Standardization & Validation of Immune Monitoring

Cytokine and Chemokine Immunoassay Quantification
- Multiplex vs. Singleplex validation
- Regulatory aspects and benefits of GMP and CLIA validated assays
- Sample types and sample handling
- QC: Levy- Jennings plots for lot-to-lot standardization
- Rejection/Acceptance Criteria

Standards and Controls
- Recombinant vs. native standards
- In-plate controls: 3 levels (H, M, L) incorporation of pooled donor native controls.
ex vivo Immune Biomarker Monitoring in the Clinic

The Challenge of Collecting active PBMCs in the Clinic
- Multi-step processing, variable time intervals & temperature, preservation, transportation
- Loss of signaling elements (granulocytes, platelets, RBCs)
- Rejection/Acceptance Criteria?

Whole Blood Cultures – Standardization and Incorporation into Clinical Trials
- Novel technology; validation, reproducibility, and suitability for the clinic.
- Cytokine, Chemokine and gene expression end-points.
- Monitoring for Safety (Immunotoxicity) and Pharmacodynamics in cancer trials.