

Reviewer's approach to the premarket review – PMDA

Takatomo EZURA, Reviewer

Office of Software as a Medical Device

Pharmaceuticals and Medical device agency (PMDA), Japan

the Japanese Association of
Cardiovascular Intervention and Therapeutics

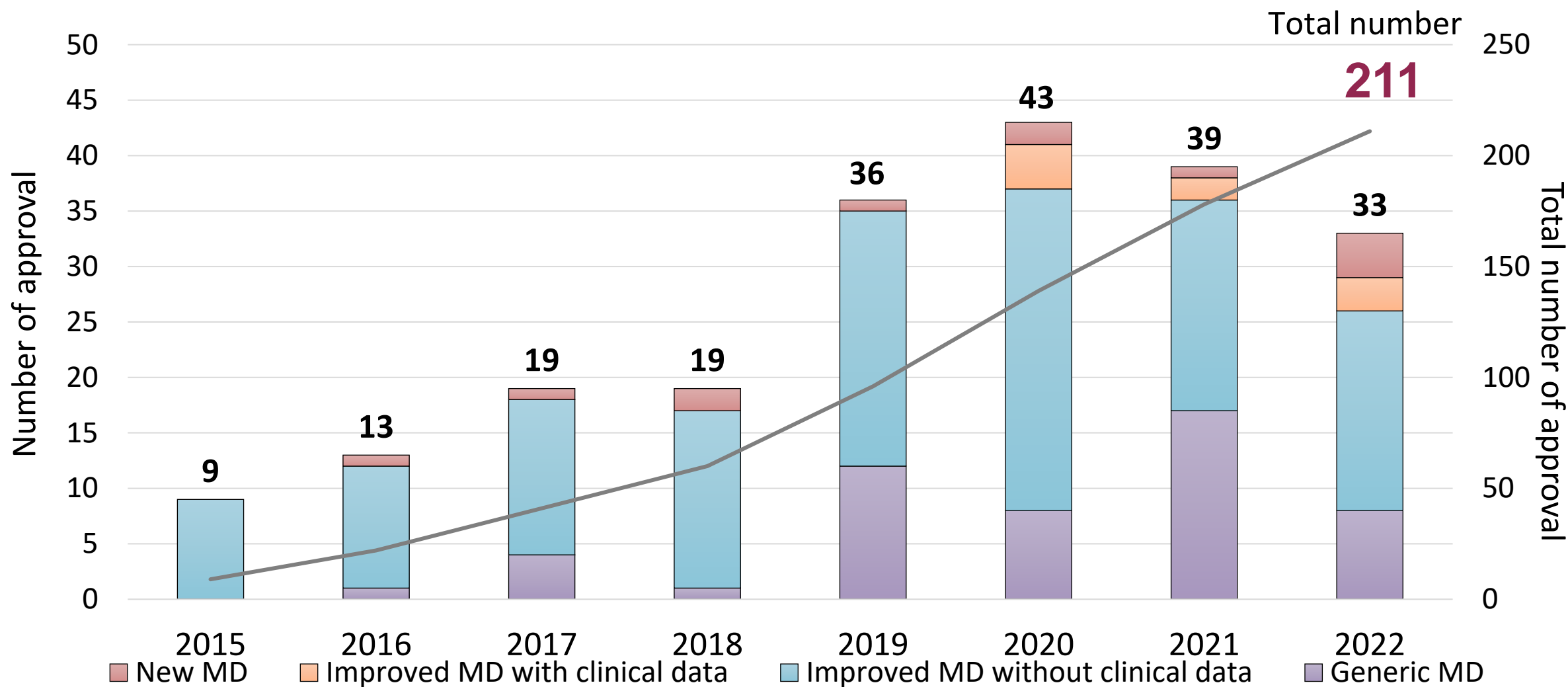


COI Disclosure

Name of First Author : Takatomo EZURA

The authors have no financial conflicts of interest to disclose concerning the presentation.

The annual number of approved SaMD



What is a SaMD Intended to Support Behavioral Therapy?

CureApp HT Hypertension Treatment Aid App (CureApp)



<https://cureapp.co.jp/productsite/ht/>

CureApp SC Nicotine Dependence Treatment App and CO Checker (CureApp)



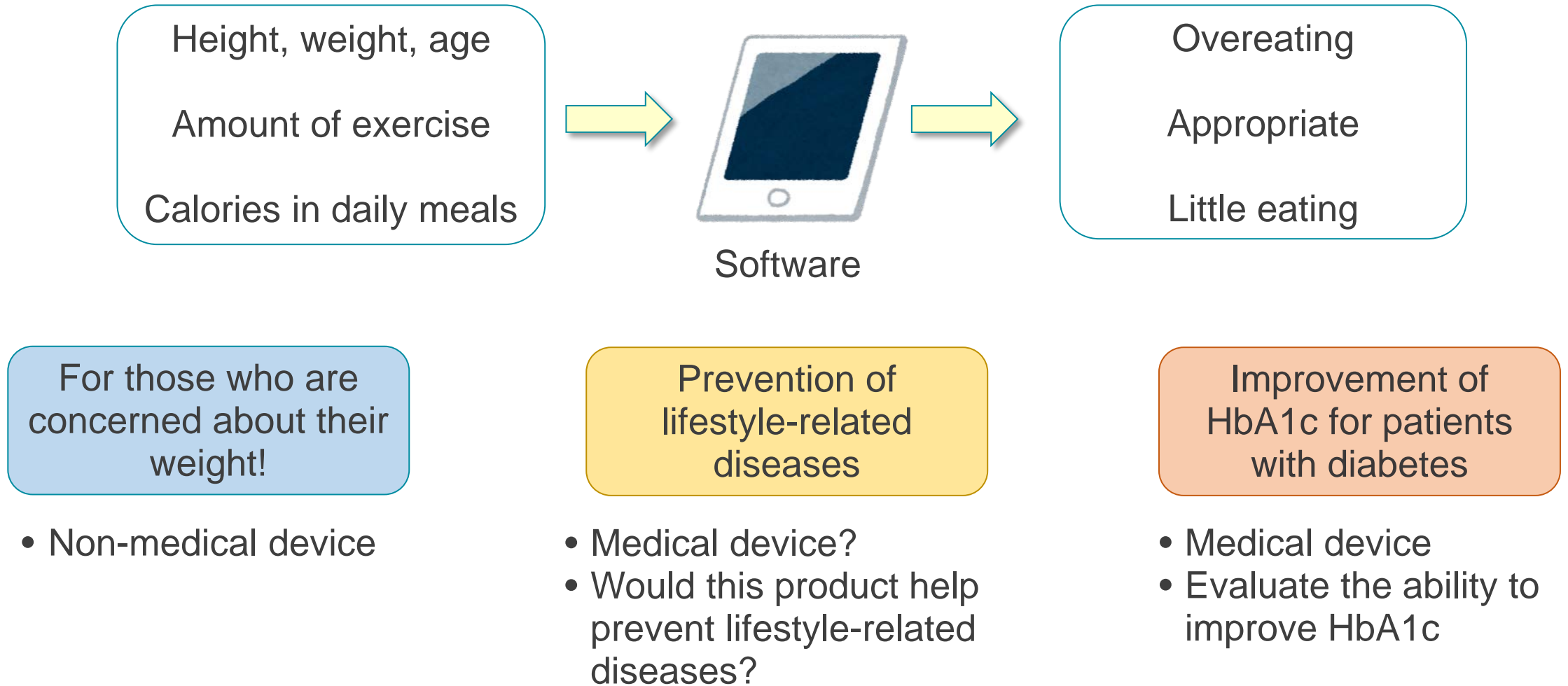
<https://sc.cureapp.com/d/>

Today's Outline

1. Intended Use and Claims of Medical Devices
2. Evaluation and Review of SaMD
3. Introduction of Recent Efforts Related to Program Medical Devices

1. Intended Use and Claims of Medical Devices

Why is Determination of the Role of SaMD in Clinical Practice Important?

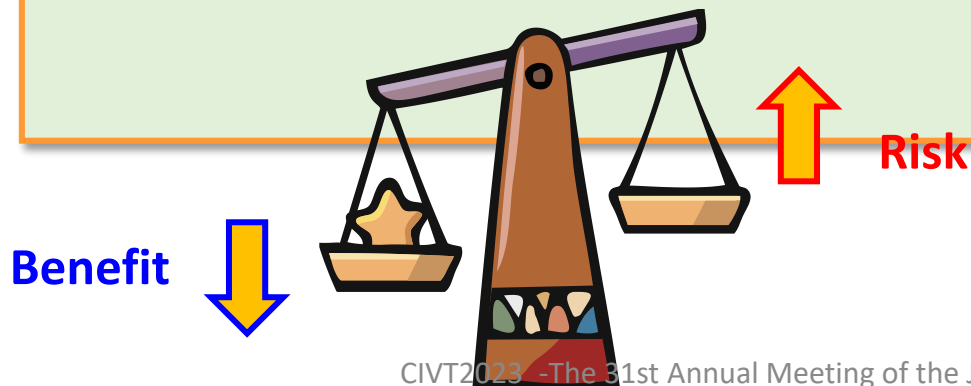


2. Evaluation and Review of SaMD

Reasons of Approval Rejection

- (a) The given device is judged that it does **NOT** have its own effectiveness and/or performance as to be concerned in the application.
- (b) The given device is judged of **NO** value for medical use because its adverse effect(s) far exceed its effectiveness and/or performance.

*PMD Act, Article 23-2-5 paragraph (2),
item (iii), (a) & (b)*



Risk of SaMD



SaMD is trying to improve the user's decision better

Possibility to induce improper decision

【e.g.】

- CAD which provides doctors' reference information for diagnostic support
⇒ inducing improper diagnosis decision
- DTx promotes behavioral modification
⇒ promote excessive intervention and loss of treatment opportunity.

To Understand the Proposed Product

- What are the functions?
(What are the inputs? What are the outputs?)

Development Concept

- What medical needs do you want to solve?
 - Who will use it and how?
- What will result in patients and clinical practice?

- What function did you try to realize for that?
 - What performance did you aim at?

Design Concept



3. Introduction of Recent Efforts Related to Program Medical Devices

Evaluation Index for SaMD Intended to Support Behavioral Therapy

薬生機審発0609第1号
令和4年6月9日

各都道府県衛生主管部（局）長 殿

厚生労働省医薬・生活衛生局医療機器審査管理課長
（ 公 印 省 略 ）

次世代医療機器評価指標の公表について

厚生労働省では医療ニーズが高く実用可能性のある次世代医療機器について、審査時に用いる技術評価指標等をあらかじめ作成し公表することにより、製品開発の効率化及び承認審査の迅速化を図るとともに、評価指標を公表してきたところです。

今般、乳がん診断支援装置について、当たって必要と考えられる評価指標を公表してとりまとめたので、

令和3年度
次世代医療機器・再生医療等製品
評価指標作成事業

行動変容を伴う医療機器プログラム
評価指標公表報告書

Next Generation
Evaluation Guidance

<https://dmd.nihs.go.jp/jisedai/koudouhenyou/index.html>

Evaluation Index for SaMD Intended to Support Behavioral Therapy

Points to consider for evaluation:

(1) Basic matters (Items Affecting Efficacy/Safety)

(2) Matters related to non-clinical studies

(3) Matters related to clinical evaluation



Take home messages

If you are trying to market a medical device, you should

1. consider the intended use and claims for SaMD
2. consider the risks of SaMD based on clinical performance
3. consider collecting data for evaluation as well as for development

Thank you for your kind attention!



**Takatomo EZURA, Reviewer
Office of Software as a Medical Device**

ezura-takatomo@pmda.go.jp