



Industry Perspective: Biomarker Pathways



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Industry Perspective: Biomarkers Uses

- Industry biomarker uses:
 - Internally for drug development programs (e.g. fit for purpose)
 - To support regulatory submission (e.g. IND, NDA, BLA)
 - Submitted for qualification (e.g. qualification program)

While all biomarker types are important in drug development, biomarkers that will have the greatest impact on speed and efficiency of drug development are those biomarkers accepted as surrogate endpoints considered suitable to inform regulatory review and for assessing efficacy & safety

Industry Perspective: Biomarker Pathways

- There are advantages to developing and qualifying BM in the precompetitive space; industry ability to cooperate and coordinate time, effort, resources, samples, and data is critical
- Decreases in cycle time and administrative burden from initial acceptance through review could help increase use and impact of qualification pathways
- Sponsors would benefit from increased certainty in process

Biomarker Qualification: Evidentiary Framework Guidance Comments

- Outline the process, timing and expected communications to sponsors regarding review of the qualification components
 - Add process and timing for letter of intent, qualification plan, full qualification package to draft guidance to improve clarity and regulatory predictability for sponsors
 - Criteria used to determine whether a submission is “reviewable”? (as discussed at the December 11, 2018 “Drug Dev Tool Process under the 21st Century Cures Act and PDUFA VI” public meeting)
- Consider a pilot for engaging external experts in qualification review, when appropriate.
- Provide additional flexibility in the biomarker categories listed in BEST and the Biomarker Qualification: Evidentiary Standards draft guidance.
 - Limiting the list of biomarker categories may not allow for new or novel biomarkers and some biomarkers may fit into more than one category
- Include an explanation of the relationship between “Bioanalytical Method Validation” guidance and the biomarker qualification evidentiary framework in planned subsequent guidance documents
- Include the perspective of patients in the evidentiary framework where appropriate

Industry Perspective: Advancing Pathways

- Increase predictability/transparency of the qualification process
- Explore opportunities to incorporate qualification into the drug development process
- Develop incentives for industry to develop and seek qualification for innovative biomarkers
- Develop metrics on usage of qualified biomarkers in regulatory submissions
- Collaboration between stakeholders:
 - Industry
 - FDA
 - Academia
 - Patient Groups