Medical Device Machine Learning Principles Published Jointly by FDA, MHRA, and Health Canada

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The U.S. Food and Drug Administration (FDA) and its counterparts Health Canada and the UK's Medicines and Healthcare products Regulatory Agency (MHRA) have jointly issued 10 guiding principles to inform the development of Good Machine Learning Practices, or GMLP, in medical device development.

According to the FDA, the principles in **Good Machine Learning Practice for Medical Device Development: Guiding Principles** may be used to adopt good practices proven in other sectors, tailor practices from other sectors so they are applicable to medical technology and the health care sector, and create new practices specific for medical technology and the health care sector.

"These 10 guiding principles are intended to lay the foundation for developing Good Machine Learning Practice that addresses the unique nature of these products. They will also help cultivate future growth in this rapidly progressing field," the FDA wrote on its website.

The 10 guiding ML principles identify areas where the International Medical Device Regulators Forum (IMDRF) and other international standards organizations, work along with FDA's **Digital Health Center of Excellence** to advance GMLP and align their efforts to advance digital health.

The 10 Guiding ML Principles

- Multi-Disciplinary Expertise Leveraged Throughout the Total Product Life
- Good Software Engineering and Security Practices Implemented
- Clinical Study Participants and Data Sets Are Representative of the Intended Patient Population
- Training Data Sets Independent of Test Sets
- Selected Reference Datasets Based Upon Best Available Methods
- Model Design Is Tailored to the Available Data and Reflects the Intended Use of the Device
- Focus Is Placed on the Performance of the Human-AI Team
- Testing Demonstrates Device Performance During Clinically Relevant Conditions
- Users Are Provided Clear, Essential Information

- Deployed Models Monitored for Performance and Re-training Risks Managed

More detail on each of the principles is available on the **FDA's website**.

The FDA is seeking feedback through the public docket (FDA-2019-N-1185) at **www.regulations.gov** and directly via email at **Digitalhealth@fda.hhs.gov**