TrialComplete Early Phase Edition:
Study documentation, process management and subject management

The TrialComplete Early Phase Edition (TCEP) data management system simplifies the organization of complex clinical studies – particularly the three-phase approval process for drugs. It is designed for conducting brief studies and coordinating process schedules of studies in early phases. Organizations spread across multiple countries and continents can elect to use decentralized, consolidated data processing in the worldwide data centers of Deutsche Telekom and its partners. This approach guarantees productivity and performance in all regions. At the same time, the clinical study documentation system enables a pan-organizational overview of all studies, while the individual centers and users work on their studies based on their own roles and permissions.

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

Subject management

Subject management is very important in the early stages of studies, in particular, because volunteers often take part in studies repeatedly. As such, the corresponding features have been integrated in the Early Phase Edition:

- Consolidation of volunteer data from previous study participation in modularly delimited subject management
- Targeted suggestion of volunteer invitations (waiting period after last study, known matches with inclusion/exclusion criteria) and management of responses
- Organization of volunteers in cohorts for joint execution of studies

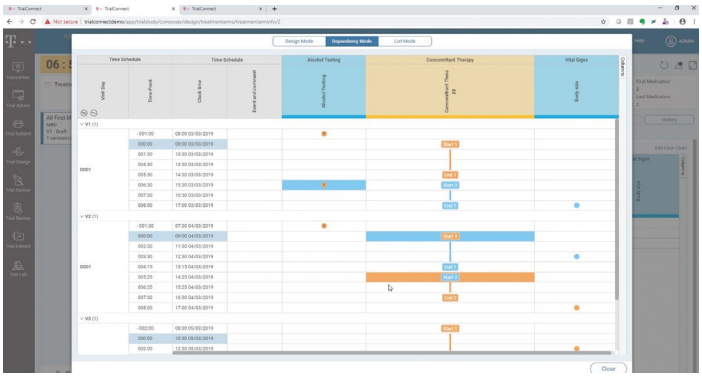
Process control

While most clinical studies focus on recording data in eCRFs (electronic case report forms), in the early phases, they are closely linked with other processes, which can be easily controlled with TrialComplete:

- Creation and reuse of custom eSource CRFs and their components, in line with the CDISC standard
- Customer configuration of workflows (such as the study cycle or status transitions of volunteers)
- Adaptation of procedures (such as blood sampling, examinations, lab work), including time dependencies and conformation (such as scan of employee ID card, password entry at the beginning or end of the procedure) and specification of work steps.

Device integration

TrialComplete features an interface framework that enables the inclusion of data from medical measurement devices (scales, blood pressure, ECG, etc.) directly in the procedures. This ensures that all data can be processed free of media fragmentation.



Lab integration

Laboratory data is a crucial, data-intensive part of clinical trials. The lab module of TCEP simplifies the handling of these complex datasets:

- Creation and dispatch of lab orders and accompanying documentation within the corresponding procedures
- Accept lab results from multiple external laboratories and submit them to the responsible clinical physician for review
- The clinical physician can reject the data, send it back to the lab for another review, or accept it – thus adopting it in the involved eCRF.

Libraries and Catalogs

In contrast to other solutions, T-Systems TrialComplete libraries and catalogs are extremely configurable to meet your needs.

- With 160+ catalogs
- Use of any language, including internationalization of user-maintained date and time formats
- Ability to coordinate global data across multiple time zones (use of UTC times)
- Easy to adjust your master date to a myriad of study combinations

Validation support

Researching pharmaceuticals companies and contract research organizations (CROs) are responsible for validating their processes for the FDA (U.S. Food and Drug Administration) and/or the EMA (European Medicines Agency) – the use of TrialComplete Early Phase is no exception. In this regard, the solution supports validation through:

- A software development life cycle organized and documented in compliance with GAMP 5.
- A modular approach that restricts the scope of validation after updates of sub-components, by risk assessment.
- Pre-validation of the software and operation as software-as-a-service in the framework of Telekom Healthcare Solutions-internal quality assurance and release („Validation Package“ with release certificate and accompanying documentation).
- Professional customer service..

Reports

A report management feature is integrated in the data management system as a convenient option for outputting study information. This method makes it possible to generate a variety of existing reports in Excel and/or PDF format, as well as generate new reports.

Find out more at
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