

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

# E-Crf <sup>®</sup> 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 <sup>®</sup> price configure as a real Total Cost of software relieving the Sponsor of the hidden costs often related with traditional software ownership.

# e-Crf<sup>®</sup> 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<sup>®</sup> software features

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#### 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<sup>®</sup> 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 <sup>®</sup> 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

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