Best Practices for Structuring Clinical Data in Medical Device Studies

LIVE

Webinar December 7th 2022 | 15 CET / 9 am ET

Presenters

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Co-Founder

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Product Manager

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Housekeeping

Questions

Recording

Polls

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Learn how to overcome common pitfalls and optimize your clinical data collection efforts.

Jon I. Bergsteinsson
Co-Founder

Rasmus Blendal
Product Manager

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What Is SMART-TRIAL?

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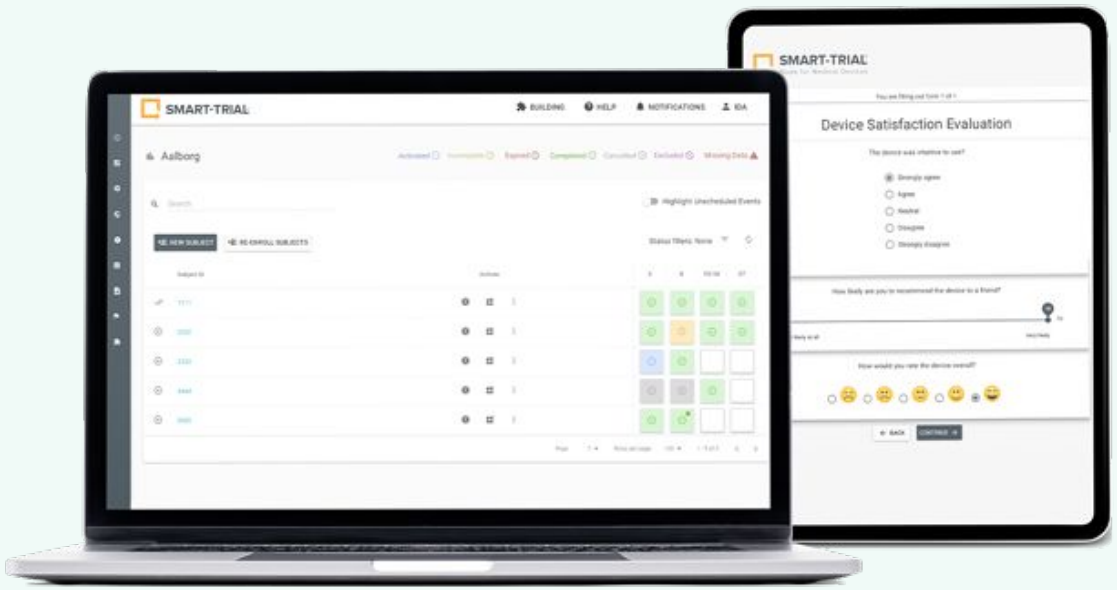

est. 2013

The First and Only Electronic Data Capture (EDC) system designed for MedTech

- Supported 400+ MedTech studies
- 100+ MedTech companies across 16 countries with sites all over the world
- Medical Device classes I, II(a&b), III and IVDs
- Clinical activities from pre- and post-market
- Customer audits from USA and EU authorities
- Customers completed clinical data submissions in N-America, EMEA, Oceania, and Asia

POLL #1

On your screen now

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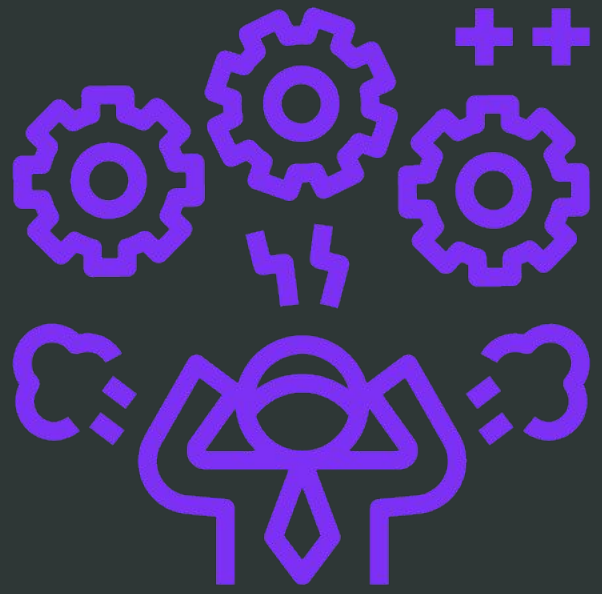
Why This Topic?



We've talked to too many frustrated clinicians.

We've seen too many datasets and reports end up needing additional work.

Increasing study cost, data quality and crucial time.

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Clinical Study Data Collection

Correct Data

VS

Clinical Workflow

What Happens When...

we only think about
collecting the correct data?

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Common Pitfalls

- New challenges for data entry staff at the site
- Increase the risk of erroneous and missing data
- Adds complexity to data analysis and reporting

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What Happens When...

we think solely about the clinical workflow?

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Common Pitfalls

- Data structure becomes partitioned
- Increases time from export to reporting
- Introduces QA challenges for monitors and reviewers

What Is Data Structure?

original Table

ID	Name	Age	Batch	Major
001	Andy	20	2023	CS
002	Ben	18	2025	Mathematics
003	Lee	22	2022	CS
004	Eva	21	2022	Architecture

Sharding

Partition 1

ID	Name	Age	Batch	Major
001	Andy	20	2023	CS
002	Ben	18	2025	Mathematics

Partition 2

ID	Name	Age	Batch	Major
003	Lee	22	2022	CS
004	Eva	21	2022	Architecture

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From Protocol to Results

Study Protocol

Complex study protocols introduce additional intervention and measurements that increase complexity of clinical workflow.

Data Entry

Complex clinical workflows, reduce the likelihood of people entering correct data at the “correct time”, resulting in frustration, missing data and lack of oversight.

Data Analysis

More time spent on data cleaning, restructuring and understanding the data structure, than the data itself. Increases cost and time to reporting.

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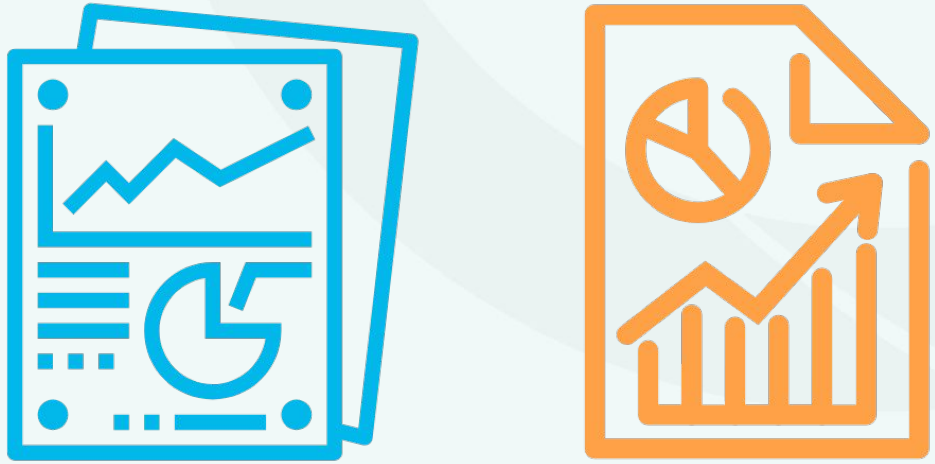
Start With the End in Mind

Define your reporting requirements before designing your data entry forms



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Common Pitfalls

During EDC setup and eCRF/ePRO designs

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POLL #2

On your screen now

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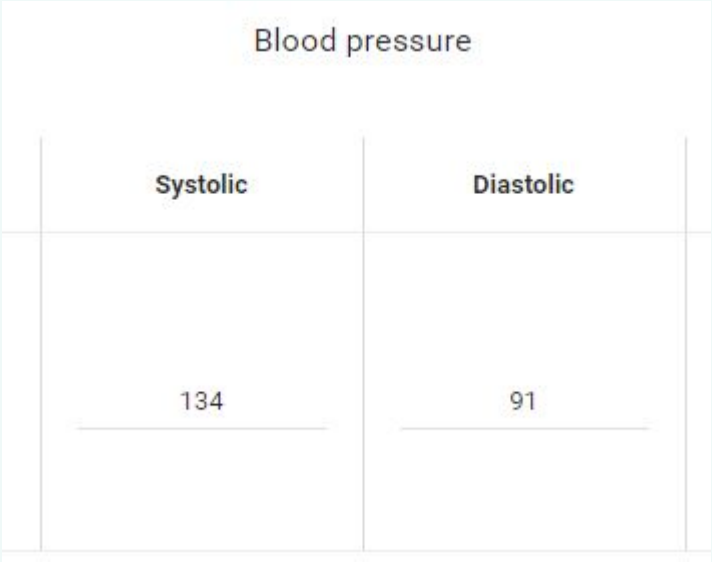
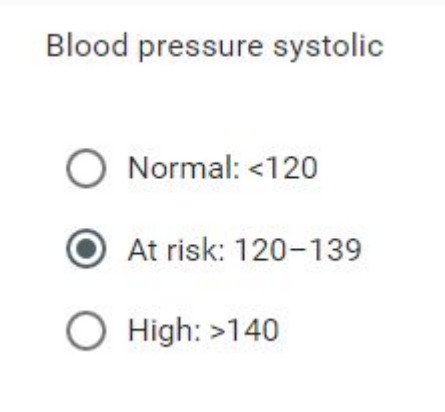
Problem #1 - Repeated Variables

When the same value/outcome is collected in multiple ways and places





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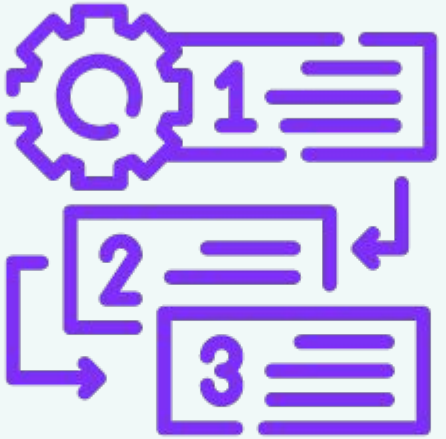
Solution #1 - Repeated Variables

Plan the eCRF setup **before** you start

Standardize how variables are collected



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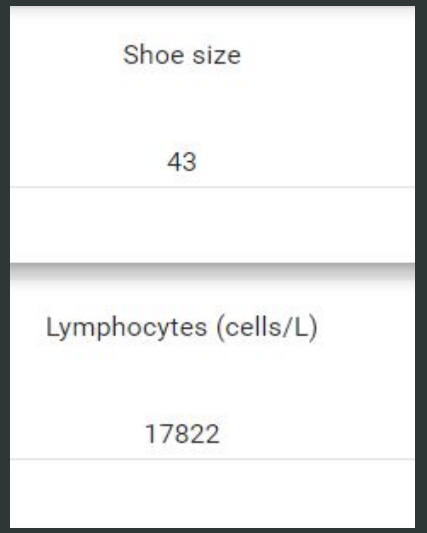
Problem #2 - One Visit, One Form

Excessively long forms

Requires additional work to analyze



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Solution #2 - One Visit, One Form

Think in domains and results

One Form, One Domain

Don’t forget: Clinical Workflow

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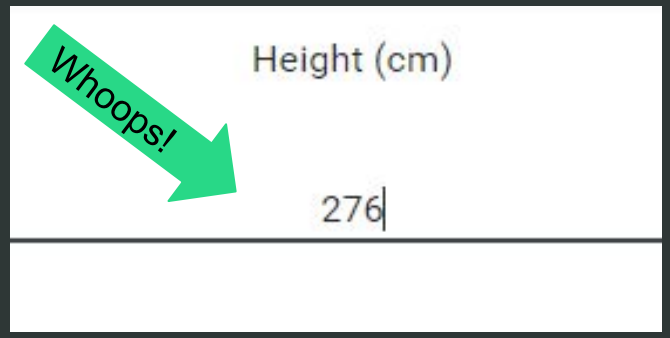
Problem #3 - Validation Rules

Not using them.



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Solution #3 - Validation Rules

Use an eCRF setup template.

No.	Question Text	Type	Export Label (optional)	Answer possibilities (optional)	Showrule (optional)	Help text (optional)	Mandatory?	Decimal? (only for no.)	Validation Rules (optional)
1	Date of Visit	Date	dateOfVisit			Please specify the date of the visit	Yes		<= date of fill out
2	Is the subject healthy?	Yes/No	subjectHealthy	0=No, 1=Yes		According to protocol description	Yes		
3	What's wrong?	Free text			if Q2 = 1		Yes		
4	Subject's height (m)	Number	height			meters	Yes	Yes	<1,0 (block answer) <1,0 (alert: People below 1 meter are not eligible in this study) >2,5 (block answer)

Problem #4 - Validation Rules in the Wild

Studies happen in the real world.

With real people.

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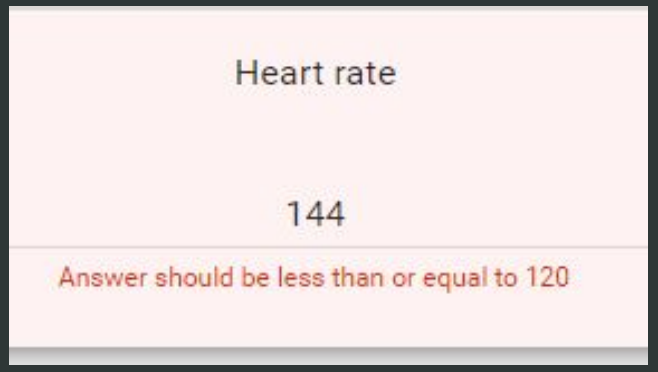
Solution #4 - Validation Rules in the Wild

Remember outliers.

Allow for flexibility.



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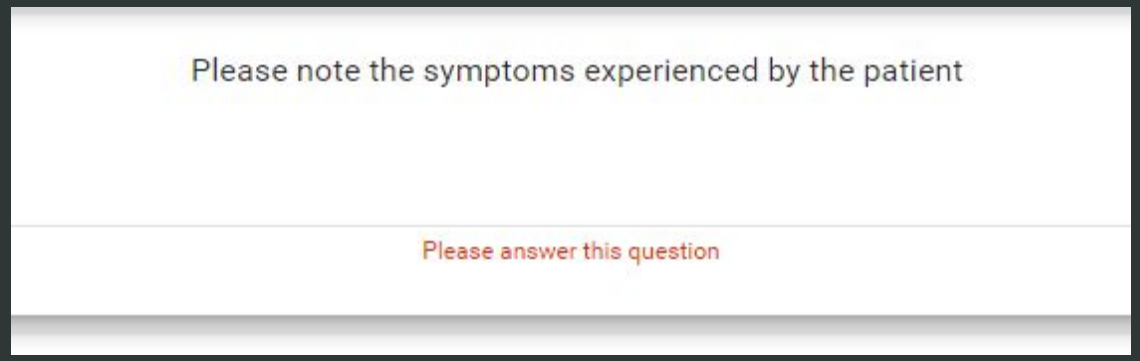
Problem #5 - Using Free Text

Fast to set up!

Expensive to analyze.



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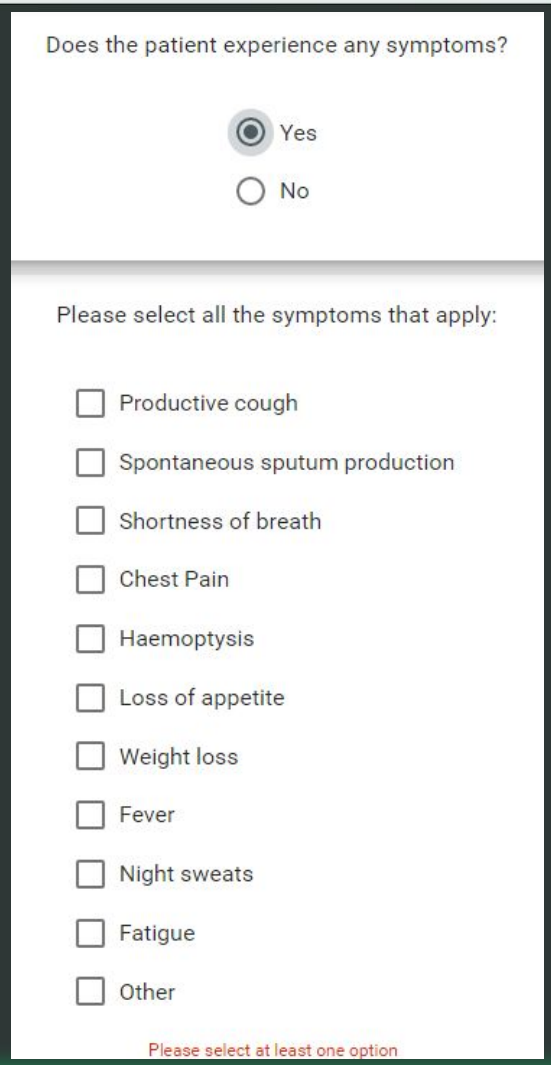
Solution #5 - Using Free Text

Create options!



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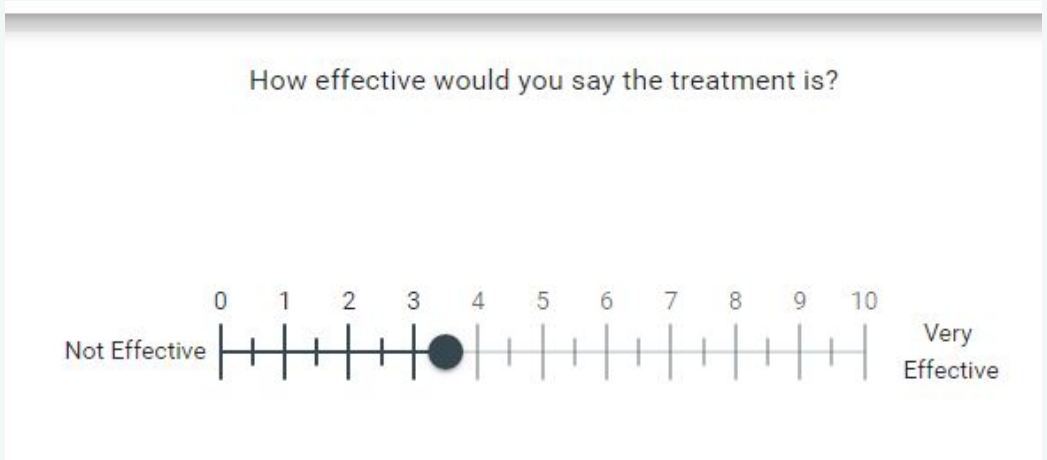
Problem #6 - Using Patient Reported Outcomes

Setup as ePRO
Fill out as CRF



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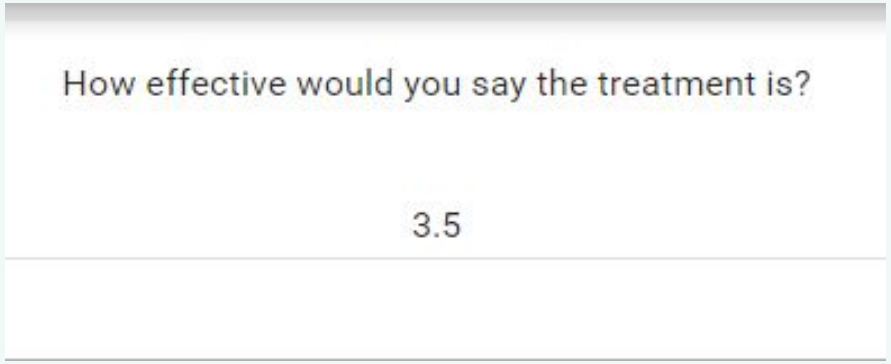
Solution #6 - Using Patient Reported Outcomes

Optimize for transcribing



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Problem #7 - Patient Reported Outcomes

NOT using ePRO

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Solution #7 - Patient Reported Outcomes

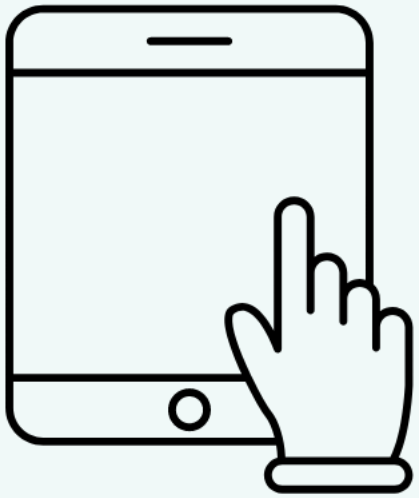
Try it!

Consider

Study population

Where to fill it out?

Language



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Common Pitfalls

With data export and preparations for data analysis

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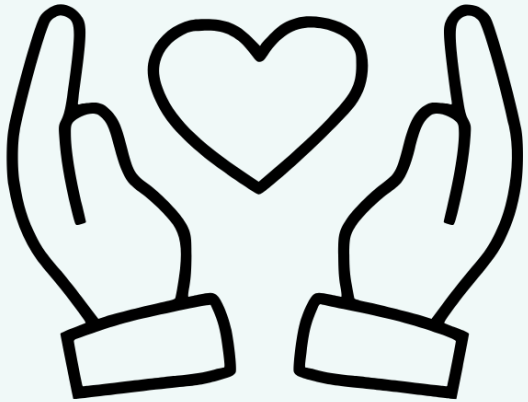
Mishandling Raw Data

Raw data files, such as .CSV should be treated with care



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Do Not

Double Click

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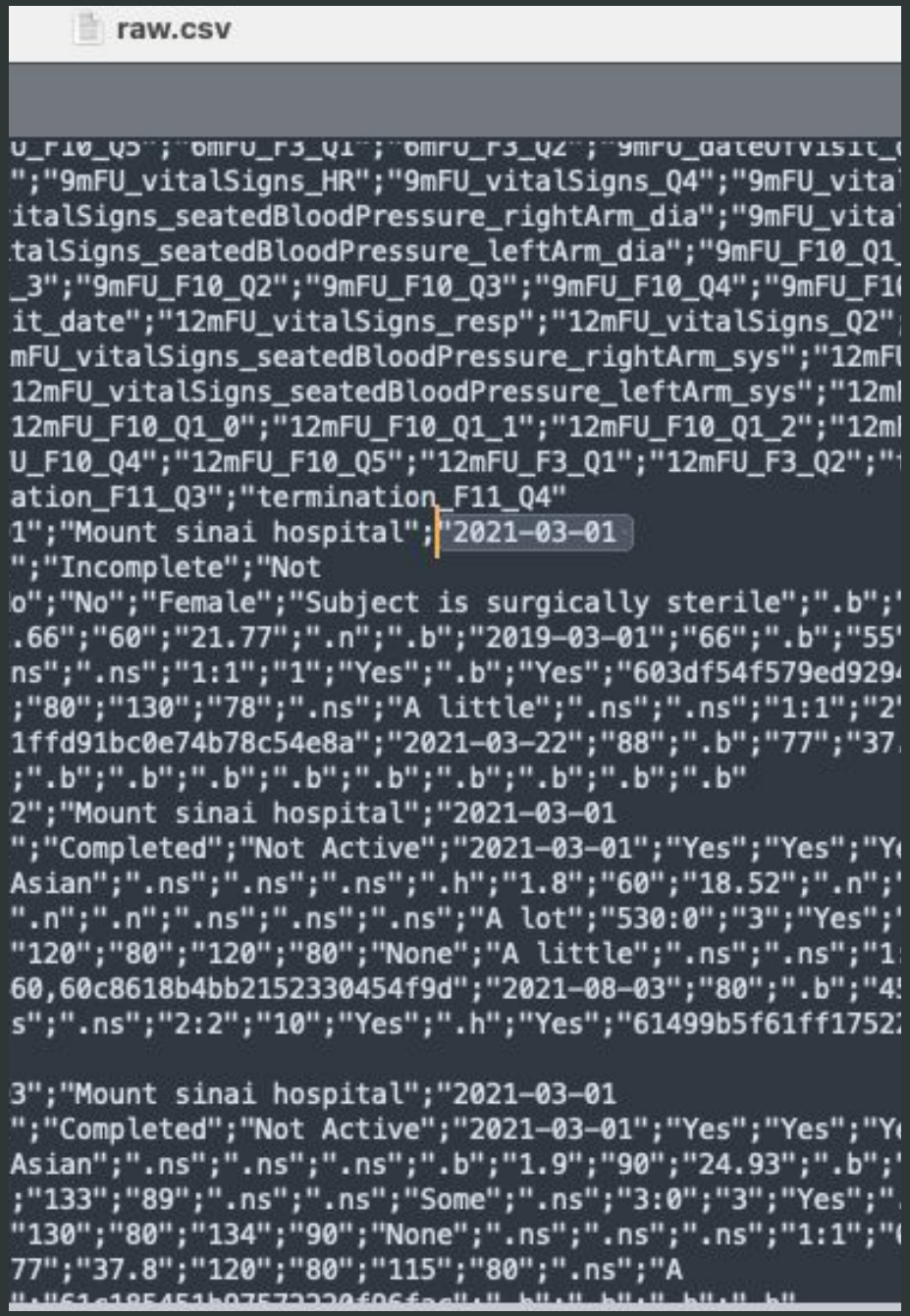
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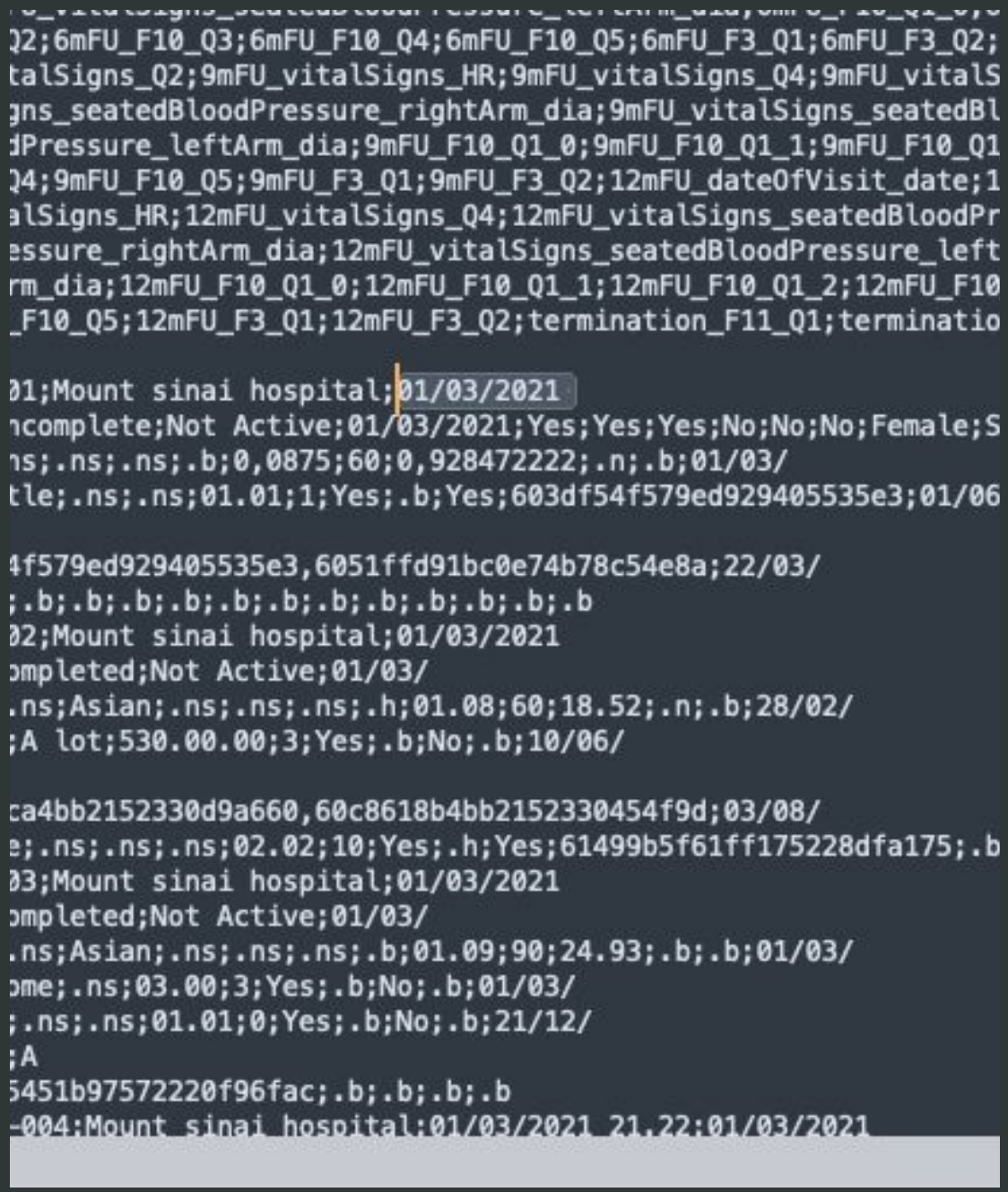
VS.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gns_seatedBloodPressure_rightArm_dia;9mFU_vitalSigns_seatedBl
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;A
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-004;Mount sinai hospital;01/03/2021 21.22;01/03/2021

Software such as MS Excel and Numbers can change your data

- Date and time can be reformatted
- Numbers changed, because of decimals and periods
- Splitting text into separate rows

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Standardize the Data Export

Different configs result in different data.

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Remember to..

- Include only one header at a time
- Be consistent with date/time formats
- Include the same attributes/identifiers
- Define work instructions

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Export Labels

The important first

There can be a lot of variables in a study.
Start with labeling the primary outcomes, and build from there.

The statistician

Involve the statistician in the label creation. This ensures the labels can be imported/used in their statistical software.

The company

Same outcomes/variables are often collected across studies/departments.
Create a company wide structure for labels!

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Time for

Q&A

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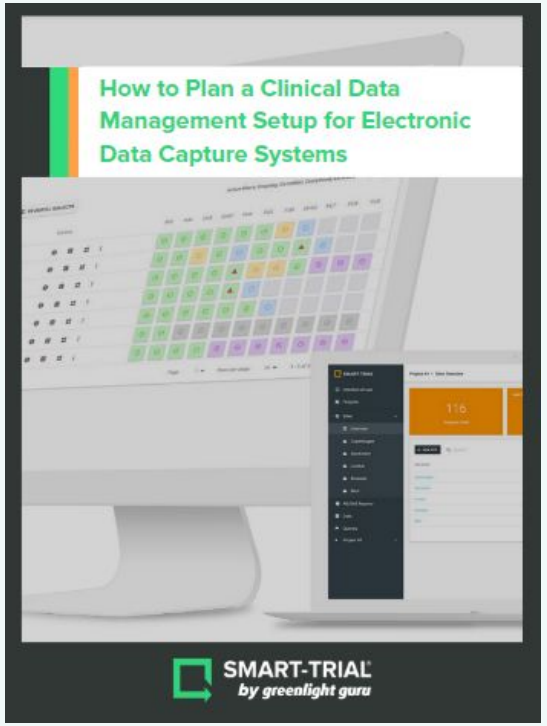

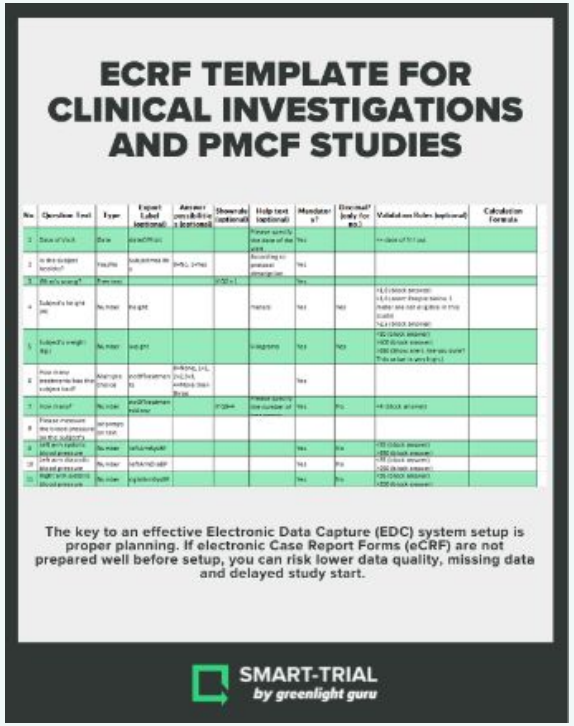

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