



# RxTrials

## Research Site Experts

RxTrials enjoys a highly regarded reputation providing critical business services that elevate research sites to a new level of competency in the conduct of clinical research studies and the management of their clinical research business. We leverage our experience and expertise to help sites achieve research and business successes.

We recognize that sites have different business needs. Some find it beneficial to engage in a comprehensive relationship with RxTrials, while others seek our consulting services for specific needs. Regardless of the nature of the relationship, the services available include:

- Investigative Site Evaluation
- Site Marketing Evaluation
- Business Development
- Financial Management
- Clinical Research Education
- Compliance Program

## Partnering with RxTrials Ensuring Business Success for Investigative Sites

### Who is RxTrials?

RxTrials, Inc. is a provider of Investigative Site Support Services to an elite network of private physician practices, clinics, and hospitals, referred to as the RxTrials Network. RxTrials manages and coordinates Phase II-IV in-patient and out-patient industry sponsored clinical research studies. Established in 1994, RxTrials is the first and only organization in the Mid-Atlantic to offer such a distinct level of service to the medical research community. Due to a growing demand from industry, RxTrials is engaged in a strategic growth initiative to bring additional sites into the RxTrials Network.

Through our affiliated company, RxTrials Institute, an educational organization, we have set industry standards with courses like *The Hidden Costs of Conducting Clinical Research at the Site* and the one-of-a-kind Site Solutions Summit, which brings site thought leaders and industry decision makers together to tackle the industry's most problematic business challenges and to create strategic site partnerships. We are recognized and sought worldwide for our training because we teach what we know and do.

When you are a part of the RxTrials Network you can be confident that you are partnered with the industry leader in the field of clinical research and the business of running your clinical research site. Attached as **Appendix A** are short biographies of the core management team at RxTrials. Additionally, you can see what some of our Sponsors have to say about working with the RxTrials Network in **Appendix B**.

## Executive Overview

The clinical research industry is dynamic and fast-growing, presenting exciting business opportunities for physicians and medical practices. The current environment is both challenging and rewarding:

- Across the industry, there is pressure to lower costs and increase efficiencies.
- There is a huge turnover in investigative sites, leaving a critical shortage of quality sites.
- Thousands of compounds move through the pipeline, representing millions of dollars of investment, but only a select few receive FDA approval.
- Competition for good studies is tough and Sponsors want only the best sites. Their chief criterion is the quality of data that individual sites deliver.
- Top-performing sites are more likely to see Sponsors return with repeat business.

As Sponsors look for ways to streamline the clinical research process and identify qualified and committed clinical research Investigators and sites, RxTrials offers them this unique service. Through our portfolio of essential Investigative Site Services, RxTrials manages the process at the most fundamental level — the site — where the clinical research actually occurs. This portfolio of services provides core competencies in areas critical for the efficient and effective conduct of research studies and the management of profitable clinical research centers.

RxTrials partners with sites to ensure a successful research enterprise. Without question, our experience and expertise give sites a distinct business edge.

## How the Partnership Works

Because study Sponsors have come to depend on RxTrials for a high caliber of professionalism and quality, we are very selective about the sites that become a part of the RxTrials Network. We focus on long-term partnerships with sites that are as committed to quality and success as we are.

We keenly identify the best clinical research sites through both abstract and fundamental assessments. We look not only at such aspects as equipment and capacity, but also at commitment to quality and professional integrity. We are committed to supporting sites to realize the value of running a successful clinical research site. We believe that patient safety and data integrity should never be compromised due to a lack of resources or knowledge. We make sure that all of our sites are positioned to meet the increasing challenges of the industry.

As new sites are added to the RxTrials Network, they maintain their independence in every way. RxTrials supports, guides, and educates them on the regulations and business of clinical research. All decisions that sites make; such as which studies to take, the ability to talk with Sponsors, etc., are made independent of RxTrials' recommendations. RxTrials will negotiate the budget and contract on behalf of the research site, but the agreement and the cash flow is directly between the Sponsor and the site.

Not only does RxTrials have a reputation for excellence and quality in conducting and managing clinical research sites, we consistently and successfully negotiate further compensation for the site than the original offer, plus additional non-refundable compensation and favorable language terms to help address the cash crunch that most clinical research sites experience. A robust recruitment budget is also sought to help ensure compensation for recruitment activities. We are able to accomplish this through our deep understanding of the expectations of the industry and study protocols.

RxTrials is very proud of the longevity that we have shared with many of our sites and colleagues over the years. **Appendix C** provides you with a list of references that we encourage you to contact. You will learn how RxTrials can help you achieve your goals, as we have for them.



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## Investigative Site Evaluation

**Why You Need This Service:** Perhaps you are new to the clinical research industry and you want to fast-track your path to success, or you are an experienced site seeking guidance to improve your site's results.

**How RxTrials Will Help:** Our senior management team will visit your site for a comprehensive evaluation of your research capabilities and business practices. You will receive detailed recommendations in a follow-up report to help you position and enhance your success.

**RxTrials Will Provide:**

- On-site visit and follow-up by a member of our management team;
- A review of various documents provided by you;
- Comprehensive assessment of the following:
  - Resources (space & equipment)
  - Research personnel related activities (Job descriptions of staff; Personnel ads for placement, Career ladder process, Interviewing techniques specific to our industry, etc.)
  - Research staff productivity
  - Recruitment capabilities
  - Business Development
  - Standard Operating Procedure evaluation
  - Compliance and education process
- A report identifying strengths and weaknesses, areas for improvement, and recommendations for greater business success.

After this evaluation and implementation of the recommendations, your site will be best positioned for success in demonstrating the first step, your commitment to clinical research.



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## Site Marketing Evaluation

**Why You Need This Service:** Marketing and business development are the lifeblood of research sites. Yet many sites are not able to give these functions the attention they need. Often they lack the time or resources, or simply do not have the experience.

**How RxTrials Will Help:** Through an on-site visit and evaluation of key information, we will assess your site's strengths and opportunities. You will receive a marketing plan to distinguish your site from others.

**RxTrials Will Provide:**

- On-site visit by a member of our management team;
- A comprehensive evaluation of your current marketing practices compared to industry practices;
- Detailed recommendations for strengthening the opportunities to gain greater visibility of your site;
- A follow-up report to assist you in the creation of a plan.

Our insightful recommendations will be prioritized so that you can maximize the return on your investment related to marketing results.



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### Business Development

**Why You Need This Service:** You are a quality site with solid experience, desiring growth, or are a novice site seeking to enter the industry.

**How RxTrials Will Help:** Our position within the clinical research industry is that of expert, innovator, and leader. RxTrials has a reputation of associating with sites of the highest quality, because of this we are “A Partner of Choice” for many CROs and Sponsors. We are now offering unique business development opportunities for select sites that meet our criteria of quality and commitment to clinical research. We work with sites at all levels, from the most experienced to novice sites.

We do not function as a study broker, but rather as a virtual business development partner. As part of the RxTrials Network, all sites operate under their own name and brand, but under the umbrella of “An RxTrials Network site.”

We will provide business development opportunities for your clinical research site and, through our joint feasibility process, help you understand which are the right studies for your site. Within this arrangement, you control 100% which studies you accept or decline.

#### **RxTrials Will Provide:**

- Introduction of your site to industry;
- Promote your site at various industry and association meetings;
- Represent your site for clinical studies in your therapeutic area(s);
- Educate you, using a study feasibility process, to select studies in which you will succeed;
- Weekly meetings during the first 12-18 months and then every other week to review business development activity and explore growth opportunities.

Many sites say that finding clinical research opportunities is the hardest part of being involved in clinical research. We consistently demonstrate that this is not the case — you will have a plethora of clinical research studies to consider — guaranteed!



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### Financial Management

**Why You Need This Service:** The financial health of your research site dictates the ongoing success of your business. Understanding and following financial best practices can make the difference between a thriving site and one that struggles to remain viable.

Historically, research study budgets have fallen short of compensating sites for the true and complete costs to conduct the studies. This happens most often because sites are unaware of how to represent themselves in an optimum negotiating position. Budgets typically are presented with little or no room for negotiation. Often sites will agree to budgets and budget terms even though the terms are less than favorable. If you have found your site in this situation, you are not alone.

**How RxTrials Will Help:** By evaluating your current practices, we will be able to identify any areas of weakness and help you move toward greater financial stability. We will bring our financial expertise to your site to assess your current financial status related to study budget negotiation.

As industry experts, we have set the standard for budget and contract negotiations that assure sites of fair and equitable payment for their professional services. We have a reputation of consistently receiving considerably more compensation than the original offer, plus additional non-refundable compensation and favorable language terms. With our knowledge of the fine points of budgeting and our skill at negotiation, we will provide invaluable support and services for profitable budgeting.

#### RxTrials Will Provide:

- RxTrials will provide negotiation of contracts, study budgets, recruitment budgets, non-refundable up-front compensation and so much more.
- Evaluation of current price structure utilized by your site;
- Financial site benchmarking metrics;
- Evaluation of contract language typically agreed upon;
- Suggest language options to utilize during negotiation;
- Help you understand the importance of monitoring amendments and other “incidental” costs that occur during a study;
- Assist in determining your research site’s overhead;
- Clinical trial management software options;
- A post mortem study financial assessment;
  - RxTrials will not be a party to your contract; you retain full control of what you accept with each budget and contract.

RxTrials is committed to ensuring the conduct of quality clinical research and knows that without fiscal stability the entire process is placed in jeopardy. We will do our part to ensure that you are adequately compensated for your commitment to conduct quality clinical research.

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## Clinical Research Education

**Why You Need This Service:** Training and education of your clinical research team is one of the foundations of your clinical research site. Ensuring the education of your personnel is the most worthwhile investment that you can make in your business. Increasingly study sponsors and regulators want evidence that the people involved with their studies are well-trained, qualified professionals.

**How RxTrials Will Help:** Through our affiliate company, RxTrials Institute, we provide a variety of training opportunities for your entire clinical research team.

**RxTrials Will Provide:**

- An initial assessment of GCP and regulatory knowledge of your research team;
- An assessment of clinical research business knowledge of your research team;
- Needed education for deficiencies, as mutually agreed upon;
- Ongoing education via monthly “Do You Know” (DYK) emails

A strong foundation of knowledge pertaining to human subject protection is the cornerstone of a successful clinical research site.



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## Compliance Program

**Why You Need This Service:** Compliance with regulatory directives and industry standards provides assurance that your site is an exceptional provider of clinical research services. The product you produce – study data – must be of the highest quality and assuring that level of quality must be a priority.

**How RxTrials Will Help:** Our Concurrent Compliance Program will set your site apart from others in demonstrating a commitment to excellence. To help you raise your compliance efforts to the top tier, we will provide guidance and tools to be utilized by your site.

**RxTrials Will Provide:**

- Initial compliance review to determine a base line of activity;
- Necessary tools to implement the Site Compliance Review Process;
- Resources readily available to answer your regulatory questions.

Sites that utilize our Compliance Program will not only meet the regulatory requirements, but if conducted as per the plan, will exceed that of the average clinical research site. Our Program will help to ensure that human subject protection regulations are being followed and that the site's own SOPs are being implemented and adhered to rigorously. This emphasis on compliance ultimately positions the site as a more reputable clinical research site.



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### Appendix A RxTrials' Core Management Team's Short Biographies

#### Christine Pierre, President and CEO, RxTrials, Inc.

Ms. Pierre has been committed to human subject protection and clinical site operations for more than 20 years. She founded and is President of RxTrials Inc., established in 1994. In addition, she is founder and President of RxTrials Institute (RxTi), which provides both public and customized clinical research training courses and is the host of the Site Solutions Summit, bringing together site stakeholders to identify and establish best clinical research site business practices. Ms. Pierre is the past chair of the board of trustees of the Association of Clinical Research Professionals (ACRP).

Ms. Pierre has dedicated nearly two decades as a clinical research professional. She has been the co-principal investigator of a multi-center clinical trial and various single-center trials. She frequently lectures, moderates panels and conducts workshops at national and international conferences and is on the editorial board of *Clinical Trials Advisor*. She co-authored the book *Responsible Research: A Coordinators Guide* and is currently writing the first-of-its-kind book on clinical research site business management. In 2003, she was nominated as one of the top female business professionals in Maryland.

#### Michael Jay, Vice-President, RxTrials, Inc.

Mr. Jay is Vice President at RxTrials, Inc. Since joining RxTrials in 2001, he has successfully negotiated and executed hundreds of clinical research contracts. He is recognized in the industry for his comprehensive understanding of the financial aspects of conducting clinical research. He also advises hospitals, private practices and research sites on financial and contractual operational activities. He is frequently invited to speak at national research conferences. Mr. Jay holds a master degree in music from Johns Hopkins University.

#### Anne-Marie Baughn, Director of Business Development, RxTrials, Inc.

Since joining RxTrials in 1986, Ms. Baughn has been the director of marketing and business development for RxTrials, Inc. She is responsible for marketing the RxTrials Network of sites to the industry. Prior to this position, she was the director of The Congestive Heart Failure Clinic at Georgetown University Medical Center. As director, she was responsible for all clinical trial related activities for the department. Ms. Baughn is a former cardiac critical care nurse and holds a BSN and MSN in administration from Georgetown University.



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### Appendix B Testimonials

“RxTrials runs an extremely organized operation. They are well-staffed and committed to quality work.”

– Marie Salaki, Quintiles

“We thoroughly enjoy working with RxTrials, Inc. Their doctors are very responsive and cooperative. Plus, their staff is extremely experienced and will take care of everything. Thanks to RxTrials, we have no worries.”

– Nicole Cecil, Quintiles

“RxTrials is an on-the-ball company. They are accessible and handle all details with ease. We can count on them to make everything run smoothly.”

– Jason Johnson, Parexel

“We would absolutely recommend RxTrials!”

– Jennifer Shi, Quintiles

“Our experience with RxTrials was good. Both their sites and doctors are very strong and involved. We would recommend them to other pharmaceutical companies.”

– Conn Harrington, Ingenix

“The Site Solutions Summit is destined to become the premier destination for business savvy, quality sites.”

– Donna Percy, Sterling Research Group

“The information that I gained in the first two hours of the Site Solutions Summit will be an incredible boost to our business!”

– Claire Saunders, Palmetto Clinical Trial Services, LLC.

“The Site Solutions Summit was a great idea for getting sites together to discuss topics of interest to us. I cannot begin to tell you how much valuable information I have gained from this Summit.”

– Mary S. Sanda, Palmetto Clinical Trials Services, LLC.



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## Appendix C

### RxTrials Corporate References

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