Clinius
More than a device CRO

Case Elekta

Specialist increases the effectiveness of clinical investigation

A clinical investigation of a medical device is a complex process, involving several stages. With the help of specialists, the entire process can be carried out quickly, effectively and successfully.

Elekta Oy carried out its very first clinical device trial in cooperation with Clinius Ltd. The trial was a so-called multi-centre study that was conducted at Meilahti Hospital and in Elekta's own research laboratory. The required medical expertise was provided by the BioMag Laboratory of Meilahti Hospital. In addition to designing the trial, Clinius was also responsible for its implementation as well as the provision of clinical expertise, both at the planning stage and during the conduct of the trial.

Clinius provides clinical services for technology companies. The services offered by Clinius include formal clinical trials, user-centric device testing, clinical training and user requirement assessments.

"We needed the expertise of Clinius in the planning and implementation of the trial, since we did not have the required resources. We never once considered doing it all on our own – you are faced with such a myriad of legal requirements and other specialised knowledge", says **Miikka Putaala**, Product Manager at Elekta.

Carrying out a clinical trial with an external expert organisation who are responsible for not only the planning and implementation of the trial but the provision of the clinical expertise as well, presented BioMag Laboratories with a new experience.

"This is a unique operating concept, and the experience was positive. Everything was handled well and efficiently", states Specialist Psychiatrist, Docent **Seppo Kähkönen** from BioMag, who was the investigator in charge of testing. Putaala also commends Clinius for the effective execution of the project.

Clinical trials of new devices and new features

Elektra's magnetoencephalography (MEG) system provides the means for the accurate localization of various brain functions, such as hearing or vision, on the cortex. In addition, it enables the monitoring of a variety of activities on the cortex with a precision of a millisecond. The product is based on measuring the magnetic field of the head using low-temperature superconductors. This is a globally unique system, representing Finnish excellence in the field of magnetoencephalography.

"By combining the geometric image acquired through MRI with MEG localization, we obtain a map of the brain's activity, which can then be utilised, for instance, during surgery. The MEG system has proved to be excellent in epilepsy research", explains Elekta's technical expert, Doctor of Technology **Jukka Nenonen**.

"The measurement process is painless and comfortable for the patient, but is, however, technically very complex. The signals are recorded with over 300 sensors immersed in liquid helium."

Brain research utilises highly sophisticated technology and the clinical trials of devices are extremely demanding. In Elekta's case, the study population had to include children, whose recruitment is particularly challenging.

Clinical trials must be conducted for new devices, as well as for new features to existing devices. Until now, Elekta has had no need for clinical trials, as it has been able to reference existing

medical research in its product development. However, this time, Elekta wanted to introduce new features that were based on patents held by the company and that were therefore not covered in existing literature.

Elekta's clinical trial consisted of testing the software which enables the device to tolerate head movements during the acquisition process, without compromising the accuracy of the results and which provides immunity to magnetic objects, such as braces and pacemakers, in the patient's body. During the trial, a lightweight magnetically shielded room and an active shielding method were also tested. These technologies represent a way to eliminate external interference on MEG systems using lighter and less expensive solutions.

Clinical trial plans, both quickly and to a high quality

Device trials, which are carried out in a clinical setting, are tightly regulated. Each trial must have an investigator in charge, who must be a physician. The protocols have to be documented in a trial plan that must be approved by competent authorities. These authorities include an Ethical Committee and the National Supervisory Authority for Welfare and Health. Once the plan has received appropriate approval, the trial can be launched.

"Even when a company has suitable contacts, the planning of a clinical trial can be a very time-consuming process, and the quality of the outcome may still leave a great deal to be desired. An appropriate trial protocol opens the way for respectable and valid results. In addition, it expedites the authority approval process as well as the implementation of the trial", states **Timo Parkkari**, Clinical Director at Clinius.

The trial that was conducted for Elekta was not entirely typical for Clinius; brain research is a rare field with highly sophisticated technologies. As Parkkari puts it, the entire process was at the frontier. Exceptionally, users were not interviewed, as the focus of the trial was on the analysis of measurement results.

Tailored recruitment

According to Seppo Kähkönen, a valid study protocol is crucially important for each trial and must be specified in the trial plan. In Elekta's case, the protocol included a definition concerning how to reliably study interference on the measurement caused by head movements and metal objects, as well as the criteria of reliable results.

"The study protocol is the basis for determining the types of subjects needed for the trial. Clinius then carried out the recruitment process according to the criteria. One central criterion was to have heads of different sizes, which meant the recruitment of children as well." Kähkönen commends Clinius for its well-executed recruitment process. Miikka Putaala and Jukka Nenonen are of the same opinion.

"Whereas the adult subjects were found from the registers maintained by Clinius, the recruitment of children was carried out as a tailored service. The youngest children were three years old. All in all, the recruitment process was handled very effectively", Putaala and Nenonen continue.

One or two of Clinius' Clinical Specialists were present during each study session. In addition, both BioMag and Elekta had their experts present. The measurements were carried out in collaboration by the experts from Clinius and Elekta.

"Elekta's system and the protocol are such a complex combination that the presence of Elekta's experts was indispensable. Although it is generally desirable for the technical expert of any given product to be present during all the testing sessions, this is not always the case. In any event, our clinical experts will also observe the performance of the tested device throughout each project", emphasises **Miikka Maijala**, CEO of Clinius.

Maijala continues: "There was no need to search for a location for Elekta's trial, as the company was already working in close cooperation with the BioMag Laboratory. In the more common scenario, our clinical trial service includes the selection of the trial site, as well as taking care of the related agreements."

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