GLOBAL | CRO

5 Tips & Tricks

Developing a Comprehensive Performance Evaluation Plan (PEP)

5 Tips & Tricks

Developing a Comprehensive Performance Evaluation Plan (PEP)

Have a new in vitro diagnostic seeking approval? Transitioning a legacy device from compliance under IVDD to compliance under IVDR? Check out our tips and tricks for starting the performance evaluation process under EU Regulation 2017/746 (IVDR).

1) What is the risk classification of your device?

Routes of conformity under IVDR are dependent on the risk classification of the device. Legacy devices will need to be reevaluated to determine their risk classification as stated in Annex VIII of IVDR, as significant changes have been made to the original classifications provided in IVDD. See MDCG 2020-16 rev. 1 for guidance on classification rules for IVDs under IVDR.

2) Has the intended purpose been updated to be compliant with the GSPRs per Annex I, Chapter III, Section 20.4.1c?

IVDR outlines a series of bullet points that should be addressed in the instructions for use and intended purpose statement. These include, but are not limited to, the analyte or marker being detected or measured, the function of the device, physiological or pathological state, type of specimen required, testing population, whether the device is automated, and whether the device is qualitative or quantitative. In addition to the intended purpose, target patient groups with clear indications, limitations, and contraindications need to be clearly defined.

5 Tips & Tricks

Developing a Comprehensive Performance Evaluation Plan (PEP)

3) How will the state-of-the-art be established?

The state of the art discussion will be used to determine where the subject device fits into the diagnostic or treatment landscape for disease management. To this end, the state of the art will typically include at a minimum a discussion of the medical condition under evaluation; existing relevant standards, common specifications, guidelines, or best practice documents; alternative diagnostic technologies; an evaluation of benchmark/similar devices; and risks and benefits associated with false positive or false negative results. The findings in the state of the art will be used to evaluate the safety, performance, and risk-benefit profile of the subject device.

4) How will scientific validity, analytical performance, and clinical performance be demonstrated?

Scientific validity refers to the association of an analyte or marker with a clinical condition or a physiological state. Analytical performance is used to demonstrate the ability for the IVD to reliably, accurately, and consistently detect or measure the analyte or marker. Clinical performance means the ability of a device to yield suitable results when used with the target population and intended user. See MDCG 2022-2 for guidance on demonstrating scientific validity, analytical performance, and clinical performance in the PER.

5) What is the status of the Post-Market Performance Follow-up (PMPF) Plan?

Unless you have a high-risk in vitro diagnostic device that has been the focus of proactive post-market activities, the PMPF Plan is likely a new and unfamiliar process. The PMPF Plan outlines the plan the manufacturer has established to proactively collect and evaluate data to confirm the safety and performance of the device throughout its lifetime, to ensure the acceptability of the risk-benefit profile, and to detect emerging risks after the device is released to the market.