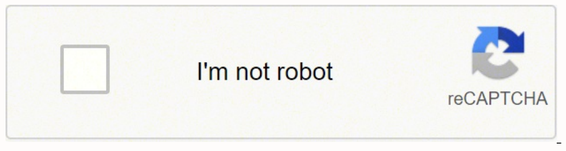


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# Writing clinical evaluation reports

January 25, 2020 Writing a Clinical Evaluation Report: CERtips “Writing a clinical evaluation report: Sophie Laurenson, healthcare and technology innovator on Kolabtree, shares 5 tips for writing a clinical evaluation report and defining a CER strategy.” The EU MDR has significantly impacted the way medical devices are regulated in Europe. As part of regulatory compliance, medical device manufacturers need to create and maintain a Clinical Evaluation Report (CER), a document essential for CE Marking. Here are expert tips on what to take into account to define a robust CER strategy. 1. Define a CER protocol and strategy Identify the Essential Requirements (Safety and Performance Requirements in the MDR) that need to be supported by clinical evidence. Define metrics relative to performance, safety and risk/benefit endpoints. 2. Demonstrate equivalence Equivalence is determined based on the comparison between a medical device and other pre-existing, similar CE-marked devices. The demonstration of equivalence is evaluated on relevant parameters that are defined by the manufacturer. The rationale for equivalence must be fully explained in the CER. The criteria for equivalence have become complex and stringent, with stronger connections to the Essential Requirements. It is critical to avoid the common mistake of selecting equivalent devices that are not relevant to your product. Documented data must be identified and analyzed for each equivalent device and for the differences between devices. 3. Evaluate literature review data If equivalency can be demonstrated adequately, clinical data extracted from the literature on previous studies is a valuable tool in compiling a CER. However, it is critical that literature surveys are conducted in a systematic process: Prepare a comprehensive protocol for the literature review, • Define inputs and parameters such as databases, search terms and exclusion criteria (languages, study type / design, study setting, endpoints), • Define the required safety and performance criteria based on the equivalent products and risk analysis, • Systematically gather relevant articles from different data sources, • Analyze the data using an objective method such as a framework and using multiple reviewers, and, • Document conclusions of the literature evaluation for inclusion in the CER document. 4. Determine the requirement for clinical investigation The requirement for a clinical investigation is determined by the risk profile of the device. High risk and Class III devices must be subject to a clinical investigation. Novelty is also a determining factor, and devices based on innovative technologies or for a new intended use require clinical investigation. The available clinical evidence must address all the pertinent ERs. This can be ensured by sharing the Clinical Investigational Plan (CIP) with the relevant NB prior to implementation. 5. Monitor post-market activities Under the MDR, PMS activities must be adequately planned and documented in the CER. The processes for evaluating ongoing clinical data and updating CERs must also be documented. To ensure that the CER remains relevant throughout the product life cycle, it must be updated regularly through a documented process. This includes evaluating the data and weighing the relevance of all equivalent devices. If you need help with writing a CER, it’s worth hiring a freelance Clinical Evaluation Report writer who can help you prepare and maintain a robust CER that meets all regulatory requirements. Author bio: Sophie Laurenson BSc. (Hons), Ph.D. (Cantab) has over 17 years of professional experience in healthcare, in both industry and academia. She consults on Kolabtree for medtech startups and SMBs. She previously worked in R&D functions at Abbott Laboratories in the United Kingdom, Germany, and Switzerland. She has experience in academic spin-outs and is the Founder and Managing Director of a health technology start-up specializing in emerging markets. Her areas of expertise include medical technology, digital health, and healthcare delivery technology. She is an expert on the subject of writing a clinical evaluation report. Another article of interest for device companies can be found here. Evaluating yourself can be a challenge. You don’t want to sell yourself short, but you also need to make sure you don’t come off as too full of yourself either. Use these tips to write a self evaluation that hits the mark.Overview of a Self EvaluationA self evaluation is a tool used by many managers to get their employees’ perspectives about performance, attributes and weaknesses. Although self evaluations are not useful as a stand-alone tool for assessing performance, they can be invaluable when it comes to reviewing past events and learning how employees feel about work processes. Using this information, managers can make changes to improve work environments and processes.Benefits of a Self EvaluationManagers will request self evaluations for several reasons. Learning how you see yourself within an organization and how you understand expectations helps managers be more effective. Your manager can gain insight about inter-personnel communication as well. These evaluations can also be effective for motivating employees, especially those that are intrinsically motivated to grow and improve.Points to CoverYour self evaluation should include specific data and quantifiable results you produced during the review period. These details demonstrate specific skills and tangible results. Make sure to include these points: Organize your accomplishments into a few categories. If unexpected projects came up, include these items too, so you can demonstrate your adaptability. Include quotes and feedback you’ve received that supports your skills and performance. This feedback might come from coworkers, managers or customers. Highlight strengths you have to show how your skills had a positive impact. List a couple of goals you have or skills you’d like to develop over the coming year. Inquire about opportunities for growth that might arise. Use action words and phrases to describe your accomplishments. What to SkipYou may be tempted to include the following, but doing so will likely reflect poorly on you. Resist the urge to criticize others in your self-evaluation. You are writing about yourself, no one else. Avoid taking a defensive tact as well. Address any weaknesses you have as an opportunity to improve instead of focusing on negatives. Don’t make excuses for errors or failures. Instead, frame these situations as learning experiences, taking responsibility and making specific goals to succeed. Using Self Evaluation ExamplesIt may help to review a few self evaluation examples as you work on your own self examination. These examples will usually show organized accomplishments and projects, highlighting skills used and actions taken to finish these tasks. You’ll also get ideas for how to describe challenges with positive framing and how to ask for new growth opportunities for the coming year.Once you finish writing your self-evaluation, ask a coworker or family member to read it. Make sure you proofread it carefully so that it’s free of errors and typos. MORE FROM QUESTIONSANSWERED.NET A clinical evaluation report (CER) is an important technical document required for a medical device to be CE marked and therefore sold in Europe. Under the new EU Medical Device Regulations (MDR), which come into place in May 2020, the emphasis on CERs has greatly increased. Medical device companies without experience in the new process may therefore find CER writing a challenging process.  All medical devices already on the market require recertification, making preparation for the MDR a big task. It involves evaluating your product to check for compliance, while gathering all the relevant technical documentation needed for the technical file. The CER is a vital part of a medical device’s technical file, and CERs must be approached carefully if a product is to be approved. Familiarise yourself Firstly, familiarise yourself with the new regulations. You may want to attend conferences to help stay up to date with the changing regulatory landscape. You’re not too late because before the May 2020 deadline there are several events that will take place across the UK. This includes Future Health 2020, held March 17-18 in London, Med-Tech Innovation Expo, hosted April 1-2 in Birmingham and Drug/Device and Device/Drug Combinations in the EU and USA, happening on April 2-3 in London. You can also access trusted resources to help you brush up your knowledge. For example, the European Commission has shared a guide to the new regulations and the EU has released one for CE marking. For those in the UK, the British Standards Industry offers guidance on what has changed under the MDR and how best to prepare. Kolabtree has produced a series of blog posts, as well as a whitepaper, which can be accessed for free. Be strategic Producing a CER is a complex and ongoing process — complying with the MDR on this aspect is not quite as simple as just updating your previous document.  For example, the emphasis on clinical investigations has increased, as have the criteria for establishing equivalence and many devices have been reclassified. You will need to establish across your portfolio of medical devices, whether they conform to the new specifications, and then produce the corresponding CER report. Because CERs are an ongoing process, you will need a strategy for including post market surveillance and update the CER as required. A structured, coordinated approach across the whole organisation is the most effective way to meet the requirements of the MDR. Hire a specialist The changes required by the MDR are extensive, so it is understandable if you do not have an in-house CER expert. Luckily, there are freelance clinical evaluation report writers available to help you. Before hiring, check they have the relevant skills and experience — an established CER writer would be familiar with the scientific literature, the regulatory documents recommended earlier and they will have been to regulatory conferences and meetings. The more regulatory challenges the freelancer has dealt with in the past, the better. The ideal scenario is to have the experienced clinical evaluation report writer guide your quality control team through the entire process, in an efficient manner.

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