**Laboratory Service Requirements**

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Project Title:** | | | | | | | | | |
| **REC ref:** | | | **CTIMP project** | **YES** | | | **□** | **NO** | **□** |
| **Sponsor ref:** | | |
| **EudraCT ref** *(if required***):** | | |
| **Laboratory Manager/Contact (for project):**  *Name, address and e-mail* | | | **Chief/Principal Investigator:**  *Name, address and e-mail* | | | | | | |
| **Laboratory Certification/Accreditation or Licence details (***if applicable***):** | | |  | | | | | | |
| **The terms of informed consent for the trial permit analysis of the trial samples, in accordance with the requirements, in this Laboratory** | | | | | **YES □ NO □** | | | | |
| **Laboratory has reviewed Patient Information Sheet /Consent text relating to samples and agree they are compliant with GDPR.** | | | | | **YES □ NO □** | | | | |
|  | | | | |  | | | | |
| **LABORATORY STAFF TRAINING:** | | | | | | | | | |
| **All laboratory staff involved in the trial have received the appropriate training to enable them to perform the required tasks** | | | | | **YES □ NO □** | | | | |
| **Trial Delegation Log will be completed** | | | | | **YES □ NO □** | | | | |
|  | | | | |  | | | | |
| **SAMPLES AND SERVICES:** | | | | | | | | | |
| **Description of Samples** | ***e.g. Whole blood*** | | | | | | | | |
| **Quantity of Samples** | Number of patients :  Number of visits :  Total number of samples:  **Please note:** *In the event of an amendment to the trial protocol which changes the number of participants or number of samples collected from each participant, a review of this questionnaire will be required. This will be in conjunction with the necessary amendment to the trial protocol and other trial documentation.* | | | | | | | | |
| **Informed Consent** | The CI/PI is responsible for ensuring written informed consent is obtained from the patient prior to sample shipment to Laboratory.  The laboratory is responsible for ensuring the terms of informed consent permit the required analysis of the samples. | | | | | | | | |
| **Sample labelling requirements** | ***e.g. Trial Samples will be labelled in the format: trial name, participant reference, date, sample type.***  The CI/PI is responsible for ensuring all patient identifiable information is removed prior to sample shipment. In the event Laboratory staff receive samples with participant identifiable information, they must notify the CI/PI of the issue, and remove or obscure these details before proceeding with testing. | | | | | | | | |
| **Transport arrangements for samples to Laboratory** | ***e.g. Samples will be transported directly to the Laboratory by the trial research team. Sample receipt will be recorded by the Laboratory staff.*** | | | | | | | | |
| **Analyses to be Undertaken** | ***e.g. Full blood count, liver function test and electrolytes analysis***  The Laboratory Manager is responsible for ensuring methods are validated, and internal quality controls are used for all trial analyses. The Laboratory Manager will provide normal ranges, for the analyses performed, to the CI/PI. | | | | | | | | |
| **Analytical Method**  **(**as detailed in Laboratory SOPs**)** | The Laboratory Manager is responsible for appending a list of SOP titles and version numbers to this Laboratory Services Requirements. | | | | | | | | |
| **Laboratory equipment to be used** | Laboratory equipment used:  ***Equipment name and number (if available)***  The Laboratory Manager is responsible for ensuring all critical laboratory equipment used to process trial samples have current safety, maintenance and calibration records. | | | | | | | | |
| **Storage requirements of trial samples** | ***e.g. Samples will be stored at 2-8C in fridge #2 within the Laboratory cold storage area***  The Laboratory Manager is responsible for ensuring secure sample storage, routinely monitored to ensure no temperature excursions occur. The Laboratory Manager will notify the CI/PI in the event of a temperature excursion and agree the appropriate action to be taken. | | | | | | | | |
| **Trial Sample destruction/returns** | ***e.g. Trial Samples will be destroyed at the request of the CI/PI either at completion of the trial or due to patient withdrawal from trial. The Laboratory Manager will ensure appropriate sample reconciliation, biobank or disposal records are completed.*** | | | | | | | | |
| **Timescale for Analysis** | ***e.g. Samples will be sent to the Laboratory from mmm/yyyy until approx. mmm/yyyy.*** | | | | | | | | |
| **Data handling** | The Laboratory Manager is responsible for ensuring all applicable instrument-based analytical computer software is validated. All data copied, or transcribed, from the original source into a spreadsheet, or report, will be reviewed as a minimum by one additional member of staff for accuracy. The Laboratory Manager is responsible for storage and archiving of computer source data. | | | | | | | | |
| **Data transfer/Result reporting** | ***e.g. The laboratory will issue results electronically as contracted by the CI/PI, usually in a spreadsheet format on completion of analysis for each batch of samples or at the end of the trial. The results will be identified using the same labelling nomenclature as sample labelling required. Any unexpected results, which may impact patient safety, will be reported immediately to the CI/PI. Any out of range results, incidental findings, or laboratory investigations, which may not impact patient safety, will be reported to the CI/PI on an agreed regular basis****.* | | | | | | | | |
| **Deviation handling** | The Laboratory Manager is responsible for ensuring all sample analysis deviations are recorded and reported immediately to the CI/PI. | | | | | | | | |
| Laboratory Methods | Any changes to Laboratory methods used must be agreed in writing between all signatories to this Laboratory Services Requirements prior to implementation. | | | | | | | | |
| **Archiving** | ***NB. Refer to trial protocol for requirements*** | | | | | | | | |
| **Conditions of blinding and unblinding** | ***NB for a blinded trial the results may unblind the participants. In this case confirmation of who may receive unblinded results for the trial should be obtained or results should not be reported until the final trial analysis, unless the results impact on participant safety****.* | | | | | | | | |
| **Costs** | ***List costs for trial****.* | | | | | | | | |
| ***Chief Investigator*** | |  | | | |  | | | |
| PRINT NAME: | | SIGNATURE: | | | | DATE: | | | |
| ***Laboratory Project Manager*** | |  | | | |  | | | |
| PRINT NAME: | | SIGNATURE: | | | | DATE: | | | |
| ***STU Representative*** | |  | | | |  | | | |
| PRINT NAME: | | SIGNATURE: | | | | DATE: | | | |