FDA and EMA issue ten joint principles for AI in drug development

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CDER and CBER have collaborated with the European Medicines Agency (EMA) to develop 10 guiding principles that industry and product developers can consider when using artificial intelligence (AI) to advance drug and biological product development. To fully realize the potential of AI while ensuring reliability of the information to ensure patient safety and regulatory excellence, it is essential to establish guiding principles that address the unique challenges and considerations of AI applications in drug development. The 10 principles are tailored to the drug development cycle and emphasize the importance of: Human-centric by design Risk-based approach Adherence to standards Clear context of use Multidisciplinary expertise Data governance and documentation Model design and development practices Risk-based performance assessment Life cycle management Clear, essential information