Quality Control Document:

Site-Initiation Checklist

# Purpose

The purpose of this document is to provide a site-initiation checklist template to help ensure a site’s full preparedness to conduct a study/trial. This checklist has been designed to document evidence of site-initiation activities undertaken as part of clinical trials of investigational medicinal products (CTIMPs), but it can be adapted for use in other trials or studies. Please note that the use of this template is optional. Refer to *UoB-SMA-SOP-001 Investigational Site Management* for guidance on site initiation.

# Instructions

1. Remove this first instruction page.
2. Update identifier in header e.g. study/trial identifier or research group.
3. Update footer; keeping reference information to this quality control document (QCD).
4. When using this site-initiation checklist, customise it to the specific needs and requirements of your trial.

* This may involve adding/adapting/removing entries/sections on the checklist.
* There are various methods that can be used to initiate a site, and this may influence the content of the checklist. For example, a site-initiation visit may be conducted via a telephone conference. Therefore, you may want your checklist to include additional information such as ‘prepare handouts and send to site prior to site-initiation date’.
* If representatives from pharmacy, radiology, laboratories etc. are involved in the study/trial, ensure that representatives from these supporting departments are present for the site initiation. The checklist can be adapted to incorporate this check.

1. For each entry on the checklist, provide a ‘Yes/No/Not Applicable’ option for completion. Add a ‘comments’ box at the end of each section.
2. Ensure appropriate version control to manage the document when changes are made.

# Related documents

* UoB-SMA-SOP-001 Investigator Site Management
* UoB-SMA-QCD-001 Site Signature and Delegation Log

Note the UoB QMS documents can be found on the [Clinical Research Compliance Team (CRCT) website](https://www.birmingham.ac.uk/research/activity/mds/mds-rkto/governance/index.aspx). Internal work instructions can be obtained from the CRCT ([crct@contacts.bham.ac.uk](mailto:crct@contacts.bham.ac.uk)) and/or from the RGT ([researchgovernance@contacts.bham.ac.uk](mailto:researchgovernance@contacts.bham.ac.uk)).

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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Project Details | | | | | | | | | | | |
| Name of project: | |  | | | | | | | | | |
| Name of site: | |  | | | | | | | | | |
| Principal investigator: | |  | | | | | | | | | |
| Name of person(s) conducting site initiation: | |  | | | | | | | | | |
| Date(s) of site initiation: | |  | | | | | | | | | |
| Comments: | | | | | | | | | | | |
| Method Selected for Initiation of Site | | | | | | | | | | | |
| Preparation for the site initiation will vary depending on the method employed | | | | | | | | | | | |
| Method of site initiation | | | Visit / Investigator meeting (IM) | | |  | Please continue to complete the remainder of this document | | | | |
| Web / Teleconference | | |  |
| Postal | | |  | Use the remainder of this document to ensure the training pack provided fulfils all the relevant details | | | | |
| Email | | |  |
| Justification for method of site initiation selected | | | Please provide the rationale for selecting the method of site initiation here | | | | | | | | |
| Please tick to confirm whether the following has been completed | | | | | | | YES | | NO | | N/A |
| Site visit log signed (where applicable) | | | | | | |  | |  | |  |
| Comments: | | | | | | | | | | | |
| Site Initiation Attendee | | | | | | | | | | | |
| Documentation must be available to support who took part in the site initiation activities | | | | | | | | | | | |
| Attendance Log | | | | | | | | | | | |
| Name of study personnel | Position in the study | | | | Visit | | | Remote | | Date (dd/mmm/yy) | |
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| Study and Documentation | | | | | | | | | | | |
| *Discuss the delegation of roles with the PI and the importance of the delegation of responsibilities/authority log. Documented evidence of PI oversight and involvement in the trial should be discussed.* | | | | | | | | | | | |
| Please tick to confirm whether each of the following have been discussed/verified with the investigator and the relevant site staff, or enter N/A where not applicable | | | | | | | YES | | NO | | N/A |
| Document version control | | | | | | |  | |  | |  |
| Protocol overview, study conduct | | | | | | |  | |  | |  |
| Participant eligibility criteria | | | | | | |  | |  | |  |
| Protocol design, rationale, aims of the research | | | | | | |  | |  | |  |
| Study flow chart (schedule of visits, procedures, timelines) | | | | | | |  | |  | |  |
| PI oversight and delegation of duties | | | | | | |  | |  | |  |
| Enrolment procedure, screening and randomisation | | | | | | |  | |  | |  |
| Instructions on testing procedures/treatment plan | | | | | | |  | |  | |  |
| Adverse event (AE) reporting procedures including timelines for reporting, reporting mechanism and sign-off of completed serious adverse event (SAE) forms | | | | | | |  | |  | |  |
| Pregnancy reporting procedures | | | | | | |  | |  | |  |
| 24hr emergency contact arrangements | | | | | | |  | |  | |  |
| Procedure for breaking the blind | | | | | | |  | |  | |  |
| Procedure for participant/trial discontinuation and withdrawal | | | | | | |  | |  | |  |
| Timeframes for expedited reporting to the MHRA and the REC | | | | | | |  | |  | |  |
| Protocol deviations and notification of Serious Breaches | | | | | | |  | |  | |  |
| Procedure for reporting urgent safety measures | | | | | | |  | |  | |  |
| Email correspondence | | | | | | |  | |  | |  |
| Informed consent procedure | | | | | | |  | |  | |  |
| Approved PIS | | | | | | |  | |  | |  |
| Approved consent form and completion of, including signatory | | | | | | |  | |  | |  |
| Documentation of consent in patients’ notes and ongoing willingness to continue | | | | | | |  | |  | |  |
| Notification to GP | | | | | | |  | |  | |  |
| Filing consent forms | | | | | | |  | |  | |  |
| Patient confidentiality | | | | | | |  | |  | |  |
| Comments: | | | | | | | | | | | |
| Case Report Forms (CRFs) and Data Handling | | | | | | | | | | | |
| Please tick to confirm whether each of the following have been discussed/verified with the investigator and the relevant site staff, or enter N/A where not applicable | | | | | | | YES | | NO | | N/A |
| CRF completion training and responsibilities for review | | | | | | |  | |  | |  |
| Highlight important issues | | | | | | |  | |  | |  |
| Study identifiers, study no. patients’ initials | | | | | | |  | |  | |  |
| Data entry & correction procedures including self-evident corrections, where appropriate, and documented agreement of this | | | | | | |  | |  | |  |
| Visit schedule | | | | | | |  | |  | |  |
| Source documents (highlighting any data items not normally captured in the source data) | | | | | | |  | |  | |  |
| Documented review of incoming clinical data (e.g. laboratory results, imaging) | | | | | | |  | |  | |  |
| Filing, storage and security | | | | | | |  | |  | |  |
| DCF process and return CRFs | | | | | | |  | |  | |  |
| Comments: | | | | | | | | | | | |
| Investigator Site File (ISF) | | | | | | | | | | | |
| Please tick to confirm whether each of the following have been discussed/verified with the investigator and the relevant site staff, or enter N/A where not applicable | | | | | | | YES | | NO | | N/A |
| Overview of ISF and maintenance | | | | | | |  | |  | |  |
| Essential documents and amendments | | | | | | |  | |  | |  |
| Check all documentation is present | | | | | | |  | |  | |  |
| Site delegation log has been completed | | | | | | |  | |  | |  |
| Evidence of appropriate qualification and training, including GCP training of all staff listed on the delegation log (e.g. signed and dated CV, GCP certificates) has been filed in the ISF | | | | | | |  | |  | |  |
| Comments: | | | | | | | | | | | |
| Monitoring, Audit and Inspection | | | | | | | | | | | |
| Please tick to confirm whether each of the following have been discussed/verified with the investigator and the relevant site staff, or enter N/A where not applicable | | | | | | | YES | | NO | | N/A |
| Participant recruitment and recruitment targets | | | | | | |  | |  | |  |
| Site monitoring visit attendance | | | | | | |  | |  | |  |
| Monitors access to source data including medical notes and CRFs | | | | | | |  | |  | |  |
| Audit/inspections | | | | | | |  | |  | |  |
| Comments: | | | | | | | | | | | |
| IMP/Medicine This section may also be applicable/adapted for use of food and/or nutritional components. | | | | | | | | | | | |
| Please tick to confirm whether each of the following have been discussed/verified with the investigator and the relevant site staff, or enter N/A where not applicable | | | | | | | YES | | NO | | N/A |
| Product information: supply, handling, receipt, storage, location, labelling | | | | | | |  | |  | |  |
| Temperature logs and monitoring | | | | | | |  | |  | |  |
| IB/ SmPC | | | | | | |  | |  | |  |
| Dose modification plans: treatment, duration, side effects | | | | | | |  | |  | |  |
| Dispensing logs and accountability procedures | | | | | | |  | |  | |  |
| Recall procedures | | | | | | |  | |  | |  |
| Comments: | | | | | | | | | | | |
| Site Equipment | | | | | | | | | | | |
| Please tick to confirm whether each of the following have been discussed/verified with the investigator and the relevant site staff, or enter N/A where not applicable | | | | | | | YES | | NO | | N/A |
| Accreditation, calibration and maintenance programmes | | | | | | |  | |  | |  |
| Comments: | | | | | | | | | | | |
| Archiving | | | | | | | | | | | |
| Please tick to confirm whether each of the following have been discussed/verified with the investigator and the relevant site staff, or enter N/A where not applicable | | | | | | | YES | | NO | | N/A |
| Responsibilities of the site | | | | | | |  | |  | |  |
| Timeframes | | | | | | |  | |  | |  |
| Archiving facilities | | | | | | |  | |  | |  |
| Comments: | | | | | | | | | | | |
| Training | | | | | | | | | | | |
| *Project-specific training should be delivered as required. Training may be delivered face to face or using an alternative method such as an online training video, PowerPoint WebEx, postal pack or CD etc.* | | | | | | | | | | | |
| Please tick to confirm whether each of the following have been discussed/verified with the investigator and the relevant site staff, or enter N/A where not applicable | | | | | | | YES | | NO | | N/A |
| Were any training requirements identified during the visit? | | | | | | |  | |  | |  |
| Was training provided during the visit? | | | | | | |  | |  | |  |
| Training was provided in the following areas: | | | | | | | | | | | |
| Other Departments | | | | | | | | | | | |
| Where other departments are involved in the project (e.g. pharmacy, radiology, laboratories), responsibilities are expected to be discussed. Amend this section accordingly to ensure any protocol-specific requirements are addressed. | | | | | | | | | | | |
| Have any additional training requirements been identified? | | | | | | | | | | | |
| Has the site been provided with a file containing the essential documents for the project? | | | | | | | | | | | |
| Comments: | | | | | | | | | | | |
| Follow-up Actions (Where Applicable) | | | | | | | | | | | |
| Comments: | | | | | | | | | | | |
| Sign off by Person Performing Visit | | | | | | | | | | | |
| For CTIMPs, prior to site activation, once site initiation is complete, please ensure the regulatory green light has been completed and the site is notified in writing of the authorisation to commence. | | | | | | | | | | | |
| Name: | | | |  | | | | | | | |
| Signature: | | | |  | | | | | | | |
| Date (dd-mmm-yyyy): | | | |  | | | | | | | |