Pre-Market Medical Device Studies and GCP Strategies for Success

LIVE

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Questions

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Answers

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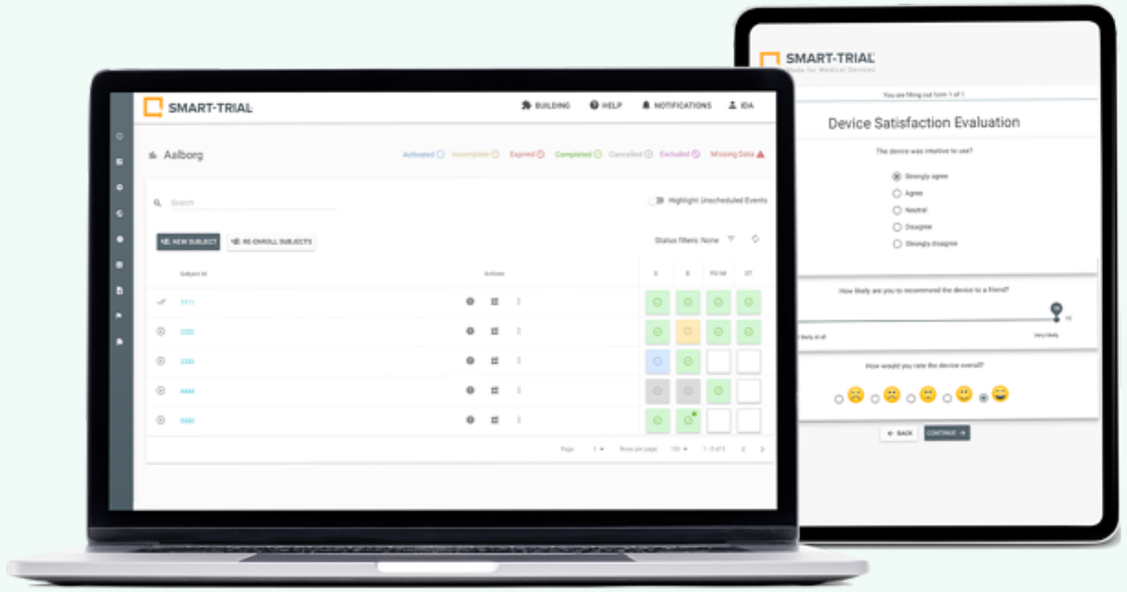

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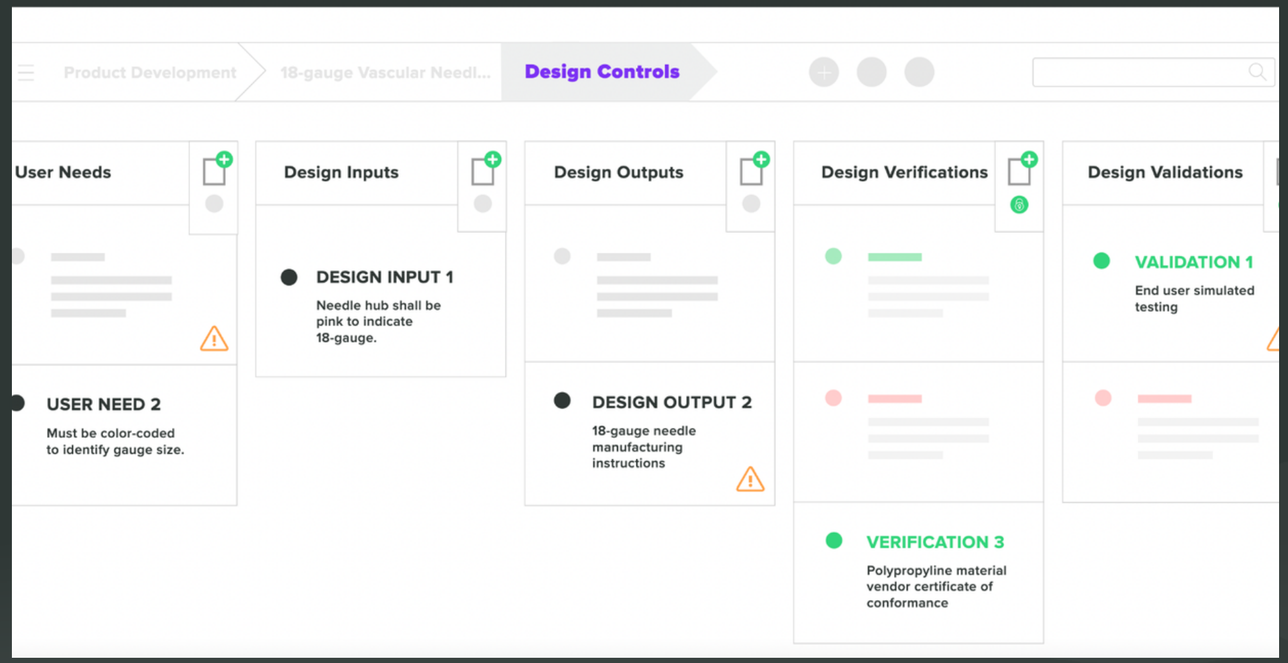

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Today's Presenters

Maria Nyåkern
Medical Device and ISO 14155:2020 Expert

Jon I. Bergsteinsson
Co-Founder

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Why This Topic?

Requirements for clinical evidence are increasing worldwide.

ISO 14155:2020 introduces new requirements for medical device clinical studies.

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What Is The Role of Good Clinical Practice?

What does GCP mean, why is it essential, and when is it relevant?

Jon I. Bergsteinsson

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Good Clinical Practice

An international ethical and scientific quality standard for designing, recording and reporting trials that involve the participation of human subjects.

Consistent with principles set out in the "Declaration of Helsinki" adopted by the by the World Medical Association in Helsinki, Finland, June 1964.

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Good Clinical Practice

Compliance with this standard provides public assurance that the rights, safety and wellbeing of trial subjects are protected and that clinical-trial data are credible.

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ISO 14155:2020

Applicable for:

Clinical Investigation
Clinical Study
Clinical Trial

of **medical devices**

for **human subjects**

INTERNATIONAL STANDARD

ISO 14155

Third edition
2020-07

Clinical investigation of medical devices for human subjects — Good clinical practice

Investigation clinique des dispositifs médicaux pour sujets humains — Bonne pratique clinique

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Replacing Existing Standard

EU MDR

(64) The rules on clinical investigations should be in line with well-established international guidance in this field, such as the international standard ISO 14155:2011 on good clinical practice for clinical investigations of medical devices for human subjects, so as to make it easier for the results of clinical investigations conducted in the Union to be accepted as documentation outside the Union and to make it easier for the results of clinical investigations conducted outside the Union in accordance with international guidelines to be accepted within the Union. In addition, the rules should be in line with the most recent version of the World Medical Association Declaration of Helsinki on Ethical Principles for Medical Research Involving Human Subjects.

This third edition cancels and replaces the second edition (ISO 14155:2011), which has been technically revised. The main changes to the previous edition are as follows:

Major Changes

- Summary of GCP principles
- Registration of the CI in a public database
- Risk-based monitoring
- Clinical QMS
- Statistical considerations
- Guidance for Ethical Committees
- Overall Risk Management
- Application of ISO 14155 pre and post-market
- Guidance on CI audits

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	PRE-MARKET			POST-MARKET	
Clinical Development Stage	**Pre-Clinical**	**Pilot**	**Pivotal**	**Post-Market Surveillance (PMS)**	
Type	Exploratory	Exploratory & Confirmatory	Confirmatory		Observational
Descriptors	 - In-Vitro - In-Vivo - Bench-test	 - First-in-Human - Pilot Study - Safety Study - Exploratory Study - Early/Traditional Feasibility Study - Proof-of-Concept - Investigator Initiated*	 - Pre-Market CI/Study - Pivotal CI/Study - PMA CI/Study - Phase III Study	 - Post-market CI/Study - Investigator Initiated* - PMCF Study - Post-Authorization Study (PAS) - Validation Study	 - Post-Market CI/Study - PMCF Study - Investigator Initiated* - Registry - Survey - Case Series - Cohort - Post-Authorization Study (PAS)
Burden to Human Subject	**None**	**Interventional**			**Non-Interventional**

*Investigator-Initiated Studies can be interventional and non-interventional. Investigator-initiated Studies don't have to be sponsored by investigators.

How is GCP related to legal requirements?

Europe

- Integral part of the EU MDR
- Requirement of local ECs and CAs

US FDA

- An integral part of 21 CFR (for IDE)
- Requirements by IRBs
- ISO 14155:2020 is consensus standard

Elsewhere

- An integral part of local EC requirements
- Local legal adoptations

Major requirements of GCP for a Clinical Investigation per ISO 14155

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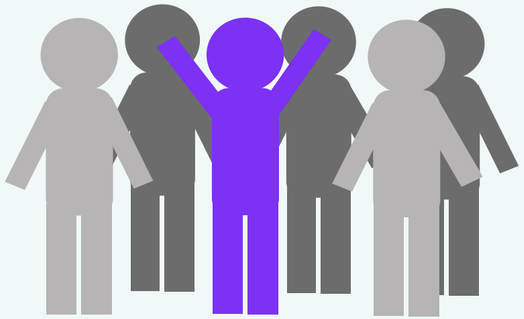
Summary of GCP principles

Ethical Principles

Anticipated Benefits must justify the risk

"People over Science and Society"



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Summary of GCP principles

Adequate previous preclinical data

Detailed CIP

EC and CA approval

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Summary of GCP principles

Best Medical Care

Qualified Professionals

Informed Consent

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Summary of GCP principles

Accurate data recording and storing

Subject privacy and confidentiality

Appropriate device use

13. QUALITY SYSTEM WITH PROCEDURES

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How do you ensure GCP compliance in your organisation?

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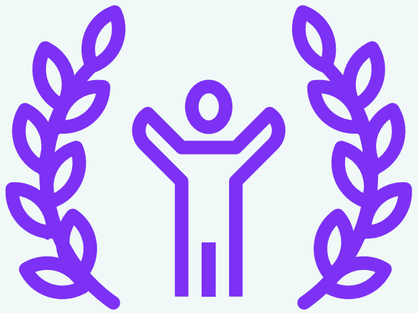
Key Stakeholders



SPONSOR

Investigator

Ethics Committee

Regulatory Authority

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Who Ensures Compliance?

- Sponsor
- Principal Investigator
- Ethics Committees
- Competent Authorities
- Research Nurses
- Clinical Research Coordinators
- Data Entry Coordinator
- Contract Research Organization (CRO)
- Monitors and Clinical Research Associates (CRA)
- Medical Safety Monitor
- Data Managers & Biostatisticians
- Quality Assurance Personnel

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3 Takeaways

Pre & Post Market

Obligations are the same. But individual requirements can differ. You must justify compliance with ISO 14155.

What if I Change Something?

"I am CE marked, but I am changing something."

Do I need to generate new clinical evidence?

Clinical Evidence is Everywhere

Clinical Investigation is just a small part of your lifecycle. But clinical evidence is everywhere.

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Time for

Q&A

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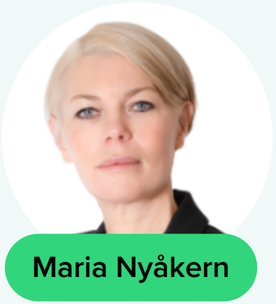

Maria Nyåkern

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Introduction to Clinical Investigation for Medical Devices and ISO 14155

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academy.greenlight.guru/iso14155

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