Provisional Translation (as of June 2026)

This English version of the Japanese review points is provided for reference purposes only.
In the event of any inconsistency between the Japanese original and the English translation, the former shall prevail.

Review Points for Home-Use Software as a Medical Device (SaMD) to Detect Signs of Disease and Encourage Medical Consultation

Pharmaceuticals and Medical Devices Agency
Office of Software as a Medical Device
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<Revision History>

Version	Date	Main Changes
1	26 May 2026	Initial version issued

Note:

- The review points indicate the necessary evaluation items for medical devices within the specified scope, with the aim of improving efficiency in document preparation and facilitating the review process for marketing approval applications.
- The review points present the concept of review for marketing approval based on current scientific knowledge and should be reviewed and revised as needed in accordance with future advances in science and technology.

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1. Products Covered by This Document

The scope of these review points covers Home-Use Software as a Medical Device (SaMD) that is used at the user's choice, rather than SaMD for Clinical Settings that is used under a physician's instructions or prescription. The products covered by this document use vital data collected through sensors of general-purpose digital devices[1], such as smartphone cameras, smartwatches, and smart earphones, which are non-medical devices distributed for purposes unrelated to medical device applications, as input data, and are intended for one of the following purposes. In these review points, the following purposes are collectively referred to as "home-use disease sign detection."

- Products that encourage medical consultation by detecting signs of disease through testing or monitoring at home for healthy individuals or those who have not been diagnosed with any disease.
- Products that encourage medical consultation by detecting or monitoring signs such as changes in one's own symptoms at home, at the patient's own discretion and independently of a physician's guidance, for those who have been diagnosed with a disease.

In addition, products with the following intended purposes are not covered by these review points.

- Products that assist physicians in making a diagnosis or assist in diagnosis of the disease itself.
- Products that are prescribed based on a physician's judgment to manage symptoms or conditions
- Products that change established medical management.
- Products that provide treatment such as symptom relief
- Products that include tangible objects
- Products that require dedicated hardware whose use is limited to medical device applications when using the software[2].
- Products that do not fall under the definition of medical devices in the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices (hereinafter referred to as the "PMD Act").

Depending on the disease subject to sign detection, such as cancer, intractable diseases, or dementia, special consideration may be required regarding the risks associated with false positives or false negatives, and psychological burden on patients. Note that for such diseases, it is necessary to adjust the matters to be discussed and evaluated according to the product, separately from and/or in addition to the contents of these review points. Similarly, it is anticipated that functions may be fulfilled using various technologies that will develop in the future. Also, note that it is necessary to adjust the

[1] If there is uncertainty on whether the general-purpose digital device need to be handled as medical devices, confirmation should be obtained in advance.
[2] Such products need to be handled as tangible medical devices rather than SaMD.

evaluation content separately from and/or in addition to the contents of these review points, depending on the technology used for product realization.

Note: The scope of these review points is premised on products that fall under the definition of medical devices in the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices (hereinafter referred to as the "PMD Act"). Note that for products that detect signs of disease and encourage medical consultation, whether directly or indirectly, whether it qualifies as a medical device is determined from various viewpoints such as the detection target, claims, and methods of presenting results to users. It is recommended to confirm at an early stage of development whether the product being developed qualifies as a medical device under the PMD Act.

2. Definition

- Software as a Medical Device (SaMD):

  Medical device software (medical device that is software), or storage media containing such software.

- SaMD for Clinical Settings:

  SaMD used by patients under a physician's instructions or prescription. SaMD for Clinical Settings includes SaMD used exclusively at home, as well as SaMD used in clinical settings.

- Home-Use SaMD:

  SaMD that can be used at the user's choice, without visiting a medical institution or a physician's instructions or prescription. This does not include SaMD for Clinical Settings that is instructed or prescribed by a physician and used exclusively at home. In this document, Home-Use SaMD refers to products intended to detect disease signs used at home.

- User:

  A person who uses Home-Use SaMD regardless of the presence or absence of disease or symptoms, or a person who assists in the use of Home-Use SaMD, such as family members or caregivers.

- Product under application:

  Home-Use SaMD seeking approval.

3. Description of the Product Under Application

3.1. Define Clinical Positioning

For products under application intended to detect disease signs at home, it is necessary to clarify that it is intended for home use and intended to detect disease signs (not to assist diagnosis). It is also important to investigate and define how the signs of the disease, the detection targets, currently lead to medical consultation in Japan. This enables smooth consideration of the impact of introducing the

product under application, and the risks of false positives and false negatives. If there are descriptions related to the product under application or its detection targets in guidelines prepared by relevant academic societies, it is desirable to explain the directions for use of the product under application in reference to them.

Note that some products may have functions similar to products for clinical settings or may be easily applied for clinical settings. During consultation with the Pharmaceuticals and Medical Devices Agency (hereinafter referred to as "PMDA") for development as a home-use product, discussions may proceed without clearly distinguishing such products from those that may later be developed for clinical settings. In such cases, note that the positioning of the product under application may become unclear from PMDA's perspective, potentially preventing smooth review and consultation.

[Reference] General Discussion on Clinical Positioning

The clinical positioning of Home-Use SaMD covered by these review points is as defined in Section 2. In general, to discuss the sufficiency of the evaluation package and the appropriateness of evaluation considered by the applicant, it is important not only to clarify the specifications of the product under application (e.g. input data, output data, and performance values) but also to clarify and share its clinical positioning with PMDA.

Clinical positioning refers to the purpose for which the developed SaMD is used, its effects on disease conditions, patient situations, and existing treatment and diagnostic methods, as well as differences in performance compared to other treatment and diagnostic methods, and priority in treatment. It is a key factor in determining the characteristics of the medical device. When adapting products covered by these review points to clinical setting in the future, it is important to proceed with discussions after clarifying the clinical positioning.

Note that general matters regarding development concepts, clinical positioning, and the organization of associated conceptual requirements are summarized in the "Guidance for Appropriate and Prompt Approval and Development Based on the Characteristics of Software as a Medical Device [Second Version]." [3] Refer to the document as needed.

3.2. Design Concept

Based on Section 3.1, it is necessary to define the design concept of the product under application. Here, it is important to justify what functions were considered necessary to achieve the clinical positioning, and what level of performance was considered necessary for those functions.

Based on the design concept of products intended for home-use disease sign detection, organize the matters regarding Sections 3.2.1 to 3.2.3.

Based on the design concept of products intended for home-use disease sign detection, organize the

[3] https://www.pmda.go.jp/files/000281012.pdf

matters regarding Sections 3.2.1 to 3.2.3.

3.2.1. Configuration

Since products intended for home-use disease sign detection covered by these review points are software products, their functions are generally provided by being installed on general-purpose digital devices or via cloud-based services through the internet. The product under application is often used in conjunction with non-medical device functions that the general-purpose digital device has unrelated to the medical device (hereinafter referred to as "general-purpose functions"). In application, it is necessary to clarify the relationship between the general-purpose functions and the product under application and then clarify the scope of the product under application. Since there may be differences in understanding between the applicant and PMDA regarding the scope of the product under application, it is desirable to utilize PMDA consultation procedures as necessary.

3.2.2. Functions

Since it is necessary to specifically explain all functions that the product under application has, explain each function of the product under application with reference to the following matters. Although functions and specifications need to be specified at the time of approval application, it is inevitable that some functions and specifications may be undetermined, depending on the development phase at the time of consultation. In this case, clearly explain that those specifications are under consideration. However, note that if there are many undetermined points, advice may be provided with conditions.

(1) Input

- What is the input data to be analyzed?
- Does the input data required for the product under application to demonstrate appropriate performance have any conditions (e.g. conditions for general-purpose digital devices and their sensors, etc.)? (Also refer to (5).) (5)

(2) Detection Target

- What signs of disease are detected?
- What symptoms or signs of disease are not detected?

(3) Analysis Principle

- What is the analysis principle?
  - If filtering such as noise processing is performed on the acquired data, how is it done?

- For parts designed deductively, what is the processing algorithm?
- If models or modules are realized using machine learning, what is the training algorithm? What is the development data (data collection facility, method to label training data, the volume of training data, etc.)?

- How is the final output determined?
  - What is the determination threshold?

(4) Output

- How are the analysis results presented?
- Are the analysis results presented with suggestions or explanations?
  - The content of outputs and information provided must consider that the users of the product under application are those without specialized medical knowledge.

(5) Functions Related to Restrictions on Users

In general, there are no user restrictions for general-purpose digital devices themselves. On the other hand, products intended for home-use disease sign detection may have specific intended users (e.g. age, presence or absence of disease) depending on the developer's risk management and evaluation. Therefore, design considerations are necessary to ensure that the use of the product under application is limited to appropriate users. As a design consideration, one option is to implement a pre-use activation function that enables the function only after confirming that the user is appropriate.

(6) Function to Determine the Appropriateness of Use Conditions and Environment

For the product under application to demonstrate appropriate performance, adjustment of the general-purpose digital device status and use environment (hereinafter collectively referred to as "use environment") may be required. If the product under application itself has a function to determine the appropriateness of the use environment, it is necessary to clarify the details of the function and explain the relationship between the principle of sign detection and the use environment, as well as the necessity of the function.

(7) Others

Functions other than the disease sign detection function need to be clarified. For other functions, explain the details of the functions in reference to the sections above.

3.2.3. Directions for Use

It is necessary to explain the specific directions for use of the product under application, including how to start using the product under application and its daily use. Also, if there are matters to be

considered to demonstrate appropriate performance, as in the following examples, these should be clarified.

- The user's condition at the time of sign detection determination (e.g. whether the user needs to be at rest during data acquisition, or when there are restrictions on measurement posture).
- If it is necessary to prepare an appropriate use environment, its procedures.
- If there is a pre-use activation function, its procedures.

Although directions for use need to be specified at the time of approval application, it is inevitable that there are partially uncertain directions for use at the time of consultation. In this case, clearly explain that the directions for use are under consideration.

3.3. Information on Similar Products

If there is a similar product to the product under application, provide information on the product under application while comparing with the similar product. For methods to compare similar products, refer to "Points to Consider in Preparing Documents Attached to Application for Marketing Approval of Medical Devices" (PFSB/MDRMPE Notification No. 0120-9, dated January 20, 2015) (in Japanese). In addition, if there are differences from similar products particularly regarding clinical positioning, explain the development concept sufficiently.

4. Evaluation Package

Based on Sections 3.1 to 3.3, it is necessary to consider an evaluation package to evaluate the clinical utility, clinical performance, and basic performance of the product under application.

High-level conceptual requirements common to many products intended for home-use disease sign detection are shown below. While it is beneficial to refer to protocols used in similar precedent product evaluations, it should be noted that adjustments basically need to be made according to the details of each product under application.

<Conceptual Requirements> *Adjust according to the characteristics of the product under application

(1) The product under application should be able to detect disease signs with clinically significant accuracy for the intended user population. (Clinical utility, clinical performance)
(2) When displaying vital data, they should be measured and displayed with appropriate accuracy. (Clinical performance)
(3) Other functions should operate as intended. (Basic performance)
(4) The software development life cycle should be managed appropriately.
(5) Cybersecurity measures should be implemented appropriately.
(6) The usability engineering process is appropriately managed.

As a basic concept, all functions that the product under application has require a certain level of evaluation. Also, even if the internal analysis is the same, the matters to be evaluated may vary on the displayed content. For example, when the product specifies the name of the suspected disease or diagnosis, it may be necessary to evaluate whether the presented disease name matches the disease the patient has. On the other hand, if these are not displayed and only a message prompting medical consultation is shown, it may be more important to evaluate whether the condition required medical consultation, rather than its performance to determine the disease. However, whether to evaluate a function in a confirmatory study, through secondary testing, or simply confirm its operation need to be examined based on the positioning of the function and the impact on users due to incorrect output. In general, (1) mentioned above is often evaluated in a confirmatory manner.

The term, **"evaluate"** does not refer only to conducting tests, but also includes conclusions derived through discussion based on the results of a conducted test. For example, if clinical utility can be explained without conducting a test that directly evaluates it, it can be said to have "evaluated clinical utility" by considering clinical performance test results together with relevant literature.

4.1. Evaluation of Utility and Clinical Performance

The main purpose of evaluating utility is to evaluate whether the development concept of the product under application has been achieved. When directly evaluating utility through studies, the study should be conducted to directly evaluate the clinical value and effect of introducing the product under application while simulating the situation where it is introduced to the market. In this case, since the clinical value and effect of the product under application as a medical device are directly evaluated through studies, very convincing results can be obtained for the approval application.

When directly evaluating the utility of products intended for home-use disease sign detection, evaluation focuses on whether long-term events can be reduced, and prognosis can be improved by prompting appropriate actions by users such as recognizing the signs of disease and seeking medical consultation, rather than the correctness of disease sign detection. However, it is practically difficult to conduct studies that directly evaluate these.

On the other hand, considering that the product under application detects disease signs that would have been missed (or would have had no opportunity to be discovered) without the product under application, the risk of false positives and false negatives may be considered low. If the product under application can detect disease signs to a certain extent, it may be concluded to have utility.

Based on the above, for products intended for home-use disease sign detection, a reasonable approach is to set a success criteria that can support the expected utility, and conduct studies to evaluate clinical performance. (However, if possible, conducting studies that directly demonstrate clinical utility and providing the results to users may make the product easier for use.)

Note that for products intended for home-use disease sign detection, it is sometimes argued that the

risk of false positives and false negatives is low, considering that no action would be taken at all if the product were not used. On the other hand, users who are positive but received false negative results may refrain from seeking medical consultation if they misunderstand the implication of product output, which may pose associated risks. Appropriate risk management should be implemented in accordance with the section on information provision in this document.

For many products intended for home-use disease sign detection, users conduct tests in their daily life using general-purpose digital devices to detect signs of disease. Since there is no non-clinical model that can evaluate whether appropriate accuracy can be demonstrated in such situations, evaluation through human studies will be necessary. Therefore, it is considered that clinical studies will be necessary for many products.

4.2. Other Functions

In addition to the function to detect disease signs, it is necessary to evaluate whether the functions provided by the product under application operate appropriately.

4.3. Software Development Life Cycle, Cybersecurity, and Usability Engineering Process

For software development life cycle, cybersecurity, and usability engineering process, it is necessary to take measures in accordance with relevant notifications.

For products developed and evaluated overseas, the usability engineering process may be evaluated based on conformity to IEC62366-1 conducted in the manufacturer's country. In such cases, note that it is necessary to assess whether the results can be extrapolated to users in Japan for products localized for Japan.

5. Points to Consider for Study Design in Clinical Studies

Appropriate study protocols should be established according to the positioning of the product under application. However, when evaluating clinical performance as described in Section 4.1, a study is generally expected to evaluate the degree of agreement between the determination results of the product under application and the ground truth label. This section describes matters to be considered when designing study protocols under such evaluation policy. Since there are issues regarding study protocols other than those described below, use PMDA consultation as necessary.

5.1. Evaluation Samples and Subjects

It is necessary to assess the differences between the evaluation samples and the product under application and justify its appropriateness as an evaluation sample. If the performance of the general-purpose digital device, software functions, or version differ between the evaluation samples and the

product under application, clarify the differences and assess whether it can be extrapolated as an evaluation of the product under application prior to submission.

Similarly, it is necessary to assess the differences between the intended users in actual clinical practice of the product under application and the evaluation subjects in the study and justify its appropriateness as evaluation subjects.

5.2. Ground Truth Label

It is appropriate to define ground truth labels as events that have clear clinical relevance to disease signs (e.g. atrial fibrillation (AF) that can be identified from electrocardiograms, arrhythmia from heart rate data). Note that if defining such ground truth labels is difficult, it is also possible to evaluate the presence or absence of the disease itself as ground truths. In either case, it is necessary to be able to evaluate the accuracy of "detection of disease signs" by the product under application based on clinically significant events.

Note that depending on the disease, it is also expected that there may be variability among determining physicians for events or diagnoses that have clear association with disease signs. In such cases, consideration should also be given to defining the ground truth label by majority vote based on the results from multiple physicians.

5.3. Endpoints

In general, a variable to obtain the most appropriate and convincing results directly related to the primary objective of the study is selected as the primary endpoint, and variables to obtain results of effects related to secondary objectives are selected as secondary endpoint. Depending on the positioning of the product under application, multiple indicators (e.g., sensitivity and specificity) may be considered important. In this case, it is necessary to consider them as a composite endpoint.

Even for secondary endpoints, if the obtained results raise suspicion about the clinical utility, it may become a significant issue in obtaining approval. Considering the overall results, it is necessary to examine whether its utility and safety are ensured, and whether necessary measures, such as provision of information, are sufficient.

In addition, the specifications of the product under application should also be considered when selecting the primary endpoint in a confirmatory study. For products intended to detect signs of disease at home, evaluation of determination performance using sensitivity and specificity, which are not affected by the prevalence in the evaluation population, is recommended. On the other hand, if the development concept is to detect signs of disease that would have been missed conventionally, evaluation using positive predictive value can also be considered. However, since positive predictive value is an indicator affected by prevalence, it is necessary to examine the appropriateness of the evaluation method, including the prevalence level the evaluation population should have. In addition,

since positive predictive value alone cannot evaluate the false negative output by the product under application, it is also necessary to consider indicators to evaluate whether false negatives are within an acceptable range.

6. Points to Consider in the Interpretation (Evaluation) of Study Results

As stated in Section 5.3, even if the results for the primary endpoint meet the predefined success criteria, if there are matters that should be considered during use based on study results including secondary endpoints, the reproducibility of such results, the degree of risk, and the necessity of cautionary statements and information provision should be examined. For example, the handling of the following cases should be carefully examined.

- When the product under application has a specification to present an analysis result as "indeterminate" (or likewise) when the test was completed but the confidence level of the determination is low (e.g., results are classified to 3 types: "positive," "indeterminate," and "negative"), the evaluation of the determination accuracy should include indeterminate cases in the analysis, and its utility needs to be explained accordingly.
- When outliers occur in results, it is necessary to analyze the cause and reproducibility, and to examine whether information should be provided regarding the possibility that appropriate determination cannot be made.
- When a certain number of cases occur in the group using the product under application where the test could not be completed and analysis results could not be obtained (test failure cases), it is necessary to examine the conditions when tests succeed (or fail) and provide information to ensure appropriate testing. [4]

7. Information Provision

Regarding home-use medical devices that detect signs of disease and encourage medical consultation, the notification "Partial Revision of "Points to Consider in Approval Applications for Home-Use Medical Devices to Detect Signs of Disease and Encourage Medical Consultation"" (PSEHB/MDED Notification No. 1213-4 and PSEHB/PSD Notification No. 1213-3, dated 13 December 2022; partially revised on 21 June 2024) has been issued, which describes points to consider regarding information provision. When submitting an approval application for products subject to the relevant notification, it is first necessary to comply with the notification.

In particular, it should be noted that users of the product under application are those without specialized medical knowledge, and it is necessary to consider measures such as providing information based on it. To avoid misunderstanding or causing unnecessary concern, information should be

[4] When there are many test failure cases, even if the agreement rate with the ground truth label is positive, it may raise concerns that the tests may not be performed successfully in clinical practice, if only the results when tests were completed are being evaluated. The appropriateness of study results needs to be carefully explained.

provided to ensure correct understanding of the positioning of the product under application, interpretation and meaning (significance) of output results, and the limitations of the product's performance (e.g. it detects signs of disease that can be read from analyzed data and not inherently capable of diagnosing disease). In addition, when indicators presented as evidence along with the results are not used in daily life, sufficient consideration should be given to providing information about the intent and interpretation of those indicators.

Furthermore, since users of the product under application will seek medical consultation based on the output results, information should also be provided to healthcare professionals to ensure correct understanding of the interpretation of the results and performance of the product under application. In particular, when the product under application provides information similar to that presented by existing medical devices (hereinafter referred to as "existing information"), and when the evaluation required for such existing medical devices or evaluations of equivalence has not been conducted, it is necessary to clearly state that the product under application does not present information equivalent to such existing information, and that medical care should not be performed based on its output.

Regarding the analysis principle of the product under application, there are cases where data directly indicating signs of disease are detected (e.g., detection of AF from electrocardiograms), and cases where data indicating signs of disease are estimated indirectly (e.g., estimation of sleep apnea syndrome (SAS) from body movement during sleep). Especially in the latter case, disclosing the analysis principle may help users and healthcare professionals who receive the results understand the limitations of its performance. Therefore, it is appropriate to provide information to ensure correct understanding of the product's analysis principle.

It should be noted that in the notification mentioned above, applicants are required to prepare and manage a website to provide information on directions for use and precautions regarding the product under application.

8. Other Matters

8.1. Brand Name, Function Name, Labeling

As stated in Section 7, when obtaining approval, consideration such as providing information is necessary to avoid causing misunderstanding to users and healthcare professionals. Consideration is also necessary regarding the Brand Name and intended use, to avoid causing misunderstanding based on the principle. For example, care should be taken to ensure that the Brand Name or function name does not lead to misunderstanding that the product under application (or function) is diagnosing a disease.

8.2. Coordination with Relevant Academic Societies

In general, many products under application intended to detect signs of disease at home have a

concept to capture signs of disease and prompt medical consultation. Therefore, in the case of diseases with a large number of potential patients, there is a possibility to significantly increase the number of people seeking medical consultation. Especially in such cases, the impact of false positives from the product under application to the clinical practice is significant, and its performance may lead to confusion in clinical practice. In addition, considering that users of these products are general consumers, it is also expected that they may over-rely on negative results output by the product under application and may not undergo tests that they should receive through medical consultation. Therefore, it is important to promote appropriate cautionary statements and product understanding, such as the possibility that the product under application may output false negatives, and that medical consultation should be conducted based on the user's symptoms regardless of the results from the product under application. It is necessary to explain and discuss the positioning of the product under application and the appropriateness of provided information with relevant academic societies.

In addition, depending on the product under application, there may be differences between the decision indicators published by relevant academic societies in Japan and the determination criteria presented by the product under application. It is also necessary to discuss whether detection of disease signs through such determination are acceptable.

8.3. Distribution Form

In many cases, software with medical device functions (product under application) will be implemented on general-purpose digital devices that are non-medical devices. Preparation should be made to explain the procedures to determine its release and measures to limit use to appropriate users. It should be noted that statutory labeling and provision of package inserts also need to be appropriately addressed based on notifications.