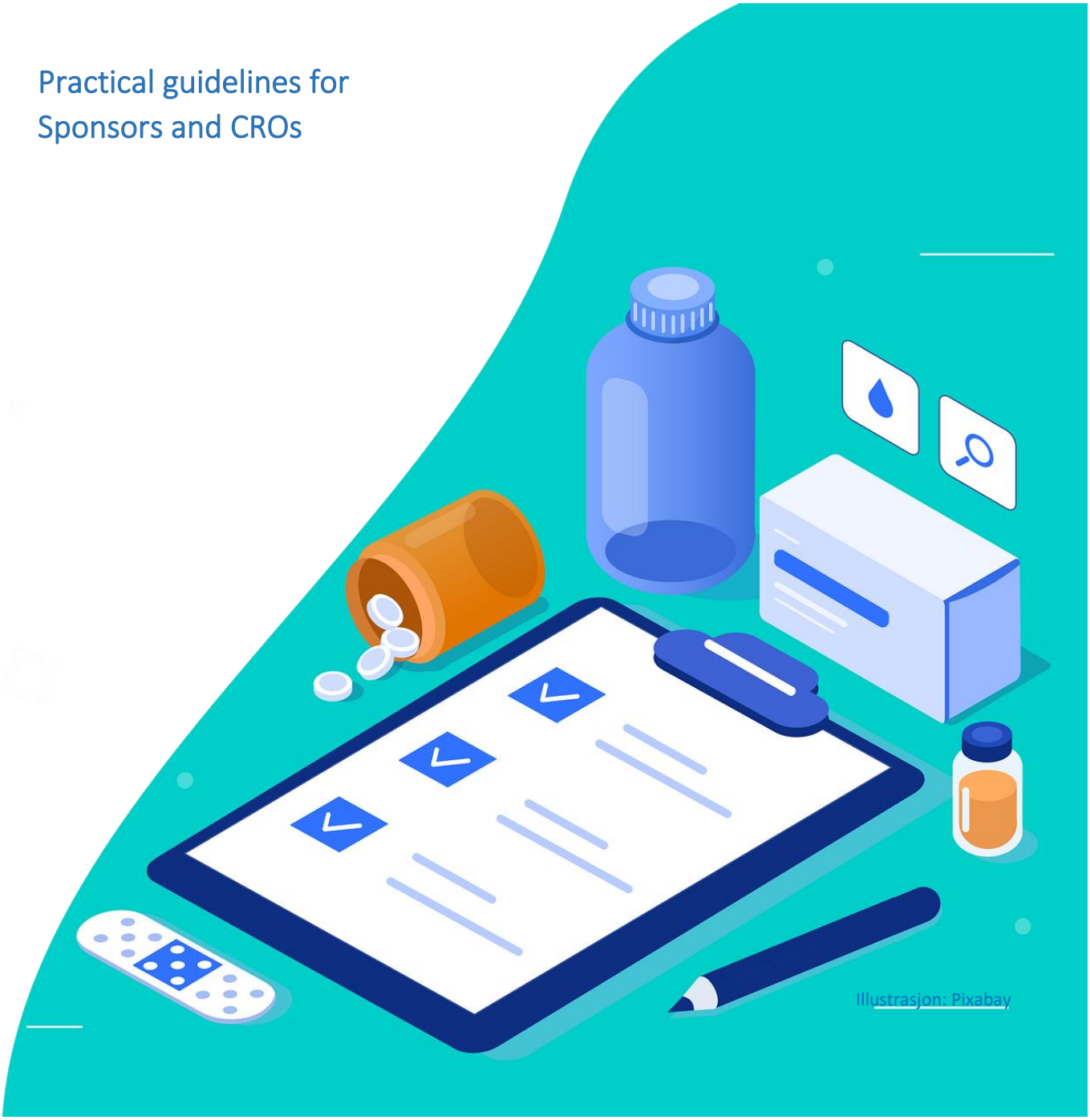
Pharmaceutical Industry–funded Clinical Drug Trials in Norway

Practical guidelines for
Sponsors and CROs



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NorTrials

1 Introduction and Background

This guidance document has been developed to support sponsors and CROs conducting clinical drug trials in Norway. The purpose of the guide is to provide an overview of the national requirements that apply in addition to the GDPR/Clinical Trials Regulation (CTR), and it is not intended to repeat information already documented through other channels.

Clinical drug trials in Norway are subject to the European Regulation EU Clinical Trials Regulation (EU CTR 536/2014), as well as national legislation. The most relevant national laws are the Health Research Act and the personal Data Protection Act.

Comments to this guideline can be submitted to contactnortrials@ous-hf.no.

1.1 Responsibilities Related to Submission of Clinical Trial Applications in CTIS

The sponsor or CRO has the formal responsibility for submitting and following up in the Clinical Trials Information System (CTIS) and serves as the system's primary users.

A successful CTIS application for Norway requires close collaboration between the sponsor or CRO and the Norwegian trial sites. It is strongly recommended to establish an agreement with the trial site regarding the review of the participant information sheet and other Norwegian-language materials for trial participants, as well as other tasks that require local knowledge.
In multicenter studies, one (lead) site should preferably be assigned this task on behalf of all participating sites. Collaboration between the sponsor or CRO and the institution is essential for ensuring the quality of the application and helps the trial receive approval without unnecessary delays.

2 Legislation

2.1 Health Research Act

The Health Research Act regulates the use of health data and human biological material in research (including requirements for consent, biobanking, documentation, and specific rules for transfers to third countries). This is a national regulatory framework that applies in addition to the GDPR/CTR requirements.

2.2 Data Protection Legislation (GDPR) and Personal Data Act

For clinical drug trials conducted in Norway, the EU General Data Protection Regulation (GDPR) applies directly through the EEA Agreement, and in Norwegian law through the Personal Data Act. The regulatory framework requires that the processing of personal data has a valid legal basis and that information security is ensured. Responsibility for assessing GDPR compliance lies with the institution and the data controller.

2.2.1 Legal Basis for Processing

For guidance on the use of the correct legal basis for processing personal data in a clinical trial, please refer to the Normen guidelines; «Personvern og informasjonssikkerhet i forsknings- og kvalitetsprosjekter» (Data Protection and Information Security in Research and Quality Improvement Projects - in Norwegian only).

The patient information material and consent form must not include information about the legal basis for processing personal data.

Information about the legal basis is provided in the institutions and the sponsor's own information material. These must not be included in the documentation submitted as part of the application for studies regulated under the CTR, the Medical Device Regulation (MDR), or the In Vitro Diagnostic Device Regulation (IVDR).

2.2.2 Insurance

The sponsor is responsible for obtaining insurance through Norsk Legemiddelforsikring AS, which is owned by the Norwegian Pharmaceutical Liability Association (LAF). The insurance is mandatory under Chapter 3 of the Product Liability Act. If the trial is conducted by a pharmaceutical company that markets medicinal products in Norway and the manufacturer is a member of LAF, the insurance is considered to be in place. More information is available on LAF's website (Norwegian), where you can also find contact details if you have questions.

Injuries must be reported to the Norwegian System of Patient Injury Compensation (NPE), which receives and handles pharmaceutical injury cases. NPE is a governmental agency under the Ministry of Health and Care Services that processes compensation claims from patients who believe they have been harmed within the public healthcare sector. In addition, NPE has taken responsibility for handling compensation claims related to medicinal product injuries and injuries arising from clinical trials.

3 Participant Information Material and Consent Form

We recommend following REK KULMU's templates for consent forms. There are separate templates for information sheets for future research, medical device trials, medicinal product trials, general biobanks, as well as information sheets for children under 12 years and for adolescents aged 12–16 years.

Clinical drug trials that include children and adolescents under the age of 18 require consent from both parents/guardians. For medicinal product trials, this applies until the child turns 18, regardless of the general healthcare age of consent, which is otherwise 16 years in Norway.

Informed consent must include clear and understandable information about the purpose of the trial, what types of data will be collected, who may access the information, and a contact point for questions and complaints.

If patient records are to be reviewed for recruitment purposes, an exemption from the duty of confidentiality is required (ref. Health Personnel Act §29, Health Registry Act §19e).

4 Institutional Approval

The local principal investigator is responsible for ensuring that the trial is approved within their institution, both with institutional leadership and the data protection function. Under Article 30 of the GDPR, the institution is required to maintain an overview of all personal data processing activities carried out by the institution. Before the trial can begin, approval must be granted for its conduct at the institution. The procedures for obtaining such approval may vary between institutions. At Oslo University Hospital (OUS), for example, this is done by submitting an electronic notification form to the Data Protection Officer.

5 Transfer of Data and Biological Material to Countries Outside the EU/EEA and the UK

For clinical drug trials conducted in Norway, different regulations and requirements apply depending on the country to which personal data or human biological material is transferred. The sponsor is responsible for ensuring that both types of transfers are carried out in accordance with applicable laws and ethical guidelines, including those governing their subcontractors.

5.1 Transfer of personal data to the United States and other third countries

When personal data from a clinical drug trial is to be transferred to a country outside the EU/EEA/UK (a “third country”), for example to a sponsor or CRO in the United States, a valid legal basis for the transfer must be in place. This is a requirement under the General Data Protection Regulation (GDPR). In the Clinical Trial Agreement (CTA) entered between the sponsor and the institutions, the sponsor confirms that they comply with the applicable regulations and procedures.

5.1.1 Transfer of Data and Biological material to the USA

For transfers of data from the EU/EEA to the United States, the EU–U.S. Data Privacy Framework (DPF) may be used when the recipient is certified under the DPF scheme, which means that the U.S. is considered to provide an adequate level of protection and that the transfer can therefore be carried out without additional documentation (GDPR Article 45). The U.S. recipient (e.g., the sponsor) must be able to document their certification. The Data Privacy Framework website can be used to verify whether an organization appears on the list of approved companies.

The transfer of biological material and/or personal data requires a Material Transfer Agreement (MTA) and/or a Data Transfer Agreement (DTA), unless this is already included in the agreement between the sponsor and the institution. This applies regardless of whether the recipient is in the United States, another third country, or within the EU/EEA.

5.1.2 Transfer of Data and Biological Material to Countries Outside the EU/EEA, UK and the USA (other third countries)

For all third countries outside the EU/EEA/UK that are not certified under the DPF, the transfer of personal data must be based on the EU's standardized agreement, the Standard Contractual Clauses (SCC). The SCCs are preapproved contractual clauses adopted by the EU, requiring the recipient to comply with the same data protection standards that apply within the EU.

For more information, see the Norwegian Data Protection Authority's website: Overføring av personopplysninger ut av EØS | Datatilsynet (Norwegian).

6 Clinical Trial Agreement

6.1 Submission of a New Clinical Trial

Before a clinical trial can begin, a Clinical Trial Agreement must be established between the sponsor/CRO and the institution, and, if applicable, the contracting authority at each institution. The sponsor/CRO is responsible for initiating this process. An overview of the contract management offices within the four regional health authorities (RHFs) in Norway can be found on the NorTrials website: Agreements between sponsors and hospitals - NorTrials. The contract process is initiated when the sponsor or CRO notifies the relevant contract management office by submitting a notification form.

The contract negotiation process begins once the final protocol and draft budget have been submitted. Processing times vary between the contract management offices at each health trust, and the process may be delayed if all required documentation is not available at the time of notification.

6.2 Food and Drug Admininstration (FDA)

Norwegian investigators must not sign the FDA Form 1572. This document is tailored to U.S. regulatory conditions and does not apply in Norway, where clinical drug trials are conducted in accordance with the Clinical Trial Regulation (EU) 536/2014, ICH GCP, and Norwegian legislation. For trials with a U.S. sponsor, an "FDA IRB waiver" may be placed in the Trial Master File (TMF) as documentation that the IRB (Institutional Review Board) requirements in Form 1572 do not apply to Norwegian trial sites. Alternatively, this may be described in the agreement between the sponsor and the institution.

In the event of an FDA inspection, the inspector will assess whether the trial has been conducted in accordance with standards comparable to FDA requirements. It is therefore important that it is clearly documented—e.g., through the agreement or contract between the sponsor and the investigator/site— which legislation and guidelines have been followed in conducting the trial in Norway, including the Clinical Trial Regulation (EU) 536/2014 and the applicable version of ICH GCP.

6.3 Data Protection in the Clinical Trial Agreement

The Clinical Trial Agreement must include information on the data protection arrangements for the trial. If the sponsor or CRO does not have its own templates, the various contract management offices can provide their agreement templates. Examples of template agreements can be found on

Inven2's website. NorCRIN has developed templates adapted for academic trials, which can also be adjusted and used by industry sponsors/CROs.

A standard GDPR text has been prepared and verified by the Association of the Pharmaceutical Industry in Norway (LMI), the hospitals, and the contract management offices in Norway. This text is included in the agreement template, and the text—or the principles contained within it—must be included in the Clinical Trial Agreement. The main principles are as follows:

- *The sponsor and the hospital are independent data controllers ("Independent Controllers").*
- *The sponsor is responsible for ensuring that the solutions through which the hospital submits study data (e.g., eCRF) comply with the GDPR.*
- *If the contracting party is located outside the EU and the UK, Standard Contractual Clauses ("SCC"), Controller-to-Controller module, must be included. The SCCs are attached as an appendix to the agreement.*
- *If the contracting party is located in the United States and confirms that they are certified under the "EU–US Data Privacy Framework adopted in the adequacy decision from the European Commission on 10 July 2023," and the sponsor appears on the "EU–US Data Privacy Framework List" publicly maintained by the U.S. Department of Commerce, a reference to this in the agreement is sufficient, and SCCs are not required.*

6.4 Pharmacy Agreement

A separate agreement must be established between the hospital pharmacy and the sponsor or CRO. Inven2 is responsible for negotiating the legal part of the agreement on behalf of the hospital pharmacy enterprises in Norway. There are a total of 34 hospital pharmacies, owned by four regional hospital pharmacy enterprises. The hospital pharmacy itself is responsible for defining the pharmacy-related tasks and negotiating the price for these services, which are included as an appendix to the agreement.

In the notification form submitted to Inven2, the sponsor or CRO must specify whether a hospital pharmacy will perform services in the trial, including import activities. Inven2 initiates the pharmacy agreement process and informs the sponsor/CRO about the next steps. One hospital pharmacy from each hospital pharmacy enterprise is responsible for clarifying the scope of work and the pricing of the services. This will then apply to all hospital pharmacies owned by that enterprise. Once the agreement has been quality-assured by Inven2, and the services and pricing have been agreed upon between the sponsor/CRO and the hospital pharmacy, the agreement can be signed. Signing takes place directly between the hospital pharmacy and the sponsor/CRO, without involvement from Inven2.

More information about the process and templates for pharmacy agreements can be found on Inven2's website.

6.5 National Registration and Trial Visibility

In addition to registration in the EU/CTR/CTIS, clinical trials that include Norwegian participants must be registered on the hospitals' websites. An overview of all ongoing clinical trials in Norway is available on all hospital websites and is mirrored on Clinical trials in Norway - Helsenorge.

The clinical trial should only be registered once on the hospital's website, but for multicenter studies, information about all participating sites must be included. Only hospital employees can register trials, so we recommend that the sponsor/CRO agrees with the trial sites on which hospital will handle this task. It is advisable to assist in drafting the trial description to ensure high-quality content.

Hospitals currently have slightly different templates and routines for registration, even though all studies are published in the same national web solution. See, for example, the instructions for trial registration at OUS (Norwegian). Remember that the information must be updated when recruitment ends and when the trial is completed.

7 Guidance, Services and Useful Resources

7.1 Advisory Services from the Norwegian Medicines Agency (NoMa)

As part of its mandate, NoMa offers advisory and guidance services for stakeholders in drug development, research, and industry. NoMa can assist with interpreting regulations and documentation requirements and provide advice on clinical drug trials and approval processes. In addition, NoMa can contribute to the assessment of regulatory strategies. More information can be found here on the NoMa website.

7.2 Regional Committees for Medical Health Research Ethics – Clinical Trials (REK KULMU)

REK KULMU assesses ethical aspects of clinical drug trials in Norway. Approval is required before recruitment can begin. For questions about ethical review under CTR, MDR or IVDR: rek-kulmu@medisin.uio.no

7.3 NorTrials

7.3.1 Feasibility Portal

NorTrials provides national support for feasibility requests and processes. The Feasibility Portal distributes requests to relevant hospitals and follows up in a timely manner. Once contact is established, dialogue continues directly between parties, with NorTrials available for support if needed.

7.3.2 Quality Assurance of Participant Information and Consent Forms

NorTrials' coordinating unit offers free quality assurance of patient information material for industry-sponsored clinical drug trials. The aim is to reduce comments from REK KULMU. The service includes language editing, verification of REK's consent templates (Norwegian), and assessment in accordance with ICH-GCP and the national SOP. The sponsor submits both the original and the Norwegian translation of the informational material. The normal processing time is up to five working days.

7.4 NorCRIN Standard Operating Procedures

NorCRIN's SOPs provide researchers and trial personnel with a structured framework for conducting clinical drug trials in Norway. Although developed primarily for academic studies, they also offer support for industry-sponsored trials.

7.5 Framework Confidentiality Agreements

It is possible for sponsors and CROs to enter into framework confidentiality agreements (master Confidential Disclosure Agreement ("mCDA")) with the various hospitals. Contact the contract management office at the relevant hospital if you wish to establish such an agreement. The contract management office also has its own templates that may be used for this purpose.