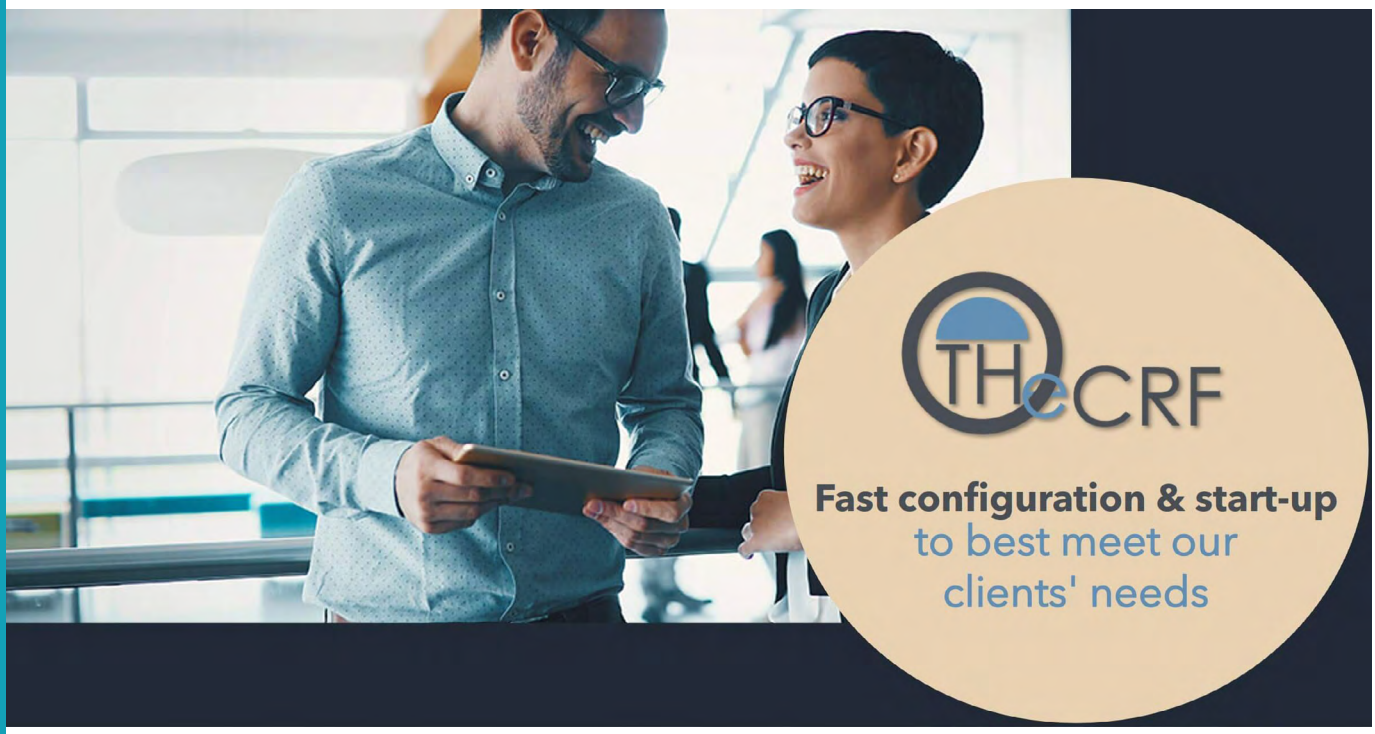
Techorizon
ADVANCED TECHNOLOGY SOLUTIONS

THeCRF:
Our Electronic Data Capture (EDC) since 2009



Techorizon is a worldwide provider of technology solutions for the Life Sciences and supplies advanced solutions and services to the healthcare environment. It is an ISO certified Italian company that combines technical expertise with 15 years of experience and deep understanding of clinical research processes to deliver innovative and customised technology solutions to its clients.

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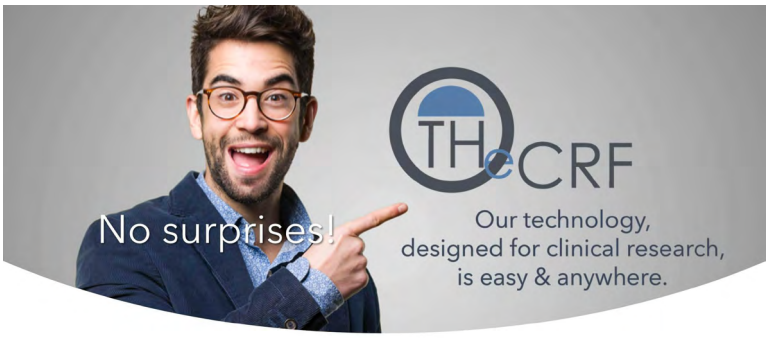
What's new with THeCRF?

- It is self-configurable and quick and easy to build.

What about the involvement of your IT department?

- Your choice.



You can have THeCRF as a standalone tool, and according to your needs, we can tailor our provisions with any **add-ons or any EDC services.**

Why Choose THeCRF

With 15 years of experience of providing high-quality e-tools and services for the Life Sciences, THeCRF is built from the experience of hundreds of Project Managers, Investigators and Monitors designed to make your clinical project a success.

THeCRF combines technical expertise with a deep understanding of clinical research processes to provide you with innovative and customized technological solutions that integrate perfectly to support all aspects of your clinical project.

THeCRF is for everyone

Pharma, Medical Devices, Biotech Industries, Academic, Non-Profit Organizations, ... Interventional, Observational, Retrospective, Registries, ... whatever the Industry or type of clinical project, THeCRF captures data efficiently and cost-effectively so that you can focus on making the right decisions for your project.

All the functionalities you need

The most appreciated capabilities of THeCRF include:

• **Welcome Dashboard with a customizable widget**	• **On-demand reporting schedules**
• **The automatized set up**	• **Data export in the most popular formats**
• **Third party integration module**	• **Post-it comment and note functionality**
• **Digital Signature: Principal Investigator can sign directly in eCRF**	• **Images & DICOM management and evaluation**

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THeCRF for your IT department

Users, Access Management & Data Encryption

The authentication of users is provided only once, at the time of access to the application. It is generated by Techorizon staff after the user having completed the THeLearning associated to his/her role.

At any time of the clinical study, the sponsor can activate a new user or deactivate other ones according to our internal working instruction. To protect data the application uses an https protocol.

Additional encryption systems to protect data backups and use security certificates to ensure encryption of client-server communication are available.

Data Security

All production processes and assistance are carried out in compliance with and in accordance with the Quality Manual and all related procedures referred to in the ISO 9001:2015 certification owned, adopting systems to prevent the vulnerability of source codes.

THeCRF uses a qualified infrastructure according to the GAMP5 Guidelines which guarantees the integrity of the data even in the face of errors and anomalous situations.

Services and Maintenance

The assistance is guaranteed through a help-desk service, to provide technical and operational support to the users of the client interested in the use of the services of the technological and application infrastructure.

The help-desk service provides its activities to users in order to solve problems that arise and for which the sponsor's staff is not autonomous in the solution.

Our help desk service is provided by highly qualified personnel, trained and experienced in the field of Clinical Research and is able to solve the problem reported in a quick and timely manner.

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Our EDC Add-Ons

SAE Management

Inside a clinical project, Serious Adverse Event (SAE) management is fundamental to trigger a prompt action for patient safety and also to ensure related data collection accuracy. The SAE Management add-on facilitates and supports site staff in the collection, management, and analysis of any SAE recorded in a clinical project.

The automated population feature of the SAE form allows the site staff to capture all the needed data in just a few clicks. Relevant information is automatically disclosed to those in need without losing time with long e-mails, guaranteeing confidentiality of the data with a robust and reliable communication flow.

The SAE Management is a must have add-on to manage the SAE process in a secure and automated way and guarantee prompt action is taken for the safety of the patients involved.

Images & DICOM Management

Clinical Research is based on data proving the efficacy of a diagnostic, a drug or a medical device. In the era of the digitalisation of processes and decentralised data collection, more and more use of digital/medical images (for example, but not limited to, x-rays, CT scan, photos and videos) is preferred.

The Image & DICOM Management add-on allows site staff to upload these "special" data directly in the EDC with only a few clicks, ensuring a secure collection of data in compliance with CFR part 11.

It is no longer necessary to use external systems, increasing the number of passwords to remember and third party vendors to manage. THeCRF can contain images, DICOM (Digital Imaging and Communications in Medicine), videos and many other digital medical files, simplifying the activities of the site staff who will benefit from a single platform to collect all the clinical study data.

Multi Access Module (MAM) for Independent External Aggiudication Assessor Management

The Multi Access add-on allows you to provide the data collected in the EDC to independent expert users (for example Key Opinion Leaders) who can evaluate the decisions made by the site medical staff.

The add-on allows you to have access only to the necessary data and if needed also in a double-blind way, in order to guarantee the evaluation of the data independently. If there are discrepancies with respect to the choices made by the site staff, it is possible to intervene in a documented way in compliance with regulatory requirements.

With more than 15 years of experience in the life sciences sector and the proven satisfaction of our clients, we are confident that we can find and tailor a technological solution to help you with your project!
Contact us for more information on how Techorizon can help you with your technology needs.

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