Contribution ID: **117** Type: **not specified**

Software Tool Implementation of Standard Guidelines in Technical Documentation of In Vitro Diagnosis Medical Devices

Wednesday, 13 September 2023 11:05 (20 minutes)

In vitro diagnostics Medical Devices (IVDs) market has had exponential growth in recent years, IVDs are a crucial part of today's healthcare. Around the world, IVDs needs to be approved for specific regulations to market on different countries. To do so, manufacturers need to submit the Technical Documentation to ensure safety and performance for approval to U.S. Food and Drug Administration (FDA), In Vitro Diagnosis Medical Devices Regulation (IVDR), Health Canada, Japan Regulations among others.
Technical Documentation includes the Analytical Performance Report that describes the product accuracy, specificity, stability, interferences, limits of detection and quantitation among others. In all cases it should also include a description of the study design, populations, statistical methods used, acceptance criteria and rationale for sample size. Guidelines as Clinical and Laboratory Standards Institute (CLSI) are generally used to help describing, designing, and analyzing most of the studies presented in the Technical Documentation. Those guidelines allow organizations to improve their testing outcomes, maintain accreditation, bring products faster to and navigate regulatory hurdles.
Getting compliant reports including all relevant information through an organization and through all products is a time-consuming process for most device manufacturers. To time-saving and automate the statistical methods used, Datancia, working with Werfen, has developed and implemented a software tool to facilitate the statistical analysis related to the execution of CLSI Guidelines and to improve the report generation of those analysis in preparation of the submission of Technical Documentation. In this presentation we will show the tool and share its use at Werfen.

Keywords

In Vitro Diagnosis Medical Device, Technical Documentation, CLSI Guidelines

Classification

Mainly application

Primary authors: Dr VIVES-MESTRES, Marina (Datancia); Mr PUIG, Ignasi (Datancia); Mr MORENO, Alejandro (Werfen); Mr CARRETERO, Guillem (Werfen); Ms CARBONERO, Carmen (Werfen)

Presenter: Dr VIVES-MESTRES, Marina (Datancia)

Session Classification: CONTRIBUTED Biostatistics 2

Track Classification: Healthcare