

# FUJITSU Life Science Solution

## tsClinical Clinical Service Bus

## tsClinical Clinical Repository

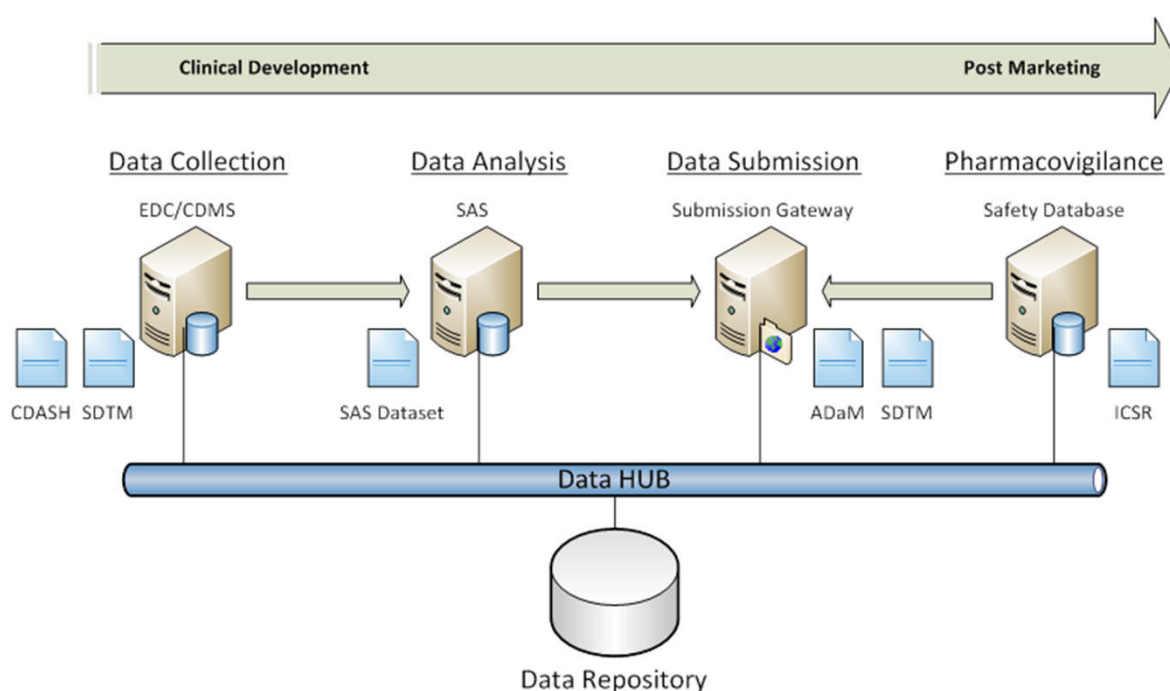
### Data Integration in Modern Clinical Development

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 need to be involved very frequently for data collection, reformatting, validation and analysis, which causes negative impacts on quality, timeliness, and cost of the information.

### 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. The solution applies industry data standards such as CDISC, ICSR, and provides for data mapping and validation of data exchange processes with the least possible effort not to mention reducing the impact of upgrades or replacement of business applications.



## WHAT WE OFFER - tsClinical OVERVIEW

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

- Clinical Service Bus: Data transformation technology specialized for clinical and pharmacovigilance information with using format conversion, code list and unit set, and custom plug-ins.
- Clinical Repository: XML-based file repository that provides versioning, access control, and retrieval functionality.

tsClinical combines Clinical Service Bus and Clinical Repository. The software is built on Fujitsu's Interstage technology, a robust application integration software suite, with built-in capabilities to effectively handle clinical and pharmacovigilance data. Clinical Service Bus serves as a buffer between business software applications and provides a common 'language' of communication. Clinical Repository serves as a central repository that retains clinical and pharmacovigilance information leveraging industry data standards. tsClinical is available as either an in-house or SaaS-based system.

## Benefits and Examples

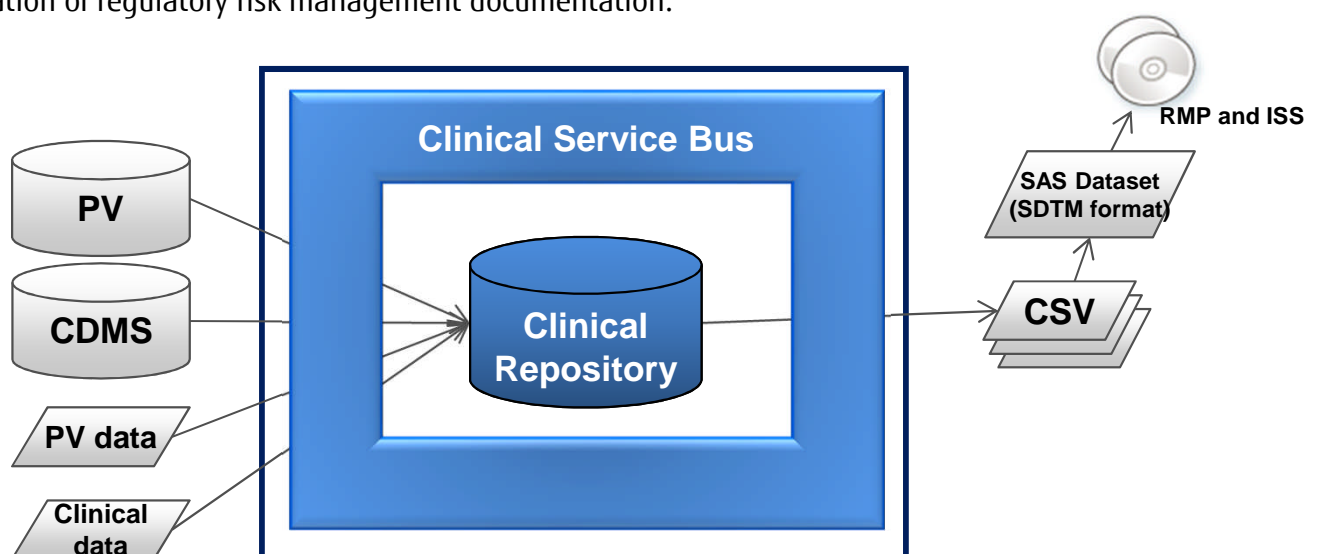
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### ■ Benefits

- ✓ Reduce system operation and maintenance costs by centralized and automated data integration.
- ✓ Increase quality of information and reduce cost of quality by establishing single data source.
- ✓ Provides accurate and timely information to help management decision making.

### ■ Examples

- ✓ 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 creation of regulatory risk management documentation.



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