From Possibility to Clinical Imperative:

Why Standardizing Precision Medicine Should Be a Top Priority for Cancer Centers and Oncology Practices of Every Size

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INSIDE:

- *Why* testing and treatment decisions may be inconsistent across your practice
- *How* to prevent over- and under-testing and align on appropriate treatments, including clinical trials
- *What* an advanced technology solution could look like

Table of Contents

Abstract

The field of oncology is rapidly changing. Not only is treatment becoming more precise, but the speed of innovation is compounding each year. As more targeted therapies come to market, more patients have the hope of living a longer life.

For oncologists, however, the amount of critical information that must be taken into account at the point of care is steadily increasing, which has made it nearly impossible for general providers—and even specialists—to keep up. This information overload is creating knowledge gaps that can lead to over- or under-testing and inconsistent treatment decisions, even for providers within the same practice.

Some cancer centers and community oncology groups have implemented clinical data systems, but those do not connect the dots between diagnosis, the most appropriate tests and treatments, what a patient could be pre-approved for, or what payers are most likely to cover. This lack of alignment with payer policies exacerbates an already complex system by slowing the decision-making process when time matters most for patients.

Combined, these challenges make it difficult for practices to standardize quality care regardless of their size or resources. **Finding a solution that empowers providers in their daily practice is imperative to speed progress in the effective use of precision medicine.**

In this paper, we will explore seven key reasons it is now critical to standardize precision medicine in oncology care and the ways that leading cancer centers and community oncologists are successfully implementing standardization solutions and driving change.

As a greater number of targeted therapies come to market, more cancer patients have real hope for improved outcomes.

Introduction

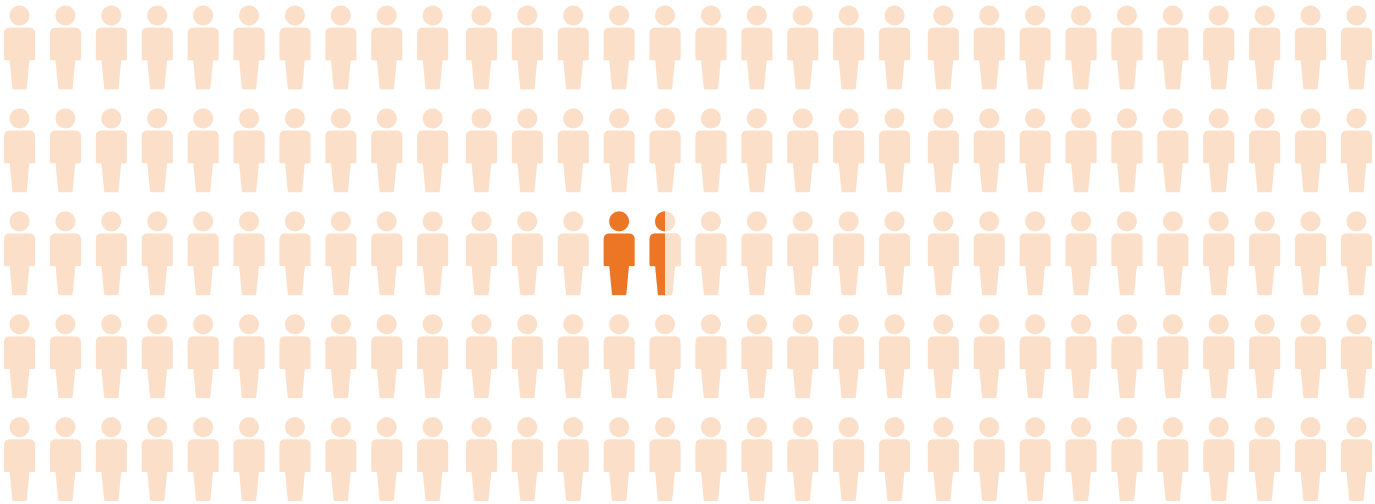
As of 2017, 73% of oncology drugs in the development pipeline were personalized medicines (PMC, 2017). By 2018, they accounted for over 55% of all FDA drug approvals (PMC, 2018). The pace of science continues to accelerate, and more life-saving precision therapies are coming to market each year, particularly those that target lung, breast, and prostate cancers, as well as melanoma and acute myeloid leukemia.

Precision medicine is promising, but not all oncologists have the same level of certainty or the resources they need to keep pace with advances and apply them appropriately at the point of care. Even those in the same practice may choose different molecular tests and labs, and some are hesitant to order molecular testing at all. Meanwhile, burdensome prior-authorization processes amplify decision-making complexities, often causing treatment delays.

Today, personalized treatments are routinely offered in academic medical centers, yet about 80% of cancer patients across the U.S. are treated outside of those institutes by a community oncologist, making it more important than ever to standardize the application of precision medicine at every level (Amgen, 2019).

Whether at large cancer centers or within community practices, new processes and technologies are needed to help all oncologists manage these complexities and provide the most appropriate treatment for their patients without unnecessary delays. Oncology practices and providers that do not have supportive solutions in place at the point of care will quickly fall behind.

Of the nearly 2 MILLION people diagnosed with cancer in the U.S. each year, precision medicine is still only reaching a small percentage.
(Newsweek, 2019)



The benefits of standardizing precision medicine

BENEFIT 1:

Keeps oncologists up-to-date with all available clinical evidence for precision medicine

Oncologists dedicate much of their lives to giving patients the best chance in their journey with cancer, but the pressures they face today are tremendous. There is simply too much information published too frequently from too many sources, making it difficult if not impossible for them to keep up in real time.

Oncologists must factor in thousands of data points for each patient's treatment, ever-changing clinical information, and complex insurance and reimbursement policies, all while making life and death decisions. And, they must do this for an increasing number of patients. The cognitive burden has never been greater.

Today, there are decision-support technologies that help oncologists keep up with the changing information so they can focus more time on helping patients, but they are not all equally beneficial. Ideally, cancer centers and community practices will choose a system that is continuously updated by a team of molecular scientists and oncology specialists to ensure that physicians have access to the most up-to-date, published clinical evidence and clinical trial information and can access real-time, patient-centered insights at the point of care. It is just as important that the decision support provided aligns with payer policies to avoid the complications of prior authorization.

In 2017, The Academy published a survey that surprised many people.

100%

of responding executives reported that it is either important or very important for oncologists to have easy and fast access to integrated clinical and molecular information at the point of care.

(The Academy, 2017)

"The rapid expansion of knowledge is outpacing our ability to incorporate it into our daily clinical practice, even for experts in the field. We must ensure that we bridge this gap so all patients may reap the benefits of our progress." (ASCO, 2019)

DR. JOHN L. MARSHALL

Chief, Oncology Division at MedStar Georgetown Director, Otto J. Ruesch Center for the Cure of Gastrointestinal Cancer at Georgetown Lombardi

BENEFIT 2:

Ensures every patient is tested appropriately, resulting in better treatment and better outcomes

Molecular testing plays a foundational role in the application of precision medicine, but ambiguity and variability in the tests and panels offered across laboratories can be difficult for oncologists to sort through. The lack of a centralized and comprehensive source of testing information can further complicate their ability to make informed decisions. For instance, it may not be clear **which tests or testing panels can provide all the necessary and most valuable results for a particular patient. Additionally, because testing information is often decentralized, it can be challenging to translate results and then determine the most appropriate treatment.**

Oncologists need evidence-based guidance to decide which tests to run for each patient, which lab to use, how best to interpret the results, and how they can inform treatment decisions. In addition, they need to know whether the tests and treatments they choose will align with their patients' insurance guidelines.

By standardizing the molecular testing process, practice leaders can be confident that up and down the halls of their organizations, every patient has access to the potential benefits of precision medicine and is being treated with the highest level of care.

When oncologists do use molecular testing, it does not always drive better treatment decisions. A 2019 ASCO abstract revealed that

oncologists incorrectly matched the molecular alteration to the targeted therapy in up to

69%

[of cases].

This reflects a large knowledge gap among community oncologists with regards to the correct application of MP [molecular profiling] to currently FDA-approved, targeted therapies.

Having a technology that demystifies lab test ordering and results interpretation could help oncologists avoid under- or over-testing and enable them to make better decisions faster.

BENEFIT 3:

Gives oncologists confidence and promotes accuracy

In practice today, some oncologists are simply more comfortable using precision medicine than others. They are more confident ordering molecular tests and interpreting the results, and they know that their treatment choices will reflect the latest evidence. But for the vast majority, this is not the case.

Dr. Jack West, Associate Clinical Professor at the City of Hope, attributes much of this gap to a divide in the level of specialization academic physicians have versus community physicians. He says, "Specialists and academic oncologists can more easily—and with more certainty—convince patients that it's okay to wait a couple of weeks for the data to ensure they are prescribing the most appropriate treatment and not just the most rapid treatment. On the other hand, community oncologists often treat between 10–15 different types of cancer in a single day, and they are time-pressed by expectations to treat quickly with well-established approaches."

Dr. West suggests that bridging this gap will be necessary to maintain or improve the quality of care as precision medicine grows. Technologies that disseminate knowledge and best practices based on the most current clinical evidence level the playing field, enabling ***all*** oncologists to provide care with the same, expert-level of precision.

Specialists and academic oncologists can more easily—and with more certainty—convince patients that it's okay to wait a couple of weeks for the data to ensure they are prescribing the most appropriate treatment and not just the most rapid treatment."

(The Precision Medicine Podcast, 2019)

DR. JACK WEST
Associate Clinical Professor,
City of Hope National Medical Center

59%

of physicians currently report challenges in understanding molecular testing results in a clinical context.
(Cardinal Health, 2018)

BENEFIT 4:

Resolves stakeholder conflicts

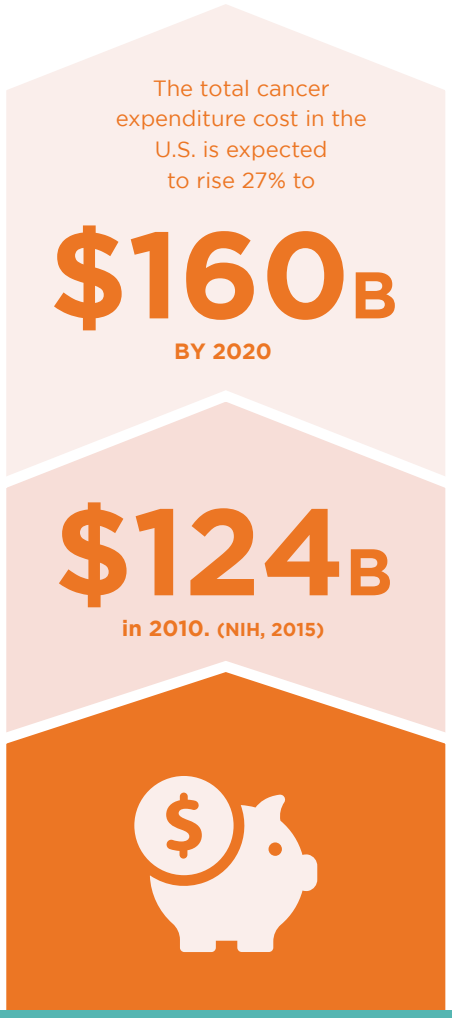
There are many stakeholders involved in the use of precision medicine, some of whom may have competing or conflicting perspectives.

For instance, labs encourage the use of their own tests in more and more clinical scenarios, leaving providers and payers to sort out what is appropriate and should be covered.

Understandably, payers feel pressure from all sides as they try to balance the cost of precision medicine against rising deductibles and out-of-pocket expenses for their members, yet they too lack the resources and expertise to sift through the evidence and evolving options. The result is that payer coverage policies may lag behind the latest evidence.

Doctors want better information at the point of care to give their patients the treatment most likely to result in the best outcome. But the market is dependent on disparate systems and divergent points of view, so they cannot always be sure their decisions will be reimbursed.

Collaborative solutions facilitate the appropriate use of molecular testing, help labs get reimbursed for the value they provide, and give doctors easy ordering from high-quality labs and interpretable, actionable results—all while automatically complying with the medical policies of each patient's insurance. Today's most sophisticated decision-support technologies use models like these to enable standardization while optimizing precision care for better patient outcomes.



The effective, scalable use of precision medicine requires a coordinated, collaborative and transparent solution that is based on the most current clinical evidence.

BENEFIT 5:

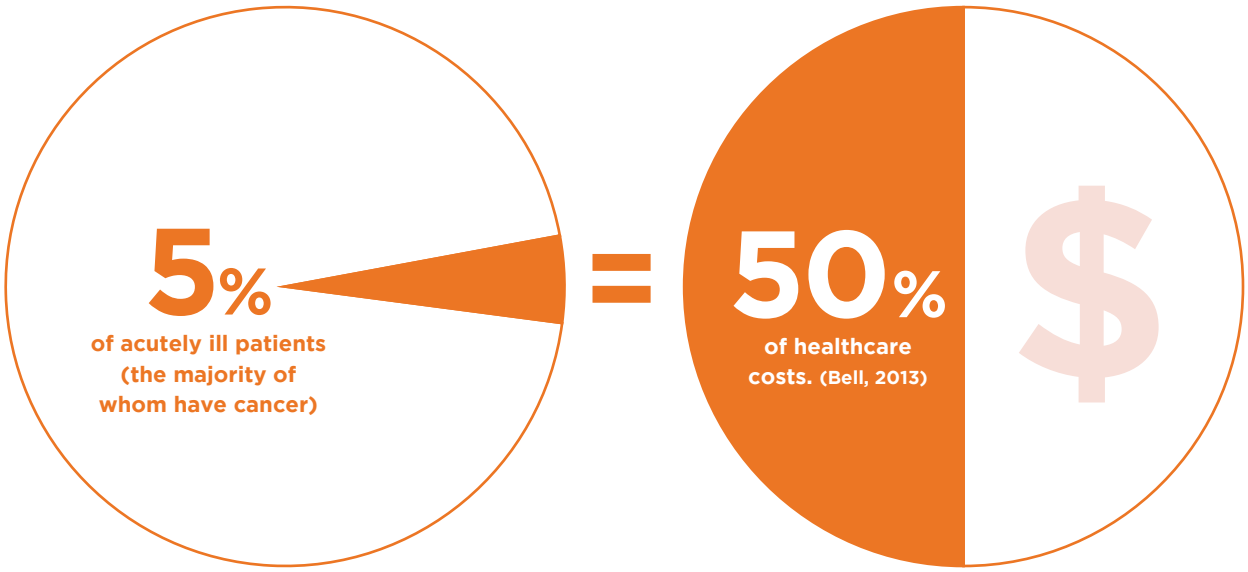
Creates value-based care models that encourage higher quality and cost management

Treating cancer is expensive, but is especially costly when treatments don't work, come with high toxicity or long-term side effects. More targeted testing can ensure interventions are used for those most likely to benefit while sparing others the expense and side effects of ineffective treatment. But to realize the value of precision medicine, practices must optimize how they are applying it. They must know:

- **which practice locations are most compliant with established precision-medicine standards;**
- **which doctors ordered more molecular tests than clinically necessary and which ordered fewer; and**
- **whether the practice's overall use of precision medicine is better this year over last.**

Some practices have specific technology designed to provide this type of data, but for most, it is simply not available. It should be. Practice directors perform a never-ending balancing act between providing the best care to cancer patients while meeting productivity requirements and ensuring optimum reimbursement. Having the ability to track data, analyze the practice, and evaluate business operations can provide the insights they need to generate more revenue while also ensuring patients receive the most appropriate and highest-quality care across the practice.

To realize the value of precision medicine, practices must standardize how they are applying it.



BENEFIT 6:

Simplifies reimbursement complexities and streamlines prior authorization

Molecular labs actively promote the use of their tests to oncologists who may or may not understand everything that is included in a testing panel. Many times these panels will not be reimbursed by payers because it is unclear what was tested or whether current clinical evidence supports their use.

For doctors to make fully informed decisions, they need test recommendations based on current evidence, guidance on practice and preferred laboratories, and information on payer coverage policies before they order a test. Greater transparency throughout the process can ensure that reimbursement is working in tandem with, and not in opposition to, a practice's workflow process.

Chet Burrell, former president and CEO of Care First Blue Cross Blue Shield, believes that aligning with payers from the start is the key to simplifying the complexities associated with prior authorization. He says, "Clearly the prior-authorization process is cumbersome and expensive for both the provider and the payer. There's often a struggle by the payer to understand what tests were ordered, why they were ordered, and how those tests will affect treatment. If a system can automatically tell payers what test will be conducted, why they are valid, and what treatment the patient will receive based on the results, payers will not have to approve every single test and every single treatment. That will save money."

Technologies that address covered services at the point of care before decisions are made will ultimately help providers and payers work together to manage the growth of precision oncology and provide better member care at a lower cost.

> **"If you can automate the answers... payers will not have to approve every single test and every single treatment, and that will save money."**
>
> (The Precision Medicine Podcast, 2019)
>
> **CHET BURRELL**
> former president and CEO,
> Care First Blue Cross Blue Shield

In a survey...

26%
of payers reported publishing guidance on biomarker coverage.

19%
of payers reported having coverage for Genomic Sequencing Panels (GSPs).
(Novartis, 2016)

BENEFIT 7:

Facilitates efficient matching of patients to clinical trials

Most oncologists today believe that clinical trials should be considered when evaluating treatment options, but too often clinical trials are overlooked or come into the decision-making process too late.

The best time to start thinking about clinical trials is from the start.

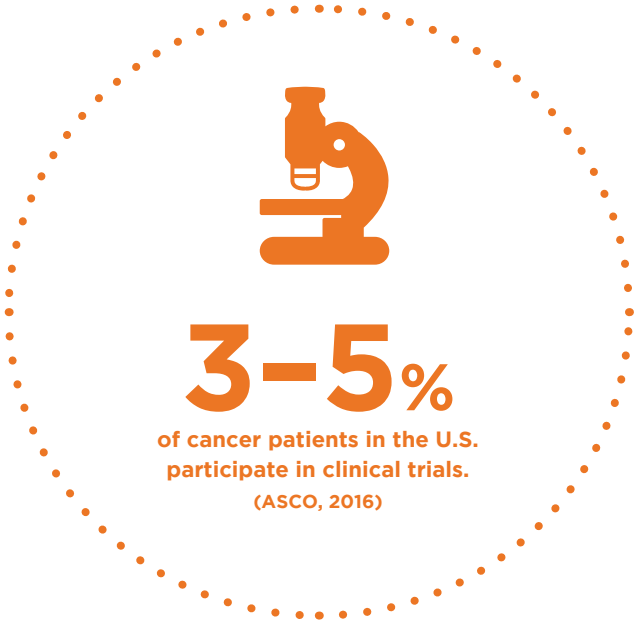
By providing on-demand access to updated clinical trial information within the clinical workflow, everyone in the practice—from doctors to research coordinators—can identify clinical-trial candidates early in the process.

Advanced technology platforms can match patients to appropriate clinical trials based on molecular eligibility as well as clinical and geographic specificity. Further, the practice can be alerted of potential clinical-trial options during the initial test-ordering process and select the appropriate trial laboratory. This upfront intelligence simplifies and shortens the eligibility process and enrollment time period for the patient. Such advanced systems can also help practices accrue patients for their own clinical trials by prioritizing in-network trials.

"Making sure that every oncology patient can access treatment options according to their genetic or molecular profile is really the future of cancer care. I'll never forget my oncologist telling me that if I had come in five years before, he would have had no treatment options to suggest to me and how quickly the science moves."

(The Precision Medicine Podcast, 2019)

LAURA HOLMES HADDAD
author, *This is Cancer,* stage 4 inflammatory breast cancer survivor, and clinical trial advocate.



What's needed: an advanced solution for the new age of precision oncology

There are clear benefits to standardizing precision oncology across practices, yet there are equally clear challenges, including:

- how to ensure all oncologists have access to the same level of clinical insight at the point of care;
- how to automate the process of molecular test ordering;
- how to optimize results interpretation;
- how to make doctors aware of available clinical trials in and out of network; and
- how to address prior-authorization before clinical decisions are made.

Because the use of molecular testing is inconsistent among physicians, precision medicine is only reaching a small percentage of those who need it, and an equally small percentage of cancer patients participate in clinical trials. By using technology to standardize and track the use of precision medicine at the point of care, practices can ensure that patients who may benefit from precision therapy and clinical trials are afforded that opportunity.

Practices have access to more technology options than ever before to manage the growth and complexities of precision oncology in real time, and provide oncologists with the insights they need, exactly when they need them. Evidence-based technology guidance can ensure physicians don't miss opportunities to prescribe precision therapies when appropriate or identify ideal candidates for clinical trials. While many technology solutions rely on artificial intelligence (AI), an ideal solution would merge AI with intelligence from highly trained clinical scientists who can ensure that the system is adapting to new scientific and clinical discoveries and that new information is interpreted and communicated accurately to ensure patients benefit safely at the frontlines of clinical care.

While many decision-support technologies offer some of these benefits, most only support a single stakeholder, which ignores the real problem—misalignment between stakeholders in cancer care, including practices, oncologists, labs, payers, and pharmaceutical companies.

For a solution to effectively manage the growth and complexities of precision oncology, it must merge AI and real intelligence, ensuring that technological recommendations and information have been audited by a team of highly trained scientific experts in the field.

As Clynt Taylor, CEO of Trapelo Health, points out, "If we can't find a way to fix these problems by aligning the interests of all the stakeholders, then we are doing a disservice to everyone, and we're going to exacerbate the problem, making it tougher for cancer patients to get the best care. The promise of precision medicine cannot be realized without collaboration between all key stakeholders."

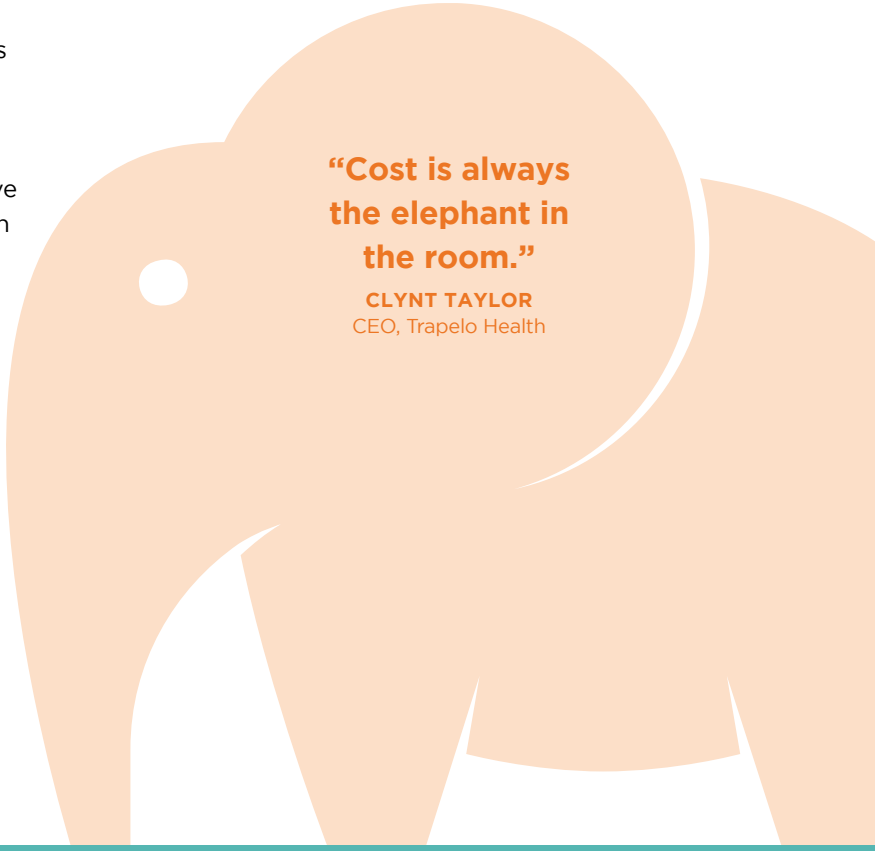
Insurers struggle to maintain policies that keep pace with the rapid evolution of precision medicine. This is placing increased pressure on all stakeholders as they continue to rely on traditional and unscalable prior-authorization processes.

To be fair, payers are not simply protecting their bottom lines. They are also protecting consumers from the rising deductibles and out-of-pocket costs exacerbated by the high cost of oncological care. In the long run, evidence-based decision-support offers the reassurance payers need that precision oncology tests and treatments are being chosen and applied appropriately.

In a Precision Medicine Podcast interview, Dr. Lee Newcomer, board-certified oncologist and former Senior Vice President of Oncology and Genetics at UnitedHealthcare, was asked: who should be controlling the development and reimbursement of lab tests? He responded, "I believe there's an immediate future in which payers will work in tandem with molecular labs and oncology practices to ensure patients are getting the right test, that they are clinically validated, and that they are reimbursed fairly." (The Precision Medicine Podcast, 2019)

A technology that can automate reimbursement policies based on the most current clinical evidence may protect payer interests as much as those of oncologists. Assuring payers that the molecular tests run are actionable and will produce clinically-valid results—and that oncologists are applying treatments that are connected to the results of those tests—is the most effective way to establish a record of evidence-based treatment decisions.

There are a few technology platforms that integrate prior authorization into the established workflow and more that provide evidence-based decision support at the point of care. What's truly needed to help practices standardize the use of precision medicine is an advanced, data-driven solution that combines these functions by aligning stakeholders to truly ensure better outcomes for more patients.



Conclusion

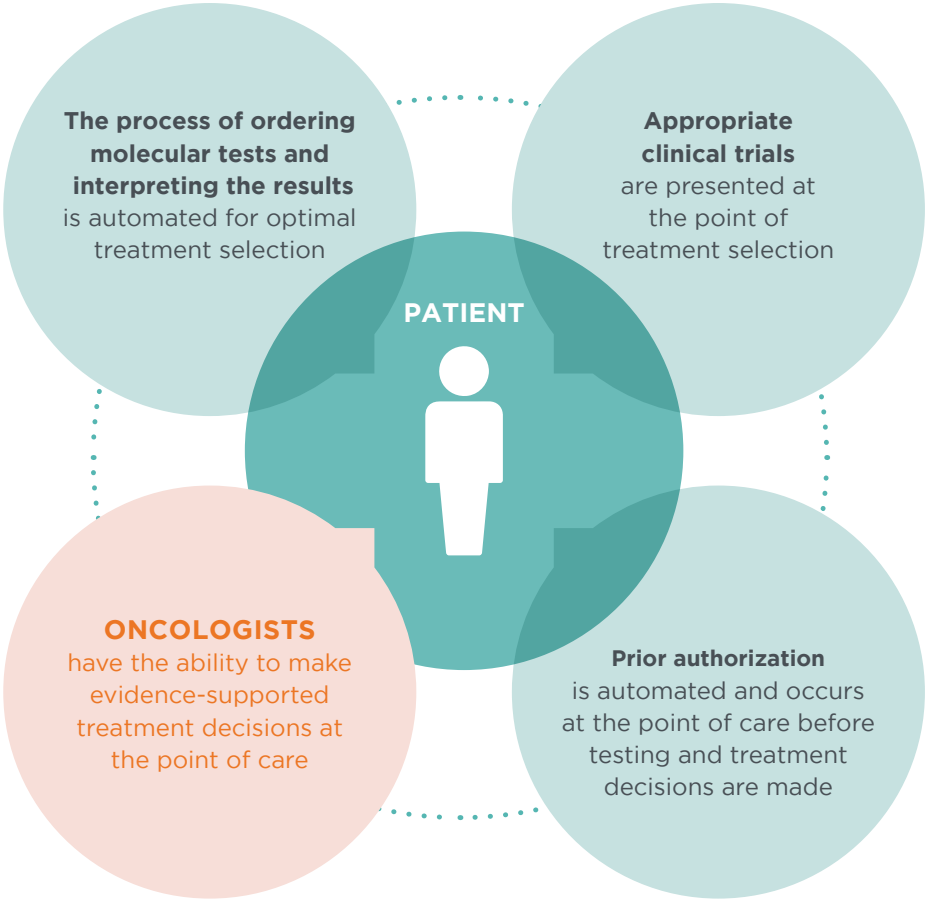
The time to standardize precision oncology at the point of care is now.

Today, there are more technology tools available to help leading cancer centers and community oncologists streamline their approaches to ensure every patient has the best chance in his or her journey with cancer.

The question is, what will it take to encourage practices to really optimize precision-medicine best practices?

Understanding that precision medicine is imperative is a good start, but more important is understanding the challenges that must be addressed. The complexities facing all stakeholders are intertwined and can only be untangled by aligning everyone around shared solutions that make decision-making, standardization, and reimbursement manageable while keeping the focus where it should be—on the patient.

An Ideal Approach to Standardizing Precision Medicine



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Prior to joining City of Hope, Dr. Salgia served as tenured professor of medicine, pathology, and dermatology; Director of the Thoracic Oncology Program and the Aerodigestive Tract Program Translational Research Lab in the section of hematology/oncology; Vice Chair for translational research in the department of medicine; and Associate Director for translational science at the University of Chicago Comprehensive Cancer Center in Chicago. Dr. Salgia was also on the faculty for a decade at Dana Farber Cancer Institute (the principal teaching affiliate of Harvard Medical School) /Brigham and Women's Cancer Center.

Dr. Salgia earned his medical doctorate and Ph.D. from Loyola University in Chicago, IL, where he also completed fellowships in neurochemistry and physiology. He continued his postgraduate training in internal medicine at The Johns Hopkins Hospital in Baltimore, MD, followed by a fellowship in medical oncology at Dana-Farber Cancer Institute, during which time he also served as a clinical fellow at Harvard Medical School.

Board-certified in both internal medicine and medical oncology, Dr. Salgia serves on various panels for the National Cancer Institute. He has consistently received research grants from the NIH for his research work and has been awarded several invention discoveries and patents related to his work. He is the current Chief Editor for Cancer Commons, and Co-chief Editor for the Journal of Carcinogenesis. Dr. Salgia also serves on the editorial advisory board of four additional journals.
He has authored 286 peer-reviewed articles, reviews and editorials, one book, and 34 book chapters.

Janine Morales, Ph.D.
Trapelo Health

Janine Morales, Ph.D. joined the Trapelo Health team in 2011, and oversees a team of editors and curators with deep expertise in molecular oncology as Senior Director of Clinical Knowledge Systems Janine's group is responsible for maintaining the company's clinical information asset; a comprehensive knowledge-base that summarizes published data pertaining to molecular biomarkers as predictors of response to targeted therapies in oncology. Janine also led the development of Trapelo Healths' framework for the systematic evaluation and synthesis of molecular clinical evidence as well as the principles guiding the presentation of molecular evidence in patient-specific reports.

Janine has 15 years of editorial and information-management experience in the biotech and medical sectors and was a member of research and development teams at Elan Corp. and DNAX Research Institute (acquired by Merck & Co). Janine received a BS in Biochemistry from the University of Rochester and earned her Ph.D. in Pharmacology from the University of California, San Francisco.

About Trapelo Health

Trapelo Health (formerly Intervention Insights) is an information technology company on a mission to address the challenges that result from rapid changes in the science, technology, and business of next-generation cancer care. Its decision-support technology, Trapelo, is a win-win solution for doctors, labs, and payers that need real-time, evidence-based information and full transparency to make patient-based decisions faster.

To learn more about how Trapelo supports oncologists and their practices, visit trapelohealth.com.

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