



Project to develop Guidelines for Guidelines

The purpose of Guidelines-for-Guidelines (GFG) is to establish a firm foundation 1) to facilitate the development, maintenance, harmonization, and adoption of adequate and accepted research guidelines and 2) to permit the meaningful evaluation of the quality of existing research guidelines. The key to developing authoritative GFG is a transparent process that permits gathering input from the world's experts and users of the envisioned product.

Principles for meta-guidelines

The Health Improvement Institute (Institute) 1) has created a set of "Principles for meta-guidelines" to conduct the process for developing GFG and 2) expects that the resultant GFG will operationally replace this set of principles [1]. The GFG development process requires establishing 4 panels, each created according to established criteria. The functions of these panels are: 1) management, 2) drafting, 3) review, and 4) publication. The principles for meta-guidelines describe each panel's role and key areas of operation. They include 1) transparency, 2) establishing the need for GFG to learn from work to date, 3) openness, 4) standardization, and 5) quality and safety.

Partners & sponsors

The Institute is actively seeking like-minded partners and sponsors to ensure that resultant GFG are authoritative and receive worldwide recognition in order to be useful and to be used. Moreover, the Institute has agreed to co-branding of the product. Several alliances, associations, and other similar organizations have already expressed interested in participating in the GFG Project.

Context of GFG Project

Health research is essential for innovation and decision-making. In response to perceived inadequacies in the research enterprise, a number of organizations and individuals developed guidelines to address these problems. Today, 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 harmonization.

Project to harmonize health research guidelines

To address these problems, in 2010, the Institute launched the *Project to harmonize health research guidelines* [2]. The Project is expected to facilitate a dialogue among and to enable the work of regulators, biopharmas, academic researchers, and other stakeholders that comprise the health research enterprise. In November 2011, the Institute held a successful 1-day interactive workshop of experts to chart the way forward. As noted in the workshop report, the development of GFG - including provisions to evaluate guidelines' utility and impact - was one of participants' main recommendations [3]. In 2012, the Institute initiated the GFG Project.

For additional information - Contact the Project Coordinator at hii@hii.org or 301-320-0965.

Footnotes

1, 2, 3 - Referenced documents are available on the Institute's website - www.hii.org

Version 1.0; Revised October 09, 2012