CTIMP - CTIMP Co-Enrolment Checklist

This checklist must be completed by the CI and reviewed the by the Sponsor Representative(s) for all instances where participants are intended to be enrolled in more than one CTIMP concurrently.

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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Trial A** | | | | | | **Trial B** | | | | | | |
| **Trial Name:** | | |  | | | **Trial Name:** | |  | | | | |
| **Registry Number:** | | |  | | | **Registry Number:** | |  | | | | |
| **REC Number:** | | |  | | | **REC Number:** | |  | | | | |
| **Chief Investigator:** | | |  | | | **Chief Investigator:** | |  | | | | |
| **Sponsor:** | | | UoE and NHSL | | | **Sponsor:** | |  | | | | |
| **Action** | | | | | | | **Completed** | | **Comment** *(if N/A, provide justification)* | | | |
| 1 | | [Trial A] Chief Investigator (CI) has been informed of the plan to co-enrol with [Trial B] and has provided written agreement for this to take place.  *The CI must be prompted to consider the potential impact on trial endpoints and consult the [Trial A] TMG or the TSC/DMC, including the statistician....* | | | | | ☐ Yes | |  | | | |
| 2 | | [Trial B] CI has been informed of the plan to co-enrol with [Trial A] and has provided written agreement for this to take place.  *It is the responsibility of the [Trial B] CI to inform their Sponsor (if required) of the intention to co-enrol and to comply with their relevant sponsor processes.* | | | | | ☐ Yes | |  | | | |
| 3 | | The Sponsor of [Trial B] has provided written authorisation for co-enrolment to proceed. If the policy of the sponsor is not to adjudicate co-enrolment decisions, authorisation from the delegated individual (e.g. TM/CI) will suffice as sponsor authorisation. | | | | | ☐ Yes | |  | | | |
| 4 | | University of Edinburgh insurance office has been notified of the planned co-enrolment. | | | | | ☐ Yes | |  | | | |
| 5 | | A Clinical Pharmacologist has been consulted regarding the co-enrolment and has confirmed in writing that there are no safety concerns prohibiting the co-enrolment.  *Where there is potential for drug interactions (e.g. all active CTIMP-CTIMP scenarios), the protocols and IMP (and NIMP if applicable) information (i.e. SPCs/IBs) should be sent to the clinical pharmacologist for review.* | | | | | ☐ Yes  ☐ N/A | |  | | | |
| 6 | | [Trial A] CI will be advised by Sponsor Representative that co-enrolment should be documented in all co-enrolled participants medical notes when providing the completed checklist. | | | | | ☐ Yes  ☐ N/A | |  | | | |
| 7 | | [Trial A] ACCORD Risk Assessment has been appraised and signed off.  *Please select N/A if proposed co-enrolment is compatible with the co-enrolment rules described in the current risk assessment tool and protocol for the UoE/NHSL sponsored project(s).* | | | | | ☐ Yes  ☐ N/A | |  | | | |
| **Approvals** | | | | | | | | | | | | | |
| Action points 1-7 must be completed and evidenced prior to sign-off by the co-Sponsors. The co-enrolment cannot take place until this checklist has been completed and the Sponsor has provided written authorisation for the co-enrolment to proceed. | | | | | | | | | | | | | |
| **Sponsor Representative Sign-Off** | | | | | | | | | | | | | |
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|  | | **Sponsor Representative Signature** | | |  | **Position** | | | | |  | **Date** |  |