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## LANDING PAGE

Delivering the highest quality clinical research services.

**SYNTACTX**

|sin-'tak-tiks| = “bring together with structure”

Syntactx designs and executes innovative, technology-driven, and customized full- service clinical trial experiences that integrate subject matter expertise with unparalleled access to our internal thought leaders and a global network of key industry influencers.

## ABOUT US

Syntactx began as a family business and has quickly grown into a leading Contract Research Organization that has maintained the integrity, ethics, and values upon which it was founded. A core mission of Syntactx and its passionate and highly qualified team is to contribute positive improvement to the quality of life of others.

We deliver the highest quality clinical research services based on a well-defined strategy, collaboration, and transparency, thereby reducing time to execution and minimizing the overall risk of a project. Clients benefit from our agility, decades of experience, on-staff physicians, and excellent relationships.

Ranked #241 on the 2015 Inc. 500 list of the fastest-growing private companies in America, Syntactx is headquartered in New York City, has offices in Belgium, and partners across the United States and in Europe.

## WHAT WE DO

Syntactx provides a variety of life-changing services tailored to meet the specific needs of our clients. We take clinical trials from product inception through market introduction and post-market studies.

In addition to our in-house team, Syntactx’s strategic partners include clinicians, academic and non-academic institutions, and regulatory agencies with whom we work on a regular basis to develop, execute, and deliver the highest quality clinical trials.

## SERVICES

***Overview***

Syntactx provides a variety of services tailored to meet the specific needs of our clients. We take clinical trials from product inception through market introduction and post-market studies.

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## PROTOCOL DEVELOPMENT

## REGULATORY AFFAIRS

Working with the FDA and other agencies around the world, Syntactx helps clients navigate through the stringent requirements to gain regulatory approval.

In addition to regulatory submissions, we identify and report any issues in an accurate and timely manner to avoid potential setbacks. Our team knows what elements are needed for submission and can anticipate potential questions or obstacles. Ultimately, we determine the fastest and most efficient route to regulatory approval, thereby enabling our clients to introduce products into the marketplace as quickly as possible.

Services include:

- Preparation for Institutional Review Board (IRB) submission, central IRB management, consultation on local and central IRB related matters, and management of clinical trial websites such as ClinicalTrials.gov
- Preparation of regulatory authority submissions including IND/IDE clinical trial submissions, clinical trial applications, and report management services such as primary endpoint and periodic reports
- Strategic planning, product life-cycle management, and investigator compensation

## CLINICAL PROJECT MANAGEMENT

Paramount to optimal Clinical Project Management is having a seasoned team that understands how to handle all the elements involved in meeting the varied needs of study Sponsors, Investigators, site research staff, and study subjects. Our Clinical Project Management Team oversees project execution throughout the entire study lifecycle to ensure that critical milestones are met on time. In addition, throughout the conduct of a study, our team continuously implements process improvement and an effective communication strategy.

Clinical Project Management services include:

- Site identification and qualification
- Investigator identification, qualification, and recruitment
- Site start-up
- Ensuring site regulatory compliance
- Facilitation of clinical trial enrollment
- On-site and in-house monitoring, coordination of monitors, and data collection
- Monitoring of CRF completion, data collection, and query resolution
- Adverse-event reporting and medical coding
- Study payment distribution and tracking

- Remote monitoring in U.S. and Europe
- Site close-out

## SAFETY

Syntactx works closely with key opinion leaders globally to maintain the integrity and overall conduct of all clinical trials. We ensure study credibility, trial participant safety, and protect Sponsor interests. Our in-house Safety team has extensive knowledge of how to conduct studies, evaluate Safety endpoints, and determine adverse event issues and severity.

When necessary, we assemble and manage the appropriate Clinical Events Committee and Data Safety Monitoring Board.

### *Clinical Events Committee (CEC) & Adverse Event Reporting*

Syntactx takes full responsibility for the creation and management of the CEC, which is central to establish standardized, reliable reporting of trial data.

Our CECs are comprised of top-level professionals who work in conjunction with our team to ensure accurate and timely reporting and classification of adverse events.

Using MedDRA certified coders and a Part 11 compliant database, Syntactx performs appropriate coding of adverse events, collects, and collates source documentation, translates source documents as needed, and reports any adverse events in a timely manner to the study Sponsor and other appropriate parties. A clinical endpoint adjudication system provides an electronic method to manage Safety events.

### *Data Safety Monitoring Board (DSMB)*

The safety of study participants is the highest priority of any clinical trial. As with the CEC, Syntactx assists in organizing and managing a DSMB to protect participant safety and ensure the credibility of the study results.

A DSMB is comprised of individuals with relevant clinical experience, previous DSMB/CEC experience, and no conflicts of interest. Collectively, we safeguard the interests of the Sponsor and ensure the safety of study participants. Our team works with the DSMB to review of Safety data and make thoughtful, data-driven recommendations to continue, modify, or terminate the study.

### *Additional Safety management services include:*

- MedDRA Coding**:** Coding adverse events using the latest version of the MedDRA dictionary.
- CM Coding (medication)**:** Coding drugs using WHO ATC Drug Dictionary
- Independent Clinical Event Review: Physician assessment of Safety endpoints, and Medical Monitoring – physician oversight of study conduct

## DATA MANAGEMENT

Our data management services support the clinical research process and provide data in customized, client-specific structures and formats that integrate data from Core Laboratories, event committees, and patient reports.

As the scientific and regulatory requirements increase the complexities of today's clinical trials, Syntactx works to procure and manage the appropriate data systems to provide reliable, accurate, and timely results.

Data Management services include:

- Paper and electronic database development
- Electronic Data Capture (EDC) support:
    - Custom database design
    - Database programming
    - 21CFRpart11compliantvalidation
- Monitoring of case report form completion, data collection, and query resolution
- Interim data analysis and study status reporting
- Medical writing of manuscripts for peer-reviewed journals
- Abstracts and presentations for scientific meetings
- Final data analysis and reporting

## ELECTRONIC DATA CAPTURE

For the most sophisticated level of efficiency and accuracy in collecting, tracking, and storing clinical trial data, Syntactx has a proprietary, customizable, and fully secure cloud-based system to house data for both small- and large-scale trials.

Features include:

- Multiple tiers of redundancy to protect confidential data.
- 21 CFR Part 11 Compliant digital touch screen signature capabilities for straightforward use among subject population to streamline a proprietary electronic consenting process.
- Blinded data to maintain HIPAA compliance.
- Highly secure cloud servers and web portal entry.

We also offer personalized electronic case report forms and customized data reporting. Workflow is designed to improve Protocol adherence while maintaining a user-friendly experience. In addition, with encrypted API or sFTP, data can easily be transferred to clients on an as-needed basis to track trial progress.

## CORE LABORATORY

The Syntactx Core Laboratory works with advanced technology and an experienced and knowledgeable staff to produce precise and top tier results for our clients. A study site-friendly image transfer process and standardized, reproducible results are critical aspects of our Core Laboratory operation. We constantly monitor the performance of our image readers to generate the most accurate and consistent results possible.

Our Core Laboratory analysis encompasses a variety of modalities including arteriography/venography, pulmonary angiography/venography, echocardiography and cardiac CT, CT angiography of the aorta, and head CT/MR. These services are currently provided for a spectrum of needs ranging from investigational studies to Pre- and Post-Market Approval Studies. Additionally, Syntactx utilizes web-based, secure image transfer technologies and 3D rendering software to ensure that our laboratory remains on the cutting edge.

Our network of skilled image readers, in-house physicians, and a broad reach to key opinion leaders make the Syntactx Core Laboratory a pioneer in the image review arena.

## MEDICAL WRITING

Published medical writing is a highly effective marketing tool and provides the opportunity to share ideas with professionals around the world. Syntactx offers full-service, high-quality medical writing services that include content concept, copywriting, copyediting, biostatistics and graphics, and publication submissions.

At Syntactx, our team of expert writers covers regulatory submissions, study Protocols, clinical investigational Protocols, investigator brochures, clinical study reports, abstracts and presentations for scientific meetings, and manuscripts for leading academic peer-reviewed journals.

### *Strategy*

Using our extensive experience and insight, we help clients develop a strategy that targets the most suitable publications and follows the standards of the International Society for Medical Publication Professionals and Good Publication Practice guidelines for journal authorship. We collaborate with well-regarded physicians that are experts in subject matter for either lead or co-authorship, and tailor manuscript submissions to meet the requirements of leading journals.