

Dana Farber Poised to Shift 'Profile' Tumor Analysis Program From Research Study to Clinical Test

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 **Premium**

NEW YORK (GenomeWeb) – When Dana Farber Cancer Institute began its "Profile" tumor molecular analysis program more than five years ago, the practice of scrutinizing cancers for a wide range of informative genomic alterations was still in its infancy. In the meantime, the program has successfully analyzed close to 15,000 patient samples.

Profile [began in 2011](#) with the implementation of a Sequenom genotyping assay called OncoMap, which was limited to a couple of hundred well-characterized mutations in about 40 genes.

In 2013, Dana Farber moved from that first platform to a 270-gene and then to a 300-gene (soon to be 450-gene) targeted next-generation sequencing assay it calls OncoPanel.

Neal Lindeman, head of Brigham and Women's Center for Advanced Molecular Diagnostics — home to the CLIA lab that does the sequencing for Profile — told GenomeWeb this week that the program has now analyzed close to 15,000 patient samples.

The lab, which hosts two Illumina HiSeq 2500s, is adding about 400 new OncoPanel profiles to its database every month.

The institute is now working on transitioning the profile from a research program — which is offered to every adult and pediatric cancer patient that enters treatment at the hospital, regardless of stage — to a quasi-clinical test.

"We wanted to see if we could turn comprehensive genetic testing into a routine [practice], as simple as getting a blood test," said Dana Farber chief scientific officer Barrett Rollins. "It's become pretty clear that within the next five years or so, every cancer patient is going to need to have some sort of broad-based genetic profile of their cancer. In order for that to happen, you have to answer the question 'can you just turn the crank and do this?'"

"This has really been the triumph of this project, to show that we can actually make this happen," he said.

As a research study, Profile currently stores tumor molecular data in an isolated database, separately from patients' medical records, although data from the two sources can be linked in order to study molecular features or lesions in the context of patient outcomes or responses to particular therapies.

Dana Farber or Brigham physicians can request access to patients' Profile sequencing results in order to use them to guide treatment decision making or to funnel patients into available clinical trials, but

they have to seek that out actively.

Like many other cancer sequencing programs, Profile breaks down mutations or other alterations detected by the test into four tiers, Lindeman said. Tier one alterations have well-established links to an approved targeted therapy; tier two mutations have a connection to something more investigational; tier three mutations have links to data from animal or cell line experiments that may lend plausibility to a particular treatment, and tier four mutations have an unknown impact.

As a clinical service, the test results will move to being fully integrated into Dana Farber and its partners' medical recording systems, and according to Rollins and Lindeman, the expectation is that this shift will happen within about a year or two.

This month, the lab is taking some first steps in that direction, planning to launch a third version of OncoPanel, with about 450 genes, which Lindeman and Rollins described as a "hybrid, more clinical assay."

An important consideration in shifting Profile toward a clinical service is reimbursement, Lindeman and Rollins said.

"As a research test, we get no reimbursement. The cost is borne 100 percent by the institution, and we use philanthropic funds to cover what is about a \$6 million per year ongoing run rate," Rollins said. "Once it becomes clinical or even quasi-clinical ... we'll start getting some reimbursement, but you may know that the ability to get reimbursement doesn't mean you actually get it, so [we expect that] the majority of costs will still be philanthropy-supported."

"Most insurance companies are still not covering a test like this and when they do, reimbursement doesn't usually cover the cost of running the assay," Lindeman added. "But we think it's important to do this for our patients, and thankfully, the institution has an endowment to cover that gap."

To move not only Dana Farber, but also the field of cancer as a whole toward broader implementation of this type of sequencing program, Lindeman and his team are also working on a pilot study with Blue Cross and Blue Shield of Massachusetts, he said.

Although Profile is one of the largest programs of its kind, Dana Farber is not alone in pushing forward schemes for comprehensive genomic sequencing of cancers.

Memorial Sloan Kettering Cancer Center, for example, [reported earlier this year](#) that it had reached a milestone of 10,000 cases sequenced so far with its MSK-IMPACT assay, a 410-gene matched tumor/normal NGS panel.

In addition to the upcoming launch of the new version of OncoPanel, Lindeman said there are also other important changes in the works for Profile. For one, the program is planning to implement paired germline sequencing as part of the Profile analysis, probably by the end of this winter.

Research has [highlighted the importance of sequencing both tumor and normal tissue](#) from the same patient, other large-scale tumor sequencing programs, and other programs, like MSKCC's MSK-IMPACT, have chosen to implement paired germline sequencing alongside tumor sequencing.

Another recent change for the lab is the implementation of liquid biopsy-based cancer analyses in certain patients, Lindeman said.

The project added blood-based EGFR testing for lung cancer patients a few months ago, which Lindeman said is working "really well."

Right now, the lab's liquid biopsy program is limited to that single test. But based on the good results so far, the plan is to slowly expand to other cancers, and with that, to move from EGFR testing to a broader NGS-based approach.

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