A partnership between the clinical research community and New York-based academic research centers, hospitals, health information technology companies & physician groups to build an advanced, on-line, clinical research capability
PACeR: The Partnership to Accelerate Clinical electronic Research - Improves Predictive Success

Est. in 2010, public-private partnership to develop economically sustainable businesses that support Translational Medical Research across the U.S. Not just a technology— a Collaborative Effort to Standardize and Improve the Science of Evidence-based Medicine.

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<th>Founded Members</th>
<th>Participating Hospitals</th>
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<td>Bayer</td>
<td>Albany Medical Center</td>
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<td>Pfizer</td>
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<td>Johnson &amp; Johnson</td>
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<td>HANYS</td>
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<td>SUNY Downstate</td>
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Collects, Aggregate & Organizes Knowledge Across Domains; Facilitates eCommunication across Silos

**Discovery, Development, Outcomes, Safety & Commercial disciplines**

**Federated Collaborative Platform**

- Cross-domain knowledge architecture
- Integrated science, clinical, industry & business data aggregation
- Cross-institution semantic data standardization
- Bayesian Model Development - A.I. Training
- Neural Network pattern analytics - Knowledge formulation
- Common research policies & procedures
- Non-competitive knowledge exchange
- Standardized Policies, Procedures, Contracts
- Common Patient Privacy Protections
- Clinical & Patient Social Networks
- Real-time bidirectional communication between scientists, hospitals, clinicians, regulators & patients.
- Protects companies from legal MD conflict exposure
- Cloud based to eliminate operational expenses.
PACeR Platform Summary

PACeR is a central entity that
1. Provides a single source to researchers for clinical data of many origins (institutions, physician practices, home, etc), and a single buyer for the data suppliers
2. Provides tools, systems, processes to hospitals to advance clinical research capabilities
3. Drives standards in data capture and quality
4. Incubates businesses leveraging the data platform for specific applications and use cases

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<th>Trial Modeling</th>
<th>Patient Selection</th>
<th>Protocol Validation</th>
<th>Safety / Compliance</th>
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<td>Disease</td>
<td>Therapeutic</td>
<td>Population</td>
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**PACeR Application Businesses**

- **Data Query and Aggregation**
- **Data Standards Management**
- **Build, Deploy, and Analyze**

**PACeR Analytics, PACeR Clinical Data Franchises & Data Factory**

- **Existing Data**
  - Hospital 1: Current State 80%
  - Hospital 2: Current State 55%
  - Hospital 3: Current State 35%

- **New Capture Tools**

**Standardized Methods Data Types & Nomenclatures Across all N.Y. State Hospitals, Maintained by a Single Source for all EMR Implementations**

The PACeR data system goes beyond existing EMRs
- Mines ancillary repositories (e.g., pharmacy, imaging remarks)
- Captures data directly from patients and physicians
- Institutions with poor EMRs can still provide high-quality data
PACeR Uniformity® Provides Common Clinical Terminology & Coding Across all Sites and is Cloud-based, Eliminating Company & Institution-based IT Support

All PACeR databases and applications are cloud utility–based virtualized resources and available to hospital, ambulatory, community and home for collection of clinical data used for longitudinal evidence-based medical device & diagnostic test development and safety. No institutional IT maintenance. Quintiles Trains sites and Supports the system.
Demonstration Project Examples and Early Interests

Sponsors are currently designing a series of proof-of-concept projects that will provide them with data needed for real-world applications. Examples include:

– Patient identification, selection, and enrollment
– Trial protocol refinement
– Safety/outcomes monitoring
– Principal investigator and site selection
– Medical device retrospective data extraction and safety/outcomes monitoring
– Standard of care and clinical endpoint study
– Comparative effectiveness longitudinal outcomes study
– Infrastructure building: central standards management, EDC/EMR aggregation, physician/patient info pull/push, etc.
Progress to Date

• All major NY State hospital in HANYS network in the system – 55 Million patients
• Five Pharmaceutical companies; three pending
• Five active projects
• PACeR-2 in start-up: University of Georgia Alzheimer’s Network
• In discussions with five health networks: North Carolina, Indiana, Texas, Arizona, University of Michigan
• Developing standards for patient identification, consent, contracts, IRB processes
Back-Up
PACeR’s governance and team structure enables the collaborative nature of the project

A Project Leadership Committee governs the project, supported by 4 discrete work groups

**Project Leadership Committee (PLC)**

**Key Decisions & Approvals**
Committee Members: HANYS, Pharma, Technology, Medical Centers, Practicing MD, Consumer Representative, Ethicist

**Informed Insight**
Advisors/Observers: FDA, NYSDOH, NYeC, CDISC, HL7, LAC, Hastings, NYSTAR etc.

**Advisors/Observers**

**Project Management**

**Project Oversight & QA**
Booz & Company Quintiles

**Work Groups**

1. **Clinical Data Analysis & Trial Recruitment**
2. **Business Model Development**
3. **Regulatory & Legal Policy**
4. **New Process and System Design**

**Sponsorship – HANYS**
- Project sponsor
- Program & funding administrator
- Convene and participate in PLC & WGs
- Work closely with hospitals
- Coordinate with all partners
A series of data-driven “filters” enables the precise identification of eligible patients.

1. **EMR Data Mining**
   - Query existing data repositories against patient eligibility criteria captured currently to determine potential population.

2. **Patient Survey**
   - Via their physicians, survey patients highlighted during data mining in order to capture data not residing in EMRs (e.g., family history, symptoms).

3. **Physician Survey**
   - Survey physicians of the remaining patients to capture any remaining data not able to be provided by patients (e.g., clinically complex questions).

4. **Patient Education and Consent**
   - Inform target patients, providing education materials, gauge interest, and obtain consent to be identified and contacted for screening.

5. **Analysis, Strategy, Reporting**
   - Synthesize data and report on the number of eligible and interested patients at each site. Analysis may also be integrated with performance data to provide informed recommendations for site selection.
A Flexible and Modular Research Process

The example project approach can adapt according to data findings and evolving needs.

1. EMR Data Mining
2. Patient Survey
3. Physician Survey
4. Patient Education and Consent
5. Analysis, Strategy, Reporting

Decision points after each stage of data capture allow opportunities to determine whether insights from more granular data are needed. Example uses include:

- further filtering of population for patient selection
- additional variables for protocol refinement
- additional variables available to establish causation in evidence-based scientific research

Repetition of select data capture stages allows for multiple refinements to protocol design until eligibility criteria and population size align as desired.

Various supporting services may also optionally be provided such as patient education, consent, enrollment, and feasibility and site selection analytics.
The PACeR system fills the EMR clinical data gaps and captures uniform data across all clinical data capture sites, which is needed for evidence-based research.

**Key PACeR Features**
- Common User Community
- Portable Data Capture
- Standardized Applications
- Common Foundation