



Survey of Precision Oncology Programs:  
**Rapid Pace of Advance  
Still a Major Challenge  
for Oncologists**

*By Turna Ray*

AS MORE PRECISION oncology drugs are coming to market, expert bodies are recommending a variety of biomarker tests for patients during earlier stages of disease. Consequently, cancer centers around the country are engaging molecular tumor boards to help oncologists keep up with advances and make clinical decisions based on test reports, according to a recent survey.

From July to November 2021, *Precision Oncology News* queried oncology leaders including practicing oncologists, program directors, and administrators with knowledge of precision oncology efforts at 20 healthcare institutions around the country to understand the investments they are making to facilitate cancer patients' access to biomarker testing and precision oncology treatments, and to address barriers that remain.

In this 3rd Annual Precision Oncology News Survey, 45 percent of respondents were from a National Cancer Institute-designated comprehensive cancer center, 30 percent were at a cancer center within a healthcare system, and the rest were from a university-affiliated cancer center, a nonprofit healthcare network, or private oncology practice.

As captured in the 2020 survey, this year, institutions are continuing to invest in internal capabilities to assess single genes associated with response to targeted drugs as well as immunotherapy biomarkers and are conducting targeted next-generation sequencing panels. Specifically, half of respondents this year indicated the ability to perform single-gene testing in-house, 45 percent said they could internally test for immunotherapy biomarkers, and 35 percent said they had in-house targeted NGS capabilities.

A 2019 survey by Novartis showed that a growing number of institutions had begun investing in internal NGS capabilities. While 83 percent of respondents to that survey said their organizations ordered NGS testing from commercial labs, there was a 58 percent increase from 2018 to 2019 in respondents reporting they could do NGS testing within their own labs.

### Testing for more biomarkers, earlier

However, in 2021, *Precision Oncology News'* survey still shows a lot of biomarker testing is still reliant on commercial labs, most popular being Foundation Medicine, Guardant Health, Tempus, and Caris Life Sciences (see **Figure 1**). For example, three-fourths of respondents indicated they send out liquid biopsy testing, at least half said they use commercial labs for whole-genome, RNA, and exome sequencing, and 45 percent said doctors order targeted NGS panels from outside labs.

In terms of immunotherapy biomarkers, the vast majority of respondents indicated that at

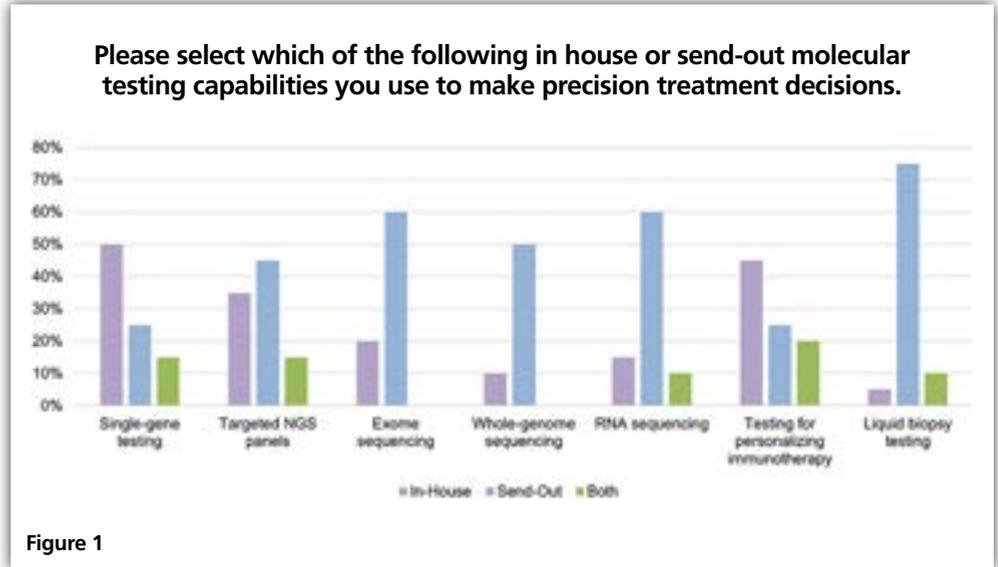


Figure 1

their institutions, patients under consideration for treatment with checkpoint inhibitors are tested for microsatellite instability and PD-L1 expression. Eighty percent of respondents said patients are also assessed for tumor mutational burden to guide immunotherapy decisions compared to around two-thirds of respondents in last year's survey who noted TMB was performed. The uptick in TMB analysis is likely the result of the US Food and Drug Administration's June 2020 approval of pembrolizumab (Merck's Keytruda) for any refractory solid tumor with TMB of at least 10 mutations per megabase (see **Figure 2**).

Over the past year, the FDA has also approved more biomarker-informed treatments in earlier disease settings (see **Figure 3**). For example, the agency last December approved osimertinib (AstraZeneca's Tagrisso) as an adjuvant treatment

for patients with EGFR mutations in stage IB to IIIA tumors that have been surgically removed. In October, the FDA approved atezolizumab (Genentech's Tecentriq) for NSCLC patients with PD-L1-expressing tumors as an adjuvant treatment after surgery and platinum chemotherapy. And AstraZeneca and Merck will soon hear from the FDA about their application seeking approval for olaparib (Lynparza) as an adjuvant treatment for BRCA1/2-mutated early-stage breast cancer patients at high risk of relapse (see indication updates on Lynparza site).

The emergence of these treatments is likely the reason why respondents from six institutions, or 30 percent, said they offer biomarker testing to certain cancer patients with stage I tumors. Eleven institutions offer testing to patients with stage II or III tumors, while only three cancer

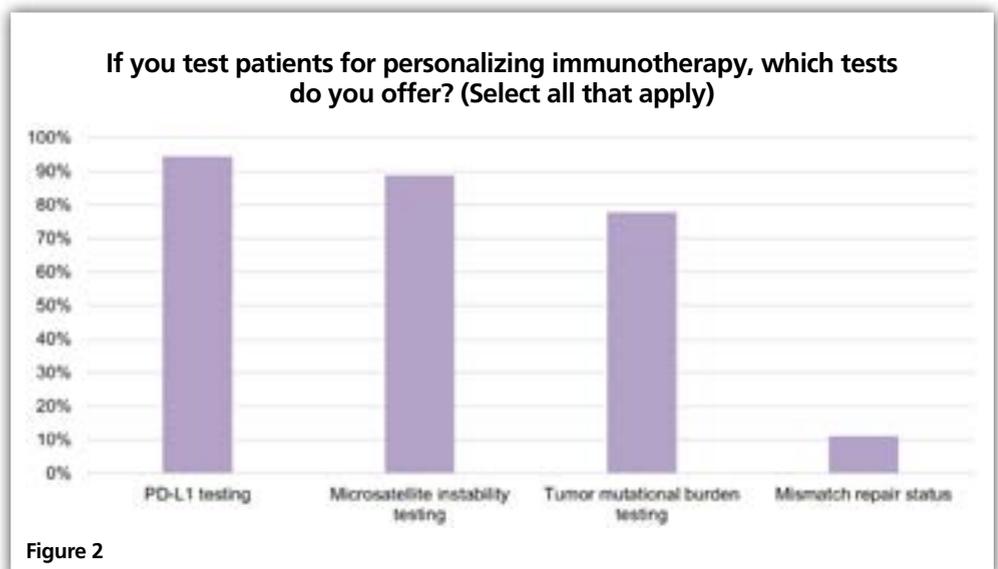
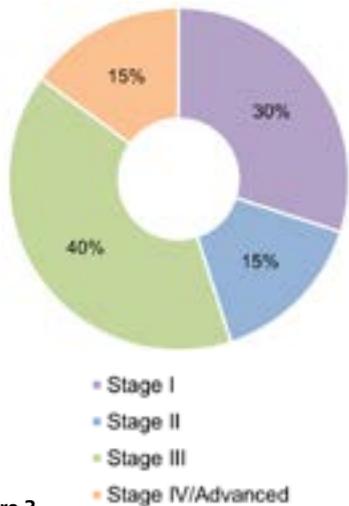


Figure 2

**What is the earliest stage of disease that cancer patients at your center are offered molecular testing to explore precision oncology options?**



**Figure 3**

centers offer biomarker testing mostly to patients with stage IV disease. Respondents specified that oncologists may order biomarker testing for patients with lung cancer, melanoma, rare cancers, and breast and gastrointestinal tumors in earlier stages.

The survey also asked respondents when

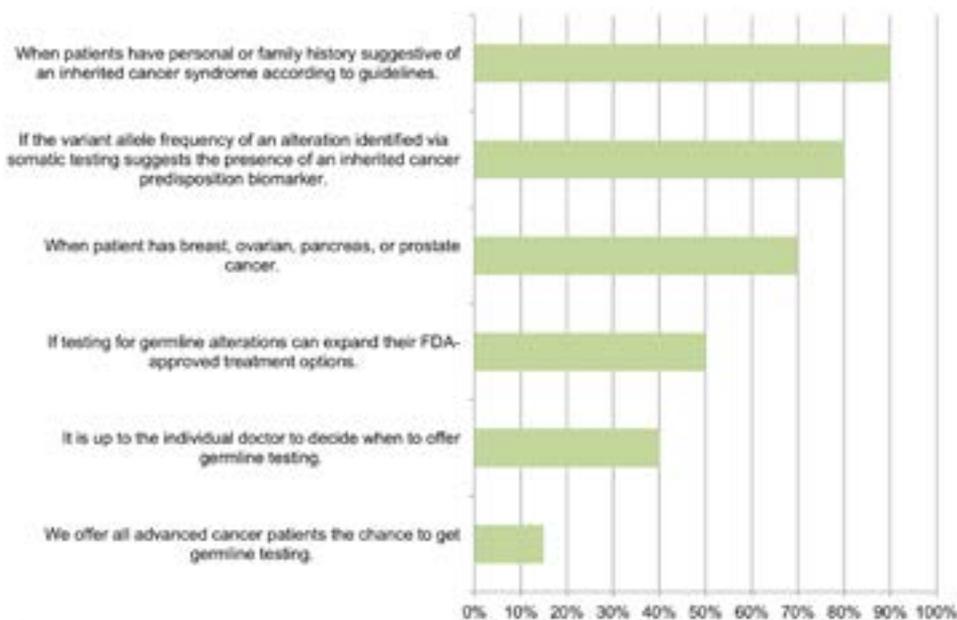
their institutions encouraged oncologists to order germline genetic tests for cancer patients (see **Figure 4**). Expert bodies such as the American College of Medical Genetics and Genomics have noted the importance of germline genetics alongside somatic testing when developing a treatment plan for cancer patients, since many

*“Expert bodies such as the American College of Medical Genetics and Genomics have noted the importance of germline genetics alongside somatic testing when developing a treatment plan for cancer patients.”*

studies have shown that using family cancer history alone may miss more than half of those with inherited risk mutations. The FDA has also approved drugs for tumors that harbor germline and somatic mutations in cancer-associated genes, such as BRCA1 and BRCA2. Knowledge of these mutations can inform not only treatment but also management strategies to reduce patients’ and their relatives’ future cancer risks.

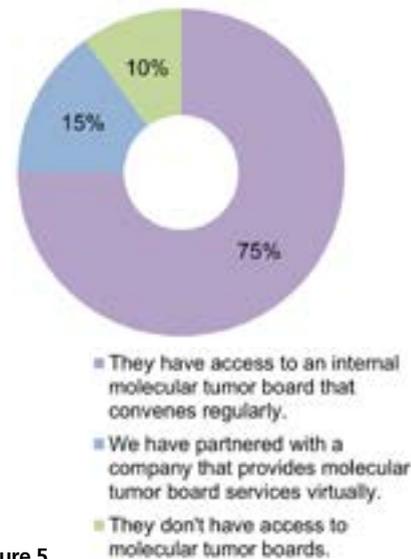
Eighteen out of 20 respondents to this survey said oncologists at their institutions relied on family cancer history to guide germline genetic testing decisions. However, since using family history alone can miss a significant number of patients

**At your institution/practice, when are oncologists encouraged to order germline genetic testing on cancer patients? (Select all that apply)**



**Figure 4**

**Do oncologists at your institution or practice have access to a molecular tumor board to help them make care decisions based on biomarker test results?**



**Figure 5**

who harbor cancer risk mutations, respondents encouragingly indicated that oncologists are also using other parameters when deciding whether to assess germline genetics for a patient.

Notably, 80 percent of those surveyed said oncologists are urged to order germline testing when the variant allele frequency of an alteration detected via somatic analysis suggests a patient may harbor an inherited cancer predisposition marker. Seventy percent said doctors are encouraged to order germline testing when patients have breast, ovarian, prostate, or pancreas cancer, which are tumor types that tend to harbor high-risk mutations. And half said doctors order germline testing if it can help patients get on an FDA-approved treatment.

Respondents from only three institutions said all advanced cancer patients are offered germline genetic testing, while respondents from eight institutions said the decision to order germline genetic testing is up to the doctor.

**From testing to precision treatment**

Given the growing number of therapeutically actionable biomarkers and the range of tests available to oncologists today, it’s no surprise that they need help making sense of test reports. In this survey, the majority of institutions are providing support through internal molecular tumor boards (see **Figure 5**) or bringing in precision oncology expertise via virtual MTBs.

Fifteen out of 20 respondents, or 75 percent,

**At your institution or practice, what are the main reasons why a cancer patient may not receive biomarker testing or the results in time to influence therapy decisions? (Select all that apply)**

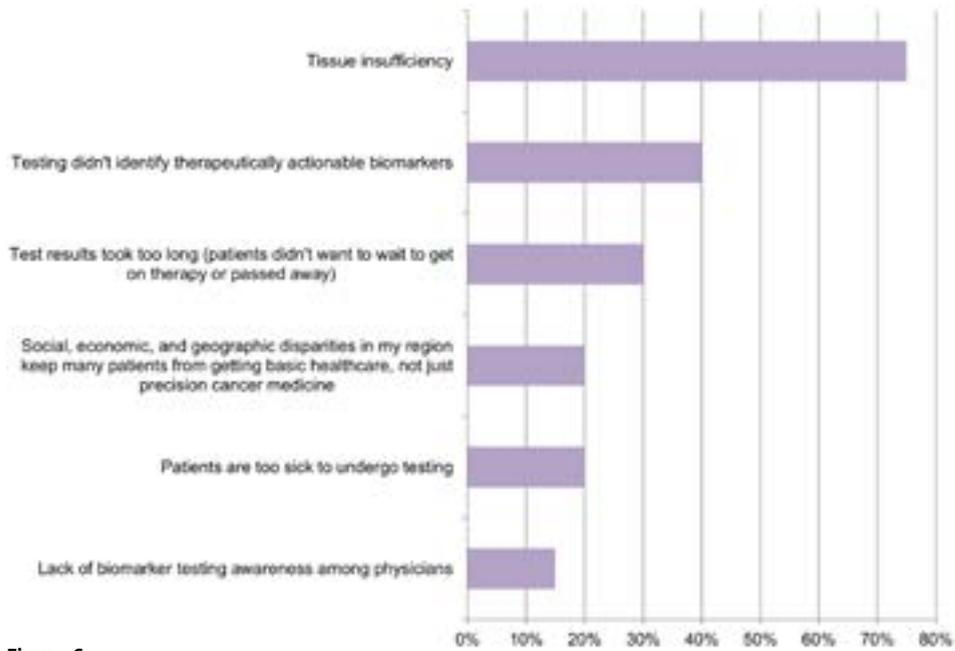


Figure 6

basic services as well as advanced treatments, like precision cancer drugs. In fact, several studies at the American Society of Clinical Oncology's annual meeting this year highlighted inequities in access to therapeutically actionable biomarker testing among lung and prostate cancer patients.

In this survey, respondents from four institutions acknowledged that social, economic, and geographic disparities in the region in which their institution is located hinder many patients from getting basic healthcare including precision medicine. Four respondents, meanwhile, said often patients are too sick to undergo biomarker testing, and three cited physicians' lack of awareness about testing as a barrier.

Since a cancer patient's best chance of getting precision treatment is often within a clinical trial, this survey also explored the accessibility of readily biomarker-informed studies (see Figure 7). Even though all institutions, except one, represented in this survey are running precision oncology trials, such as biomarker-informed single- and multi-cohort studies, a minority of tested patients are getting the chance to partake in them.

According to six respondents, less than 10 percent of patients at their institutions get on

said oncologists at their institution had access to an internal MTB to help them make sense of biomarker test reports. Three respondents said their institutions had partnered with a company providing MTB services virtually. Oncologists

*"While some cancer centers are trying to improve tissue requisition and turnaround time for biomarker testing by streamlining organizational procedures, other challenges limiting healthcare access, such as longstanding racial biases, will take longer to mitigate."*

**What percentage of your current patients are enrolled in precision oncology trials based on a molecular marker?**

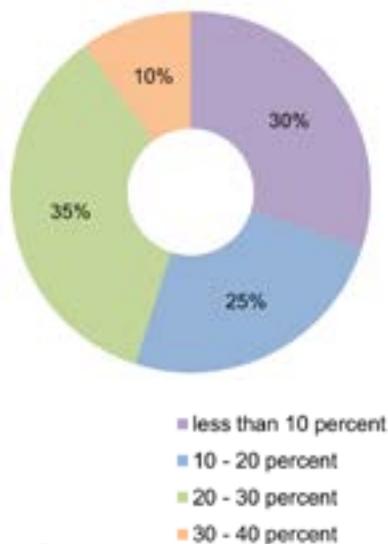


Figure 7

at two institutions in the survey don't have access to MTBs.

However, even when patients receive biomarker tests, they may not receive actionable results, or the results may come too late to influence decisions about treatment or clinical trials (see Figure 6). Tissue insufficiency was the most frequently cited reason in this survey for why patients aren't receiving precision cancer care, followed by the lack of identified actionable biomarkers and slow test turnaround time.

While some cancer centers are trying to improve tissue requisition and turnaround time for biomarker testing by streamlining organizational procedures, other challenges limiting healthcare access, such as longstanding racial biases, will take longer to mitigate. The pandemic put a spotlight on these issues and energized discussions around how to improve systemic and racial barriers to accessing

**What is the biggest challenge for oncologists at your institution or practice in implementing precision oncology? (Select one)**

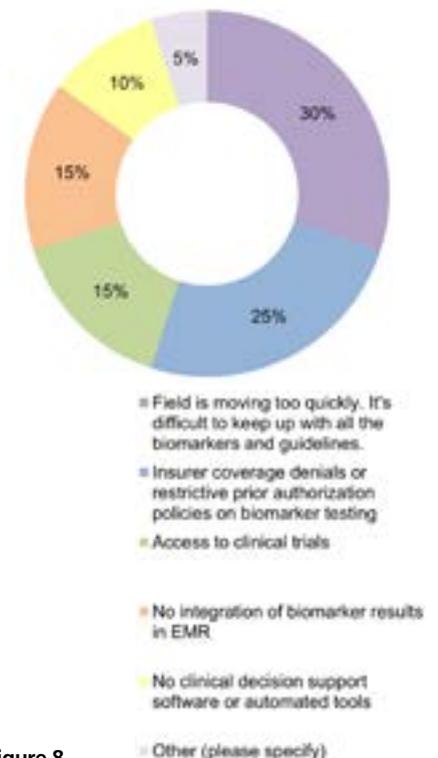


Figure 8

### What resources does your institution or practice have to identify and address gaps in biomarker testing and precision oncology treatment access? (Select all that apply)

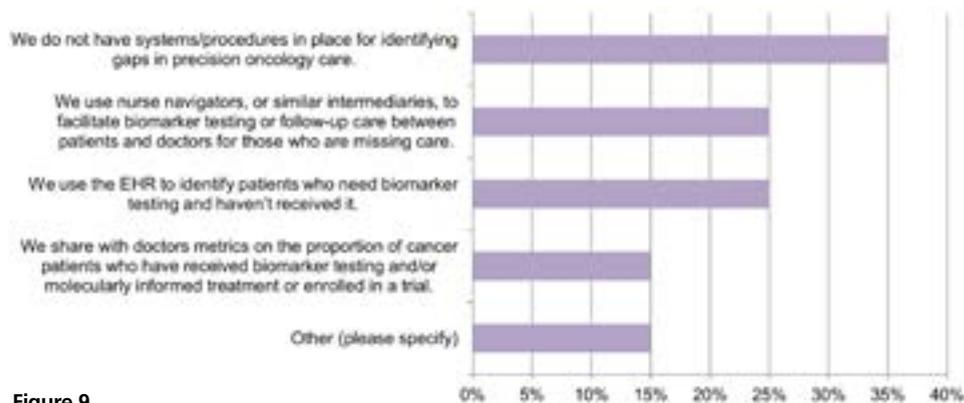


Figure 9

a biomarker-informed trial. A dozen respondents estimated the proportion of enrolled patients to be between 10 percent and 30 percent, while only two respondents said that between 30 percent and 40 percent of biomarker-tested patients at their institutions enroll in a trial based on an identified tumor alteration.

Out of 12 respondents that indicated 20 percent or fewer patients at their institutions typically enroll in precision oncology trials, the majority said other enrollment criteria often hindered patients from getting on a study for which they matched a tumor marker. Around 25 percent said patients' unwillingness to travel limited their ability to access trials. Of the respondents who wrote in other reasons, one cited that the time and effort necessary to find trials for patients were barriers.

Difficulty accessing clinical trials, however, is not the biggest challenge oncologists face in delivering precision oncology to patients. Respondents most

frequently cited the rapid pace of advances in terms of actionable biomarkers and changing guidelines as the top hurdle for oncologists trying to practice precision oncology, overtaking restrictive insurer policies, which was the top challenge for the field in the 2019 and 2020 surveys (see Figure 8). Like in past surveys, respondents continue to flag IT challenges, such as the lack of biomarker test result integration in electronic medical records and no clinical decision support.

One respondent said it can be particularly challenging to justify the cost of keeping clinical trials open that aren't enrolling because the biomarker of interest shows up rarely in cancer patients. In such cases, when the precision oncology trial is taking a long time to enroll, the institution may want to shut it down, the respondent said.

When asked what resources institutions have to flag access gaps in precision oncology, a quarter of respondents noted the use of nurse navigators

or the EHR to identify patients not receiving appropriate care (see Figure 9). At one respondent's institution, the precision medicine team identifies the needs and opportunities for improvement for patients with specific disease states.

Ultimately, 15 percent of respondents said that doctors at their institutions are aware of the proportion of patients receiving biomarker testing and molecularly informed care. However, 35 percent, or seven respondents, said their cancer center or health system didn't have any systems in place for tracking whether patients have equitable access to biomarker testing, trials, and precision therapies.

On the other hand, when asked how their institutions are measuring the success of their precision oncology programs – as opposed to how they're measuring gaps in access – only two respondents said their cancer centers don't have such metrics in place (see Figure 10). This year, as in last year's survey, respondents commonly said they looked at the number of patients enrolled in trials or receiving treatments based on biomarker test results, as well as the proportion of patients who received testing. Notably, nine respondents, or 45 percent, said their institutions considered patients' outcomes on molecularly informed treatments when assessing if precision oncology programs are actually benefiting patients – an improvement compared to only four respondents who cited this in 2020.

In conducting this survey, *Precision Oncology News* reached out to individuals in leadership positions at cancer centers, hospitals, and community practices around the country, and made a particular effort to reach smaller institutions and practices. While the 20 respondents are from institutions located all over the US, more NCI-designated comprehensive cancer centers and large regional facilities are included, and therefore, facilities that have made early and significant investments in precision oncology continue to be overrepresented in the survey. The challenges and access gaps identified in this survey are sure to be more pronounced within community practices with limited resources, where most cancer patients in the US receive care. [JOPM](#)

### What metrics do you use to gauge the success of your precision medicine program? (Select all that apply)

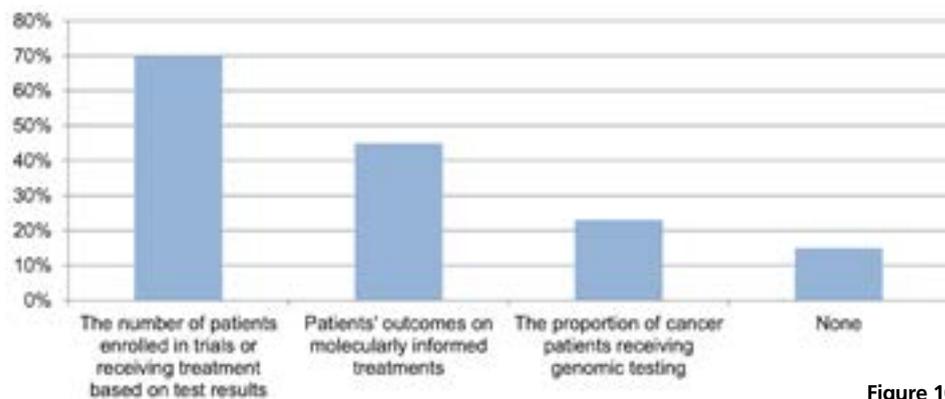


Figure 10



Turna Ray

Turna has been covering the personalized medicine and molecular diagnostics industries for GenomeWeb since 2006. She closely tracks the evolving regulatory, reimbursement, and business environment for precision medicine products. In 2019, she became managing editor of *Precision Oncology News*, and guides coverage for the publication.