

THE BULLETIN

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Relax, Recharge, Renew



Collaborating to Build an Electronic Clinical Trials Network

Clinical data capture and clinical data exchange for quality and outcome measurement is now a requirement for managing hospitals and physician practices given the federal mandates that became law in 2009 and upheld by the Supreme Court in 2012. As a result, hospitals and physician practices, as the primary source of clinical data capture and ownership, are in a position to develop a common business and operating model that generates new sources of revenue and streamlines clinical practice and research as a result of these mandates. However, most clinical systems that exist today are not adequate for the task at hand, which is compounded by the fragmentation and large number of electronic medical record (EMR) system providers. In addition, claims and EMR data are insufficient for evidence-based medicine and many clinical research applications. Therefore, multi-site EMR data is becoming an increasingly important resource for clinical researchers, yet additional information is needed for true evidence-based research.

Partnership to Advance Clinical electronic Research (PACeR)
PACeR is a collaborative effort between the pharmaceutical industry, the healthcare delivery system and a select group of technology companies to create the new business model, operating model and clinical data platform to address the needs of hospital networks and physician practices impacted by these changes.

The goal of PACeR is to increase the speed, quality, and efficacy of

clinical studies, 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

PACeR IS A DIVERSE COLLABORATION OF MEDICAL CENTERS, INDUSTRY, PATIENT GROUPS, & ADVISORS

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)
		SUNY Upstate University Hospital	Oracle	CDISC and HL7
Legal Action Center	New York Hospital Queens	University of Rochester Medical Center	Pfizer	
	North Shore-Long Island Jewish Health System	Weill Cornell Medical College	Quintiles	New York State Foundation for Science, Technology, and Innovation (NYSTAR)
	NYU Langone Medical Center	Westchester Medical Center	Roche	
Project Management	Booz & Company and Quintiles Consulting			

*CRO = clinical research organization

collaborative. The guiding principle behind this endeavor is the benefit to patients, and ensuring robust patient privacy and consent protections is paramount.

Phase 1 of PACeR identified barriers to the secondary use of electronic health data for evidence-based research, and developed recommendations to address those barriers. Phase 2 of PACeR will consist of demonstration projects to address these barriers and develop an infrastructure for an efficient clinical research data network in New York State. Phase 2 is an opportunity to demonstrate and implement unique PACeR capabilities, including the standardization of data, the market making service, and the dynamic collection of data directly from physicians and patients. The dedication, expertise, and breadth of PACeR's participants will enable the collaboration to succeed.

University of Rochester Medical Center at the Forefront
The University of Rochester Medical Center is at the forefront of this collaboration, leading the way with a scheduled demonstration project beginning this fall (start date to be confirmed). Dr. Anton Porsteinsson, located at the Monroe Community Hospital, will serve as Principal Investigator on a Mild to Moderate Alzheimer's Disease study that will look to recruit patients using the PACeR technology platform. The study welcomes participation and collaboration on

this demonstration project given that the capacity of the PACeR technology is enhanced as more referring physicians and data sources are identified.

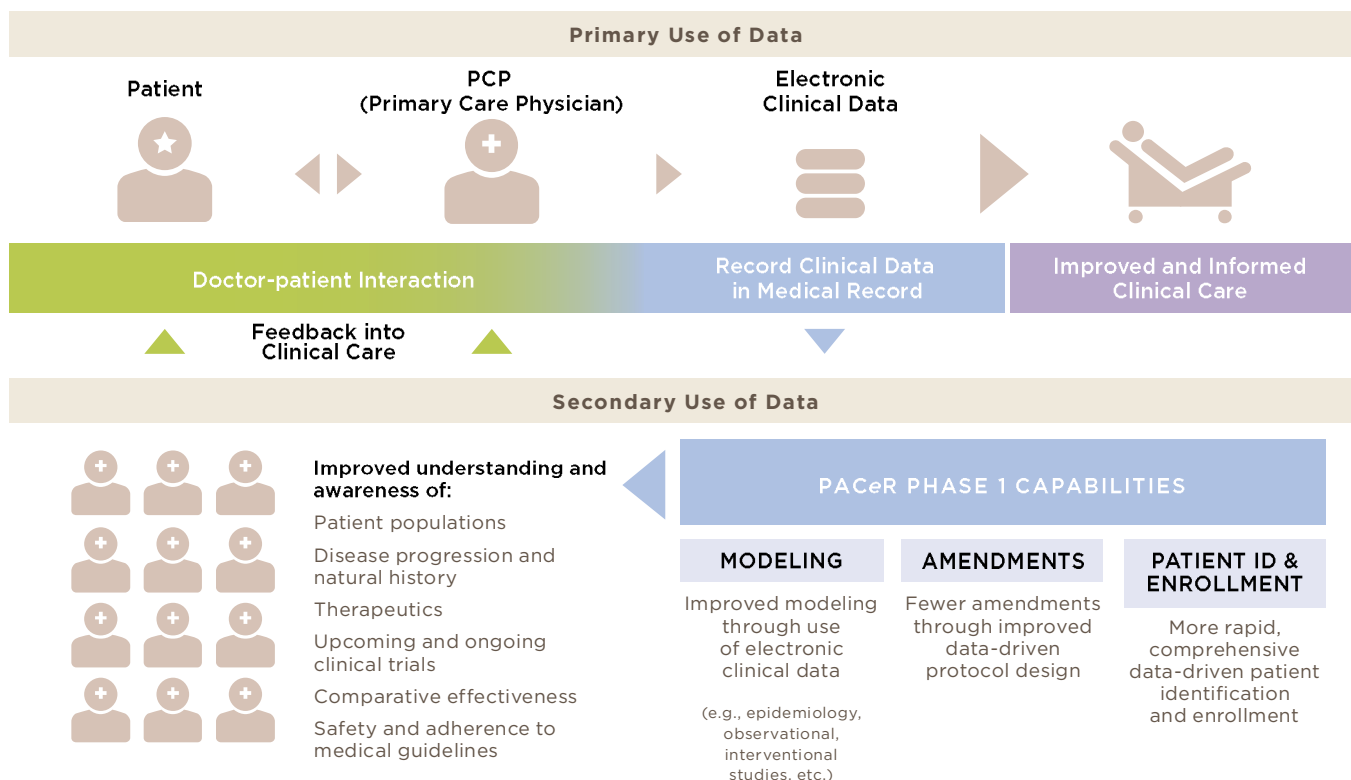
This first step in the PACeR patient identification process is to query the EMR systems against high-level patient eligibility criteria to identify a blinded potential patient population (see Exhibit 1). The PACeR platform will also capture EMR data longitudinally across various clinical workflow domains within the participating hospital and physician networks. The type of data available for screening in the system will include :

- Patient histories
- History of present illnesses / differential diagnoses
- Physical diagnoses such as physical exam, ICD primary diagnoses and comorbidity, labs, imaging remarks, etc.
- Therapies such as CPT(s), assessments, allergies, adverse events, orders (labs; Rx dispensed)
- Outcomes such as patient/disease progress, side effects, adverse events, compliance, adherence, and quality of life

The platform will also provide real-time patient identification via alerts for care providers or researchers. For example, participating primary care physicians are sent alerts notifying them if any of

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PACeR ENABLES THE SECONDARY USE OF DATA TO BENEFIT PATIENTS, PCPS, & ULTIMATELY, CLINICAL CARE



³ "Roadmap for implementing value driven healthcare in the traditional Medicare fee-for-service program." Centers for Medicare and Medicaid Services. https://www.cms.gov/QualityInitiativesGenInfo/downloads/VBPRoadmap_OEA_116_508.pdf

⁴ "Eligible professional meaningful use core measures." 2010. <https://www.cms.gov/EHRIncentivePrograms/Downloads/EP-MU-TOC-Core-and-MenuSet-Objectives.pdf>

Clinical Trials Network

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their patients may be eligible for the study based on the pre-screening criteria, and a survey can be sent to patients via their physicians to gather more granular data, such as symptoms and family history, to further determine patient eligibility. Physicians can also be surveyed to help answer more clinically complex questions

that can help fill gaps in the survey data provided by the potential patients. Once the potential patients are identified, the PACeR system is able to provide educational and informed consent materials to further gauge study interest and initiate contact with the patient. The PACeR system also has reporting capabilities to help researchers and sponsors determine the number of eligible subjects per site but also assists Sponsors in determining site suitability

based on available patient populations.

The study will also deploy a secure patient internet portal, where patients will be able to pre-screen themselves by answering a series of questions to see if they may be a candidate for the study. Proper awareness of the patient portal will increase the number of potential subjects available for prescreening while decreasing the workload on the study site. Patients can complete the informed consent and get more information about the study if they qualify and are interested.

The PACeR platform also has the capability to standardize data captured within the system. The cloud-based network is built on top of a centrally managed clinical terminology foundation that standardizes all terminology, incorporating all of the clinically validated medical coding and terminology platforms such as Medical Dictionary for Regulatory Activities (MedDRA), Systematized Nomenclature of Medicine Clinical Terms (SNOMED CT), and WHO Adverse Reactions Terminology (WHOART). This uniform data allows provides a common foundation, which is needed for true evidence-based research.

What is developed under PACeR for pharmaceutical R&D will be equally useful for all forms of clinical evidence-based research and will prepare member institutions for the regulatory and industry requirements in the future. PACeR, along with its partners throughout NY State, is in a unique position to take advantage of these changes given the unique collaboration of so many stakeholders across the health care spectrum.

If you would like more information or have questions about the PACeR initiative or the upcoming Alzheimer's demonstration project beginning this fall at URM, contact: John Murphy, Practice Lead, Clinical Analytics, Quintiles Consulting, john.murphy@quintiles.com or Ben Smith, Principal Consultant, Quintiles Consulting, benjamin.smith@quintiles.com.



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