Letter 2026 – Clinical Trials Unit, Department of Oncology, Linkoping University Hospital

Dear Sponsor and Partner,

We would like to provide you with practical information about how the Clinical Trials Unit, Department of Oncology, Linkoping University Hospital, operates. This overview is intended to facilitate a smooth and fast study start-up, efficient communication, and mutual understanding between our site and your organization.

- Please make sure you have familiarized yourself and relevant staff members with the Code of Conduct. This is a thorough guidance on how clinical trials are managed at our site and a mutual agreement between Lif (Swedish pharma organization), ASCRO (Swedish CRO organization) and NASTRO (network for all Oncology Clinical Trial Units at the University Hospitals in Sweden) Nastro | Code of Conduct
- We do not allocate formal resources to the study before it has passed through the Priority Committee Review, please see further details under section 2.
- Please also pay close attention to the different addresses to be used (section 12 of this document) This causes challenges at our site if not adhered to.
- Confidentiality Disclosure Form is not required between our site and the sponsor as the public healthcare sector is covered by OSL (the Swedish Public Access to Information and Secrecy Act), providing an equivalent level of confidentiality, please see the Code of Conduct for further information.

1. Study request

Study requests should be submitted through the Clinical Trials Unit functional mailbox: KPEOnkklinCKOCUS@regionostergotland.se.

Use that email address for all contact with us until you have been assigned a contact person. Please include the following information when submitting a study inquiry:

- Study timeline
- Contact person at the sponsor/CRO
- Study protocol/study synopsis

2. Priority Committee

Review All studies involving patients from Department of Oncology must be presented and reviewed at the Priority Committee. Sponsor will be informed immediately after the meeting about the decision. The Principal Investigator (PI) presents the study. Sponsors may provide 3–4 PowerPoint slides to support the presentation. External representatives cannot attend.

A Study Coordinator is assigned to your study when it has passed the Priority Committee Review and thereafter study specific activities can commence.

3. CTIS Application and Pre-meeting Documents

To secure an efficient start-up phase, the following documents can be collected to facilitate the CTIS application before the Research Council meeting.

- PI's CV (in Swedish)
- Site Suitability Statement
- Declaration of Interest

If Department of Oncology will not participate, the sponsor will be informed directly after the Priority Committee review.

OMS-number for CTIS submission (Linkoping University Hospital):

Organisation name: Linkoping University Hospital
Organisations ID: ORG-100 010 599
Location ID: LOC-100 059 379
Universitetssjukhuset I Linkoping, 581 85 Linkoping

4. Study Start-up

We need to have the most updated timelines available to provide the necessary resources and the best planning for study execution.

Please provide planned dates for Submission to CTIS, planned approval dates, planned dates for Site Initiation Visits and any other important milestones. Please note that it is very important to communicate any changes to planned dates. We do understand the complexity and it can be difficult to set confirmed dates, but please communicate any changes as soon as they are available.

Please provide the following documents to the Study Coordinator (even if they are in draft) for us to speed up our internal processes to be ready to start at the agreed timelines. Please make sure to send updated documents as soon as they become available.

- Protocol
- Patient information sheets
- Biobank submission

- Lab/imaging manuals
- Pharmacy manual
- Study title
- Site number

We need to have a clear view on the contact persons from your side. Please provide name, title, contact details and role in the study.

5. Collection of Documents

The following documents can be collected before Site Initiation Visit, if deemed necessary: CV, GCP certificate and Financial Disclosure Form for PI (and one Sub-Investigator if deemed necessary from sponsor.)

CV and GCP certificate for Study Coordinator.

Remaining documents will be collected at the Site Initiation Visit when the complete study-team is selected.

6. Study Contract and Budget

The management of all Contract and Budgets are under the responsibility of the Head of the Department.

The allocated Study Coordinator needs to initiate the start-up process and understand the study execution before the budget negotiation can start.

All Clinical Trial Agreements are reviewed by the legal department at Linkoping University Hospital.

We need the following documents to start the negotiation process:

- Clinical Trial Agreement
- Protocol
- Patient information
- Budget in an excel sheet with per visit specification

All study agreements are signed by the respective Head of the Department. Principal Investigator signs the contract as “read and acknowledged” only.

7. Internal Agreements

We will establish Internal agreements and coordinates necessary planning meetings with other units at Linkoping university hospital such as: Radiology, MR/Imaging units, and other hospital departments involved in study procedures. Please ensure all study-related requirements are clearly communicated early to avoid delays.

If central reading is needed, sponsor needs to reach out directly to radiology unit, contact name will be given from study coordinator.

8. Local Laboratory and Biobank Applications

The address to the local laboratory is:
Diagnostikcentrum i Östergötland, Linköping Universitetssjukhuset, SE 581 85 Linköping

This is the accreditation information:
SWEDAC SS-EN ISO 15189, GLP, CLIA, CAP, ISO

If the accreditation certificate is needed, please ask the Study Coordinator. Local Laboratory Reference Ranges can be found at the hospital web page:
Provtagningsanvisningar A-Ö

The application to the Biobank is the sponsor's responsibility. For information on the Biobank, please see A national infrastructure for biobanking – Biobank Sverige.

We would like to review the application form before submission.

Östergötland Medical Biobank ID is: 242. If you need contact with the Pathology unit before the submission, please contact: Camilla.Hildesjo@regionostergotland.se

9. Investigational Medicinal Product (IMP) and Pharmacy Agreement

IMP management generally follows Linkoping University Hospitals processes. Intravenous IMP administration is performed at the Oncology Clinic Treatment Unit. Patients is monitored during treatment and vital signs are assessed before, during, and after infusion according to protocol. Emergency equipment is available at the unit. Infusions are supervised on-site, and any infusion-related reactions are managed per clinical routine.

IMP as Cytostatic and similar is prescribed and required through our internal system CytoDos. The PI is responsible to enter applicable IMP information according to the study protocol in CytoDos.

The Pharmacy agreement is the sponsor's responsibility. Please note that a separate Pharmacy agreement is mandatory in Sweden. Please start the agreement process with the Pharmacy early in the start-up phase as the agreement needs to be in place before the Site Initiation Visit. We need the information on what IMPs are provided by the sponsor.

For all IMP that needs preparation, agreement with Pharmaceutical Compounding Unit, Hospital Pharmacy University Linkoping is mandatory. Please contact Pharmaceutical Compounding Unit at:
sjukhusapoteket.kliniskprovning@regionostergotland.se

Address to Hospital Pharmacy:

Linkoping University Hospital
Att: Name of PI and Study Coordinator
Pharmaceutical Compounding Unit, Hospital Pharmacy
581 85 Linkoping

For other IMP that does not require preparation, agreement can be made with other Pharmacies/Vendors as applicable per Swedish regulation.

10. Equipment and Calibration

If no sponsor equipment is provided, hospital equipment is used. All devices are calibrated annually per our internal process by the Medicinteknik department at Linkoping University Hospital. All individual equipment is labelled with the latest calibration date. Additional documents related to the calibration can be provided upon request. All our freezers, refrigerators and cabinets are temperature controlled and alarmed. Documentation on the temperature for a given period can be provided upon request.

In addition, sponsor-provided equipment must be listed in the Site Equipment Log and undergo technical approval by the Medicinteknik department before use. Calibration certificates and maintenance documentation must accompany any sponsor devices. Any equipment requiring special installation or temperature/environmental stability must be coordinated in advance with the Study Coordinator.

11. Site Initiation Visit (SIV)

We would like to get the Investigator Site File (ISF) and all other study specific material and documents approximately 2-3 weeks before the Site Initiation Visit. The ISF will be stored at Clinical Trials Unit, Department of Oncology, during the study.

Please make sure to send to the correct addresses, see section 12.

We would ask to get all study documentation sent to us both electronically and per mail with clear filing instructions. Please address documents to Study Coordinator ONLY. Study Coordinator will arrange with PI signature as needed.

Please plan and schedule for SIV well in advance when the following is fulfilled:

- Regulatory approval available
- Biobank approval available
- Signed CTA and budget approvals
- Preferably signed Pharmacy Agreement
- System training and accesses provided

12. Monitoring, access to medical records and confidentiality

Please make sure that the confidentiality agreement for access to medical records is provided to Clinical Trials Unit for signature by the Head of Department **at least one week in advance of the first monitoring visit.** No access to patient medical records can be given without the confidentiality agreement in place. Please find a template for the confidentiality agreement template. Mallar för kliniska prövningar – Apotekarsocieteten

Our electronic medical record system is called **Cosmic**. Due to system design and Swedish data protection regulations, individual monitor access cannot be granted. Therefore, the Study Coordinator will print the relevant source documentation for each monitoring visit. Please ensure that required source data verification is performed during the on-site visit, as remote access is not possible.

We ask you to make sure that all necessary copying and access to data is made during the on site visit to prevent unnecessary scanning of documents between visits.

13. Addresses

Address for study documentation:
Universitetssjukhuset i Linköping
Onkologiska kliniken
Allmänna mottagningen plan 11, KPE
Att: (namn of PI and Study Coordinator)
Sjukhusvägen 27 581 85 Linköping
SWEDEN

Address for lab kits and lab supply:
Universitetssjukhuset i Linköping
Onkologiska kliniken
Allmänna mottagningen plan 11, KPE
Att: (namn of PI and Study Coordinator)
Sjukhusvägen 27 581 85 Linköping
SWEDEN

Delivery of Investigational Medical Product to site from external Pharmacy:
Linkoping University Hospital
Att: Name of PI and Study Coordinator
Pharmaceutical Compounding Unit, Hospital Pharmacy
581 85 Linkoping

Collection of lab samples and Dry Ice (address on the requisition forms):
Universitetssjukhuset i Linköping
Onkologiska kliniken
Allmänna mottagningen plan 11, KPE
Att: (namn of PI and Study Coordinator)
Sjukhusvägen 27
581 85 Linköping
SWEDEN

We look forward to collaborating with you and your team.

Warm regards,
Erik Hilborn
Head of Clinical Trials Unit, Department of Oncology, Linkoping University Hospital