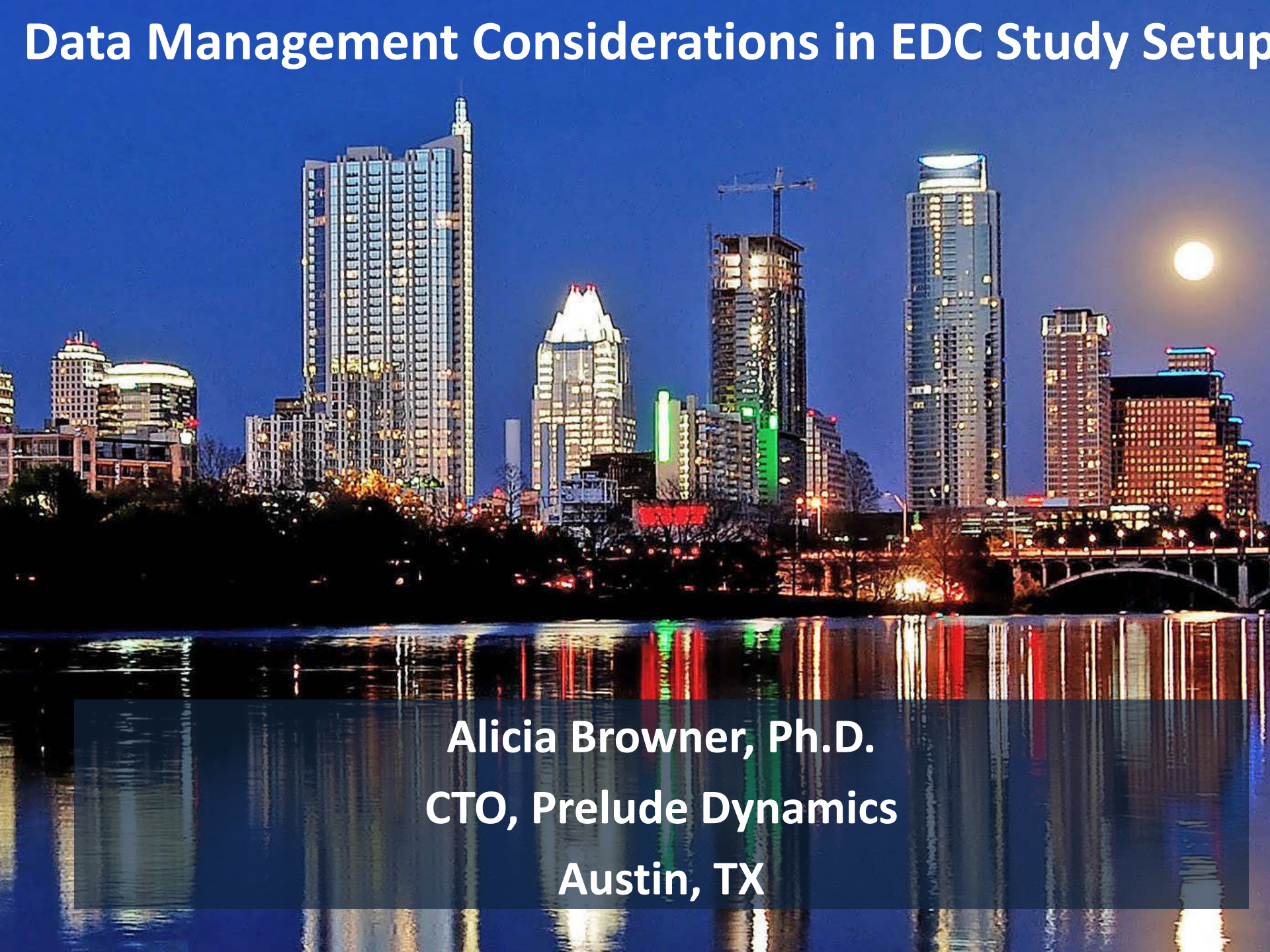
Data Management Considerations in EDC Study Setup



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Austin, TX

Types of EDC Solutions

Custom Built to Order

Someone builds a custom study for you.

- Provide a protocol & sample CRFs
- Provide study specifications
- Provide feedback

Pre-Built Templates

Someone builds a custom set of templates for you.

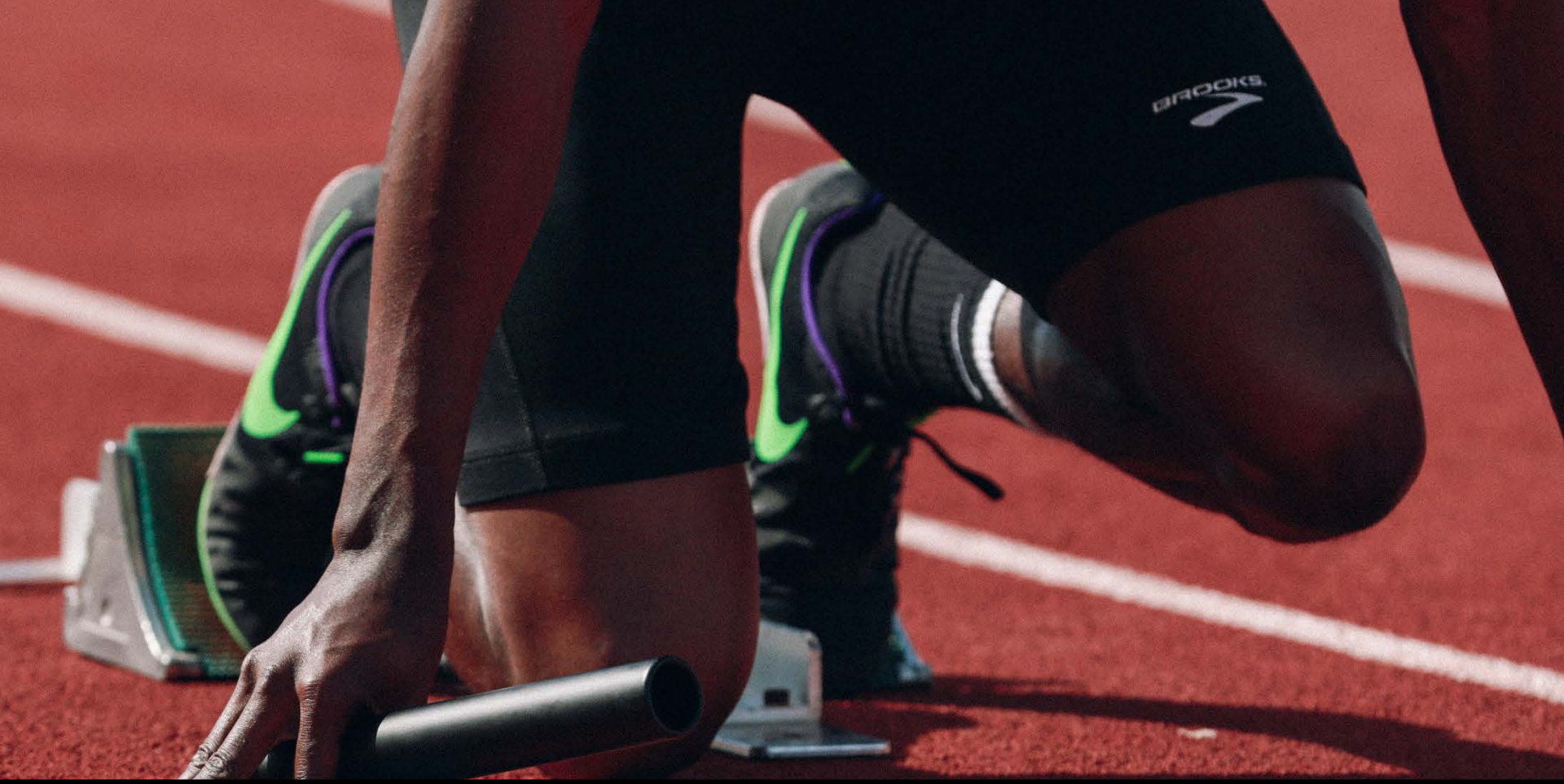
- Provide sample CRFs and modularized components
- Recognize patterns and anticipate variations
- Validate once, use many

Do-it-Yourself

You build your own study.

- Design eCRFs
- Specify constraints and calculations
- Specify visit schedule
- Publish

- *Test and accept*
- *Anticipate how the data are coming out at the back end*



EDC sets up the study database at the front end instead of the back end.

Data Managers now think about what *should* happen instead of what *did* happen


EDC/CTMS/CDMS are changing the world of study development and operations.
How does one assess the quality of the setup?

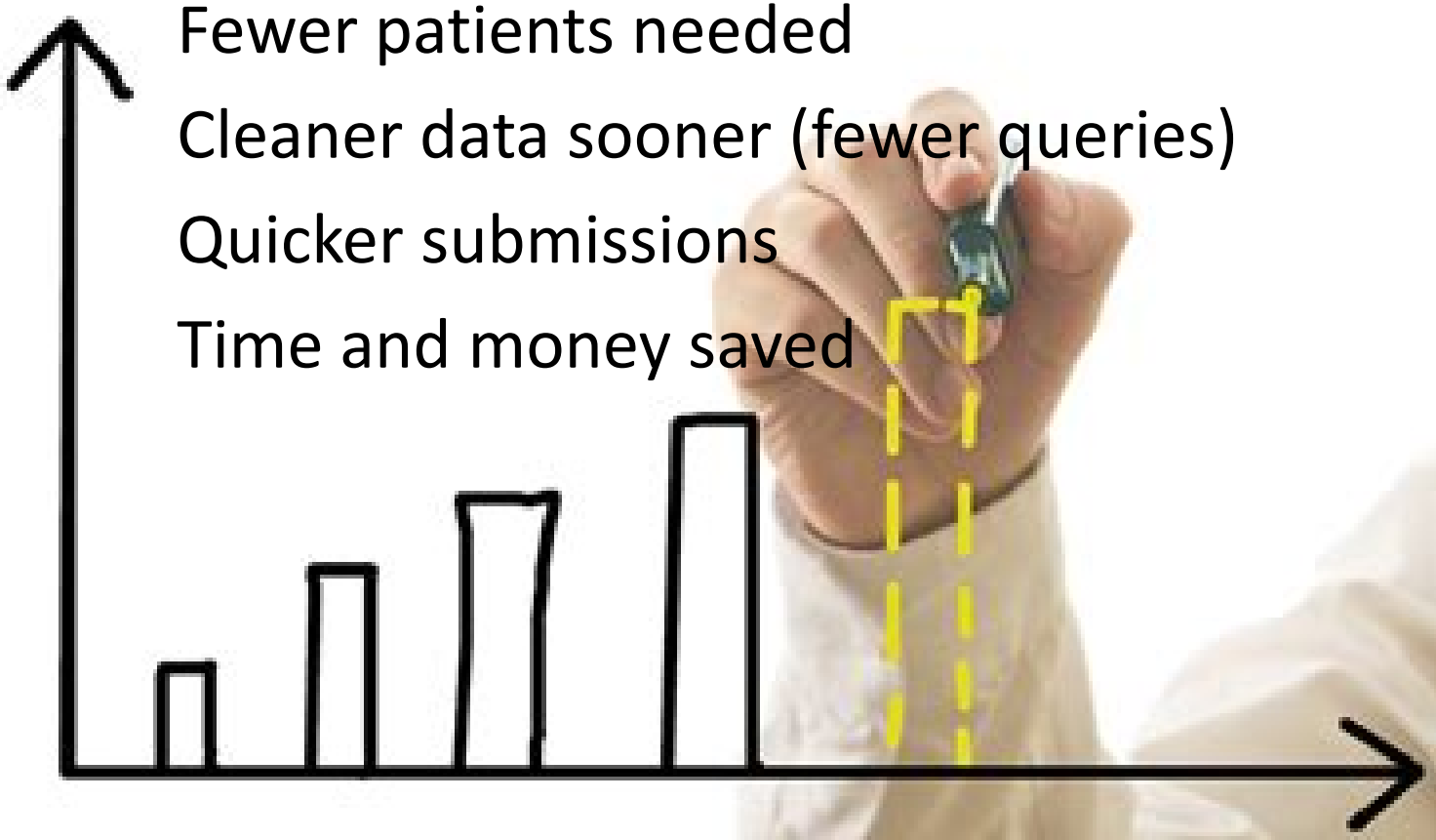
Efficiency measures include:

Fewer patients needed

Cleaner data sooner (fewer queries)

Quicker submissions

Time and money saved



Quality of the research goes beyond obvious measures to include overall performance.

Edit Checks (Constraints/Calculations)

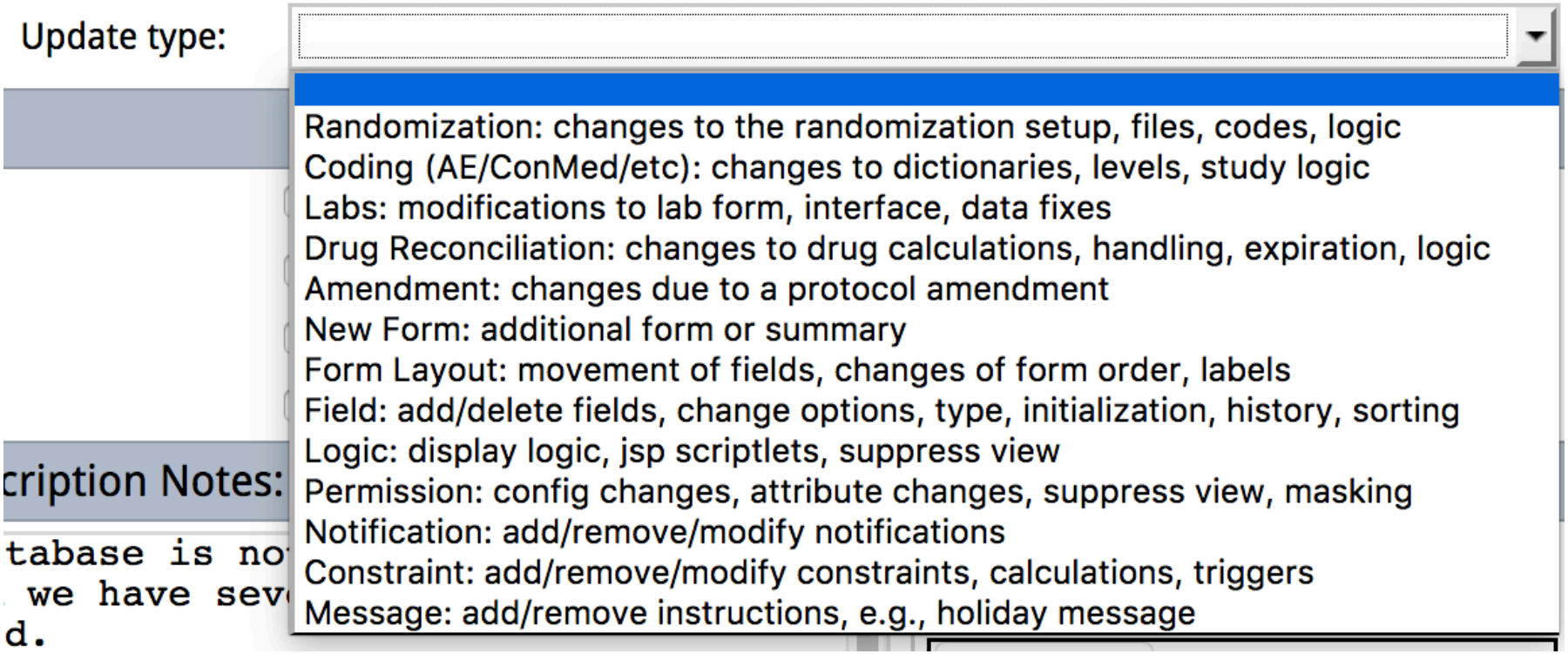
Are the appropriate edits in place to reduce queries?

Change Controls

How are change controls being tracked?

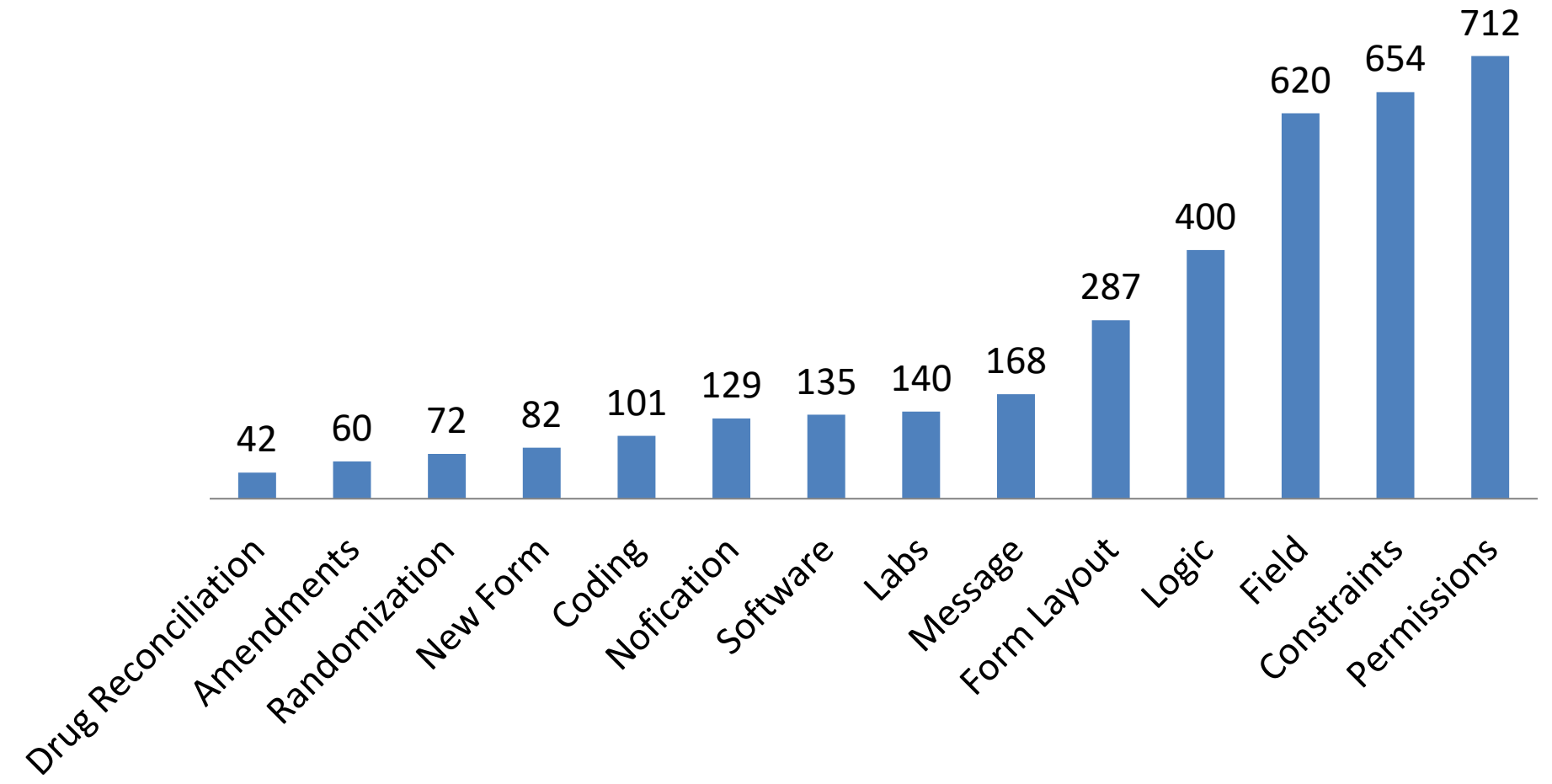
What are you learning from them?

To leverage automation, reexamine and think through even common EDC functions.



Categorizing change controls helps provide insight into opportunities for quality improvement.

Analysis of reasons for mid-study updates shows where effort should be increased before Go-Live.



Analysis of reasons for mid-study updates shows where effort should be increased before Go-Live.

1. **Permissions**: which roles can see/edit/query/sign forms, fields; which roles get which notifications

Focusing on the top reasons for mid-study changes provides an opportunity for improved pre-live quality.

1. Permissions
2. **Constraints/Calculations**: changes from errors to warnings, triggers, cross-form edit checks; calculation precision; additional calculations

Focusing on the top reasons for mid-study changes provides an opportunity for improved pre-live quality.

1. **Permissions**
2. **Constraints/Calculations**
3. **Field Changes**: change drop-down values, add fields, remove fields

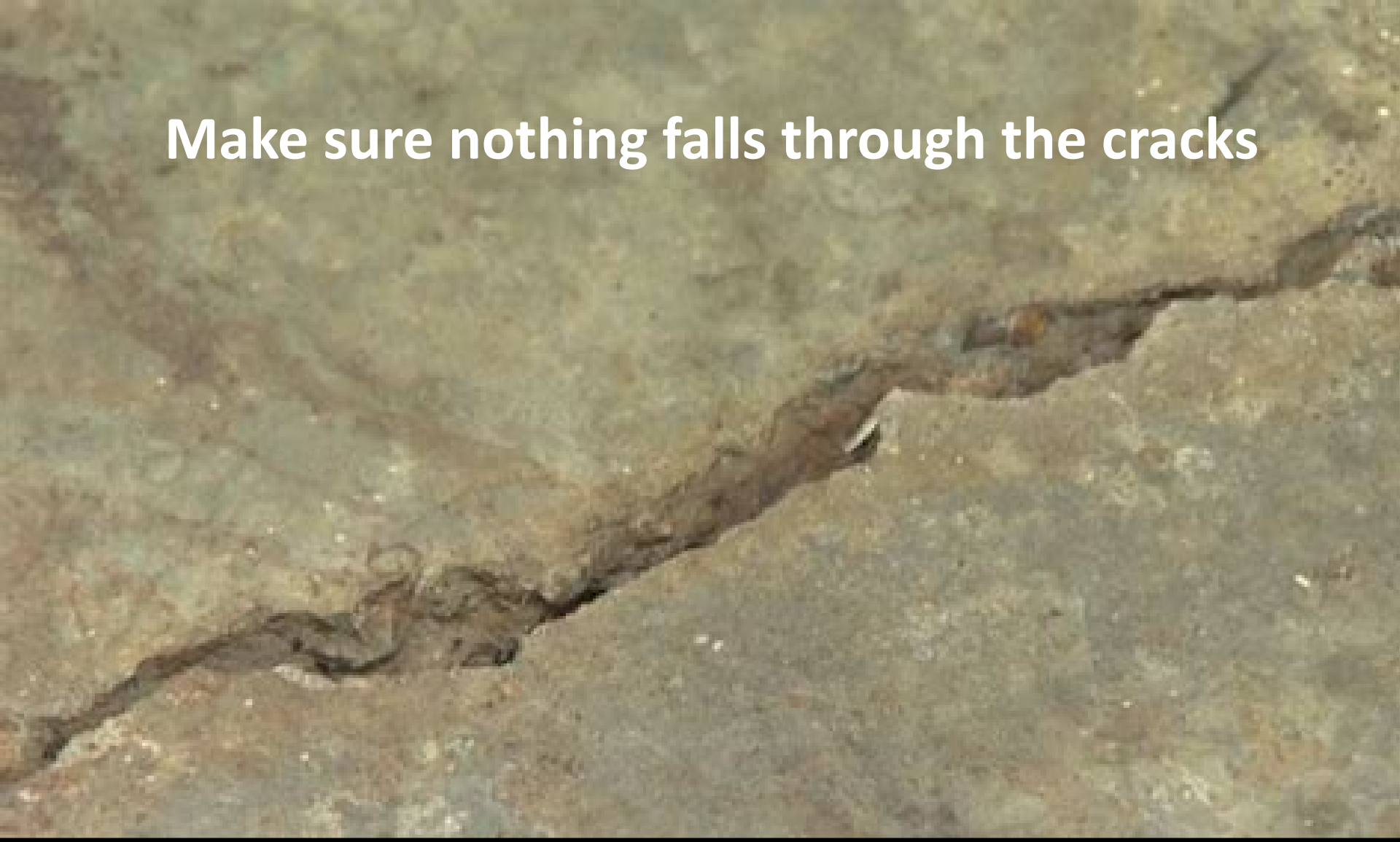
Focusing on the top reasons for mid-study changes provides an opportunity for improved pre-live quality.

1. **Permissions**
2. **Constraints/Calculations**
3. **Field Changes**
4. **Logic**: when to show what, flow of data

Focusing on the top reasons for mid-study changes provides an opportunity for improved pre-live quality.

1. Permissions
2. Constraints/Calculations
3. Field Changes
4. Logic
5. **Form layout: move fields, change form order, update labels, change font/color**

Focusing on the top reasons for mid-study changes provides an opportunity for improved pre-live quality.



Think through setup and automation options using EDC beyond form layout.

Vital Signs Date:

Exp Time	Actual Time 0000-2359 or check if not done	SBP	DBP	HR	Temp	RR	GCS			Intubated	ICP	Therapy Intensity Level (Check all that apply) *Hover cursor over symbol to view explanation*									
							E	V	M			0	S/P	VD	M	BP ↑	BP ↓	H	B	SD	F
0000	:				°F °C					Y N											
0100	:				°F °C					Y N											
0200	:				°F °C					Y N											
0300	:				°F °C					Y N											
0400	:				°F °C					Y N											
0500	:				°F °C					Y N											
0600	:				°F °C					Y N											
0700	:				°F °C					Y N											
0800	:				°F °C					Y N											
0900	:				°F °C					Y N											
1000	:				°F °C					Y N											
1100	:				°F °C					Y N											
1200	:				°F °C					Y N											
1300	:				°F °C					Y N											
1400	:				°F °C					Y N											
1500	:				°F °C					Y N											
1600	:				°F °C					Y N											
1700	:				°F °C					Y N											
1800	:				°F °C					Y N											
1900	:				°F °C					Y N											
2000	:				°F °C					Y N											
2100	:				°F °C					Y N											
2200	:				°F °C					Y N											
2300	:				°F °C					Y N											

Ensure that the right data is being collected

– not too much (!) or too little

Does body weight matter?
Lbs?
Kgs?

What is the big deal?

11 lbs 6 oz

Human conversion…

11.6 * 2.24 = 25.98 kg

Right?

Wrong!!!

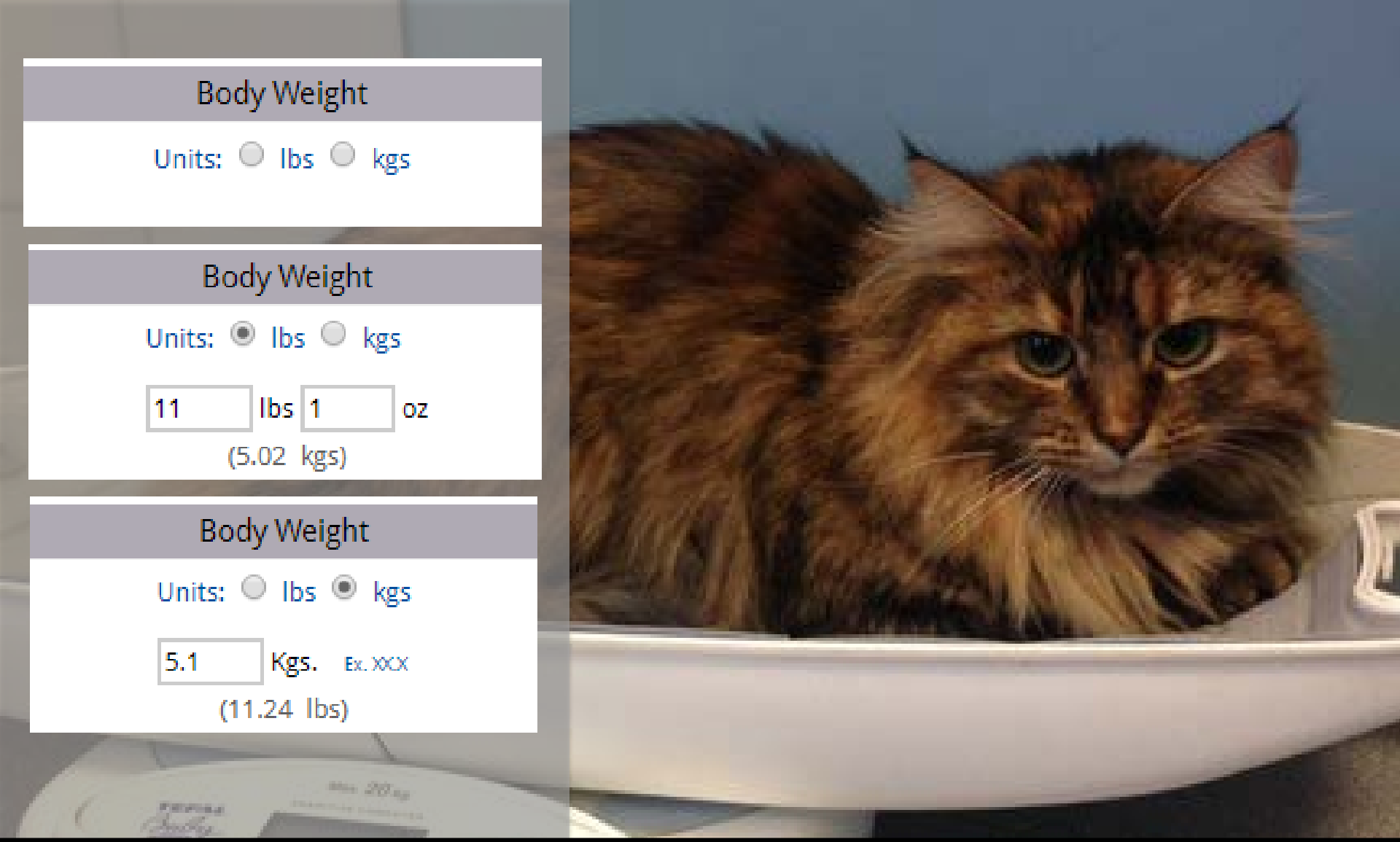
11 lbs 6 oz is 11.375 lbs

So it is

25.48 kg

The difference is

½ Kg!



Leverage automation to help avoid human induced errors into your data.

Clinical Signs of Adverse Event (one sign per row)	Severity	Serious	Start Date / End Date
Vomited Coded Low Level Term (Monitors to enter) +/–	Mild	○ Yes ● No	Start 04-Apr-2018 End 04-Apr-2018 ☐ Ongoing at termination
Vomited Coded Low Level Term (Monitors to enter) +/–	Mild	○ Yes ● No	Start 04-Apr-2018 End 04-Apr-2018 ☐ Ongoing at termination
Vomited Coded Low Level Term (Monitors to enter) +/–	Mild	○ Yes ● No	Start 04-Apr-2018 End 04-Apr-2018 ☐ Ongoing at termination
Vomited Coded Low Level Term (Monitors to enter) +/–	Mild	○ Yes ● No	Start 04-Apr-2018 End 04-Apr-2018 ☐ Ongoing at termination
Vomited Coded Low Level Term (Monitors to enter) +/–	Mild	○ Yes ● No	Start 04-Apr-2018 End 04-Apr-2018 ☐ Ongoing at termination

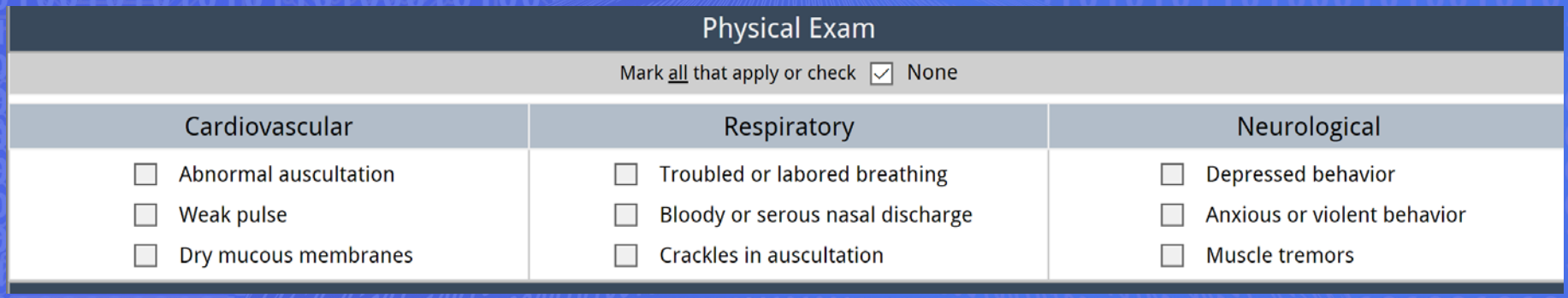
Adverse Event # 3

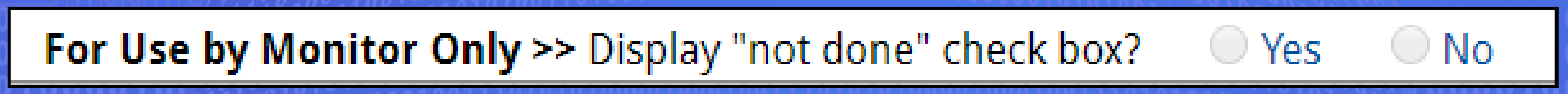
<<< MONITOR USE ONLY >>>

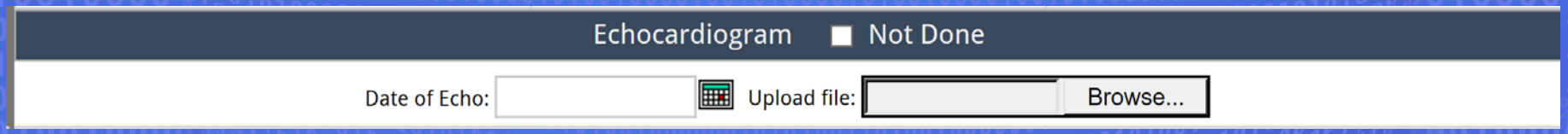
☐ Show "Remove AE"

#	Clinical Signs of Adverse Event (one sign per row)	Severity	Serious	Start Date / End Date
1 INVESTIGATOR ONLY ☐ Remove this AE	Vomited Coded Low Level Term (Monitors to enter) +/–	Mild	○ Yes ◉ No	Start 04-Apr-2018 End 04-Apr-2018 ☐ Ongoing at termination
2 INVESTIGATOR ONLY ☑ Remove this AE » reason for removing AE: captured in AE 1	Coded Low Level Term (Monitors to enter) +/–		○ Yes ○ No	Start End ☐ Ongoing at termination
3 INVESTIGATOR ONLY ☑ Remove this AE » reason for removing AE: captured in AE 1	Coded Low Level Term (Monitors to enter) +/–		○ Yes ○ No	Start End ☐ Ongoing at termination

Because we are all human… give us a way out! … an easy way to fix things.







Knowing if something was intentionally left blank or not done or not applicable is better than not knowing.

Patient Forms | Roles can add patients: CINA

#	Form Title	Tab Label	Roles						
			Can View	Can Edit	Can Sign	Can Review	Can Query	Can Finalize	Can Lock
1	Patient Information-Patient Demographics *info.form.name.demographics (demographics.jsp)*	Demographics	ACIMDPSZN	CIN	CIN	PMD	PMD	PMD	PMD
2	Patient Information-Patient Profile *info.form.name.patient.profile (patientProfile.jsp)*	Patient Profile	CITA	CITA		PMD	PMD	PMD	PMD
3	Patient Information-Medical History *info.form.name.medical.history (medicalHistory.jsp)*	Med. Hist.	ACIMDPSNX	CIN	CIN	PMD	PMD	PMD	PMD
4	Screening Visit-Vital Signs/Physical Exam *screening.form.name.vitals.physical.exam (physicalExam.jsp)*	Vitals/Phys Exam	ACIMDPSN	CIN	CIN	PMD	PMD	PMD	PMD
5	Screening Visit-Laboratory Values(on-demand: Add Lab) *screening.form.name.blood.lab (labBlood.jsp)*	Blood Chem. Labs	ACIMDPSN	CIN	CIN	PMD	PMD		PMD
6	Screening Visit-Itching (Pruritus) Scale *screening.form.name.pruritus (pruritus.jsp)*	Itching Scale	ACIMDPSN	CI	CI	PMD	PMD	PMD	PMD
7	Screening Visit-Oral Ulceration Measurements *screening.form.name.oral.wart.measurements (oralUlcerationMeasurements.jsp)*	Measurements	ACIMDPSN	CIN	CIN	PMD	PMD	PMD	PMD
8	Screening Visit-Inclusion/Exclusion *screening.form.name.inclusion.exclusion (inclusionExclusion.jsp)*	Incl/Excl	ACIMDPSN	CIN	CIN	PMD	PMD	PMD	PMD
9	Screening Visit-Laboratory Values(on-demand: Add Lab) *screening.form.name.cbc.diff (labCbc.jsp)*	Labs	LA	L	L	PMD	PMD	PMD	PMD
10	Screening Visit-Treatment *screening.form.name.treatment (treatment.jsp)*	Treatment	ACIMDPSN	CIN	IN	PMD	PMD	PMD	PMD
11	Visit One-Vital Signs/Physical Exam *visit1.form.name.vitals.physical.exam (physicalExam.jsp)*	Vitals/Phys Exam	ACIMDPSN	CIN	CIN	PMD	PMD	PMD	PMD
12	Visit One-Oral Ulceration Measurements *visit1.form.name.oral.wart.measurements (oralUlcerationMeasurements.jsp)*	Measurements	ACIMDPSN	CIN	CIN	PMD	PMD	PMD	PMD
13	Visit One-Study Drug Administration/Dosing *visit1.form.name.dosing (dosing.jsp)*	Dosing	ACIMDPSN	CIPLN	CIPLN	PMD	PMD	PMD	PMD
14	Visit One-Post Dose Monitoring *visit1.form.name.post.dosing (postDose.jsp)*	Post-Dosing	ACIMDPSN	CIN	CIN	PMD	PMD	PMD	PMD
15	Visit One-Thoracic Radiographs *visit1.form.name.thoracic.radiographs (thoracicRadiographs.jsp)*	Radiographs	ACIMDPSN	CILN	CILN	PM	PMD	PMD	PMD
16	Visit One-Laboratory Values(on-demand: Add Lab) *visit1.form.name.cbc.diff (labCbc.jsp)*	Labs	LA	L	L	PMD	PMD	PMD	PMD
	Visit Two-Vital Signs/Physical Exam								

Improve study quality through adequate use of role based permissions.

Set up Automatic Notifications for

Lab result receipt

Invoices ready for payment

Check mailed

No appointment scheduled within expected window in danger of protocol deviation

Adequate alerts improve study operations and quality.

Images

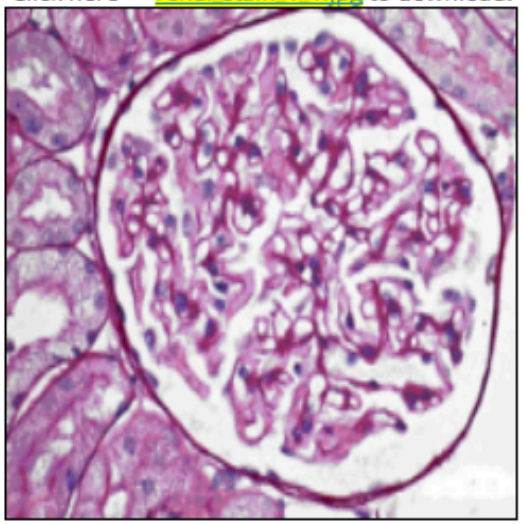
Did subject have images taken Today? ◉ Yes ○ No

» If Yes, upload the following:

Slides

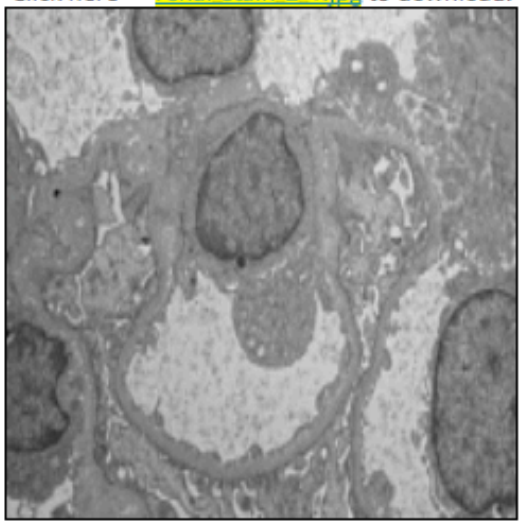
A: Browse... No file selected.

Click here → renal_stain_1_1.jpg to download.



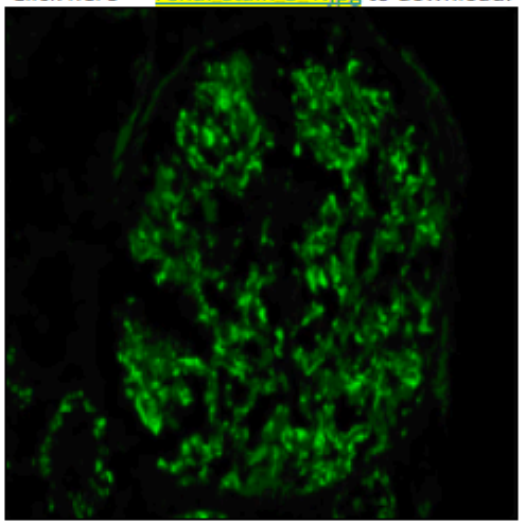
B: Browse... No file selected.

Click here → renal_stain_2_1.jpg to download.



C: Browse... No file selected.

Click here → renal_stain_3_1.jpg to download.



Previews can help the reviewer know whether to view the image in more detail saving time.

Dosing Information

Dose Calculation for IVP and CP

+/– Click ± to expand calculations

1. Treatment assignment based on randomization: Treatment B

2. Record dog's body weight (from CRF 6) in lbs and divide by 2.2 to obtain body weight in kgs: 20.1 kgs 44.31 lbs

3. Using the weight in kg, select the number of tablets to be given as a single dose:

Body Weight (kg)	Minimum Dose to be Administered	Tablet Size	Number of Tablets
Body weight ≤ 2.5 kg	31.25 mg	62.5 mg	0.5
2.5 kg < body weight ≤ 5.0 kg	62.5 mg	62.5 mg	1
5.0 kg < body weight ≤ 7.5 kg	93.75 mg	62.5 mg	1.5
7.5 kg < body weight ≤ 10.0 kg	125 mg	250 mg	0.5
10.0 kg < body weight ≤ 20.0 kg	250 mg	250 mg	1
20.0 kg < body weight ≤ 30.0 kg	375 mg	250 mg	1.5
30.0 kg < body weight ≤ 40.0 kg	500 mg	500 mg	1
40.0 kg < body weight ≤ 60.0 kg	750 mg	500 mg	1.5
60.0 < body weight ≤ 80.0 kg	1000 mg	500 mg	2
80.0 kg < body weight ≤ 100.0	1250 mg	500 mg	2.5

4. Record # of tablets/dose: 1.5 tablets/dose 250 Tablet size

5. Multiply # of tablets/dose by 2 to obtain the # of tablets needed per day: 3 tablets/day

6. Number of tablets **to be dispensed on Day 0** = 30 days (28 days + 2 days) of treatment plus dispensing of additional tablets for re-dosing (to dispense intact 7 tablet blister packs). 90 tablets to dispense

Automate critical calculations to reduce human error.

Dose Calculation

Note: There are warnings on the page...see below.

Dosing Information

Warning: Fields 'day0 packs expected dispensed, day0 quantity dispensed' should match.

Dose Calculation for IVP and CP

+/– Click ± to expand calculations

Expected Dosing Information

Treatment Assigned: Treatment B

Dispensing Information

Visit Date	Daily Tablets		Total Pills to Dispense		Dispensed Packs	
	Size	Quantity	Pills Needed	Pill Packs	Quantity	Date
Day 0	250 mg	1.5	69	10	11	01-Mar-2018
Day 14			33	5		Today

Tablets Returned Information

Maximum Expected Pills Returned Quantity	Total Returned	Date Returned
21		Today

Better yet, show them just want they need to know.
This reduces treatment errors.

Dose Calculation

Note: There are warnings on the page...see below.

Dosing Information

Warning: Fields 'day0 packs expected dispensed, day0 quantity dispensed' should match.

Dose Calculation for IVP and CP

+/– Click ± to expand calculations

Expected Dosing Information

Treatment Assigned: Treatment B

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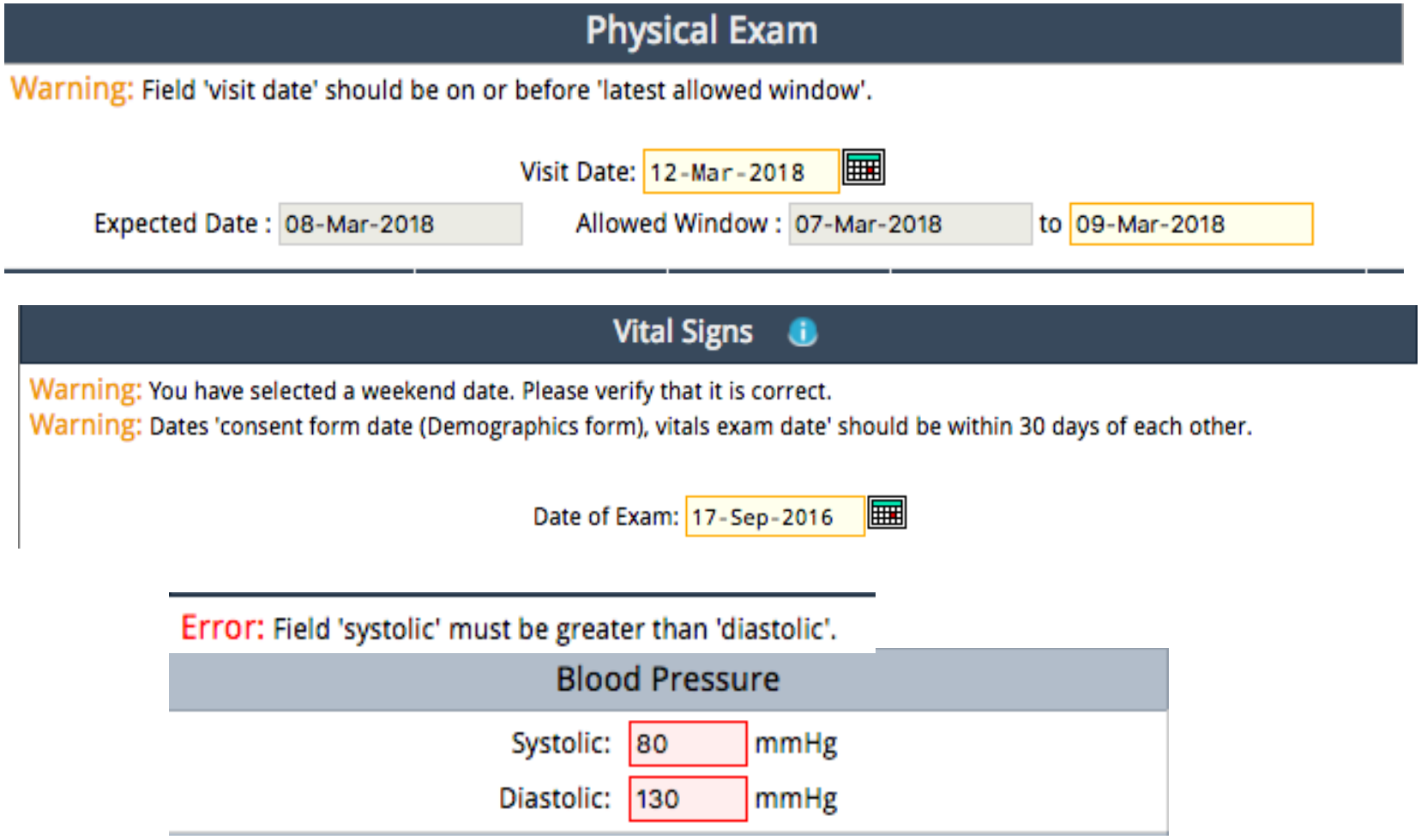
Visit Date	Daily Tablets		Total Pills to Dispense		Dispensed Packs	
	Size	Quantity	Pills Needed	Pill Packs	Quantity	Date
Day 0	250 mg	1.5	69	10	11	01-Mar-2018
Day 14			33	5		Today

Tablets Returned Information

Maximum Expected Pills Returned Quantity	Total Returned	Date Returned
21		Today

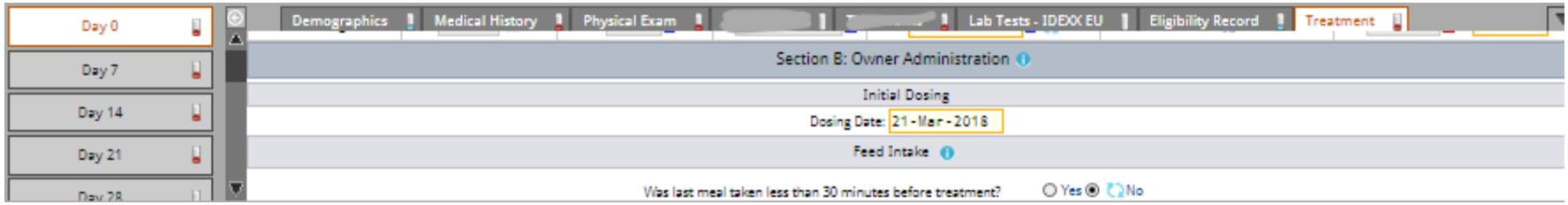
But what happens if they lose their pills?

Make sure there's a way to handle the unexpected.

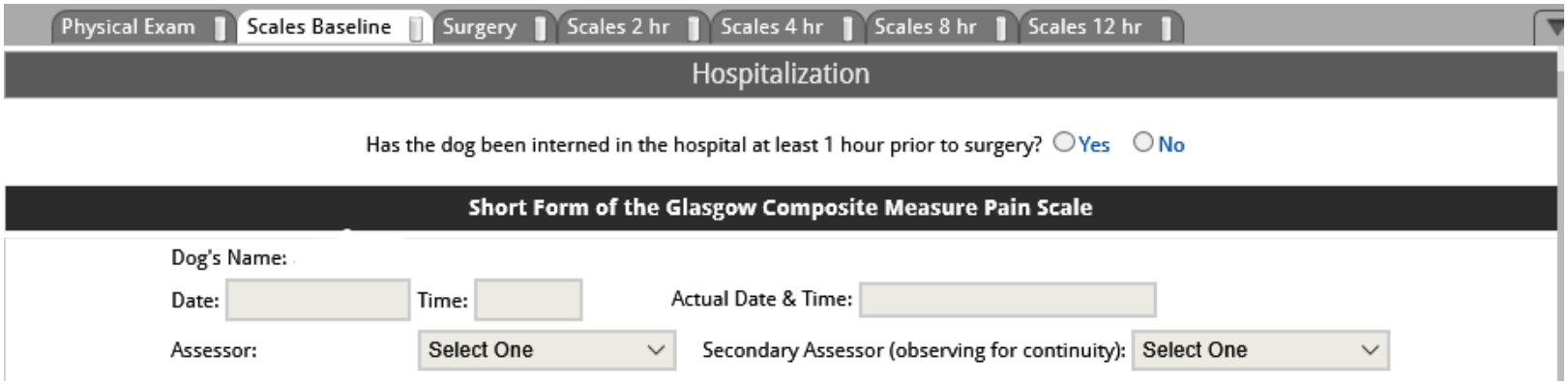


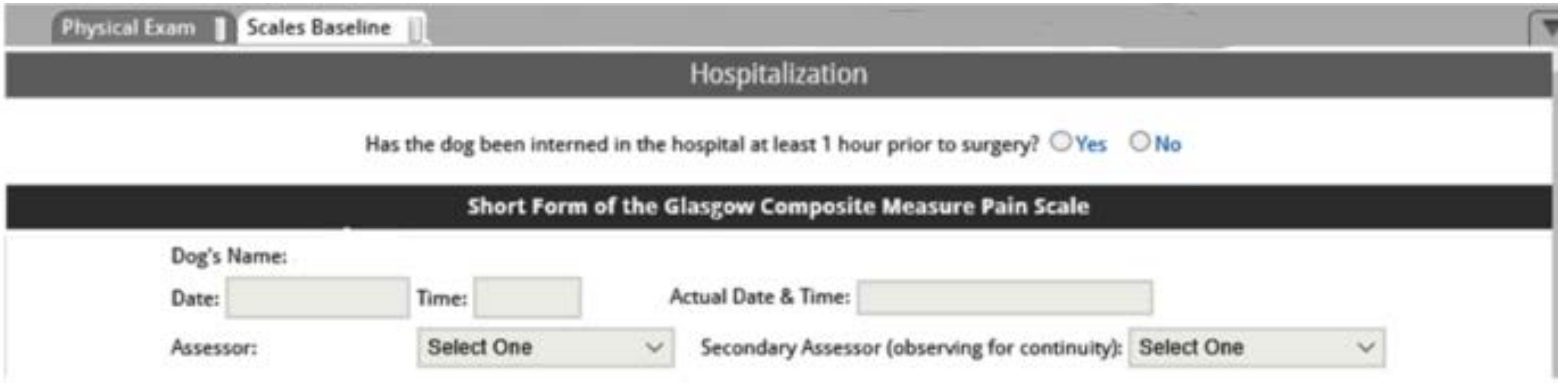
Edit checks provide the opportunity to "clean" the data as you go. Thinking through these can make the difference between evaluable/non-evaluable cases.

All in one group versus on different visit dates.



When transcribing, e.g., owner questionnaires, group them together to reduce navigating.





Make repeated measure scales available one at a time to reduce bias.

Medical History

Area	Not Done	Normal	Abnormal
Allergic/Immunologic	allergic_immuno_result="not done"	allergic_immuno_result="normal"	allergic_immuno_result="abnormal"
Cardiovascular	cardiovascular_result="not done"	cardiovascular_result="normal"	cardiovascular_result="abnormal"
Dermatological	dermatological_result="not done"	dermatological_result="normal"	dermatological_result="abnormal"
Endocrine	endocrine_result="not done"	endocrine_result="normal"	endocrine_result="abnormal"
Gastrointestinal	gastrointestinal_result="not done"	gastrointestinal_result="normal"	gastrointestinal_result="abnormal"
Genitourinary	genitourinary_result="not done"	genitourinary_result="normal"	genitourinary_result="abnormal"
Hematological	hematological_result="not done"	hematological_result="normal"	hematological_result="abnormal"
Musculoskeletal	musculoskeletal_result="not done"	musculoskeletal_result="normal"	musculoskeletal_result="abnormal"

Medical History

System Observed	Result		
	Normal	Abnormal*	Not Examined
1. Allergic/Immunologic	system_result(1)="Normal"	system_result(1)="Abnormal"	system_result(1)="Not Done"
2. Cardiovascular	system_result(2)="Normal"	system_result(2)="Abnormal"	system_result(2)="Not Done"
3. Dermatological	system_result(3)="Normal"	system_result(3)="Abnormal"	system_result(3)="Not Done"
4. Endocrine	system_result(4)="Normal"	system_result(4)="Abnormal"	system_result(4)="Not Done"
5. Gastrointestinal	system_result(5)="Normal"	system_result(5)="Abnormal"	system_result(5)="Not Done"
6. Genitourinary	system_result(6)="Normal"	system_result(6)="Abnormal"	system_result(6)="Not Done"
7. Hematological	system_result(7)="Normal"	system_result(7)="Abnormal"	system_result(7)="Not Done"
8. Musculoskeletal	system_result(8)="Normal"	system_result(8)="Abnormal"	system_result(8)="Not Done"

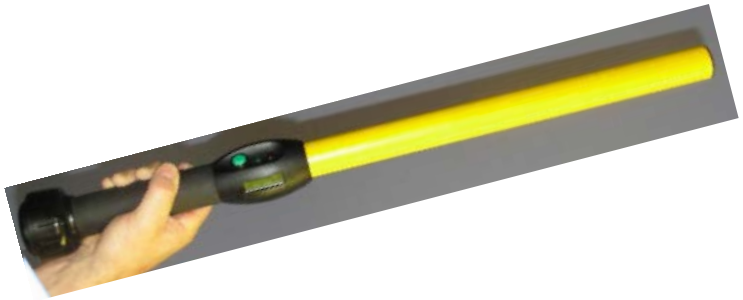
Consider how data can be easily analyzed on the back end, with minimal post-processing

Integrated Invoicing

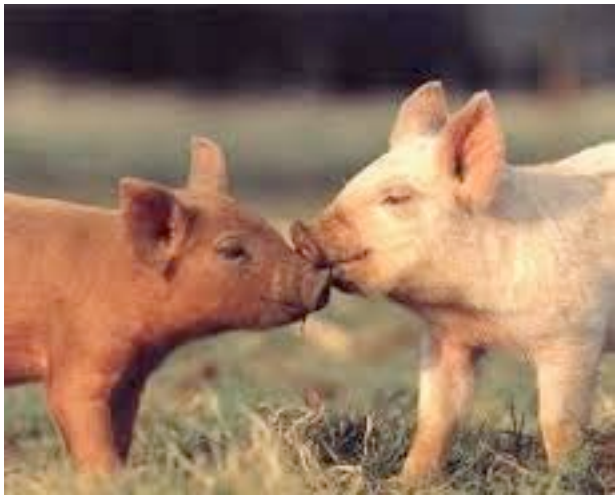
Lab integration

Inventory Management

Study Operations



Barcode and RFID Readers and other medical devices



Operational considerations drive the flow of data collection and hence, EDC setup

Asynchronous (e.g., Phase II / III / IV, After-Market Trials and Registries)	Synchronous (e.g., POC/Phase I Studies)
Data entered for individual subject on each form	Data entered concurrently for multiple subjects on a single form
Randomization as subject is enrolled	Randomization for groups of subjects
Typically, single user editing form	Often, multiple users editing form
Tend to be more customized studies	Can often be templated (“Pre-Built”)
Observations and dosing are for a single subject.	Observations & dosing can be for a group of subjects

Consider the workflow for data collection

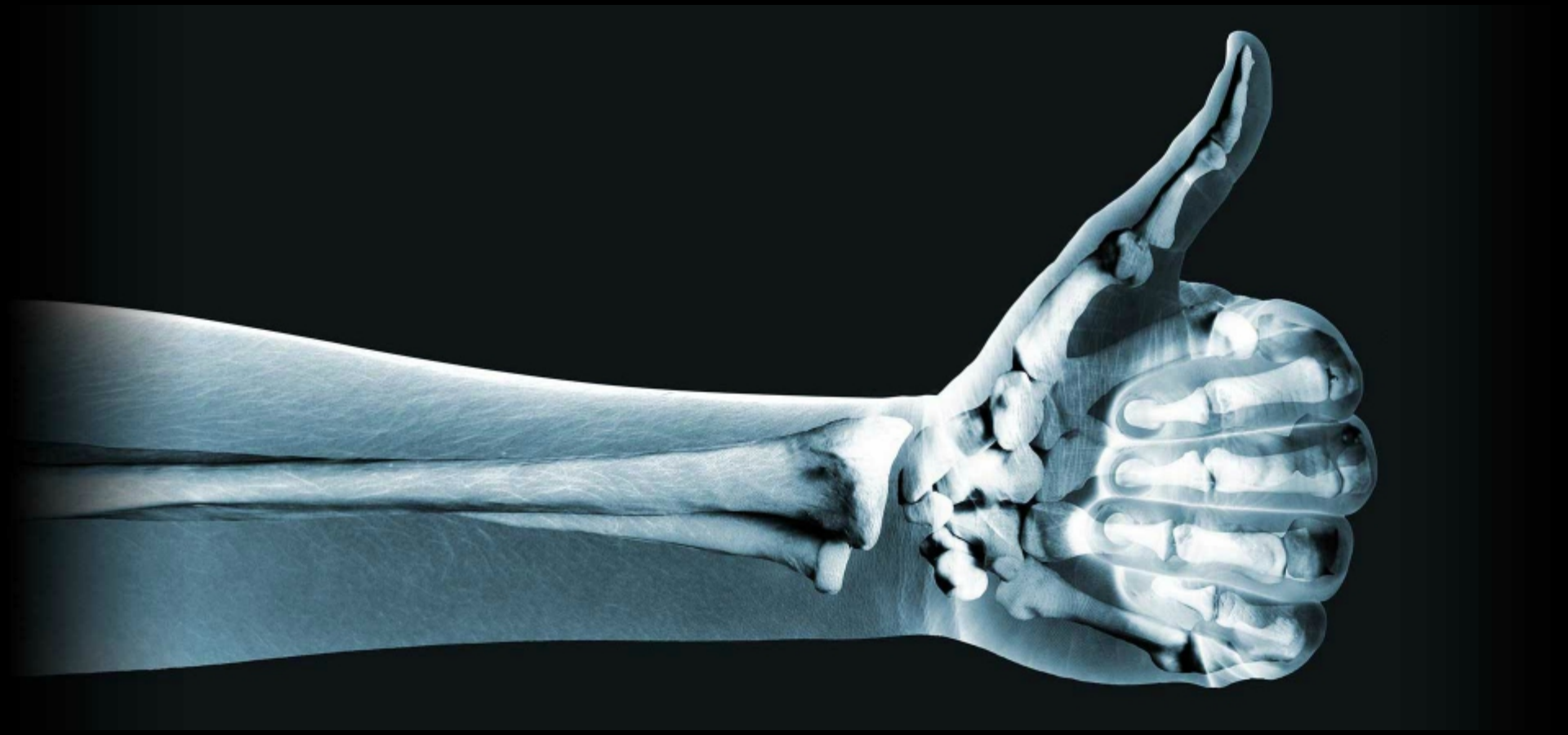
Consider the environment and use of integrated technology to facilitate safety & rapid data collection.

Integrated labs make results available faster at point-of-decision.

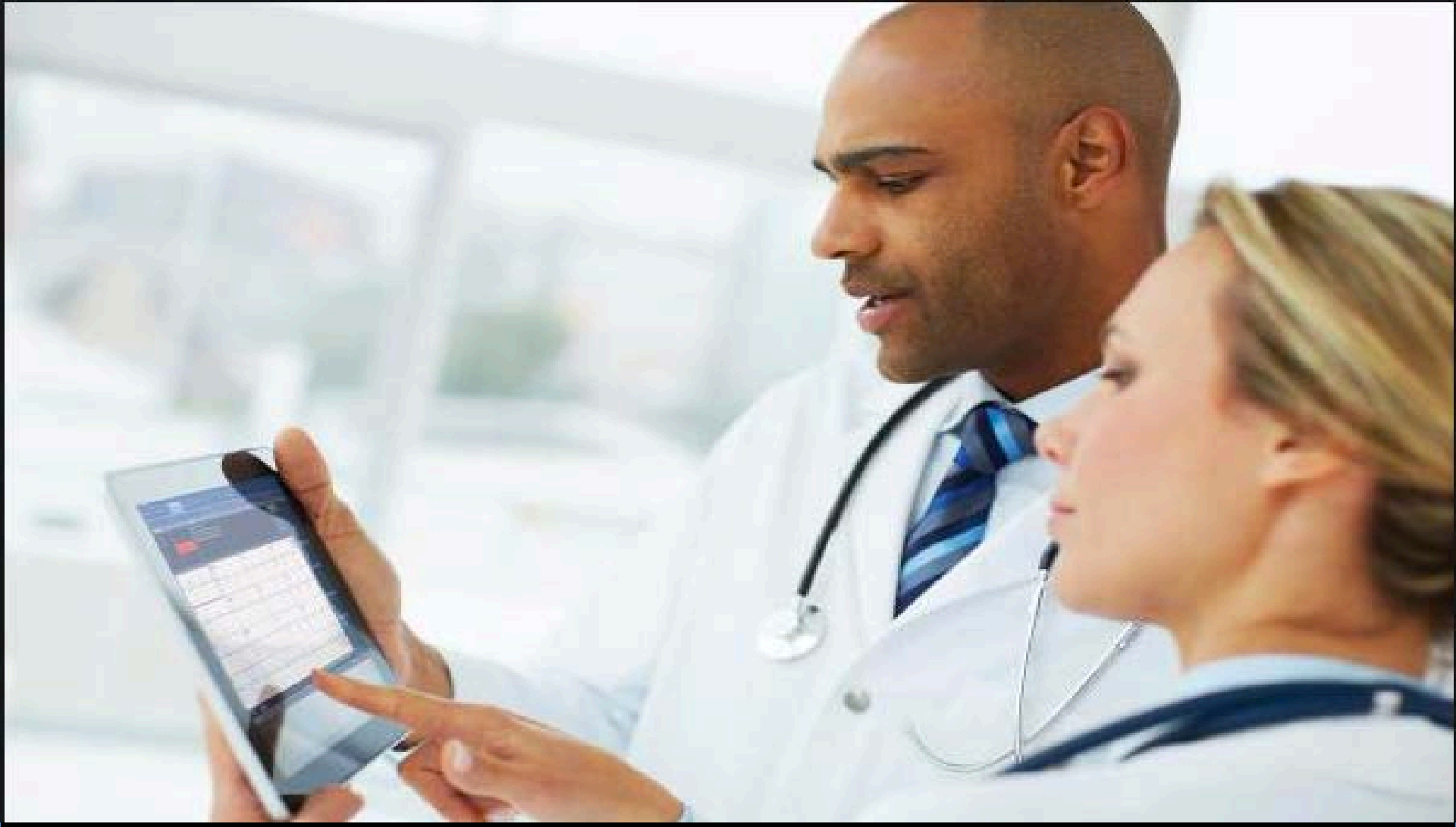
Barcode readers can improve quality and patient safety.

Integrated invoicing improves accurate and timely payments to sites while freeing up monitor’s time to monitor data.

Multi-site inventory management can be automated, as can automatic reordering.



Use smart medical devices and integration to increase quality of data.

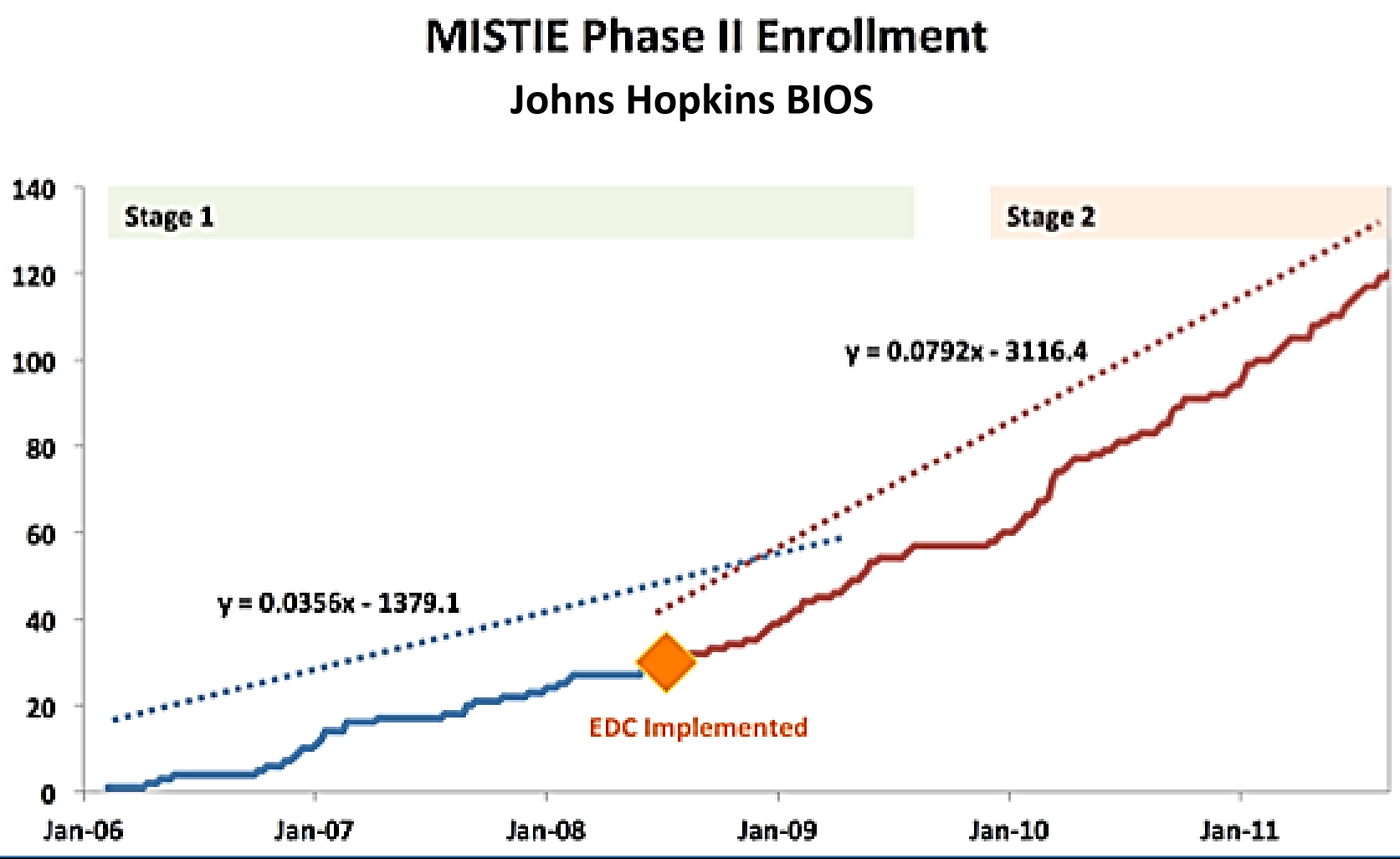


Reduce data errors by using the EDC as e-Source.

All Field Entries

Date	Section	Field	Entry
23-Mar-2018 08:31:33 CDT	Exam	body_weight_kg	20.13
23-Mar-2018 08:33:17 CDT	Instance	gen_appearance_result	normal
23-Mar-2018 08:33:17 CDT	Exam	heart_rate	78
23-Mar-2018 08:34:32 CDT	Instance	integument_result	normal
23-Mar-2018 08:33:50 CDT	Instance	optic_result	normal
23-Mar-2018 08:33:34 CDT	Instance	oral_exam_result	normal
23-Mar-2018 08:34:32 CDT	Instance	otic_result	normal
23-Mar-2018 08:31:51 CDT	Exam	respiratory_rate	65
23-Mar-2018 08:34:46 CDT	Instance	respiratory_result	normal
23-Mar-2018 08:32:14 CDT	Exam	temperature_entered	101.2
23-Mar-2018 08:31:33 CDT	Exam	visit_date	23-Mar-2018

Contemporaneous is redefined by the EDC…
When a real-time audit trail is created as upon data entry.



EDC implementation significantly impacts study enrollment and provides access to care quickly.

Using the nuts and bolts of the software solution strategically can reduce risk and improve quality and efficiency in clinical research.