

SocraMetrics - The EDC Professionals



Are you looking for...



...a **highly flexible and cyber-secure eCRF** which is set-up according to your needs or available as **SaaS**?



...an **efficient and user-friendly** EDC 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?



The answer: SocraMate and SocraMia!

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.



ASK JULIANA BRUDEL
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VISIT US ONLINE
<https://ecrf.pro>

Our highly flexible and cyber-secure eCRF SocraMate

available as full-service or SaaS solution

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.

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.

Whether you choose our **full-service option** or prefer to use the software as a **SaaS solution**, **cybersecurity and flexibility** remain uncompromised at the highest level.



NO OPPOSITES

With **SocraMate** there is no contradiction between user-friendliness and cyber security!

The screenshot displays the SocraMetrics eCRF interface. At the top, there are navigation tabs for 'Data Entry', 'View Data', and 'Administration'. Below this, a blue header bar indicates the current context: 'Data Entry. Site 01. Subject 001. Screening No. 111. Visit study day -01'. The main content area is titled 'VITAL SIGNS: STUDY DAY -01' and contains three columns of data entry forms:

- Systolic Blood Pressure:** Includes fields for 'time of measurement' (07:03), 'result in original units' (120), 'original units' (mmHg), and 'classification of result' (radio buttons for 'abnormal, not clinically significant' and 'abnormal, clinically significant').
- Diastolic Blood Pressure:** Includes fields for 'result in original units' (055), 'original units' (mmHg), and 'classification of result' (radio buttons for 'abnormal, not clinically significant' and 'abnormal, clinically significant').
- Pulse Rate:** Includes fields for 'result in original units' (042), 'original units' (beats/min), and 'classification of result' (radio buttons for 'abnormal, not clinically significant' and 'abnormal, clinically significant').

Each input field has a small 'A' icon in the top right corner, likely representing an audit trail or validation status. The interface is clean and user-focused, with clear labels and intuitive controls.

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

An efficient and user-friendly System

which easily becomes part of the study team

Needless to say, we designed **SocraMate** from the user's perspective. We wanted a system which would never cause frustration when entering data and would provide all essential information at a glance.

One of its unique selling points is **SocraMate's inherent speed**, thanks to its modular design and reduced complexity – particularly valuable in trials with large amounts of data. The system's speed is just one of many reasons why **SocraMate** stands out. Extremely short click paths and a highly intuitive input concept complete the picture.

When users see **SocraMate** as an integral part of the study team, we know we have achieved 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, **SocraMate includes but is not limited to the following features:**

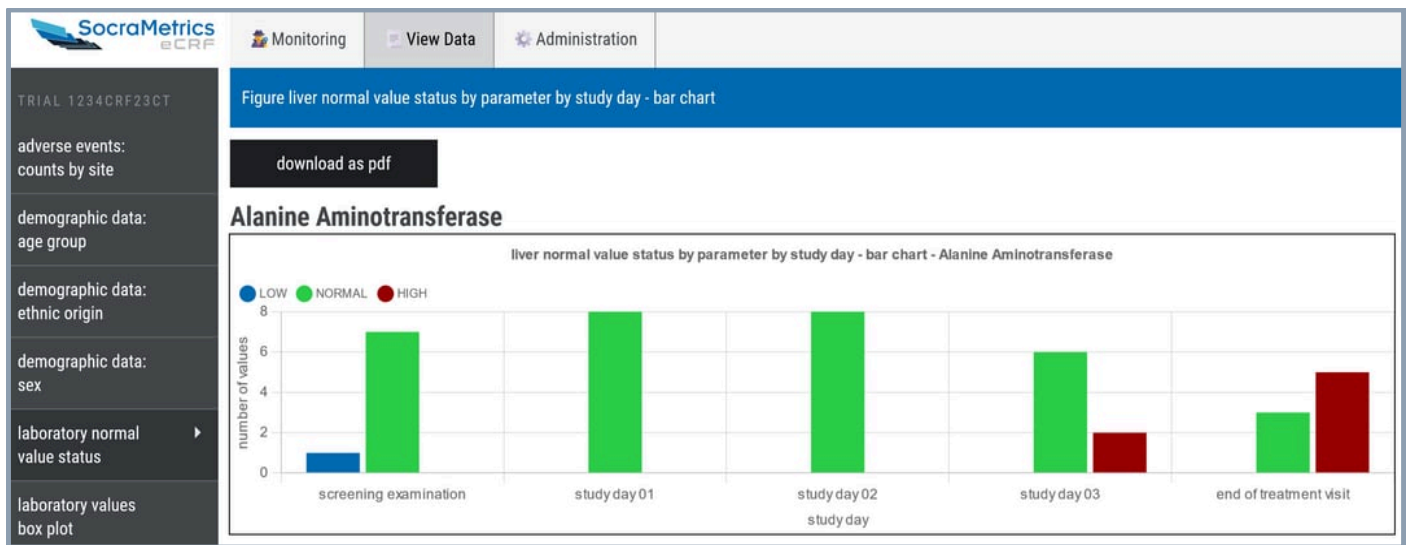
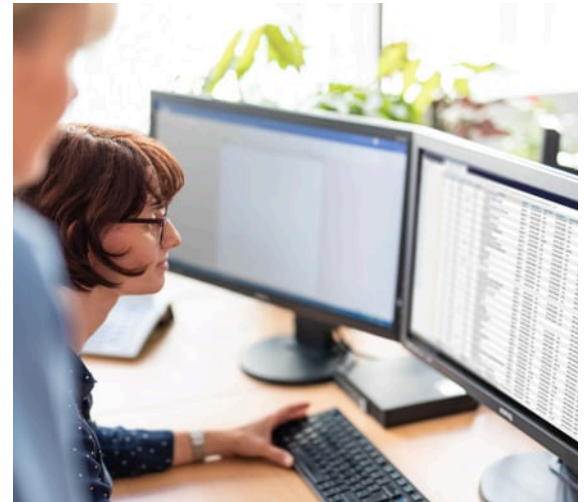
- ◆ **Mobile-friendly data entry**
including dark mode
- ◆ **Complex randomisation and stratification procedures**
- ◆ **Kit monitoring**
- ◆ **Edit checks at different complexity levels**
which easily span different time points and different entry screens
- ◆ **Time-saving Query process**
which is easily 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, fast-loading Audit Trail**
- ◆ **Fast export of blank and filled CRFs**
for archiving and storage
- ◆ **Data-driven eMail notifications**
of customised events

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 **SocraMate**.

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.



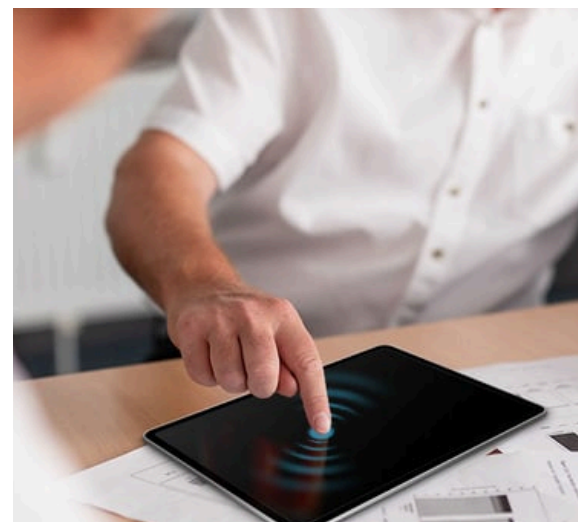
Statistical figures can be accessed at any time based on real-time data

Think eCRF – Think Statistics!

We believe that **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 set-up, our highly skilled team ensures the collection of the appropriate **CDISC compliant 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 **SocraMate** 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.



Our eDiary/ePRO SocraMia

Bring-Your-Own-Device

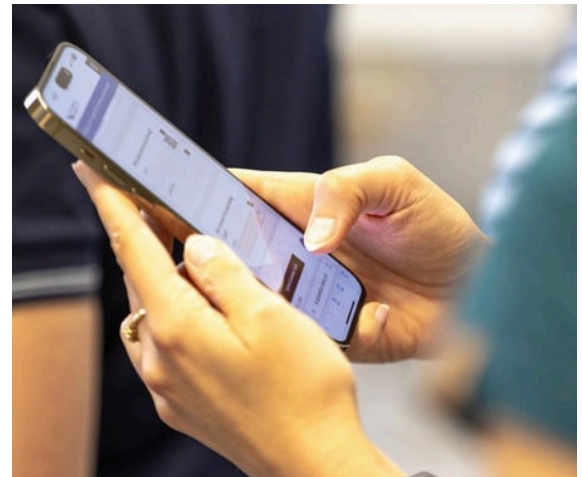
Your study participants will appreciate our convenient, browser-based application: **SocraMia**!

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.

Of course, we protect privacy! Participants use **SocraMia** **without disclosing personal data** such as email-addresses. We have integrated a sophisticated password recovery process that eliminates the need to store any non-pseudomised data.

Thanks to its **intuitive and clear design, data collection becomes part** of the participant's **daily routine**, especially in combination with the offered reminder function. The result? **Compliance** will increase.

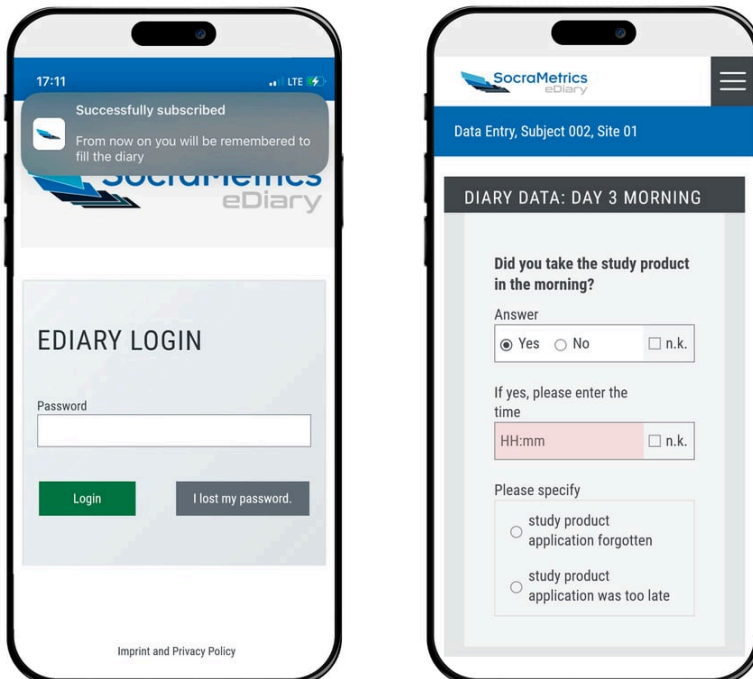
As **SocraMia eDiary** is fully integrated into **SocraMate eCRF**, study staff has **real-time access** to all diary entries, enabling timely compliance checks and immediate follow-up with participants if issues arise.



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.



SocraMetrics eDiary - easy to use on smartphones

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.

WHY US?

SocraMate 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**.

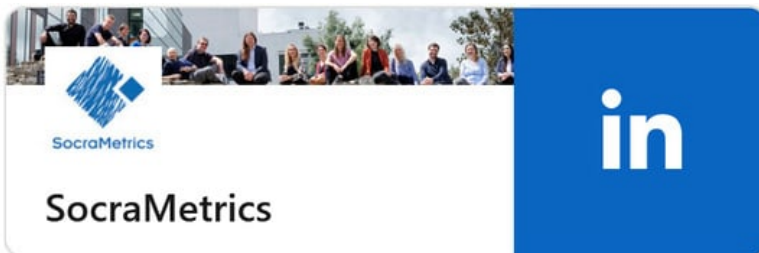
SocraMetrics offers the full-service or SaaS solution for your digital clinical trial!

Training and support - full-service and SaaS

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.

SaaS: We are happy to provide **SocraMate** as **SaaS solution** if you prefer to purchase the system only and set up the eCRF yourself after thorough training.

Follow us on LinkedIn!



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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 services.

Find out more:
<https://socrametrics.com>

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