A CLOSER LOOK AT CONTEXT OF USE

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The **Biomarker Qualification Program** was established to support CDER’s work with external stakeholders to develop biomarkers that aid in the drug development process.

Through CDER’s Biomarker Qualification Program, a biomarker *once qualified for a particular context of use* becomes publicly available and can be applied in any applicable drug development program.
Context of use is central to biomarker qualification.

The context of use is a complete and precise statement that describes the appropriate use of the biomarker and how the qualified biomarker is applied in drug development and regulatory review.

The context of use statement also describes important criteria regarding the circumstances under which the biomarker is qualified.
CONTEXT OF USE IN BIOMARKER QUALIFICATION

Context of Use

Use Statement
Concise statement that includes the name and identity of the biomarker and its purpose in drug development

Conditions for Qualified Use
Comprehensive description of conditions for the biomarker to be used in the qualified setting
BIOMARKER CATEGORIES AND CONTEXT OF USE

CONSIDERATIONS WHEN DEVELOPING A CONTEXT OF USE

• Identity of the biomarker
• Aspect of the biomarker that is measured and the form in which it is used for biological interpretation
• Species and characteristics of the animal or subjects studied
• Purpose of use in drug development
• Drug development circumstances for applying the biomarker
• Interpretation and decision/action based on the biomarker
A. Use Statement

This guidance provides qualification recommendations for the use of TKV, measured at baseline, as a prognostic enrichment biomarker to select patients with ADPKD at high risk for a progressive decline in renal function (defined as a confirmed 30% decline in the patient’s estimated glomerular filtration rate (eGFR)) for inclusion in interventional clinical trials. This biomarker may be used in combination with the patient’s age and baseline eGFR as an enrichment factor in these trials.

B. Conditions for Qualified Use

- Use of TKV as a quantitative imaging biomarker by applying a validated, standardized image acquisition and analysis protocol.
- Use of TKV for patient selection in a clinical trial.
- Acceptable imaging modalities (MRI, CT, ultrasound).
- Acceptable post-processing methods (stereology, ellipsoid calculations).
CONTEXT OF USE

Qualification for a limited context of use: Facilitate the integration of the biomarker in drug development.

Potential for qualification for an expanded context of use: Facilitate broader utilization of the biomarker as additional evidence accumulates.
Access Tools and Information:

- BEST (Biomarkers, EndpointS, and other Tools) Resource
- Table of Biomarkers Used as Outcomes in Development of FDA-Approved Therapeutics (October 2007-December 2015)
- Critical Path Innovation Meetings (CPIM)
- Letter of Support (LOS) Initiative