

Flow Cytometry at PRA's Laboratories for Drug Development

Introduction

PRA has 10+ years of experience performing flow cytometry in clinical trials, and we implemented a broad range of assay types to analyze sample types such as whole blood, bone marrow, and isolated PBMC. Assays vary from immune phenotyping (straight-forward TBNK to high-parameter deep phenotyping), receptor occupancy, and phosflow. We support single-site early phase studies (PRA's early phase clinics are in close proximity to the flow labs), as well as late phase global trials, and are able to run samples from global trials in our US and NL laboratories in parallel. We understand the challenges of clinical flow cytometry and have set the teams up to handle time critical samples, while our scientists develop assays that provide cost-effective, yet compliant and high-quality data to our sponsors.

Innovation

Limited sample stability is a challenge for clinical flow analyses. We address sample stability early on in assay development and look for opportunities to stabilize samples. We have experience with multiple strategies, for multiple assay types, and we are able to obtain stability that enabled either (global) shipment of samples, or improved cost effectiveness by enabling efficient batching of samples. For example:

Assay	Stability	Sample stabilization (storage)
Immune phenotyping (T-, B-, NK-cells)	4-8 weeks	Stabilization tube (ambient/frozen)
Phenotyping T-reg (multiple assays)	1-3 weeks	Lyse-fix-freeze protocol
Receptor Occupancy (MAb drug)	2 weeks	Stabilization tube (ambient)

Next to improving standard flow cytometry applications, we always look for improvements and new applications. For example, we have developed multiple cell-based neutralizing antibody assays with flow cytometry read out and are able to perform less standard flow cytometry such as cytometric bead array, and enzyme activity bead assays.



Capabilities and Equipment

- Ten BD FACS Canto II - analysis up to 10 parameters (8 colors)
- Three BD LSR Fortessa X-20 - analysis up to 20 parameters (18 colors)
- Automation: 96-well plate assays, automated liquid handlers (Mantis, Viaflo)
- Global harmonization: equipment, SOPs, weekly interaction on operational and scientific level

Capacity and People

	NL	US
Analysts	15	20
Scientists & Senior Analysts	5	5
Project Managers	4	3

Both teams are experienced in handling time critical samples, and are set up to analyze outside standard office hours, if required. Our team of scientists has a wealth of experience with flow cytometry in multiple disease areas. We work with our sponsors from early on to ensure that assays are robust, optimized for a clinical setting, and provide the high-quality data that our sponsors expect.

Contact Our Expert

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Associate Director of Bioanalytical Science in the Assen, NL, Bioanalytical Laboratory. Global PRA Lead Scientist for flow cytometry, focusing on globally harmonized, high quality flow analysis, as well as cell-based NAb and PD assays. Over 10 years of experience in flow cytometry and cell-based assay development.

Experience

Flow cytometry analysis at PRA originated more than 10 years ago in the NL lab, supporting studies in our Phase I clinic. This quickly expanded to include Late Phase (global) study support. In 2015, flow cytometry was implemented in the US Lenexa laboratory. They support both Early and Late Phase clinical studies.

Equipment



BD FACS Canto II



BD LSR Fortessa X-20



Liquid handlers (Viaflo)



Sysmex hematology analyzer