#### ONCOLOGY COMPASS

# Digest

THE PULSE OF ONCOLOGY COMPASS



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**Impressum** 

MAPPING TUMOR BEHAVIOR IN REAL TIME

# THE POWER OF FUNCTIONAL PRECISION MEDICINE IN ONCOLOGY

BY ANĐELIKA KALEZIĆ

The article explores how ex vivo tumor sample testing, drug responsiveness analysis, and resistance profiling are reshaping decision making in oncology. By examining how patient cancer cells respond to standard or novel therapies, these approaches provide clinicians with valuable insights to support more personalized and effective treatment strategies. Additionally, resistance profiling helps identify potential treatment challenges early, enabling more proactive and targeted interventions in cancer care.

Dr. Aleksej Drino is a molecular biologist and RNA specialist currently based in Vienna. He earned his PhD from the Medical University of Vienna, focusing on RNA biology and gene expression regulation, with a particular interest in the biochemistry of RNA-protein complexes. After completing his postdoctoral research, Dr. Drino transitioned into industrial



Photo credit: 'Dr. Aleksej Drino, photo courtesy of Dr. Aleksej Drino



Photo credit: Dr. Aleksej Drino in his laboratory, photo courtesy of Dr. Aleksej Drino

research as a senior scientist, where he now leads biological research efforts at Vienna-based Exscientia GmbH, aiming to integrate primary patient tissue samples into precision medicine and drug discovery workflows. In this interview, Oncology Compass Digest discusses the evolution of functional precision medicine with Dr. Drino, highlighting the limitations of purely genomic approaches and how ex vivo testing, AI, and ethical clinical collaborations are reshaping the future of oncology care and clinical research.

#### Dr. Drino, your academic background is in RNA biology. How did that foundation influence your current focus on oncology and functional precision medicine?

My background in RNA biology gave me a profound appreciation for how cells regulate their fate and respond to stress. I studied non-coding RNAs and RNA-binding proteins, which are involved in immune evasion, gene regulation, and the control of endogenous viral elementsmechanisms that are also relevant in cancer. This naturally led to an interest in how cancer cells exploit these layers of regulation to survive therapeutic pressure regarding epigenetics, epitranscriptomics, and RNA-protein interactions. That interest evolved into a focus on functional precision medicine, where the aim is not only to interpret genetic information but also to directly observe how tumor cells behave and respond to treatment ex vivo.

My PhD training in RNA biology and biochemistry taught me that hard-coded genetic information is only part of the story. It is the additional regulatory layers that often drive phenotypic responses and, ultimately, clinical outcomes.

#### Genomic profiling has traditionally dominated the field of precision oncology. What are its limitations, and how can functional precision medicine complement it?

Genomic stratification remains essential, especially in identifying targetable mutations, classifying disease subtypes, predicting therapeutic responses, and guiding treatment decisions. In some instances, genetic mutations directly affect drug binding and effectiveness, or are responsible for drug detoxification mechanisms; in these situations, genomic profiling provides significant predictive insights.

However, genetic profiling often falls short in predicting drug response and resistance in intermediate cases, particularly when non-genetic mechanisms, such as epigenetic or metabolic adaptations or dynamic cell interactions within the tumor

microenvironment, are involved. Functional precision medicine adds a complementary layer by capturing how cancer cells truly respond to therapies in a more dynamic and comprehensive manner. It is particularly powerful for predicting the effectiveness of standard-of-care therapy in instances where genomic data are inconclusive.

# Can you explain the real-time, ex vivo testing process for patient-derived tumor samples, and why a rapid turnaround time is crucial?

Our workflow involves isolating viable tumor cells from blood, bone marrow, or tissue samples and exposing them to a panel of clinically relevant drugs within hours of collection.

Using Al-driven high-throughput microscopy, we can evaluate both on-target and off-target drug effects in under 72 hours, which could make the entire process clinically applicable.

This speed is crucial in hematologic malignancies, such as acute myeloid leukemia, where prompt clinical decisions must be made. Rapid functional readouts can provide clinicians with meaningful information regarding therapy choices in real-time.

# Beyond selecting the appropriate therapy, your work also aims to predict drug resistance. How does functional profiling assist in identifying resistance mechanisms that might not be evident in genomic data?

Resistance often arises from adaptive cellular responses rather than fixed genetic mutations. Variations in iron or energy metabolism, epigenetic changes, or stress responses can enable tumors to evade treatment.

By exposing patient samples to different drugs and analyzing the outcomes along with transcriptomic and proteomic profiles, we can uncover emerging resistance pathways that might not be apparent through genomic analysis alone.

# What role does functional precision medicine play in improving clinical trial design and patient stratification?

A major issue in oncology clinical trials is data dilution caused by the enrollment of patients unlikely to benefit from the therapy. There is a clear translational gap between drug target discovery and testing on cells and animal models, and their application in clinical trials, where the drug often proves ineffective for a significant subset of patients.

Functional precision medicine allows us to pre-screen patients using various biomarkers to identify those most likely to respond to either standard-of-care drugs or newly developed therapies.

This approach enhances the statistical power of trials, reduces costs, and improves patient outcomes. Integrating functional precision medicine into clinical trial design is a highly promising direction.

Many organizations are already adopting this method within their pipelines, creating a win-win scenario for patients, who receive more tailored treatments; for companies, which achieve clearer trial outcomes; and for clinicians, who can make more informed therapeutic decisions.

#### Working with ex vivo patient samples raises ethical considerations. How do you maintain ethical integrity in this research?

Ethical rigor is crucial. We only work with samples from patients who have provided informed consent, and we maintain complete transparency regarding how samples are processed and how data is managed.

Data security, access control, and responsible communication— especially concerning incidental findings—are all central to our workflow. We collaborate closely with hospitals and ethics boards to ensure compliance.

# How do successful collaborations among researchers, clinicians, and industry shape the field of functional precision medicine?

Interdisciplinary collaboration between academia, industry, and medical institutions is essential. Clinicians provide context and ensure the clinical relevance of our work in a patient-centric way, while we provide them with functional data that could ultimately guide care.

To make this translation work, we need integrated data systems, aligned diagnostic workflows, and mutual understanding.

In my opinion, the intersection of industrial research and clinical practice is where the future of functional precision medicine lies, especially when it comes to translating research findings into real-world patient care.

# How realistic is it to stratify patients based on functional response? Are there any recent success stories or pilot studies that highlight this trend?

There's growing evidence that it's not only realistic but necessary in some cases. Recent research has shown that, in addition to established biomarkers, functional readouts have achieved comparable and, in some cases, higher predictive power in terms of clinical responses.

A standout example is the VenEx trial in acute myeloid leukemia, which used flow cytometry-based functional testing to predict real-world treatment outcomes of venetoclax and differentiate responders from non-responders.

Ex vivo venetoclax sensitivity emerged as the most robust predictor for favorable treatment response. This trial demonstrated the feasibility of integrating ex vivo drug sensitivity testing into clinical practice and showed that functional profiling can, and should, play a larger role in patient stratification.

# With the FDA moving towards reduced animal testing, how do ex vivo models align with this trend?

While patient-derived xenograft models remain the gold standard in preclinical research, ex vivo models are certainly gaining traction. Depending on the model, ex vivo systems can be developed relatively quickly and cost-effectively while providing clinically relevant biological insights.

It is important to acknowledge that they do not fully capture certain aspects of tumor biology, such as interactions within the tumor microenvironment; however, advancements like co-cultures and organoid systems are bridging this gap. Both clinical and academic studies have demonstrated the significant potential of ex vivo drug response models to inform patient stratification in preclinical development. These models are particularly beneficial in preclinical drug validation, testing combination therapy designs, and discovering novel biomarkers.

# While AI is not central to this discussion, how does it contribute to your work with high-throughput microscopy and omics approaches?

Al plays a supportive role in our work, but it's an incredibly powerful one. When working with complex datasets, whether from high-throughput microscopy or multi-omics analyses, Al helps us identify patterns and correlations that are extremely difficult, if not impossible, to detect manually. It enables us to integrate diverse data types, ranging from imaging to genomics to clinical variables, in a coherent and actionable manner. Certain companies in this landscape are also using Al tools for molecule optimization and to inform more adaptive, efficient clinical trial design. Ultimately, Al doesn't replace human decision-making; rather, it helps us bridge the gap between data and insight more effectively, accelerating the path from discovery to real-world application.

FINANCIAL DIGNITY FOR CANCER PATIENTS

# FROM CRISIS TO CHANGE: HOW THE PINK FUND FIGHTS THE ECONOMIC FALLOUT OF CANCER

BY ANNE JÄKEL

For many patients, a cancer diagnosis brings not only physical and emotional turmoil but also devastating financial consequences. While oncologists work tirelessly to provide the best possible care, too often their efforts are undermined by a hidden crisis: patients unable to afford the basic costs of living while undergoing treatment.

Studies have shown that a significant percentage of cancer patients experience severe economic hardship, with many forced to delay or even abandon treatment due to financial pressures.<sup>1</sup> This reality doesn't just impact patient well-being, it directly affects clinical outcomes.<sup>2</sup> The Pink Fund, a U.S. nonprofit organization founded by Molly MacDonald, has transformed a deeply personal struggle into a nationwide mission. The Pink Fund provides direct financial assistance to breast cancer patients in active treatment, covering essential non-medical expenses like housing, transportation, and utilities. But beyond offering critical relief, The Pink Fund is now at the forefront of advocacy, lobbying for systemic change to address the broader economic fallout of cancer care.3



Photo credit: pinkfund.org

The birth of The Pink Fund: a personal crisis turned national mission

Molly MacDonald's journey began

in 2005 when she was diagnosed with early-stage breast cancer. Her diagnosis triggered an immediate halt to her income, and although her medical treatment was covered, her day-to-day living expenses were not. Within months, she faced foreclosure and the terrifying prospect of homelessness.<sup>4</sup>

It was this harrowing experience that inspired MacDonald to found The Pink Fund. Recognizing a gap that no one was addressing, how patients in active treatment manage to keep a roof over their heads and the lights on, she created a program offering direct financial support for those in need.<sup>4</sup>

### The hidden epidemic: economic strain in cancer care

Cancer's financial burden is not a side effect—it is a crisis in its own right. According to a 2021 study published in Cancer Nursing, nearly half of working-age cancer survivors report experiencing significant financial hardship.¹These include loss of income, mounting debt, and in severe cases, bankruptcy. The emotional toll is equally devastating, with patients often reporting anxiety, depression, and feelings of helplessness stemming from economic strain.⁵

For oncologists, these financial pressures have clinical implications. Research shows that patients under economic stress are more likely to miss appointments, skip medications, or discontinue treatment altogether. In short, economic instability can sabotage even the most advanced medical interventions.

Yet despite growing awareness, oncologists are often left without adequate tools to address this challenge. Screening for financial hardship is not yet routine in many clinics, and resources to assist patients are often fragmented or hard to access. The Pink Fund steps into this void with a streamlined, practical solution that directly supports patients where it matters most: at home.

# The Pink Fund's impact: direct support that changes lives

The Pink Fund offers a simple but powerful model. Patients in active treatment for breast cancer can

apply for up to 90 days of financial assistance to cover non-medical costs that insurance does not touch. This includes housing, transportation, utilities, and insurance premiums—expenses that are essential for maintaining stability during treatment.<sup>7</sup>

Since its inception, The Pink Fund has disbursed over \$7 million in bill payments on behalf of breast cancer patients in active treatment.8

One such recipient, Candy S., described how cancer turned her daily life upside down—not just medically, but logistically and emotionally.

Far from being a time of rest, her diagnosis brought a dramatic increase in responsibilities: constant medical appointments, managing and organizing bills, dealing with insurance, and coping with the emotional toll on her family.

On top of this, the loss of income created impossible choices about which bills to pay. For Candy, support from The Pink Fund provided a vital lifeline during one of the most difficult periods of her life, offering her the stability she needed to focus on treatment and recovery.<sup>8</sup>

For oncology clinics in the U.S., The Pink Fund offers a reliable referral pathway. Healthcare providers can connect eligible patients with The Pink Fund's application process, ensuring that financial aid is delivered quickly and effectively.

# From relief to reform: lobbying for systemic change

While The Pink Fund's direct aid is vital, MacDonald and her team understand that charity alone cannot solve a systemic problem. Over the past several years, The Pink Fund has increasingly focused on advocacy, raising awareness about the economic side effects of cancer and pushing for legislative reforms.<sup>3</sup>

MacDonald herself has become a recognized voice in this arena,

speaking at national events to highlight the urgent need for policy change.<sup>9</sup> Her message is clear: patients should not have to choose between medical care and financial survival.

Although The Pink Fund operates in the U.S., its message is globally relevant. Across diverse healthcare systems—whether publicly funded, insurance-based, or resource-constrained, patients often struggle to manage the hidden costs of cancer care: lost income, travel expenses, childcare, and more.

For oncologists worldwide, this presents an opportunity to lead change. By routinely screening for financial strain, referring patients to local support networks, and advocating within their institutions or national associations for the integration of financial navigation services, oncologists can help bridge the gap between treatment and true access to care. In doing so, they become champions for equity in oncology.

## Conclusion: bridging the gap between care and daily life

The economic fallout of cancer care is a crisis that no patient should face alone. Through its combination of direct support and determined advocacy, The Pink Fund is helping to bridge the gap between medical treatment and the daily realities of life with cancer. Its work reminds us that going through a medical treatment is not just about medicine, it's about ensuring patients have the stability they need to focus fully on recovery.

As the push for systemic change gains momentum, The Pink Fund stands as a model of what's possible when personal experience, practical solutions, and advocacy come together.

For oncologists and healthcare providers, joining this effort means not only improving individual patient outcomes but contributing to a future where no one has to choose between health and hardship.

AI IN ONCOLOGY

# AI IS UNLIKELY TO REPLACE THE ONCOLOGIST, BUT IT MAY RESHAPE THE WAY ONCOLOGY IS PRACTICED

BY ANNE JÄKEL

Artificial intelligence (AI) is increasingly embedded in oncology, with applications ranging from radiologic interpretation and pathology to treatment planning and symptom triage. This shift has sparked considerable interest, along with a degree of professional unease. Some observers have questioned whether AI might one day replace physicians altogether.

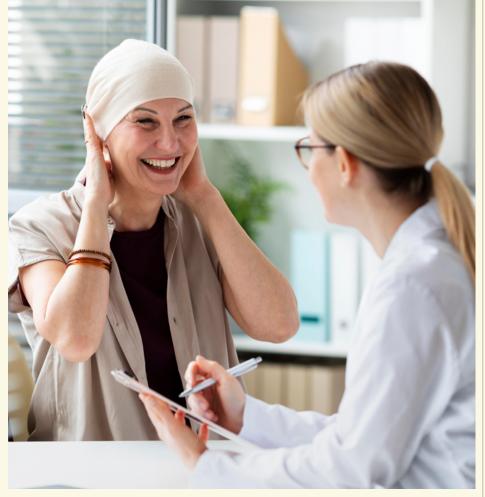


Photo credit: Freepik

While the trajectory of AI development remains uncertain, current evidence suggests that oncology is more likely to be transformed than replaced. AI may augment clinical tasks, enhance diagnostic processes, and streamline workflows—but it lacks many of the human faculties that remain central to cancer care.

The focus for oncology professionals may therefore be less about competition with machines and more about guiding responsible integration and maintaining patient-centered care in a digital environment.

# **Evolving capabilities of AI in oncology**

Al technologies are already supporting many aspects of oncologic practice. Image-based deep learning systems have demonstrated utility in tumor detection, histopathological classification, and radiomic analysis.<sup>1,2</sup>

Predictive models are being used to estimate treatment responses based on genomic and clinical data,<sup>3</sup> while Al-driven triage tools are helping to prioritize cases and flag abnormalities.<sup>4</sup>

For example, a 2025 ASCO study by Zhai et al. evaluated the performance of several large language models (LLMs) in supporting decision-making for multiple myeloma scenarios.

While one system (HopeAI) demonstrated higher accuracy and

lower hallucination rates compared to other models, clinical readiness scores remained low across all tools, underscoring the continued need for expert supervision in oncology workflows.<sup>5</sup>

Similarly, A 2023 review by Wang et al. examined the development and application of Al-based clinical decision support systems (CDSSs) in oncology.

The authors discussed how such systems integrate clinical guidelines, patient data, and literature evidence to assist oncologists in treatment scheme selection and personalized decision-making.

However, they also noted common limitations such as the inability to account for individual patient nuances, limited applicability to unsupported or atypical cases, and the need for expert oversight in ethically complex decisions.<sup>6</sup>

These examples show that, despite these advances, AI systems continue to have important limitations.

They rely on structured inputs, struggle to generalize beyond their training data, and may underperform when applied to diverse or atypical patient populations.

Al cannot evaluate psychosocial nuance, navigate moral ambiguity, or respond empathically to a patient's distress. These are areas where clinical expertise, judgment, and human connection remain essential.

# From replacement anxiety to responsible oversight

Media narratives and speculative commentary sometimes portray Al as a future replacement for physicians. However, such projections may not align with current technological realities or ethical standards in clinical care.

The World Health Organization's 2024 guidance on the ethics and governance of Al in health underscores that Al should remain

human-centered, with clinical professionals involved in supervision, interpretation, and decision-making at all stages.<sup>7</sup>

Lotter et al. (2024) note that Al models, even those with strong performance in controlled settings, may falter when faced with real-world data complexity or underrepresented populations.<sup>8</sup>

These performance gaps are not trivial; they suggest a continuing need for clinical oversight to ensure patient safety and relevance of care.

Rather than displacing the oncologist, Al may shift the nature of the role—emphasizing interpretive, ethical, and communicative responsibilities.

Oncology professionals may increasingly serve as interpreters and validators of Al-generated outputs, rather than as sole sources of diagnostic or therapeutic recommendations.

## Key areas requiring clinical leadership

There are several domains in which human oversight appears to remain critical:

#### 1. Transparency and explainability

Many Al models, particularly those using deep learning, do not provide clear reasoning behind their outputs.<sup>9</sup> This lack of transparency may complicate trust, informed consent, and shared decision-making.

Clinicians may be required to evaluate these outputs critically and ensure they are used appropriately in practice.

#### 2. Equity and bias

Concerns about algorithmic bias are growing. If training datasets are not diverse, Al systems may perform less effectively in certain demographic groups.

A recent review noted variability in Al performance across different ethnic

and socioeconomic backgrounds.8 Without proactive clinical scrutiny, these tools could unintentionally contribute to disparities in care.

#### 3. Ethical complexity

Al systems are not designed to handle moral or ethical dilemmas.

Decisions regarding end-of-life care, balancing risks and benefits, or managing limited resources involve values and judgment that current Al cannot replicate.

Clinicians remain the central arbiters of such decisions.

## The changing role of the oncology professional

As Al becomes more integrated into clinical practice, the oncologist's role may evolve rather than disappear.

The future may involve less time spent on repetitive data analysis and more on tasks that require interpersonal skills, nuanced reasoning, and ethical deliberation.

Studies exploring oncologists' perspectives on AI found a cautious openness. Respondents generally supported AI as a supportive tool but expressed concern regarding interpretability, liability, and the impact on patient relationships.<sup>10,11</sup>

This suggests that oncology professionals may be well-positioned to take on leadership roles in digital implementation, helping to guide institutional policies, participate in validation efforts, and advocate for transparency and equity in Al design.

### Practical considerations moving forward

Several practical strategies may help oncology professionals engage constructively with the integration of Al:

#### **Developing Al literacy:**

A foundational understanding of



#### **OPINION PIECE**

how Al tools are trained, validated, and deployed can support critical evaluation and safe use.

## Participating in interdisciplinary collaboration:

Working with data scientists, informatics specialists, and ethicists may support the development of tools that align with clinical needs.

## Advocating for inclusive data practices:

Ensuring that AI systems are validated across diverse populations is key to avoiding unintended harm.

#### Protecting patient-centered care:

Al may streamline administrative or analytical tasks, but it should not diminish opportunities for meaningful patient engagement.

#### Conclusion

Al continues to gain relevance in oncology, with many tools already showing clinical utility.

While no one can predict the exact trajectory of Al development, current evidence suggests that it is more likely to reshape oncology than replace the clinicians who practice it.

Ongoing integration of AI may bring changes in workflows, priorities, and professional identity.

However, areas such as communication, ethics, and patient-centered care are unlikely to be automated in the near term.

Oncologists may remain essential not despite AI, but because of it—ensuring that care remains safe, equitable, and grounded in human values.

By engaging with Al actively and responsibly, the oncology community may help shape a future in which innovation supports—not displaces—the core mission of compassionate cancer care.



Photo credit: Freepik



**BOOSTING TRIAL ACCESS** 

# FROM AWARENESS TO ACTION: HOW ONCOLOGISTS CAN DRIVE TRIAL PARTICIPATION

BY ANĐELIKA KALEZIĆ

Oncologists are pivotal in advancing cancer treatment by identifying and referring patients for clinical trials.¹ These studies remain the engine of innovation in oncology, offering access to therapies that can redefine standards of care.²

However, despite the expanding number of trials, enrollment challenges are common across practice settings. This is partly due to the shift towards precision medicine that embraces novel molecular targets and improvements in genetic sequencing technologies, which makes it harder to find patients that fit highly selective criteria.<sup>3</sup>

Additionally, oncologists frequently encounter barriers such as patient hesitancy, administrative burden, and limited visibility into active trials.<sup>4, 5</sup>

Addressing these challenges is critical for the future of equitable cancer care, ensuring that trial participation becomes a routine aspect of comprehensive cancer care.

## Aligning trial design with clinical reality

While oncologists are well-acquainted with trial structure and regulatory standards, integrating trial options into patient care often requires navigating logistical and eligibility challenges. Though



Photo credit: Freepik



#### **ONCOLOGY BREAKTHROUGHS**

usually associated with safety and pharmacodynamic endpoints, earlyphase studies can offer therapeutic potential, mainly when other options are limited.<sup>6</sup>

Later-phase trials may generate comparative effectiveness data, yet their eligibility criteria can inadvertently exclude patients due to performance status, comorbid conditions, or prior treatments.<sup>3</sup>

This misalignment between protocol design and patient populations seen in daily practice limits trial accessibility and reduces the relevancy of results.

As a result, the populations that might benefit most from novel therapies are excluded, and trial data becomes less representative of the patients seen in daily practice.<sup>7</sup>

Oncologists can play a key role in advocating for more inclusive designs and collaborating with sponsors to ensure that trials reflect the diversity found in real-world clinical practice.<sup>8</sup>

# Reframing misconceptions: addressing patient concerns with clarity and context

Patient reluctance to participate in clinical trials often stems from common misconceptions, including concerns about safety, placebo use, or treatment costs.<sup>9</sup>

Oncologists are uniquely positioned to help fight these misunderstandings through evidence-based communication.

Meeting patient's fears with transparency can help quickly reframe common misconceptions.<sup>10</sup>

Explaining that cancer trials rarely involve placebo-only arms and that participants typically receive either the investigational therapy or standard of care helps clarify expectations.

Reassuring patients that ethical oversight and regulatory safeguards are in place reinforces trust. Trial

discussions are more effective when tailored to the patient's individual goals—whether they seek extended survival, improved quality of life, or access to new treatment modalities.<sup>11</sup> The oncologist's role is vital in informing and translating complex protocols into meaningful, relevant choices for each individual.

### Enhancing oncologist-led patient recruitment

Many oncologists express a strong interest in supporting research but encounter logistical barriers within their workplace environments.

Competing demands on time, limited support staff, and the administrative complexity of trial enrollment can hinder consistent patient referrals.<sup>1</sup>

In these settings, systemic solutions are necessary. Incorporating dedicated research coordinators or clinical trial navigators into care teams can significantly reduce administrative burden.<sup>12</sup>

Emerging digital tools that match patient profiles with available trials can streamline eligibility identification and improve the efficiency of referral pathways.<sup>13</sup>

Incorporating trial eligibility screening into electronic health records, tumor boards, or routine case reviews helps ensure clinical research is consistently considered part of the treatment plan.<sup>14</sup>

These process improvements help transform trial participation from an exception to an integrated component of care delivery.

# Industry-oncologist collaboration to expand access

Pharmaceutical sponsors are increasingly focused on improving trial enrollment and patient diversity, yet collaboration with treating oncologists remains underutilized.8

Greater engagement between sponsors and clinicians can improve trial design, accessibility, and relevance.15

Oncologists can provide valuable input on eligibility criteria, visit schedules, and trial procedures to ensure feasibility in routine care. Broader eligibility, reduced travel requirements, and hybrid models incorporating virtual follow-up are practical adjustments that can significantly expand trial access, especially in community settings.<sup>16</sup>

Educational outreach is another important lever. Oncologists often cite limited awareness of ongoing trials as a barrier to referral.

Sponsor-supported education, streamlined trial registries, and updates embedded into continuing medical education opportunities can help ensure clinicians remain informed about relevant research opportunities without increasing workload.<sup>17</sup>

### Reframing clinical trials as standard practice

Clinical trials shouldn't be seen as an alternative to treatment—they are treatment. They represent the cutting edge of care, backed by rigorous oversight and the potential to change outcomes for individual patients and entire disease groups.

For oncologists, the path forward involves more than awareness. It requires integrating trial discussions into the treatment planning, advocating for accessible study designs, and establishing systems to support referral and enrollment. When oncologists lead the charge, patients follow. And when patients participate, progress accelerates.

Improving access to clinical trials requires collaboration across the oncology ecosystem, from clinicians and coordinators to sponsors and institutions.

When trials are embedded into routine care, patients benefit from early access to innovation, and the field advances with greater speed and equity.



**NEXT-GEN CANCER DETECTION** 

# LIQUID BIOPSIES: THE FUTURE OF NON-INVASIVE CANCER DETECTION

BY ANĐELIKA KALEZIĆ

Cancer remains one of the leading causes of morbidity and mortality worldwide, with early detection being crucial for improving patient outcomes.¹ Traditional diagnostic methods often depend on invasive tissue biopsies, which, while remaining the gold standard for tumor diagnosis, have limitations regarding patient comfort and the ability to monitor disease progression continuously.² In recent years, liquid biopsies have emerged as a promising, minimally invasive alternative, offering potential advancements in early cancer diagnosis, prognosis, and selection of personalized treatment strategies.³



Photo credit: Freepik

#### **Understanding liquid biopsies**

A liquid biopsy is a laboratory test that analyzes components derived from tumors found in blood, urine, saliva, or other bodily fluids.

These components may include circulating tumor cells, cell-free DNA, circulating tumor DNA, exosomes, and various types of non-coding RNA.<sup>4</sup>

The primary purpose of liquid biopsies is to detect cancer and monitor progression dynamics by examining these biomarkers in real-time.

While traditional biopsy captures a static snapshot, liquid biopsy provides a dynamic overview of disease progression, detecting genetic mutations, tumor behavior, signaling pathways, potential therapeutic targets, and resistance mechanisms.<sup>5</sup>

As a result, liquid biopsies enable early diagnosis, ongoing monitoring, treatment effectiveness evaluation, minimal residual disease detection, and the identification of mechanisms contributing to therapeutic resistance.<sup>6</sup>

## Advantages over traditional biopsy methods

Liquid biopsies present several significant advantages when compared to traditional tissue biopsies.

One of the most notable benefits is that the procedure is minimally invasive and associated with a reduced risk of complications and shorter recovery times; drawing a blood sample is much less burdensome for patients than undergoing a surgical biopsy.<sup>7</sup>

In addition to enhancing patient comfort, liquid biopsies allow for real-time monitoring of disease progression and treatment effectiveness. By analyzing tumorderived components in bodily fluids over time, clinicians can evaluate tumor progression, treatment responses, emerging resistance,

and tumor recurrence, enabling timely and personalized therapeutic interventions.8

For example, continual analysis of circulating tumor DNA expression levels in patients with advanced bladder cancer has been shown as a highly sensitive tool for treatment response monitoring and early detection of metastatic relapse.<sup>9</sup>

Another key advantage of liquid biopsies is their ability to provide a more comprehensive view of the tumor's genetic makeup, including heterogeneity within primary tumors and between distant metastasis.

Unlike standard biopsies that sample a single tumor site, liquid biopsies can detect circulating DNA from multiple tumor locations, thus capturing the disease's heterogeneity.<sup>10</sup>

Most importantly, liquid biopsies have the potential for earlier cancer detection, which can significantly impact overall survival and disease outcomes.

By identifying tumor-specific biomarkers before symptoms manifest, liquid biopsies may facilitate the diagnosis of cancer at a stage when it is more treatable, leading to more favorable outcomes.<sup>11</sup>

### Limitations and challenges in clinical implementation

Liquid biopsies hold significant potential, but several limitations and challenges currently hinder their integration into routine clinical practice. A primary concern is their sensitivity and specificity.

Detecting and accurately interpreting the often low concentrations of tumor-derived biomarkers in bodily fluids can be technically difficult, leading to an increased risk of falsenegative and false-positive results.<sup>12</sup>

Another major barrier is the lack of standardization across various methodologies.

Variability in sample collection, processing, and analysis protocols results in inconsistencies between laboratories, which undermines the reproducibility of results and diminishes clinical confidence.<sup>13</sup>

Additionally, liquid biopsy assays require thorough clinical validation and regulatory approval to ensure their analytical and clinical reliability before being incorporated into standard oncologic care.

Finally, the high costs associated with next-generation sequencing and omics technologies, as well as the complexity of data interpretation, may limit accessibility, particularly in low-resource healthcare settings.<sup>14</sup>

These challenges highlight the need for ongoing refinement and standardization of liquid biopsy technologies to facilitate their wider clinical implementation.

# Promising FDA-approved applications in specific cancer types

Liquid biopsies are steadily moving from research into real-world clinical settings, with several assays receiving FDA approval for use in cancer care.

These approved tests showcase how liquid biopsy technologies are applied across different cancer types, from screening and diagnosis to disease progression monitoring.

Each assay targets specific tumor-derived biomarkers, such as circulating tumor DNA or cells, offering a non-invasive insight into the molecular landscape of cancer.

One of the earliest FDA-cleared liquid biopsy tools is the CellSearch® Circulating Tumor Cell Kit, which enumerates circulating tumor cells in peripheral blood.

This test is used in patients with metastatic breast, colorectal, or prostate cancer and serves as a prognostic tool.

The number of circulating tumor cells correlates with progression-free and overall survival.
CellSearch® is not a diagnostic



test but is used to monitor disease progression and assess treatment efficacy in patients diagnosed with metastatic disease.<sup>15</sup>

In contrast, the cobas® EGFR Mutation Test v2 focuses on detecting specific genetic alterations in circulating tumor DNA extracted from plasma samples.

It identifies mutations in the epidermal growth factor receptor gene to identify patients with metastatic non-small cell lung cancer. selecting targeted therapies, such as tyrosine kinase inhibitors, making the test an important companion diagnostic tool to guide treatment decisions.<sup>16</sup>

Building on this foundation, broader genomic profiling is now possible through assays like Guardant360® CDx and FoundationOne® Liquid CDx, both of which are FDA-approved to detect multiple genomic alterations in circulating tumor DNA from blood samples.

These tests are designed for patients with solid tumors and are used

to match individuals to precision therapies based on their unique tumor mutation profile.

Guardant360® CDx provides information that can inform treatment decisions for patients with non-small cell lung cancer <sup>17</sup> and breast cancer <sup>18</sup>, while FoundationOne® Liquid CDx supports similar applications, identifying actionable mutations to guide therapy selection for patients with non-small cell lung cancer.<sup>19</sup>

Most recently, the Shield™ blood test represents a new direction for liquid biopsy—its use in early cancer detection and screening.

Approved by the FDA for colorectal cancer screening in average-risk adults, Shield analyzes circulating tumor DNA in plasma to detect mutations and epigenetic alterations associated with colorectal cancer.

In a pivotal clinical study involving 7,861 participants, the test demonstrated an 83% sensitivity in detecting colorectal cancer.

Unlike the other liquid biopsy assays primarily used in patients with a confirmed cancer diagnosis, Shield offers a potential alternative to conventional screening tools, marking a critical advancement in early detection strategies.<sup>20</sup>

#### **Future directions and clinical impact**

Liquid biopsies represent a transformative approach in oncology, offering a minimally invasive means for early cancer detection, real-time monitoring, and personalized treatment planning.

While sensitivity, standardization, and implementation challenges persist, ongoing research and technological advancements continue to address these issues.

As the field evolves, liquid biopsies are poised to become integral to cancer management, ultimately improving patient outcomes and advancing the precision medicine paradigm.

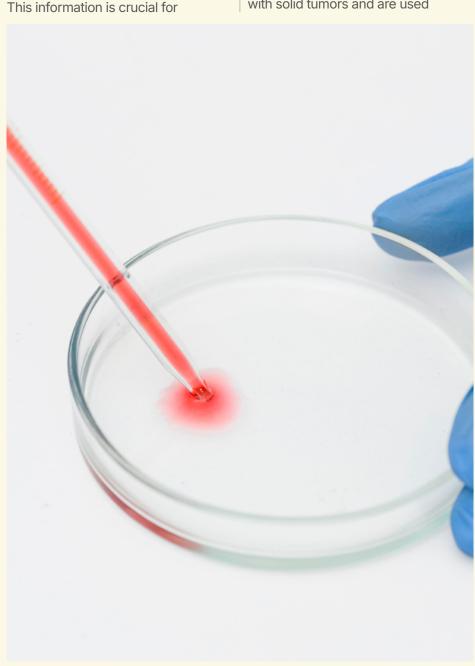


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**CANCER IMMUNOTHERAPY** 

# MRNA VACCINES: A NEW FRONTIER IN CANCER IMMUNOTHERAPY

BY ANĐELIKA KALEZIĆ

Cancer immunotherapy has revolutionized oncology by shifting the focus from directly targeting tumors to empowering the immune system to fight cancer. By unblocking immune responses that tumors often suppress, immunotherapy has provided a durable and, in some cases, curative option for patients with advanced disease.<sup>1</sup>

Unlike conventional treatments such as chemotherapy and radiation, which affect both malignant and healthy cells, immunotherapy offers a more targeted approach by dynamically modulating the immune system's ability to recognize and destroy cancer cells.<sup>2</sup> Immune checkpoint inhibitors, CAR T-cell therapies, and monoclonal antibodies have become integral components of contemporary cancer care, significantly enhancing survival rates for various malignancies.<sup>3</sup> More recently, mRNA vaccines are joining the expanding pool of tools that immunotherapy can offer in the clinical setting of cancer care.<sup>4</sup>

#### **Emergence of mRNA vaccines in cancer treatment**

The success of mRNA vaccines against COVID-19 reignited interest in their application beyond infectious diseases, particularly in oncology. mRNA vaccines deliver encapsulated synthetic messenger RNA into the patients' cells, which are translated into tumor-specific proteins that act as antigens.

These antigens, presented on the surface of cells, stimulate the adaptive immune system's cytotoxic and helper T lymphocytes, along with innate immune responses, to identify and attack cells that express these markers.<sup>6,7</sup>

The key benefits of mRNA technology are its safety, flexibility, high efficiency

in inducing both humoral and cellular immunity, cost-effectiveness, and rapid production.8

The concept of using mRNA to activate anti-cancer immunity has existed for several decades. Still, recent technological advancements in mRNA stability, delivery systems, and manufacturing have made clinical applications viable.<sup>9</sup>

In oncology, mRNA vaccines are designed to target widespread tumor-associated antigens or to be personalized based on the unique mutations within a patient's tumor.<sup>10</sup>

This tailored approach aims to fully utilize the immune system's ability to precisely recognize and eliminate cancer cells.

#### Early clinical evidence

While no mRNA vaccine currently has regulatory approval, multiple clinical trials have shown highly promising results in improving survival and patients' quality of life for various malignancies. One of the most notable examples is mRNA-4157/V940, a personalized mRNA vaccine.

In a Phase 2b clinical trial involving patients with resected stage III and IV melanoma, the combination of mRNA-4157/V940 with pembrolizumab, an anti-PD-1 checkpoint inhibitor, resulted in recurrence-free survival of 79% (95% CI: 69.0–85.6) compared to 62% (95% CI: 46.9–74.3) with pembrolizumab monotherapy alone.<sup>11</sup>

The findings, published in The Lancet journal, also demonstrated that adjuvant mRNA-4157/V940 showed a manageable safety profile.

Another promising candidate is autogene cevumeran, an individualized neoantigen vaccine based on uridine mRNA–lipoplex nanoparticles targeting pancreatic ductal adenocarcinoma, one of the most aggressive and lethal malignancies.

Data from the Phase 1 trial published in Nature journal showed that patients



who received autogene cevumeran had potent neoantigen-specific T cell responses (neoantigen-specific T cells were found in 8 out of 16 patients), and early data suggested a correlation between vaccine-expanded T cells and delayed cancer recurrence.<sup>12</sup>

Beyond melanoma and pancreatic cancer, several ongoing clinical trials are investigating mRNA vaccines across a range of malignancies, including breast cancer, non-small cell lung cancer, colorectal cancer, and head and neck squamous cell carcinoma.<sup>7,13</sup>

## Promise and advantages of mRNA cancer vaccines

mRNA vaccines offer numerous advantages that position them as a promising new modality in cancer immunotherapy.

Their design and manufacturing processes are highly flexible, enabling rapid adaptation to individual tumor antigen profiles.<sup>14</sup>

From a logistical perspective, the speed at which mRNA vaccines can be produced makes them especially suited for personalized medicine.

Manufacturing timelines of a few weeks make it feasible to create individualized vaccines for patients with newly diagnosed cancers, a feat that would have been inconceivable with earlier technologies.<sup>15</sup>

This personalization holds the potential to overcome tumor heterogeneity, a major barrier to effective cancer treatment.

Additionally, mRNA vaccines do not require the use of live viruses or DNA integration, which reduces safety concerns associated with some earlier vaccine technologies.<sup>16</sup>

Moreover, mRNA vaccines can stimulate both arms of the adaptive immune response: the humoral response, through antibody production, and the cellular response, through cytotoxic T lymphocyte activation.<sup>17</sup>



Photo credit: Freepik

#### Challenges and future directions

Despite their immense promise, several challenges must be addressed before mRNA vaccines can achieve widespread clinical adoption in oncology. A primary concern for the clinical application of mRNA vaccines is the inherent instability of mRNA and the efficiency of delivery vehicles necessary to achieve proper antigen expression and immune system activation.<sup>18</sup>

Advances in lipid nanoparticle delivery systems have enhanced the stability and efficacy of mRNA vaccines, allowing for efficient antigen presentation and robust immune activation.<sup>19</sup>

Another major hurdle lies in the identification of appropriate tumor-specific neoantigens for each patient. This process requires sophisticated bioinformatics pipelines and high-quality tumor and normal

tissue sequencing, adding logistical complexity and cost.<sup>20</sup>

An additional challenge is posed by tumor immune evasion and the creation of an immunosuppressive tumor microenvironment, which can inhibit the effectiveness of vaccine-induced immune responses. Combining mRNA vaccines with other modalities, such as checkpoint inhibitors or other immune modulators, may be necessary to overcome these barriers.<sup>21</sup>

Nonetheless, this field is advancing rapidly. Ongoing clinical trials will provide critical data on the efficacy and safety of mRNA cancer vaccines in larger patient populations.

As technology continues to mature, mRNA vaccines have the potential to become a cornerstone of personalized cancer immunotherapy, offering new hope to patients facing even the most challenging malignancies.

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# From crisis to change: how The Pink Fund fights the economic fallout of cancer

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#### **OPINION PIECE**

#### AI IN ONCOLOGY

# All is unlikely to replace the oncologist, but it may reshape the way oncology is practiced

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21 Aug - 23 Aug



Cancer Indication:
Genitourinary cancer



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#### OCTOBER 2025

#### NCCN 2025 Annual Congress: Hematologic Malignancies



Location: San Diego, California



Date: 10 Oct - 11 Oct



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Date: 17 Oct - 21 Oct



Cancer Indication: General



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Date: 21 Aug - 23 Aug



Cancer Indication:
Genitourinary cancer



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#### IASLC World Conference on Lung Cancer 2025



Location: Barcelona, Spain



Date:

6 Sep 2025 - 9 Sep



Cancer Indication: Lung cancer



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28 Sep - 1 Oct



Cancer Indication:
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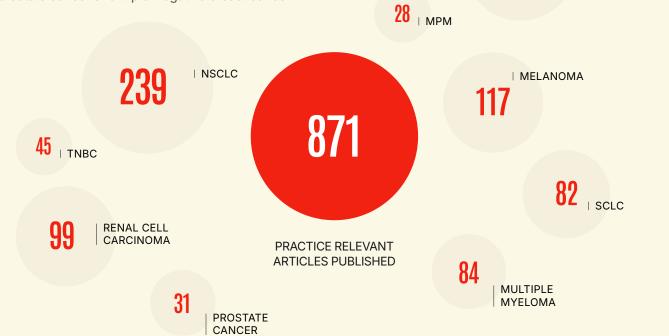




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PAGEVIEWS	12,389
SESSIONS	7,542
AVG. SESSION	01:31
PAGES PER SESSION	1.64

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DEVICE CATEGORY	TOTAL VISITORS	PAGEVIEWS
Mobile	3,472	2,392
Desktop	2,774	1,948
TABLET	204	152

#### VISITORS BY GENDER

<u>Q</u> 1	TOTAL FEMALE	590/0
<b>Q</b> 1	TOTAL MALE	410/0

#### TOP 10 COUNTRIES WHERE VISITORS COME FROM:

COUNTRY	VISITORS	SESSIONS
1. United States	1,627	1,030
2. Ireland	889	590
3. Germany	615	459
4. Poland	270	190
5. Sweden	242	148
6. Switzerland	232	193
7. China	225	203
8. United Kingdom	224	189
9. Netherlands	222	154
10. Malta	1	107

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# ONCOLOGY COMPASS Digest

# THE NEXT ISSUE **WILL BE PUBLISHED IN OCTOBER 2025**

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