In-Home Services: A Patient-Centric Approach to Improving Recruitment and Retention in Clinical Trials

The Future of Clinical Trials

Advances in wearables, telemedicine and remote monitoring technology along with the convenience of in-home visits were bound to make decentralised and hybrid clinical trials standard with enough time. However, the COVID-19 pandemic accelerated their adoption and now, even with the hope that the pandemic will soon be behind us, hybrid and decentralised models are poised to become viable solutions in clinical trial design because of their inherent agility, inclusivity and most importantly, patient centricity.

The adoption of in-home clinical services increased during the pandemic to reduce risks around bringing patients on site and it is likely that this approach is set to increase as sponsors see how it can support increased patient compliance, while also giving patients more flexibility in how they participate and increasing recruitment and retention.

To Include or Not Include – That is the Question…

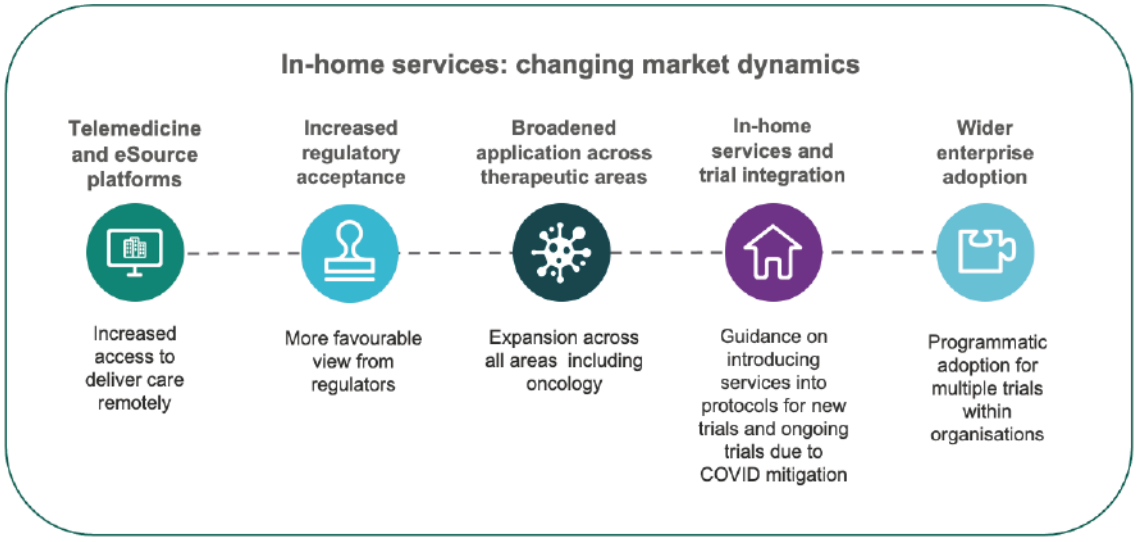
In-home clinical trial services are beneficial in a wide range of studies across all trial phases and therapeutic areas, and can also be used as a strategy to rescue studies that are struggling to reach enrolment targets. However, there are certain study types that are particularly suitable for in-home trial visits. For instance, including in-home visits in a study that requires frequent assessments over a long period will reduce the overall patient burden, making it easier for them to continue in the trial.

The inclusion of in-home services also expands the geographical patient outreach of any single site. This approach can be particularly advantageous for both patient recruitment and retention in rare disease studies, where patients are more likely to be geographically dispersed.

A wide range of services can be performed in a home setting by licensed healthcare professionals including:

- Administration of investigational product and comparator drugs (IV, injection, oral, nasal, or topical routes)
- Biological specimen collection and processing
- Body systems assessments
- Measuring and recording vital signs which can also be supported by wearables and data-collection sensors
- Adverse event and concomitant medication reconciliation.

These activities can also be performed at an alternative location designated by the patient, for instance in suitable room at a workplace, at school or while on vacation, making trial participation less disruptive for the patient.



What does the participant think?

In a recent survey conducted by ICON to gauge the willingness of respondents to participate in clinical trials featuring this and other components of decentralised and hybrid clinical trials, 33% indicated that they would opt for a hybrid of locations (in-home and in-site) for assessments and 30% had no preference for location. While not a unanimous vote for in-home services it does reflect the patient preference for options and convenience.

And as for the experience it seems like when conducted correctly in-home services can improve patient experience. In one study when 57 rare disease patients were asked about their experience, they collectively rated in-home clinical trial experience to be 9.5 out of 10. Moreover, 75 percent of the respondents indicated that having in-home services available was a major factor in choosing to participate in the clinical trial in the first place, while 81 percent cited it as a factor for their ongoing participation in the study.

Regulatory, Logistical and Training Considerations

It's important to be aware that if you are planning to incorporate in-home visits, it must be stated in the protocol, submitted for institutional review board and ethics committee approval and included in the patient's informed consent form. Additionally, adding in-home services mid-study is considered a protocol change and, therefore, must be reviewed and documented appropriately. Therefore, making an early decision to include in-home clinical services can help minimise costly and time-consuming protocol changes down the road. The lead time to set up in-home services usually takes six to eight weeks. However, with upfront planning and consultation from an experienced in-home services provider, this initiation can be done efficiently without greatly affecting study start-up timelines.

In addition to the regulatory requirements for in-home patient visits, you also need to consider additional logistical and operational elements. This includes specialised training for nurses who will be meeting with patients in their homes (or other preferred locations); procuring and delivering clinical supplies and equipment and ensuring that a reliable digital and data collection framework is in place. Selecting the right sites is also essential, since they will always perform a critical role in the medical oversight of in-home services.

What Benefits the Patient, Benefits the Sponsor

For patients, in-home services add flexibility in how they participate, empowering the patient to enrol in the study without the risk of compromising their lifestyle and making it easy to stay the course.

For sponsors, in-home clinical services can increase protocol compliance, expand the geographic reach of a clinical trial, and ultimately accelerate patient recruitment and enhance patient engagement.

It is important to assess the suitability of in-home services for the study in upfront study planning to ensure inclusion in the protocol and that the appropriate logistics are in place. With the support of an experienced partner, patient assessments can be conducted efficiently in-home and this can positively impact patient recruitment and retention targets.

Read more about the best ways to operationalise decentralised and hybrid clinical trials in our whitepaper.[1] For additional information on Accellacare In-Home Services and their role in decentralised clinical trials, please visit accellacare.com/in-home.

REFERENCES

1. https://iconplc.com/insights/transforming-trials/decentralised-and-hybrid-clinical-trials/practical-considerations-in-transitioning-to-dct/index.xml

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Jodie Huddleston is the Vice President of Accellacare In-Home Services, part of ICON plc. She has over 25 years of leadership experience in clinical research, including translational research, clinical strategy, business development and clinical operations. Prior to joining Accellacare, Jodie was the Senior Director, Mobile Research Solutions for IQVIA, where she built a new division within IQVIA'S Decentralized Trials division specialising in mobile research nursing and phlebotomy services to support clinical trial visits in the home. Jodie also built homecare clinical trials strategy and operations as the Principal of Huddleston Consultancy and worked as the Director of Clinical Trials for CVS/Coram Specialty Infusion, leading their direct-to-patient clinical trials division. Throughout her career, she has also built new service offerings for several large organisations in academia, community hospitals, and clinical trial support organisations. Jodie received her BS in Nutrition and Exercise Physiology from Miami University and has completed graduate work in Pharmaceutical Management and Healthcare Administration from the University of Colorado.