Project to harmonize health research guidelines

Arrangements Development Committee (ADC)
Initial meeting

Meeting report

December 12, 2011

Dedicated to improving the quality and productivity of America's health care
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Arrangements Development Committee (ADC) Initial Meeting

This report is a compilation of views expressed during the ADC meeting by participants. These views do not necessarily reflect the official views of Health Improvement Institute, meeting sponsors, participants' organizations, or any other organization associated with the meeting.

Suggested citation:
Goldschmidt PG, Ye Y. Arrangements Development Committee (ADC) Initial Meeting Report. Bethesda, MD: Health Improvement Institute, 2011.

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For additional information about the ADC meeting, visit www.hii.org.

Executive Summary

Health research is essential for innovation and decision-making. However, over the years, different authors have expressed concerns about its quality. In response, a number of organizations and individuals developed guidelines to address perceived problems. 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) decided that the time was right for a project to explore opportunities to harmonize health research guidelines. To chart the way forward, the Institute decided to hold an initial meeting of an Arrangements Development Committee (ADC).

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 and academe, and guideline use-facilitators and end-users, including regulators, funders, and providers.

The meeting used an interactive workshop format. The agenda consisted of three components: expert presentations to set the scene, workgroup discussions, and plenary presentations of workgroup results and discussion of next steps. Discussion workgroup topics included:

- Institute sustainable mechanism to harmonize health research guidelines
- Determine priorities for guidelines: mapping the health research enterprise
- Assess the quality of guidelines: guidelines for guidelines
- Inventory relevant guidelines and metrics
- Promote marketing and uptake of health research guidelines.

A number of cross-cutting themes and common recommendations emerged from the different discussion groups. 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). Other recommendations included the following:

- Identify worldwide, and seek the participation in the Project of, relevant alliances, associations, networks, etc
- Inventory guidelines meeting defined criteria (to create a knowledge base)
- Determine appropriate criteria
- Create a profile template to describe inventoried guidelines
- Produce a glossary to standardize key terms
- Draw a map of the research enterprise to use to establish boundaries and to classify guidelines in order to facilitate harmonization and to identify overlaps and gaps
- Maintain, using a transparent process, "guidelines for guidelines" to facilitate guidelines' development, to assess their quality, and to aid in their harmonization; including provisions to evaluate guidelines' utility and impact
- Work with stakeholders to harmonize, to improve, and to elaborate needed but missing health research guidelines ("good research practices") and to promote their adoption.

The Institute intends 1) to explore the ideas expressed at the meeting, and to the extent that resources permit, to realize participants' recommendations and 2) to seek additional funding to support the Project's development.

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Arrangements Development Committee (ADC) Initial Meeting

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.

Guidelines for health research

Guidelines are needed for a variety of purposes. They include 1) improving the quality and value of health research, 2) educating, and 3) communicating expectations. Harmonization is needed to improve, among other things, 1) use and customer confidence, 2) design, quality and reliability, 3) productivity and efficiency, 4) communication (eliminate ambiguity), 5) transactions (eliminate technical barriers), 6) interchangeability and interpenetration, and 7) interoperability. 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

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) decided that the time was right for a project to explore opportunities to harmonize health research guidelines. The Project's goal is to establish a sustainable mechanism 1) to harmonize systematically and to maintain consistently worldwide guidelines for the selection, design, conduct, and publication of various types of health research (to include metrics of the quality of research results and of studies' success) and 2) to promote their use in policy decision-making, practice, education, and research itself. 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.

Arrangements Development Committee

To chart the way forward, the Institute decided to hold an initial meeting of an Arrangements Development Committee (ADC). In planning and holding the meeting, the Institute received input from Clinical Data Interchange Standards Consortium (CDISC) [1], cooperation from Alliance for Clinical Research Excellence and Safety (ACRES) [2], and support from Nuovo Biologics LLC [3] and Digital Infuzion [4].

Meeting objectives

The objectives of the ADC initial meeting were to:

- Facilitate reaching agreement on organizational arrangements for a sustainable mechanism to harmonize health research guidelines, including its governance and funding.
- Identify the boundaries of health research and priorities for guidelines harmonization.
- Create resources that are needed to harmonize and to maintain worldwide guidelines for health research.
- Establish a database of relevant guidelines and metrics.
- Promote marketing and uptake of health research guidelines.

Meeting methods

Health Improvement Institute developed the ADC initial meeting over a one-year period. Participation in the meeting was by invitation; limited to 35 experts. The meeting was held in Rockville, Maryland, USA, on November 1, 2011. The Institute used an interaction workshop format.

Meeting participants

Health Improvement Institute decided to limit the number of participants to approximately 35 experts, in order to promote discussion in workgroups. To identify potential participants, the Institute asked experts and stakeholders known to the Institute and 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 a balance among the experts and types of organizations represented, until it reached the preset limit on the number of attendees. The 35 experts who participated in the meeting represented the following types of organizations:

- Health research guideline developers
- Guideline users from industry and academe
- Guidelines use-facilitators and end-users, including regulators, funders, and health care providers.

Meeting workbook

At the meeting, participants received a workbook that contained the following materials:

- Meeting information - Project and meeting descriptions, agenda, taxi request form, and evaluation form
- Participants' information - list of participants and their biographical sketches
- Speakers' presentation materials - slides and handouts
- Workgroup assignments and instructions - orientation to meeting materials, assignments and location of workgroups, venue room location map, roles and responsibilities for workgroup moderators, and specific assignment for workgroup moderators
- Workgroup descriptions and issues, including where available relevant resources
- Reference materials - information about Health Improvement Institute, Clinical Data Interchange Standards Consortium, and Alliance for Clinical Research Excellence and Safety
- Meeting sponsors - information about Nuovo Biologics, LLC and Digital Infuzion
- Glossary.

Meeting agenda

The ADC meeting agenda consisted of the following three components:

- Scene-setting presentations
- Discussion workgroups
- Plenary presentation of workgroup results and discussion of next steps.

Scene-setting presentations

The workshop began with five scene-setting presentations. They provided a context for the five discussion workgroups that followed. These presentations 1) gave background information about the Project and ADC initial meeting, 2) provided an overview of the need for and uses of health research guidelines, and 3) summarized experience to date in terms of present efforts, successful uptake, and obstacles to the harmonization and use of health research guidelines.

Discussion workgroups

Following the scene-setting presentations, meeting participants assembled in their assigned discussion workgroup. The purpose of these workgroups was to give participants the opportunity to express their ideas and to contribute their expertise to a conversation regarding the workgroup topic. To jump-start the conversation, in the meeting workbook, the Institute described the rationale for each workgroup, identified relevant resources, and suggested issues to be discussed. For each workgroup, the Institute selected a participant to serve as the moderator and provided a staff member to assist the moderator. The five discussion workgroups 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.

Plenary session

Following the discussion workgroups, participants gathered again in plenary session to share and to discuss workgroup findings. Each workgroup selected one of its members to present discussion results and to answer questions or field them to other workgroup members. A general discussion followed workgroup presentations. The meeting rapporteur, who had observed each workgroup, summarized the views and opinions expressed during meeting presentations and plenary session discussions. In closing the meeting, its organizer emphasized next steps and echoed participants' sentiments that the meeting had achieved its objectives and that its success represented an important step forward in advancing the Project's goals.

Meeting report

Following the meeting, the Institute 1) prepared a draft report of results and circulated it to participants for comment and 2) edited the draft for publication. This report is the result of that process.

Meeting results

This section summarizes meeting results for each workgroup. Cross-cutting themes are summarized in the next section of the report.

Institute sustainable mechanism to harmonize health research guidelines

Participants agreed that there was a great need to institute a sustainable mechanism to coordinate the harmonization of health research guidelines. They addressed a number of pertinent subjects, including:

- Form of mechanism
- Mission
- Potential benefits
- Challenges and potential pitfalls
- Best next steps.

Form of mechanism

Participants recommended that the sustainable mechanism take the form of a collaborative virtual global network. The goal is to harmonize existing efforts; not to duplicate them. There are already many organizations developing standards, and otherwise working to coordinate activities. Other desirable characteristics of the mechanism (network) include:

- Leadership
- Alliances with existing or emerging relevant global networks
- Credible, visible arrangement capable of achieving the network's mission
- Clear communications with constituents
- Diverse funding streams
- Accountable organization; perhaps a non-profit institute, for benefits corporation, or public-private partnership.

Mission

The main motivator for the network was the perceived need to reinvent the research enterprise to support emerging requirements for health and health care in the 21st century. The main drivers are the need to reduce duplication in disconnected silos, to improve efficiency through the better use of scarce resources, and to ensure the utility of research results. The network's specific mission would include:
Create a sense of clarity within the health research enterprise

- Identify (and promote the adoption of) good (clinical) research practices; prevent the worst by promoting the best
- Promote (and protect) quality and (ethical) integrity within the health research enterprise; be a quality assurance mechanism
- Operate a clearinghouse of public and private parties that are involved in the health research enterprise; promote coordination
- Develop a common language to foster communication; maintain a glossary
- Act as a forum to engage subject matter experts.

Potential benefits

Participants recognized that the potential benefits of an effective mechanism (network) would be many. Among other things, the network could accomplish the following:

- Improve global public health and safety
- Improve research quality
- Coordinate health care research among industry, sponsors, and investigators which would improve liner relationship among those professions
- Protect research integrity

- Increase social responsibility and public trust; increase buy-in among affected groups
- Increase the credibility of guidelines; identify, and work to fill gaps in, health research guidelines
- Promote the acceptability of knowledge transfer
- Facilitate efficient use of scarce resource; decrease waste; promote quality
    - Increase synergy; build effective partnerships
    - Increase reporting of so-called "negative findings"
    - Assist with access to research site selection; manage risk
    - Increase quality assurance (better guidelines will entice more companies to participate)
    - Develop specific strategies that assist with implementation efforts
- Provide a framework for education and teaching
- Produce a sense of clarity with understandable, clear parameters
- Create a meta-language that assists public discourse.

Challenges & potential pitfalls

Many coordination have been tried and have failed; many others exist or are emerging. Those mentioned specifically by participants included: ACRES [2], CDISC [1], and EQUATOR [5]. The many challenges and pitfalls for any harmonization mechanism include the following:

- Mission failure
    - Too broad a mission; getting nowhere (perhaps at great effort and cost)
    - Too narrow a mission; being insufficiently inclusive; failing to engage key constituents
- Organizational failure
    - Lack of focus, given the enormity of the health research enterprise
    - Inability to manage a network, public-private partnership, etc
    - Poor understanding of organization management
    - Being too bureaucratic; hence ineffective
    - Lack of appropriate education and training
    - Insufficient resources
- Functional failure
- Lack of intellectual awareness
    - Caught up in self-interest; competing rather than harmonizing
    - Poor understanding of the health research enterprise and its ways of working; inability to recognize the interdisciplinary nature of research, collegiality, etc.

Best next steps

In order to establishing a sustainable mechanism, participants believed it is necessary to:

- Build immediate credibility and visibility for the Project
- Develop a clearinghouse to identity all private and public parties that are involved in the research enterprise
- Identify diverse funding streams
- Affiliate with existing alliances, associations, networks, and partnerships, both domestically and internationally
- Create a global harmonization network.

Determine priorities for guidelines: mapping the health research enterprise

Participants acknowledged the need to and value of mapping the health research enterprise, but were unable to define rigorously either its boundaries or its dimensions. They left unanswered how to define 1) the value/quality of research guidelines and, hence, 2) their legitimacy/credibility. Clearly, additional work is required to develop a useful map, to identify what is within the health research enterprise for purposes of classifying, developing, and harmonizing guidelines, and to answer questions about their utility. Participants addressed principles and gaps.

Principles

Guidelines should establish principles and adhere to common ground. Based on established principles, they should specify processes (good research practices) and lead to performance measures. Metrics are essential for assessing research success.

Gaps in health research guidelines

In some instances standards/guidelines exist but need to be better; in others, they are needed but missing. Such guidelines encompass the following subjects:

- Protocol design and development
- Design of outcome measures, including 1) patient reported outcomes, 2) biomarkers, and 3) definition of "benefit" (what is meant by "living better," from whose perspective?). Researchers should 1) focus on developing a broad outcome measure useful generally, instead of narrow outcome measures useful only in specific types of research study, 2) assess its benefit, and 3) identify its dimensions.
- Development plans - to fill a big gap in research development, encompassing how to write protocols for studies and how to gather studies' information to form a plan; development plans for devices and pharmaceuticals are especially in need of improvement
- Linking a series of protocols to generate coherent evidence
- Analysis of complex outcomes, integrated analyses, risk-benefit determinations, etc
- Systematic reviews/meta analyses
- Moving research results from publication into practice
- Impact of guidelines 1) to identity the benefits/harms that flow from implementing guidelines and 2) to address the iron-rule of unintended consequences (which need to be reassessed continually).

Gaps in health research practice

Participants identified the need for guidelines to cover multiple aspects of and roles within the health research enterprise. Such guidelines include those for:

- Generating a research agenda; for setting priorities that encompass and integrate components of public health needs, scientific feasibility, and costs
- Assessing quality and value, for example, to permit ongoing improvement in research development, implementation, and oversight.

Assess the quality of guidelines: guidelines for guidelines

Participants agreed that we need to develop and to maintain, using a transparent process, authoritative "guidelines for guidelines" in order 1) to facilitate guidelines' development, 2) to assess their quality, 3) to guide their improvement, and 4) to aid their harmonization. Guidelines for guidelines must describe a development process, must include provisions for evaluating guidelines' utility and their impact, and

must be useful for judging the quality of health research guidelines. The principles and processes that participants addressed included the following.

Principles for guidelines for guidelines
Participants identified the following two essential principles for guidelines for guidelines:

- State clearly their purpose and goals
- Be viewed as a credible process for developing health research guidelines.

Guidelines for guidelines developers
Guidelines developers, among other things, should:

- Identify the need for guidelines that they want to develop
  - Scan existing guidelines and review relevant literature
  - Define the value proposition: 1) Is this guideline necessary? 2) Is the proposed scope of the guideline the right scope?
- Define the guideline's scope; its study stage, etc
- Address feasibility and usability; dissemination and knowledge translation/implementation
- Describe a process for measuring and evaluating impact
- Include a process for updating, and ensuring consistency with subsequently published guidelines.

Guidelines development process
A guidelines development process should:

- Be transparent; publish the process for developing guidelines
- Establish a steering group
- Use an accepted decision-making process, such as the Delphi method
- Engage stakeholders and describe
  - Process for identifying participants
  - Rationale for their selection
  - Roles for participants
- Manage conflict of interest or commitment, including financial or other non-financial commitments.

Inventory relevant guidelines & metrics
Participants agreed on the usefulness of inventorying health research guidelines as a valuable resource for harmonization. They evaluated ways in which guidelines and metrics could be inventoried. They called for creating a glossary to define such key terms as "research" (and categories of research), "guidelines" (and differentiating them from "standards" and "regulations"), and "good practice" (and "best practice"). They also 1) identified attributes of a guidelines' inventory and its contents and 2) discussed how a guidelines inventory might be established and governed. Once established, the inventory could act as a clearinghouse for health research guidelines.

Attributes of guidelines inventory & contents
Participants determined that requirements for an inventory should include the following attributes and contents:

- Attributes of inventory
    - Specific intended use and audience
    - Defined inclusion and exclusion criteria
    - Transparency in creating and maintaining the inventory
    - General availability
    - Evaluation/measurement (of process, utility, etc)
    - Sustainability
- Contents should be described using a standard profile ("meta-data"), including for profiled guidelines
    - Purpose and scope
    - Developers and development process; transparency (in developing guideline)
    - Evaluation measures and results, including utility
    - Sustainability (including frequency of revisions).

Establishing & governing inventory

Participants identified two main ways in which an inventory of guidelines might be built: 1) an accreditation process whereby guidelines developers submit their products for assessment (which might lead to a limited inventory of high-quality guidelines) and 2) a social-network model requesting developers to submit their guidelines to the inventory or simply searching for them (which might lead to a large inventory of mixed-quality guidelines). They also discussed whether the inventory should be 1) virtual, eg, link to where a guidelines could be found (with little of no descriptive or evaluative information) or 2) an actual, centralized repository, possibly involving cloud computing or "geo-dome" with interlinked processes). Participants also identified the following recommendations regarding a guidelines inventory:

- Governance
    - Inventory should be maintained by a credible organization; debated private and public-private partnership versus government
    - Model should be appropriate; examined various models of governance and control
    - Processes should be open and transparent; include ways to assess needs and to evaluate utility.
- Operations
    - Should leverage existing organizations and network existing inventories and, possibly, related relevant contents such as clinical trial registries
    - Should consider building on and expanding an existing inventory.
    - Should establish criteria for contents; standard profile for describing guidelines and their evaluation
    - Should start with a pilot in order to be able to refine criteria, processes, etc based on lessons learned.

Promote marketing & uptake of health research guidelines

Participants recommended working with stakeholders to promote the adoption of health research guidelines. They 1) outlined a workflow process from receipt of a guideline to sustaining a message to promote its adoption and 2) elaborated key steps necessary to implement various aspects of the workflow. They identified the challenges of promoting standardization through adoption of guidelines; not simply their harmonization.

Marketing workflow
Participants identified the following workflow as necessary to market health research guidelines.

- Receive and understand the product (guidelines)
- Understand stakeholders
    - Who is affected?
    - How are they impacted?
    - Which ones are potential champions or opponents of adoption?
- Develop and sustain appropriate message; sustain guidelines' adoption.

Understand guidelines as product
Participants described a variety of ways to understand guidelines as a product. They included the following:

- Conducting a joint discussion between workgroups to define the product and their perceptions of the needs it addresses
- Form a steering committee with both credibility and authority
- Define product, features, benefits, and proof
- Develop a pilot test to gather empirical data
- Identify specifics of where the product fits
- Understand what type of organization is needed to make a proposed product a possibility.

Understand stakeholders
Participants identified stakeholders' considerations as key to successful adoption of guidelines. They include the following:

- Identify and gain acceptance of such stakeholders as
    - Regulatory agencies, including, as appropriate, US Food and Drug Administration, Federal Trade Commission, International Committee for Harmonization, and other applicable transnational and international organizations
    - Pharmaceutical industry - both "Big Pharma" and small biotechnology firms
    - Institutional review boards ("IRBs")
    - Public and private providers and payers
    - Advocacy groups
    - Patients and families
    - Scholarly journals
    - News media
- Evaluate how stakeholders are impacted; consider
    - Value proposition which 1) may be fundamentally the same for all stakeholders but 2) may also vary with respect to such specifics as quality, safety, improved patient care, better science, cost, efficiency, time to market, etc
    - Identify resistance and obstacles to changes (which may include privacy issues, competing initiatives, resource constraints, and proprietary concern), and ways to overcome them
- Determine which stakeholders are potential champions or opponents
    - Define champions based on value proposition and communication; "pre-marketing" possibilities may exist
    - Communicate a strategy or business plan and evaluate metrics for adoption.

Maximize adoption

In order to maximize the potential for adoption, participants suggested the following strategy:

- Develop an appropriate message (to create awareness and to foster adoption)
  - Tailor the message to targeted stakeholders
  - Stay consistent and transparent
- Collaborate with international standards development organizations
  - Create a collaborative effort; establish a working process
  - Work with and lobby international organizations to facilitate adoption and to expand guidelines' influence and impact
- Sustain the message and its adoption
  - Establish an oversight committee to monitor guidelines' adoption and to evaluate their impact; if applicable, to enforce standards
  - Develop training protocols to maintain uniform adoption
  - Evaluate guidelines' utility; revise them continually to avoid becoming irrelevant or ignored.

Meeting conclusions & recommendations

Participants agreed that the Project was ambitious; achieving its goal would make a meaningful contribution to advancing the health research enterprise and its contributing to improving health care and people's health. The meeting's success in charting a way forward was the first step toward realizing this goal. Speakers set the scene for workgroups that addressed various facets of harmonizing health research guidelines. A number of cross-cutting themes emerged from these discussions and, consequently, recommended action steps.

Cross-cutting themes

A number of cross-cutting themes and common ideas and directions emerged from workgroup discussions. They included the following:

- Harmonize; don't duplicate effort
- Network to achieve the broad vision; don't create another narrow interest organization
- Set priorities
- Engage stakeholders to create a sense of ownership
- Foster credibility and trustworthiness to empower success
- Ensure transparency of process to advance credibility
- Create openness to gain visibility and to promote adoption; avoid intellectual property restrictions
- Promote the adoption of high-quality guidelines to achieve standardization; revise them continually to avoid becoming irrelevant or ignored
- Obtain feedback and measure performance at every stage to ensure relevance, quality, and value
- Plan for sustainability; diversify funding.

Action steps

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). Other recommendations included the following:

- Identify worldwide, and seek the participation in the Project of, relevant alliances, associations, networks, etc
- Inventory guidelines meeting defined criteria (to create a knowledge base)
    - Determine appropriate criteria
    - Create a profile template to describe inventoried guidelines
    - Produce a glossary to standardize key terms
- Draw a map of the research enterprise to use to establish boundaries and to classify guidelines in order to facilitate harmonization and to identify overlaps and gaps
- Maintain, using a transparent process, "guidelines for guidelines" to facilitate guidelines' development, to assess their quality, and to aid in their harmonization; including provisions to evaluate guidelines' utility and impact
- Work with stakeholders to harmonize, to improve, and to elaborate needed but missing health research guidelines ("good research practices") and to promote their adoption.

Going forward

Health Improvement Institute intends 1) to explore the ideas expressed at the meeting and, to the extent resources permit, to realize participants' recommendations and 2) to seek additional funding to support the Project's development. Planned activities may include a follow-on meeting which the Institute may hold in concert with other organizations that choose to participate in the emergent network of organizations that share the goal of advancing the harmonization of health research guidelines.

References & footnotes

1. Clinical Data Interchange Standards Consortium - www.cdisc.org
2. Alliance for Clinical Research Excellence and Safety - www.acresglobal.net
3. Nuovo Biologics LLC - www.nuovobiologics.com
4. Digital Infuzion - www.digitalinfuzion.com
5. EQUATOR Network - www. equator-network.org

Acknowledgements

Health Improvement Institute gratefully acknowledges the assistance of the following individuals and organizations in planning and presenting the ADC initial meeting. Their efforts contributed substantially to its success.

- Yanan Ye, who coordinated the meeting
- Simon Chivi, Hannah Dee, Purva Jain, Stella Lin, and Rohit Mukherjee, who supported discussion workgroups
- David Gemzik, Steven Hirschfeld, Greg Koski, and David Moher for volunteering to present their work at the meeting
- Nuovo Biologics, LLC and Digital Infuzion for their generous contributions
- Michael Zimmerman, Hilton Washington DC/Rockville Executive Meeting Center, for working with the Institute to stage the meeting.