Harmonization By Doing
Working Group 1: Global Clinical Trials
2010 Milestones

Introduction: With development of the MHLW-FDA Collaborative Program for POC clinical trials with fully preserved confidentiality boundaries for manufacturers, the emphasis of WG1 will shift toward its interaction with educational programs and practical scientific discussions that help identify, provide insight into and develop solutions for barriers that confound pragmatic global clinical trial efforts, as well as to aid in closing the device lag.

This is not considered a change in the core mission of the WG1 Charter, but more simply a change in emphasis for WG1 deliverables and "doing". This shift in emphasis will include "liason" interactions, where relevant and necessary, with professional societies, government agencies and other unique collaborative entities who are not HBD members per se, as well as interactions with other HBD WGs as needed.

The educational programs and scientific discussions WG1 will interact with will include, but not be limited to:

1. **Scientific educational programs/Barrier focus thinktanks** (sessions at appropriate professional society and academic meetings)
    a. Identify and discuss key issues facing Japan-USA global clinical trials to help solve scientific obstacles to global clinical trials(e.g. differences in patient demographics, practice of medicine etc)
    b. Discuss global clinical trial design issues for specific device areas or technology (e.g. novel technologies, superficial femoral artery stents, carotid stenting, cardiac ablation technology, cardiac resynchronization therapy, etc)
    c. Discussion on regulatory science (e.g. evaluation of next generation DES, adequate gender/ethnicity representation, pediatric device development etc)
    d. Evaluate/investigate global (US-Japan) clinical trials conducted inside/outside of HBD to better understand circumstances of these trials, and discuss/share lessons learned.
        i. Discuss differences that are observed in US and Japanese patients (e.g. differences in late stent thrombosis rates, etc)
        ii. Aid in the development of consensus common definitions (e.g. destination vs. bridge to transplant for left ventricular assist devices, etc)
    e. Update on progress of Collaborative Scheme and share general lessons learned in a manner that does not disclose confidential or trade secret information of participating industry sponsors
        i. Identification of topics for WG1 discussion based on experience from Collaborative Scheme

2. **Public education programs**
    a. Publicize value of research; protection of human subjects, for the lay public awareness (e.g. Kamakura Live Public Forum)

3. **Professional awareness programs:**
    a. Publicize/announce WG1 and HBD's mission as well as past and future activities to elevate interest in academia and industry to participate in HBD.and conduct global clinical trials. This may be through participation in meetings of other groups such as GHTF, RAPS, JFMDA/Advamed/industry meetings, professional societies, NIH, etc.

4. **Methodological/infrastructure programs**
    a. Address challenges and solutions for contracting, ethics review, electronic data capture, global event adjudication, novel pre-/post-market continuum study designs in collaboration with WG3

5. **Training programs** (CRA training, PI training, etc)

How WG1 interacts with the educational programs

The modes of interaction include but are not limited to:
1. WG1 discussions prior to various programs etc. among its members and feed appropriate topics to the meetings.
2. WG1 members actively lead the relevant discussions in the programs.
3. WG1 members summarize the discussions and formulate WG1's views/positions/opinions on the topics.
4. WG1 publishes its view etc. using an appropriate vehicle including HBD ThinkTank Meeting and HBD Website with due respect to the program etc.'s rules

WG1 Timelines/Deliverables:

I. Develop annual calendar of key meetings: POC using sample from/for 2010
    a. Spreadsheet dates, locations of annual professional society and trade meetings (completed for the upcoming year)
    b. Identify topics that WG1 will contribute to / use to interact with each meeting/program, (for each meeting WG1 participates in) (discussions on biodegradable cardiovascular devices has been identified to be a key topic for the upcoming year; other topics may be identified as well)
    c. Identify program teams for each 2010 HBD program (content, faculty, etc; ongoing)

II. Develop targets and timelines for liason interactions with other HBD WGs or outside professional groups as needed for above including:
    a. Projects with WG2 WG3 and WG4
    b. Educational liasons with CSRC (critical path cardiac safety)
    c. Collaboration with academic professional societies CVIT, TRI, ACC
    d. Educational liaisons with patient advocacy group(s)

III. Develop WG1 face-to-face and telecon meeting schedule (leveraging the educational program schedule above) (ongoing)

IV. Publish WG1's views/positions/opinions(as appropriate)