Experts agree on need to harmonize health research guidelines

Representatives of 35 organizations met on November 1, 2011, in Rockville, MD, at the invitation of Health Improvement Institute, to discuss the harmonization of health research guidelines. They represented guideline developers, guidelines users from industry & academe, and guideline use-facilitators & end-users; regulators, funders, and providers. In his opening remarks, Dr. Peter G. Goldschmidt, President and Founder of the Institute, emphasized the potential contribution that harmonizing guidelines harbors for improving the quality of health research. The meeting’s success in charting a way forward is the first step toward realizing this goal. Participants agreed on the need to establish a mechanism to coordinate guidelines’ harmonization (to foster excellence), to involve relevant alliances, networks, etc. (to avoid duplication), and to work closely with standards development organizations like the Clinical Data Interchange Standards Consortium (to promote adoption); CDISC provided input to this initial meeting.

Objectives
The meeting was part of the Institute’s Project to harmonize health research guidelines. Forces driving the Project included 1) there are many duplicative guidelines yet relevant aspects of health research remain unaddressed, 2) many guidelines are not adequate, 3) relevant, adequate guidelines have not been universally adopted, and 4) existing guidelines lack of harmonization. Meeting objectives were 1) to facilitate reaching agreement on organizational arrangements for a sustainable mechanism to harmonize health research guidelines, including its governance and funding, 2) to identify the boundaries of health research and priorities for guidelines harmonization, 3) to create resources that are needed to harmonize and to maintain worldwide guidelines for health research, 4) to establish a database of relevant guidelines and metrics, 5) to promote marketing and uptake of health research guidelines.

Participants
Health Improvement Institute limited the number of participants to 35, to promote discussion among experts at the meeting. To identify potential participants, the Institute asked experts and stakeholders known to the Institute and those identified by CDISC to nominate peers to attend the meeting; self nomination was acceptable. Nomination criteria include 1) recognized knowledge and experience in developing, evaluating, and/or harmonizing guidelines and/or metrics for any aspect of health research, 2) membership of or participation in existing guidelines or standards development organization, and 3) working in any country. More than 100 individuals were nominated. The Institute invited experts to attend the meeting in waves, to ensure balance among types of experts and organizations represented, until it reached the preset number of attendees.

Meeting agenda
The meeting consisted of three components: 1) scene-setting presentations, 2) discussion workgroups, and 3) plenary presentation of workgroup results and discussion of next steps. The five scene-setting presentations provided a context for the five discussion workgroups that followed. They were:
1: Institute sustainable mechanism to harmonize health research guidelines
2: Determine priorities for guidelines: mapping the health research enterprise
3: Assess the quality of guidelines: guidelines for guidelines
4: Inventory relevant guidelines and metrics
5: Promote marketing and uptake of health research guidelines

Following the discussion workgroups, participants gathered in plenary session to discuss workgroup findings. Each workgroup selected one of its members to present discussion results. The meeting rapporteur, Dr. Greg Koski, who had observed each workgroup, summarized the views and opinions expressed during the meeting. In closing the meeting, Dr. Goldschmidt outlined next steps and echoed participants’ suggestion for a follow on meeting in 2012.

Results
There was general agreement that 1) the Project was worthwhile, 2) the meeting achieved its objectives, and 3) a mechanism should be established to harmonize health research guidelines. Such entity would coordinate - but not duplicate – guidelines’ harmonization and work closely with relevant standards development organizations like CDISC. Other recommendations include:

- Identifying worldwide, and seeking the participation in the Project of, relevant alliances, associations, networks, etc.
- Inventorying guidelines meeting defined criteria (to create a knowledge base); determining such criteria
- Creating a profile template to describe inventoried guidelines
- Drawing a map of the research enterprise to use to classify guidelines in order to identify overlaps and gaps; producing a glossary
- Maintaining, using a transparent process, authoritative “guidelines for guidelines” to facilitate guidelines’ development, to assess their quality, and to aid their harmonization; including provisions to evaluate guidelines’ utility and impact
- Working with stakeholders to harmonize, to improve, and to elaborate needed but missing health research guidelines and to promote their adoption.

The Institute is preparing a report of the meeting which will be added to its website, www.hii.org. The website already contains meeting presentations and lists meeting participants. The meeting was sponsored in part by Nuovo Biologics, LLC and Digital Infuzion.

CDISC members who are interested in participating in the next place of the Project should send an email to the Meeting Coordinator, Yanan Ye, at hii@hii.org describing their interest.