

Clinical Investigations in Japan then and now

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Disclosure Statement of Financial Interest

Within the past 12 months, I or my spouse/partner have had a financial interest/arrangement or affiliation with the organization (s) listed below.

Affiliation/Financial Relationship

- Employee

Company

- Abbott

15 Years Of HBD

December 7, 2017

HBD EAST 2017 Meeting

3

HBD Was Launched in 2003



2003

2004

2005

2006

2007

2008

2009

2010

2011

2012

2013

2014

2015

2016

2017



December 7, 2017



HBD EAST 2017 Meeting

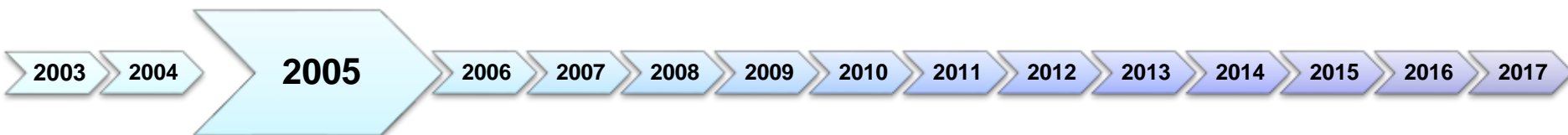


New Japanese Medical Device GCP was released in 2005

Challenges

- ❑ Medical Device Lag
- ❑ Infrastructure
- ❑ Understanding regulations

**New Japanese
Medical Device
GCP**

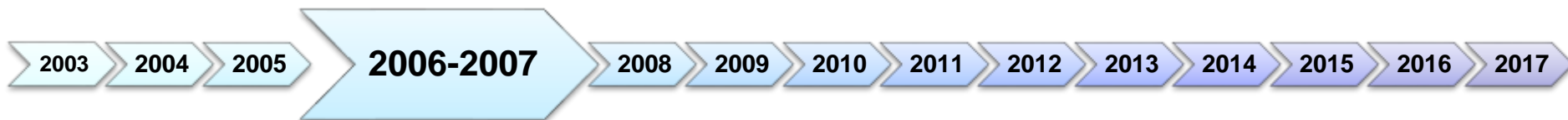


**HBD Symposium
in Tokyo**

HBD WGs and First Think Tank Meeting

4 Working Groups Organized on Oct 20, 2006

- ❑ WG1: Global pre-marketing clinical trials
- ❑ WG2: Post-marketing registries
- ❑ WG3: Clinical trial infrastructure/methodology
- ❑ WG4: Regulatory convergence/communication

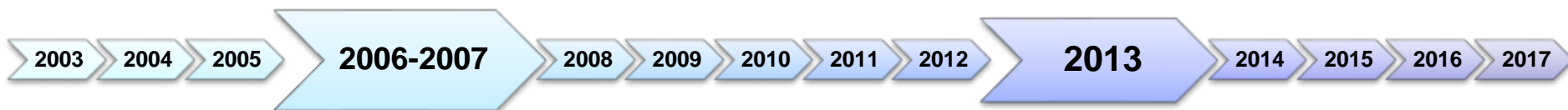


**HBD West 2007
Think Tank Meeting**

HBD WGs and First Think Tank Meeting

4 Working Groups Organized on Oct 20, 2006

- ❑ WG1: Global pre-marketing clinical trials
- ❑ WG2: Post-marketing registries
- ❑ WG3: Clinical trial infrastructure/methodology
- ❑ WG4: Regulatory convergence/communication



**HBD West 2007
Think Tank Meeting**

Achievements from HBD

4 Working Groups Organized on Oct 20, 2006

- ❑ WG1: Global pre-marketing clinical trials
- ❑ WG2: Post-marketing registries
- ❑ WG3: Successfully complete
- ❑ WG4: Successfully complete



JFDA HBD sub-committee meetings

2003

2004

2005

2006-2007

2008

2009

17

**HBD West 2007
Think Tank Meeting**

Achievements

- ❑ Improved infrastructure for global study
- ❑ Comparative analysis of GCP, STED, data reliability assessment, and orphan device-related regulations
- ❑ Scientific sessions
- ❑ Guideline development
- ❑ US – Japan vascular clinical trials
- ❑ Simultaneous products approval
- ❑ J-MACS registry harmonized with INTERMACS

Publications from HBD

Sase K. Harmonization by Doing : A Systems Approach to Conducting Responsible Reserch(Clinical Development of Antithrombotic Agents in Japan, The 69th Annual Scientific Meeting of the Japanese Circulation Society). *Circulation journal : official journal of the Japanese Circulation Society*. 69(Supplemnt_I), 79, 2005-03-01

Sase K. Harmonization by Doing (HBD) : Global Harmonization of Clinical Investigation and Research Infrastructure in Japan(Morning Lecture 2 (ML2) (H),The 70th Anniversary Annual Scientific Meeting of the Japanese Circulation Society). *Circulation journal : official journal of the Japanese Circulation Society*. 70(Supplement_I), 96, 2006-03-01

Chen E. FDA PERSPECTIVES ON GLOBAL TRIAL DEVELOPMENT FOR MECHANICAL CIRCULATORY SUPPORT DEVICES: INTERMACS AND HARMONIZATION BY DOING PROGRAMS. *Journal of the Japanese Society for Artificial Organs and Tissues*. 36(2Supplement), s1-s1, 2007

Sase K. Current Trend of Reviewing and Regulation for Medical Devices : Complementary Approach with Global Regulatory Harmonization by GHTF and Practical International Clinical Trial by HBD [in Japanese] *Jpn. J. Clin. Pharmacol. Ther.* 41(4), 133-139, 2010-07-31

Kouzaki Y, Fukuzawa I, Akabori M, et al. The First-ever Report on Multi-Company Survey of the Cost of Medical Device Clinical Trials in Japan : Results of a Collaborative Study [in Japanese] *Pharmaceutical and Medical Device Regulatory Science*, 43(5), 452-463, 2012

Harmonization-by-Doing Working Group 4. GCP Convergence Improves Transportability of Medical Device Clinical Data. Available at: www.raps.org/WorkArea/DownloadAsset.aspx?id=5103

Publications from HBD

Uchida T, Ikeno F, Ikeda K et al. Global Cardiovascular Device Innovation : Japan-USA Synergies : Harmonization by Doing (HBD) Program, a Consortium of Regulatory Agencies, Medical Device Industry, and Academic Institutions. *Circ J*, Volume 77 (2013) Issue 7 Pages 1714-1718

Iwamoto S, Ho M, Suzuki Y. Collaborative Review Scheme with US FDA and Harmonization By Doing (HBD) Activities Towards Speedier Review of Medical Devices. *RSMP*, Volume 5 (2015) Issue 3 Pages 227-234

Murakami M, Suzuki Y, Tominaga T. Rapid Globalization of Medical Device Clinical Development Programs in Japan - The Case of Drug-Eluting Stents - *Circ J*, doi: 10.1253/circj.CJ-17-0533

Nakatani T, Sase K, Oshiyama H, et al. Japanese registry for Mechanically Assisted Circulatory Support: First report. *The Journal of Heart and Lung Transplantation*. Volume 36, Issue 10, October 2017, Pages 1087-1096

Past HBD presentation slides are available at: <http://www.jfmda.gr.jp/hbd/e/index.html>

HBD Activities Now



2003

2004

2005

2006

2007

2008

2009

2010

2011

2012

2013

2014

2015

2016

2017

Further Needs

- POC projects (Session 1)
- Sub-WG: HBD for Children (Session 1)
- Real World Evidence (Session 2)
- Early Feasibility Study (Session 3)
- Non-vascular Clinical Trials (Round Table Discussion)
- And more...



Thank You!

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