

"TrialComplete is a professional, contemporary tool that lets us input our trial image data regardless of location and make it available to researchers without complication."

Dr. Julia Hoffmann, German Centre for Cardiovascular Research (Deutsches Zentrum für Herz-Kreislauf-Forschung e.V.)

Cardiovascular diseases are still the number one cause of death in Germany. Heart disease is often chronic, dragging on for years and decades, burdening the lives of patients and their families – and the healthcare system. In 2012, Germany's Federal Ministry of Education and Research launched an initiative under which five nationwide centers for widespread disease were founded. One of them is the German Centre for Cardiovascular Research (Deutsche Zentrum für Herz-Kreislauf-Forschung e.V., or DZHK for short), with its main office in Berlin. It contributes to the development of new diagnostic methods, therapies, and drugs to make life easier for disease sufferers. To this end, the DZHK brings basic researchers together with clinical researchers. It promotes collaboration to speed up the development of new methods.

The DZHK has a decentralized organization. It consists of 32 partner institutions at seven locations, which all have a high degree of autonomy in their research. They cover the full spectrum of cardiovascular research – and even achieve a high standard by international comparison The partner institutions include 14 university hospitals and universities, as well as centers of the Helmholtz Association, Leibniz and Max Planck Institutes, and a departmental

research institute. As such, the DZHK unifies the activities of more than 1,800 scientists under its roof, capturing synergy effects. A key step in translation – the transfer of results from basic research to application – is having reliable, high-quality, well-documented clinical trials. To accomplish this, the DZHK relies on TrialComplete as an important component of its system landscape.

At a glance

- · Reliable, privacy-compliant use of image data from clinical trials
- · Consolidation of data from various sources
- Pseudonymization
- Audit compliance: Traceability of data mapping
- Solution: TrialComplete, developed by Telekom Healthcare Solutions
- · Single point of truth for data
- · Operation in Deutsche Telekom data centers
- · Needs-based use as a web application
- · Used for Covid-19 trials



Reference in detail

The challenge

To move forward in research, you need verifiable data. And the need for data continues to grow: cardiovascular research, in particular, requires ever-larger trials, patient registries, and biobanks to make progress. Research institutes have to comply with certain rules to participate in clinical trials: for example, participants have to keep their trial results ready transparently and verifiably over a period of 10 years. The data also has to be compiled from different sources, such as patient data, clinical data, data from imaging techniques, and trial data - and without violating privacy requirements. This poses a particular challenge when research projects are distributed across multiple locations: different documentation and archiving methods (some of them not even digital) are used in a variety of systems. Critical points include the pseudonymization of image material and media disruption due to distributed teams. The trial employees are often only involved for the duration of the trial; in the worst case, documents and records end up in drawers on or shelves. This impedes the work of the scientists and makes it more difficult to verify trial results subsequently. In 2017, the DZHK with its federal structure decided to tackle these challenges fundamentally: with a professional image management system for professional research – one that can be used across locations.

The solution

The DZHK decided in favor of TrialComplete from Telekom Healthcare Solutions. This solution supports the full trial process end to end. It enables pseudonymization and archiving of medical and image data in standardized data formats, such as DICOM and CDISC-ODM). This means the data is saved in a central location. All authorized scientists have access to a standardized, consolidated data pool. Since the solution is provided as a web application, no local software installation is needed. The application and the image data are provided from Deutsche Telekom's secure, privacycompliant, mirrored data centers in Germany. The researchers access TrialComplete using browsers on their institutions' internal PCs. TrialComplete scales with demand, which means if many researchers access the system concurrently, additional resources are provided to maintain performance. Storage space grows along with the continuously increasing data volume. In addition, Telekom Healthcare Solutions integrated TrialComplete with the existing system landscape at the DZHK, making it possible to consolidate work over multiple resources.

Customer benefit

With TrialComplete, the DZHK has a professional system to support clinical trials. Scientists can use the image data they need quickly and easily. Audits are no problem, either: the data is consolidated in a typical trial structure using electronic case report forms for each specific project, making the mapping verifiable – and ultimately the results as well. Most importantly, TrialComplete supports collaboration across multiple locations. A differentiated role/permissions concept makes the relevant results and raw data from participants in the network available to other connected research institutions, easily and selectively. New research projects can be created easily at any time and supported by an extensive scope of functions. The platform is currently (2021) supporting Covid-19 research: On behalf of the National Research Network of University Medicine (NUM), medical image data from 11,000 subjects is being recorded for three cohorts, to gain insights into the long-term consequences of Covid-19 illnesses. As such, the data can also be used to explore legitimate questions that go beyond the objective of individual trials.

Further advantages:

- · Project support with full privacy compliance
- · Efficient cross-site collaboration
- · Needs-based usage and costs
- Rapid deployment
- Can be used flexibly for current study requests

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