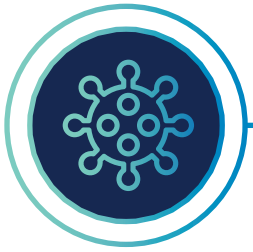
A PHASE I CLINICAL RECEPTOR ACTIVATION ASSAY BY INTRACELLULAR FLOW CYTOMETRY



PROJECT OBJECTIVE

Assess safety and receptor activation status as a biomarker on circulating immunocytes for a novel way to manage the COVID-19 pandemic.

CLINICAL STUDY CHALLENGES

For a method transferred to Medpace's central laboratory flow cytometry team, it was quickly identified that quantification of receptor phosphorylation was a highly time-sensitive parameter. It was determined that a reliable, effective, yet easy-to-use, fixation system was required to ensure that all participating sites would able to carry it out with ease and standardization with minimal collection/ collector bias.

SCIENTISTS TAKE CHARGE

A specialized Medpace task force was formed and they identified an innovative matrix, commercially named "smart tubes". The team also implemented a traditional fixation method as a backup plan and merit reference. With the validation work advancing forward, the team confirmed that the smart tube platform outperformed the traditional fixation method in several aspects and then primarily focused on the new platform in subsequent validation components obtaining quality data.

RESULTS

The validation finished in time with 200 samples run in only 15 business days to meet the Sponsor's deadline and to accommodate the sample stability. Each sample had 42 reportable results, that were uploaded to Medpace's laboratory system in time for the database lock. The results showed pronounced and stable activation signal, and the trial proceeded to Phase II with an aim to demonstrate the true efficacy of the drug in combating COVID-19.

FLOW CYTOMETRY AT MEDPACE

Medpace has an experienced flow cytometry team overseen by PhD-level scientists with over 10 years of 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 up to 10 colors (soon to be expanded to 20). 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: whole blood, CSF, human bone marrow aspirate, and PBMCs	Intracellular cytokine assays
CAR T-cell assays (PK and PD)	Receptor occupancy assays
Intracellular measurement of second messengers (e.g. CAMP, Mg2+ and Ca2+)	Receptor functional assays (such as phosphorylation – phosphoFlow)
Immune cell, rare cells, progenitor enumeration	PNH assay (CAP PT)
Immune cell phenotyping and Immune cell function assays	TBNK assay (CAP PT)
Our service is always bundled with High-Parameter analysis (FlowJo, FACSuite, FACSDiva)	

Medpace has a strategic lab partnership that has extensive experience performing flow cytometry hematomalignancies, LAIP (leukemia-associated immunophenotypes), and MRD (minimal residual disease) analysis requiring a pathologist review and interpretation.

Key Instrumentation	
BD FACSLyricTM – 10 Color	
Therapeutic Indications Supported	
Autoimmune Diseases and Allergy	Oncology-Hematology:
Cardiovascular Diseases and Pulmonary Diseases	– Solid Tumors
Hematology	– Leukemia
Inflammatory-Infectious Diseases:	– Lymphoma
– COVID-19	– Multiple Myeloma
AIDS	– Squamous Cell Carcinoma

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