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Clinical Research Innovation Initiatives

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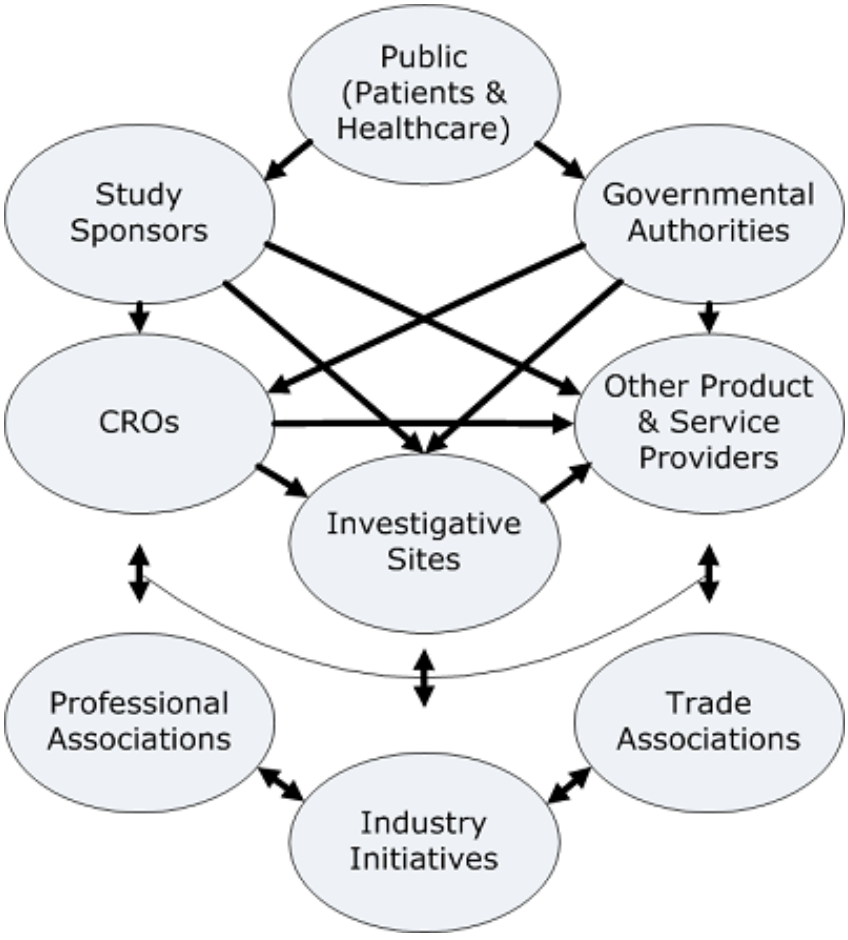
The public — patients and heathcare providers — rely on study sponsors (pharmaceutical, biotechnology and medical device companies, along with the National Institutes of Health) and governmental authorities like the U.S. Food & Drug Administration to ensure that clinical research is conducted properly. Investigative sites, contract research organizations (CROs), and other product and service providers participate in the clinical research enterprise. Many of these organizations are constantly innovating, albeit often slowly and usually in a fragmented manner. Professional and trade associations, along with numerous publications and educational organizations, propagate knowledge about innovations across the industry. Figure 1 summarizes the ecosystem in which clinical research innovation occurs:

Figure 1. The Clinical Research Innovation Ecosystem



Initiatives

The industry initiatives described below are working to catalyze the generation and propagation of innovations, especially those that are effective only if they are widely adopted. Please support their efforts. In addition, there are over 170 other relevant professional associations and trade organizations, many of which conduct their own initiatives. (See: http://firstclinical.com/directories/associations.html.)

Alliance for Clinical Research Excellence and Safety (ACRES)

Founded: 2012

Website: www.acresglobal.net

Mission: Build a global system for clinical and health research that aligns ethical principles with good business practices while leveraging information technology, regulatory science, and the tools of professionalism to addresses critical challenges facing the drug development enterprise in a socially responsible manner.

Description: ACRES is a private, nonprofit, multi-sector organization working collaboratively with experts and stakeholders world-wide to establish a global network of accredited, sustainable clinical research sites supported by a robust information technology platform to ensure safety and continually monitor and improve performance. This network will provide a shared infrastructure for clinical and health research to enhance safety, quality and efficiency, while reducing the cost and time required to bring new medical products to the people of the world.

Association for the Accreditation of Human Research Protection Programs (AAHRPP)

Website: www.aahrpp.org

Founded: 2001

Mission: Protect the rights and welfare of research participants and promote scientifically meritorious and ethically sound research by fostering and advancing the ethical and professional conduct of persons and organizations that engage in research with human participants.

Description: AAHRPP, as an independent accrediting body, uses an accreditation process based on self-assessment, peer review, and education. AHHRPP has accredited 174 organizations, representing nearly 1,000 entities (e.g., hospitals), in Canada, China, India, Korea, Singapore and United States.

Avoca Quality Consortium

Website: www.theavocagroup.com/QualityConsortium

Founded: 2012

Mission: Improve the quality and outcomes of outsourced trials. Over the long term, the consortium's goal is to develop a new paradigm in the industry's approach to quality management and partnering to ensure high quality and risk mitigation.

Description: Sponsored by Eli Lilly and Pfizer, the consortium brings together quality, outsourcing and operational professionals from member pharma, biotech and CRO organizations to accelerate the development of an industry standard and best practice approach to quality management. The initial areas of focus are on quality agreements and metrics.

Center for Information & Study on Clinical Research Participation (CISCRP)

Website: http://www.ciscrp.org and http://www.medhero.org

Founded: 2003

Mission: Educate and inform the public, patients, medical/research communities, the media, and policy makers about clinical research and the role each party plays in the process.

Description: CISCRP is an independent nonprofit organization that is helping to restore public trust in the clinical research enterprise. It provides the Medical Heroes public service campaign, grassroots educational programs and educational resources on how to become an informed clinical research participant. It assists thousands of patients having difficulty locating clinical trials and translates clinical trial results into lay language. CISCRP also provides resources for research professionals to better understand the study volunteer, including facts and figures, polls and surveys, whitepapers and peer-reviewed manuscripts on the results of patient focus groups and novel communications programs. The CISCRP store includes brochures, DVDs, books, posters and newsletters.

Clinical Data Interchange Standards Consortium (CDISC)

Website: www.cdisc.org

Founded: 2000

Mission: Develop and support global, platform-independent data standards that enable information system interoperability to improve medical research and related areas of healthcare.

Description: CDISC is a global, open, multidisciplinary, nonprofit organization that has established standards to support the acquisition, exchange, submission and archive of clinical research data and metadata. CDISC standards are vendor-neutral, platform-independent and freely available via the CDISC website.

Consortium of Academic Programs in Clinical Research (CoAPCR)

Website: www.coapcr.org

Founded: 2003

Mission: Facilitate the development and maintenance of high-quality educational programs encompassing all areas of clinical research that are based in academic credit-granting institutions.

Description: CoAPCR's members include 30 academic institutions that offer certificate or degree programs in clinical research. Activities include the definition of core competencies for clinical research personnel, forming the basis for the development of an accreditation process for academic programs.

Critical Path Institute (C-Path)

Website: www.c-path.org

Founded: 2005

Mission: Accelerate the pace and reduce the costs of medical product development through the creation of new data standards, measurement standards, and methods standards that aid in the scientific evaluation of the efficacy and safety of new therapies.

Description: C-Path is a nonprofit, public-private partnership with the Food and Drug Administration (FDA), created under the auspices of the FDA's Critical Path Initiative

program in 2005. C-Path orchestrates the development of "drug development tools" (DDTs), pre-competitive standards and approaches. The process culminates in a formal application to FDA for official "qualification" of the DDT for a given use in product development.

Metrics Champion Consortium (MCC)

Website: www.metricschampion.org

Founded: 2006

Mission: Help study sponsor, investigative site, and service provider organizations involved in pharmaceutical, biotechnology and medical device clinical research improve their overall clinical trial development processes through the utilization of MCC standardized clinical trial performance metrics (time, cost & quality) and quality scoring tools.

Description: MCC is an open, multidisciplinary, non-profit organization comprised of more than 80 organizations.

Model Agreements & Guidelines International (MAGI)

Website: www.magiworld.org

Founded: 2003

Mission: Streamline clinical research by standardizing best practices for clinical operations, business and regulatory compliance.

Description: MAGI's 10,000 members represent most of the major players in the industry. Membership is free. MAGI publishes numerous standard forms and documents, including a model clinical trial agreement. It also conducts two conferences each year. "MAGI" is pronounced with "G" as in Georgia and "I" as in Ireland.

Multi-Regional Clinical Trials (MRCT) Center

Website: www.globalhealth.harvard.edu/multi-regional-clinical-trials-mrct-center

Founded: 2011

Mission: Improve the design, conduct and oversight of multi-regional clinical trials, especially trials sited in or involving the developing world; simplify research through the use of best practices; and foster respect for research participants, efficacy, safety and fairness in transnational, transcultural human subject research.

Description: The MRCT Center, working in collaboration with participating life sciences companies and other essential partners (e.g., leading clinical research organizations, not-for-profit associations and foundations, academic centers, leading institutions, researchers and regulatory agencies in the developing world), will help to design and build efficiencies in conducting transnational research, and improve the industrial and academic standards for the conduct of clinical trials. The Harvard Global Health Institute at Harvard University serves as the administrative home for the center.

TransCelerate BioPharma

Website: www.transcelerate.org (See: http://www.bio-itworld.com/2012/09/20/new-pharma-collaboration-focuses-clinical-standards.html)

Founded: 2012

Mission: Identify and solve common drug development challenges, starting with clinical study execution.

Description: Ten companies created TransCelerate BioPharma — Abbott, AstraZeneca, Boehringer Ingelheim, Bristol-Myers Squibb, Eli Lilly, GlaxoSmithKline, Johnson & Johnson, Pfizer, Genentech (a member of the Roche Group), and Sanofi — all of which have pooled financial, personnel and other resources to solve industry-wide challenges in a collaborative environment. Currently, five projects have been selected by the group for funding and development, including: development of a shared user interface for investigator site portals, mutual recognition of study site qualification and training, development of risk-based site monitoring approaches and standards, development of clinical data standards, and establishment of a comparator drug supply model.

Author

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