Abstract

The Partnership to Advance Clinical Electronic Research (PACeR) is a collaborative of leading healthcare and biopharmaceutical organizations, New York State medical centers, and technology companies that is developing tools, business models, and processes to advance clinical research. A key component of this effort is leveraging existing and new types of clinical care data in scientific research by engaging and connecting patients, physicians, and institutions throughout the research process.

Mission

Key work is focused on four areas:

Consortium History

January 2012: PACeR Institute incorporated as a nonprofit organization
Structure & Governance

The Healthcare Association of New York (HANYS), the only statewide healthcare association representing New York’s hospitals and health systems, has been the sponsor and administrator of PACeR to date. As of January 2012, the PACeR Institute was incorporated as a nonprofit organization to take on leadership and administrative roles for PACeR activities. During a transition period, HANYS representatives and other members of the PACeR Project Leadership Committee serve in executive roles and as members of the Board of the PACeR Institute.

During Phase 1 of the project, before the incorporation of the PACeR Institute, PACeR was governed by the Project Leadership Committee, with support from four workgroups. The Project Leadership Committee addressed major issues, prioritized work, and facilitated ongoing communication with PACeR members and external parties. The committee consisted of representatives from the hospital, pharmaceutical, and information technology industries, a consumer advocate, an ethicist, and a physician representative. The committee chair was David Krusch, M.D., director of medical informatics; associate professor surgery, medical informatics; and chief medical information officer at University of Rochester Medical Center’s Strong Memorial Hospital. Krusch continues in his leadership role as an executive of the PACeR Institute.

During Phase 1, the four workgroups focused on clinical and data analysis, legal and regulatory issues, business model development, and new processes. Each workgroup identified and addressed major issues and opportunities, and provided recommendations to the committee.

Patent Engagement

PACeR Education is a growing library providing the definition, symptoms, causes, and risk factors of major diseases. It also, as available, provides a description of new clinical trials and research projects in which people with a specific disease may want to enroll. Associated with a specific project will be a survey that will help a person determine whether they are qualified to participate and the location of research sites for the study. Once a study is under way, PACeR Education will make it possible for researchers to host a forum to allow study participants to communicate with the researchers and with one another.
Data Sharing

Medical centers and physicians will continue to be stewards of PACeR data on behalf of their patients. Pharmaceutical companies will not have direct access to hospital data. Under PACeR’s federated database approach, participating institutions continue to own and control access to patient data. Each institution decides what data are available to PACeR.

PACeR’s design does not involve direct access to an institution’s health databases by data users, but rather use of database queries to answer specific questions. Only answers to the queries will be shared with PACeR users/customers. Access to patientspecific data is through a uniform informed consent process controlled by physicians and their patients.

Options will be provided for medical institutions to approve PACeR’s use of their data on a caseby-case basis, or for all queries that meet predetermined criteria. Data accessed by PACeR will be de-identified (stripped of all identifiers) and will contain no personal health information.

Impact/Accomplishment

PACeR Phase 1 generated a practical plan for improving the quality and speed of the clinical trial process. PACeR published Phase 1 results in a white paper, “Transforming and Improving Clinical Research Capabilities in New York State to Benefit Patients,” available to the public at www.pacerhealth.org. Ongoing PACeR activities to implement Phase 1 recommendations and build capability will be publicly reported.

Phase 2 is working to demonstrate the practical feasibility of the secondary use of electronic clinical data through projects in 2012-2014. Specific Phase 2 goals include the following:

Homepage  http://pacerhealth.org/index.cfm

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