Key Pitfalls to Avoid in MedTech Clinical Data Collection

Broadcast starts at
19:00 CET/13 PM ET, April 7th

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Today's Hosts

Jón I. Bergsteinsson
Co-Founder & CCO - EMEA

Páll Jóhannesson
Co-Founder & CEO

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Electronic Data Capture Platform for MedTech

Our Experience

- Supported over 250 device studies with Electronic Data Capture
- Medical Devices Classes I to III and Diagnostics
- Assisting throughout the whole MedTech life-cycle
- EU, Americas, Middle-East, New Zealand, Australia, SE Asia

The Challenges for Devices & Diagnostics

1 MedTech clinical operations are different

Device studies are small, require different and variated data. Clinical data collection includes studies, experience surveys, case-series, design validation and more.

2 Changes in Regulations and Focus

New regulations in Europe (MDR and IVDR). together with increased focus on clinical data by the FDA, impact the amount and quality of clinical data needed for market access.

3 Updated Standards

ISO 14155:2020 places heightened requirements on clinical operations, both pre- and post-market. Electronic data capture has become a must.

4 Value-Based Procurement

MedTech solutions are being evaluated based on the performance and safety measured before and after application. Clinical data collection is not solely bound to regulatory affairs.

The Problem with Traditional eClinical Solutions

- Data collection options are limited to ”Phase 1-4” trials
- Data formats are standardized to pharmaceutical standards
- Licensing and pricing is designed for ”big pharma” studies
- Set up, maintenance, and data management operations are costly and resource demanding
- Compliance documentation to support MedTech standards is non-existing

7 Common Pitfalls in MedTech Clinical Data Collection

#1 - Starting Off on Paper

1. Starting off on paper
2. Collect too much data
3. Forgetting the individual
4. Rely too much on KOL
5. Forgetting the clinical workflow
6. Mixing data collection tools
7. Forgetting GCP and validation

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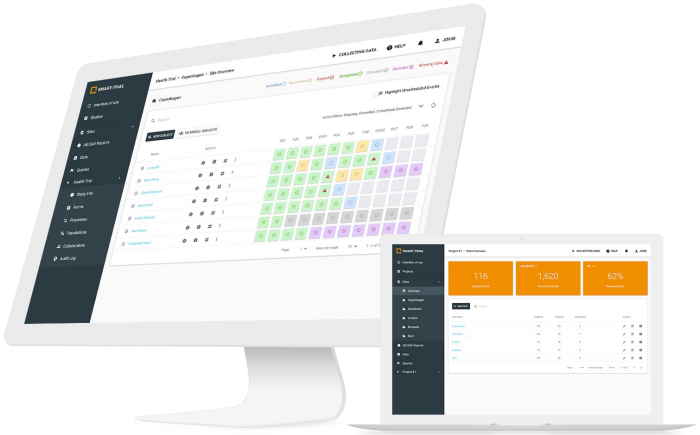
Go Digital



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Go Digital

- Efficient data collection and monitoring
- Assistance with GCP requirements
- Live continuous access and oversight
- Save time and resources

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#2 Collect too Much Data

- Heavy workload on clinical staff
- Increases complexity of operation and monitoring of data
- Increases time and effort on data management and data analysis

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Start at the End

01 HYPOTHESIS

02 STATISTICAL ANALYSIS PLAN

03 DATA COLLECTION PLAN

04 DATA COLLECTION

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#3 Forgetting the Individual

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Include PRO Data in Your Study

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#4 Rely too Much on KOLs

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Go Beyond Clinical Evidence

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#5 Forgetting the Clinical Workflow

- Good study design does not equal quality data
- Variation between sites & countries
- Missing and erroneous data, dropouts, and lack of motivation

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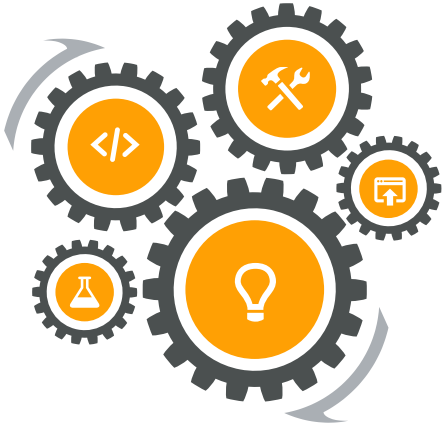
Test, Test, and Test

- Analyze the workflow and differences
- Identify risks and how to mitigate them
- Test, test, and test, and seek feedback



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#6 Mixing Data Collection Tools

Excel/Access Files

Free Survey Tool

In-house Databases

Paper

EDC

Multiple Native Applications

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Define a Standard

ONE STANDARD FOR ALL DATA

- Brings overview and control to chaos
- Improves data quality
- One access to all data
- Enhances regulatory compliance

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#7 Forgetting GCP & Validation

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Go with Compliance

- *“Better safe than sorry”*
- Choose tools that are validated, e.g., according to PIC/S
- Request documented compliance with ISO14155 (GCP), GDPR, FDA CFR21 Part11 etc.

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6. Mixing data collection tools → Define a standard
7. Forgetting GCP and validation → Go with compliance

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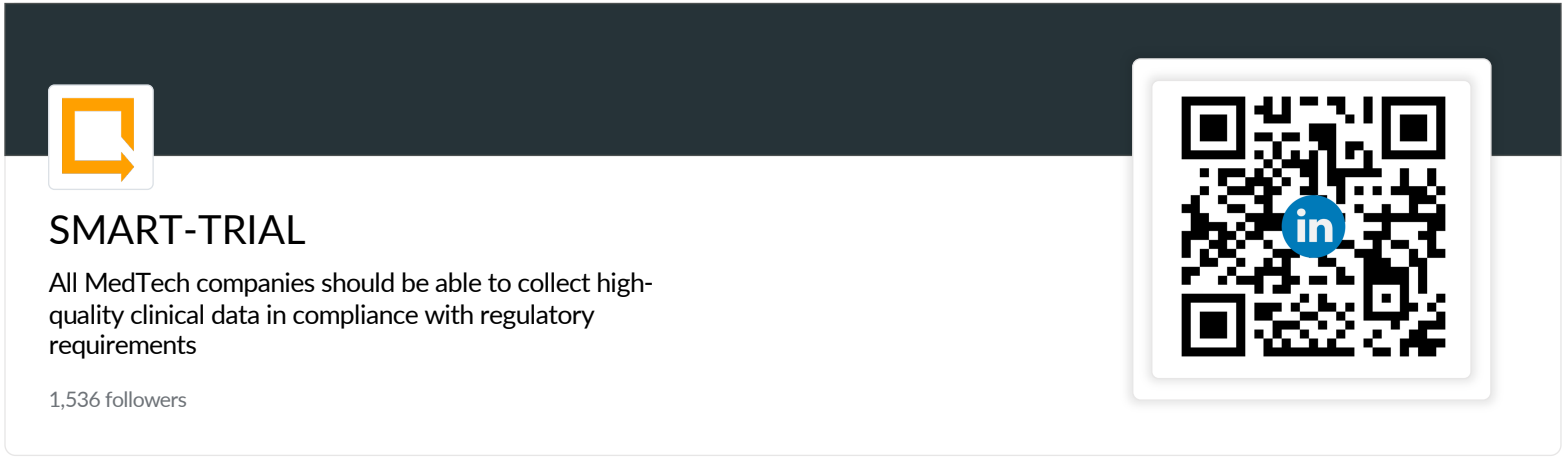

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