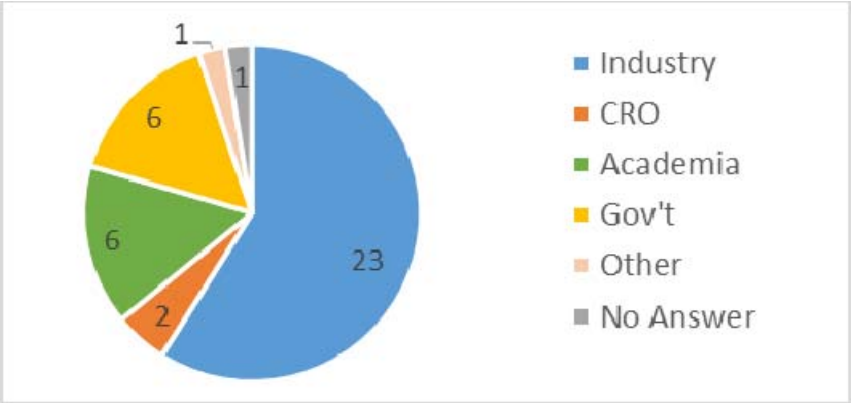
HBD East 2017 Think Tank Meeting: Survey results

(conducted from Jan.11 to 31: 39 responses)

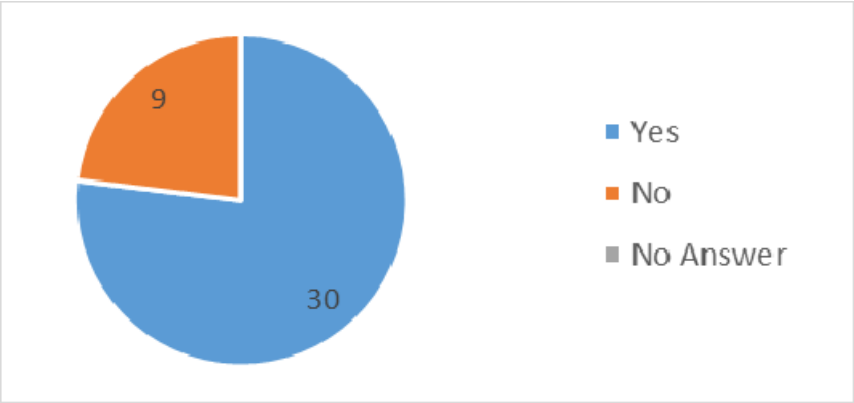
Questionnaire Items

1. Affiliation
2. Did you know about the HBD activity?
3. Do you get interested in the HBD activity after your participation in the HBD East 2017?
4. About program
5. Operation of the HBD East 2017 Think Tank Meeting.
6. The most exciting session
7. The most exciting presentation (Max. 2)
8. Any ideas you think interesting for future HBD Activity
9. Any topics you want to listen to at future HBD Think Tank Meetings
10. Any comments or impression

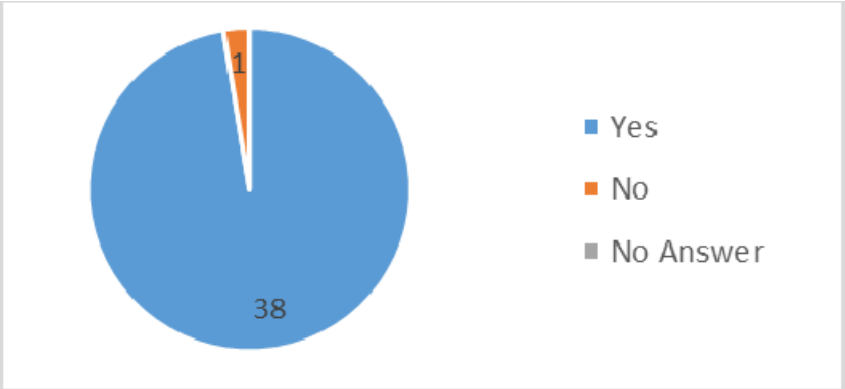
1. Affiliation



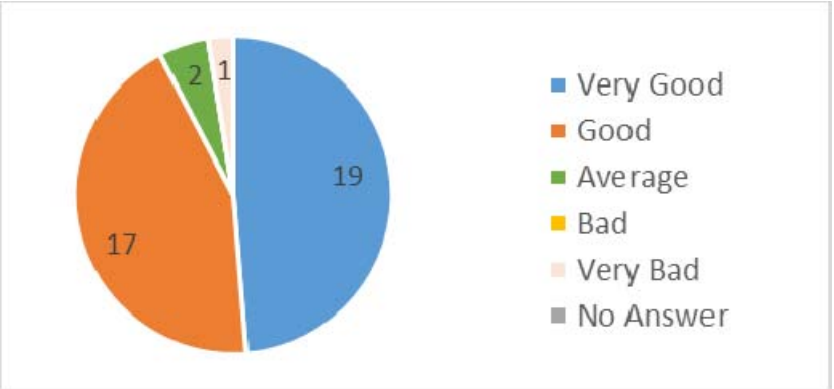
2. Did you know about the HBD activity?



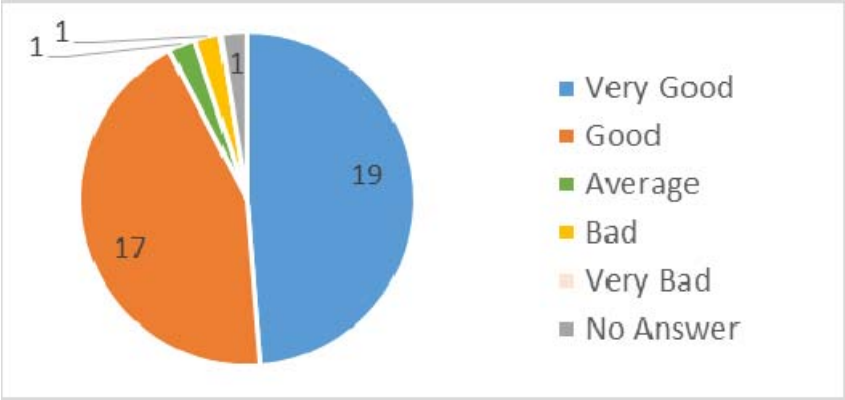
3. Do you get interested in the HBD activity after your participation in the HBD East 2017?



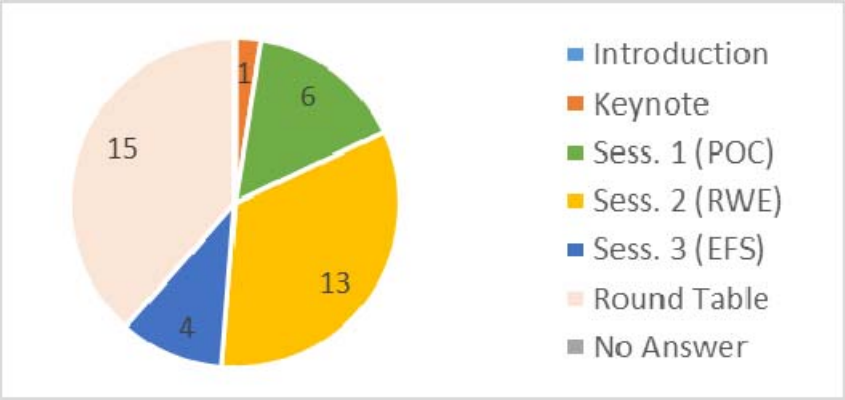
4. About program



5. Operation of the HBD East 2017 Think Tank Meeting.



6. The most exciting session



7. The most exciting presentation (Max. 2)

Top 3:

1. HBD for Children: Progress and Challenges
2. Round Table Discussion: Where Do We Go From Here?
3. National and International Efforts for Developing RWE

8. Any ideas you think interesting for future HBD Activity

Area	Comments
New device/technology	- Efforts for new device development (device for 21st century, proposal from academia, industry and regulators).
	- Product group to be taken up for HBD in the future: presentations from academia and industry.
	- Robotics tech, surgery, rehab, support and more.
Post-marketing	- Post-marketing vigilance activities, post-marketing surveillance.
Approval application in the US	- Possibility of obtaining foreign approvals with Japanese data.
	- How to resolve "device lag" issue in the US for Japanese devices, as device lag in Japan has been addressed.
Clinical trials	- How to build up clinical data or database for device promotion.
	- Comparison of GCP among several jurisdictions.
	- How to improve efficiency of clinical trial systems in Japan (e.g. elimination of formality-only data, as discussed at roundtable)
	- Over-quality issue in the Japanese clinical trials (as discussed at roundtable)
	- Cost of clinical trials
Real World Evidence	- Promotion of smaller-scale clinical trials, through utilization of real-world evidence, as used in the conditional early approval system.
	- Real world, again and more.
	- Utilization of big data for approval application.
HBD achievements	- Detailed discussion on the specific achievement of regulatory harmonization.
	- More specific update of POC.
	'- HBD for Children
	- Follow-up of HBD for Children
EFS	- Continuous discussion on early feasibility study.
Global harmonization	- Involvement of other countries for multi-national harmonization.
	- Develop measures that track the differences between Japan, USA, EU and any other major geography approval time. The concept of 'Japan Lag' should go away as now Japan may be 'Leading' (Negative Lag).
Wider scope	- May be too focused on cardiovascular area. Much wider area is desirable to be covered.
Other	- Is anything like an ICH for JP/US possible?
	- Safety reporting alliance in global trial

9. Any topics you want to listen to at future HBD Think Tank Meetings

Area	Comments
More details on HBD	- Further sharing of examples.
	- Detailed discussion on the specific achievement of regulatory harmonization.
	- Discussions were very interesting. I would like to hear more.
	- Sharing failed examples of the program, not only successful cases.
	- More HBD for Children
New device/technology	- Product group to be taken up for HBD in the future: presentations from academia and industry.
	- Efforts for new device development (device for 21st century, proposal from academia, industry and regulators).
	- AI application to diagnostic devices.
Clinical trials	- Deeper discussion and studies on "challenges in medical device clinical trials" based on more reliable data and literatures, as superficial questions and abstract answers would not help.
	- How to build up clinical data or database for device promotion.
	- Comparison of GCP among several jurisdictions.
	- Clinincal trials leveraged by RBM or clinical QMS
	- Cost of clinical trials (how to reduce the cost of the trials)
EFS	- Introduction of approved cases resulted from early feasibility study (specific actions and schedule).
	- Feasibility and case study.
Regulatory application	- Focused discussion on the differences of submission dossiers for generic medical devices between the US and Japan, as many Japanese companies face difficulties in submission in the US.
	- How to effectively approach two or more regulatory bodies in a single meeting.
Wider scope	- Areas othjer than cardiovascular
Real world evidence	- Follow-up of Real-world evidence utilization.
Data analysis	- Bayesian statistics.

10. Any comments or impression (1)

Area	Comments
More time/participants for discussion	- For the next meeting, it may help to make sure speakers do not exceed their allotted time, to ensure there is enough time for discussion. Also, while the discussion about future HBD topics was very interesting and useful, it was not clear which topics were the ones that the majority of the participants thought we should focus on. Perhaps next time, there could be a survey either at the end of the meeting, or after the meeting like this survey, to learn everyone's thoughts?
	- More participation from academia and industry are desired.
	- I expected more free time to talk about the topics with participants. And the advanced notification of the next meeting is also helpful.
	- It seems that participating companies in HBD are narrowly distributed. Topics should be chosen so that wider range of companies can join.
Better understanding	- Very useful seminar, as each presentation provided abundant information.
	- By learning the history of HBD, I recognized again the great value of current activities and the significance of continued efforts.
	- Thank you for your open discussion. Sharing a lots of detailed experience was very usable for our future development.
	- I was able to understand the fruit of HBD activities by hearing opinions from various aspects in the panel discussions. As my company's products are not cardiovascular devices, I cannot participate directly in HBD at this moment, I would like to join when the target area is expanded.
	- I was very much interested in the answers to the question why CRO-related costs for medical device is higher than those for drugs in the round table discussion.
Global harmonization	- This kind of effort should be pursued not only between Japan and the US bur also with European countries to achieve global harmonization.

10. Any comments or impression (2)

Area	Comments
Clinical trials in Japan	- There seemed to be some opinions/presentations that may give wrong impression about CRO. For both industry and academia, CRO is indispensable for conducting clinical trials in Japan or in any other country, with limited exceptions. It may be true that the cost of CRO/SMO in Japan is higher than in other countries, however, it is because CRO/SMO are relied upon more heavily, since investigators are too busy and/or supporting system of trial centers are too poor. Therefore, in order to reduce the cost of clinical trials, measures for improving clinical trial quality by both industry and academia (meaning less monitoring) and for reinforcing supporting systems at trial centers should be also considered. Taking into account that J-GCP will be revised in accordance with ICH-E6 (R2), and that RBA will be introduced and clinical quality management will be required then, I think it is necessary to pursue further impovement of quality and monitoring efficiency in clinical trials in Japan.
Arrangements	- Round table discussion seemed a bit disorganized, with too many panelists on the stage.
	- Providing abstracts of presentations in advance would be helpful for easy understanding.
	- Tables were not available for some seats. It is desirable that all seats have tables.
Compliments	- Thank you. I look forward to attending the next think tank meeting.
	- Thanks so much.
	- I am grateful to be able to participate in this think tank meeting. I thank all the people involved in organizing the meeting.
	- It's really precious chance to discuss with goverment, academia and industries. For my personal impression, I'm keen on round table discussion.
	- Think Tank Meeting was very informative. I hope to continue this type of meeting.
	- I re-realized the great value of HBD activities after hearing valuable presentations. I hope I can learn further achievements of HBD in the future meetings.
	- Appreciate the hard work and planning that goes into a major meeting like these. Please keep up the great work.