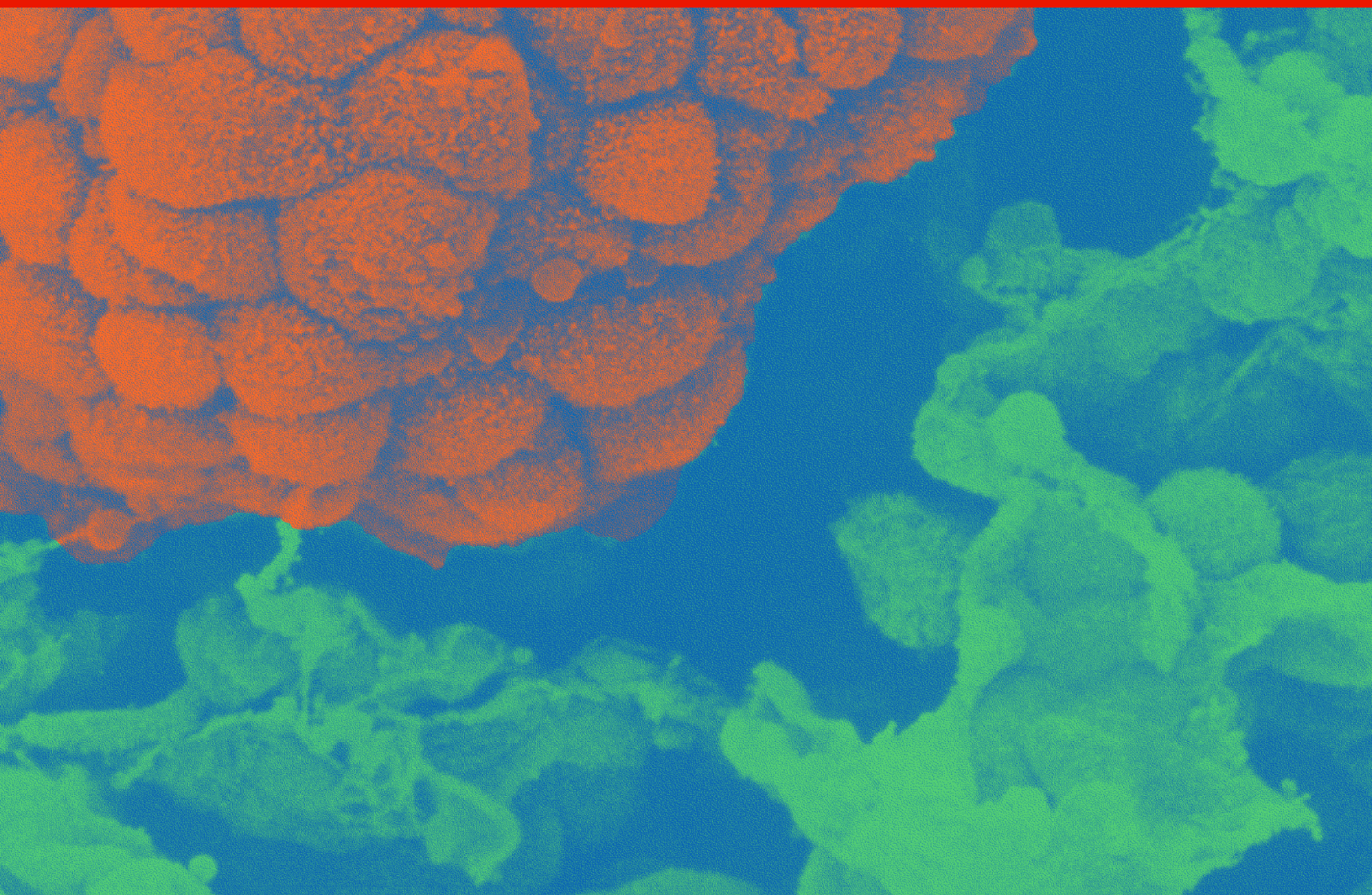
Overview of Precision Medicine in

Solid Tumor Oncology

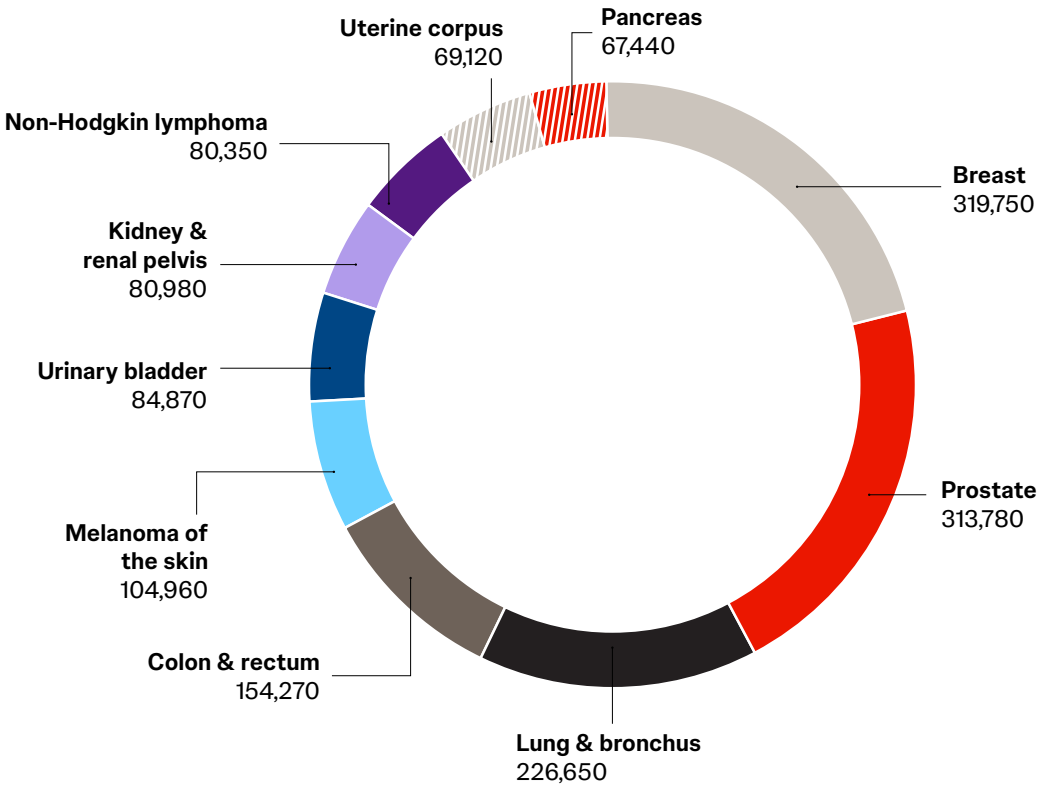
J&J
Precision Medicine



Cancer in the United States

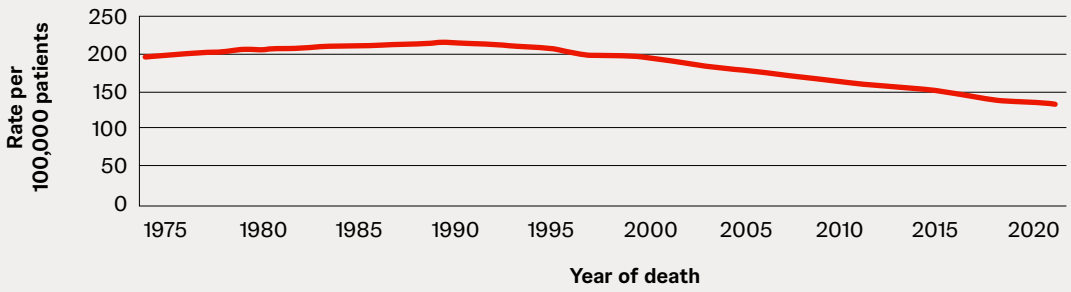
With over **2 million new cases** projected to be diagnosed in 2025, **cancer is the second most common cause of death** in the United States[1]

Top 10 cancers in the United States
Cancer site, estimated new cases[1]



However, overall cancer mortality is decreasing[2]

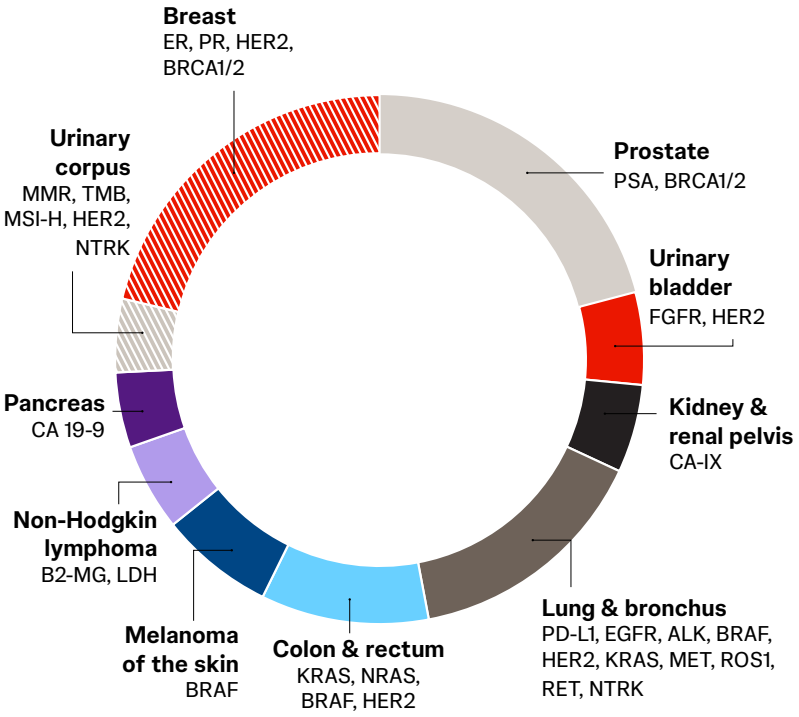
All cancer sites combined, age-adjusted mortality[3]



Advances in diagnosis and treatment of cancer have contributed to the decrease of mortality over the last 30 years[2]

Biomarkers are changing the clinical approach to cancer

Top 10 cancers in the United States
Cancer site, example biomarkers[1,4–16]



Biomarkers are measurable indicators of clinical or biological characteristics[4,5]

Biomarkers may be:

Diagnostic:
To help confirm that a patient has a particular disease[5]

Prognostic:
To indicate the severity or aggressiveness of the disease[5]

Predictive:
To indicate a patient may benefit (or not benefit) from particular therapeutic options[5]

Actionable biomarkers are predicted to confer sensitivity or resistance to an **FDA-approved therapy** in that indication[4]

An increasing number of biomarker-informed therapies are available

Since 2000, targeted therapies like kinase inhibitors have seen the most FDA approvals in cancer[17]

As of 2025 there are:

89
biomarkers recognized by the FDA or recommended in professional guidelines for predictive biomarker testing[18]

110
FDA-approved precision oncology therapies, including targeted therapies and ICIs[18,19]

11
FDA-approved immune checkpoint inhibitors (ICIs)[19]

1 in 3 patients
with cancer may be eligible for biomarker-informed therapy[4,20]

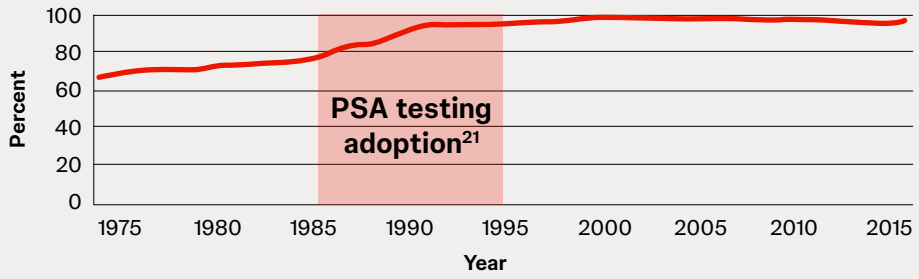
Examples of biomarker-informed screening and treatment

Biomarker-based screening in prostate cancer

SEER data suggest **PSA screening** contributed to

- Earlier-stage diagnosis[21]
- **A 46.0%–63.7% decrease in prostate cancer deaths** between 1980 and 2016[21]*

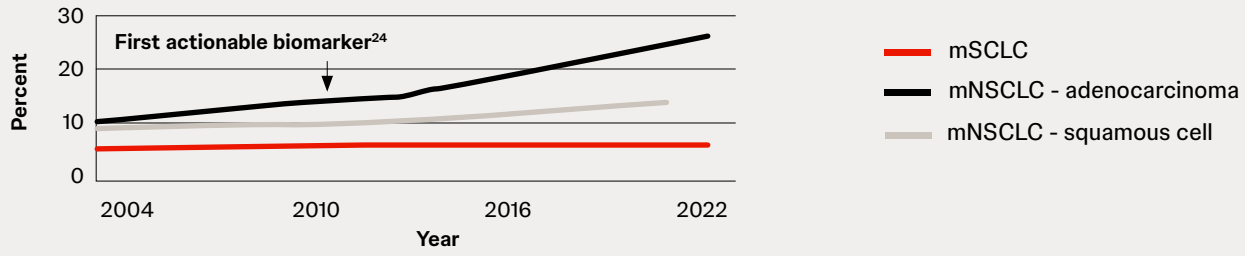
Five-year prostate cancer survival[22]



Biomarker-informed treatment options in mNSCLC[23]

- Since 2011, **11 biomarkers have become therapeutically actionable**, and **the three-year relative survival has nearly doubled** in mNSCLC[23–26]†
- In mSCLC, biomarkers are emerging, but the **three-year relative survival has yet not changed**[23,27]

Three-year relative survival in metastatic lung cancer[23]



Biomarker testing is key in many of the screening initiatives and new therapeutic options that contribute to survival gains in cancer[21, 28–31]

*In areas with baseline mortality >10/100,000.[21]
†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.

Biomarker tests include FDA-approved CDxs and LDTs

Companion diagnostic (CDx)

A medical device, often an IVD, which provides information that is essential for the safe and effective use of a corresponding drug or biological product. The FDA requires a CDx for the approval of certain targeted therapies[32]

CDxs can:

- Identify patients who are most likely to benefit from a specific therapeutic product[33]
- Identify patients likely to be at increased risk for serious side effects as a result of treatment with a specific therapeutic product[33]
- Monitor response to treatment with a specific therapeutic product for the purpose of adjusting treatment to achieve improved safety or effectiveness[33]

Laboratory-developed test (LDT)

IVDs intended for clinical use and designed, manufactured, and used within a single clinical laboratory that is certified under the CLIA of 1988 and meets the regulatory requirements under the CLIA to perform high-complexity testing[34,35]

LDTs can:

- Be used to measure or detect analytes to provide information about a patient's health, including to diagnose, monitor, and determine treatment[34]
- LDTs are used in a growing number of healthcare decisions, but variability among institutions has raised questions about the safety and effectiveness of these tests to be used to make treatment decisions[34]

Biomarker testing impacts multiple aspects of cancer care

Guiding treatment decisions to identify patients most likely to respond to a therapy[36–38]

Guiding treatment decisions to prevent ineffective treatments or unneeded systemic chemotherapy and decrease economic burden for patients with early-stage disease[36,38,39]

Identifying resistance or co-mutations that may impact treatment response and influence treatment decisions[4,37,40,41]

Biomarker testing results may inform both current therapeutic decisions and decisions made in the future as **new biomarkers become actionable**[4,37]

Connecting eligible patients to **clinical trials or compassionate-use programs**[36,41,42]

Improve concordance with guideline-recommended biomarker testing with EMR-based nudges[43,44]

One study demonstrated that:

- **A higher proportion of patients underwent comprehensive molecular testing** in the post-intervention vs the pre-intervention cohort
- **A higher proportion had results of comprehensive molecular testing available before initiating 1L treatment** after implementing an EMR-based nudge system

Opportunity to optimize

Comprehensive biomarker testing with NGS may provide information on actionable and emerging biomarkers simultaneously[4]

Professional society guidelines for biomarker testing

Multiple organizations provide disease-specific and more general recommendations to help guide treatment

Organization	Number of guidelines/ cancer types*	Guideline process	Update frequency
National Comprehensive Cancer Network® (NCCN®)†	Covers ≥67 cancer types and specific populations[45]	Developed and updated by consensus of multidisciplinary panel members[45]	Updated when new treatments are approved, in addition to **annual institutional review**[45]
ASCO	Covers 17 clinical areas, including molecular and biomarker testing[46]	Evidence-based consensus based on a systematic literature review and an open-comment period for stakeholders[47,48]	New evidence and topics submitted for consideration are **reviewed annually and updated only if evidence requires an update**[49]
CAP/IASLC/AMP	Covers 33 areas of molecular pathology, including colorectal and lung cancer biomarker testing[37,50]	Evidence-based and drafts are open for public comment[37,50]	There is **no set schedule** for updates, but ≥5 years between updates is not uncommon[37,50]

EHR-integrated clinical pathways are built around treatment guideline recommendations[51]

Opportunity to optimize

Reference the most recent professional guidelines for a particular cancer to ensure your patients receive appropriate biomarker testing

*Subject to change as new guidelines are published.
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Rates of biomarker testing

A growing number of **patients with advanced cancer are eligible for biomarker-informed care** because of increases in[4,17]:

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

In 1 large, retrospective study, multigene NGS panel biomarker testing rates in advanced cancers were[52,53]:

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

Many patients with advanced cancer do not receive biomarker-informed care because they are **not tested**[52–57]

Opportunity to optimize

Biomarker testing rates are not optimal across different cancer types which decreases the options for patients to receive biomarker-informed care[52–57]

*In a retrospective study of 16,931 breast; 16,838 NSCLC; 8,755 CRC; 4,244 pancreatic; 2,610 ovarian; 1,231 gastric advanced cancer patients with commercial or Medicare advantage.[52] †Biomarker testing was captured using Current Procedural Terminology (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.[52] ‡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.[53]

Disparities in biomarker testing

Rates of biomarker testing may be impacted by:

Academic vs community hospitals

In 1 study of patients with NSCLC, NGS testing rates were[58]:

- **100%** in academic care centers
- **~76% in community-based practices**

Technology and resources

In a retrospective chart review on aNSCLC, patients treated at a community hospital[59]:

- **87.9%** did not have core results available at the time of referral
- **79.7%** did not have core results available at consultation

Geographic location

In a retrospective cohort study, patients with metastatic CRC from **rural communities** were found to be **less likely to receive MSI testing** (RR, 0.80) than patients from urban communities[56]

Race & ethnicity

In a large US cohort study, **compared with white patients, Black/African American patients were less likely to undergo biomarker testing[60]**:

- At any given time during their NSCLC treatment trajectory or
- Before the start of first-line CRC therapy

Socioeconomic status

In a systematic review covering 7 cancer types, low socioeconomic status was associated with[61]:

- **Lower predictive biomarker test utilization** (OR, 0.86)
- **Lower biological and precision therapy utilization** (OR, 0.83)

Strategies to optimize the impact of biomarker testing

Important considerations for treatment selection

Proper test selection[4,26*]	**Appropriate sample collection[62]**
Practice guideline-recommended testing[4,62]	**Test at diagnosis[4,26*]**
Wait on test results, if clinically feasible[26*]	**Ensure MDT coordination[62]**

Leverage tests for treatment decisions:

Test turnaround time should NOT drive treatment decisions, if clinically feasible[26,62*]

Opportunity to optimize

Taking a comprehensive look at your process may identify opportunities for patients who may potentially benefit from targeted therapies[26,62*]

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1L, first line; ALK, anaplastic lymphoma kinase; AMP, Association for Molecular Pathology; aNSCLC, advanced non-small cell lung cancer; ASCO, American Society of Clinical Oncology; B2-MG, beta-2 microglobin; BRAF, B-Raf proto-oncogene, serine/threonine kinase; BRCA1/2, breast cancer gene 1/2; CA 19-9, carbohydrate antigen 19-9; CA-IX, carbonic anhydrase IX; CAP, College of American Pathologists; CDx, companion diagnostics; CGP, comprehensive genomic profiling; CLIA, Clinical Laboratory Improvement Amendments; CPT, Current Procedural Terminology; CRC, colorectal cancer; DNA, EGFR, epidermal growth factor receptor; EHR, electronic health record; EMR, electronic medical record; ER, estrogen receptor; FDA, U.S. Food and Drug Administration; FGFR, fibroblast growth factor receptor; HER2, human epidermal growth factor receptor 2; IASLC, International Association for the Study of Lung Cancer; ICI, immune checkpoint inhibitor; IVD, in vitro diagnostic; KRAS, Kirsten rat sarcoma virus; LDH, lactate dehydrogenase; LDT, laboratory-developed test; MDT, multidisciplinary team; MET, mesenchymal epithelial transition; MMR, mismatch repair; mNSCLC, metastatic non-small cell lung cancer; mSCLC, metastatic small cell lung cancer; MSI, microsatellite instability; MSI-H, microsatellite instability–high; NCCN, National Comprehensive Cancer Network; NGS, next-generation sequencing; NRAS, neuroblastoma rat sarcoma virus; NSCLC, non-small cell lung cancer; NTRK, neurotrophic tyrosine receptor kinase; OR, odds ratio; PD-L1, programmed death-ligand 1; PR, progesterone receptor; PSA, prostate-specific antigen; RET, receptor tyrosine kinase; ROS1, ROS proto-oncogene 1, receptor tyrosine kinase; RR, relative ratio; SEER, Surveillance, Epidemiology, and End Results Program; TMB, tumor mutational burden.

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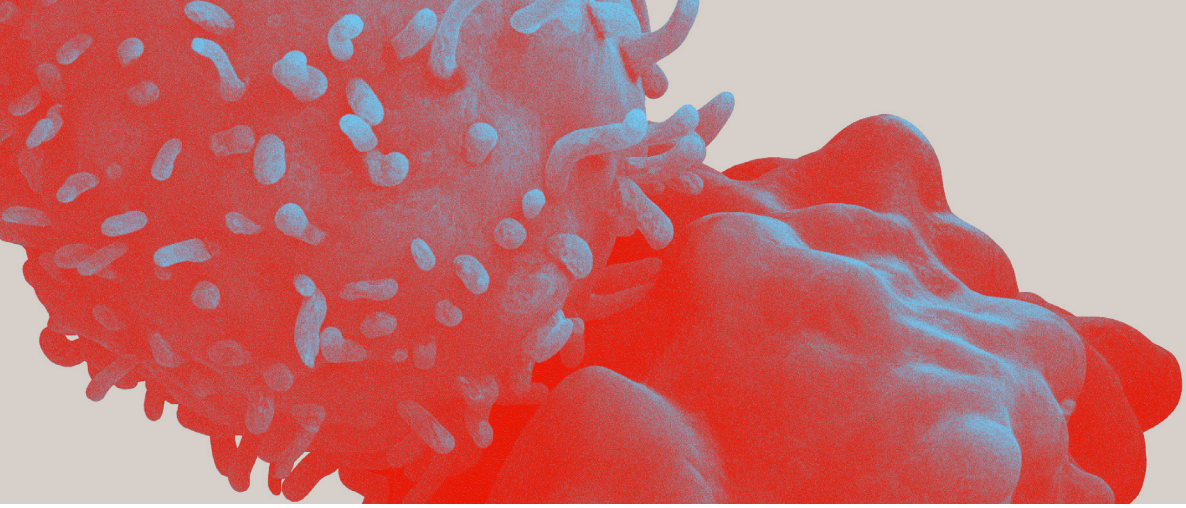

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