Home Trial Support Service: A flexible and comfortable clinical trial service for patients and sponsors

Participating in a clinical trial can be demanding for patients. Depending on the trial, patients need to visit the investigational site monthly, weekly or maybe even daily, for study drug administration, blood draws, or other trial related assessments. This burden can result in recruitment difficulties, or even more disappointing, a high drop-out rate. Which is a pity, knowing that patients are the crucial part to conduct a successful clinical trial and can have a real benefit from the experimental treatment. The last decade a new phenomenon is seen more frequently: home trial support service for patients participating in a clinical research trial.

The success of a clinical trial depends on amount of study data collected from the planned number of participating patients. Only with sufficient data, the objectives set in the protocol can be achieved. Low patient recruitment or premature discontinuations can lead to unreliable study data, which can result in study delay. On the long-term, this can influence the time to bring the investigational product to the market and to make it available for a large patient population. Depending on the development stage of the investigational product, numerous patients are needed to be treated according to the treatment protocol. This varies from around fifty patients in the early stage of the development of a new product to thousands of patients to get the market authorisation approval. Once the product is marketed, observational trials are needed to follow-up and report the safety and efficacy of the product. While trials on rare diseases are often performed with lower amounts of patients, this doesn't make patient recruitment and retention easier, as you cannot afford losing any patients – you need every single patient for the trial. So it doesn't matter what kind of clinical trial, or how many patients need to participate, in every single trial patient recruitment and retention is extremely important!

There are many reasons and examples why patients can't participate in a clinical trial. They can't combine their daily activities with the study visit schedule since they have a daily job or need to attend school. Other difficulties can be the distance to the investigational site, being too sick to travel or not having access to transportation to the site. Home trial support service offers patients and sponsors the possibility to carry out study visits according to protocol at the patient's home or alternate sites. Depending on the study related activities, many assessments can be performed at the patient's home. Taking visits to the patients will reduce the number of hospital visits dramatically and makes participation for the patient more convenient! A benefit both for the patient as well as for the pharmaceutical company.

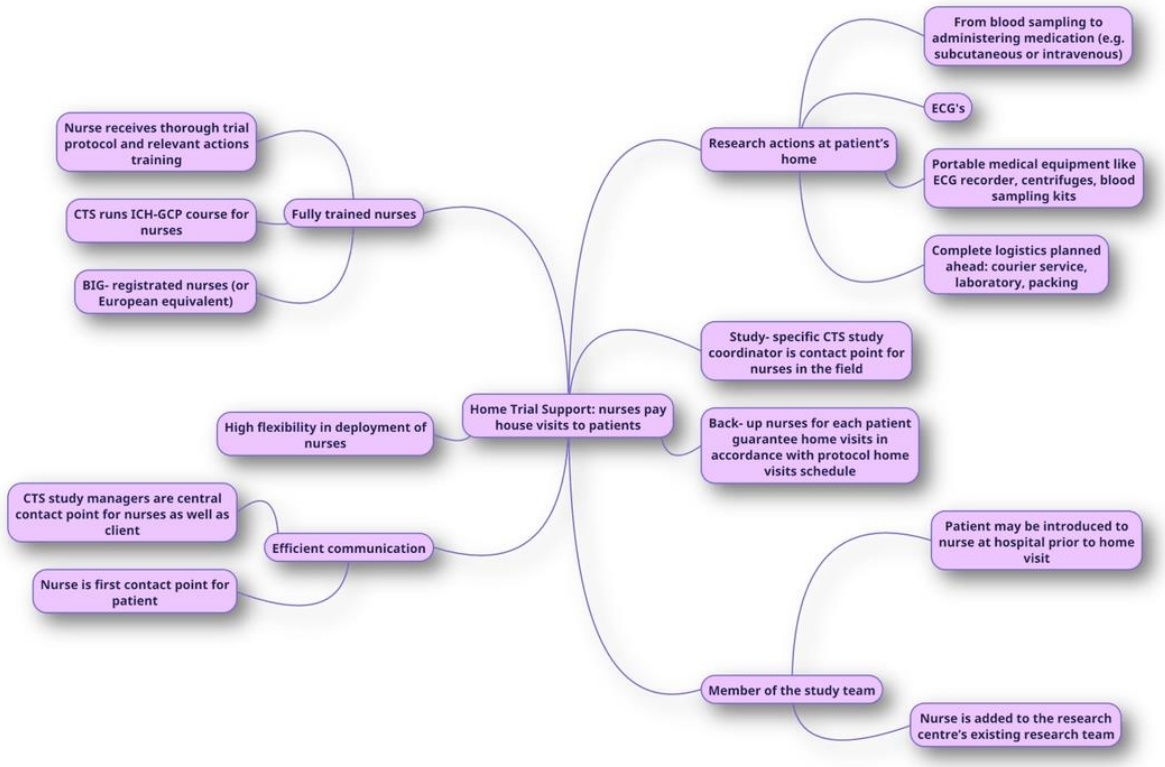
Testimonial of a research nurse:
"For more than three years, I'm visiting two siblings on a bi-weekly basis. They are suffering a rare disease. Only four children in the Netherlands are participating in the trial. The goal of this study is to test the new product in children (given as a subcutaneous injection) instead of taking oral medication every day.
The subcutaneous injections are given every two weeks, but the family lives a two-hours' drive from the site and both parents do have a job. During the first three months of the trial, the children were very closely monitored, meaning they had to visit the site every two weeks. This led to that the children missed a day at school and one of the parents needed to take a day off.
After these three months, we could introduce the home trial support service and study drug administration and regular blood sampling could be done at home. I can visit the patients after school- and working hours. They only need to be home for just one hour, instead of being occupied for a whole day! After each study drug administration, the children need to be observed for any side effects. But instead of waiting in a hospital atmosphere, the children are at home, can do any activity they prefer and even invite friends to come over. The number of visits to the hospital are reduced to once every six months.
The parents are very happy with the new investigational product and they experience their children are doing very well on this new medication. From the start they were motivated to participate in this trial, but without home trial support, it would not have been feasible. This emphasises the importance of the trial support service. For patients, but also for pharmaceutical companies!"

Research Nurse

Thousands of visits are performed in paediatrics, adolescents, adults and elderly patients in the past few years. We expect an approximately 50% growth in the number of visit in 2019 in comparison to 2018. The expectation is that home trial support service will be more and more integrated as an innovative service in the clinical trials by pharma-, food and medical device companies, because they all want to experience this success factor for their trials and their patients.

Experienced, qualified and registered nurses are recruited on their specialisation, experience, flexibility and creativity, matching the pharmaceutical area, disease state of the patient, patient population, nurse technical activities and travel distance from the patient home. A fixed team of specialised nurses work uniformly in accordance with the same procedures. Study specific tasks are executed according to the study protocol, standard procedures and national regulations. Common tasks that can be carried out at the patient home include but are not limited to: vital signs assessment; completion of questionnaires; reporting of side effects and use of concomitant medications; performing ECG; urine, stool and/or blood sample collection; processing of collected specimen by using portable centrifuges and preparing it for shipment to a (central) laboratory by courier; study drug administration via subcutaneous or intramuscular injections or intravenous infusions; and many more. Visits can be performed at home, work, school or alternate locations, adjusted to the patients preference. Depending on the study protocol and visit window, appointments are tailor made and visits can be performed 24/7. There are a lot of possibilities!
Studies are coordinated by a project manager to manage the home care on top level and by a country study manager in every participating country. We call these persons the spider in the web because they are the linking factor between the sponsors, sites, nurses, couriers, laboratories and suppliers. Making sure that every single patient can be visited by the right nurse, that couriers come to pick-up

samples and bring them to the right lab or site, that sponsors are informed about the visit and sites will get the correct study data. And last but not least, assuring high quality services.



Patient data integrity and privacy is our main focus. To request home trial support service for a specific subject, we need the patient name, phone number and address to be able to contact and visit the patient. Within a hospital, sharing this data is done on a daily basis, but to share this data outside the hospital can worry the site. As after the data leaves the hospital, the site is out of control where this data will be shared. The investigational team need to send this data outside the hospital. We can reassure that we treat this data with the highest care. A PI will complete patient data and visit(s) request on a specifically designed order form, and emails a signed scan to the country study manager (CSM). The CSM saves this form on the highly secured server, and also protects the file with a password. The attachment of the email will be deleted, so no patient details stays unprotected in the email inbox. Only the password protected order form will be shared with the nurses, and nurses are trained on how to handle these documents. That they can never leave it unprotected and that after a visit, any hardcopy will be destroyed and any digital version will be deleted from their computer. Nurses professional secrecy will never allow them to share any of this information with anyone they are not supposed to and the nurses confirm this also in a separate agreement with their employer.
Internally we also anonymise the order form, making sure no patient privacy details are on it anymore. We also save this document on our secured server. This is the document we share with parties that are not allowed to see any patient identity revealing information, such as sponsors. This is also the document we save in our hard copy trial master files.

When performing a visit, the nurse collect study specific patient data, such as vital signs, questionnaire, but also time points on which samples are collected etc. Study specific worksheets are created on which the nurse collects all this data, and which serve as a source document. These worksheets are only allowed to be completed and signed off by the nurse that performed the visit and study specific activities. These nurses are on the site's Delegation of Authority log, so handwriting and signatures can be double checked when needed. After the visit, the nurse emails a scan to the project manager, which

checks the data on being realistic and accurate. The project manager reviews every single document after every single visit, to ensure the highest level of data integrity. Besides, documents are reviewed on good documentation practices and any unclear issues are solved. Only the nurse that performed the visit is allowed to make any corrections, which are also only allowed to be made on the original source document. When a source document is completely reviewed, corrected when needed and marked as correct, the scan is shared with the investigational site, and the nurse will ship the original source document to the site. On site the source documents will be added to the patient dossier, which will be monitored by the CRA.

In first instance it can be difficult for some principle investigators (PI) and/or investigational teams to share patient identifiable information and hand over the responsibility of a patient and the related study activities to a second party like a home trial support service provider as sites are used to closely monitoring their patients themselves. But even though the patients are visited by a home care nurse outside the regular investigation team, and it's been guaranteed that the patient data is strictly protected and handled confidential and the PI always stays closely involved in the process of adding nurses to the team and always stays responsible for the patients' health. Credentials of the home care nurse are sent to the PI for review, and when preferred an introduction meeting with the site and the patient can be organised. When the PI agrees, the nurse will be added to the delegation of authority log. This way, the home care nurse is part of the investigational site team. Also it is the PI that need to request the specific patient visits, by completing, signing and sending in the order form. Nurses are not allowed to conduct any visit without the visit being requested by the PI on the order form. Therefore the PI is in full control which nurses are involved, which patient will be visited and for which specific study visits. Visits will never be performed without approval from the PI. Throughout the trial and the visits, the home care nurse and country study manager keep in close contact with the PI. Reporting scheduled visits in advance, patient health status and essential findings during or directly after visits, which is essential for a good communication between the parties. In this way the PI is always able to monitor the patient very closely.

We believe home trial support helps to make clinical trials more successful, finally resulting in a faster access of investigational products to the market, making it available for all patients. Therefore it is important that everyday more PI's and investigational teams feel comfortable with the home trail support, having our trust that patient data is handled confidential, patients are in good and professional hands, and obtained data during visits is accurate. Home trial support is a fast growing area, and will become a general part of most clinical research trials, because many companies are convinced of its huge benefits. We see a repeat business of 86%. To summarise, the advantages of home trial support are noteworthy:

- It reduces the number of hospital visits, which makes it less demanding for the patient and his/her family;
- It raises patient's inclusion and prevents from premature discontinuation of the trial;
- Site can recruit more patients – less workload for site staff;
- It results in high compliance. Fixed team of specialised trial nurses who work uniformly in accordance with the same procedures;
- Tailor-made appointments, in which the protocol is leading;
- Best possible service for the patient!

Authors:

Mirjam Bruggink, CEO of Clinical Trial Service B.V. in the Netherlands.

Mirjam.bruggink@clinicaltrialservice.com

Marieke Bons, Project Manager, Country Study Manager and Research Nurse at Clinical Trial Service B.V. in the Netherlands.

Marieke.bons@clinicaltrialservice.com

www.clinicaltrialservice.com