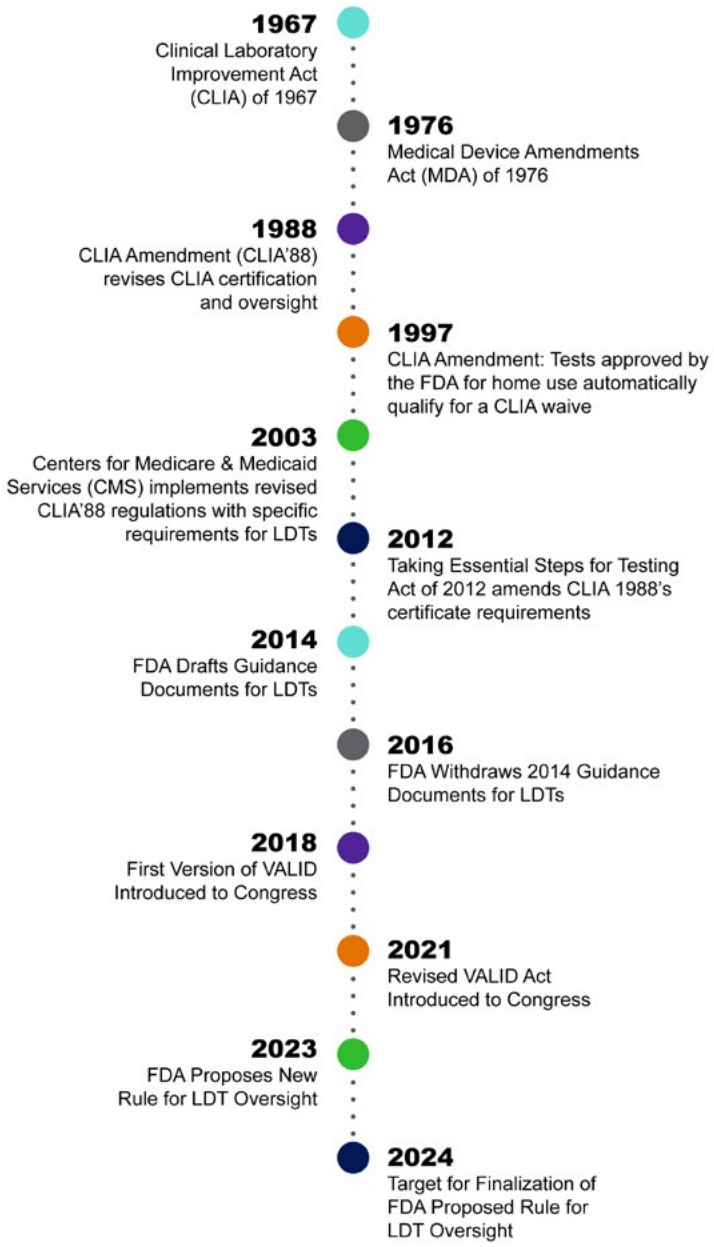
The Food and Drug Administration's (FDA) Oversight and Regulation of Laboratory Developed Tests (LDTs)

Executive summary

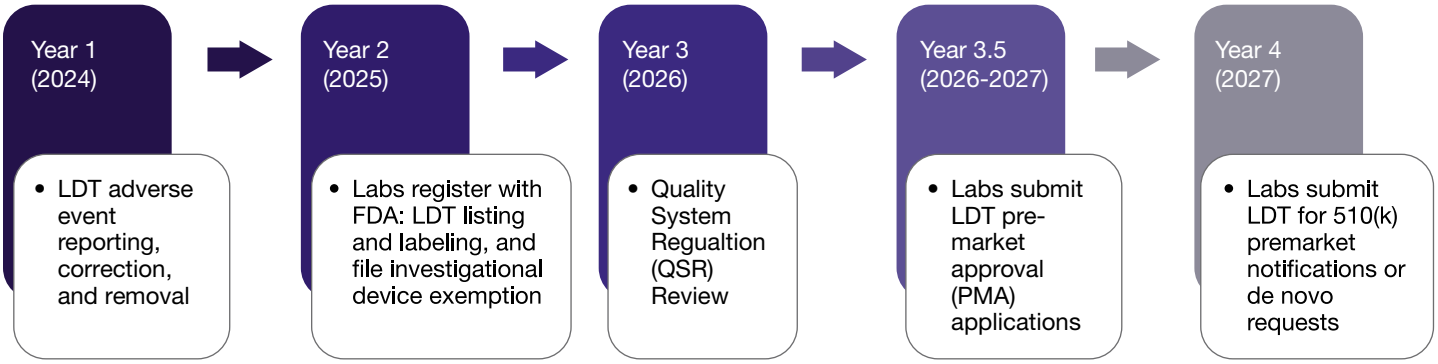
The FDA has regulated laboratory developed tests (LDTs) by enforcement discretion since 1976. Since 1976, LDT use and capabilities have soared to the point where they are an essential component of the medical ecosystem, particularly in diagnostics. With the increased use of LDTs, the FDA released a proposed new rule for LDT regulation in September 2023. The new rule re-classifies LDTs as medical devices/in vitro diagnostic tests, subjecting them to the entire FDA approval process. Changing how hundreds of thousands of tests are regulated is a massive undertaking; therefore, the FDA has proposed a 5-year phase-out of the current enforcement discretion policy and implementation of the new rule. The current target finalization date for the rule is April 2024. In the meantime, the FDA is reviewing public response to the rule and deciding on official next steps.

Timeline



Policy and Program Analysis Branch

If implemented, the following timeline would ensue:



2024: Labs would be required to submit LDT reports including adverse events that have or could have caused harm. FDA reviews the reports and decides what tests should be corrected or removed.

2025: Labs conducting LDTs must register with the FDA and list all LDTs, and file investigational device exemptions (IDEs)

2026: LDTs and labs would undergo Quality System Regulation (QSR) Review, which is used to assess device manufacturers that intend to distribute medical devices commercially.

2027: Labs would submit pre-market approval applications, a process in which the FDA conducts a scientific and regulatory review of the LDT to determine safety and effectiveness.

- After pre-market approval, labs submit either 510(k) or de novo requests to the FDA for full approval. A 510(k) application is designed for tests with a predicate on the market, while de novo applications are for tests without an analog on the market.

Sources

https://www.federalregister.gov/documents/2023/10/03/2023-21662/medical-devices-laboratory-developed-tests

https://www.ropesgray.com/en/insights/alerts/2023/10/regulation-without-legislation-fda-proposes-rule-to-regulate-laboratory-developed-tests

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4593508/

https://www.acla.com/wp-content/uploads/2015/01/Tribe-Clement-White-Paper-1-6-15.pdf

https://www.genome.gov/about-genomics/policy-issues/Regulation-of-Genetic-Tests

https://petrieflom.law.harvard.edu/resources/article/fda-further-explains-delay-on-ldt-guidance