Strengthening the FDA Biomarker Qualification Program:
A more reliable pathway for biomarker-driven drug development

What are biomarkers and why do they matter?

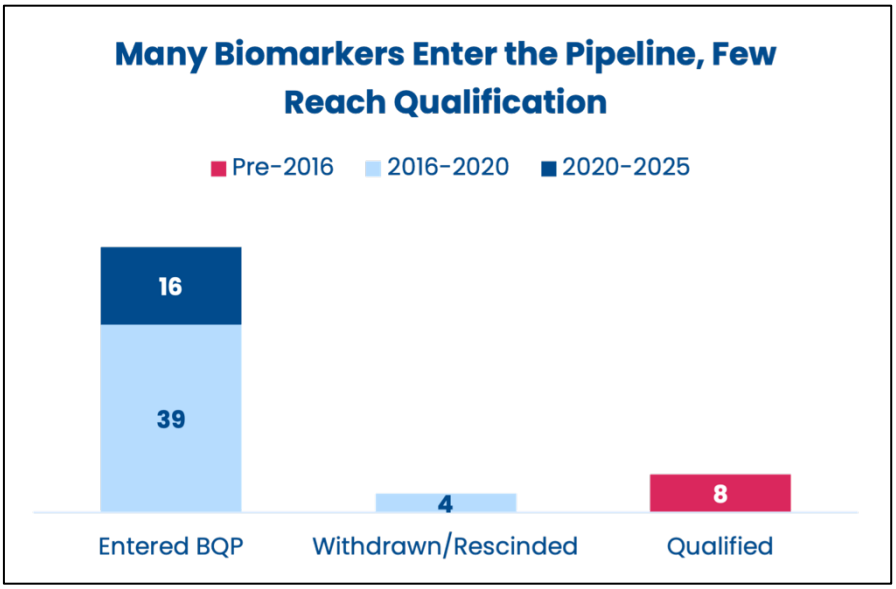
Biomarkers are measurable signs in the body, such as genetic information, imaging signals, or disease characteristics that help researchers detect disease, guide treatment, monitor safety, and evaluate whether a therapy is working. Researchers use biomarkers in clinical trials to identify which patients may benefit from treatment, evaluate response, and in some cases support regulatory decisions about safety and efficacy. Biomarkers are increasingly important to improve clinical trials, support accelerated approvals, and facilitate drug development for rare diseases—but the FDA program for biomarker oversight is not working as intended.

What is the goal of the FDA Biomarker Qualification Program?

Established under the 21st Century Cures Act, the FDA's Biomarker Qualification Program was designed to evaluate and validate biomarkers for use across drug development programs without repeated review. Its goal is simple: make biomarker use more predictable, consistent, and efficient so high quality biomarkers can readily support drug development and regulatory decision-making.

The Biomarker Pathway Is Falling Short

Congress created a formal pathway in 2016, but qualification remains rare, and the program has not delivered qualified surrogate endpoint biomarkers.



More than a decade after its establishment, the program has not become a reliable or predictable pathway for biomarker development.

- Too few biomarkers reach qualification
- Many remain stalled early in the process
- Review timelines are long and unpredictable
- Requestors lack clarity on what evidence FDA expects
- Data from Collins et al 2025

Delays and uncertainty in the pathway make it harder to develop and use biomarkers that could improve clinical trials, strengthen regulatory decisions, and help patients access promising therapies sooner.

What Did We Do?

Wrote a multi-stakeholder white paper providing recommendations for improving the BQP →

Workgroup Members: Amgen, AstraZeneca, Biogen, Biotechnology Innovation Organization (BIO), Biomarker Solutions, LLC, Critical Path Institute, Foundation for the National Institutes of Health (FNIH), Genentech, Kendall Square Policy Strategies, Leavitt Partners, PathAI, Vertex Pharmaceuticals.

What Can Congress Do?

Congress can ensure FDA's Biomarker Qualification Program functions as a more reliable and effective tool for modern drug development. As biomarkers play a growing role in accelerated approval, precision medicine, and drug development for rare diseases, Congress has a clear role in ensuring FDA has a regulatory framework to evaluate and apply biomarkers efficiently and consistently.

1. Make the program more reliable

Congress can reinforce expectations for program performance and ensure the Biomarker Qualification Program operates with greater transparency, consistency, and timeliness.

- Increase oversight of review timelines and program performance
- Ensure FDA reports on delays, outcomes, and program progress
- Reinforce expectations for timely and consistent feedback

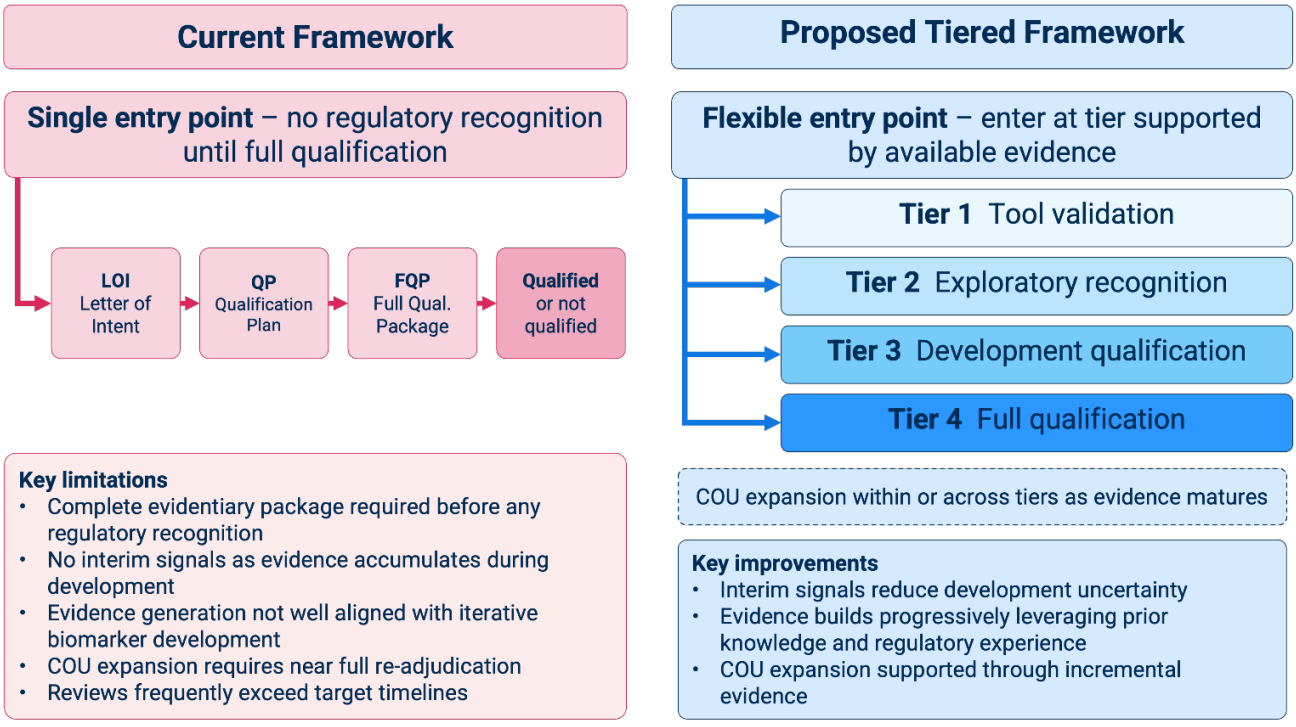
2. Make qualification more useful

Congress can help ensure biomarker qualification provides a clearer and more consistent signal for how to use biomarkers in drug development and regulatory review.

- Clarify how to use qualified biomarkers in clinical trials
- Improve consistency across FDA review divisions
- Align qualification with drug development pathways

3. Make the pathway more flexible

Congress can support a more practical framework that better reflects how biomarkers are developed, validated, and improved over time.



Congress has already recognized the need to strengthen the BQP. The House FY2027 Agriculture-FDA appropriations report language directs FDA to assess challenges facing the program and identify recommendations to improve its efficiency, transparency, and predictability. **Building on this momentum, Congress can help ensure the BQP functions as a more reliable and effective tool for modern drug development.**