

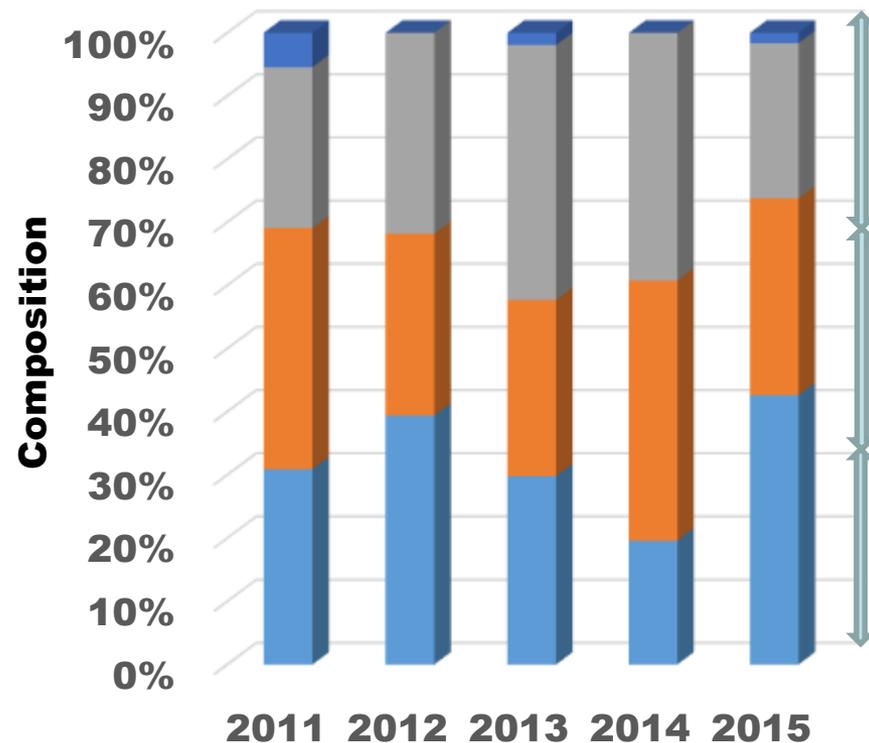
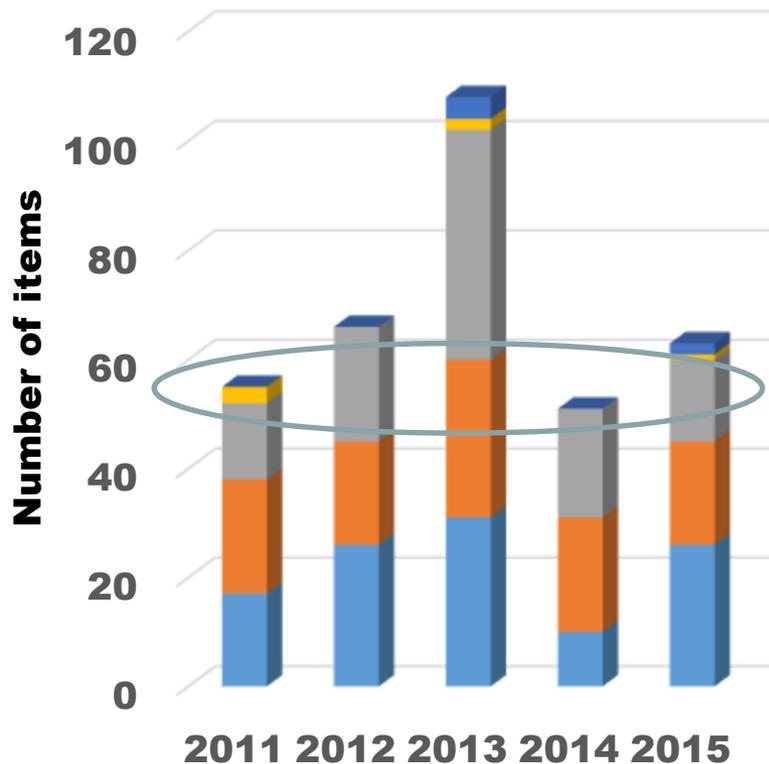
Issues Brought Up by Japanese Medical Device Industry

Insight from the results of surveillance on clinical trials conducted for JFMDA member companies

Seigo Nakano
Terumo Corporation, Tokyo, Japan
On behalf of clinical evaluation committee WG2,
JFMDA

From PMDA HP

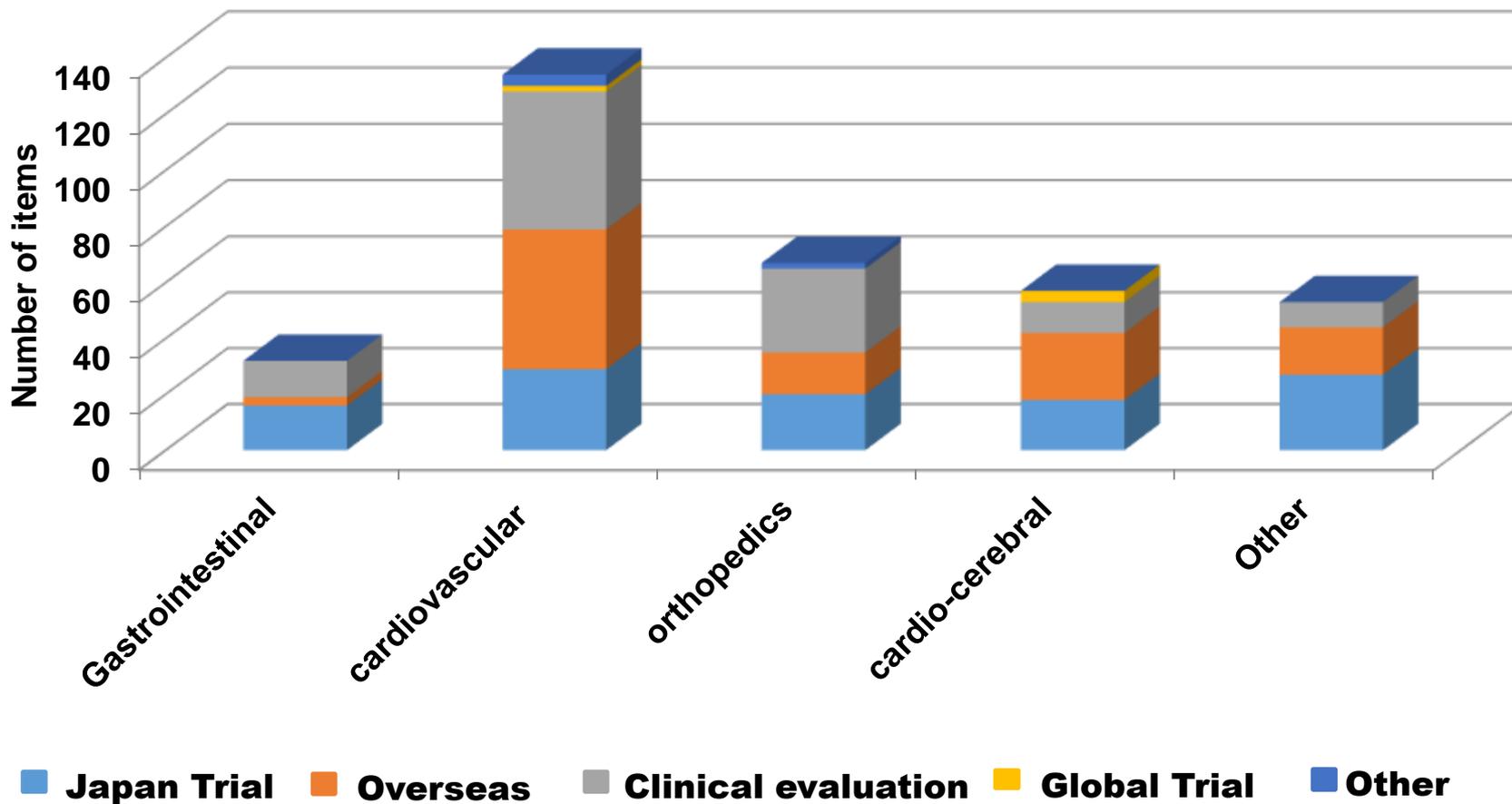
Clinical Data for Application in JAPAN (2011~2015)



■ Japan Trial
 ■ Overseas
 ■ Clinical evaluation
 ■ Global Trial
 ■ Other

From PMDA HP

Clinical Data for Application in JAPAN ② (2011~2015)



Results from surveillance (1)

Notification of Clinical Trial (financial year) in JAPAN (2010~2015)

Field	Notification of Clinical Trial (financial year)					
	2010	2011	2012	2013	2014	2015
Cardiovascular	1	2	7	5	5	4
Dialysis	3	1	1	2	1	4
Radiopharmaceuticals	1		1	2		3
Ophthalmologic	2	1	1		1	1
Orthopedic		1		1	1	1
Thoracic Surgery	2		1			
Endoscope				1		
Other		1	1	2	1	2
Total	9	6	12	13	9	15

Results from surveillance (2)

Number of Site of Clinical Trials in JAPAN (2010~2015)

Field	Numbers of Site												
	1	2	3	4	5	6	7	8	9	10	11	12	≥15
Cardiovascular	1	4	1	5	2	1	1		1		1	3	4
Dialysis	1	5		2	2								2
Radiopharmaceuticals		3			2			1					1
Ophthalmologic		1	3	1	1								
Orthopedic	1	2						1					
Thoracic Surgery		2	1										
Endoscope				1									
Other			1			1		1	1	1			1
Total	3	17	6	9	7	2	1	3	2	1	1	3	8

Results from surveillance (3)

Target Sample Size of Clinical Trials in JAPAN (2010~2015)

Field	Target Sample Size					
	≤ 20	21~40	41~100	101~200	≥ 200	unknown
Cardiovascular	3	6	9	3	1	2
Dialysis	6	1	1			4
Radiopharmaceuticals		3	1	3		
Ophthalmologic		3	2		1	
Orthopedic	3	1				
Thoracic Surgery		1	1	1		
Endoscope					1	
Other		1	4	2	1	
Total	12	16	18	9	4	6

Results from surveillance (4)

Global Clinical Trials in JAPAN (2010~2015)

Field	Global Study	Only Japan
Cardiovascular	6	18
Dialysis		12
Radiopharmaceuticals	5	2
Ophthalmologic		6
Orthopedic		4
Thoracic Surgery	2	1
Endoscope		1
Other		8
Total	13	52

Total cost and Breakdown per Protocol

	Total (n=21)	Cardiology (n=3)	Ophthalmology (n=5)	Orthopedic (n=5)
Mean	23,253.1	62,816.3	16,970.0	17,353.0
Max.	137,950	137,950	36,379	58,376
Median	13,417	40,255	13,417	7,129
Min.	2,422	10,244	5,364	2,836

Unit: 10K Yen, (): Protocols

Kozaki, et al. Pharmaceutical and Medical Device
Regulatory Science, Vol. 43. No. 5, 452-463 (2012)

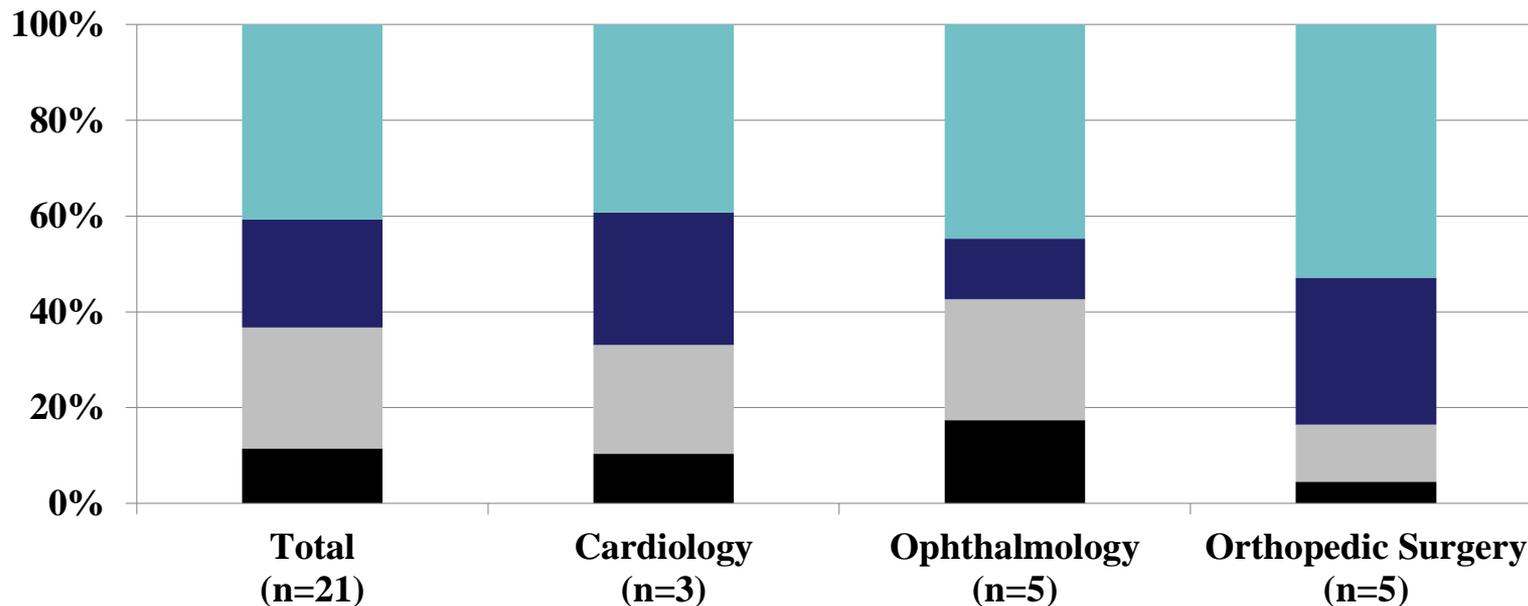
Total cost and Breakdown per Patient

	Total (n=21)	Cardiology (n=3)	Ophthalmology (n=5)	Orthopedic (n=5)
Mean	458.4	333.0	144.2	265.8
Max.	2,245	457	289	721
Median	289	412	106	178
Min.	43	130	75	43

Unit: 10K Yen, (): Protocols

Kozaki, et al. Pharmaceutical and Medical Device
Regulatory Science, Vol. 43. No. 5, 452-463 (2012)

Composition of clinical trial cost



- Site payment and others(e.g., PMDA consultation fee)
- Final visit and preparation of clinical study report (including audit)
- Operation and management of clinical trials
- Preparation of clinical trials before starting

Kozaki, et al. Pharmaceutical and Medical Device Regulatory Science, Vol. 43. No. 5, 452-463 (2012)

Conclusion

- Clinical trial with five or less institutions per trial was 67%.
- Multicenter trials with more than 15 institutions was 12.7%.
- Clinical trials whose target number of patient was from 21 to 100 accounted 52%. On the other hand, there were also 18% of the clinical trials with 20 or fewer patients enrollment..
- 20% of clinical trials was global trials.
- In many cases, the other expenses such as operating costs were greater than the procedure costs to the trial site.



Many of the trials conducted in Japan were small and domestic trials, few global trials. One of the causes may be that the trial cost in Japan is higher than in foreign countries. Cost can be reduced by improving the over-quality of the trial. If so, global trial might be increased also in Japan.

Thank you for your attention!