidence of the assessment, as such all key documents must be attached to the record. This will included, but not be limited to the completed Vendor Assessment record, any additional documents supplied by the vendor to support their assessment, any key correspondence, any final approval or rejection forms, etc. Ongoing communication will be held in the Vendor Assessment mailbox in addition to the final records.

3.2.2. On-site Vendor Assessment

An on-site Vendor Assessment will only be conducted as required, if it is considered more appropriate or in the event of a critical systems failure at site. This may be a requirement as part of the assessment of IMP Manufacturers depending on the outcome of the associated Risk Assessment and the activity may be sub contracted.

An on-site Vendor Assessment and reason(s) should be discussed by the R&I QA Manager, R&I Research Governance Manager and/or R&I Lead Clinical Trial Pharmacist, as appropriate. The decision may however be made that an on-site vendor assessment should not be conducted and a remote assessment is carried out.

In some circumstances, it may be appropriate for an external company to conduct the on-site vendor assessment on behalf of NHSGGC. This decision will be made by the R&I QA Manager, Research Governance Manager and/or R&I Lead Pharmacist.

Following an on-site vendor assessment, the Assessor will recommend if the vendor is acceptable or if an alternative vendor should be found through discussion with R&I Research Governance Manager, R&I QA Manager and/or R&I Lead Pharmacist. The same process will be applied of gathering the required information outlined in the appropriate form of the vendor type but additional information may be assessed through witnessing specific records or an assessment of processes carried out on site.

3.2.3. Assessment of Collaborators

In some instances, particularly with Innovation based trials, a collaborator will be involved with the conduct of a trial in which they may act as the funder and also provide goods or services that are core to the conduct of the trial. As they take on this key role it is not a standard Vendor relationship but it may be required to have a level of assurance of the capabilities of the organisation. Not all instances will require an assessment of the collaborator, for example if they supply a device but it is CA/CE marked and being used with in its normal intended purposes then an assessment may not be required. This is a determination that can be made through discussions of those involved with the trial and the QA Manager at the beginning of the trial or the Risk Assessment stage. The ultimate decision of whether an assessment is needed or not will be recorded during the Risk Assessment. In the event an assessment is required, Form 51.015H will be utilised to provide an overview of the organisation that NHSGGC will be working with and provide a level of confidence for their capabilities in the appropriate areas. As the nature of the products/services offered may vary, Form 51.015H may need to be tailored to the specifics of the trial and the collaborator, for example, to include specifics relating to Device manufacturing. This process will be in place for all CTIMP/CIMD studies applicable and will follow the same process as all other Vendors.

3.3. Following a favourable review

Following a favourable review of the documentation returned and information provided, the vendor assessment form will be signed off by the Assessor and attached to the assessment recorded in Q-Pulse as well as updating the vendor record in the sites module as detailed in Guideline 51.015B. This will be approved by the R&I Governance Manager, Lead R&I Pharmacist or QA manager.

An E-mail will then be sent to the vendor and CC in the Sponsor R&I Co-Ordinator /Project Manager/Sponsor Pharmacist as required in order notify them of their approval and progress the contract with the vendor. In this approval it will be stated that the Vendor is responsible for notifying the Sponsor of any change of circumstances which may impact their approval, i.e. change of location, significant staff changes, accreditation, etc.

A list of approved vendors and what service they are approved for will be located in Q-Pulse.

3.3.1. Favourable review with Pending actions

In some circumstances, a review may be deemed to be favourable but still require the vendor to complete certain actions. These actions will still be recorded and managed to completion within Q-Pulse as discussed previously, however it is acceptable to approve the vendor with conditions in place that agreed actions must be addressed.

3.4. Following an un-favourable review

In the event a vendor assessment determines that the proposed vendor does not meet the requirements put forward in the assessment, this should be escalated to the Research Governance Manager and/or Lead R&I Pharmacist as well as informing to the Sponsor R&I Co-Ordinator and/or Project Manager/CI, as appropriate by the Assessor. In the event the vendor is a University of Glasgow Lab the Glasgow University Head of Research Regulation & Compliance will be notified also. The vendor will also be advised of the outcome by the Assessor following the internal discussions and notifications mentioned above and it is agreed that the vendor is not suitable for the planned services.

At this stage it may be required to seek an alternative vendor, this activity will be undertaken by the Chief Investigator and the extended research team. Once an alternative vendor has been identified, the sponsor Co-Ordinator should be notified. This alternative vendor must be approved for use through this same process and may be selected from a list of existing approved vendors or a new assessment carried out. This may impact on trial timelines as the vendor assessment process will need to take place again with the new vendor.

3.5. Re-assessment of vendors

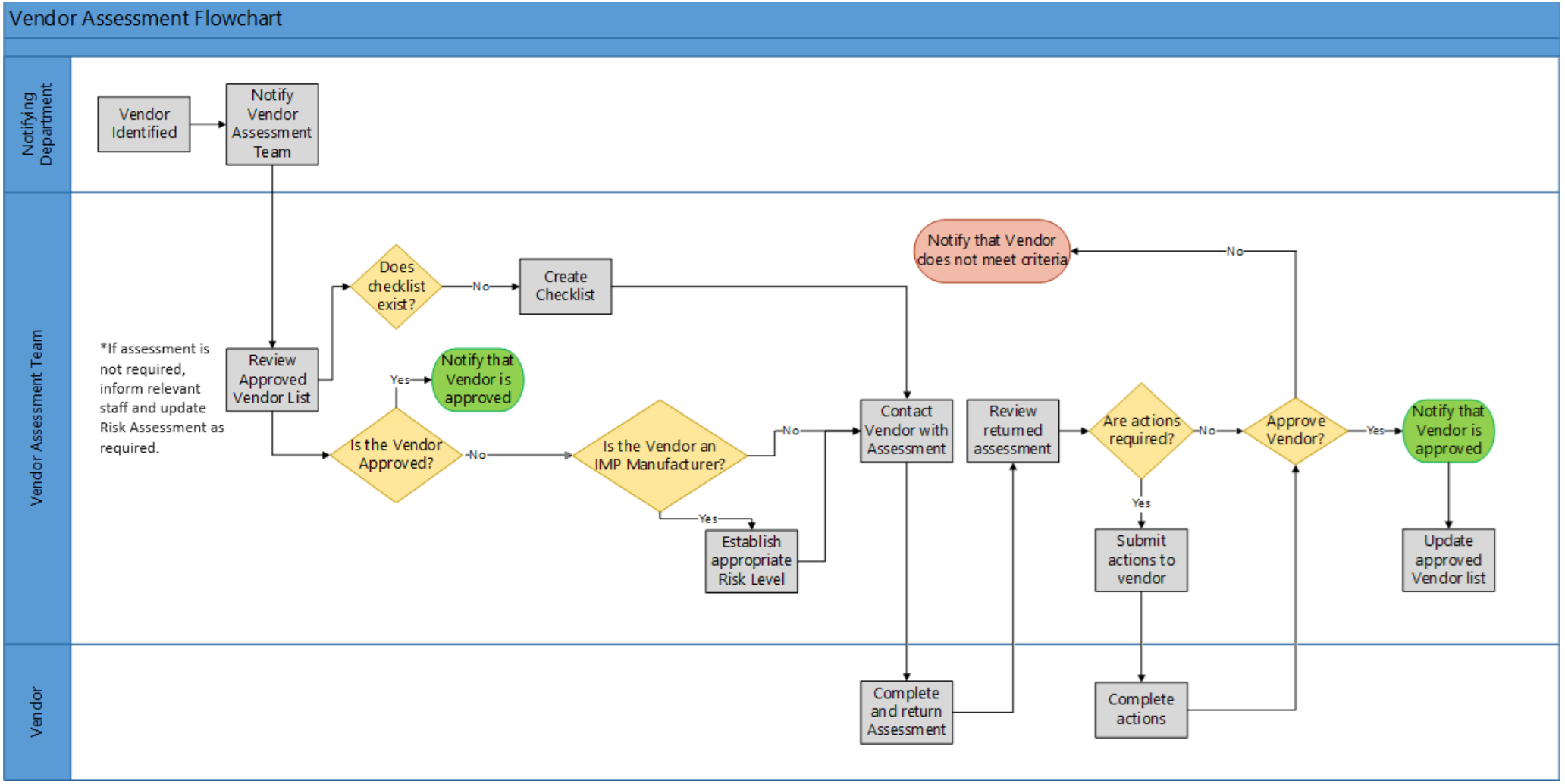
All vendors will be re-assessed every 3 years or sooner if Sponsor are made aware of any significant changes to the vendor, this may include changes to certification, change of premises or a recurrence of non-compliances with GCP. This re-assessment will be in line with the procedures set out within this SOP. A reminder will be sent to the vendor assessment mail box (RAndDVendorAssessment@ggc.scot.nhs.uk) when a vendor is within 6 months of their renewal date, the assessment will be conducted using the appropriate form for the vendor. This process will involve a review of the previous assessment conducted against the vendor to identify any gaps from the question list at the time as compared to the current. If there are no changes then the vendor will be asked to confirm all details previously provided are still accurate and to update on any changes. If a vendor is no longer in use for a trial, their approval will be allowed to lapse without further assessment.

3.5.1. Additional Service for an Approved Vendor

In the event an additional service is to be requested for an existing vendor which already has approval for other services, a bespoke approach will be taken. The vendor will not need to be re-assessed for any elements which their approvals already covers, it will only be elements relevant to the new services that must be addressed. This may range from something as simple as confirming existing details are still applicable to the new services or something more complex in which a different facility, staff or equipment are utilised.

3.6. Process Flow Chart

Below is a process flow chart for the vendor assessment process, this can be used to identify the sequence of events which must take place in the approval of a vendor.



4. Referenced documents

- Form 51.015B – Data Management Vendor Assessment Form
- Form 51.015C – Laboratory Vendor Assessment Form
- Form 51.015D – IMP Manufacturer Vendor Assessment Form
- Form 51.015E – NHS GG&C Vendor Assessment Tool for IMP Manufactures
- Form 51.015H – Collaborator Assessment Questionnaire
- Form 51.015I – Vendor Exemption Letter Template
- Form 51.015L – Imaging Facility Vendor Assessment
- GUI 51.015A – IMP Manufacturer Vendor Assessment Process
- GUI 51.015B – Use of Q-Pulse for Vendor Assessment Guide

5. Related documents

- SOP 52.004 - R&I Contract development and review NHS

6. Document history

Version	Date	Description
1.0	02/05/2013	Release of first version
2.0	14/07/2016	Updated to template v1.4 and renumbered
3.0	24/05/2018	Statement relating to University of Glasgow Laboratories added
4.0	18/11/2021	Substantial updates to process to include the use of Q-Pulse and how assessment are to be conducted. Change of Author.
5.0	04/10/2024	Updates and clarifications to process, removal of forms.