SERVICE SHEET

WAINWRIGHT associates
Regulatory Affairs

Clinical consultancy

Our experienced consultants can advise on clinical and regulatory strategy for new product development, design clinical trial protocols and prepare applications for CTAs.

Clinical consultancy

A wealth of expertise in clinical research exists within our team. Specialists in the design and conduct of clinical development plans, we can offer consultancy skills advising on clinical and regulatory strategy for new product development, design of clinical trial protocols and preparation of applications for Clinical Trial Authorisations (CTAs).

GCP audits of investigational sites and CROs can be undertaken by our staff. We also offer pharmacovigilance services, both pre- and post-marketing, including reporting to the appropriate European Competent Authorities.

Clinical consultancy, including development of clinical reports, is also available in the context of applications for Orphan Medicinal Product Designation, scientific advice, Paediatric Investigation Plans and Marketing Authorisations, including appeals and oral explanations.

Clinical Trial Authorisations

Under the Clinical Trial Directive 2001/20, authorisation by a Competent Authority is required to conduct trials on human volunteers or patients in any EU member state.

The procedure involves applying to the European Medicines Agency (EMA) for a EudraCT number and then submitting an application for a CTA to the Competent Authority of each member state where the trial will be conducted.

We can advise on the requirements for and prepare the necessary documents that constitute the CTA as well as handle communications between the authorities and sponsor or legal representative.

The specific data requirements for the CTA differ between member states and we can assemble a core document and customise it for specific authorities, including translating any documents that may be needed locally.

Post-approval, we can maintain your CTAs by submitting variations for any changes to the protocol and notify the Competent Authority of study completion.

CTD clinical modules

As part of the preparation for Marketing Authorisation applications our team can advise on or write the Clinical Overview (Module 2.5) and Clinical Summary (Module 2.7). We can either draft content for internal review and sign-off by a company signatory or if required we can provide expert review and medical sign-off from within our team.

WAINWRIGHT associates

Having regulatory agency 'buy-in' will help facilitate preparing a feasible plan and aid the subsequent approval of your MAA.

Clinical report writing

Once the trial is completed, if required, we will be happy to write the clinical study report. We can do this by liaison with your clinical and statistical departments or responsible CRO in provision of trial information and data. Once the report is in a late draft, we will work with your clinical department, auditors and investigators on reviewing and updating the document.

Scientific advice

Obtaining the 'buy-in' from regulatory agencies to company development plans can greatly facilitate the preparation of a feasible plan and can facilitate subsequent approval of Marketing Authorisation Applications. Our team has a wealth of experience in leading our clients through the Competent Authority scientific advice process both at the European and national levels. We can co-ordinate the process of applying for meetings, prepare questions and company justifications, prepare company briefing documents and presentations and facilitate rehearsal meetings, as well as attending meetings with or on behalf of client companies to facilitate the process and capture minutes.

Paediatric Investigation Plans

All applications for new medicinal products in the EU are subject to the provisions of Regulation 1901/2006 (the 'paediatric regulation'). Our team is experienced in the preparation of Paediatric Investigation Plans (PIPs), and applications for product-specific waivers or deferrals. We can manage the process of submitting the PIP to Paediatric Committee (PDCO) members.

GCP audits

Sponsors need to satisfy themselves that a CRO is capable of conducting a clinical trial to the appropriate standards and that it has the appropriate GCP quality systems in place.

Once the study has started, the sponsor needs to know that the investigational site is GCP compliant, is following the protocol and is being adequately monitored by the CRO.

Our auditors are experienced in both clinical research and regulatory affairs and, at an early stage, can advise on any matters requiring attention and discuss solutions.

Audits commence with a review of the study documentation, such as SOPs, protocol and training manuals. After the required time on site, including interviews with the relevant personnel, a detailed report of our findings will be issued.

We can also conduct data management audits by on-site interviews and review of study documentation.

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**

www.wainwrightassociates.co.uk