MEDICAL UNIVERSITY OF VIENNA

Wiener Biometrische Sektion
der Internationalen Biometrischen Gesellschaft
Region Österreich – Schweiz

Please join the Biometric Colloquium

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OVERVIEW OF CDISC: IMPLEMENTATION FOR CLINICAL TRIALS, BENEFITS AND CHALLENGES

June 25th, 2025 at 9:00 am

Seminarraum Center for Medical Data Science (previously CeMSIIS),
Spitalgasse 23, Room 88.03.513
Medical University of Vienna, 1090 Wien
Host: Sonja Zehetmayer

Abstract:

Standardizing clinical trial data is essential for ensuring data integrity, facilitating cross-study comparisons, and meeting global regulatory requirements. The Clinical Data Interchange Standards Consortium (CDISC) offers a suite of internationally recognized data standards that are mandated by regulatory authorities for electronic submissions. Despite their importance, adoption of CDISC standards remains limited, particularly in investigator-initiated studies.

While the benefits of CDISC implementation are well recognized, including improved data quality, enhanced data reusability, and regulatory compliance, several challenges hinder broader uptake. These include a steep learning curve for new users, limited resources, difficulties in converting legacy data, and complexities in interpreting guidance documents.

This presentation offers practical strategies to support CDISC implementation, including capacity building, workflow integration, and use of available tools and support from CDISC and regulatory agencies. Embracing CDISC standards represents a valuable investment for ensuring high-quality, submission-ready clinical data—not only in sponsor-initiated trials but also in investigator-initiated studies.