

Re: EBF comment on Bioanalytical Method Validation for Biomarkers Guidance for Industry

<https://www.fda.gov/media/185276/download>

Dear Scientific Community,

The EBF fully acknowledges the vital role of health authorities in safeguarding public health and ensuring the delivery of safe, effective medicines to patients. Clear and unambiguous guidelines are an integral part of this responsibility.

The recent release of the FDA Guidance on Bioanalytical Method Validation for Biomarkers has raised significant concerns within our community. The Guidance continues a path - debated since the Crystal City-VI Meeting in 2015 - of treating biomarker assays as PK assays by suggesting they fall under the ICH M10 framework (as many in the industry will interpret it). However, ICH M10 explicitly states that biomarker assays are out of scope. This publication risks influencing other regulators to follow the same path.

Its publication feels like a bypass of sound principles of engaging with industry in depth before issuing Guidance, especially in a field where 'common ground' is absent and an open discussion is still needed.

The Guidance itself does not introduce new concepts. However, by connecting biomarker assay validation with ICH M10 and pointing them toward PK criteria, it may influence the biomarker assay landscape for years to come.

*We want to highlight the growing consensus in the industry that biomarker assays benefit from **Context of Use (CoU)** principles approach, rather than a PK SOP-driven approach. The EBF, among others, strongly advocates for this perspective and remains committed to fostering open dialogue and sharing insights, emphasizing that CoU principles should be the cornerstone for biomarker assays.*

We invite all stakeholders globally to join this discussion and collaborate in building a unified, forward-thinking, and science-based approach to biomarker assays.

Kindest regards
Philip Timmerman,
Chairman of the EBF
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EBF publications on the critical role of CoU principles for biomarker assay development and validation

1. European Bioanalysis Forum recommendation on method establishment and bioanalysis of biomarkers in support of drug development, <https://pubmed.ncbi.nlm.nih.gov/22943619/>
2. Update to the European Bioanalysis Forum recommendation on biomarkers assays; bringing context of use into practice, <https://pubmed.ncbi.nlm.nih.gov/33025797/>
3. Biomarker context-of-use: how organizational design can impact the implementation of the appropriate biomarker assay strategy, <https://pubmed.ncbi.nlm.nih.gov/35904153/>
4. A European Bioanalysis Forum recommendation for requiring a context-of-use statement for successful development and validation of biomarker assays, <https://pubmed.ncbi.nlm.nih.gov/39101487/>