EBOOK

How to Achieve a Patient-centric Clinical Trial

Recruit, engage, and retain more patients with this one change—and improve your clinical trial.

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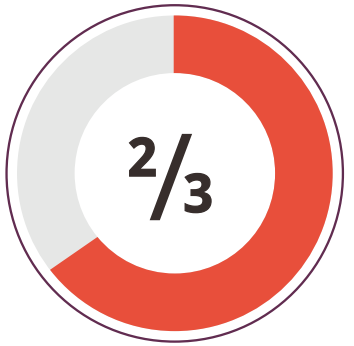
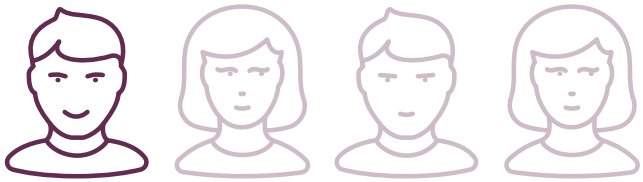
As competition within the drug development landscape intensifies and product and protocol complexity increase, sponsors continue searching for new strategies to improve operational efficiency, better engage with their clinical trial patients, and speed development timelines.

While patient recruitment and compliance are critical to the success of clinical trials, the focus on engaging and retaining appropriate patients is key. These challenges, along with ensuring protocol compliance, directly influence overall study costs, results, and timelines.

In this eBook, you will learn how integrating and applying alternative site visit options, including advanced home trial visits, improves the patient centricity of your clinical trials, supports efficient, high-quality data collection, and enhances patient recruitment and retention.



The vast majority of investigative sites fail to meet patient enrollment requirements.[1]

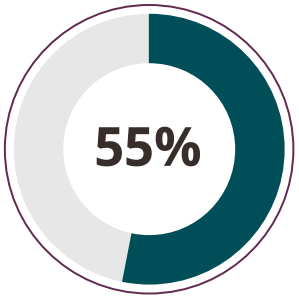


Only 25% of screened patients make it to the end of treatment.[1]

1 http://csdd.tufts.edu/news/complete_story/rd_pr_apr_2011

Minimize the Patient Burden, Maximize Retention & Compliance

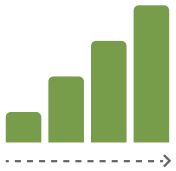
Inconvenient site locations, schedule conflicts, logistical concerns, financial constraints, and missed visits all lead to patient dropout and elevated non-compliance rates. Incorporating a more patient-centered approach that minimizes patient burden can improve those rates.



More than half of clinical trial participants surveyed said location was the most important factor in their participation[2]

Home trial visits minimize the burden of site visits and may also improve patient retention as the study progresses. Instead of requiring patients to visit a designated investigative site multiple times over the course of a study, patients can complete study visits at locations and times convenient and comfortable for them. Conducting protocol visits in homes or other convenient or non-traditional locations expands your clinical trials to individuals who otherwise may not have the option to participate given their schedule or the traditional protocol requirements of frequent office visits.

Additionally, home trial visits give site staff more time to focus on other methods of increasing patient recruitment, further benefiting the trial research, the site, and the patients.



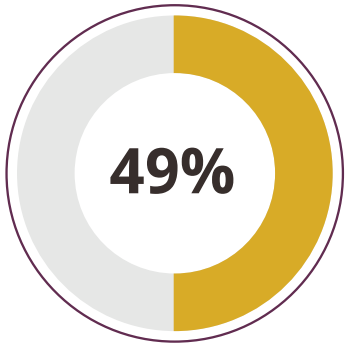
Home trial visits can increase trial participation regardless of study duration, frequency of visits, disease state or distance to study site.

2 http://social.eyeforpharma.com/clinical/siteless-future-clinical-trials

What Study Protocols Can Be Performed at a Home Trial Visit

Home trial visits can be used to perform a variety of services required by your study protocol, including:

- Vital sign collection
- ECG/EKG administration
- Blood draw, processing, and shipping
- Investigational product (IP) administration and infusion
- Drug reconstitution
- Caregiver/patient training
- Questionnaire administration
- Chaperoning service



The number of patient procedures performed during a clinical trial have increased by 49% in recent years.[3]

Controlling the number of procedures could provide substantial benefits.

3 http://social.eyeforpharma.com/clinical/siteless-future-clinical-trials

Amplify the Impact for Rare Disease and Other Therapeutic Areas

The regulatory focus to increase the patient centricity of clinical trial protocols[4] makes home trial visits ideally suited for most any study. However, there are a number of therapeutic areas in which there is significant precedent for home trial visits, including:

- Rare and orphan diseases
- Pediatric and elderly
- Pulmonary and respiratory
- Oncology
- Central nervous system (CNS), including Alzheimer's and dementia trials
- Mega and longitudinal trials relying on patient retention (i.e., cardiovascular outcomes and vaccine trials)
- Long-term trials or those that require frequent site visits

These patient populations and therapeutic areas have more quickly adopted additional home trial services to support patient recruitment and reduce drop-out rates.[5] For example, a recent study on rare disease patients published in *Neurology* reported 54% of patients indicated that home trial visits would increase their likelihood of participating in a clinical trial.[6]

54%

The number of patient procedures performed during a clinical trial have increased by 49% in recent years.

4 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4504054/
5 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4504054/
6 "Rare Disease Clinical Research: Caregivers' Perspectives on Barriers and Solutions for Clinical Research Participation." Neurology April 5, 2016 vol. 86 no. 16 Supplement I8.001

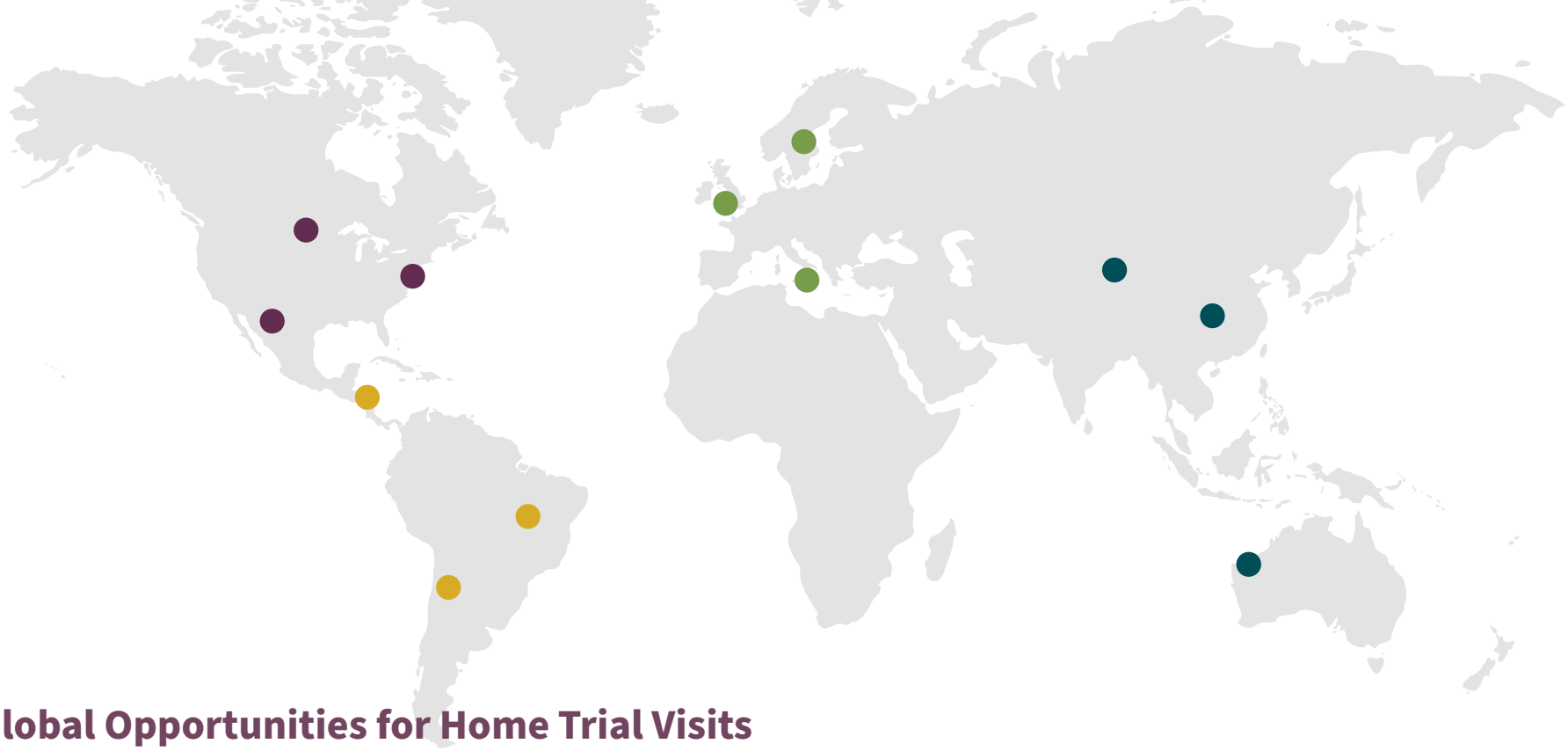
Home Trial Visit Best Practices

There are a number of common misconceptions about the integration of home trial visits within clinical trials. As with many innovations and enhancements, avoiding myths and understanding the adoption of best practices better prepares you for clinical trial success. Check out the table below for a summary of some common do's and don'ts.

DON'T	DO
Adopt a "one-size-fits-all" strategy Many sponsors and CROs have the misconception that they must deploy the same visit strategy across all investigative sites and locations.	**Implement strategy as appropriate** Home trial visits is not a one-size-fits-all strategy. Including this strategy in your protocol provides an option for a different type of trial visit. Advanced education and communication may help sites and patients become more comfortable with the strategy.
Ignore regional variation Cultural understanding and acceptance of home trial visits are variable. It's important to leverage expert resources to help understand regional differences.	**Understand regional cultural acceptance** In general, there is cultural acceptance for the use of home trial visits throughout North America, South America, Europe, and Australia/New Zealand. Countries within Asia Pacific may have cultural norms preventing widespread adoption of this service. We suggest including a question regarding home trial services in feasibility questionnaires to assess acceptance of service.
Only use home trial visits as a rescue mechanism Site education and understanding of the service is much harder to communicate when the trial is already underway. Delayed implementation can result in patient recruitment and enrollment delays, and increased study start-up costs.	**Incorporate strategy (early) into protocol and ICFs** Listing and detailing home trial services in your trial protocol and informed consent form (ICF) can be a distinct differentiator. If incorporated early in the development process, the inclusion of home trial visits saves time and deployment costs.

DON'T	DO
Assume home trial visits will increase costs Home trial visits are often assumed to be costly and time-consuming given the need for diverse resources and medical proficiency.	**Look at the long-term cost-benefit of home trial visits** Despite incurring an initial set-up fee, home trial visits have been shown to be cost neutral.[8]
Rely on outdated geographical-centered models Clinical trial models are currently built around the use of geographical investigative sites. Unfortunately, this model eliminates potential trial patients who don't have access to these sites, including those with mobility issues, elderly, those who live in rural areas, and other concerns.	**Expand geographical reach and provide greater access to patients** Home health visits can help provide a more diverse and representative patient population. Increasing the geographical reach of patients provides greater access to patients who otherwise would be unable to participate.[9] Fewer site visits address some of the inherent inefficiencies and logistical concerns of the traditional trial model.[10]
Limit home trial visits to only small or less complex trials There is a common misconception that sites, especially large academic medical centers, don't like using home trial services. The misconception is that this model is more difficult to implement for trials that require complex study visit procedures, or those that can only be conducted by expert medical specialists using technical equipment.[7]	**Leverage patient-centric home trial visits for large sites and complex trials as appropriate** Implementing increased patient centricity ensures patients are the focus of a trial, regardless of protocol complexity, site size or location. With home trial visits, you can enhance transparency and site involvement in home trial service details.
Ignore data quality and security concerns Your desire to employ home trial visits on your global clinical research study might also be affected by data security concerns. Given the volume of sensitive patient data being transmitted over the lifetime of a study, data privacy and security are valid concerns that must be proactively addressed.	**Implement proactive security and quality checks** Deploying home trial visits with well-controlled processes which address data privacy and security can allow for a more reliable and accurate data collection. Centralizing that data and performing automated quality assurance (QA) checks allows you to meet your endpoints faster and achieve regulatory and commercialization goals.[11]

7 https://www.dddmag.com/article/2017/08/are-clinical-research-sites-dying-paradigm
8 Bowrey, D. et al., "A Randomized controlled trial of six weeks of home enteral nutrition versus standard care after oesophagetomy or total gastrectomy for cancer: report on pilot and feasibility study." Trials 16:531 (2015)
9 Mendes de Oliveira, J., etl al. "Outpatient vs. home-based pulmonary rehabilitation in COPD: a randomized controlled trial," Multidisciplinary Respiratory Medicine 5(6) 401 -408 (2010)
10 http://social.eyeforpharma.com/clinical/siteless-future-clinical-trials
11 https://www.dddmag.com/article/2017/08/are-clinical-research-sites-dying-paradigm



Global Opportunities for Home Trial Visits

North America

- Home trial visits widely accepted
- Few regulatory issues
- Limited local institution restrictions
- Significant population of home trial service providers across NA

Latin America

- Up-and-coming region for home trial service

Europe

- Home trial visits widely accepted
- Early involvement is important to appropriately plan for local laws and patient privacy considerations
- Home trial service providers may have to travel great distances to reach patients

Asia Pacific

- Limited regulatory issues in Australia or New Zealand

Why Use Home Trial Services?

SPONSORS & CROs

- Greater access to diverse patient population
- Expanded geographical reach
- Positive impact on patient recruitment and enrollment rates
- Enhanced safety monitoring
- Enhanced efficacy reporting
- Better study compliance
- Higher patient retention rates

SITES & INVESTIGATORS

- Greater time and focus on additional patient enrollment
- Enhanced support offering to patients
- Enhanced transparency in caregiver training and study documentation

PATIENTS & CAREGIVERS

- Comfort and convenience of completing visits in locations and at times most convenient for them: *home, work, school, evenings, weekends*
- Improved quality of life
- Reduced inconvenience in clinical trial participation
- Enhanced support from healthcare team to educate and administer study protocol

STUDIES THAT IMPLEMENT HOME TRIAL VISITS SEE:

60% **Better patient retention**[12]

30% **Better patient compliance**[13]

12 http://www.pemag-digital.org/pemag/packaging_oct_2014?pg=14#pg14
13 http://www.pemag-digital.org/pemag/packaging_oct_2014?pg=14#pg14

5 Steps to Home Trial Visit Success

In what ways can you begin to prepare now to successfully implement a home trial visit strategy in your clinical trial protocol? Take these steps to fully harness patient centricity and ensure success.

Plan early and proactively

Assess the potential success of home trial services in your clinical trial by reviewing your protocols and study concept documents. Expediting documentation and proactively listing home trial visits in your protocol ensures integration of the service beginning with the first patient enrolled. You can anticipate IRC/EC questions with proactive responses, while reviewing ICF/IRB language provides additional detail.

Establish and maintain transparent communication

Maintain transparency of your home trial visit status throughout your trial to improve patient engagement and operational efficiency. Start your study off right by determining required reporting, and providing regular status reports of KPIs to measure ongoing performance. Increased communication and understanding of the service allays concerns, improves recruitment, and supports retention options.

The 5 steps to success

- Plan early and proactively
- Establish and maintain transparent communication
- Use quality-based KPIs
- Use high-quality deliverables
- Find providers that best fit your unique trial needs

Maintain transparency to improve patient engagement and operational efficiency.

Use quality-based key performance indicators

Quality certification should drive the collection, review, and improvement of your service-related key performance indicators (KPIs). Relevant KPIs may include:

- Percentage of visits conducted within protocol window (target = 100%)
- Percentage of ordered visits completed (target = 95%)
- Time elapsed between home trial visit and receipt of source documents by site (target = within 2 business days)
- Delegation of Authority Log executed before visit
- Patient and site satisfaction rates (via survey or questionnaire)
- Meeting of enrollment goals and timelines
- Percentage of patient drop-out across trials

KPI TARGETS

100%
Clinical study reports written

95%
In-home patient visits completed

2
Business days time elapsed between visit and source document receipt

Require high-quality deliverables from global home trial visits

Concerned about adding confusion to the site staff resulting in lost data or data errors? We leverage our ISO 9001:2015 certified quality processes to outline expectations in your training manual, perform QC of all source documents, and track DCFs and queries in our proprietary home trial visit management system (HTMS) to ensure high-quality data.

Find the right providers that are a best fit for your unique trial needs

Ensure success by identifying and training the right providers. Providers should be qualified per local requirements and hold valid certifications (e.g., insurance). Routine and practical training should be protocol-specific, tested, and verified prior to the provision of services. All providers should have knowledge of and compliance with local and regional privacy laws and regulations.

Conclusion

Home trial visits can be a valuable tool to improve operational efficiency, increase patient engagement, and speed development timelines, benefiting everyone from study sponsors, CROs, and sites to patients and caregivers. As the industry continues to invest more heavily in patient-centric systems and processes, trials will become more efficient, data collection and reporting will be higher quality, and patient recruitment and retention will improve.

The clear winner in this shift towards patient centricity is the patient. As trials become more efficient, costs are driven down, and timelines are shortened due to improved enrollment and retention. Ultimately, patients will benefit from having faster access to treatments.

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About Firma Clinical Research

Firma is a boutique contract research organization (CRO) that believes a patient-centric approach is the key to unlocking positive outcomes in the drug and medical device development process. Using an integrated suite of specialized solutions, Firma makes the clinical trials process easier and more valuable for patients and produces higher-quality data for sites and sponsors.

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