GMED LNE GROUP Newsletter

N°8 | JULY 2022

Version Française

SUMMARY OF SAFETY AND CLINICAL PERFORMANCE (SSCP): 5 CHALLENGES TO BE MET

The Summary of Safety and Clinical Performance (SSCP) is a requirement under the Regulation (EU) 2017/745 for class III and implantable devices other than custom-made or investigational devices. The requirement is outlined in article 32 of the Medical Device Regulation (MDR) along with some of the expectations for content. The SSCP is available to the public via the EU database system EUDAMED. The EU medical device regulators have implemented this requirement to allow public access to up-to-date clinical safety and performance data for higher risk devices. The intention is to provide patients, healthcare providers, and the public a summary of the clinical data, thus enhancing transparency and creating a higher level of confidence in the clinical data on which CE Mark decisions are based.

In August of 2019 the Medical Device Coordination Group (MDCG) published a guidance document, MDCG 2019-9[1] (revised in March 2022), to aid manufacturers in compiling the information required for the SSCP. It includes general requirements and recommendations for the SSCP, along with guidance and clarifications for each of the sections. Overall, manufacturers who follow this guidance closely should be able to produce SSCPs with minimal questions coming from the Notified Body that comply with Regulation (EU) 2017/745. However, there will be questions involving interpretation as well as the depth and extent of information to be provided.

[1] *MDCG 2019-9 Rev. 1: Summary of safety and clinical performance, A guide for manufacturers and notified bodies (March 2022)*

In order to help medical device manufacturers better anticipate and prepare for the SSCP submissions, GMED teams have identified 5 pitfalls to avoid:

- Inconsistencies between SSCP and Clinical Evaluation Report (CER);
- Lack of complete PMS (Post-Marketing Surveillance) data for legacy devices;
- Lack of a Basic UDI-DI;
- Parallel problems between SSCP and CER;
- Residual risks not quantified and/or no relation to time.

These are discussed in further detail below.

A INCONSISTENCIES BETWEEN SSCP AND CER

One of the primary responsibilities of the notified body during the review of the SSCP is to validate the content to ensure that it accurately represents the device in terms of overall clinical safety and performance. To do this, the notified body will compare the SSCP closely to the information submitted in the CER. As an example of one problem in this area, a manufacturer may present only information from one clinical trial in the SSCP, although the CER included clinical data from many other sources. As another example, one common issue we have noticed is that the SSCP does not contain sufficient details regarding PMCF (Post-Market Clinical Follow-Up). The manufacturer should be certain that the provisions for PMCF are completely described within the SSCP, following Section 5.5 of the MDCG 2019-9 Rev. 1.
The manufacturer should always be sure that the information contained in the SSCP and CER are consistent.

B LACK OF COMPLETE PMS DATA FOR LEGACY DEVICES

For devices that were approved previously under the Medical Device Directive (MDD), it is important to include all available PMS data starting with the initial CE Mark. For instance, if your device was approved under the MDD in 2010 and now you are applying for MDR certification, it is expected that PMS data be provided going all the way back to 2010. This is necessary so that all stakeholders can have a full picture of the device's history.

C LACK OF A BASIC UDI-DI

The Basic UDI-DI is the main key in the EUDAMED database, and therefore all SSCPs must have at least one Basic UDI-DI. However, one common nonconformity is that of the SSCP missing a Basic UDI-DI. All UDI-DIs/devices associated with this Basic UDI-DI will be understood to have the same SSCP. A UDI-DI/device must always be associated with one and only one Basic UDI-DI. Some issues may arise if the device is part of a system of several components/devices. In this case, each device in the system should have a Basic UDI-DI but also one Basic UDI-DI for the whole system. In this instance, it will be the system Basic UDI-DI that should be provided in Section 1.4 of the SSCP template provided in MDCG 2019-9 Rev. 1. The device system, and any Basic UDI-DIs of included devices, should be described in section 3.1 of the SSCP. More information on this requirement can be found in Section 3.1 of MDCG 2019-9 Rev. 1.

D PARALLEL CONCERNS BETWEEN SSCP AND CER

Keep in mind that whatever concerns are identified in the CER will likely also be found with your SSCP, assuming they were created in alignment with each other. For instance, if it was raised within the CER that the intended patient population was not properly identified, then it is likely that your SSCP will have the same lack. The good news is that once this is corrected within the CER it will be easy to correct for the SSCP.

E RESIDUAL RISKS NOT QUANTIFIED AND/OR NO RELATION TO TIME

The SSCP should list all relevant residual risks and undesirable effects, and these should be in complete alignment with the Instructions for Use (IFU) and CER. The probability of occurrence of the risks should be identified, along with the timepoint to which the numbers relate. The idea is to inform healthcare professionals or patients how likely this event will occur over a time period.
As an example, an adverse event frequently encountered after the implantation of an abdominal aortic endoprosthesis is the endoleak (type I, type II or type III). Type II endoleaks are the earliest and most frequent, with rates between 10.4% and 29.9% at 1 year post implantation.
However, in some cases, this information may not be fully described in the source of data, such as data from state-of-the-art literature where timepoint may not be detailed.
It is important as the MDCG specifies to detail from which source, the data is generated and/or collected, and to highlight depending on the source of data if the events might be under-reported or over-reported. For example, data coming from spontaneously reported incidents might be underestimated, or data coming from a clinical study in which the target population is more likely to encounter this event might be overestimated.
This is discussed in more detail in Section 4.1 of MDCG 2019-9 Rev. 1.

.

Conclusion

These are just a few examples provided to help manufacturers fine-tune their SSCPs to prevent possible nonconformities.

Please also remember that the SSCP document is intended for both healthcare professionals and, when relevant, patients. The version created for patients should avoid highly specialized language. Again, the intention is to make available to the public the latest data on clinical performance and safety in a way that is accessible and easily understood.

To go further

TRAINING FOR NORTH AMERICA REGION

The Clinical Evaluation Requirements (CER) under the EU MDR 2017/745
1-day training session | Virtual Classroom | July 11, 2022

→ CHECK OUT THE PROGRAM AND REGISTER

TRAINING FOR EUROPE AND OTHER PART OF THE WORLD (EXCL. US)

Understand the regulatory requirements of the clinical evaluation and the post-market clinical follow-up
SA65 | 1-day training session | On demand

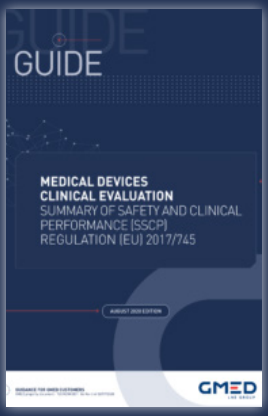
Clinical evaluation of medical devices using the literature route
SA09 | 1-day training session | On demand

Clinical evaluation of medical devices using the clinical investigation route
SA26 | 1-day training session | On demand

→ CONTACT GMED TRAINING CENTER

GUIDE

Medical Devices Clinical Evaluation – Summary of Safety and Clinical Performance (SSCP) – Regulation (EU) 2017/745



It is the manufacturer's responsibility to specify and justify the level of clinical evidence necessary to demonstrate conformity with the relevant general safety and performance requirements under Regulation (EU) 2017/745.

This guide recalls the principles of clinical evaluation and describes the different elements to be included in:

- The clinical evaluation plan
- The clinical evaluation report
- The post-market surveillance plan including the post-market clinical follow-up (PMCF) plan
- The PMCF evaluation report

All these documents are part of the technical documentation, within the framework of CE marking procedures for medical devices, regardless of the medical device class

→ DOWNLOAD THE GUIDE

Newsletter

Do not miss the latest updates of the Medical Device Industry

Subscribe

→ HEADQUARTERS

GMED SAS
1 rue Gaston Boissier
75015 PARIS • FRANCE
+33 (0)1 40 43 37 00
info@lne-gmed.com

→ FRENCH REGIONAL OFFICE

GMED SAS
19 D rue de la Télématique
42000 SAINT-ETIENNE • FRANCE
+33 (0)4 77 10 11 11

→ NORTH AMERICAN SUBSIDIARY

GMED NORTH AMERICA, INC
6550 Rock Spring Drive - Suite # 280
BETHESDA, MD 20817 • USA
+1 (301) 495 0477
gmedna@lne-gmed.com