



Project to harmonize health research guidelines (“Project”)

Introduction

Health research is essential for innovation and decision-making. However, over the years, different authors have expressed concern about the quality of the medical literature, and hence, of health research. These concerns encompass the accessibility, relevance, and validity of research results. In response, a number of organizations and individuals developed guidelines to address perceived problems. Most of this work centered on the quality of research reports published in journals, particularly clinical trials, and the analysis of published results to inform research proposals and evidence-based clinical practice. Adjuncts to these initiatives include requirements in some countries to report clinical trials. However, to date, there has been little effort to assure the quality of research designs and even less effort to measure studies' success. Moreover, new concerns have surfaced, including those centered on financial disclosure and conflicts of interests, while many old ones have largely gone unaddressed. Given 1) the increasing recognition of the importance and magnitude of the problem and 2) the growing variety of guidelines-related efforts, in 2010, Health Improvement Institute (Institute) [1] decided that the time was right for a project to explore opportunities to harmonize health research guidelines.

Goals

The goal of the Project is to establish a sustainable mechanism to coordinate systematically the development, harmonization, and promotion of the use of “health research guidelines,” and thereby to improve the quality and the utility of health research and to contribute to maintaining and improving the health of individuals and populations. The Project focuses exclusively on guidelines pertaining to health research, considered broadly to include 1) priority-setting, funding, design, conduct, publication and dissemination of results, synthesis of resultant information, for both primary and secondary research, and evidence-based practice, and 2) relevant metrics, e.g., to assess studies’ success. Importantly, the Project will endeavor 1) to encourage the participation of and to facilitate a dialogue among individuals and organizations working in the field (e.g., regulators, biopharmas, academic researchers, other stakeholders that comprise the health research enterprise) and 2) to avoid duplication of effort with existing guidelines and standards development organizations.

Project objectives

The Project is expected to remain a work in progress throughout its life; its objectives and work plan, to evolve dynamically. Immediate Project objectives are: 1) to establish the health research guidelines Network (“Network”) - a sustainable mechanism to achieve Project goals, 2) to develop guidelines for guidelines, 3) to create a map to define the domain, and 4) to inventory health research guidelines and metrics. The Project expects to accomplish these objectives through or by working with Network members and other appropriate entities. In the long run, the Institute expects to establish the Network as an independent entity governed by its own executive advisory board.



Work to date

In 2011, the Institute entered into working relationships with several organizations, including the Alliance for Clinical Research Excellence and Safety [2] and Clinical Data Interchange Standards Consortium [3]. Working with those organizations, the Institute established an Arrangements Development Committee (ADC) which consists of 35 experts. The initial meeting of the ADC was held in Rockville, MD, on November 1, 2011. Participants agreed on the need 1) to establish a mechanism to coordinate guidelines' harmonization (to foster excellence), 2) to involve relevant alliances, network, etc (to void duplication), and 3) to work closely with standards development organizations (to promote adoption). The ADC meeting report documents participants' recommendations. Subsequently, the Institute established the Project Planning Group (PPG) to assist the Project to adhere to its objectives and to implement ADC meeting participants' recommendations.

Institute harmonization mechanism

The Network is a virtual organization, whose members share a common interest in developing, harmonizing and promoting the use of the health research guidelines. Among other activities, the Project/Network is expected 1) to set priorities for harmonizing health research guidelines, 2) to promote the use of its endorsed guidelines by such applicable authoritative entities as funding organizations, regulatory agencies, journals, etc, thereby reinforcing their worldwide acceptance, and, hence, their utility, and 3) to evaluate routinely and rigorously the uptake of guidelines and metrics, their fitness for purpose, and any unintended negative consequences that might occur. The Network expects to utilize seconded staff, volunteer experts, and other in-kind contributions, and to work through other established organizations.

Develop guidelines for guidelines

An authoritative statement regarding guidelines for guidelines ("GFG") is essential to establish a firm foundation 1) to facilitate guidelines' development, 2) to assess their quality, 3) to guide their improvement, and 4) to aid in their harmonization. Resultant GFG must include a basis for 1) accrediting organizations to produce acceptable health research guidelines and 2) their periodic review and revision in light of rigorous evaluation. These GFG 1) must describe the development process, 2) must include provisions for systematically evaluating 2a) the adequacy of existing guidelines and 2b) their utility, quality and impact and 3) must allow organizations that develop guidelines to know the standards to which their processes and products must conform for resultant guidelines to be acceptable. Thus, GFG must be developed using a rigorous transparent process.

Create map to define domain

Relevant guidelines should exist for all essential aspects of the health research enterprise. The Project intends to develop a useful map 1) to identify what is within the health research enterprise for purposes of classifying, developing, and harmonizing health research guidelines and 2) to answer questions about their value and utility. The resultant map will permit identifying gaps and overlaps in health research guidelines.

Inventory guidelines & metrics

Considerable work has already been done by a variety of organizations and individuals 1) to develop guidelines for different types of health research and 2) to inventory such guidelines. Such work includes 1) Ratified Research Guidelines Directory (RRGD) [4], 2) guidelines indexed by EQUATOR [5], and 3) such focused guidelines as those of the International Conference on Harmonization [6]. It would be useful to develop and to maintain an inventory of health research guidelines and metrics as a valuable resource for harmonization. Initial activities are expected 1) to identify attributes and contents of such inventory and 2) to determine how the inventory might be established and governed. Once established, the inventory could 1) act as a clearinghouse for health research guidelines and 2) serve as a valuable resource not only to ratify guidelines for guidelines but also to harmonize coherent health research guidelines. A glossary to standardize such key terms as “research” (and categories of research), “guidelines” (and differentiating them from “standards” and “regulations”), and “good practice” (and “best practice”) will be useful to advance this goal.

Promote marketing & update of health research guidelines

Working with stakeholders, the Project/Network will promote the adoption of health research guidelines. Initial activities are expected 1) to outline a workflow process from receipt of a guideline to sustaining a message to promote its adoption and 2) to elaborate key steps necessary to implement various aspects of the workflow.

References & end notes

1. www.hii.org
2. <http://www.acresglobal.net/>
3. www.cdisc.org
4. www.worlddg.com
5. www.equator-network.org
6. <http://ichgcp.net/>

For more information

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Version 2.1; revised April 19, 2012