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Simplifying repetitive manual work: AI application to summarizing Technical Documentation of In Vitro Diagnosis Medical Devices in preparation for regulatory submission

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In various global regions, In Vitro Diagnostic Medical Devices (IVDs) must adhere to specific regulations in order to be marketed. To obtain approval from entities such as the U.S. Food and Drug Administration (FDA), the In Vitro Diagnostic Medical Devices Regulation (IVDR) in Europe, Health Canada, or Japanese regulatory bodies, manufacturers are required to submit Technical Documentation to guarantee the products' safety and performance.

The Technical Documentation encompasses the Analytical Performance Report (APR), detailing product accuracy, specificity, stability, interference, and detection and quantitation limits, among other analytical capabilities of the marketed product. Each study is outlined in a distinct report, providing insights into study design, target populations, statistical methodologies employed, acceptance criteria and reasoning behind sample size calculations. The comprehensive APR is the amalgamation of these individual reports and adheres to a standardized structure.

Traditionally compiled manually, the creation of the APR involves labor-intensive tasks such as repetitive data entry and verification of study consistency against methodological guidelines, such as those provided by the Clinical and Laboratory Standards Institute (CLSI). Our presentation will introduce a prototype tool leveraging Large Language Models to automate and streamline the preparation process of the final APR, reducing manual intervention and enhancing efficiency.

Type of presentation

Talk

Classification

Mainly application

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Large Language Models, In Vitro Diagnosis Medical Device Regulation, Technical Documentation

Primary authors: Dr VIVES-MESTRES, Marina (Datancia); Mr MONTE-TALAVERA, Pol (Datancia); Mr PUIG DE DOU, Ignasi (Datancia)

Presenter: Dr VIVES-MESTRES, Marina (Datancia)

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