Guidance

– Key success factors when initiating and conducting clinical trials in Sweden.

De forskande läkemedelsföretagen

ASCRO

NASTRO

Guidance

In order to optimise the collaborative framework when conducting clinical studies in oncology and haematology at Swedish university hospitals, the parties have agreed to endeavour to comply with the following guidance including appendices.

The objective of this guidance is to set out common key success factors identified by the parties when initiating and conducting clinical studies in Sweden. It should therefore contribute to improving the mutual understanding of the work of the parties, their members, collaborators and subcontractors, and their respective personnel.

This guidance is based on several underlying principles. Specific examples of its application are provided in Appendix 1.

About the parties

ASCRO

ASCRO is the industry organisation for life science service providers and CROs active in Sweden. It currently has 21 members, including full-service CRO companies as well as more specialised enterprises. CRO companies carry out the majority of the clinical studies in the Swedish healthcare sector on behalf of pharmaceutical enterprises and medical device manufacturers.
ASCRO is affiliated with Lif (see below), and both are committed to resolving problems and improving conditions in clinical studies in Sweden.

Lif (the Swedish Association of the Pharmaceutical Industry)

Lif is the trade association for the research-based pharmaceutical industry in Sweden. It has approximately 100 members, all of which are involved in clinical drug development research, many of them in Sweden. Lif is party to the Agreement Regarding Rules of Cooperation adopted for the publicly funded healthcare sector in Sweden by the Swedish Association of Local Authorities and Regions (SKR) and the trade organisations for the pharmaceutical industry, the medical technology industry and the laboratory technology industry. Both Lif and its member companies have undertaken to adhere to the rules.

Nastro

Nastro is the national network for the university hospitals' oncology and haematology study units. As a network, Nastro addresses common issues at national level in order to change, improve and facilitate clinical studies. Nastro also collaborates within the network in order to ensure shared best practices.

Ethical standards

The guidance supports collaboration between the parties that is characterised by respect, reciprocity and responsibility.

Communication

The parties will ensure that the latest version of the document is always accessible and that all the people for whom the guidance is relevant have read and understand it.

Regular reviews and updates

Reviews and, if applicable, updates will take place once a year. The parties agree that the responsibility for initiating and leading reviews will alternate as described below. All three parties will participate in the annual reviews and updates and each party will appoint representatives to perform the associated work on their behalf.

In connection with the reviews, the so-called "escalation list" should also be reviewed to ensure that the sponsor and CRO contact details are always up to date. The escalation list ensures that the parties can contact each other quickly and easily if any queries or problems arise during a trial.

Responsible party	Review year	Updated version
Nastro	2024	Q1 2025
ASCRO	2025	Q1 2026
Lif	2026	Q1 2027

Compliance

The parties agree to strive for compliance with the guidance at all times. In the event of non-compliance, the party that notices unintentional or deliberate deviations will notify the non-compliant party that deviations have occurred as well as the party responsible for initiating and leading the review in the current year.

This document has been drawn up in three copies, all of which are signed by the respective parties' representatives, see

below. The document has been digitally signed by all parties.

ASCRO

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1	Country- and site-level requests (feasibility)		
	Current issue	**Guidance**	**Comments**
1.1	Country-level requests	Country-level requests for oncology and haematology studies are sent to Feasibility Sweden, which forwards them to the Nastro network. Requests related to phase I are handled separately. (This applies to both country- and site-level requests).	*Link to Feasibility Sweden website:* *https://feasibility.kliniskastudier.se/*
1.2	Confidentiality	*See Appendix 2 to this document.* Whenever possible a signed CDA will not be requested as the public healthcare sector is covered by OSL (the Swedish Public Access to Information and Secrecy Act), providing an equivalent level of confidentiality. CDAs should be signed digitally.	*Possible wording when informing the recipient at the healthcare provider's office that information being shared in connection with the feasibility process is covered by the OSL.* "The recipient is hereby reminded of their duty of confidentiality under section 2, sub-section 1 of the Swedish Public Access to Information and Secrecy Act (OSL), and that the right to communicate and publish information according to section 1, sub-section 1, of the Swedish Freedom of the Press Act – so-called freedom of information – does not apply to the data in question. The data contains confidential information which is to be treated as such in accordance with the provisions of the OSL and other applicable legislation." "The recipient is hereby reminded of their duty of confidentiality under section 2, sub-section 1, of the Swedish Public Access to Information and Secrecy Act (OSL), and that the right to communicate and publish information according to section 1, sub-section 1, of the Swedish Freedom of the Press Act – so-called freedom of information – does not apply to the data in question. The data contains confidential information which is to be treated as such in accordance with the provisions of the OSL and other applicable legislation."
1.3	Site-level feasibility process	The feasibility material should include relevant information on inclusion / exclusion criteria, type of treatment as well as information corresponding to a study synopsis.	*This works if relevant information about the site is publicly available and if the feasibility survey response form is not electronic / web-based.*

1	Continued		
	Current issue	**Guidance**	**Comments**
Cont. 1.3		The general contact information is to be filled in prior to sending the survey to the respective site where possible for the convenience of the sites (information is available on Nastro's website). Only ask the site to provide relevant documentation such as: • General site information • Investigator CV	
1.4	Identify and appoint contact persons at the site and the sponsor	The site's head of department or another appointed person is the primary contact person for the sponsor until the head of department or a person in an equivalent function notifies the sponsor otherwise.	

2	Prior to study site selection		
	Current issue	**Guidance**	**Comments**
2.1	Selection visit	Information shared by the site prior to the selection visit is listed in 1.3. The selection visit is always agenda driven and conducted as a web-based meeting or in-person meeting. From site, the potential investigator resp. study coordinator participates. If the selection visit is a remote web-based meeting, it cannot include an inspection of the premises – this must be completed on-site. If the nature of the study means that another site will also be involved (e.g. critical procedures are carried out at another clinic, such as advanced pathology, radiopharmaceuticals, advanced preparation in a pharmacy, including ATMP,), the external site should ideally also be represented at the selection visit. This ensures transparency, results in fewer open queries after the meeting and provides an opportunity to identify potential logistics problems early in the process.	
2.2	General information and study-specific queries during the selection visit.	If possible, the sponsor should primarily rely on the information published on the Nastro website.	*Link to Nastro's website: https://nastro.se/*

3	During the selection visit		
	Current issue	**Guidance**	**Comments**
3.1	Provide information about site-specific routines	• Refer to the site-specific information document on Nastro's website • Discussions and contract negotiations, including local subcontracts/agreements (X-ray, lab, pharmacy, etc.)	
3.2	Review of expected time schedule for initiation and recruitment.	The time schedule as well as the recruitment targets need to be agreed in writing between the sponsor and the site.	*The sponsor is responsible for drafting the time schedule.* *The time schedule also states when the contract process is initiated and finalised*
3.3	GMO – ATMP studies	The sponsor should provide information about any study-specific requirements, e.g. GMO, ATMP or any other routines and regulatory requirements that need to be taken into account.	

4	After study site selection		
	Current issue	**Guidance**	**Comments**
4.1	Prior to the Research Council / Priority Council meeting at the sites	Planned dates for Research Council / Priority Council meetings are stated on Nastro's website. The Research Council / Priority Council should be informed about the study at its next meeting after the selection decision has been announced by the sponsor. A supporting PPT presentation for the Research Council / Priority Council meeting should include: • Study design • Rationale for the study • Relevant inclusion and exclusion criteria • IMP mechanism including any prior toxicity • Endpoint • Specific criteria / requirements and estimated number of sites and patients in Sweden and globally • Time schedule	*The sponsor may assist the site with support and material for the presentation to the Research Council / Priority Council meeting.*

4.2	*After* the Research Council / Priority Council meeting at the site	The site notifies the sponsor when a decision has been made by the Research Council / Priority Council, including information about any adjustment in the time schedule.	*All contact between the sponsor and the site should be motivated as well as reasonable in order to facilitate project progress.* *As far as possible, outgoing emails from the sponsor should take into account the current status of the individual site and be based on new relevant information.*

4	Continued		
	Current issue	**Guidance**	**Comments**
4.3	Contract process	Communication related to budget- and contract should be sent together with other study documents such as protocol, manuals and draft patient information. Negotiations cannot commence until the study start-up work has been initiated at the site and by the responsible study nurse, so that the study procedure is clear for all involved. The start of the contract process takes place according to the time schedule. Although contract-related negotiations (start of the contract process) can be initiated, the signing requires final versions of the relevant study-specific documents.	
4.3 B	Pharmacy contract • Pharmacy contract • Radiopharmacy • ATMP In accordance with regulatory and legislative requirements, Investigational Medicinal Products (IMPs) must always be sent via a pharmacy function in Sweden.	Pharmacy contracts must always be drawn up between the sponsor and the pharmacy. Agreements concerning preparation of medicinal products/IMPs must be set out in a local pharmacy contract. The sponsor should involve the responsible study coordinator in the final phase of the contracting process between the pharmacy and the sponsor and in the practical aspects of drug handling (requisitions, etc.).	*The sponsor should contribute to practical issues relating to IMPs in the dialogue between the site and the pharmacy operator.*
4.4 C	Negotiating contracts A separate "investigator agreement" in addition to the site contract is not applicable or relevant in Sweden as the sponsor never enters into a contract with an individual investigator but always with the healthcare provider. In fact, "investigator agreements" are not compatible with Swedish law.	The sponsor is encouraged to use published price lists (www.nastro.se) for budgeting purposes. The fees paid to one healthcare provider for different levels of staff and assessments should not vary from study to study.	*Specification of what (procedures and assessments) will be included in the respective patient visits during the study shall be stated in the budget and substantiated by the protocol (schedule of events).* *The sponsor's budget proposals are presumed to be based on the price lists published on Nastro's website or equivalent.* *In the context of negotiating contracts, the sponsor should ensure the availability of a Swedish-speaking contact at the sponsor's company in cases where specific issues arise.*

4	Continued		
	Current issue	**Guidance**	**Comments**
4.5	Discussion related to the Investigator Site File (ISF): digital, physical or hybrid.	If a combined digital/physical ISF will be used in the study, the discussion should define what will be handled digitally and what will be managed physically, respectively. If a digital ISF is being considered, it is necessary to discuss what will be uploaded into the ISF. The ISF, irrespective of its format, has to be made available to the site prior to the start meeting.	*Early discussion about digital/hybrid ISF is to be planned, and a decision needs to be taken by the site during the start-up work.*
4.6	Preparing a CTIS application / general considerations: • The PI's CV must be in *Swedish* for submission to CTIS in Part II. • The PI's CV must be in *English* for the study-related documentation. In Part II, *all* the documentation must be in Swedish.	Documents must be clearly marked as drafts (with a watermark or equivalent). The site provides the documents to be included in the CTIS application even before the Research Council / Priority Council meeting has taken place and the contract is fully negotiated. The patient information should be verified (in terms of its content) with an investigator in Sweden, if time permits. The Research Council / Priority Council may decide that the study should not start, regardless of whether or not a CTIS application has been made. Separate medical licenses for the study personnel do not need to be obtained. The employer (the healthcare provider) takes responsibility for controlling the medical licenses for its personnel. However, if this needs to be verified, the Swedish National Board of Health and Welfare should be contacted with a view to requesting an extract from the HOSP register. Enquiries about specific licenses for specific individuals should be made via email to hosp@socialstyrelsen.se or phone to +46 (0)75-247 42 42, Tuesday to Friday (working days) 09:00-10:00.	*The sponsor is required to provide site-specific documents in Part II.* *The remuneration payable to the site for the time used to prepare the application to CTIS is paid by the sponsor.* *Transparency is important, and all investigators concerned know who verified the patient information in Sweden.* *If the study requires a patient diary or source data from the patient stating how the IMP was administered, such documentation will be prepared by the sponsor.* *An application to the biobank, including the ICF text submitted concomitantly to CTIS, is to be discussed with the biobank in case of any queries so as to not delay the approval of the study.* *Any update of the patient information required by the RFI in CTIS cannot be reviewed and validated by the investigator due to time constraints.*
4.7	Study-specific training	Prepare a study-specific training plan for site personnel (which/what/when/how) prior to the start of the study. Only mandatory training in study-specific procedures/systems that has not previously been completed by site personnel should be provided. Training already completed and still valid (according to certificates/attestations/ authorisations) should not be carried out.	*See Nastro's website (www.nastro.se) for guidance on common Nastro routines related to study-specific trainings.* *Serious breach training, for example, has been provided in the context of all ICH-GCP training programmes since August 2023.*

4	Continued		
	Current issue	**Guidance**	**Comments**
4.8	Final study documents	Protocol · Patient information · Recruitment plan · Appendices (CTIS) Manuals (lab, X-ray, pharmacy)	*The sponsor is responsible for sharing/ sending all documents in final versions to the site.* *Draft versions are necessary during site start-up phase.* *The latest approved versions must be received by the site not later than at the start meeting.*
4.9	Study-specific logs	Discuss and decide what logs are relevant and applicable during the study. • Ensure that double documentation linked to logs is avoided. • The logs used must be documentable in line with Swedish practices, e.g. using the format of Swedish social security numbers. • Logs justified according to GCP are used in studies or as agreed, nothing more. Drug prescription, administration and accountability logs – both the patient compliance and the standard IP log – should be included.	
4.10	Contact details	Ensure that contact details (the so-called escalation list) for the sponsor and the CRO, respectively, are updated and correct for the study.	*In case of a CRA change, the CRO/sponsor is responsible for ensuring that the handover takes place without affecting the site and without data already monitored having to be re-monitored.*
4.11	Investigational Medicinal Product (IMP) (documentation)	The sponsor is responsible for ensuring that a pharmacy contract is set up and that the site receives instructions on how to manage the IMP. The site is responsible for ensuring that IMP handling routines are implemented. The site ensures that the IMP is requisitioned and prescribed in accordance with the routines of the site. The sponsor and the site should jointly ensure that routines are in place at the site prior to the start meeting (assumptions: pharmacy contract is set up, the site has routines in place, start meeting has taken place). If a patient is already waiting to be included *before* the start meeting has taken place, this should be communicated to the sponsor.	*It is important to communicate and plan the number of days required for the IMP to be available at the site after the start meeting so that the patient inclusion can be scheduled (it is important that this issue is resolved before the start meeting takes place)*

4	Continued		
	Current issue	**Guidance**	**Comments**
4.12	Communication with the site	Study-specific issues should be communicated collectively (not one issue per email) The protocol name or study name should always be indicated in the subject line of email communications between the site and the sponsor concerning the study.	*The site provides the sponsor's representative with information on who to contact regarding various issues on an ongoing basis.*
4.13	The study material should be sent to the site 2-4 weeks prior to the planned f start meeting date.	Published information about the site via Nastro's website (www.nastro.se) states which addresses and contacts should be used in connection with ordering study-specific material to the site. The sponsor/CRO has to verify the volume of lab kits and packing material that the site needs so as to ensure that only reasonable amounts are forwarded and, thus, that the risk of unnecessary destruction is reduced.	*If this information is not available, the sponsor ensures (by obtaining verification from the site) that the recipient and the recipient address are correct.* *This verification can be obtained during the selection visit.*
4.14	System access and study-specific training	The site communicates the names of the study team members and who need system access to the sponsor. Based on this information, the sponsor can see who needs access to what and who should receive e-training prior to the start meeting (e.g. eCRF and protocol-related training). The sponsor should ensure the availability of documents and PTT images so that the site is able to train personnel quickly and involve more personnel in the study while it is ongoing. Also refer to section 4.7.	*The sponsor should ensure that the study team personnel at the site have access to relevant systems prior to the start meeting. This involves clarifying which systems are to be used and which team members will be using them based on the delegation list drawn up by the investigator.*
4.15	Start-up work to be completed prior to the start meeting: Review of routines, processes, recruitment of patients and flow chart for how the study will be conducted in detail. Preparing this carefully prior to the start meeting is important to ensure an efficient (fast and quality-driven) meeting as well as a fast inclusion process.	The representative of the sponsor/CRO should have knowledge about clinical routines for oncology and haematology in the Swedish healthcare sector as well as a good understanding of the study protocol and how the study is to be conducted.	*It is important to document relevant contacts and who are primary contact persons at site and the sponsor.*

5	Start meeting		
	Current issue	**Guidance**	**Comments**
5.1	The Investigator Site File (ISF) must be available at the site when the start meeting is held.	Any training in electronic ISF systems must take place before the start meeting so it can be accessed during the start meeting.	
5.2	Start meeting - execution Plan and adapt the start meeting based on the type of study to be conducted and the site's (process- and study-specific) experience.	Establish a clear agenda for the meeting that focuses on the following: · *Which* patients are to be included? · *How* will the study be conducted? · *Information* on the IMP, prescription and management / administration Encourage the investigator to play an active role in the start meeting, which focuses on the current patient population, screening and recruitment. As far as possible, the sponsor should attend the start meeting with a medical representative. Parts of the meeting that only concern the study coordinator can be held separately.	*The sponsor's representatives such as the monitor/CRA/project manager/medical advisor must all be familiar with and knowledgeable about the protocol as well as the site's experience and conditions.* *From this point onwards, the designated CRA is the primary communication link between the site and the CRO/sponsor.* *The sponsor's representatives in the role of CRA/monitor must be fluent in spoken and written Swedish.*
5.3	Secrecy agreement (non-disclosure agreement, NDA) between the site and the sponsor's representative - The secrecy agreement (NDA) must be established and signed by both parties (the sponsor representative and the head of department) *before* the visit takes place.	· A secrecy agreement must always be established in connection with audits, visits, monitoring, etc. · The secrecy agreement is specific for the sponsor's representative. · The study coordinator at the site ensures that the secrecy agreement is signed by the person responsible for medical records at the site (often the head of department).	*The CRA must ensure that a signed secrecy agreement is available in a timely manner prior to the planned visit in order to get access to patient information such as medical records and the like.* *Electronic equipment, e.g. for translating medical records (e.g. translation apps) may not be used in connection with monitoring.* *The sponsor should minimise the number of employees having access to individual study participants' medical records.*
5.4	Source data	· Identify and define the source data for the study · Ensure documentation of what information constitutes the source data for the study and in which systems such source data information is available. A thorough review of the source data list should take place in connection with the start meeting to establish where the defined source data can be accessed at the site.	

5	Continued		
	Current issue	**Guidance**	**Comments**
5.5	Contact details for the site in HiKS (database for clinical studies)	The site has to provide the sponsor's representative with the contact details for the study in question to be published in HiKS (often a phone number for a unit)	*Link to the HiKS website: www.hiks.se*
5.6	Other topics to be discussed at the start meeting:	Routines for regular communication / reporting between the site and the sponsor are to be discussed. Recruitment plan – how should site communicate with the CRO/sponsor regarding screening and inclusion. Brief explanation of the monitoring plan – how should updates and communication take place during the study Both parties' expectations have to be addressed.	

6	Inclusion of the first patient and onwards (ongoing study)		
	Current issue	**Guidance**	**Comments**
6.1	Planning prior to monitoring visits	It is important to know how much time to schedule. Source data has to be prepared and medical record extracts must be available. The investigator must also be available. Issues identified during monitoring visits should, as far as possible, be addressed directly and on site, not handled as open queries after the visit. Similarly, the monitoring should be completed at the site in connection with the visit.	*Avoid scanning and submission of copies between monitoring visits as far as possible. To be verified in connection with the next monitoring visit.*
6.2	Contract/invoicing	The study contract should be updated when study procedures are changed. If the site invoices contractually agreed additional costs, the costs have to be stated on a per-patient basis. The sponsor will provide invoicing specifications if the site's own templates are not sufficient.	*The sponsor cannot pay for work or services that are not performed.* *If additional procedures are performed, additional remuneration is payable.* *The sponsor has to provide the site with invoicing specifications for payable visits.* *The sponsor will have a contact person for invoicing / payment issues.*

6	Continued		
	Current issue	**Guidance**	**Comments**
6.3	Study documentation	Relevant information concerning the patients' care and treatment is documented in the patients' medical records. Location of other documentation in other places is per the source data agreement. Double documentation should always be avoided. "Note to files" should only be made in case of significant systematic deviations that are not already documented in the medical records or the CRF.	
6.4	Protocol amendments	Clear communication concerning upcoming amendments between sponsor and site (investigator or study coordinator). Clear communication on approval date following an approval of an amendment.	
6.5	Data cleaning	The sponsor must clearly communicate planned timelines (when and how quickly the site is expected to reply). Normally affects both the responsible investigator and the study coordinator	

7	Final activities		
	Current issue	**Guidance**	**Comments**

7.1	Close-out visit	The following issues should be discussed in connection with closing the study: · Unused material · IMP · Outstanding invoices · Ensure eCRF copy available at the site · Responsibility for study documentation (archiving), including where the archives are located at the healthcare provider's facilities · Termination of system accesses. · How and when the study results will be communicated to the patients · Final report	*Discuss whether archiving can be done before the sponsor submits the final report.*

Statement on the Public Access to Information and Secrecy Act

The principle of public access to information is a fundamental principle in Sweden's form of government. One of the fundamental laws, the Freedom of the Press Act, (Tryckfrihetsförordningen, TF (1949:105)) contains provisions on the right to access official documents, which is a manifestation of the principle of public access to information. This means that a *public authority*[1] *in Sweden must register received or drawn up documents*[2] *held by* them, which then makes these documents *official documents*. These official documents can be made publicly available and be retrieved by another party. There are, however, provisions on secrecy that restrict the right to access official documents. These provisions are found in the Public Access to Information and Secrecy Act ("Offentlighets- och sekretesslagen, OSL, 2009:400"). Some provisions govern the restriction of confidentiality within the public sector and do under certain circumstances prohibit the disclosure of official documents; however, disclosure can be ordered after balancing economic interest and the general public interest, for example general public health issues.

According to section 31, sub-section 12, of the OSL, confidentiality applies to information relating to testing, determination of properties or quantity, valuation, scientific, technical, economic or statistical research or other such assignment that an authority carries out on behalf of an individual (physical/judicial) if it must be assumed that the assignment has been submitted on the condition that the information is not to be disclosed. This encompasses for example information stated in the synopsis, study protocol including appendices. This provision means that hospital or care provider controlled by municipalities, regions and country councils are not allowed to share or make such information publicly available. Also, section 31, sub-section 16, of the OSL which applies to information about business or operating conditions and legislation regarding trade secrets (Lag (2018:558) om företagshemligheter) can be applicable.

Since the information stated in the synopsis and study protocol including appendices, are subject to confidentiality under law it is not necessary to enter into a separate confidentiality agreement with the hospital. Furthermore, employees of publicly owned hospitals are also bound by a confidentiality obligation according to OSL. Therefore, a separate confidentiality agreement with the involved researchers will typically not be necessary either.

Privately owned hospitals or care providers where neither municipalities, regions nor country councils exercise control over the hospitals/care provider will not be subject to the rules on confidentiality under OSL. In these cases, a separate confidentiality agreement is necessary.

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[1] Public authorities refer to bodies that are part of the central government and local government administration; this includes hospitals and care providers offered by municipalities, regions or county councils (public sector). Companies, associations and foundations that are not controlled by a municipality, region or country council are not a public authority, e.g. hospitals and care providers run by privately owned companies.

[2] Document refers not only to writing or images on paper but also tape recordings, emails or text messages. In general, a document is any object that contains information of some kind.

The following documents have been signed on 3 July 2024

Guidance for clinical studies.pdf
(241575 byte)
SHA-512: e37ee8e0732425cae9e9a26c6478a4505045b
6aea1914dde7ad042f3c061885936286ca4c63133d2d54
70aef8302d0e7d78dc4ce37e30f18d2a1adda00bdd629

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Guidance for clinical studies

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