TrialComplete Clinical Data Management System

The TrialComplete Early Phase Edition (TCEP) data management system streamlines the intricacies of organizing complex clinical studies, with a focus on the three-phase drug approval process. Tailored for concise studies and seamless coordination of early-phase processes, TCEP offers a dynamic solution. Organizations spanning multiple countries can leverage decentralized, consolidated data processing in Deutsche Telekom's global data centers, ensuring productivity and performance across diverse regions. The system provides a pan-organizational overview of all studies, allowing individual centers and users to collaborate based on their roles and permissions.
Security is paramount, upheld by ISO/IEC 27001-certified data centers operated by Deutsche Telekom, fully compliant with the General Data Protection Regulation (GDPR). This ensures the safeguarding of sensitive clinical study data throughout its lifecycle.

Key Features:

Science Edition:
- Manages and archives clinical study data, including DICOM format image data.
- Integrates large image datasets from multicentric networks into one flexible data management system.
- Enables seamless collaboration for research teams with a web-based work environment.

Subject Management:
- Consolidates volunteer data from previous study participation.
- Offers targeted volunteer invitations based on inclusion/exclusion criteria.
- Organizes volunteers in cohorts for joint execution of studies.

Lab Integration:
- Simplifies handling of complex, data-intensive laboratory datasets.
- Facilitates creation and dispatch of lab orders within corresponding procedures.
- Enables acceptance of lab results from external laboratories, with clinical physician review.

Validation Support:
- Supports validation processes for FDA and EMA compliance.
- Adheres to GAMP 5 guidelines with a modular approach for risk assessment.
- Pre-validation of software-as-a-service within Telekom Healthcare Solutions.
- Professional customer service and a comprehensive "Validation Package" with release certificate.

Early Phase Edition (TCEP):
- Streamlines complex clinical studies, especially in the three-phase medication approval process.
- Specialized features for subject management, process control, lab integration, libraries, catalogs, and validation support

Process Control:
- Customizable eSource GRFs aligned with CDISC standards.
- Customer-configurable workflows and procedures.
- Adaptation of procedures, including time dependencies and confirmation steps.

Libraries and Catalogs:
- Highly configurable libraries and catalogs (160+ catalogs).
- Supports any language, including internationalization of user-maintained date and time formats.
- Coordinates global data across multiple time zones using UTC times.

TrialComplete empowers researchers, pharmaceutical companies, and CROs by providing a secure, flexible, and validated platform for efficient and compliant clinical data management.

For more information and personalized 1:1 sessions to explore TrialComplete's capabilities, contact T-Systems. Elevate your clinical data management experience and accelerate your research journey with TrialComplete.

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T Systems

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