bsi.

...making excellence a habit.™

Guidance on MDCG 2019-9: Summary of Safety and Clinical Performance

Author - Amie Smirthwaite

Contents

1 Introduction 3
2 Background: why was the requirement for an SSCP introduced? 4
3 Purpose of the SSCP and key requirements 4
4 Structure and content of the SSCP 6
4.1 General 6
4.2 Device identification and general information 6
4.3 Intended use of the device 7
4.4 Device description 7
4.5 Risks and warnings 8
4.6 Summary of clinical evaluation and post-market clinical follow-up (PMCF) 9
4.7 Possible diagnostic or therapeutic alternatives 10
4.8 Suggested profile and training for users 11
4.9 Reference to any harmonized standards and common specifications applied 11
5 What's the best way to test for readability of the patient-specific SSCP? 12
6 Validation by the notified body 12
7. Potential pitfalls 13
8. Potential application for SSP under IVDR? 13
9. Summary and conclusions 13
10 Acronyms 14

1. Introduction

The Summary of Safety and Clinical Performance (SSCP) is a new requirement under the European Medical Devices Regulation 2017/745 (EU MDR), applicable to Class III and implantable devices. It summarizes the evidence for the safety, performance and clinical benefit of the device in light of its intended purpose, and places this in the context of outcomes achievable with other diagnostic or therapeutic alternatives for the same patient population. The SSCP forms part of the technical documentation; following validation by a notified body it will be uploaded to Eudamed, where it will be publicly available to professional and lay persons.

The public nature of the document, and the specificity of the requirements for disclosure of clinical evidence, adverse event and risk data are a source of concern for some manufacturers. With the exception of the SSCP, user information included in the technical documentation such as the IFU (information for use), surgical technique brochures and implant cards, are not required to directly reference the objective evidence for safety, performance and clinical benefit. Neither are other forms of user communication, such as marketing brochures, websites and apps. In particular, the SSCP must summarize unfavourable as well as favourable data; i.e. it is intended not just to demonstrate that the device is safe and effective but also to highlight residual risks and potential safety or performance concerns, and how these have been mitigated. The publication of the SSCP on Eudamed will also allow a direct comparison of the clinical evidence available for similar competitor devices. This positioning of the SSCP, as a publicly available document with very specific requirements for objectivity and transparency, may present challenges to manufacturers as to how to achieve regulatory compliance within the framework of the associated marketing, legal and commercial implications.

The basic requirements for the SSCP are described in Article 32 of the EU MDR. Further guidance was issued by the Medical Device Coordination Group (MDCG) in August 2019: MDCG 2019-9 Summary of safety and clinical performance – A guide for manufacturers and notified bodies. Although the MDCG guidance is careful to distinguish between requirements and recommendations ('shall' = requirement arising directly from the MDR, 'should' = recommendation based on the expert group's interpretation of that requirement), it represents current best practice, and regulators will look for conformity with all of its recommendations. This White Paper explains the purpose and contextual background of the SSCP and summarizes the key requirements and recommendations from the MDR and MDCG 2019-9 guidance.

2. Background: why was the requirement for an SSCP introduced?

The MDR was drafted following a number of high-profile medical device failures which received significant media attention. The subsequent investigations undertaken by EU Member States identified two recurring themes, both of which are indirectly related to transparency. These were considered fundamental weaknesses of the existing European Medical Devices Directive 93/42/EEC (EU MDD) and European Active Implantable Medical Devices Directive (EU AIMDD), which needed to be corrected by new instruments in the EU MDR. One of these themes was focused on the perception within the medical community that insufficient clinical expertise was involved in regulatory decision-making. Associated with this was an acknowledgement that objective criteria and clinical benchmarks upon which to make these decisions were often lacking or poorly defined. The other theme was related to access to information. For example, if the clinical evidence available in the public domain for a given device seemed inadequate, clinical stakeholders may have approached the notified body or competent authority responsible, expecting to get a better understanding of the basis for certification. However, under EU MDD, none of this information could be disclosed without the manufacturer's consent. Similarly, patients suffering the consequences of a device failure would have struggled to obtain further information if not readily disclosed by the manufacturer.

These challenges related to transparency are due to confidentiality clauses common to all EU Directives and Regulations. Under the EU MDD, notified bodies cannot legally disclose any information provided to them as part of a conformity assessment, including information relating to the evidence for safety, performance and clinical benefit of a device. Although this prohibition is not changed under the EU MDR, there are several new provisions to increase transparency and access to information. The foundation for these instruments is encapsulated in the recitals. With respect to the SSCP, Recital 43 is particularly relevant:

> "(43) Transparency and adequate access to information, appropriately presented for the intended user, are essential in the public interest, to protect public health, to empower patients and healthcare professionals and to enable them to make informed decisions, to provide a sound basis for regulatory decision-making and to build confidence in the regulatory system."

The SSCP is therefore one means by which the objectives of Recital 43 of the EU MDR are intended to be fulfilled.

3. Purpose of the SSCP and key requirements

One of the most important things to understand about the SSCP is that, although the SSCP will be assessed and validated by notified bodies, the notified body is not the intended audience. The intended audience is the end user (clinicians and, if relevant, patients).

In the context described above, the associated objectives of the SSCP are:

- greater transparency of information to healthcare providers, to give them confidence that they are presenting the best treatment options and making the right decisions for their patients
- empowerment to patients, to give them the information they need to be able to discuss available treatment options with their clinician and guide their decision-making

Because lay persons may not have the depth of technical or clinical knowledge required to understand an SSCP intended for professional users, Article 32 specifies that, 'if relevant', the SSCP should be clear to patients. MDCG 2019-9 indicates that this requirement should be met with a separate, patient-specific SSCP. 'If relevant' is interpreted to apply to:

- implantable devices requiring implant cards
- class III devices intended to be used directly by patients
- any other device where the manufacturer considers it relevant to provide specific information for patients

Underpinning these broad objectives of transparency and empowerment are fundamental principles related to accuracy, completeness, scientific validity of conclusions and clarity.

In terms of accuracy and completeness, the SSCP will be assessed to ensure that it adequately reflects the totality of the clinical evidence. This does not necessarily mean that every single data point must be discussed in exhaustive detail, but rather that the evidence presented appropriately reflects its weighting and does not skew interpretation by selective omission of data.

The terms 'scientific validity' and 'scientific validity of conclusions' are not used in the MDCG 2019-9 guidance, but they are ones that manufacturers and regulators should be familiar with from MEDDEV 2.7/1 rev. 4. This terminology is used in Annex XV of the EU MDR and some of the subsequent MDCG guidance documents (e.g. MDCG 2020-5, MDCG 2020-6, MDCG 2020-13). It frames regulator expectations and is a core principle woven into almost every aspect of the EU MDR clinical evidence requirements. In brief, it implies that the objective evidence provided is sufficient in terms of quantity and quality to support the conclusions drawn. Although scientific validity is primarily demonstrated in the clinical evaluation report (CER) and other parts of the technical documentation that will not be publicly available, the notified body reviewer will cross-reference the data presented in the SSCP against the data appraised and evaluated in the CER. Data sets which are not considered to meet acceptable thresholds for scientific validity would not normally be expected to be included in an SSCP.

MDCG 2019-9 is somewhat unusual in comparison to many other European guidance documents in that it includes many stylistic recommendations. These are intended to enhance clarity. For example, the guidance recommends that the medical terms in the patient-specific SSCP are first described in lay language followed by the appropriate medical term in brackets. It also cross-references other guidance documents for clarity and simplicity of language, including the EU Commission guidance 'Summaries of Clinical Trial Results for Laypersons'. This latter guidance was developed to address requirements for lay summaries of clinical trials for medicinal substances, as set out in the EU Clinical Trials Regulation 536/2014. Cross-referencing this guidance reveals that many of the concepts have been transferred more or less directly into MDCG 2019-9. For example, the following requirements from MDCG 2019-9 are based on guidance in the 'Summaries of Clinical Trial Results for Laypersons':

- don't assume any prior knowledge of medical terminology or clinical research in general, and follow principles of health literacy and numeracy
- ensure the layout and content is suitable for the patient in terms of style, language and literacy level
- focus on factual information and do not include content of a promotional nature
- aim for clarity and brevity – long, poorly organized documents can be as difficult to understand as jargon-packed documents
- test for readability of the document (e.g. by a test given to lay persons)

Although these are some of the core principles, 'Summaries of Clinical Trial Results for Laypersons' provides much more detail and should be referenced alongside MDCG 2019-9.

4. Structure and content of the SSCP

4.1. General

The minimum content elements of the SSCP are described in Article 32(2) of the EU MDR. These have been slightly restructured in the MDCG 2019-9 templates. For the SSCP intended for the clinician, the top-level headings are:

1. Device identification and general information;
2. Intended use of the device;
3. Device description;
4. Risks and warnings;
5. Summary of clinical evaluation and Post-Market Clinical Follow-up (PMCF);
6. Possible diagnostic or therapeutic alternatives;
7. Suggested profile and training for users;
8. Reference to any harmonized standards and common specifications applied.

These are essentially the same headings as listed in Article 32(2), but with information on risks and warnings moved up from item 8 in Article 32(2) to item 4 in the MDCG template. The guidance says that this change is intended to improve the narrative flow, but it also reflects the relative importance of each topic to a clinical user – risks and warnings were considered to be of greater interest to the average clinical user than (for example) reference to harmonized standards or common specifications.

The patient-specific SSCP template in the guidance follows the same high level structure as the clinician SSCP, but does not include item 8: reference to harmonized standards and common specifications. This decision was taken to streamline the patient-specific SSCP and focus on the information most relevant to patient health, on the basis that the information is still available to more technically-oriented lay persons via the clinician SSCP.

4.2. Device identification and general information

The recommended content for the clinician SSCP is much more detailed in MDCG 2019-9 compared to the requirement in EU MDR Article 32(2a). This reflects the appeals from key opinion leaders in the medical community to give them access to information that would help in tracing the device – for example, if they wanted to find out more about adverse events. The notified body name was included to answer a frequent question that arose during the high-profile device failures alluded to in Section 2: 'Who is certifying these devices? How can we find them and where can we get more information?'

The information indicated for the patient-specific SSCP is more streamlined, and actually requires less than Article 32(2a). It does not, for example, request the manufacturer single registration number (SRN).

4.3. Intended use of the device

This section includes the intended purpose, specific indications and any contraindications or restrictions for use. It is interesting to note that Section 2 of the SSCP template has the 'intended purpose' and 'indication(s) and target populations(s)' as separate line items, whereas Article 32 of the EU MDR has these as a single line item. This may seem a small distinction, but it is significant: the intent was to address a perception that intended purpose statements frequently focus only on the function of the device (i.e. what it does) rather than on the specifics of the medical conditions and patients for whom the device should be used. Further, it was considered that indications were too broad for many devices under the EU MDD, allowing devices to be used for treatment indications, patient populations or anatomical locations where the benefit-risk conclusion was unclear or even unfavourable.

Intended purpose statements are under increased scrutiny from notified bodies. It is important to ensure that these are sufficiently specific to include only those indications for which a positive benefit-risk conclusion can be demonstrated with objective evidence. It is also important to ensure that the contraindications clearly define those conditions or patient populations, etc. for which the devices are not suitable. Depending on the type of device, the intended purpose may need to include details of the end stage or severity of disease, or specifics of the diagnosis.

4.4. Device description

The clinician SSCP should include detailed information about the device, its design history, materials of construction and accessories or devices it is intended to be used with. This section has three main objectives:

1. To enable an understanding of the device design principles, how it is used and how it achieves its intended effects. This includes an explanation of the reasons for specific design features – for example, if two devices in a family have different design features, what is the intent of a difference and when should one variant be used over another;
2. To allow the clinician to understand the evolution of the device design, including reasons for design changes and any factors which may have led to adverse events in the past, or which may indicate uncertainties with respect to clinical safety and performance in future;
3. To highlight materials or design features for which there may be a higher risk of 'unknown unknowns' due to the nature of their interaction with the body. These might include biological effects, such as those associated with medicinal substances or CMRs (carcinogenic, mutagenic or toxic to reproduction), or unanticipated effects associated with wear debris or cellular responses to the surface topography of an implant.

While the clinician SSCP requests very detailed information, the patient-specific version may be much simpler. The information in the patient-specific SSCP may be limited to the information the patient needs to understand the potential health impacts of the device.

4.5. Risks and warnings

This section has been a source of confusion for both manufacturers and regulators. Two key questions are:

- Does the requirement for disclosure of 'any' residual risks, as indicated in EU MDR Article 32(2h) and Section 4 of MDCG 2019-9, really mean disclosure of 'all' risks? Where should the manufacturer draw the line when disclosing risks?
- How can you quantify the probability of occurrence of harm when the source data do not lend themselves to interpretation?

The threshold for risk disclosure has been extensively debated. Because the Regulation is a legal document, guidance such as MDCG guidance cannot add to or amend the Regulation. The wording in Article 32(2h) is *'information on any residual risks and any undesirable effects, warnings and precautions'*. The word *'any'* implies *'all'*, and the guidance seems to reinforce this with the words *'i.e. no sort of residual risk or undesirable side-effect related to the device is excluded from disclosure'*. However, if taken literally, this could mean the inclusion of literally thousands of risks, many of which may be purely theoretical or highly improbable. Furthermore, GSPR 23.1(g) states that *'Residual risks which are required to be communicated to the user and/or other person shall be included as limitations, contra-indications, precautions or warnings in the information supplied by the manufacturer'*. This seems to suggest that there are two types of risks: those which must be communicated, and those which do not need to be communicated. The recommendation here would be to justify the level of reporting in relation to the relevance to patient and clinician, ensuring consistency with the IFU and conclusions of the CER.

The second point is equally tricky. The guidance recommends that risks be quantified in terms of frequency over time (i.e. *'How likely is it this will happen to me or my patient over a given time period?'*), but many sources of information on risks lack details necessary for this quantification. For example, adverse event databases do not typically provide information on usage frequency. On the other hand, more robust sources such as clinical study reports may be misleading: for example, the study may be focused on a specific patient population that is more prone to a given risk, and not representative of the general patient population. This links back to the quality of clinical evidence available to demonstrate device safety and performance: it should be sufficient to enable firm conclusions to be drawn. For some well-established, standard of care devices, it may be possible to extrapolate from state of the art data, but normally there would be an expectation that post-market surveillance mechanisms enable the collection of quantifiable data. Based on feedback from manufacturers and notified body reviewers, this is an area frequently identified for remediation by the notified body reviewers.

4.6. Summary of clinical evaluation and post-market clinical follow-up (PMCF)

This section is intended to allow the clinician and patient to understand the strength of clinical evidence supporting the device, particularly the extent of evidence available on the device itself and its variants. Four main areas of concern amongst the clinical community drove the requirements of this section:

- Over/inappropriate use of equivalence data. In part this concern was due to confusion of the EU model of equivalence with the FDA concept of 'substantial equivalence'. Under the FDA model, fairly significant design differences are allowed, providing that a conclusion of substantial equivalence regarding safety and effectiveness can be reached. Under the EU model, equivalence is much more strictly interpreted; it is also not sufficient for an equivalent device to simply exist – there must be 'sufficient clinical evidence' to demonstrate safety and performance of the claimed equivalent. These differences, and the belief that the EU and FDA models were the same, perpetuated the perception that there were many high risk devices on the EU market based on chains of equivalence which ultimately lead to no data.
- Level of clinical expertise involved in the notified body conformity assessment – i.e. did the assessment team have enough input from medical practitioners with experience of using these devices? Did the team include experts with device and clinical study experience to understand the pitfalls of clinical study design, and what 'good' safety and performance should look like for a given device?
- Insufficient evidence to support benefit-risk conclusions for all treatment indications included or implied by the intended use statement
- Inadequate post-market clinical follow-up

This is why the guidance for this section asks for the data to be grouped by source type (e.g. equivalence data, pre-market clinical investigations, post-market studies), and why it requests the UDI-DI of the equivalent device and link to its associated SSCP if available. This information enables clinicians to double-check the strength of evidence and basis of equivalence for themselves. It is also why the guidance requests a benefit-risk assessment for each individual treatment indication, so that potential gaps in the evidence can be more readily spotted.

Emphasis is placed on clinical benefits: i.e. the SSCP should not just demonstrate the device successfully performs its intended function. It should also demonstrate that there is an objective and measurable benefit to the patient of performing that intervention, and that the overall benefit-risk profile compares favourably to other state of the art treatment options. Equally, claims presented in the IFU or marketing literature must be substantiated.

Finally, it should be apparent to the reader that the PMCF mechanisms employed are appropriate in light of the strength of clinical evidence, residual risks and rate of change of the state of the art.

Depending on how the CER is structured, this section could be largely copy-pasted from the CER results and conclusions for the clinician SSCP. For the patient-specific SSCP, this section will need to be greatly simplified, following the principles described in the European guidance 'Summaries of Clinical Trial Results for Laypersons'.

4.7. Possible diagnostic or therapeutic alternatives

The intent of this section is fairly clear to enable clinicians and patients to see how well other treatment options perform in comparison to the subject device and to assist in deciding when this device would be preferable to these other options. Manufacturers sometimes find this section daunting: where is the dividing line between their own assessment of the device benefit-risk profile in relation to the state of the art versus clinical best practice guidelines issued by professional speciality medical societies? It may be helpful to reframe this question in terms of the purpose of comparisons to 'state of the art'. It is specifically the safety, performance and clinical benefit outcomes achievable that are of interest, therefore claims that a device is 'state of the art' are meaningless without an evaluation of the outcomes that are achievable or are considered standard of care for the specific patient populations and treatment indications. The hierarchy of sources for consideration of what constitutes 'state of the art' safety, performance and clinical benefit is illustrated in Table 1:

Table 1. Hierarchy of evidence for determining state of the art benchmarks for safety, performance and clinical benefit

Level	Source	Comments
Highest  Lowest	Common Specifications (if these exist)	Common Specifications (CS) and medical society guidelines represent current best practice at the time of publication. However, in some circumstances significant clinical experience may accumulate before these documents can be updated. Review of the peer-reviewed scientific literature may indicate that a higher benchmark is required than specified by a CS or medical society guideline. In addition, CS/medical society guidelines may not address every aspect of safety, performance and clinical benefit required for the demonstration of conformity for a given device. These sources should therefore be considered as the minimum requirement, and should be coupled with review of relevant systematic reviews published in the peer-reviewed scientific literature, to ensure that this minimum standard is still satisfactory in light of the current state of the art. Use of non-EU speciality medical society guidelines requires careful justification, to ensure that these are appropriate taking into account potential differences in standard of care or patient populations between Europe and other countries. Meta-analyses should only be used to justify state of the art benchmarks if there is insufficient evidence at the higher levels. Meta-analyses are prone to bias, and there is significant potential for misinterpretation. Justifications based on non-clinical evidence are typically applicable only to very low risk, non-novel devices, or those with no direct clinical benefit, and where no other relevant guidance at a higher level exists.
	European speciality medical society guidelines	
	Non-EU speciality medical society guidelines, where adequately justified	
	Systematic reviews from the peer-reviewed literature	
	Meta-analyses of data published in the peer-reviewed scientific literature	
	Justifications based on non-clinical evidence	

In general, the expectation is that the manufacturer will incorporate any common specification and speciality medical society guidelines into its state of the art assessment, taking account of the other relevant sources of information and the risks and benefits of each potential alternative treatment option as it relates to specifics of patient populations and treatment indications.

4.8. Suggested profile and training for users

The intent of this section is also straightforward, but it links to a new requirement in General Safety and Performance Requirement (GSPR) 4. Whereas the EU MDD required only that manufacturers take into account the training and knowledge of potential users, the EU MDR requires the manufacturer to provide training to users where appropriate. If the patient is the end user, or the devices are handled directly by the patient, this section will also be required in the patient SSCP. Where training is required, verification of effectiveness of that training should be demonstrated through clinical evidence. While this would be expected to be documented in the CER, it is not explicitly required in the SSCP; good clinical outcomes, combined with a specification of training requirements would imply a verification of effectiveness.

4.9. Reference to any harmonized standards and common specifications applied

Given the drivers behind the SSCP, the brevity of this section is interesting. Clinical experts who contributed to the development of the guidance were clear that they wanted to know the details of the testing that had been undertaken as well as the clinical evidence. However, the guidance asks only that this section indicate:

- the standard/common specification/monograph
- year/revision
- whether it was applied in full or in part

It does not suggest that relevant standards that were not applied be listed, nor does it ask for information on the deviations for those standards which are only partially applied. However, as this is a publicly available document, manufacturers may wish to provide some narrative context in these instances. For example, if a competitor device appears to have more extensive compliance to standards, readers may conclude that it is safer, even though there may be good reasons for non-compliances/non-application of standards.

5. What's the best way to test for readability of the patient-specific SSCP?

Because Article 32(1) says that the SSCP *'shall be written in a way that is clear to the intended user and, if relevant, to the patient'*, the MDCG guidance suggests that readability might be assessed *'for example by a test given to lay persons'*. Although it goes on to say *'The manufacturer may use a method it finds adequate for the readability test'*, early feedback from notified bodies indicates that some may expect involvement of actual lay persons, rather than relying solely on algorithmic scoring systems such as Flesch-Kincaid or SMOG (Simple Measure of Gobblydegook). The 'Summaries of Clinical Trial Results for Laypersons' guidance similarly recommends *'Where feasible, sponsors should consider testing the readability of the summary with a small number of people who represent the target population. Depending on the nature of the study, this could be patients with a particular disease or members of the public. Their feedback and suggestions could be helpful in developing a summary that lay people will understand'.*

Key principles in 'Summaries of Clinical Trial Results for Laypersons' include:

- short, succinct sentences conveying factual and objective information; the data should not be skewed or include promotional language
- simple language, avoiding acronyms, medical/technical terms and multisyllabic words
- visuals and illustrations to convey information where appropriate
- numerical data presented in a way that is understandable to the target audience
- eye-friendly formatting, including minimum size 12 font and plenty of white space

For many devices, particularly those with no comprehension risks specific to the intended patient population, it may be sufficient to test a generic lay population rather than a device-specific patient population. However, in cases where patient factors could affect their comprehension, or for devices used directly by the patient, it would be preferable to test the actual patient population. An exception may be devices intended specifically for a paediatric or neonatal population: if the intended patient population is likely to have a reading age lower than the average for an adult lay population, it may be assumed that the parent or guardian is the target audience for the SSCP.

If determined to be required, comprehension tests should include understanding of key messages and information points in the SSCP, rather than just confirmation of acceptable readability in generic terms.

6. Validation by the notified body

SSCPs for Class III and IIb implantable devices (excluding those listed in Article 52(4)) will be validated by the notified body during the initial conformity assessment, and subsequently for certificate updates and renewals. For implantable Class IIa and the exempted Article 52(4) devices, a sample will be assessed during the initial conformity assessment, and the remainder over the period of certification. Notified body 'validation' means that the notified body has assessed the SSCP against the technical documentation and has concluded that the SSCP is a true and accurate representation of the relevant information from that documentation. The notified body is also responsible for uploading the SSCP, as well as any required translations, to Eudamed.

7. Potential pitfalls

One of the most frequent errors we at RQM+ have encountered in manufacturer SSCPs (provided to us for gap assessments or remediation) is over-use of regulatory and quality systems language. The average clinician and patient do not have specialist knowledge of regulatory or quality system requirements, so references to ISO standards or generic quality systems processes will not be particularly helpful to them. Regulatory teams may have become accustomed to using verbiage that they feel enables notified body assessors to tick off specific requirements in a checklist, but these should be avoided in the SSCP.

Another frequent error is underestimating the complexity of the language used in a patient-specific SSCP. As experts in a given device or clinical area, we may consider some medical terms 'simple' that are not in the vocabulary of the average lay person. This is where it becomes useful to involve patients, their advocates or members of the public in the development and/or review of the summary to assess comprehension and the value of the information provided. Condensing complex medical information into language understandable to a lay person is a skillset in its own right. It is therefore a good idea to employ medical writers with this experience, including those with an understanding of health literacy and numeracy principles, in drafting the patient-specific SSCP.

The third most common error is not providing enough objective evidence. Manufacturers may be wary of putting specific numbers in the public domain, particularly if they consider that their device might not compare favourably with similar devices, or that in some way these data might give an advantage to competitors. But the notified body will be assessing the SSCP in terms of its accuracy, completeness and meaningfulness to the clinician and patient, so skimping on specifics is likely to lead to questions, non-compliances and delays to validation and certification.

8. Potential application for SSP under IVDR?

Article 29 of the European In Vitro Diagnostics Regulation 2017/746 (EU IVDR) describes an analogous requirement to the SSCP: the Summary of Safety and Performance (SSP). The requirements of the SSP are almost identical to those of the SSP, swapping out 'clinical' for 'performance' evaluation, and including a requirement for metrological traceability of assigned values. Given the pressure on commission expert groups to draft guidance documents, it is likely that MDCG 2019-9 will be used as a model for SSP guidance – so IVDR manufacturers may wish to take an advance look to prepare themselves for what is coming.

9. Summary and conclusions

The SSCP will provide a new level of transparency for clinical users and patients alike – it applies only to Class III and implantable devices. For the first time, the objective evidence to support safety, performance and benefit-risk will be publicly available. The first SSCPs have already been validated by designated notified bodies, but the Eudamed module supporting these may not be available until May 2022. Although there may be challenges involved in writing for a new kind of audience, deciding where to set the bar for the level of information disclosed and concerns over the associated commercial implications, ultimately these documents should raise confidence in the devices and the clinical evidence supporting their safety and performance.

10. Acronyms

CER: Clinical Evaluation Report

CMR: substances which are carcinogenic, mutagenic or toxic to reproduction

CS: Common Specification

GSPR: General Safety and Performance Requirement

EU AIMDD: European Active Implantable Medical Devices Directive

EU IVDR: In Vitro Diagnostic Medical Device Directive

EU MDD: European Medical Devices Directive, 93/42/EEC

EU MDR: European Medical Devices Regulation 2017/745

MDCG: Medical Device Coordination Group

PMCF: Post-Market Clinical Follow-Up

SRN: Single Registration Number

SSCP: Summary of safety and clinical performance

SSP: Summary of safety and performance

Author

Amie Smirthwaite is Global VP for Clinical Services at RQM+, where she leads the clinical, performance evaluation and post-market surveillance team, providing clinical regulatory strategy and MDR and IVDR compliant technical documentation. Amie has a PhD in biomedical engineering and over 25 years' postdoctoral experience spanning new product development, academic research, and QARA. Prior to joining RQM+, Amie was Global Head of Clinical Compliance at BSI, where she grew BSI's clinical compliance team and lead clinical aspects of successful MDR designation. She was also a significant contributor to successful IVDR designation on performance evaluation requirements. A former stakeholder representative of the European Commission Clinical Investigations and Evaluations Expert Group, Amie has contributed to the development of several MDCG clinical evaluation and post-market surveillance guidance documents, including the subject of this White Paper, MDCG 2019-9. Amie is currently a member of ISO standard technical committees ISO/TC 194 Biological and clinical evaluation of medical devices, and ISO/TC 150 Implants for surgery.

Technical reviewers

Maria E. Donawa, MD is President, Donawa Lifescience, headquartered in Rome, Italy, with over 30 years' regulatory experience including six years with the US FDA in medical device regulation. In 1986, after moving to Rome, Italy, she founded two consecutively operating companies, which have become Donawa Lifescience (DL). DL provides clinical services to life science companies worldwide and US and European quality system and regulatory services. Dr Donawa has assisted a wide range of medical device and IVD medical device companies in complying with European requirements; is an active member of ISO TC 194 Working Group 4, responsible for the development and revision of ISO 14155:2020 – *Clinical investigation of medical devices for human subjects – Good clinical practice*; and, is an observer in the Clinical Investigation and Evaluation subgroup of the Medical Devices Coordination Group (MDCG). For five years, Dr Donawa served as a registered lead auditor, providing notified body auditing services to a German notified body. For over 25 years until closure of the publication, she was the regulatory columnist for *European Medical Device Technology*. Dr Donawa has US degrees in pharmacy and medicine and post-doctoral specialization in clinical and anatomical pathology.

Jane Edwards is Head of Communications, Global Product Management, at the British Standards Institution (BSI). She holds a BSc in Chemistry and an MBA from Durham University. She has over 13 years' experience in the medical device industry, having previously worked for Coloplast in its ostomy and continence business. Jane's experience includes working within the pharmaceutical, chemical and telecoms industries for Glaxo Wellcome, ICI and Ericsson, allowing her to bring depth of knowledge from many industries and technologies. Her current role at BSI allows her to work with technical reviewers across all disciplines, ensuring that BSI communications are accurate and relevant. She is a member of the European Medical Writers Association.

Eamonn Hoxey is a technical author, trainer and consultant in a range of life science areas, including regulatory compliance, quality management, sterility assurance and standards development. Eamonn worked for Johnson & Johnson (J&J) for 17 years in positions of increasing responsibility for quality and regulatory compliance for medical devices, pharmaceuticals and consumer products. These included Vice President of Compliance, Vice President of Market Quality and Vice President of Quality & Compliance Strategic Programs, leading quality implementation for the EU MDR for J&J's medical devices companies. Prior to joining J&J, Eamonn spent 16 years with the UK Medical Devices Agency, including 6 years as Head of Device Technology and Safety. Eamonn is Chair of CEN/TC 204 – *Sterilization of medical devices*, and chaired ISO/TC 198 – *Sterilization of health care products*, from 2011 to 2019. Eamonn is also a past chair of ISO/TC 210 – *Quality management and corresponding general aspects for medical devices,* and the current Chair of the Board of Directors of AAMI. He received the BSI Wolfe Barry medal in 2016 for his contribution to standards development.

Paul Sim has worked in the health care industry for over 35 years. He joined BSI in 2010 to lead the organization in Saudi Arabia, where it had been designated as a Conformity Assessment Body. Later, he managed BSI's Unannounced Audit programme. Since October 2015, he has been working with the notified body and standards organizations looking at how best to use knowledge, competencies and expertise in both. Previously, he held senior RA/QA leadership positions at Spacelabs Healthcare, Teleflex Medical, Smiths Medical and Ohmeda (formerly BOC Healthcare). Paul is a member of the Association of British Healthcare Industries (ABHI) Technical Policy Group and Convener of the ABHI ISO/TC 210 Mirror Group. He is Convener of the BSI committee that monitors all of the work undertaken by ISO/TC 210, and Convener of the BSI subcommittee dealing with quality systems. As UK Delegation Leader to ISO/TC 210, he is also actively involved in the work of national, European and international standards committees.

Published white papers

- *The proposed EU regulations for medical and in vitro diagnostic devices: An overview of the likely outcomes and consequences for the market,* Gert Bos and Erik Vollebregt
- *Generating clinical evaluation reports: A guide to effectively analysing medical device safety and performance,* Hassan Achakri, Peter Fennema and Itoro Udofia
- *Effective post-market surveillance: Understanding and conducting vigilance and post-market clinical follow-up,* Ibim Tariah and Rebecca Pine
- *What you need to know about the FDA's UDI system final rule*, Jay Crowley and Amy Fowler
- *Engaging stakeholders in the home medical device market: Delivering personalized and integrated care,* Kristin Bayer, Laura Mitchell, Sharmila Gardner and Rebecca Pine
- *Negotiating the innovation and regulatory conundrum,* Mike Schmidt and Jon Sherman
- *The growing role of human factors and usability engineering for medical devices: What's required in the new regulatory landscape?* Bob North
- *ISO 13485: The proposed changes and what they mean for you*, Bill Enos and Mark Swanson
- *The differences and similarities between ISO 9001:2015 and ISO 13485:2016: Can we integrate these quality management standards?* Mark Swanson
- *How to prepare for and implement the upcoming MDR – Dos and don'ts*, Gert Bos and Erik Vollebregt
- *How to prepare for and implement the upcoming IVDR – Dos and don'ts*, Erik Vollebregt and Gert Bos
- *Planning for implementation of the European Union Medical Devices Regulations – Are You Prepared?* Eamonn Hoxey
- *Cybersecurity of medical devices: Addressing patient safety and the security of patient health information*, Richard Piggin
- *The European Medical Devices Regulations: What are the requirements for vigilance reporting and post-market surveillance?* Eamonn Hoxey
- *General Safety and Performance Requirements (Annex 1) in the New Medical Device Regulation: Comparison with the Essential Requirements of the Medical Device Directive and Active Implantable Device Directive*, Laurel Macomber and Alexandra Schroeder
- *Do you know the requirements and your responsibilities for medical device vigilance reporting? A detailed review on the requirements of MDSAP participating countries in comparison with the European Medical Device Regulation 2017/745*, Cait Gatt and Suzanne Halliday
- *Technical Documentation and Medical Device Regulation: A Guide for Manufacturers to Ensure Technical Documentation Complies with EU Medical Device Regulation 2017/745*, Dr Julianne Bobela, Dr Benjamin Frisch, Kim Rochat and Michael Maier
- *Nanotechnology: What does the future look like for the medical devices industry?* Professor Peter J Dobson, with Dr Matthew O'Donnell 23

- *Developing and maintaining a quality management system for IVDs*, Melissa Finocchio
- *Digital maturity in an age of digital excitement: Digital maturity goes beyond excitement to quality,* Professor Harold Thimbleby
- *Recent advancements in AI – implications for medical device technology and certification,* Anil Anthony Bharath
- *Risk management for medical devices and the new ISO 14971,* Jos van Vroonhoven
- *The impact and potential for 3D printing and bioprinting in the medical devices industry,* Kenny Dalgarno
- *Sterilization – Regulatory requirements and supporting standards,* Eamonn Hoxey
- *Medical device clinical investigations – What's new under the MDR?* Maria Donawa
- *Software as a medical device – A comparison of the EU's approach with the US's approach,* Pat Baird and Koen Cobbaert
- *The convergence of the pharmaceutical and medical devices industries: Navigating the innovations and regulations,* Barbara Nasto and Jonathan Sutch
- *Phthalates and endocrine disruptors – An overview of their safety requirements and evaluations and the standards that support them,* Benjamin Seery

Forthcoming white papers

- *CER generation* (working title), Amy Smirthwaite
- *Requirements of EU-GDPR and PMCF studies, registries and surveys under the MDR (working title),* Richard Holborow
- *UDI* (working title), Mary Gray
- *Performance evaluation under IVDR,* Fiona Gould
- *Clinical investigation,* Maria Donawa

About BSI Group

BSI (British Standards Institution) is the business standards company that equips businesses with the necessary solutions to turn standards of best practice into habits of excellence. Formed in 1901, BSI was the world's first National Standards Body and a founding member of the International Organization for Standardization (ISO). Over a century later it continues to facilitate business improvement across the globe by helping its clients drive performance, manage risk and grow sustainably through the adoption of international management systems standards, many of which BSI originated. Renowned for its marks of excellence including the consumer recognized BSI Kitemark™, BSI's influence spans multiple sectors including aerospace, construction, energy, engineering, finance, healthcare, IT and retail. With over 70,000 clients in 150 countries, BSI is an organization whose standards inspire excellence across the globe.
BSI is keen to hear your views on this paper, or for further information please contact us here: julia.helmsley@bsigroup.com

This paper was published by BSI Standards Ltd

For more information please visit:
http://www.bsigroup.com/en-GB/our-services/medical-device-services/BSI-Medical-Devices-Whitepapers/

BSI National Standards Body
389, Chiswick High Road
London W4 4AL
United Kingdom

T: +44 (0) 845 086 9001
E: cservices@bsigroup.com
bsigroup.com