IVDR CE-marking of INR Calibrator

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Introduction

This presentation provides an overview of the ongoing project at Nordic Biomarker, where we aim to CE-mark an INR calibrator in accordance with IVDR. We will share the current project status, outline the next steps, and present a preliminary timeline.

Materials and Methods

The project involves the development and validation of an INR calibrator aligned with IVDR requirements. The performance evaluation will focus on traceability to the international reference thromboplastin preparation, along with complementary stability studies.

Results

The project is currently in the development phase. As the material used is based on an already established manufacturing processes, preliminary results show good repeatability and stability over time. Contact with the external laboratory responsible for the assignment has been initiated and is ongoing.

Discussion

The calibrator is being developed to suit the most common instrument platforms in the Nordics. Key challenges include maintaining essential characteristics of current calibrators while meeting IVDR requirements. Additionally, the project must be planned to avoid delivery gaps between current supplier’s and NB’s coming calibrators.

Conclusion

The project is progressing according to plan, with CE-marking targeted for Q2 2027. By adhering to IVDR and working closely with users and experts, we aim to deliver a reliable and user-friendly INR calibrator to the market.