



FDA

U.S. FOOD & DRUG
ADMINISTRATION

CENTER FOR DRUG EVALUATION & RESEARCH



FDA'S BIOMARKER QUALIFICATION PROGRAM
EDUCATIONAL MODULE SERIES—MODULE 6

OPPORTUNITIES TO ENGAGE WITH THE FDA ABOUT QUALIFICATION DURING BIOMARKER DEVELOPMENT

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ENGAGING WITH FDA DURING BIOMARKER DEVELOPMENT

FDA



Critical Path Innovation Meeting

Discussion on
potential biomarkers
that might enhance
drug development



Letter of Support Program

Letter issued for
promising
biomarkers based on
research findings



Biomarker Qualification Program

Qualification
decision made public



CRITICAL PATH INNOVATION MEETING

FDA

- Explore innovative strategies to overcome challenges in drug development
- Early opportunity for CDER and biomarker developer to explore potential of proposed biomarker
- Covers science, medicine, and regulatory aspects related to proposed biomarker
- Not a forum to discuss specific approval pathways



Critical Path Innovation Meetings

Guidance for Industry

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)

April 2015
Procedural

<https://www.fda.gov/drugs/developmentapprovalprocess/druginnovation/ucm395888.htm>



LETTER OF SUPPORT PROGRAM

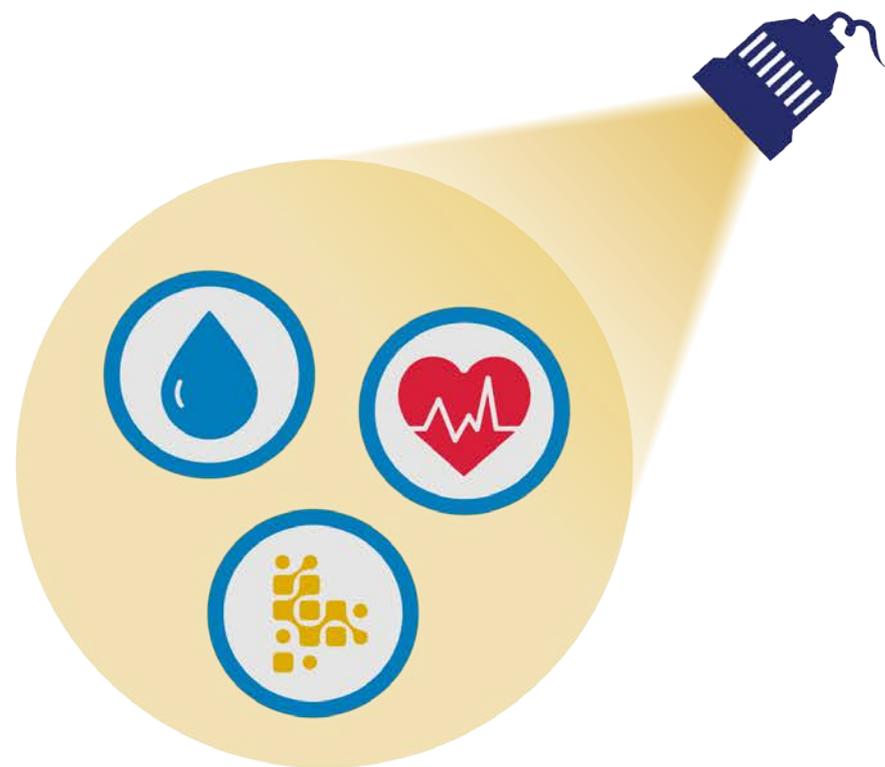


Letter of Support issued to promising biomarkers with potential application in drug development to:

- Demonstrate FDA's support for development
- Encourage collaborative efforts
- Stimulate additional studies

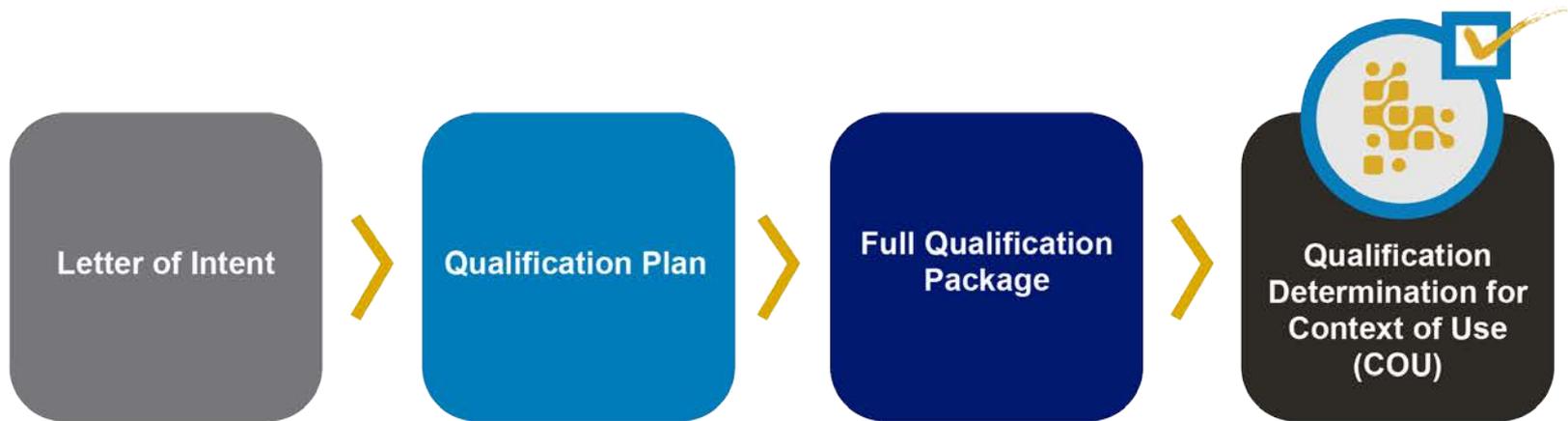
Letter of Support does not:

- Connote qualification
- Endorse a specific biomarker test or device





BIOMARKER QUALIFICATION PROGRAM



www.fda.gov/BiomarkerQualificationProgram



BIOMARKER QUALIFICATION PROGRAM



At each milestone, the requester will receive a formal written determination letter from the FDA accepting or declining the submission.



BIOMARKER QUALIFICATION PROGRAM



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Throughout the process, requesters can:

- Engage the program to seek clarification regarding the content of a determination letter.
- Obtain additional information about the qualification process.



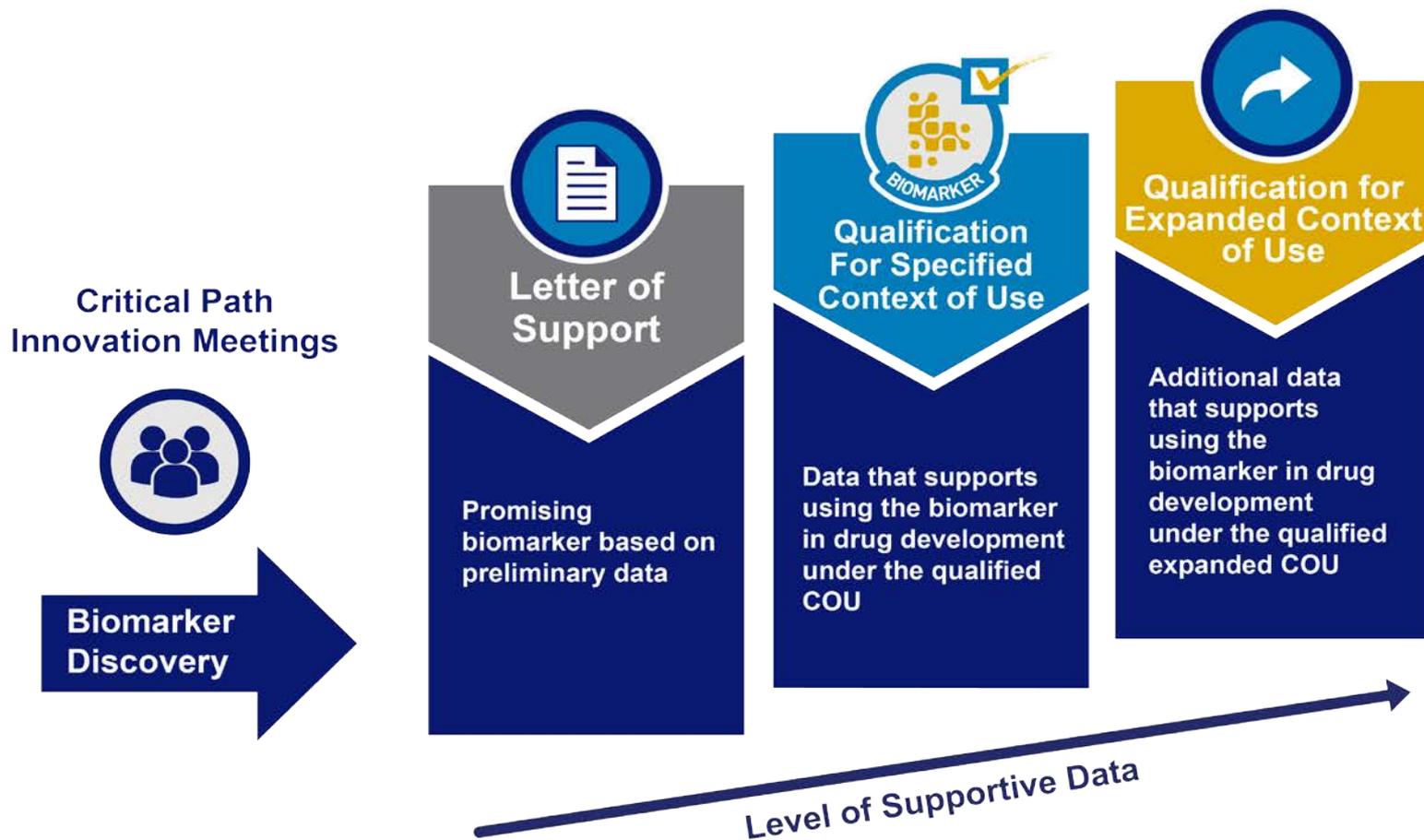
BIOMARKER QUALIFICATION PROGRAM





BIOMARKER DEVELOPMENT ENGAGEMENT OPPORTUNITIES

FDA





LEARN MORE

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www.fda.gov/BiomarkerQualificationProgram

Find detailed information about:

Critical Path Innovation Meetings

<https://www.fda.gov/drugs/developmentapprovalprocess/druginnovation/ucm395888.htm>

Letter of Support Program

<https://www.fda.gov/drugs/developmentapprovalprocess/ucm434382.htm>