SMART-TRIAL provides Medtech with answers to the MDR

A unique opportunity to gain insights on how Surveys can help fulfill the requirements on Post-Market Clinical Follow-Up under the EU Medical Device Regulation

SMART-TRIAL's Jon I. Bergsteinsson and Pall Johannesson

AALBORG, DENMARK, June 9, 2020 /EINPresswire.com/ -- Clinical Data Experts, SMART-TRIAL announced a unique online Q&A session where MedTech clinical teams are encouraged to ask questions about using surveys for Post-Market Clinical Follow-up (PMCF), to comply with the EU Medical Device Regulation (MDR). Participants can submit their PMCF questions before and during the live event which is scheduled for the 11th of June 2020 at 15:00 CEST.

The Live Q&A will be hosted by Jon I. Bergsteinsson VP Global Business Development, SMART-TRIAL, and Pall Johannesson CEO, SMART-TRIAL who together will provide insights on how to conduct a successful PMCF survey, and answer the audience questions.

“Since my webinar on PMCF back in January, I have continued to receive various questions on PMCF and even more so on surveys as a tool to collect PMCF data. It’s clear to me that the industry is looking for insights and guidance, which I will be sharing in the Live Q&A session, while also taking questions from the audience,” added Jon I. Bergsteinsson, VP Global Business Development, SMART-TRIAL.

This live Q&A provides MedTech industry professionals with a chance to get actionable insights by getting their own questions answered and also derive inspiration from the questions asked by their peers. The focus for this PMCF Survey Live Q&A session is to ‘provide answers’ to the otherwise unmet questions and to enable teams to sufficiently prepare to comply with the new

MDR date of application.
A PMCF survey under the MDR is not like a traditional survey. As a sponsor, you need to ensure that the methods and data will pass the scrutiny of the Notified Bodies. But due to the lack of experience and guidance on the topic, clinical teams are finding it hard to navigate and are left with open questions like:

How can a survey comply with Annex XIV (B) of the EU MDR?
How does GDPR impact a survey?
How can a survey comply with ISO14155?
How many people should I recruit (sample size)?
How do I ensure the quality and traceability of data?
What's the max no. of questions to ask a clinician?

Ask your PMCF Survey questions: https://info.smart-trial.co/liveqa/post-market-clinical-follow-up-survey

Hosts
Jón I. Bergsteinsson, M.Sc. Biomed. Eng. is the VP of Global Business Development and the co-founder of SMART-TRIAL, he also served as the CTO until 2017 where he paved the way for the platform's quality standards, data security, and compliance. With a strong technical background, and 10 years of experience in clinical informatics, research, and medical devices, Jón's primary mission is to share valuable insights and know-how on clinical data management with the MedTech industry.

Páll Jóhannesson, M.Sc. Medical Market Access is the co-founder and CEO of SMART-TRIAL. Páll has over 10 years of experience with the development of eClinical tools for clinical studies for medical devices. Páll is an experienced professional within health economic outcome research, clinical data management, and clinical trial design for industry and public-funded research. Páll serves as the Chairman of the Board of the MedTech Cluster Life-Science Innovation North Denmark and as well as being a board member in the Danish MedTech startup MOTI.

About SMART-TRIAL
SMART-TRIAL is helping MedTech clinical teams to comply with regulations on clinical evidence, by simplifying the collection and management of data. Tailor-made for MedTech, SMART-TRIAL offers a do-it-yourself Electronic Data Capture for clinical investigations and PMCF activities, including surveys. SMART-TRIAL is built to empower clinical teams to be their best, and in full control of their data, without compromising on features, design, or compliance. Find out more on SMART-TRIAL - Made for Medical Devices

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