WHITE PAPER

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Use of Retrospective RWD for EU MDR Compliance

As EU MDR has already entered into force and will be applicable in May 2020, the device companies are getting geared up to be MDR compliant. EU MDR enforces stringent requirements related to clinical evidence and post marketing obligations on device companies in proportion with risk class and the type of device. The device companies are exploring different approaches, considering both reactive and proactive, to develop a system to collect real world data and use it appropriately for generating clinical evidence and at the same time to be EU MDR compliant. This white paper focuses on retrospective data that device companies can use cost effectively to support clinical evidence, update risk-benefit determination and fulfill PMS requirements as per EU-MDR.

There are various options that device companies can explore to use prospective data collection from the real world setting such as observational or PMCF studies. However, most of the device companies might not willing to plan such prospective studies as these formal studies could be costly affairs for them and bring an additional burden on their budget. Also, for some of the devices (except class III & Implantable devices) depending on the risk levels, such prospective clinical investigations are not necessary also considering what existing clinical data they have. Therefore, one of the cost effective and smart approaches is to use retrospective data effectively to generate clinical evidence, establish/update risk-benefit and at the same time full-fill the post marketing obligations as per EU MDR requirements. Let's look at first what type of these retrospective, real world data that device companies can use to fulfill EU MDR requirements.

1. Retrospective - Reactive Data

As a part of quality management system, the device companies routinely collect, maintain this data such as complaints, feedback, vigilance data etc.

This data includes:

- Information including feedback and complaints provided by users
- Information about serious incidents
- Records referring to non-serious incidents and data on undesirable side effects
- Information and actions from trend reporting

2. Retrospective - EMR, Chart Review and Registries Data

EMR & Chart Review: The device companies can obtain this retrospective data from some of the physicians/ hospitals, based on the knowledge of their device being used. This includes data already reported in EMR, hospital files and charts related to device safety, performance and effectiveness etc. This data includes clinical case records in the outpatient or inpatient service, registration entries, adverse event monitoring systems, investigation report filing systems and so on. It is not necessary that the device companies would need all the data reported in EMR or hospital files or charts, however, depending on the clinical evaluation need and gaps they need to address in providing clinical evidence for safety and performance, they can collect the relevant data points. The only thing they need to pay attention to statistical significance in terms of the number of patients' data to have meaningful and conclusive analysis/results of this data. Sometimes even aggregate data can be helpful to fulfill the gaps related to clinical evidence.

The following data points would be adequate to derive meaningful clinical evidence such as:

- Patient key demographics,
- Critical safety data points -AEs/ Serious incidences
- Device performance/effectiveness data points
- Duration of follow up/use
- Any specific feedback etc.

Device Registries Data: Device registries allow assessment of medical device performance in a real-world setting. Registries contain data on large numbers of patients receiving care in diverse clinical settings and capturing the clinical outcome over an extensive period. The registries data is also great sources of retrospective data; however, sometimes challenge could be identification of my device in the data. However, if it is possible to identify my device or predicate device, the data can be used effectively for clinical evidence. With the implementation of UDI system, device registries would be great a source of retrospective data to assess long term outcomes.

The following aspects of this retrospective patient data if addressed properly, the data can be used effectively in generating clinical evidence as per EU- MDR requirements, instead of planning any costly prospective clinical study.

- Identification device from EMR, insurance claims and registries data
- Patient number – statistical significance
- Need of more granular and procedural data
- Adequate duration of follow up
- Appropriate use of data in text format such as surgical notes

This data can be used and analyzed further using appropriate statistical rationale to derive conclusive results which can be used for clinical evaluation and evidence as per MDR requirements. Similarly, one can smartly use this above retrospective data and plan activities to continually assess the balance between the risk of the device and the clinical benefit, update risk-benefit determination and to improve the risk management. Also, the information from reactive data such as complaints related to device performance and users' feedback can also be assessed to see if the performance of the device is within the acceptable limit or not, which can be used to update the clinical evaluation.

Thus retrospective data if used and analyzed properly, it has a multifold use for MDR compliance and which again cost effective approach for the device companies. This retrospective data will serve as a rich source to generate clinical evidence to fulfill almost all of the MDR requirements for class I, Class IIa, Class IIb and most of the requirements of class III & Implantable devices. Of course, there might be a need to carry out additional prospective clinical investigations for class III and implantable devices.

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