Addressing the Challenges of Clinical Trials Insurance

Often thought of as a simple off-the-shelf product, clinical trials insurance can be considerably more complex, as Allianz Global Corporate & Specialty's Victoria Cockayne and Johannes Klose explain.

The process of obtaining insurance for a clinical trial can be a challenging exercise for all parties involved, be they the company electing to conduct a trial or the insurance professionals involved in arranging or providing coverage.

Firstly, there is the speed in which a client requires documentation. After many months of planning and organising the study to get to a stage where they are ready to submit to the independent ethics committee (EC), it can be a sudden realisation to a company engaging in clinical research that insurance is required and required fast! Combine this with: 1) the number of countries involved, each requiring an individual policy and certificate compliant with local regulations; and 2) a need for absolute accuracy with no room for error, and it is clear that the insurance broker and carrier have been set quite a task to turn around a company's programme within a matter of days.

This time pressure becomes even more intensified if the insurer has a technical or administrative question about the trial which hinders them from providing insurance terms as quickly as the company requires. Factors such as inadequate information when submitting the trial to the insurance company can delay the process of approval and therefore coverage for the trial. This can stretch the capabilities of an insurer, particularly when it comes to first-time testing of products/interventions in humans. Sometimes there is no protocol or investigational brochure available, meaning the insurer has not received adequate information to proceed with. Even if there is a protocol, it may not provide sufficient information about preclinical data of an investigational product or procedure and instead refers to the investigational brochure. It is a challenging task for an insurer to measure the risk adequately without this document. If missing, additional time is required to obtain it. The process can be further delayed if the sponsor has confidentiality issues, which can be resolved with a non-disclosure agreement, but, again, this adds to the time it takes for an insurer to be able to provide adequate terms for the risk.

Administering the Programme

Administration of the programme can provide many hurdles too. In order to achieve a complete solution for the company, the insurer is reliant on its global network of offices, some of which may be in different time zones where immediate response to a documentation request is not always possible. Coordination of such programmes involves a high level of organisation from the lead office and invaluable cooperation from the network.

This is not a challenge that is unique to the insurer, however. The company or sponsor will face many administrative and operational challenges of their own when managing the many interfaces internally and externally, such as, for example, various research and development, legal/compliance and manufacturing functions, study managers, regulators, ethics committees, internal committees, investigators and contract research organisations (CROs) and other third party service providers. A central approach to coordinate the information necessary to obtain insurance is often not in place and individual study managers are often not aware of the requirements of their country which can lead to further delays.

It is no surprise, therefore, that insurers are coming under increasing pressure to find more centralised solutions for this with automatisation of the entire process being the holy grail for companies engaging in this market, but even that has its challenges.

Technical Factors to Consider when Assessing Risks

For example, consider the issue of risk-adequate pricing. The range of clinical trial risks is extensive. Besides the testing of drugs or medical devices by commercial sponsors, there are many investigator-initiated trials that may investigate a commercial product and/or compare non-product-based therapeutic interventions or look at other areas of research. Assessment systems centred on investigational products (nature, novelty, safety profile, route of administration, etc.) may easily struggle with such trials.

Other important factors when assessing a clinical trial risk are: the scope of inclusion and exclusion criteria; completeness, accuracy and readability of the informed consent form; medical and scientific quality and performance of the investigators and trial sites; and early-phase risk management in human or dose-finding trials, (i.e. not exposing too many patients at the same time, careful selection and staggered increase of dosing ranges, allowing time for clinical observation and interpretation and not quickly exposing too many patients in short and overlapping timeframes to a broad range of single and multiple dose ranges). These risk factors are quite difficult and sometimes even impossible to be easily captured/measured by an insurer. However, they can at times be major drivers of clinical trial risk, as is evident from past high-profile clinical trial losses.

Overly simplistic risk assessment systems, which only consider the trial phase and the number of patients, ignore the large spectrum of risks and are unlikely to produce risk-adequate pricing. Individual losses in the hundreds of thousands range can heavily impact profitability of clinical trial books – especially smaller ones. Considering complex and challenging upcoming new trial risks involving gene therapy or cell therapy, for example, makes it even more evident that a simple "one-size-fits-all" risk assessment and pricing approach is not the right solution.

Of particular note is the fact that the sponsor themselves can significantly impact the covered risk by determining the scope of interventions which are included in the trial. Protocols can be drafted in a smart way, with particular focus on the point in time when trial inclusion starts and thereby take out interventions (which also means risk) from trial cover which are not (directly) linked to the investigational interventions of interest.

Industry Growth and Improvement Lies Ahead

Despite all of these challenges, it is not all doom and gloom for medical research companies seeking insurance or for those providing it. While the perfect solution to placing a multinational programme for a multicentre clinical trial does not yet exist, there are many insurance carriers out there who have the expertise to manage this and are rising to the challenge of providing consistent risk solutions to streamline the process and meet companies' needs.

Never before have medical professionals had as many choices of insurance carriers as they do today, with recent years seeing an increase in companies providing a product for this type of insurance.

As companies start to look further afield with their studies,

reaching into previously unchartered territories such as China, India and the African continent, the global reach of the insurance company is key to offer a product fully able to attend to companies' needs.

Meanwhile, improvement of the whole process of conducting clinical trials in the European Union (EU) is expected in 2019 with the implementation of Clinical Trials EU directive 536/2044. The harmonisation of assessment and supervision processes across the Member States will improve both the rules relating to the insurance industry and other areas of clinical trials, and will negate the need for the sponsor and insurance company to meet the myriad different EC requirements they now have to deal with.

With the global clinical trials market expected to reach USD65.2bn by 2025, according to a report by Grand View Research[1], it could provide the perfect opportunity for insurance companies to develop their product offerings further, leading to more risk appetite and the incentive to invest in technology such as platforms that can provide a one-stop-shop solution for certain types of studies, an advancement that would be welcomed by everyone in the industry.

REFERENCES

1. Clinical Trials Market Size Worth $65.2 Billion by 2025. CAGR 5.7%, August 2017, Grand View Research

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