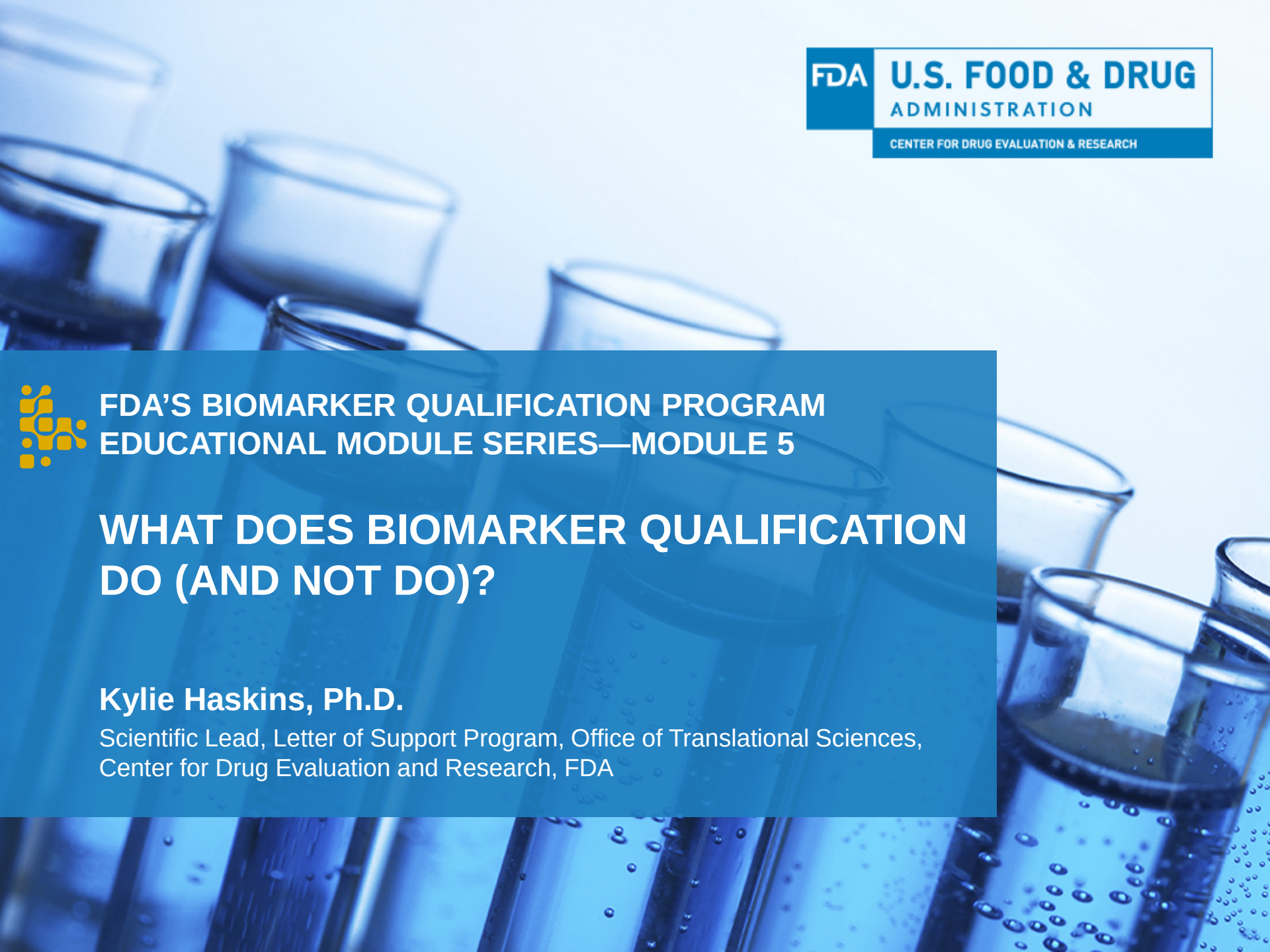

FDA U.S. FOOD & DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION & RESEARCH

FDA'S BIOMARKER QUALIFICATION PROGRAM EDUCATIONAL MODULE SERIES—MODULE 5

WHAT DOES BIOMARKER QUALIFICATION DO (AND NOT DO)?

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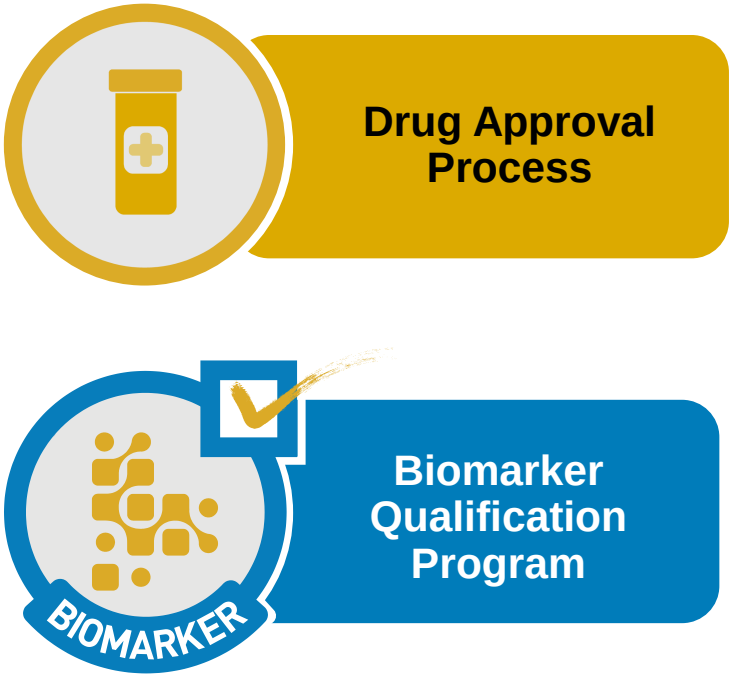
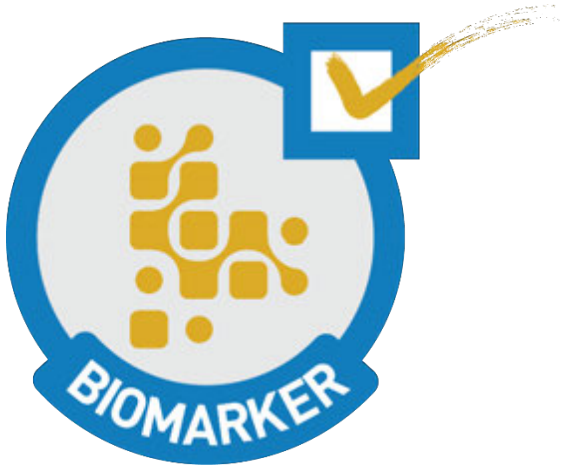
REGULATORY PATHWAYS FOR BIOMARKER USE IN DRUG DEVELOPMENT



BIOMARKER QUALIFICATION PROGRAM

- **Concept:** CDER developed the Biomarker Qualification Program to make biomarker data publicly available by establishing a biomarker's value for a particular context of use in drug development and regulatory review

- **Regulatory Implication:** No need to resubmit extensive data and request that the CDER review group reconsider or reconfirm the biomarker for the specific context of use



WHAT DOES BIOMARKER QUALIFICATION DO?

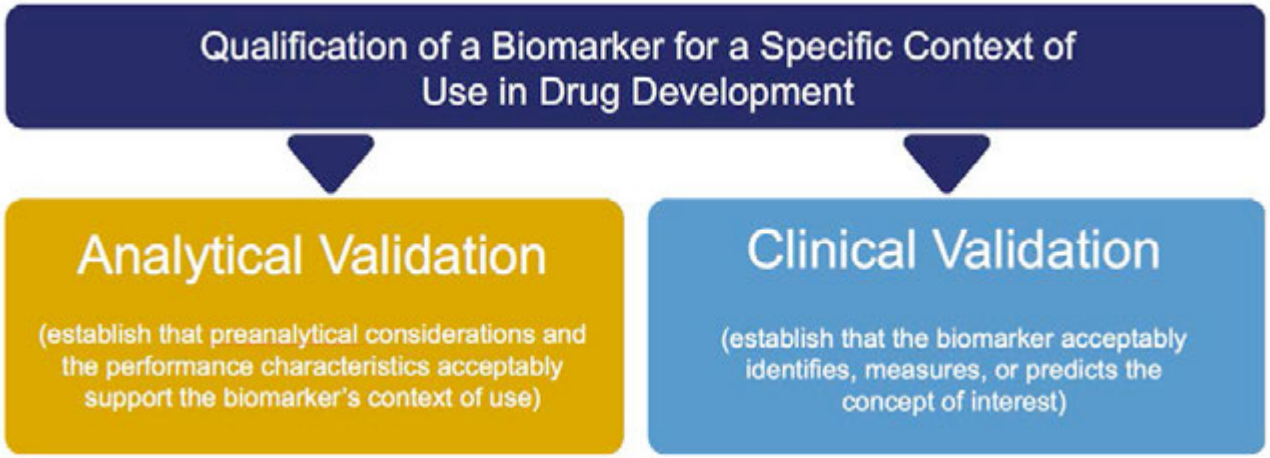
Qualifies biomarker to reliably support a specific context of use in drug development

Qualification is a regulatory conclusion that means a biomarker…

- Has data to support its specific context of use in drug development
- Has evidence that supports the potential benefit for its use in clinical trials to aid in developing new therapeutics
- Can be used in any drug development program under the qualified context of use
- Has a guidance document and FDA review documentation publicly available on the Biomarker Qualification Program's website

WHAT DOES BIOMARKER QUALIFICATION NOT DO?

- Biomarkers considered for qualification are conceptually independent of the specific test/assay performing the measurement
    - However, preanalytical considerations and the performance characteristics of the test/assay used to provide the biomarker data will be considered during the qualification review



- Qualification of a biomarker **does not** imply the test/assay has been reviewed by FDA and cleared or approved for use in patient care
- Qualification **does not** qualify the biomarker for use in clinical practice

LEARN MORE

www.fda.gov/BiomarkerQualificationProgram