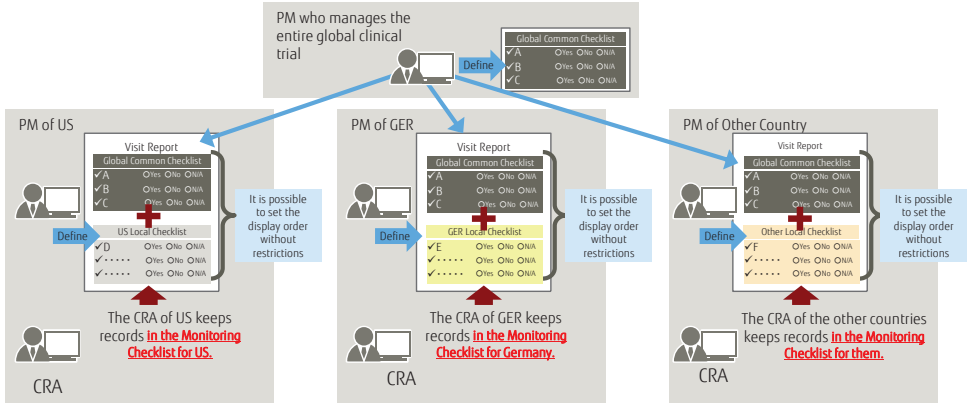
Image of Operational Flow

Monitoring

In global clinical trials, you can carry out appropriate monitoring processes in compliance with requirements for clinical trials and regulations specific to your country by defining a monitoring checklist for each country.

- Standardizing a format for monitoring records ensures reliable quality and reduces the workload for evaluating, analyzing and making decisions regarding the collected monitoring data.



Managing Issues

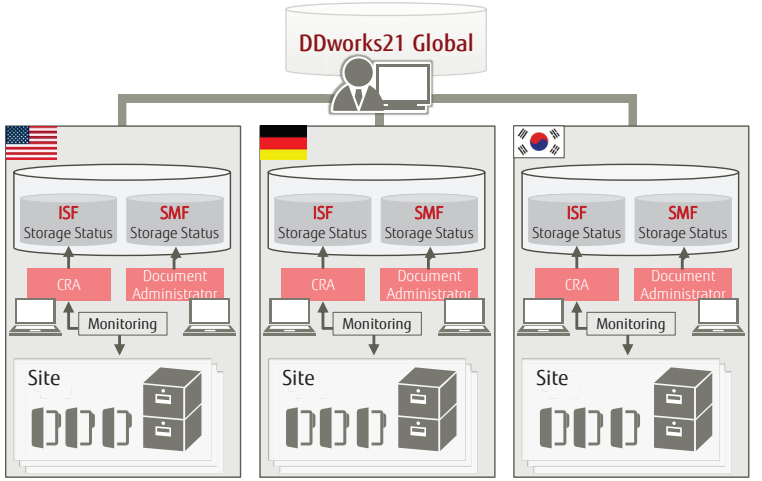
Regarding issues that occur during a clinical trial, you can confirm their impact on the study and necessity for corrective/preventive actions and implementing countermeasures.

- You can manage issues by country, site, or CRA, and analyze them from various aspects, such as situation of occurrence or response and the amount of time required to respond to issues and categories, so that you can utilize the results to evaluate the clinical trial.

TMF Management

You can be flexible in adding or deleting documents for each protocol or country based on the standard document master data (based on the DIA TMF Reference Model version 2.0) so that TMF tracking and management suitable for that country becomes available.

- By viewing stored TMF in a timely manner, you can effectively and efficiently check the GCP compliance status by each protocol/country.



ISF: Investigator Site File SMF: Sponsor Master File

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http://www.fujitsu.com/global/solutions/life-science/tsclinical/ddworks21global/

FUJITSU

Overview of Service/Solution
FUJITSU Life science Solution tsClinical DDworks21 Global

Enhance the Quality and Visualization of Global Clinical Trials without Compromising Good Clinical Practice (GCP) Compliance.

tsClinical DDworks21 Global

Customer Benefit

Streamline and Accelerate Clinical Trials with the DDworks21 Global Software Solution

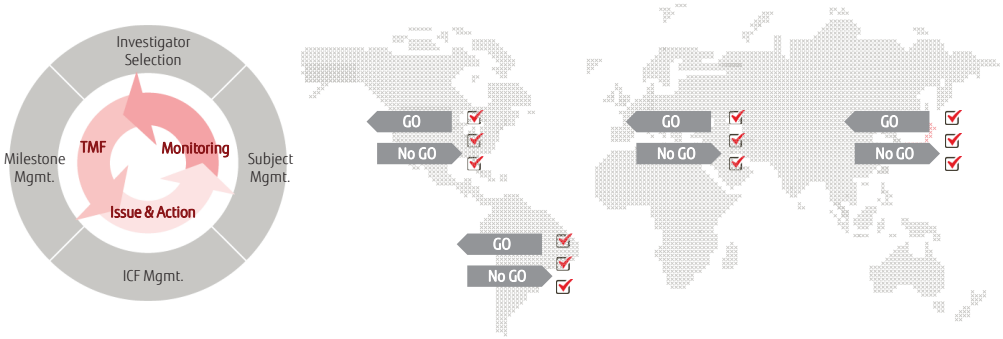
Fujitsu's DDworks21 Global is a software package designed to ensure that clinical trials are conducted according to GCP guidelines and are enabled to provide accurate and real-time reporting of clinical trial status. The solution is specifically engineered to enhance visualization of global clinical trials and standardize and streamline operations. DDworks21 Global helps reduce risks and provides assurance of the quality of clinical trials regardless of region, while also proving to third parties that clinical trial processes are consistently properly conducted.

Enhanced Reaction: DDworks21 Global allows organizations to make timely decisions, immediately detect problems, and maintain regulatory accountability.

Improved Information Access: With DDworks21 Global, study information can be obtained in a timely manner. Additionally, the solution offers multi-dimensional information analysis and eliminates reformatting workloads.

Mitigated Quality/Compliance Risk: DDworks21 Global offers access to best-in-class monitoring and TMF tools, and ensures a GCP compliance baseline through proactive GCP alerts.

Resource Savings: The solution reduces the workload and time duration of clinical trials while improving their quality.



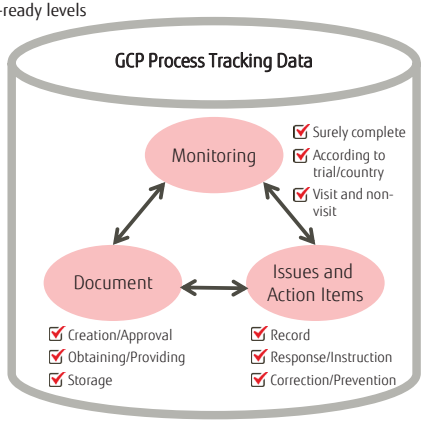
What is DDworks21 Global?

Ensure GCP Compliance with DDworks21 Global

DDworks21 Global performs appropriate and comprehensive monitoring of clinical trials–while complying with country-specific regulations and requirements for clinical trials–by defining a monitoring visit checklist for each clinical trial or country. This solution accurately records and tracks support and regulation violations so that corrective actions can be taken as needed. DDworks21 Global provides all stakeholders associated with the clinical trials a comprehensive view of issues to be observed, action plans, and follow-up review statuses. Using DDworks21 Global, you can not only create, manage, and track TMF throughout the document's life cycle, but you can also manage and track TMF status and keep TMF documents after enabling them.

Features:
- Database structure that provides complete visualization and tracking of monitoring, compliance, and issues
- Meets 21 CFR Part 11 Rule on electronic records and signatures
- Company-wide system that ensures work performance is sustained at inspection-ready levels
- Relational database of monitoring, documents, issues and action items

Monitoring	- Monitoring visit reports and contact reports (PI/Site, CRO and Vendor etc.) can be created, submitted, approved, and managed - Can define the report type, report checklist, and approval route without restriction
Issues and Action Items	- Eliminating time lags in detecting issues - Having the capability to quickly identify causes and completely resolve problems - Facilitating prompt and appropriate measures without any omissions - Having built-in preventative measures for problems of an identical or similar nature - Reducing the workload, eliminating unnecessary processes, and preventing a loss of credibility
Document	- Simplifying management-targeted TMF documentation lists that can be easily distributed to essential personnel - Visualizing TMF document status from creation to storage - Immediately detecting missing TMF documents - Master data of TMF is based on the DIA TMF Reference Model version 2.0



Why Fujitsu?

Why Choose Fujitsu Healthcare Life Science Solutions?

Fujitsu has proven business expertise in life sciences industries and a tradition of excellence in system application and integration. Since entering the life sciences market in the 1980s with the development of software packages in the drug design field, Fujitsu has accumulated considerable experience in providing IT solutions that add value to customers' businesses and help them to improve their competitive position and make more informed decisions.

Offering integrated care concepts that bridge various medical disciplines, Fujitsu provides more than 60 solution packages that cover entire business areas, such as drug discovery, R&D, and sales. With its wide range of technologies and specialized product design and manufacturing, Fujitsu also has the flexibility to address rising costs while promoting new, effective delivery of life sciences.

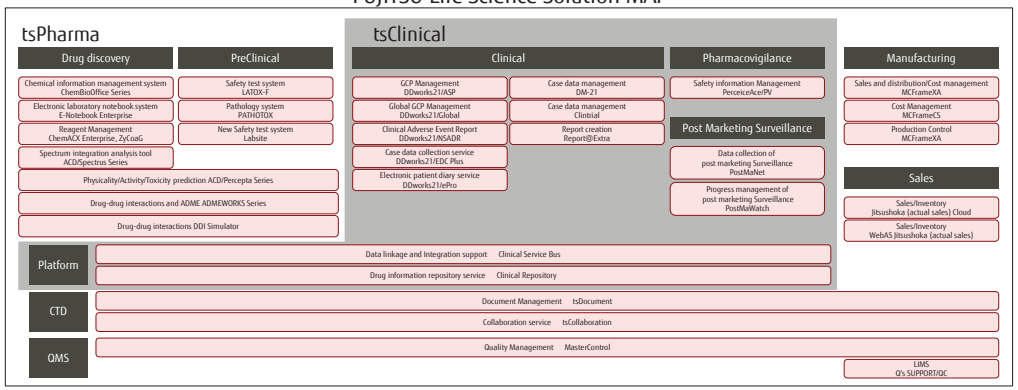
Fujitsu has the strongest presence in the medical IT market in Japan with approximately 300 systems engineers for life sciences companies that provide support for large and mid-size companies. For medical institutions such as university hospitals, municipal hospitals, and hospital complexes, Fujitsu's market share is approximately 50%. In addition, our global presence–combined with an ability to react locally–provides Fujitsu with a comprehensive knowledge of vertical market needs.

Our vast experience in developing CSV-related information systems and integrating in GxP areas includes CTMS, CDMS, EDC and Statistics, PV, and CTD/eCTD-related areas utilizing EMC Documentum ECM suites. Fujitsu also has a strong knowledge of non-CSV information systems and developing and integrating such business applications as CRM, SFA, BI/DWH, scientific information retrieval, intellectual properties management, and so on.

Fujitsu's benefits-driven approach to the design and delivery of programs ensures an effective, comprehensive project lifecycle from the lab to the patient's bedside.

GxP: Good Laboratory Practice, Good Clinical Practice, Good Manufacturing Practice CTMS: Clinical Trial Management System CDMS: Clinical Data Management System
EDC: Electronic Data Capture PV: Pharmacovigilance

FUJITSU Life Science Solution MAP



Case Study

Customer	A Pharmaceuticals
Customer's Requirements	Ensure quality and mitigate risks: Common issues cited in FDA warning letters under "Violations Pertaining to Patients" (above) fell under three areas of informed consent, protocol deviations, and drug disposition.
Key Points	Establish and Maintain an Effective CQMS (Clinical Quality Management System) - Effective Clinical Trial Management: - Timely Notification, Effective Monitoring: - Thorough Data Collection: - Standardized Documents and Processes:
Customer Benefits	-Inspection Readiness: A CQMS will serve as a structure and platform that will keep you always prepared for an inspection, allowing all stakeholders to focus on quality and compliance processes and also make it easier to manage those processes on a daily basis.
Customer	B Pharmaceuticals
Customer's Requirements	- CAPA as a Supplement to Risk-Based Monitoring - the PDCA Approach - Ensure that the TMF is Complete - Leverage the Flexibility of Monitoring Visit Reports
Key Points	Establish CAPA and Risk Management as Part of CQMS
Customer Benefits	A robust CQMS that will help you mitigate risks, maintain high quality data and information across trial sites, and ensure compliance throughout the life of the clinical research.