Real Regulatory

Finding ways to improve the regulatory submission process for clinical trial authorisations

Are you prepared to take the plunge and use a niche provider to deliver your Clinical Trial Authorisation (CTA), or would you prefer to play it safe by using a large CRO? With an increased emphasis on quality control, specialised providers now have an admirable track record for delivering results.

Building a Regulatory Alliance with an Expert Provider for CTA Submissions

When clinical trials are outsourced to third parties, regulatory expertise and local knowledge often resides within the clinical trial CRO rather than with the sponsor. It is a positive attribute that the clinical trial CRO has broad regulatory expertise. However, in this situation it may be difficult for the sponsor to adequately assess the clinical trial CRO's performance. To add value, a balance is required between sponsor oversight and adherence to regulatory requirements without duplication of effort.

Sponsors and niche regulatory providers are looking to balance the productivity equation so that resources with the appropriate level of expertise are available during periods of high workload, but can be phased out during periods of lower regulatory activity. A sponsor which does not have sufficient in-house expertise of the CTA process could consider supporting their internal team with the services of a regulatory contractor on a flexible basis. The objective of this third party quality oversight and expertise is to interact with the clinical trial CRO on behalf of the sponsor, thus providing the required oversight. The aim is to maintain the relationship over the life of the clinical development process, thereby reducing the learning curve as the regulatory contractor is familiar with internal processes and provides access to experienced staff.

How to Improve the CTA Submission Process

Predictability and efficiency are key to ensuring regulatory approvals are received in a timely manner. Predictability can be increased by ensuring your regulatory affairs contractor has access to local regulatory requirements. The use of some fairly straightforward tools can improve efficiency and increase transparency of the regulatory submissions process. A systematic approach will lead to a more reliable regulatory submissions process.

What Processes Might Help?

It can be challenging for sponsors to create detailed country-specific procedures for CTA submissions as the regulatory requirements can and do change regularly. It is hoped that the proposal from the European Commission for a new regulation governing clinical trial applications in Europe will improve the situation. As a regulation, as opposed to a directive, which is the basis for the current rules, regulatory review of CTAs by member states will be based on one text rather than the current situation where the transposition of a directive allowed for country specific modifications. However, implementation of such a regulation is some time away. In the meantime, there are certain procedures or processes which the sponsor can implement to increase internal transparency, manage approval timeline expectations and provide evidence of sponsor oversight of the clinical trial CRO; see Steps for Sponsors.

Conclusion

Both volume providers such as CROs and niche providers such as those with specific regulatory expertise may provide the sponsor with solutions for different business needs. The added value in creating an alliance with a niche provider of regulatory services for clinical trial applications lies in the support provided to the sponsor in preparation and management of creating a consistent and locally compliant submission, while also providing evidence of sponsor oversight of the clinical trial CRO activities.

Steps for Sponsors

- Consider regulatory quality oversight at contractual stage
- Prepare a regulatory management plan which clarifies key areas such as roles and responsibilities, communication process for regulatory authorities, quality control/review of submission packages
- Set up trackers to identify exactly what documents and translations are required for the regulatory submission
- Identify rate limiting documents, planned submission dates and planned approval dates. Potential regulatory hurdles should be anticipated, and steps should be taken to address them
- Communicate clearly decisions about managing risk and potential impact on approval timelines
- Establish a process to agree and document whether changes are substantial or non-substantial
- Conduct a quality control check to ensure that the correct documentation is included in the CTA dossier prior to submission

Real Regulatory is a team of proven and committed experts in regulatory affairs, providing consultancy and hands on assistance to the pharmaceutical, medical device and related industries. Our team of professionals have many years experience and a wide range of expertise across the spectrum of regulatory affairs activities.

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