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BSI Clinical Masterclass FAQs

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The Clinical Evaluation Plan (CEP)

How is the intended purpose defined in the case of devices that have multiple functions (e.g., a console that enables the operation of various attachments)?

It is important to define the intended purpose in a way that captures the overall purpose of the device by specifying, for example, the field or surgical intervention in which the device is used. In rare cases, it may be appropriate to document a conditional intended purpose statement, (e.g., “when used in combination with attachment(s) x, the device is intended for y.” Be aware that where a device is assigned multiple functions, this may have an impact on its classification.

Indications? Intended purpose? What is the difference and can’t they simply be combined?

There is often confusion over these terms. Importantly, the MDR mandates the specification of the intended purpose in the Clinical Evaluation and defines it (in Article 2(12)) as "the use for which a device is intended...". The intended purpose often describes the action of the device, whereas indications are normally understood to refer to the medical conditions for which the device is appropriate. By way of an example, a device that is intended to transmit radio frequency current for ablation purposes may be indicated in the treatment of atrial fibrillation. Some devices have a generic intended purpose and therefore may not have specific medical indications. When this is the case, this should be clearly documented by the manufacturer and there should be adequate evidence to support the intended purpose of the device, which is not only limited to specific indications, populations, or subgroups, etc.

Is a Clinical Development Plan (CDP) always required? If so, can it be part of the CEP?

Yes, a CDP is always required, also when following Article 61(10). In the case of legacy devices, most of the clinical development activities will have already concluded. However, the requirements for PMCF should still be addressed in the CDP as per Annex XIV Part A 1(a) indent 8. Note that where it is anticipated that changes will be made to legacy devices, these should be considered within the CDP. It is acceptable to incorporate the CDP within the CEP.

If the CDP covers the PMCF plan, why is a separate PMCF plan required?

The CDP should consider the requirement for PMCF, based on the overall clinical development strategy pertaining to the device. It does not substitute the PMCF plan, which details the activities to be conducted in the post-market phase, based on the findings of the clinical evaluation.

When preparing a CEP, what are the key considerations and how often should the CEP be updated.

There is no template or specific guidance on the CEP, however MDR Annex XIV Part A provides direction on what should be considered. All devices, whether legacy or new, require their own CEP. The CEP may be presented within the body of the CER, provided as a standalone document or included as an appendix. When developing the CEP, manufacturers need to consider which GSPRs require clinical evidence to support them, the methodologies they will employ to identify and analyse clinical data, to define the state of the art, the objectives and PMCF activities. The CEP should include the regulatory history of the device. The CEP is a living document and should be updated based upon the risk classification of the device and outputs from post-market activities.

What is the role of the state of the art (SOTA) and benchmark devices and are we required to conduct a literature review to establish the SOTA?

When defining the SOTA, the manufacturer needs to consider the following questions:

- What is current best practice for the condition being treated?
- What are the alternative treatments?
- Are there benchmark devices and, if so, what is their benefit-risk profile?

To answer these questions, it is normally required to conduct a specific literature review. It is the output of this literature review that will guide manufacturers in the defining their own measurable and meaningful safety and performance objectives, in-line with the SOTA.

What is the best method of documenting the qualitative and quantitative aspects of clinical safety and what type of data constitutes clinical data?

Manufacturers should consider qualitative aspects of clinical safety as referring to the details of an identified clinical safety issue. For example, if the safety issue is an adverse event, then the qualitative aspects should include details of the adverse event, e.g., bleeding, or infection, etc. The quantitative aspects refer to the frequency of occurrence, or severity (or both). When documenting frequency, it is important to provide context, including the timeframe, the number of devices sold/used and a comparison of the data with the SOTA. Clinical data can include any information concerning safety or performance that is generated from the use of a device. It is possible, therefore, that complaint data may constitute clinical data, particularly where it relates to safety. For example, if a device reportedly broke during a surgical procedure, this may have placed a user or patient at risk of harm or caused actual harm.

How should manufacturers approach the setting of performance objectives? Is there a preferred methodology to quantify these? What should these objective be based upon?

Performance objectives should be established based upon the SOTA and considering the intended purpose of the device and its clinical benefits. If alternative treatments or benchmark devices have been identified, then the reported performance of these must be taken into account when specifying performance objectives. For example, for a device that monitors a physiological parameter in a patient, a performance objective may be the percentage of time in range (70-180 mg/dL) > x %. It is normally expected that the targets for performance objectives should at least equal the reported performance(s) of benchmark devices and/or conform to standards or guidelines (where available), in order for the manufacturer to demonstrate that their device is SOTA.

Is it acceptable to claim that there is no clinical benefit of a device, for example in cases where Article 61(10) applies? If so, what are the consequences of this in terms of clinical evidence requirements?

Article 2 (44) provides a definition of Clinical Evaluation, which includes reference to the clinical benefits of the device. The term is also referred to in Article 2 paragraphs 51-53, Article 62 paragraph 1(b) and in several other sections of the MDR text. Specifically, Annex XIV Part A paragraphs 1(a) and (e) mandate its definition in order that conclusions regarding the safety and clinical performance of the device may be drawn. It may be the case for some devices that the clinical benefit is indirect, for example, when the device is a component of a system or is used within the clinical workflow and does not, in and of itself, afford benefits directly to the patient. For such devices, manufacturers should still consider the clinical benefit of the device as a constituent part of the system or workflow, but the performance/safety objectives may relate more specifically to the function of the device itself. When this is the case, it is important to clearly document the link between the performance/ safety objectives of the device and the clinical benefits delivered by the system. The manufacturer will still need to demonstrate that the performance/safety objectives have been met. Where clinical data is not deemed appropriate (i.e., under Article 61(10)), clinical benefits, direct or indirect, must still be documented. Note that the requirement to document clinical benefits is exempted in the case of devices that fall under Annex XVI (Article 61(9)).

What if the device has clinical benefits that can't be defined, (e.g., a simple surgical tool)?

Where a device has generic use, it can be challenging to document a clinical benefit statement. However, ultimately, the use of the device still has a benefit that is afforded to a patient and/or user. Therefore, even in the case of a simple surgical tool, the manufacturer must define the clinical benefit. It is then up to the manufacturer to determine the level of evidence required to support the clinical performance/ safety objectives, based on their claims relating to the performance and safety of the device and other factors such as the presence of any novel features.

The Clinical Evaluation Report (Parts I & II)

Is MEDDEV 2.7/1 rev. 4 still applicable for benefit-risk assessment and clinical evaluations performed under MDR?

MEDDEV 2.7.1 rev 4 was written with respect to the MDD and AIMDD to provide guidance on conducting a clinical evaluation, which includes the benefit-risk analysis. However, MDCG 2020-6 specifically calls out this guidance as applicable under MDR and it should therefore be followed where relevant, until further updates are provided. Appendix I of MDCG 2020-6 identifies which sections of MEDDEV 2.7.1 rev 4 are relevant to MDR.

How does BSI define 'variant'?

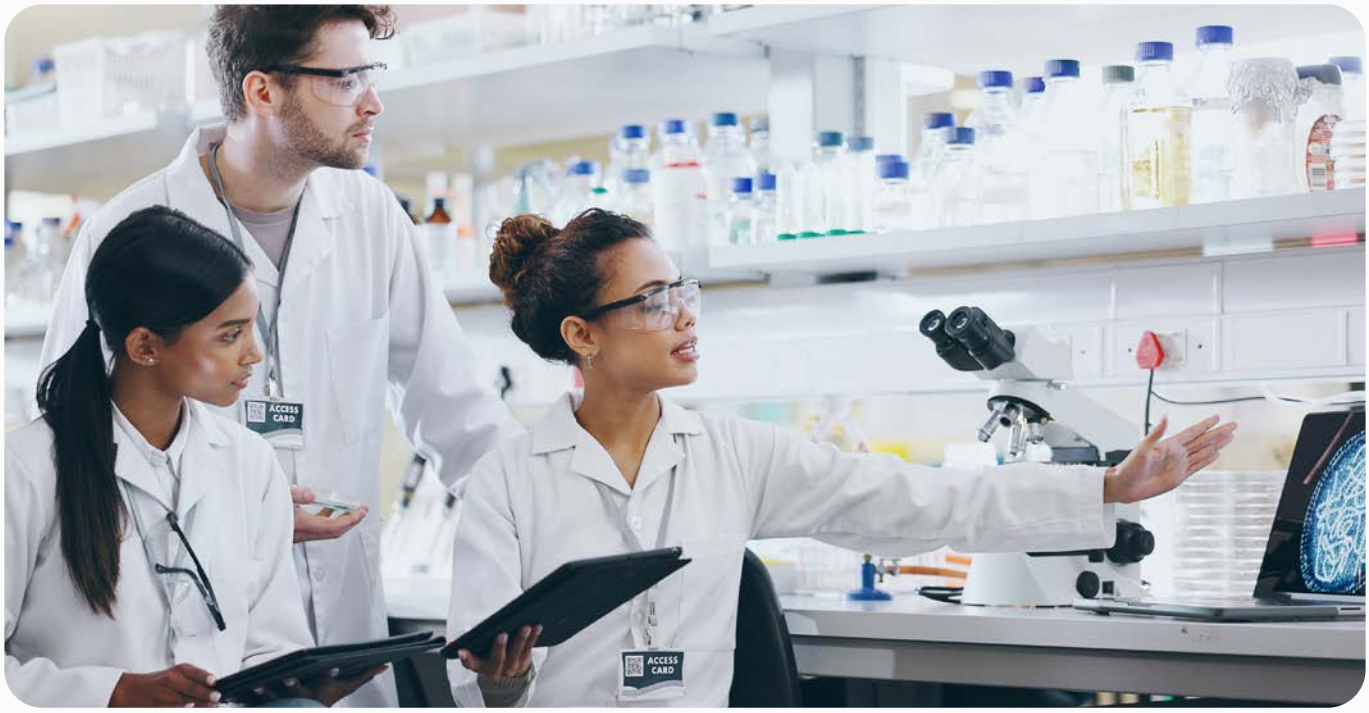
Every product family will typically include multiple variants/configurations. When we assess clinical data we always need to be able to see that the data collected is relevant to all variants. As a simple example, a family of catheters could include multiple lengths - we would view this as multiple variants. Similarly, the catheter could be available in different body stiffness designs, e.g., standard, firm, heavy duty, which again would be classed as different variants. Data will probably not be needed on every single variant, but the manufacturer would need to be able to justify and explain why the data is representative of the entire range.

Is the demonstration of equivalence required between variants pertaining to the same technical documentation?

If data from a different device or variant within the same device family is required to demonstrate safety and performance of the subject device/ variant then demonstration of equivalence is required. This includes device variants within the same technical documentation submission where all may be subject devices to the conformity assessment, but data is required to be leveraged from one variant for another.

When claiming equivalence for Class IIa and IIb non-implantable devices, the MDR requires that manufacturers have sufficient levels of access to the data relating to equivalent devices. What is considered 'sufficient levels of access' to the data?

Sufficient access is judged on the ability of the manufacturer to identify the key characteristics of the equivalent device, in order to make comprehensive comparisons of devices in terms of the three equivalence criteria. Unknowns or assumptions are not acceptable to the Notified Body: it is likely that the Notified Body will challenge manufacturers to disclose the source of the data they present in respect of claimed equivalent devices.



If a corporation has multiple Legal Manufacturing entities, A and B, does Legal Manufacturer A need a contract between Legal Manufacturer B if Legal Manufacturer A wants to claim equivalence to device from Legal Manufacturer B?

Yes, a contract would still be required as the Legal Manufacturer and SRN will be different. The equivalent device would also need to be certified under the MDR.

Do you need to continue to demonstrate equivalence after obtaining the initial CE mark? If not, how should a manufacturer manage this in subsequent updates to the CER?

Data is required to support the full lifetime of the device and so the demonstration of equivalence may still be required on a continued basis. However, data on the subject device should be collected post-certification, per the PMCF plan, so that the reliance on equivalence should diminish over time.

How is the lifetime of a software only device defined?

Although it is common for manufacturers of software only devices to claim indefinite lifetime, it is expected that software only device lifetime is specified on the basis of a statistical determination that takes into account, (e.g., the mean time before failure, risk of cybersecurity events, anticipated servicing frequency and any usability considerations). It is generally unacceptable for manufacturers to claim indefinite lifetime for any medical device. Lifetime claims will need to be supported by relevant data.

How does BSI define/interpret the term "novelty"?

BSI follows the European Commission guidance for the MD Expert Panels 2020/C 259/02 in relation to novelty. This establishes the degree of novelty based on "dimensions" associated with clinical or surgical procedure and physical device related characteristics. Degree of novelty should be considered for all classifications of device regardless of whether they are considered standard of care. BSI has put together a Novelty Table to help manufacturers in this area. The table will be made available to all manufacturers as part of the toolkit released as part of the Clinical Masterclass Series.

Can you confirm that "clinical investigation" refers to a pre-market clinical study? What are the best practices and considerations when determining the appropriate number of patients for clinical investigations? Should the accompanying documentation relating to clinical investigations be included as appendices to the CER?

Refer to Article 2 of the MDR for a definition of a clinical investigation: (45) "clinical investigation" means any systematic investigation involving one or more human subjects, undertaken to assess the safety or performance of a device. Clinical Investigations can therefore be performed in both the pre and post-market phases of the device lifecycle. Patient sample sizes for clinical investigations should be justified and align to what may be considered reasonable, in light of the SOTA and depending on the research question. The expectation is that sample size is based on a well-defined statistical analysis plan that includes a statistically calculated sample size.

However, it is understood that sample size calculations can be manipulated to provide a desired outcome and so reviewers may adopt a common-sense approach as well as a degree of pragmatism. Please be aware that unusual statistical methods may invoke extra scrutiny and result in the involvement of external experts in the review process. The clinical investigation documentation should be submitted as part of the clinical section of the technical documentation. This could be presented as appendices to the CER, if this is the format preferred by the manufacturer.

If only limited clinical data on a Class IIa legacy device can be found, can article 61(10) be used?

Article 61(10) can only be used where the demonstration of conformity with GSPRs based on clinical data is not deemed appropriate. Limited availability of clinical data on a legacy device does not support the justification that the use of clinical data is inappropriate.

Post Market Surveillance (PMS) and Post Market Clinical Follow Up (PMCF)

How does the PMCF evaluation report evaluate clinical data differently than the CER? If new clinical data is incorporated in the CER directly, would the generation of a separate PMCF evaluation report not be considered 'double work'?

All relevant data (both pre- and post-market) should be considered within the CER and benchmarked against appropriate measures of safety and performance. The PMCF evaluation report is a specific report on the output of PMCF activities: please refer to MDCG 2020-8 for a suggested template. Provided that data from PMCF activities is appropriately evaluated, it may be acceptable for the evaluation of PMCF activities to be undertaken within the CER, however, manufacturers should take care to explain how such an approach meets the requirements of PMCF evaluation, as outlined in MDR Annex XIV part B.

Where a device has multiple indications, is it acceptable for the majority of PMCF data to support one indication?

PMCF data should reflect real-world use and should therefore consider all indications, especially where there may be gaps in the clinical evidence. If an 'open-label' PMCF study is taking place and there are comparably few patients for one indication versus the others, this may be acceptable with adequate justification. It is expected that manufacturers consider usage frequency and expected usage, when planning PMCF activities. Ultimately there must be 'sufficient clinical data' for all indications.

Is PMCF always required, even for Well-Established Technology (WET) devices with many years of data?

A PMCF plan is expected for all devices, including WET devices with a long history of usage. If the manufacturer decides not to undertake PMCF activities, this should be clearly justified in the plan per MDR Annex III, 1(b), indent 10. Periodic reconsideration of the need for PMCF should be undertaken at an appropriately justified time interval. For a WET device, it may be possible to perform only general activities, but this would need to be duly justified. Given that PMCF under MDR is a continuous process which encompasses general activities - such as gathering feedback from users and screening of the scientific literature - it may be challenging to justify not undertaking any PMCF.

Complaints and feedback gathering is mentioned both as a PMS and a PMCF activity. Are complaints a source of clinical data for PMCF?

Complaints are not specifically identified in the MDR or the relevant MDCG guidance as a source of PMCF data. Per MDR Annex XIV part B, an aim of PMCF is the identification of unknown side-effects and emergent risks. General PMCF activities mentioned in the MDR include collecting feedback from users and, although the intent of this requirement is not clearly defined anywhere, it could be taken to refer to the proactive collection of feedback via, (e.g., user surveys, as opposed to passive data collection via complaints). All PMS and PMCF activities should have a clear purpose and be appropriately justified: the relative quality of clinical data that the activity will generate is an important consideration.

When PMCF activities uncover off-label use how should this be handled and what is deemed to be 'systematic misuse'? Can this data be used for an expansion of the indications?

MDR Annex XIV requires that the manufacturer's post market clinical follow up (PMCF) plan must identify systematic misuse or off-label use of the device with a view to verifying that the intended purpose of the device is correct. When off-label use is identified, regardless of whether this is systematic or not, it should be recorded and appropriately assessed. Systematic misuse refers to when there is evidence that the device is being used repeatedly or continuously outside its approved intended purpose and indications, (e.g., where multiple articles from the literature describe the same kind of off label-use).

Off-label use could refer to the use of a device.

- Outside specified populations, such as in paediatric patients.
- For a different stage or severity of disease.
- For a similar (not identical) clinical condition.
- Where it is introduced to the body through alternative routes.

When systematic misuse is identified the manufacturer shall eliminate or control the risks in accordance with risk control measures, for example, the addition of an explicit warning, or contraindication. Any data relating to off-label use should be considered within the clinical evaluation to determine whether there is a genuine unmet medical need – if it is concluded that there is, then a formal clinical investigation should be performed. There is some useful guidance in Team-NB Position Paper - Off-Label Use, V1, 20221005.

What are the expectations of a PMCF plan for a Class I or IIa device?

The MDR requirements for a PMCF Plan are the same regardless of the class of device. Any plan should consider general and specific activities. Activities should be proportionate to the device under evaluation and designed to address unanswered questions identified during the clinical evaluation. For lower risk devices, it may be acceptable to undertake activities which are regarded as generating a relatively low quality of clinical data.

Can third party studies where the manufacturer is not the sponsor of the trial be listed as PMCF activities in the PMCF Plan?

As stated in MDR Annex XIV, specific methods and procedures of PMCF include evaluation of suitable registers. Therefore, provided the manufacturer has access to the results and methodology, third party studies could be appropriate, (e.g., an evaluation of international device registries run by medical societies/consensus groups).

Does PMCF documentation (Plan, Evaluation Report) need to be updated if planned investigations are delayed, or not progressing as planned, even if no other concerns or safety signals are identified?

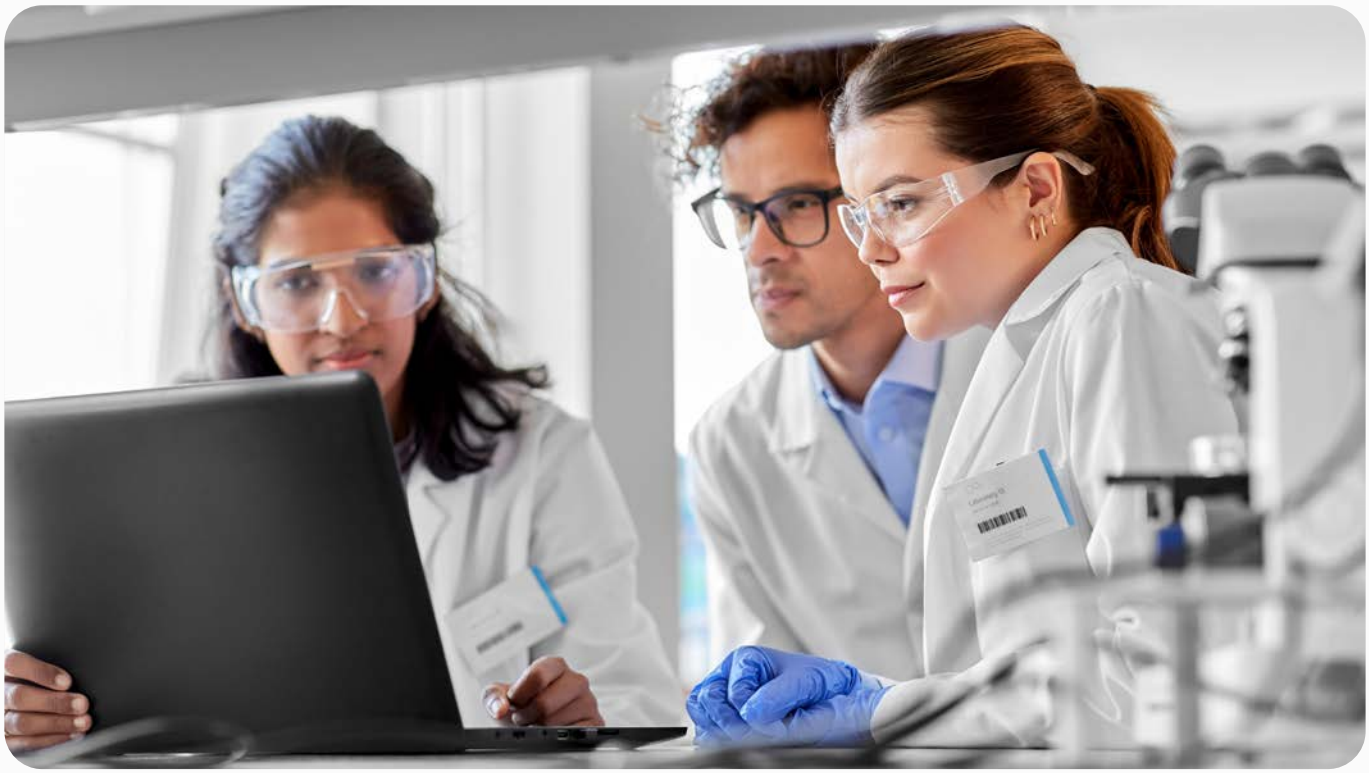
Yes: Annex XIV part 6.2 (h) states that the PMCF Plan shall include a detailed and adequately justified time schedule for PMCF activities. Delays and disruptions to planned PMCF activities alter the timeline and therefore need to be appropriately justified and the Notified Body needs to be convinced that these activities are not being delayed for unacceptable reasons. The PMCF Evaluation Report should provide information on all PMCF activities. A delay to one specific activity should not delay the evaluation of data from other activities.

Can clinical data generated in a PMCF study performed according to the MDD be considered clinical data to demonstrate the safety and the performance of the device for MDR?

Yes, absolutely. All data, whether favourable or unfavourable, should be included and presented in the clinical evaluation for which PMCF evaluation is a requirement. Whether or not this is sufficient to enable demonstration of conformity with MDR GSPRs depends on the quality of the data generated by the PMCF study – please refer to MEDDEV 2.12/2 rev. 2 and the Clinical Masterclass Series 2 Webinar on PMCF for information on what makes a good PMCF study and potential pitfalls to avoid. MDCG 2020-6 provides guidance on sufficient data for legacy devices presented for certification under the MDR.

Literature searches seem to be required everywhere to address the state of the art, similar devices, and the subject device (in the CEP, CER, and here again in the PMCF Plan). Is it expected that separate literature searches are performed for each document?

It is possible that results from literature searches can be leveraged for each document. Multiple literature searches may be required. The PMCF Plan requests an evaluation of clinical data related to similar and equivalent devices. It is expected that the manufacturer performs this evaluation within the PMCF Plan to inform the plan itself.



Summary of Safety and Clinical performance (SSCP)

The SSCP can contain two parts, the first part for the Healthcare Professional and, where relevant, a second part for the patient. Are the readability checks only applicable to the patient part?

Article 32(1) states that the SSCP 'shall be written in a way that is clear to the intended user and, if relevant, to the patient'. Whereas both parts should be clear and provide information at an appropriate depth for the different levels of knowledge, readability checks will focus on the patient part. When the Notified Body conducts SSCP validation and verifies the readability of the patient section of the SSCP, it is open to solutions which demonstrate that the information is written in a way that will be clear to a lay person. Either a test given to lay persons or readability tests conducted by software methods including the Flesch-Kincaid Scoring system are acceptable methods to demonstrate readability. Regardless of the method used, the Notified Body needs to be satisfied that medical terms are simplified, and that the patient information is communicated in a simple, clear way.

When the SSCP is updated, does the readability of the patient section need to be reassessed?

Readability of the patient part of the SSCP will be verified each time that the SSCP is validated by the Notified Body. As information is added to each SSCP it is important that the manufacturer confirms that the information throughout the SSCP remains clear and appropriate for its intended audience. The need to repeat readability checks on the patient part of the SSCP should be considered for all updates but whether this is needed will depend on the type of information being added to the Patient SSCP. Where

readability tests are not repeated on updated Patient SSCPs, a rationale explaining why this was not considered necessary should be provided within the Technical Documentation.

Should the SSCP be updated or 'reviewed' annually?

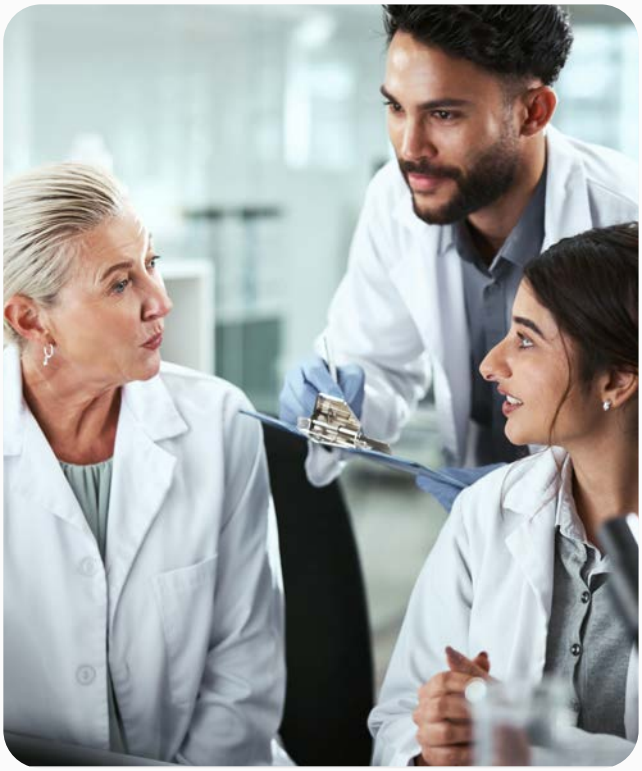
For Class III and Implantable devices, the PMCF Evaluation Report should be updated at least annually. When PMCF reports are updated, the SSCP should be reviewed and updated to ensure that the clinical and safety information in it remains correct and complete. When updating the SSCP, all sections should be updated to maintain alignment with the current version of the Technical Documentation.

What if the SSCP is reviewed at the annual timepoint, but no updates are needed. Should the SSCP still be submitted to the NB?

The manufacturer is obligated to keep the SSCP updated. The SSCPs should be reviewed and, if indicated, updated on an annual basis. If the manufacturer's annual review confirms that the clinical and safety information in the SSCP remains correct, complete, and aligned with the Technical Documentation there is no need to update or reissue the SSCP. Where the annual review confirms that no updates are required to the SSCP, a justification should be made for not updating the SSCP. The SSCP only needs to be submitted to the NB at the time of the next scheduled PSUR review if it includes new or amended information when compared to the latest SSCP provided to BSI.

The initial validation of my SSCP was completed several months ago, after which it took some time to complete the other elements in the conformity assessment. I'm now in the process of performing the annual CER update. Do I need to update the SSCP at the time as the CER updates and does BSI expect the updated SSCP to be submitted for validation?

The update schedule can get complex as you will have updates to the CER, Risk Management File, PMCF Evaluation Report, the PSUR and other parts of the Technical Documentation. The SSCP requires annual review and, if indicated, updates to ensure that the clinical and safety information presented remains correct, complete, and aligned with the current version of the Technical Documentation. It is up to the manufacturer to determine an appropriate update schedule for all documentation which meets the requirements outlined in the MDR. From a Notified Body perspective, we do not expect to see updates to the SSCP until the next scheduled PSUR Evaluation. Outside of the scheduled PSUR evaluations it is possible for the Notified Body to validate SSCP updates at the time of a Supplementary Conformity Assessment supporting a certificate change. BSI will not



validate SSCP updates outside of either the PSUR Evaluation or a Supplementary Conformity Assessment supporting the approval of certificate changes.

For Class IIa Implantable and IIb Implantable WET devices which are certified with a QMS certificate and for which the Technical Documentation is assessed on a representative sampling basis, can you clarify at what point the manufacturer should provide the final copies of SSCPs?

We need the final SSCPs, both validated and unvalidated for all devices in the group, before we complete the initial conformity assessment and issue a QMS certificate for the corresponding product family within the scope. All final SSCPs (validated and not validated) will be uploaded to EUDAMED when the QMS certificate is issued and registered within EUDAMED. Both the validated and unvalidated final SSCPs will be made available to the public via EUDAMED. The versions which have not been validated will be replaced with a validated version when we assess the corresponding Technical File as per the Technical File sampling plan throughout the certification cycle for QMS surveillance purposes.

If the SSCP has been updated earlier than the planned PSUR submission, can the manufacturer translate that non-validated SSCP and provide it to Health Care Professionals and patients or can only validated SSCPs be made available to the public?

Both validated and unvalidated SSCPs will be uploaded to EUDAMED and therefore made available to the public. The only scenario in which an unvalidated SSCP would be uploaded to EUDAMED is for Class IIa Implantable or IIb Implantable WET devices for which we are deferring the SSCP validation until the corresponding Technical Documentation is assessed as part of the surveillance plan. Until EUDAMED is fully functioning, and SSCPs are actually being uploaded to EUDAMED, it is the manufacturer's responsibility to have a process in place to make final SSCPs available to Health Care Professionals, patients and the public without undue delay. The versions made available to these stakeholders should align with what would normally be available in EUDAMED if it was fully-functional, which will be the final SSCPs (validated or non-validated in the case of some Class IIa Implantable and IIb Implantable WET devices) that were provided to the Notified Body during either an initial Conformity Assessment, or SSCP updates validated either as part of a PSUR Evaluation or a Supplementary Conformity Assessment supporting the approval of certificate changes.

As the SSCP is provided for patients do we need to translate it into each official language where the device is commercialised as for the IFU?

The product IFU often includes additional (non-EU) languages to support worldwide distribution. The SSCP should be translated into the EU languages accepted in the Member States where the device is envisaged to be sold. Each translated SSCP should identify the language. It will only be possible to upload official EU language translations to EUDAMED.

It is not clear how the SSCP should be compiled with respect to the language requirements to allow efficient upload to EUDAMED? For example, should each language version be provided as a separate document, and should the tick box be selected indicating that the Notified Body has validated the SSCP?

There should be a separate SSCP document for each EU language. The validation of the SSCP by a Notified Body covers only one language accepted by that Notified Body and agreed with the manufacturer; within BSI the Master SSCP is the English language SSCP. The Notified Body does not validate the translated SSCP documents. Where the SSCP has been validated, the manufacturer should state in the revision history of both the Master and translated SSCP documents in which language the SSCP was validated by the Notified Body. In cases where the Master SSCP is not validated, the revision history for both the Master SSCP and the translated SSCP documents should have "No" selected in the "Revision validated by the Notified Body" column of the revision history so that it is transparent to the public that the SSCP document has yet to be validated by the Notified Body.

Is the SSCP expected to reflect changes in the overall clinical data (CER and PMCF Evaluation Report) or just the PSUR; is this taken into consideration when the SSCP update validation by the Notified Body is aligned with the PSUR evaluation?

The SSCP validation check verifies that the content of the SSCP aligns with data that has been assessed within the manufacturer's Technical Documentation. The source Technical Documentation always needs to be assessed before the corresponding information in the SSCP can be validated. SSCP validations at the time of the PSUR Evaluation need to be within the scope of the information contained in the PSUR. Editorial updates can also be validated along with the PSUR. If there are any updates to the SSCP that are outside the scope of the PSUR (excluding editorial changes), then the Technical Documentation will need to be submitted to allow the validation checks to be conducted.

Get in touch

Whether you are starting the certification process, looking to transfer or need to discuss your options, we can guide you through the process.

Talk to us

Your partner in progress

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