

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,

A handwritten signature in black ink that reads "Juliana Brudel". The script is fluid and cursive, with the first letters of each name being capitalized and prominent.

Managing Director SocraMetrics GmbH



CDMs



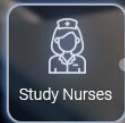
Investigators



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.





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



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



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!



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.

screening

Data was saved.

Subject 00

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

+

☐ 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			

#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

000102030405060708091011

121314151617181920212223

a.m.

p.m.

select minutes

000102030405060708091011121314

151617181920212223242526272829

303132333435363738394041424344

454647484950515253545556575859

Data was saved.

Q

A

<<<

<

March

>

>>>

Mon

Tue

Wed

Thu

Fri

Sat

Sun

26

27

28

29

1

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4

5

6

7

8

9

10

11

12

13

14

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18

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30

31

NK.03.2024

NK.NK.2024

n.k.

#6

OUR EDC
FEATURE
of the week

SocraMetrics

CDRP

Data Entry

PD Tracker

Data was saved.

Data Entry, Site 03, Subject 010, Screening No. 124, Visit screening examination

original units

cm

Systolic Blood Pressure

time of measurement

11:25

result in original units

142

original units

mmHg

classification of result

abnormal, not clinically significant

original units

kg

Diastolic Blood Pressure

result in original units

Number: NNN

original

normal range: 50 - 100 mmHg
Format: number with 3 digits

classification of result

abnormal, not clinically significant

original units

kg/m2

Pulse Rate

result in original units

Number: NNN

original units

beats/min

classification of result

abnormal, not clinically significant

Data Entry, Site 03, Subject 009, Screening No. 173, Visit screening examination

VITAL SIGNS: SCREENING EXAMINATION

Height

result in original units

182

original units

cm

Weight

result in original units

686.0

original units

kg

Body Mass Index

result in original units

26

Autocalculated

Systolic Blood Pressure

time of measurement

08:25

result in original units

Number: NNN

original units

mmHg

classification of result

abnormal, not clinically significant

Diastolic Blood Pressure

result in original units

Number: NNN

original units

mmHg

classification of result

abnormal, not clinically significant

Pulse Rate

result in original units

Number: NNN

original units

beats/min

classification of result

abnormal, not clinically significant



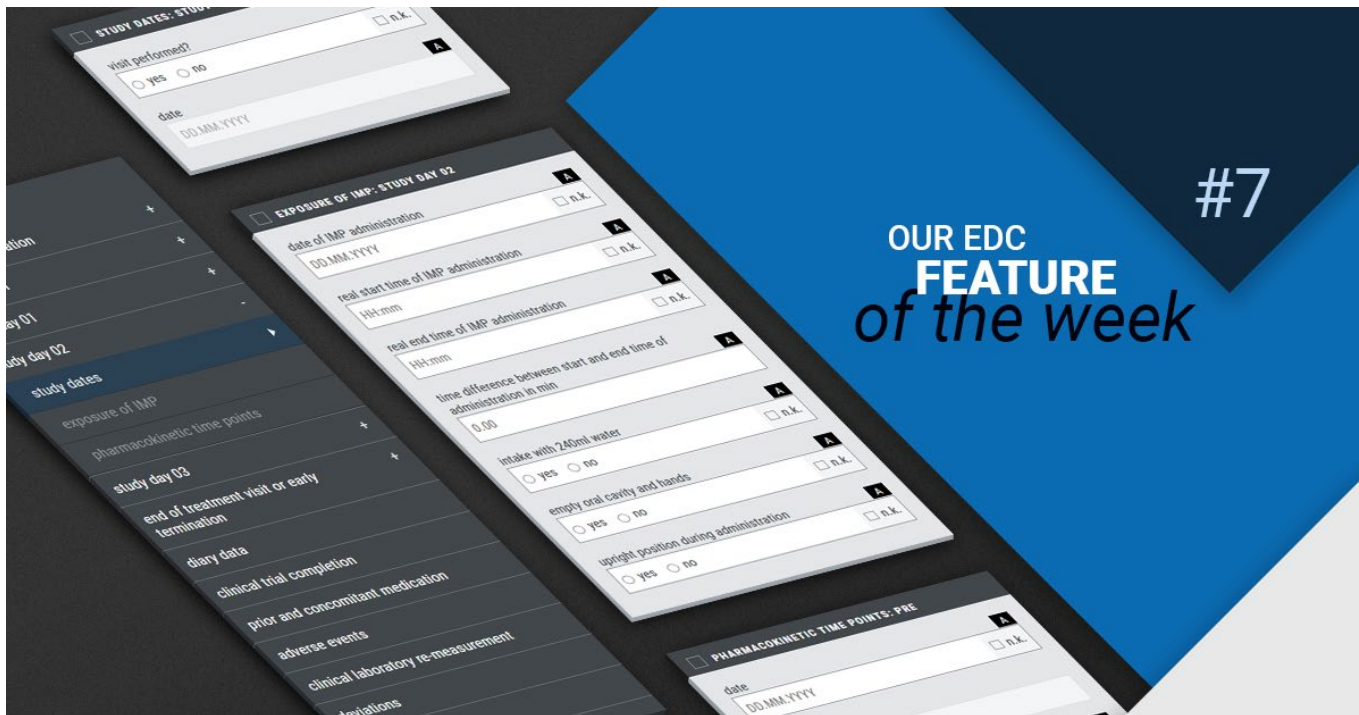
Data Entry in Detail - Part I: Simplify your Life

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	82	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!

☐ 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

☐ n.k.

☐ ADVERSE EVENTS

AE No.

Number: NN

☐ n.k.

type (symptom, diagnosis)

☐ n.k.

AE start date

DD.MM.YYYY

☐ n.k.

AE start time

HH:mm

☐ n.k.

AE end date

DD.MM.YYYY

☐ n.k.

#8

OUR EDC
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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!

DEVIATIONS AND VIOLATION OF RESTRICTION: STUDY DAY 166



date of deviation

A

18.12.2023

💡 date of deviation is implausible

answer

kind of deviation

A



☐ n.k.

specification of deviation

A

#9

OUR EDC
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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.



#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!



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

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

PD Tracker

View Data

Administration

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

TRIAL 1234CRF23CT

screening examination

study day 01

study day 01

study day 02

study dates

exposure of IMP

pharmacokinetic time points

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

?

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

n.k.

real end time of IMP administration

08:09

n.k.

End time of IMP administration seems implausible. Please check.

answered

n.k.

time diff

Format: HH:mm

1:00

intake with 240ml water

yes

no

empty oral cavity and hands

yes

no

upright position during administration

yes

no

n.k.

Original value: 20:09

Entered value: 08:09

Add new query message to field 'real end time of IMP admin...'

Corrected

Abbrechsen

SocraMetrics

eCRF

TRIAL 1234CRF23CT

screening examination

study day 01

study day 01

study day 02

study dates

exposure of IMP

pharmacokinetic time points

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

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

n.k.

real end time of IMP administration

08:09

n.k.

End time of IMP administration seems implausible. Please check.

answered

n.k.

time difference between start and end time of administration in min

1:00

intake with 240ml water

yes

no

n.k.

empty oral cavity and hands

yes

no

n.k.

upright position during administration

yes

no

n.k.



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.

TRIAL 1234CRF230CT

adverse events: counts by site

changed fields (medical monitoring)

changed fields (monitoring)

general subject overview

laboratory: external data

LDP

overall query list

EXCEL EXPORT

Report queries of all patients

download as xlsx

download as pdf

No. domain label site no. patient no. time point field value query message

534	clinical laboratory						
-----	---------------------	--	--	--	--	--	--

PDF EXPORT

Study label	domain label	site no.	patient no.	time point	field	value	query message	created by	created on	modified on	status	date of entry	date of update	date of deletion	date of archiving	date of deletion	date of archiving
2001	demographic data	01	001	baseline	sex	female	1 female is 0 - female is 1 - male	monitoring	2024-04-17	2024-04-17	open	2024-04-17	2024-04-17	2024-04-17	2024-04-17	2024-04-17	2024-04-17
2002	demographic data	01	001	baseline	race	caucasian	1 caucasian is 0 - caucasian is 1 - african american is 2 - hispanic or latino is 3 - asian is 4 - native hawaiian or other pacific islander is 5 - other	monitoring	2024-04-17	2024-04-17	open	2024-04-17	2024-04-17	2024-04-17	2024-04-17	2024-04-17	2024-04-17
2003	demographic data	01	001	baseline	ethnicity	caucasian	1 caucasian is 0 - caucasian is 1 - african american is 2 - hispanic or latino is 3 - asian is 4 - native hawaiian or other pacific islander is 5 - other	monitoring	2024-04-17	2024-04-17	open	2024-04-17	2024-04-17	2024-04-17	2024-04-17	2024-04-17	2024-04-17
2004	demographic data	01	001	baseline	weight	70 kg	1 70 kg is 0 - 70 kg is 1 - 75 kg is 2 - 80 kg is 3 - 85 kg is 4 - 90 kg is 5 - 95 kg is 6 - 100 kg is 7 - 105 kg is 8 - 110 kg is 9 - 115 kg is 10 - 120 kg is 11 - 125 kg is 12 - 130 kg is 13 - 135 kg is 14 - 140 kg is 15 - 145 kg is 16 - 150 kg is 17 - 155 kg is 18 - 160 kg is 19 - 165 kg is 20 - 170 kg is 21 - 175 kg is 22 - 180 kg is 23 - 185 kg is 24 - 190 kg is 25 - 195 kg is 26 - 200 kg is 27 - 205 kg is 28 - 210 kg is 29 - 215 kg is 30 - 220 kg is 31 - 225 kg is 32 - 230 kg is 33 - 235 kg is 34 - 240 kg is 35 - 245 kg is 36 - 250 kg is 37 - 255 kg is 38 - 260 kg is 39 - 265 kg is 40 - 270 kg is 41 - 275 kg is 42 - 280 kg is 43 - 285 kg is 44 - 290 kg is 45 - 295 kg is 46 - 300 kg is 47 - 305 kg is 48 - 310 kg is 49 - 315 kg is 50 - 320 kg is 51 - 325 kg is 52 - 330 kg is 53 - 335 kg is 54 - 340 kg is 55 - 345 kg is 56 - 350 kg is 57 - 355 kg is 58 - 360 kg is 59 - 365 kg is 60 - 370 kg is 61 - 375 kg is 62 - 380 kg is 63 - 385 kg is 64 - 390 kg is 65 - 395 kg is 66 - 400 kg is 67 - 405 kg is 68 - 410 kg is 69 - 415 kg is 70 - 420 kg is 71 - 425 kg is 72 - 430 kg is 73 - 435 kg is 74 - 440 kg is 75 - 445 kg is 76 - 450 kg is 77 - 455 kg is 78 - 460 kg is 79 - 465 kg is 80 - 470 kg is 81 - 475 kg is 82 - 480 kg is 83 - 485 kg is 84 - 490 kg is 85 - 495 kg is 86 - 500 kg is 87 - 505 kg is 88 - 510 kg is 89 - 515 kg is 90 - 520 kg is 91 - 525 kg is 92 - 530 kg is 93 - 535 kg is 94 - 540 kg is 95 - 545 kg is 96 - 550 kg is 97 - 555 kg is 98 - 560 kg is 99 - 565 kg is 100 - 570 kg is 101 - 575 kg is 102 - 580 kg is 103 - 585 kg is 104 - 590 kg is 105 - 595 kg is 106 - 600 kg is 107 - 605 kg is 108 - 610 kg is 109 - 615 kg is 110 - 620 kg is 111 - 625 kg is 112 - 630 kg is 113 - 635 kg is 114 - 640 kg is 115 - 645 kg is 116 - 650 kg is 117 - 655 kg is 118 - 660 kg is 119 - 665 kg is 120 - 670 kg is 121 - 675 kg is 122 - 680 kg is 123 - 685 kg is 124 - 690 kg is 125 - 695 kg is 126 - 700 kg is 127 - 705 kg is 128 - 710 kg is 129 - 715 kg is 130 - 720 kg is 131 - 725 kg is 132 - 730 kg is 133 - 735 kg is 134 - 740 kg is 135 - 745 kg is 136 - 750 kg is 137 - 755 kg is 138 - 760 kg is 139 - 765 kg is 140 - 770 kg is 141 - 775 kg is 142 - 780 kg is 143 - 785 kg is 144 - 790 kg is 145 - 795 kg is 146 - 800 kg is 147 - 805 kg is 148 - 810 kg is 149 - 815 kg is 150 - 820 kg is 151 - 825 kg is 152 - 830 kg is 153 - 835 kg is 154 - 840 kg is 155 - 845 kg is 156 - 850 kg is 157 - 855 kg is 158 - 860 kg is 159 - 865 kg is 160 - 870 kg is 161 - 875 kg is 162 - 880 kg is 163 - 885 kg is 164 - 890 kg is 165 - 895 kg is 166 - 900 kg is 167 - 905 kg is 168 - 910 kg is 169 - 915 kg is 170 - 920 kg is 171 - 925 kg is 172 - 930 kg is 173 - 935 kg is 174 - 940 kg is 175 - 945 kg is 176 - 950 kg is 177 - 955 kg is 178 - 960 kg is 179 - 965 kg is 180 - 970 kg is 181 - 975 kg is 182 - 980 kg is 183 - 985 kg is 184 - 990 kg is 185 - 995 kg is 186 - 1000 kg is 187 - 1005 kg is 188 - 1010 kg is 189 - 1015 kg is 190 - 1020 kg is 191 - 1025 kg is 192 - 1030 kg is 193 - 1035 kg is 194 - 1040 kg is 195 - 1045 kg is 196 - 1050 kg is 197 - 1055 kg is 198 - 1060 kg is 199 - 1065 kg is 200 - 1070 kg is 201 - 1075 kg is 202 - 1080 kg is 203 - 1085 kg is 204 - 1090 kg is 205 - 1095 kg is 206 - 1100 kg is 207 - 1105 kg is 208 - 1110 kg is 209 - 1115 kg is 210 - 1120 kg is 211 - 1125 kg is 212 - 1130 kg is 213 - 1135 kg is 214 - 1140 kg is 215 - 1145 kg is 216 - 1150 kg is 217 - 1155 kg is 218 - 1160 kg is 219 - 1165 kg is 220 - 1170 kg is 221 - 1175 kg is 222 - 1180 kg is 223 - 1185 kg is 224 - 1190 kg is 225 - 1195 kg is 226 - 1200 kg is 227 - 1205 kg is 228 - 1210 kg is 229 - 1215 kg is 230 - 1220 kg is 231 - 1225 kg is 232 - 1230 kg is 233 - 1235 kg is 234 - 1240 kg is 235 - 1245 kg is 236 - 1250 kg is 237 - 1255 kg is 238 - 1260 kg is 239 - 1265 kg is 240 - 1270 kg is 241 - 1275 kg is 242 - 1280 kg is 243 - 1285 kg is 244 - 1290 kg is 245 - 1295 kg is 246 - 1300 kg is 247 - 1305 kg is 248 - 1310 kg is 249 - 1315 kg is 250 - 1320 kg is 251 - 1325 kg is 252 - 1330 kg is 253 - 1335 kg is 254 - 1340 kg is 255 - 1345 kg is 256 - 1350 kg is 257 - 1355 kg is 258 - 1360 kg is 259 - 1365 kg is 260 - 1370 kg is 261 - 1375 kg is 262 - 1380 kg is 263 - 1385 kg is 264 - 1390 kg is 265 - 1395 kg is 266 - 1400 kg is 267 - 1405 kg is 268 - 1410 kg is 269 - 1415 kg is 270 - 1420 kg is 271 - 1425 kg is 272 - 1430 kg is 273 - 1435 kg is 274 - 1440 kg is 275 - 1445 kg is 276 - 1450 kg is 277 - 1455 kg is 278 - 1460 kg is 279 - 1465 kg is 280 - 1470 kg is 281 - 1475 kg is 282 - 1480 kg is 283 - 1485 kg is 284 - 1490 kg is 285 - 1495 kg is 286 - 1500 kg is 287 - 1505 kg is 288 - 1510 kg is 289 - 1515 kg is 290 - 1520 kg is 291 - 1525 kg is 292 - 1530 kg is 293 - 1535 kg is 294 - 1540 kg is 295 - 1545 kg is 296 - 1550 kg is 297 - 1555 kg is 298 - 1560 kg is 299 - 1565 kg is 300 - 1570 kg is 301 - 1575 kg is 302 - 1580 kg is 303 - 1585 kg is 304 - 1590 kg is 305 - 1595 kg is 306 - 1600 kg is 307 - 1605 kg is 308 - 1610 kg is 309 - 1615 kg is 310 - 1620 kg is 311 - 1625 kg is 312 - 1630 kg is 313 - 1635 kg is 314 - 1640 kg is 315 - 1645 kg is 316 - 1650 kg is 317 - 1655 kg is 318 - 1660 kg is 319 - 1665 kg is 320 - 1670 kg is 321 - 1675 kg is 322 - 1680 kg is 323 - 1685 kg is 324 - 1690 kg is 325 - 1695 kg is 326 - 1700 kg is 327 - 1705 kg is 328 - 1710 kg is 329 - 1715 kg is 330 - 1720 kg is 331 - 1725 kg is 332 - 1730 kg is 333 - 1735 kg is 334 - 1740 kg is 335 - 1745 kg is 336 - 1750 kg is 337 - 1755 kg is 338 - 1760 kg is 339 - 1765 kg is 340 - 1770 kg is 341 - 1775 kg is 342 - 1780 kg is 343 - 1785 kg is 344 - 1790 kg is 345 - 1795 kg is 346 - 1800 kg is 347 - 1805 kg is 348 - 1810 kg is 349 - 1815 kg is 350 - 1820 kg is 351 - 1825 kg is 352 - 1830 kg is 353 - 1835 kg is 354 - 1840 kg is 355 - 1845 kg is 356 - 1850 kg is 357 - 1855 kg is 358 - 1860 kg is 359 - 1865 kg is 360 - 1870 kg is 361 - 1875 kg is 362 - 1880 kg is 363 - 1885 kg is 364 - 1890 kg is 365 - 1895 kg is 366 - 1900 kg is 367 - 1905 kg is 368 - 1910 kg is 369 - 1915 kg is 370 - 1920 kg is 371 - 1925 kg is 372 - 1930 kg is 373 - 1935 kg is 374 - 1940 kg is 375 - 1945 kg is 376 - 1950 kg is 377 - 1955 kg is 378 - 1960 kg is 379 - 1965 kg is 380 - 1970 kg is 381 - 1975 kg is 382 - 1980 kg is 383 - 1985 kg is 384 - 1990 kg is 385 - 1995 kg is 386 - 2000 kg is 387 - 2005 kg is 388 - 2010 kg is 389 - 2015 kg is 390 - 2020 kg is 391 - 2025 kg is 392 - 2030 kg is 393 - 2035 kg is 394 - 2040 kg is 395 - 2045 kg is 396 - 2050 kg is 397 - 2055 kg is 398 - 2060 kg is 399 - 2065 kg is 400 - 2070 kg is 401 - 2075 kg is 402 - 2080 kg is 403 - 2085 kg is 404 - 2090 kg is 405 - 2095 kg is 406 - 2100 kg is 407 - 2105 kg is 408 - 2110 kg is 409 - 2115 kg is 410 - 2120 kg is 411 - 2125 kg is 412 - 2130 kg is 413 - 2135 kg is 414 - 2140 kg is 415 - 2145 kg is 416 - 2150 kg is 417 - 2155 kg is 418 - 2160 kg is 419 - 2165 kg is 420 - 2170 kg is 421 - 2175 kg is 422 - 2180 kg is 423 - 2185 kg is 424 - 2190 kg is 425 - 2195 kg is 426 - 2200 kg is 427 - 2205 kg is 428 - 2210 kg is 429 - 2215 kg is 430 - 2220 kg is 431 - 2225 kg is 432 - 2230 kg is 433 - 2235 kg is 434 - 2240 kg is 435 - 2245 kg is 436 - 2250 kg is 437 - 2255 kg is 438 - 2260 kg is 439 - 2265 kg is 440 - 2270 kg is 441 - 2275 kg is 442 - 2280 kg is 443 - 2285 kg is 444 - 2290 kg is 445 - 2295 kg is 446 - 2300 kg is 447 - 2305 kg is 448 - 2310 kg is 449 - 2315 kg is 450 - 2320 kg is 451 - 2325 kg is 452 - 2330 kg is 453 - 2335 kg is 454 - 2340 kg is 455 - 2345 kg is 456 - 2350 kg is 457 - 2355 kg is 458 - 2360 kg is 459 - 2365 kg is 460 - 2370 kg is 461 - 2375 kg is 462 - 2380 kg is 463 - 2385 kg is 464 - 2390 kg is 465 - 2395 kg is 466 - 2400 kg is 467 - 2405 kg is 468 - 2410 kg is 469 - 2415 kg is 470 - 2420 kg is 471 - 2425 kg is 472 - 2430 kg is 473 - 2435 kg is 474 - 2440 kg is 475 - 2445 kg is 476 - 2450 kg is 477 - 2455 kg is 478 - 2460 kg is 479 - 2465 kg is 480 - 2470 kg is 481 - 2475 kg is 482 - 2480 kg is 483 - 2485 kg is 484 - 2490 kg is 485 - 2495 kg is 486 - 2500 kg is 487 - 2505 kg is 488 - 2510 kg is 489 - 2515 kg is 490 - 2520 kg is 491 - 2525 kg is 492 - 2530 kg is 493 - 2535 kg is 494 - 2540 kg is 495 - 2545 kg is 496 - 2550 kg is 497 - 2555 kg is 498 - 2560 kg is 499 - 2565 kg is 500 - 2570 kg is 501 - 2575 kg is 502 - 2580 kg is 503 - 2585 kg is 504 - 2590 kg is 505 - 2595 kg is 506 - 2600 kg is 507 - 2605 kg is 508 - 2610 kg is 509 - 2615 kg is 510 - 2620 kg is 511 - 2625 kg is 512 - 2630 kg is 513 - 2635 kg is 514 - 2640 kg is 515 - 2645 kg is 516 - 2650 kg is 517 - 2655 kg is 518 - 2660 kg is 519 - 2665 kg is 520 - 2670 kg is 521 - 2675 kg is 522 - 2680 kg is 523 - 2685 kg is 524 - 2690 kg is 525 - 2695 kg is 526 - 2700 kg is 527 - 2705 kg is 528 - 2710 kg is 529 - 2715 kg is 530 - 2720 kg is 531 - 2725 kg is 532 - 2730 kg is 533 - 2735 kg is 534 - 2740 kg is 535 - 2745 kg is 536 - 2750 kg is 537 - 2755 kg is 538 - 2760 kg is 539 - 2765 kg is 540 - 2770 kg is 541 - 2775 kg is 542 - 2780 kg is 543 - 2785 kg is 544 - 2790 kg is 545 - 2795 kg is 546 - 2800 kg is 547 - 2805 kg is 548 - 2810 kg is 549 - 2815 kg is 550 - 2820 kg is 551 - 2825 kg is 552 - 2830 kg is 553 - 2835 kg is 554 - 2840 kg is 555 - 2845 kg is 556 - 2850 kg is 557 - 2855 kg is 558 - 2860 kg is 559 - 2865 kg is 560 - 2870 kg is 561 - 2875 kg is 562 - 2880 kg is 563 - 2885 kg is 564 - 2890 kg is 565 - 2895 kg is 566 - 2900 kg is 567 - 2905 kg is 568 - 2910 kg is 569 - 2915 kg is 570 - 2920 kg is 571 - 2925 kg is 572 - 2930 kg is 573 - 2935 kg is 574 - 2940 kg is 575 - 2945 kg is 576 - 2950 kg is 577 - 2955 kg is 578 - 2960 kg is 579 - 2965 kg is 580 - 2970 kg is 581 - 2975 kg is 582 - 2980 kg is 583 - 2985 kg is 584 - 2990 kg is 585 - 2995 kg is 586 - 3000 kg is 587 - 3005 kg is 588 - 3010 kg is 589 - 3015 kg is 590 - 3020 kg is 591 - 3025 kg is 592 - 3030 kg is 593 - 3035 kg is 594 - 3040 kg is 595 - 3045 kg is 596 - 3050 kg is 597 - 3055 kg is 598 - 3060 kg is 599 - 3065 kg is 600 - 3070 kg is 601 - 3075 kg is 602 - 3080 kg is 603 - 3085 kg is 604 - 3090 kg is 605 - 3095 kg is 606 - 3100 kg is 607 - 3105 kg is 608 - 3110 kg is 609 - 3115 kg is 610 - 3120 kg is 611 - 3125 kg is 612 - 3130 kg is 613 - 3135 kg is 614 - 3140 kg is 615 - 3145 kg is 616 - 3150 kg is 617 - 3155 kg is 618 - 3160 kg is 619 - 3165 kg is 620 - 3170 kg is 621 - 3175 kg is 622 - 3180 kg is 623 - 3185 kg is 624 - 3190 kg is 625 - 3195 kg is 626 - 3200 kg is 627 - 3205 kg is 628 - 3210 kg is 629 - 3215 kg is 630 - 3220 kg is 631 - 3225 kg is 632 - 3230 kg is 633 - 3235 kg is 634 - 3240 kg is 635 - 3245 kg is 636 - 3250 kg is 637 - 3255 kg is 638 - 3260 kg is 639 - 3265 kg is 640 - 3270 kg is 641 - 3275 kg is 642 - 3280 kg is 643 - 3285 kg is 644 - 3290 kg is 645 - 3295 kg is 646 - 3300 kg is 647 - 3305 kg is 648 - 3310 kg is 649 - 3315 kg is 650 - 3320 kg is 651 - 3325 kg is 652 - 3330 kg is 653 - 3335 kg is 654 - 3340 kg is 655 - 3345 kg is 656 - 3350 kg is 657 - 3355 kg is 658 - 3360 kg is 659 - 3365 kg is 660 - 3370 kg is 661 - 3375 kg is 662 - 3380 kg is 663 - 3385 kg is 664 - 3390 kg is 665 - 3395 kg is 666 - 3400 kg is 667 - 3405 kg is 668 - 3410 kg is 669 - 3415 kg is 670 - 3420 kg is 671 - 3425 kg is 672 - 3430 kg is 673 - 3435 kg is 674 - 3440 kg is 675 - 3445 kg is 676 - 3450 kg is 677 - 3455 kg is 678 - 3460 kg is 679 - 3465 kg is 680 - 3470 kg is 681 - 3475 kg is 682 - 3480 kg is 683 - 3485 kg is 684 - 3490 kg is 685 - 3495 kg is 686 - 3500 kg is 687 - 3505 kg is 688 - 3510 kg is 689 - 3515 kg is 690 - 3520 kg is 691 - 3525 kg is 692 - 3530 kg is 693 - 3535 kg is 694 - 3540 kg is 695 - 3545 kg is 696 - 3550 kg is 697 - 3555 kg is 698 - 3560 kg is 699 - 3565 kg is 700 - 3570 kg is 701 - 3575 kg is 702 - 3580 kg is 703 - 3585 kg is 704 - 3590 kg is 705 - 3595 kg is 706 - 3600 kg is 707 - 3605 kg is 708 - 3610 kg is 709 - 3615 kg is 710 - 3620 kg is 711 - 3625 kg is 712 - 3630 kg is 713 - 3635 kg is 714 - 3640 kg is 715 - 3645 kg is 716 - 3650 kg is 717 - 3655 kg is 718 - 3660 kg is 719 - 3665 kg is 720 - 3670 kg is 721 - 3675 kg is 722 - 3680 kg is 723 - 3685 kg is 724 - 3690 kg is 725 - 3695 kg is 726 - 3700 kg is 727 - 3705 kg is 728 - 3710 kg is 729 - 3715 kg is 730 - 3720 kg is 731 - 3725 kg is 732 - 3730 kg is 733 - 3735 kg is 734 - 3740 kg is 735 - 3745 kg is 736 - 3750 kg is 737 - 3755 kg is 738 - 3760 kg is 739 - 3765 kg is 740 - 3770 kg is 741 - 3775 kg is 742 - 3780 kg is 743 - 3785 kg is 744 - 3790 kg is 745 - 3795 kg is 746 - 3800 kg is 747 - 3805 kg is 748 - 3810 kg is 749 - 3815 kg is 750 - 3820 kg is 751 - 3825 kg is 752 - 3830 kg is 753 - 3835 kg is 754 - 3840 kg is 755 - 3845 kg is 756 - 3850 kg is 757 - 3855 kg is 758 - 3860 kg is 759 - 3865 kg is 760 - 3870 kg is 761 - 3875 kg is 762 - 3880 kg is 763 - 3885 kg is 764 - 3890 kg is 765 - 3895 kg is 766 - 3900 kg is 767 - 3905 kg is 768 - 3910 kg is 769 - 3915 kg is 770 - 3920 kg is 771 - 3925 kg is 772 - 3930 kg is 773 - 3935 kg is 774 - 3940 kg is 775 - 3945 kg is 776 - 3950 kg is 777 - 3955 kg is 778 - 3960 kg is 779 - 3965 kg is 780 - 3970 kg is 781 - 3975 kg is 782 - 3980 kg is 783 - 3985 kg is 784 - 3990 kg is 785 - 3995 kg is 786 - 4000 kg is 787 - 4005 kg is 788 - 4010 kg is 789 - 4015 kg is 790 - 4020 kg is 791 - 4025 kg is 792 - 4030 kg is 793 - 4035 kg is 794 - 4040 kg is 795 - 4045 kg is 796 - 4050 kg is 797 - 4055 kg is 798 - 4060 kg is 799 - 4065 kg is 800 - 4070 kg is 801 - 4075 kg is 802 - 4080 kg is 803 - 4085 kg is 804 - 4090 kg is 805 - 4095 kg is 806 - 4100 kg is 807 - 4105 kg is 808 - 4110 kg is 809 - 4115 kg is 810 - 4120 kg is 811 - 4125 kg is 812 - 4130 kg is 813 - 4135 kg is 814 - 4140 kg is 815 - 4145 kg is 816 - 4150 kg is 817 - 4155 kg is 818 - 4160 kg is 819 - 4165 kg is 820 - 4170 kg is 821 - 4175 kg is 822 - 4180 kg is 823 - 4185 kg is 824 - 4190 kg is 825 - 4195 kg is 826 - 4200 kg is 827 - 4205 kg is 828 - 4210 kg is 829 - 4215 kg is 830 - 4220 kg is 831 - 4225 kg is 832 - 4230 kg is 833 - 4235 kg is 834 - 4240 kg is 835 - 4245 kg is 836 - 4250 kg is 837 - 4255 kg is 838 - 4260 kg is 839 - 4265 kg is 840 - 4270 kg is 841 - 4275 kg is 842 - 4280 kg is 843 - 4285 kg is 844 - 4290 kg is 845 - 4295 kg is 846 - 4300 kg is 847 - 4305 kg is 848 - 4310 kg is 849 - 4315 kg is 850 - 4320 kg is 851 - 4325 kg is 852 - 4330 kg is 853 - 4335 kg is 854 - 4340 kg is 855 - 4345 kg is 856 - 4350 kg is 857 - 4355 kg is 858 - 4360 kg is 859 - 4365 kg is 860 - 4370 kg is 861 - 4375 kg is 862 - 4380 kg is 863 - 4385 kg is 864 - 4390 kg is 865 - 4395 kg is 866 - 4400 kg is 867 - 4405 kg is 868 - 4410 kg is 869 - 4415 kg is 870 - 4420 kg is 871 - 4425 kg is 872 - 4430 kg is 873 - 4435 kg is 874 - 4440 kg is 875 - 4445 kg is 876 - 4450 kg is 877 - 4455 kg is 878 - 4460 kg is 879 - 4465 kg is 880 - 4470 kg is 881 - 4475 kg is 882 - 4480 kg is 883 - 4485 kg is 884 - 4490 kg is 885 - 4495 kg is 886 - 4500 kg is 887 - 4505 kg is 888 - 4510 kg is 889 - 4515 kg is 890 - 4520 kg is 891 - 4525 kg is 892 - 4530 kg is 893 - 4535 kg is 894 - 4540 kg is 895 - 4545 kg is 896 - 4550 kg is 897 - 4555 kg is 898 - 4560 kg is 899 - 4565 kg is 900 - 4570 kg is 901 - 4575 kg is 902 - 4580 kg is 903 - 4585 kg is 904 - 4590 kg is 905 - 4595 kg is 906 - 4600 kg is 907 - 4605 kg is 908 - 4610 kg is 909 - 4615 kg is 910 - 4620 kg is 911 - 4625 kg is 912 - 4630 kg is 913 - 4635 kg is 914 - 4640 kg is 915 - 4645 kg is 916 - 4650 kg is 917 - 4655 kg is 918 - 4660 kg is 919 - 4665 kg is 920 - 4670 kg is 921 - 4675 kg is 922 - 4680 kg is 923 - 4685 kg is 924 - 4690 kg is 925 - 4695 kg is 926 - 4700 kg is 927 - 4705 kg is 928 - 4710 kg is 929 - 4715 kg is 930 - 4720 kg is 931 - 4725 kg is 932 - 4730 kg is 933 - 4735 kg is 934 - 4740 kg is 935 - 4745 kg is 936 - 4750 kg is 937 - 4755 kg is 938 - 4760 kg is 939 - 4765 kg is 940 - 4770 kg is 941 - 4775 kg is 942 - 4780 kg is 943 - 4785 kg is 944 - 4790 kg is 945 - 4795 kg is 946 - 4800 kg is 947 - 4805 kg is 948 - 4810 kg is 949 - 4815 kg is 950 - 4820 kg is 951 - 4825 kg is 952 - 4830 kg is 953 - 4835 kg is 954 - 4840 kg is 955 - 4845 kg is 956 - 4850 kg is 957 - 4855 kg is 958 - 4860 kg is 959 - 4865 kg is 960 - 4870 kg is 961 - 4875 kg is 962 - 4880 kg is 963 - 4885 kg is 964 - 4890 kg is 965 - 4895 kg is 966 - 4900 kg is 967 - 4905 kg is 968 - 4910 kg is 969 - 4915 kg is 970 - 4920 kg is 971 - 4925 kg is 972 - 4930 kg is 973 - 4935 kg is 974 - 4940 kg is 975 - 4945 kg is 976 - 4950 kg is 977 - 4955 kg is 978 - 4960 kg is 979 - 4965 kg is 980 - 4970 kg is 981 - 4975 kg is 982 - 4980 kg is										



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.

■ EXPOSURE OF IMP: STUDY DAY

☐ date of IMP administration
02.05.2024

☒ real start time of IMP administration
07:10

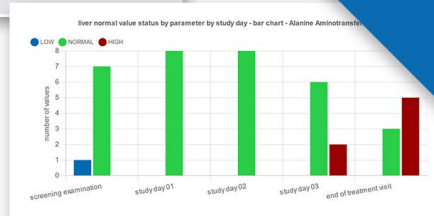
☒ real end time of IMP administration
07:11

☒ time difference between start and end time of administration in min
1.00

☐ intake with 240ml water **Q A**
☒ yes ☐ no ☐ n.k.

☐ empty oral cavity and hands **Q A**
☒ yes ☐ no ☐ n.k.

☐ upright position during administration **Q A**
☒ yes ☐ no ☐ n.k.

☒ mark monitoring for page as completed





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.

SDV flag was set

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	current 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.

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	entry opened		No. 42 message: AE is resolved according to source. Please check and correct.	monitoring	Sato
2024-05-27 08:52:46			Answer: Corrected.	dataEntry	Schneider
2024-05-27 08:53:03			entry 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 11:41:11				medicalMonitoring	Wójcik
2024-05-27 12:07:00	resolved		initially unset	dataEntry	Schneider

☒ resolved with sequelae

☐ not yet resolved ☐ death

☐ unknown

☐ n.k.

AE is resolved according to source. Please check and correct.

➤ Corrected.



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.



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



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.



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

Reference
This Post on [LinkedIn](#)

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 A

Head tightness ☐ n.k.

Lowest Level Term Code A

10019205

Preferred Term A

Tension headache

Preferred Term Code A

10043269

High Level Term A

Headaches NEC

High Level Term Code A

10019233

High Level Group Term A

Headaches

High Level Group Term Code A

10019231

Primary System Organ Class A

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 change

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

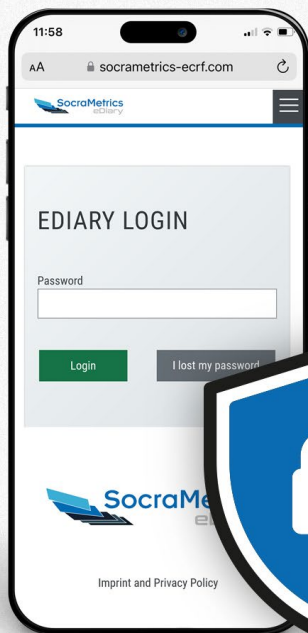
Do you know how to make life easier for Clinical Data Managers when it comes to MedDRA Coding?

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!



#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.

01:00

SocraMetrics
diary

Dateneingabe, Subject 042, Site 01

TAGEBUCHDATEN: TAG 3

Datum

19.12.2023

Haben Sie das Studienprodukt
Morgen eingenommen?

Antwort

☒ Ja ☐ Nein

Falls ja, bitte Uhrzeit eingeben

07:15

☐ Applikation des Studienprodukts vergessen
☐ Applikation des Studienprodukts zu spät

02:00

SocraMetrics
diary

Data Entry, Subject 001, Site 01

DIARY DATA: DAY 3 MORNING

date

19.12.2023

Did you take the study product
this morning?

answer

☒ Yes ☐ No

if yes, please enter the time

07:15

☐ study product application forgotten
☐ study product application too late

03:00

SocraMetrics
diary

データ入力, Subject 042, Site 01

記録データ: 3日目午前

日付

09.09.2024

朝、試験薬品を服用しましたか?

回答

☒ はい ☐ いいえ

「はい」の場合は時間を記入してください。

07:15

☐ 試験薬品の服用を忘れた
☐ 試験薬品の服用が遅い

04:00

SocraMetrics
diary

データ入力, Subject 042, Site 01

記録データ: 3日目午後

日付

09.09.2024

午後、試験薬品を服用しましたか?

回答

☒ はい ☐ いいえ ☐ n.k.

「はい」の場合は時間を記入してください。

07:15

☐ 試験薬品の服用を忘れた
☐ 試験薬品の服用が遅い

#22

OUR EDC
FEATURE
of the week

 German

 English

 Japanese

 Klingon would be possible, too



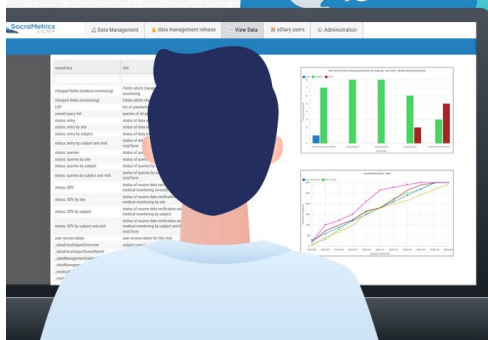
The eDiary That Speaks Your Language

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!

OUR EDC
FEATURE
of the week





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

The moment participants 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!



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.



		N	min	mean	max
	time of measurement	0			
RRES	result in original units	4	22	2061.7500	8148
					21.6.
					24.2: 1
					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			
					009:
	result in original units	4	9	121.2500	180
					12'
	time of measurement	0			

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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...

Data Entry

Monitoring

Data Management

data management release

PD Tracker

PD-Tracker 1234grf23ct

+ 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	27.06.2024
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
15	03	008	study dates	period I, study day 1	dataManagement	Visit Scheme	Study day 1 was performed one day too late due to unavailability of subject.		06.08.2024	10.09.2024
16	03	003	demographic data	screening examination	autoQuery	Other Deviations	Query Message: 29 according to source. Please check. Answer: Entry is correct - 19 according to source.		05.09.2024	12.09.2024

PD from Study Nurse

PD from Monitoring

PD from Data Management

PD from (Auto)Queries

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OUR EDC
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of the week



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 continuous updates.

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' (EMA/

Keywords	Computerised systems, electronic data management, security, electronic data capture (eCOA), interactive response technology (IRT), electronic signatures, artificial intelligence
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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.





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!



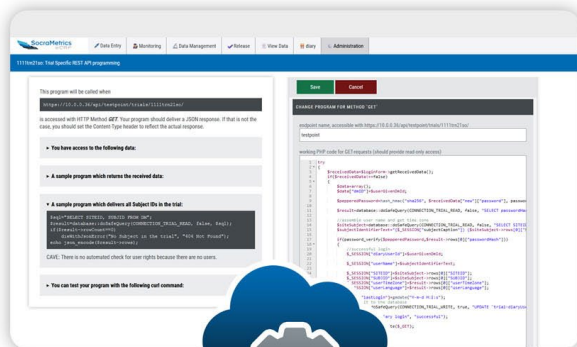
Annotated eCRF with Dual Bookmarks - Just 2 Clicks Away!

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!



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/edc-users/"
```

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OUR EDC
FEATURE
of the week



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.





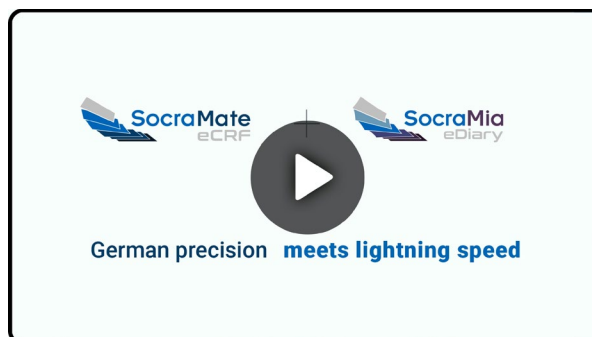
Exciting News!

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



Interested? Request a Demo!



Get in touch with
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When German precision meets lightning speed

