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Supplementary information

Artificial intelligence in European medicines regulation

In the format provided by the authors

Supplementary Table 1 | **Examples of AI potential in medicines development**

Domain of medicines development	Example use of AI
Preclinical evidence generation	To predict molecular interactions and pharmacokinetics/pharmacodynamics, and thus drug safety or efficacy. This could be used to shape preclinical testing regimens.
Clinical evidence generation	Within a digital diagnostic, biomarker or endpoint such as measuring neurodegenerative disease or AI-driven tumour imaging.
	To predict the relationship between different patient characteristics and a medicine's safety and efficacy and help optimize the patient populations in clinical trials accordingly.
Clinical use	To support medicine administration; for example, a digital insulin pump that uses AI as part of its administration, monitoring or feedback control.
Manufacturing	To predict the outcomes of process or reagent changes and continually improve production.
Pharmacovigilance	To screen academic literature for safety signals, rank them by relevance and refer them to a human assessor.
	To screen real-world data (RWD) for the safety effects of co-medications on a medicine.
	Classification of individual case safety reports (ICSRs) by seriousness.
Post-authorization management	To screen real-world data and suggest changes to dosing or patient populations (repurposing).