



FDA

**U.S. FOOD & DRUG  
ADMINISTRATION**

CENTER FOR DRUG EVALUATION & RESEARCH



**FDA'S BIOMARKER QUALIFICATION PROGRAM  
EDUCATIONAL MODULE SERIES—MODULE 8**

# **THE BIOMARKER QUALIFICATION PROCESS: A ROADMAP FOR REQUESTORS**

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# BIOMARKER QUALIFICATION PROGRAM

FDA

- The Biomarker Qualification Program (BQP) was established to encourage the development of biomarkers for use in drug development, facilitate an efficient review process, and make information on qualified biomarkers publicly available.
- A qualified biomarker can be used in multiple drug development program without the need for CDER to reconfirm the suitability of the biomarker's qualified context of use.
- Potential to streamline the drug development paradigm.





# 21<sup>ST</sup> CENTURY CURES ACT: QUALIFICATION PROCESS FOR DRUG DEVELOPMENT TOOLS



- The 21st Century Cures Act was signed into law on December 13, 2016.
- Section 507, Qualification of Drug Development Tools, was added to the Food, Drug, and Cosmetic Act and formally establishes an updated multistage process for biomarker qualification.
- The Act specifies three submission stages:
  - Letter of Intent
  - Qualification Plan
  - Full Qualification Package
- The law specifies that FDA can decide whether to accept a qualification submission at any of these stages based on a number of factors including the scientific merit of the qualification submission.



# BIOMARKER QUALIFICATION PROCESS

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**Letter of Intent  
(LOI)**

Initiates the qualification process of a biomarker for a proposed context of use (COU) in drug development



**Qualification  
Plan (QP)**

Defines the intended development to generate the necessary supportive data to qualify the biomarker for the proposed COU



**Full Qualification  
Package (FQP)**

Contains all accumulated data to support the qualification of the biomarker for the proposed COU



**Qualification  
Recommendation**

Contains FDA's determination on whether the biomarker is qualified for the proposed COU based on a comprehensive review of the FQP





# **PUBLIC POSTING ON BIOMARKER QUALIFICATION PROGRAM WEBSITE**



**FDA will publicly post information with respect to each biomarker qualification submission under the qualification process, including—**

- Stage of the qualification process
- Date of most recent submission
- Summary data and evidence contained in such submissions
- FDA's formal written determinations in response to qualification submissions

**Upon issuing a qualification determination, FDA will post:**

- Summary reviews that document the assessment of the submission
- Any rescissions or modifications to the qualification determination

**Information updated at least twice a year.**



**LEARN MORE**

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[www.fda.gov/BiomarkerQualificationProgram](http://www.fda.gov/BiomarkerQualificationProgram)

Learn more about the updated drug development tool qualification process:

<https://www.fda.gov/Drugs/DevelopmentApprovalProcess/DrugDevelopmentToolsQualificationProgram/ucm561587.htm>