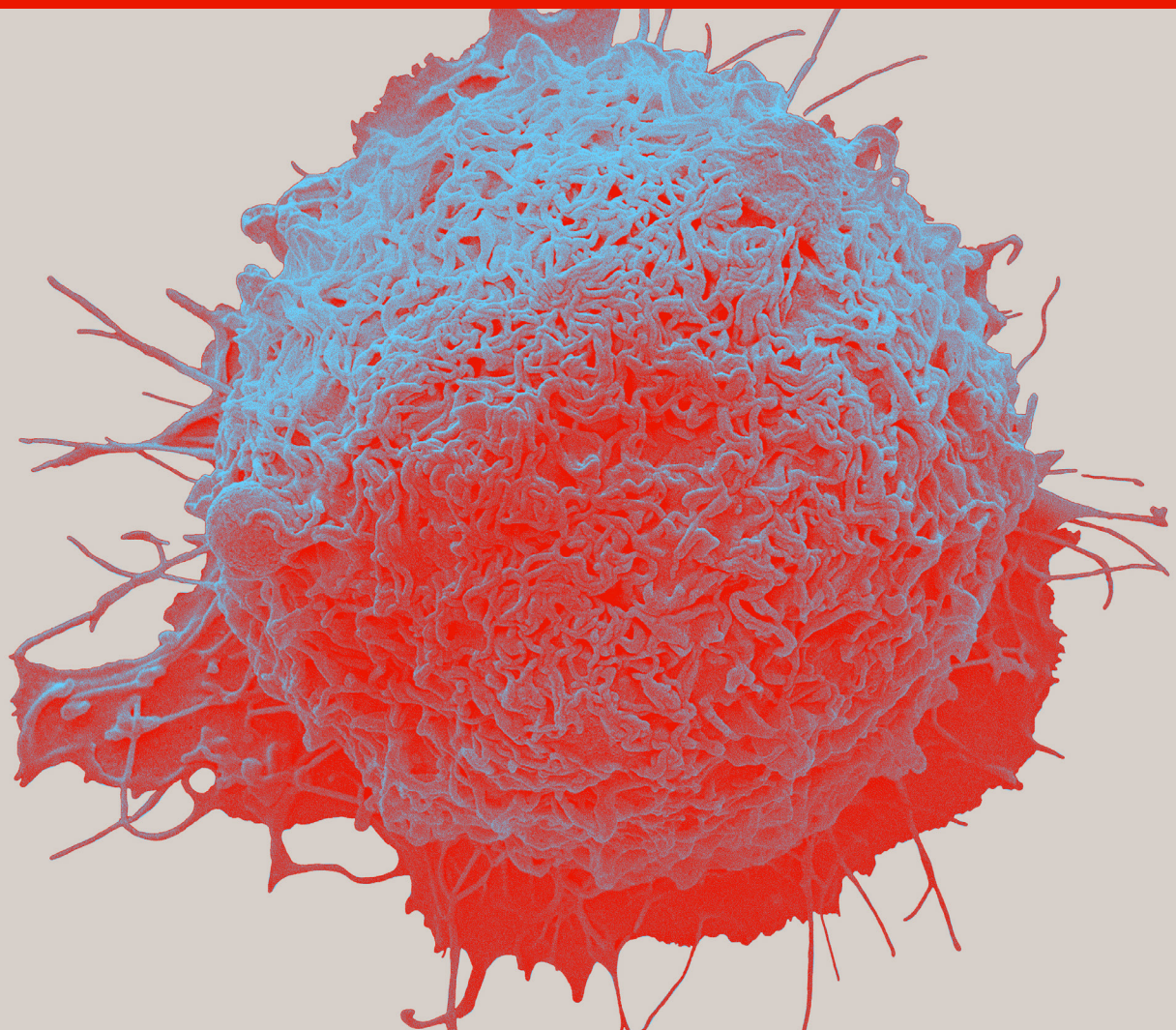
Precision Medicine:

Biomarker Testing Challenges, Opportunities, and the MDT

J&J
Precision Medicine



Predictive biomarkers transform patient care by informing therapy decisions[1–4]

As of 2025 there are:

89
biomarkers **recognized by the U.S. FDA** or **recommended in professional guidelines** for predictive biomarker testing[1]

110
FDA-approved precision oncology therapies, including targeted therapies and ICIs[1,2]

11
ICIs approved[2]

1 in 3 patients
with cancer may be eligible for biomarker-informed therapy[3,4]

Opportunities in biomarker testing

A growing number of **patients with advanced cancer are eligible for biomarker-informed care** because of increases in[5,6]:

- Number of tumor types with biomarker-informed therapies
- Number of tumor-agnostic approvals

However, many patients with advanced cancer **do not receive multi-gene NGS panel testing**[7–12]

In retrospective studies, NGS biomarker testing rates in advanced cancers were[11,12]:

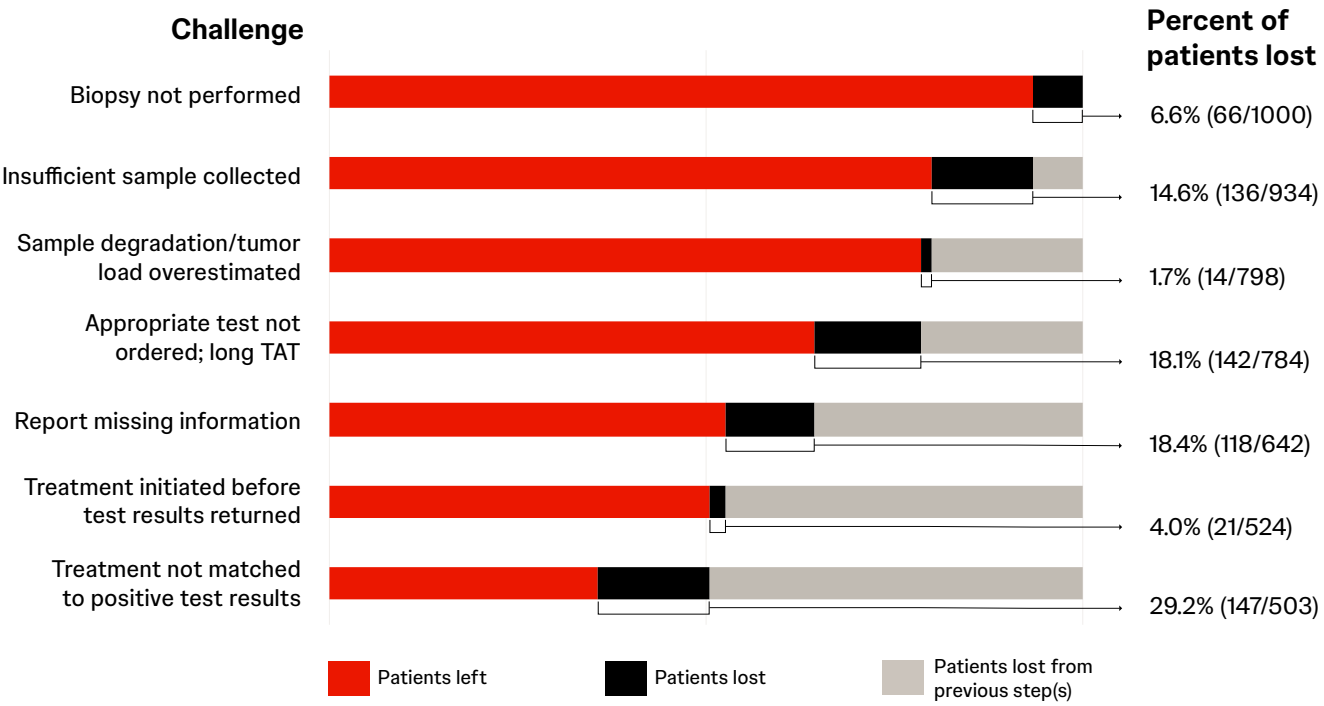
NSCLC*†	Ovarian*†	CRC*†	Breast*†	Gastric*†	Prostate‡
48%	56%	47%	27%	41%	29%

*In a retrospective study of 16,931 breast, 16,838 NSCLC, 8755 CRC, 4244 pancreatic, 2610 ovarian, 1231 gastric advanced cancer patients with commercial or Medicare advantage.[11]
†Biomarker testing was captured using CPT codes indicating CGP (>50 gene panels), non-CGP (at most 5–50 gene panels), or CPT code 81479 (unlisted molecular pathology procedure) between January 2018 and August 2021.[11]
‡In a retrospective study of 11,927 patients with metastatic prostate cancer. Represents rate of NGS testing among patients diagnosed between March 1, 2015, and December 31, 2022.[12]

In mNSCLC, critical gaps in the biomarker testing journey have been identified[13]

While there are numerous matched therapies available in mNSCLC, rates of biomarker testing remain suboptimal[4,11]

A study by the Personalized Medicine Coalition utilizing the Diaceutics' proprietary DXRX Data Repository examined points along the biomarker testing journey where patients are lost because of these gaps and found[13]*:



The expansion in cancer treatment options coupled with the specific requirements of biomarker testing calls for a coordinated and integrated approach[14]

Choosing the appropriate treatment informed by biomarker testing involves diverse perspectives.

Complex challenges need collaborative solutions.[6,14–16]

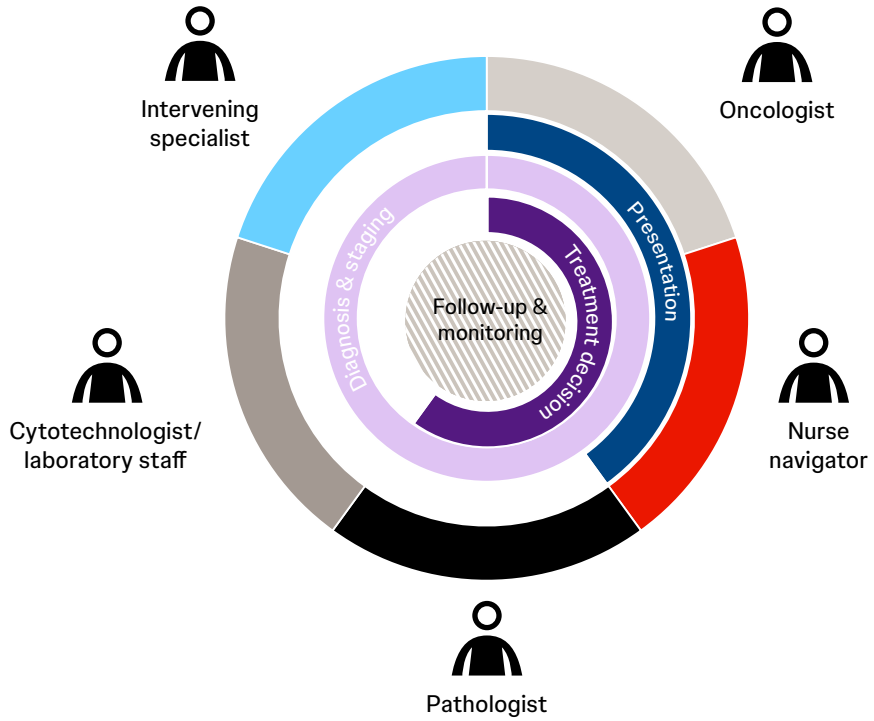
*Diaceutics' multisource database, which includes commercial and Medicare claims and laboratory data from the US health system of >38,000 patients with mNSCLC.[13]

MDTs play a critical role in managing care for patients with cancer[17–20]

MDTs draw on diverse expertise to handle the complexities of disease management[17,20]

MDTs help optimize clinical care to align to current guideline treatment standards[17,20]

MDT members[14,15,17–19]



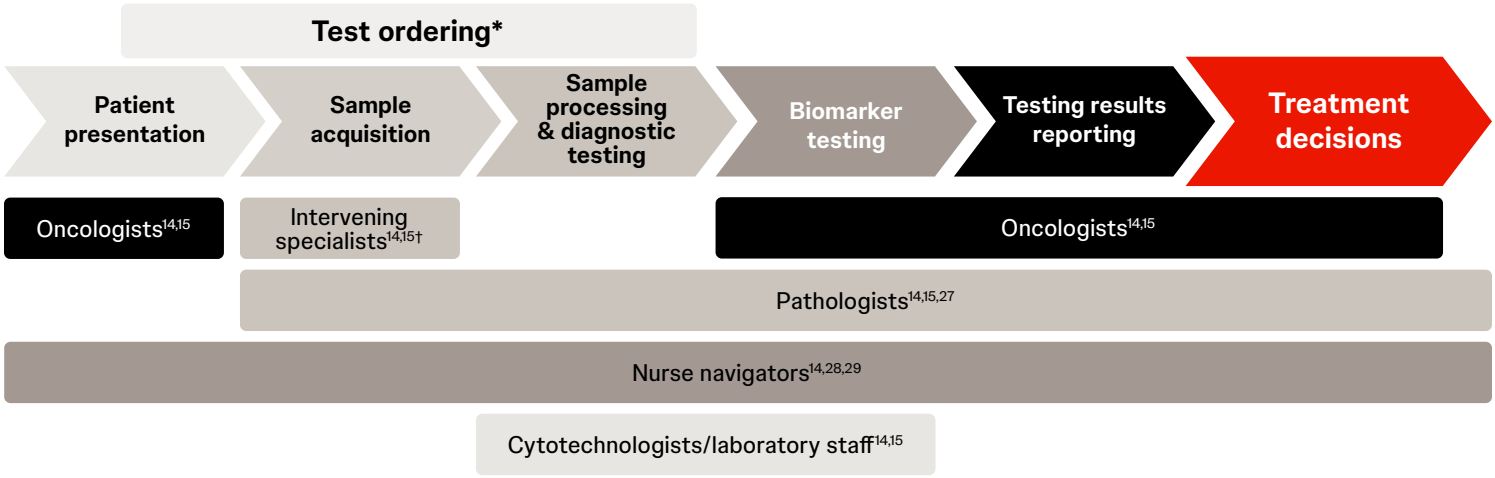
Precision medicine directors are emerging stakeholders

Some institutions have begun to create these positions to help[21,22]:

- Ensure appropriate testing is carried out[21]
- Interpret testing report to identify appropriate treatment options[21,22]
- Identify options at recurrence or progression[21]

Multistakeholder collaboration among MDTs, patients, researchers, and policymakers may overcome barriers to biomarker testing and improve precision oncology[23,24]

MDT stakeholders may encounter challenges throughout the biomarker testing journey[13,25,26]



Patient presentation	• Initial biopsy not performed (patient medically unfit or tumor inaccessible)[13,30,31]
Sample acquisition	• Insufficient sample collected[13,15,32]
Sample processing & diagnostic testing	• Sample degradation from inappropriate tissue handling/processing[15,25,27] • Overestimated tumor content[13]
Biomarker testing	• Appropriate test not ordered[13] • Long TAT[13] • Tissue exhaustion preventing further testing[6]
Testing results reporting	• Report missing information[28] • Report difficult to interpret[27,28,33]
Treatment decisions	• Treatment initiated before test results returned[13,26] • Treatment not matched to positive test results[13]

MDT coordination can help overcome hurdles in the diagnostic journey[14–16]

*Includes reflex testing.[5] †Dependent on cancer type and procedure, an intervening specialist (eg, oncologist, surgeon, interventional radiologist, pathologist) may be consulted for tissue sufficiency.[14,15]

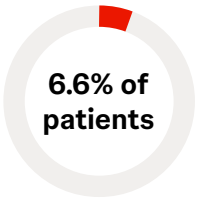
At patient presentation, a sample may be challenging to obtain[34,35]

In an audit of 178 patients presenting with a new diagnosis of cancer

27.5% of patients

were **unfit or unsuitable** for a diagnostic tissue biopsy due to advanced age and/or poor performance status[36]

A study using laboratory and claims-based data from the US health system of >38,000 patients with mNSCLC found that[13,27]*:



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never had an initial biopsy

Potential solutions:

- Consulting with the MDT may help choose the best biopsy approach so that a sample may be obtained [27,37]
- Performing a liquid biopsy allows a minimally invasive, low-risk option for obtaining samples if tissue is unavailable or if clinically necessary[38]

Patient presentation

- Oncologists[14,15]
- Nurse navigators[14]

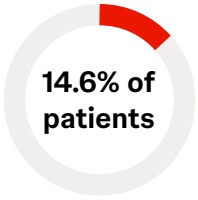
During sample acquisition, an insufficient amount of tissue collected may impact testing ability[13,15,32]

In an analysis of research biopsy core variability from >5000 samples

55.8%

of **core needle biopsies** from various cancer types were **inadequate** for successful NGS testing[39]

A study using laboratory and claims-based data from the US health system of >38,000 patients with mNSCLC found that[13,27]*:



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were unable to receive biomarker testing due to **insufficient tissue**

Potential solutions:

- Implementing ROSE and checking samples immediately may assess the need for another pass for an additional sample[14,27]
- Involving the intervening specialist and pathologist during sample collection is important to obtain optimal diagnostic material, meet downstream testing needs, and deliver an accurate cancer diagnosis[14,16,27]

Sample acquisition

- Intervening specialists[14,15†]
- Pathologists[14,15,27]
- Nurse navigators[14]

*Diaceutics' multisource database, which includes commercial and Medicare claims and laboratory data.[13,27]

†For example, an oncologist, surgeon, interventional radiologist, and/or pathologist may be consulted for tissue sufficiency depending on cancer type and procedure.[14,15]

Sample processing and tissue handling during the diagnostic testing journey may impact sample quality[15,25,27]

In some studies, inappropriate fixation resulted in[40,41]

Up to 20% of NSCLC samples having reduced PD-L1 IHC staining, which may result in **inappropriate treatment selection[40]**

&

Up to 48% of breast cancer samples having reduced IHC biomarker staining, which may result in **suboptimal selection of patients for hormonal therapies[41]**

A study using laboratory and claims-based data from the US health system of >38,000 patients with mNSCLC found that[13]*:

had **<20% tumor content** and may not have met the threshold requirements for specific testing platforms

Potential solutions:

- Considering downstream biomarker testing during initial tissue processing may ensure proper handling[14,16,25]
- Avoiding delays in fixation may help preserve biomarkers, which could impact patient selection for biomarker-directed treatment[41]
- Utilizing microdissections may help histopathologic sections meet tumor cellularity requirements[14,15,25]
- Having a robust SOP for sample processing may help avoid errors and improve specimen quality requirements[14–16]

Sample processing & diagnostic testing

- Pathologists[14,15,27]
- Nurse navigators[14]
- Cytotechnologists/ laboratory staff[14,15]

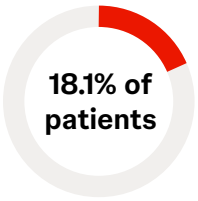
Testing delays or incorrect testing orders may impact biomarker-informed treatment decisions[13,42]

For patients with CRC, **time to receiving test results** may reach up to

~22.5 days

from test order **delaying delivery of matched therapy[42]**

A study using laboratory and claims-based data from the US health system of >38,000 patients with mNSCLC found that[13,27]*:



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were unable to receive biomarker testing due to the **appropriate test not being ordered**

Potential solutions:

- Implementing NGS-based testing and reflex/routine biomarker test ordering practices may help ensure patients receive timely and appropriate testing[27]
- Integrating automated platforms and EHRs may facilitate time-efficient and accurate biomarker testing[43,44]

Biomarker testing

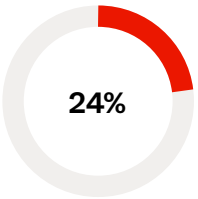
- Oncologists[14,15]
- Pathologists[14,15,27]
- Nurse navigators[14]
- Cytotechnologists/ laboratory staff[14,15]

*Diaceutics' multisource database, which includes commercial and Medicare claims and laboratory data[13,27]

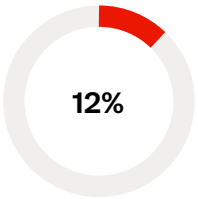
Interpretation of test reports may be challenging due to various factors[28,33,45]

- At times, scanned reports may be **missing pages**[28]
- Missing information may lead to **waste, suboptimal care, and patient harm**[28]
- An **incomplete/unclear** representation of the data may also lead to **clinical errors and incorrect patient management**[33]

In a survey of 99 oncologists, **issues with test reports** were viewed as barriers to testing patients with mCRC for biomarkers[45]:



Uncertainty
how biomarker results will impact clinical decision-making



Difficulty
interpreting the results

Potential solutions:

- Including essential elements of a complete report, like variant annotations, pertinent negatives, and suboptimal signals, delivered in a consistent format[28,33]
- Consolidating key actionable results from pathology and ancillary test reports into a single comprehensive summary[28]
- Staying up to date on available biomarkers and treatment options and collaborating with pathologists and nurses[14,45]

Testing results reporting

- Oncologists[14,15]
- Pathologists[14,15,27]
- Nurse navigators[14,28]

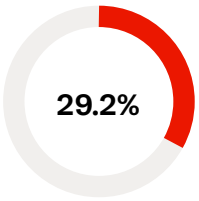
Treatment may have been initiated before complete test results are returned[13,26,27]

In a 2021 ACCC survey of 111 community oncology practitioners, treatment of patients with unresectable/mCRC with systemic medical therapy before biomarker test results were available reportedly occurred "almost always," "frequently," or "occasionally" in

up to 76%

of respondent cancer programs[26]

A study using laboratory and claims-based data from the US health system of >38,000 patients with mNSCLC found that[13,27]*:



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of patients did not receive appropriate targeted treatment due to:

- Reporting issues
- Lacking awareness of targeted treatment options and/or guidance
- Social determinants of health access/disparities

Potential solutions:

- Waiting for biomarker test results may help optimize treatment options by identifying biomarker-informed therapies[27]
- Test results clearly indicating alterations eligible for appropriate guideline-recommended therapies[3,27,46]
- Collaborating with the pathologist, which may assist in the interpretation of the results, leading to treatment decisions[15]
- Integrating structured biomarker results into EHRs, which can help facilitate patient care[27]

Treatment decisions

- Oncologists[14,15]
- Pathologists[14,15,27]
- Nurse navigators[14,29]

*Diaceutics' multisource database, which includes commercial and Medicare claims and laboratory data.[13,27]

MDTs may positively impact cancer treatment[29,47]

Diagnosis and clinical decision-making

MDT re-evaluation:
- **May change diagnoses and treatment decisions** in patients with cancer[48]

MDT collaboration:
- **May improve the amount** of collected tissue[49]
- May recommend the **most efficient biopsy** approach[50*]

MDT evaluation:
- **May assist** in cancer diagnosis and the **optimal diagnostic or follow-up strategy**[50*]

Guideline adherence and racial bias

Creation of an MDT was associated with **greater adherence to guidelines**[29,51]
- Treatment decisions are based on **complete and comprehensive data**[51]

Compared with national trends, **MDTs reduced racial bias** in treatment selection[52]
- For example, African American males with prostate cancer may opt for more definitive treatment when **presented with treatment options by an MDT**[52]

Treatment outcomes

Compared with national trends, **MDT care** was associated with:
- Higher and longer OS[29,47]
- Higher PFS[29]
- Lower mortality[29]
- Lower median time from diagnosis to treatment[29]
- Higher rates of complete staging and receiving treatment[29]

Opportunity to optimize

Implementing MDTs may improve access to precision medicine and quality care through functional expertise and collaboration[27,29,47]

*NCCN makes no warranties of any kind whatsoever regarding their content, use or application and disclaims any responsibility for their application or use in any way.

MDTs can help create internal standards to help reduce barriers for testing at your institution[6,53–55]

Internal standards to consider:

- **Precision medicine terminology**[6,54,55]
- **Incorporating guideline updates into SOPs**[54]
- **Testing forms and reporting**[54]
- **Use of precision oncology knowledge databases**[6,54]

Summary

- Caring for patients with cancer requires collaboration among various specialties[14,15]
- The MDT may increase optimized guideline-recommended care[17,20]
- MDT coordination can help reduce barriers by creating standards for terminology, guideline updates, test reports, and databases[6,53–55]
- MDT care may impact patient outcomes by helping to improve patient access to precision medicine and quality care[27,29,47]

ACCC, Association of Community Cancer Centers; CGP, comprehensive genomic profiling; CPT, current procedural terminology; CRC, colorectal cancer; EHR, electronic health record; FDA, U.S. Food and Drug Administration; ICI, immune checkpoint inhibitor; IHC, immunohistochemistry; mCRC, metastatic colorectal cancer; MDT, multidisciplinary team; mNSCLC, metastatic non-small cell lung cancer; NCCN, National Comprehensive Cancer Network; NGS, next-generation sequencing; NSCLC, non-small cell lung cancer; OS, overall survival; PD-L1, programmed death-ligand 1; PFS, progression-free survival; ROSE, rapid on-site evaluation; SOP, standard operating procedure; TAT, turnaround time; US, United States.

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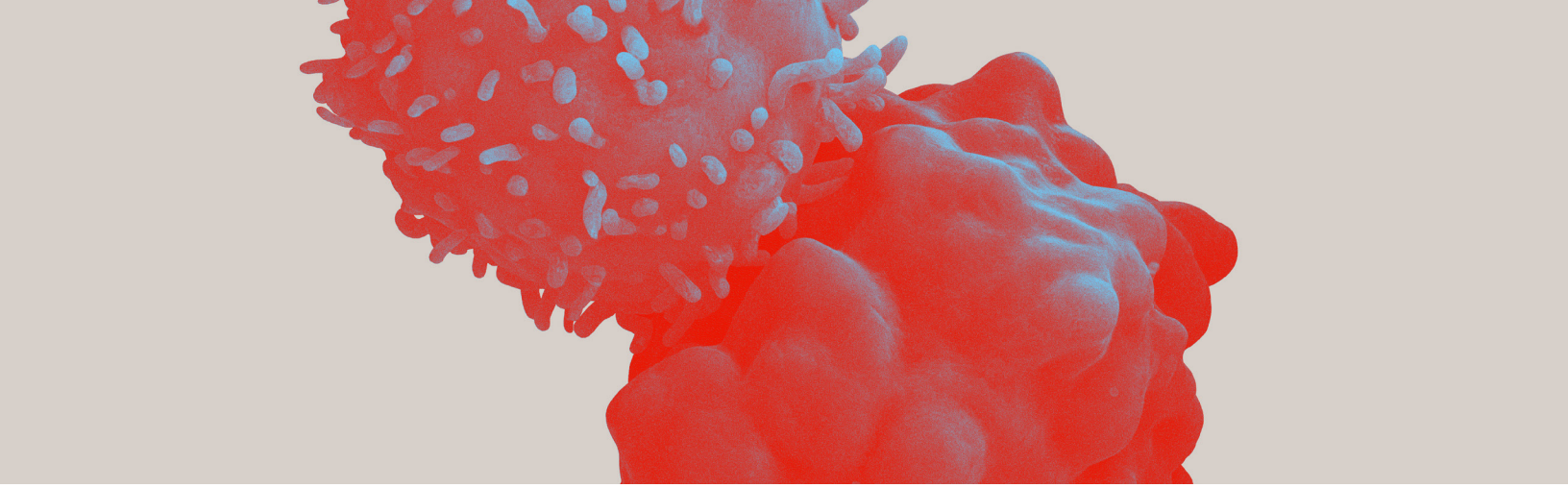

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