

Information about insurance arrangements for multi-national trials in Europe

ESO Trials Network Committee

1 Introduction

Insurance is often prohibitively expensive, and it is often difficult for investigators of a multinational trial to obtain insurance in accordance with national laws. Investigators therefore need to access to information about the European and national regulations for insurance, and there is a need to explore the possibility for joint insurance cover for multinational trials in Europe.

2 New EU regulation on clinical trials

Insurance is addressed as an important topic in the proposal from the European Commission for a new EU Regulation on Clinical Trials

(http://ec.europa.eu/health/files/clinicaltrials/2012_07/proposal/2012_07_proposal_en.pdf).

In addition, the German Network of the Coordinating Centres for Clinical Trials (KKS-Network) has addressed this topic (http://www.gesundheitsforschung-bmbf.de/_media/TOP5_1Probandenversicherung_Empfehlungen_mitTN.pdf).

3 National indemnification systems

The former EU regulation (Directive 2001/20/EC) introduced an “obligatory insurance/indemnity”, but liability regimes differ widely between EU member states, and it is difficult for the sponsor of a multinational trial to obtain insurance in accordance with those national laws. Therefore, each member state should establish a national indemnification mechanism which compensates subjects in accordance with the laws of that state, but only a few states have done so (<http://www.patientforsikringen.dk>, <http://www.lff.se>, <http://www.lvp.fi/sv>, www.laf.no).

4 Insurance through pan-European legal entities

4.1 European Research Infrastructure Consortium (ERIC)

Insurance packages for multinational trials could also be set up within existing research infrastructures. However, a major difficulty in setting up research infrastructures between EU countries is the lack of an adequate legal framework allowing the creation of appropriate partnerships. Existing legal forms under national law do not fulfil the needs of these new European infrastructures, and the same applies to legal forms under international or EU law. The European Commission has therefore proposed a legal framework for a European research infrastructure (RI) adapted to the needs of such facilities.

A European Research Infrastructure Consortium (ERIC) is a specific legal form designed to facilitate the joint establishment and operation of research infrastructures of European interest. ECRIN has the legal form of an ERIC (ECRIN-ERIC), and is a so-called “ESFRI Roadmap” project (European Strategy Forum on Research Infrastructure, http://ec.europa.eu/research/infrastructures/index_en.cfm?pg=esfri). This means that, in theory, ECRIN-ERIC can negotiate insurance arrangements for multinational trials, but packages will have to be negotiated for individual countries, since insurance is regulated by insurance regulations that are national (not by trial regulations, that are multinational). Again, ESO may choose to become an ECRIN-ERIC partner, which will give access to the possibility of joint insurance cover for multinational trials.

4.2 Creation of an ESO legal entity

This possibility could also be explored. Such an organisation could assist trialists in other ways, for example by acting as sponsor for investigator-initiated trials.

5 Insurance brokers and individual insurance companies

We have been in contact with the insurance broker AON (www.aon.com). They write: “In principle it should be possible to arrange clinical trial coverage for a group of researching physicians. But the underwriters need detail information about the trial, patients, doctors, locations On the other hand the insurance should follow the law where the trial will take place. So additional questions will occur, especially concerning existing insurance coverage.” This means that any sponsor will need to give much information before an insurance policy can be agreed, and the price is likely to be high.

A number of insurance companies can provide insurance of patients in multinational trials (e.g. Zurich Insurance Group, <http://www.zurich.com>), but, again they will need detailed information, and the price is likely to be considerable.