Top 5 Pitfalls of Spirometry
And How to Avoid Them

Is your company moving into the respiratory clinical trials market? Maybe you’ve ventured into spirometry, learned some hard lessons, and now you’re looking for a new partner. Either way, take a look at the top 5 problems encountered when collecting spirometry data in a clinical research setting and how CompleWare makes every breath count.

Not to burst your bubble, but there are countless things that can go wrong in a clinical trial. Below are stories from the front lines, taken directly from the CompleWare Help Desk, in an effort to help you avoid these mistakes.
To avoid equipment-related nightmares, CompleWare recommends standardized spirometers and calibration syringes at all study sites. Our software, CompleClinical, ensures calibration verification requirements are enforced.

We make sure the equipment recommended for your study fits the specific requirements of your program, and we rigorously test all equipment prior to shipment. Most importantly, we provide in-person training to all users on the specific equipment selected for the study.

“\text{"We had a site call in that was unable to collect spirometry data due to an error message that kept appearing. It turned out that the mouthpiece was not inserted into the spirometer properly. Another site called about being unable to confirm calibration. The user was pulling out instead of pushing in on the calibration syringe."}"

\text{~CW Help Desk}

\text{Professional tip:}
Your study partner should deliver replacement equipment and supplies within 1-2 business days of a site request.
Proper training can reduce or eliminate many of the problems encountered with spirometry data collection. We instruct all sites on how to prepare subjects to perform spirometry.

We emphasize that coaching during spirometry is a vital component in collecting accurate data. Subjects **must** be instructed to forcefully and quickly exhale in a FVC maneuver. Technicians are trained to watch subjects at all times for proper positioning of the mouthpiece and to ensure full inhalations and exhalations. Does your existing solution provide alerts for maneuvers that don’t match ATS/ERS standards and/or protocol requirements? CompleClinical does!

“We sometimes get calls that the spirometer is not working only to find out that the subject is having a really difficult time breathing. The subject is unable to produce enough flow to get a measurement and there is nothing wrong with the device at all.”

~CW Help Desk

“Your frequent emails to the sites to provide suggestions and updates as we went along were always very relevant and helpful. It is rare to work with a (study) manager that has such a fundamental understanding of asthma as well as a detailed understanding of the entire protocol.”

~Study Site
Small variations in data can have large consequences. Avoid chaos in your spirometry data by instituting central review. CompleWare offers review by Registered Respiratory Therapists (or other SMEs) within 24 hours, using configurable standardized grading to confirm sites adhere to protocol and ATS/ERS standards.

These services further ensure data integrity by confirming that site personnel are instructing subjects and capturing data correctly. Central review also allows for quick recognition, and resolution, of any errors that may arise throughout a study.

Professional tip:
Your study partner should allow access to real time data anytime from anywhere. Our RRTs can offer remote support live while in a session, saving a lost or failed subject.

“A site called in to ask about why the subject was not meeting repeatability criteria. I explained that the efforts were not meeting ATS/ERS guidelines. Then the site wanted to know why she was only allowed to perform 4 efforts in the software. I explained that the protocol required the limit of 4 efforts. I showed the site how to review the efforts individually and told the site not to delete it, as the effort was acceptable.”

~CW Help Desk
Even a simple typo can lead to confusion. From qualifying spirometry completed incorrectly, to the loss of drug due to a temperature excursion, even the smallest errors have major consequences on your timeline and budget.

In the course of our decades of experience, we have authored numerous protocols, mostly in the respiratory therapeutic area. We’ve seen plenty of protocol inconsistencies as well, which cause confused sites and result in added time and effort to qualify, and complete, subjects.

With our expertise in study design and protocol development, we provide protocols with end users in mind. Consistent protocols reduce site questions and help avoid the mistakes that lead to study delays and greater variability in your data.

“It was identified that page 7 of the protocol stated that FEV1 at Visit 1 Screening must be ≥80% of predicted but on page 22 it said >80% of predicted. Everywhere else in the protocol said ≥80%, but we just wanted to be sure which one was correct.”

~CW Help Desk

Drug Storage: 62°F - 86°F

Nine is the minimum number of years of protocol writing experience on our Medical Writing team.
Inadequate Customer Service

“A site called asking for help in getting the PI logged in for the first time. The site coordinator was getting frustrated, so I helped the coordinator step-by-step through the entire process until the PI was able to get logged in.”

~CW Help Desk

Sites require assistance with forgotten passwords, equipment problems, logging on—you name it, we’ve heard it. What happens when sites require immediate assistance? Wasting time on the phone upsets sites and subjects, squanders precious study time and resources, and can result in lost subjects.

Whether it’s the first step or the last step, when sites get stuck, our Help Desk is one call away. We are always available with highly-trained, personalized help, 24 hours a day, 365 days a year. Post-study follow-up survey results indicate that we have some of the best customer service sites have ever encountered.

We go the extra mile to meet Sponsor needs as well. If a change is needed in the protocol and/or software configuration, we make it happen as quickly and painlessly as possible, while adhering to all regulations regarding IRB/EC approval, user acceptance testing, and software validation.

Professional Tip:
Response time shouldn’t be an issue. Our live Help Desk answers calls in 2 rings with immediate help.
How CompleWare Helps
Make Every Breath Count

Despite the potential pitfalls, high quality spirometry data can be collected even in large, multicenter clinical trials. Here’s how CompleWare does it:

#1 Centrally sourced, tested, and monitored equipment with study-specific manuals provided to all sites

#2 Hands on training with clear instructional materials (manuals, videos, webinars) for all users

#3 Centralized review to confirm “best effort,” inclusion/exclusion criteria, and provide standardized grading of efforts to accompany configurable compliance alerts in CompleClinical

#4 Protocols written with end users in mind, offering the simplest, clearest requirements possible

#5 Comprehensive, courteous, knowledgeable, and friendly customer service with live help via web, chat, email and remote desktop

“CompleWare has been a very valuable partner in our phase 2/3 program as the central spirometry vendor. The oversight they provide to this important component of the program from training of the sites, shipment of supplies, providing timely quality reviews of study visit spirometry, and the cleaning and validating of the data has been a key factor in the success of the program. Sites have told us that CW is very responsive and customer-oriented when responding to site issues and requests. At the end of the study they provide a validated database that is ready for analysis. To not use a vendor such as CompleWare in a large respiratory program would make executing the studies much more difficult and greatly limit our confidence in the spirometry data.”

~Study Sponsor