Frontiers in Regulatory evolvement, AI Innovation and Bayesian advancement in China Biopharmaceutical Industry

This seminar talk will highlight the industry's progress in the new technology directions, as well as the proactive exploration conducted by both regulators and the industry in their application. Firstly, the talk will elaborate on the proactive evolution of China's regulatory framework led by the National Medical Products Administration (NMPA)—a core driver of industry innovation—including but not limited to formulating and issuing digital transformation guidelines, proactively enhancing full-chain supportive measures for innovative drugs, and exploring the establishment of market exclusivity mechanisms for pediatric and rare disease drugs. The NMPA has demonstrated a proactive stance in adapting to technological advancements and fostering an enabling environment to facilitate the industry's technological progress.

Driven by this evolving regulatory environment, the talk will introduce the industry's remarkable advancements in AI innovation. By proactively integrating AI with biopharmaceutical research and development (R&D), the industry has achieved significant progress in innovation investment, R&D efficiency, and industrial scale. By 2025, China had more than 100 AI-aided drug R&D enterprises; leading firms have proactively established biocomputing platforms to shorten drug discovery cycles, with some AI-originated drugs completing the process from target discovery to clinical verification within two years. As the industry actively advances the application of AI across the entire drug R&D, production, and clinical practice processes, it has also proactively explored more rigorous methodologies to address unmet clinical needs, with Bayesian methods emerging as a key technological advancement.

Recently, regulatory authorities in China and the United States have issued relevant guidelines, formally recognizing and accepting Bayesian methods—a reflection of regulators' proactive adaptation to this technological advancement. Both guidelines emphasize core principles, with key differences aligned with each country's regulatory priorities: China's Center for Drug Evaluation (CDE) has issued a practice-oriented guideline that proactively supports the accelerated approval of drugs for rare diseases and pediatric indications, while the U.S. Food and Drug Administration (FDA) has released a more comprehensive guidance incorporating detailed technical specifications. These regulatory initiatives, combined with the industry's active application of Bayesian methods, have standardized and advanced the use of this methodology, thereby accelerating drug development, promoting the high-quality growth of the biopharmaceutical industry, and embodying the joint proactive exploration of regulatory evolution and technological innovation.

About G-Plume

G-Plume (website: g-plume.com) is a rare disease-focused platform that integrates patient registries, diagnostics, genomics, clinical execution and real-world evidence. We optimize decision-making and increase success rates throughout the entire therapeutic development lifecycle.

Unlike generalist CROs or standalone data vendors, G-Plume is purpose-built for rare and genetic diseases. We operate in environments where patient access, endpoint definition, data fragmentation, and regulatory uncertainty must be addressed together—not sequentially. Our positioning reflects a platform mindset: integrating data, execution, and evidence into a unified system designed for learning, risk management, and long-term value creation.

About Me

Dr. Luyan Dai, the founder of G-Plume Consulting, possesses nearly two decades of industrial experience in healthcare and pharmaceutical industry in both US and Asia. She is an accomplished innovative drug developer and serial entrepreneur. She has extensive hands-on experience in business deal transaction, pipeline strategy, product development, regulatory interactions and strategy, project management, clinical operation, statistics and data sciences. She is a long term industry advocator and recognized advisor for applications of complex innovative designs, Bayesian analysis, multi-region clinical trials, real-world data and evidence, AI intelligent applications and digital technology in healthcare. Dr. Dai established the biostatistics function for Boehringer Ingelheim China. Since she left Boehringer Ingelheim, she worked at two start-up companies and made significant contributions for the companies in IPO listings on the Hong Kong Stock Exchange. In 2018, she joined Harbour Biomed as the head of clinical research. In 2020, she joined Yidu Tech as the vice president of strategy and innovation with a dual role as the chief statistics expert. Dr. Dai also served as a venture capital partner of YD Capital. In her earlier years, she worked at Pfizer Global Research & Development Center and Boehringer Ingelheim Medicine in the US, contributing to global projects for clinical development and regulatory submissions in therapeutic areas including the central nervous system, hepatitis C, respiratory, oncology,