



***Navigating a Sponsor's NDA through a maze of regulatory requirements, requires strategic partners who can provide regulatory collaboration to complete the journey in record time.***

***Collaboration between development partners who can provide necessary expertise to execute a successful New Drug Approval (NDA) calls for a measure of trust and reliance when driving a project to completion. Integrating the necessary functions across both the CRO and the Sponsor in a seamless manner is a study in managing excellence.***

#### **A track record of strategic partnering**

When Medpace was asked by a Sponsor to submit a new NDA for a pain relief treatment, Medpace realized that both parties could benefit based on the long-term strategic relationship that had already been forged. This relationship was historically built on a platform of earned trust in the area of regulatory expertise. The level of collaboration between the two entities allowed Medpace to save the Sponsor time and money through the NDA phase of the trial and to create long-term benefits to be enjoyed by both parties for future projects.

**CHALLENGE:**

Develop a submissions document supporting a 505(b)(2) NDA for an alternative means to administer a previously approved drug for a pain medication.

Medpace was asked to oversee the compilation of the NDA 505 (b) (2) application, an FDA submission enabling a company to obtain FDA approval of a drug relying, in part, on the agency's findings for a previously approved drug. This method, created in 1984 as part of the Hatch-Waxman Amendment, encourages Sponsors to develop innovative medicines using currently available products without conducting a full complement of safety and efficacy trials and without a "right of reference" from the original applicant.

Medpace was asked to manage the process with the Sponsor using previously submitted NDA data. The issue at hand was how best to prepare the NDA document in such a way as to improve the document review process, expediting approval by the FDA and the required Advisory Committee Meeting.

**SOLUTION:**

A unique method of compiling the submission document as a literature-based document made the FDA review process go more smoothly.

The Sponsor allowed Medpace a great deal of freedom to suggest and ultimately drive the submissions process. Medpace's knowledge with regard to NDA submissions allowed them to quickly engage a project team well known by the Sponsor. The regulatory submissions process, well integrated with medical writing, data management, and biostatistics, allowed the Sponsor a greater comfort level knowing they were using a known entity, familiar with how the Sponsor worked and having broad expertise in regulatory matters.

No stranger to the NDA process, Medpace developed concise and accurate reports that contained deeper discussion for FDA consideration, and placed the clinical results within the context of the entire trial. Medpace produced and included secondary research as a white paper for FDA review. The document was crafted with an eye for the analysis of the previously submitted data, and designed in such way as to bring a greater clarity to the FDA Advisory Committee.

Three distinct sections were created:

1. A manuscript-style white paper written as an overview of all data found in the literature supporting the compound
2. A pivotal study inclusive of secondary review articles and tertiary supportive literature presented
3. A highly detailed Statistical Consideration Report to be presented as a separate document

**RESULT:**

Medpace produced the necessary submissions for the NDA in a manner highly impressive to the Sponsor and well received by the FDA.

Use of a highly collaborative process between the CRO and the Sponsor created the best possible solutions and regulatory documentation. As a by-product of this process, both Sponsor and Medpace have developed a long-term strategic relationship of trust and excellent rapport. This relationship bodes well for future working projects.

Medpace gained not only a strategic Sponsor relationship, but a depth of experience in NDA submission work, creating new best practices that can be utilized in future projects.

## **A Reputation for Regulatory Expertise**

The Medpace reputation for putting together the best teams in regulatory knowledge, medical writing, data management, and biostatistics were a reason that this project was awarded. The Medpace reputation for having former FDA regulatory as company leaders gives the Sponsor an advantage over others to understand the best methods in approaching an NDA submission. In fact, Medpace has previously submitted 22 NDAs, (14 eCTD format), a number unmatched by many other CROs.

## **Services provided by the Medpace Regulatory Affairs department**

- Strategic guidance on the clinical development plan of a new product, including new chemical entity and 505(b)(2) applications
- Development and submission of pre-IND and pre-NDA briefing packages
  - Formulation of pre-IND and pre-NDA questions to the FDA
  - Authoring and compilation of briefing package materials
  - Correspondence with the FDA on pre- and post-meeting logistics, action items, etc.
  - Participation in FDA meetings
- Preparation of the Initial IND
  - Authoring of clinical components (e.g., Introductory Statement, Investigator's Brochure, and Protocol)
  - Compilation of additional submission components
  - Verification of consistency in presentation across all components of the IND
- Preparation and coordination of responses to FDA Requests for Information
- IND Amendments
  - Project management and strategic guidance for the life of the IND
  - Compilation and submission of Protocols, CMC Updates, Nonclinical Study Reports, and Clinical Study Reports
- Preparation and submission of 7-Day and 15-Day Safety Reports
- Preparation and submission of Annual Reports
- Preparation and submission of NDA and sNDA as eCTD

## **About Medpace**

Medpace is a leading global full-service Clinical Research Organization providing Phase I-IV core development services for drug, biologic, and device programs. With medical and regulatory expertise in multiple therapeutic specialties, Medpace has assembled the industry's most experienced and therapeutically focused teams to execute at every level of the company's operations, providing complete and seamless drug development services. In June 2009, Medpace was rated as the best CRO by US Investigative Sites in the 2009 CenterWatch Site Survey.

Medpace creates strategic partnerships with pharmaceutical and biotechnology companies to provide the most efficient and cost-effective path to drug development, from program planning and execution to product approval.

With more than 1,000 employees and clinical trial experience in over 40 countries, Medpace has the global reach and capability to conduct studies and navigate regulatory requirements worldwide.

In addition to Phase II-IV development services, Medpace provides Phase I / IIA clinical services from Medpace Clinical Pharmacology; central laboratory and therapeutically specialized testing from Medpace Reference Laboratories; complete bioanalytical services in all stages of drug development from Medpace Bioanalytical Laboratories; and central image management and reading from Imagepace.

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