**E-Crf® EDC Software Service**

**The Ethical e-Crf®**

is a Software service providing a cloud portal designed to support Sponsors, Study Leaders and Q.A. Staff during clinical trials patient data collection and Data Management.

Electronic Data Capture (EDC), SDV, Screening & Randomization, data Cleaning & Queries, data Export & Reporting are the software main features.

Included in the service the Ethical Staff takes completely care of the operations for:

- configuration of software to map the Protocol and the CRF fields with their edit checks;
- ISO 27001 system and database hosting, management & backups;
- training & technical support (help desk);
- Documenting software to support Computer System Validation.

This way the e-Crf® price configure as a real Total Cost of software relieving the Sponsor of the hidden costs often related with traditional software ownership.

**e-Crf® as Service benefits**

as **STUDY LEADERS & STAFF** you could

> delegate to fast and experienced staff the implementation of the Trial Protocol and CRF inside the system;

> lower the time needed to setup, configure and deliver the system;

> centrally manage & monitoring all the relevant events;

> trust on a Service Level ruled professional support.

As **QUALITY ASSURANCE** you could

> easily validate the system with the provided validation documentation package;

> benefit of Staff support and documentation to rapidly implement your SOPs;

> use your "stage" clone environment for users acceptance tests and training;

> audit the supplier and the ISO 27001 hosting environment.

As **IT STAFF** you could

> reduce the software adoption time & costs through a full outsourced application management (ISO 27001 hosting, security, backups, monitoring, business continuity, etc.);

> limit the support to internal and external users to a standard browser connectivity;

> exploit the integration interfaces to feed the system and easily get back trial data in a timely and coherent way.

As result the **SPONSORS** can

- budget the Trial software operations with a real all inclusive pre-defined Total Cost;

- lower time and costs of Trial Data Collection & Management operations.
**e-Crf® software features**

- **SINGLE SIGN-ON TO DIFFERENT TOOLS / STUDIES**
  - the same customer portal can host different trials and CRFs sharing common functions while segregating environments, users, data and access rights

- **PATIENT DATA COLLECTION (EDC)**
  - the flexibility and efficiency of EDC forms with edit checks, queries and audit trail integration;

- **TRIAL DATA MANAGEMENT**
  - centralized trial data management environment, with patients planners and visits scheduler;

- **SCREENING & RANDOMIZATION (IWRS)**
  - patients’ enrolment strict management with drug delivery tracking and central randomization: inclusion exclusion criteria validation;

- **DATA CLEANING, QUERIES & DCFs**
  - data cleaning and queries management with DCF generation, delivery and central data updates tracking integrated in eCrf interface;

- **DATA EXPORT & REPORTING**
  - patients’ and trial data Export standard tools (ASCII, XML, SAS) & reporting (Pdf)

- **INTEGRATION INTERFACES & CUSTOMIZATION**
  - standard interfaces for legacy system data integration & system customization through Professional Services.

**CONTACT US for a free DEMO session: info@ethical.ch**

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**e-Crf® is a full Service**

- included in the software service:
  - unlimited users Licenses for software;
  - system configuration to exactly map the Protocol and the CRF with edit checks;
  - system & database hosting & complete management (ISO 27001);
  - users training / testing in a clone “Stage” environment;
  - users support through integrated online Helpdesk;
  - Computer System validation (GAMP5 - CFR 21 part 11) documentation & support.

**e-Crf® staff is experienced**

Since 1997 our software’s solutions supported about 300 international trials with more than 10,000 investigators’ sites and hundreds of thousands patients.

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