



Drug Development Tools Qualification Guidance

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Biomarker Qualification



- Concept: Qualification is a conclusion that within the stated context of use, the results of biomarker measurements can be relied upon to have a stated interpretation and utility
- Regulatory implication: Industry can rely upon using the biomarker in the qualified manner in the IND period, and in NDA and BLA submissions, without needing to resubmit extensive data and request that the relevant CDER review group consider and reconfirm the biomarker

Qualification Process



- A framework for interactions between CDER and drug development tool (DDT) sponsors so that CDER can guide them towards compiling comprehensive evidence to support qualification of their selected DDT
- A mechanism enabling CDER to have a well-organized, multi-disciplinary, CDER unified, formal review of the data supporting a DDT, eventually leading to a CDER decision to qualify or not
- Enables a scientifically well-supported statement by CDER of qualification providing confidence that the evaluation has been comprehensive and the conclusions can be relied upon

CDER Qualification Program Goals



- To support outside groups who are attempting to establish a DDT for generalizable use
- To provide organized structure for interactions in a consistent and responsive manner while minimizing burdens on product review divisions
- Establishes a process for interactions with DDT sponsors

Process with CDER



- Two phases : Consultation/Advice and Review
- ‘Sponsor’ brings project to CDER
- Interdisciplinary working team assembled within CDER & other components of FDA as appropriate
- Information Package reviewed
- Advice given as needed on how to further progress development for intended use
- ‘Sponsor’ submits data package to FDA
- Full detailed review and decision on qualification
- Formal statement of qualification as appropriate

Qualification Guidance for Drug Development Tools



- High-level document
- Biomarkers and Patient Reported Outcome Instruments
- Definitions for biomarkers, PROs and qualification
- Rationale for qualification
- Process
- Procedures for making recommendations available
- Does not discuss evidentiary standards