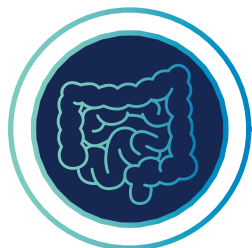


Case Study:

A PHASE I CLINICAL RECEPTOR OCCUPANCY ASSAY BY FLOW CYTOMETRY



OVERVIEW

The Flow Cytometry team at Medpace's central laboratory was engaged to assess the safety, tolerance and Phase IIa dosage on a small compound targeting a specific receptor on pathogenic T cells for an innovative management of inflammatory bowel disease.



CLINICAL STUDY CHALLENGES

During the validation, a suboptimal stability of < 12 hours was found on this receptor occupancy assay, and experimental optimization yielded no further room for improvement.



SCIENTISTS TAKE CHARGE

After thorough evaluation and optimization efforts, the scientific team (consisting of experienced medical technologists and highly-skilled flow cytometry scientists) determined that performing an experiment before the samples lost their stability was the best next step. The task force team, including the lead technologists and primary scientist in charge, arranged three relaying shifts (totaling 36 hours) and routinely in the lab until 3:00 AM to ensure all samples were processed in a probe-stable fashion.



RESULTS

The Phase I RO assay was finished in time with large amount of insightful RO data obtained, providing precise guidance to the subsequent phase II studies on the same drug. The results also enlightened the sponsor's R&D team to substantiate the probe synthesis technology to accommodate longer stability rendering overnight shipping from multiple sites feasible for extended Phase II studies.

FLOW CYTOMETRY AT MEDPACE

Medpace has an experienced flow cytometry team overseen by PhD-level scientists with over 50 years of team cumulative experience designing, analyzing, and interpreting multicolor flow cytometry assays. In addition to those in-house validated ready-to-go panels (e.g. TBNK), we also offer study-specific full customized panels with more than 20 colors. Whether a custom panel needs to be developed or a method needs to be transferred to our laboratory to support a global clinical trial, we have the experience to quickly validate and implement the flow cytometry testing. Medpace has global flow cytometry capabilities at the US, Belgium, and Singapore laboratories.

Central Lab Services	
Analysis on sample types: <ul style="list-style-type: none">Whole blood, CSF, human bone marrow aspirate, and PBMCs	Intracellular cytokine assays
CAR T-cell assays (PK and PD)	Receptor occupancy assays
Monocytes <ul style="list-style-type: none">Classical, intermediate and non-classical monocytes (HLA-DR+/-)	TBNK assay (CAP PT) Absolute counts of CD4, CD8, CD19, CD16/56 (IVD, CAP PT)
Dendritic Cells <ul style="list-style-type: none">Conventional dendritic cells 1 and 2, plasmacytoid DCs	26 colors panel, TCR $\gamma\delta$ + T cells, dendritic cells, B cells, ILCs, basophils, CD8+ T cells, CD4+ regulatory and effector T cells, monocytes, NK and NKT cells
Stem/Progenitor Panel <ul style="list-style-type: none">CD34 stem cell enumeration	T Cells <ul style="list-style-type: none">Helper and cytotoxic T-cells.Memory, activation, exhaustion and T-reg T-cells
<ul style="list-style-type: none">Our service is always bundled with High-Parameter analysis (FlowJo, FACSuite, SpectroFlo®)	NK Cells <ul style="list-style-type: none">Regulatory, cytotoxic and NKG2D positive NK cells
	B Cells <ul style="list-style-type: none">Transitional, plasmablast, activated, IgD/IgM memory, mature naïve, atypical, class-switched and non-switched B-cells

Key Instrumentation	
BD FACSLytic™ – 10 Color, Cytex Aurora™ 5 lasers	
Therapeutic Indications Supported	
Autoimmune Diseases and Allergy	Oncology-Hematology: <ul style="list-style-type: none">Solid TumorsLeukemiaLymphomaMultiple MyelomaSquamous Cell Carcinoma
Cardiovascular Diseases and Pulmonary Diseases	
AIDS	Inflammatory-Infectious Diseases: <ul style="list-style-type: none">COVID-19

MRL-0012-R0425

MAKING THE COMPLEX
SEAMLESS®

