



Topaz Clinical

International Clinical Trials = Increased Risk and Exposure

Introduction

The tipping point has been reached: an analysis of the data set derived from 5,167 clinical trials involving 126,980 study sites between from October 2005 and September 2007 (source: www.clinicaltrials.gov) reflects that almost half (49.4%) of all industry sponsored clinical trials reported a non-North American component as related to patient identification, recruitment and retention. This trend will continue to grow across the pharmaceutical, biotechnology and medical device industries, as the factors associated with offshore clinical trial strategies are indeed compelling:

- Large treatment-naïve patient populations
- Large, readily available patient flows in disease specific protocols
- In many cases less costly
- Strong interest and support from local physicians
- Equally strong patient interest in access to medical care
- A stable population is ideal for long term longitudinal studies

Yet entering into these foreign countries is not without its challenges and risks. Changing national laws, shifting regulatory statutes and capricious local authorities (ethics committees, government officials, judges) need to be considered before any international clinical trial is undertaken.

In the past, some global CROs have promised sponsors a complete A to Z package to totally execute, manage, oversee and supervise 100% of the entire international clinical trial project. “Just write us a check for \$X...and we’ll take care of everything” was the sale pitch. But reality is different from fantasy; no CRO has offices and employees everywhere, so daisy-chain relationships are often stitched together to provide the “global” coverage so easily represented by CROs in their efforts to secure international business from the sponsor community.

The Shifting Landscape

The strengths and weaknesses of global CROs is not the subject of this article; most US sponsors already initiate rigorous due diligence analysis on any CRO before signing a Master Services Agreement to retain their services. But all clinical trial sponsors need to know and understand: there is no escaping the fact that the sponsor of the trial cannot delegate or shift major clinical trial liability exposure to the CRO, the investigator or the site. Around the world there is one universal agreed upon fact: the sponsor of any clinical trial is responsible, and will be held accountable, for specifically define direct and indirect damages based upon country-by-country laws and regulations.

Of particular concern are the “emerging markets” where, in recent years, clinical trial activity has been increasing in geometric proportions, with no slowdown in sight. India and China in particular, with their huge patient populations providing excellent patient recruitment potentials in certain targeted disease states (e.g. respiratory, infectious diseases, HIV/AIDS), will lead this trend as

more validated, GxP compliant sites and investigators come “on-line” and enter into the marketplace.

BUYER UNDERSTAND vs. BUYER BEWARE

The ever elusive search, for the three-legged Holy Grail of site initiation and patient recruitment (better-faster-cheaper), will continue unabated throughout the global clinical trial industry into the foreseeable future. There is no choice: the demands of the competitive marketplace that dictate this sense of urgency, is now in the DNA of every life science executive and company around the world. Not surprisingly, this never-ending 24x7 road race contains serious risks, liabilities and exposures that must be identified and addressed, all which become magnified across time zones, continents and cultures. In today’s global environment, risk management for life science companies is becoming a critical function within the corporation. Not only the identification and quantification of risk, but also the development of strategies and tactics to mitigate potential liabilities is now a mandatory skill set that needs to be part of the operational staff.

Legally binding contracts and agreements define these liabilities, but it is the role of a well thought out, well constructed insurance program that must ultimately protect and secure the assets of the company against claims seeking financial remedies. It is no surprise that both inside and outside of the US, life science companies are seen as “deep pocket” targets for legal action in the event anything, anywhere, at anytime something goes wrong that can either directly or indirectly be associated with the company and its products, people, operations, etc. This “halo effect” of potential liability must be recognized, and each country, each governmental body and each judge will see the facts differently.

Location, Location, Location

Insurance – the well-established concept and product we all look to for protection against financial ruin. But what kind of “protection?” Against what risk? How is that risk defined? How is this protection to be priced? For international clinical trials, sponsor companies need to recognize the serious nature of these questions. More importantly, specific in-country resources are needed to give guidance to address these issues.

Location-specific underwriters and brokers, who know and understand the life science industry and the clinical trial process, can and should be engaged in the clinical trial planning process as early as possible. Use them as a valuable resource; they know the insurance and indemnity regulations of the country that govern clinical trials, but more importantly they know the unwritten trends, customs and lay-of-the-land details that cannot be found in books or laws.

Going Forward: a final comment

“Better-Faster-Cheaper.” Don’t expect this mantra to change anytime soon. It’s part of the fabric of our industry, and everyday it governs the nearly 15,000 clinical trials that are taking place around the world. Every trial has a profile unique unto itself, and every principal investigator and every site has their own personality and culture. International clinical trials are a fact of life: they are big, complex projects that will become more challenging as treatment therapies continue to evolve, and advances in genomic and proteomic science begin changing the clinical trial landscape.

For life science companies, a well thought out, well designed insurance and indemnification program is not only smart from a legal standpoint, but makes good business sense in mitigating risk across the entire corporate enterprise.

AUTHOR

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