

Flow Cytometry, a Pivotal Technology Platform in Immuno-Oncology Drug Development: Embracing new opportunities and overcoming new challenges

Dianna Wu PhD, Director, Janssen R&D

Immuno-oncology is shining new light on cancer research and providing promising clinical treatment strategies for both solid and hematologic malignancies. Innovative immunotherapies are activating patients' immune cells, altering local immune suppressive signals or amplifying anti-tumor activity through injection of autologous cells after ex vivo manipulation. Since immune cells are a major target population in Immunotherapy, flow cytometry serves as a powerful technology for the assessment of their expansion, redistribution, phenotypical and functional changes in drug development. In addition, flow cytometry has been utilized in clinical trials to monitor drug efficacy in certain hematologic malignant diseases.

Prior to deploying flow cytometry assays in a clinical trial, assay robustness and performance characteristics need to be evaluated. Fit-for-purpose assay validation as well as efforts to minimize pre-analytical variability and post-analytical deviation are key activities during assay implementation. With increasing demand for clinical flow cytometry assays across multiple immuno-oncology drug programs, we overcame resource constraints by effectively managing the quality and quantity of flow cytometry assays thereby ensuring the receipt of reliable data supporting drug development.