Innovation Dialogue Event – the MDR Breakfast Club

Organised by University Medical Center Schleswig-Holstein (UKSH)

31. May 2018 Lübeck

Summary

Topic of the day

Definition of problem zones and possible solutions for the planning and implementation of post-marketing clinical follow-ups in the hospital environment.

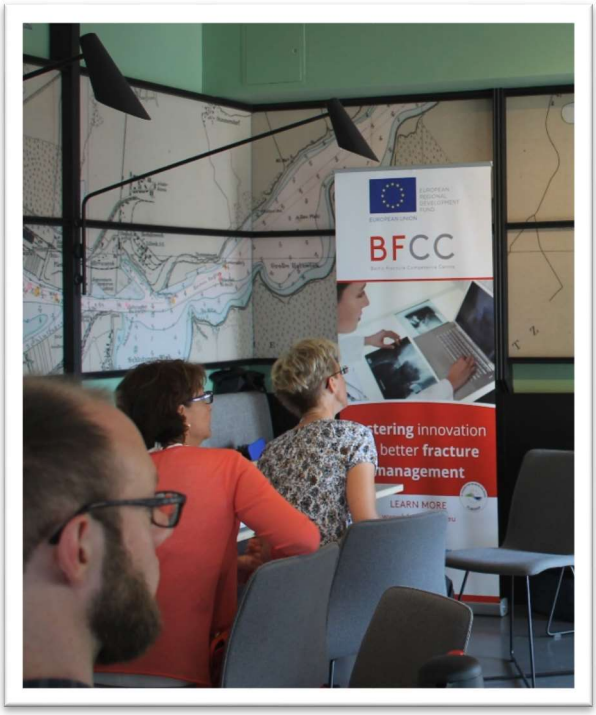
Welcome and introduction

At the invitation of Prof. Schulz (UKSH), numerous representatives of industry met in Lübeck for the Innovation Dialogue Event - the MDR Breakfastclub - to develop the problem zones on the topic: "MDR PMCF - are joint strategies of clinics and manufacturers necessary? The representatives of industry consisted of technical personnel involved in the approval of medical devices as well as innovation managers, R&D employees and other affected employees of companies took part in the event and tried to elaborate the problem areas.

Participants from the industry

Söring GmbH
Olympus Europa SE & Co. KG
Litos GmbH
MedDevConsult
Codan Medizinische Geräte GmbH und Co KG
Mathys Orthopädie GmbH
Drägerwerk AG und Co. KgaA
Qualitätsplan 24 GmbH

Presentation of focus areas



Ralf Stuckert (DSN) and Prof. Schulz presented a semi-structured development of focus areas to the participants. These were suggestions that pointed out possible problem areas to be discussed and were intended to provide the participants with inspiration for further brainstorming. Some of the proposed ideas are listed below.

Focus areas
Do you already know which clinics you want to work with?
Do the clinics have enough patients at all?
What are the ideas regarding comparison data of competing products?
Are there any compliance problems? If so, which ones?
Does a competitive situation arise between different manufacturers/medical products "for the same patient data"?

Brainstorming and discussion of problems

After the presentation of possible problem areas, the participants presented the current problems as to how the decision of the MDR influences their daily work, what concrete problems exist in their companies, what developments are seen with concern. It turned out that the problems and concerns of the individual participants did not differ so much. On the contrary, the concern for the cooperation and interest of the doctors in the clinics when it comes to carrying out PMCF, the question of how much data is sufficient for a PMFC, how to obtain data of very good quality at all, etc. - these were all topics that affected practically all participants.

Prioritisation

Each of the participants was asked to award a total of 5 points in order to prioritize the topics to be discussed in a subsequent discussion, as these are very important for the manufacturers with regard to MDR. Industry is facing a great challenge, which the new EU Medical Devices Regulation brings with it for the PMCF and there is great uncertainty. The 5 problems listed below were identified as the most important by the participants.

Problem area	Points
How much data is enough.	8
Do the clinics have sufficient resources at all.	6
The knowledge of clinics about post market studies.	6
How is the cooperation between companies and hospitals.	5
Data quality.	5

After the prioritisation round, the participants tried to find answers to the questions: How much data is enough and how can a very good data quality be ensured? There was agreement that it was important to answer this question because data collection takes a lot of time and money. In practice, the manufacturers themselves can determine how much data they ultimately want to collect, because there is no regulation for this. This is also the reason for the great uncertainty. Risk management defines conditions, the number of products/number of responses and can decide that a certain percentage of data is sufficient. But each manufacturer determines this in principle itself. Relying on common sense is not enough; there must be a statistical justification. There is a concern: that with a rational statistical approach the required sample can become very large. Statistical methods would therefore have to be defined and there are standards for this in turn.

Next steps

All participants agreed that this meeting of the MDR Breakfast Club was only the first step in the right direction. Pharmaceutical manufacturers need to get together, exchange ideas, develop joint strategies and involve the doctors in the hospitals in finding solutions.

The next steps:

- Contacting the Association of University Hospitals to find out how members assess this problem.
- On the one hand, the manufacturers agree on how complex the implementation of the guidelines by the MDR is; on the other hand, the doctors are no longer even aware of this problem. For this reason one should try to enlighten the physicians through the specialized journals.
- Further work on the topic is to be carried out within the framework of the Clinical Studies Working Group.
- A next joint meeting could take place with a representative of the the notified body for medical devices - among other things to clarify whether an register is an acceptable database in relation to MDR that could be available.

End

Prof. Schulz thanked all participants for their willingness to discuss, the interesting contributions and questions of each individual and explicitly stated once again that this meeting represents only a first step towards joint strategy development by manufacturers and hospitals, but that the path should be taken even further, because the interest among manufacturers is very great.