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| **FACILITATION CHECKLIST** | | | | | | |
| **Study Title:** |  | | | | | |
| **Chief Investigator:** |  | | **Sites:** | | | ☐ Single ☐Multi |
| **Sponsor Reference:** |  | **Lead Sponsor Representative:** | | |  | |
| **Trial:** | ☐CTIMP ☐ATIMP ☐ Other | | **Trial Phase:** | ☐Phase I ☐ Phase II ☐ Phase III ☐Phase IV | | |

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|  | |  |  | **Details** |
| **Documentation** | | | | |
| SharePoint Study Tracker Updated | | *Reference numbers and dates of approvals should be added to the SharePoint Tracker* | ☐ No ☐Yes |  |
| Has statistical input been sought for the trial? | | *All CTIMPs must have sufficient statistical input prior to RA. There should be a Trial Statistician sign off on the Signature page of the protocol unless a recognised Statistician has provided a written statement instructing that formal Statistician sign off is not required.* | ☐ No ☐Yes |  |
| Trial Manager in place? | | *Trial manager required for multi-site trials* | ☐ No ☐Yes ☐ N/A |  |
| Feasibility questionnaires obtained for multi-site trials, for sites planned to open immediately? | | *See ACCORD Feasibility Questionnaire (SOP GS013)* | ☐ No ☐Yes ☐ N/A |  |
| Is a DMC required? | | *Discuss and agree with Co-Sponsors and Statistician. DMC Charter will need to be drafted and reviewed by Sponsor.* | ☐ No ☐Yes |  |
| Is a TSC required? | | *Discuss and agree with Co-Sponsors and Statistician* | ☐ No ☐Yes |  |
| Who will provide the database / eCRF? | | *For example, ECTU / external contractor* |  |  |
| Will identifiable information be held on the database / e-CRF? | | *If yes, discuss Caldicott/PBPP/CAG approval requirements with an NHS Lothian research governance staff member if necessary. The discussion can include what constitutes ‘identifiable’* | ☐ No ☐Yes ☐ N/A |  |
| Are details of database / e-CRF archiving provided in the protocol? | | *The protocol should detail who will have responsibility for archiving the trial database, how long it will be archived for and where it will be archived. The protocol should also provide details of the server the database will be held/archived on.* | ☐ No ☐Yes ☐ N/A |  |
| Are protocol compliant randomisation procedures in place? | |  | ☐ No ☐Yes ☐ N/A |  |
| Who is providing randomisation? | |  | ☐ No ☐Yes ☐ N/A |  |
| Who will hold the code break for emergency unblinding? | |  | ☐ No ☐Yes ☐ N/A |  |
| Pharmacovigilance check of SUSAR unblinding undertaken? | | *Unblinding mechanism for SUSARs must be tested to ensure Sponsor mechanism for unblinding potential SUSARs for regulatory reporting works.* | ☐ No ☐Yes ☐ N/A |  |
| Will biological samples be obtained as part of the trial? | |  | ☐ No ☐Yes |  |
| Are details of where samples will be stored / analysed listed | | *Location of labs to be detailed in the protocol and how these relate to primary / secondary endpoints* | ☐ No ☐Yes |  |
| Does IB/SPC Booklet have signature page? If so, has it been signed by a member of the PV team? | | *If there is a signature page, this must be signed and dated by the relevant individuals and a copy retained by the Sponsor. There may not be a sponsor signature section if the product will be used in multiple trials.* | ☐ No ☐Yes ☐ N/A |  |
| **Clinical Trials Authorisation** | | | | |
| **If not completed, please justify:** |  | | | |
| Checklist of Documents Required for Competent Authority submission:  ☐Cover letter (when applicable, subject line should state that the submission is for a Phase I trial and is eligible for a shortened assessment time, or if it is submitted as part of the [notification scheme](https://www.gov.uk/guidance/clinical-trials-for-medicines-apply-for-authorisation-in-the-uk#notification-scheme). Check with PV additional requirements, e.g. highlight lack of frequency tables)  ☐ Medicines form in PDF and XML versions or medical device equivalent  ☐ Protocol  ☐ Investigator’s Brochure (IB) or document replacing the IB, e.g. Summary of Product Characteristics.  ☐Investigational medical product dossier (IMPD) or a simplified IMPD or medical device technical file (this includes, for example, the IFU, Risk Register etc)  ☐Non-investigational medicinal product dossier (if required)  ☐Manufacturer’s authorisation, including the importer’s authorisation and QP declaration on [good manufacturing practice](https://www.gov.uk/guidance/good-manufacturing-practice-and-good-distribution-practice) for each manufacturing site if the product is manufactured outside the EU  ☐Content of the labelling of the investigational medicinal product (IMP) (or justification for its absence) or medical device  ☐ (other study specific documentation required by the CA) | | | | |
| Who will submit the CTA? | | *This should be detailed within the CTA and should also be covered within the relevant agreements. If delegate, please comment. If delegated, Sponsor Rep can should create user account on the MHRA submission portal and other relevant portals (e.g. CESP in the EU) for delegate. If the trial is running in more than one country, details of the required submissions (and who will be responsible for making the submissions) should be added to this checklist.* | ☐Sponsor ☐Delegate |  |
| **Agreements *(copies of all relevant, signed agreements must be retained by the Sponsor)*** | | | | |
| Funding Award Agreement/Letter | | *Any terms and conditions that should flow into site agreements.* | ☐ No ☐Yes ☐ N/A |  |
| Co-Sponsorship Agreement | | *Required for all regulated trials to define responsibilities of UoE, NHS Lothian and CI (Please note: site/PI may also be included in this agreement. If a trials unit is involved, their role may also be included here). An NHS Lothian site agreement may be incorporated within this agreement.* | ☐ No ☐Yes ☐ N/A |  |
| Site Agreement (mNCA) | | *Required for all multi-site studies to define responsibilities of UoE, NHS Lothian, CI and site. An mNCA will need to be submitted as part of the R&D submission of studies.* | ☐ No ☐Yes ☐ N/A |  |
| Drug Supply Agreement | | *To formalise arrangements with drug manufacturer / supplier.*  *Should ensure that there is two-way exchange of information relating to safety. Ensure any QA qualification activities, in relation to manufacturer selection, have been completed prior to agreement execution.* | ☐ No ☐Yes ☐ N/A |  |
| Technical Agreement/Note | | *Formalise arrangements and responsibilities, typically with third parties involved with supplying a service for example labelling/packaging/QP release of IMP. GCP compliance requirements should be described in the agreement where applicable – the Sponsor Reviewer should advise the Contracts Team Member. Ensure any QA qualification activities, in relation to vendor selection, have been completed prior to agreement execution. An agreement/note will be required with ISG, even though they are part of the UoE legal entity.* | ☐ No ☐Yes ☐ N/A |  |
| Service Level Agreement | | *Typically required when a Trials Unit (not usually ECTU) are involved. Will outline the responsibilities of Co-Sponsors CI and trials unit. May also be used for particular services not appropriate for a technical agreement, e.g. translation services or biological sample processing, server/database host/build. GCP compliance requirements should be described in the agreement where applicable – the Sponsor Reviewer should advise the Contracts Team Member. Ensure any QA qualification activities in, relation to vendor selection, have been completed prior to agreement execution.* | ☐ No ☐Yes ☐ N/A |  |
| Material Transfer agreement | | *Required where biological samples are being shipped between sites. Ensure any QA qualification activities in, relation to laboratory selection, have been completed prior to agreement execution* | ☐ No ☐Yes ☐ N/A |  |
| Collaboration Agreement | | *Typically in place for large trials with collaborators from various institutions. Agreement will detail the nature of the collaborative arrangements and how results and any subsequent IP will be handled. GCP compliance requirements should be described in the agreement where applicable – the Sponsor Reviewer should advise the Contracts Team Member* | ☐ No ☐Yes ☐ N/A |  |
| International Agreement | | *May be required to confer status of ‘Country Lead’ or delegate stated sponsor responsibilities to a particular organisation. International stipulations and conditions should also be considered, if applicable to any of the aforementioned agreements. It may also be required to establish a Legal Representative in a territory out with Great Britain, for example in an EU member state. GCP compliance requirements should be described in the agreement where applicable – the Sponsor Reviewer should advise the Contracts Team Member.* | ☐ No ☐Yes ☐ N/A |  |
| **Pharmacovigilance** | | | | |
| Are there any onward safety reporting requirements? | | *These should be detailed within the protocol. There may also be extra requirements within Drug Supply Agreements – so this should be checked. Country-specific reporting requirements should be accounted for.* | ☐ No ☐Yes |  |
| SAE Onward Safety Requirement document updated? | | *This can be found in the University Pharmacovigilance folder.* | ☐ No ☐Yes ☐ N/A |  |
| DSUR onward reporting tracker updated? | | *Check if there are any requirements to onward report the DSUR. This information is often contained within the Drug Supply Agreement.* | ☐ No ☐Yes ☐ N/A |  |
| RSI tracker been updated? | | *The relevant information relating to the appropriate SPC/IB for the IMP(s) involved in the trial must be added to the tracker.* | ☐ No ☐Yes ☐ N/A |  |
| **GCP Training** | | | | |
| Has the CI undergone recent GCP training (within the preceding 2 years)? | | *Evidence of GCP (GCP certificate or CV) must be retained by the Sponsor.* | ☐ No ☐Yes |  |
| **Registration** | | | | |
| Commitment to register trials on publically available database documented in the protocol? | | *Registration with ISRCTN may be provided automatically by the HRA upon approval(s).clinicaltrials.gov is an acceptable alternative.* | ☐ No ☐Yes |  |
| **Trial Master File** | | | | |
| Where will the TMF be held? | | *The TMF may be held by ACCORD monitors or externally (e.g. by trial manager). If externally, this should be formally delegated within agreements and in writing from the ACCORD Monitoring team.* |  |  |
| Who will be responsible for archiving the TMF? | | *Archiving of the TMF will typically be undertaken by the Trial Unit (where involved). This may be conducted via NHS Lothian archiving service or another third party.* |  |  |
| **Charters** | | | | |
| Has the DMC charter been signed and filed? | | *A signed copy of the DMC charter must be retained by the Sponsor. Signatures required at this stage: Chair, Lead Statistician and Chief Investigator.* | ☐ No ☐Yes ☐ N/A |  |
| Has the TSC charter been signed and filed? | | *A signed copy of the TSC charter must be retained by the Sponsor. Signatures required at this stage: Chair, Trial Manager and Chief Investigator.* | ☐ No ☐Yes ☐ N/A |  |
| **IMP/Medical Device** | | | | |
| Who is manufacturing the IMP/device? | |  | | |
| Who is labelling the IMP/device? | |  | | |
| Who is packaging the IMP/device? | |  | | |
| Will the IMP be QP released? | | *QP certification (or technical release) may be required for the IMP(s) in the trial. QP certification is not required for* ***unaltered*** *products with EU authorisations which are sourced from within the EU.* |  | |
| Who will provide QP release? Describe device release arrangements. | | *This should be detailed within the appropriate Drug Supply / Technical Agreement(s)*  *If more than 1 IMP, please add additional rows.* |  | |
| Do manufacturing facilities require ACCORD QA audit? | | *This should be identified as part of the Risk Assessment.* |  | |
| Who is responsible for authorising release of IMP/device to site (Regulatory Green Light as per CM001)? | | *IMP should not be released to site until:*   * *REC, Competent Authority and R&D approval(s) are in place,* * *Batch release certification provided (where applicable)* * *Receipt, storage, destruction and recall arrangements in place* * *Code break and IMP handling documentation in place (where applicable)*   *For studies involving ISG, sponsor authorisation to release IMP is recorded on batch release certificate. Where delegated please confirm delegate in comments.*  *Regulatory Release is only required where there is clinical trial stock and requires shipment to site.* | ☐Monitor (single site trials)  ☐Trial Manager (multisite trials)  ☐ N/A |  |
| Where will destruction of unused/expired IMP/devices take place? | | *This should be detailed within the trial protocol and must align with appropriate agreements (e.g. technical and/or drug supply agreements)* | ☐Returned to Manufacturer ☐Site ☐Other |  |
| **Sample Storage and Analysis** | | | | |
| Do these facilities, identified in the combined risk assessment document, require ACCORD QA audit / vendor assessment? | | *If labs other than NHS accredited labs are being used, check with QA whether these need to be audited. Document in comments any auditing which is required or whether lab is covered by existing audit.* | ☐ No ☐Yes |  |
| **Data** | | | | |
| Have QA audited / applied the Computer System Validation Checklist to vendors identified in the combined risk assessment document? | |  | ☐ No ☐Yes ☐ N/A |  |
| **Approvals (relevant approvals MUST be in place prior to confirmation of Regulatory Checks Complete – for any “No” responses, details of justification must be provided)** | | | | |
| REC Approval Obtained and conditions met | | *Copy of approval letter, for each country, to be filed electronically and in TMF.* | ☐ No ☐Yes |  |
| Competent Authority Approval Obtained and conditions met | | *Copy of approval letters, from each country, to be filed electronically and in TMF.* | ☐ No ☐Yes |  |
| A copy of the Competent Authority(ies) approval letter should be forwarded onto the REC who provided the trial if appropriate | | *As per REC conditions on FO letter – any similar requirements in any other countries should also be complied with. Evidence of notification filed.* | ☐ No ☐Yes |  |
| Technical / QP release obtained | | *Copy of certification to be filed electronically and in TMF.* | ☐ No ☐Yes ☐ N/A |  |
| ARSAC Approval Obtained | | *Copy of approval letter to be filed electronically and in TMF.* | ☐ No ☐Yes ☐ N/A |  |
| Phase I Committee Approval Obtained | | *Copy of approval letter to be filed electronically and in TMF.* | ☐ No ☐Yes ☐ N/A |  |
| Advanced Therapy and Gene Modification Safety Committee Approval | | *Copy of approval letter to be filed electronically and in TMF.* | ☐ No ☐Yes ☐ N/A |  |
| Other Approval \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | *Copy of approval letter to be filed electronically and in TMF. There may be country-specific approvals not listed above.* | ☐ No ☐Yes ☐ N/A |  |
| ACCORD Combined Risk Assessment Signed-off | | *All points must be addressed and signatures obtained* | ☐ No ☐Yes |  |
| Ensure all signature pages (e.g. protocol, IB) are signed | | *Signatures must be in place prior to trial commencing* | ☐ No ☐Yes |  |

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| **Facilitation Checklist Sign - Off** | | | | | | |
| To be signed once **all sections** of the Facilitation Checklist have been completed. | | | | | | |
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|  | **Lead Sponsor Representative Signature** |  | **Position** |  | **Date** |  |

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| **Regulatory Checks** | | | | | | |
| Following completion and sign-off of the Facilitation Checklist, the Sponsor Representative (in agreement with the Clinical Trial Monitor) should provide confirmation of Regulatory Checks Complete to the Chief Investigator.  This should take the form of an email to the CI confirming written authorisation to start the trial.  **A copy of the Regulatory Checks Complete email must be filed with the completed Facilitation Checklist.** | | | | | | |
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|  | **Lead Sponsor Representative Name** |  | **Lead Sponsor Representative Signature** |  | **Date of email to CI** |  |
|  |  |  |  |  |  |  |
|  | **Clinical Trials Monitor Name** |  | **Clinical Trials Monitor Signature** |  | **Date** |  |
| In **exceptional circumstances**, confirmation of Regulatory Checks Complete may be provided prior to completion of the Facilitation Checklist. Such instances should only occur following discussion and agreement with the QA and/or Monitoring lead.  The rationale and justification for this decision must be documented below: | | | | | | |
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