"Sponsor, CRO, or SMO?
Plan and manage
all aspects of your clinical
trial with BSI CTMS."

Jan Nielsen, BSI

BSI CTMS
Trouble-free software for clinical trials

1 **Intuitive yet sophisticated**
Don't be deceived by our user-friendly interface. BSI packs a serious punch with the powerful ability to pull and view data from every angle. Workflows guide your users through all processes including our signature monitoring visit process which is completely integrated from the start through to the electronic signature.

2 **Flexible to your changing needs**
The business needs you have today may change tomorrow. Thanks to the way we've developed the software, you're not stuck with something that only worked yesterday. Design your own reports and set up customized risk indicators and more – without dependency on a vendor.

3 **Transparent pricing and manageable costs**
When you work with BSI you'll know your costs up front. Pricing is transparent and fixed, and new releases are not mandatory. Because the software is so easy to learn and use, you'll also be pleasantly surprised that you'll need significantly fewer hours to train your staff.
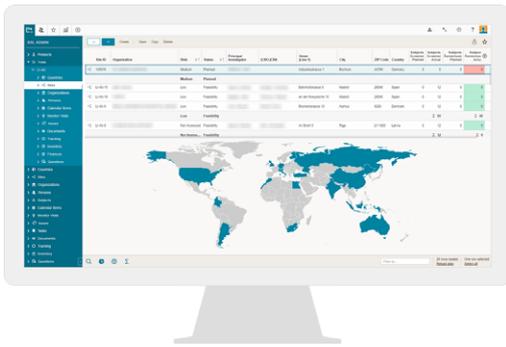
4 **We love customers and software**
Satisfied customers, experienced teams, pioneering technologies, and strict adherence to deadlines are what make us special. We produce software that is integrated and easily maintained in-house. And your teams will actually *want* to use it because it's built on your business needs.

These customers count on BSI CTMS:

ACTELION   ALK   Allergopharma   Dokumeds CLINICAL RESEARCH ORGANIZATION   Fortune 500 Pharmaceutical Company

bsi

BSI Business Systems Integration AG
www.bsi-software.com/ctms

"The best CTMS is also the one everyone will *want* to use."

Let our signature processes take the variability out of trial management

Set up any study with any design

→ Have total control over how you design your trial
→ Define your own fields as needed, or use standard fields
→ Set up trial specific milestones and activities
→ Configure trial specific monitor visit questionnaires
→ Configure individual document plans for your trial
→ Decide on where your subject/sample data is coming from and on the level of detail of the data you want to track

Easily manage investigators and sites

→ Maintain a clean database: Avoid duplicate contacts with our advanced contact validator
→ Search and select trial centers based on site/investigator performance or use customized selection criteria
→ Track patient recruitment and plan milestones
→ Easily manage contacts and contracts

Monitor sites with our patented guided process

→ Plan and track site and patient visits/enrollment
→ Plan and conduct monitoring visits, even offline
→ Track protocol deviations and violations
→ Significantly reduce CRA training time thanks to wizard driven processes that ensure consistency, compliance, and adherence

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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.

BSI CTMS is the cornerstone of clinical project management

Simplify daily task and project management

→ Check and track milestones and activities
→ Event-based updating of milestones, incl. notification: personal cockpit with action items for the day (future, current, past due)
→ Configure alerts, notifications and escalation

Comprehensive and flexible reports function

→ Configure your own custom reports "on the fly"
→ Run pre-configured reports
→ Evaluate specific trial teams
→ Export it all to Excel, Word, and PDF

Keep track of finances

→ Plan budget and compare actual costs
→ Track investigator payments
→ Create invoices
→ Pay trial centers and suppliers easily and on time

Help clinical operations to run more efficiently

Easily see, create, and manage documents from one place

→ Create and approve documents, while maintaining version control
→ Create and store document templates (e.g. monitoring reports and correspondence)
→ View, control, and approve all documents stored in eTMF

Oversight and total control of materials and drug product

→ Plan and track inventory of medical and non-medical materials
→ Plan and execute orders and shipments
→ Oversight of global and local stock
→ Set inventory alerts

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