



Clinical Bioanalysis

We Are Your Competent Partner for
Analysis of Clinical Samples under GCLP



FyoniBio has many years of experience in assay development and validation to analyze blood samples from patients in the course of clinical trials. Sample handling, storage and analysis are performed under “Good Clinical Laboratory Practice” (GCLP).

We offer ISO 9001 compliant services to ensure controlled quality of immunomonitoring and bioanalytical services. Assay validation and bioanalysis is performed according to the current ICH, FDA, and EMA guidelines.

Our core competencies are the evaluation of pharmacokinetic and pharmacodynamic characteristics of biotherapeutics as well as their immunogenic and neutralizing potential.

Therefore, drug-tailored sophisticated assays and techniques are developed to meet customer-specific requirements.

The portfolio is complemented by analysis of single nucleotide polymorphisms (SNP), such as the Fc gamma receptor SNPs, supporting patient selection and stratification.

We are able to analyze your clinical and non-clinical samples to support your drug development.

Our Core Competencies

- Project consultancy
- Assay establishment
- Assay validation according to current guidelines
- Bioanalysis of clinical samples
- Immunomonitoring of clinical trials
- Sample management and storage

Immunogenicity Testing, PK and PD Assessment

- Analysis for anti-drug-antibodies (ADAs) using screening/confirmatory/titration assays
- Analysis of ADA for neutralizing activity
- PK analysis
- Biomarker serum levels
- Cytokine release
- Cellular immune status (CD marker)
- Immune cell function (e.g., CDC activity)
- Genetic mutations (SNP)



Available Technologies

- ELISA in all formats
- Electrochemiluminescence (MSD)
- Mass spectrometry (LC-MS/MS) based PK analysis
- Flow cytometry
- Cytotoxicity & cellular immunoassays with more than 100 human cell lines and primary cell preparations
- FcγR binding assays (alphaScreen®)
- DNA melting curve analytics (LightCycler®)

The FyoniBio Team Is All Set to Bring Your CMC Project to the Next Level!

FyoniBio offers high quality ISO-9001 compliant services. For more information please contact us.



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