FUJITSU

Fujitsu Life Science Solution

tsClinical DDworks21 Global

What is tsClinical DDworks21 Global?

tsClinical DDworks21 Global is a solution focusing on the quality management in global clinical trial. Recently, the U.S. Food and Drug Administration and European Medicines Agency start to consider quality management processes of clinical trials by pharmaceutical companies as important. tsClinical DDworks21 Global can provide reliable and efficient quality management for the clinical trials by visualizing the quality management processes of the global clinical trials (e.g., deviation from a protocol).

Concept

tsClinical DDworks21 Global manages GCP compliance, responses to issues, visualization/tracking of risks to be addressed, monitoring, and TMF all together, therefore, it provides you with high-quality support of clinical trial operations with the effective and efficient quality management process.

*TMF: Trial Master File

Features and Merits

Provides flexible settings for each country based on ICH-GCP

With the templates of global common monitoring items and TMF lists that Fujitsu provides, you can manage monitoring process of each country only by making simple changes on the setting.

Visualizes progress of global clinical trials and standardizes the quality

You can manage monitoring records meet requirements of clinical trial or country and track the responses/instructions and correction/prevention regarding issues. With these functions, you can visualize progress of clinical trials in a timely manner and standardize the quality of clinical trials without depending on regions/people.

Ensures the traceability by linking monitoring information, issues, and TMF

Monitoring information links with information of responses to issues and obtaining/providing TMF, it becomes possible to ensure traceability easily and effectively and enable third parties to view the situation (internal audit, on-site inspection).

shaping tomorrow with you

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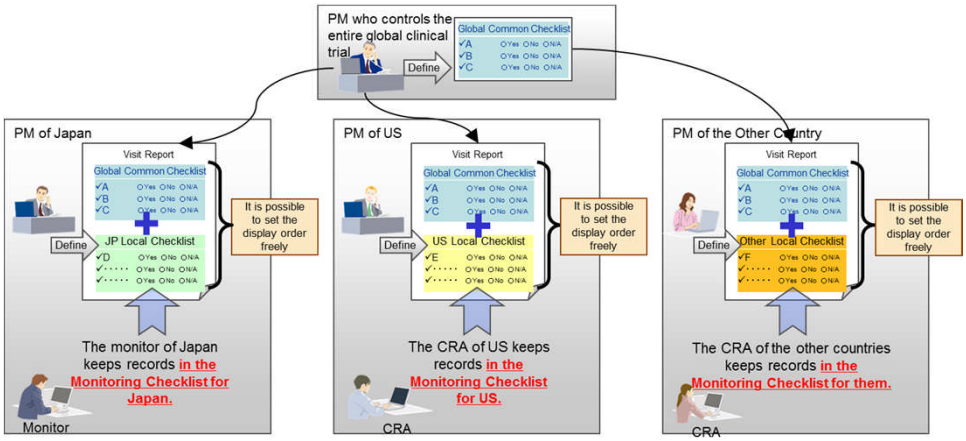
Introduction of Main Functions

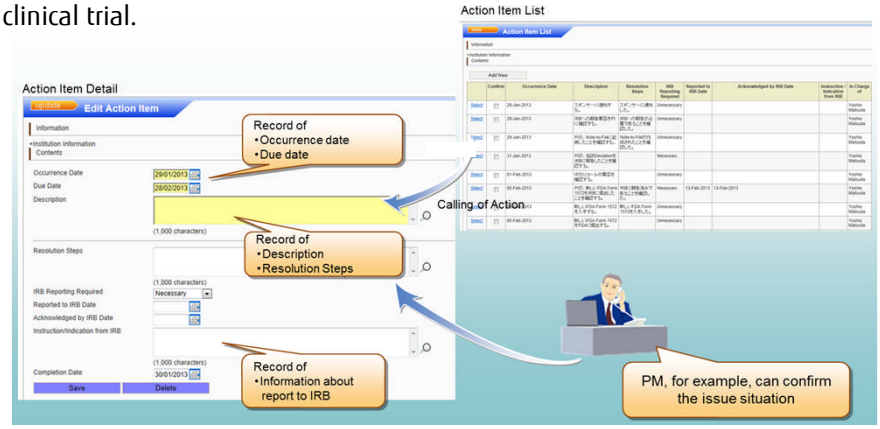
Monitoring

- In the global clinical trials, you can perform appropriate monitoring in compliance with requirements for clinical trials and regulations specific to the country by defining a monitoring checklist for each country.
- Standardizing a format of monitoring records ensures stable quality and reduces workload of evaluation/analysis and decision-making to the collected monitoring data.



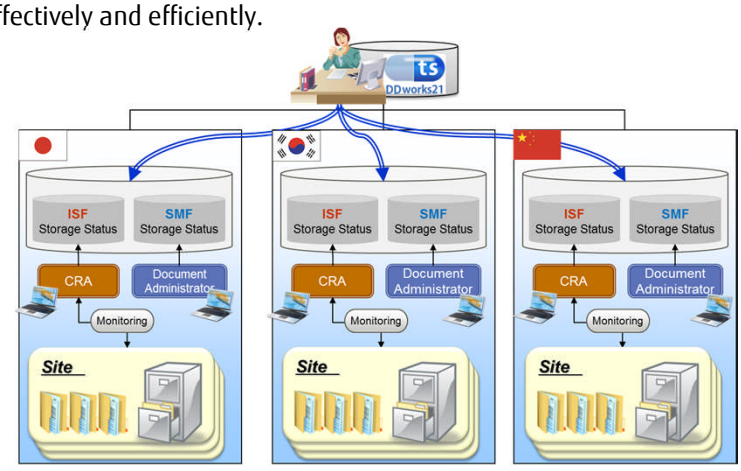
Issue Management

- Regarding issues that occur during a clinical trial, you can confirm their impacts on the study and necessity of corrective/preventive actions and implement countermeasures.
- You can manage issues by country, site, or CRA, and analyze them from various aspects, such as situation of occurrence or response, the period required to respond to them, and categories, so that you can utilize the results to evaluate the clinical trial.



TMF Management

- You can flexibly add or delete 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 the country becomes available.
- Regardless of ISF/SMF, by viewing sored TMF in a timely manner, you can check the GCP compliance status by each protocol/country effectively and efficiently.



*ISF: Investigator Site File
SMF: Study Master File

Fujitsu Limited

Life Science Industry Sales Division, Manufacturing Industry Business Unit
Shiodome City Center, 1-5-2, Higashishinbashi, Minato-ku, Tokyo, 105-7123, Japan
TEL: 03-6252-2366
Details are available on the Internet.
http://www.fujitsu.com/global/solutions/life-science/tsclinical/ddworks21global/