WAINWRIGHT associates
Strategic Development

Strategic regulatory planning

Designing suitable studies from the outset will help prevent unnecessary delays and costs hindering your route to market.

The need for planning

Applications for EU Marketing Authorisations from non-European companies frequently fail because there is a difference in the way a particular medical condition is managed or because the standard therapy in one country is not licensed in another.

Introduction of a novel medicinal product or medical device into any new market must take into account national legislation, relevant local guidelines and current medical practice in the territories of interest. This information can sometimes be difficult to obtain without access to specialists based within the appropriate area.

Sometimes a significant amount of research is needed to determine which comparator or endpoints in a clinical trial will satisfy the requirements of the local regulatory authority. This is particularly true for innovative therapies or for orphan indications.

We will advise on these issues with a view to guiding clients towards a successful regulatory strategy.

Regulatory strategy

Successful regulatory approvals and timely product launches start with sound strategic planning during the early development phases. The design of suitable studies from the outset of product development is essential if unnecessary delays and costs are to be avoided in reaching the market.

We can assist drug, device and healthcare companies by:

- Advising on appropriate regulatory strategy
- Recommending the best route to the market
- Drawing up formal project plans with resource allocation and cash flow analysis
- Design of suitable studies and protocol preparation
- Monitoring to keep the project on track

This service is particularly suited to US, Japanese and other overseas companies wishing to introduce their products to the European marketplace.

Our team of discipline experts can advise on applications to the European Medicines Agency (EMA) for Scientific Advice; presentation of dossiers for Orphan Medicinal Product Designation and, of course, preparation of all the necessary submissions for clinical trial and marketing approvals as well as writing the CTD Overviews and Summaries.

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National legislation must be taken into account when introducing a novel medicinal product or medical device into a new market.

We will also advise on the applicability and benefits of various EU incentives such as Conditional Marketing Authorisations, MAs under exceptional circumstances, accelerated review and fee reductions/deferrals for small and medium sized enterprises.

Formal project planning

Our team is fully versed in the principles of project planning and is skilled in the art of preparing elegant plans using Microsoft Project software.

After a client's briefing, our experts assess the existing data package to determine whether the studies conducted to date, or planned, will meet the scientific and regulatory requirements of the target territories.

Next, the actions necessary to complete the development programme are defined and arranged in order of precedence. The interrelationships between tasks are linked, having regard to the client's preference for an aggressive or low-risk approach, to create a PERT network which defines the critical path and time to launch.

For each task, resource is allocated either from in-house personnel or sub-contractors as appropriate for an efficient development programme.

When the client is satisfied with the logic and timings of the draft plan, the programme is costed and this allows cash flow projections to be generated for the whole project or any part of it. In this way the client can predict when capital funding is required or adjust the plan to meet current commitments.

The full benefit of a project plan is not realised unless product development actually follows the planned sequence of events, to the predicted timings and budgets. We are able to prepare regular management reports during the execution of the work to ensure the plan is adhered to or that, given an unexpected result in one of the studies, the plan can be reworked with minimal loss of time and resource, leading to the most propitious launch date.

Contact us:

For a more detailed discussion on how we can help you, contact us on **+44 (0)1628 530554** or email us on **info@wainwrightassociates.co.uk**

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