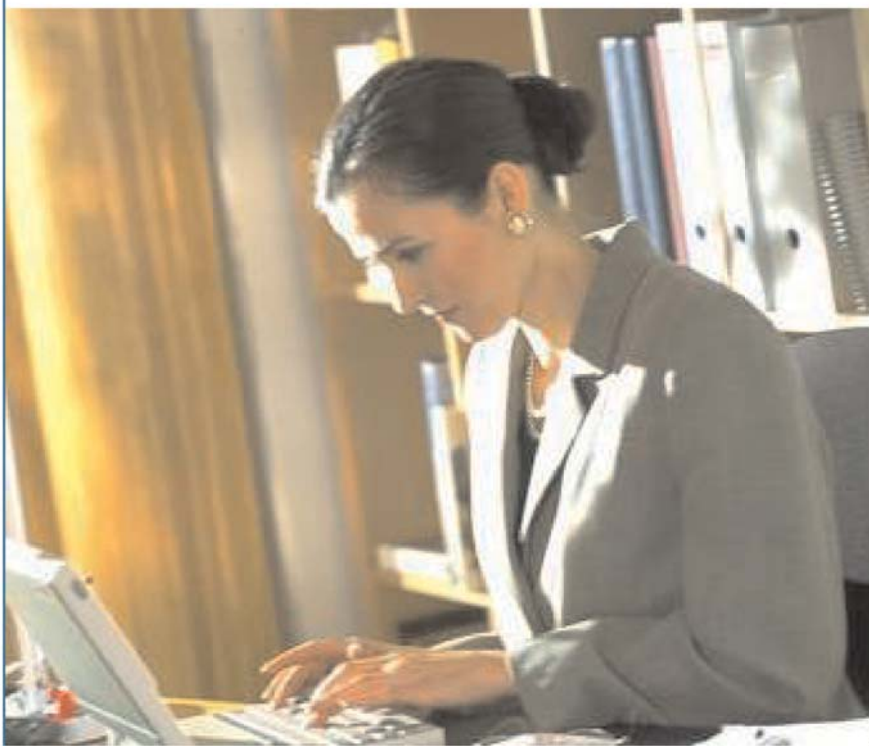




Clinical-Trial Engine



Precisely Dosed Use of Technology

Trium stands for the professional realization of controlled clinical trials, research and development plans, registers, benchmarking and QA projects. With »Clinical-Trial Engine«, we offer you a smooth migration to efficient and secure processing of these projects exploiting the advantages of the Internet. This is combined with the in-depth expertise of our staff and partners. All services provided are of convincing quality with guaranteed flexibility, customer focus and helpfulness. Trium is accustomed to the challenges of drug studies and clinical research through its long term experience and - as a medical device manufacturer - also from a customer's perspective. In line with our primary company objective »Improving Human Health«, our knowledge will support you in bringing new drugs and other innovative medical products quickly and safely to market.

Service and Security

The »Clinical-Trial Engine« is an eTrial software suite for EDC and management of clinical studies especially where prompt decision making and high flexibility are required. Productive and professional remote data entry, carefully designed and intelligent query management as well as online analysis and reporting for real-time decision support warrant accelerated progress. Successful large scale research projects dealing with more than 20,000 patients and several perennial clinical trials with hundreds of study sites involved have demonstrated our proficiency. We have mastered the challenge of being compliant with regulatory requirements without sacrificing user-friendliness or losing the customer focus.

»Clinical-Trial Engine« enables study data to be acquired, retrieved and analysed at any time, anywhere and using almost any device. Users do not need to install special software or maintain a local data base. State-of-the-art technology guarantees the highest degree of security in terms of access control, data archiving and availability.



Benefits

Our aim is to create an optimal environment for study sites and researchers since their commitment and motivation is the key to our own success.

Hence our solution offers clear advantages

- easy access via the Internet at any time, anywhere
- optimized, user-friendly and intuitive user guidance
- work-flow oriented eCRF design and appropriate online validity checks
- flexible reduction of paper - from paperless to printouts of all screens
- efficient monitoring and accelerated trial implementation
- technical support hotline

According to the customer's individual needs, various extensions are possible. These include the incorporation of external data bases or tailor-made online tools like registration and randomisation systems, scheduling, memory and reminder functions. Family tree data can be collected and analysed for the evaluation of genetic data. An essentially unlimited use of OLAP technologies is also possible.

Features for Complex Challenges

Trium grants the licensee a non-exclusive and non-transferable licence to use the current version of the Clinical-Trial Engine within a specific project. This licence does entitle the licensee to receive the following services from Trium:

- unlimited number of patients and study sites
- identical demo environment for registered users for training purposes
- graphical display of recruitment figures
- monitoring interface / patient summary display
- automated fax transmission of SAE forms
- application and content user-based security concept
- automated comparison of double data entry with monthly status report
- electronic audit trail and export of data into standard SAS transport datasets
- user manual and quick guides in electronic PDF format
- set-up and servicing of user accounts
- technical hotline by telephone; unlimited email support.

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