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Clinical trials in Greece

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Clinical trials

Authorisation

What is the authorisation procedure for conducting clinical trials in your jurisdiction?

The Good Clinical Practice authorisation procedure is governed by Ministerial Decision G5a/59676/2016, which implements the EU Clinical Trials Regulation (2014/536). A strict procedure must be followed, starting with written approval from the National Ethics Committee (NEC), the competent authority for the clinical trials in Greece, along with the National Organisation for Medicines. This approval should be given within 60 days (at most) of the study sponsor submitting the application and completed file. In the meantime, the Scientific Boards and Administrations of the Health Region Administrations of the relevant hospitals must also inform the NEC, within 30 days of the application, of any problems regarding the adequacy of the investigator and the suitability of the hospital facilities. In all cases of interventional clinical trials, the national template agreement must be used.

Clinical practices

How robust are the standard good clinical practices followed in your jurisdiction?

The Guideline on the Good Clinical Practice adopted by the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use sets out a set of international ethical and scientific rules aimed to achieve a quality standard for designing, conducting, recording and reporting trials that involve the participation of human subjects. In Greece, good clinical practices are adopted and, to that end, Greece participates in the Eudract and Eudravigilance databases in order to ensure the safety and transparency of clinical trials.

Reporting, disclosure and consent

What are the reporting and disclosure requirements for the results of clinical trials?

In accordance with Article 37 of EU Regulation 536/2014, the sponsor must notify each member state concerned following the completion of a clinical trial, as well as all third countries in which the clinical trial was conducted through the EU portal. Notification must be made within 15 days from the completion of the clinical trial in the last member state concerned and any third countries where the clinical trial was conducted.

Irrespective of the outcome the sponsor must submit a summary of the study's results to the EU database within one year from the completion of a clinical trial. This should be accompanied by a summary written in a manner that is understandable to laypersons. However, where for any scientific reasons detailed in the study protocol it is not possible to submit a summary of the results within one year, the summary must be submitted as soon as it is available. In this case, the protocol should specify when the results will be submitted, together with a justification. In addition to the summary of the results and the location where the clinical trial is intended to be used to obtain a marketing authorisation for the investigational medicinal product, the applicant must submit the clinical study report within 30 days of the grant of the marketing authorisation or withdrawal of the application to the EU database.

What are the informed consent obligations with respect to clinical trial subjects?

Every clinical trial subject must provide his or her informed consent to participation in writing, following an explicit and elaborate explanation by the physician in charge. Children under the age of 18 and persons incapable of representing themselves can also participate in clinical trials under certain conditions. In all cases, an interview must take place before the trial and a competent,

qualified healthcare professional must ensure that the participant has understood the objectives, risks and the possible side effects of the study. Moreover, the subject of the clinical trials must be fully informed as to the duration and conditions of the clinical trial, as well as the cost and amount of insurance coverage. Finally, the subject of the trial is free to withdraw his or her consent at any time.

Insurance

What are the insurance requirements for clinical trials?

In order to conduct a clinical trial, the sponsor should conclude and maintain an insurance contract with a reputable insurer registered in an EU member state to cover the liability of the sponsor, principal investigator and research members. Thus, the amount of the insurance contract should cover any damage or disability resulting from participation in the clinical trial and, in case of death or permanent disability to work, the reparation should be at least €200,000 per participant.

Data protection

What data protection issues should be considered when conducting clinical trials?

One of the issues commonly addressed in the context of a clinical trial is the use of subjects' personal data. The National Organisation for Medicines has explicitly taken the stance that the codified (anonymised) data of study subjects continues to be considered personal data and authorisation from the Data Protection Authority is necessary. Under the new General Data Protection Regulation (European Regulation 679/2016), which will enter into force in May 2018, compliance with the Data Protection Authority will no longer be required.

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