niche science& technology

Regulatory Writing
Clinical Project Management
Strategic Communications

FLEXIBLE. STRATEGIC. INFORMED. COMPLIANT.

For over 15 years, Niche Science and Technology has been providing outstanding medical writing and project management services to some of the biggest names in the business. Our clients regularly turn to us to overcome gaps in their resources and knowledge and they know they can rely on us to get the job done.

The highly experienced Niche team consists of specialists in regulatory writing, scientific communications and clinical project management. Over the years we have built up relationships with many different clients, providing pivotal writing and project management support for hundreds of clinical studies, regulatory documents and manuscripts. Our clients request our services time and time again, and recommend us to others in turn. Most importantly, every member of the Niche team is driven by an enthusiasm for the brief, a passion for quality, and the satisfaction of providing the personal touch to everything we deliver.

HOW CAN WE HELP?

- ✓ Regulatory documents and submissions
- ✓ Clinical study protocols and reports
- ✓ Clinical project management
- ✓ Standard operating procedures
- ✓ Primary manuscripts
- ✓ Data management and statistical analysis
- ✓ Training packages
- ✓ Conference materials, posters, abstracts and slide sets
- ✓ Reviews, monographs and brochures

REGULATORY DOCUMENTS AND SUBMISSIONS

On-time delivery and submission of your regulatory documents helps achieve your development targets and shortens time to market. We provide medical writing, editing and project co-ordination services for CTAs (Clinical Trial Applications), IBs (Investigator Brochures), IMPDs (Investigational Medicinal Product Dossiers) and CTD (Common Technical Document) submissions and all other regulatory documentation. Our knowledge of the changing regulatory environment and extensive experience of co-ordinating submissions means we can offer a total service tailored to your requirements.

CLINICAL STUDY PROTOCOLS AND REPORTS

These are the foundation documents of your development programme. Integrating with your team, we can produce high quality clinical study protocols and reports using either your preferred templates or our own ICH compliant templates. Our experience extends across a wide range of therapeutic areas including oncology, respiratory, diabetes and infectious diseases. We have extensive experience of writing study reports; over the last decade we have written over 500 CSRs (Clinical Study Reports) for one Blue Chip Pharmaceutical company alone.

CLINICAL PROJECT MANAGEMENT

Integral to the successful delivery of any clinical study, we can support you in the management of specific aspects of a study through to managing the entire development programme. Our team have experience across all phases of development and we have run studies using biologicals as well as new chemical entities. Services that can be contracted individually or as a package include study design, site selection, document development, ethics submissions, organisation of Investigator meetings, clinical governance of ongoing studies, management of the TMF (Trial Master File), vendor management, budget control, risk management and contingency planning.

STANDARD OPERATING PROCEDURES (SOPs)

Standard operating procedures are required both by GCP (Good Clinical Practice) and local regulations and will form a key part of any audit review. We can help you develop either a single SOP or an entire set of documents according to your needs while ensuring that they also meet prescribed requirements. We have developed entire quality management systems for several companies. In addition, we can develop document templates drawing on our knowledge of ICH and GCP recommendations, local requirements and our extensive experience in writing these documents.

PRIMARY MANUSCRIPTS

Now an essential tool in demonstrating the transparency of the pharmaceutical industry, primary manuscripts also provide a major contribution to the successful launch of a product. Published materials provide the reference source for monographs, advertising, sales force documents and other promotional materials before and after launch.
We can write and submit manuscripts for publication in peer-reviewed journals. Our experience also allows us to optimise the communication of key messages through publication planning, targeting your audience through journal selection.

DATA MANAGEMENT AND STATISTICAL ANALYSIS

Data management and statistical analysis planning are essential to ensure that the study produces reliable, robust results which are powered to meet the study endpoints. Our services support the acquisition, analysis and presentation of data. Either directly or in conjunction with our strategic partners we can perform sample size calculations; write or review statistical analysis plans and the statistical section of the protocol; generate randomisation schedules; and design and validate source documents, CRFs (paper or electronic) and databases.
We can also review and enter data; undertake statistical programming; and generate compliant and report-ready tables, listings and figures.

TRAINING PACKAGES

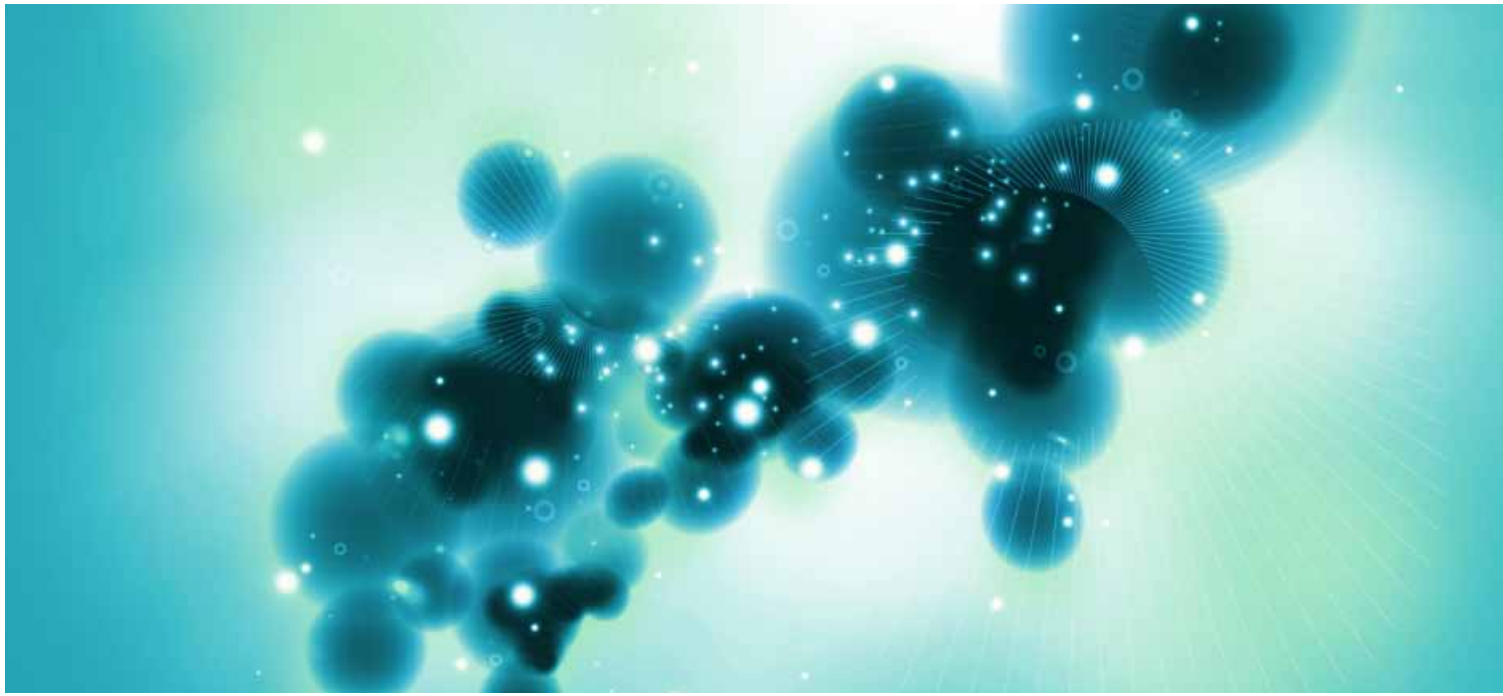
Training packages form a core resource for any company. Robust new media materials communicate messages and information in an engaging way, enhancing the learning experience. We can create innovative training programmes for the effective education of your target audience: customers, representatives, scientists or patients. Our distance learning materials are varied and easy to use, providing a cost-effective and convenient way to train and brief your team members.

CONFERENCE MATERIALS, POSTERS, ABSTRACTS AND SLIDE SETS

We can help you raise awareness, maintain market interest, and communicate important data to key audiences, long before publication in peer-reviewed journals. Carefully written delegate materials ensure that attendees retain your conference materials and take your key findings away from symposia. We can provide well-written materials for a variety of media and have covered many congresses and symposia.

REVIEWS, MONOGRAPHS AND BROCHURES

Stimulating product interest and debate before launch or during a product's lifetime is key. These documents often have shorter lead times to publication and provide an opportunity to reach defined target groups. Our scientists combine their experience with client requirements to select the appropriate data for reviews, monographs and brochures. Through these publications we are able to convey your key messages to your chosen audiences.



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