Customer Case Study:

Foundation Medicine's Breakthrough Personalized Cancer Care Relies on Thermo Scientific Clinical LIMS

Founded by world leaders in genome technology, cancer biology and medical oncology, Foundation Medicine is a cancer diagnostics company at the forefront of bringing comprehensive genomic analysis to routine cancer care. The Cambridge, Mass.-based company's clinical laboratory services help physicians and their patients develop customized cancer treatment and therapy based on an individual tumor's molecular subtype. Key to this process is Foundation Medicine's Next-Generation Sequencing (NGS) platform, which extracts relevant genomic information from small amounts of cancer tissue. The organization's revolutionary process requires precise management of data collected from disparate sources, so Foundation uses Thermo Scientific Clinical LIMS to integrate its lab, clinical and EMR information.

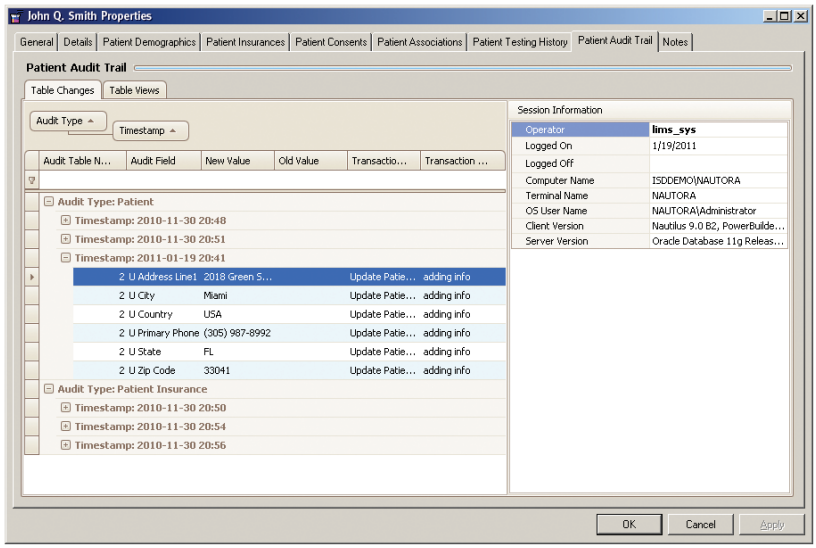
For decades, all cancer patients, regardless of their genetic background, the nature of their disease or their overall health, have had three basic options for treatment: surgery, radiation therapy and/or chemotherapy. While these therapies are often very effective, they are broad-sweeping treatments that attack both healthy and cancerous tissue and cells.

Companies such as Foundation Medicine, however, have ushered in a new era in patient care: the age of personalized cancer treatment. This emerging field of medicine offers physicians the opportunity to attack cancer at the genomic level by identifying and targeting the molecular changes found in cancer cells. Scientists use the same technology developed more than a decade ago to decode the human genome, but instead sequence the genomes of tumors and cancer cells for two purposes: to capture the molecular subtypes of the specific cancer and to learn why some patients respond to certain therapies while others do not. These findings are ushering in a true revolution in cancer care—getting the right therapy to the right patient at the right time.

"The care of oncology patients is on the verge of being individualized," says Michael Pellini, Foundation Medicine's CEO. "The molecular makeup of each tumor is going to drive personalized medicine. Our goal is to work with oncologists and pathologists and do nothing short of transform cancer care. We want to change the way cancer patients are managed, not just in academic medical centers but in communities across the U.S. and internationally."

Challenging the Status Quo in Cancer Care

Though Foundation Medicine is working to revolutionize cancer care, battling cancer in this personalized manner also means the cancer's diagnostic paradigm must change. That requires new systems to manage the collection and distribution of diagnostic data among providers, physicians and patients. In other words, to bring the concept of personalized medicine to life, life science technology and information technology need to evolve in parallel—and eventually become integrated.



Foundation Medicine is working to solve the life science technology piece of the equation. The company has developed a clinical diagnostic test, called FoundationOne, which performs next-generation sequencing on a very small amount of genomic material. The test is used to develop a "molecular" blueprint of a patient's tumor; the blueprint is then shared with the patient's physician, who in turn uses it to outline relevant therapies, treatments and/or clinical trials. The test is optimized to fit easily into the clinical workflow of a practicing oncologist, and it can be used with DNA samples as small as 50 ng.

Meanwhile, changes in information technology are an absolute necessity to support Foundation Medicine's groundbreaking work. Research labs require software that can manage samples, integrate with internal applications and laboratory instrumentation, track research processes and support analysis and reporting. Laboratory Information Management Systems (LIMS) predominate in laboratory settings; these systems manage and track samples from the lab and communicate results to physicians.

Clinics, on the other hand, need logical, patient-centered ways to request tests and view results in the context of an organization's administrative and business rules and in ways that don't violate regulations concerning data security and patient privacy. Clinics, clinical labs and hospitals often use Laboratory Information Systems (LIS) to handle the business side of diagnostic transactions, including requisition management and reporting. A clinical LIS also ensures that patient data is managed securely and with the appropriate privacy settings to keep a facility in compliance with Health Insurance Portability and Accountability Act (HIPAA) and CLIA regulations.

To further complicate matters, patient management also occurs in Electronic Medical Record systems (EMRs). EMRs not only record and store all information associated with a patient, from a doctor's notes about a medical visit to medication history to medical test results, but also serve as the physician's main interface into the LIS.

Vendor Selection

The choice of LIMS partner was a crucial decision for John Curran, Foundation Medicine's lab manager. After narrowing the choices to three vendors—Core LIMS, STARLIMS and Thermo Fisher—Curran and his team selected the Thermo Fisher Clinical LIMS over STARLIMS based on references and demonstrations.

Clinical LIMS provided a single informatics solution that combined the research-centered functionality of a traditional LIMS with capabilities typically found in a LIS. This allowed Foundation to integrate the critical but disparate system of lab (LIMS), clinical (LIS) and patient (EMR) data. In addition to its ability to evolve as Foundation's needs change, the LIMS assists with a series of state and national inspections designed to ensure the lab is processing clinical samples correctly. Such inspections include random selection of several patient samples, a review of the entire paper trail from requisition forms to training documentation forms (for anyone who handles the sample), maintenance documentation (for all equipment that touches the samples), reagent logs, control verification logs and Quality Control (QC) documentation.

In the past, Curran would have pulled these forms and records from a filing cabinet, but the new LIMS enables him to simply key in an accession number and download what he needs. "Even though the LIMS is not a reagent management system, we can capture all the information as we process it, and I can get it all in one easy format at the end," he says.

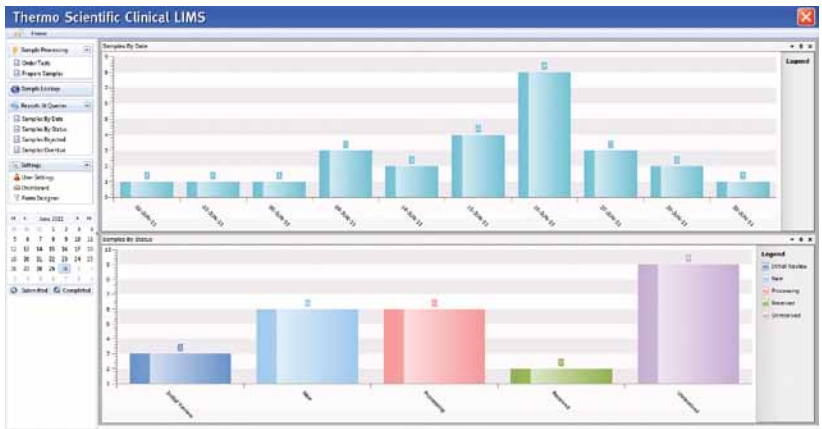
Integrating Life Sciences with IT

The Foundation Medicine labs include adjoining rooms where samples are received, the DNA is extracted and manipulated and the sequencing work is performed. Clinical LIMS ties the entire process together. "The informatics platform handles information management, aggregates information across the enterprise and handles a very dynamic business process," says Curran.

The Clinical LIMS tracks the receipt of samples, and doctors can access a lab web portal to receive information or order tests. "We send the shipping kit with barcodes, they apply the barcodes to the samples and forms, put it back in the box and send it here. We can track it, because it's already in the system," says Curran. "We envisage a turnaround time that starts when the oncologist orders a test. With the portal, we can track, call up and ask if it's on the way. My biggest fear is sample switching and sample contamination. That's why the LIMS is critical.

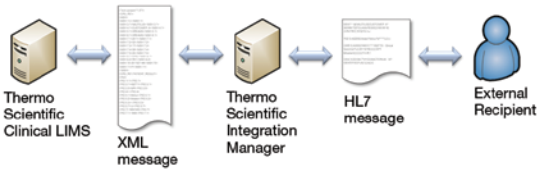
Technical Details of Thermo Fisher's Clinical LIMS Solution

- A physicians' interface provides a secure web-based interface for submitting test requests to the lab, tracking sample progress and accessing published patient reports. The Lab Web Portal features an integrated dashboard with tailored KPI alerts, on-demand querying and pre-packaged reports.
- Patient management functionality facilitates comprehensive patient clinical record tracking including insurance information, consent information, family and medical history, clinical notes and testing results history. All Protected Health Information (PHI) is stored and managed in compliance with the privacy and security rules of HIPAA.
- Clinical vocabularies and health level 7 (HL7) messaging supports CLIA mandated exchange of laboratory information between clinical laboratories and external partners.
- The Clinical LIMS supports compliance with CLIA and 21 CFR Part 11. All patient reports are stored in a read-only format (PDF) and corrections or amendments to reports are handled in accordance with CLIA sec. 493.1291.
- Configurable hierarchy manages data collected during the sample testing process and accommodates varying laboratory needs. The configurable hierarchy is integrated with chain-of-custody, location management, aliquot/derivative and pooled sample tracking.
- Biospecimen and plate management includes graphical workflows and plate editors, as well as built-in integration functionality that facilitates increased throughput and automation.
- Instrument integration and automation includes robotics, next-generation sequencing, analyzers, etc., and facilitates standardization of processes and simplifies operations across the clinical network.



Advantages of Routine Clinical Sequencing

The implications of routine clinical sequencing are enormous. For starters, it will expand the number of specialized cancer therapies that target gene variations; therapies have already been developed for specific mutations found in breast tumors as well as lung, colorectal and pancreatic cancers. Routine clinical sequencing can also bring new pharmaceutical options to market faster, as fewer patients are required to prove the drug's efficacy, and the collected data will be more closely targeted to the specific issues researchers are trying to address. Routine clinical sequencing also requires much smaller samples, in turn reducing the number of tests or procedures a patient must undergo.



If I see a barcode I wasn't expecting or misplaced, I know we have a problem."

Next, the DNA is sized and normalized for hybrid capture, the main portion of the testing. Foundation Medicine uses proprietary RNA baits to capture the genomic content; this material is then normalized for sequencing. The informatics team processes the sequence data and performs variant analysis; the detected alterations are fed back to the knowledge base, which in turn correlates the results to medical and scientific information. The final result report is delivered to the doctor through the lab web portal, ideally no more than 14 days after the test was ordered.

The report summarizes the key mutations, relevant drugs and clinical trials. Although Foundation Medicine can't recommend a particular action—in large part because it doesn't have all of the patient's information—it can supply critical information for the physician. "We can't recommend a particular action, but we can say, here are the genomic alterations and what they mean for this patient," says Mary Pat Lancelotta, Foundation Medicine's director of strategic marketing. "Based on an exhaustive search of the literature, here are the therapeutic agents and clinical trials that you and your patient could consider. We're giving the physician a fully informative genomic profile as a tool to help them make the next treatment decision with their patient."

What the Future Holds

The disparate systems traditionally used by labs and clinics have obstructed the absolutely necessary, unbroken information stream that must exist in order to revolutionize patient care. A clinical LIMS is a natural extension of the clinical diagnostics market's need for a streamlined, end-to-end informatics solution that follows the patient from the point of disease testing through results analysis, diagnosis and treatment so that physicians can use the latest molecular tests, like those being developed at Foundation Medicine, to deliver advanced, personalized care.

And, as ground-breaking life science organizations such as Foundation Medicine continue to search for ways to innovate, the informatics tools that support them will evolve as well. It's not just about making the lab run better and faster—it's about finding entirely new ways of approaching a scientific question or tackling a therapeutic problem.

Foundation Medicine's Pellini agrees with that goal. "The more cancers we sequence, the more information we'll have to mine—and the more information we'll need to find a way to mine. There's no telling what we'll find."

Partnering with Thermo Fisher Scientific

Thermo Fisher Scientific is the worldwide leader in laboratory software and services, providing enterprise-wide, multi-laboratory solutions. To support our Thermo Scientific installations, we provide implementation, validation, training, maintenance and support from the industry's largest worldwide informatics services network.

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