PACeR PARTNERSHIP TO ADVANCE CLINICAL ELECTRONIC RESEARCH

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Collaborative to Speed Clinical Research and Reduce Costs

PAC*e*R Initiative Maps Path to Reduce the Cost of Clinical Studies, While Dramatically Increasing Speed, Quality, and Efficacy

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

Reporters: Representatives from the following PAC*e*R participating organizations will be available to take your questions via conference call on **Wednesday, May 25 at 10:30 a.m.** Albany Medical Center, Booz & Company, Continuum Health Partners, HANYS, Johnson and Johnson, Legal Action Committee, North Shore-Long Island Jewish Health System, Oracle, Pfizer, Inc., Quintiles, Stony Brook University, and University of Rochester Medical Center/Strong Memorial Hospital. **Access the call at (866) 527-7795 and reference PAC*e*R.**

ALBANY, N.Y. — The Partnership to Advance Clinical electronic Research (PAC*e*R), a broad-based health care collaborative, aims to make clinical trials faster and less expensive by identifying potential candidates more efficiently and enhancing protocol modeling and data collection. To achieve this, PAC*e*R is working to create an electronic clinical data process for evidence-based research in New York State.

Most importantly, by testing and making needed therapies available to patients faster, PAC*e*R will help improve the quality of life for patients.

A Strong Model with Benefits for All Stakeholders

Launched in 2010, PAC*e*R's first phase of work confirmed the feasibility of developing a sophisticated, statewide clinical data process for evidence-based research and offered a plan to address the challenges and improvement opportunities associated with the design of existing electronic medical records (EMRs) and patient health data confidentiality.

Fewer protocol amendments and more rapid patient recruitment and enrollment can result in earlier, less expensive product launches, and significant benefits to patients from earlier access to innovative therapies. PAC*e*R's revenue potential for clinical study protocol modeling alone is

substantial: more than $50 million annually. PAC*e*R Phase 1 estimates show that for an average protocol, modeling, and amendments savings will range from $100,000 to $200,000 per protocol, and cost reductions associated with trial conduct will range from $400,000 to $500,000.

PAC*e*R's Phase 1 results also point to significant benefits for major health care stakeholders, including patients, academic medical centers, the research community, health information technology companies (HIT), regulators, public and private initiatives, and the State of New York.

A white paper describing PAC*e*R's Phase I results and Phase 2 plans is available online at www.pacerhealth.org.

Who Is PAC*e*R?

PAC*e*R is a collaborative of leading medical research centers, pharmaceutical companies, and HIT organizations. Participants include:

- **Sponsor:** Healthcare Association of New York State (HANYS)
- **Patient Advocacy Groups:** The Hastings Center and Legal Action Center
- **Academic Medical Centers:** Albany Medical Center, Bassett Medical Center, Continuum Health Partners (St. Luke's-Roosevelt Hospital and Beth Israel Medical Center), New York Hospital Queens, North Shore-Long Island Jewish Health System, NYU Langone Medical Center, Roswell Park Cancer Institute Corporation, Stony Brook University Medical Center, SUNY Downstate Medical Center, SUNY Upstate University Hospital, University of Rochester Medical Center, Weill Cornell Medical College, and Westchester Medical Center
- **Clinical Research, Pharmaceutical, and HIT Organizations:** Bayer HealthCare Pharmaceuticals, Inc., F. Hoffman-La Roche, Ltd., Johnson and Johnson, Merck & Co., Inc., Oracle, Pfizer, Inc., and Quintiles
- **Project Management:** Booz & Company and Quintiles Consulting

The guiding principle behind PAC*e*R is the benefit to patients. Ensuring robust patient privacy and consent protections is paramount. Incorporating patient advocacy groups in PAC*e*R's participation and governance ensures that their role and benefits are a top priority. PAC*e*R will continue to ensure that all solutions deployed will allow patients to decide how their personal medical information will be used.

HANYS' President Daniel Sisto said, "The rapid change we see in the health care system is also occurring in medical research, and the PAC*e*R collaborative is at the forefront of revolutionizing

how medical research is conducted and how the benefits of this research are shared. The PAC*e*R collaborative has proven that bringing together diverse stakeholders is an effective approach to finding ways to improve clinical trials using electronic data. HANYS looks forward to continuing this important work, which promises to help speed new, effective treatments to patients, while improving the efficiency of the entire clinical trial process."

David A. Krusch, M.D., Chief Medical Information Officer, University of Rochester Medical Center, and Chair of the PAC*e*R Governing Group, commented, "PAC*e*R brings tremendous opportunities to enhance the entire clinical trials research process; from study design, patient identification, to the actual conduct of the trial itself. Most importantly, PAC*e*R not only facilitates clinical research, but in doing so it brings new and novel therapeutic opportunities to patients who may never have had such options if not for this new and exciting technology. One can think of PAC*e*R as introducing a new era in the development of dramatic increases in quality of care."

PAC*e*R's Next Phase: Building Infrastructure for Enhanced Clinical Research

PAC*e*R is currently soliciting funding for Phase 2, to begin demonstration projects to develop the infrastructure needed to advance more efficient and effective clinical research. Consistent with PAC*e*R's objectives, the projects will all involve multiple academic medical centers to demonstrate the capability to provide protocol modeling input across many institutions. Pending funding, projects under consideration include:

- a statewide "Center for the Support of Clinical Terminology and Ontology Mapping" to oversee use of a common set of standards by participating institutions;
- deliver protocol modeling and patient selection services using data from multiple institutions;
- data aggregation and reporting capability to support the "one-stop shop" role of delivering analytical services spanning multiple institutions;
- deploy clinical software solutions that "wrap around" currently deployed EMR systems, where those systems will not accommodate the capture of data required for clinical research;
- public education about the responsible use of personal clinical information for the treatment and cure of disease and for the development of new diagnostics, medications, and medical devices.

"Pfizer, Inc. remains deeply committed to the PAC*e*R Collaborative as a novel means of advancing new therapies through the long and complex process of Clinical Development," said David Leventhal, Director, Healthcare Informatics at Pfizer, and PAC*e*R Project Leadership Committee member. "We further view multi-stakeholder collaborations, like PAC*e*R, as an important driver of research and development productivity that will ultimately bring important medicines to patients around the world."

PAC*e*R will continue to engage the full range of stakeholders, including practicing physicians and patients who will be affected by, and will benefit from, PAC*e*R.

"Oracle is committed to being part of PAC*e*R's groundbreaking work aimed at creating a sustainable, electronic clinical research data network in New York to support more efficient and effective clinical trial participant recruitment," said Neil de Crescenzo, Senior Vice President and General Manager, Oracle Health Sciences. "The group's Phase 1 findings confirm the feasibility of such a network and define a clear path forward. Oracle looks forward to continuing to work as part of PAC*e*R to advance this important initiative."

Rebecca Kush, Ph.D., President and Chief Executive Officer of the Clinical Data Interchange Standards Consortium (CDISC**),** stated, "As the leader of an organization that is dedicated to improving the clinical research process, I applaud the PAC*e*R goals and efforts in this direction. I look forward to continuing as an advisor on this project and to potential synergies in the activities of PAC*e*R and CDISC to provide innovative means for biopharmaceutical companies and medical centers to work together to better link research and care for the ultimate benefit of patients."

"Quintiles is excited about the progress made by PAC*e*R toward speeding up clinical trials through more rapid patient recruitment and enrollment, and a reduced need for protocol amendments," said John Murphy, Head, Clinical Analytics in Consulting at Quintiles, and project manager for PAC*e*R. "In addition to the benefit to patients of earlier access to innovative therapies, this could bring multi-million dollar savings to our biopharma customers as they work to respond to ever-changing conditions in the New Health, where managing risk is a constant."

New PAC*e*R Participants Welcome

PAC*e*R strongly encourages participation of additional members in Phase 2, and welcomes the perspectives of new members such as physician professional societies, community hospitals, device manufacturers, EMR vendors, disease societies, and others. The more comprehensive PAC*e*R's membership, the more sustainable its approach becomes.

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