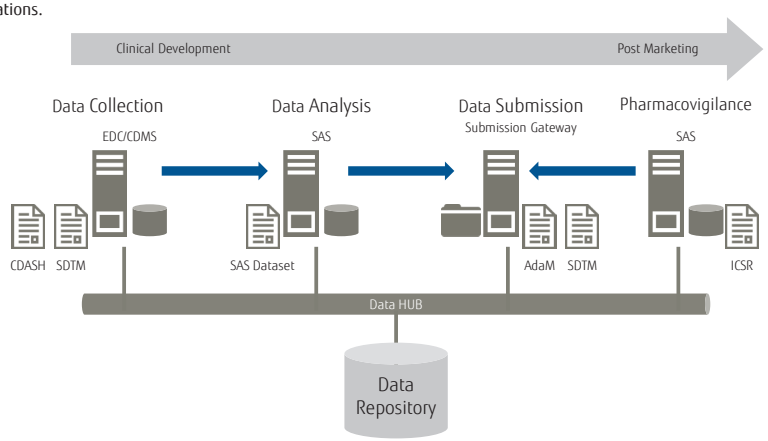
Image of Operational Flow

How does Clinical Service Bus and Clinical Repository Help?

Fujitsu's tsClinical software serves as a central platform to manage the accurate and timely exchange of information among business software applications running on various technology infrastructures. This solution applies industry data standards such as CDISC, ICSR, and provides for data mapping and validating data exchange processes with minimal effort–not to mention it reduces the impact of upgrading or replacing business applications.

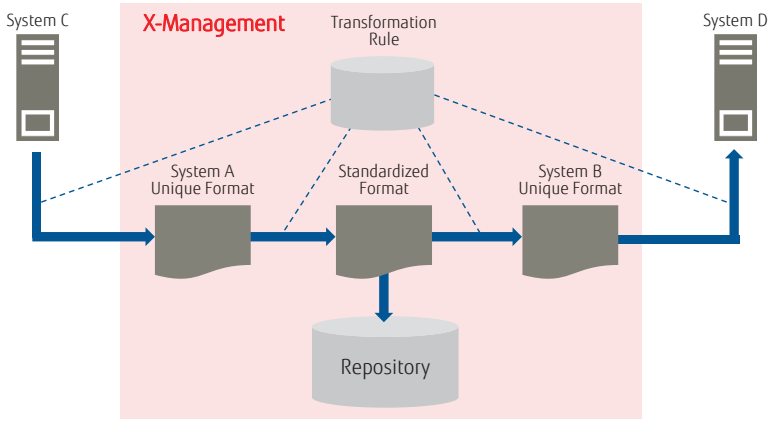


WHAT WE OFFER - tsClinical OVERVIEW

Our tsClinical Clinical Service Bus and Clinical Repository are designed to enable lifecycle management of clinical and safety data by leveraging the power of standardization. The tsClinical technology supports the entire lifecycle of clinical data–from collection to analysis and then to submission–by supporting industry standards used at each stage. This technology also supports safety databases to enable full integration of clinical and safety information.

Clinical Service Bus: Data transformation technology specialized for clinical and pharmacovigilance information using format conversion, code lists and unit sets, and custom plug-ins.

Clinical Repository: XML-based file repository that provides versioning, access control, and retrieval functionality.



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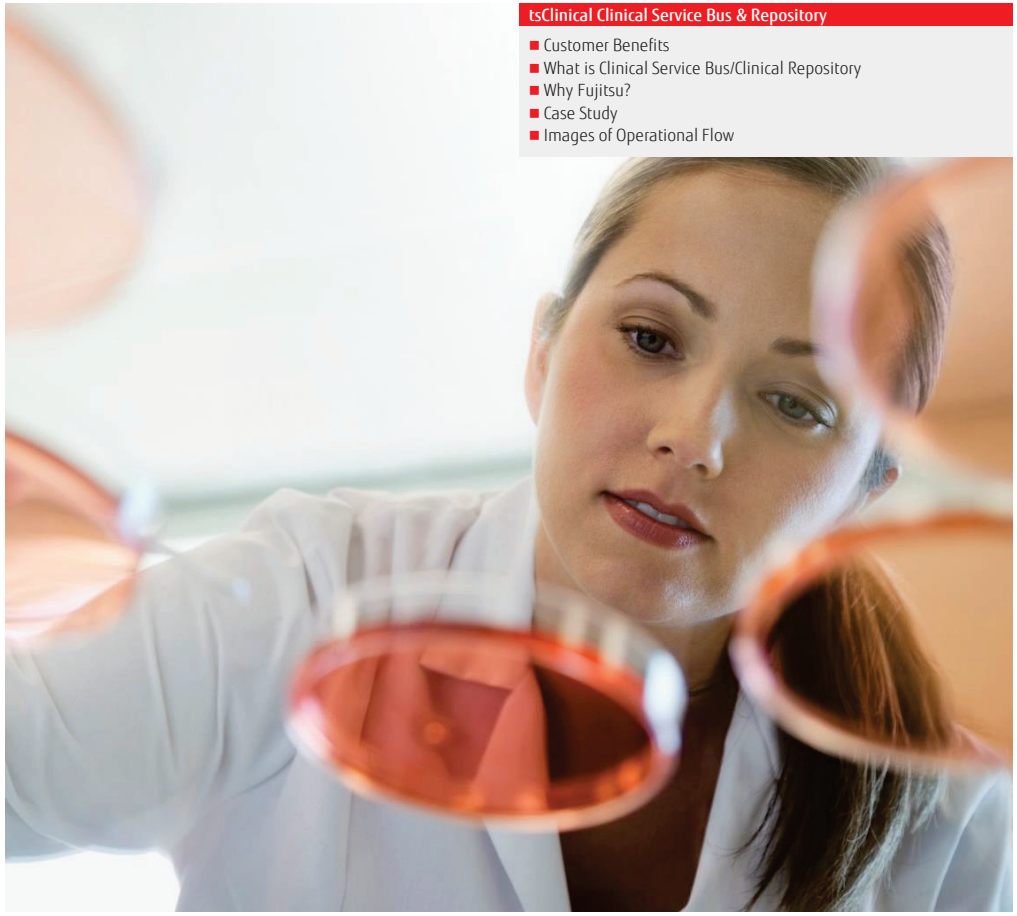
FUJITSU

Overview of Service/Solution
FUJITSU Life Science Solution tsClinical Clinical Service Bus & Repository

Specialized Data Linkage and Integration Support for Pharmaceutical Companies



tsClinical Clinical Service Bus & Repository

Customer Benefits

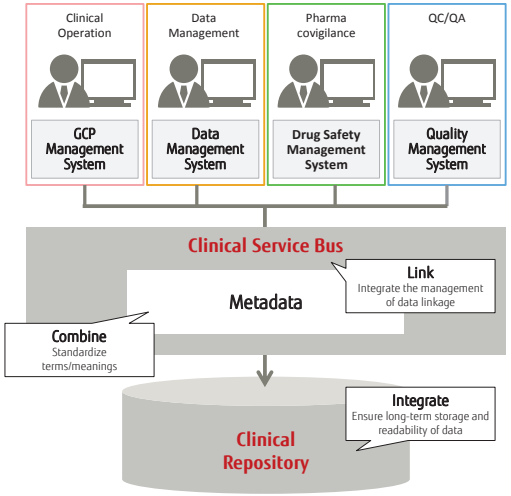
Data Integration in Modern Clinical Development

Have you ever thought of exchanging and sharing clinical development information easily? In fact, having access to accurate information in a timely manner is one of the greatest technical challenges in a modern pharmaceutical, biotech and medical device organization as information is scattered across many systems, files, offices, or vendors.

Modern clinical development relies on various information systems such as EDC, CDMS, IXRS, CTMS, Supply Management, and Pharmacovigilance. These systems are developed by different vendors, support different data formats, and therefore do not communicate with each other. As a result, manual processes are often required for data collection, reformatting, validation and analysis, which negatively impacts the quality, timeliness, and cost of the information.

Integrate, Link, and Combine Data with Clinical Service Bus/Clinical Repository

The tsClinical Clinical Service Bus/Clinical Repository solution provides seamless links between various departments and business systems related to the development of new drugs. It provides Pharmacovigilance Departments, Clinical Development Departments, IT Departments, and other teams with a collaborative environment where vital information can be shared, managed, and reused.



With Clinical Service Bus/ Clinical Repository organizations can:

- easily accumulate, search for, and track converted data
- simplify mapping conversion definitions
- reduce maintenance burdens
- have access to the support necessary to meet validation requirements

What is Clinical Service Bus/Clinical Repository?

Features and Benefits of the X-Management Software Solution

Fujitsu's tsClinical software serves as a central platform to manage the accurate and timely exchange of information among business software applications running on various technology infrastructures. The solution applies industry data standards such as CDISC, ICSR, and provides for data mapping and validating data exchange processes with minimum effort–not to mention reducing the impact of upgrading or replacing business applications.

Features:

- "As Is" Data Accumulation: The system's Clinical Repository stores data converted on the Clinical Service Bus in an XML format, accumulates data in a recordable manner, and provides a feature for searching the accumulated data. Because data in XML format can be stored without an index, the solution obviates the need to design detailed indexes.
- Fast Conversion Functionality: Data that is specific to drug development (i.e., safety information or clinical data) can be quickly converted into a standardized format such as CDISC.
- Validation Assurance: The conversion program is also applied to validating computer systems. Clients always have a direct connection to the validation support they need to meet regulatory requirements.
- Familiar Operational Environment: X-Management provides users with services in a secure and private SaaS environment simply by connecting to the Internet via Internet Explorer.
- Affordability: The solution's original patented compression technology enables the system to reduce disk usage, thereby reducing the cost of storing and managing data.
- Stable Search Performance: Even if there is a large amount of data, the solution's Clinical Repository maintains its ability to perform searches at a high level. The powerful search function can refer to information of defined and stored data and can access targeted files by filtering according to search criteria based on category definition information.
- Multiprocessing Functionality: Patented concurrent multiprocessing capabilities enable the system to process multiple requests at once and still provide reliable search performance.

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 our customers' businesses and help them improve their competitive position and make more informed decisions.

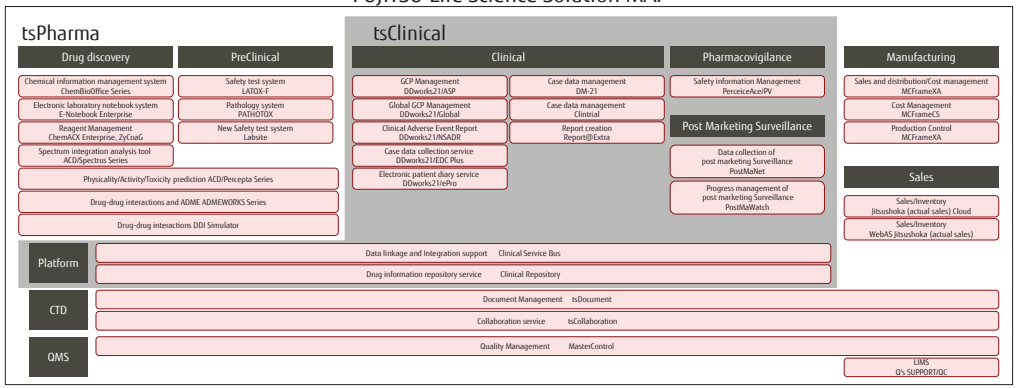
Offering integrated care concepts that bridge various medical disciplines, Fujitsu provides more than 60 solution packages that cover entire business areas, such as drug discovery, R&D, and sales. With its wide range of technologies and specialized product design and manufacturing, Fujitsu also has the 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 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 designing and delivering programs ensures an effective, comprehensive project lifecycle from the lab to the patient's bedside.

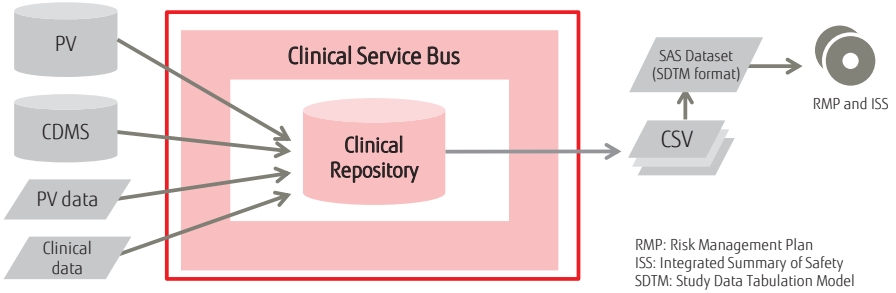
GxP: Good Laboratory Practice, Good Clinical Practice, Good Manufacturing Practice CTMS: Clinical Trial Management System CSV: Computer System Validation
CDMS: Clinical Data Management System EDC: Electronic Data Capture PV: Pharmacovigilance CTD: Common Technical Document

FUJITSU Life Science Solution MAP



Case Study

Customer	A Pharmaceuticals
Customer's Requirements	- Carry out data integration between clinical and pharmacovigilance systems via tsClinical for enhanced consistency of adverse events information between the systems. - Compile pharmacovigilance data from pharmaceutical company partners via tsClinical to accelerate the creation of regulatory risk management documentation.
Key Points	Pharmacovigilance Data Repository
Customer Benefits	- Reduces system operation and maintenance costs by centralizing and automating data integration. - Increases the quality of information and reduces the cost of quality by establishing a single data source. - Provides accurate and timely information to help management make decisions.



RMP: Risk Management Plan
ISS: Integrated Summary of Safety
SDTM: Study Data Tabulation Model