December 2014: Update to Optum Labs: Building a Novel Node in The Learning Health Care System; *Health Affairs*, 33, no.7 (2014):1187-1194

Partners As of December 2014, Optum Labs, is now comprised of 15 partner institutions. In addition to the original co-founding partners, Optum and Mayo Clinic, active partners include founding consumer advocate organization AARP, the American Medical Group Association, Boston Scientific Corporation, the Boston University School of Public Health, Harvard Medical School Department of Health Care Policy, Lehigh Valley Health Network, Medica Research Institute, Merck, Pfizer, Rensselaer, Tufts Medical Center, The University of Maryland, Baltimore and the University of Minnesota School of Nursing.

The Data The Optum Labs Data Warehouse (OLDW) includes 7.7 terabytes of de-identified data derived from administrative claims for over 110 million individuals, collected over 20 years, clinical data from both structured and unstructured fields of electronic health records for over 25 million patients, plus consumer data on approximately 30 million Americans. De-identified data is linked across data sets at the individual level using the hashing techniques described in the original article. After confirmation of the appropriateness of study protocols, data is provided to researchers through a secure enclave as one of several de-identified views certified as HIPAA compliant. Researchers are not allowed to download any patient-level data from the enclave, further reducing the risk of re-identification.

Research and Translation Approximately 130 investigator initiated studies have commenced, involving 15 partners. Studies have addressed a wide range of problem formulations with the most common topics addressing conditions such as cardiovascular disease and cancer, several aspects of methodology research, and domains including comparative effectiveness, variations in care and predictive modeling research.

Research findings are being translated into clinical practice by partner institutions.

Translation is systematically integrated with individual study problem formulation and discovery as shown in figure 1. Collaboration among researchers and translators is facilitated by regular conference calls, webinars and in person forums.



Constellations Major initiatives addressing big health system challenges by leveraging the Optum Labs assets of big data, diverse partnerships and end to end design from discovery to care improvement

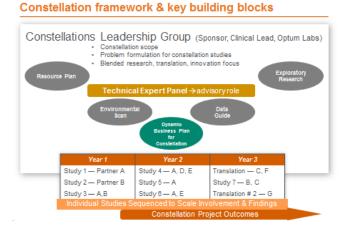
Some core problems confronting the US health care system are larger than a single research problem formulation and require multiple perspectives and a portfolio of integrated activities from discovery through translation to yield desired change. These *big* problems may center on a clinical condition, a

policy need, and/or a major business challenge and have often been resistant to traditional approaches to investigation and implementation. They likely require a combination of new research, innovation, and creative approaches for embedding into practice and policy.

We have termed these *big* problems, *Constellations*, to capture their scale, complex and intertwined contributing factors, and need for a systematic themed and coordinated approach over time to reveal meaningful findings and to enable substantive impact and change. In working with current and potential Optum Labs partner organizations, several Constellations have emerged and are in varying stages of development, including:

- Heart failure
- Performance measurement incubator
- Alzheimer's disease
- Complex co-morbidity
- Cancer prevention
- Diabetes

While each constellation is unique, a common portfolio framework and key building blocks that draw upon Optum Labs capabilities has emerged as shown at right:



Key Policy Opportunities As noted in the original article, key policy issues that relate to the Learning Health Care System include:

- **Methods Development Opportunities**, especially to leverage the substantial potential for the safe and innovative use of de-identified data, including
 - Extending observational approaches (RCT replication, efficacy to effectiveness extension)
 - Coordination of de-identification approaches with use of HPI (e.g. Registry specifications, care personalization)
 - Development and leverage of machine learning approaches
- Governance opportunities
 - Informing and engaging IRBs, especially as methods and data sources evolve
 - Refining the relationship between QI and research
 - Guidance in use of observational methods and de-identification
- **Development of approaches for sustainability** of key aspects of the Learning Health System including databases, research organizations, and facilitators of translation and spread
- Balancing research, translation and commercialization, including:
 - Institutional needs for rapidly implementable knowledge and
 - Time-related aspects of competitive advantage and market positioning.