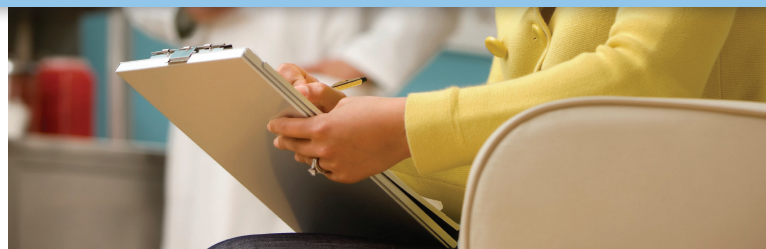
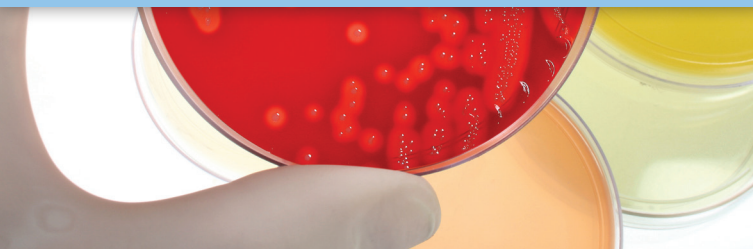


TRANSFORMING AND IMPROVING CLINICAL RESEARCH
CAPABILITIES IN NEW YORK STATE TO BENEFIT PATIENTS



Phase 1 Findings & the Path Forward



PACeR PHASE 2 GOALS

PACeR Phase 2 will demonstrate the practical feasibility of the secondary use of electronic clinical data through projects in 2011. Specific Phase 2 goals include:

- establishing a PACeR clinical data nomenclature standardization entity;
- forming a PACeR “market making” capability to streamline and deliver protocol modeling and patient selection services using data from multiple institutions;
- exploring the feasibility of establishing a PACeR Privacy Board to create an improved approach for the use of de-identified clinical data for trial modeling;
- developing and implementing software solutions that “wrap around” currently used EMR systems

to capture additional data, using standardized clinical nomenclature;

- creating technology, methods, policies, and procedures that will allow patients to determine when and how their data are used for research; and
- developing a statewide PACeR patient education program.

Phase 2 will continue to be led by a broadly representative leadership committee. PACeR strongly encourages additional participants in Phase 2. We welcome the perspectives of new members such as physician professional societies, community hospitals, device manufacturers, EMR vendors, disease societies, and others. The more comprehensive PACeR’s membership, the more sustainable its approach becomes.



The goal of the Partnership to Advance Clinical electronic Research (PACeR) is to improve the speed, quality and cost of clinical trials, helping to provide patients with quicker access to new treatments and life-saving medicines.

PACeR aims to achieve this goal by designing and launching an economically sustainable, electronic clinical research data network in New York State to more efficiently identify potential candidates for clinical research trials and manage their care.

In creating this data network, PACeR endeavors to:

- support improvement in patient care and the research missions of participating institutions;
- improve the operational efficiency and scientific integrity of clinical research;
- advance the objectives of medical institutions regarding the primary and secondary use of clinical data; and
- serve as a viable, practical model for other states, regions, and the nation, that recommends solutions to relevant technical, legal, regulatory, economic, and operational issues.

PACeR stands apart from other attempts to improve the clinical research process because of its inclusiveness and responsiveness to the needs of multiple stakeholders. The Healthcare Association of New York State (HANYs) serves as a neutral partner and coordinator, bringing together multiple medical centers, health systems, community hospitals, patient representatives, pharmaceutical companies, health information technology companies, and others to engage in a multi-year collaborative. The guiding principle behind this endeavor is the benefit to patients, and ensuring robust patient privacy and consent protections is paramount.

PACeR's objectives are aligned with those of other important public and private sector health care initiatives. For example, investments and programs developed by the American Recovery and Reinvestment Act, Health Information Technology

for Economic and Clinical Health (HITECH) Act, Food and Drug Administration, and Regional Health Information Organizations (RHIOs) focus on collecting high-quality, standardized electronic health data and rigorous research methodologies.

Phase 1 was designed to confirm the feasibility of developing a sophisticated clinical data network across New York State that can be used for evidence-based research, with the long-term aim of extending the network across the country. Component pieces to develop this system exist within each of the participating medical networks, but much work needs to be done to build a statewide, standardized, consistent, and complete platform. That is PACeR's future work plan and goal.

PACeR Phase I Findings

PACeR's Phase 1 findings provide, in addition to a short-term way forward, a long-term perspective on how to address the current challenges and improvement opportunities associated with the design of existing electronic medical records (EMRs) and the confidentiality and ownership of patient health data.

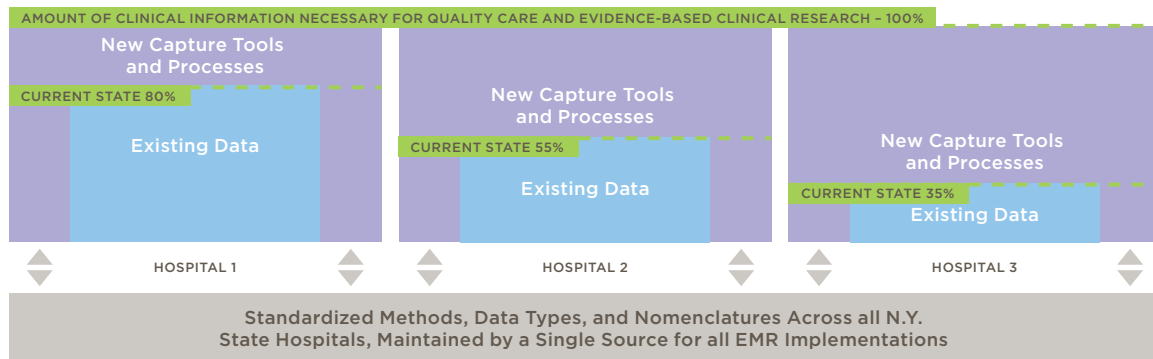
PACeR's Phase 1 results confirm that significant benefits are achievable for all health care stakeholders, including:

- *Patients:* PACeR will improve identification and matching of patients for clinical trials and accelerate the process of getting innovative medicines to the public.
- *Academic Medical Centers, Community Hospitals, Principal Investigators, and Other Scientists:* PACeR identified opportunities to improve the

underlying data and processes for conducting clinical research and improving patient care, and confirmed that highly variable gaps in available data can be addressed with new capture tools and processes (see exhibit).

- *The Research Community:* Timely analysis of large amounts of high-quality clinical care data will streamline the clinical trial protocol development process.
- *Health Information Technology Companies:* PACeR will provide input to functional specifications for health IT systems to capture and organize the data necessary to meet the needs of scientific, evidence-based research, observational research, and cost effectiveness analysis.
- *Regulators:* Access to improved data and analysis will support safety surveillance initiatives and causal analysis of adverse events.
- *Public/Private Initiatives Such as RHIOs:* PACeR offers a mechanism for clinical data nomenclature standardization and interoperability across hospitals and physician networks.
- *New York State:* PACeR will enhance the state's position as a center for medical research and home to some of the world's most prominent academic medical centers, and ensure that it captures a greater share of strategic investment in clinical research.
- Data completeness and quality varied significantly across participating institutions, but in all cases new capture tools and processes can be designed and implemented to enable PACeR to meet its goals (see exhibit).

DATA COMPLETENESS



Data completeness and quality varied significantly across participating institutions, but in all cases new capture tools and processes can be designed and implemented to enable PACeR to meet its goals.

PACeR PHASE 1 RECOMMENDATIONS FEATURE:

- policies, procedures, standards, and methods to reconcile disparate clinical data in individual clinical systems to common terminology;
- a short-term approach to capture additional clinical data for evidence-based research beyond that currently available in EMRs and other repositories;
- a “federated” database approach where institutions continue to own and control access to their data—PACeR will enable database queries to conduct analyses;
- a design that addresses technical, legal, regulatory, and economic challenge inherent in the use of patient specific-data, and that protects patient privacy;
- an economically viable, sustainable operational business model for a statewide electronic clinical research system that provides a single point of access for all;
- a comprehensive, long-term roadmap for improving clinical data and facilitating relationships among participants in evidence-based research; and
- an institutional infrastructure to deliver high-quality, evidence-based research.

TO ACCESS THE COMPLETE PHASE 1 WHITE PAPER,
FEASIBILITY ASSESSMENT AND PHASE 2 PLAN, PLEASE VISIT

WWW.PACERHEALTH.ORG