Considerations in Japanese academia in advancing pediatric medical device development: Insight from Japan's Agency for Medical Research and Development

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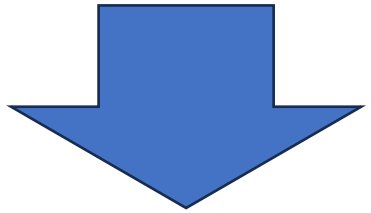
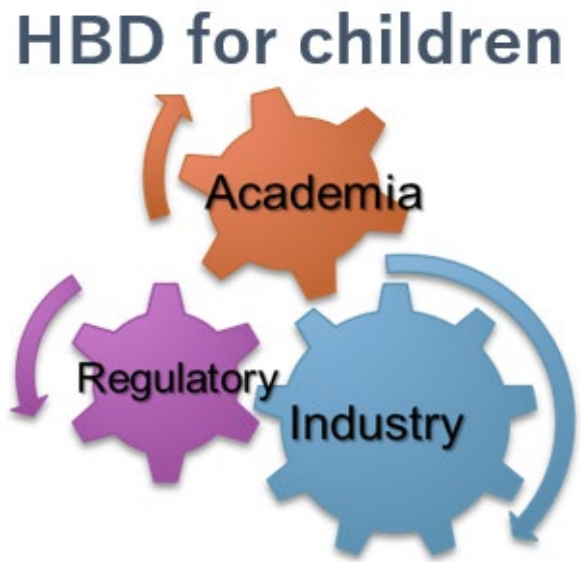
Environment of pediatric medical device development

Barriers for pediatric medical device development

1. **Universal problems specific to children**
   - Small market size
   - Rare disease
   - Wide variety in body and lesion size (Somatic growth of children)
2. **High cost for device development**



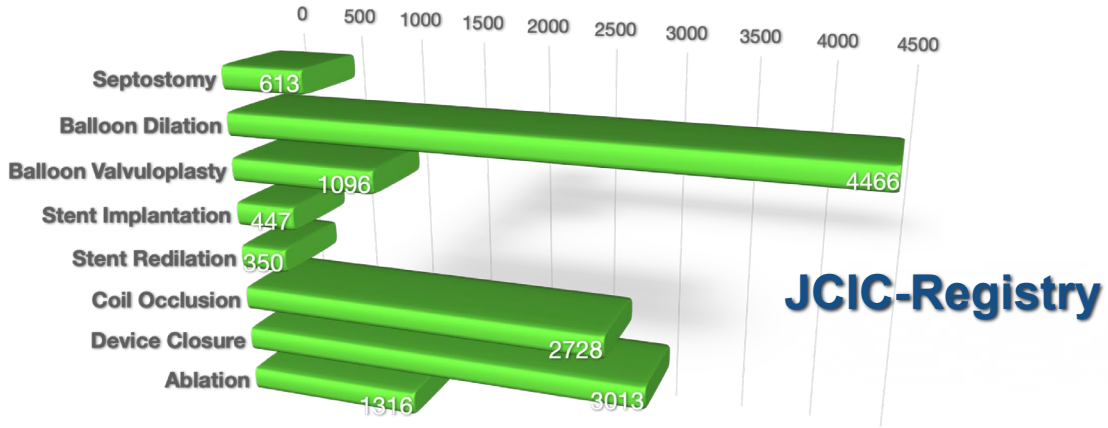
Device-lag　Off-label use



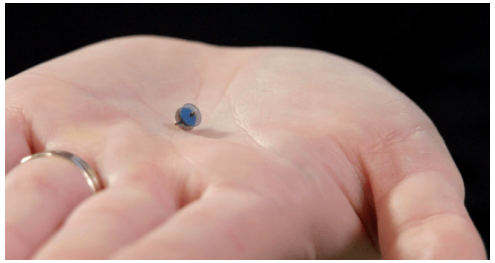
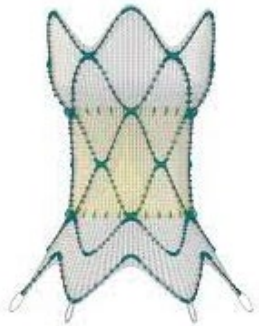
JCIC
REGISTRY

JCIC Registry

- ✓ Conducted by National Clinical Database（NCD） and JCIC
- ✓ High completeness（>90% of procedures in Japan）



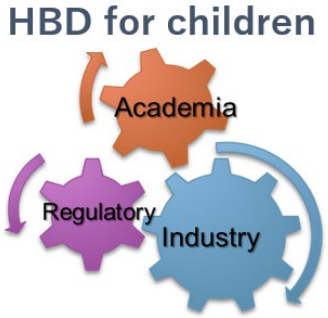
- ✓ Previously used for post-marketing database surveys in some devices


Update - AMED research

Japan Agency for Medical Research and Development

Research on the Improvement of the Environment to Promote Pediatric Medical Device Development



July 2023 – March 2026

Budget approved for 2023-2024
9100,000 USD

Objectives

- ✓ To reconstruct the JCIC-R database to be able to applicate effective PMS of the different types of devices and reduce the time/cost of PMS while securing the quality of surveillance.
- ✓ To improve the environment of pediatric medical devices development by strengthen the global collaboration of the stakeholders.

Update - AMED research

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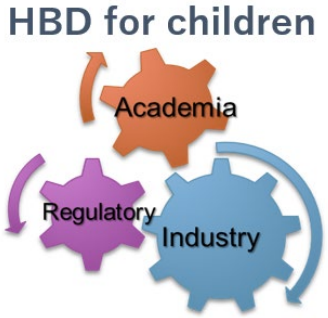

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Projects

#1 Reconstitution of the JCIC-R database to facilitate device development

#2 Standardization of definitions and endpoints (PAS-ARC project)

#3 Quality Improvement of the JCIC-R dataset

#4 Research of the clinical needs based on the RWD on the JCIC-R

Reconstitution of the JCIC-R database to facilitate device development

“Minimum data set” project

The new concept to minimize the number of data-set while ensuring effectiveness and safety evaluation in PMS using JCIC-R.

PMS of CP stent

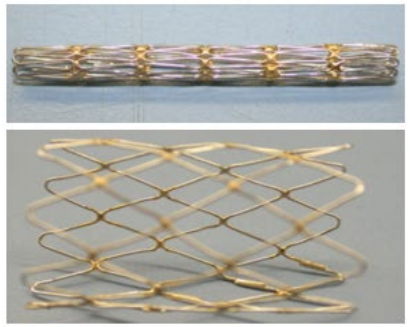
Heart and Vessels
https://doi.org/10.1007/s00380-020-01691-0

ORIGINAL ARTICLE

Check for updates

Clinical trial of the CP stent for pulmonary artery stenosis: the first investigator-initiated clinical trial for pediatric interventional cardiology in Japan

Takanari Fujii[1] · Hideshi Tomita[1] · Toshiki Kobayashi[2] · Hitoshi Kato[3] · Hisashi Sugiyama[4] · Ayumi Mizukami[5] · Hideaki Ueda[6]



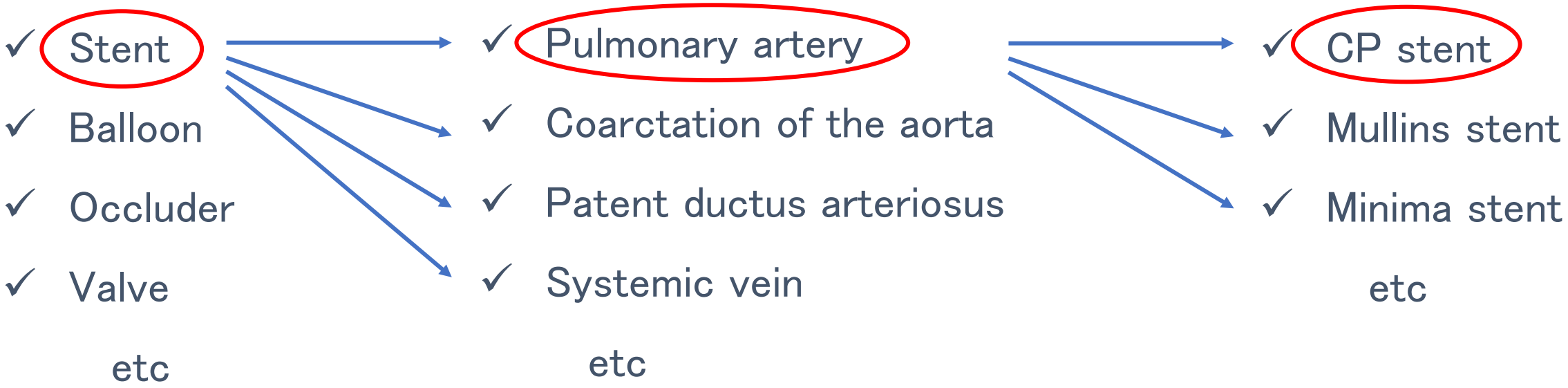
CP Stent™ Specifications

Stent Length (CM)	Configuration (Number of Zigs)	Platinum Wire (Inches)	Bare Stent Catalog No.	Covered Stent Catalog No.
1.6	8	0.013	CP8Z16	Cvrd. CP8Z16
2.2	8	0.013	CP8Z22	Cvrd. CP8Z22
2.8	8	0.013	CP8Z28	Cvrd. CP8Z28
3.4	8	0.013	CP8Z34	Cvrd. CP8Z34
3.9	8	0.013	CP8Z39	Cvrd. CP8Z39
4.5	8	0.013	CP8Z45	Cvrd. CP8Z45

Reconstitution of the JCIC-R database to facilitate device development

“Minimum data set” project

The new concept to minimize the number of data-set while ensuring effectiveness and safety evaluation in PMS using JCIC-R.



“Minimum data set” project

Minimizing collection frequency

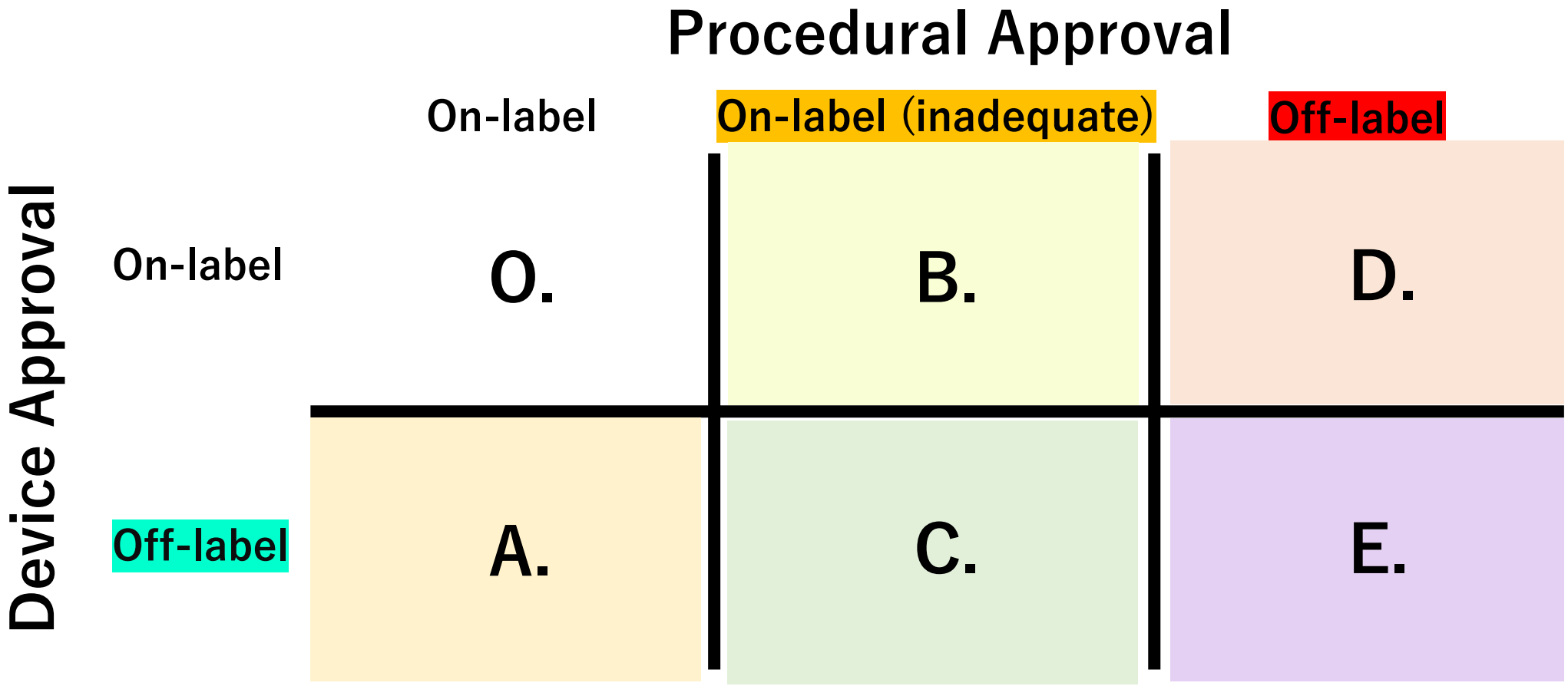
Minimizing the No. of items

	Hopital	1M	3M	6M	1Y	2Y	3Y
Effectiveness							
Clinical outcome							
Device performance							
Procedure-related endpoints							
Safety Issues							
Device related AEs							
Procedure related AEs							
Unknown AEs							

88% Reduction !!

Patient background is collected from existing JCIC-R data

Research of the clinical needs based on the RWD on the JCIC-R

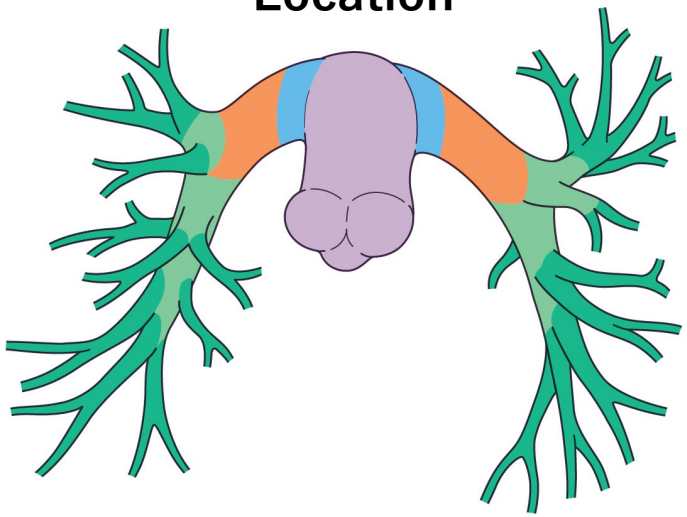


Procedure registered in the JCIC-R (2016-2023) are being analyzed, categorized into the above six categories.

Standardization of definitions and endpoints (PAS-ARC project)

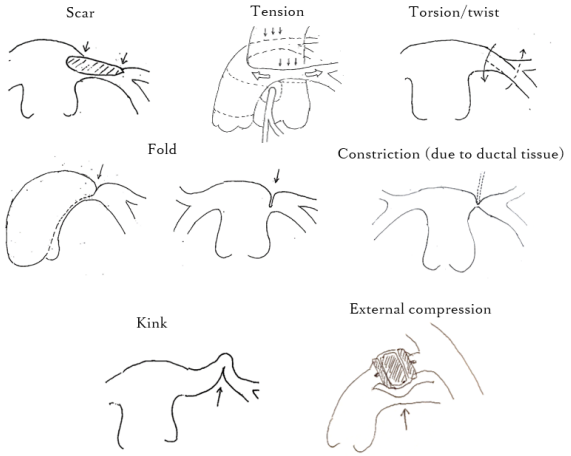
“PAS” Pulmonary Artery Stenosis

“Location”



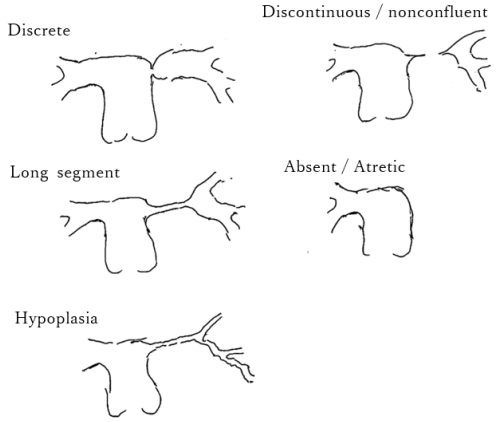
Type I	Ostial BPS	
Type II	BPS proximal to hilar bifurcation (not involbing the ostium)	
Type III	Peripheral BPS	
	IIIa	Lobar BPS
	IIIb	Segmental and sub-segmental BPS

“Mechanism”



1) Scar
2) Inadequate PA-plasty
3) Stretching
4) Torsion/ twist
5) Fold/kink
6) External compression
7) Constriction (due to ductal tissue)
8) Somatic growth
9) Low blood flow
10) Inflammation/thromboembolic disease
11) Other iatrogenic obstruction (due to endovascular devices)

“Morphology”



1) Discrete
2) Long segment (tubular)
3) Hypoplasia
4) Discontinuous / nonconfluent
5) Absent / Atretic

Summary of Our Current Effort

Current Activities

HBD for children
- Deregulation
- Global Clinical Trials
- Utilization of RWD

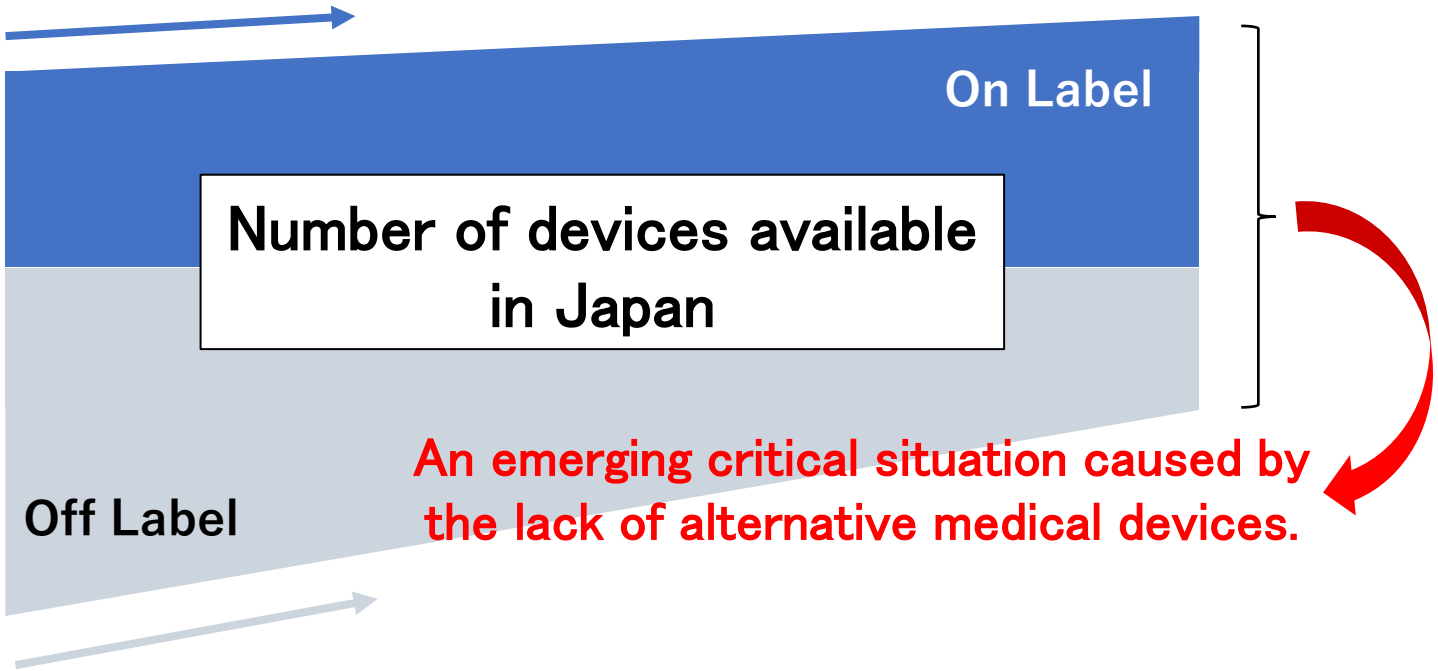
Challenges remaining :
- Birthrate deceleration
- Growing unprofitability
- Difficulty of introducing devices with foreign regulatory approvals

New device development

Barriers for pediatric medical device development

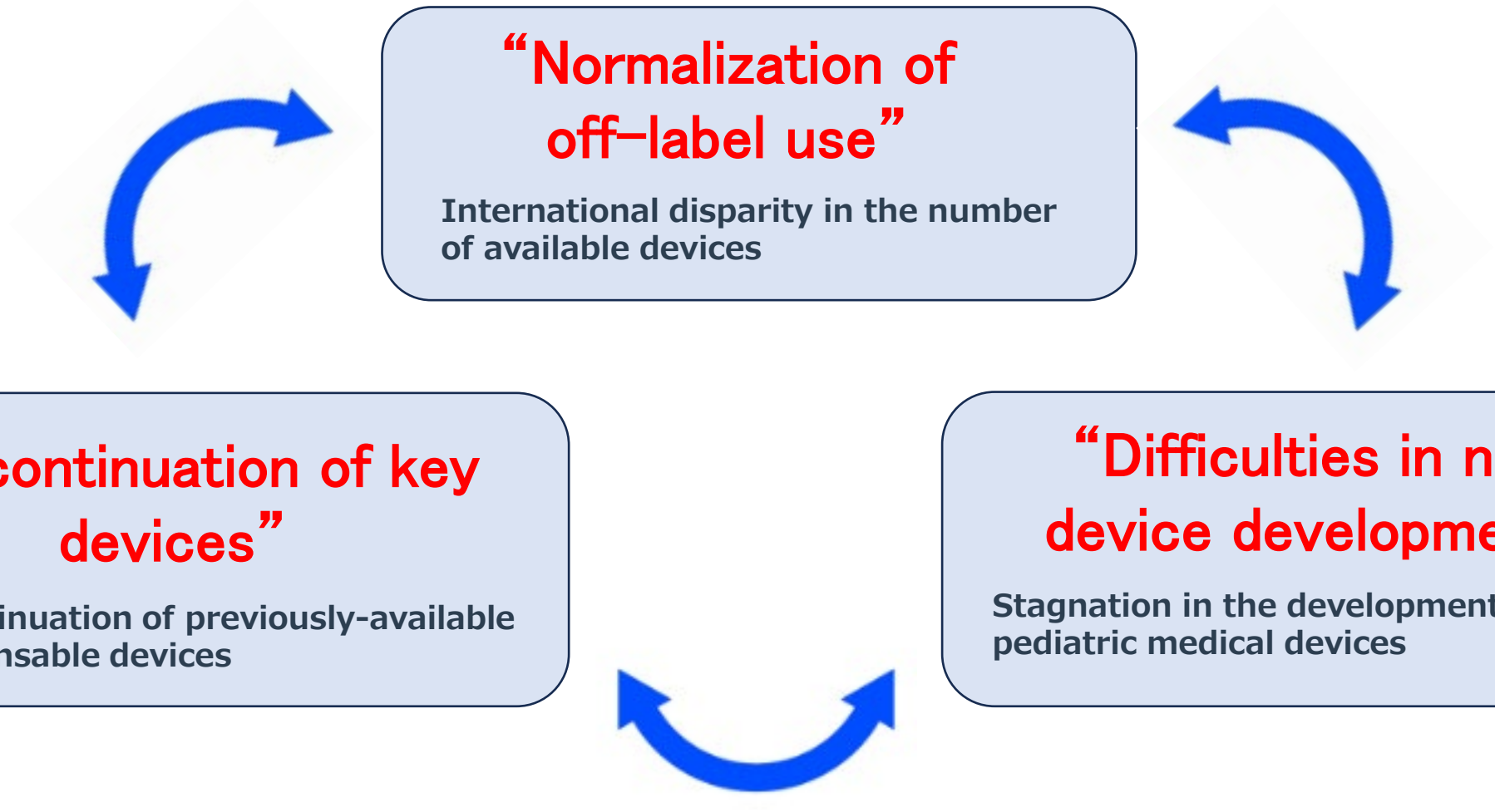
1. Universal problems specific to children
   - ・Small market size
   - ・Rare disease
   - ・Wide variety in body and lesion size (Somatic growth of children)
2. High cost for device development

Off-label use

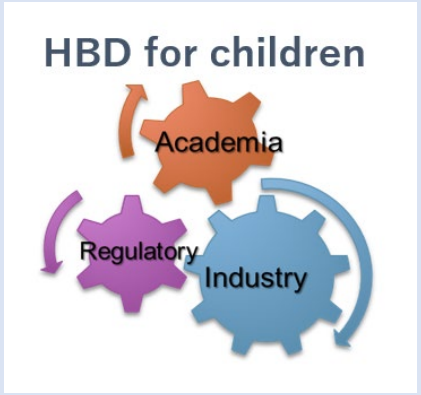


Off-label use is becoming more difficult due to...
- Tighter regulations under the Clinical Research Act.
- Discontinuation of device due to the transition to the MDR.

Currently identified challenges



To overcome this dilemma, further deregulation, improved reimbursement, and the establishment of a new legal framework specifically for pediatric medical devices may be required.



JSPCCS
HBD for children

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JCIC
REGISTRY

JCIC-R WG

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JSPCCS
JCIC

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2023-2026 AMED research