SocraMate® and SocraMia®
Functionality eBook

An EDC Feature Collection

A product of SocraMetrics GmbH

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This eBook is the result of an experiment. Through a series of weekly LinkedIn posts titled “EDC Feature of the Week” our team has been sharing insights into our outstanding and user-friendly EDC system, highlighting different features from various user perspectives in an informative, yet entertaining way.

What started as a simple lunchtime idea quickly turned into a successful series that we’ve really enjoyed creating. To give you an easy way to revisit or discover the full collection we‘ve now compiled all these posts into an eBook. However, it‘s definitely worth checking out the original posts on LinkedIn. Many of them include GIFs, videos, and other extras that bring the content to life in a way this format can‘t fully capture.

As part of the campaign, we revealed the name of our software in the final post – so you‘ll find that post and a link to the hilarious name drop video at the end of this eBook, even though the names – SocraMate and SocraMia – may already be familiar to you.

I hope you enjoy reading it as much as we enjoyed producing it!

Best regards,

Juliana Brudel

Managing Director SocraMetrics GmbH

CDMs
Investigators
CRAs
PMs
Study Nurses
eCRF
OPENER
OUR EDC
FEATURE
of the week

Curious about SocraMate?

Drawing on many years of experience, a variety of perspectives and the collective wisdom of many, our EDC system has been developed

- by CDMs for CDMs
- by CRAs for CRAs
- by study nurses for study nurses
- by investigators for investigators
- by PMs for PMs

Don't just take our word for it! Dive deeper into the innovation - read the full story here.

#1
OUR EDC
FEATURE
of the week
SocraMetrics
eCRF

Fast, Faster, Fastest

As data accumulates, many EDC systems tend to slow down. But with our intelligent database and page loading concepts, we ensure smooth performance, even with huge amounts of data.

Fancy a few numbers?
Average page load time: 50ms
Generation of summary reports: 30ms

Join us in pioneering data capture without compromising speed!

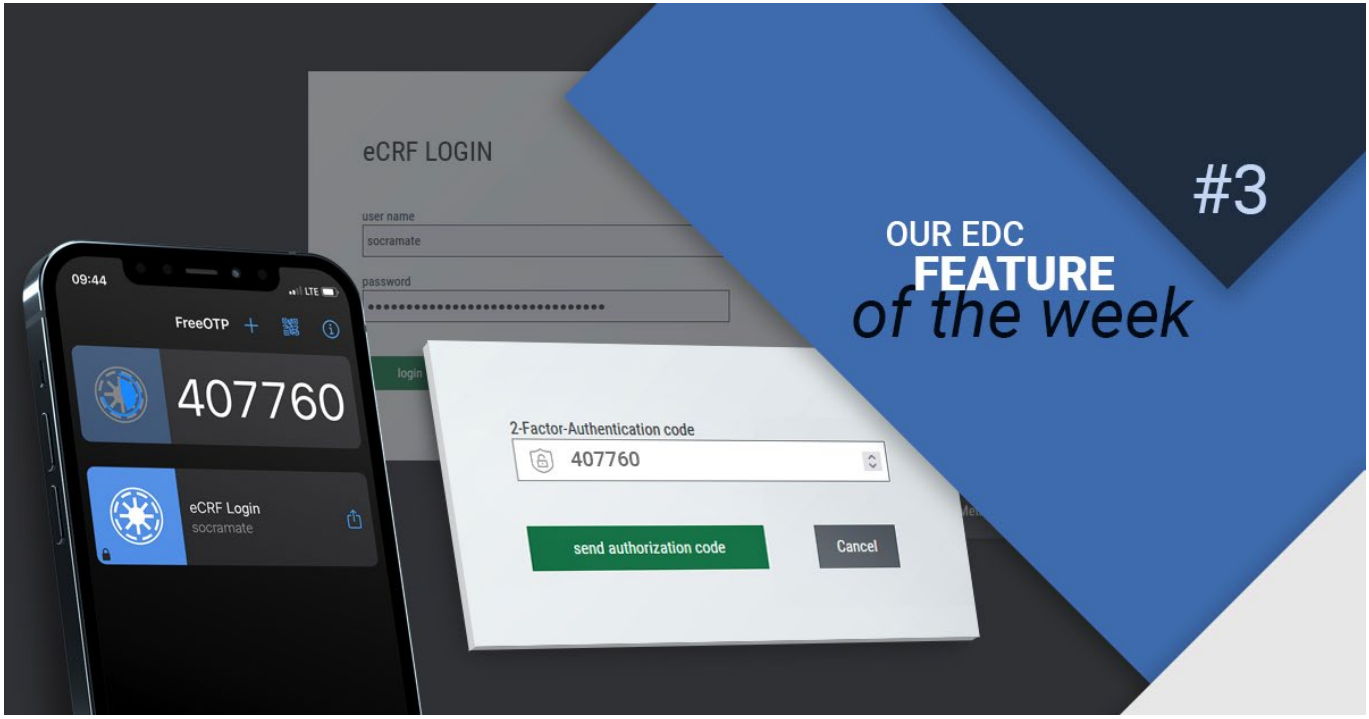
#2
OUR EDC
FEATURE
of the week
config

Fast, Faster, Fastest - Part II

Speed isn‘t just about the system itself. We‘ve also designed a setup process that makes life easier for everyone involved. Forget about endless form generation!

With our table-based setup, you can create 90% of a trial-specific EDC without advanced programming skills. All you need is a basic understanding of SQL, using software you‘re already familiar with.

And the best part? You can go from scratch to study start in a few weeks (6 weeks at maximum for very complex projects)!

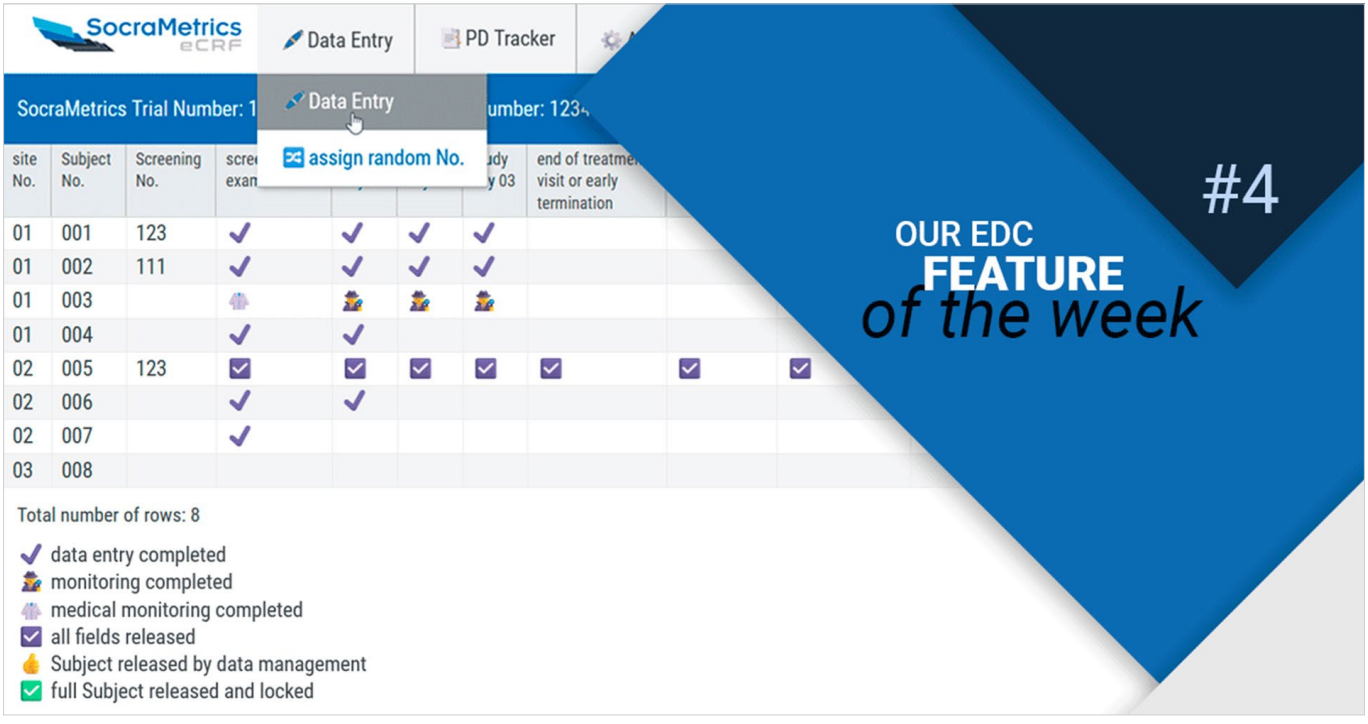

#3
OUR EDC
FEATURE
of the week
eCRF LOGIN
user name
socramate
password
login
2-Factor-Authentication code
407760
send authorization code
Cancel
09:44
FreeOTP
407760
eCRF Login
socramate

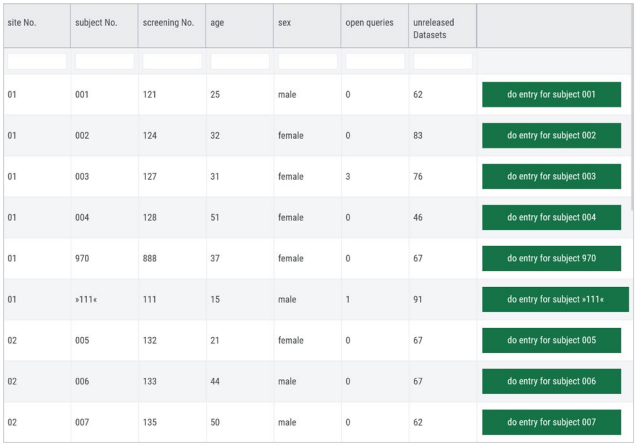
Login with speed and security in mind!

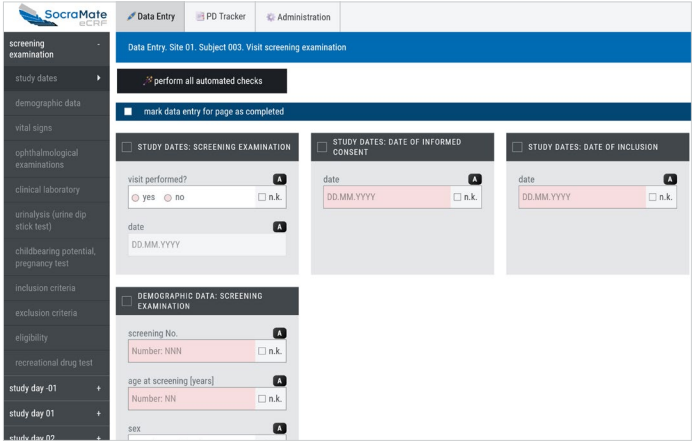
Ever experienced this? You're trying to log into an EDC system, you've entered your username and password, and then find yourself wasting precious time waiting for the one-time pin to arrive via email or text message.

At SocraMetrics, we've chosen a different approach to enhance cyber security through the use of OTPs. Our login system is based on the TOTP standard. Your phone generates a new number every 30 seconds. To log in, simply enter the current number displayed. No delays, even when your phone is offline!

Our login process - as quick as it can be while remaining highly secure with 30s password age!


SocraMetrics eCRF
Data Entry
PD Tracker
Data Entry
assign random No.
SocraMetrics Trial Number: 1
umber: 123
site No.
Subject No.
Screening No.
end of treatme visit or early termination
01 001 123
01 002 111
01 003
01 004
02 005 123
02 006
02 007
03 008
Total number of rows: 8
data entry completed
monitoring completed
medical monitoring completed
all fields released
Subject released by data management
full Subject released and locked
#4
OUR EDC
FEATURE
of the week


site No.
subject No.
screening No.
age
sex
open queries
unreleased Datasets
01 001 121 25 male 0 62 do entry for subject 001
01 002 124 32 female 0 83 do entry for subject 002
01 003 127 31 female 3 76 do entry for subject 003
01 004 128 51 female 0 46 do entry for subject 004
01 970 888 37 female 0 67 do entry for subject 970
01 »111« 111 15 male 1 91 do entry for subject »111«
02 005 132 21 female 0 67 do entry for subject 005
02 006 133 44 male 0 67 do entry for subject 006
02 007 135 50 male 0 62 do entry for subject 007


SocraMate eCRF
Data Entry
PD Tracker
Administration
screening examination
study dates
demographic data
vital signs
ophthalmological examinations
clinical laboratory
urinalysis (urine dip stick test)
childbearing potential, pregnancy test
inclusion criteria
exclusion criteria
eligibility
recreational drug test
study day -01
study day 01
Data Entry. Site 01. Subject 003. Visit screening examination
perform all automated checks
mark data entry for page as completed
STUDY DATES: SCREENING EXAMINATION
visit performed?
yes
no
n.k.
date
DD.MM.YYYY
STUDY DATES: DATE OF INFORMED CONSENT
STUDY DATES: DATE OF INCLUSION
DEMOGRAPHIC DATA: SCREENING EXAMINATION
screening No.
Number: NNN
age at screening [years]
Number: NN
sex

Structured simplicity

Following trial selection, users are directed to a project overview featuring status indication. This indicator utilizes intuitive icons to visually represent the status of each individual patient.

Important information, such as protocol amendments and their impact on study conduct and data entry, is always prominently displayed in the patient overview in real time.

A well-structured menu ensures short click paths from login to the actual data entry fields. Forget about features that cannot be found. Key details are always in sight and just a few clicks away.

Data was saved.
screenin
study day -01 +
study day 01 -
study dates
vital signs
eligibility
exposure of IMP
pharmacokinetic time points
study day 02 +
study day 03 +
end of treatment visit or early termination +
Subject 0
STUDY DATES:
visit performed?
yes
no
date
14.03.2024
<< < March 2024 > >>
Mon Tue Wed Thu Fri Sat Sun
26 27 28 29 1 2 3
4 5 6 7 8 9 10
11 12 13 14 15 16 17
18 19 20 21 22 23 24
25 26 27 28 29 30 31
NK.03.2024
NK.NK.2024
A
n.k.
#5
OUR EDC
FEATURE
of the week

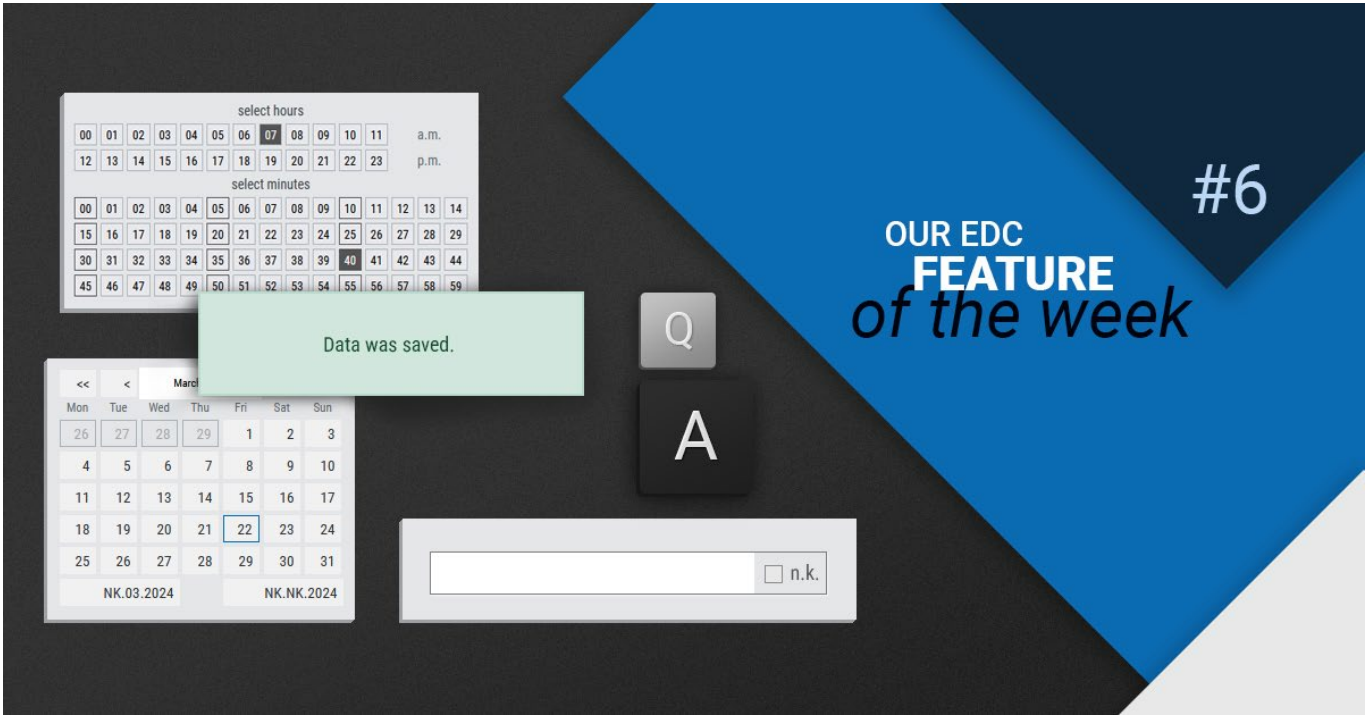
Experience lightning-fast data entry with our system

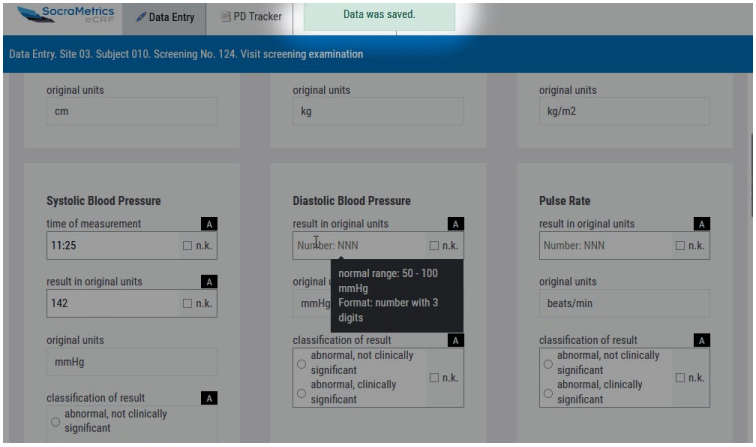
We could write lengthy posts about the speed and comfort of our system when it comes to the core of data entry.

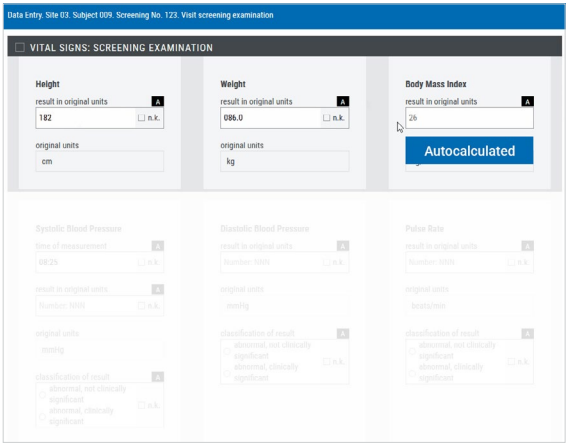
But we prefer to let the facts speak for themselves rather than engage in idle chatter:

- **Direct access** to entry fields - no „Edit“ buttons or waiting for the Audit Trail
- **Auto-save** within milliseconds when leaving a data entry field - no „Save“ buttons
- Entering patient data from top to bottom during a visit - **no interruptions**
- Moving between forms instantly through innovative navigation - **no delays**
- A **75% reduction in clicks** compared to other systems
- **Filter and sort the patient lists** within a fraction of a second

Rest assured:
You won‘t see any loading bars during data entry – that‘s a promise!


select hours
00 01 02 03 04 05 06 07 08 09 10 11 a.m.
12 13 14 15 16 17 18 19 20 21 22 23 p.m.
select minutes
00 01 02 03 04 05 06 07 08 09 10 11 12 13 14
15 16 17 18 19 20 21 22 23 24 25 26 27 28 29
30 31 32 33 34 35 36 37 38 39 40 41 42 43 44
45 46 47 48 49 50 51 52 53 54 55 56 57 58 59
Data was saved.
Mon Tue Wed Thu Fri Sat Sun
NK.03.2024
NK.NK.2024
n.k.
#6
OUR EDC
FEATURE
of the week
Q
A


SocraMetrics eCRF
Data Entry
PD Tracker
Data was saved.
Data Entry. Site 03. Subject 010. Screening No. 124. Visit screening examination
original units
cm
kg
kg/m2
Systolic Blood Pressure
time of measurement
11:25
result in original units
142
original units
mmHg
classification of result
abnormal, not clinically significant
Diastolic Blood Pressure
result in original units
Number: NNN
normal range: 50 - 100 mmHg
Format: number with 3 digits
classification of result
abnormal, not clinically significant
abnormal, clinically significant
Pulse Rate
result in original units
Number: NNN
original units
beats/min
classification of result
abnormal, not clinically significant
abnormal, clinically significant
n.k.


Data Entry. Site 03. Subject 009. Screening No. 123. Visit screening examination
VITAL SIGNS: SCREENING EXAMINATION
Height
result in original units
182
original units
cm
Weight
result in original units
086.0
original units
kg
Body Mass Index
result in original units
26
Autocalculated
n.k.

Data Entry in Detail - Part I: Simplify your Life

Gone are the days of clicking through multiple forms or sections to input crucial data! In our system, your data is automatically saved the moment you leave the entry field. No more Save or Edit buttons - it‘s all taken care of seamlessly in the background.

In our example, systolic blood pressure is auto-saved, while diastolic blood pressure can already be entered.

This means you can focus on what matters most, without worrying about losing data or getting lost in complex interfaces.

At SocraMetrics, we‘re simplifying the data entry process to make your life easier.

subject overview

clear filter/sorting

site No.	subject No.	screening No.	age	sex	open queries	unreleased Datasets	
				female			
03	009	123		female	0	83	do entry for subject 009
03	011	125		female	0	83	do entry for subject 011
02	006	142		female	1	83	do entry for subject 006
02	007			female	3	83	do entry for subject 007
01	002	111	19	female	2	83	do entry for subject 002
01	003		15	female	7	76	do entry for subject 003

Sort data ASC / DESC

Filter for values

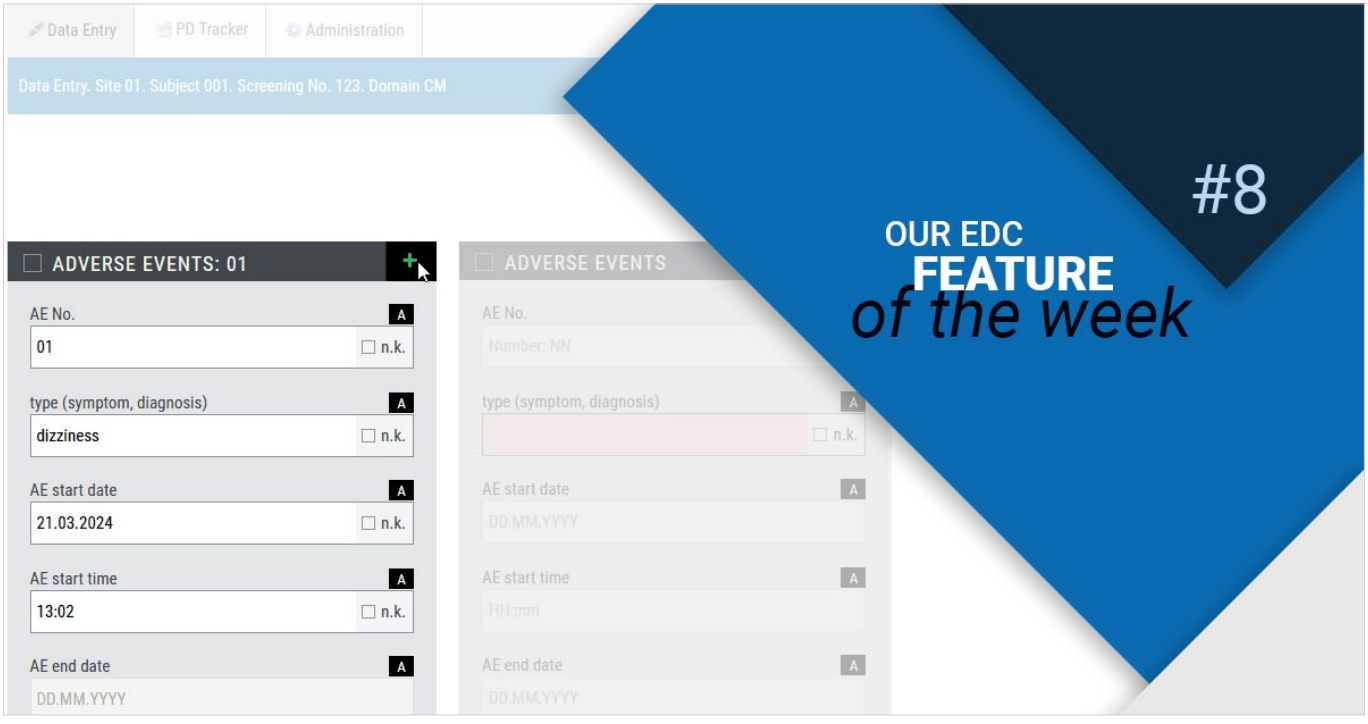
Mark rows

Data Entry in Detail - Part II: Empower your Workflow

Need to find a specific patient quickly? No problem! Our **advanced filtering** and sorting capabilities allow you to browse through patient lists within a fraction of a second, ensuring prompt access to the data you need when you need it.

To ensure efficient data entry, patient data of a visit can be entered from top to bottom, or users can **rapidly navigate through different forms** according to their personal preferences.

Experience streamlined data entry with our intuitive solutions!

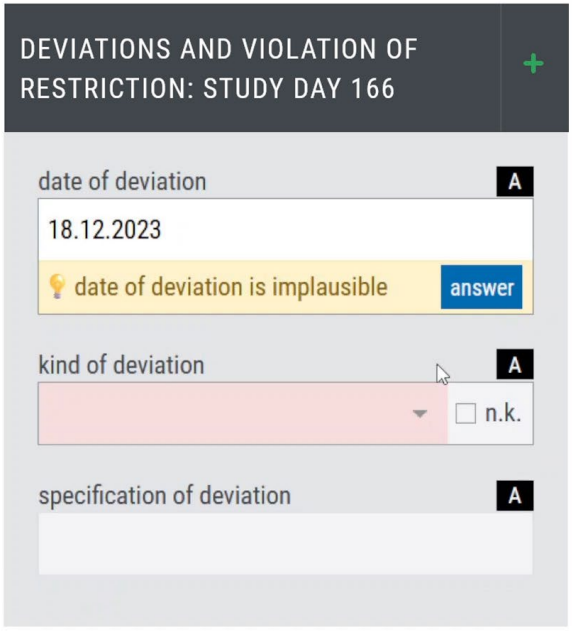

Data Entry
PD Tracker
Administration
Data Entry. Site 01. Subject 001. Screening No. 123. Domain CM
ADVERSE EVENTS: 01
AE No.
01
n.k.
type (symptom, diagnosis)
dizziness
n.k.
AE start date
21.03.2024
n.k.
AE start time
13:02
n.k.
AE end date
DD.MM.YYYY
ADVERSE EVENTS
AE No.
Number: NN
type (symptom, diagnosis)
n.k.
AE start date
DD.MM.YYYY
AE start time
HH:mm
AE end date
DD.MM.YYYY
#8
OUR EDC
FEATURE
of the week

Data Entry in Detail - Part III: Running Records

Data Entry of ongoing records such as Adverse Events and Medication has never been easier! Regardless of the number of events, you can effortlessly duplicate entry forms to suit your needs.

In our system, navigating through AEs and ConMeds is a breeze - fast and completely independent of visit-specific data.

Enjoy streamlined navigation and user-friendly features: whether it's updating AEs or inputting drug indications, it's all at your fingertips!



#9

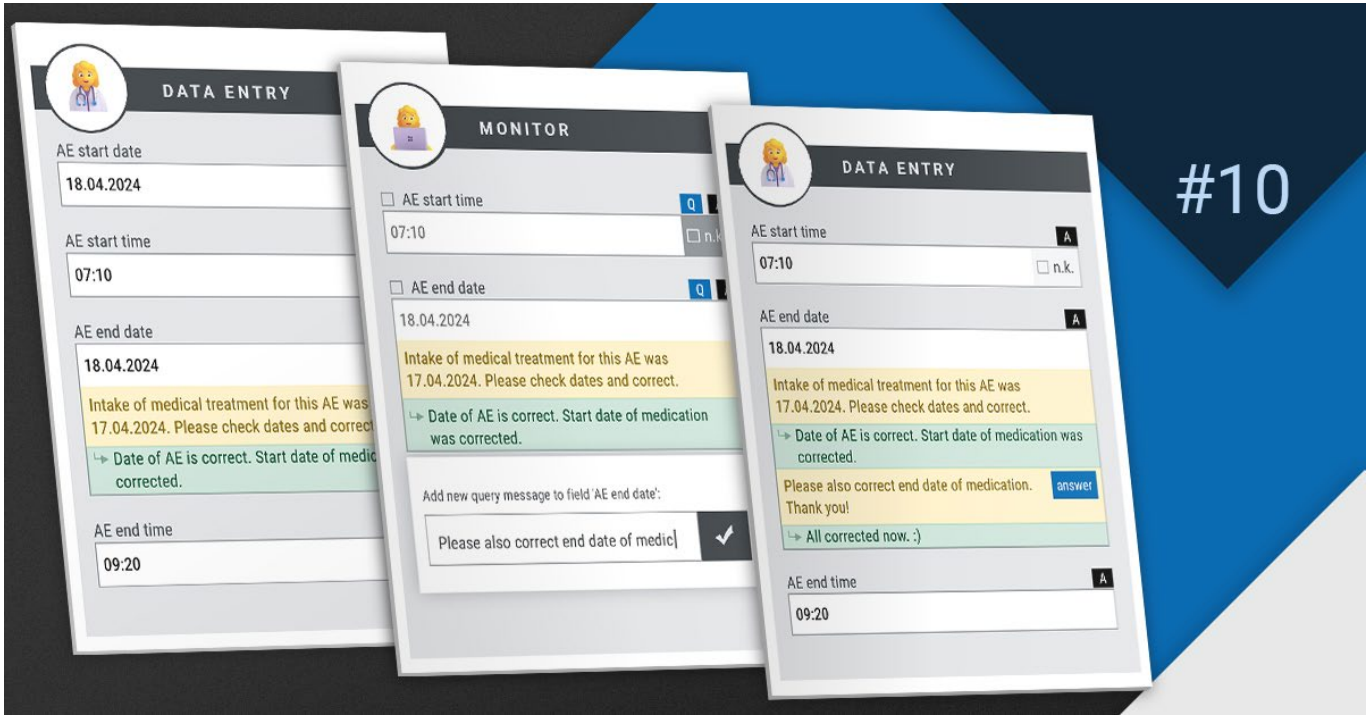
OUR EDC
FEATURE
of the week

Query Management - Part I: Auto Queries on the fly

We‘ve all been there: a typo slips through your fingers as you‘re entering data. That‘s just life, isn‘t it? But don‘t worry.

Our system doesn‘t ask you to hit ‚save‘ or wait for all the edit checks to run, but gives you an immediate response.

With pre-defined edit checks kicking in the moment you leave the entry field, our mission is crystal clear: ensuring best data quality with minimal hassle.

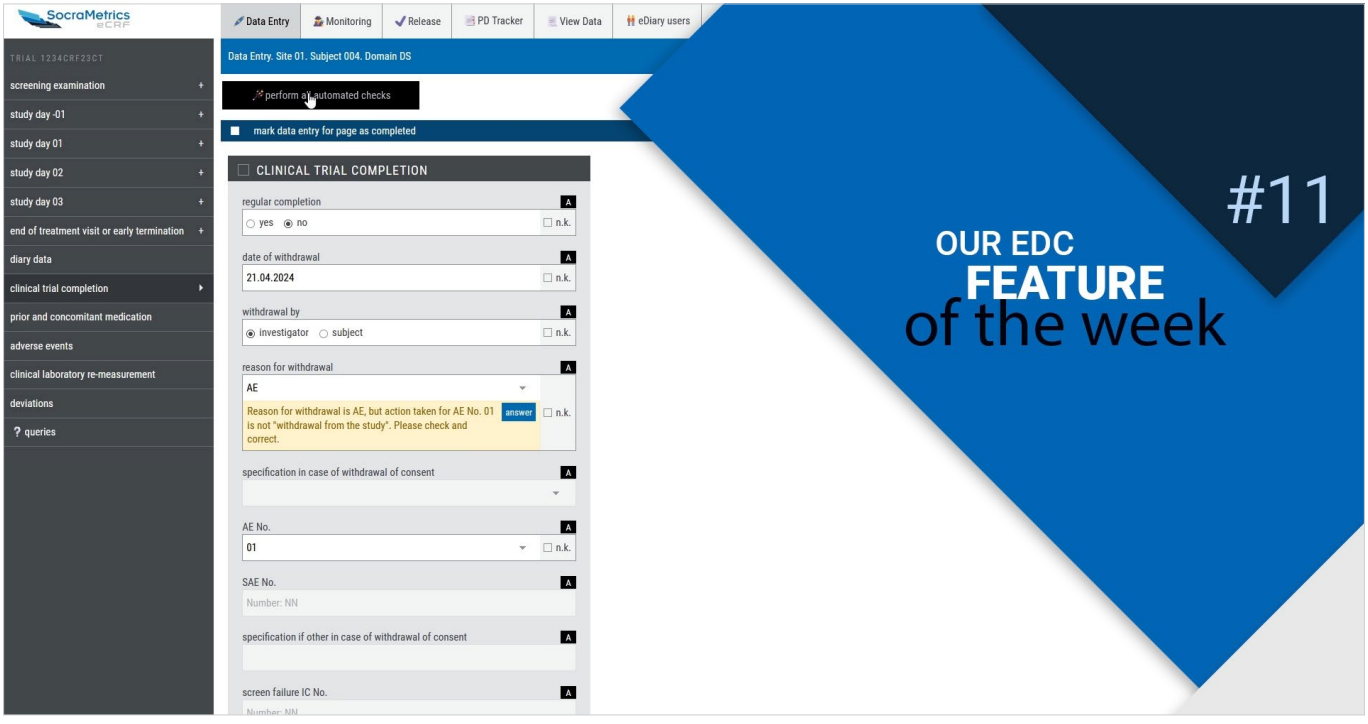

DATA ENTRY
AE start date
18.04.2024
AE start time
07:10
AE end date
18.04.2024
Intake of medical treatment for this AE was
17.04.2024. Please check dates and correct
Date of AE is correct. Start date of medic
corrected.
AE end time
09:20
MONITOR
AE start time
07:10
AE end date
18.04.2024
Intake of medical treatment for this AE was
17.04.2024. Please check dates and correct.
Date of AE is correct. Start date of medication
was corrected.
Add new query message to field 'AE end date':
Please also correct end date of medic
DATA ENTRY
AE start time
07:10
n.k.
AE end date
18.04.2024
Intake of medical treatment for this AE was
17.04.2024. Please check dates and correct.
Date of AE is correct. Start date of medication was
corrected.
Please also correct end date of medication.
Thank you!
answer
All corrected now. :)
AE end time
09:20
#10

Query Management - Part II: Conversational Queries

These featured queries are called conversational for a reason - initiate queries, correct entries, and follow entire dialogues across different roles, all in one glance. No need to navigate away from your page just to address a query!

Imagine a scenario where an investigator and a monitor work together to resolve issues within moments, thanks to short click paths. What may seem trivial is, in fact, crucial: both users share the exact same interface and design, which ensures that communication and coordination run smoothly.

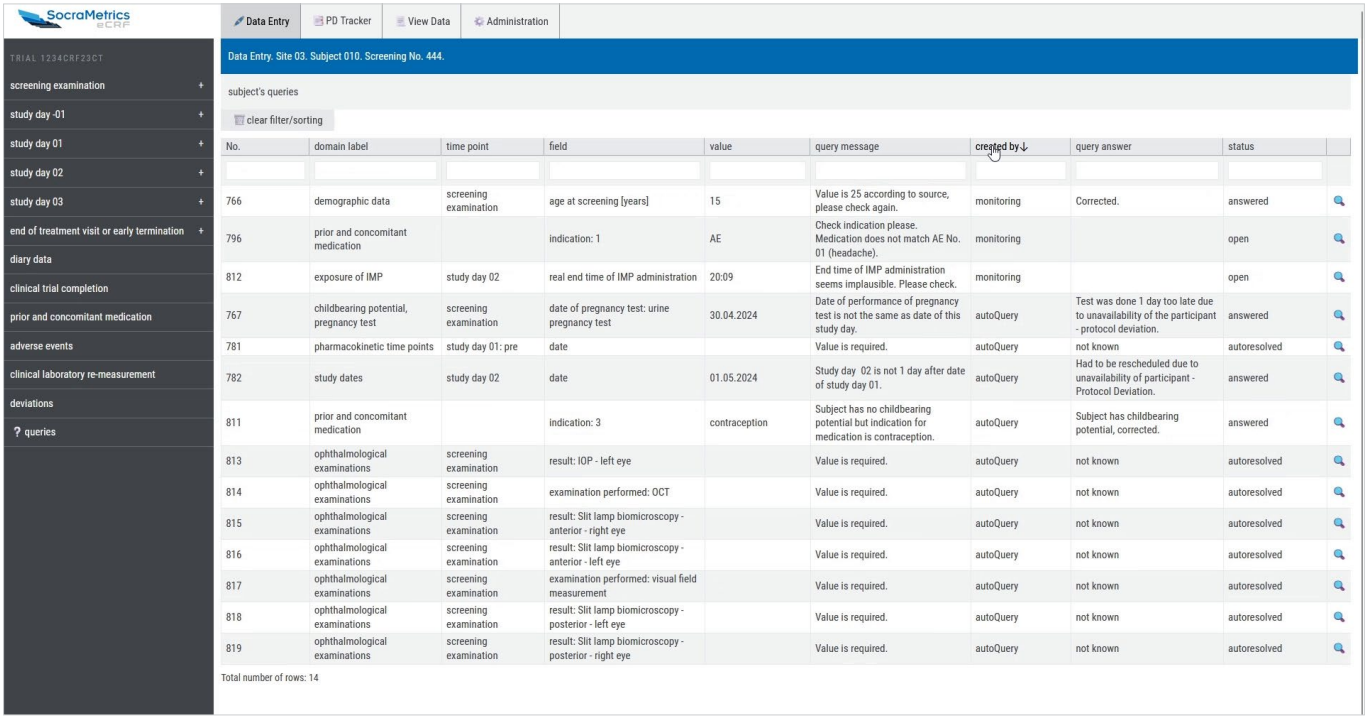
Experience Query Management at its finest - where efficiency meets collaboration in a seamless way!

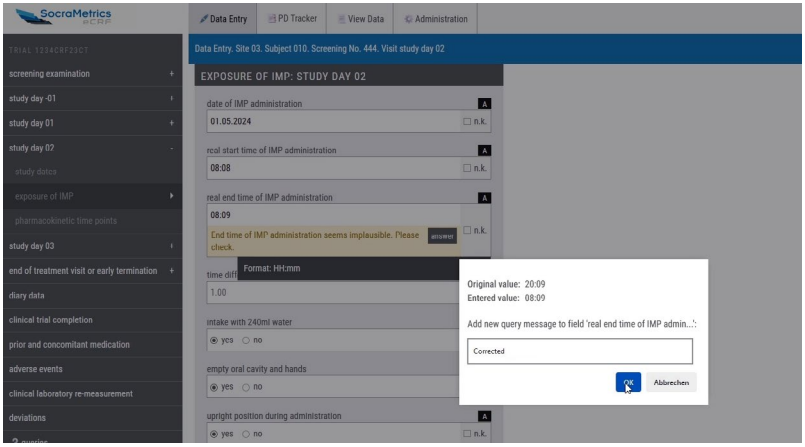

SocraMetrics
eCRF
Data Entry
Monitoring
Release
PD Tracker
View Data
eDiary users
TRIAL 1234CRF23CT
screening examination
study day -01
study day 01
study day 02
study day 03
end of treatment visit or early termination
diary data
clinical trial completion
prior and concomitant medication
adverse events
clinical laboratory re-measurement
deviations
queries
Data Entry. Site 01. Subject 004. Domain DS
perform all automated checks
mark data entry for page as completed
CLINICAL TRIAL COMPLETION
regular completion
yes
no
n.k.
date of withdrawal
21.04.2024
withdrawal by
investigator
subject
reason for withdrawal
AE
Reason for withdrawal is AE, but action taken for AE No. 01 is not "withdrawal from the study". Please check and correct.
answer
specification in case of withdrawal of consent
AE No.
01
SAE No.
Number: NN
specification if other in case of withdrawal of consent
screen failure IC No.
#11
OUR EDC
FEATURE
of the week

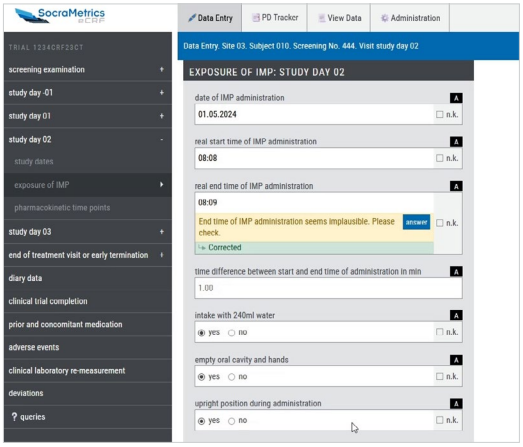
Query Management - Part III: Running Automated Checks

Once data entry is complete, a simple click can initiate automated checks to ensure accuracy and consistency. Complementing the field-based edit checks introduced in Feature #9, these cross-field checks can provide additional support for data entry staff or assist during monitoring.

As soon as you click the magic button, edit checks are triggered and any issues are flagged for attention. Our example today demonstrates how efficiently open issues can be resolved, thanks to a well-designed workflow.


SocraMetrics eCRF
Data Entry
PD Tracker
View Data
Administration
TRIAL 1234CRF23CT
screening examination
study day -01
study day 01
study day 02
study day 03
end of treatment visit or early termination
diary data
clinical trial completion
prior and concomitant medication
adverse events
clinical laboratory re-measurement
deviations
? queries
Data Entry. Site 03. Subject 010. Screening No. 444.
subject's queries
clear filter/sorting
No. | domain label | time point | field | value | query message | created by | query answer | status
766 | demographic data | screening examination | age at screening [years] | 15 | Value is 25 according to source, please check again. | monitoring | Corrected. | answered
796 | prior and concomitant medication | | indication: 1 | AE | Check indication please. Medication does not match AE No. 01 (headache). | monitoring | | open
812 | exposure of IMP | study day 02 | real end time of IMP administration | 20:09 | End time of IMP administration seems implausible. Please check. | monitoring | | open
767 | childbearing potential, pregnancy test | screening examination | date of pregnancy test: urine pregnancy test | 30.04.2024 | Date of performance of pregnancy test is not the same as date of this study day. | autoQuery | Test was done 1 day too late due to unavailability of the participant - protocol deviation. | answered
781 | pharmacokinetic time points | study day 01: pre | date | | Value is required. | autoQuery | not known | autoresolved
782 | study dates | study day 02 | date | 01.05.2024 | Study day 02 is not 1 day after date of study day 01. | autoQuery | Had to be rescheduled due to unavailability of participant - Protocol Deviation. | answered
811 | prior and concomitant medication | | indication: 3 | contraception | Subject has no childbearing potential but indication for medication is contraception. | autoQuery | Subject has childbearing potential, corrected. | answered
813 | ophthalmological examinations | screening examination | result: IOP - left eye | | Value is required. | autoQuery | not known | autoresolved
814 | ophthalmological examinations | screening examination | examination performed: OCT | | Value is required. | autoQuery | not known | autoresolved
815 | ophthalmological examinations | screening examination | result: Slit lamp biomicroscopy - anterior - right eye | | Value is required. | autoQuery | not known | autoresolved
816 | ophthalmological examinations | screening examination | result: Slit lamp biomicroscopy - anterior - left eye | | Value is required. | autoQuery | not known | autoresolved
817 | ophthalmological examinations | screening examination | examination performed: visual field measurement | | Value is required. | autoQuery | not known | autoresolved
818 | ophthalmological examinations | screening examination | result: Slit lamp biomicroscopy - posterior - left eye | | Value is required. | autoQuery | not known | autoresolved
819 | ophthalmological examinations | screening examination | result: Slit lamp biomicroscopy - posterior - right eye | | Value is required. | autoQuery | not known | autoresolved
Total number of rows: 14


SocraMetrics eCRF
Data Entry
PD Tracker
View Data
Administration
Data Entry. Site 03. Subject 010. Screening No. 444. Visit study day 02
EXPOSURE OF IMP: STUDY DAY 02
date of IMP administration
01.05.2024
n.k.
real start time of IMP administration
08:08
real end time of IMP administration
08:09
End time of IMP administration seems implausible. Please check.
answer
Format: HH:mm
Original value: 20:09
Entered value: 08:09
Add new query message to field 'real end time of IMP admin...':
Corrected
OK
Abbrechen
time diff
1.00
intake with 240ml water
yes
no
empty oral cavity and hands
upright position during administration


SocraMetrics eCRF
Data Entry
PD Tracker
View Data
Administration
Data Entry. Site 03. Subject 010. Screening No. 444. Visit study day 02
EXPOSURE OF IMP: STUDY DAY 02
date of IMP administration
01.05.2024
n.k.
real start time of IMP administration
08:08
real end time of IMP administration
08:09
End time of IMP administration seems implausible. Please check.
answer
Corrected
time difference between start and end time of administration in min
1.00
intake with 240ml water
yes
no
empty oral cavity and hands
upright position during administration

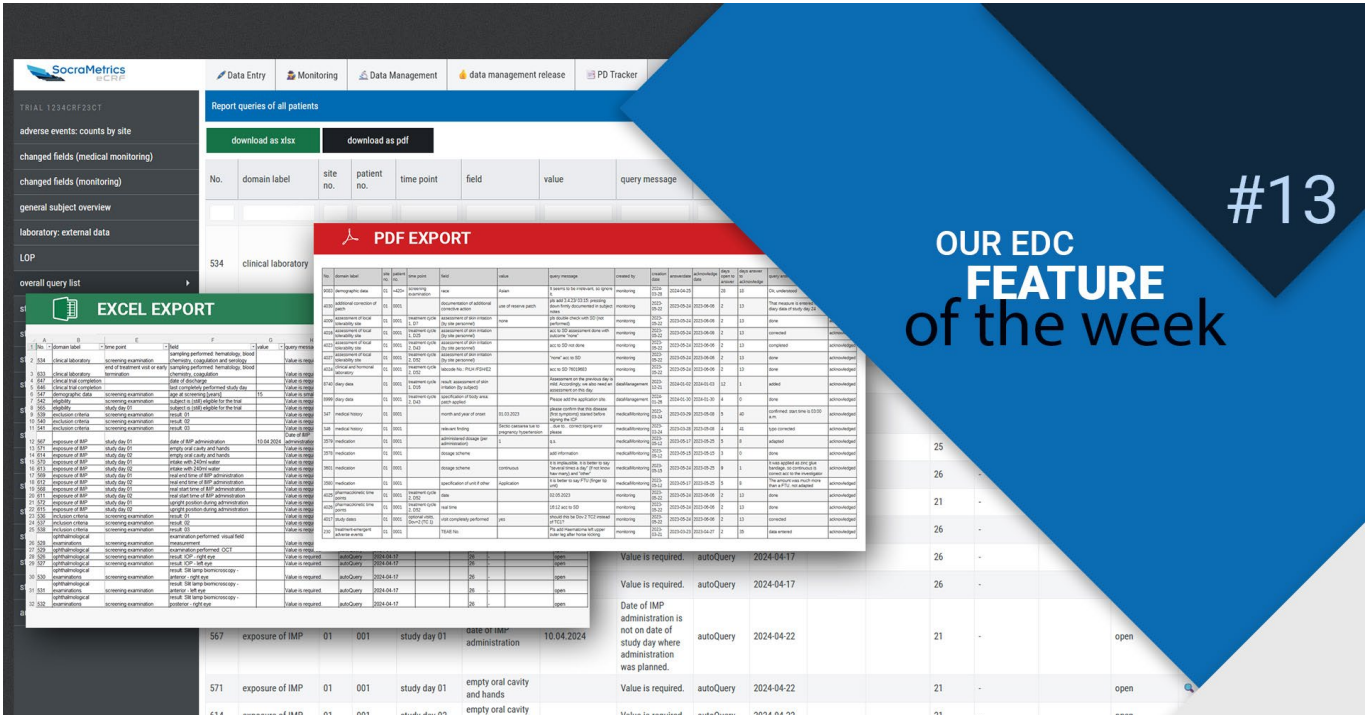
Query Management - Part IV: Subject Query List

Are you tired of endlessly searching for crucial query information?
Allow us to introduce our sophisticated query list then!

Key features include:

- ♦Quick access to all queries organised by subject
- ♦Various filter and sort options
- ♦Real-time overview of query status
- ♦Hassle-free location of queries with a concise clickpath to relevant data

Now, efficiently manage queries and access them directly, eliminating the need for time-consuming searches or waiting on slow systems.



No.	domain label	site no.	patient no.	time point	field	value	query message	created by	creation date	answer date	days open to answer	days answer to acknowledge	query status
567	exposure of IMP	01	001	study day 01	date of IMP administration	10.04.2024	Date of IMP administration is not on date of study day where administration was planned.	autoQuery	2024-04-22		21	-	open
571	exposure of IMP	01	001	study day 01	empty oral cavity and hands		Value is required.	autoQuery	2024-04-22		21	-	open

Query Management - Part V: Overall Query List

No surprises here: building on our previous demonstration of the subject query list, we've also integrated an overall query list into our system!

And yes, all the fantastic features we introduced in Feature #12 apply here too: instant access, the ability to filter and sort, real-time status updates, and user-friendly navigation paths.

Plus, you can export filtered or complete lists to formats such as Excel or PDF for quick and easy reporting.

Whether you focus on subjects or look at the big picture, you have the flexibility to search and manage queries according to your preferences. Choose the method that aligns best with your workflow.

#14

OUR EDC
FEATURE
of the week

Risk-based Monitoring - Insights Part I

Curious about what CRAs find most beneficial about our eCRF and how our EDC system simplifies their daily work? We asked our users for expert feedback and here are some of the answers (spoiler alert: it‘s about the well-structured workflow and our system‘s speed):

Efficient Data Verification: During eCRF setup it is already taken into account which parameters are collected and checked together. This simplifies the SDV process and makes it more efficient.

Speed: The eCRF‘s rapid functionality speeds up the monitoring process, enabling immediate on-site confirmations. This speed is of crucial importance, as delays can lead to errors and limit efficacy.

This tool offers no opportunities to leave the computer and get a coffee while waiting...

Ruwen, Medical Director

Precise Release: On the one hand, the system allows individual parameter release, providing an efficient workflow for risk-based monitoring. Unlike the visit-based approach of other systems, this feature increases accuracy and eliminates unnecessary documentation. On the other hand, the system also provides the flexibility to release entire sections as required.

Centralised Monitoring Graphs & Notifications: Graphs and notifications tailored to a study's QTLs and KRIs are an outstanding feature, especially for complex studies.

These customisable features provide a comprehensive overview for centralised monitoring as one tool for perfect sponsor oversight.

SocraMetrics
eCRF
Monitoring
PD Tracker
SDV flag was set
TRIAL 8009DM09SO
screening examination
period I, study day 01
period I, study day 02
period II, study day 01
period II, study day 02
end of study examination
adverse events
diary data
clinical trial completion
queries
changed fields
Monitoring. Site 01. Subject 001. Screening
Fields which changed after monitoring SDV
clear filter/sorting
domain label
site no.
subject no.
time point
field
confirmed value
monitoring value
vital signs 01 001 screening examination result in original units: Height 1.70 1.71
vital signs 01 001 screening examination result in original units: Body Mass Index 21.1 20.9
vital signs 01 001 period I, study day 01: prior to administration result in original units: Systolic Blood Pressure 122 121
study dates 01 001 period I, study day 01 date 14.05.2024 15.05.2024
study dates 01 001 period II, study day 01 date 15.05.2024
study dates 01 001 period II, study day 01 visit performed? yes
adverse events 01 001 AE end date: 1 23.05.2024
adverse events 01 001 AE end time: 1 17:30
adverse events 01 001 outcome: 1 not yet resolved not yet resolved
#15
OUR EDC
FEATURE
of the week

Risk-based Monitoring - Insights Part II

Is there anything else that monitor users particularly like about our system? Yes, indeed, there is. Further feedback included the following aspects:

Data changes after SDV: Monitors highlighted the importance of being able to track data changes after SDV and being offered a quick way to recheck, as demonstrated in today's short video.

Auto Queries and Edit Checks: Remember the posts on Auto Queries and Running Automated Checks (Features #9 and #11)? CRAs also emphasised the effectiveness of the interaction between auto queries and well-defined edit checks in our system, which help to reduce the number of manual queries and ensure high data quality from the start.

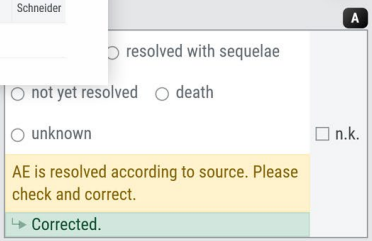
To sum up our little survey: **Our EDC system accelerates workflows**, enhances data quality, and provides tools for efficient monitoring, earning high praise from CRA users.

#16

OUR EDC
FEATURE
of the week

Audit Trail for adverse events, outcome, AE No. 1

date/time (UTC±0)	value	category	reason/description	role	user
2024-05-23 10:54:12	not yet resolved	entry	initial entry	dataEntry	Davies
2024-05-27 08:23:18		autoquery	No. 41 message: Value is required.	dataEntry	Schneider
2024-05-27 08:23:20	not yet resolved	entry	entry correction	dataEntry	Schneider
2024-05-27 08:23:20	not yet resolved	query deleted	No. 41 automatically deleted due to change of value	dataEntry	Schneider
2024-05-27 08:45:10		ery opened	No. 42 message: AE is resolved according to source. Please check and correct.	monitoring	Sato
2024-05-27 08:52:46			nswer: Corrected.	dataEntry	Schneider
2024-05-27 08:53:03			ry Correction	dataEntry	Schneider
2024-05-27 08:57:18				monitoring	Sato
2024-05-27 08:57:19				monitoring	Sato
2024-05-27 11:41:13				visitRelease	Almeida
2024-05-27 11:44:11				medicalMonitoring	Wójcik
2024-05-27 12:07:1			ically unset	dataEntry	Schneider



Field Focus: The Smarter Audit Trail Solution

Ever gone mad searching for a tiny detail in a comprehensive and crowded audit trail?

Our system comes with a field-based audit trail, a game changer for Query Management and SDV. CRAs love this feature as it allows them to see exactly what changes have been made to a particular entry field without leaving the page.

No more lengthy searches in a full audit trail, no more waiting for a slow system to open it.

An audit trail button right at the entry field takes you straight to the field-based audit trail, helping you find what you need to know quickly.

SocraMetrics eCRF

Monitoring | visit release | PD Tracker | View Data | Administration

TRIAL 8009DM09SO

audit trail

Report Audit Trail

download as xlsx | download as pdf

Go to page 1 2 3 4 5 ... 9

Site No.	Subject No.	domain	time point	field	date/time (UTC±0)↓	value			
	7001								
01	»7001«	vital signs	period I, study day 01: 4h after administration	result in original units: Temperature	2024-06-10 10:51:42	37.0	entry		
01	»7001«	vital signs	period I, study day 01: 4h after administration	result in original units: Temperature	2024-06-10 10:51:36	03.7	query answered	No. 91 Corrected error.	
01	»7001«	vital signs	period I, study day 01: 4h after administration	result in original units: Temperature	2024-06-10 10:50:16	03.7	query opened	No. 91 message: Value is implausible. Please check.	sato
01	»7001«	study dates	date of informed consent	visit performed?	2024-06-10 10:49:50		query opened	No. 90 message: Date is missing. Please add.	sato
01	»7001«	clinical trial completion		date of discharge	2024-06-10 10:37:36	10.06.2024	entry	initial entry	davies	dataEntry
01	»7001«	clinical trial completion		regular completion	2024-06-10 10:37:31	yes	entry	initial entry	davies	dataEntry
01	»7001«	adverse events	AE No. 1	High Level Group Term	2024-06-10 10:37:25	Headaches	entry	MedDRA coding primary axis, version 27.0, initial entry	davies	dataEntry
01	»7001«	adverse events	AE No. 1	High Level Group Term Code	2024-06-10 10:37:25	10019231	entry	MedDRA coding primary axis, version 27.0, initial entry	davies	dataEntry
01	»7001«	adverse events	AE No. 1	High Level Term	2024-06-10 10:37:25	Headaches NEC	entry	MedDRA coding primary axis, version 27.0, initial entry	davies	dataEntry
01	»7001«	adverse events	AE No. 1	High Level Term Code	2024-06-10 10:37:25	10019233	entry	MedDRA coding primary axis, version 27.0	davies	dataEntry

#17

OUR EDC
FEATURE
of the week

Full Spectrum: The Overall Audit Trail Solution

Unlike other systems where finding a specific detail in the audit trail can be a nightmare, our Audit Trail is **well-organized**, **comprehensive**, and **QUICK**!

Our comprehensive audit trail allows for efficient filtering, sorting, and exporting. We offer a clear, easy-to-read format with PDF or Excel outputs for your reporting needs.

Using UTC in the Audit Trail ensures comparability across different time zones. And yes, loading audit trails with more than 1 million entries might take a few seconds.

If you‘re really quick, you might be able to grab a coffee while waiting. But don‘t count on it – as you’ve learned the system barely offers any opportunities for that...

OUR EDSEA
FEATURE
of the week

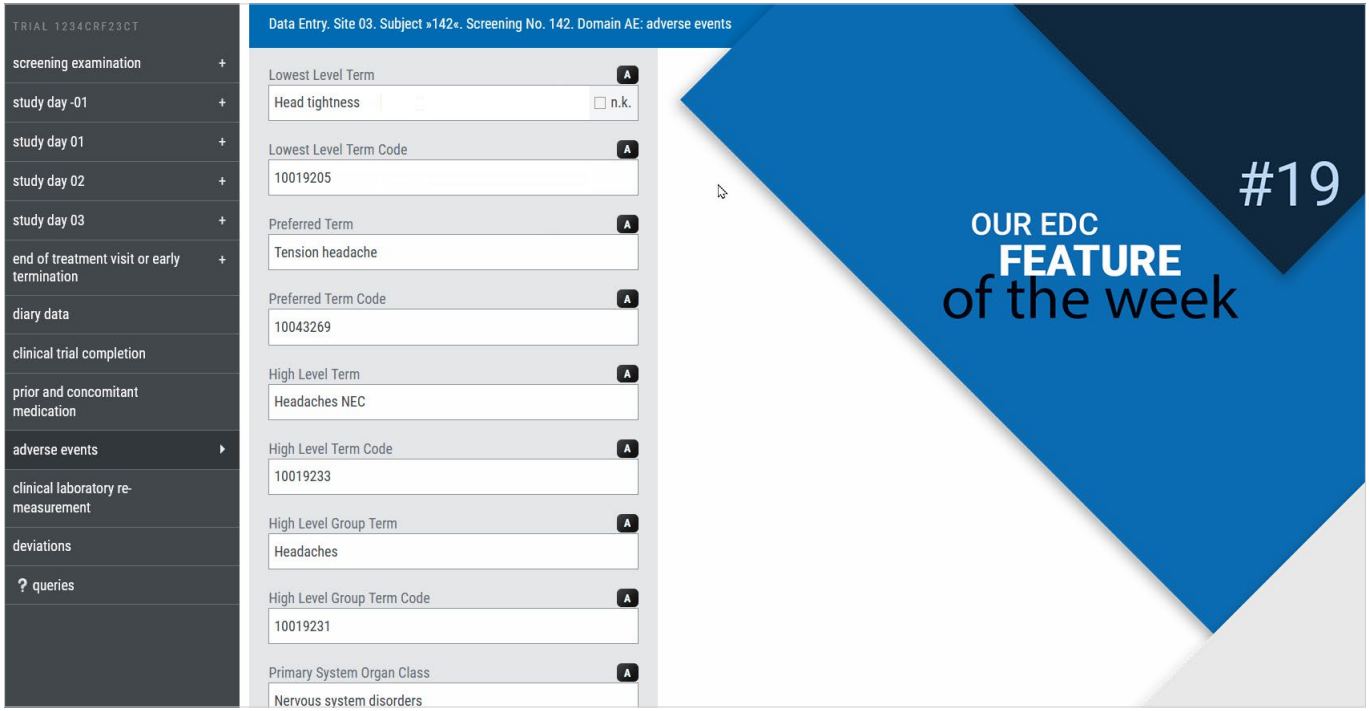
FEATURE OF THE
LEAK
SocraMetrics
screening examination
period I, study day 01
period I, study day 02
period II, study day 01
period II, study day 02
end of study examination
adverse events
prior and concomitant medication
diary data
clinical trial completion
queries
Data Entry
PQ Tracker
Administration
Data Entry: Site 01, Subject 001 - Domain AE: adverse events
Lowest Level Term
Headache
Headache: Horton's headache
Headache: Hypnic headache
Headache: Ice cream headache
Headache: Ice pick headache
Headache: Initial epileptic headache
Headache: Intermittent headache
Preferred Term Code
10019211
High Level Term
Headaches NEC

As an attentive reader, you might expect Feature #18 to appear at this point. In our original LinkedIn series, we took a short summer break.

During that time, we shared some updates on a new SocraMate module, which became post #18.

Therefore, in this eBook, we'll continue with Feature #19.

But...to keep things exciting, have a look at our **LinkedIn post** featuring a short video about SocraMate.

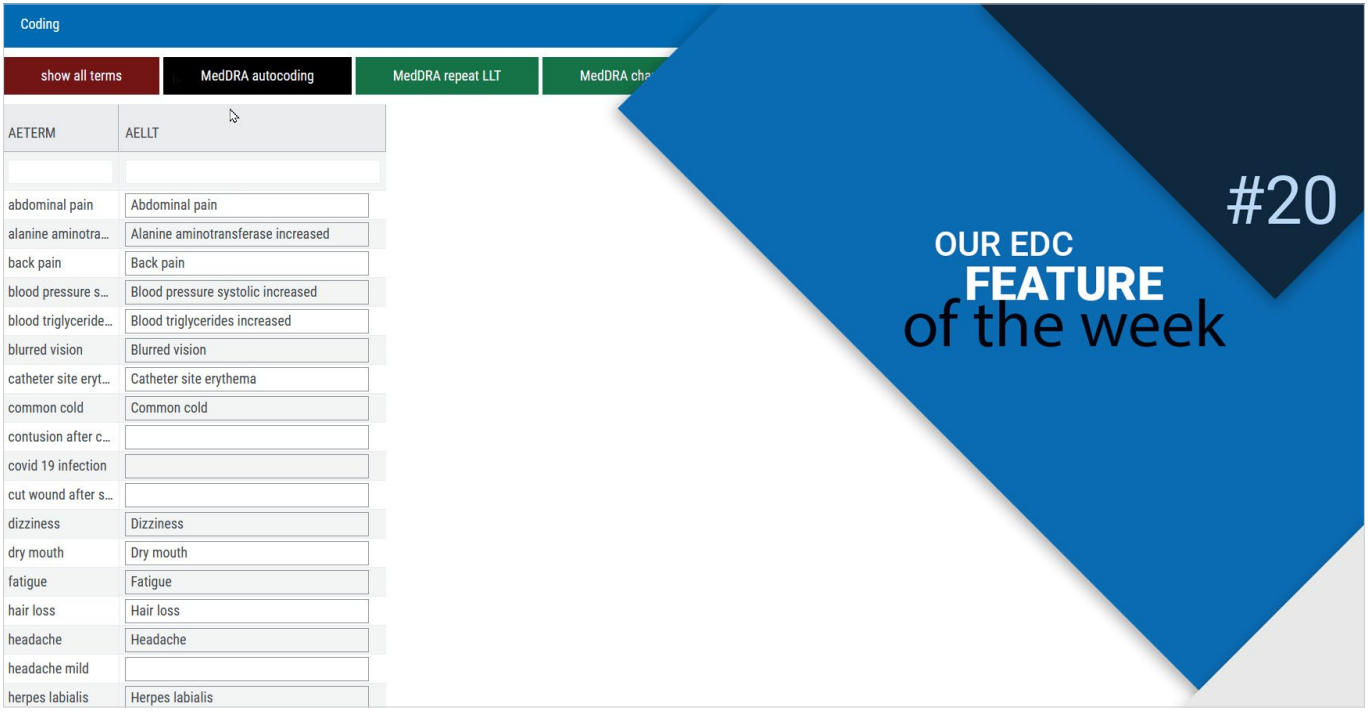

TRIAL 1234CRF23CT
screening examination
study day -01
study day 01
study day 02
study day 03
end of treatment visit or early termination
diary data
clinical trial completion
prior and concomitant medication
adverse events
clinical laboratory re-measurement
deviations
queries
Data Entry. Site 03. Subject »142«. Screening No. 142. Domain AE: adverse events
Lowest Level Term
Head tightness
n.k.
Lowest Level Term Code
10019205
Preferred Term
Tension headache
Preferred Term Code
10043269
High Level Term
Headaches NEC
High Level Term Code
10019233
High Level Group Term
Headaches
High Level Group Term Code
10019231
Primary System Organ Class
Nervous system disorders
#19
OUR EDC
FEATURE
of the week

MedDRA Coding Excellence - The Data Entry Perspective

Beyond its intuitive and fast operation (as with all our EDC features), our MedDRA Coding Tool provides the following benefits:

- Search for terms in any language that MedDRA offers - e.g. the national language of the site
- Coding on-the-fly during Data Entry - Search directly in data entry forms
- Automatic completion of codes and terms based on the selected LLT
- Full documentation in the comprehensive Audit Trail

But wait, there's even more. Our MedDRA tool includes convenient features specifically designed to make life easier for Data Managers.


Coding
show all terms
MedDRA autocoding
MedDRA repeat LLT
MedDRA cha
AETERM
AELLT
abdominal pain
Abdominal pain
alanine aminotra...
Alanine aminotransferase increased
back pain
Back pain
blood pressure s...
Blood pressure systolic increased
blood triglyceride...
Blood triglycerides increased
blurred vision
Blurred vision
catheter site eryt...
Catheter site erythema
common cold
Common cold
contusion after c...
covid 19 infection
cut wound after s...
dizziness
Dizziness
dry mouth
Dry mouth
fatigue
Fatigue
hair loss
Hair loss
headache
Headache
headache mild
herpes labialis
Herpes labialis
#20
OUR EDC
FEATURE
of the week

MedDRA Coding Excellence - The Data Management Perspective

Do you know how to make life easier for Clinical Data Managers when it comes to MedDRA Coding?
Provide them with the following MedDRA coding toolset:

- An Autocoder tool that serves as a sophisticated coding assistant, cleverly combining autocoding and a study-specific library for complex terms
- Use of various MedDRA versions and languages for different studies
- Storage of data in any configurable alternative language offered by MedDRA
- Selection of the applicable axis for multiaxial terms with justification
- Configuration of MedDRA version and multiaxiality on a study specific basis
- Easy and user-friendly maintenance of MedDRA versions

No surprise - all of these fantastic features are included in our eCRF!
Request a demo to see for yourself!

11:58
AA
socrametrics-ecrf.com
SocraMetrics
eDiary
EDIARY LOGIN
Password
Login
I lost my password
Imprint and Privacy Policy
#21
OUR EDC
FEATURE
of the week

Sign Up with a Smile: No Email Addresses Needed for Our eDiary!

Our eDiary offers a hassle-free and convenient data entry experience without the need for additional software.

Participants can use any device of their choice - smartphones, tablets, or PCs - while maintaining their privacy as no personal details such as email addresses are required.

Our system features a robust password recovery option, ensuring data remains secure.

#22

OUR EDC
FEATURE
of the week

The eDiary That Speaks Your Language

Our eDiary is like a linguistic chameleon - whether it's Mandarin, Cyrillic, or even Klingon (okay, maybe not Klingon), it's ready to adapt to your needs!

Imagine an eDiary as easy to use as your favorite streaming service, perfectly integrating into daily routines with an intuitive color-coded system that provides clear guidance during data entry.

Who says data entry can't be fun? Our approach to data collection is efficient, effortless, and engaging. Happy collecting!

#23
OUR EDC
FEATURE
of the week

Real-Time Data Meets Time Zone Harmony - eCRF and eDiary, Perfect Together!

The moment particpants enter their data, the information is instantly available within the eCRF. Study teams benefit from real-time data access, enabling immediate compliance checks and participant follow-up.

Bonus point: Our eDiary is truly global and time zone aware! Whether participants are entering data in Tokyo or Timbuktu, study teams can view and compare data across different time zones, even if they‘re sitting halfway around the world.

As for Klingon time zones… well, we‘re still working on that one.

Oh, and by the way: Of course, we can do ePRO too!

CONFIG FILE
eCRF SUCCESSFULLY CONFIGURED
#24
OUR EDC
FEATURE
of the week

The Life of a Data Manager - Part I

Clinical Data Management isn't just about handling data - it's about taking on different roles throughout the entire study process.
Let's take a closer look at eCRF setup.

To err is human, and mistakes are part of the journey. That's why it was important for us to design a setup process that gives immediate and unmistakable feedback in case of errors. Our eCRF test environment provides prompt response and clear error messages, so any issues can quickly be fixed in the Setup File and re-uploaded in no time. All with just basic SQL knowledge.

No endless searching for errors, no complicated interfaces - just fast, efficient setup.

So, being a Data Manager is about laying the groundwork for smooth workflows. Find out what else the life of a Data Manager has in store.

Hm, a BMI of 8148 and a height of 9? That's odd.
I'll need to check back with the study team.
#25
OUR EDC
FEATURE
of the week
N
min
mean
max
time of measurement 0
RRES result in original units 4 22 2061.7500 8148
21.6:
24.2:
52.8: 1
8148.1: 1
VSTIM time of measurement 0
VSORRES result in original units 10 50 70.1000 90
050: 2
090: 2
058: 1
064: 1
070: 1
IM time of measurement 0
result in original units 4 9 121.2500 180
009:
measurement 0

The Life of a Data Manager - Part II

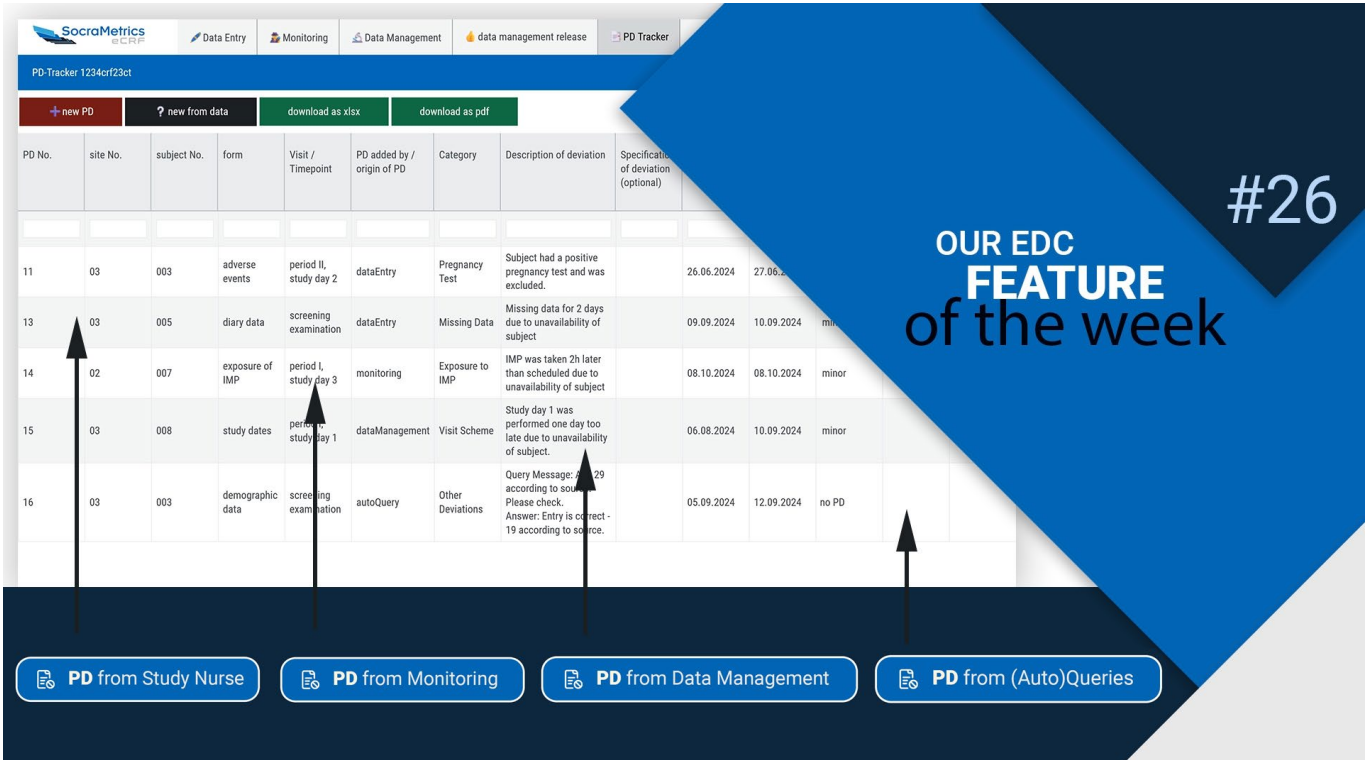
Another DM‘s role: ensuring data quality throughout the study.

Of course, Data Management goes beyond the initial eCRF setup. During the study, a Data Manager needs to keep an eye on the data and, among other things, identify outliers or hidden issues.

The key? Our system provides valuable tools for data review. From cleverly designed CheckMetrics to various overview statistics for spotting implausible entries - everything is just a click away.

So, being a Data Manager is about ensuring data quality through strategic oversight and insightful analysis.

Discover how our fabulous PD Tracker can save time and reduce stress, not just in Data Management...


SocraMetrics eCRF
Data Entry
Monitoring
Data Management
data management release
PD Tracker
PD-Tracker 1234crf23ct
new PD
new from data
download as xlsx
download as pdf
PD No.
site No.
subject No.
form
Visit / Timepoint
PD added by / origin of PD
Category
Description of deviation
Specification of deviation (optional)
11 03 003 adverse events period II, study day 2 dataEntry Pregnancy Test Subject had a positive pregnancy test and was excluded. 26.06.2024
13 03 005 diary data screening examination dataEntry Missing Data Missing data for 2 days due to unavailability of subject 09.09.2024 10.09.2024
14 02 007 exposure of IMP period I, study day 3 monitoring Exposure to IMP IMP was taken 2h later than scheduled due to unavailability of subject 08.10.2024 08.10.2024 minor
15 03 008 study dates dataManagement Visit Scheme Study day 1 was performed one day too late due to unavailability of subject. 06.08.2024 10.09.2024 minor
16 03 003 demographic data screening examination autoQuery Other Deviations 05.09.2024 12.09.2024 no PD
#26
OUR EDC
FEATURE
of the week
PD from Study Nurse
PD from Monitoring
PD from Data Management
PD from (Auto)Queries

The Life of a Data Manager - Part III

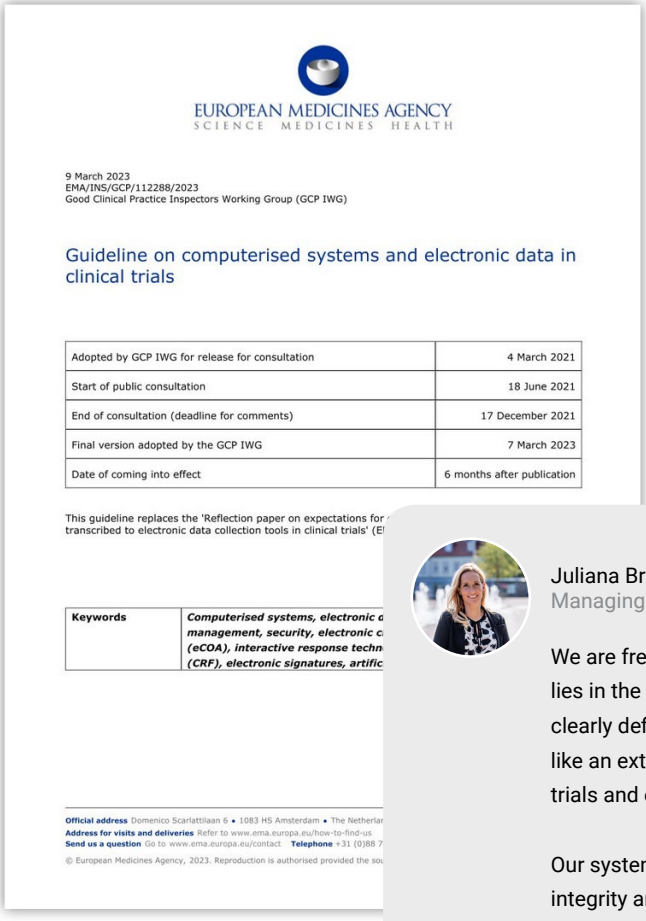
Navigating Protocol Deviations from a DM perspective can feel like steering through a turbulent data storm, especially just before the final Data Review Meeting. At this point, data must be complete, comprehensive, and accessible to all parties involved to ensure informed decision-making.

To eliminate the hassle of synchronising multiple PD sources and endless cross-checking for duplicates we developed a PD Tracker.

Fully embedded in our eCRF, this tool gives all parties access to enter and view PDs anytime. With all critical information centrally available and a one-click assignment feature to determine whether Queries represent PDs, the process becomes far more streamlined. Ongoing collection, review, and assessment of PDs throughout the study save time and keep everyone informed. Sponsors also benefit from real-time access and continous updates.

Need more information?
Check out https://ecrf.pro

Reference
This Post on LinkedIn



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

9 March 2023
EMA/INS/GCP/112288/2023
Good Clinical Practice Inspectors Working Group (GCP IWG)

Guideline on computerised systems and electronic data in clinical trials

Adopted by GCP IWG for release for consultation	4 March 2021
Start of public consultation	18 June 2021
End of consultation (deadline for comments)	17 December 2021
Final version adopted by the GCP IWG	7 March 2023
Date of coming into effect	6 months after publication

This guideline replaces the 'Reflection paper on expectations for
transcribed to electronic data collection tools in clinical trials' (E

Keywords	***Computerised systems, electronic d management, security, electronic c (eCOA), interactive response techn (CRF), electronic signatures, artific***

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Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 7

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Juliana Brudel
Managing Director and Head of Clinical Data Management, SocraMetrics GmbH

We are frequently asked why data cannot be signed off in batches. The answer lies in the guidelines, particularly the EMA regulations and GCP standards, which clearly define that visit-by-visit review and approval are necessary. It might feel like an extra step, but it's a vital one for maintaining the integrity of your clinical trials and ensuring success.

Our system is designed to fully comply with these requirements to ensure the integrity and quality of clinical trial data. At the same time, we are very committed to making the user experience as smooth as possible.

The Life of a Data Manager - Part III

DID YOU KNOW…
…that batch signing does not comply with GCP regulations according to the position of the European Medicines Agency?

EMA's position on this is clear: "Therefore, it will rarely be sufficient to just provide one signature immediately prior to database lock. Signing of batches of workbooks is also not suited to ensure high data quality and undermines the purpose of timely and thorough data review."
(Guideline on computerised systems and electronic data in clinical trials EMA Guideline, 6.3. Sign-off of data)

We've designed our system to meet all regulatory requirements while keeping it user-friendly. To align with EMA's position, our system enables a convenient and quick visit-by-visit electronic sign-off, ensuring full compliance.

#28
OUR EDC
FEATURE
of the week
SocraMetrics
Data Entry
PD Tracker
View Data
Administration
Figure liver values by subject by parameter by study day - line chart
download as pdf
Alanine Aminotransferase
adverse events: counts by site
demographic data: age group
demographic data: ethnic origin
demographic data: sex
laboratory normal value status
laboratory values box plot
laboratory values line graph
recruitment status

How Can Sponsor Oversight Be Made More Efficient?

We asked ourselves the same question - and we've found the answer!

In our EDC, clear visual insights into study data are guaranteed through on-the-spot figures, graphs, and reports, tailored to each study's KRIs and QTLs.

Additionally, our PD Tracker gives sponsors real-time access to all documented Protocol Deviations, alerting them to major issues. Sponsors can easily comment on or assess deviations directly in the eCRF - a feature highly appreciated by regulators!

With real-time insights, visualisations and the PD Tracker, we lay the foundation for perfect sponsor oversight!

Need more information?
Check out https://ecrf.pro

Reference
This Post on LinkedIn

#29

OUR EDC FEATURE of the week

SocraMetrics eCRF | Data Management | data management release | PD Tracker | View Data | eDiary users

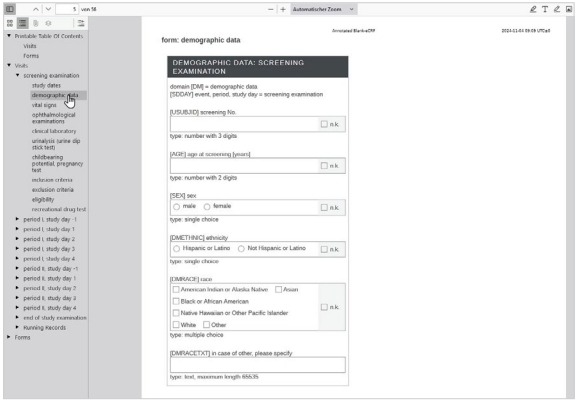
Subject's PDF Copies

Creating a full export of a subject might take a while. Please be patient.

Site No.	Subject No.	Screening No.	
01	001	099	print PDF of Subject 001
01	002		print PDF of Subject 002
01	003	123	print PDF of Subject 003
01	004		print PDF of Subject 004
02	005	101	print PDF of Subject 005
02	006		print PDF of Subject 006
02	007		print PDF of Subject 007
03	008		print PDF of Subject 008

Total number of rows: 8

print blank eCRF | print annotated eCRF | print basis for SDTM aCRF | download all



Annotated eCRF with Dual Bookmarks - Just 2 Clicks Away!

Generate a fully annotated eCRF PDF in seconds, with zero wait time!

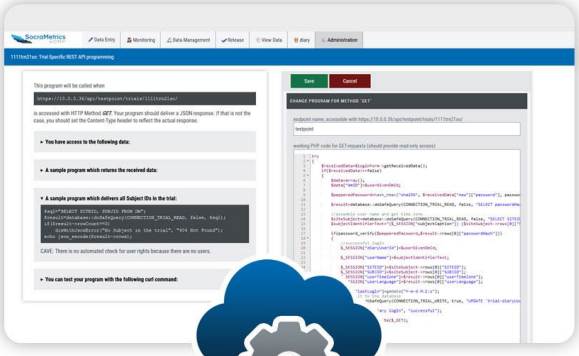
Our annotated eCRF includes dual bookmarks, meeting FDA requirements for SDTM submissions - one set organised by visit, the other by form.

This annotated CRF not only replicates the user view from the eCRF but also displays data formats, database variables, labels, and all possible dropdown options.

It’s the ultimate tool for complete transparency and efficiency in clinical data submission!

#30

OUR EDC
FEATURE
of the week



eCRF **REST API**

```
ecrf@socrametrics ~ %
curl -X GET -H
"Authorization: api-key d8589a6" -H
"Content-Type: application/json" -d
"https://socramate.com/api/testpoint/trials/1111trn21so/ediary-users/"
```

Unlock the Power of Our New REST-API-Feature!

Techies, watch out! You - or your server - can communicate directly with our EDC system.

This is made possible by our trial-specific REST API – you can use it to connect external IWRS systems or pseudonymisation services.

Does your central lab offer electronic data transfer? Go for it!

The whole solution is freely programmable and is protected with strong but flexible authentication.

Click here
START
You can click this
CLICK!
Play video
or here
Start here
Click here
FINAL
FEATURE

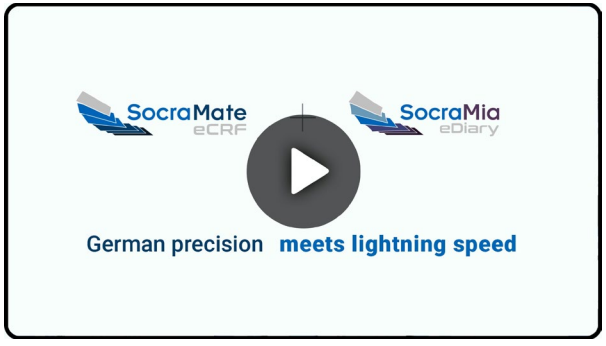
Exciting News!

As our EDC series comes to an end, we're thrilled to announce the NAMES many of you have been asking for!

Check out the video to meet our software dream team - the perfect combination of lightning-fast eCRF functionality and a user-friendly eDiary. Together, they ensure perfect data quality and enhance participant compliance!

Thank you for joining us on this EDC journey! We've loved sharing our weekly features with you, and this is our final one (for now)!

Best regards,
Your SocraMates



Need more information?
Check out https://ecrf.pro

Reference
This Post on LinkedIn

Interested?
Request a Demo!

Get in touch with
Juliana Brudel on LinkedIn

SocraMetrics GmbH

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When German precision
meets lightning speed

SocraMate
eCRF