# GOOD MACHINE LEARNING PRACTICE FOR MEDICAL DEVICE DEVELOPMENT – TEN GUIDING PRINCIPLES

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Artificial intelligence (AI) and machine learning (ML) technologies possess the transformative potential to revolutionize healthcare by extracting valuable insights from the vast amount of data generated daily during the delivery of medical services. Through the utilization of software algorithms, they learn from real-world usage and, in some instances, enhance their performance based on this knowledge. Nevertheless, the complexity and iterative, data-driven nature of AI and ML development also present unique challenges.

Consequently, the U.S. Food and Drug Administration (FDA), Health Canada, and the United Kingdom's Medicines and Healthcare products Regulatory Agency (MHRA) have collaboratively established ten guiding principles to facilitate the development of Good Machine Learning Practice (GMLP). These principles aim to ensure the production of safe, effective, and high-quality medical devices employing AI and ML.

**01**

## Include Experts

Include multi-disciplinary experts throughout the entire life cycle of medical devices.

**02**

## Ensure Security

Implement good software engineering and security across the entire life cycle of medical devices.

**03**

## Representativeness

Ensure that study participants used in device development are representative of the intended patient population.

**04**

## Independent Data

Ensure the datasets used to train medical devices are independent of the test datasets.

05

## Best Method

Employ the best available methods to select training datasets.

06

## Intended Use

Adapt the design of medical devices to the available data and aligning it with the device's intended use.

07

## Human Factor

Incorporate human factors and human interpretability into the assessment of medical devices.

08

## Clinically Relevant

Test the performance of the medical device using clinically relevant conditions.

09

## Provide Information

Provide clear and essential information about medical devices to the target users.

10

## Monitoring

Establish continuous monitoring of device post-deployment, with re-training mechanisms in place.