

CRO's at hand for biotechs planning to launch a new product for the first time

Being a young biotech company about to embark on its first pre-clinical or clinical trials, or about to launch its first product on the market, can be an overwhelming task. But many CRO's offer services that help at each stage of the process.

By Karin Jensen

Discovering and developing a new drug is a very long process that requires multiple resources and the success rate of getting a new product to market is very low. However, with the right consultancy services, the chances of obtaining approval for a new drug can be increased many times over.

BioXpedia is a contract research laboratory active in preclinical trials, working with both small biotech companies and large pharma groups. Preclinical trials are trials carried out prior to clinical trials in humans, and where feasibility, iterative tests and drug safety data are collected.

Mogens Kruhøffer, CEO and founder of BioXpedia.

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BioXpedia’s consulting service always starts with a discussion of the project and the goals the life science company plans to reach.

“Together with the client we determine what the best methods are, the best technology platform to use, how many tests are needed to obtain sufficient statistical power in the analytical work but also try to establish what obstacles we may encounter during testing,” says Mogens Kruhøffer, CEO and founder of BioXpedia.

If a company orders clinical tests such as animal tests or cell culture samples, BioXpedia helps establish how these samples should be carried out and how to make sure the samples are reproducible and standardised from beginning.

“Minimising pre-analytical variation in samples is very, very important. You also need sufficient standardisation in the way you do the samples and how you store them,” says Kruhøffer.

Working with a contract research laboratory provides a biotech company with access to the most advanced and up-to-date technology but also to a network of very experienced people in the industry, who apart from experience with clinical trials also have in-depth knowledge of regulatory affairs in various markets.

“I have worked with clinical researchers, large pharma and biotech companies over many years. We may not necessarily have the answer to all questions, but we know how to find the answers,” says Kruhøffer.

The Scandinavian contract research organisation, LINK Medical, offers a service for young biotech companies about to enter clinical trials with their compound. An initial meeting is held to discuss the business model as well as the parties go through the trial protocol and design.

“Our clients get the safety profile of the product evaluated just as we

evaluate the market for this type of product and which markets to focus on, which patient group to start with, how to design the trials,” says Ola Gudmundsen, CEO at LINK Medical.

Gudmundsen says LINK Medical is a multi-disciplinary company with many different competencies in-house, including several doctors and an experienced oncology team, who can help a small biotech company getting ready to go to market.

“Perhaps it’s a small company with just two employees and an excellent product that may be in need of a broader evaluation of the product,” says Gudmundsen.

A clear strategy and well thought out target profile are also essential if a biotech company is looking for new investors.

“The new biotech companies that succeed and get investments, are those who know where they want to go and who have a clear strategy of how to get there,” says Gudmundsen. ■

