IMDRF International Medical Device Regulators Forum

Japan Update

IMDRF Open Stakeholder Forum

September 2017

厚生労働省
Ministry of Health, Labour and Welfare

pmda

- Regulatory Authorities in Japan -

MHLW

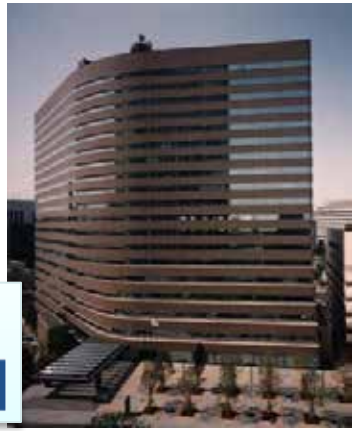
Ministry of Health, Labor and Welfare

- Final Authorization of applications
- Publishing Guidelines
- Advisory committee
- Supervising PMDA Activities

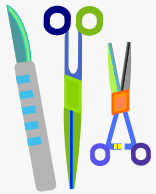
PMDA

Pharmaceuticals and Medical Devices Agency

- Scientific Review for Drugs & MD
- GCP, GMP Inspection
- Consultation on Clinical Trials etc.



Medical Device Regulations in Japan

Classification	Class I	Class II	Class III	Class IV
Category	General MDs	Controlled MDs	Specially controlled MDs	
Premarket regulation	Self-declaration	Third party certification	MHLW approval (PMDA review)	
Example		 	 	  
Post market safety (vigilance/surveillance)	PMDA and MHLW			

Registered Certification Bodies *(Ninsho-Kikan)*

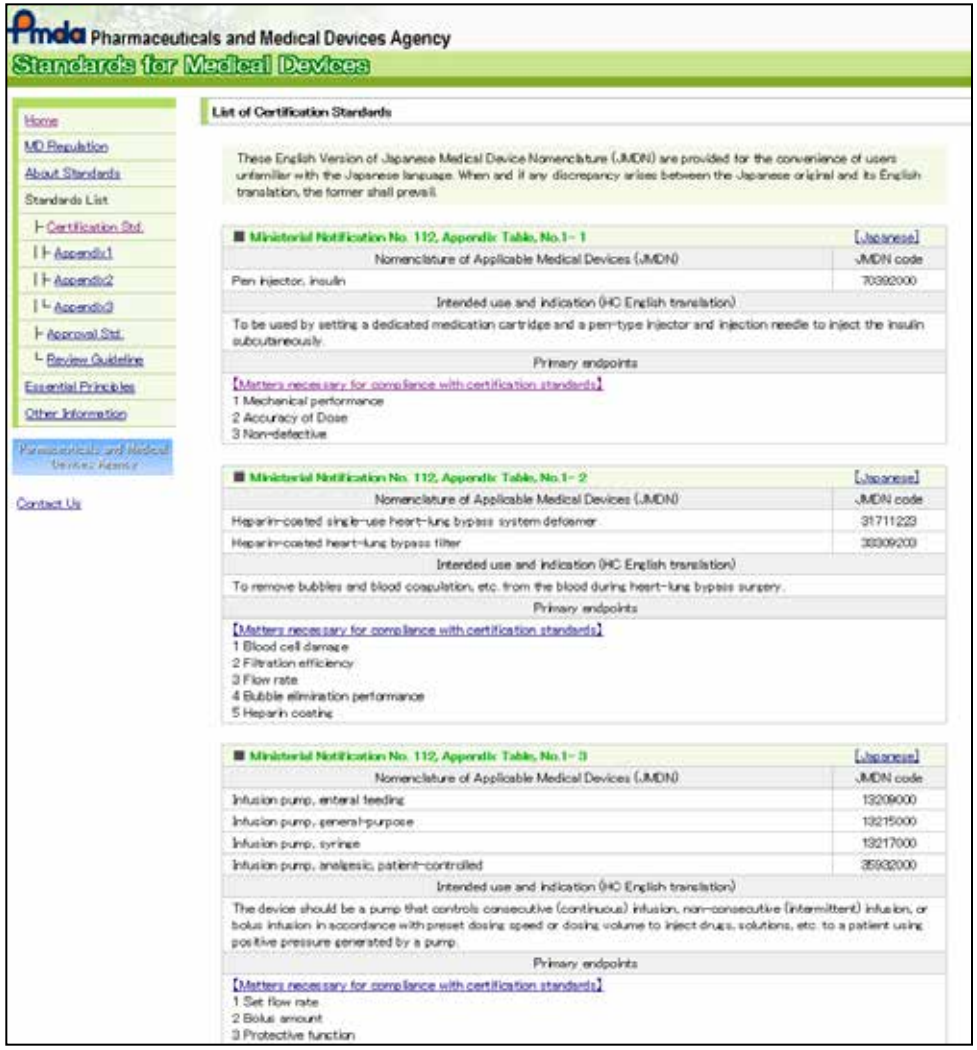
As of Sep. 2017

TÜV SÜD Japan
TÜV Rheinland Japan
DQS Japan
BSI Group Japan
SGS Japan
Cosmos Corporation
Japan Quality Assurance Organization(JQA)
Nanotec Spindler Corporation
Japan Electrical Safety & Environment Technology Laboratories(JET)
Japan Association for the Advancement of Medical Equipment(JAAME)
Fuji Pharma
DEKRA Certification Japan
Bureau Veritas Japan
NEW Intertek Japan

Further information (in Japanese)
http://www.pmda.go.jp/operations/shonin/info/attestation/ninsyokikan.html
http://www.jaame.or.jp/jyusho/ninjyu.html

(Reference) List of Certification Standards for Third Party Certification

Essential Principles Checklist with applicable standards



Pmda Pharmaceuticals and Medical Devices Agency

Standards for Medical Devices

Home
MD Regulation
About Standards
Standards List
- Certification Std.
  - Appendix1
  - Appendix2
  - Appendix3
- Approval Std.
- Review Guideline

Essential Principles
Other Information

Pharmaceuticals and Medical Devices Agency

Contact Us

List of Certification Standards

These English Version of Japanese Medical Device Nomenclature (JMDN) are provided for the convenience of users unfamiliar with the Japanese language. When and if any discrepancy arises between the Japanese original and its English translation, the former shall prevail.

■ Ministerial Notification No. 112, Appendix Table, No.1- 1 [Japanese]

Nomenclature of Applicable Medical Devices (JMDN)	JMDN code
Pen injector, insulin	70392000

Intended use and indication (HC English translation)

To be used by setting a dedicated medication cartridge and a pen-type injector and injection needle to inject the insulin subcutaneously.

Primary endpoints

[Matters necessary for compliance with certification standards]
1 Mechanical performance
2 Accuracy of Dose
3 Non-defective

■ Ministerial Notification No. 112, Appendix Table, No.1- 2 [Japanese]

Nomenclature of Applicable Medical Devices (JMDN)	JMDN code
Heparin-coated single-use heart-lung bypass system defoamer	31711223
Heparin-coated heart-lung bypass filter	33309203

Intended use and indication (HC English translation)

To remove bubbles and blood coagulation, etc. from the blood during heart-lung bypass surgery.

Primary endpoints

[Matters necessary for compliance with certification standards]
1 Blood cell damage
2 Filtration efficiency
3 Flow rate
4 Bubble elimination performance
5 Heparin coating

■ Ministerial Notification No. 112, Appendix Table, No.1- 3 [Japanese]

Nomenclature of Applicable Medical Devices (JMDN)	JMDN code
Infusion pump, enteral feeding	13209000
Infusion pump, general-purpose	13215000
Infusion pump, syringe	13217000
Infusion pump, analgesic, patient-controlled	35932000

Intended use and indication (HC English translation)

The device should be a pump that controls consecutive (continuous) infusion, non-consecutive (intermittent) infusion, or bolus infusion in accordance with preset dosing speed or dosing volume to inject drugs, solutions, etc. to a patient using positive pressure generated by a pump.

Primary endpoints

[Matters necessary for compliance with certification standards]
1 Set flow rate
2 Bolus amount
3 Protective function

March 30,2016

Ministerial Notification No. 112, Appendix Table, No.1- 9
Essential Principles Checklist (Glucose meter self testing kit)

Essential Principles in Japan: Version2014			Applied / Not applied	Identity of Specific Documents
Chapter 1 General Requirements				
Article1			Applied	MHLW Ministerial Ordinance No. 169 dated December 17, 2004,JIS T 14971
Article2			Applied	JIS T 14971
Article3			Applied	MHLW Ministerial Ordinance No. 169 dated December 17, 2004
Article4			Applied	MHLW Ministerial Ordinance No. 169 dated December 17, 2004,JIS T 14971
Article5			Applied	MHLW Ministerial Ordinance No. 169 dated December 17, 2004,JIS T 14971
Article6			Applied	JIS T 14971: To assess the following primary endpoints based on their criteria prescribed as related notification. 1.Measurement repeatability 2.Intermediate measurement precision 3.System accuracy 4.Packed cell volume evaluation 5.Interference testing
Chapter 2 Requirements for design and manufacture				
Article7	1			
		1	Applied	JIS T 14971,JIS C 1010-1:2014
		2	Not applied	
		3	Applied	JIS T 14971,JIS C 1010-1:2014
	2		Applied	JIS T 14971
	3		Not applied	
	4	first	Applied	JIS T 14971
		second	Not applied	
	5		Not applied	
	6		Partially applied	JIS T 14971,JIS C 1010-1:2014
	7		Applied	JIS T 14971,JIS C 1010-1:2014
Article8	1			
		1	Applied	JIS T 14971,JIS C 1010-2-101:2013
		2	Not applied	
		3	Applied	JIS T 14971:PFSB Notification No. 1002-6 dated October 2, 2014,JIS C 1010-2-101:2013
	2		Not applied	
	3		Not applied	
	4		Not applied	
	5		Not applied	
	6		Not applied	
	7		Not applied	
	8		Not applied	
	9		Not applied	
	10		Not applied	
Article9	1		Applied	JIS T 14971:ISO 15197:2013
	2		Applied	JIS T 14971:ISO 15197:2013,JIS C 1010-1:2014,PFSB Notification No. 1002-6 dated October 2, 2014

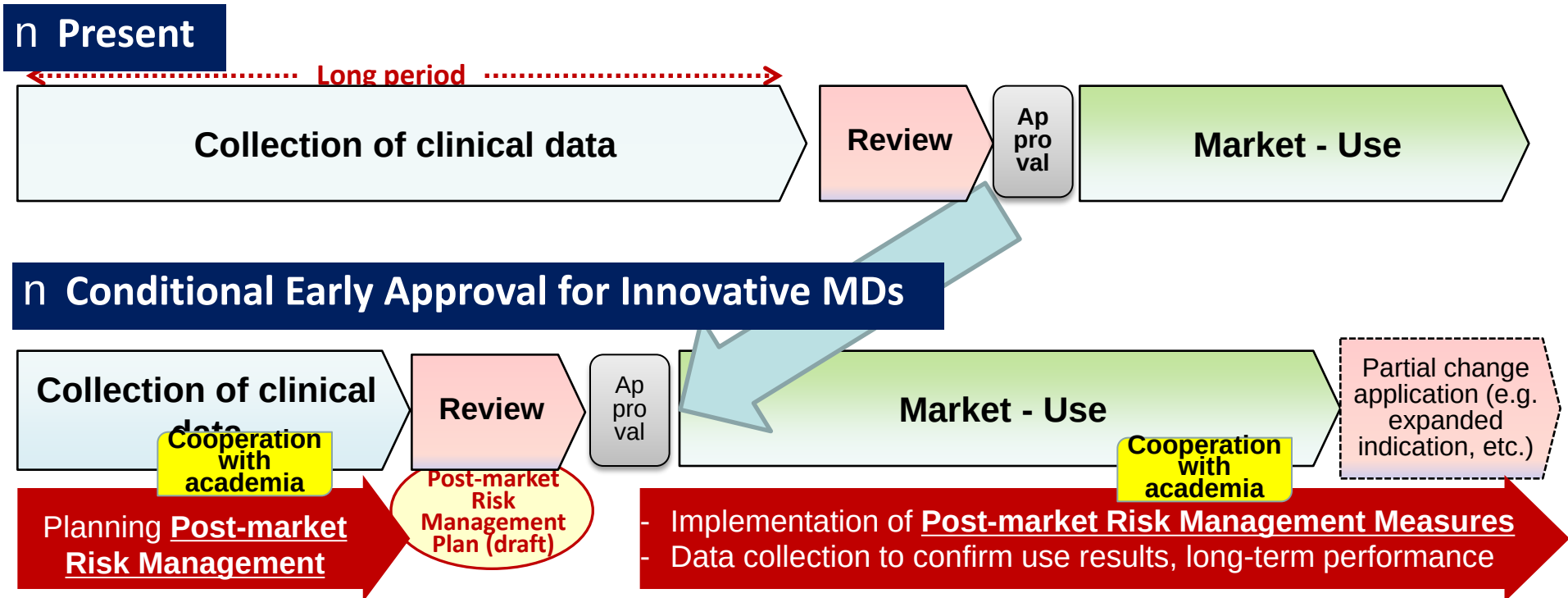
DRAFT

JAPAN UPDATE

1. Introduction of Conditional Early Approval Scheme
2. Introduction of SUD Reprocessing
3. Sakigake Designation
4. International Standard Approach

Conditional Early Approval for Innovative Medical

Accelerate approval of MDs in high clinical needs by balancing the pre- and post-market requirements, based on the lifecycle management of the MDs.

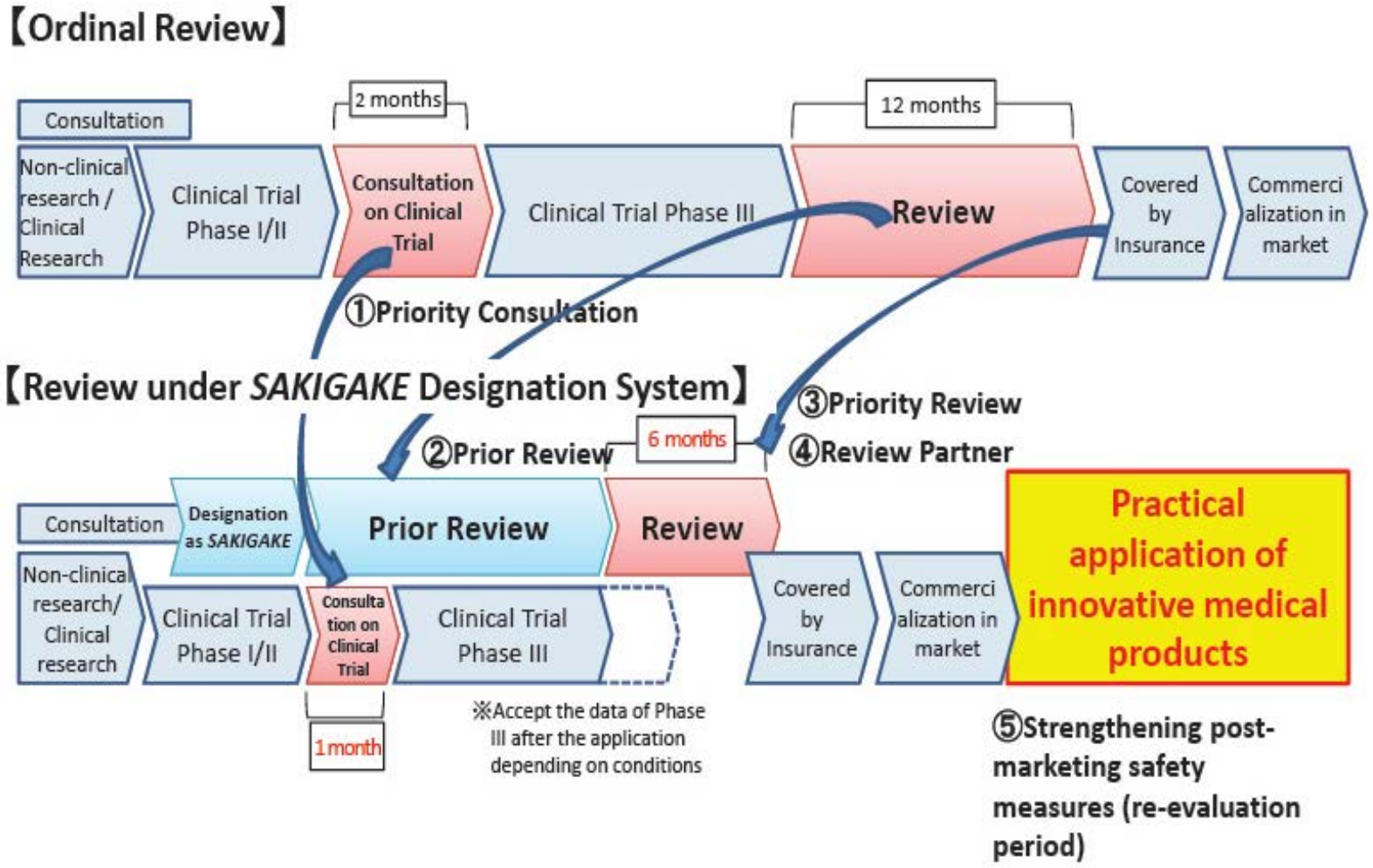


- Reprocessers needs MAH
- Reprocessed SUD needs Approval as R-SUD
- Reprocessers take responsibility for R-SUD's safety issue

Single-use Medical Device (SUD) Reprocessing

- Japan has introduced SUD Reprocessing from July 2017

SAKIGAKE Designation System



(Reference) Implementation of Strategy of Sakigake

An ***innovative MD/IVD for patients in urgent need of innovative therapy*** may be designated as a Sakigake Product if;
1)its premarket application will be filed in the first in the world ***AND***
2)prominent effectiveness can be expected.

Once an MD/IVD is designated, its developer can enjoy such benefits as:

A) Prioritized Consultation by PMDA

B) Pre-application substantive review

C) Prioritized Review
(12 months à 6 months [MD])

D) Review Concierge assigned by PMDA

Designation of Sakigake products in 2016

The first designated medical device submitted application in June 2017
It will reviewed in priority review scheme and will approved within 6 months!

No.	Product name	Expected performance/effectiveness
MD1	**Titanium Bridge** (Hinge-type plate with titanium)	Adduction-type spasmodic dysphonia
RP1	**STR01** (Autologous bone marrow-derived stem cells)	Improvement of neurological symptoms and functional impairment due to spinal cord injury
RP2	**G47Δ** (Recombinant herpes virus)	Glioma
RP3	**Autologous intracardiac stem cells**	Improvement of heart function in infants with congenital heart disease

(Reference)Designation of Sakigake products

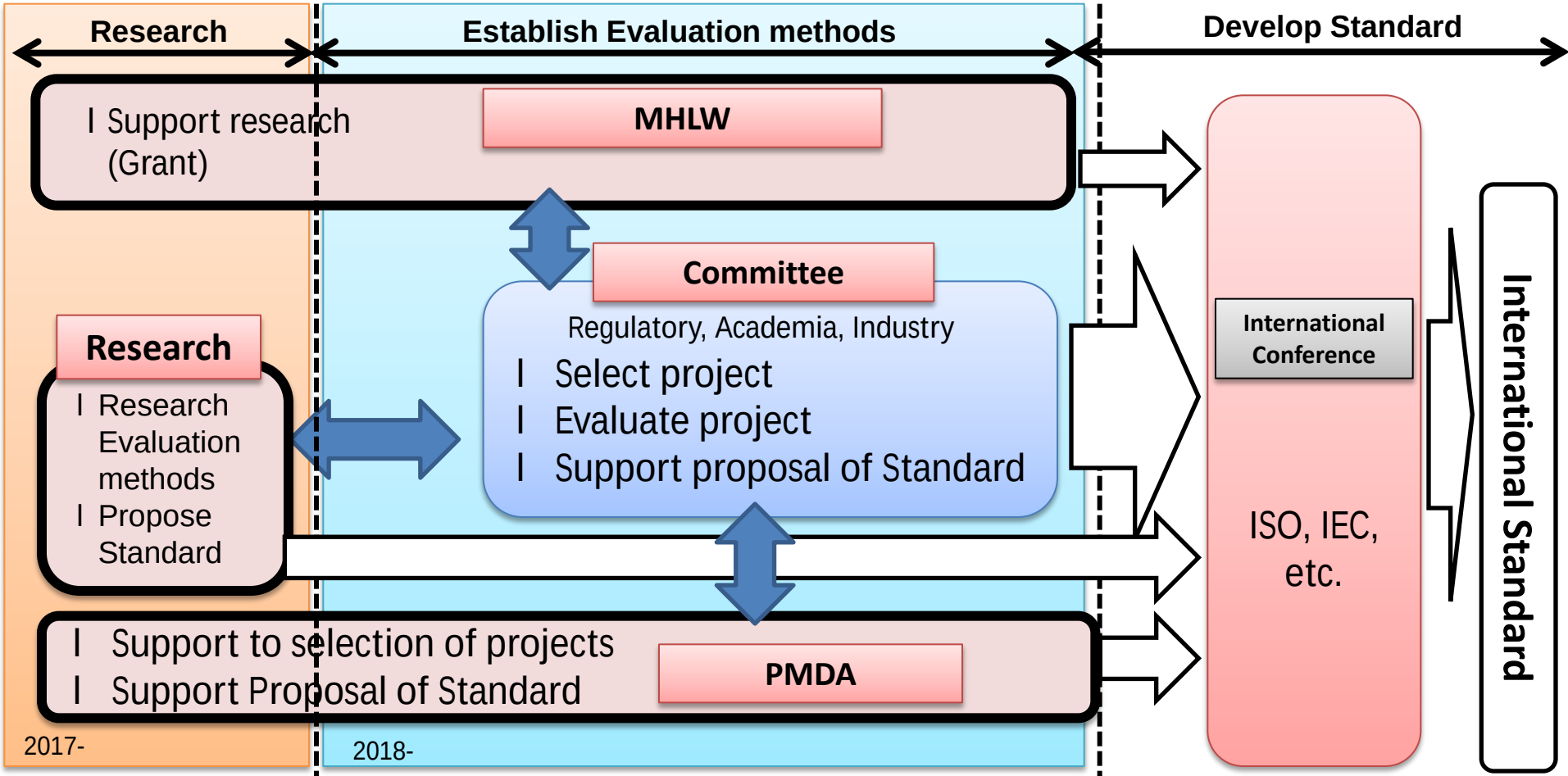
As of 28 February 2017, 7 more products (3 medical devices, 1 IVD and 3 regenerative medicines) have been designated as Sakigake products.

No.	Product name	Expected performance/effectiveness
MD3	**Artificial tracheal** (made of polypropylene mesh and collagen sponge)	Aiding reconstruction of tracheal while maintaining intratracheal structure after partial removal.
MD4	**Boron neutron capture therapy (BNCT) system** (Neutron irradiation system for BNCT)	Glioblastoma, head and neck cancer; Selective destruction of tumor cells marked by boron agents, without damaging normal cells.
MD5	**UT-Heart** (Software program to aid prediction of effectiveness of cardiac resynchronization therapy)	Higher accuracy of prediction of effectiveness of cardiac resynchronization therapy for patients with serious heart failure.
IVD1	**Cancer-related gene panel examination system** (Diagnostic system for DNA sequencer)	Collective examination of cancer-related genes to aid decisions on cancer treatment strategies

No.	Product name	Expected performance/effectiveness
RP4	**CLS2702C/D** (Oral mucosa-derived esophageal cell sheet)	Shorter re-epithelialization period after extensive endoscopic submucosa dissection (ESD) in esophageal cancer.
RP5	**Dopamine neural precursor cell derived from non-autologous iPS cell** (Therapeutic stem cell for Parkinson's disease)	Novel therapy by inducing dopamine discharge to mitigate neural symptoms of patients with Parkinson's disease.
RP6	**Pluripotent progenitor cell derived form human (allogeneic) adult bone marrow** (Stem cell suspension derived from adult marrow)	Novel therapy for improving functional impairment caused by acute brain infarction.

Facilitate Development of International Standard for Evaluation method for Innovative MDs

To Enable early introduction of innovative MDs all over the world
I.Facilitate development of evaluation method (Practical, non-clinical, properly predict effectiveness and safety)
II.Facilitate development of such evaluation method into International Standard



Thank you!