Innovative Approaches in SaMD Regulation

Industry Perspective

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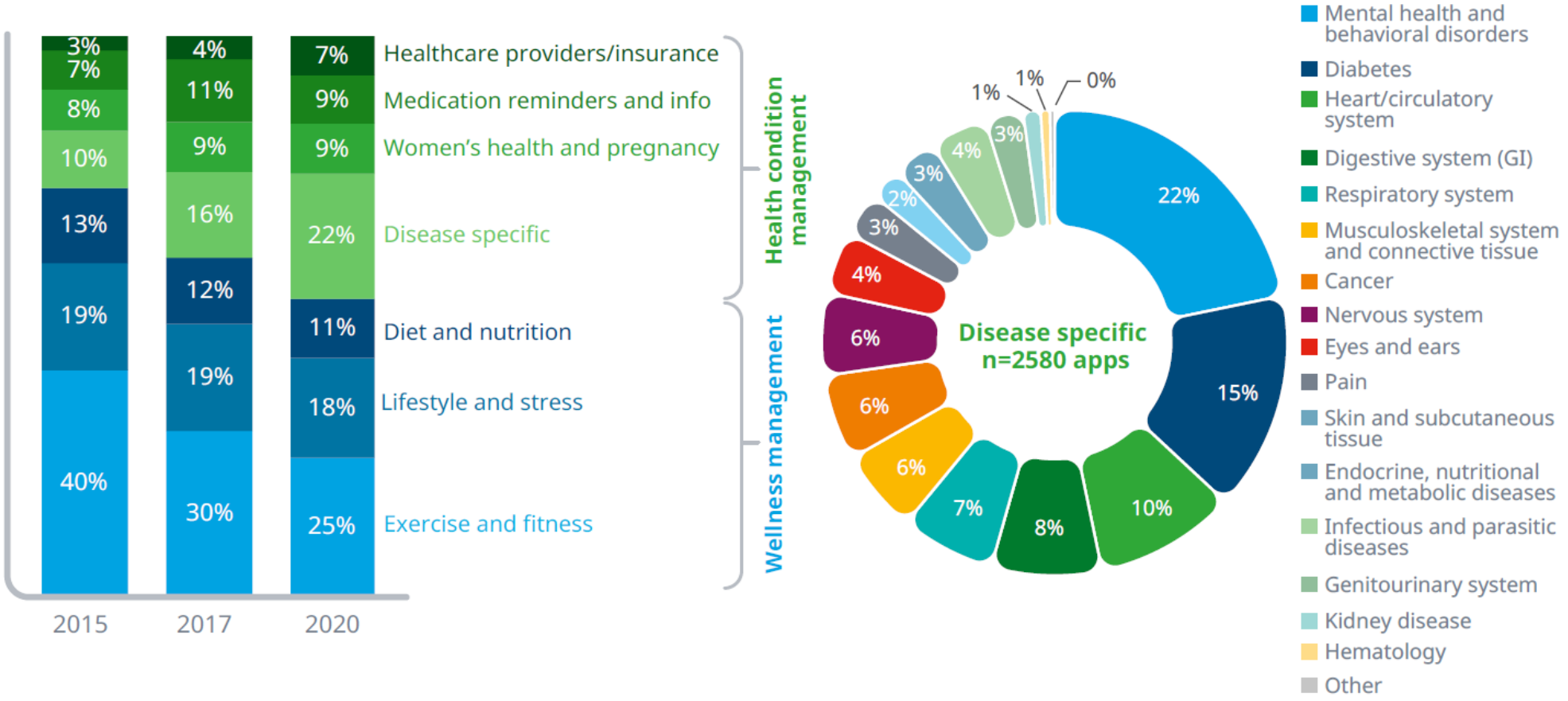
Digital Health Apps by Category and Disease

State in 2021

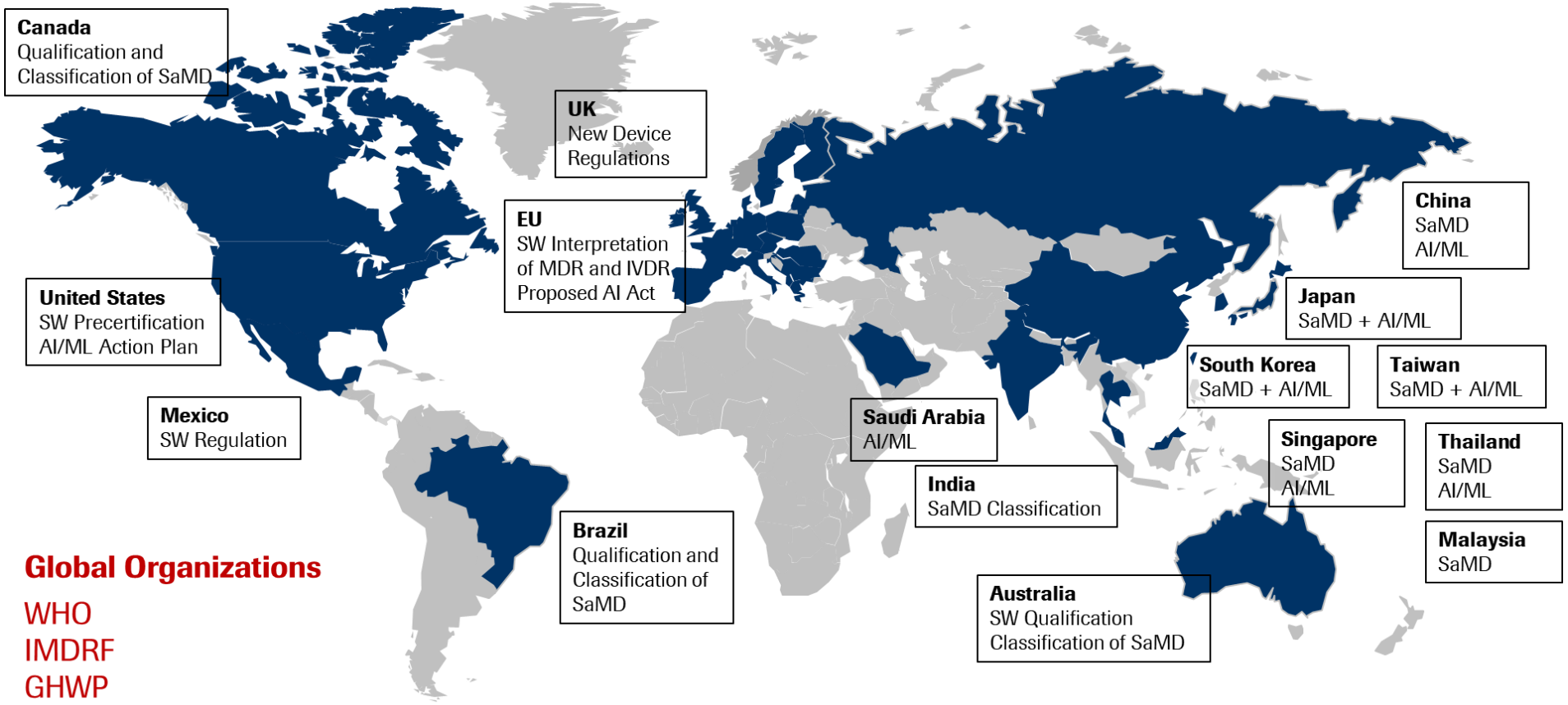


The development and commercialization of **digital health solutions** is **accelerating** at a rapid rate.

Digital Health Trends 2021: Innovation, Evidence, Regulation, and Adoption. IQVIA Institute for Human Data Science.
https://www.iqvia.com/-/media/iqvia/pdfs/institute-reports/digital-health-trends-2021/iqvia-institute-digital-health-trends-2021.pdf

Software as a Medical Device Regulation

Growing Global Regulatory Interest



Global Organizations

WHO
IMDRF
GHWP

Key Considerations in Digital Health Regulation

For a robust fit-for-purpose framework

- Software Qualification
- SaMD Classification
- Innovative SaMD Regulatory Pathways
- Artificial Intelligence / Machine Learning

Software Qualification

Australia' Therapeutic Goods Administration (TGA) Best Practice

EXCLUSION

means that the devices are completely unregulated by TGA

Examples include software functions used for:

- *Consumer health life-cycle prevention, management and follow up*
- *Enabling technology for telehealth, health care facility management*
- *Digitization of paper based or other published clinical rules or data*
- *Population based analytics*
- *Laboratory Information Management Systems (LIMS) and Laboratory Information Systems (LIS)*

EXEMPTION

means that TGA retains some oversight for advertising, adverse events and notification, but registration is not required

A clinical decision support system is exempt if it meets all 3 of the following criteria:

- *Does NOT directly process or analyze a medical image or a signal from another medical device (including an in vitro diagnostic device); and*
- *Is solely used to provide or support a recommendation to a health professional about prevention, diagnosis, curing or alleviating a disease, ailment, defect or injury; and*
- *Does NOT replace the clinical judgement of a health professional in relation to making a clinical diagnosis or decision about the treatment of patients.*

Examples of regulated and unregulated software (excluded) software based medical devices, v1.3. TGA. October 2021.
https://www.tga.gov.au/sites/default/files/examples-regulated-and-unregulated-software-excluded-software-based-medical-devices.pdf

Software Classification

Singapore's Health Sciences Authority (HSA) Best Practice

State of Healthcare situation or condition	Significance of information provided by SaMD to healthcare decision		
	Treat or diagnose	Drive clinical management	Inform clinical management
Critical	IV	III	II
Serious	III	II	I
Non-serious	II	I	I

Software as Medical Device: Possible Framework for Risk Categorization and Corresponding Considerations, IMDRF/SaMD WG/N12FINAL:2014

Guidelines on Risk Classification of Standalone Medical Mobile Applications and Qualification of Clinical Decision Support Software (CDSS).

State of healthcare situation or condition	Significance of information provided by SaMD to healthcare decision		
	Treat or diagnose	Drive clinical / patient management	Inform clinical / patient management
Critical	C	C	B
Serious	C	B	A
Non-serious	B	A*	A

* Standalone Medical Mobile Applications will be classified as Class B if intended to image, measure or monitor a physiological process to drive clinical/patient management; consistent with rule 10(i) of GN-13

Guidelines on Risk Classification of Standalone Medical Mobile Applications and Qualification of Clinical Decision Support Software (CDSS). Medical Devices Cluster. HSA. April 2022.
https://asiaactual.com/wp-content/uploads/2022/07/Singapore-HSA-guidelines-risk-classification-samd-cdss-2022-apr.pdf

Innovative SaMD Regulatory Pathways

A wide range of possibilities. . .

Recognition and/or Reliance on Reference Countries

Software Precertification-Type Programs

Predetermined Change Control Plans

Streamlined Review

Innovative SaMD Regulatory Pathways

Reliance and/or Recognition

Singapore HSA's Reliance and Recognition Approach for SaMD

Abridged Evaluation Route

Abridged Evaluation Route Condition	Independent Reference Regulatory Agencies	SaMD Abridged Routes Immediate Class B Registration [IBR] Evaluation Route Immediate Class C Registration [ICR] Evaluation Route
Any new product approved by at least one (1) reference regulatory agency is eligible.	Australia TGA Health Canada US FDA EU Notified Bodies Japan MHLW	✓ Product is eligible if approved by at least one (1) of HSA's Independent Reference Regulatory Agencies (IRRAs). ✓ No safety issues globally associated with the use in the last 3 years or since market introduction of the product globally. ✓ No rejection/withdrawal of the Medical Device from any IRRAs due to quality, performance or safety issues.

Register Class B medical device via immediate route. HSA. 2022. *https://www.hsa.gov.sg/medical-devices/registration/guides/class-b-immediate-registration*

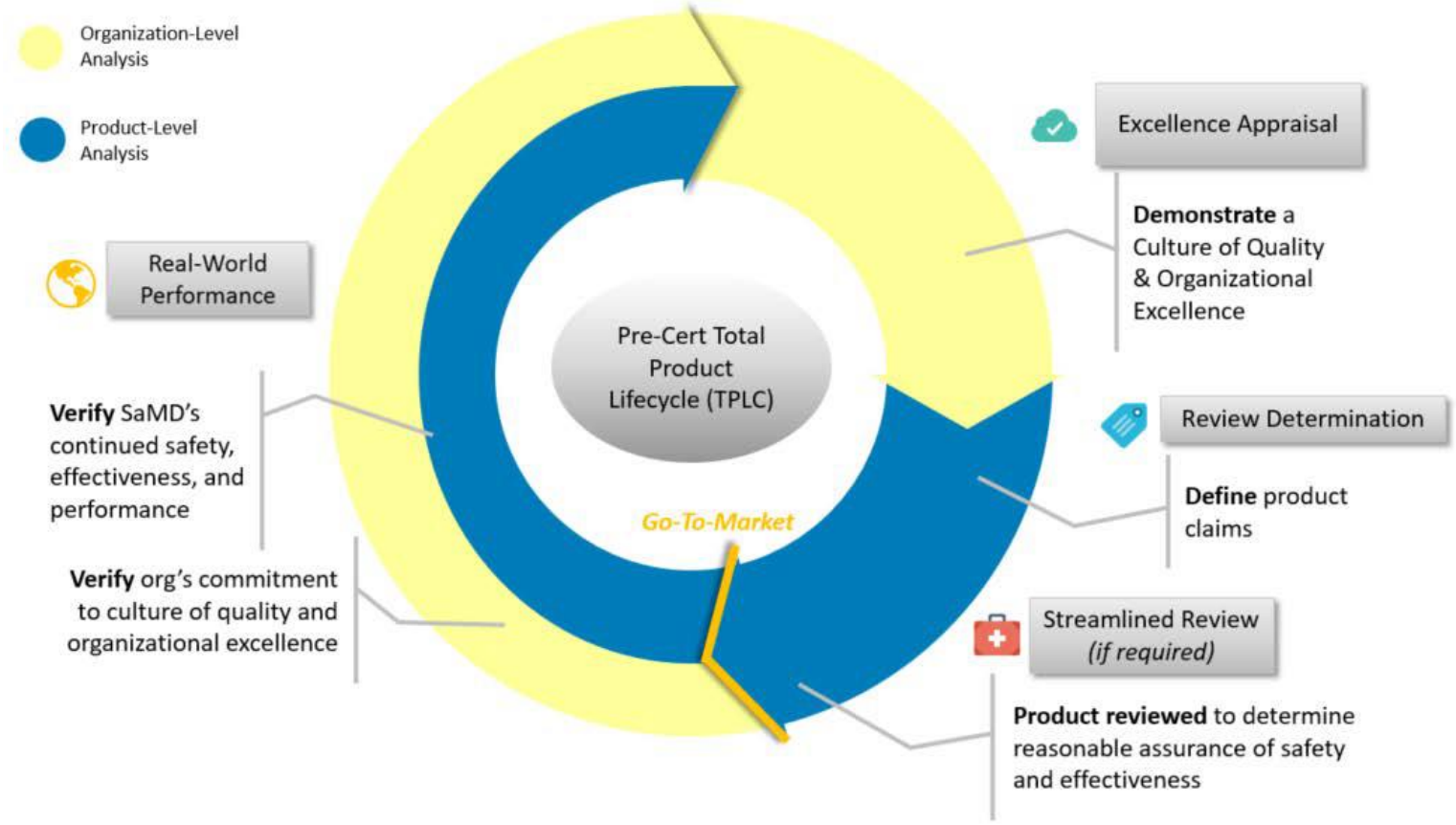
Register Class C medical device via immediate route guide. HSA. 2022. *https://www.hsa.gov.sg/medical-devices/registration/guides/class-c-immediate-registration*

Innovative SaMD Regulatory Pathways

Software Precertification-Type Programs

USA FDA Software Precertification-Type Approach

Software Precertification Pilot Program



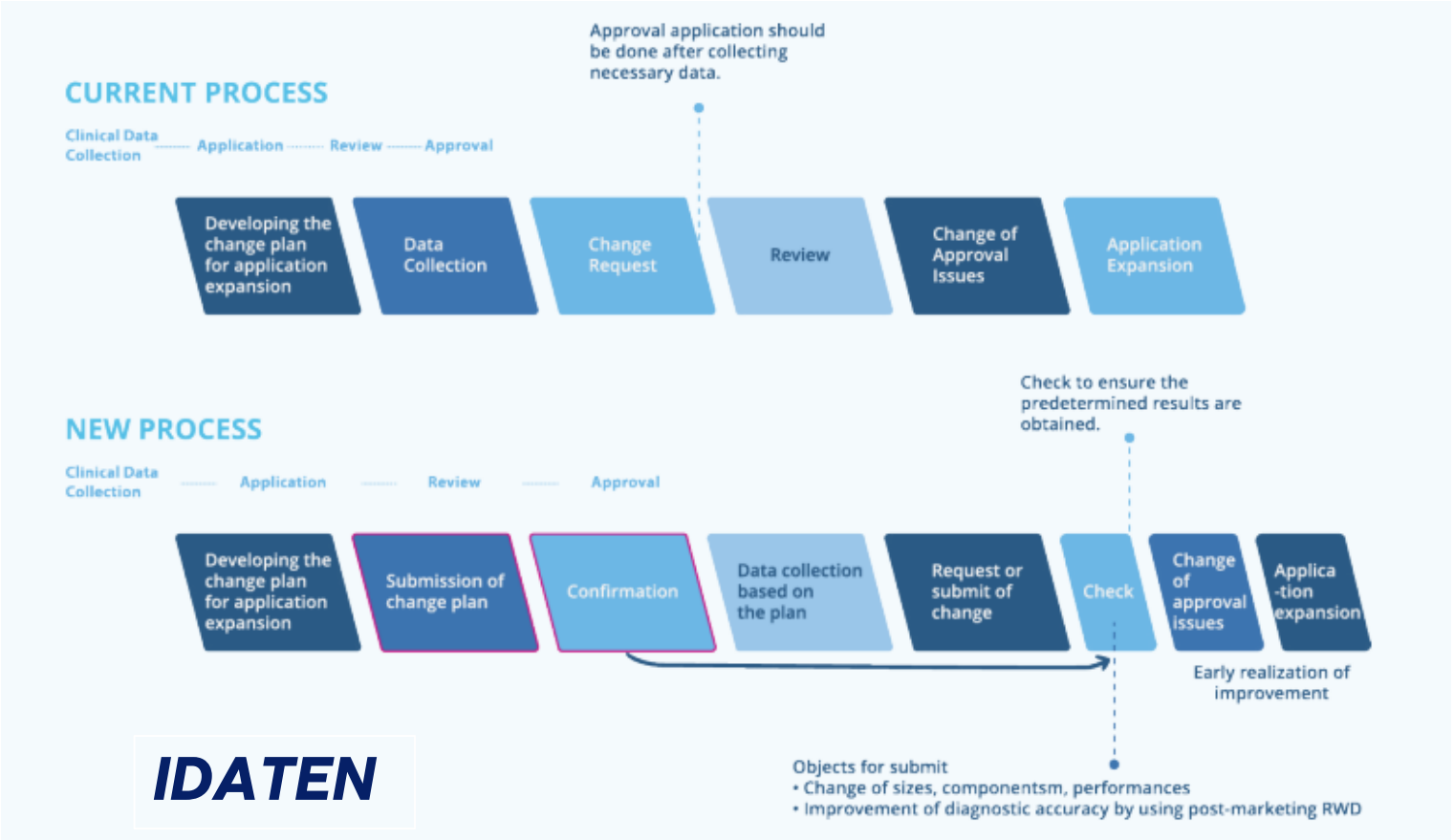
FDA Software Precertification Program: Working Model v1.0. January 2019.
https://www.fda.gov/downloads/MedicalDevices/DigitalHealth/DigitalHealthPreCertProgram/UCM629276.pdf

Innovative SaMD Regulatory Pathways

Predetermined Change Control Plans

Japan MHLW/PMDA Predetermined Change Control Plan Approach

Improvement Design within Approval for Timely Evaluation and Notice

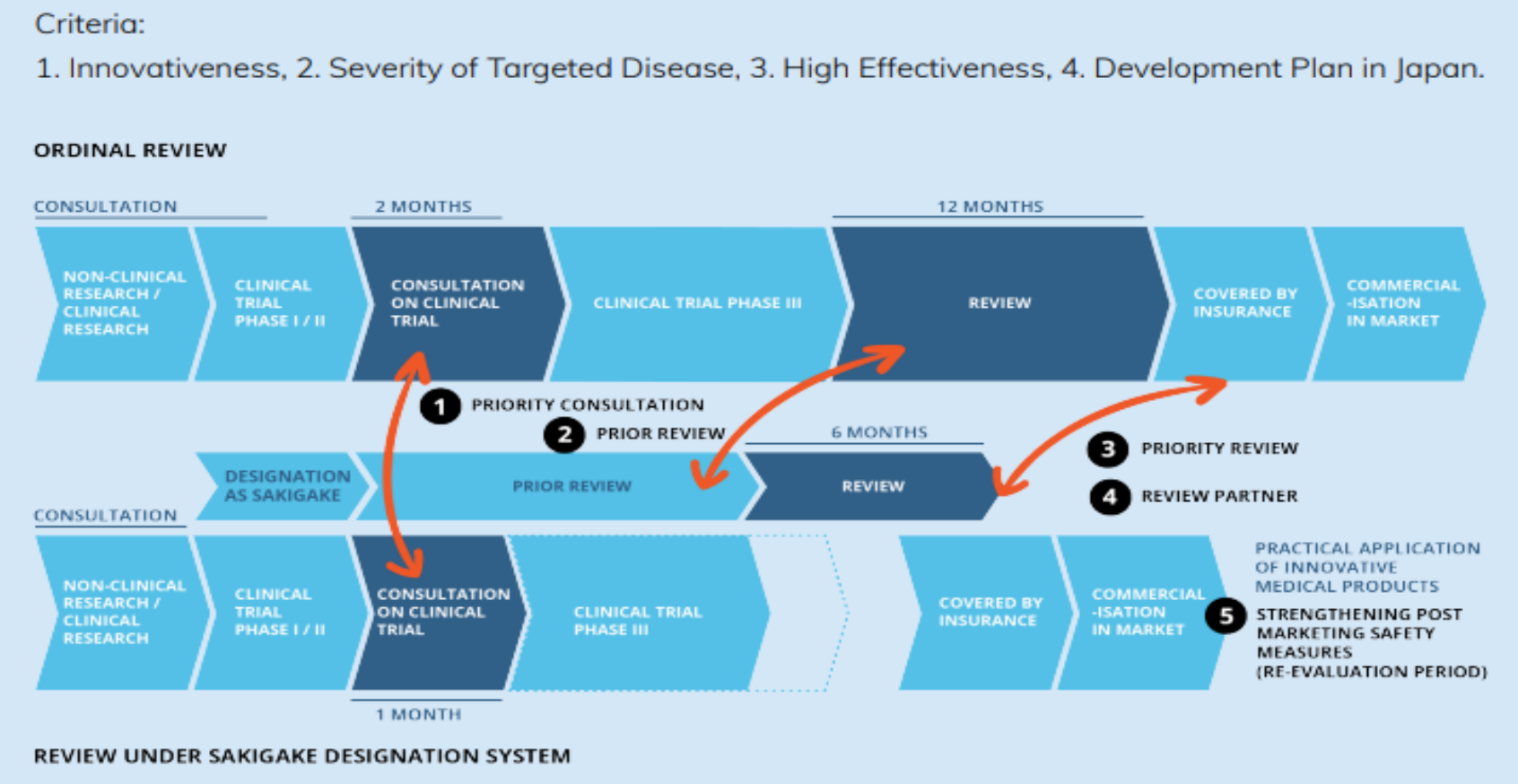


Digital Health Regulation In Asia-Pacific. Overview And Best Practices. APACMed Digital Health Committee. Regulatory Working Group. 2021.
https://apacmed.org/content/uploads/2021/01/APACMed-Digital-Health-Regulation-in-APAC.pdf

Innovative SaMD Regulatory Pathways

Streamlined Review

Japan MHLW/PMDA Streamlined Review Approach
SAKIGAKE Designation Track



Digital Health Regulation In Asia-Pacific. Overview And Best Practices. APACMed Digital Health Committee. Regulatory Working Group. 2021.
https://apacmed.org/content/uploads/2021/01/APACMed-Digital-Health-Regulation-in-APAC.pdf

Innovative Approaches in SaMD Regulation

Key Takeaways

- ✓ Regulators in the LATAM region should consider alternative, fit-for-purpose regulatory pathways tailored to the unique and iterative aspects of SaMD products.
- ✓ Reliance and recognition models, streamlined review pathways, predetermined change control plans, and precertification type programs are some examples to assess potential reapplication.
- ✓ Regulators should choose those approaches that enable efficient and focused use of their available resources. SaMD regulatory approaches by Australia's TGA, Singapore's HSA, Japan's MHLW, USA's FDA can serve as models for LATAM regulators.
- ✓ Partnerships between regulators and industry can further enable the advancement of robust digital health regulatory frameworks in the LATAM region.

Doing now what patients need next