OPPORTUNITIES TO ENGAGE WITH THE FDA ABOUT QUALIFICATION DURING BIOMARKER DEVELOPMENT

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ENGAGING WITH FDA DURING BIOMARKER DEVELOPMENT

- 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

- 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

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

Letter of Intent ➔ Qualification Plan ➔ Full Qualification Package ➔ Qualification Determination for Context of Use (COU)

New Submission ➔ Decide to Seek Qualification for Expanded COU ➔ Additional Data
BIOMARKER DEVELOPMENT ENGAGEMENT OPPORTUNITIES

Critical Path Innovation Meetings

Biomarker Discovery

Letter of Support
Promising biomarker based on preliminary data

Qualification For Specified Context of Use
Data that supports using the biomarker in drug development under the qualified COU

Qualification for Expanded Context of Use
Additional data that supports using the biomarker in drug development under the qualified expanded COU

Level of Supportive Data
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