SocraMetrics - The EDC Professionals

Are you looking for...

- ...a **highly flexible and cyber-secure eCRF** which is set-up according to your needs?
- ...an **efficient and user-friendly** system which easily becomes part of the study team?
- ...an eCRF solution to generate **real-time figures and reports** of study data?
- ...a switched-on Data Management team which already has **statistical evaluation** in mind while setting up the eCRF?
- ...a device-independent and self-evident **eDiary/ePRO** for your study participants?

SocraMetrics eCRF

Then our state-of-the-art eCRF is the answer!

By the way... Who we are

SocraMetrics - a specialised biometric CRO with strong focus on IT and Electronic Data Capture within the area of Clinical Data Management.

Since 1998, we have been a successful provider of services in the field of Data Management, Biometrics and Pharmacokinetics - initially as a division of SocraTec R&D, and from 2007 as an independent company.

In 2023 we added full-scope pharmacovigilance services to our portfolio.

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A highly flexible and cyber-secure eCRF

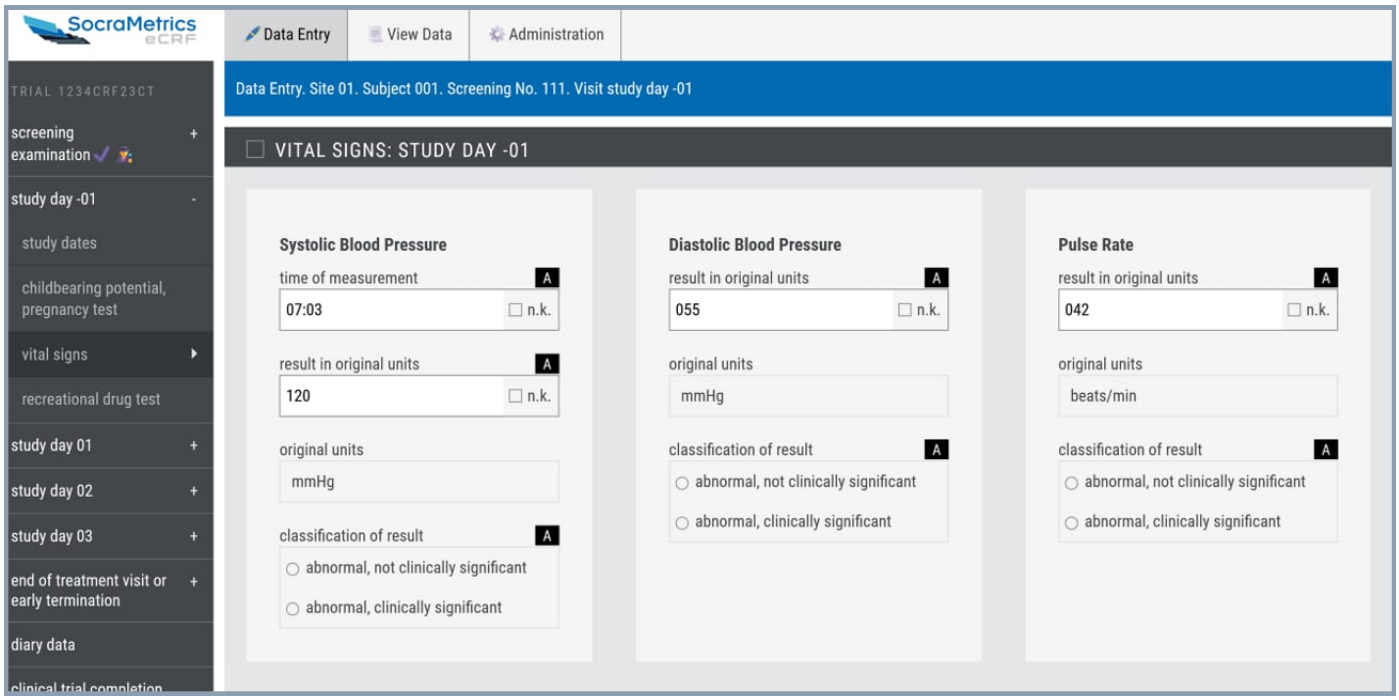
which is set-up according to your needs

We work according to internationally accepted IT-standards and our system is fully compliant to FDA 21 CFR Part 11 and EMA Annex 11 by following GAMP5 principles. The safety and integrity of your data is our priority.

Nevertheless, in our philosophy an EDC system used in clinical trials has to be as secure as flexible. This is why we developed a modular system in line with our cyber security concept which is easily adaptable to your needs and the complexity of your project.

NO OPPOSITES

With our EDC there is no contradiction between user-friendliness and cyber security!



Forms, input fields, buttons and dimensions are focused on user experience

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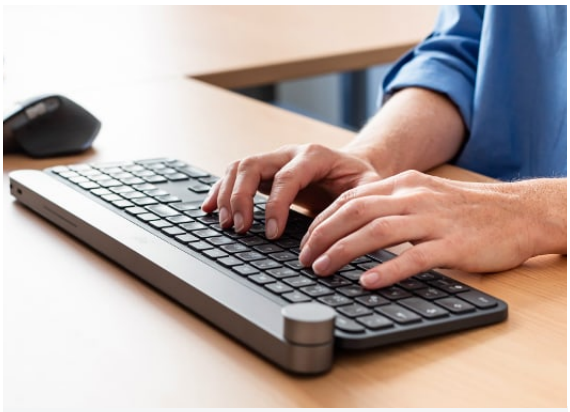
An efficient and user-friendly system

which easily becomes part of the study team

Needless to say, that we thought of our system from the user's perspective. We wanted a system which would never cause frustration when entering data and would provide all necessary information at a glance.

One of the unique selling propositions is the system's inherent speed due to modular design and reduced complexity – especially in trials with large amounts of data. The system's speed is just one among numerous reasons which make our EDC exceptionally appealing. Extremely short click paths and a highly intuitive input concept complete the picture.

When users perceive the system as an integral part of the study team, we have realised our vision.



USER ACCEPTANCE TESTS

During set-up process, the level of complexity and required functionality of the system will be thoroughly discussed with you, tailored to your requirements and quickly integrated by our experienced team including User Acceptance Tests (UATs).

Besides entering and storing data,
our eCRF includes but is not limited to the following features:

- **Mobile-friendly data entry**
  including dark mode
- **Complex randomisation and stratification procedures**
- **Kit monitoring**
- **Edit checks at different complexity levels**
  which easily span different time points and different entry screens
- **Time-saving Query process**
  which is easily understood even for sites without any trial experience
- **Prompt reports and figures**
  of any data and protocol deviations (PD Tracker) in real time
- **A variety of data export formats**
- **An efficient SDV and release process**
- **A comprehensive Audit Trail**
- **Fast export of blank and filled CRFs**
  for archiving and storage
- **Data-driven eMail notifications**
  of any event

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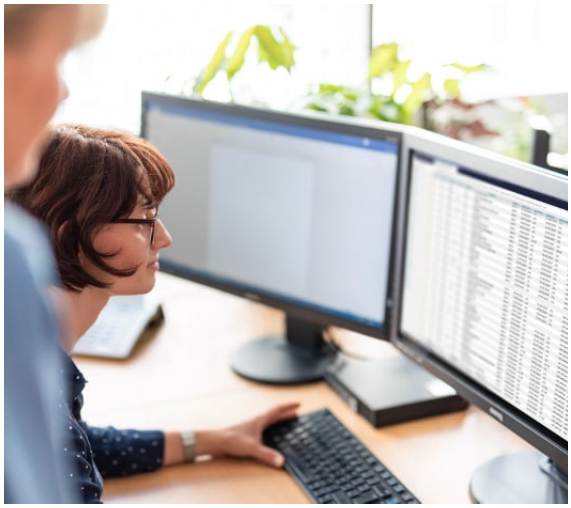
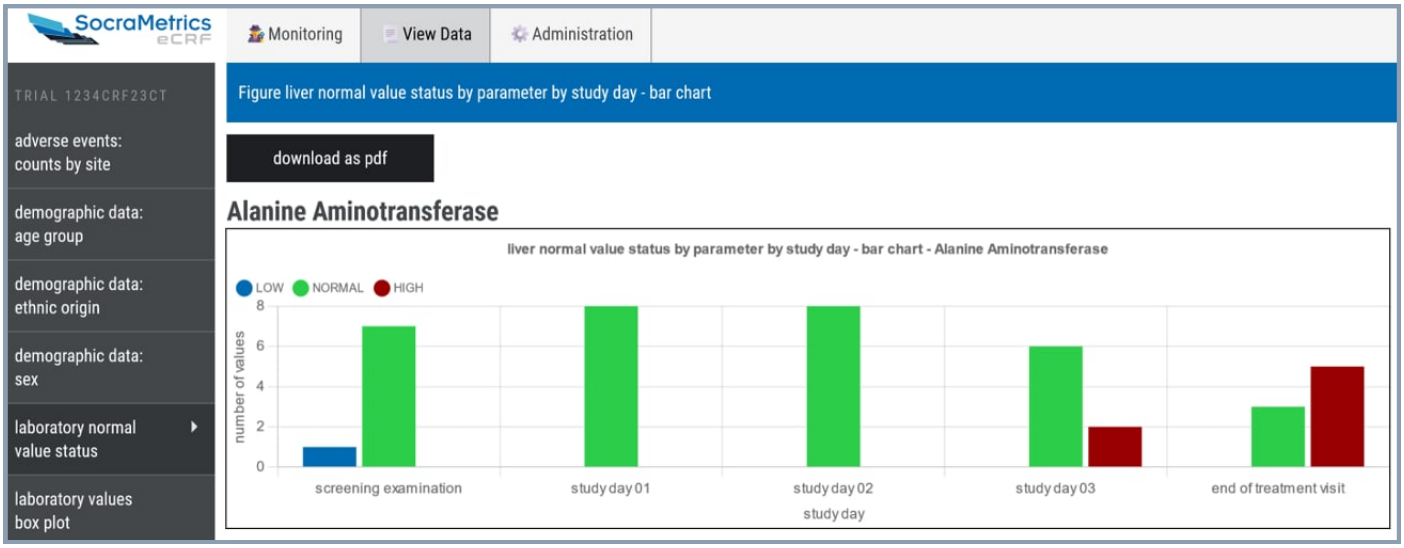
Sponsor Oversight



Real-time figures and reports

No matter whether you need an interim Adverse Events report, a summary of Protocol Deviations or laboratory figures – exportable real-time reports and graphs are accessible at any time in the system.

Real-time data access for clinical trial sponsors, investigators, study site staff and CRAs facilitates identifying and addressing issues promptly, in order to ensure patient safety and maintain data integrity.



Statistical figures can be accessed at any time based on real-time data

Think eCRF – Think statistics!

Statistical analysis begins at the design stage of a clinical trial. In order to generate accurate and relevant data, it is crucial to consider the evaluation criteria when configuring the eCRF. During eCRF set-up, our highly skilled team ensures the collection of the appropriate data for meaningful statistical analysis (as little as possible but as much as needed).

We will assist you from the initial planning phase, through the setup of the EDC system and all the way to the statistical analysis. If you prefer to conduct the statistical analysis yourself, we will provide you with the appropriate data formats for your analysis needs.

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Our eDiary/ePRO

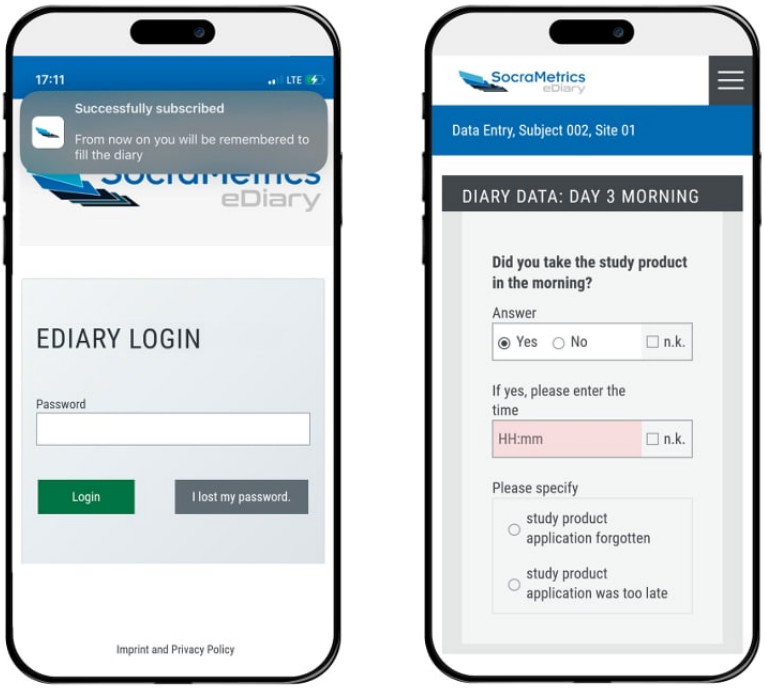
Bring-Your-Own-Device

Your study participants will appreciate our convenient browser-based application!

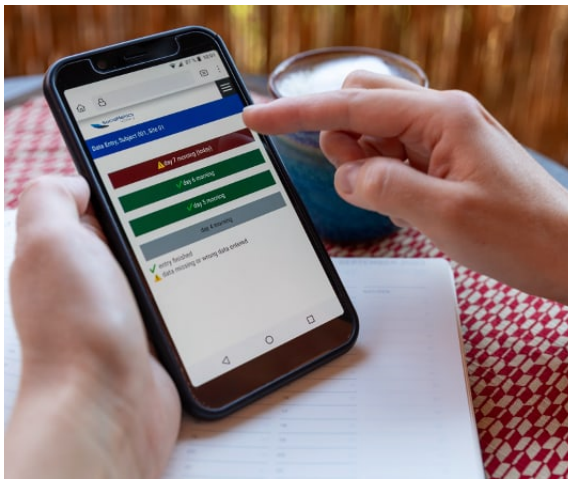
No additional software is required to use the eDiary. Volunteers can enter data on their own smartphone, tablet or any other device of their choice.
In doing so, they do not have to disclose any personal information, such as email-addresses. We have integrated a sophisticated password recovery process, eliminating the need to store any non-pseudomised data.

Data collection in an intuitive and clear design will become part of the daily routine, especially in combination with the integrated reminder function. Your subjects' compliance will increase!

As the eDiary is fully integrated into the eCRF system, study staff has real-time access to all diary data enabling them to perform compliance checks and contact volunteers promptly in case of any problems.



SocraMetrics eDiary - easy to use on smartphones



Convenient data entry any place any time

NO ADDITIONAL SOFTWARE

Our entire eCRF and eDiary is browser-based – no additional software needs to be installed. All you need is an internet connection and a browser.

OUR PROMISE

Our experienced and exceptionally qualified team will work out the EDC solution which is perfectly tailored to your project.

No matter whether you plan a multinational phase III project or a monocentric early phase trial/low-budget IIT – we have a cost-efficient, cyber-secure and user-friendly solution for every type of clinical project.

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WHY US?

Our EDC puts you – the customer and the user – into the pole position when it comes to modern and efficient technology for clinical trials. High levels of efficiency are guaranteed by our own software solutions, which are of course not limited to the EDC system. Our passion for data and data integrity, our client-centric approach, our commitment to excellence and our exceptional team spirit are particularly evident in the timely resolution of any issues.

We understand that every client and every project is unique – that is why we make customisation our number one priority. Our well-established and highly experienced team seeks the close contact to you as the client and supports you in all aspects of Data Management with tailored solutions and processes. We really care about your needs, your products and your success while ensuring full regulatory compliance.

SocraMetrics offers the full-service solution for your digital clinical trial!

Training and support

Needless to say, that our service includes intensive training and support for study nurses, investigators, CRAs, Project Managers and Data Managers to operate the system.

If you prefer to purchase the system only and set up the eCRF yourself after thorough training this can also be arranged.

Get in touch:

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ANY OTHER SERVICES NEEDED?

We do not only offer EDC services but also the full range of Clinical Data Management services, SDTM and ADaM submission packages, Pharmacokinetics, Biostatistics and Pharmacovigilance.

Find out more:
https://socrametrics.com

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