Modern CTMS for Pharma and Biotech

Manage your clinical trials with BSI CTMS, just like Actelion does. BSI CTMS – probably the most 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, inventory tracking of supplies, CRF tracking and document handling bring your business further. 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 and monitors, plan medication supply 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 doctor'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.

"I love to program lean solutions. Especially for demanding processes."

Anna-Nina Simonetto
Software Engineer at BSI

bsi

meet your clients

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.

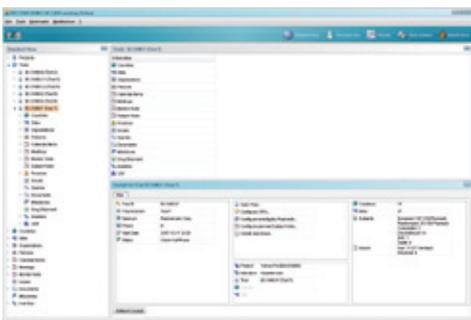|	
Study design and setup	Products I indications I trials I sites I investigators I CRAs I individuals & teams I monitor visits I CRFs I reports
Site management	Recruiting I screening I visit status I patient status I medication delivery I site personal I contact reports
Trial planner	Time planning I progress reporting I milestones I inventory planning and tracking I budget planning and controlling
Site monitoring and reporting	Wizard-driven: patient visits I site visits I reviews I updating I protocol violation I SDV I Word export I follow-up letter I issues I queries
Reports	Indications I products I trials I trial persons I organizations I monitor visits I subjects I regional reports I timelines
Investigators/Monitors	Addresses I personal data sheets I address import I duplicate control I interest management I contact reports I campaign management I synchronized calendars I CVs
Material and medication administration	Planning I budgeting I supply management I supplier management I track & trace
Finances	Budget planning and tracking I investigator and CRA compensation I contracts
Calendar	Contacts I visits I fax, letters I phone calls I vacations I meetings (with agenda, minutes and issues) I attach documents
Productivity improvement	MS Office integration I Outlook synchronization I Lotus Notes integration I Data Management integration I short keys I favourites settings I third-party interfaces I Web services (SOA) I computer telephone integration CTI (inbound, outbound) I automatic update I document handling (including versioning and full-text searches) I synchronization I replication I drag & drop of documents and e-mails I spell checking

Study design and setup: easy data entry, fast search, structured display with drill-down
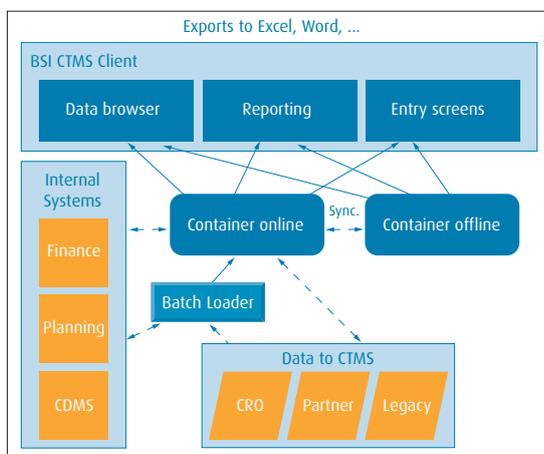
Including special features like:
– Offline functionality
– Audit Trail: automatically created protocol (author, time, type of data entry and modification), you ensure the reproducibility of the study
– 21 CFR Part 11 technical compliance facility
– Separate monitor visit templates for each visit type, questionnaire individually configurable for each trial
– Role granting, 40 standard roles available
– User substitution during absence
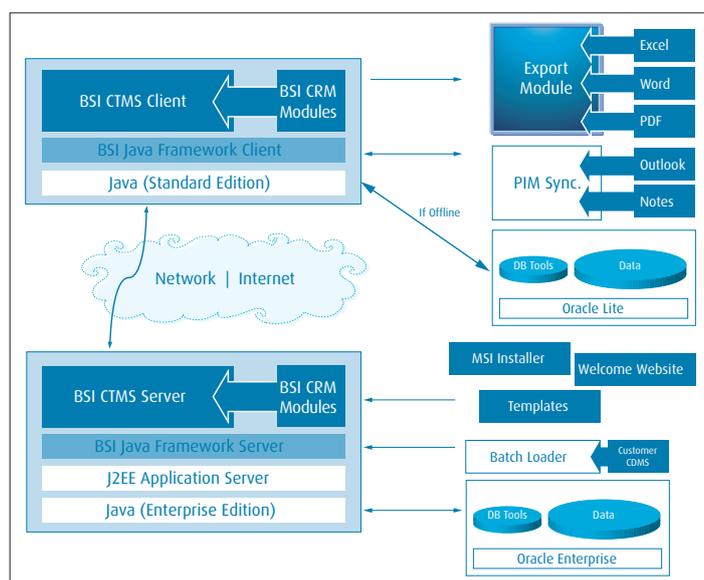
Technology

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 SOA
- Open architecture
- Easily customized to meet individual standard operation procedures (SOPs)
- Easily integrated with existing CDMS, finance or other clinical 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

Reference

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 SWX 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.ch

We develop software at the interface to the customer.

BSI CTMS is the Swiss solution for clinical studies in the pharmaceutical industry. BSI CRM is the leading Swiss solution for any task and every relationship – sales, marketing, service and multichannel contact center. BSI counter for clear-cut processes at the counter and the cash register. The simplicity and the versatility of our software have convinced more than 70,000 users: ABB, APG, Commerzbank, Hermes Logistik, Holcim, Landis+Gyr, PostFinance, PricewaterhouseCoopers, Roche, the Swiss Post, Sika, Swiss Life, Tamedia, Viseca and other market leaders rely on BSI products. 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.

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