**Data Management Vendor Assessment Form**

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| **Purpose**  This assessment form is to evaluate a vendor sulpplying a research service to NHS Greater Glasgow and Clyde prior to adding to an approved vendor list. | |
| **Name and location of facility:**  Click here to enter text. | **Date of evaluation:**  Click here to enter a date. |
| **Name and position of person completing the form:**  Click here to enter text. | **Contact details**  **Email:**Click here to enter text.  **Tel:**Click here to enter text. |
| **Trial Name:** Click here to enter text. **R&I Ref No:** Click here to enter text. | |
| This form must be completed by a person with appropriate authority to respond on behalf of the organisation on matters relating to the service provided and quality management systems in place.  **Please complete the sections as fully as possible and return to sender by** Click here to enter a date. If information is not submitted, please indicate in the box provided the reason for non-provision or if not applicable. Insufficient responses will be followed up and an on site audit may be undertaken.  If an SOP or working instruction (or equivalent) covers any of the criteria, please reference the SOP, or equivalent.  On conclusion of the assessment, NHS GG&C will provide feedback where appropriate and indicate if the organisation is accepted as vendor for provision of the service(s). | |

**Evaluation criteria**

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| **1** | **Quality Overview** | |
| **a)** | Please use the table beside to detail any accreditation held by the facility e.g. ISO-9001, ISO-27001, etc  If not applicable, please leave blank. | |  |  |  | | --- | --- | --- | | **Accreditation** | **Approval Date** | **Renewal Date** | | Click here to enter text. | Click here to enter a date. | Click here to enter a date. | | Click here to enter text. | Click here to enter a date. | Click here to enter a date. | | Click here to enter text. | Click here to enter a date. | Click here to enter a date. | | Click here to enter text. | Click here to enter a date. | Click here to enter a date. | | Click here to enter text. | Click here to enter a date. | Click here to enter a date. | | Click here to enter text. | Click here to enter a date. | Click here to enter a date. | | Click here to enter text. | Click here to enter a date. | Click here to enter a date. | | Click here to enter text. | Click here to enter a date. | Click here to enter a date. | | Click here to enter text. | Click here to enter a date. | Click here to enter a date. | |
| **b)** | Who is responsible for the Quality Assurance for the facility | Click here to enter text. |
| **c)** | Please identify the SOPs/Processes by their unique ID number which cover the following key elements of your Quality Management System.  (If more than one, add all relevant) | |  |  |  | | --- | --- | --- | | **Area** | **ID** | **Title** | | Document Management/Control | Click here to enter text. | Click here to enter text. | | Non-Conformance Management | Click here to enter text. | Click here to enter text. | | Training and Competencies | Click here to enter text. | Click here to enter text. | | Risk Management | Click here to enter text. | Click here to enter text. | | Audit | Click here to enter text. | Click here to enter text. | |
| **d)** | If required, will the sponsor be given access to audit the facility? | Click here to enter text. |
| **e)** | Please provide an organisational chart |  |
| **f)** | Please list the service(s) provided by the facility for this trial and highlight if they impact on any of the areas list.  n.b. If not known please state NK.  (expand if required) | |  |  |  |  |  | | --- | --- | --- | --- | --- | | **Service Title** | **Service Description** | **Primary / Secondary Endpoint** | **Safety** | **Clinical Care** | | Click here to enter text. | Click here to enter text. | Choose an item. | Choose an item. | Choose an item. | | Click here to enter text. | Click here to enter text. | Choose an item. | Choose an item. | Choose an item. | | Click here to enter text. | Click here to enter text. | Choose an item. | Choose an item. | Choose an item. | | Click here to enter text. | Click here to enter text. | Choose an item. | Choose an item. | Choose an item. | | Click here to enter text. | Click here to enter text. | Choose an item. | Choose an item. | Choose an item. | | Click here to enter text. | Click here to enter text. | Choose an item. | Choose an item. | Choose an item. | | Click here to enter text. | Click here to enter text. | Choose an item. | Choose an item. | Choose an item. | | Click here to enter text. | Click here to enter text. | Choose an item. | Choose an item. | Choose an item. | | Click here to enter text. | Click here to enter text. | Choose an item. | Choose an item. | Choose an item. | | Click here to enter text. | Click here to enter text. | Choose an item. | Choose an item. | Choose an item. | | Click here to enter text. | Click here to enter text. | Choose an item. | Choose an item. | Choose an item. | |

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| **g)** | If your facility provides additional services not utilised by this trial, please detail in the following table  (expand if required) | |  |  | | --- | --- | | **Service Title** | **Service Description** | | Click here to enter text. | Click here to enter text. | | Click here to enter text. | Click here to enter text. | | Click here to enter text. | Click here to enter text. | | Click here to enter text. | Click here to enter text. | | Click here to enter text. | Click here to enter text. | | Click here to enter text. | Click here to enter text. | | Click here to enter text. | Click here to enter text. | | Click here to enter text. | Click here to enter text. | | Click here to enter text. | Click here to enter text. | | Click here to enter text. | Click here to enter text. | | Click here to enter text. | Click here to enter text. | | Click here to enter text. | Click here to enter text. | | Click here to enter text. | Click here to enter text. | |

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| **2** | **SOPs/working instruction(s)** | |
| **a)** | Please provide a list of all SOPs/working instructions/Policy documents used within the facility  (expand table to accommodate) | |  |  |  |  | | --- | --- | --- | --- | | **ID Number** | **Title** | **Version** | **Release Date** | |  |  |  |  | |  |  |  |  | |  |  |  |  | |  |  |  |  | |  |  |  |  | |  |  |  |  | |  |  |  |  | |  |  |  |  | |  |  |  |  | |
| **b)** | Describe the process for reporting deviations from the facilities SOPs or policies to the Sponsor. Include reference to any timelines for reporting.  n.b. if this process is described within an SOP you may provide this SOP in place of summary. | Click here to enter text. |
| **c)** | Please confirm the process followed when considering the impact of Non-Compliances and/or deviations on the data.  Also detail in this any notification or escalation to Sponsor and associated timelines.  Please also confirm how this consideration is evidenced. | Click here to enter text. |

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| **3** | **Training** | |
| a) | Are staff involved in the specific activities appropriately educated, experienced and trained? | Click here to enter text. |
| b) | Please describe what training staff have received in relation to GCP. | Click here to enter text. |
| c) | Please describe the process for training of staff including how this is evidenced and any review periods of training.  n.b. if this is detailed with an SOP you may provide the SOP in place of this summary. | Click here to enter text. |
| d) | Do the training records include up to date signed and dated CV’s and job descriptions? | Click here to enter text. |

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| **4.** | **Computer systems** | |
| a) | Describe the type of computer system used for the following activities and include if bespoke or commercial off the shelf:   * eCRF generation * IVRS * Data management * Statistical analysis * Portal for clinical trial management | Click here to enter text. |
| b) | Please provide the validation report(s) for the installation of the system(s) and the validation report for any trail specific builds | Click here to enter text. |
| c) | Describe the system for change control (version control) | Click here to enter text. |
| d) | Describe the procedure for loss of information due to systems failure | Click here to enter text. |
| e) | Describe the security system for access to the systems used | Click here to enter text. |

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| **Please provide any additional information that may be useful as part of the vendor assessment programme** |

**Evaluation completed by:**

**Position:**

**Date:**