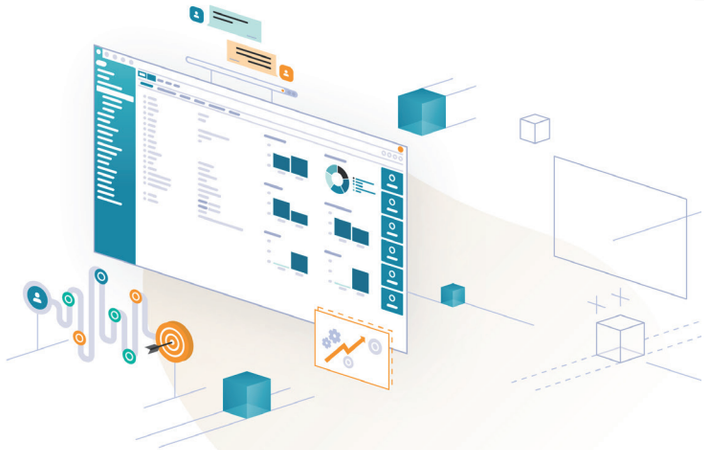
# BSI Life Sciences: The Software you will want to use all the time



BSI CTMS

# Trouble-free software for clinical trials

**1 Comprehensive functionality**

BSI CTMS delivers comprehensive functionality for all aspects of clinical trials: From study startup, to execution, flexible reporting and closing; along with the management of sites and investigators, integrated active trial master file (eTMF) and trial supply management, suitable for local, regional and global trials. Everything you need is in one software application, configured to the needs of the individual customer.

**2 Easy to use**

With the modern HTML5 web-based user interface, BSI CTMS is one step ahead regarding optics and ergonomics. The feedback of our customers proves it: The intuitive interface and the intelligent functions in BSI CTMS make our users' daily work easier and more efficient, and it's a product that they actually enjoy using. We are confident you'll find BSI CTMS just as delightful and indispensable.

**3 Easy to implement and integrate**

Due to the BSI standardized and proven processes BSI CTMS can be made available for new customers within very short time. BSI supports the customer during configuration and rollout. As the central "hub" and backbone for your clinical trials management BSI CTMS enables easy integration with other clinical systems. Standard interfaces are available to external eTMF, EDC, portfolio and project management tools, clinical data warehouses, active directory for single-sign-on, and more.

**4 Lowest total cost of ownership (TCO)**

BSI CTMS is not only attractive when it comes to functionality and usage, but also in operation. Thanks to the open software architecture you receive future-oriented innovative software with no dependencies on vendors. Upgrades to new standard versions are included in the monthly SaaS fee.

**5 Mirroring Industry Needs**

Using our thorough data security processes, system validation and quality assurance processes, BSI CTMS complies with international industry standards like 21 CFR Part 11, ICH GCP and EU GDPR.

**Some of the customers who count on BSI CTMS:**

ascendis pharma · ALK · proinnovera · Dokumeds CLINICAL RESEARCH ORGANIZATION · CHARITÉ UNIVERSITÄTSMEDIZIN BERLIN

**BSI Business Systems Integration AG**
www.bsi-lifesciences.com

bsi Software for Life Sciences

# «The best CTMS is also the one everyone will want to use.»

## BSI CTMS is the cornerstone of clinical trial management

### Study design and management

**Individually set up the requirements of your clinical trials entirely in BSI CTMS according to the study protocol.**

- → Flexible study data setup with high-level information for phase 1...4 trials, such as therapeutic area, cost estimate, number of planned sites and patients
- → Group trials below products and indications (diseases)
- → Countries and regions
- → Milestones and activity plans
- → Risk based monitoring plan
- → Trial teams
- → Involved organizations
- → Patient enrollment plan

### Investigator and site management

**Select investigators and sites based on post-study site assessments, experience and capabilities, set up site contracts and plan patient enrollment with our all-in-one software.**

- → Set up a post-study site assessment questionnaire
- → Search for trial centers based on historic site and investigator performance
- → Plan and track patient recruitment
- → Patient visit plan and track the status of the patient visits
- → Track and train personnel at trial centers
- → Manage site contracts

### Risk-based site monitoring

**Say goodbye to paper! Complete the planning and execution of monitoring visits entirely in BSI CTMS.**

- → Set up a risk-based monitoring plan (RBM)
- → Plan and conduct monitoring visits
- → Workflow process for creation, review and approval of MVRs (monitoring visit report) including electronic signatures
- → Automatic creation of follow-up letters
- → Offline monitoring
- → Planning and tracking of patient visits and enrollment
- → Tracking of risks, issues, protocol deviations and (S)AEs

BSI CTMS adheres to industry standards and has been developed and validated according to procedures based on GAMP 5. BSI CTMS is 21 CFR part 11 (eRecords / eSignatures) and EU Annex 11 Computerized Systems compliant.

### Electronic Trial Master File eTMF

**With BSI CTMS you manage your documents within the integrated trial master file (eTMF) in the same software that you use to conduct your trials.**

- → Integrated eTMF with full support of your eTMF structure or the TMF Reference Model
- → Controlled trial master file access for all study partners e.g. sponsors and sites. Dashboard with action items for the day (future, current, past due)
- → Process workflow for creating, reviewing, approving and electronically signing documents
- → Version management for documents
- → Set up of document plan and document tracking
- → Set up of your own document templates, e.g. for monitoring reports and follow-up letters
- → Download of individual documents or the complete trial master file with meta data cover page for each document
- → Optional PDF/A document conversion on download
- → ... and many more functions

### Trial supply management

**You can track your complete medical and non-medical study material in BSI CTMS in order to keep track of your various stocks, orders and the next shipments.**

- → Manage medical and non-medical study material
- → Set up a study material plan for a trial
- → Manage and track orders and shipments
- → Manage global and local stocks and warehouses

## Help clinical operations to run more efficiently

### Finance management

**Keep track of your clinical trial budget and costs. Carry out all financial activities directly in BSI CTMS.**

- → Create budget proposals and plans
- → Plan and track a study and site budget based on activities
- → Compare planned and actual costs
- → Track investigator payments and invoices
- → Sunshine Act reporting

### Reporting

**BSI CTMS empowers every user with our unique flexible reporting functionality. Create your own personal reports using all available data in BSI CTMS by pure configuration and export the data to Word, Excel and PowerPoint. Or simply use the out-of-the box reports.**

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