



AVOIDING PITFALLS AND PROBLEMS IN CLINICAL TRIAL INSURANCE

The landscape affecting clinical trial insurance has changed over the last few years. This has had knock-on effects on administration requirements and insurance buying practices.

This article highlights legislative changes within the European Community, insurance ramifications and how insurers now view the risks.

The Background

The EU Clinical Trial Directive of 2001 was designed to simplify and harmonise the administrative provisions of studies as well as protect subjects and improve the quality of clinical research.

The Directive states also that trials may only be undertaken if "... (f) provision has been made for insurance or indemnity to cover the liability of the investigator and sponsor." The lack of specific requirements accompanied by a varied different local implementation of the directive has created new insurance issues that require some explanation.

The EU Directive was implemented in the UK through the 'Medicines for Human Use (Clinical Trials) Regulations 2004'. Other countries in the EU implemented it through their own legislation at a similar time, but some legislation was more thorough than others. In summary, the general result was that countries did not implement the Directive in exactly the same way, and local legislation is somewhat varied in scope and direction.

Areas that stand out in these differing approaches by countries in their implementation of the EU directive include:

- Some countries have made insurance compulsory, in others it is not.
- Some countries require insurance to be provided by a local insurer, known as 'admitted' insurance, whereas other countries will accept insurance provided by an insurer from another country ('non-admitted' insurance).
- Some countries require cover for legal liability only whereas others require non-fault cover.
- Some countries have specified minimum limits per patient and per trial whereas others do not mention limits at all.



Bulletin

- Some countries insist that cover be maintained for some years after the study has finished whereas other countries do not mention this requirement.
- The EU Directive also empowered Ethics Committees to consider the insurance or indemnity to cover the liabilities of the investigator and the sponsor. This, naturally, increased scope for variation in the practical local implementation.

Local implementation

Since implementation of the Directive insurers have seen more requests to cover trials than ever before. This has been amplified by other external factors such as the requirement of regulatory authorities like the US Food & Drug Administration (FDA) for more clinical trial safety data.

This has arguably led to lengthier and a larger number of trials now than in the past, and substantially more trials are being conducted outside of the USA. The disparate nature of the rules governing insurance around Europe has made the job of administration very confusing. Indeed, the documents required by insurers may include local translations of Protocols, Patient Information Forms and Informed Consent Forms. In short, a greater number of admitted insurance policies are being required, which has led to a longer lead-in time when accessing insurance and an increase in costs. This has also resulted in less insurer choice, especially if a sponsor wants to employ buying power and control by implementing a global insurance programme.

Insurance ramifications

The issues highlighted above have led to a variety of problems. The issuance of separate local policies with minimum limits per patient and per trial has led to an aggregation of insurance limits that insurers need to commit to any one trial. Insurers will often attempt to restrict this aggregation by imposing a 'cap' or overall limit, which means that more than one insurer may be required to support multi-national trials, depending on the countries involved. Recognising this issue early on will save time since appropriate insurers can be engaged at an early stage of the process, rather than just before the trials are due to begin.

There are some tools at a sponsor's disposal to help manage some of the insurance challenges and to ensure acceptable insurance paper is delivered to Ethics Committees in good time:

- Early engagement with Ethics Committees to ascertain exact insurance requirements.
- Development of protocols per territory including information requirements, flow of information, contacts etc.
- Selection of insurance brokers and insurers who understand the business and issues.
- Early engagement with selected broker and insurer.

How do insurers assess risk?

Notwithstanding the local insurance variances, in today's litigious climate it is essential to ensure that every step has been taken to avoid the possibility of a products liability suit. Certain key risk mitigation factors remain true in whatever country, or countries, a trial is taking place.

In order to understand the risk factors and rate a trial accordingly insurance companies will look at the following main areas and consider some aspects that can often be overlooked:

- The Research Protocol, which is the bedrock of any clinical trial. It is vital to have a comprehensive and well-designed protocol. The trial must be 'ethical' and the information must be easily understood and support the goals of the research. Once established, the protocol must be adhered to closely.
- Informed Consent Documents. Once the subjects have been enrolled it is the clinical investigator's responsibility to ensure they fully understand the informed consent form. The consent document must be easy to read and to understand, so ideally it should be written at or below 14-year old reading level.

- Although the Ethics Committee has an independent obligation to review and approve a trial, including consent forms, sponsors of clinical research should not place too much reliance on that backstop but should focus their efforts on providing the Ethics Committee with well designed documentation.
- Insurers will also consider how the trials are managed, the type of drug or device being studied, the stage of development (Phase I, II or III), the condition of the subjects and where the trial is taking place, as some countries are more litigious than others. Other information of importance will be the sponsor's and investigator's own previous experience in handling trials.
- Risk mitigation is essential. For example, as the number of clinical trials increases, so does the demand for subjects. However, industry estimates suggest that of all patients eligible for a trial, only 5-10% actually become involved. Accessing those individuals presents an enticing challenge for recruiters, as well as a temptation to be 'creative' in the sign-up procedure. Avoiding this temptation can help manage risk.

Summary

Clinical trial insurance has changed over the last few years. The 'insured parties' and the information requirements differ by territory. Insurance needs also vary and therefore insurers will respond differently in different territories. Understanding the environment will help ensure that the insurance process is as streamlined as possible. It is therefore important to choose your partner broker and insurer(s) carefully based on their experience, knowledge and ability to deal efficiently and accurately with trials cover requirements.

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Our Capabilities

JLT's Life Science Team has an excellent knowledge of the risks faced by life science companies, including challenges related to Clinical Trials. If you are interested in this particular area and wish to find out more about it or wish to discuss any other risk financing needs do not hesitate to contact the individuals below.

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Events

Life Science & Chemicals Forum

17-19th September 2007

Hotel Villa Padierna, Marbella, Spain

In the past 2 years, the Life Science & Chemicals Forum has become a leading platform for insurance buyers, insurers and advisers to come together and openly discuss and debate issues key to the Life Science & Chemicals industries. This year the focus will be on key themes including:

- Emerging Risks in Technology
- Managing Increasing Complexity
- Trends and Tactics in Mass Tort
- The European Environmental Directive

The panel sessions will be led by experts and recognised specialists in their fields, drawing on their deep insight and experience to help you recognise and manage the emerging risks and key issues facing the industry today and tomorrow.

If you would like to receive more information or to register, please contact Celine Lachevre on +44 (0) 207 558 3356 or celine_lachevre@jltgroup.com, or visit http://www.jltgroup.com/lifeSciences_new.shtml.

Business Continuity Management - Avoiding Common Pitfalls and Maximising Value

Almost one hundred senior executives from large and international organisations participated in this Business Continuity Management (BCM) web seminar on 5th July 2007. To hear what JLT's specialist consultants had to say and see the results of an online poll taken before and after the event visit www.jltgroup.com/events.php4?EventID=55.

Business Continuity Planning is an issue for most organisations. Globalisation has created more complex supply chains, as businesses take advantage of outsourcing and cheaper production. Creating a successful BCM programme is no mean feat. Many plans are far too complex, ambitious or suffer from a lack of clarity. They are often rigid rather than flexible and judgements made without being challenged.

Chris Rigby Smith and Tim Cracknell from JLT's specialist Consultancy Services presented the tools and methodology to overcome common pitfalls such as:

- How to set realistic 'project' objectives
- How to set realistic 'project' timeframes
- How to keep the programme structure and content simple
- How to differentiate between 'the business continuity plans' and a 'capability' to use them effectively