How to Design the Optimal eCRF for MedTech Clinical Investigations

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LIVE

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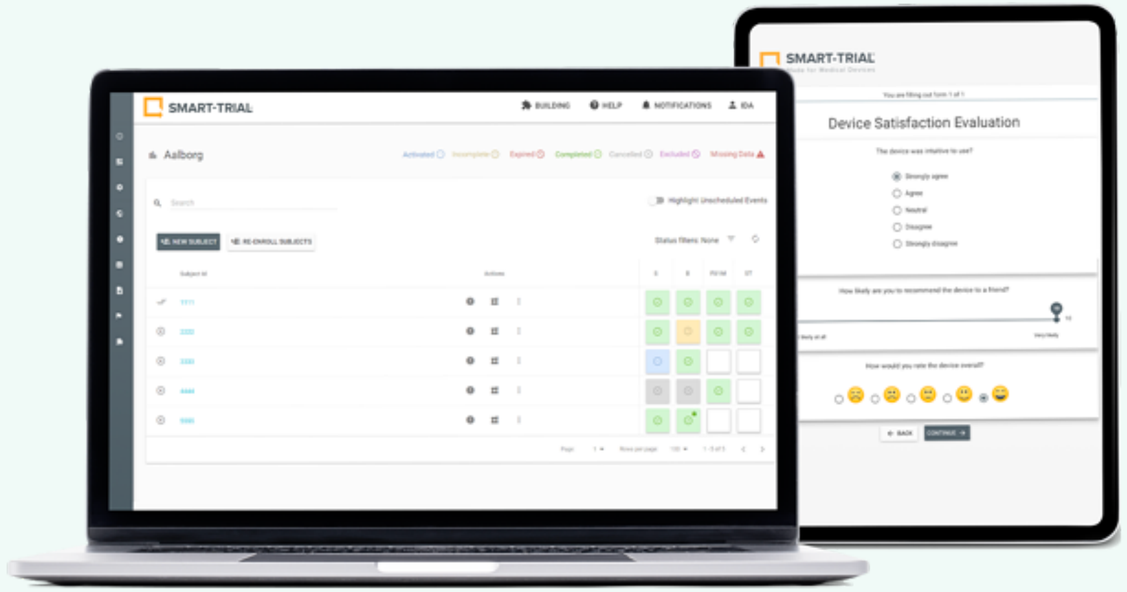

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The Bridge Between MedTech and Clinical Data

The leading cloud-based platform to manage and collect clinical data throughout the lifecycle

Today's Presenter

Pall Johannesson
Managing Director
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WHY THIS TOPIC?

Because small mistakes can make or break the quality of your clinical data

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DESIGNING YOUR DATA COLLECTION IS LIKE PRODUCING A MOVIE

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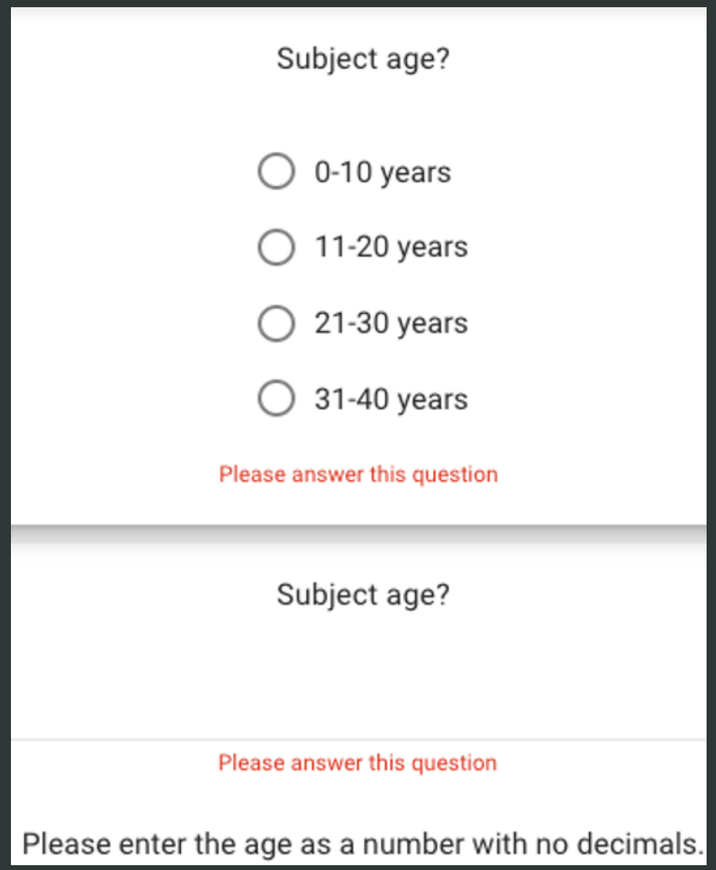
START AT THE END - DEFINE YOUR DATA REPORTING NEEDS

What story are you trying to tell from your data/study?

Does the background match the scene?

Did you consider the format of your variables?



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KNOW YOUR ACTORS, SET, AND PLANS

Who is involved in the clinical and study workflow when it comes to data collection?

Does workflow differ between sites?

In which sequence will we collect the data from our stakeholders?

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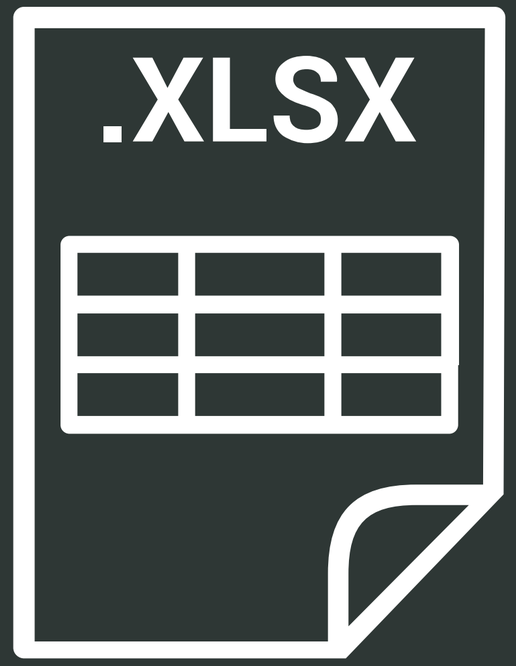
KNOW YOUR AUDIENCE AND STAGE

What does my export look like? Can I test this without actual data?

When can I touch the export file? Or can I...?

Don’t rush into amendments!



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PRACTICING MATTERS!

When you practice with your stakeholders the end result will improve.

Make changes as feedback is gathered from testing!

”Finalize the script”

Prepare by defining EDC-specific requirement specifications and test plans.

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THINK "DIGITAL FIRST"

Digital questionnaires, not paper.

What integrations are needed?

Don't plan analog and transfer later.

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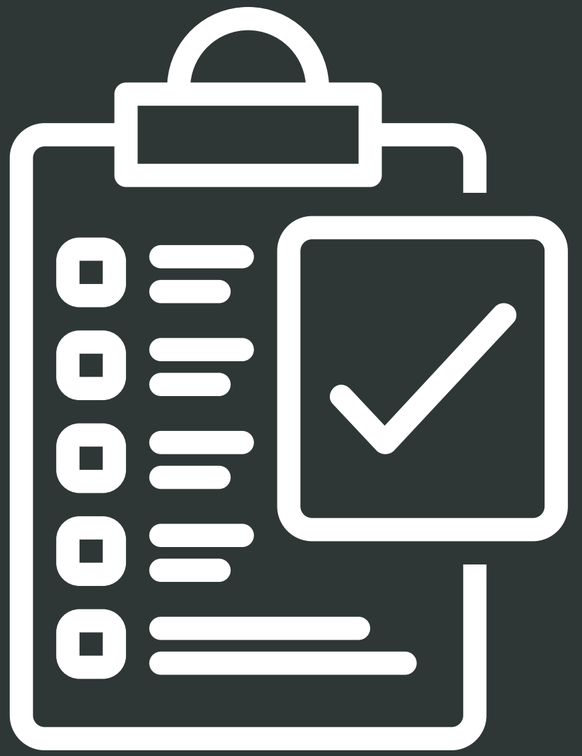
COMPLIANCE

Compliance is just the annoying thing that gets in our way.....?

No! Quality and Compliance = Better Results

Validation of setup is crucial for ISO 14155 (GCP) compliance.



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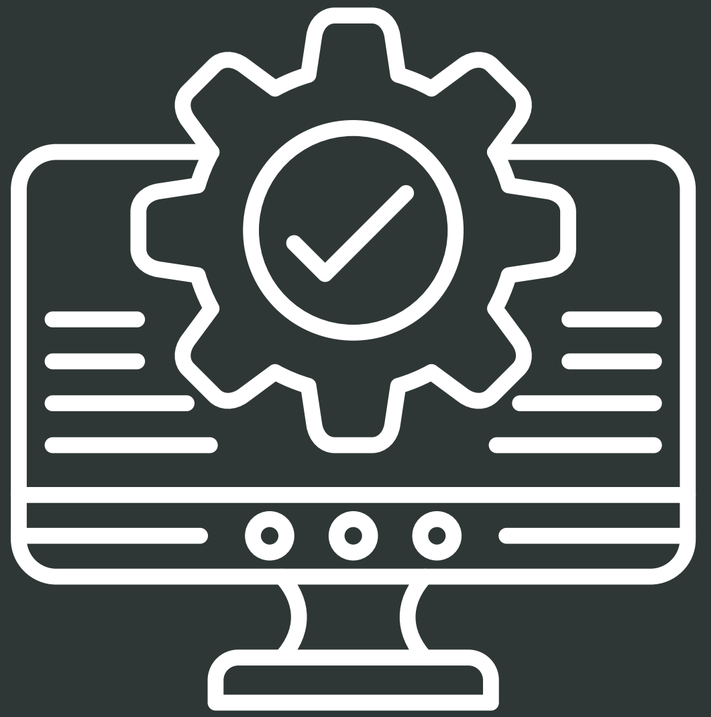
ISO 14155:2020 COMPLIANCE

Good Clinical Practice (GCP) is a set of ethical and scientific quality standards, recognized internationally.

Section 7.8.3, covers electronic clinical data systems

12 written procedures to be followed and implemented when using any electronic system for clinical data collection!



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5

"ADVENTUROUS HORROR STORIES"

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1 THE DATA KING

Collecting way too much data can be exciting, but can become a catastrophic failure...

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2 JAMES AND THE GIANT STACK OF DATA

Collecting paper-based data uses the most valuable resource you have...
TIME

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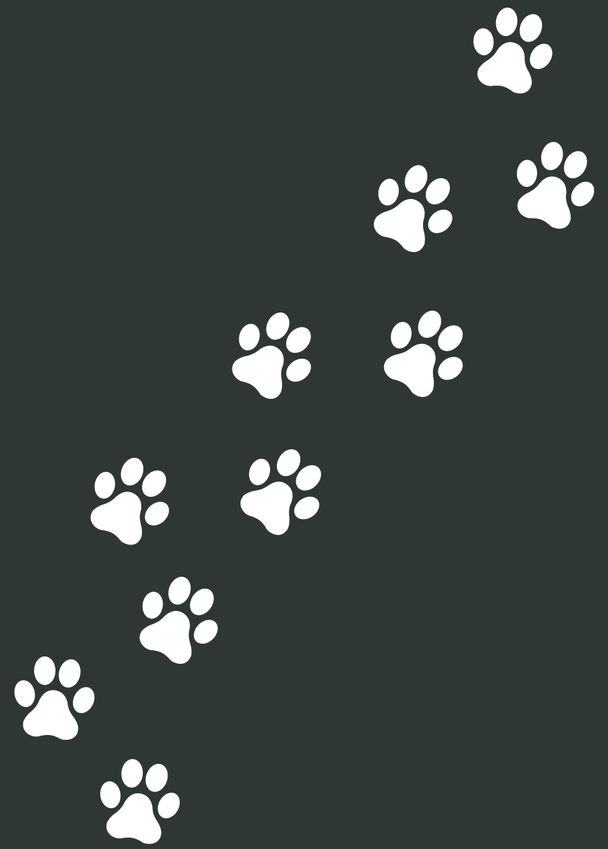
3 101 AMENDMENTS

Study amendments can fix things (and break things equally).

When you plan your amendments, think about the consequences and if this provides you with an opportunity to change more things!



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4 RAYA AND THE LAST TEST RUN

When you do a proper test with your stakeholders you will have a better working environment around your study.

This results in higher quality data.

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5 CLINICIANS THROUGH THE LOOKING GLASS

Avoid putting extra strain on clinicians at the wrong timepoints.

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01 - LACK OF PLANNING

Results in poor data formatting and study structure in your EDC system

02 - LACK OF STRUCTURE

Results in confusing data entry, variance in data and gaps

03 - MISLEADING DATA

Misleading data results in poor quality of evidence and decision making

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Time for

Q&A

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