



Recombinant Translational Research Solution Fact Sheet

What It Is

Recombinant's translational research solution, built around the NIH's i2b2 open source technology, provides an Institutional Review Board (IRB)-compliant environment for managing and analyzing clinical data for population-based research, genomic research, clinical trials, and the development of new interventions and technologies. While research is critical to the mission of many hospitals and academic medical centers, the clinical research groups often are paralyzed waiting for data since IT teams do not have the resources to support their custom requests. Recombinant's translational research solution provides researchers with a simple self-service cohort selection interface to generate hypotheses using de-identified data from the Recombinant Data Trust. The system complies with IRB requirements and supports integration with lab information systems, Natural Language Processing (NLP) concept extraction, and collaboration between institutions to allow researchers to establish high-throughput mechanisms to collect genomic data for studies that require large sets of research subjects. Computational tools for data clustering and pathway visualization support researchers working to stratify disease conditions and identify biomarkers for personalized medicine.

This streamlined research process improves the pace, cost, and quality of clinical research across the organization and makes scalable translational research possible.

In addition, Recombinant offers consulting services, including governance and compliance expertise, to resolve non-technical issues related to data sharing between clinicians and researchers and for multi-institution collaborations.

How It Works

The Recombinant Translational Research solution is built around the i2b2 open source technology funded by the NIH. The core of the i2b2 platform, the clinical research chart (CRC) data repository and workbench cohort query interface, provide researchers direct access to make queries on patient information using de-identification and process controls to ensure access to personal health information (PHI) is always managed through the proper IRB processes. Additional tools extend the core to enable researchers with informatics tools like Natural Language

Processing (NLP) capabilities to extract structured data from free text notes and with cluster analysis systems to find novel results from collected samples.

The bio-informatics research applications of i2b2 are used for establishing large-n cohorts across a wide population that in the past would have been cost-prohibitive and slow. In addition, the central repository closes the gap between genomic and clinical data, making it possible to combine genetic data with clinical phenotypes in an ethical manner so bio repositories and tissue banks can gain added research value.

Success with the i2b2 analytics tools is dependent upon establishment of a reliable centralized source of high-quality data through a clinical data warehouse. Recombinant delivers data to researchers through a packaged adapter to the multitude of data stored in the Recombinant Data Trust, including electronic health records (EHRs), billing system information, and laboratory results.

Translational research solutions include expert consulting, training, integration, development, and support to lower implementation risks and costs.

Solutions include:

- Data repository development
- Authenticating and authorization (identity management)
- Installation (hardware and software)
- System integration to key research IT systems
 - eIRB
 - Tissue banks/bio-repositories
 - Clinical trial management systems (CTMS)
 - Collaboration/federation systems like caBIG and local Clinical and Translational Science Awards (CTSA) projects

Recombinant is committed to supporting the i2b2 platform by providing technical, planning, and implementation assistance, and offers a number of structured workshops ranging from introductions to programming. It also promotes the NIH goal of improving cooperation and data sharing among institutions through public presentations, training, and documentation.



Recombinant Translational Research Solution Fact Sheet (continued)

Benefits

For Medical Researchers

- Improves site infrastructure for conducting clinical research, a key component of readiness for successful CTSA grant submissions
- Accelerates researchers' ability to get relevant data quickly, allowing them to evaluate cohort participation potential and submit IRB requests for fully identified data faster
- Achieves superior results for grant-funded research by allowing researchers to prove study feasibility and secure project extensions
- Establishes and enhances pharma partnerships to improve medical technologies by allowing rapid modeling to demonstrate how trial protocols would be populated within the patient community
- Reduces patient recruitment costs and time by centralized access to database and protocols for ethical patient recruitment, allowing more time to focus on writing grants and conducting experiments
- Identifies emerging risks in the patient population by uniquely leveraging the wealth of knowledge stored in clinical data repositories

For Provider IT Departments

- Lowers costs/risks related to deployment of open source collaboration software
- Centralized repository of de-identified data eliminates "gray market" for research data and improves governance and audit capabilities for IRB and Health Insurance Portability and Accountability Act (HIPAA) protocol compliance
- Lowers the load on EHR and database analysts by reducing redundancy that comes with custom requests
- Drives interoperable data standards (without interfering with production systems) to establish ontologies in transactional applications
- Ultimately provides the tools needed to reach mainstream point-of-care applications that achieve the vision of personalized medicine