MITA®

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Bakul Patel
Chief Digital Health Officer of Global Strategy and Innovation
Digital Health Center of Excellence
U.S. Food and Drug Administration
10903 New Hampshire Ave.
Silver Spring, MD 20993

Re: Good Machine Learning Practice for Medical Device Development: Guiding Principles

Dear Mr. Patel:

As the leading trade association representing the manufacturers of medical imaging equipment, radiopharmaceuticals, contrast media, and focused ultrasound therapeutic devices, the Medical Imaging & Technology Alliance (MITA) and its Members applaud the continued work by the US Food and Drug Administration (FDA) towards a workable regulatory framework that enables innovative Artificial Intelligence (AI) and Machine Learning (ML) medical devices to improve patient care and healthcare delivery. Moreover, we applaud FDA, Health Canada, and the Medicines & Healthcare products Regulatory Agency for their collective work in this area which hastens patient access to innovative technologies and improved care.

MITA and its members were pleased to see references to intended use and intended population within the guiding principles and agree that these concepts are a core characteristic for good machine learning practices. We also agree that multi-disciplinary expertise is critical throughout the total product life cycle, as reflected in Item 1. This first principle highlights the complexity and multidisciplinary nature of the necessary information and skills needed to ensure a safe, effective ML device.

This is further underlined in Item 2, "Good Software Engineering and Security", which is an important reminder to new and existing healthcare stakeholders about the unique requirements necessitated for healthcare organizations. So too is Item 8, "Testing Demonstrates Device Performance During Clinically Relevant Conditions", which underscores how important rigorous quality processes are to algorithm development and patient safety.

We also appreciate the clarity provided by Item 4, "Training Data Sets", and the expectations it relays—such that dataset content must be justified by the product's intended use and that dataset source is not sufficient for such justification. This clarity is welcome and should be encouraged for other AI/ML processes.

MITA and its Members request that the FDA provide further information to scope and clarify the guidelines and their applicability. How, for instance, should MITA Members expect the FDA to use these principles? Will FDA staff apply them to review processes? Clear answers that describe expectations are welcome.

Item 3, "Clinical Study Participants", describes several generalized expectations that MITA supports. They exemplify how medical device manufacturers take great care to provide quality devices and deliver patient benefits, and suggests these expectations are important and should be applied to any organization which wants to develop and deploy medical software.

However, the phrase "relevant characteristics" in list item 3 raises some concerns. What are these? How are they defined? How is relevant defined? Who decides what is relevant? We encourage the agency to make clear that the manufacturer is responsible to determine relevance and that the agency is responsible to affirm that relevance upon review.

Item 5, "Selected Reference Datasets", rightly references "best available" methods and provides examples of potential limitations. This is an important concept which acknowledges that perfect data does not exist. Still, this principle should go further and avoid any suggestion that there are only a handful of specific "good practices" which must be adhered to by all developers in all situations.

Item 6, "Model Design", appears to support the importance of intended use in model design and development, with which we agree. But the reference within this item to cybersecurity creates confusion about its purpose. The phrase, "…supports the active mitigation of known risks…" is confusing. What risks? Bias risks? User risks? Patient risks? Cybersecurity risks? Since cybersecurity risks are already addressed in Item 2, so we recommend the reference be removed or clarified to highlight the differences.

Item 7, "Focus Is Placed on the Performance of the Human-AI Team", is not well-suited for general guidance principles. Such concerns are dependent upon the level of risk of the device and could easily create serious hurdles. It should only be applied when device risk necessitates it.

Item #9, "Users Are Provided Clear, Essential Information" does not do enough to differentiate between labelling and submission data. The principle seems to suggest that "data characteristics" (which are not described in detail by the principles) should be provided to users so they can assess whether the device is fit for use with its intended population. However, this review this is part of the regulatory clearance process and shouldn't need to be re-done by providers.

Finally, the term "characteristics of the data" is vague in its presented context. Is it meant to capture characteristics of the data, like pixel count and image dimension, or characteristics of the data subject (i.e., patient) like race or gender? More detail about what the term means would be welcome.

Thank you for your attention to these comments. We look forward to working with FDA on how best to operationalize and apply these guidelines.

If you have any questions, please contact Zack Hornberger, Director of Cybersecurity & Informatics, at zhornberger@medicalimaging.org or by phone at 703-841-3285.

Sincerely,

Patrick Hope
Executive Director, MITA

MITA is the collective voice of manufacturers of medical imaging equipment, radiopharmaceuticals, contrast media, and focused ultrasound therapeutic devices. It represents companies whose sales comprise more than 90 percent of the global market for medical imaging innovations. These products include: magnetic resonance imaging (MRI), medical X-Ray equipment, computed tomography (CT) scanners, ultrasound, nuclear imaging, radiopharmaceuticals, and imaging information systems. MITA Member company technologies are an important part of our nation's healthcare infrastructure and are essential for the screening, diagnosis, staging, managing and effectively treating patients with cancer, heart disease, neurological degeneration, and numerous other medical conditions.