

Immunomodulatory drugs modify the response of the immune system by either stimulation or suppression. These drugs have been changing the landscape of medical treatment in cancer, auto-immune and infectious diseases, and in the disease prevention field, with vaccines. Immunomodulators exist in the form of proteins, oligonucleotides, biologics, bispecific antibodies, gene therapy, and others.

Altasciences provides rigorous, precise drug quantitation and biomarker assessment crucial to support robust **toxicokinetic, pharmacokinetic, and pharmacodynamic assessments** necessary for your therapeutic development program.

Our **fit-for-purpose assays** are developed and validated for your specific program, with progression from preclinical to clinical at the forefront. Altasciences' integrated solutions ensure seamless transition from preclinical to clinical studies, supported by proactive communication and timely responses.

Bioanalytical Platforms for Immunomodulatory Drugs

Altasciences has [state-of-the-art bioanalytical platforms](#) to monitor multiple aspects of immunomodulation, in various species, all with high sensitivity and specificity of detection. Common endpoints include biomarkers such as cytokines and complement factors, immune cell subtyping and functional readouts through cytokine release, and proliferation assays.

Our bioanalytical teams have extensive experience handling pathogens and working with infectious samples for your vaccine development programs. Our labs are equipped with containment Level 2 areas for handling pathogens within the Risk Group 2.

Below, we highlight key features of **common platforms used to monitor intended immunomodulation**.

ELISA/ MULTIPLEXED ASSAYS	ELISPOT	FLOW CYTOMETRY	CELL-BASED ASSAYS
Can be adapted for a wide range of applications to monitor drug levels, ADA, or biomarkers, when the matrix is in liquid form.	Can be used to monitor functional immune responses at the cellular level for a wide range of applications and drug products.	Can be used to enumerate specific immune cells through the use of multiple markers at the single cell level for various applications, such as intracellular cytokine production, receptor occupancy, and immune-phenotyping.	Can be used for a wide range of applications, such as supporting immunogenicity assessment by characterizing the neutralization capacity of the ADA response generated, or pharmacological activity of the immunomodulator.
Ability to measure multiple samples simultaneously, and multiple analytes in a single sample for multiplexing assays.	Ability to measure a functional readout at the single cell level; suitable for testing many samples simultaneously.	Can combine several markers to characterize the phenotype of the responding cells.	May be optimized and adapted for different applications during the drug development cycle, such as clinical immune monitoring.

ELISA/ MULTIPLEXED ASSAYS	ELISPOT	FLOW CYTOMETRY	CELL-BASED ASSAYS
Quantitative detection of analytes and/or qualitative in the case of ADA.	Semi-quantitative measurement of cytokine/ antibody production.	Quantitative, when absolute count is considered, or qualitative readout.	Qualitative, or semi-quantitative in some cases.
Reduced sample volume and cost when multiplexing.	Lower number of cells are required per test when compared with flow cytometry.	Can detect and quantify rare populations when frequency is very low.	Can assess the entire biological activity, as opposed to a fraction of the interactions obtained by ligand binding assays.
Common biomarkers include cytokines and complement factors.	Common endpoints include inflammatory cytokine release assays. Can be used with a variety of cell types, including T cells, B cells, and NK cells.	Common endpoints include standard T, B, NK cell panels; with possibility for more numerous and elaborate panels when required.	
Ability to scale up for large clinical studies.			
Offers improved efficiency and throughput when compared with ELISA.			
MSD platform can provide increased sensitivity.			

Integrated Preclinical to Clinical Solutions

Altasciences is ideally positioned to advance your immunomodulatory drug from **preclinical** to early phase **clinical trials**. Our integrated services ensure that preclinical data is available without delay to inform downstream clinical analyses. Taking into consideration the specifics of your program, our experts will verify how assays developed for preclinical studies can be adapted and validated for use in clinical trials. Having comprehensive and early understanding of challenges experienced during preclinical studies can set the stage for addressing those issues during the clinical phase.

