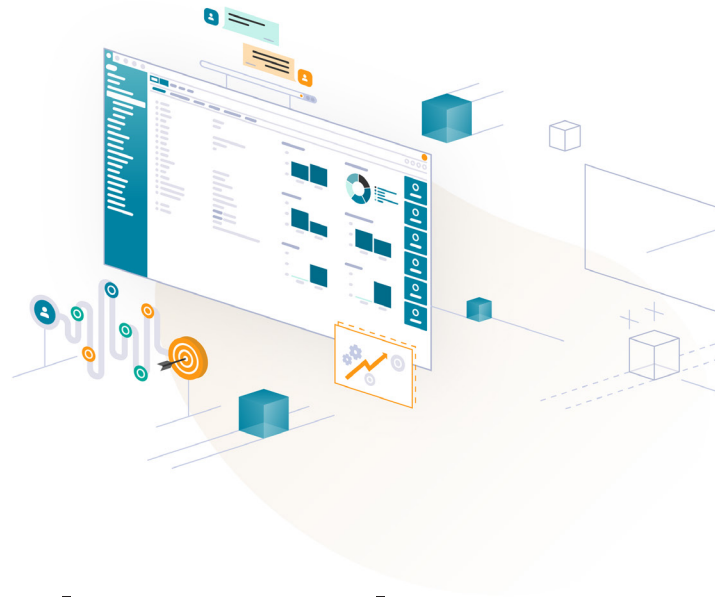


BSI Life Sciences: The Software you will want to use all the time



BSI eTMF

Affordable electronic Trial Master File management for clinical trials

1

Comprehensive functionality

BSI eTMF delivers comprehensive functionality for all aspects of trial master file management for your clinical trials: From study startup, to execution, flexible reporting and closing. Full support of your own TMF structure or the TMF Reference Model from DIA with controlled access for all study partners e.g. sponsors, CRO and sites. Setup document plans and track the creation, reviewing and approval process with enhanced alerting functions. BSI eTMF provides real-time audit and inspection readiness.

2

Easy to use

With the modern HTML5 web-based user interface, BSI eTMF is one step ahead regarding optics and ergonomics. The feedback of our customers proves it: The intuitive interface and the intelligent functions in BSI eTMF 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 eTMF just as delightful and indispensable.

3

Easy to implement and integrate

Due to the BSI standardized and proven processes BSI eTMF can be made available for new customers within very short time. BSI supports the customer during configuration and rollout, no external system integrators are required.

4

Lowest total cost of ownership (TCO)

BSI eTMF is not only attractive when it comes to functionality and usage, but also in operation. The intuitive user guidance keeps training costs minimal, while the easy operation supported by processes accelerates data entry. The open software architecture makes sure that you'll receive future-oriented innovative software with no dependencies on vendors. Upgrades to new standard versions are included in the SaaS monthly fee.

5

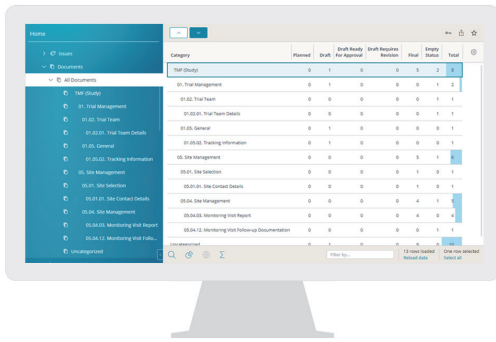
Investigator Site File (ISF)

Give the sites restricted access via the BSI Portal to upload essential documents.

6

Controlled Access

Besides your own access as sponsor or CRO, you can allow controlled access for all study partners, e.g. sites and vendors; And of course, also for inspectors and auditors. This thanks to the sophisticated access right and granting system of BSI eTMF.



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

Say goodbye to local document files or any other non-validated document management solutions. With BSI eTMF you have an instant overview of your trial master file documents.

Study design and management

Individually set up your clinical trials entirely in BSI eTMF 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)
- Regions and countries
- Trial teams
- Involved organizations

Trial master file setup

Setup your individual trial master file structure or use the TMF reference model from DIA.

- Optimize the trial master file structure per trial or (as a CRO) per sponsor
- Keep the sponsor TMF and Investigator Site File (ISF) in one place
- Define the required meta data for all documents of the eTMF e.g. granting rights, review and approval workflows, required signatures ...
- Enhance the document meta data with your own additional fields
- Organize documents in folders
- Create document plans. Document placeholders will automatically be created for each document listed in the plan
- Configure document templates for each category where required

Work with your trial master file

Your various study partners will enjoy working on the trial master file documents using BSI eTMF.

- Upload, link or save documents
- Drag & drop e-mails into your trial master file
- View documents with the integrated document viewer functionality
- Create and upload new versions
- Setup review and approval workflows
- Review, approve and electronically sign documents
- Document deadlines with alerting function
- Download individual documents or the complete trial master file with a meta data cover page for each document, including audit trail information
- Open PDF/A document conversion by download

Reporting

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

- Search documents using the Global Search function
- Get completeness status of documents on e.g. trial, country and site level
- Create general document reports for all users or for specific user groups
- Export documents according to the trial master file structure as XML including cover pages
- Limited access to inspectors and audit

Some of the customers who count on BSI eTMF:

