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| **KAMAKURA LIVE Special Program**  **From JAPAN to US!**  **Medical Device Innovation through HBD**  **December 18, 2015**  **Hamagin Hall, Yokohama, Japan** | |
| **Introduction & Welcome** | |
| 11:00 | Dr. Shigeru Saito (Shonan Kamakura Hosp) |
| **Plenary Session: Introducing Medical Devices of Japan to the World**  **Moderators: Fumiaki Ikeno, Toshi Tominaga** | |
| 11:10 | **The PMDA View of Mr Abe’s Emphasis on Medical Technology from Outside World Into Japan and From Japan Exported to Outside World**  Dr. Tatsuya Kondo (PMDA) |
| 11:25 | **From Japan Last to “Japan First”: Success of More Than 10 Years of HBD On Cardiac Devices Availability & Clinical Care In Japan**  Dr. Shigeru Saito (Shonan Kamakura) |
| 11:40 | **Development of Innovative Medical Devices with Team Japan AS A WHOLE Efforts of AMED**  Dr. Makoto Suematsu (AMED, Keio) |
| 11:55 | **Encouraging Medical Device Innovation & Exportation From Japan to Outside: Importance for Japanese Medical Industry**  TBA (JFMDA) |
| 12:10 | **The Changing Landscape of Global Medical Device Evaluation: What We Can Do When We Work Together the HBD Way**  Dr. Mitchell Krucoff (Duke University Medical Center) |
| **Session1: Stimulating Japan Medical Device Innovation and Reaching Global Markets: Lessons Learned from Regulatory Harmonization & Global Trials**  **Moderators: Neal Fearnot, Taka Uchida** | |
| 12:25 | **Regulatory Science Based Development of Medical Devices**  Mitsuo Umezu (Waseda) |
| 12:40 | **Lessons Learned from HBD and PMDA’s Effort to Encourage Medical Device Innovation**  PMDA |
| 12:50 | **Experience of PMA Submission in USA**  Terumo |
| 13:00 | **Experience of Japan-US Clinical Trial through HBD as an US-based Venture Company**  CSI |
| 13:10 | **Cultivation of Venture and Entrepreneur**  MEXT |
| 13:20 | **Encouraging Industry to Make a Step towards the globe**  METI |
| 13:30 | **Experience in the Silicon Valley: Venture Cultivation**  Dr. Fumiaki Ikeno (Stanford) |
| **Session 2: Operational Challenges & Opportunities With Medical Device Registries & Novel Clinical Trial Infrastructure To Stimulate Innovation & Market Entry**  **Moderators: Dr. Allison Handler, Dr. Kazuhiro Sase** | |
| 13:40 | **Discussions and Achievement through HBD and IMDRF**  Dr. Kazuhiro Sase (Juntendo) |
| 13:50 | **Converging GCP & Clinical Trial Operations In Japan & USA: Lessons Learned**  Allison Handler (Duke Clinical Research Institute) |
| 14:00 | **Japan TAVI Registry**  Dr. Nobuhiro Handa (PMDA) |
| 14:10 | **RAPID Project, New Challenge in US**  Dr. Neal Fearnot (COOK) |
| 14:20 | **Japan Arthroplasty Register**  Dr. Haruhiko Akiyama (Gifu) |
| 14:30 | **Challenges of National Clinical Database (NCD) Data Center**  Dr. Hiroshi Ohtsu (NCGM) |
| 14:40 | **EHR in the Era of Big Data**  NEC |
| 14:50 | **Introduction of Clinical Innovation Network (CIN)**  MHLW |
| **Panel Discussion: Summarizing the Day, Envisioning the Path Forward**  **Moderators: Dr. Mitchell Krucoff, Dr. Shigeru Saito** | |
| 15:00 | Panelists: |
| **Closing remarks** | |
| 15:50 - | Dr. Mitchell Krucoff (DCRI) |
| **Adjourn** | |