Provisional Translation (as of November 2026)
This English version of the Japanese presentation is provided for reference purposes only.
In the event of any inconsistency between the Japanese original and the English translation, the former shall prevail.

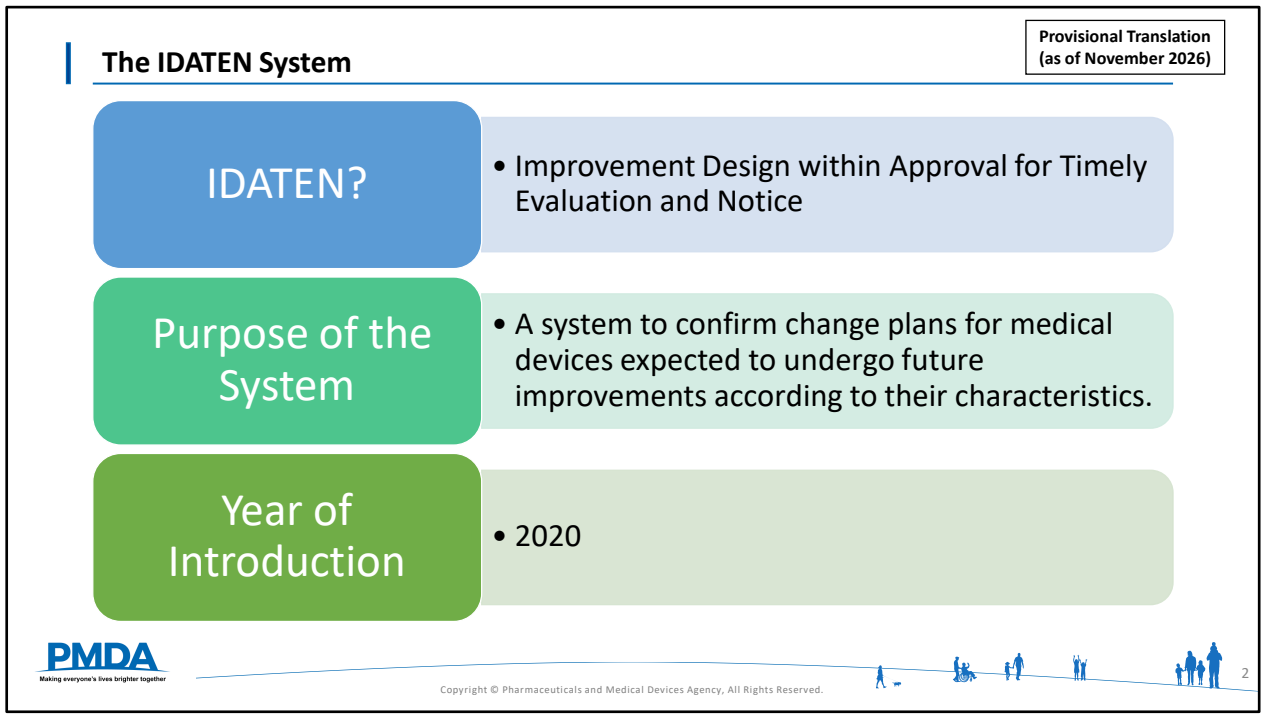
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Overview of the IDATEN System



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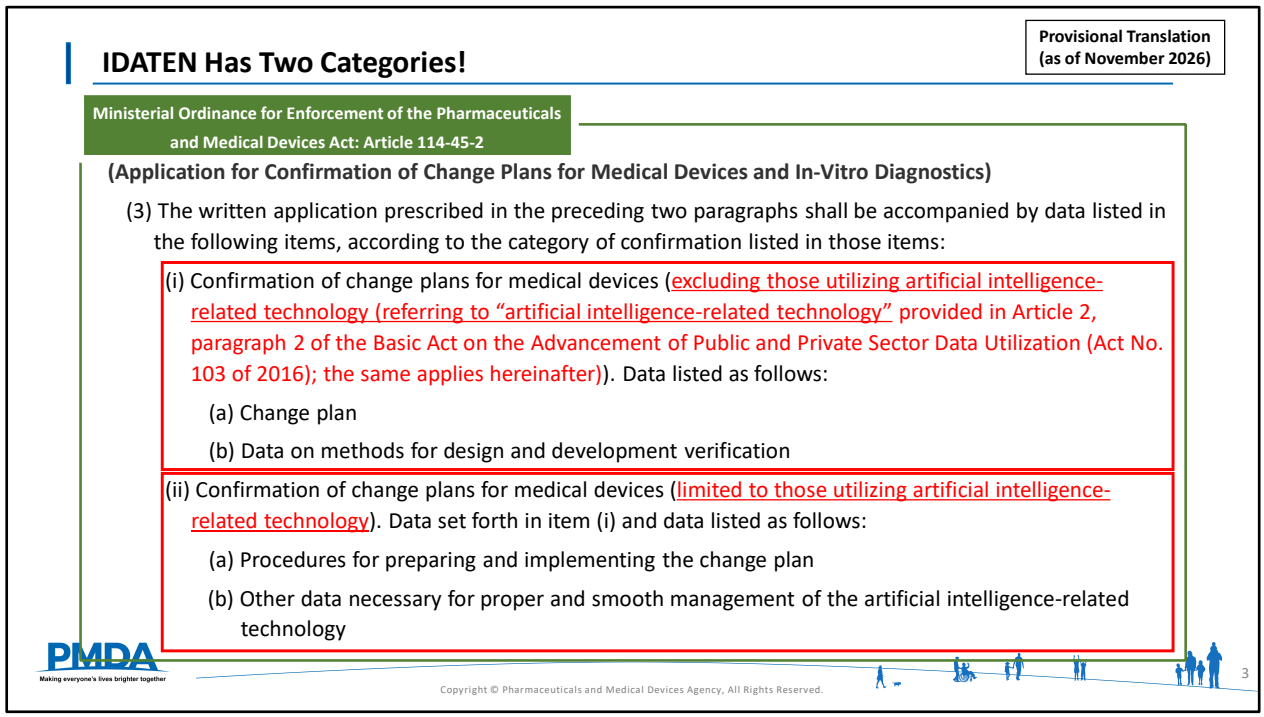
This presentation provides an overview of the IDATEN System.



Idaten is a guardian deity in Buddhism, known for his astonishing speed. Today, Idaten is used as a word meaning “a person who runs very fast”.

IDATEN is an acronym for “Improvement Design within Approval for Timely Evaluation and Notice”. This name reflects its aim of enabling expedited changes.

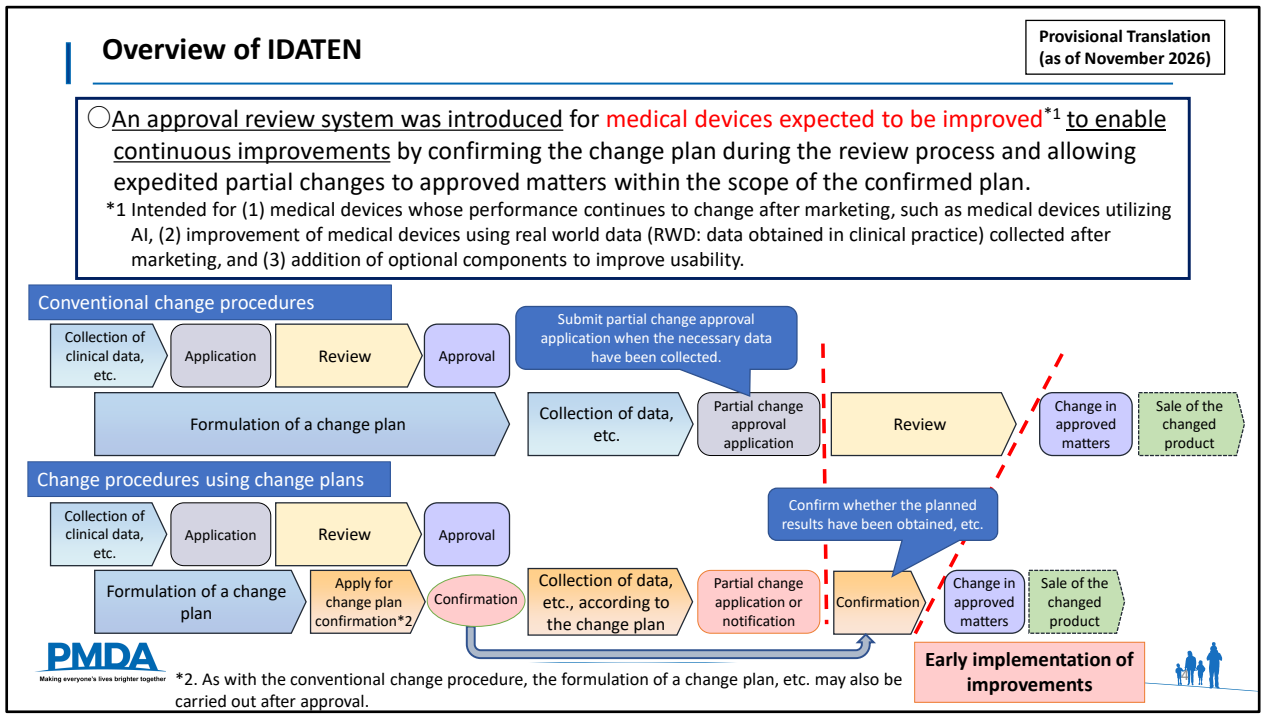
IDATEN was introduced in 2020 to confirm change plans for medical devices expected to undergo future improvements according to their characteristics.



IDATEN is divided into two categories under the Pharmaceuticals and Medical Devices Act according to the differences in the documents to be submitted to confirm change plans.

For change plans for medical devices that do not use artificial intelligence-related technology, applicants are required to submit the change plan and documents on methods for design and development verification, i.e., performance evaluation test methods.

For change plans for medical devices that use artificial intelligence-related technology, two additional documents are required.
The first describes the procedures for preparing and implementing the change plan.
This is required to ensure the quality, efficacy, and safety of artificial intelligence-related technology by ensuring that improvements are made in accordance with an appropriate change plan under an appropriate organizational framework.
In addition, as documents necessary for the proper and smooth management of artificial intelligence-related technology, documents describing the procedures for managing performance are required for medical devices whose performance is expected to change after marketing.
To date, no medical device whose performance is expected to change after marketing has been approved in Japan.



When confirmation of the change plan is completed, approved matters may be changed through a notification.
Under the conventional change procedure, data necessary to change approved matters are collected after the initial approval.
Partial change approval application is submitted when the necessary data have been collected.
Approved matters may be changed when the review is completed.

On the other hand, under the change procedure using a change plan, the procedure is the same until the initial approval is obtained.
By completing the confirmation of change plans in parallel with the review for initial approval, a notification can be submitted when the necessary data have been collected.
Change plans can be formulated after approval as with conventional change procedures.

PMDA checks the notification to confirm, among other matters, whether the planned results have been obtained.
When there are no issues, approved matters may be changed 30 days after the notification.
However, changes that require submission of clinical study results, such as expansion of the intended use, are not subject to notifications.
These require an approval review as under the conventional procedure.

Approved Matters that can be Changed with IDATEN

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Ministerial Ordinance for Enforcement of the Pharmaceuticals and Medical Devices Act: Article 114-45-3

(Cases in which a Change Plan may be Confirmed)

Concerning medical devices, the changes in the matters specified by Order of the Ministry of Health, Labour and Welfare prescribed in Article 23-2-10-2, paragraph (1), item (i) of the Act shall be the changes in the matters set forth in the following items:

(i) Intended use
(ii) Structure, components and principles of operation
(iii) Raw materials
(iv) Performance and safety specifications
(v) Directions for use
(vi) Storage method
(vii) Shelf life
(viii) Manufacturing process
(ix) Manufacturing site(s) of the marketed product

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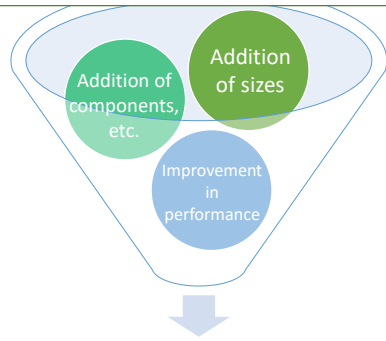
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This slide shows the approved matters that can be changed using IDATEN.
All the items stipulated in the marketing approval document are subject to IDATEN.

What Can be Achieved by Using the IDATEN System

Provisional Translation (as of November 2026)

☐ To enable continuous improvement, changes that require a partial change approval application may be handled as a notification*, provided that it is within the scope of the change plan confirmed in advance by PMDA.



Utilization of the IDATEN System

*Changes that require submission of clinical study results, such as expansion of the intended use, are not subject to notifications.

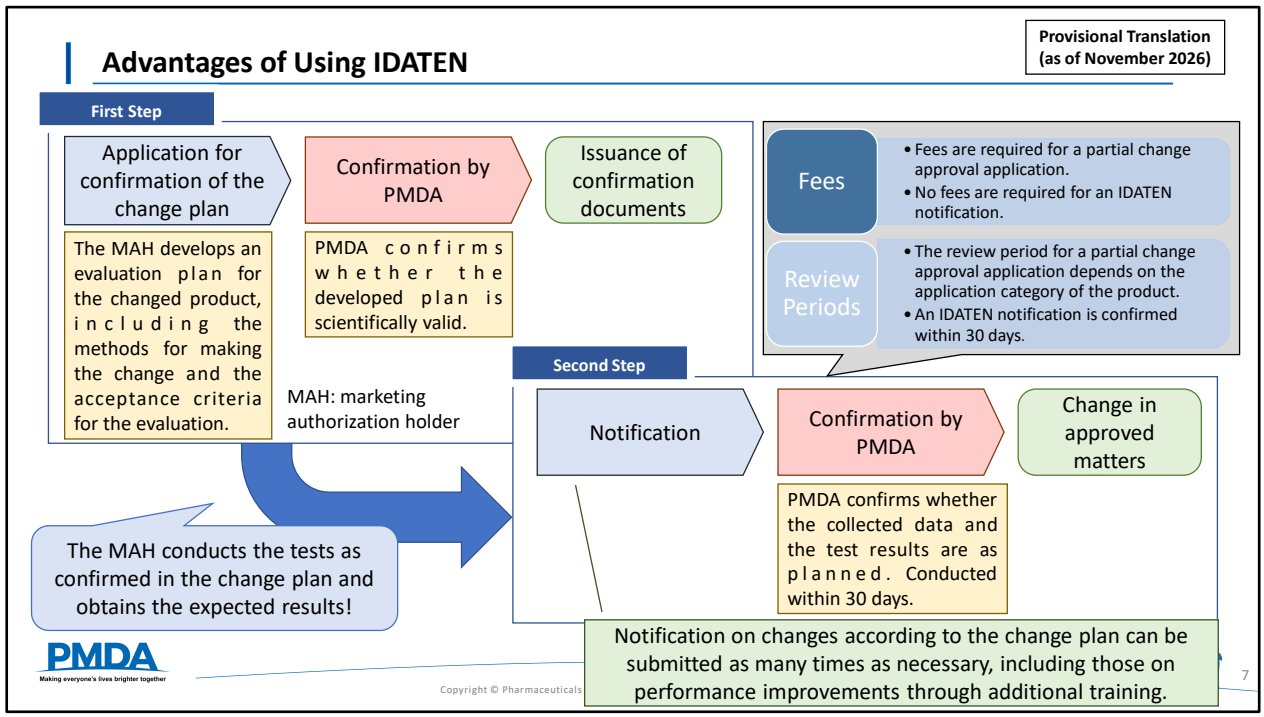
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To enable continuous improvement, changes that require a partial change approval application may be handled as a notification*, provided that they fall within the scope of the change plan confirmed in advance by PMDA.

IDATEN is advantageous in cases where changes are expected to be made repeatedly, such as the addition of size variations and components, and improvement in performance due to retraining of medical devices utilizing AI.



This slide explains the advantages of using IDATEN in terms of fees and review periods.
First, an application for confirmation of the change plan is submitted, and PMDA will confirm the application.
A change plan for which confirmation has been completed may also be revised through this procedure.

After that, the marketing authorization holder (MAH) will conduct performance evaluation according to the plan and submit a notification if the results are as expected.
PMDA confirms whether the collected data and the test results are as planned within 30 days.
If there are no issues, the MAH can change the approved matters.

For changes in approved matters, the conventional procedure is to submit a partial change approval application, for which a fee is required.
In contrast, no fee is required for an IDATEN notification, which is advantageous in terms of cost.
In addition, the review period for a partial change approval application depends on the application category of the product, taking 4 months or longer, whereas an IDATEN notification is confirmed within 30 days.
Notification on changes according to the change plan can be submitted as many times as necessary, including those on performance improvements through additional training.

This concludes the overview of the IDATEN system.
Thank you for your attention.

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