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Essential Principles and Content of Predetermined Change Control Plans

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Preface

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1. Introduction

Software has become an integral part of modern healthcare, driving transformative advancements in diagnostics, treatment, and patient management. A critical subset of this technology is medical device software that meets the definition of a medical device and is defined in *IMDRF's N81 Characterization Considerations for Medical Device Software and Software-Specific Risk*. Given its critical role in patient care, medical device software is subject to rigorous regulatory oversight to ensure it consistently meets high standards of safety and performance.

While patients benefit immensely from timely access to medical device technologies, the rapid pace of software development presents a challenge for traditional regulatory processes, which can lead to delays in deploying important updates, thereby hindering patient access. As with most software applications, medical device software may benefit from frequent updates to improve functionality, address real-world use, and respond to evolving clinical environments. A Predetermined Change Control Plan (PCCP) allows manufacturers to seek authorization to implement planned changes while ensuring the continued safety and effectiveness of their medical device software. A PCCP is appropriate for certain changes that would otherwise be subject to regulatory authorization prior to implementation while also remaining within the original intended use/intended purpose.

A PCCP describes a plan, proposed by a manufacturer, that states:

1. the specific planned changes to the medical device software,
2. the change plan/protocol for implementing and controlling those changes with pre-defined acceptance criteria/pre-specified performance criteria, and
3. the assessment of impacts from those changes.

This approach allows for more rapid adaptation of medical device software, faster access, and the ability to responsibly evolve in response to new data and technological advancements. By enabling the authorization of certain planned changes, PCCPs can help maintain the balance between innovation and regulatory oversight without compromising patient safety.

The adoption of PCCPs offers numerous benefits. For patients, the authorization of PCCPs may support quicker access to improved medical device software, which may lead to better health outcomes. For healthcare systems, PCCPs can enhance operational efficiency and patient outcomes through the continuous improvement of medical device software. For manufacturers and regulatory bodies, PCCPs can increase administrative efficiency, streamlining the regulatory process by reducing the burden of multiple regulatory submissions. In doing so, manufacturers may improve their planning and accelerate time-to-market for updates while maintaining the safety and effectiveness of the medical device software. On a broader scale, PCCPs encourage early interaction and collaboration between manufacturers and regulatory authorities.

Despite the benefits, there are also some challenges to overcome. Regulatory bodies will face increased submission complexity at the time of the initial regulatory review. This complexity also applies to manufacturers, who will need to prepare the necessary documentation for PCCPs at the time of submission. Clear documentation and communication between manufacturers and regulatory authorities is crucial to ensure traceability and implementation around the acceleration of modifications of medical device software within the context of a robust quality management system. Additionally, manufacturers should be cognizant of the differences in jurisdictional adoption of PCCPs as this may complicate their PCCP authorization plans and/or their global reliance strategies.

PCCPs have the potential to be applied beyond medical device software to other areas of medical technology. The evolution of PCCPs could lead to more flexible and responsive regulatory frameworks, better suited to the fast-paced nature of technological innovation in healthcare. However, the focus of this document is on medical device software.

Given the emerging nature of PCCPs at the time of this publication, their implementation may vary across different regulatory jurisdictions. This document serves to facilitate international convergence and harmonize approaches across jurisdictions by describing essential principles for PCCPs.

Throughout this document, the terms “change” and “modification” are used interchangeably. Additionally, the term “user” refers to people who interact with medical device software, including the intended healthcare professionals, patients, and/or caregivers. Ensuring patient safety and meeting patients’ needs is paramount in the development and regulation of these technologies.

The approach developed in this document is intended only to establish a common understanding for PCCPs and can be used as a reference. This document is not intended to replace or modify existing regulatory classification schemes or requirements.

2. Scope

2.1 Purpose of the document

The purpose of this document is to share high-level principles on the use of PCCPs as a way of authorizing certain planned medical device software modifications for which regulatory authorization is otherwise required. Additionally, it aims to identify the elements that manufacturers may consider when developing and documenting a PCCP to support regulatory review. The document outlines a broad, but harmonized framework for PCCPs, allowing each jurisdiction to apply the concepts within the scope of regulations applicable to their jurisdiction.

This document is intended to:

1. Identify essential principles for developing a PCCP for medical device software;
2. Establish the elements of a PCCP for modifications to medical device software;
3. Highlight the scope of changes that could be considered within the bounds of a PCCP; and
4. Highlight the benefits and challenges of PCCPs for users, regulatory bodies, and manufacturers.

2.2 Scope of the document

This document applies to the subset of software that meets the definition of a medical device (referred to throughout as medical device software, as described in IMDRF SaMD WG N81). This document focuses on best practices for manufacturers to consider when developing PCCPs and aims to support international convergence on the principles of PCCPs and to encourage their use as the concept is leveraged or referenced across jurisdictions.

This document is not intended to:

1. Be an interpretation or replacement of any jurisdiction's laws and regulations;
2. Establish regulatory requirements for a PCCP;
3. Define specific types of changes acceptable for inclusion in a PCCP; or
4. Serve as regulation or guidance regarding PCCPs or similar plans across jurisdictions. Additional work may be required to apply and align these concepts in a given jurisdiction. Furthermore, not all jurisdictions may be accepting PCCPs or similar plans for regulatory review.

3. References

1. *IMDRF/SaMD WG/N10FINAL:2013 Software as a Medical Device: Key Definitions*
2. *IMDRF/SaMD WG/N81FINAL:2025 Characterization Considerations for Medical Device Software and Software-Specific Risk*
3. *IMDRF/RPS WG/N9FINAL:2024 (Edition 4) Non-In Vitro Diagnostic Device Regulatory Submission Table of Contents (nIVD ToC)*
4. *Predetermined Change Control Plans for Machine Learning-Enabled Medical Devices: Guiding Principles (https://www.fda.gov/medical-devices/software-medical-device-samd/predetermined-change-control-plans-machine-learning-enabled-medical-devices-guiding-principles)*
5. *IEC 62304:2006 Medical device software – Software life cycle processes*

4. Essential Principles

Robust PCCPs, including those for medical device software, encompass the foundational concepts outlined below.

1. **Focused and bounded**: A PCCP describes certain changes that a manufacturer intends to implement with enough specificity to ensure the continued safety and effectiveness of the medical device software. Such changes are limited to modifications within the intended use or intended purpose of the original medical device software.

2. **Risk-based**: The value and reliability of a PCCP are strengthened when the intent, design, and implementation of a PCCP are driven by a risk-based approach. This approach adheres to the principles of risk management to ensure that risks are adequately managed, controlled, and are integrated within an existing risk management framework.

3. **Evidence-based**: Evidence generated throughout the Total Product Lifecycle (TPLC) of the medical device software with a PCCP is important to ensure the ongoing safety and effectiveness of the medical device software and that the benefits outweigh the associated risks.

4. **Transparent**: For PCCPs, the best practice is to provide clear, meaningful, timely, and appropriate transparency to intended users consistent with the authorized PCCP for the medical device software. This helps ensure that intended users remain aware of the medical device software's performance and use before and after changes are implemented. Providing relevant and robust information in the PCCP also helps regulatory bodies make an informed decision regarding the continued safety and effectiveness of the medical device software with a PCCP.

5. **TPLC Perspective**: Creating and using a PCCP from a TPLC perspective helps enhance its quality and integrity. This is achieved by continuously considering input from intended users, integrating new data as it becomes available, and applying risk management practices throughout the TPLC. The use and support of established regulatory, quality, and risk management frameworks throughout the TPLC helps to strengthen device safety.

5. Fundamentals of a PCCP

A PCCP is an optional mechanism for manufacturers to convey planned changes in their initial regulatory submissions or when submitting a change to their marketed medical device software to regulatory authorities. Changes consistent with an authorized PCCP do not require manufacturers to seek additional authorization when implementing these changes. PCCPs may be utilized to support iterative and planned improvements to medical device software, while improving or ensuring continued safety and effectiveness. The PCCP should be developed and managed within the manufacturer's existing quality management system, including the risk management process. Changes included in a PCCP, which may include planned maintenance activities, are limited to changes *within* the medical device software's original intended use or intended purpose.[1]

A manufacturer's quality management system, specifically the risk management and change management processes, is critical to ensure that medical device software consistently meets applicable regulatory requirements and pre-defined specifications. This is particularly important for medical device software that is authorized with a PCCP, as PCCPs include changes that would otherwise require a new submission. Device changes authorized via a PCCP within a regulatory submission are expected to be implemented according to the manufacturer's quality system, particularly the change management and risk management processes, and in line with existing regulatory requirements and international standards for medical device software (e.g., IEC 62304).

Version control for a PCCP is important to ensure that regulatory bodies and manufacturers clearly understand which version of the PCCP was authorized. This is also important to adequately track new authorized versions when a manufacturer revises a previously authorized PCCP. Because PCCPs contain modifications that would otherwise require a new submission, revisions to a previously authorized PCCP are generally considered to be a change that will affect the safety and performance of the medical device software and will therefore likely require re-authorization. However, some jurisdictions may allow for some minor changes to PCCPs without re-authorization.

To promote adequate traceability within a given PCCP, it can also be useful for the manufacturer to connect each change provided in the Description of Changes section to the specific verification and/or validation plan provided in the PCCP's Change Plan section. This may help regulatory bodies to easily identify where comprehensive information on each change is located as well as how the changes may affect the medical device's safety and performance, if applicable.

[1] For example, model updates using newer data to expand the subset of an existing patient population may be appropriate for inclusion in a PCCP, provided these changes fall within the original intended use or intended purpose.

5.1 Elements of a PCCP

Together, the elements of a well-formulated PCCP clearly capture the changes a manufacturer plans to make to its authorized medical device software, and how those changes will be made in a structured manner to ensure that the medical device software will remain safe and effective when used as intended.

The changes included in the PCCP may be interconnected or independent from each other. It is therefore important to provide an analysis of the anticipated benefits and risks of implementing the PCCP, in part and as a whole, to ensure that the benefits of implementing the PCCP will outweigh the risks.

Generally, a PCCP consists of a detailed Description of Changes, a Change Plan, and an Impact Assessment, as these elements are intended to provide the regulatory authorities with comprehensive information that will enable a detailed review of the proposed changes, along with other required documentation. The level of detail provided in the PCCP should generally be commensurate with the risk or complexity of the planned change and should include enough detail for a regulatory body to conduct a comprehensive assessment.

1. The **Description of Changes** details the changes that a manufacturer plans to make to the medical device software and a specific rationale for these changes.

2. The **Change Plan** supports each change detailed in the Description of Changes and describes the verification and validation activities, including pre-defined acceptance criteria, how the changes will be deployed, and how the changes will be communicated (e.g., labelling updates) to intended users.

3. The **Impact Assessment** links the Description of Changes to the Change Plan, by evaluating the impact of the changes (individually and collectively), as well as the anticipated benefits, risks, and mitigations of these risks. It addresses how the activities described in the Change Plan will continue to assure the safety and effectiveness of the device when used as intended, as changes are deployed. As such, the elements of a PCCP are interconnected.

A detailed description of each of the elements is provided below.

5.1.1 Description of Changes

A dedicated Description of Changes section in a PCCP identifies the planned changes with enough specificity to allow for assessment of the continued safety and effectiveness of the device. The Description of Changes section details the list and description of individual device changes for future software releases, as well as the specific rationale for each device change. This section in a PCCP also includes details on specifications of the characteristics and performance of the device that can be verified, validated, and deployed.

To promote traceability, it can be useful for each change proposed by the manufacturer to be connected to specific verification and validation plans or protocols within the Change Plan. Importantly, because a robust PCCP includes only select changes that can be verified, validated, and deployed, manufacturers should clearly establish boundaries that define the range of the proposed changes to the medical device software in their PCCP.

The Description of Changes is also the section of the PCCP where the implementation of the proposed changes can be specified. For example, a Description of Changes is where a manufacturer may specify if the proposed changes in a PCCP will be implemented in a uniform manner across all devices on the market (sometimes referred to as homogeneous or global changes, or global adaptations), and/or implemented differently for different devices on the market. The implementation may be based on the unique characteristics of a specific clinical site or individual patients (sometimes referred to as heterogeneous or local changes, or local adaptations). Manufacturers may describe the implementation control procedures that will be used to ensure appropriate application of homogeneous and heterogeneous changes, including any mechanisms for independent deployments, monitoring, verification, and documentation. In addition, manufacturers can include information regarding the expected frequency of updates, if known.

Where applicable, the Description of Changes is where a manufacturer specifies if a proposed change will be implemented automatically (i.e., whether the changes are implemented automatically by software), manually, (i.e., involving steps that require user, manufacturer, health institution, healthcare provider, or patient input, action, review, and/or decision-making), or a combination of both. The specific requirements for specifying implementation changes in a PCCP may vary between jurisdictions.

5.1.2 Change Plan

The primary goals of the Change Plan are to:

1. Identify the performance evaluation methods, i.e., the data, test and evaluation methods, analysis methods, and prespecified acceptance criteria, that will be used to verify and validate the modifications; and

2. Identify the update procedures, i.e., the process to deploy proposed changes mapped out in the Description of Changes and the plan to communicate these changes to the intended users, as needed.

Performance Evaluation Methods: It is important that the performance evaluation of the medical device software demonstrates that the proposed changes meet the pre-specified acceptance criteria in the PCCP and continue to meet performance requirements of the previously authorized medical device software. Thoroughly presented performance evaluation methods generally include the plans to verify and validate that the changed medical device software will meet the specifications identified as part of a specific change, in addition to maintaining the requirements that are not part of the change but may be impacted by the change.

Performance evaluation methods may also include, as applicable, the plans for verification and validation testing of the medical device software following the implementation of each individual change, and in aggregate. Specifically, the Change Plan may provide, as applicable, details on the planned changes, including:

- a summary of the medical device software performance at the time of submission and expected software performance upon implementation of the changes;
- a description of the relevant data, data management practices, and methods used to evaluate the change;
- associated inputs/outputs;
- performance metrics;

- pre-defined acceptance criteria that are quantitative, statistically sound, appropriate to the risk, and clinically meaningful; and
- statistical tests for each planned change

A robust Change Plan also includes information about how a manufacturer intends to document and address any failures in the performance evaluation methods for a specific change. The Change Plan is expected to document how the failure(s) will be recorded in compliance with the jurisdiction's regulations, as well as a mechanism for assuring the specific change(s) will not be implemented if they cannot meet pre-defined acceptance criteria per the performance evaluation methods specified in the Change Plan.

Update Procedures: The update procedures specify how the manufacturer will deploy the changes proposed in the Description of Changes, including the plan for communication to and/or training of intended users on the implemented changes, as needed. The Change Plan may include appropriate labelling update plans, post-market surveillance plans, procedures (such as real-world monitoring), and notification requirements. For local adaptations, the Change Plan may also outline the interaction between the manufacturer and local health institutions.

It is important for a manufacturer to ensure that the update procedures address, as appropriate, how labelling will be updated when changes are implemented to ensure clear information is provided to users when they need it. It is also important to include a description of the labelling sections that are anticipated to be impacted by the implementation of the changes. Different types of changes may warrant different types or timings of notifications (e.g., software release notification that has minimal operational impact vs. an advanced warning for major changes to the software that may have operational impact). For marketed medical device software, labelling provided to intended users should reflect information about the version of the medical device software they use. To minimize confusion about the marketed version(s) of the medical device software, available labelling should reflect only implemented changes. Changes in the PCCP that have not yet been implemented should not be included in labelling.

5.1.3 Impact Assessment

The Impact Assessment is the evaluation of the anticipated benefits and risks of implementing the individual and cumulative changes outlined in the PCCP for medical device software, as well as the mitigations for those risks. The Impact Assessment provides assurance that the proposed changes in a PCCP are unlikely to introduce additional, unmitigated risks and that the safety and effectiveness of the medical device software as a whole are maintained or improved when the changes are implemented. Notably, the Impact Assessment includes additional considerations (e.g., cumulative impact of implementing all changes) to the typical risk assessment that is meant to support the risk management activities for the medical device software. This assessment may include consideration of updated risks related to cybersecurity and interoperability, for example. The manufacturer's existing quality system should serve as the framework for conducting an Impact Assessment for the modifications set forth in the PCCP.

Manufacturers may consider the following when developing the Impact Assessment within a PCCP:

1. Comparison of the version of the medical device software with each change implemented individually against the version of the medical device software without any changes implemented;

2. Discussion of the anticipated benefits and risks of each individual change – which should also include any anticipated benefits and risks introduced by the process of changing the medical device software in the post-market phase after the device has been deployed;

3. Discussion of how the methods described in the Change Plan will maintain the medical device software's safety and effectiveness;

4. Discussion of how the implementation of each change may impact other planned changes, as applicable;[2] and

5. A description of the cumulative impact of implementing all changes, where possible.

[2] For manufacturers considering implementation of local changes within a single health institution or for single patients, the interplay between planned global and local adaptations should be given careful consideration. Such changes may not be allowable in certain jurisdictions.

6. Benefits and Challenges of PCCPs

6.1 Benefits of PCCPs

Innovations in medical device software are transforming healthcare by improving diagnostics, treatment, and patient monitoring. When appropriately utilized, PCCPs allow for authorized, well-documented modifications to occur after the medical device software is placed on the market without a new regulatory submission. This enables patients and healthcare systems to benefit from accelerated access to innovation while regulatory bodies maintain oversight and manufacturers maintain regulatory compliance and device safety.

6.1.1 Better health outcomes for patients

One of the key health benefits of PCCPs is that they may give patients quicker access to enhancements in medical device software. Under PCCPs, certain innovations can progress expeditiously, enabling the efficient implementation of authorized changes to marketed medical device software. Timely access helps ensure that patients can benefit from the latest advancements in medical technology, ultimately leading to better health outcomes and more effective treatments for patients.

PCCPs allow for the incorporation of new clinical evidence, ensuring clinicians have reliable medical device software to deliver accurate and appropriate care. This may not only reduce the risk of errors but may also lead to better clinical outcomes.

By supporting a proactive and flexible update process, which can include local manufacturer-led adaptations of medical device software, PCCPs can enable manufacturers to respond swiftly to real-world use and specific patient or patient population needs, helping to ensure patients have timely access to technological advancements and tailored, clinically relevant solutions.

For regulatory authorities, PCCPs can simplify processes by reducing the need to review medical device software changes as separate submissions. They can also provide regulatory authorities with deeper insights into expected market developments and can support horizon scanning efforts.

6.1.2 Enhanced operational efficiency across healthcare systems

PCCPs support forward-planning of improvements to medical device software based on authorization of planned changes. These modifications can be scheduled and deployed to minimize disruption to clinical workflows, reducing downtime and potential risks to patients.

PCCPs align well with the evolving nature of modern healthcare systems by supporting adaptive software – systems that can learn from new data, incorporate clinical updates, and adjust their performance over time. This adaptability is essential in dynamic care environments, where rapid changes in evidence, patient populations, and technologies demand flexible solutions. Despite this adaptability, the manufacturer still needs to consider potential unintended performance of updated, deployed software and may need to take steps to remediate any issues encountered. By enabling well-planned, quicker, and more efficient updates, PCCPs can facilitate the delivery of medical device software that is frequently improved, more responsive to clinical needs, and increasingly tailored for individual patients.

6.1.3 Increased administrative efficiency

Over the lifetime of the medical device software, the administrative efficiency that results from using PCCPs can lead to continuous improvements that provide patients with more timely access to important device updates.

Advancements in medical device software over time have the potential to enhance the quality of healthcare and treatment more efficiently. A reduced administrative burden, such as the time required for new or improved versions of medical device software to reach the market, may positively impact patients and/or users.

Over a medical device software's TPLC, PCCPs can support an agile, compliant, and safety-conscious approach to development and enhancement, fostering continuous innovation without compromising regulatory standards. PCCPs can also be an efficient mechanism to support planned changes to medical device software that are implemented repeatedly.

By extension, any efficiency gains achieved by manufacturers and regulatory bodies may allow scarce resources to be allocated toward other regulatory activities and submission reviews. PCCPs enable regulatory bodies to authorize specific modifications to medical device software, thereby eliminating the need for multiple subsequent submissions for each change. This process optimizes the authorization timeline, conserving resources for both regulatory bodies and manufacturers. For manufacturers, this flexibility may allow for the consideration of new methodologies and modifications that were previously deprioritized due to high costs. It may also increase efficacy within healthcare facilities, for example, by implementing local changes to medical device software to better meet the needs of local or underserved patient populations.

Furthermore, evaluating potential modifications may encourage an increase in initial interactions between manufacturers and regulatory bodies, ensuring both parties are aligned with the planned modifications early in the product lifecycle.

The potential benefits of PCCPs are considerable. PCCPs can drive innovation, aligning with the goal of every regulatory authority to balance advancements in patient care within their respective countries or jurisdictions with strict regulatory compliance. Additionally, PCCPs can provide a structured yet flexible framework that can adapt to the rapid pace of technological advancements in the medical device industry, ultimately resulting in a positive impact for patients.

6.2 Challenges of PCCPs

In addition to the risks associated with modifying medical device software, PCCPs can introduce further challenges.

Distinct challenges of PCCPs include:

- more complex regulatory submissions for manufacturers;
- more complex regulatory submissions for regulatory authorities to review and authorize;
- additional submissions by manufacturers if modifications are made to the previously authorized PCCP;
- traceability and implementation; and
- varying levels of PCCP adoption internationally and added reliance complexities.

6.2.1 Submissions that include PCCPs

Regulatory submissions with PCCPs will likely require additional preparation time due to the need for extensive planning, risk analysis, and documentation compared to a traditional submission. This can increase preparation time for manufacturers, raise initial costs, and extend the duration between preparation of a submission and the submission reaching the regulatory authority, potentially increasing the time-to-market and reducing initial return on investment. Also, additional submissions by manufacturers may be necessary if modifications are made to the originally authorized PCCP. Concerns with delayed launches can be mitigated by submitting a PCCP with the first change submission for the medical device software, rather than as part of the initial submission. Although this requires initial resource investment and expertise to create the PCCP document, it may subsequently enable more efficient management of future device modifications.

6.2.2 PCCP review and authorization

Certain jurisdictions have statutory requirements for reviewing a regulatory submission within a specific time period, regardless of whether a PCCP is included. The PCCP is an additional component of a submission and can require that additional resources be allocated for the regulatory review. The increasing complexity of PCCPs may be challenging while regulatory bodies become familiar with new proposals, such as those involving site-specific changes. Other jurisdictions could have different review timelines and authorization processes due to the inclusion of a PCCP.

In general, from a regulatory authority's perspective, the inclusion of a PCCP can make the assessment process more complex. When and where applicable, early engagement with the regulatory authority to discuss the proposed PCCP prior to a submission is encouraged to facilitate the review process and allows the regulatory authority to address a manufacturer's questions on PCCP acceptability. A PCCP focusing on a limited number of proposed changes can also be a helpful approach to ensure that regulatory bodies are reasonably able to review the PCCP. Although there may be some added complexity in the submission, the benefits of overall efficiency are realized later in the medical device software lifecycle.

6.2.3 Traceability and implementation

PCCPs can redistribute risks across the lifecycle by introducing a more stepwise and adaptable approach to product development and maintenance. This requires robust traceability mechanisms and comprehensive risk management frameworks to safeguard the integrity and functionality of the medical device software, posing a significant challenge to both manufacturers and regulatory bodies.

PCCPs should include ongoing monitoring of cumulative changes, along with confirmation that the growing body of evidence continues to support the medical device software's intended use and risk profile. Manufacturers will need to ensure that PCCPs are managed within a robust quality management system to ensure that there is accountability and so that implemented changes are appropriately documented and communicated.

6.2.4 International alignment and recognition

Not all jurisdictions may accept PCCPs or similar plans for review at this time. For those that do, the differences between regulatory jurisdictions have the potential to complicate a PCCP designed for use in multiple jurisdictions. For example, each jurisdiction may define differently which types of medical device software changes require a new regulatory submission, which in turn affects what changes are appropriate for inclusion in a PCCP. Although the intention of this document is to harmonize the approach for PCCPs across jurisdictions by describing essential principles for PCCPs, manufacturers should be aware of jurisdictional differences in implementation. Additionally, some jurisdictions utilize self-certification routes to regulatory conformity. It is the responsibility of manufacturers to ensure any existing or planned PCCPs are compatible with such routes when accounting for international alignment.

Jurisdictions that have a reliance framework will need to consider PCCPs in this context alongside jurisdictional differences. This may impact factors such as generalizability, acceptable standards, and evidence requirements. Ultimately, it is the responsibility of manufacturers to ensure that all factors relevant to jurisdictional differences are addressed when they use a reliance mechanism to apply for marketing authorization.

7. Conclusion

Patients can benefit when medical device software is able to evolve in a timely manner through regular updates and thoughtfully planned changes. Medical device software changes can be helpful to allow manufacturers to potentially address real-world use or adapt to changing healthcare environments. A PCCP is one way, in certain jurisdictions, manufacturers can gain authorization to make planned updates to their medical device software before they are implemented, while providing assurance that their devices will remain safe and effective. Although adopting a PCCP approach requires manufacturers and regulatory bodies to invest early in strong collaboration and the development of well-defined, mature modification plans, this approach ultimately benefits patients and manufacturers alike. PCCPs can enable patients to gain timelier access to high-quality medical device software while giving manufacturers greater flexibility to implement planned changes in a manner that aligns with their operational needs. This document highlights essential principles for the PCCP approach and serves to facilitate international convergence and harmonized approaches across jurisdictions for medical device software advancements.

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