

Quintiles' Blended Site Monitoring Speeds Up Database Lock

Use of Project Coordination Center (PCC) produces cleaner data, speeds 100% query resolution.

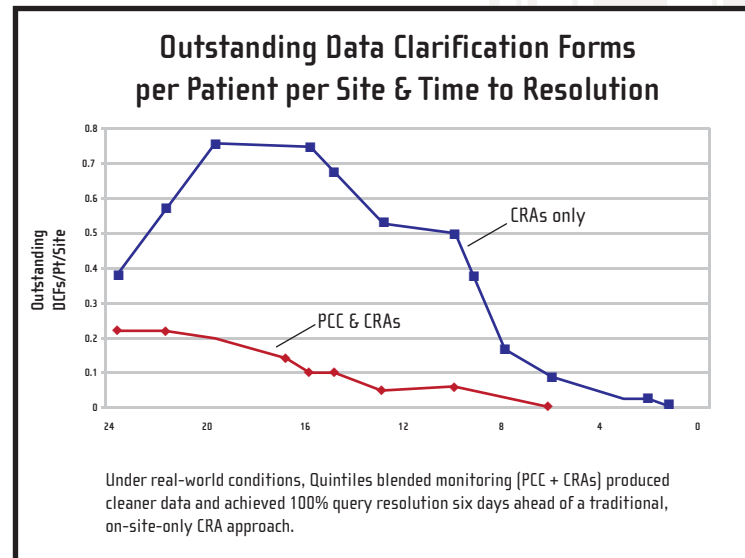
One day, a few years back, Quintiles dared to ask, “Why not?” Why not make investigators’ lives easier – and CRAs’ performance more efficient – by supplementing regular on-site visits with remote monitoring and investigator support?

Why not have someone always available – not traveling half the time – to provide continuous guidance, answer questions and resolve study issues early on, before they become problems?

Why not, indeed. So Quintiles developed the Project Coordination Center delivery model.

More Efficient CRAs, More Productive Investigators

Quintiles Project Coordination Centers provide centralized support to investigators and sites in collaboration with traditional on-site staff (CRAs). These dedicated operations centers leverage global SOPs and fit-for-purpose IT tools to efficiently deliver a blend of centralized and on-site monitoring activities in a manner that is scalable across the globe.



This combination of on-site and remote monitoring enables CRAs to use their on-site time more effectively, and to devote more attention to critical activities such as source data verification and investigator site file reconciliation.

And, the early and continuous support of the Research Coordinators enables investigators to avoid many potential issues altogether, and to resolve those that do arise before they become troublesome sources of error. ➤

A Real-World Test

A recent multi-country clinical trial for a large global pharmaceutical company gave us the opportunity to evaluate blended monitoring in a real-world situation. Quintiles monitored 72 sites in one geographic area, using a PCC/CRA blended team. In another geographic area, CRAs alone monitored 41 sites. Same study, same protocols, same start date and deadline.

Quintiles' blended approach produced far fewer outstanding data clarification forms (DCFs) and quicker error resolution as the study headed toward the final deadline. In fact, our blended monitoring approach achieved complete resolution of queries and database lock a full six days earlier than the CRA-only arm of the study.

Blended Monitoring Meets ICH GCP Guidelines

The use of a blend of centralized and on-site monitoring is consistent with ICH GCP guidelines. It has been accepted by regulatory agencies worldwide. And, Quintiles has demonstrated its effectiveness in over 50 Phase III, Phase IIIb, and Phase IV studies involving almost 10,000 sites. Bottom line, there is no better way to manage site workflow, decrease investigator burden, improve data quality and accelerate database lock.

So if you haven't tried using a Quintiles Project Coordination Center in one of your recent studies, just ask yourself this: "Why not?"

At Quintiles, *it's all about results.*TM

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