



Project to harmonize health research guidelines
Arrangements Development Committee (ADC) Initial Meeting
(To be held on November 1, 2011 in Rockville, MD, USA)

The initial meeting of the Arrangements Development Committee (ADC) is a unique opportunity for various communities interested in health research to convene and to collaborate in a project to improve the quality and the utility of research and thereby to maintain and to improve the health of individuals and populations. Coordinating efforts pertaining to research guidelines is key to establishing a sustainable mechanism 1) to agree worldwide on a common set of guidelines for different types of health research, 2) to promote the use of these guidelines in policy decision-making, practice, education and research, and 3) to measure the quality and success of research studies. Please refer to the attached Project description for more details. The *Project to harmonize health research guidelines* is being developed by the Health Improvement Institute (HII) and the Clinical Data Interchange Standards Consortium (CDISC).

Objectives: The objectives of the ADC initial meeting are 1) to facilitate reaching agreement on organizational arrangements for a sustainable mechanism to harmonize health research guidelines, such as a guideline harmonization organization (GHO), 2) to identify governance & funding of such mechanism, 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, and 5) to promote marketing and uptake of health research guidelines.

Participation: Members of the ADC are volunteers recruited from among nominated experts worldwide to represent: 1) guidelines developers, 2) guidelines users (such as drug companies and academic researchers), and 3) use-facilitators (such as regulators, funding agencies, and accrediting organizations). Attendance at the initial meeting is by invitation only and is limited to about 30 experts. There is no meeting fee. Each meeting attendee is expected to pay his or her expenditures incurred in attending the meeting.

Format: The one-day meeting will use an interactive workshop format. This format comprises: 1) a limited number of scene-setting presentations at the start of the workshop; 2) moderated small workgroup discussions; and 3) a plenary session during which workgroups will present the results of their discussions and participants will consider these results and plan next steps.

Report & next steps: The Institute is planning to produce a workshop report that summarizes participants' findings, conclusions, and recommendations for implementing next steps in the project to harmonize and to maintain health research guidelines including corresponding metrics. This report, which the Institute plans to distribute broadly, is expected to have an international impact and the potential to influence future research, policy, and practice.

Health Improvement Institute (HII) is a non-profit, tax exempt, 501(c)3, charitable organization dedicated to improving the quality and productivity of America's health care. The Institute conducts workshops and sponsors national awards programs to recognize excellence, including the *Aesculapius Award* (for health communications) and *Award for Excellence in Human Research Protection*.

Clinical Data Interchange Standards Consortium (CDISC) is a global, open, multidisciplinary, non-profit organization that develops and supports global, platform-independent data standards that enable information system interoperability to improve medical research and related areas of healthcare. The CDISC vision is "informing patient care and safety through higher quality medical research".

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