IMPROVING YOUR CLINICAL TRIAL & ENHANCING THE PATIENT EXPERIENCE

Applying a patient-centered approach to enhance clinical trial performance, improve data quality, and ensure safety and efficacy.

FIRMA
CLINICAL RESEARCH
Expert Insights | Quality Outcomes
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 advances in home health support services improves the patient centricity of your clinical trials, supports efficient, high-quality data collection, and enhances patient recruitment and retention.

1 http://csdd.tufts.edu/news/complete_story/rd_pr_apr_2011
MINIMIZE BURDEN, IMPROVE RETENTION, AND MAXIMIZE COMPLIANCE WITH A PATIENT-CENTRIC PROTOCOL

Inconvenient site locations, schedule conflicts, logistical concerns, financial constraints, and missed visits are often cited as reasons patient dropouts occur and non-compliance rates increase. Incorporating a more patient-centered approach that minimizes patient burden can improve those rates.

Incorporating home health visits is a valuable strategy that helps 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.

Importantly, the use of home health visits can allow sites to increase their time and focus to further patient recruitment efforts; benefiting trial research, the site, and patients.

People citing site location as the most important factor in clinical trial participation²

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
INCORPORATE SERVICE-RELATED HOME HEALTH VISITS IN YOUR CLINICAL TRIAL PROTOCOL

Home health 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

Increase in median number of patient procedures per clinical trial in recent years²

Controlling the number of procedures could provide substantial benefits

² http://social.eyeforpharma.com/clinical/siteless-future-clinical-trials
LEVERAGE HOME HEALTH VISITS IN APPROPRIATE THERAPEUTIC STUDIES

The regulatory focus to increase the patient centricity of clinical trial protocols\(^3\) makes home health visits ideally suited for most any study. However, there are number of therapeutic areas in which there is significant precedent for home health 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 outcome 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 health support to support patient recruitment and reduce drop-out rates.\(^3\) For example, a recent study on rare disease patients published in Neurology reported 54% of patients indicated that home health visits would increase their likelihood of participating in a clinical trial.\(^4\)

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3 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4504054/
4 “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
**MAXIMIZE THE BENEFITS OF REMOTE VISIT SERVICES FOR PATIENT SUPPORT**

There are a number of common misconceptions about the integration of home health 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 misconceptions/challenges and their accompanying solutions/opportunities:

<table>
<thead>
<tr>
<th>MISCONCEPTIONS &amp; CHALLENGES</th>
<th>SOLUTIONS &amp; OPPORTUNITIES</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Adopting a “one-size-fits-all” strategy</strong></td>
<td>Home health care visits is not a one-size-fits-all strategy. Including this strategy in your protocol provides an option of a different type of trial visit. Advance education and communication may help sites and patients become more comfortable with the strategy.</td>
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<td><strong>Failing to consider regional variation</strong></td>
<td>In general, there is cultural acceptance for the use of home health 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 health care services in feasibility questionnaires to assess acceptance of service.</td>
</tr>
<tr>
<td><strong>Applying home health visits as a rescue mechanism</strong></td>
<td>Listing and detailing home health visit 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 health visits saves time and deployment costs.</td>
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### MISCONCEPTIONS & CHALLENGES

**Assuming home health visits will increase costs**
Home health visits are often assumed to be costly and time-consuming given the need for diverse resources and medical proficiency.

**Conducting home health visits outside of major cities is too difficult**
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, illness and other concerns.

**Home health services won’t work for large sites or complex trials**
There is a common misconception that sites, especially large academic medical centers, don’t like using home health services. To some, 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.

**Ensuring data quality and security is impossible**
Your desire to employ home health care 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.

### SOLUTIONS & OPPORTUNITIES

**Home health visits can be efficient and cost-effective**
Despite incurring an initial set-up fee, home health visits have been shown to be cost neutral.

**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. Fewer site visits address some of the inherent inefficiencies and logistical concerns of the traditional trial model.

**Leverage advances in patient support services and technology to increase patient centricity**
Implementing increased patient centricity ensures patients are the focus of a trial, regardless of protocol complexity, site size or location. With home health visits, you can enhance transparency and site involvement in home care details.

**Implement proactive security and quality checks**
Deploying home health 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 allow you to meet your endpoints faster and achieve regulatory and commercialization goals.

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4 [https://www.dddmag.com/article/2017/08/are-clinical-research-sites-dying-paradigm](https://www.dddmag.com/article/2017/08/are-clinical-research-sites-dying-paradigm)
CONSIDER REGIONAL VARIATION AND UNDERSTAND CULTURAL ACCEPTANCE

**North America**
- Home health visits widely accepted
- Few regulatory issues
- Limited local institution restrictions
- Significant population of home health care providers across NA

**Latin America**
- Up-and-coming region for home health care
- Challenging regulatory environment
- Patient locations compared to home health care provider availability occasionally challenging

**Europe**
- Home health visits widely accepted
- Early involvement important to appropriately plan for local laws and patient privacy considerations
- Home health care providers may have to travel great distances to reach patients

**Asia Pacific**
- Limited regulatory issues in Australia or New Zealand
- Most other countries within Asia Pacific currently have cultural norms preventing widespread adoption of in-home clinical trial services
WHY USE HOME HEALTH VISIT SERVICES?

Sponsors and CROs, patients, caregivers, and investigative sites have tremendous opportunity to benefit from deploying trial visits in home.

**BENEFITS FOR:**

<table>
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<tr>
<th>SPONSORS &amp; CROs</th>
<th>SITES &amp; INVESTIGATORS</th>
<th>PATIENTS &amp; CAREGIVERS</th>
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<tr>
<td>▶ Greater access to diverse patient population</td>
<td>▶ Greater time and focus on additional patient enrollment</td>
<td>▶ Comfort and convenience of completing visits in locations and at times most convenient for them: home, work, school, evenings, weekends</td>
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<td>▶ Expanded geographical reach</td>
<td>▶ Enhanced support offering to patients</td>
<td>▶ Improved quality of life</td>
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<tr>
<td>▶ Positive impact on patient recruitment and enrollment rates</td>
<td>▶ Enhanced transparency in caregiver training and study documentation</td>
<td>▶ Reduced inconvenience in clinical trial participation</td>
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<td>▶ Enhanced safety monitoring</td>
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<td>▶ Enhanced support from healthcare team to educate and administer study protocol</td>
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<td>▶ Enhanced efficacy reporting</td>
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<tr>
<td>▶ Better study compliance</td>
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<td>▶ Higher patient-retention rates</td>
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**STUDIES THAT IMPLEMENT HOME HEALTH VISITS SEE:**

- 60% Increase in patient retention<sup>8</sup>
- 30% Increase in patient compliance<sup>8</sup>

<sup>8</sup> http://www.pemag-digital.org/pemag/packaging_oct_2014?pg=14#pg14
BEST PRACTICES FOR MEASURING SUCCESS WITH HOME HEALTH VISIT TRIALS

In what ways can you begin to prepare now to successfully implement a home health visit strategy in your clinical trial protocol? There are several best practices we recommend to fully harness patient centricity and ensure success.

Assess the potential for rapid deployment
Assess the potential success of home health services in your clinical trial by reviewing your protocols and study concept documents. Expediting documentation and proactively listing home care 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.

Enhance transparency through integrated technology and communication
Maintain transparency of your home health visit status throughout your trial to improve patient engagement and operational efficiency. Start your study off right by determining

MEASURING SUCCESS
▷ Assess potential for rapid deployment
▷ Enhance transparency through integrated technology & communication
▷ Establish quality-based KPIs
▷ Manage visits with high-quality deliverables
▷ Find providers that best fit your unique trial needs

Maintain transparency to improve patient engagement and operational efficiency
required reporting, and provide regular status reports of KPIs to measure ongoing performance. Increased communication and understanding of the service allays concerns, improves recruitment and supports retention options.

**Establish 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 in-home 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
Successfully manage global home health care visits with high-quality deliverables

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 remote visit management system RVMS 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.

FDA Commissioner, Scott Gottlieb, M.D., recently released a statement on new steps by the FDA to advance patient engagement in the agency’s regulatory work. The FDA hosted the first meeting of the Patient Engagement Advisory Committee (PEAC). It’s a significant step forward in the FDA’s efforts to broaden its engagement with patients — and to deepen the involvement of patients in regulatory activities.

For more information, click here to read Commissioner Gottlieb’s full statement.

Photo credit: U.S. Food and Drug Administration
CONCLUSION

As the competition within the drug development landscape intensifies, the complexity of drugs being developed increases, and clinical trial protocols become more complex. Sponsors are searching for new strategies to improve operational efficiency, better engage with their clinical trial patients, and speed development timelines.

Home health visits can be a valuable tool to solve these known issues and provide significant benefits to study sponsors, CROs, 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.

FIRMA CLINICAL REMOTE VISIT SERVICES (RVS)

Enhance your trial. Improve their experience.

To schedule a call with our RVS Leadership team for a free protocol evaluation and feedback, email info@firmaclinical.com or visit firmaclinical.com.
About Firma Clinical Research
An ISO 9001:2015 quality-certified organization, Firma Clinical provides focused CRO services enabling pharmaceutical and biotech clients to plan for and advance research in the dynamic drug development landscape. This support enables clients to make informed decisions that lead to better outcomes. Built on decades of clinical leadership and expertise, Firma is dedicated to a collaborative approach that accelerates the development of safe and effective treatments for the pharmaceutical, biotechnology, and medical device industries. The company offers a wide array of tailored processes and services across all phases of clinical development, strategically focusing on flexible solutions, transparent communication, and on-time deliverables.