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Legal framework for conducting clinical trials in Poland

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Clinical trials in Poland are regulated at both EU and national levels. At the EU level, this area is regulated by:

- **Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials of medicinal products for human use**
- **Executive Commission Regulation (EU) 2017/556 of 24 March 2017 on detailed arrangements concerning good clinical practice inspection procedures.**

However, since April 2023, Poland has had a law on clinical trials of medicinal products for human use, which implements and clarifies regulations issued at the EU level.

Below, we answer the most common questions on the conduct of clinical trials by reference to common principles derived from EU legislation with consideration of Polish legal specifications.

Who can sponsor a clinical trial?

A sponsor is an individual, company, institution, or organisation responsible for undertaking, managing and organising the funding of a clinical trial. The sponsor does not have to be from Poland or other EU country. For third-country entities, legislation requires a sponsor to appoint a legal representative resident or established in the EU. The sponsor's representative will be responsible for fulfilling the sponsor's obligations under clinical trial legislation.

What is the CRO?

The CRO, or Contract Research Organisation, is the entity conducting a clinical trial on behalf of the sponsor. This is usually an individual or an academic or commercial institution contractually entrusted by the sponsor to perform specific tasks related to the clinical trial.

Who comprises the research team?

POLISH LAW

The research team is comprised of researchers, who are responsible for conducting a clinical trial at the clinical trial site. The research team is led by the principal researcher, who heads the team. The research team may also be a single person. In that case, the sole member performs the functions of the

principal researcher and is responsible for this role in the trial. The Clinical Trials Act states that the principal researcher may be the holder of a licence to practice in Poland:

- doctor
- dentist
- nurse holding a diploma in nursing
- midwife holding a diploma in midwifery.

The Act nevertheless stipulates that if a nurse or midwife is the principal researcher, one of the other researchers on the team must be a doctor or dentist. Thus, a research team cannot consist only of nurses or midwives.

What agreements should be concluded in clinical trials?

According to the guidelines adopted by the Committee for Medicinal Products for Human Use of the European Medicines Agency (known as the ICH GCP guidelines), it is recommended to conclude a conduct of trial agreement (so-called CTA), which defines rights and responsibilities of the sponsor, researcher and trial site. This is the basic agreement in any clinical trial. In addition, agreements with co-researchers and CROs can also be concluded. The sponsor and researcher obligation to take out civil insurance for a clinical trial should also not be overlooked.

Are clinical trial contracts public?

Clinical trial contracts are not public. They do not have to be submitted to authorities during the authorisation procedure—with the exception of proof of a civil insurance policy between the sponsor and researcher. Instead, a description of the contracts must be submitted, primarily those governing trial funding.

Who issues a clinical trial permit?

POLISH LAW

The authority competent to issue an authorisation for clinical trials is the President of the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products ('URPL President'). The URPL President issues an authorisation through an administrative decision based on a positive opinion of the Bioethics Committee.

Where should a permit application be filed?

According to art. 5 of Regulation 536/2014, the sponsor submits an application and its annexes on the European Union portal (Clinical Trials Information System — 'CTIS'), which is also used for further contact between the authority and applicant. To use the CTIS portal, an active EMA Account Management account is required.

How much time does the URPL President have to issue a permit?

The clinical trial authorisation procedure has a strict timeframe. The URPL President has:

- **16 days** from the date of submitting the application dossier to notify the sponsor of which country acts as the rapporteur and to validate the application and report on trial coverage and completeness of the application dossier,
- **45 days** from the date of validation of the application[1] to submit the final Part I and Part II assessment reports, including its conclusions. This deadline may be extended by a further 50 days for expert consultation in the case of advanced therapy and by up to 31 days for additional information from the sponsor,
- **5 days** from the date of submission of the report (i.e. date on which the final version of Part I of the assessment report is submitted to the sponsor) or from the last day of assessment of aspects covered by Part II of the report, whichever is later, to notify the sponsor of whether the authority authorises a clinical trial, whether authorisation will be granted on conditions, or whether the authority refuses to grant authorisation (date of notification).

How to challenge a decision refusing to issue a trial permit?

Refusal to issue a trial authorisation may be challenged through a complaint to the provincial administrative court. The sponsor has 30 days from the date of delivery of the authority's decision to file a complaint with the court.

POLISH LAW

1 the date of validation of the application is the date on which information on completeness of the application dossier is communicated to the sponsor

Can a negative opinion of the Bioethics Committee be appealed?

POLISH LAW

No. Neither EU nor Polish law allow an appeal against a negative ethical opinion of the Bioethics Committee. An amendment to an ethical opinion is only possible through an appeal against a decision of the URPL President refusing authorisation for clinical trials. In such case, the URPL President requests the Supreme Bioethics Committee to prepare a new assessment within 3 days of receiving the appeal.

When can a clinical trial commence?

A clinical trial can commence after an authorisation decision has been obtained. In contrast, art. 8 sec. 6 and art. 14 sec. 11 of Regulation 536/2014 stipulate that if the sponsor is not notified of the authority's decision in time, conclusion of Part I of the assessment report is the decision on an application for authorisation of a clinical trial. This means that the authority's inaction may be tantamount to acceptance of the application.

Who supplies the subject medicinal product and trial devices in a commercial clinical trial?

A sponsor must provide the subject medicinal product and devices used to administer it to trial subjects free of charge. The sponsor also finances healthcare services related to a clinical trial that are not within the scope of publicly guaranteed healthcare services.

Is insurance associated with a trial always required?

POLISH LAW

In principle, the sponsor and researcher are subject to mandatory third-party liability insurance for damages caused in connection with a clinical trial. The sponsor does not need to conclude a liability insurance contract for a low-intervention clinical trial. A liability insurance contract must be concluded at the latest on the date of submission of an application for authorisation, and proof of its conclusion (policy) as an attachment to the application.

What fees does the sponsor pay prior to the start of a clinical trial?

POLISH LAW

A sponsor must pay a clinical trial application fee, the amount of which depends on the nature of the clinical trial and the reporting country. In addition, for each submitted clinical trial application, the sponsor must pay a single payment to the bank account of the Clinical Trial Compensation Fund. Proof of payment of this deposit is attached to the application. The amount of payment to the Fund depends on the planned number of participants in the trial and is the PLN equivalent of €2,000 to €10,000.

What should informed consent documentation include?

Informed consent must be in writing. If a participant is unable to write, consent shall be recorded by suitable alternative means in the presence of one impartial witness.

Documentation of informed consent shall include:

- information about the trial, particularly its nature, objectives, benefits and implications, including associated risks and inconveniences, trial conditions and possible alternative treatments,
- an informed consent form including the date and signature of the subject or its representative and a member of the investigative team,
- consent to the processing the subject's personal data.

How much time should the subject have to read the informed consent form?

The Act and Regulations do not set the minimum or maximum deadline for a subject to read the informed consent form for participation in a clinical trial. They only state that time to consider a decision to participate in a trial should be adequate.

When can a clinical trial inspection be expected?

An inspection of clinical trials conducted by the URPL President through an authorised inspector or competent authorities of EU or EFTA Member States may be carried out at any stage of a trial *ex officio* or at the request of the European Commission or competent authorities of EU or EFTA countries. An inspection can take place before commencement of a trial and during or after its completion.

How long should research records be kept and who is responsible for archiving them?

Basic clinical trial documentation should be retained for at least 25 years after the end of a trial. The sponsor must archive these records and designates the party responsible for archives and the investigator. However, if ownership of clinical trial documentation is transferred to another entity, this will transfer all documentation archiving obligations to the acquirer.

This material is for information purposes only and does not constitute a legal opinion. Please contact us if you have any questions.

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