
Frequently Asked Questions

PACeR's Guiding Principles and Goals

- Patient benefit is the guiding “north star” of the project.
- Improve the state-of-the-art for clinical trials/research in a manner that benefits all stakeholders.
- Establish a research system that is self-supporting and maintains institutional autonomy, and requires minimum government support.
- Create an accurate, high-quality, and complete clinical data capture system that can withstand the rigors of the scientific method for meaningful clinical research, evidence-based decision making, bio-surveillance, and protection of public health.
- Develop a practical, actionable, and high-impact implementation program.
- Ensure that approaches and implementation programs benefit both investigator-initiated and industry-sponsored studies.
- Maintain a governance approach consistent with serving the needs of all participants, with ongoing collaboration among participants.
- Aspire to comprehensive “reinvention” of clinical trials/research; accept meaningful incremental change.

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What is PACeR and what are its objectives?

The Partnership to Advance Clinical electronic Research (PACeR) is a collaborative project designed to improve the clinical trial process, giving patients fast, efficient access to innovative medicines, medical devices, and protocols.

PACeR is a unique public-private partnership that brings together global health care organizations and experts to share the task of creating and sustaining efficient and economically self-sustaining processes to help more quickly and easily match patients with clinical trials.

PACeR is focused on patient benefit, recognizing the importance of adhering to strict safeguards to protect patients' interests, including safety, quality, individualized care, privacy, and access to timely care. PACeR has worked closely with its participating members to assess current data capabilities and leverage the opportunities presented to integrate clinical trial elements into electronic clinical records repositories.

PACeR is designed to benefit all participants by:

- accelerating the process of delivering new medicines to patients;
- improving the efficiency, efficacy, and scientific integrity of clinical research;
- advancing the objectives of medical institutions regarding the primary and secondary use of clinical data;
- improving the ability of information technology companies to understand patient and provider needs, resulting in enhanced system offerings;
- increasing efficiency and lowering costs for pharmaceutical research; and
- serving as a viable, practical model for other states, regions, and the nation, offering solutions that address relevant technical, legal, regulatory, economic, and operational issues.

PACeR has completed its first phase, which identified opportunities to improve the clinical trial process and developed a practical plan for acting on these opportunities. The plan will take into account regulatory, legal, economic, and information technology issues.

PACeR has worked with and built on related initiatives underway. For example, it has engaged in dialogue with the Office of the National Coordinator on Health Information Technology, as well as regulators and standard-setting bodies to learn from and inform their ongoing activities.

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Who is involved in PACeR?

Participants include the Healthcare Association of New York State (HANYS), leading medical institutions in New York State, pharmaceutical companies, clinical research organizations, health information technology companies, regulators such as the U.S. Food and Drug Administration (FDA), standard-setting bodies, patient representatives, ethicists, physician representatives, New York eHealth Collaborative, and the New York State Department of Health.

Sponsor/ Patient Advocacy	Academic Medical Centers		CRO*, Pharmaceutical, and Health Information Technology Companies	Advisors/Observers
HANYS	Albany Medical Center	Roswell Park Cancer Institute	Bayer	U.S. Food and Drug Administration
	Bassett Medical Center	Stony Brook University Medical Center	Johnson & Johnson	New York State Department of Health (DOH)
The Hastings Center	Continuum Health Partners (St. Luke's-Roosevelt, Beth Israel)	SUNY Downstate Medical Center	Merck	New York eHealth Collaborative (NYeC)
	New York Hospital Queens	SUNY Upstate University Hospital	Oracle	CDISC and HL7
Legal Action Center	North Shore-Long Island Jewish Health System	University of Rochester Medical Center	Pfizer	New York State Foundation for Science, Technology, and Innovation (NYSTAR)
	NYU Langone Medical Center	Weill Cornell Medical College	Quintiles	
		Westchester Medical Center	Roche	
Project Management	Booz & Company and Quintiles Consulting			

*CRO = clinical research organization

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What are the benefits of PACeR to participating medical institutions?

PACeR will provide a federated framework of participating institutions' electronic medical records (EMRs) that will facilitate:

- protocol modeling and cohort identification;
- participation in industry-sponsored (pharmaceutical, device, etc.) single- and multi-site clinical trials more effectively and efficiently;
- investigator-initiated internal clinical trials;
- the ability to sponsor multi-site, investigator-initiated clinical trials driven by the PACeR framework; and
- the use of supplementary tools to enhance the value of the EMR data.

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How is PACeR structured? Who runs the project?

HANYS, the only statewide health care 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 non-profit 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 consists of representatives from the hospital, pharmaceutical, and information technology industries; a consumer advocate, an ethicist, and a physician representative. The Committee Chair is 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. Dr. 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.

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What will be the output of PACeR? Will it be public?

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 pacerhealth.org. Ongoing PACeR activities to implement Phase 1 recommendations and build capability will be publicly reported.

PACeR Phase 2 will include a series of demonstration projects. Since many of these demonstration projects are proprietary to specific companies and institutions, they will not be in the public domain.

6 How is patient confidentiality protected? Does PACeR allow access to patient data among PACeR partners?

PACeR is operating in full compliance with the Health Insurance Portability and Accountability Act (HIPAA); therefore, patient data are strictly protected, and no identifying information will be used or shared at any time by PACeR participants. PACeR is focused on patient benefit, adhering to strict safeguards to protect patients' interests. This focus on patient benefit is evident in the composition of the Project Leadership Committee, which includes a consumer advocate and an ethicist. During Phase 1 of PACeR, medical institutions evaluated data availability and suitability for clinical work using de-identified data, and all data protection and privacy laws were adhered to and enforced by the Project Leadership Committee.

This approach to maintaining confidentiality of patient data will continue under the PACeR Institute. To the extent that access to patient-specific data is desired, the access will be through a uniform informed consent process under the control of physicians and their patients.

7 Is PACeR a data mining project?

While the analysis of clinical data available in EMRs in the context of clinical trials is an important part of PACeR's work, PACeR's scope is broader than data mining alone. PACeR has examined how the quality and speed of clinical trial work is affected by clinical workflow and business practices of pharmaceutical companies, medical institutions, and investigators, as well as by regulatory and legal requirements.

8 How is PACeR different from other health information technology (HIT) projects?

PACeR is more than an HIT project. It includes a broad range of participants to ensure the outcome is an improved capability to undertake clinical research and other activities involving the use of electronic clinical data, spanning all relevant participants. The clinical research capability will build on better data and enhanced information systems, but will also define how data and systems will be used to generate valuable results and output for participants and patients. In addition, PACeR is a leader in standardizing data nomenclature across multiple institutions, providing access to a larger and more diverse set of data than most other HIT initiatives, and is a model for integrating health data across multiple organizations.

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Is PACeR focused only on hospitals? What about clinics and other sites of care where many patients are seen and treated?

PACeR's participants include health care organizations that encompass institutions with clinics and physician practices, as well as hospitals. PACeR will look beyond the hospital setting, adjusting the full scope of its coverage as opportunities emerge for secondary use of data from new settings. PACeR hopes to expand clinical research and trials to patients who otherwise would not have an opportunity to learn about and participate in clinical trials.

DATA INTEGRITY AND MANAGEMENT

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Who controls access to data? Do pharmaceutical companies have direct access to hospital data?

Medical centers and physicians will continue to be stewards of 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 patient-specific 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 case-by-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.

II

Where will the data be stored and how will it be accessed?

De-identified (stripped of potential patient identifiers) patient data from each institution will be “mirrored” in the federated database. Each institution’s data will be segregated in the federated database; there will be no commingling of data across institutions. The primary purpose of the mirrored database is to put data in common nomenclature so it is easily usable for queries. Each institution decides what data are available to be mirrored by PACeR. However, because it will be more difficult to query data that are not mirrored, compensation levels to institutions whose databases are not mirrored will be reduced.

I2

Who benefits financially from PACeR? What investments will be required by medical centers to participate in PACeR?

PACeR is designed to be financially self-sustaining and to provide financial benefits for all participants. PACeR is a non-profit entity, setting fees to cover its cost of operation. PACeR participants providing clinical data (data sources), including medical centers, are compensated for providing data to PACeR. PACeR participants who gain access to the results of queries (data users), including pharmaceutical and device companies, pay fees for the access. The benefit for users of data is more rapid and cost-effective development of new therapies. HIT companies that provide services to PACeR are compensated for the services. PACeR investments in data standardization across institutions and in capabilities to conduct data queries and business transactions among participants, will be made by voluntary contributions from a variety of organizations.

Investments for participating medical centers will initially be limited to the information technology resources needed to connect to the PACeR data network and to standardize data nomenclature. Over time, institutions may decide to make additional investments in upgrading the quality of their electronic clinical data, based on clinical and financial benefits. Future PACeR investments will be covered by fees for services as these services become functional.

13 **How are the proprietary and financial interests of participants protected? Is there a potential for the competitive interests of participants to be compromised?**

PACeR is unique in that its participants include competing organizations. Participants believe system-wide inefficiencies can be improved to the benefit of all parties, without compromising competitive advantage. For example, most HIT companies want to maintain proprietary advantage for their EMRs. That is consistent with PACeR's approach. PACeR will define the EMR functionality needed to improve the clinical trial process, but it will be up to the HIT companies to build these functional requirements into their proprietary software. HIT companies, medical centers, and pharmaceutical companies will benefit from productive, open engagement about needs related to the conduct of clinical trials, which will be addressed by competing parties.

14 **Is PACeR open to hospitals outside of New York State? Is PACeR open to any participants?**

PACeR's initial focus is on medical institutions in New York State that are members of HANYS, the project sponsor. The findings from Phase 1 are broadly applicable to many other medical institutions, and decisions about the potential expansion of scope to other states will be made in the future.

PACeR welcomes and encourages participation by pharmaceutical, medical device, and information technology companies, as well as medical institutions. Interested companies should contact HANYS for information on the funding and participation requirements.

15 **Where is the latest information on PACeR's status available?**

Updates are provided on the pacerhealth.org Web site.

PACeR is currently pursuing two major implementation work streams. The first involves the federated database that will be used for analysis of data in standard nomenclature, and the second includes a number of demonstration projects where clinical research questions are being addressed for participating pharmaceutical companies and principal investigators.

To learn more about PACeR or about how to become a PACeR partner, contact Terri Straub at tstraub@hanys.org or Kristen Hines at khines@hanys.org or at (518) 431-7820.