



International Alliance for
Biological Standardization

12th Annual Statistics Workshop: From Data to Patients – CMC Statisticians' Contributions to Quality, Safety, and Efficacy of Pharmaceutical Products

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From Data Foundations to Data Products: The Statistician's Role in Shaping CMC Data Strategy and Driving Scalable Analytics – Dan (Cassie) Liu, Ruojia Li – BMS

As CMC organizations accelerate their digital transformation journeys, the ability to enable robust, scalable analytics, digital innovation, and advanced modeling depends on more than sophisticated methods—it requires high-quality, well-structured, and interoperable data. This presentation explores the evolution from fragmented data landscapes to integrated data ecosystems and highlights the critical role statisticians can play in shaping data strategy, not only as consumers of data but also as architects of how data is defined, structured, governed, transformed into reusable data products, and leveraged for decision-making.

Drawing on practical experiences from CMC data transformation initiatives, we will share key lessons learned in building data foundations that enable scalable analytics. Topics include fostering effective collaboration among statisticians, domain scientists, and IT partners, designing data assets with analytical objectives in mind, and establishing scalable approaches to data governance and stewardship. We will also discuss the organizational and cultural transformations required to operationalize data strategy, including defining clear data ownership, promoting data literacy, and embedding data stewardship practices across functions.

The presentation highlights the unique strengths statisticians bring to data strategy. Their deep understanding of data context, variability, uncertainty, and analytical intent positions them to bridge domain science, data engineering, and advanced analytics. By expanding their impact beyond statistical analysis, statisticians can help create purposeful data products that accelerate analytics, enhance decision-making, and drive digital innovation. Embedding statisticians in data strategy ultimately enables more scalable analytics and contributes to improved product quality, patient safety, and development outcomes across the CMC lifecycle.

Importantly, we will discuss practical pathways for statisticians to evolve from analytical contributors to strategic leaders, expanding their influence across the data-to-decision value chain and helping shape the future of data-driven CMC organizations. Attendees will leave with an actionable framework for advancing from analysis-focused roles to data strategy leadership, enabling broader organizational impact and accelerating digital transformation across CMC.

