独立行政法人 医薬品医療機器総合機構
Pharmaceuticals and Medical Devices Agency

Overview of regulations for SaMD and recent challenges in Japan

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Classification and regulations of SaMD in Japan (2014-)

Risk based

Class II/Class III without Certification Standards, Class IV
->MHLW approval with PMDA review

Novel Device

Class II/Class III with Certification Standards
->3rd party Certification by Registered Certification Bodies

Software corresponded to Class I
Exempted from medical device regulations

MD Standards (English)

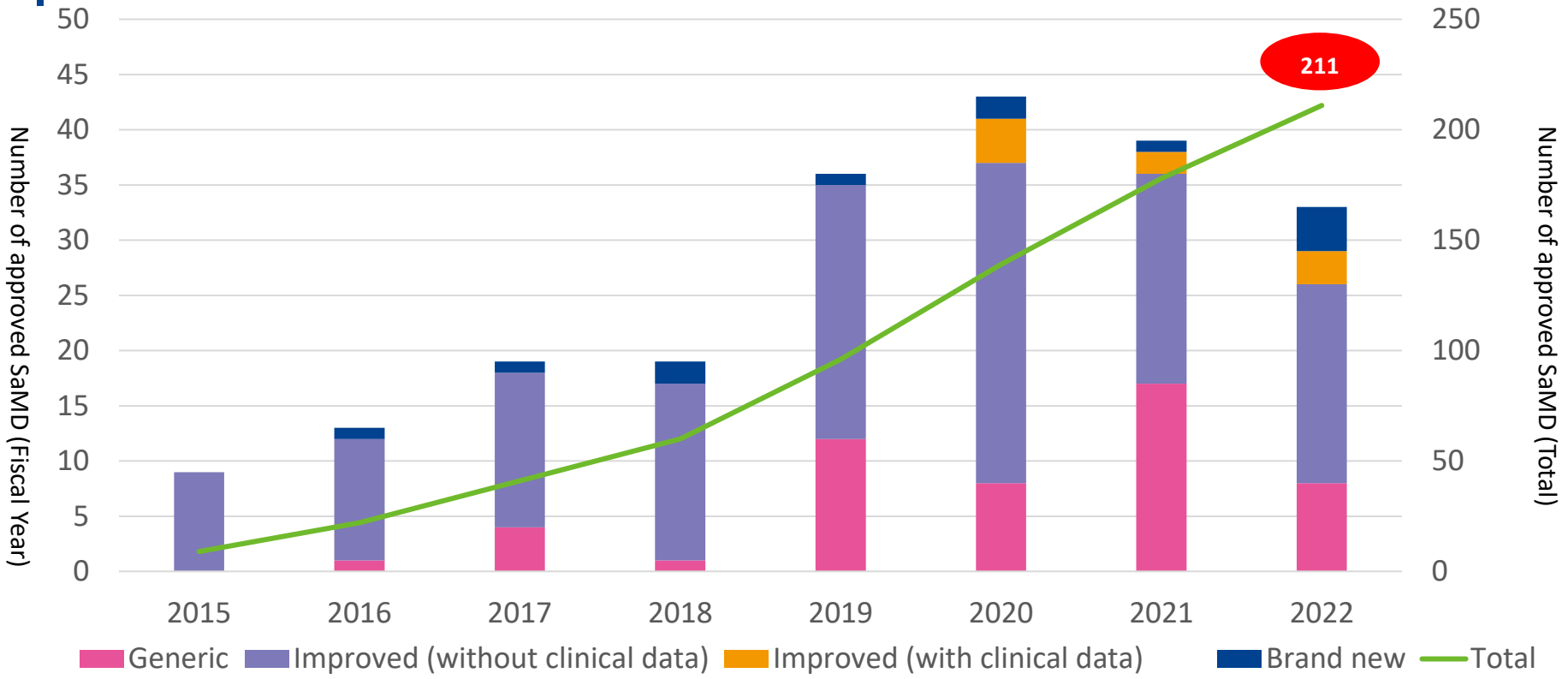
SaMD (Japanese)

Standards for medical devices		Those for SaMD
Japanese Medical Device Nomenclature	4451	190
Approval Standards	44	-
Review Guidelines	10	-
Review Points	5	5
Certification Standards	950	109

(as of Sep 30,2023)

Number of Approved SaMD by PMDA

As of March 2023



Numbers of approved/certificated SaMD by product categories

Non-SaMD	SaMD		
	Class II	Class III	Class IV
● For health control ● Educational program ● In-hospital business support program ● Programs corresponded to class I	**For treatment at home**: for used exclusively at home — 2		
	For diagnostics: for computer assisted Imaging diagnostics — 322		
	for computer assisted diagnostics other than imaging — 89		
	for gene mutation analysis — 11		
	For treatment: Application for behavioral therapy — 3	for therapy planning support — 58	
		for Surgical Support — 1	
		for controlling MD — 3	

DASH for SaMD2

DASH for SaMD 2 （2023/9/6）

- ◆ Organize and publicize the two-step approval scheme for SaMD
- ◆ Develop guidelines for approval review and marketing procedures for SaMD for the general public
- ◆ Promotion of overseas acceptance of our review results (such as English translation of review reports)
- ◆ Subsidies for development funds for SaMD developers
- ◆ Support for SaMD developers to actively business overseas

DASH for SaMD（2020/11/24）

- ◆ Setup an office to review SaMD in MHLW and PMDA
- ◆ Establishment of SaMD centralized consultation service
- ◆ Next-generation medical device evaluation index, development guidance, audit points, and certification criteria formulation
- ◆ Trial implementation of priority review, etc. for innovative SaMD
- ◆ Promote the use of IDATEN (Improvement Design within Approval for Timely Evaluation and Notice) and streamline procedures, etc.

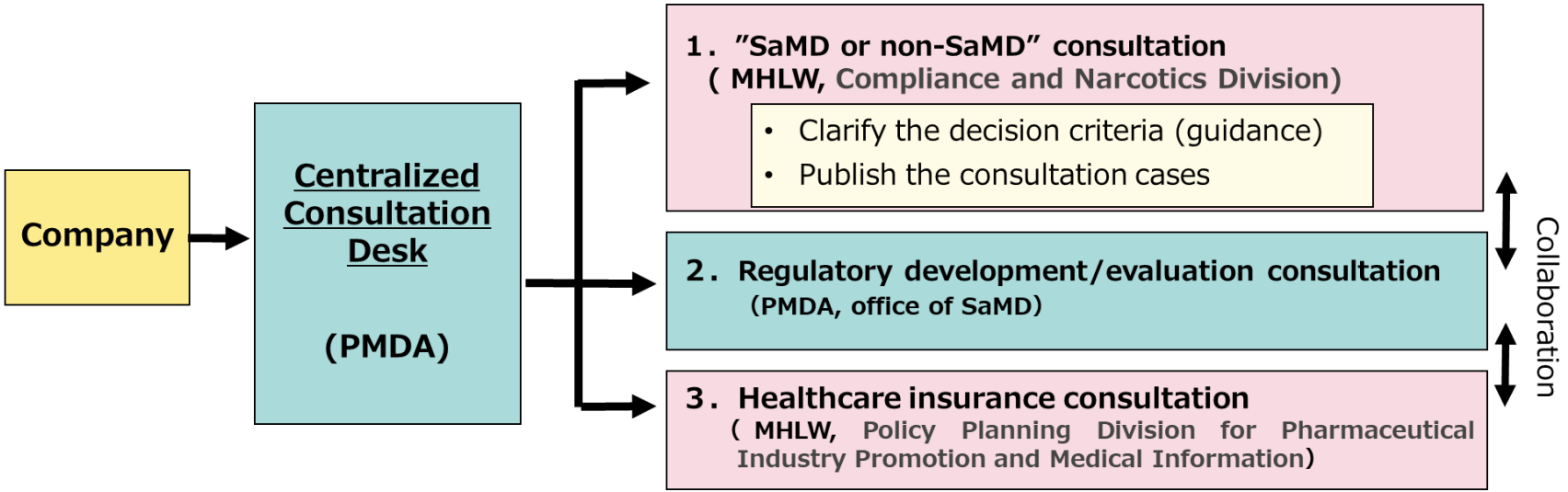
<Expand and continue>

- ◆ Upgrade from office to Department for reviewing SaMD in PMDA
- ◆ Establishment of SaMD-specific consultation service
- ◆ (Continue)
- ◆ (Continue)
- ◆ (Continue)

Goals for the next 5 years under DASH for SaMD 2

- Achieve early market introduction and establish clinical significance
- Expansion of more enhanced self-care options
- Promotion of better health for the public
- Exporting more and market acquisition of innovative SaMD developed in Japan
- Shorten the development cycle time of SaMD by contributing to a smooth and efficient market introduction
- Realization of efficient commercialization of SaMD
- Creation and early commercialization of innovative SaMD
- Smooth and efficient post-marketing performance improvement of SaMD

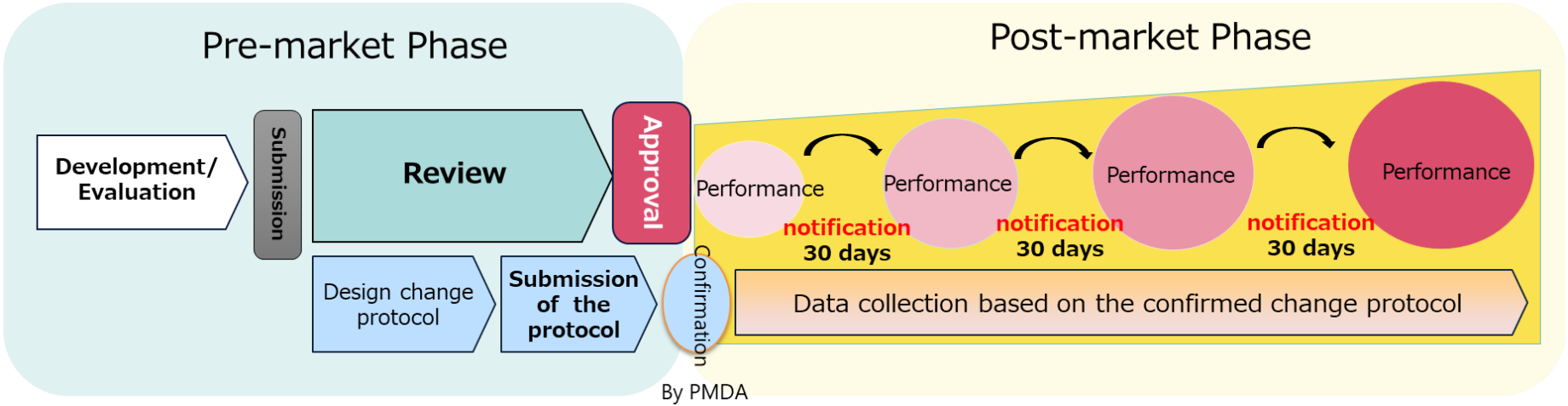
Centralization of the consultation contact desk



FY	Total	SaMD or non-SaMD	Development/evaluation	Healthcare insurance
2021	238	175	110	43
2022	159	122	58	27

Post-Approval Change Management Protocol (PACMP/IDATEN) for MDs

PACMP is introduced for medical devices to enable continuous and timely improvements through product lifecycle.



Published in 2019, In force in 2020

Two-step Approval scheme for SaMD *(draft)*

- Two-step Approval scheme was introduced in 2017.
- This scheme is mainly used for diagnostic MD whose analytical performance is reliable but its clinical benefit of the analyte is not established. By using this scheme, it is possible to claim that “physiologic parameter “A” can be measured" in the First-step Approval, and, after concreting the clinical benefit, claim that "measuring A will lead to diagnose of specific disease B" in the Second-step Approval.
- MHLW is currently considering to **expand this scheme to SaMD for the treatment** such as the next slide image. In the case of SaMD for the treatment, if safety and a certain level of efficacy based on some evidences (including non-clinical trial) for alleviation and improvement of specific symptoms caused by disease “C” can be confirmed, the First-step Approval will be granted at that point. Then, after concreting the clinical benefit, the Second-step Approval will be granted to claim the final clinical benefit.

※This scheme is under consideration, but is being studied with the aim of introducing it by the end of 2023.

Two-step Approval scheme for SaMD *(draft)*

SaMD for diagnosis

Reliable performance for analyzing physiologic parameter “A”

First-step Approval

Diagnosis of disease “B” by analyzing physiologic parameter “A”

Second-step Approval

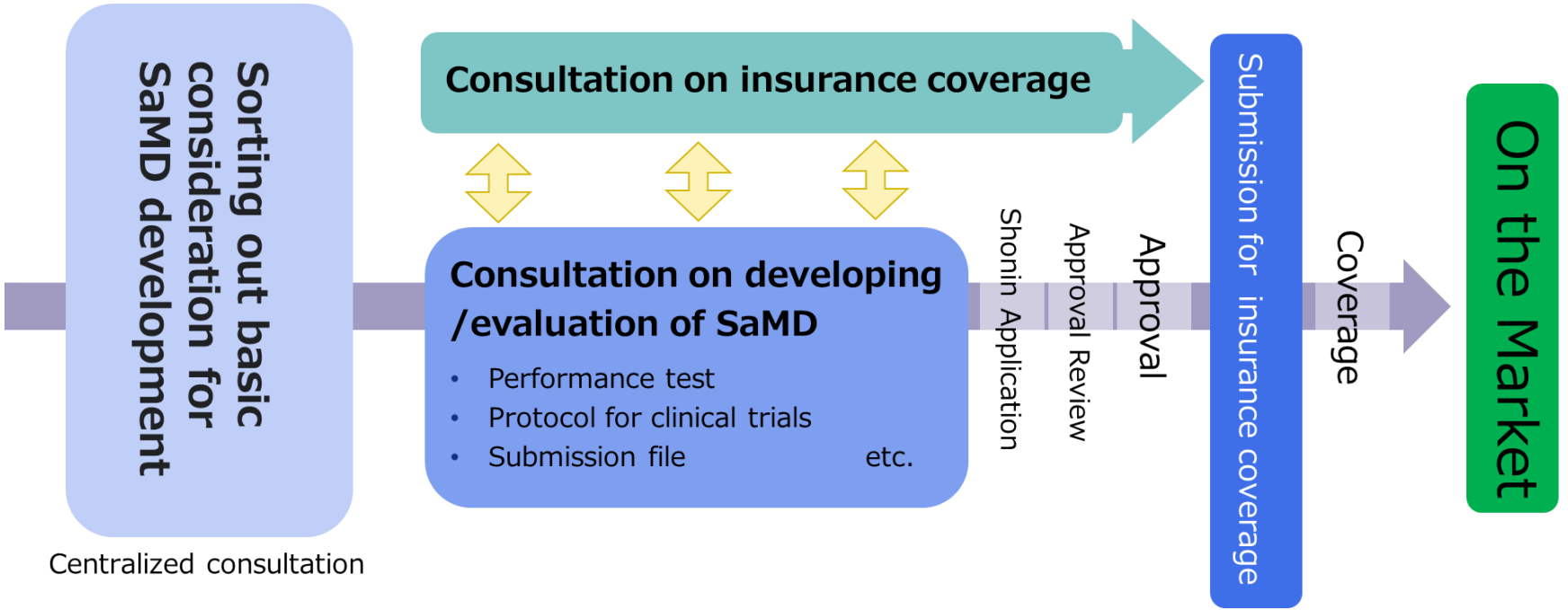
Clinical Evidence for Efficacy
(Post-marketing CT, RWE)

SaMD for treatment

Alleviation and improvement of specific symptoms caused by disease “C”

Treatment support and improvement of disease “C”

Early Engagement among Applicants, Review team and Insurance Bureau



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Any Questions??