

Insurance Coverage for European Device Clinical Studies

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The requirements for insurance coverage of subjects participating in European medical device clinical studies, and the cost of this coverage, vary significantly throughout Europe. This article discusses this variability and the importance of identifying insurance coverage needs in the early stages of planning European clinical studies.

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Insuring clinical study subjects

Under the European medical device Directives, the primary purpose of conducting a clinical study with devices that do not yet carry the CE mark is to verify that, under normal conditions of use, the device conforms to the performance specified by the manufacturer; to determine any undesirable side-effects; and to assess whether risks are acceptable when weighed against the intended performance of the device. The very nature of this type of clinical study means that the risks to patients participating in the study have not been fully identified; they are the subject of the clinical investigation. It is, therefore, understandable that if a subject suffers an injury or dies while participating in a medical device clinical study, or even during a defined period after the study is concluded or terminated, the manufacturer, clinical site and/or clinical investigator(s) may be held responsible. As a result, one or more of these parties may be expected to pay damages related to this type of an event, depending on the nature and cause of the event and whether or not any fault is attributed to the device or to any of the parties. This article discusses the need for sponsors of medical device clinical studies to obtain adequate insurance to cover the injury or death of a study subject. It will not cover insurance needs of clinical sites or clinical investigators.

An important cost component

Recently, a medical device manufacturer became aware that the cumulative cost of insurance coverage for 10 subjects in a European clinical study could be as high

as €40 000. This was a problem because the company had not included the cost of insurance in planning the clinical study. Another company planning a European multicentred study of a high-risk medical device had to face even higher unplanned insurance costs. This company was also surprised to learn that insurance coverage is mandatory in some European countries, while in others it is not, and that the cost of coverage varies significantly throughout Europe. In addition, the company was not allowed to use its own insurance provider because the provider was located outside Europe. For these reasons, it is important that clinical study sponsors identify insurance costs and requirements in the early stages of planning a European clinical study. This is particularly important when the European study is a multicentred study that involves more than one European country.

Lack of harmonised requirements

The European Directives for medical devices contain no requirements for obtaining insurance to cover damages that injured parties may claim as a result of participating in a clinical study. Therefore, some clinical study sponsors who have never conducted a medical device clinical study or have not conducted a study in Europe may not understand the importance of appropriate insurance coverage.

The absence of any mention of clinical study insurance coverage will change if the proposed amendments to the Medical Device Directive (MDD) (93/42/EEC)¹ are adopted. Annex VIII, Statement Concerning Devices for Special Purposes, of the MDD specifies the information



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that must be in a statement that is drawn up for devices intended for clinical investigations before the investigations are conducted. This statement must contain information such as

- data allowing identification of the device in question
- an investigation plan stating in particular the purpose, scientific, technical or medical grounds, scope and number of devices concerned
- the opinion of the ethics committee concerned and details of the aspects covered by its opinion.

Section 2.2 of Annex VIII of the proposed amendments to the MDD will require the statement to also include confirmation of the insurance of subjects participating in the clinical study. It is important to note that the information contained in the statement is the same information that most Competent Authorities expect to receive when they receive notification of a clinical study to be conducted in their territory.

Guidance from clinical standards

The European harmonised standards for clinical devices, EN ISO 14155:2003, Clinical Investigation of Medical Devices for Human Subjects, include general references to insurance and insurance certificates. That is,

- Clause 7 of Part 1, General Requirements, describes the documentation that needs to be prepared before the initiation of a clinical study.
- Clause 7.2 lists the information that must be contained in the clinical investigator's brochure.
- Clause 7.3 lists the other documents that should be maintained in investigator and/or sponsor files; among these are "appropriate insurance certificates, if applicable."
- The informative Annex B, Information for the Ethics Committees, includes a list of information that can be of relevance to the ethics committee, including "a copy of the patient insurance policy when legally relevant."

Good clinical practice guidance

Good clinical practice (GCP) regulations and guidance that apply to clinical trials of medicinal products contain more specific requirements for insurance coverage. This is important because most medical device clinical study sites and their ethics committees operate under the regulations, principles and practices of medicinal product clinical trials. For this reason, it is advisable that sponsors of medical device clinical studies are aware of the provisions of the European GCP Directive that applies to the conduct of clinical trials on medicinal products.² This will allow them to understand the origin of certain requirements such as those pertaining to insurance of clinical study subjects.

For example, Article 3, Protection of Clinical Trial Subjects, of the GCP Directive states that a clinical trial may be undertaken only if, among other required actions, provision has been made for insurance or indemnity to cover the liability of the investigator and sponsor. In addition,

Article 6, Ethics Committee, requires that in preparing its opinion, the ethics committee shall consider

- the relevance of the clinical trial and the trial design
- whether the evaluation of the anticipated benefits and risks is satisfactory
- the clinical protocol and other aspects of the clinical trial.

The Ethics Committee must also consider

- provision for indemnity or compensation in the event of injury or death attributable to a clinical trial
- any insurance or indemnity to cover the liability of the investigator and sponsor
- the amounts, and where appropriate the arrangements for rewarding or compensating investigators and trial subjects, and the relevant aspects of any agreement between the sponsor and the site.

Even before the adoption of the GCP Directive, similar requirements for insurance coverage relating to the conduct of medicinal product clinical studies were included in international GCP guidance. Therefore, ethics committees have been evaluating insurance coverage related to clinical studies for many years. In spite of this, the evaluation is not always as effective as it should be, as discussed later.

Varying national requirements

The requirements and costs of insurance coverage for medical device clinical studies vary throughout Europe. This variation can be significant. In some countries, the requirements are mandated by local laws and regulations. In other countries they are not and it is left to the sponsor's discretion to obtain coverage. In other countries, ethics committees will not render a favourable opinion on the conduct of the study unless the insurance coverage complies with their expectations. Some countries require the insurance company that provides coverage to be located in the country where the clinical study is being conducted; other countries require only that the insurance provider be located in Europe. In some cases, damages are paid only if the cause of the injury or death can be proved to be attributed to the clinical study. The minimum coverage for each subject and each protocol also varies widely. For these reasons, sponsors of medical device clinical studies must not assume that the requirements and costs of insurance can be applied from one European country to another.

Avoiding common misconceptions

Some sponsors believe that the insurance policy that they maintain for marketed medical devices will also cover a clinical study. These types of policies are usually unsuitable for medical device clinical studies where the risks associated with the device being studied are unknown. Other sponsors believe that a general liability policy that does not include any mention of the investigational medical →

→ devices or a reference to the clinical investigation protocol is sufficient for a medical device clinical study. On the contrary, in most cases, an insurance policy should be obtained that specifies the medical device involved in the study and the clinical investigation protocol. In this way, the particular risks associated with the study of the device, which are described in the clinical investigation protocol, will have been taken into account.

Unfortunately, ethics committees do not always recognise the shortcomings in the policies that are submitted to them by sponsors. This not only places subjects at significant financial risk, but also the sponsors of studies. Thus, sponsors should ensure that they have secured insurance policies that cover the specific needs and risks associated with a particular clinical study.

Another area of confusion that some sponsors face is whether or not they should submit an insurance policy to the Competent Authority during the clinical study notification process. Some Competent Authorities require the notification of the intent to conduct a medical device clinical study to include only a statement for confirmation of insurance coverage. In these cases, it is expected that the ethics committee has evaluated or will evaluate the entire policy to determine adequacy of coverage. Nonetheless, some sponsors submit the complete policy to the Competent Authority, which can lead to questions being raised not only by the ethics committee, but also by the Competent Authority. This can be avoided when sponsors are fully informed of national requirements for clinical study notification and adhere to those requirements.

References

1. The proposed amendments to the European Medical Device Directive (93/42/EEC) can be downloaded from the European Commission website: http://ec.europa.eu/enterprise/medical_devices/revision_mdd_en.htm.
2. Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001 on the Approximation of the Laws, Regulations and Administrative Provisions of the Member States Relating to the Implementation of Good Clinical Practice in the Conduct of Clinical Trials on Medicinal Products for Human Use. This Directive can be downloaded from the European Commission website: <http://ec.europa.eu/enterprise/pharmaceuticals/eudralex/homev1.htm> **mdt**

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