ETHICAL

e-Crf ® as Service: budget Electronic Data Capture (EDC) of your next Clinical Trial with a real all inclusive pre-defined TOTAL COST .

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 & tecnical 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.);

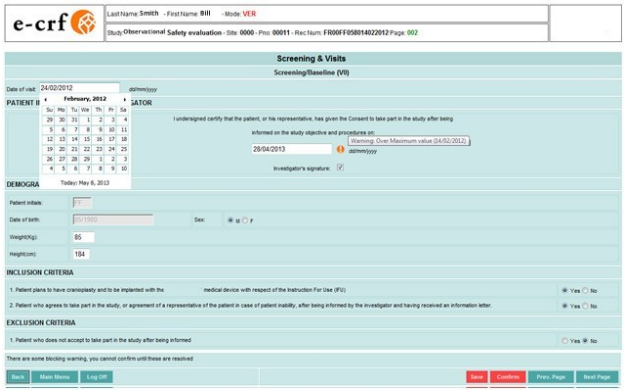
> limit the support to internal and external users to a standard browser connectivity;

> 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.

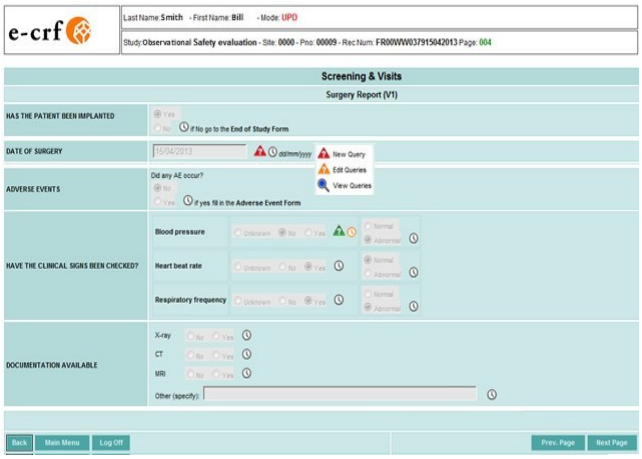
e-Crf ® is a full Service

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.



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

ETHICAL

Ethical GmbH
Wartembergstrasse 40 CH 4052 Basel - SWITZERLAND
+41 (0) 61 271 30 30

www.ethical.ch | info@ethical.ch