Interest Statement — ISAC Translational and Clinical Councilor

Megan M. McCausland, BS

Director, Assay Development and Scientific Advisor, Flow Cytometry, IQVIA Laboratories

I seek to serve as ISAC's Translational and Clinical Councilor to advance the Society's mission of fostering an inclusive, multidisciplinary, international cytometry community and to help ensure that technological innovation translates into reliable clinical decision making that benefits patients worldwide.

For more than 25 years, my work has focused on translating flow cytometry into fit for purpose assays supporting studies from basic research through Phase I to III global clinical trials across oncology, immunology, infectious disease, autoimmune indications, and cell and gene therapy. In my current role at IQVIA, I advise sponsors on assay readiness, operational risk mitigation, data quality frameworks, regulatory alignment, and deployment across global laboratory networks. This experience places me at the intersection of discovery, operations, and clinical impact, supporting the effective translation of cytometry into real world clinical use.

Through deploying assays across diverse geographic regions and resource settings, I have seen how unequal access to training, instrumentation guidance, and standardized practices can limit successful clinical translation. Clear, implementation focused guidance and high-quality education are essential for enabling laboratories at different stages of maturity to generate reproducible, clinically meaningful data. As a Councilor, I would advocate for globally accessible educational programming that emphasizes practical application, harmonization, and data integrity.

My career spans academia and the CRO environment, with close collaboration among scientists, clinicians, regulators, and operations leaders. This breadth has shaped my commitment to inclusive and representative leadership, as well as the intentional development of diverse voices across volunteer service and leadership pathways. Within Council, I would bring a translational and sponsor facing perspective while supporting ISAC's efforts to broaden engagement across disciplines and geographies.

I actively contribute to standards development and community consensus through service on the CLSI H42 Document Development Committee, authorship of WRIB white papers, and publication of peer reviewed clinical cytometry guidance. I am also an active ISAC member, with regular participation at CYTO meetings and continued involvement in workshops, tutorials, and best practice efforts.

As Translational and Clinical Councilor, I will bring a sponsor-engaged, operations-savvy perspective to Council deliberations, support consensus guidance that strengthens reproducibility and regulatory confidence, and contribute to the long-term health and impact of the Society. Above all, I will work collaboratively to ensure that cytometry innovation reliably informs clinical decisions and improves outcomes for patients globally.

Megan McCausland, BS
Director, Assay Development & Scientific Advisor for Flow Cytometry, IQVIA Laboratories

Megan McCausland is a Director in the Translational Science Laboratory at IQVIA, where she serves as the Scientific Advisor for Flow Cytometry and a global subject matter expert in high-parameter spectral cytometry. She partners with clients across pharma and biotech to design, optimize, and implement state-of-the-art multi-color spectral flow cytometry panels supporting global clinical trials across oncology, immunology, infectious disease, autoimmune disorders, and advanced therapeutic modalities.

Since joining IQVIA in 2013, Megan has led end-to-end assay development, validation, and global technology transfer for complex immunophenotyping workflows. She also spearheaded the enterprise-wide rollout of the Cytek Aurora spectral cytometry platform, establishing harmonized SOPs, data-quality frameworks, and multi-site reproducibility standards across IQVIA's global laboratory network.

Before transitioning to industry, Megan spent 13 years in academia at the Emory Vaccine Center and the La Jolla Institute for Immunology, where her research focused on the generation and maintenance of immune memory, vaccine-induced responses, and mechanisms of T-cell and B-cell immunity. Her work contributed to numerous high-impact publications spanning Science, Cell, Nature, PNAS, J Virol, and Immunity.

Megan holds a B.S. in Biology from James Madison University and has authored more than 30 peer-reviewed publications. She is an active contributor to cross-industry best-practice efforts, an invited speaker at scientific conferences, and a frequent workshop leader at CYTO focused on spectral flow cytometry standardization and harmonization.

Megan M. McCausland

Director, Assay Development | Scientific Advisor, Flow Cytometry

Specialist in High-Parameter Spectral Cytometry for Global Clinical Trials

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Executive Summary

Director-level scientific leader with 25+ years of experience advancing immunology research, complex assay development, and regulated clinical trial support across academia and global CRO environments. Widely recognized as an SME in high-parameter (>30-color) spectral flow cytometry, with deep expertise spanning assay design, optimization, validation, data review, instrument harmonization, and multi-site deployment. Strategic advisor to global clients on assay readiness, risk mitigation, regulatory alignment, and data-quality frameworks. Contributor to 30+ peer-reviewed publications, cross-industry best-practice initiatives, and scientific working groups shaping standards for next-generation cytometry in clinical programs.

Core Strengths & Leadership Profile

• Scientific Leadership: Drives development of complex immunophenotyping assays supporting global Phase I–III clinical studies across oncology, immunology, autoimmune disease, infectious disease, and advanced therapy programs.

• Spectral Cytometry SME: Expert in panel architecture, spectral unmixing, gating strategy design, QC frameworks, troubleshooting, and reviewer-ready data packages aligned with CLSI H62 best practices.

• Global Platform Standardization: Led enterprise-wide rollout of the Cytek Aurora platform across international laboratories; established SOPs, workflow harmonization, instrumentation alignment, and data-quality reproducibility standards.

• Operational Excellence: Leads cross-functional execution across bioanalysis, clinical operations, data sciences, regulatory, and quality; delivers scalable assay deployments and multi-site technology transfers.

• Industry Thought Leadership: Contributes to cross-industry guidance; invited speaker at scientific conferences; leads CYTO workshops and training focused on spectral flow cytometry standardization.

• Team Development: Builds organizational cytometry capabilities through training, mentorship, and best-practice toolkits.

Professional Experience

IQVIA - Director, Assay Development / Scientific Advisor, Flow Cytometry *(2013 to Present)*

• SME for high-parameter spectral flow cytometry across global clinical programs; provides strategic scientific oversight and regulatory-aligned assay guidance.

• Leads design, development, validation, and lifecycle control of complex multi-color spectral assays, ensuring robust performance and high-quality data outputs.

• Directs global rollout and harmonization of the Cytek Aurora platform; drives technology transfer, SOP alignment, and multi-site reproducibility.

• Leads cross-industry best-practice and consensus efforts; invited speaker and workshop leader (including CYTO) supporting community-wide standardization.

Emory University - Research Technical Specialist *(2008 to 2013)*

• Led human immunology and vaccine-response research supporting publications in Science, Cell, Nature, PNAS, and J Virol; coordinated IRB-compliant workflows across collaborations.

La Jolla Institute for Allergy & Immunology - Research Technician IV *(2003 to 2008)*

• Contributed to poxvirus immunology and vaccinology studies; performed high-complexity assays and supported lab setup, compliance, and training (J Virol, Immunity, Vaccine, Antiviral Therapy).

Emory University - Lead Research Specialist *(2000 to 2003)*

• Supported CD137 (4-1BB) co-stimulation and immune-modulation studies; contributed to foundational work on T-cell regulatory mechanisms.

Publications (Complete List)

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Education

• B.S., Biology — James Madison University