The challenges of Utilizing Registry Data For Regulatory Use - Academic View

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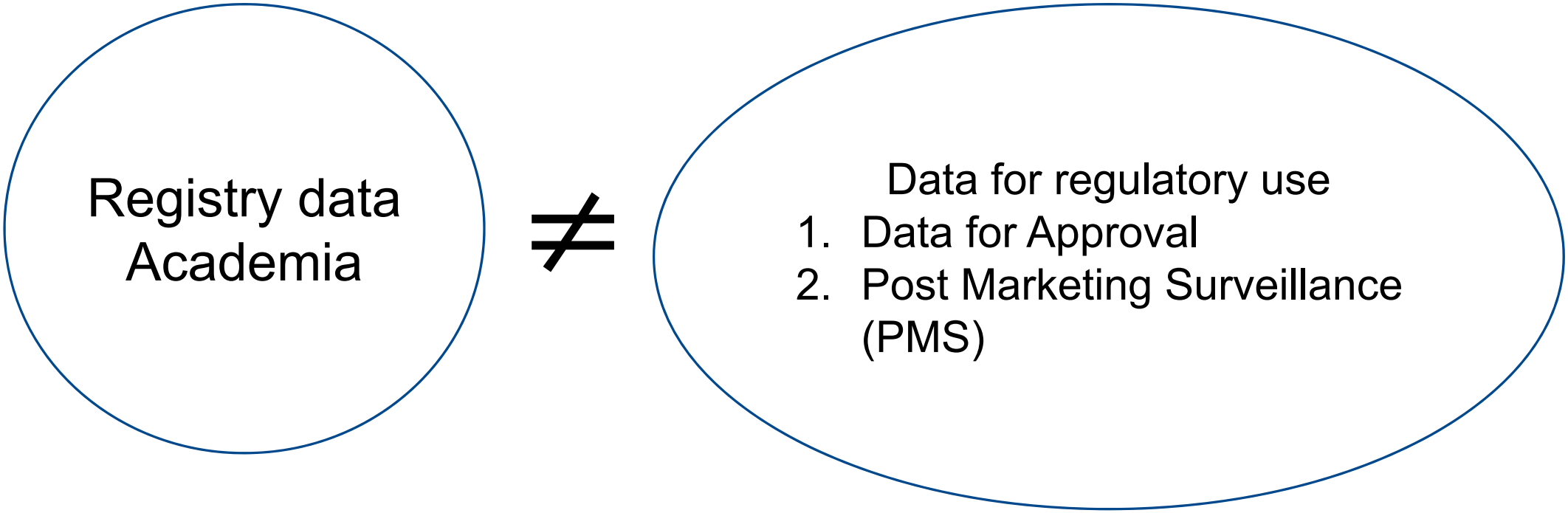
On behalf of JPIC database working group

Utilization of Registry Data for Introduction of Pediatric Medical Devices



An experience with PMS using registry data
: TAVI registry

Development of New database

Individual data

NCD National Clinical Database JCVSD

Existing surgical database
≠ GPSP-compliant
(Good Post-marketing Study Practice)

Pmda JAPAN

PMDA: Pharmaceuticals and Medical Device Agency

Features of Pediatric Medical Device in Japan

- **Small market** due to the rarity of the diseases
- Requires **variable kinds and sizes** of devices
- Difficult to perform clinical trials due to small number of patients and too many institutions

Cost reduction of PMS is crucial

Cost reduction of PMS using JPIC-Registry

JPIC: Japanese society of Pediatric Interventional Cardiology

PMS
for pediatric medical device

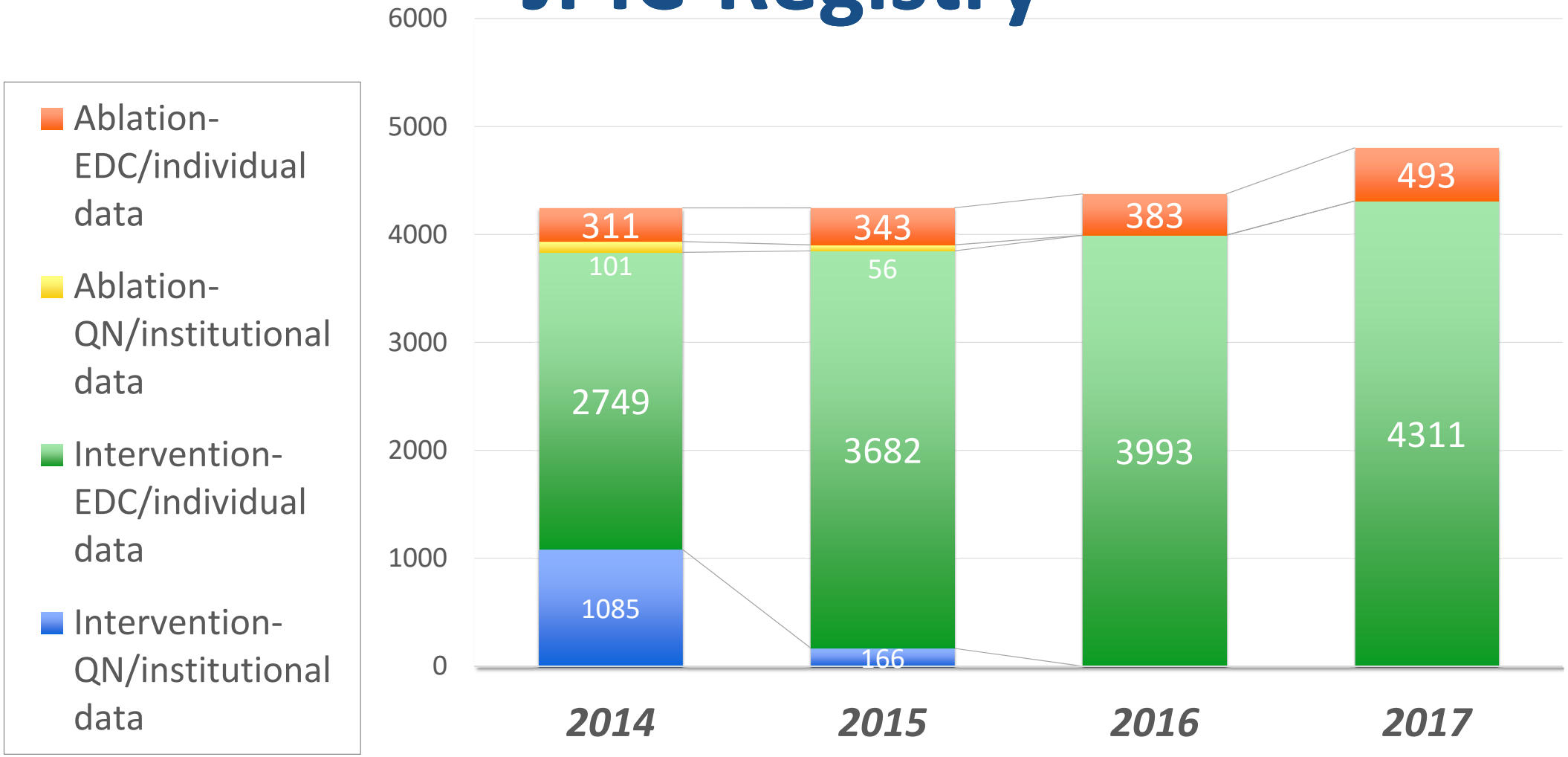
Development of universal platform for PMS on pediatric medical devices
Needs to be compliant with GPSP
(Good Post-marketing Study Practice)

JPIC registry (2013-)

Operated by National clinical database (NCD)

- Pediatric interventional cardiac catheter procedures from ～90 institutions
- 4000 cases/year
  (almost all pediatric cases in Japan)
- 140 variables/case
- Meticulous collection of complications

JPIC-Registry



Aims of JPIC-Registry

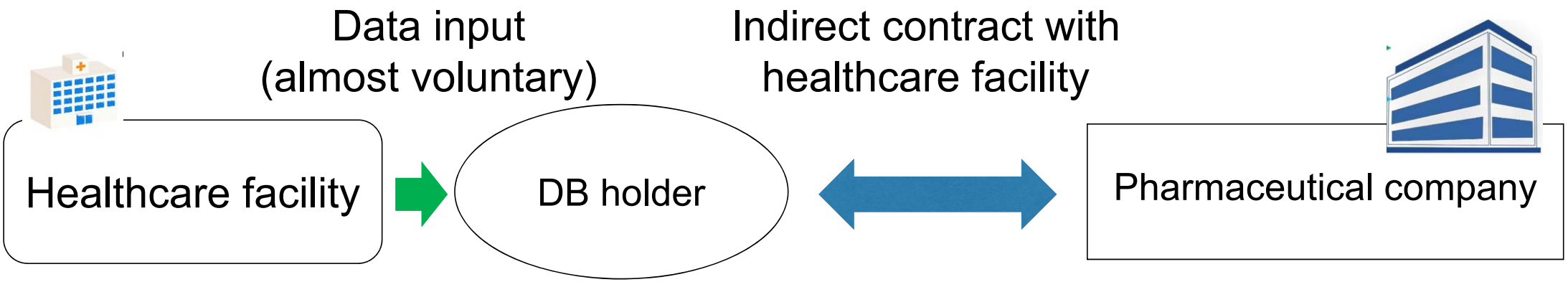
- ✓ Benchmarking function
- ✓ Explanation to patients regarding complication rate
- ✓ Operator / Institutional certification for new devices
- ✓ Approval for new devices
- ✓ Pre- and **Post- marketing surveillance**

Regulatory Use

- ✓ Multi-institutional study

Academic Use

Contractual relationship of postmarketing database survey



Work of data collection by healthcare facilities can become a hidden cost!

Challenge 1: survey items

- **Too many** items increase the cost (input/error check/query)
- **Too different** from academic survey items
- Includes information on **medical device failure**
- Needs to be fit into database format
- **Longer follow-up** (until discharge/1m⇒3y)

Survey items need to be minimized by cooperation among PMDA, industry and academia!

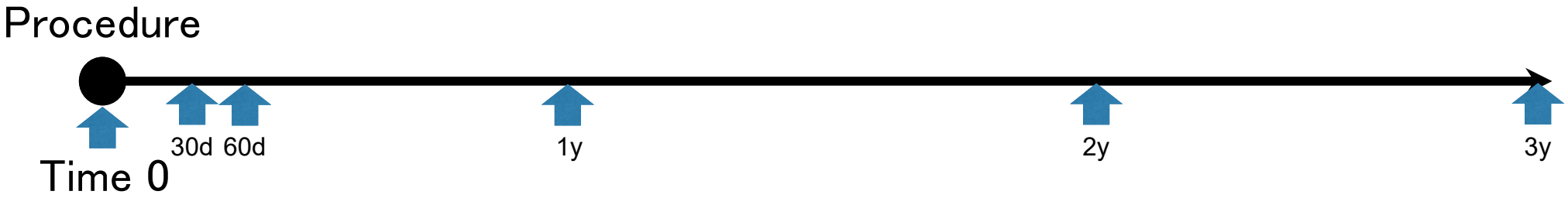
Challenge 2: SOP (Standard Operating Procedures)

SOPs required according to GPSP

- Establishment/management of registry
- Data cleaning
- Coding
- Security
- Data backup and recovery
- Quality control of healthcare data from information sources
- Data management
- Quality assurance
- Storage of records
- Education and training

These need to be prepared with the aid of CRO (⇒initial cost).

Challenge 3: Progress management



- Period between procedure and data entry is 0d-1y for academic use.

⇔Data needs to be entered in timely manner (in several wks) for PMS.

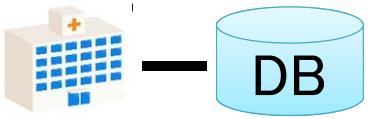
- Finding “time 0” is important to send reminders to healthcare facilities.

Idea is to use shipping records to trigger reminders for data entry

Challenge 4: Patient Consent

Opt-out

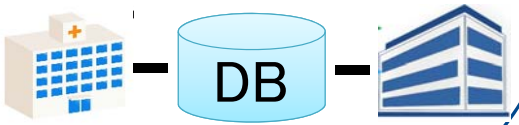
Academic registry



Non-academic use

＝Opt-in?

Registry PMS



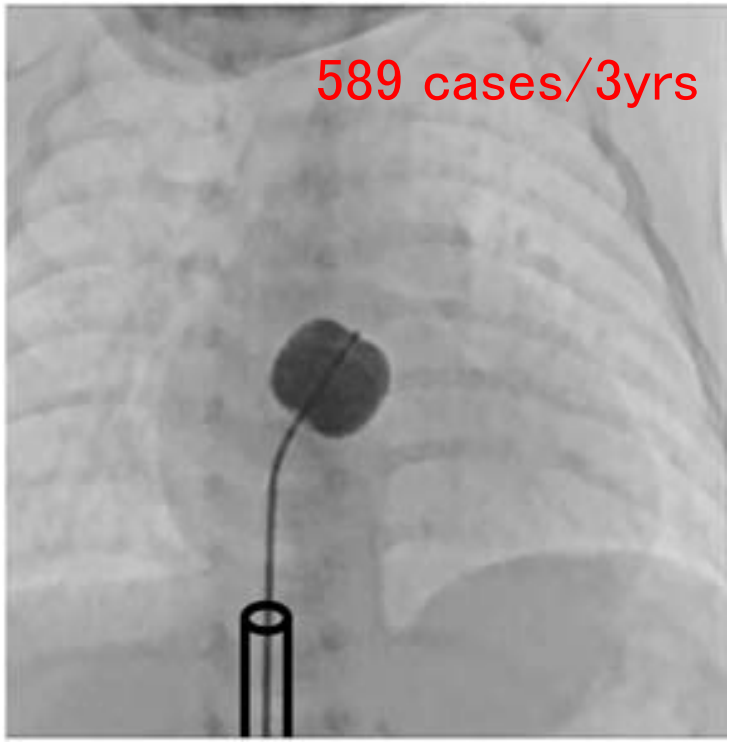
unnecessary

Normal PMS

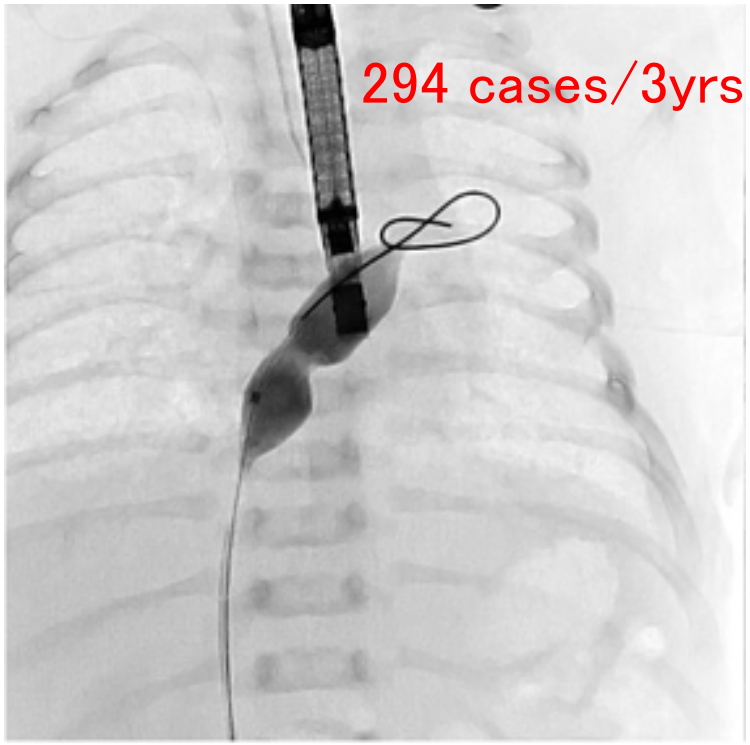
Legal framework for registry PMS may be needed

An example of pediatric medical device used as off-label: static BAS

Balloon atrial septostomy



Rashkind BAS: On-label use



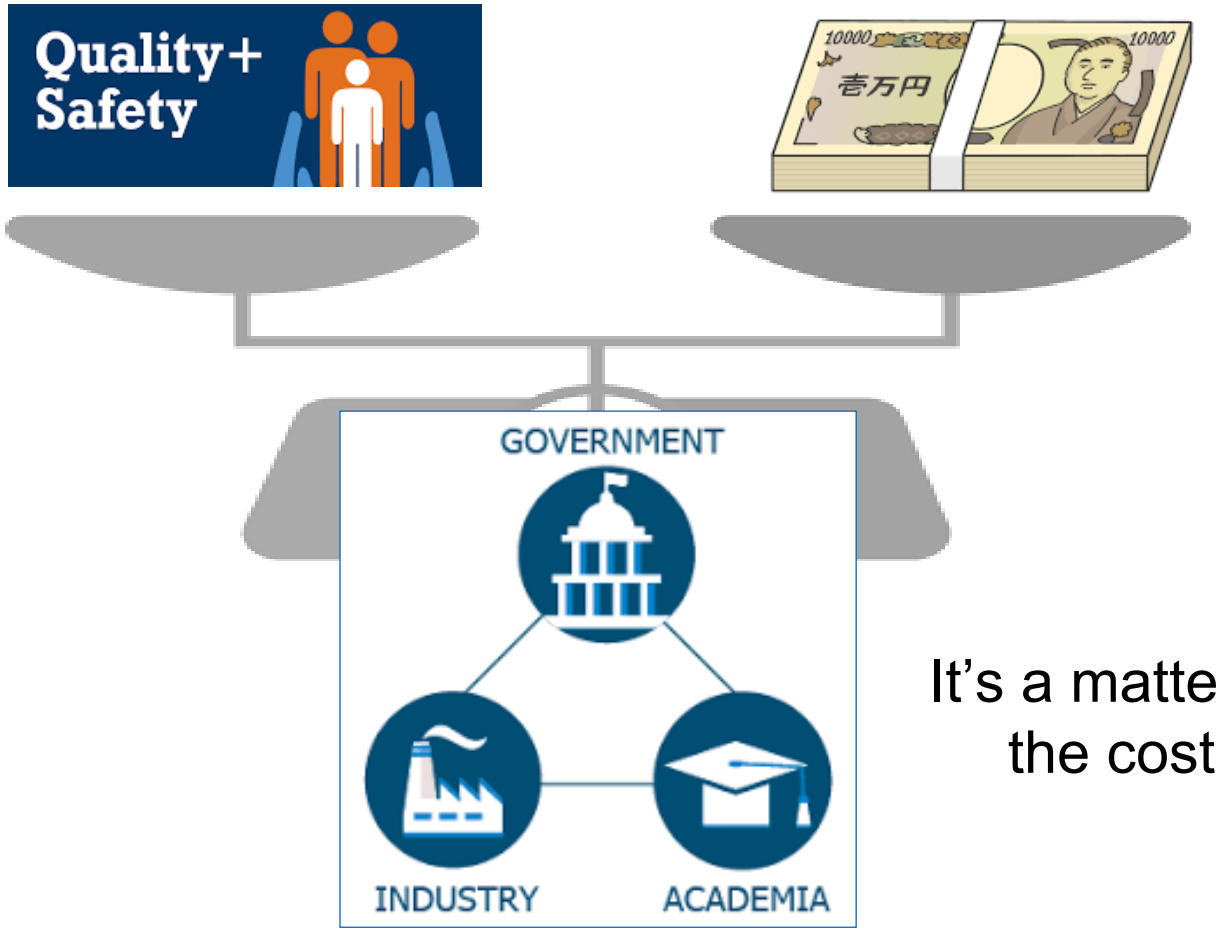
static BAS: Off-label use

static BAS survey for device approval

Supported by Ministry of Health, Labor and Welfare

- Specify clinical situation (Why)
  e.g. cases in which Rashkind BAS was ineffective
- Identify concomitantly used devices (How)
  e.g. Double balloon/stenting/Brockenbrough etc
- Confirm safety
  i.e. difference in complication rate between off-label v.s. on-label use

Summary



It’s a matter of how to balance the cost and the benefit!