PCM TRIALS
QUALITY MOBILE RESEARCH

FAQ

Q: Why should sponsors and CROs consider using mobile research nurse visits in their clinical trials?

A: Mobile visits are more convenient for patients and reduce the burden of participating in clinical research. As part of a patient-centric approach, they can improve recruitment, retention, and adherence while expanding a trial's geographic reach. They can also improve trial availability for diverse populations that lack access to traditional sites. Impacts can include fewer sites, faster study enrollment, reduced risk, lower overall cost, and shorter timelines.

Q: How do mobile nurse visits benefit study patients?

A: Mobile nurse visits…

- Save time and money for those who live long distances from the site
- Alleviate stress and scheduling challenges for study participants who depend on others for transportation such as elderly, disabled or pediatric patients, as well as their caregivers
- Enable home-bound patients to take part in clinical trials
- Eliminate "visit fatigue," which can cause study dropouts

Q: Who delivers mobile nurse visits for PCM Trials?

A: PCM Trials directly recruits, hires, trains, certifies, and manages registered nurses with appropriate clinical backgrounds. These Certified Mobile Research Nurses (CMRNs) are located across the United States and in select international markets. We recognize that our team – and our commitment to quality – directly impacts your clinical trial.

Q: What can CMRNs do during a mobile research nurse visit?

A: CMRN activities in the home setting can include anything within the scope of practice of a registered nurse, that can be done with portable equipment, and that has an acceptable risk profile. Frequent procedures include:

- Infusions
- Injections
- Sample collection and processing
- Adverse Event Assessments
- Concomitant medications
- Vitals
- Subject training
- Drug accountability

Q: How do I incorporate mobile nurse visits into my clinical trial?

A: In general, the option of using mobile research nurse visits must be specified in the study protocol and the Informed Consent document. This can be done either during initial protocol development or afterwards as part of a "rescue" strategy to improve study participant recruitment and/or retention. Earlier development of a mobile research strategy maximizes the benefits of this patient-centric approach.

Q: How do CMRNs work with site personnel?

A: PCM Trials Project Management Team will discuss a site engagement plan during study start-up. PCMT CMRNs work collaboratively with each Investigator and Site Coordinator to ensure Site staff is comfortable with the clinician supporting their patient, and is delegating authority appropriately, most commonly through the Delegation of Authority Log. CMRNs may have an introductory call with the site or participant, or both, and may be available to travel to the site for a meeting or to pick up IP and supplies as needed.

Q: How do you coordinate with central lab and pharmacy?

A: Central labs typically send pre-made lab kits to PCM Trials depot for the PCM Trials team to monitor, manage, and distribute to CMRNs in advance of mobile visits. The PCM Trials Project Management team will work with the CMRN to coordinate shipment of the samples back to the central laboratory for analysis. When investigational product administration is part of the home visit, the PCM Trials Project Management team coordinates with a central or site pharmacy to have the product shipped within required parameters of the drug (stability, temperature control, limited access, etc.) and targeted time frame for its administration.

Q: What is your experience with mobile nurse visits?

A: Since 2008, PCM Trials has worked on 300+ protocols for 150+ different sponsors and dozens of CROs. We have completed 55,000+ direct-to-patient visits. We have supported studies across all phases of development, for patients ranging from infants to the elderly, in a wide range of therapeutic areas, including rare diseases. Our mobile nurse visit services are available throughout the U.S. and around the world.

PCM Trials can help improve patient recruitment, retention, and adherence, which can enable your company to complete clinical trials faster, at lower cost, and with reduced risk.

To learn more, visit www.pcmtrials.com, contact info@pcmtrials.com or call 888-628-9707.