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| **R&I ref:** | Click here to enter text. |
| **Name of Trial:** | Click here to enter text. |
| **Name of Collaborator:** | Click here to enter text. |
| **Summary of involvement in Trial:**  **(Please include details of any trial related activities organisation will perform, services or products provided.)** | Click here to enter text. |

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| **Organisation Overview** | | |
|  | Does your facility have a Quality Management System in place covering the following areas? | |  |  | | --- | --- | | **Area** | **Response** | | **Overall QMS** | Choose an item. | | **Management of SOPs** | Choose an item. | | **Internal Audit** | Choose an item. | | **Training** | Choose an item. | | **Non-Compliances** | Choose an item. | | **Risk Management** | Choose an item. | | **GDPR** | Choose an item. | |

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|  | Does your facility hold any accreditation? e.g. ISO-9001  If N/A then leave blank | |  |  | | --- | --- | | **Accreditation** | **Renewal Date** | | Click here to enter text. | Click here to enter a date. | | Click here to enter text. | Click here to enter a date. | | Click here to enter text. | Click here to enter a date. | | Click here to enter text. | Click here to enter a date. | | Click here to enter text. | Click here to enter a date. | | Click here to enter text. | Click here to enter a date. | | Click here to enter text. | Click here to enter a date. | | Click here to enter text. | Click here to enter a date. | |

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|  | Is an organisation chart in place which includes the following roles? If role is not present please indicate who is responsible, or state N/A. | |  |  | | --- | --- | | Role | Response | | Facility Manager | Choose an item. | | Quality Manager | Choose an item. | | Governance Manager | Choose an item. | | Archivist | Choose an item. | |

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| **Staff Management Training (Relevant to Trial)** | | |
|  | Does each staff member involved with providing services for this trial have an up to date training file | Click here to enter text. |
|  | Does each staff member have an up to date CV and Job Description? | Click here to enter text. |

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| **Study Management** | | |
|  | Does the organisation have previous experience of working with a trial specific file which will be maintained during the lifecycle of the trial, containing the current version of the protocol and any applicable amendments? | Click here to enter text. |

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| **SOPs/Working Instruction(s)** | | |
|  | Are SOPs currently in place to cover the following topics? | |  |  | | --- | --- | | Topic | Response | | Technical Processes relating to those required for trial | Choose an item. | | The following SOPs should discuss reporting to Sponsor | | | Non-Compliance/Deviations | Choose an item. | |

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| **Audits/Inspections** | | |
|  | Has the organisation undergone any external audits or inspections within the last year? | Click here to enter text. |
|  | If the answer to the previous question is yes, were any major or critical issues identified? | Click here to enter text. |
|  | If any major or critical issues were identified, have all now been rectified and closed? | Click here to enter text. |

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| **Systems and Security** | | |
|  | Is the facility safe and secure? | Click here to enter text. |
|  | Does your facility have a process for data backup? | Click here to enter text. |
|  | Does your facility have a process for disaster recovery? | Click here to enter text. |

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