



**DRUG DEVELOPMENT TOOL
QUALIFICATION DETERMINATION
DDT-BMQ-000050**

November 12, 2025

Critical-Path Institute
Attention: Nicholas King
1730 E. River
Tucson, AZ 85718

Dear Mr. King:

We have completed our review of the Full Qualification Package (FQP) for Drug Development Tool (DDT), DDT-BMQ-000050-FQP-2, received on December 2, 2023, by the CDER/CBER Biomarker Qualification Program (BQP), submitted under section 507 of the Federal Food, Drug, and Cosmetic (FD&C) Act.¹

FDA has completed review of your FQP for the biomarker Glutamate Dehydrogenase (GLDH) and is **qualifying** the safety biomarker for the Context of Use (COU) described below.

The FQP is for serum glutamate dehydrogenase (GLDH), a safety biomarker to be used in clinical trials for participants with elevated serum transaminases due to muscle injury or degeneration when Drug Induced Liver Injury is being considered. GLDH should be used in conjunction with standard hepatic injury monitoring biomarkers (e.g. alanine aminotransferase (ALT), aspartate aminotransferase, gamma-glutamyl transferase (GGT), total bilirubin, and alkaline phosphatase). GLDH has not been studied in patients with pre-existing liver disease.

For full details regarding this qualification determination, including specific information about how this qualified biomarker can be used in drug development programs and clinical trials, please refer to the following information on the CDER & CBER Drug Development Tool Qualification Project Search database.²

¹ In December 2016, the 21st Century Cures Act added section 507 to the FD&C Act. FDA is now operating its DDT programs under section 507 of the FD&C Act.

² <https://force-dsc.my.site.com/ddt/s/>.

Should you have any questions, please contact the CDER/CBER Qualification Program staff at CDER-BiomarkerQualificationProgram@fda.hhs.gov and refer to DDT-BMQ-000050 in the subject line.

Sincerely,

Vanitha J.
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Vanitha J. Sekar -S
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Vanitha Sekar, PhD
Director, Division of Biomedical Informatics,
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Paul Hayashi, MD
Associate Director for Drug Induced Liver Injury
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