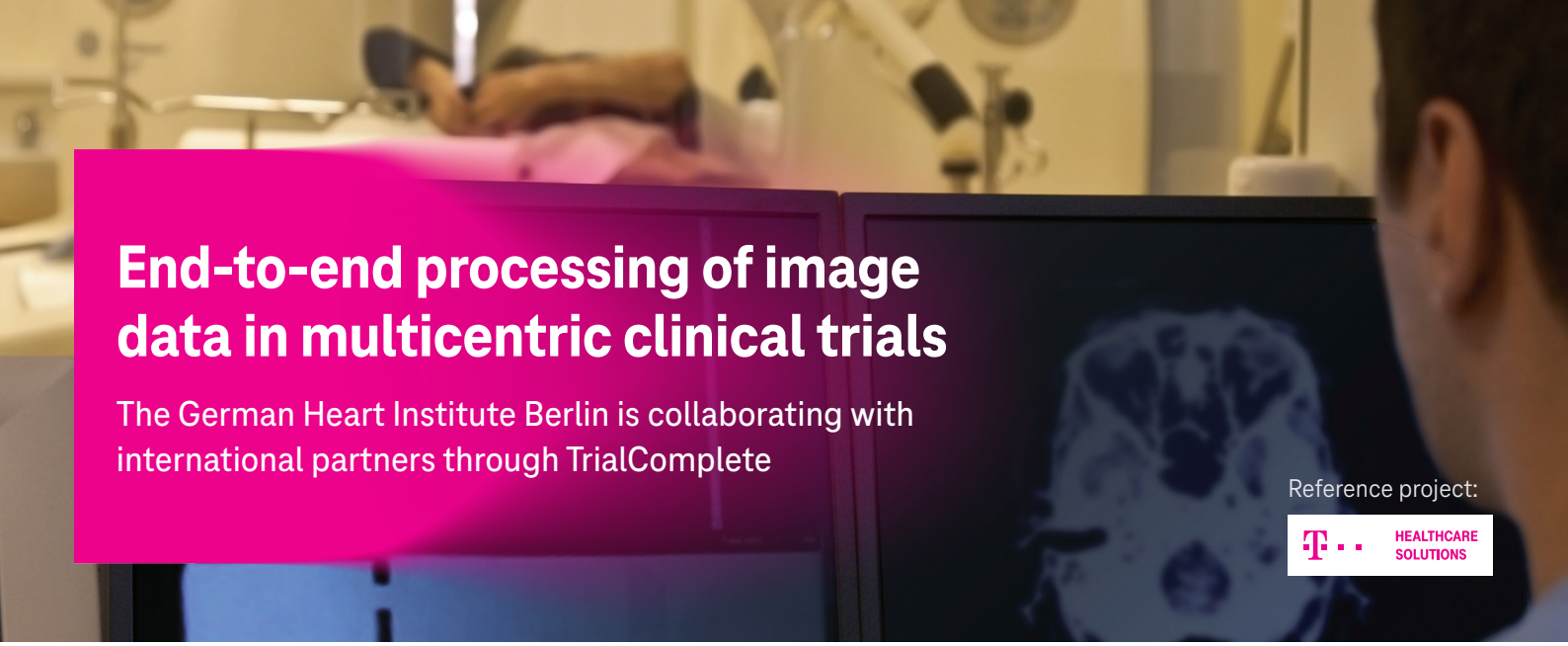

End-to-end processing of image data in multicentric clinical trials

The German Heart Institute Berlin is collaborating with international partners through TrialComplete

Reference project:

HEALTHCARE SOLUTIONS

“The TrialComplete portal solution is directly available, scalable to our needs, and easy to use. It simplifies the management of trials significantly and lets me devote my efforts more to the subject matter again.”

Prof. Dr. Titus Kühne, German Heart Institute Berlin

The German Heart Center Berlin is one of the largest heart centers in the world and a leading center of research with numerous international partners. In addition to innovations in the area of surgical and heart catheter-based procedures, a major focus of its research is non-invasive multimodal imaging. In the pan-European clinical trial Cardioproof, the heart center relies on TrialComplete to execute the trial contents with effective processes. TrialComplete is a web-based clinical trial portal that enables researchers at the participating centers to input trial and image data, analyze it, and perform quality assurance independently of location. Since it is operated in Deutsche Telekom’s data centers, all stakeholders can access the portal easily and securely, while a professional team takes care of protecting the data.

At a glance

- Clinical trial platform with integrated imaging data management
- Web-based solution enables even decentralized trials
- Operation on the Dynamic Healthcare Center (DHC) platform in Germany
- Fully scalable system, which means costs can be calculated based on the number of subjects and the duration of the trial, for example

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Reference in detail

The customer

The German Heart Institute Berlin (DHZB) was founded as a foundation under civil law in 1986. In its articles of incorporation, the DHZB declared its aim of meeting the highest standards of quality in the field of heart surgery and cardiology and ensure cutting-edge medical care in this area. Up to 3,500 open-heart surgeries are performed annually using a heart-lung machine. In addition, more than 4,000 heart catheter exams are performed at the three heart catheter laboratories each year. Of these, more than 2,000 involve highly complex interventions such as the replacement of a heart valve using catheter technology. Specialized, non-invasive diagnostics are performed by two high-performance MRI scanners, a computer tomography system, and a number of ultramodern echocardiography instruments. Another focus of the DHZB is congenital heart defects, for which all age groups are treated – from newborns to senior citizens. With 400 operations and around 700 heart catheter exams each year, the Institute is an absolute front-runner for congenital heart defects and pediatric cardiology in Germany and Europe. The German Heart Institute Berlin is very well-connected in Germany and internationally. More than 50 collaboration contracts and agreements have been signed with heart clinics, including abroad – primarily in China, but also in Eastern Europe and the Asia-Pacific region.

The challenge

As a top medical institute with international collaboration partners, the DHZB conducts a wide variety of research activities. The DHZB is diversified and covers the entire spectrum of diagnostic and therapeutic procedures. The increasing importance and further development of imaging is a strong focus here. Methods such as non-invasive imaging, as used in the EU Cardioproof trial, represent an important cornerstone. Cardioproof is coordinated by the DHZB and involves the participation of partners from the Austria, France, Italy, and the UK. The Cardioproof trial is examining innovative imaging and analysis technologies in which the image files take different routes from the exam center to assessment. A key issue here is ensuring that once initially assigned to a trial subject, image files continue to be processed in their context without media fragmentation, ensuring that the assignment between image files and subject is retained at all times. Another challenge involved developing a solution that can adequately record, format, and provide image data locally, to make the exchange of data simple and secure.

The solution

TrialComplete is a platform for image-based clinical trials, with essential functions like a permission and role concept and audit trails. It makes it possible to model a trial design easily in the user interface. TrialComplete records the image material through this interface and integrates it in the correct context within the trial without any media fragmentation. Sophisticated split and merge functions make it possible to prepare complex sets of image data for specific applications, before an expert releases them for further use. For example, TrialComplete is capable of recording DICOM data from a wide variety of modes and manufacturers, examine them in the integrated DICOM viewer, and survey them. The image files remain reliably available in context for subsequent use even after a trial is complete. What's more, since TrialComplete is used as Software as a Service and runs in Deutsche Telekom's high-security data centers in Frankfurt, the DHZB is relieved from having to perform the complex network modifications that would be required if the platform to facilitate the exchange of image data between the involved external partners ran at an internal data center.

Customer benefit

In TrialComplete, the German Heart Institute Berlin has an infrastructure that effectively supports its "Cardioproof" trial. The first step involved the simple implementation of the trial design, with the possibility to test it intensively under real conditions before going live. During the course of the trial, image data can be recorded at the exam center, assigned to the respective subject session, and stored. A central quality assurance instance releases the image data before it is assessed in other centers, using the integrated viewer, or exported to specific software systems – some of which are still experimental – and the results are stored in the right context in TrialComplete. As a result, not only is the entire trial process documented in a single system; the image documents related to the trial are also integrated. This means the context between image data and other trial data is retained even after the trial is concluded. Both are available for subsequent use, making it possible to glean further knowledge from the existing data with just a minor effort.

Contact
T-Systems International GmbH
Hahnstraße 43d
60528 Frankfurt am Main, Germany
Email: referenzen@t-systems.com
Internet: www.t-systems.com

Published by
T-Systems International GmbH
Marketing
Hahnstraße 43d
60528 Frankfurt am Main
Germany

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