How can Ergomed support you in executing clinical trials during Covid-19?

If you are wondering if it is still possible to continue or start-up a clinical trial, Ergomed can address your concerns with well-considered mitigations and solutions.

With experience in over 600 clinical trials, Ergomed has planned, managed, monitored and reported trials with a range of technologies and we continue to offer the personalized service for which we are known, even in the most challenging of circumstances.

Ergomed finds solutions

Ongoing study in Neuromuscular Disease

To overcome the challenges caused by COVID-19, Ergomed made several key changes to the study, enabling it to continue:

- Home-delivery of study medication
- Replacement of some site-visits by phone call or video
- Addressing local regulatory and data protection challenges to enable remote SDV.

Watch Ergomed's recent Webinar

"Ensuring Continuity in Rare Disease Clinical Trials During the COVID-19 Crisis".

Your concerns may include the following:

Q: Is it still possible to initiate the start-up of a non-COVID-19 clinical trial during the current crisis?

A: Yes it is. Over the past two months Ergomed has invested a great deal of time and effort making sure this is possible. We enable our clients to start their clinical trials by utilising our regulatory and local intelligence to:

- Advise on which regulatory authorities and ethics committees are accepting new, non-COVID-19 clinical trials
- Provide knowledge and awareness of which additional documents and risk assessments are required – including what format they should be submitted in – to facilitate review and approval for commencement of new non-COVID-19 clinical trials
- Provide strategic planning of expected timelines for obtaining regulatory approvals and execution of clinical trial agreement during the set-up of new studies
- Assess a site's resources, capabilities and competency to conduct clinical trials under local COVID prevention and restriction measures, while assessing and documenting those sites which will be available once the conditions change.

Q: How do you ensure data quality and study oversight during COVID-19?

A: At Ergomed we understand it is important to ensure patient safety and quality data, especially during times of crisis. We have already developed robust processes for centralized monitoring and data review. Now, with regulators being more amenable to such activities since the start of the crisis, Ergomed has moved quickly to implement the procedures for centralized data monitoring in our studies wherever possible.

Ergomed's risk-based quality management system, supported by the analysis of trends and key risk indicators, ensures the quality and continuity of oversight even in the absence of on-site monitoring activities.

Q: The current COVID-19 crisis has created travel restrictions and less available sites. Does this mean patient recruitment and retention has become more difficult?

A: Ergomed is finding that – particularly in the case of rare diseases – patients are still motivated to take part in clinical research. Our focus on ensuring patient safety is actually aiding recruitment.

By designing a robust protocol - providing home visits, timely delivery of important medicines, and utilizing our specialized "patient toolkit" - we are able to support patients and their families in their journey throughout the clinical trial.

In addition, Ergomed's medical writing team can create a new protocol or revise an existing protocol, that will contain mitigation measures for the current COVID-19 situation.

Ergomed's team is well prepared to mitigate the potential impact on all levels, ensuring timely delivery of study results.

For more information on starting up and executing clinical trials during COVID-19, and how Ergomed can support you:

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