

FAQ

Q: Why should sponsors and CROs consider using mobile nursing for in-home clinical trial visits?

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 nursing visits benefit study patients?

A: Mobile nursing 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 research nursing 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 impact your clinical trial.

Q: What can CMRNs do during a mobile nursing visit?

A: CMRN activities in the home setting can include anything within the scope of practice of an 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

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

A: In general, the option of using mobile nursing visits must be specified in the study protocol. 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: Each CMRN signs a Delegation of Authority log with the site's Principal Investigator. Our CMRNs work collaboratively with each Investigator and Site Coordinator to make sure that every mobile research visit meets its target date and is completed with the same dedication to quality as an on-site visit. If requested, CMRNs can go to the site for training. For many clinical trials, CMRNs will visit the site to pick up investigational product, lab kits, or supplies.

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

A: Central labs typically send pre-made lab kits to our CMRNs with return packaging to send back collected and processed samples. When investigational product administration is part of the home visit, the nurse coordinates with a central or local 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 nursing.

A: Since 2008, PCM Trials has worked on 270+ protocols for 130+ different sponsors and dozens of CROs. We have completed 29,000+ 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 nursing 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.

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