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INSIGHTS in FOCUS

PERSONALIZED HEALTH 2.0

Recent advances in diagnostics, therapies, and data availability have resulted in **personalized health** moving from an emerging theme to a **core driver of health care.**

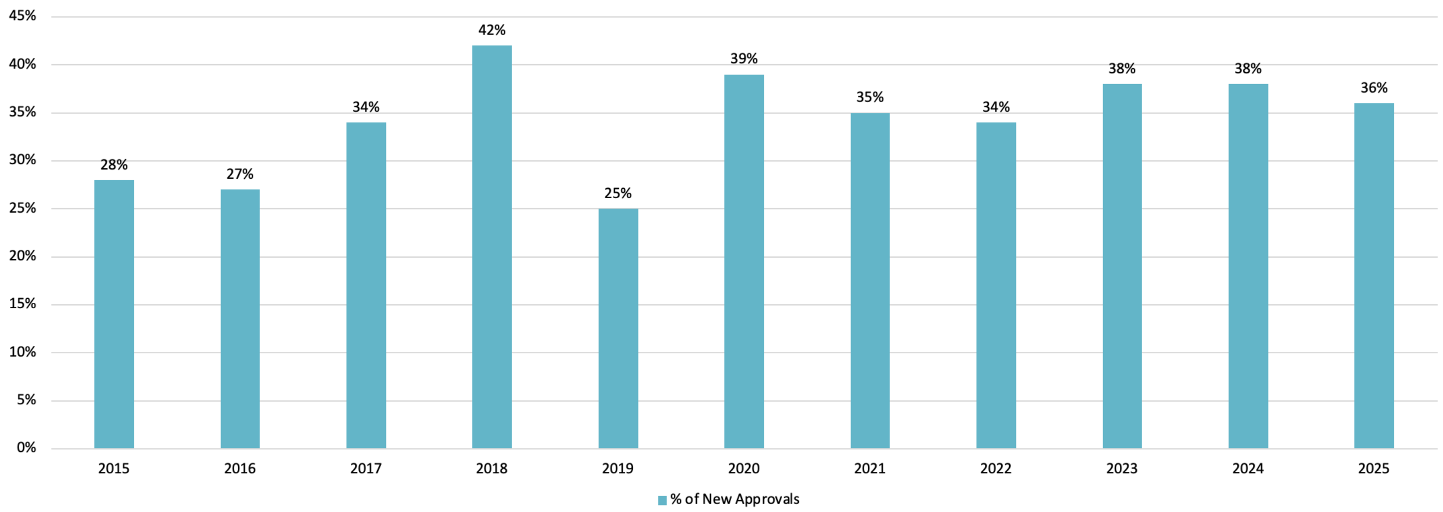
Targeted therapies represented ~36% of new FDA therapeutic approvals in 2025, marking the sixth consecutive year in which targeted therapies accounted for **more than one-third of new drug approvals.**

The theme has broadened beyond liquid biopsy. Opportunities include **new therapies, recurrence monitoring, companion diagnostics, AI-enabled tools, and continuous patient monitoring.**

Diagnostics are becoming core clinical infrastructure. Companion diagnostic non-invasive screening helps match patients with **the right therapies.**

Liquid biopsy is moving closer to routine screening. Liquid biopsy is expanding from tumor profiling toward **earlier cancer detection**, with the FDA approval of Shield underscoring the shift.

Personalized Health's Growing Share of Approvals



Note: Personalized health has remained a durable share of new drug innovation for more than a decade, accounting for at least one-quarter of new drug approvals in each year since 2015 and more than one-third in most recent years.

Source: Personalized Medicine at FDA: The Scope & Significance of Progress in 2025. Companion Diagnostics | FDA. Shield -P230009 | FDA.