Fact Sheet

Understanding Key Safety and Clinical Performance Regulations for Medical Devices

Comprehensive regulatory support to drive medtech innovation forward

What is summary of safety and clinical performance?

The Summary of Safety and Clinical Performance (SSCP) is one of the new requirements imposed by the European Commission in Medical Device Regulations (MDR) 2017/745 for implantable devices and class III devices, other than custom-made or investigational devices[1]. As per the Medical Device Coordination Group (MDCG): "This document is one of several means intended to fulfil the objectives of the MDR to enhance transparency and provide adequate access to information"[2].

EU MDR Article 32: Summary of Safety and Performance provides a brief overview of the contents of the SSCP. However, "Summary of safety and clinical performance: A guide for manufacturers and notified bodies," was published by the MDCG in August 2019. MDCG 2019-9 Revision 1 provides a comprehensive list of recommendations along with structured templates for SSCPs that can be readily used by the manufacturers.

A precise and well-written SSCP aims to provide all necessary information and up-to-date device specific information to the defined user group. An SSCP in general is written in two formats/versions each one aimed at a specific user group: a) Healthcare Professionals and b) Patients or lay persons. The language and the presentation of the data in both these sections/documents vary as they are tailored to audiences of diverse understanding levels.

It is important to note that the SSCP does not replace the implant card or instructions for use associated with the device. SSCPs should not be used to give general advice on the management of medical conditions. The primary focus of this document should be on device specific safety and performance which encompasses both the favourable and unfavourable data[2].

EUDAMED ROLLOUT OF SUMMARY OF SAFETY AND CLINICAL PERFORMANCE

The European database on medical devices (EUDAMED) is a key element of the new rules on medical devices. Up until now, the access to the technical file was limited to the quality management system of the manufacturer. However, a stern initiative by EU MDR now aims to increase transparency allowing some data to be available for public retrieval.

As per the European Commission website on EUDAMED[3]: "EUDAMED aims to enhance overall transparency, including through better access to information for the public and healthcare professionals, and to enhance coordination between the different member states in the EU".

This step is intended to provide healthcare providers with current data on the device and directly compare it with the competitor's device, allowing them to make informed decisions for patient treatment options. It also enables patients with suitable information specifically pertaining to devices risks, adverse events as well as favourable and unfavourable clinical data for a guided decision-making.

CHALLENGES FACED WHILE WRITING SUMMARY OF SAFETY AND CLINICAL PERFORMANCE

- Accuracy and completeness in presentation of data harmonized with medical device technical file specifically the clinical evaluation report and periodic safety update report
- Clarity and simplicity of language for data presented in SSCP for Patients
- Enhanced readability of the content for apt understanding without having prior knowledge of the medical field
- The focus of the document should be on factual data, promotional materials especially claim, and unique selling features are not to be included in the SSCP
- Quantification of risk/adverse event in terms of its frequency over time

KEY FACTORS THAT THE MANUFACTURER SHOULD TAKE INTO CONSIDERATION WHILE WRITING A SUMMARY OF SAFETY AND CLINICAL PERFORMANCE

The data captured in the SSCPs should always be directly sourced from the technical documentation file (TDF), also, including the instructions for use, clinical evaluation report and periodic safety update report.

Comprehensive information presented alongside or with the implant card (as per Article 18 MDR 2017/745) should be harmonized and aligned with the contents of the SSCP. Article 18 of EU MDR mandates that the device specific information should be readily understood by a lay person and shall be updated where appropriate[1]. To harmonize contents across the MDTF including the SSCPs, it becomes obligatory to align the information presented in the section/ document of SSCP for patient and the implant card.

As the SSCP for patient is targeted for individuals with limited understanding of the medical discipline, MDCG 2019-9 also recommends that the readability of the written content presented in the SSCP for Patients should be confirmed using a readability test given to laypeople or using another adequate method[2].

It is highly recommended that the SSCPs undergo a review by a legal team, or a claims manager appointed within the regulatory compliance team of the manufacturer.

The SSCPs must be made available in all accepted languages of the member states where the device is to be sold and in english. The manufacturer should ensure the accuracy of translations as well the SSCP should clearly state the language in which it was validated by the Notified Body (NB).

The SSCP is uploaded on EUDAMED following NB review and validation of the document. The manufacturers are obligated to update the SSCP, at least annually, in accordance with the new information obtained in the post market clinical follow-up report or the periodic safety update report. This ensures accuracy of the clinical data and safety information presented in the document.

Why use IQVIA MedTech for SSCPs?

IQVIA MedTech takes pride in its proven track record with regulatory document preparation and regulatory authority submissions in varied therapeutic areas. Backed up by years of experience and an extensive knowledge of the EU MDR, IQVIA MedTech can help you prepare an entire portfolio of documents including but not limited to clinical evaluation plans, clinical evaluation reports, and summary of safety and clinical performance. As a first step in the process, we can help you identify the gaps in the TDF as per the requirements and the guidance, as set out in MDR 2017/745 and MEDDEV 2.7.1 Rev. 4. We can also review existing clinical evaluation reports against the MDR 2017/745, and MEDDEV 2.7.1 Rev. 4 and create a comprehensive proposal for development of SSCPs.

WORKING WITH YOU, IQVIA MEDTECH CAN:

- Create SSCPs from scratch and help achieve agreement with your NB
- Author full product CER and SSCPs or provide updates to CERs and/or SSCPs post review
- In-house availability of medical writing expertise necessary to meet the challenges of writing the SSCPs for both technical and lay readers
- Know-how to fine tune the SSCPs to enhance the readability scale for lay people
- Support manufacturers who are currently reviewing internal procedures to ensure all procedures are robust and address all regulatory requirements and guidance
- Provide advice on best practices for post-market surveillance and reviewing relevant data for the CER and SSCP update

References

1. REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC.
2. MDCG 2019-9 Rev 1 Summary of safety and clinical performance A guide for manufacturers and notified bodies.
3. Webpage: https://ec.europa.eu/tools/eudamed/#/screen/home, Accessed on 21/04/2022.

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