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Broad-Based Health Care Collaborative to Provide Next Generation of Clinical Research for New Medicines

Global Leading Hospitals, HIT, and Pharmaceutical Companies Join PACeR Collaborative Initiative to Dramatically Increase the Speed, Quality, and Efficacy of Clinical Studies

Effort to Focus on More Efficient Delivery of Innovative Medicines to Patients in Need

Reporters:

Join us on a conference call on Wednesday, June 16 at 9:30 a.m. to learn more about PACeR.

- **Call: (866) 355-7121**
- **Passcode: 9938837#** (must hit pound sign)

Conference Call participants include:

- David A. Krusch, M.D., Chief Medical Information Officer, Strong Memorial Hospital
- Kathleen Ciccone, Executive Director, HANY Quality Institute
- John Murphy, PACeR Project Manager, Head of the Clinical Analytics Practice, Consulting Group, Quintiles
- David Leventhal, Director of Healthcare Informatics, Pfizer

ALBANY, N.Y. — Leading medical research centers, pharmaceutical companies, and health information technology (HIT) organizations joined together today to announce a new broad-based collaborative effort designed to dramatically improve the speed and quality of clinical research necessary to develop new medicines.

The Partnership to Advance Clinical electronic Research (PACeR) is unique because it brings together global health care organizations and experts to share the task of creating and sustaining efficient processes to 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 will work closely with the medical centers to assess current data capabilities and leverage the

opportunities presented to integrate clinical trial elements into electronic clinical records repositories.

Current participants include New York academic medical centers, Pfizer, Johnson & Johnson, Merck, Quintiles, Healthcare Association of New York State (HANYNS), The Hastings Center, and the Legal Action Center. PACeR will also work with the standards and regulatory-based organizations that include the Food and Drug Administration, Clinical Data Interchange Standards Consortium (CDISC), and Health Level-7. Moving forward, PACeR hopes to engage additional industry and academic medical center partners.

The adoption of electronic medical records by health providers has resulted in emerging databases of information that will be tremendously valuable to medical research. PACeR's ultimate goal is to link these data resources with clinical trials in a manner that greatly improves research and patient outcomes, while ensuring data and privacy protections.

Clinical research depends on the identification of eligible candidates to enroll in trials. Due to limited access to standardized data, the identification of patients is a time consuming challenge. Further complicating the process, enrolled candidates may ultimately be dropped from a trial because of subsequent ineligibility findings, geographic limitations, or financial challenges incurred by patients for travel and time lost from work. As patients drop from a trial, new patients must be recruited, causing delays in getting life-saving therapies to market and exponentially increasing the cost of trials. The PACeR collaborative will be the first coordinated effort to improve timeliness and maximize research capacity through the enhancement and availability of standardized data and research protocols.

The PACeR collaborative will seek to streamline and accelerate clinical research processes by providing an improved clinical network approach to support evidence-based drug studies. The resulting products developed for pharmaceutical research will be equally useful for other forms of clinical evidence-based research, such as determining the best therapy to treat individual patients for cancer, diabetes, and other diseases.

PACeR will deliver significant benefits for patients, providers, and other health care sector participants, including:

- accelerating the process of delivering new medicines to patients;

- improving the efficiency and efficacy of research conducted by academic medical centers;
- improving the ability of information technology companies to understand patient and provider needs, resulting in enhanced system offerings;
- increasing the return on investment for pharmaceutical research resources; and
- augmenting New York State’s unique position as the global epicenter for medical research.

HANYS’ President Daniel Sisto said, “New York State’s health care providers, specifically its academic medical centers, have a proud tradition of achieving breakthrough medical discoveries that have revolutionized medical care and service to patients. Medical research has changed the world, and will continue to do so in the future. We know the landscape of health care is changing. By working in concert with all stakeholders, the PACeR collaborative will be on the leading edge of defining, driving, and realizing the benefits of change, in the interest of current and future patients.”

Dr. Leonard Sacks, M.D., Acting Director for the U.S. Food and Drug Administration (FDA) Office of Critical Path, commented, “Harnessing information technology and novel scientific tools in the service of medical product development and review has been a central priority for FDA. These innovative tools provide a historic opportunity to move medical product development into the 21st century and to deal with the challenges of spiraling research and development costs in the face of diminishing returns. To accomplish these goals, FDA looks to all involved constituencies in the public, private, and academic sectors for scientific and practical expertise. In tackling issues such as the role of electronic health records in clinical research, the potential to personalize medicine using bioinformatics, and the safeguarding of medical privacy, HANYS’ Partnership to Accelerate Clinical Electronic Research has embraced the task and we enthusiastically support their effort.”

David Leventhal, Director of Healthcare Informatics, Pfizer, said, “Clinical research is one of the most critical aspects of getting innovative medicines to patients. It has been extremely challenging to conduct high quality clinical research on a timely basis. We see the PACeR initiative as a unique collaborative opportunity to move beyond talking about the challenge, and to fundamentally change the way clinical research is conducted. This is an effort and outcome where everyone wins.”

John Murphy, Head of the Clinical Analytics Practice for the Consulting Group at Quintiles, said, “By bringing together this broad range of key health care stakeholders, we can create accessible, affordable, and efficient statewide, Web-based clinical research systems. Quintiles is delighted to support efforts by this innovative, evidence-based clinical network to make valuable new therapies available to patients

more rapidly and to advance the ability of New York State’s world-class medical research hospitals to work with the pharmaceutical and medical device industries to improve understanding of disease.”

Rebecca Kush, President and Chief Executive Officer of CDISC, commented, “It has long been a vision for CDISC to provide the standards-inspired innovation to enable a key project such as PACeR. Through our Healthcare Link initiative led by Landen Bain and with the CDISC suite of clinical research standards, we look forward to collaborating on this initiative and demonstrating the value of standards in shortening the time through which research findings inform clinical decisions for the benefit of patients.”

David A. Krusch, M.D., Chief Medical Information Officer, Strong Memorial Hospital, and Chair of the PACeR Governing Group, commented, “The PACeR project, sponsored by HANYS, gives health care institutions in New York State an opportunity to participate in a groundbreaking initiative that promises to uncover opportunities to enhance the quality, safety, and cost of new therapeutic drugs for our patients. Through a unique reuse of data collected during the delivery of care, the PACeR project will create processes to accelerate the identification of clinical trials subjects for investigational drug trials, and potentially streamline and enhance the actual conduct of the trials themselves—all while preserving the privacy and confidentiality essential to any electronic health record implementation. The energy, enthusiasm, and knowledge of those collaborating on this effort is totally refreshing and represents the true spirit of the translation of information technology for the purpose of improving health care delivery.”

Jeffrey Kraut, Senior Vice President for Strategy, North Shore-Long Island Jewish Health System (NSLIJ), said, “We view participation in PACeR to be of significant strategic value to NSLIJ, as it refocuses our long-term strategy around a series of patient-centric activities. The Partnership will serve as an additional catalyst to bridge the clinical care activities of NS-LIJ with the translational research occurring in its research arm, the Feinstein Institute for Medical Research. The work products of this effort will sharpen our thinking about providing excellent, quality care through robust and fully integrated approaches to managing clinical data.”

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