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| **KAMAKURA LIVE / HBD Special Program**  **From JAPAN to US!**  **Medical Device Innovation through HBD**  **December 18, 2015**  **Hamagin Hall, Yokohama, Japan** | |
| **Introduction & Welcome** | |
| 10:00 | Shigeru Saito (Shonan Kamakura Hosp) |
| **Plenary Session: Introducing Medical Devices of Japan to the World**  **Moderators: Fumiaki Ikeno, Toshi Tominaga** | |
| 10:05 | **Medical Technology from Outside World Into Japan and From Japan Exported to Outside World**  Tatsuya Kondo (PMDA) |
| 10:20 | **調整中**  FDA CDRH (Pre-recorded) |
| 10:40 | **Development of Innovative Medical Devices with Team Japan …**  （調整中） |
| 10:55 | **The Effort for International Medical Device Promotion based on Health and Medical Care Strategy**  Medical Device and Regenerative Medicine Product Evaluation Division, (MHLW)　(調整中) |
| 11:10 | **Encouraging Medical Device Innovation & Exportation From Japan to Outside: Importance for Japanese Medical Industry**  Koji Nakao (JFMDA) (Pre-recorded) |
| 11:25 | **The Changing Landscape of Global Medical Device Evaluation: What We Can Do When We Work Together the HBD Way**  Mitchell Krucoff (Duke University Medical Center) |
| 11:40 | **Lunch　Break** |
| **Session1: Stimulating Japan Medical Device Innovation and Reaching Global Markets: Lessons Learned from Regulatory Harmonization & Global Trials**  **Moderators: Neal Fearnot, Taka Uchida（調整中）** | |
| 12:40 | **Regulatory Science Based Development of Medical Devices**  Mitsuo Umezu (Waseda) |
| 12:55 | **Lessons Learned from HBD and PMDA’s Effort to Encourage Medical Device Innovation**  PMDA |
| 13:05 | **Challenges to Develop Innovative Medical Devices in US**  Hiroaki Kasukawa (Terumo) |
| 13:15 | **Experience of Japan-US Clinical Trial through HBD as an US-based Venture Company**  Bob Thatcher (CSI) |
| 13:25 | **Education for entrepreneur and intrapreneurship of medical devices**  Masakazu Yagi (Japan biodesign) |
| 13:35 | **Encouraging Industry to Make a Step towards the globe**  Hiroshi Tsuchiya (METI) |
| 13:45 | **Medical Device Incubation in Japan**  Fumiaki Ikeno (MedVenture Partners/Stanford) |
| **Panel Discussion**  **Moderators:** | |
| 13:55 | **Panelists** |
| **Session 2: Operational Challenges & Opportunities With Medical Device Registries & Novel Clinical Trial Infrastructure To Stimulate Innovation & Market Entry**  **Moderators: Allison Handler, Kazuhiro Sase** | |
| 14:35 | **Discussions through IMDRF Registry WG**  Kazuhiro Sase (Juntendo) |
| 14:45 | **Converging GCP & Clinical Trial Operations In Japan & USA: Lessons Learned**  Allison Handler (Duke Clinical Research Institute) |
| 14:55 | **RAPID Project, New Challenge in US**  Neal Fearnot (COOK) |
| 15:05 | **Challenges of National Clinical Database (NCD) Data Center**  Hiroshi Ohtsu (NCGM)　(調整中) |
| 15:15 | **EHR in the Era of Big Data**  Naokazu Saito (NEC) |
| **Panel Discussion: Envisioning the Path Forward**  **Moderators: Mitchell Krucoff, Shigeru Saito** | |
| 15:25 | Panelists: |
| **Closing remarks** | |
| 15:55 - | Mitchell Krucoff (DCRI) |
| **Adjourn** | |