

IT solution with a heart

Hannover Medical School trusts TrialComplete for its clinical trials

Reference project:



“We are very pleased that Telekom Healthcare Solutions developed a system that securely merges both MRT image data and trial data.”

Prof. Samir Sarikouch, Head of the clinical trial and senior physician at Hannover Medical School

Children with heart problems? Usually, this topic hardly gets any public attention – but still: heart defects are the most frequent malformation afflicting unborn children. Around every 100th child is born with a heart defect. At the Clinic for Heart, Thorax, Transplant, and Vascular Surgery of Hannover Medical School (MHH), afflicted children are given new heart valves. Traditionally, these heart valves were artificial, as is the case with adults. But there are several major drawbacks to this approach: Firstly, artificial heart valves do not grow with the children’s bodies, and secondly, they are often rejected – necessitating further operations to replace them in later years. What’s more, the children have to take blood-thinning medications.

More than ten years ago, the Clinic began researching a visionary alternative: giving the children actual, decellularized heart valves from human donors. These heart valves have the donor’s proteins chemically removed. The theory: These “homografts”, suitably treated, would be better accepted by the recipient’s body and would grow as the child developed – just like a natural heart valve. The Clinic launched an internal research project that was awarded EU funding: the European clinical study of regenerative heart valves, or ESPOIR for short.

To prove the success of this new therapy, the treated children had to be meticulously monitored over many years. The development of the implanted heart valves was tracked through regular MRT (magnetic resonance tomography) scans.

At a glance

- Structured, data protection-compliant uploading of (image) data to appointment schedules
- Pseudonymization and traceability of data mapping
- Consolidation of data from different sources (medical and imaging methods)
- Solution: TrialComplete, developed by Telekom Healthcare Solutions
- Single point of truth for data
- Operation in a T-Systems data center
- Needs-based use as a web application

Reference in detail

The challenge

The multiyear study generated many terabytes of data from the imaging processes. This data is supplied by many different PAC (Picture Archiving and Communication) systems from the connected hospitals in Moldavia, Italy, France, Belgium, the United Kingdom, and the Netherlands. But the images are only one part of the study. To enable valid claims, they have to be linked with the patients' corresponding medical data, but such data is usually stored in separate systems. Another challenge was posed by the pseudonymization of the data, which was necessary for data protection reasons: experts for clinical trials assume that a significant portion of the collected data cannot be used, because the data mapping cannot be clearly reconstructed.

The process for the clinical trials required a solution that not only made it possible to reconstruct the mapped data over long trial periods, but also reliably protected the personal data of the participating children and gave targeted support to collaboration on the project.

The solution

“These requirements are obvious – yet no suitable system was available on the market,” explained Prof. Samir Sarikouch, head of the clinical trial and senior physician at MHH. A large portion of the research work was still conducted manually. The Clinic found this method to be unacceptable – especially for a project with an international dimension like this one. TrialComplete, the trial management system developed at the time by Telekom Health-care Solutions, enables pseudonymization and archiving of both the medical and imaging data in a standardized format (DICOM), supporting the trial process. The web application is accessed using browser software on hospital PCs, with the same procedure used by the participating hospitals throughout Europe. There is no need to install separate software or purchase licenses. The application itself runs in a T-Systems data center – ensuring that the infrastructure meets all demands for security and data protection. As such, TrialComplete was ideally suited to ESPOIR. “TrialComplete gives researching scientists a ‘single point of truth’ – the data is stored centrally, where we can sort and process it as needed. We can see the filtered data records completely and instantly, to get started with our work,” summarizes Prof. Sarikouch. Because it runs in a private cloud, TrialComplete is scalable. If the number of participants in a trial increases significantly, the cloud can provide additional resources, ensuring user-friendly work can continue.

Customer benefit

TrialComplete simplifies collaboration in international research projects. All interrelated data is correlated transparently, creating a solid foundation for the evaluation of clinical trials. Usability is further enhanced by the elimination of media disruption between the different systems – a single system reliably covers all requirements for conscientious treatment of the trial. The storage for the extensive image data is scaled automatically. It requires no IT investments or maintenance costs for applications or infrastructure, because T-Systems takes care of maintaining all the IT components. As a result, researchers have more time for the work that is really relevant: producing solid trial results that enable children with heart defects to live better lives.

Further advantages:

- Project support with full data protection compliance
- Efficient collaboration
- Needs-based usage and costs
- Additional use case for pharmaceutical trials
- Deployable quickly, anywhere

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