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The MADE-TO-MEASURE EDC System

Provided by OPIS

OVERVIEW

Completely developed and supported by OPIS, Clinical.net represents a combination of features and benefits to give TRUE VALUE to your data collection.

- **An OPIS brand**
- **16 years on the market**
- **An in-house developed data handling solution**
- **Integrated digital space for clinical trials**

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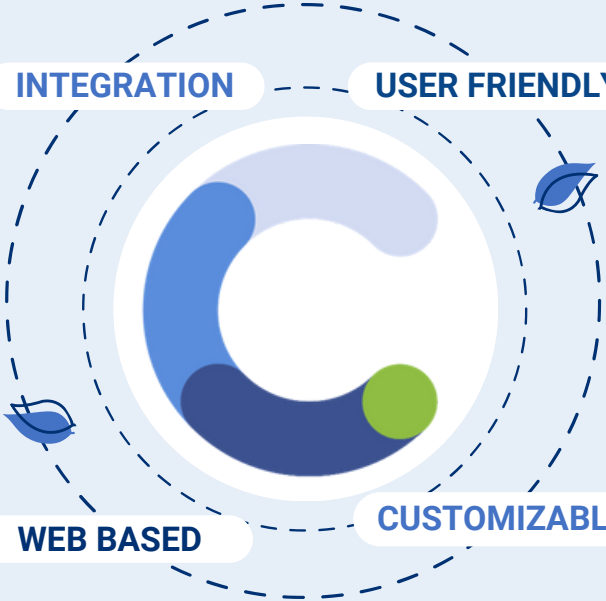
OVERVIEW

GCP & FDA Compliant



WEB PORTAL

- **Web-based software developed by OPIS**
- **GCP and FDA 21 CFR Part 11 compliant**
- **Based on a Three-Tier architecture**
- **Database Server: Microsoft SQL Server**
- **Microsoft.NET technology**
- **Cloud**

1. **Instant Modification**
2. **No Third-Part Vendors**
3. **Time and Cost Reduction**
4. **IT, Biometry and Clinical Operations work as one Team**

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SECURITY

Three-tier architecture is a software application architecture that organizes applications into three **logical and physical computing tiers**:

Application tier, where data is processed

Presentation tier, or user interface

Azure cloud technology with backup system in different regions.
The data is regionally stored according to Privacy Regulations.

Certifications ISO 27001, ISO 9001 and CyberVadis

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MODULES

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IRT/Drug Management

eLearning

Protocol deviation tool

Import from External Sources

Medical Monitoring

eSafety

ePRO/eCOA

Online randomization/IWRS

Electronic Data Capture(EDC)

EDC allows you to collect data from clinical trials, customizable eCRF documents and medical devices readings

Electronic Data Capture (EDC)

EDC systems streamline clinical trial data collection, storage, and analysis by replacing paper-based methods with a secure digital platform.

Queries Handling

Generates queries for missing or inconsistent data, ensuring complete and accurate records

2-Step Data Check

Involves initial validation and a second check for data integrity, often performed by data managers

Online Data Validation

It checks data accuracy and consistency, reducing errors and enhancing data quality

Online randomization/IWRS

The Randomization module provides the following online tools:

- **Custom randomization message to the investigator**
- **Real time Randomization number assignment**
- **Drug Kit**
- **Email notification**
- **Code break procedure**

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Medical Monitoring

The users can:

Access to patient profiles and medical monitoring reports

Perform a medical review of clinical data

Generate and manage queries

eSign the clinical data reviewed

Print the PDF report

Our Medical Monitoring tool seamlessly integrates with Clinical.Net's EDC system, creating an efficient ecosystem for clinical data management. This synergy enhances the efficiency and effectiveness of clinical data monitoring and review.

eLearning

The eLearning module serves a dual purpose, providing training not only for the trial protocol but also for the use of the system itself

Custom Training

System Training

Protocol Training

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Protocol Deviation Tool

Risk Reduction and Compliance

Custom Alerts, Adaptability

User-Friendly Interface

Status Tracking

Protocol Deviation Tool is a key component in clinical trial management. Its primary function is to minimize risks and ensure consistent adherence to study requirements and timelines, safeguarding the trials' integrity by swiftly identifying and addressing deviations or issues.

Import from external data sources:

Data import can be configured with various frequencies and methods:

sFTP

Web Services

Email

API

Clinical.net offers robust data communication capabilities for effortless data import and export.

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IRT/Drug Management

The drug management tool allows the management/tracking of the following activities:

- Drug release by Sponsor's Depot
- Drug boxes receipt at site
- Drug dispensing to patients
- Drug destruction's date by the Depot
- Drug (used/unused) returned to the Sponsor's Depot for destruction

Drug supply, re-supply, communication and re-allocation between depots, sites and team are handled through the drug management tool integrated in the Study Portal.

eSafety

The eSAE module streamlines safety information for investigators, expediting event creation, transmission, and reporting by consolidating it in one place.

SAE and Pregnancy forms management

Safety Notification sent by email to the involved users

Fully integrated with the EDC

Possible data import into Safety DB

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ePRO/eCOA App

Patient Reported Outcome and Patient Diaries can be now administered to the patients using our APP. It can be installed on patient's device or provided already configured on a device handled by us.

Patients' Device
(BYOD or provided)

Secure connection

Wearable device
(provided)

Secure integration

ePRO APP can be used both by Android and iOS users. We have a "bring your own device" policy so patients can choose whether they want to use their phone or they want to install the APP on their laptop or desktop.

ePRO App

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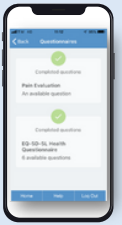
EVERY TYPE OF DATA

Multilanguage App



DYNAMIC CONTENT

GDPR

Downloadable Records

CLINICAL.NET INTEGRATED

MODULES

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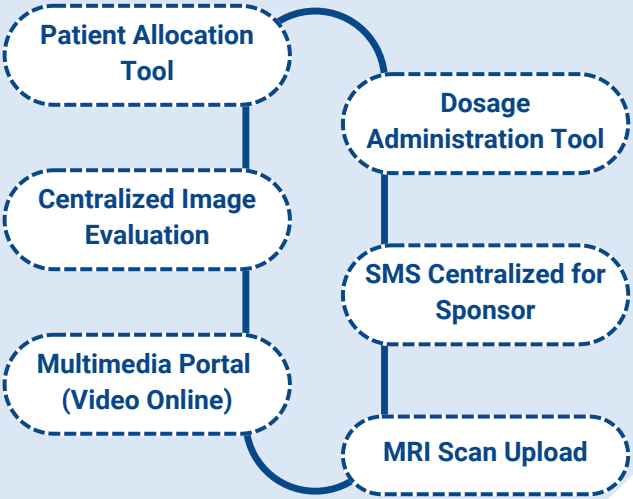

Cell and Gene Therapy Modules

OPIS's Cell and Gene Therapy Modules represent a pioneering advancement in the field, offering exceptional value to the EDC system.

PATIENT ALLOCATION

Real-time Site-sponsor interaction for complex enrolment process

- Adaptive designs
- Dose escalation
- Profile-dependent dosing

DOSAGE CALCULATION

Register viable cell-concentration and calculate dosage based on patient variables

- Automated document creation
- Audit trial

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ARCHITECT MODULE

This is a standalone solution.
With this module, we can let the customer create their own eCRF (trainings, laboratory normal ranges, protocol deviation listings…).
OPIS Staff will be in charge of complicated designs and specific tasks to help the customers .

OPIS staff tasks:

- **Other module setup: Randomization, eSafety**
- **Deployment on test and production environment**
- **eSafety: eSAE and ePregnancy PDF templates setup**
- **Automatism**
- **Tool and ePRO**

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ARCHITECT MODULE

Architect module allows you to setup eCRF (including eSAE and ePregnancy sections).

Sponsor role can setup:

- Trainings (eLearning module)
- Laboratory Normal Ranges
- Protocol Deviation list

Additional modules setup is performed by OPIS staff:

- IRT, Drug Management Tool, ePRO/eCOA
- Randomization/IWRS
- eSafety: eSAE and ePregnancy forms

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OPIS is a **Global CRO** prioritizing data-driven and quality-focused approaches.

We provide comprehensive 360° clinical trial support, from concept to closure, with **25 years of experience** in Phase I-IV interventional and non-interventional trials, including medical device studies worldwide.

Our **end-to-end services** are complemented by flexible solutions, offering full-service study execution or tailored options for specific service areas as stand-alone offerings.

+1470 Clinical Studies

+25 Years of Experience

OPIS has extensive rare diseases study experience and strong collaborations with key opinion leaders (KOLs), enabling us to tailor approaches to unique trial requirements. Our dedicated safety team provides **unwavering support**, leveraging a global network of experts with profound safety protocol knowledge to overcome research challenges.

OPIS

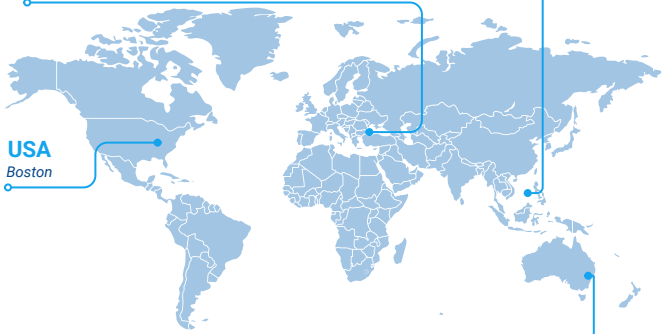
A Science Driven Biotech Focused CRO

EUROPE

ITALY (HQ) *Milan*
SWITZERLAND *Lugano*
SPAIN *Madrid*
GERMANY *Munich*
FRANCE *Paris*
BELGIUM *Brussels*
UK *London*
NETHERLANDS *Amsterdam*
SWEDEN *Stockholm*
POLAND *Warsaw*
HUNGARY *Budapest*
SERBIA *Belgrade*
BULGARIA *Sofia*

ASIA

JAPAN *Tokyo*
SOUTH KOREA *Seoul*
TAIWAN *Taipei*



USA

Boston

AUSTRALIA

Sydney

OPIS SERVICES

1470 Clinical Studies

All therapeutic areas and rare diseases

+25 years of experience

Scientific Advice

Preclinical Consultancy

Orphan Drug Designation

Medical Writing

Feasibility and Site Selection

Regulatory and Startup

Project Management

Monitoring and Site Management

Medical Monitoring

Medical Review

Quality Assurance

Auditing Services

Pharmacovigilance

Data Management

Statistical analysis and Consultancy

SAS Programming

Study Documentation Management

FSP Services

ePRO

Vendor Management

Clinical.net EDC and Study portal

Decentralized Clinical Trials

Real Word Evidence

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Learn More on clinical.net

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