FDA’S BIOMARKER QUALIFICATION PROGRAM
EDUCATIONAL MODULE SERIES—MODULE 3

PATHWAYS FOR USING BIOMARKERS IN DRUG DEVELOPMENT

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PRIMARY SOURCES FOR BIOMARKER EVIDENCE

Scientific Community Consensus

Drug-Specific Development & Approval Process

Biomarker Qualification Program
SCIENTIFIC COMMUNITY CONSENSUS

Information from published literature is a good source for hypothesis generation.
SPECIFIC DRUG APPROVAL PROCESS

Scientific Community Consensus

Information from published literature is a good source for hypothesis generation

Drug-Specific Development & Approval Process

Development of a biomarker as part of a specific new drug or biologic program

Biomarker Qualification Program
BIOMARKER QUALIFICATION PROGRAM

Information from published literature is a good source for hypothesis generation

Development of a biomarker as part of a specific new drug or biologic program

Establishes a biomarker’s value for a particular context of use in drug development and for regulatory review
CHOOSING A PATHWAY

• Each pathway has strengths and limitations.

• Consider your particular reasons and circumstances.

• Some types of biomarkers may be better suited for one path over another.

• The choice isn’t always clear, particularly in early development stages.

• More clarity is needed about when to follow one pathway or another.
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- Drug-Specific Development & Approval Process
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LEARN MORE

www.fda.gov/BiomarkerQualificationProgram