



TITLE: Opportunities and Risks: Navigating the AI Revolution in CMC Statistics

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ABSTRACT: The rise of Large Language Models (LLMs) is transforming many technical fields, and CMC statistics is no exception. For the professional statistician, AI can offer considerable opportunities by accelerating code development, streamlining documentation, and serving as a versatile tool for brainstorming analytical approaches. However, this technology also introduces fundamental professional risks: the misconception that AI enables anyone to perform complex statistical analyses without expert oversight.

A primary concern is that AI outputs often appear professional even when they are logically flawed. For instance, LLMs frequently struggle with the principle that an **absence of evidence is not evidence of absence**. In a GxP environment, treating a non-significant p-value as proof of equivalence is a critical error that AI can easily overlook or even encourage.

This raises a vital philosophical question: Will AI make the statistician obsolete? While AI can generate results, it cannot take responsibility for their validity. The role of the statistician is shifting from a "producer of code" to a "critical auditor." In an era where AI makes statistics seem easy, professional skepticism and human expertise are more essential than ever to ensure regulatory safety and scientific integrity.

BRIEF SPEAKER BIO: Silke is a member of the Statistics & Data Science group within Roche Pharma Technical Operations. Since joining the company in 2007, she has become a leading expert in biostatistics, mentoring scientists and junior statisticians on statistical methods and CMC strategies. She also conducts statistics training sessions with a particular focus on Design of Experiments (DoE). Throughout her career, Silke has served as the lead CMC statistician for several successful product approvals. She holds a master's degree in mathematics from the University of Konstanz and previously worked as a lab technician with Boehringer Ingelheim.