How Does Site Support Impact Respiratory Trials?

Site Support + Site Engagement = Faster Recruitment, Better Retention, Shortened Timelines

✔ SITE SUPPORT

MERIT's approach to any respiratory study is to tackle each project with an almost obsessive focus on quality and site support. Sponsors benefit with improved subject qualification and retention at screening and throughout the study. Our team collaborates closely with our partners to focus on details that drive study milestone achievement and increase site engagement.

- **PROMPT ACCESS TO EXPERTS**. At MERIT, our registered respiratory therapists (RRTs) can be contacted by one simple phone call or email. Sites get the swift assistance they need without waiting on hold or for a return phone call that never comes.

- **PERSONALIZED SERVICE.** When sites reach out to us, there are no scripted decision trees or chatbots involved. Instead, a real person responds to each question, allowing sites to ask follow-up questions if necessary. We address and resolve each issue individually to provide the best support possible.

- **UNIQUE TEAM APPROACH.** Not only do sites and partners have swift access to RRTs, but they can also draw on the support of our entire project management (PM) team. Our team-based approach translates into faster resolution times and less wait time.

✔ SITE ENGAGEMENT

In the dynamic landscape of the pharmaceutical industry, we all understand that clinical trials are a marathon and not a sprint. Clinical trial sites must be engaged in every stage of a study from start up to conductance to closeout. MERIT's focus on site engagement includes:

- **STANDARD PROCESSES AND COMPREHENSIVE TRAINING**. MERIT's standardized processes for site qualification, training, and certification, developed over 30+ years of respiratory trial experience, reduce site management burden. Thorough training is provided for all users with clear instructional materials including manuals, videos, and webinars.

- **EASY-TO-USE SOFTWARE PLATFORM.** Our innovative software application, CompleClinical®, simplifies and streamlines the respiratory clinical trial process, improving the efficiency and accuracy of data capture, management, and grading of spirometry data. Our software features highly customizable workflows that help facilitate rapid study startup and enrollment. CompleClinical helps sites capture spirometry data more easily, giving them more time to focus on the participant.

Your Clinical Endpoint Expert

meritcro.com

- **CONTINUOUS DATA ACCESS.** With MERIT, all study stakeholders – from site user to sponsor to CRA to data reviewer – have access to the current study data on an ongoing basis. The web-based platform is accessible 24/7 from anywhere in the world. Queries, spirometry grading reports, and signatures can be accessed in the same platform, whenever needed. Study closeout can be accomplished more quickly as data cleaning is performed throughout the study. Data transfers can take place on whatever schedule the sponsor requires.

FASTER RECRUITMENT, BETTER RETENTION, SHORTENED TIMELINES

While it may be common for companies to make assertions about their approach resulting in faster recruitment, improved retention, and shortened timelines, at MERIT, we can substantiate our claims with a concrete example of success with the following respiratory case study.

Case Study: Phase III Bioequivalence Study for Generic Asthma Treatment

A large generic pharmaceutical company conducted a Phase III clinical trial to demonstrate the bioequivalence (BE) of its generic albuterol sulfate metered dose inhaler using methacholine bronchoprovocation challenges in adult subjects with asthma.

- ✔ All sites were released to screen within one week of the Investigator's Meeting

- ✔ In the first three weeks of the study, over 30% of the total subjects were enrolled

- ✔ By week seven, we had reached our enrollment goal of 200 subjects

- ✔ Enrollment was scheduled to take approximately four months; we reached our enrollment goals in less than nine weeks

- ✔ Database lock occurred within 20 days of the Last Subject Completed

- ✔ The project was completed ahead of schedule and under budget

Read the complete case study **HERE.**

CASE STUDY

Bioequivalence with Methacholine Bronchoprovocation Challenges (MBPCs)

MERIT's spirometry and MBPC expertise form the cornerstone for successful Phase III bioequivalence study for generic asthma treatment

ABOUT MERIT

MERIT has provided spirometry capture, centralized review and grading, and data management services for respiratory clinical trials since 1993 (formerly CompleWare). Using our innovative and proven technologies and intuitive, seamless workflows, MERIT's experienced staff bring decades of clinical endpoint expertise to ensure the success and integrity of your respiratory studies.

M E R I T

Your Clinical Endpoint Expert

© 2024 MERIT CRO, Inc. All rights reserved.

Connect with us to learn more about how our expertise and approach can support bringing your product to market on-time and on-budget. Your success is our priority.

meritcro.com | in | E: Info@meritcro.com | P: (608) 284-8810

Inc. 5000
AMERICA'S FASTEST-GROWING PRIVATE COMPANIES