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New rules for carrying out clinical trials in Spain: in a faster, safer and more transparent way

Royal Decree No. 1090/2015, of 4 December on clinical trials involving medicinal products, Research Ethics Committees and the Spanish Clinical Trials Register

Following a lengthy process going back over two years, on 24 December 2015, Royal Decree No. 1090/2015, regulating clinical trials involving medicinal products was published in the Spanish Official Journal. Said Royal Decree came into force on 13 January 2016 and replaces Royal Decree No. 223/2004 and Order SCO/256/2007. The new Royal Decree seeks, on the one hand, to adapt Spanish legislation to Regulation (EU) No. 536/2014 on clinical trials involving medicinal products and, on the other, to further regulate those aspects which said Regulation leaves in the hands of the national law. According to its preamble, it seeks to "drive and facilitate clinical research with medicinal products in Spain, the creation of knowledge, transparency, the safety of participants and the usefulness of results". Below, we refer to a number of the new features of this Royal Decree that seek to secure Spain's position at the forefront of clinical research.

Simplification of the process

The procedure to obtain the authorisation to start a trial, or to make a substantial change to the conditions under which such authorisation is originally granted, have been simplified considerably, in particular for low-intervention clinical trials. The most noteworthy new feature, in addition to a shortening of timescales, is that an opinion need only be sought from one Ethics Committee (now known as Research Ethics Committee) rather than one per participating centre, as had been the case up until now. This change will lead to obvious time savings in the procedure, in addition to a reduction in costs as only one fee shall be paid as part of the assessment of the trial, regardless of whether several Committees are involved in said process.

Importance of the contract

Another important new aspect involves the contract that the sponsor must sign with each centre participating in the trial. Historically, the negotiation and signature of contracts has been a nightmare for sponsors, often leading to delays in starting trials. The Royal Decree seeks to speed up this process by implementing two measures. First, it calls on the competent health authorities to agree on just one valid contract template for the entire National Health System (SNS), the drafting of which is based on the general principles established by the Interterritorial Council of the SNS. And second, it allows for the contract to be executed at any time, and not solely upon authorisation of the trial, as had been the case up until now. In the event that the contract is signed before the trial is authorised, the regulation sets out that the contract will not become effective until authorisation is obtained.

Figure of the sponsor

The contract is particularly important when the sponsor decides to delegate all or part of its duties to a third party, such as a CRO. Thus, special care must be taken to appropriately document which tasks have been delegated and the scope of liabilities must be defined.

Furthermore, the contract is particularly important when various sponsors are involved in the same trial. For such instances, the Royal Decree establishes that all sponsors shall be liable as provided for by said law, unless otherwise decided and reflected in the corresponding contract.

New concepts

One of the new concepts introduced by the Royal Decree concerns "non-commercial clinical research", undertaken by researchers with no involvement on behalf of pharmaceutical companies, either as sponsors or as a beneficiaries of the data or results that said trials may generate. This type of research enjoys particular benefits compared to trials which do have a commercial nature, such as the opportunity to request authorisation to undertake a trial without first having taken out insurance (where necessary), or the exemption from or reduction in fees payable.

Furthermore, the different types of research have been standardised based on their level of intervention. Thus, the term "clinical study" can be broken down into two different categories: "clinical trial" and "non-interventional study". Subsequently, within the "clinical trial" category, a "low-intervention clinical trial" sub-category has been included. The prevailing features of this sub-category are that the medicinal products have already received a marketing authorisation and are used in accordance with the terms of such marketing authorisation or supported by published scientific evidence on their safety and efficacy.

Insurance and liability

Low-intervention clinical trials do not need to be covered by a specific insurance policy if the centre at which the trial is being performed has taken out civil liability insurance. However, in practice, insurance taken out by centres tends to exclude the coverage of damages experienced during trials; therefore, checking the scope of said coverage is recommended.

Furthermore, following the entry into force of the new Royal Decree, claims can be filed regarding damages caused during a trial, even when said damages are included as adverse reactions of the medicinal product administered during the trial.

Greater transparency

The new Royal Decree also elaborates on the mechanisms to disseminate the results of trials carried out in Spain. In particular, it places special emphasis on the Spanish Clinical Trials Register, for which the Spanish Agency of Medicinal Products and Medical Devices (AEMPS) is responsible; records must include the details and outcome of all clinical trials and post-authorisation non-interventional studies with medicinal products. Said register may be accessed online by anybody without restriction and free of charge, thus providing reliable and understandable information about said trials.

Another important new feature is the significant extension of the minimum period during which the sponsor and the investigator must store the essential documents of each trial: from 5 years to 25 years.

The implementation of this new Royal Decree will undoubtedly raise some questions. To answer these questions, on 13 January 2016, the AEMPS published guidelines containing practical information on its application; the AEMPS has promised to keep these guidelines up to date.