How to Validate an Electronic Data Capture Setup for a Medical Device Clinical Investigation

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LIVE

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Questions

Recording

Answers

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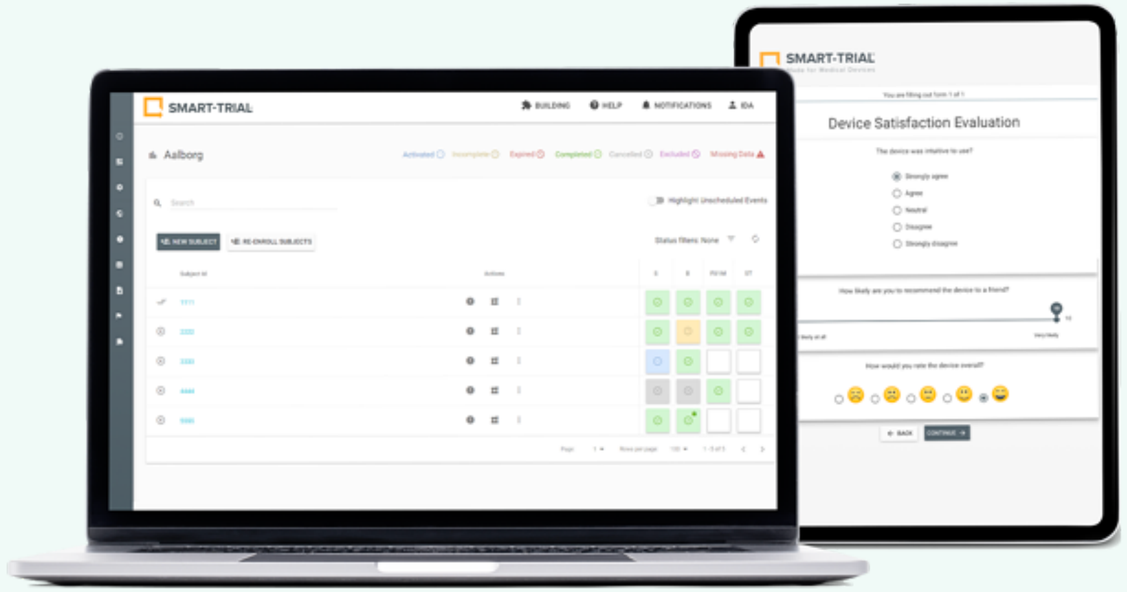

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Today's Presenters

Kimberley Lau
Solutions Engineer

Rasmus Blendal
Product Manager

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Why System Validation?

Requirements for system validation from medical device standards & regulations:

- GCP (section 5.5.3)
- FDA 21 Part 11. (section B 11.10, for closed systems)
- ISO14155 (section 7.8.3)
- (EMA CTR and guidance for combination)

Rasmus Blendal
Product Manager

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Why System Validation ? - Cont.

Enabling trust in the system & service provider, such that YOU do not have to validate each new version and the functionality hereof.

Snippet from ISO 14155:2020

When electronic clinical databases or electronic clinical data systems are used, written procedures shall be implemented to

a) describe system validation and functionality testing, data collection and handling, system maintenance, system security measures, change control, data backup, recovery, contingency planning, and decommissioning,

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System Validation vs. Study (setup) Validation

System validation is the foundation on which you can build a clinical study.

- Trust but verify the system and its functionality works as described

Study validation is ensuring the study adheres to your protocol.

- The right variables, edit checks etc. are collected.

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When Is A Validated System Needed?

Any clinical investigation!*

Also post-market activities!

*ISO14155:2020 sec. 7.8.3

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Relation to IQ, OQ, PQ

- IQ, OQ, PQ are terms from manufacturing.
- FDA guidance* states these are not related to software validation.
- Similarly, you do not find the terms in the GCP, the new guidance from EMA nor ISO 14155:2020.

IQ: Study validation (configuration validation)
OQ, PQ: System validation

*General Principles of Software Validation; Final Guidance for industry and FDA Staff

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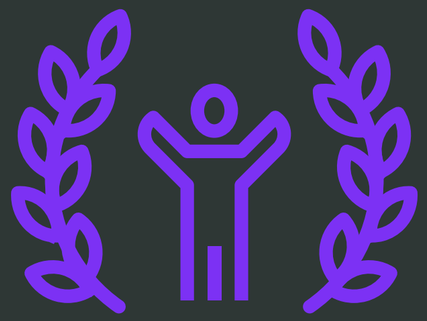
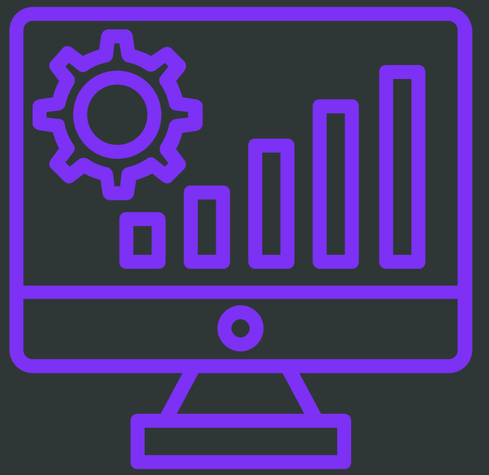
Who Is Responsible?

The Sponsor





The Sponsor is ultimately responsible for the system used.

How Is System Validation Done?

Verify and validate the requirements are consistently met

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System Validation - Actions

- Create user requirements for critical system actions
- Define test cases to perform
- Test the software consistently adheres to requirements
- Create documentation

System Validation - Outputs

- User requirements
- Test specification (What)
- Test plan (How)
- Test Report (Results)

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How Do We Help?

- We validate the system before making it available. For every version.
- Documentation available on our compliance depot for clients. Every software version.

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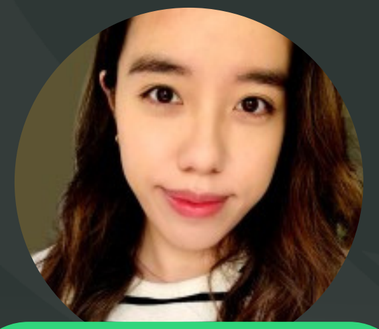
Why Study Setup Validation?

- Improve data quality
- Regulatory compliance
- Maintain trial integrity
- Streamlining data collection



Kimberley Lau
Solutions Engineer

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What Is Study Setup Validation?

EMA: Guideline on Computerized Systems and Electronic Data in Clinical Trials

Section 4.1 - ‘Validation of the trial specific configuration or customisation should ensure that the system is consistent with the requirements of the approved clinical trial protocol and that robust testing of functionality implementing such requirements is undertaken, for example, eligibility criteria questions in an eCRF..’

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Components of Study Setup Validation

Protocol Alignment

- Electronic Data Capture (EDC) systems capturing requirements as defined in the study protocol e.g. data collection forms, visit schedules etc.

Example: Measurement of primary endpoints

- ISO 14155:2020, also requires specified endpoints:
  (c) Primary and secondary endpoints with the rationale for their selection and measurement. Combined endpoints, if any, with the rationale for their choice and measurement. [...]

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Components of Study Setup Validation - Continued

Edit Checks and Validation Rules

- Ensuring that edit checks and validation rules are programmed correctly
- Consistency of data

Examples:

- Adverse Event Onset date vs. End date
- Ranges for numeric fields

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Components of Study Setup Validation - Continued

Source Data Verification (SDV)

- Site monitoring comparing source data with entered data in the eCRF to checking for discrepancies

- Ensure that it is enabled within the study setup to allow SDV activities

Example:

- Blood pressures have been transcribed correctly

Components of Study Setup Validation - Continued

Data Export

- Validation of data export processes is crucial to ensure seamless data exchange between the EDC system and other systems

Example:

- Consider how the study setup is favoring clinicians or statisticians

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User Acceptance Testing (UAT)

EMA: Guideline on Computerized Systems and Electronic data in Clinical Trials

A2.3 Trial specific configuration and customisation

‘Trial specific configuration and customisation should be quality controlled and tested as applicable before release for production. It is recommended to involve users in the testing activities…’’

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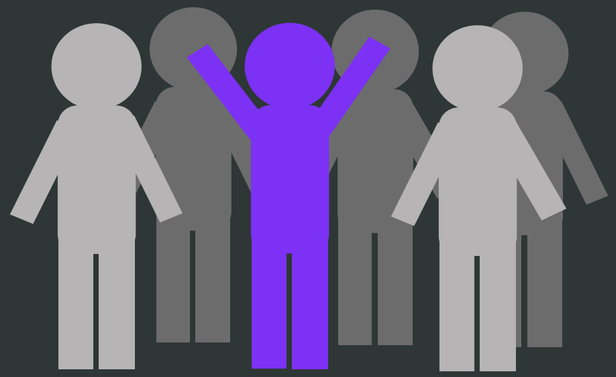
Subjects - Electronic Reported Outcomes

- Verify that the EDC system enables study participants to enter their data effectively into the system
- Simulating how study participants will interact with the EDC system during the trial
- Are the questions presented intuitively for the study participants to enter data?



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Site Personnel, Investigators

- Verify that the EDC system allows site users to efficiently and accurately enter clinical trial data.
- Is it intuitive for the site to answer? Are the order of the forms in a right order?

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How Do We Help?

- Free to use templates, e.g. eCRF template

https://help.smart-trial.com/document-templates

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SMART-TRIAL eCRF Form Template Version 3.0

Form Export Label: Demo

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)
5	Subject's weight (kg.)	Number	weight			kilograms	Yes	Yes	<30 (block answer) >500 (block answer) >250 (Show alert: Are you sure? This value is very high.)
	How many			0=None, 1=1,					

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Annotated Forms

F1-Medical History | F2-Adverse Event Form | F3-Overvalued Ideas Scale | F4-Protocol Deviation | F5-Demographics

No.	Question Text	Export Label	Type	Order of	Mandatory	Showrule	Help Text	Required for inclusion	Validation rules
1	Does the particip	Q1	YES_NO	0=Yes, 1	true	NONE	NONE	NA	NONE
2	Please select the	BodySystem	MULTIPLE	0=Respir	true	Show if Q n	NONE	NA	NONE
3	Respiratory	Respi	TABLE	NONE	false	Show if Q n	NONE	NA	NONE
3_R1_C1	Specify Abnorma	Respi_R1_Abnor	TEXT_SEN	NONE	true	NONE	NONE	NA	NONE
3_R1_C2	Start Date Row 1	Respi_R1_StartD	TEXT_SEN	NONE	true	NONE	NONE	NA	NONE
3_R1_C3	Stop Date Row 1	Respi_R1_StopDt	TEXT_SEN	NONE	true	NONE	NONE	NA	NONE
3_R1_C4	Abnormality Ong	Respi_R1_OngoY	YES_NO	0=Yes, 1	true	NONE	NONE	NA	NONE
3_R2_C1	Specify Abnorma	Respi_R2_Abnor	TEXT_SEN	NONE	true	NONE	NONE	NA	NONE
3_R2_C2	Start Date Row 2	Respi_R2_StartD	TEXT_SEN	NONE	true	NONE	NONE	NA	NONE

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Validation Report Template

3. Validation Test execution and results

3.1. General study setup

This covers test results from the study overall set up, such as correct subject attributes, number of data events, Form validation etc.

Have the correct modules been enables in the study, e.g. the Adverse Event Module, the Medication Module, eConsent, Randomization, etc.? YES/NO
Are correct demographic attributes required when enrolling a subject profile, as specified in the study protocol, such as subject ID, gender, date of birth, etc.? YES/NO
Have correct sites been created and assigned to the right process(es)? YES/NO
Clarification of failed validation, if any: Describe what is not being fulfilled for the process OR N/A

3.2. Summary of Form test results

Attached to this report, is an eCRF template for each Form, where specifications are listed. The below table covers validation test of the Forms.

Form Name	Form Version	Are Export Labels added to all Forms and questions?	Is form type and are data fields correct?	Are data field texts/translations and possibilities (if applicable) correct?	Are settings correct, such as validation rules, show rules?	If validation failed, clarify
Form name	Form version	YES/NO	YES/NO	YES/NO	YES/NO	clarify what is not being fulfilled if relevant
Demographics	0.25	YES	YES	YES	YES	NA
Vital Signs	0.57	YES	YES	YES	YES	NA
…						

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3 Takeaways

Sponsor can outsource validation

- But is ultimately responsible

System must be validated

- Documentation must be in place

Every study should be validated prior to start

- Ensure setup adheres to the protocol

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Time for

Q&A

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