1Cell.Ai
OncoIncytes®
True live single cell multi-omics

An integrated platform combining live single-cell CTC multi-omics with matched ctDNA—from a single blood draw.

Background

Precision oncology has advanced significantly with the development of targeted therapies such as antibody-drug conjugates (ADCs) and bispecific antibodies. However, their success depends on accurate assessment of tumor biology, particularly target expression, heterogeneity, and dynamic changes during treatment.

Cancer is a highly heterogeneous and evolving disease, with co-existing subclonal populations that influence therapeutic response and drive resistance. Target expression is often non-uniform and changes over time, posing a major challenge for therapies that rely on consistent antigen presence.

Current diagnostic approaches remain limited. Tissue biopsy provides a static snapshot and fails to capture tumor evolution, while conventional liquid biopsy lacks protein-level context, critical for understanding functional target expression. These gaps contribute to variable clinical responses and high significant late-stage failures in ADC and bispecific development" highlighting the need for dynamic, multi-omics approaches that can capture tumor complexity in real time.

Challenges

Patient Selection

- Incomplete representation of tumor biology at baseline: Single-site tissue sampling may not fully capture intra-patient heterogeneity, including subclonal variation in target expression, genomic alterations, potentially impacting accurate patient stratification.
- Limited ability to predict response: Current methods fail to reliably identify patients likely to benefit, including those at risk of primary resistance.
- Impact on trial outcomes: These limitations lead to suboptimal patient stratification, contributing to variable clinical responses, and reduced trial efficiency.

Assessing Target Expression & Validation

- Comprehensive representation of tumor burden: CTCs originate from multiple metastatic sites, providing a system-wide view of tumor biology compared to single-site tissue biopsy.
- Direct assessment of functional protein expression: Measures cell surface targets (e.g., HER2, PD-L1) in real time to evaluate target engagement potential.
- Dynamic monitoring of target modulation: Captures temporal changes in target expression during therapy, including upregulation, downregulation, or loss.
- Real-time tumor monitoring: Supports treatment decisions based on current tumor biology relative to archival tissue

Tumor Heterogeneity and Evolution Under Treatment Pressure

- Dynamic tumor adaptation: Under therapeutic pressure, tumors undergo continuous molecular and phenotypic changes not captured by baseline assessments.
- Emergence of resistant clones: Treatment drives subclonal selection and expansion of resistant populations, leading to disease progression.
- Temporal changes in target expression: Target expression may be heterogeneously expressed over time, which is not adequately captured by conventional methods.
- Delayed detection of progression: Emerging resistance is often identified at clinical relapse or radiographic progression, limiting timely intervention.

Inadequate Longitudinal Monitoring and Real-Time Insights

Lack of longitudinal data limits the ability to:

- Predict co-occurring mutations
- Monitor target expression, treatment response in real time
- Identify emerging resistance mechanisms

This gap reinforces the need for non-invasive, longitudinal, multi-omics monitoring platforms that can track tumor dynamics over time.

Proof of Mechanism: Current Limitations

Limited insight into mechanism of action: Critical questions around drug activity remain difficult to address in clinical settings, including:

- Is the target being effectively engaged and internalized?

- Is the payload released, engaging its target, and driving the intended biological response?
- Are downstream pathways being modulated to drive efficacy?
- Are resistance mechanisms (e.g., target loss, efflux activity, resistance markers) emerging?

These critical questions remain difficult to address, as preclinical models often fail to reliably predict human response.

Our Solution- OncoIncytes: Enabling Next Generation Precision Oncology

OncoIncytes marks the evolution of a genomics-based diagnostic approach to an AI-powered precision oncology platform, combining deep scientific expertise with advanced data science capabilities. It is a comprehensive multi-modal cancer diagnostic panel that integrates circulating tumor DNA (ctDNA) with true single-cell analysis of circulating tumor cells (CTCs), alongside RNA transcriptomics and proteomics (150+ proteins at single-cell resolution). By unifying these complementary data layers, OncoIncytes delivers a high-resolution, real-time view of tumor biology enabling unprecedented insight into heterogeneity, tumor evolution, and functional target expression to support more informed and precise clinical decision-making.

This approach offers exceptional sensitivity and specificity to optimize clinical trial success, particularly in early-stage research. In the context of antibody-drug conjugate (ADC) development, it provides a unique advantage in identifying eligible patients by accurately capturing cell surface protein expression addressing a critical challenge in translational oncology. Leveraging a 1080-gene panel and advanced AI/ML models, OncoIncytes generates deep, actionable insights that enhance patient stratification, therapy response monitoring, and resistance detection. Its ability to detect protein expression at the single-cell level beyond the capabilities of conventional liquid biopsy positions it as a transformative platform for cancer research and drug development.

Advantages of OncoIncytes: Bridging Critical Gaps in Precision Oncology

OncoIncytes directly addresses key challenges in antibody-drug conjugate (ADC) and bispecific antibodies development, where therapeutic success depends on:

- Target expression
- Tumor heterogeneity
- Dynamic changes in antigen
- Emergence of resistant clones
- Cellular and protein-level context

The platform enables:

- Precise patient selection based on real-time target expression at DNA, RNA, and protein level.
- Detection of cell surface proteins not captured by conventional liquid biopsy approaches
- Early identification of therapy responders vs non-responders
- Longitudinal monitoring of therapy response and resistance dynamics

This provides a distinct advantage in early-stage clinical trials, improving translational success, and reducing late-stage failures.

Future Directions

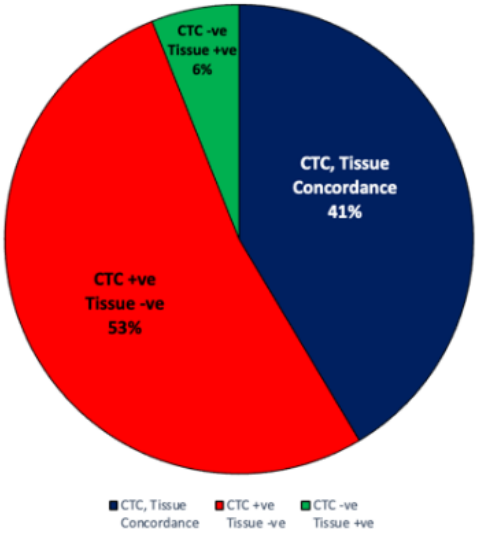
CTC-driven approaches are increasingly shaping the future of precision oncology by enabling dynamic, real-time adaptation of therapeutic strategies. As technologies continue to advance, several key applications are emerging:

- Prognostic stratification: Baseline and longitudinal CTC profiles are being explored as indicators of clinical outcomes, with higher CTC burden often correlating with poorer prognosis.
- Therapy monitoring: Serial assessment of target-positive CTCs enables real-time evaluation of treatment efficacy and early identification of resistance.
- Integrated precision medicine: Combining CTC-derived data with genomic, transcriptomic, and proteomic insights offers a comprehensive understanding of tumor biology and evolution.

CTCs are more sensitive than tissue IHC in analyzing protein expression markers

N: 376 Clinical Samples (All Solid Tumors)
No Tissue Data: 82 (~22%) samples
Concordance Data: 294

- 41% of samples where tissue and CTCs provided the same results (both +ve or both -ve)
- 53% of samples where CTCs were +ve but tissues were -ve; CTCs -> this may reflect tumor evolution since the time the tissue biopsy was taken and /or tumor heterogeneity missed by tissue but captured by CTC (more studies needed to verify this).
- 6% of sample where CTCs -ve but were +ve on tissue.
- Other published studies have suggested that expression level of PDL1 in CTCs is a better predictor of outcomes than expression levels in tissue.



1Cell.Ai
Ai-Powered Precision Oncology

CTC-PD-L1 IF [Dako 22C3]
Tissue-PD-L1 IHC

Notes:

About the Company

1Cell.Ai Inc. is on a mission to democratize precision cancer monitoring and testing to make cancer testing an Actionable, Accessible, and Affordable solution. We bring the power of Genomics data and Artificial Intelligence (AI) to healthcare. We intend to impact millions of cancer patients' lives by providing high-quality precision therapy options to all needful patients worldwide.

US Office
20380 Town Center Lane, #218 Cupertino, CA 95014

US Lab
320, Hatch Drive, Foster City, CA 94404

India Office
701, Sigma Building, Technology street, Hiranandani Gardens, Powai, Mumbai 400076

India Lab
3rd Floor, Laxmi Avenue Commercial Tower, Shankar Kalat Nagar, Wakad, Pimpri-Chinchwad, Pune 411057

Learn More at 1Cell.Ai

Mail - info@1cell.ai | **Tel -** 1800 123 12355