

BIOMARKER DEVELOPMENT AND VALIDATION

Fit-for-purpose solutions for exploratory and confirmatory biomarkers

The assessment of biomarkers in parallel with the efficacy, safety, and mechanism of action of drugs is becoming more prominent with a focus on achieving more efficient and successful drug development. The context of use for the biomarker data is a key determining factor that influences the approach taken during method development and validation to produce a robust method that can support your pre-clinical and clinical studies.



Biomarker data is extremely valuable as early predictors of drug effects and can yield important information regarding the dose response relationship and so can drive insight to achieve successful and efficient drug development. The approach taken to develop and validate a biomarker method should be based on the context of use of the biomarker whether they are intended for exploratory or confirmatory purposes. Biomarker measurements are also complicated by lack of well-defined reference standards that are representative of the biomarker and variable pre-existing endogenous levels of the biomarker.

Exploratory biomarkers comprise most of biomarkers that are measured in pre-clinical and early clinical settings. Exploratory biomarkers are not used to support patient efficacy or safety decisions of the drug; they are typically used for internal decision making on the drug's mechanism of action. A fit-for-purpose validation approach is often taken for exploratory biomarkers covering the parameters considered important for the context of use over a limited number of runs to confirm parameters such as assay range (ULOQ/LLOQ), MRD, precision, relative accuracy, dilutional linearity/parallelism and limited stability assessment.

Confirmatory Biomarkers are designed to support pivotal patient decisions and label claims. The data is intended for a higher level of

regulatory scrutiny and impact on the outcome of the clinical studies. A higher level of validation is performed to support the quality of the data generated by the method by increasing the number of validation runs performed and increasing the stringency on the method performance. The validation may also assess additional validation parameters compared to exploratory biomarkers such as specificity, selectivity, short and long term stability and drug interference.

Our approach to biomarker validation

Intertek's GLP/GCP/GMP compliant laboratories provides support to clients focused on the development of pharmaceuticals and biological medicines. Our biomarker services provide fit-for-purpose validations in support of exploratory biomarkers based on your product requirements and full validation for confirmatory biomarkers where clinical decisions are being made to understand the drug's efficacy and safety profile. We provide a continuous and iterative process supporting exploratory fit-for-purpose to full validation as your drug product moves through the development path and the context of use of the biomarker transitions from an exploratory to a confirmatory endpoint.

We deploy a diverse array of analytical platforms to support biomarker analysis including ELISA, flow cytometry, cell-based assays and ECL multiplex platforms. We also provide bioanalytical pharmacokinetic (PK) and

immunogenicity analysis for pre-clinical and clinical studies.

By establishing and maintaining the consistency of reference standards and controls throughout the duration of the biomarker studies and also screening drug naïve samples whilst taking baseline measurements, our experts build up an understanding of changes in the biomarker data following treatment. This addresses the complexity stemming from the lack of well-defined reference standards and variable pre-existing endogenous levels of the biomarker.

Total Quality Assurance

Our GLP/GCP/GMP compliant laboratories provide Total Quality Assurance for your drug development activities through regulatory-driven, phase-appropriate, world-class scientific support. We apply our experience and depth of industry knowledge to help you to navigate the challenges of new product development, scale-up, manufacturing, bioanalysis and market release to meet regulatory expectations.

FOR MORE INFORMATION

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