TrialComplete Science Edition:
Study documentation, image data management and process efficiency

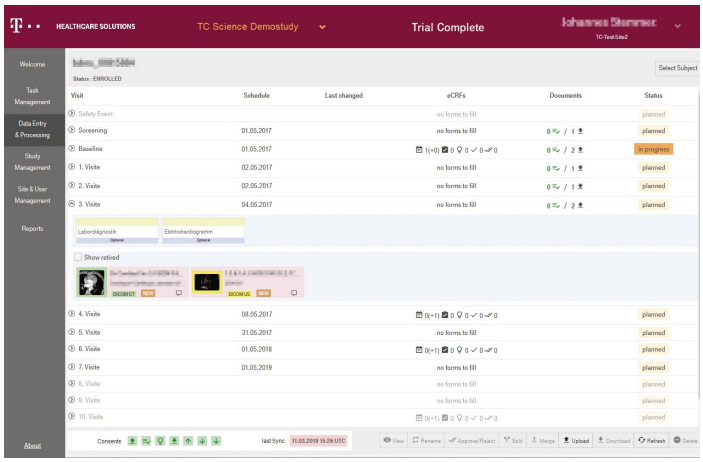
The TrialComplete Science Edition makes it possible to manage and archive clinical trial data including (image) data in DICOM format. The web-based work environment makes it easy for research teams at universities, hospitals, and pharma companies to process multicentric, pseudonymized image data without media fragmentation. Research data can be collected, shared, rated, and analyzed more efficiently. The location-independent data management system is scalable for studies of all sizes, providing transparent cost planning and control. The recorded research data can be transferred into a protected long-term archive, from which it can be easily migrated to other systems. Security is guaranteed through the use of ISO/IEC 27001-certified data centers operated by Deutsche Telekom, which of course satisfy the requirements of the General Data Protection Regulation (GDPR).

HEALTHCARE SOLUTIONS

Portal Solution

TrialComplete is an online portal that gives virtual users from study institutions cross-study access – upon authorization – to research and study data:

- Information about incoming messages (such as confirmations of image data uploads or references to received questions and queries)
- Management of tasks to be performed (such as signatures and monitoring of forms, approval of image documents)
- Processing of queries (user involved as enquirer, direct recipient, or member of a recipient group)



Study design – interoperability with external CDM-Systems

Based on CDISC ODM/SDM models, the data management system provides an established standard for study design and for sharing study data:

- Import of study designs from an external source, as well as manual creation in an Excel worksheet and download for external further use
- Synchronization of work by different groups of users in separate systems through configurable, bi-directional data exchange with the external CDMS

Pseudonymization – Collaboration with external services

The strict separation of medical and identifying data is achieved in TrialComplete through the sole use of pseudonyms:

- Customer-specific, embedded iFrame with an external pseudonymization service for the assignment of volunteers based on identifying data
- If no interface to the pseudonymization service is available users can access test subjects through known pseudonyms

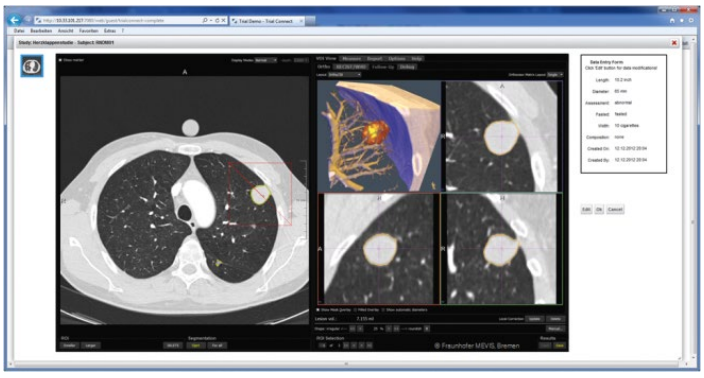


Image data – fully integrated processing

TrialComplete supports the processing of multicentrically created, pseudonymized image data free of media fragmentation – from uploading to data storage in the clinical forms:

- The TrialComplete Upload Client enables the uploading of DICOM image data as local files, without prior installation.
- The optional TrialComplete Gateway software establishes a connection to the local PACS – image data can be directly retrieved and uploaded from there.
- The uploaded image data is uniquely assigned to a test subject examination.
- Image data is pseudonymized based on a customer-specific profile and uploaded to the TrialComplete Server through a secure Internet connection.
- DICOM images from the TrialComplete Browser are displayed using the integrated viewer.
- The DICOM viewer enables the measurement of image data using standard measurement methods, as well as experimental, customer-specific algorithms, along with the automatic transfer of measurement data to configured (electronic) clinical report forms (eCRFs)..

Interfaces

A key feature of TrialComplete is its integration in customer-specific system landscapes. The following interfaces are available, among others:

- Data exchange with external CDMSes
- Pseudonymization from other service providers possible via iFrame
- Authorized systems (such as external image processing or report tools) can retrieve study and image data from TrialComplete via REST interfaces

Find out more at
www.telekom-healthcare.com
E-mail: info@telekom-healthcare.com

Publisher and Contact
Deutsche Telekom AG
Telekom Healthcare Solutions
53262 Bonn, Germany