

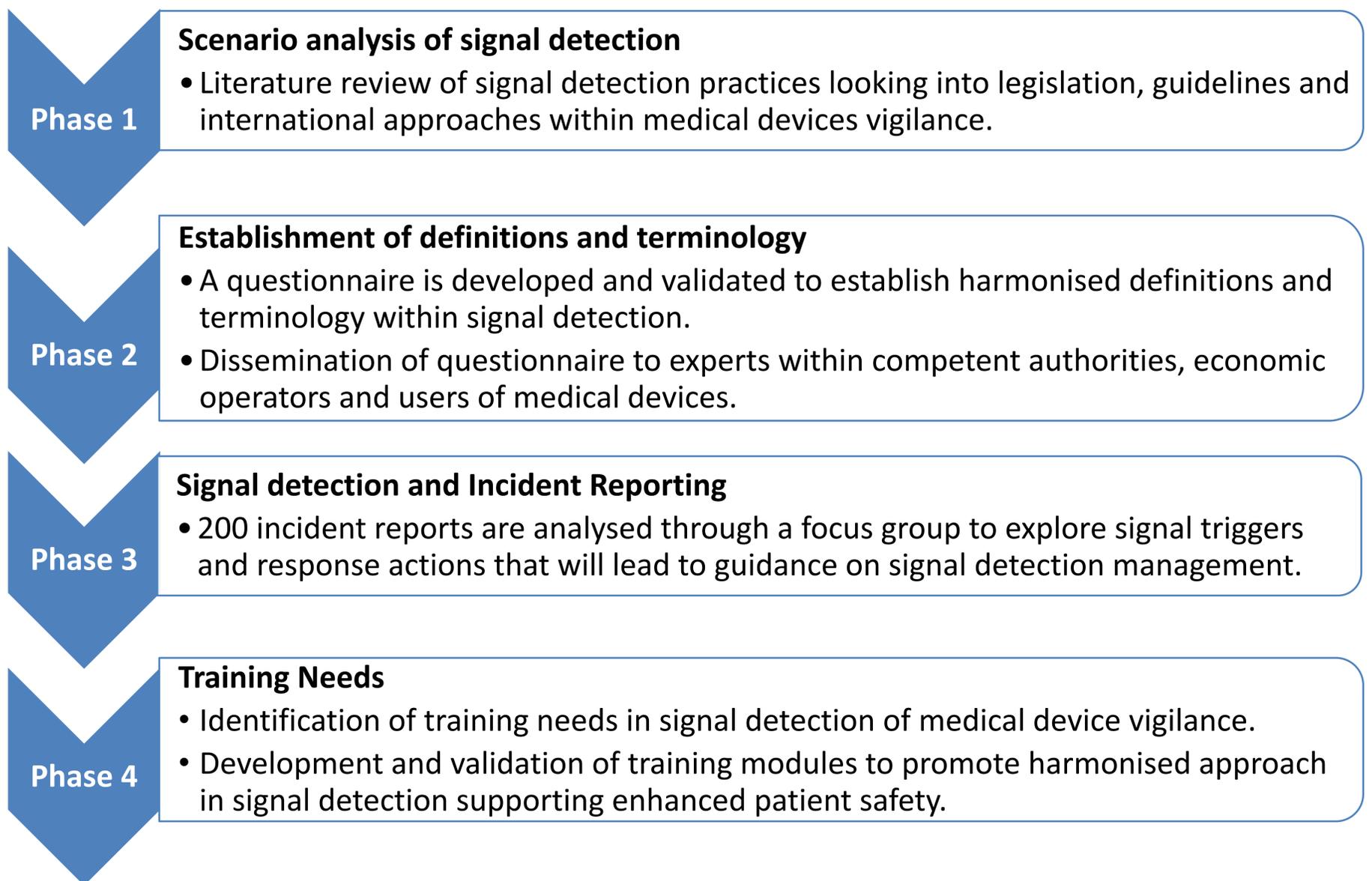


## The Contribution of Signal Detection in Promoting Safety, Quality and Efficacy of Medical Devices

### Project brief

The aim is to determine the contribution of signal detection in promoting safe, good quality and effective medical devices with a primary focus on maintaining a patient-centric approach. The objectives are to i) analyse current national and international signal detection practices in incident reporting, ii) establish and validate key definitions through stakeholder engagement, iii) assess the role of signal detection across five core phases of incident management and iv) develop a targeted training programme to support implementation and build capacity in medical device vigilance.

### Methodology



### Results and conclusion

The study design methodology leads to the development of a structured framework that improves vigilance through standardised reporting and enhanced oversight through the use of harmonized signal detection, validation, analysis and management. The research looks into the integration of artificial intelligence approaches and stakeholder engagement that strengthens signal detection in relation to medical devices vigilance supporting EU Regulations on medical devices.