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.

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<tr>
<th>Affiliation/Financial Relationship</th>
<th>Company</th>
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<td>Employee</td>
<td>Abbott</td>
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December 7, 2017
15 Years Of HBD
HBD Was Launched in 2003
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

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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

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 registry harmonized with INTERMACS
Publications from HBD


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


Publications from HBD


Past HBD presentation slides are available at: [http://www.jfmda.gr.jp/hbd/e/index.html](http://www.jfmda.gr.jp/hbd/e/index.html)
HBD Activities Now

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…

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HBD EAST 2017 Meeting
Thank You!

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