**Clinical Evaluation Reports – Tying it All Together (Article 1 of 3)**

**Forward:**

MEDIcept, an international medical device consulting firm is presenting this as an ongoing series of articles focused on Clinical Evaluation Reports in the medical device industry.

Recent changes to the Medical Device Directive (MDD) have led to a renewed focus on Clinical Evaluation Reports (CERs), and extend that requirement to all devices – regardless of classification.

Our team at MEDIcept has worked with a variety of manufacturers to develop CERs for a wide range of devices and device classifications; with these articles, we will provide an overview of the steps for completing a CER and describe the benefits of bringing clinical and safety data, risk analyses, and product literature (e.g. labeling and manuals) together in one place to provide an objective, transparent evaluation of device safety and performance.

If you have questions or comments on the issues discussed, or if you have recommendations for topics to consider in the future, please let us know. 508-231-8842.

**Some Quick History**

The 2007 amendment (2007/47/EC) to the MDD (93/42/EEC) included changes to several elements of the directive. The most notable of these was the decision to require clinical evaluation reports for all CE marked medical devices. In December 2010, the EC published *Clinical Evaluation: A Guide for Manufacturers and Notified Bodies* (MEDDEV. 2.7.1. Rev 3). Compliance was required as of March 2010. Following the release of this guidance, Notified Bodies began letting manufacturers know that these reports would be high on their list of required documents to review at their next surveillance audit and that the original Clinical Evaluation Reports may be incomplete.

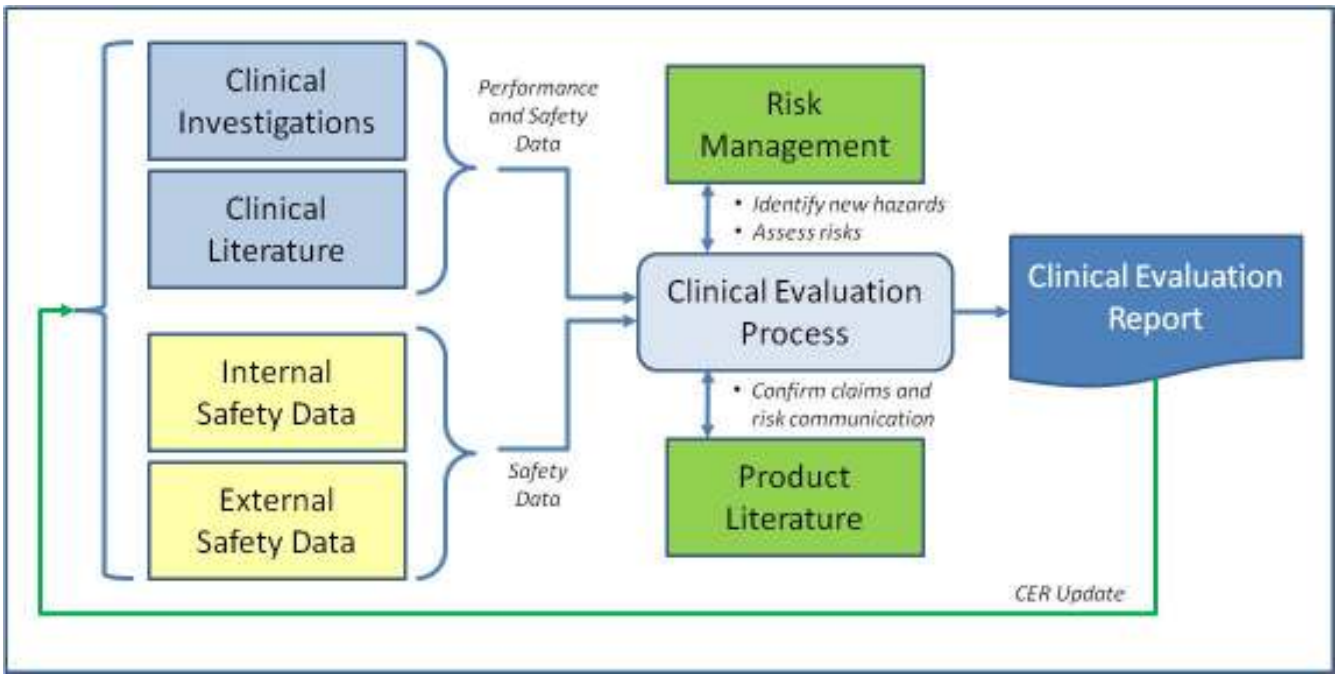
As you work to update existing clinical evaluation reports, and create reports for devices that were previously exempted from the requirement, it's important not to view these reports simply as a regulatory requirement – a report to be created, approved, filed and forgotten. The guidance is structured to help manufacturers bring important safety and performance together - providing a comprehensive evaluation of you devices, and confirming the alignment of key quality system elements. Maintaining these reports throughout the product lifecycle will support the continual improvement of your devices.

**Clinical Evaluation Report Process**

As described in the guidance for preparing clinical evaluation reports (MEDDEV. 2.7.1. Rev 3), the intent of these reports is to assess the safety and performance of the subject devices by completing an objective evaluation of clinical data. As illustrated in Figure 1, the clinical evaluation process is designed to gather clinical data from a variety of internal and external sources, confirm that any identified safety

issues are addressed by the risk management system, and verify that the information provided to users effectively communicates needed usage and safety information.

**Figure 1: Clinical Evaluation Process**




As a result, the clinical evaluation process helps manufacturers address several critical questions:

1. Do the clinical data confirm that the device is effective for its intended use?
2. Is there evidence to support the clinical claims?
3. What is the full range of safety issues that have been observed or anticipated for the device?
4. Have these safety issues been addressed by the Risk Management system?
5. Does the information provided to users communicate the appropriate indications for use for the device and safety risks associated with its use?
6. Overall, do the benefits of using the device outweigh the risks?

The clinical evaluation process is designed to provide manufacturers with an objective view of the performance and safety status of their devices. The balance of this paper provides a brief overview of the key steps to be followed during the CER process.

*But first, a few words about objectivity and transparency . . .*

One of MEDIcept's observations from following the MEDDEV guidance to complete multiple CERs, is that it is designed to help the evaluator complete an objective evaluation and to ensure that the decisions made about the relevance and quality of the clinical data included in the CER are transparent – i.e., anyone (including your Notified Body auditor) can pick up the final report and identify how the clinical data (e.g., literature, safety data, internal study data) were selected and why certain data were included/excluded. Without this effort to ensure transparency, it's very difficult to ensure that the report is free from bias – either intended or accidental.

Too often CERs are quite heavy on references, but light on transparency. If you've seen a CER with 40 citations and a summary referencing only 10 of those studies, you know what we mean. Why did the author choose to summarize results from only those 10 studies? What's wrong with the other 30? Were they excluded because they were not relevant? (If so why include them in the list of citations?) Were they excluded due to poor study design and/or poor data analysis? Where did the list of 40 citations come from in the first place? Does the report identify both the positive and the negative results from the studies? Are there other clinical data out there that would provide different/better/ more relevant information?

The same questions apply when thinking about how medical device reports (MDRs) are addressed in a clinical evaluation report. Without a well-structured clinical data collection, review, and appraisal process, you are at the mercy of the author regarding the objectivity and completeness of the report.

**Your Internal SOP:**

To complete a CER that meets the requirements, you need a process. And to ensure that the process is followed consistently, that process needs to be documented. As a result, your company's clinical evaluation report SOP will be at the top of your auditor's checklist when he/she gets to that portion of the surveillance audit. While the guidance provides many helpful examples for how the CER can be completed, the authors make it clear that:

> *The depth and extent of clinical evaluations should be flexible, not duly burdensome, and appropriate to the nature, classification, intended use, manufacturer's claims and risks of the device in question.*

Your SOP is your opportunity to identify how your firm determines what level of rigor is appropriate. If your only product is a Class III device, that determination is pretty straightforward. If, however, you manufacture a large range of devices, your SOP needs to describe how you distinguish among those devices. Otherwise, you'll find yourself applying the same approach for evaluating a Class I device that has been on the market 10 years with no major complaints, as the one you use for a Class III device that is new to the market.

MEDIcept is a medical device consulting firm dedicated to helping pre-revenue and established medical device manufactures with the complexity of international regulatory requirements. Let MEDIcept help you develop your Clinical Evaluation Report SOP and walk you through the process.

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