

Liquid Biopsies: Uncovering Insights That Drive Development and Commercialization in the Clinic

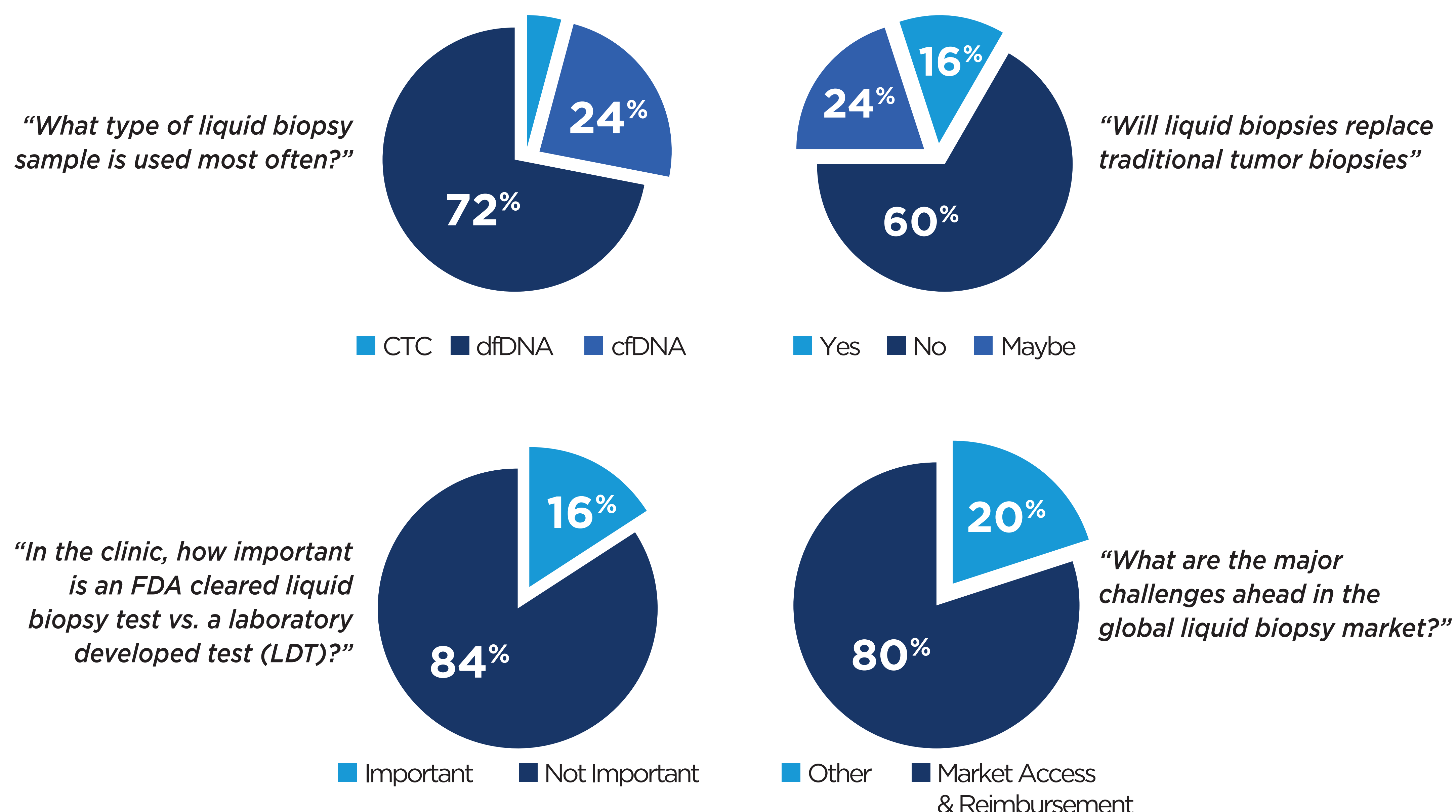
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INTRODUCTION

Liquid biopsies represent a groundbreaking technology with the potential to revolutionize cancer care. In the clinical setting, they offer promising applications such as early detection, personalized treatment guidance, and real-time monitoring of disease progression. While the widespread adoption of liquid biopsies for population-wide screening is still a subject of ongoing discussion, their use in selecting and monitoring patients receiving immunotherapy has gained traction, enabling the advancement of precision oncology. This shift is fueled by the increasing prevalence of a simple and non-invasive blood sample collection method, which renders traditional, painful, and potentially risky tissue biopsies less necessary. Consequently, next-generation sequencing (NGS)-based liquid biopsy testing options are rapidly being developed by commercial laboratories. Many of these laboratories are diligently pursuing regulatory approval, seeking companion diagnostics (CDx) claims through the Federal Drug Administration (FDA) in collaboration with their pharmaceutical co-developers. However, a major challenge for widespread acceptance lies in securing reimbursement from governmental and commercial payors, that is being actively addressed by these laboratories.

METHODS

A comprehensive synthesis of qualitative research and analysis of quantitative survey data was compiled from industry experts, clinicians, and researchers at the American Society of Clinical Oncology (ASCO) annual meeting in June 2023.



RESULTS

Key product specifications utilized in the development of liquid biopsies, along with technologies such as circulating tumor cells (CTCs), cell-free DNA (cfDNA), and circulating tumor DNA (ctDNA) are summarized. Additionally, the potential advantages and disadvantages of Next-Generation Sequencing (NGS)-based liquid biopsies, specifically in relation to their commercial use and application in clinical settings have been identified. The greatest disadvantage that liquid biopsies face, appears to be sensitivity. Furthermore, the survey found that ctDNA is the most often used technology and that 84% of respondents indicated that not having an FDA clearance is not a barrier for use in the clinic. Also, 80% of survey respondents indicated that market access and reimbursement are the greatest barriers to acceptance in the market.

DISCUSSION

The global liquid biopsy market is forecasted to be valued at \$5.4 billion in 2023, with a projected compounded annual growth rate (CAGR) of 14.5% during the forecast period, ultimately reaching a valuation of \$10.64 billion by 2028. Within this market, the research segment constitutes 28%, while the clinical sector represents a substantial 72%. Notably, there is a burgeoning demand for clinical liquid biopsy technology in hospitals and academic medical centers, contributing to 61% of the market, particularly in the United States. This growth is driven by the imperative to enhance patient care and elevate clinical outcomes. As hospitals and academic medical centers progressively embrace Next-Generation Sequencing (NGS) technology for liquid biopsy, a discernible trend towards in-house clinical NGS testing is emerging. In the realm of liquid biopsy, Cell-free DNA (cfDNA) is expected to seize the lion's share at 46% in 2023, followed closely by Circulating Tumor DNA (ctDNA) at 34%, Circulating tumor cells (CTCs) at 11%, and other constituents at 9%, including RNA and exomes. Furthermore, the cancer application segment is projected to dominate the overall market, commanding a substantial revenue share of 98% in 2023. This dominance is attributed to the escalating global prevalence of cancer, which in turn fuels the growing utilization of liquid biopsy for screening various cancer types.

CONCLUSION

This comprehensive analysis of the liquid biopsy market offers valuable insights into the product features and challenges that impact the progress and commercial viability of NGS-based liquid biopsies within the clinical setting.