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CDER initiatives to encourage biomarker use in drug development

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Biomarkers have been used in drug development and clinical practice for many years. Despite this, there has been confusion about the definitions and inconsistent use of key terms–including biomarkers and surrogates. Recently, an FDA-NIH Biomarker Working Group developed a glossary of terms and definitions to ensure consistency and clarity, termed BEST (Biomarkers, Endpoints and other Tools), to advance scientific progress. The "BEST" glossary describes seven categories of biomarkers: diagnostic, prognostic, susceptibility/risk, predictive, pharmacodynamic/response, monitoring and safety biomarkers. Concepts important in developing biomarkers for use in drug development include: need for biomarkers in a specific disease; purpose of use; how the biomarker performs compared to current standards; development and analytical validation of a reproducible, sensitive and accurate assay to measure the biomarker of interest; and clinical validation that establishes the use of the biomarker for a specific purpose. These biomarkers can be integrated into drug development through the drug approval process and through qualification of the biomarkers through the Biomarker Qualification Program. An additional route also exists where a biomarker gains regulatory acceptance of biomarkers that have evolved through scientific community consensus. CDER, FDA, has developed efforts to encourage development of biomarkers for use in drug development; Critical Path Innovation Meeting (CPIM) Program and the Letter of Support (LOS) initiative. The CPIM can be utilized to discuss biomarkers in the early phase of development and not yet ready for the Biomarker Qualification Program (BQP) with FDA and receive advice. The goal of the LOS is to enhance the visibility of the biomarker, encourage data collection and sharing and potentially stimulate additional scientific studies.

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