**STUDY & SITE INITIATION REPORT**

***Complete 1 form for each site***

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| **Study short title**  |  | **Sponsor Ref:** |  |
| **Site:** |  | **CI:****PI:** |  |
| **Date Of Visit:** |  | **Current Protocol Version:** |  |

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| **Members of the study team present:** | **Role:** |
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***For lead site only***

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| TASK - Instructions: Please provide the requested information for each of the items listed below. If not applicable put “N/A” in the comments section. |
| 1 | **Trial Master File is in place with all necessary documents in accordance with the TMF index** | Yes [ ]  No[ ]  |  |
| 2 | **Regulatory & Ethics approval in place and conditions have been met** | Yes [ ]  No[ ]  |  |
| 3 | **All required contracts are in place (Funder, CTU, University of Portsmouth, Sealed Envelope)** | Yes [ ]  No[ ]  |  |
| 4 | **Annual reporting schedule is present** | Yes [ ]  No[ ]  |  |
| 5 | **Delegation of Responsibilities for Chief Investigator is signed & filed** | Yes [ ]  No[ ]  |  |
| 6 | **Funding secured and in place** | Yes [ ]  No[ ]  |  |
| 7 | **Database in place and validated** | Yes [ ]  No[ ]  |  |
| 8 | **Monitoring plan is in place** | Yes [ ]  No[ ]  |  |
| 9 | **Randomisation procedure in place** | Yes [ ]  No[ ]  |  |
| 10 | **Unblinding procedure in place** | Yes [ ]  No[ ]  |  |
| 11 | **Blinding is sufficient and robust** | Yes [ ]  No[ ]  |  |

***For all sites***

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| STUDY PROCEDURES **Instructions:** Please provide the requested information for each of the items listed below. If not applicable put “N/A” in the comments section. |
| 1 | **Study objectives and design explained to the study team?** | Yes [ ]  No[ ]  |  |
| 2 | **Inclusion/exclusion criteria discussed?** | Yes [ ]  No[ ]  |  |
| 3 | **Study procedures including screening discussed?** | Yes [ ]  No[ ]  |  |
| 4 | **Informed consent, enrolment and retention discussed?** | Yes [ ]  No[ ]  |  |
| 5 | **Study Specific Procedures explained and distributed?** | Yes [ ]  No[ ]  |  |
| 6 | **Relevant Standard Operating Procedures explained and/or distributed?** | Yes [ ]  No[ ]  |  |
| 7 | **Investigator Site File complete?** | Yes [ ]  No[ ]  |  |
| 8 | **Delegation log filled in?** | Yes [ ]  No[ ]  |  |
| 9 | **Document versions on file are correct?** | Yes [ ]  No[ ]  |  |
| 10 | **Protocol front page / acknowledgment slip signed by the PI?** | Yes [ ]  No[ ]  |  |
| 11 | **Site added to the randomisation server?** | Yes [ ]  No[ ]  |  |
| 12 | **Randomisation procedure in place and explained?** | Yes [ ]  No[ ]  |  |
| 13 | **Completion & correction of the CRFs discussed with the study team?** | Yes [ ]  No[ ]  |  |
| 14 | **Source documents discussed with the study team?** | Yes [ ]  No[ ]  |  |
| 15 | **Patients’ data storage requirements discussed and adequate?** | Yes [ ]  No[ ]  |  |
| 16 | **Anticipated start of enrolment?** |  |  |
| 17 | **Expected enrolment target?**  |  |  |
| 18 | **Monitoring arrangements discussed?** | Yes [ ]  No[ ]  |  |
| 19 | **Invoicing arrangements discussed?** | Yes [ ]  No[ ]  |  |
| 20 | **Local R&D approvals in place?** | Yes [ ]  No[ ]  |  |
| 21 | **Safety reporting procedures discussed?** | Yes [ ]  No[ ]  |  |

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| **STUDY PERSONNEL****Instructions:** Please provide the requested information for each of the items listed below. If not applicable put “N/A” in the comments section. |
| 1 | **Study team GCP trained?** | Yes [ ]  No[ ]  |  |
| 2 | **Study team sufficiently trained for their role?**  | Yes [ ]  No[ ]  |  |
| 3 | **Site training log completed for this visit?** | Yes [ ]  No[ ]  |  |
| 4 | **All staff have substantive contracts or letters of access in place?** | Yes [ ]  No[ ]  |  |
| 5 | **Study team trained in the use of equipment / medication / device / questionnaire**  | Yes [ ]  No[ ]  |  |

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| **STUDY RESOURCES & SUPPORT DEPARTMENTS****Instructions:** Please provide the requested information for each of the items listed below. If not applicable put “N/A” in the comments section. |
| 1 | **Site provided with study packs (CRFs, patient forms, cards), & equipment?** | Yes [ ]  No[ ]  |  |
| 2 | **All support departments are ready for recruitment to start? *(List)*** | Yes [ ]  No[ ]  |  |
| 3 | **IMP / supplies are in stock, correctly labelled and stored correctly**  | Yes [ ]  No[ ]  |  |
| 4 | **Temperature monitoring controls are in place** | Yes [ ]  No[ ]  |  |
| 5 | **Support department files checked for correct versions** | Yes [ ]  No[ ]  |  |

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| **SUMMARY**  |
| **Is the study site acceptable anD ready to start recruitment? (If NO, LIST ANY ISSUES THAT NEED TO BE ADDRESSED BEFORE THE START OF RECRUITMENT)** |
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| **DESCRIBE ANY SPECIFIC DISCUSSIONS / TRAINING CONDUCTED DURING THE VISIT: (SPECIFY TYPE OF training performed and names of site personnel present at the time of the training.)**  |
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| **OUTSTANDING ACTIONS (following SIV);** |
| **Action** | **Personnel responsible** | **Date completed** |
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| Reviewed by Sponsor (Name & Role):………………………………………………………………….. | Signature………………………………………………………… | Date…………………………………….. |