



FDA

U.S. FOOD & DRUG
ADMINISTRATION

CENTER FOR DRUG EVALUATION & RESEARCH



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



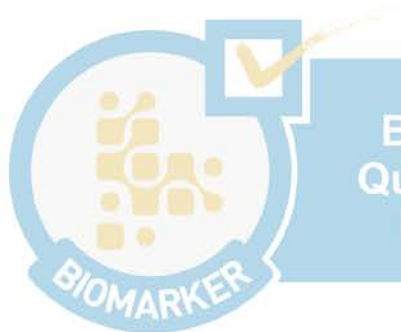
**Scientific
Community
Consensus**



**Information from published
literature is a good source for
hypothesis generation**



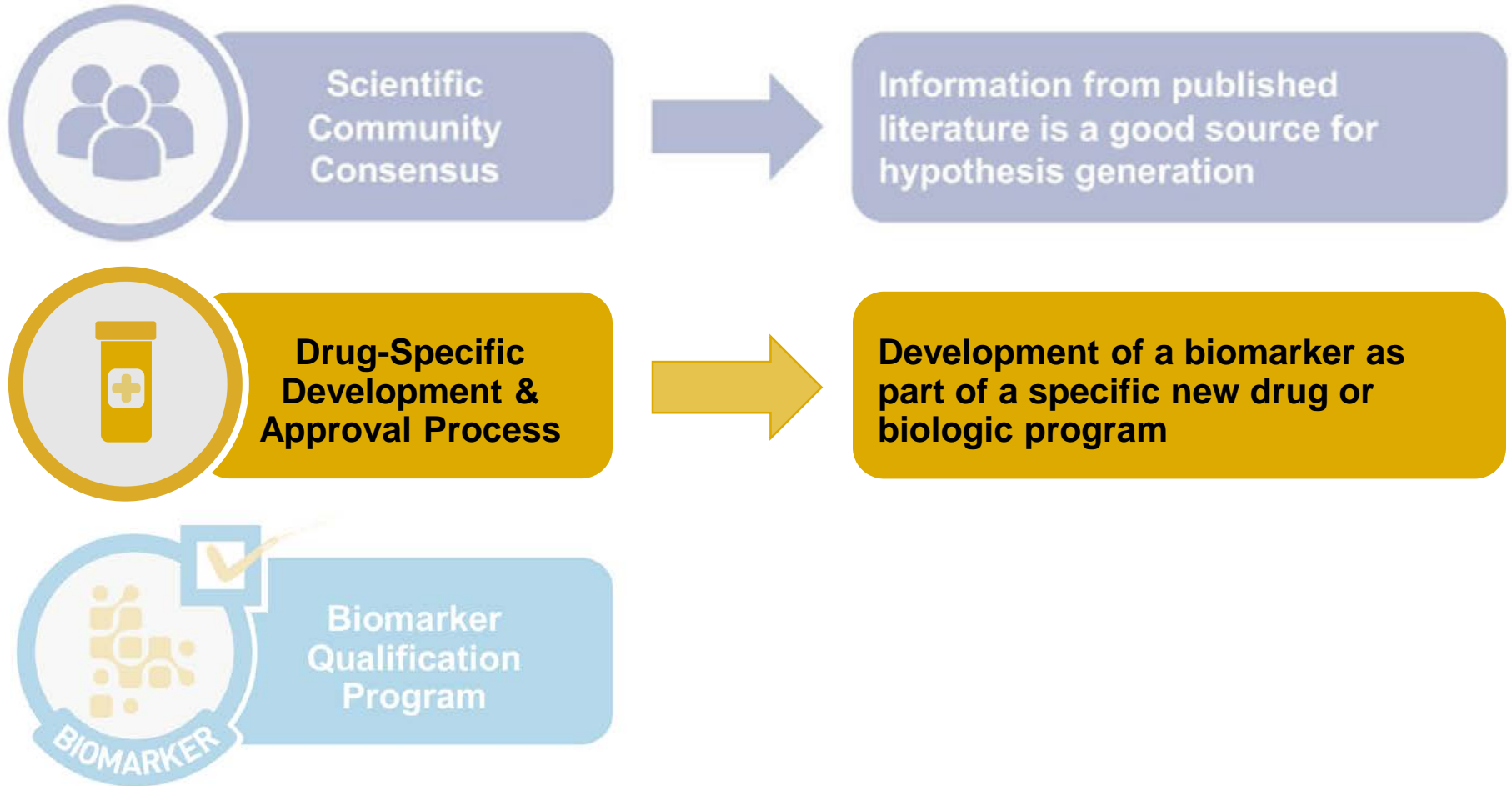
**Drug-Specific
Development &
Approval Process**



**Biomarker
Qualification
Program**



SPECIFIC DRUG APPROVAL PROCESS





BIOMARKER QUALIFICATION PROGRAM



Scientific
Community
Consensus



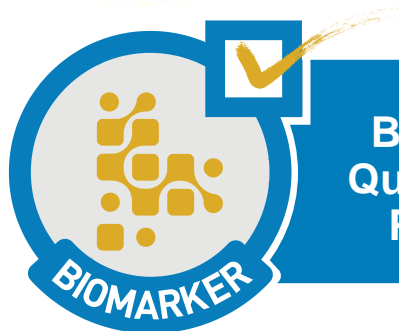
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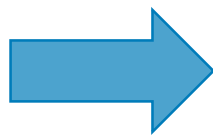
Drug-Specific
Development &
Approval Process



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



Biomarker
Qualification
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.



PATHWAYS FOR USING BIOMARKERS IN DRUG DEVELOPMENT



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BIOMARKER



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