CLINICAL LAB 2.0
A PROJECT SANTA FE FOUNDATION INITIATIVE

In Anticipation of the 10th Annual Clinical Lab 2.0 Public Workshop:

Patient Safety, the Human Condition, and the Macroeconomics of Diagnostics

Health systems are outsourcing their laboratories at the exact moment they need them most. As care moves to risk prediction, the laboratory holds the longitudinal data that proactively identifies who will become sick and when. A health system that outsources its laboratory hands that intelligence to a vendor yet still retains the risk. The laboratory that does not claim its seat at the table or create a seat for itself when there is not one, will find itself on the menu.

The Project Santa Fe Foundation marks 10 years of the Clinical Lab 2.0 movement at the upcoming Annual Public Workshop in Chicago on March 7-9, 2027. The message of the 10th year is patient safety and the human condition that laboratory medicine is positioned to change.

The laboratory's role

Every result carries information about what comes next for a patient, and when a result without a clinical action will result in escalating risk. In the era of population health and value-based care measured by risk, the laboratory must initiate care when a finding in the data triggers action but has not yet occurred. Laboratories that implement risk stratification anticipate disease rather than react to it. This brings predictability, and a business of risk requires such. The laboratory arrives at the table carrying a compass of trajectory rather than a count of test results.

From tracking tests to tracking disease

> *Our moral imperative does not end when we release a result; rather, that is where it starts.*
> *— James Crawford, MD, PhD*

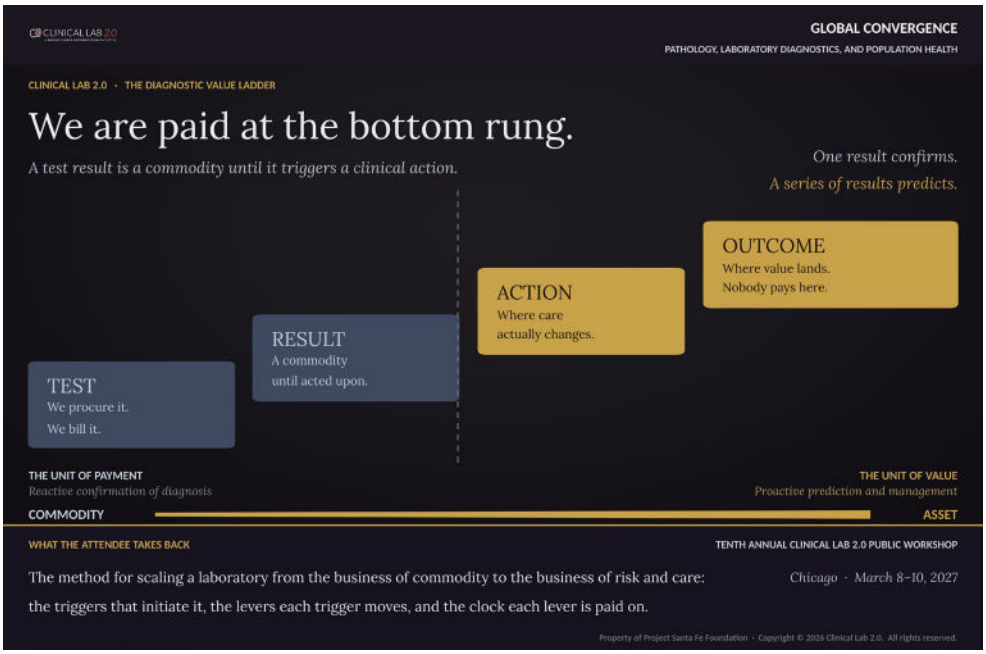
Diagnostics is not a cost to be reduced but an investment to be optimized, and time to diagnosis is part of it. Currently, we are paid for a test, but a test alone is not diagnostic until it is connected to a diagnosis and acted upon. Diagnostics receives the smallest share of reimbursement in healthcare, while diagnostic error and harm remain among the least measured injuries in medicine. It is what fragmented data and misaligned incentives produce, unfortunately, but fragmentation of data is also fragmentation of care.

The cost incurred is two-fold: one impacting the patient, when outcomes that were predictable were not acted upon, and two on the health system, in the margin it needs to deliver care. HEDIS performance, cost avoidance, and Star Ratings all involve findings the laboratory already possess. The laboratory owns the trigger; one trigger amplifies, clinical and financial levers, reaching the margin on which sustainability depends. Healthcare is a team sport and involves legislators, clinicians, payers, employers, and the consumers we all serve. We win or lose as one.

Lab 1.0 is paid for a test. Lab 2.0 is paid for what prediction it sets in motion. The difference is producing a result to acting on the result to generate a clinical insight that initiates care.

Counted as tests, the laboratory's output is volume. Counted as disease, the same data is an asset: a registry of your own population showing who has the condition, who is at risk of disease, and who is moving along the trajectory. We possess this insight today, in data already produced by laboratory results.

What that data enables are what the laboratory really sells: risk stratification, care triage, and intervention early enough to change the course of the human condition. There is no equivalent in Lab 1.0, where a test is reimbursed and the impact ends at the transaction.



At the numeric level a test result is a commodity, won by whoever produces it at the lowest cost. At the care level, it is a clinical action, and the laboratory is a participant in the decision rather than a supplier.

What the 10th Annual Workshop will offer you

Lab 1.0 is not replaced. It is the foundation the new model stands on. Attendees of the Workshop will leave with a comprehensive understanding of the elements of the Lab 2.0 business model including:

1. A method for inventorying the assets their laboratory already owns, counted by disease prediction rather than by test volume.
2. The triggers available within existing data that signal risk.
3. The four economic levers and how these can be used to measure the economic value of Lab 2.0 services.
4. The infrastructure specifications: what must be assembled, routed, and measured before a trigger can lead to providing Lab 2.0 services.
5. The laboratory's case to discuss with chief executives and financial officers as the system takes on risk.

Join us in Chicago

The future of laboratory medicine requires your involvement. Each of us and our institutions belong in the driver's seat.

Those in the room will leave with a model they can build upon. Those not in attendance will ultimately meet the same model later, defined by someone else, and implemented on terms they did not set. Claim your seat at the table.

Project Santa Fe Foundation
www.cl2lab.org
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