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Biostatistical Challenges in Medical Device Clinical Trials - newly founded Special Interest Group Medical Devices

Michael T. Mader
Nobel Biocare Services AG, Zurich, Switzerland

Michael T. Mader
Please provide a brief biography for the Presenting author(s)
Michael Mader is Senior Manager Biostatistics with over 10 year in Medical Device industry. Prior to medical devices he has held various positions in pharmaceutical biostatistics with focus on oncoloy. He holds a degree in Biology with parallel studies of Computer Sciences and started his career at the Helmholtz Center Munich with focus on Bioinformatics and Biostatistics.

He is active volunteer contributor of the CDISC Medical Device working group.

Single topic, multi-speaker session, Workshop or Single presentation submission

A single presentation/poster

Single presentation or poster submission

Clinical trials in medical devices exhibit several distinct features.

This presentation focuses on Medical Device specifics of two selected areas:

1. Regulations and regulatory context
2. Trial design and statistical analysis

Medical Devices are subject to regulations distinct from pharmaceutics in most countries (e.g. FDA 510(k) in U.S.A. and MDR in EU). Furthermore, these are commonly implemented by separate authority units. This has led to specialized clinical research strategies, trial design and leverage of external data sources including mechanical testing.

One of the major challenges in Biostatistics of Medical Devices is the presence multiple devices at the same time. These include separate study devices, combinations of study devices and non-study devices. Devices are frequently placed at different time-points. Particularly for implantable medical devices surgical techniques and device position in the participant's body make up for a substantial number of additional covariates for which adjustments are desired.

In addition, medical devices cover extremely diverse endpoints ranging from survival analysis and Receiver Operator Characteristics to composite endpoints.
In total, the characteristics of Medical Devices require dedicated statistical concepts and approaches.

The newly formed Special Interest Group Medical Devices aims to provide guidance and recommendations to Biostatistician involved in Medical Device trials and RWD analyses.

Volunteers are invited to join. All suggestions for collaboration are highly appreciated.