**CHECKLIST FOR INITIATION OF**

**SITES IN INDUSTRY-SPONSORED CLINICAL TRIALS**

This checklist is designed to present tasks to be performed by site in the initiation of an industry-sponsored clinical trial. Sponsor-related tasks without involvement from site are not presented in this checklist. Not all tasks will be relevant for all trials.

Delete tasks in the checklist that are not relevant for the site. Add any tasks that are not included in the checklist but are relevant for the site. Check that responsible person is correct. Filled in by the sponsor. Filled in by the site.

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| --- | --- |
| **Study:** Short name | **EU CT no:** Number |
| **Sponsor:** Name of sponsor institution | **Site investigator:** Name and contact information |
| **Main sponsor contact:** Name, role and contact information to main sponsor contact | **Site primary study nurse:** Name and contact information |
| **Study start-up estimated date:** dd.mm.yyyy |  |

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| **Collection of study documentation from site** | **Comments, templates and explanations** | **Responsible** | **Deadline (date)** | **Done (date)** |
| CV from investigator | Use <template> | Investigator |  |  |
| CV from sub-investigator(s) | Use <template> | Sub-investigator(s) |  |  |
| CV from study nurses | Use <template> | Study nurses |  |  |
| CV from other study personnel Specify… | Use <template> | Other study-personnel |  |  |
| GCP certificate investigator | Valid from the last <xx> years  Training provided by sponsor: <specify training> | Investigator |  |  |
| GCP certificate sub-investigator(s) | Valid from the last <xx> years  Training provided by sponsor: <specify training> | Sub-investigator(s) |  |  |
| GCP certificate study nurses | Valid from the last <xx> years  Training provided by sponsor: <specify training> | Study nurses |  |  |
| GCP certificate other study personnel Specify: <other study personnel> | Valid from the last <xx> years  Training provided by sponsor: <specify training> | Other study-personnel |  |  |
| IATA-certificate from lab personnel | Valid from the last <xx> years  Training provided by sponsor: <specify training> | Lab personnel |  |  |
| Accreditation of laboratory | See <accreditation>  In example [Akkrediteringsomfang | Norwegian Accreditation (akkreditert.no)](https://www.akkreditert.no/en/akkrediterte-organisasjoner/akkrediteringsomfang/?AkkId=489) | Lab personnel |  |  |
| Calibration of equipment/devices at hospital, specify which equipment/devices: <type of equipment/devices> | Valid from the <xx> year(s) | Study nurses |  |  |
| Source data list | Use <template> | Investigator and study nurses |  |  |
| Information about electronic patient records used in the study | Use <template or URL> | Investigator |  |  |
| Clinical Trial Information System (CTIS) documentation for application to European Medicines Agency and Ethics Commiteè: Site suitability template, informed consent and patient recruitment procedure, declaration of interest | Use <template> | Investigator |  |  |
| Delegation log | Use <template> | Investigator in cooperation with monitor/sponsor |  |  |
|  |  |  |  |  |
| Study documentation must be sent to sponsor: <e-mail adress> | | | | |
| **Systems, portals and vendors used in the study** | **Description** | **Access and training** | **Deadline (date)** | **Done (date)** |
| Shared Investigator Platform (SIP): [Shared Investigator Platform](https://www.sharedinvestigator.com/siteminderagent/dmspages/sip/index.html?TYPE=33554433&REALMOID=06-00006235-3b16-1578-8c8d-d0950a7690fd&GUID=&SMAUTHREASON=0&METHOD=GET&SMAGENTNAME=-SM-rbKfV19stvZxQrNskClhqucorYVhvJuYsiDd%2bDibIRmL5GtTuzj5JFzZkEhDM9Og&TARGET=-SM-http%3a%2f%2fwww%2esharedinvestigator%2ecom%2fhome) | Study workspace for sponsor and site. User profiles in SIP needed for access to study workspace. The sponsor will send the invitation. | Access by <investigators and study nurses>. No training needed. |  |  |
| Electronic Case Report Form (eCRF): <URL> |  | Access by <investigators and study nurses>.  Training approx. <xx> hours |  |  |
| Randomization/IWRS system: <URL> |  | Access by <investigators and study nurses>.  Training approx. <xx> hours |  |  |
| Patients Reported Outcomes (PRO) system: <URL> | Electronic collection of Patient Reported Outcomes by study patient. Each patient will receive an iPad. | Access by <investigators and study nurses>.  Training approx. <xx> hours |  |  |
| Electronic patient diaries: <URL> | Electronic collection of diary notes by study patient, iPads will be given to each patient | Access by <investigators and study nurses>.  Training approx. <xx> hours |  |  |
| Safety portal: <URL> | Electronic collection of safety data as adverse events (AE), serious adverse events (SAE) | Access by <investigators and study nurses>.  Training approx. <xx> hours |  |  |
| Central laboratory: <name and location> | Manual and kits will be sent to site | Sponsor |  |  |
| Central imaging vendor: <name and location> | Manual will be sent to site | Sponsor |  |  |
| Other vendors, specify: <name and location> | Manual will be sent to site | Sponsor |  |  |
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| **Agreements and contracts** | **Comments** | **Responsible** | **Deadline (date)** | **Done (date)** |
| Study-agreement between sponsor and site | <Legal contact or TTO> will coordinate setting up the study-agreement between sponsor and site | <Legal contact or TTO>, sponsor and site |  |  |
| Pharmacy | <Legal contact or TTO> will coordinate setting up the pharmacy agreement between pharmacy and sponsor | <Legal contact or TTO> sponsor and pharmacy |  |  |
| Local imaging department | Investigator must contact the department and arrange an internal agreement | Investigator |  |  |
| Local laboratory department | Investigator must contact the department and arrange an internal agreement | Investigator |  |  |
| Local pathology department | Investigator must contact the department and arrange an internal agreement | Investigator |  |  |
| Other local departments | Investigator must contact the department and arrange an internal agreement | Investigator |  |  |
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| **Approvals** | **Comments** | **Responsible** | **Deadline (date)** | **Done (date)** |
| Notification to data protection officer (personvernombud) | Notification to the data protection officer is done according to the institution’s routines | Investigator | Before inclusion of first patient |  |
| Reviewing and editing ”Information and informed consent” to Regional Ethics Committee |  | Investigator |  |  |
| Documents for application in Clinical Trials Information System (CTIS) – see specifications under ”Collection of document from sites” above |  | Investigator |  |  |
| **Investigational medicinal product (IMP) if stored and handled at study department at site** | **Comments** | **Responsible** | **Deadline (date)** | **Done (date)** |
| Discuss the logistics and the routines that will apply for IMP | Ordering, storage conditions, temperature-log, preparation, dispensing, accountability, return of IMP, AxMP if applicable, and destruction etc. must be claryfied with the study team | Sponsor, investigator and study nurse |  |  |
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| **Shipments to site** | **Comments** | **Responsible and address for delivery:** | **Deadline (date)** | **Done (date)** |
| Laboratory kits |  | Lab personnel <address> |  |  |
| Pathology kits |  | Study nurse <address> |  |  |
| Investigator site file |  | Study nurse <address> |  |  |
| Device for collecting patient reported outcomes |  | Study nurse <address> |  |  |
| Device for collecting patient diaries |  | Study nurse <address> |  |  |
| Investigational medicine product (IMP) |  | Pharmacy or study nurse <address> |  |  |
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| **Participation in meetings** | **Agenda, format and duration** | **Participants** | **Deadline (date)** | **Done (date)** |
| Site selection meeting | Evaluation of hospital as a study site, and view of facilities. Performed <physically at the hospital> with duration of approx. <xx> hours | Investigator and primary study nurse, research support |  |  |
| International investigator meeting | Training in study-protocol. Performed physically in <country, city> with duration of <xx> working days including travels | Investigator and primary study nurse |  |  |
| Site initiation meeting | Preparation of study-conduct with training in study-protocol, setting up investigator site file, collection of last documents, and delegation of tasks. Performed <physically at hospital> with duration of <xx> hours. | Investigator, sub-investigator, primary and back-up study nurse, pharmacy, contact person at internal departments (laboratory, image, pathology), research support |  |  |
| Other meetings, specify: <Agenda, format and duration> |  |  |  |  |
|  |  |  |  |  |
| **Other practical preparations at site** |  | **Responsible** | **Deadline (date)** | **Done (date)** |
| Arrange for storage of Investigator site file (ISF) |  | Investigator and study nurse |  |  |
| Arrange for storage of patients consents and code lists |  | Investigator and study nurse |  |  |
| Arrange for storage place for samples before shipment to central lab or sponsor biobank |  | Investigator and study nurse |  |  |
|  |  |  |  |  |

When all tasks are done and the sponsor has given the green light, the trial can start.

Date: Signature investigator