



Generating clinical evaluation reports

A guide to effectively analysing medical
device safety and performance

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Introduction

The successful establishment of the biomedical device industry in the middle of the 20th Century was the result of several factors coming together at the right time, such as advances in our understanding of the human body and the development of then unprecedented technologies and materials. An essential element contributing to the further advancement of this industry, yet one often overlooked, was the creation of a firm set of regulatory rules to govern the development, manufacturing and marketing of these devices. Regulatory oversight gives patients and clinicians alike the confidence that medical devices have been validated by an efficient system ensuring that any possible risks associated with their use are outweighed by their potential benefits. The European regulatory framework applies to those entering medical devices into markets falling within the European Economic Area, independent of their country of origin. It affects European and non-European manufacturers alike.

The story of how the current regulatory framework came to be is especially complex, given that in earlier decades each country had its own set of rules. However, a major leap forward occurred in the 1990s when the rules relating to the safety and performance of medical devices were first harmonized in the European Union (EU). For medical devices, the new rules were summarized in the European Commission's Directive 93/42/EEC and later amended by Directive 2007/47/EC. To aid this process, legally non-binding MEDDEV guidelines were created that promoted a uniform approach by manufacturers and notified bodies (NBs) involved in the conformity assessment procedures of the directives within the EU. The most recent revision of the European MEDDEV guidelines occurred in December 2009 (MEDDEV 2.7.1 Rev. 3), and pertains to the creation of clinical evaluation reports, which are defined as, 'the assessment and analysis of clinical data pertaining to a medical device in order to verify the clinical safety and performance of the device.' It is this key feature of the regulatory process that serves as the basis for this overview.

MEDDEV 2.7.1 Rev. 3 – Explaining the guidelines

The MEDDEV 2.7.1 Rev. 3 guidelines provide manufacturers with guidance regarding how to properly evaluate the clinical safety and performance of their devices. Such evaluations are particularly significant for Class III or implantable devices. They are undertaken at the beginning with the initial conformity assessment that is used to obtain the marketing license or CE mark of the device in the EU, and periodically thereafter to update the relevant authorities as new clinical information becomes available (e.g. from ongoing and/or published studies) or changes are made to the device's design or intended use. These evaluations are also used to update the risk analysis of the device, identifying potential areas of concern, which if applicable are then noted via changes made to the design, materials, manufacturing, or instructions for use. If there are no issues, the device is approved for continued marketing in the EU.

The end result of this process is the production of a clinical evaluation report (CER). According to these guidelines, you arrive at this CER by the following process:

- Identifying the essential requirements (ERs) that require support from relevant clinical data.
- Identifying available clinical data relevant to the device and its intended use.
- Evaluating data in terms of its suitability for establishing the safety and performance of the device.
- Generating any clinical data needed to address outstanding issues.
- Bringing all the clinical data together to reach conclusions about the clinical safety and performance of the device.

But what is the best way to create a CER to meet all of these points? The MEDDEV 2.7.1 Rev. 3 guidelines are not very clear in this regard. Given the wide range of medical devices on the market and their innumerable variations in design features, treatment goals, and intended patient groups, a one-size-fits-all CER is impossible. Instead, the guidelines allow manufacturers to independently choose how to go about creating these documents. This can present considerable frustrations to those responsible for creating the CER, who upon starting out may have more questions than answers. This overview was created to provide some general ideas for how to satisfy these important regulatory requirements.

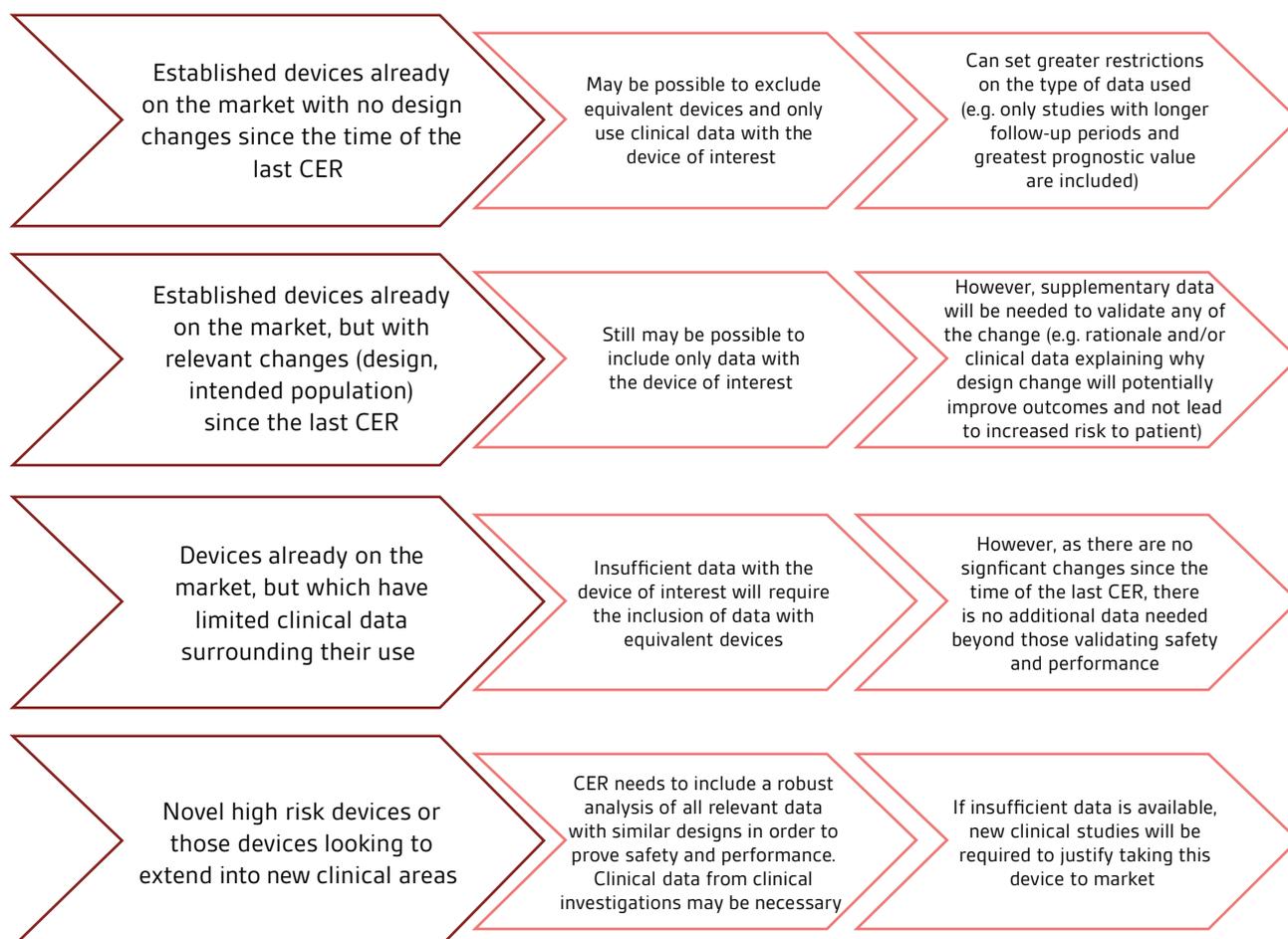
Defining the scope of your clinical evaluation

The first rule of creating a CER is that it must be objective. All relevant data should be considered systematically, regardless of whether it is positive or negative.

The second rule is that the CER should be thorough enough that any reviewers will feel as if they have had all their possible questions addressed. Yet here we encounter our first difficulty, as interpretations of the word 'thorough' will undoubtedly vary considerably according to each reader. Perhaps nothing would be more thorough than a 300-page document explaining the complete history of a device's development, from the first such devices to be clinically used, through to every subsequent iteration of this design concept leading to the device in question. Yet this document would have little value, as it would dilute the key information and evidence supporting the demonstration or confirmation of the device's safety and performance.

To determine what is in fact necessary to include in an effective CER, you must first step back and ask what kind of device you are dealing with. Generally speaking, the more established a device, the more you will be able to rely on its extensive pool of existing data and limit findings with other devices, whereas more novel designs will require the opposite approach. Figure 1 will give you a general guide in these matters.

Figure 1 — The CER process depends on available clinical data for the device



You may have noticed the phrase 'equivalent devices' in Figure 1, which is an important concept in the development of CERs. If there is insufficient data with the device of interest, results with equivalent devices can provide valuable insights. However, they are only of interest if they share the same characteristics with your own device and would therefore be expected to produce near-identical clinical safety/performance results. According to the MEDDEV guidelines, these three categories determine whether a device is an equivalent device:

1. Intended use (i.e. clinical condition being treated, site of use in the body, and patient population).
2. Technical characteristics (i.e. design of the device, including materials, dimension, principles of operation).
3. Biological characteristics (i.e. biocompatibility of materials).

An efficient way to document that your device is truly equivalent with other products is to establish a table in which each device is included in a separate column, and every row lists a separate comparison category (e.g. type of metal the device was constructed from). If all rows match up with your own device, then these can be considered equivalent. Where differences exist between the subject device and proposed equivalent device, then these differences must be identified. A rationale for why the stated difference would not impact the safety and/or performance of the subject device would need to be documented in the CER. If evidence is available to demonstrate that a particular design feature might offer better performance than the equivalent device (for example, through bench testing or clinical investigation), then this should be documented and presented in the CER.

Please also note here an essential aspect of producing CERs: they require a multidisciplinary effort from various departments within the company. This ensures that the CER is truly reflective of the entire body of knowledge surrounding a device, rather than the limited perspective of one person. For example, the clinical expert (or clinical writer) responsible for putting the CER together may not have the technical knowledge to determine what makes another device truly equivalent, but an engineer who develops the product may easily be able to provide this information for them. It is recommended that you set up a list of all experts (development, manufacturing, marketing, post-market surveillance) working on this product and have them contribute at a set time.

Step-by-step: How to create a clinical evaluation report

Once the scope of the clinical evaluation is established, it is time to get into the actual work of producing a CER for your product. To better understand how to accomplish this process, we will use a step-by-step example with a 'mock' product that is nonetheless indicative of a typical device requiring a CER.

From Figure 1, we will select 'Devices already on the market, but which have limited clinical data surrounding their use' as our scope, given that this represents a middle ground between the more straightforward and more difficult ends of the spectrum. The example device in question is an uncemented acetabular cup (a prosthetic implant replacing the socket of the hip to relieve arthritic pain) used in total hip arthroplasty, which we call the 'NEW Cup'. The design engineer and marketing department in your company have identified two devices that can be considered equivalent: the Original Cup and the X1298 Cup.

Step 1: Identifying data sources

Regardless of the type of device you are conducting a clinical evaluation for, you can assume that there will be three key sources of data that can be included:

1. Studies published in medical journals.
2. Unpublished, internal data.
3. Complaint/post-market surveillance data.

Orthopaedics products, for example, are also monitored by several national joint registries, in which 'outcomes data' e.g. the annual rate of revisions, are recorded for individual products. We can therefore include 'registry data' as a fourth source of data for this CER, though this may not be an option for other types of devices.

Uncemented acetabular cup



Studies in medical journals are a valuable source of high-quality data, given that they are (ideally) the end result of a well-controlled clinical trial process, and have been vetted by the journal's reviewers and editors. They are also the most challenging aspect of creating a CER, and will therefore serve as the focus of this example.

Step 2: Determining a search strategy

Your strategy for searching the literature must be well-defined, systematic and transparent, so that the reviewers are able to determine if you adequately sought all possible data. The first way to achieve this is by settling on your inclusion/exclusion criteria. These are important because they allow you also to limit the scope of your report and keep it manageable. Here are some examples of inclusion/exclusion criteria with the reasoning behind their use explained:

- Studies were in Italian or English – Although the majority of studies publish their results in English, there are journals published in a variety of languages. It is only necessary to include studies written in the language(s) in which the person preparing the CER is fluent. In this example, Italian was chosen because the device of interest was mainly commercialized in Italy.
- Data was available with multiple patients – Case reports have limited value, as many provide evidence of how surgeons handled rare occurrences; generally, results have more prognostic value the more patients who participated in the study.
- Study did not duplicate data from another publication – Researchers often publish data on the same cohort at multiple time periods. Repeating this data twice is misleading, however. Depending on what you believe has the most value, only include data from the largest patient cohort or from the study with the longest follow-up period, but be sure to state your reasoning for this choice.

Table 1 – Example of a table documenting the search process

PubMed search terms	Studies uncovered	Studies excluded	Reasons for exclusion	Studies included
NEW Cup, hip, uncemented	5	4	Wrong device/clinical area (4)	1 (Henderson, 2009)
Original Cup, hip, uncemented, Corporate Ltd.	7	2	Chinese language (1), Case report (1)	5 (Smith, 2003; Adams, 2008; Yu, 2014; Godard, 2012; Marker, 2011)
X1298 Cup, hip	4	0	0	4 (Marcus, 2013; Duval, 2003; Gill, 2008; Paterson, 2002)

You may find that you want additional inclusion/exclusion criteria depending on your needs. For example, if there are over 50 studies with your device of interest, it may be better to include only those with five or more years of follow-up, which would produce a higher-quality long-term analysis for a device intended to be permanently implanted.

Now you must pick a database, or multiple databases, for searching the literature. There are several that are available, and each has their respective strengths and weaknesses. For example, the Google Scholar database is extremely wide-ranging, but often uncovers lower-quality data from non-published materials (i.e. non-peer-reviewed documents) that have not been vetted with the same care as they would if they appeared in a journal. Conversely, the PubMed database is more selective in that it only deals with published data; however, unlike Google Scholar, which searches the entire text of an article for a search term, PubMed will generally only uncover search terms if they appear in a study abstract, which may overlook important studies.

It is not sufficient to explain that you have conducted a search and uncovered a certain number of studies for inclusion. Instead, you must record the particulars of your search in a specific enough manner that, if necessary, it could be recreated with the same criteria. Table 1 shows how you might record your search, accounting for exclusions. Please note that Appendix B of the MEDDEV 2.7.1. Rev. 3 guidelines, provides an alternative example of a diagram that accomplishes the same goals.

You may notice that different search terms were used for each product. This was done to account for differences in the products. We will pretend that the NEW Cup has both a cemented and uncemented version. As this CER is exclusively for the uncemented version, we've included the search term 'uncemented' to narrow the search. With the 'Original Cup,' the terms are so generic that they would threaten to overwhelm the search by uncovering thousands of hits (given the commonality of the term 'Original' in such articles). Therefore, we've narrowed the search by adding the name of the cup's fake manufacturer: Corporate Ltd. With our final device, the 'X1298 Cup' the search term is so specific that it does not need to be limited with additional terms beyond the word 'hip.' It may not be necessary to create such differences in your own search, but it may prove helpful if you encounter a similar problem.

Step 3: Assessing the data

Now that we have located 10 studies in total that meet our inclusion/exclusion criteria, we will assess their overall quality. This is required because each set of data necessarily varies in terms of its quality. For example, randomized studies with large patient groups and long-term follow-ups are known to provide very high-quality data, whereas retrospective case series with limited patient numbers and short follow-up times have their value as well but it is noticeably reduced in comparison with the former. Providing an analysis of this data allows you (and later the reviewer) to determine how much merit can be placed upon the data and conclusions made.

There are a variety of ways to assess data. However, this is also one of the few instances where the MEDDEV guidelines provide us with a specific example of how to do so (found in Appendix C and D of the guidelines). As such

Assessing the data



examples are rare in the guidelines, it is a good practice to take advantage of them. Here is an abbreviated version of the example in Appendix D.

As an example, we'll take the study uncovered with the NEW Cup, the device of interest, which has a short follow-up time of two years but is used in a representative population for the intended use of total hip arthroplasty. With the criteria shown in Table 2, this would be recorded as, 'Henderson 2009: D1/A1/P1/F2.' This assessment can be made for every published clinical study included in the analysis.

Table 2 – An abbreviated version of Appendix C and D in the MEDDEV Guidelines

Suitability criteria	Description	Grading system
Appropriate device	Was the data generated from the device in question?	D1 Actual device D2 Equivalent device D3 Other device
Appropriate device application	Was the device used for the same intended use (e.g. methods of deployment, application, etc.)?	A1 Same use A2 Minor deviation A3 Major deviation
Appropriate patient group	Was the data generated from a patient group that is representative of the intended treatment population (e.g. age, sex, etc.) and clinical condition (i.e. disease, including state and severity)?	P1 Applicable P2 Limited P3 Different population
Follow-up	Is the duration of follow-up long enough to assess whether duration of treatment effects and identify complications?	F1 Yes F2 No

Step 4: Analysing the data

It is now necessary to present the study results for analysis in terms of their safety and performance. The first challenge you will be presented with is that the types and quality of clinical data vary widely from study to study. Some studies will provide only clinical outcome scores but no radiographic data, whereas others will concentrate solely on one endpoint such as the survival of the device, and still others will include nearly everything imaginable.

Risk management plays an important role in the clinical evaluation. When done correctly, risk management is performed by a multidisciplinary team, which should also include a clinician, or the clinical writer. Through the risk management process, key clinical risks can be identified, evaluated and control measures put in place. The CER should consider the potential risks posed by the device that have been identified in the risk management report. For instance, uncemented cups (such as with our example NEW Cup), may pose an increased risk of early dislocation due to mal-positioning. It will therefore be necessary to check all studies for this endpoint, as specific risks from the risk management report would need to be addressed in the conclusion of the CER. Outlining the key specific risks at the beginning of the data analysis section will allow the reviewer to more effectively follow along with your analysis.

It is also necessary to provide relevant details on the study population, such as their mean age, diagnoses, the amount of time they were followed, etc. Providing this, outcomes related to the risks, intended purpose, and general information on major outcomes and adverse events (with a particular eye towards serious adverse events), should be sufficient.

You have one major question remaining, which is how exactly you will choose to summarize your results. This varies considerably according to personal preferences. The two general ways in which data can be conveyed in a CER, as well as the pros and cons of each approach, are as follows:

1. Text-based summaries of individual studies or of individual endpoints;
 - Pros: Allows for comprehensive discussion of all studies; assures that no detail will be overlooked.
 - Cons: Can be time-consuming for established products with considerable data; difficult to come to a conclusion about overall safety/performance if all studies are presented separately; final product can be too in-depth and difficult for reviewers to clearly interpret.
2. Visual summaries of pooled data;
 - Pros: Presents pooled data on individual endpoints in easy-to-digest manner through graphs, figures, and other descriptive imagery; allows for better understanding of overall device performance.
 - Cons: Easy to make errors when pooling data without the aid of trained statisticians; nuance can be lost; does not add much value when there is limited data to present.

Table 3 – Presentation of individual study data with pooled data calculated at the bottom

Author, year/ Device	Number of hips	Mean patient age	Diagnoses	Mean follow-up [months]	Harris hip score, pre-op/ post-op	Number of dislocated cups [%]	Cups revised
Henderson 2009/NEW Cup	20	40	10 osteoarthritis, 10 fracture	24	25/85	0 (0 %)	1 (5 %)
Smith 2003/ Original Cup	50	50	25 osteoarthritis, 25 fracture	60	40/80	2 (4 %)	0 (0 %)
Duval 2003/ X1298 Cup	100	60	50 osteoarthritis, 50 fracture	120	30/90	1 (1 %)	3 (3 %)
Overall results (Mean, total, etc.)	170	54.7	50 % osteoarthritis/ 50 % fracture	91	32.3/86.5	3 (1.76 %)	4 (2.35 %)

A compromise between these two techniques is the presentation of individual study data in tabular form, with pooled data calculated at the bottom, as shown in Table 3.

Please note that the MEDDEV guidelines do not explicitly require the aggregation of data. If you do decide to relate your findings in this manner, it is up to you which techniques you use (e.g. meta-analysis techniques or weighted averages). The important thing is that you clearly define your methodology upfront and then follow through with it.

Step 5: Conclusions

After you've presented your results, it is necessary to evaluate them in greater depth. This is similar to the discussion section of a published study, where the results are contextualized in terms of the larger picture of the device. It is best to begin by directly addressing the potential risks outlined in the Device Failure Modes Effects Analysis, and relating if and how they have been addressed and mitigated by the clinical data. After considering these, as well as any new risks encountered during the clinical evaluation, you are able to offer a final assessment.

According to the MEDDEV guidelines, it is necessary to offer a clear conclusion that 'the clinical evidence demonstrates conformity with the relevant ERs; the performance and safety of the device as claimed have been established; and the risks associated with the use of the device are acceptable when weighed against the benefits to the patient.' Conversely, if no such conclusion can be made, it will be necessary to generate new or additional clinical data to support these claims.

Other data

Although this overview concentrates on data from the published literature, it is essential not to overlook the inclusion of other clinical findings relevant to the safety and performance of your device. Here are some brief suggestions for how to handle each of these types of data:

1. Internal data (from ongoing post-market clinical follow-up (PMCF) studies, for example);
 - Contact those within your company with the greatest knowledge of the device. They will usually be able to point you to internal study data that has accumulated over the years. This could be in the form of abstracts from international medical meetings, reports offering updates on ongoing clinical studies, presentations by experts or health care professionals, etc.
 - Surveys (contact clinical or marketing professionals in your company and see if they conducted clinical surveys on the product after its launch).
 - Google Scholar is also good for tracking down data sets outside of the conventional literature. However, if you uncover any such studies in this manner, be sure to record this fact in your search results.
 - Always double-check that internal data has not been published in the interim. It is common to first present results in abstracts and other venues, prior to publishing them in journals. Repeating findings in both the literature section and the internal data section is unnecessary.
2. Complaint data;
 - Your company should have a department that specifically deals with obtaining ongoing complaints data with your device. Contact that department and ask them to provide the most up-to-date information for your report.
3. Registry data;
 - A number of registries have been set up around the globe to record device-specific outcomes. However, the quality of these registries varies considerably. If you decide to exclude certain types (e.g. non-English language reports), please provide a specific methodology for how and why you did so.

As a general rule, the less published data there is available with your device or equivalent devices, the greater should be your effort to provide these supplementary findings. Once obtained, the data can be analysed in a similar manner to the way in which it was in Step 4 of this example (when applicable).

The notified body perspective

This paper has focused primarily on the requirements for the clinical evaluation. This part of the paper will give a very brief overview of the notified body (NB) assessment of clinical data, and the focus of NB assessments under the upcoming regulations.

The role of the NB is simply to conduct conformity assessments against the ERs laid out in the Directive. For the evaluation of clinical data, the requirements are set out explicitly in Annex X, with further guidance in MEDDEV 2.7.1.

First of all, it is important to note that clinical data is required for all medical devices. The NB will verify the manufacturer's presentation and evaluation of the clinical data. In addition to that, the NB will examine the manufacturer's continuous monitoring/gathering of clinical data to validate the claims of the subject device.

The source of the clinical data is important, which should either be from the results of a clinical investigation, or from the literature of the subject device or an equivalent device. In the case where equivalence is claimed, the manufacturer must demonstrate equivalency. Pre-CE marking, for implantable or Class III devices in particular, if the source of clinical data is not from a clinical investigation (i.e. only the literature route used), then a justification must be given for not conducting a clinical investigation. In these situations, the NB will focus on the manufacturer's post-market surveillance plans, which should include a PMCF study. The PMCF study is another crucial source of clinical data.

In Annex I of the recently published 'Commission Recommendation on the Audits and Assessments Performed by Notified Bodies in the Field of Medical Devices (2013/473/EU)', the key focus areas for NB assessment are described. These are:

- review of the clinical evaluation and the PMCF undertaken or planned by the manufacturer;
- verification that the clinical evaluation is up to date;
- assessment of the need for and the appropriateness of a PMCF plan;
- if no clinical investigation has been undertaken, the NB should verify that the subject device and its associated risks are appropriately assessed by means of scientific literature or other existing clinical data. Furthermore, NBs will need to examine the special justifications for implantable and Class III devices.

Therefore, the key concepts that manufacturers should always have in mind when writing their clinical evaluation report are as follows:

- **Clinical data:** This is always required for all devices and classification. The manufacturer is expected to critically evaluate this clinical data. The data presented should support whatever claims, different indications and design variants.
- **Clinical investigation:** This should always be considered. Where a clinical investigation is deemed to be not necessary, then a justification needs to be provided. For some low risk devices, it is possible that pre-clinical testing could be utilized in lieu of clinical data, to support safety of the device. This must be justified.
- **Equivalence:** This is not just stating what is similar, but also addressing the differences and evaluating the impact of the differences on the clinical safety and performance.
- **Post-market clinical follow-up:** This should always be considered, especially for Class III and implantable devices. If not being performed, then a justification must be made and documented. This justification must be reasonable (for example, device has been on the market for 20 years, with actual clinical data on the device in question. This is difficult to justify if there is no data at all on the device, even if on the market for 20 years).
- **Conclusion:** Any conclusion on the safety and performance of the subject device must be based on the clinical data presented, the evaluation of the risks versus the benefits of the subject device, when used for its intended purpose.

Final recommendations

The CER is an important and integral part of the conformity assessment of a medical device. Their production can be time-consuming and stressful, depending on the scope of the evaluation required. However, over time you will find the techniques that work best for your specific devices, and will eventually be able to develop a template that reflects your unique needs. On the way to getting there, please remember these quick recommendations that will help lessen your burden:

- **Refer to the most recent MEDDEV guidelines**
 - Prior to creating your CER, be sure to closely read through the MEDDEV guidelines. Appendix E of these guidelines outlines a suggested format for creating a CER. Additionally, Appendix F provides a checklist for use by an NB during the assessment of a CER. Evaluating your work against this checklist will allow you to ensure that all the basic requirements have been met.
- **Give yourself time**
 - There are a number of unexpected delays that can develop in the process of creating a CER, from waiting on internal requests to be answered within your company to slow delivery of clinical data from the investigational sites. It is best to begin work well in advance of your deadline.
- **Remember you are part of a team**
 - The actual writing and preparation of the CER may fall to one person (clinical expert and writer), but it should always include the input, feedback, advice, and oversight of a multidisciplinary team of experts within the company who know this device best. Take advantage of their expertise, and build in an extended review period at the end of your timeline so that these team members can have time to appraise your first draft.
- **Be methodical and remain objective**
 - Rather than setting out to win an argument on behalf of your product, be sure to keep an open mind and let the results take you to your own conclusion. Bias will only lead to more problems down the road, and it is better for all involved if problems are dealt with quickly upfront.
- **Remember that the CER is a living document**
 - A CER needs regular updates incorporating new clinical data and findings from PMCF studies and/or publications.

Finally, this is an interesting time to be involved with medical device regulations in Europe. The current regulations are now undergoing a significant step change in their two decades of existence. One of the key focus areas is the ever-increasing emphasis on clinical data. Decisions and conclusions made by the manufacturer on the safety and performance of their devices must be made based on clinical data. The draft Medical Device Regulation (published September 2012), reinforces the current requirements and guidance on clinical evaluation. Furthermore, there will be a noticeable increase in the level of scrutiny in the assessment of clinical evaluations by the Competent Authorities and the NBs.

BSI is grateful for the help of the following people in the development of the white paper series.

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Mike is a Visiting Lecturer/Honorary Academic for the Medical Device Design Masters Degree Program at the University of Auckland, New Zealand, has held the position of Secretary for IEC Subcommittee 62D since 1997 and has been a technical expert and working group in the IEC since 1992. Mr Schmidt is currently the Co-Chair of the AAMI Electrical Safety Committee.

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Published white papers

The Proposed EU Regulations for Medical and In Vitro Diagnostic Devices – An Overview of the Likely Outcomes and the Consequences for the Market – Gert Bos and Erik Vollebregt

Forthcoming white papers

The Digital Patient, Kristin Bayley, Laura Mitchell and Sharmila Gardner (May, 2014)

Unique Device Identification (working title), Jay Crowley (June, 2014)

Post-market Surveillance (working title), Ibim Tariah (July, 2014)

Usability Engineering (working title), Edmond Israelski (August, 2014)

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