STRATEGIC REGULATORY PLANS

Testimonial:

"I was looking for a consultancy that could help us map out a development pathway for a new venture; ProTherax not only provided us with a detailed review and fully supported our efforts to seek regulatory advice, but additionally provided us with a detailed clinical protocol, allowing us to cost a project to proof of concept. Throughout the project I found them to be diligent, highly responsive, proactive, communicative and extremely good value."

Portfolio Investment Manager - Venture Capital Company

AVOID POTENTIAL DEVELOPMENT DELAYS AND UNNECESSARY COST:

Developing medicines and biotechnology products is an expensive and time consuming business, and can quickly eat into the available cash and resources within a small business / start-up. Moreover, increasingly complex regulation during early clinical development e.g. Paediatric Investigation Plans; Development Safety Update Reports; Good Practise (GXP) regulations all have the potential to impose significant delays and/or regulatory compliance penalties on companies and product developments that get it wrong!

A well-developed and robust regulatory strategy is therefore critical at early stages of development (even before clinical trials begin) to ensure future success, minimise development time and avoid wasted costs.

In addition, strategic regulatory plans can:

- Help focus your development teams on critical studies key to progressing the product's development through the next series of regulatory hurdles (e.g. ensuring adequate data to support clinical trial approvals; selection and validation of clinical endpoints, design of non-clinical and clinical studies etc.)
- Review opportunities to reduce the regulatory burden on your development plan, by ensuring studies are designed and reported in compliance with international pharmaceutical standards?
- Review opportunities to reduce data requirements by employing abridged regulatory procedures, wherever possible
- Review opportunities to alter the design of the product and/or intended claims to meet the demands of alternative legislation (e.g. medical devices / cosmetics / foods).
- Help minimise the time to market and/or increase profitability of the product development, by reviewing opportunities in early development to obtain accelerated approvals and/or extend patent

life (e.g. orphan indications; fast-track approvals; expedited approvals etc.)

- Supplement your market research and market size data by focussing on what the “licensed” indication and/or product claims may be, based on a given clinical development plan.
- Assess potential regulatory risks to the product development, allowing for contingency planning;
- Undertake gap analysis of your data sets, based on published regulatory guidance, allowing you and your potential partners to easily identify where and when additional studies may be needed;
- Assess the clinical development plan, with a view to determining when key data will become available, thereby understanding potential break points for investors.

Contact Us

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PROTHERAX LTD

ProTherax Ltd is a regulatory consultancy business with expertise in assessing early stage pharmaceutical development plans. We have already undertaken several such reports for University Technology Transfer Offices, university academics, spin-out and virtual companies, with the aim of supporting grant applications, out-licensing opportunities and of course guiding internal development decisions. We can also use this expertise by way of due diligence, to support investment decisions for Venture Capital and investment organisations.

THE COSTS ARE LESS THAN YOU MAY THINK

At ProTherax Ltd, we are very aware of the cost constraints under which many universities and small companies operate. However, you will be pleased to hear that the costs of delivering a regulatory strategy for your product development are likely to be less than you may think, with typical reports costing less than £5,000. Contact us today for a quotation.