

Modern CTMS for Pharma and Biotech

Manage your clinical trials with BSI CTMS – probably the most user friendly and flexible Clinical Trial Management System on the market. Made in Switzerland.

BSI CTMS modernizes the management of your clinical trials and sets a new benchmark in the CTMS market. Great functionalities such as full offline capabilities, finance planning and tracking, drug shipment and drug accountability, inventory tracking of non-medical supplies, subject visit planning and tracking and document handling support your clinical development team. The software adapts very flexibly to your SOP and business specifications and enables local, regional and global studies.

What's more, you can manage the data of your investigators, sites and CROs, track CRFs, manage the investigator fees, and keep an eye on financial operating figures. A fully equipped offline version enables the entering of CTM data directly at the source, such as the investigator's office. Thanks to the very intuitive user guidance developed and patented by BSI, only minimal training is needed; this means that BSI CTMS can also easily be used by inexperienced PC users.



“Our search for our CTMS was as thorough as our clinical trials. And as successful.”

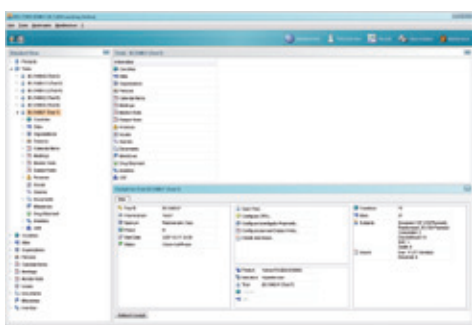
Christine Schwenninger, Head Global Clinical Monitoring, Actelion Pharmaceuticals Ltd

Functions

Comprehensive CTMS suite

BSI CTMS supports all aspects of clinical trial management: planning, preparation, execution, tracking and reporting. An enhanced granting rule system allows you to configure the system exactly to the needs of your individual users (PM, CRA, and others). The process wizard guides monitors step by step through predefined processes.

Trial design and setup	Products indications trials countries/regions sites investigators CRAs trial teams involved organizations CRF definition
Site selection and management	Selection criteria site performance recruiting status subject visit planning and status drug accountability site personnel contact reports
Trial planner	Time and milestone planning progress reporting milestone calculations authority approvals regulatory green light
Monitoring and reporting	Wizard-driven MVR answering and reviewing process monitor visits subject visits protocol violation SDV CRF tracking issues queries Word export follow-up letter
Reports	Indications products trials trial persons organizations monitor visits subjects regional reports personal reports timelines ad-hoc reports
Investigator/CRO management	Addresses personal data sheets address import duplicate control experience management contact reports campaign management CVs contracts
Medication and non-medication material administration (inventory)	Planning orders and shipments drug accountability supplier management track & trace
Finances	Budget planning, forecasting and tracking investigator and CRO compensation contracts
Calendar items	Contacts visits fax, letters phone calls vacations meetings (with agenda, minutes and issues)
Documents	Attach, link or store documents tracking template creation and management
Productivity improvement	MS Office integration Outlook synchronization Lotus Notes integration Data Management integration short keys favourites settings third-party interfaces Web services (SOA) computer telephone integration CTI (inbound, outbound) automatic update document handling (including versioning and full-text searches) synchronization replication drag & drop of documents and e-mails spell checking



Study design and setup: easy data entry, fast search, structured display with drill-down

Including special features like:

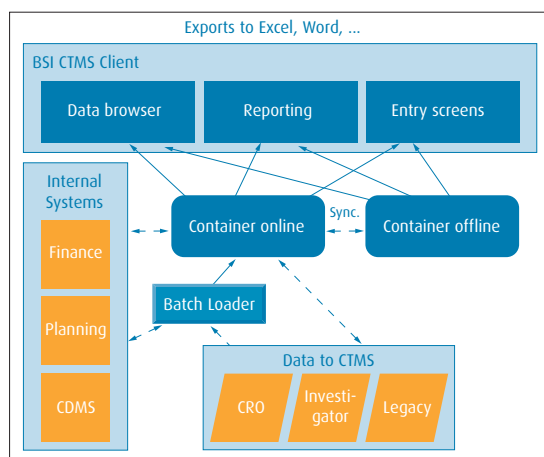
- Offline functionality
- Audit Trail: automatically created protocol (author, time, type of data entry and modification), to ensure the reproducibility of the study
- 21 CFR Part 11 technical compliance facility
- Separate monitor visit templates for each visit type, questionnaire individually configurable for each trial
- Role granting, 40 standard roles available
- User substitution during absence

Technology

State-of-the-art technology

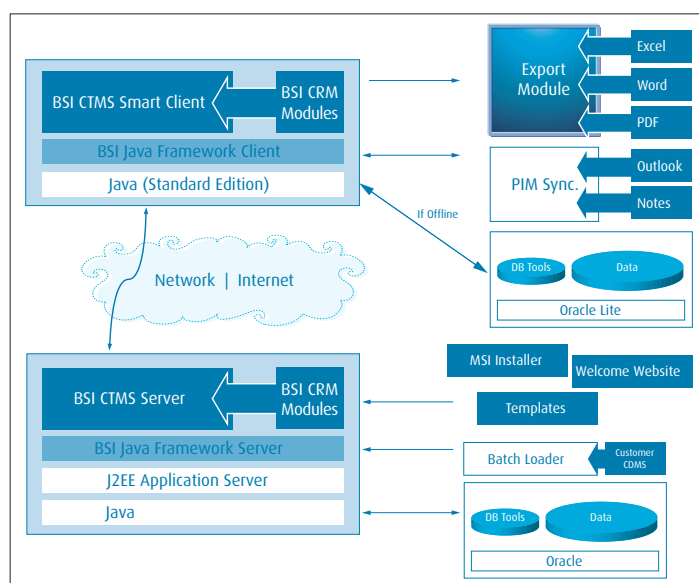
BSI CTMS is based on an established and patented **Java framework** using modern standards such as **SOA**, **XML**, **Java** and **Oracle** databases that have been thoroughly proven in the pharmaceutical industry. BSI's foremost goal is to be at the leading edge of technological development. We guarantee that the CTMS application stays technologically up to date throughout the entire life cycle.

System overview



BSI CTMS components, the client GUI is the same for online and offline usage

IT architecture



Service-Oriented Architecture (SOA) implemented on Java framework

We love software

We love software and enjoy programming proven products and custom solutions. Handcrafted quality, honesty and great customer proximity – that's BSI. We offer a seamless service system based on our own products, from the concept to ongoing operation. This 360° expertise is mirrored not only in our successful first-hand solutions, but also in shorter project times and in an excellent price/performance ratio. Our partners? Our clients IT departments.

Top technological advantages of BSI CTMS:

- 100 % based on Eclipse, Java and SOA
- Open architecture
- Easily customized to meet individual standard operation procedures (SOPs)
- Easily integrated with existing CDMS, EDC, finance or other eClinical business systems
- Rapid project implementation

Reference I Contact

Actelion

Since 2007, BSI CTMS supports all aspects of Actelion's global clinical trials. Apart from Actelion employees, also external organizations have access to the system. The access rights are easily configured and can be easily adapted to the changing needs. Actelion makes full use of the offline capability of the solution to support monitor visits.

Source: Actelion



At Actelion, high-talented people performing top quality science-driven innovation

Actelion is a biopharmaceutical company with its corporate headquarters in Allschwil/Basel, Switzerland. Actelion was founded in 1997 and its shares have been listed on the SIX Swiss Exchange (ticker symbol ALTN) since 5 April 2000. On 22 September 2008, Actelion shares traded for the first time as part of the blue-chip SMI® (Swiss Market Index).

The company is focused on the discovery, development, and commercialization of synthetic, small-molecule drugs as innovative treatments to serve high unmet medical needs.

Actelion combines the innovation, entrepreneurial spirit, and flexibility of biotech with the financial, risk management, regulatory, and commercial discipline of a large pharmaceutical company. It has the proven ability to discover new compounds and to rapidly move compounds from research through development to commercialization.

In particular, Actelion scientists were among the first to work in the field of endothelin receptor antagonists, including its lead product, Tracleer®.

Actelion has subsidiaries in more than 25 countries, including the United States, Canada, Brazil, Australia, Japan, Switzerland and a number of EU Member States. These subsidiaries provide distribution, sales, and marketing services.

www.actelion.com

Reference



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We develop software at the interface to the customer.

BSI CTMS is the Swiss solution for clinical studies in the pharmaceutical industry. The simplicity and the versatility of our software have convinced market leaders like Actelion, ALK-Abelló and Allergopharma. We specialize in system integration, software development, consulting and support. The service-oriented architecture of all BSI applications makes them easy to integrate into any IT landscape.

