



ASSOCIATION FOR MOLECULAR PATHOLOGY
Education. Innovation & Improved Patient Care. Advocacy.
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August 2, 2016

Division of Dockets Management (HFA-305)
US Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Docket No. FDA-2016-D-1255 for “E18 Genomic Sampling and Management of Genomic Data.”

Submitted electronically at www.regulations.gov

To Whom It May Concern:

Thank you for the opportunity to submit comments on the “E18 Genomic Sampling and Management of Genomic Data” draft guidance aimed at harmonizing principles of use of genomic data in clinical trials published by the International Council for Harmonization (ICH). The Association for Molecular Pathology (AMP) is an international medical and professional association representing approximately 2,300 physicians, doctoral scientists, and medical technologists who perform or are involved with laboratory testing based on knowledge derived from molecular biology, genetics, and genomics. Membership includes professionals from the government, academic medicine, clinical testing laboratories, and the in vitro diagnostics (IVD) industry.

AMP appreciates FDA’s efforts to harmonize policies across international regulatory bodies. However, prior to finalizing the document, AMP has two comments for your consideration.

AMP recommends that the Agency place any final version of the document directly in the context of United States regulatory requirements. We recommend that FDA include citations to the specific FDA statutes, regulations and guidance documents to which the document is intended to apply. This will more effectively assist readers in achieving regulatory compliance through adherence to the recommendations in a final guidance.

Clarification of Research Use: AMP respectfully requests that the ICH add language that clarifies that this document applies solely to clinical research and does not encompass the validation studies performed to develop an IVD.

Thank you again for the opportunity to share these comments with you and we hope that they will be informative to your efforts to finalize this policy. If we may be of further assistance, please contact Tara Burke at tburke@amp.org.

Sincerely,

Charles E. Hill, MD, PhD
President, AMP