# Article information:

Biomarker assay validation - PubMed  
<https://pubmed.ncbi.nlm.nih.gov/29939799/>

# Article summary:

1. This article discusses the importance of biomarker assay validation in drug development and clinical trials.

2. It outlines the regulatory considerations for biomarker assay validation, as well as the need for fit-for-purpose approaches.

3. The article also provides feedback from a European Bioanalysis Forum (EBF) workshop on bringing assay validation and analysis of biomarkers into practice.

# Article rating:

May be slightly imbalanced: The article presents the information in a generally reliable way, but there are minor points of consideration that could be explored further or claims that are not fully backed by appropriate evidence. Some perspectives may also be omitted, and you are encouraged to use the research topics section to explore the topic further.

# Article analysis:

The article is generally reliable and trustworthy, providing an overview of the importance of biomarker assay validation in drug development and clinical trials. The authors provide a comprehensive discussion of the regulatory considerations for biomarker assay validation, as well as the need for fit-for-purpose approaches. Furthermore, they provide feedback from a European Bioanalysis Forum (EBF) workshop on bringing assay validation and analysis of biomarkers into practice.

The article does not appear to be biased or one-sided, presenting both sides equally and exploring counterarguments where appropriate. There is no promotional content or partiality present in the article, and all possible risks are noted throughout. All claims made are supported by evidence, with references provided where necessary.

The only potential issue with this article is that it does not explore all points of consideration in detail; however, this is understandable given its focus on providing an overview rather than a comprehensive discussion of each point raised.

# Topics for further research:

* Biomarker assay validation guidelines
* Regulatory requirements for biomarker assay validation
* Challenges of biomarker assay validation
* Quality control measures for biomarker assays
* Analytical validation of biomarker assays
* Clinical utility of biomarker assays

# Report location:

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