Clinical Evaluation, Three Actions for Improved Medical Device Trials and Compliance

Clinical investigations for medical devices must adjust to 21st century standards. MEDEI's Vice President for Global Business Development, explains

AALBORG, DENMARK, April 17, 2018 /EINPresswire.com/ -- Global revenues of the medical technology industry are expected to jump from $425 billion in 2018 to $522 billion in 2022, according to statistics portal Statista. From helping humans to live longer to repairing the body and understanding the brain, Medtech has and will continue to have a massive impact on the wellbeing of global communities.

So, with Medtech being such a critical part of today's ageing world, the question has to be asked ... are clinical trials and evaluation methods ready for our highly-digitised era?

Clinical evaluation is one of the hottest topics in the medical device industry. With the recent updates in the European Union's Medical Device Regulation (MDR) which become mandatory in May 2018, more focus is placed on clinical evidence. With MDR, clinical evaluation of medical devices now becomes a permanent process and one that must be covered by plans and reports.

Manufacturers will have to present their clinical data if requested by Notified Bodies and this might require some organisations to have direct access to data on device benefits and safety. This can prove troublesome for an industry that's governed by basic analogue processes and legacy tools.

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> *Jón Ingi Bergsteinsson*

In order to comply with MDR and have access to the European market, the process behind clinical evaluation of medical devices has to change and adhere to more modern standards. Otherwise, manufacturers will risk increased R&D costs and further loss of knowledge. If the process behind generating clinical evidence is not optimized, manufacturers will also risk prolonged time-to-market, which impacts both budgets and revenues.

Improve the process, not just the tools

From MEDEI's experience, partners who request improvement in their method of data collection eventually end up with an enhancement in the overall process as well. The use of the study data management tool

SMART-TRIAL can often influence transformation in the overall process, not just a part of it and inspire change.

Three Governing Actions

There are three governing actions that device manufacturers should take to improve clinical evidence.

#1 Digitise clinical data collection

Because the age of paper has passed, and the requirements for an overview improved, security has increased. Not only is paper bad for the environment but time-consuming and costly. Time and money spent on transcription, missing data, and faulty collection could instead be aimed at R&D and product development.

A computer screen can display numbers and reports on status faster than any analogue report. It can become extremely time-consuming to look through paper-based reports or files.

Data security is becoming increasingly important, especially in regard to the new EU General Data Protection Regulation (GDPR). Access to sensitive data must be done in coherence with standards of the 21st century, which don't limit access to it. Stowing paper-based data away at remote locations with strong access control does not help, if the data is not easily attainable."

#2 Start at the End

What is meant by starting at the end?

Firstly, focus on the end-results of the study and how graphs should look and be presented. Work retrospectively from there before writing the clinical study protocol.

Secondly, don't leap from graphs to protocol writing. Testing the data collection methods and forms can increase the efficiency in writing the protocols. This results in less time spent on writing the protocol. Because by first creating the forms and designing the study flow, less time is spent on defining it, as the whole set up can be visualized. Additionally, early test and setup design result in fewer amendments throughout the study course.

Lastly, the study endpoints become clearer. Your data collection will represent endpoints that mirror your study-specific requirements. Not results from the adjusted protocols from a previous study, or from a protocol template.

We've seen too many cases of a waterfall process, where older protocols end up being mirrored for an upcoming study. This results in unclear results and often useless data."

#3 Design better forms

Why design better forms?

There are no benefits from electrifying paper. Paper and electronic systems, or electronic case report forms (eCRF) and electronic patient reported outcomes (ePRO) look and function differently. By modeling paper or analogous forms, we neglect the advantages of the digital solution.

We need to collect more quantifiable data. Quantifiable data is important when applying statistical methods to collected data, but people often end up collecting a lot of free text and other misleading

data that doesn’t help.

Abstracts

In today’s data hungry and highly-regulated medical device business, it’s not sufficient to only optimize a part of the clinical evidence process such as only data collection. The way we plan and conduct clinical investigations for medical devices must be adjusted to 21st century standards. This means that we have to look at all parts of the process, including the way we communicate.

MEDEI is working with medical device manufacturers who have applied these principles into standard workflow. As a result, they have cut down on the time spent on planning clinical studies from months to weeks. Employees have improved collaboration and communication, which also results in less stress and fewer delays.

About MEDEI

MEDEI ApS is a Danish medical software innovator delivering industry-leading software to facilitate data management and the R&D of medical devices. SMART-TRIAL, the firm's flagship platform, is helping medical device manufacturers to better illustrate the quality and safety of their medical devices by eliminating chaos in the collection and management of clinical data. Visit https://www.smart-trial.co

Ends

Hugh Paterson
Whoosh PR
+447768175452
email us here
