Rx RESEARCH Services CRO™
Functional Matrix Management Solutions

RxRS CRO Capabilities

We are a quality-driven contract research organization (CRO) serving the life science industries and specializing in Safety and Data Coordination services. Located entirely in the UNITED STATES, our teams produce quality results on time at costs comparable to offshore outsourcing to China or India.

What We Do – Pharmacovigilance / Safety / Medical Writing Services

RxRS CRO provides:

- Single case processing (ICSRs and related services)
- Aggregate report writing
- Medical and technical writing for clinical study reports and annual reports
- Safety coordination
- Data monitoring
- IND Maintenance

From day one, your project is handled by a dedicated team of professionals here in the UNITED STATES skilled at processing and analyzing hundreds of highly sophisticated clinical trial results from a Drug / Device Safety and Regulatory Affairs perspective. Rest assured, your sensitive and proprietary health data remains in the United States and never leaves our hands for a foreign soil.

Our services include the following therapeutic areas and form the basis of the project capabilities we offer:

- Oncology
- Infectious Disease
- Dermatology
- Cardiovascular
- Ophthalmology
- Neurology
- Complex Class III Medical Devices
- Pain

Individual Case Safety Report Processing (ICSRs) Services:

RxRS CRO processes individual case safety reports (ICSRs) originating from various sources:

- Post-Marketing Non-Solicited/Spontaneous Reports
- Clinical Reports
- Original Medical Records (electronic, hand written)
- Special Reports (Medico-legal, Literature & E2B)

Following established Quality Management Systems practices, our team of MDs, PhDs and MS-degreed regulatory compliance professionals review data from source documents sent by sites and process the data into a Drug Safety/Pharmacovigilance database. After analyzing the source documentation, our CRO team performs an initial triage and medical review/assessment of the clinical data. As part of this triage, personally identifiable health data is redacted for privacy protection and data queries are initiated with the sites so as to clarify any

inconsistent data results or entries. Once the data has been cleansed and the records complete, the CRO team member prepares the Adverse Event narrative for the case reports to be submitted to the regulatory authorities/ethics committees. The RxRS CRO has expertise processing Adverse Events and analyzing data across multiple therapeutic disciplines.

An overview of Single Case Processing:

- Receipt of adverse and serious events
- Electronic data capture, data mining/extrapolation
- Source data examination and cleansing
- Source document collection, redaction, and preparation for submission to the designated party
- Verification of angiographic images with core lab
- Query resolution, direct contact/follow-up with Sites and Sponsor for additional information
- Submission of device-related events to the Clinical Events Committee
- Adverse event subject narrative writing
- Medical and technical writing for clinical study reports and annual reports

Drug Safety Report Services:

The RxRS CRO team has expertise in drafting drug safety reports designed to present medical assessments and narrate adverse event data interpretation. Following a review of all data in its entirety, and after resolving any data queries or redacting personally identifiable health information, the CRO team member drafts a summary of the safety implications so as to allow the Sponsor company insight into the risk/benefit profile of the product and an opportunity to implement risk management/risk mitigation plans quickly if appropriate.

Medical Writing Services

RxRS CRO's Medical Writing Services entails the generation of well-structured individual reports supporting extensive medical writing programs, including:

- SAE Narratives for Clinical Study Reports
- Clinical Study Reports (ICH-E3)
- Monthly IND Maintenance
- IND Annual Reports (21 CFR 312.33)
- Clinical Summaries/Product Feasibility Reports for Medical Devices
- Patient Diary Cards (PDC), Informed Consent Form (ICF), Subject Information Sheet (SIS), Case Report Forms (CRFs)