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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? |

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| **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-9001If N/A then leave blank |

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| **Accreditation** | **Renewal 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. |

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| 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? |

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| 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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