Guiding Principles of Good AI Practice in Drug Development

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Artificial Intelligence (AI) has the potential to transform the way drugs (medicines)[1] are developed and evaluated, ultimately improving health care. In this context, AI refers to system-level technologies used to generate or analyze evidence across the drug product life cycle, including nonclinical, clinical, post-marketing, and manufacturing phases.

Drugs are authorized based on demonstrated quality, efficacy and safety, and when their benefits outweigh their risks. As new technologies emerge, including AI, it is essential that their use reinforces these requirements for the benefit and safety of patients.

The use of AI throughout the drug product life cycle has increased significantly in recent years. The complex and dynamic processes involved in developing, deploying, using, and maintaining AI technologies benefit from careful management throughout the drug product life cycle to ensure outputs are accurate and reliable. Among other innovations, AI technologies are anticipated to support a multi-faceted approach that promotes innovation, reduces time-to-market, strengthens regulatory excellence and pharmacovigilance, and decreases reliance on animal testing by improving the prediction of toxicity and efficacy in humans. This document outlines a common set of principles to inform, enhance, and promote the use of AI for generating evidence across all phases of the drug product life cycle.

These 10 guiding principles are intended to lay the foundation for developing good practice that addresses the unique nature of these technologies. They will also help cultivate future growth in this rapidly progressing field.

The 10 guiding principles identify areas where the international regulators, international standards organizations, and other collaborative bodies could work to advance good practice in drug development. Areas of collaboration include research, creating educational tools and resources, international harmonization, and consensus standards, which may help inform regulatory policies and regulatory guidelines in different jurisdictions, in line with applicable legal and regulatory frameworks.

As the use of AI in drug development evolves, so too must good practice and consensus standards. Strong partnerships with international public health partners will be crucial to empower stakeholders to advance responsible innovations in this area. Thus, this initial collaborative work can inform our broader international engagements.

1. Human-centric by design
The development and use of AI technologies align with ethical and human-centric values.

2. Risk-based approach
The development and use of AI technologies follow a risk-based approach with proportionate validation, risk mitigation, and oversight based on the context of use and determined model risk.

3. Adherence to standards
AI technologies adhere to relevant legal, ethical, technical, scientific, cybersecurity, and regulatory standards, including Good Practices (GxP).

4. Clear context of use
AI technologies have a well-defined context of use (role and scope for why it is being used).

[1] For the purpose of this document, the term "drug" is used to refer to drugs and biological products as defined in the United States of America, and medicinal products as defined in the European Union.

5. Multidisciplinary expertise
Multidisciplinary expertise covering both the AI technology and its context of use are integrated throughout the technology's life cycle.

6. Data governance and documentation
Data source provenance, processing steps, and analytical decisions are documented in a detailed, traceable, and verifiable manner, in line with GxP requirements. Appropriate governance, including privacy and protection for sensitive data, is maintained throughout the technology's life cycle.

7. Model design and development practices
The development of AI technologies follows best practices in model and system design and software engineering and leverages data that is fit-for-use, considering interpretability, explainability, and predictive performance. Good model and system development promotes transparency, reliability, generalizability, and robustness for AI technologies contributing to patient safety.

8. Risk-based performance assessment
Risk-based performance assessments evaluate the complete system including human-AI interactions, using fit-for-use data and metrics appropriate for the intended context of use, supported by validation of predictive performance through appropriately designed testing and evaluation methods.

9. Life cycle management
Risk-based quality management systems are implemented throughout the AI technologies' life cycles, including to support capturing, assessing, and addressing issues. The AI technologies undergo scheduled monitoring and periodic re-evaluation to ensure adequate performance (e.g., to address data drift).

10. Clear, essential information
Plain language is used to present clear, accessible, and contextually relevant information to the intended audience, including users and patients, regarding the AI technology's context of use, performance, limitations, underlying data, updates, and interpretability or explainability.