Vendor Pre-Questionnaire

Project Title	[Type in the information here]
RGIT ref	[Type in the information here]
Audit site	[Type in the information here]
Date of audit	[DD-MMM-YYYY]

Vendor Company Information

Company Name	[Type in the information here]
Contact Name	[Type in the information here]
Contact Number	[Include country code]
Email Address	[Type in the information here]

Sponsor Information

Contact Name	[Type in the information here]
Contact Number	[Include country code]
Email Address	[Type in the information here]
Department Information	[Type in the information here]

Author guidance notes
Dependent on the type of vendor assessment, applicable sections of the form should remain and non-applicable sections of the form should be annotated with Not Applicable (N/A).

Section 5-7 will only be completed if applicable to the vendor.

Instructions for Completing the Questionnaire
Please ensure you complete the necessary section of this questionnaire.
Follow the guidance provided below to complete the questionnaire thoroughly:

- To be completed by the delegated representative from the vendor
- Provide a summary to the questions within this document
- Where necessary, if a suitable document can be sent in place of an answer, cross reference the document including the Document Title and version and the Section within the document that provides the answer. Please be sure to provide a copy of the document when sending the questionnaire back.
- Do not cross reference any internal documents which cannot be sent for external reading
- Where necessary, please follow the prompts provided in the response section of each table below
- Once completed, send the signed copy of this questionnaire back to the Sponsor representative alongside any documents, evidence etc.

Summary of Delegated duty(s)

Insert the tasks being delegated to the vendor by the sponsor

Section 1: Company Overview

No.	Question	Response
1.1	Please provide an overview of the company covering the past 5 years.	
1.2	Please provide details of any change of ownership (last 2 years)	
1.3	Last review date of Disaster Recovery/ Business Continuity Plan	
1.4	Do you have any ongoing product roadmap. Please describe the strategic direction for the solution and the ongoing product roadmap	
1.5	Please provide evidence to demonstrate a stable financial background	

1.6	Please provide up-to-date organisational chart(s) giving the company structure, organization, and the responsibilities of key individuals within the structure responsible for the delivery of the required product/project.	*This can be provided as an attachment, please provide the name of the document and version number in this response space*
1.7	Do you have a Quality Assurance unit? If yes, how is it structured, and if not, how do you deal with Quality Assurance functions?	
1.8	Have you had any audits in the past 5 years? If so, please provide details of this including date, scope and outcome of this.	
1.9	Please provide evidence of your formal Quality Management System certification to ISO9001 including details of your most recent Certification audit by your certification body.	*Further questions regarding the Quality Management System (QMS) in section X below*
1.10	Please list any Licences/Accreditations (include dates) and provide the current certifications	*Please provide this information in a table* *i.e. GMP, GLP Certification, ISO Accreditation*
1.11	Please provide a list of regulatory inspections for the last five years (where applicable):	*This can be provided as an attachment, please provide the name of the document and version number, date in this response space*
1.12	Please list any regulatory standards to which your company works towards:	
1.13	Are there any comments/details you would like to provide?	

Section 2: Team Competency

No.	Question	Response
2.1	Please provide a list of the team who will be assigned to complete the delegated service. Please provide the most up to date CV's for the team	*Please provide the following information in a table:* - *Full name, title* - *Job Title* - *How long have they been in the position for* - *Position in the team* - *Contactable? If so, provide email/number*
2.2	Please provide evidence of GCP training and awareness certification for the delegated team members	
2.3	Please provide evidence of certification completed for? *List the mandatory training required*	
2.4	Do you have a trial of Log of protocol amendments and revision history	
2.5	Do you have serious breach SOP, spelling out what a reportable 'serious breach' is as per the UK legislation underpinning clinical trials.	
2.6	Do you hold a log of incidents reported to the sponsor?	

No.	Question	Response
2.7	Are there any comments/details you would like to provide?	

Section 3: Study Conduct/Communication

No.	Question	Response
3.1	Communication Oversight	*Regular communications (i.e. teleconferences or regular meetings)* *Review of specific activities*
3.2	Is there a procedure in place to ensure effective and timely communication with the sponsor/study site regarding any serious deviations from the clinical protocol or contract/agreement?	
3.3	Has your company been previously undertaken to provide a randomisation service for a Clinical Trial?	
3.4	Is there a process for communication with the sponsor/study site to destroy samples if a patient withdraws consent?	
3.5	Do you use study specific laboratory manuals to process research samples if not stipulated in the protocol or covered in existing SOPs? Are procedures for research samples reviewed for each clinical protocol to ensure they meet the individual protocol requirements?	
3.6	Is there a procedure for recording and reporting deviations from standard procedures?	
3.7	Are there any comments/details you would like to provide?	

Section 4: Quality Management System

No.	Question	Response
4.1	Please provide a summary of the procedures, methodologies, tools, and process followed when planning and managing quality on projects.	
4.2	How do you assure that the procedures in your QMS are followed?	
4.3	Provide details of the process followed for internal company audits	
4.4	Provide details of the process followed for implementing corrective actions.	
4.5	Provide details of the process followed to address customer complaints. How many customer complaints have been raised/resolved in the last 12 months?	

No.	Question	Response
4.6	How is the use of sub-contract resource controlled, including details of the process followed for adding and deleting companies from your list of sub-contractors?	
4.7	Please describe your written procedures for Personnel training.	
4.8	Please describe your written procedures for Document review and approval.	
4.9	Are there any comments/details you would like to provide?	

Sections 5-7 below will only be completed if applicable to the vendor.

Section 5: Computer System Development and Support (if applicable)

No.	Question	Response
5.1	Please provide the history of the [insert Computer Service being offered] development over the past five years?	
5.2	Please describe the key third party companies that you use to provide design input into the [insert Computer Service being offered].	
5.3	Please describe the software life cycle model and design methodology for this [insert Computer Service being offered].	
5.4	Is there a written procedure for the [insert Computer Service being offered] development?	*If yes, please provide procedure title and version*
5.5	Do you use any programming standards when writing software code? If so, please provide details of the process, definitions and standards used. Where external software companies are utilised, provide details of how software processes/standards are monitored/controlled.	
5.6	What is the approval process for the release of any updated [insert Computer Service being offered] required for you to complete your service?	
5.7	Please provide details of the processes/standards that are followed for the inspection/testing of your [insert Computer Service being offered]. This should include reference to the process followed for ensuring that all product specifications have been inspected and tested.	
5.8	Describe what happens when a new version of the [insert Computer Service being	

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	offered] is developed. Are there any differences between a minor release of software and a major release of software?	
5.9	Is an escrow agreement available for protection against bankruptcy or the discontinuance of any product to be supplied?	
5.10	What procedure is followed when an error or anomaly is detected (e.g. program, system, hardware, or data error)?	
5.11	What procedure is in place if there are any system malfunction? Would there be any communication sent to the Sponsor to notify them?	
5.12	Is there a system for maintaining lists of notified software bugs and enhancement requests?	
5.13	Describe your written procedure for Software problem support.	
5.14	Describe your written procedure for Archiving of documentation.	
5.15	Do you have guaranteed response times for critical and non-critical application failures? If so what are they?	
5.16	Has your company been previously undertaken to provide a database for a Clinical trial?	
5.17	Please provide a short summary of how databases are designed, and validated	
5.18	Are there any comments/details you would like to provide?	

Section 6: Laboratories
If the vendor will be completing any laboratory activities, the Vendor Laboratory GCP Questionnaire for CTIMPs - RGIT_TEMP_055 will be attached and completed by the vendor.

Please remember to send back the RGIT_TEMP_055 as an attachment.

Section 7: Patient Safety

No.	Question	Response
7.1	Have you filed a risk assessment of this trial from a GCP perspective. I.e. in terms of impact of the results on patient safety and data validation of the trial Is this trial classified as high risk as per that assessment?	

7.2	Do laboratory reports contain normal range values and identify results outside of normal ranges?	
7.3	Is there a process for expedited reporting of urgent results?	

Section 8: Pharmacy

No.	Question	Response
8.1	Is there a designated member of staff appointed who has overall responsibility for the pharmacy clinical trial service?	
8.2	Is there a procedure in place to maintain oversight on pharmacy procedures? Is this a trial specific or generic procedure? Does this process cover the following? Receipt, storage, accountability, product recall, labelling, dispense and destruction of the IMP/NIMP. Unblinding/emergency unblinding.	
8.3	How often is the process reviewed? How is training demonstrated?	
8.4	Please provide details on the source of the IMP/NIMP. E.g. are the IMP manufactured from a site that hold a MIA (IMP) license? Is there an agreement in place for this?	
8.5	Is there a system in place to ensure quality of the IMP/NIMP is maintained at all time? These include adequate temperature monitoring/control, sufficient storage space is available, oversight of product expiry dates, complaints, recalls, quarantines, locked facilities and restrictions for unauthorised access etc.	
8.6	What is the process onsite if there is a temperature excursion? Who will be notified? Will regular temperature checks be taken for the NIMP/IMP storage facilities? Do you have a valid proof calibration that will be maintained for reference for the monitoring of the storage facility temperatures?	
8.7	How do you ensure sufficient quantities remain in place throughout the study? If stock is low, who is alerted and the process to manage this?	
8.8	Do you use any accountability logs for management of the IMP/NIMP. This should include at a minimum which subject received the IMP/NIMP?	

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8.9	Is there a pharmacy site file maintained? If not, how will the above be documented and where? Are all relevant approvals filed here and what is the process to ensure all relevant approvals are in place (regulatory, local, QP etc).	
8.10	Are there any comments/details you would like to provide?	

Section 9: RGIT Comments

Vendor Documents

No.	Document Title	Version Number, Date
	Company User Guide	

Standard Operating Procedure (SOP) List

Please provide a completed list of all the current SOPs that you have within your company and provide a copy of each SOP

No.	Title of SOP	Effective Date of SOP	Version	Due date for next Review	SOP Sent?
1					
2					
3					
4					
5					
6					
7					
8					
9					

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Completed by:

Name:	Position:
Signature:	**Date:**

Please can you confirm that the SOPs that will be sent or have been sent are in compliance with ICH GCP, the statutory instruments 2004 No. 1031 - The Medicines for Human Use (Clinical Trials) Regulations and subsequent amendments. Please note, trial specific SOPs will need to be reviewed by the sponsor prior to approval.

I can confirm, that the SOPs are in compliance with ICH GCP, SI 2004 No. 1031 and subsequent amendments

Name:

Date:

Signature:

Please list the regulations and/or legislations that your SOPs complies to