Macedonian Pharmaceutical Bulletin, 72 (Suppl 1) 77 - 78 (2026)
Online ISSN: 1857-8969
DOI: 10.33320/maced.pharm.bull.2026.72.03.036
Short communication

Role of AI and ML in accelerating time-to-market for generic medicines: A literature review

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Introduction

Although the impact of Artificial intelligence (AI) and machine learning (ML) is more profound in development of originator medicines, their influence across generic medicines lifecycles should not be overlooked. ML tools can cut a standard oral formulation development cycle from 6–12 months to mere days in some cases. For more complex formulations (e.g. long-acting injectables or nanocarriers), timelines that used to span 2–4 years can be condensed to a few months by identifying promising formulation strategies early (Lou et al., 2021). The aim of this study is to investigate which stages of generic medicines development can be accelerated through the application of AI and ML tools, and to which extent.

Research methods

A structured literature review, using PMC PubMed central database was conducted. Keywords applied: ("artificial intelligence" OR "machine learning") AND ("generic drug" OR "generic medicines") AND ("time-to-market" OR "development timeline" OR "approval time"). Total of 23 articles were fully examined, along with several articles in the “similar articles” section, published within (2021-2026).

Discussion

AI is impacting time-to-market for generic industry by improving efficiency and shortening timelines across multiple stages like molecular design, drug screening, manufacturing and clinical trials (Jiménez-Luna et al., 2021). A study by Joshi and Sheth (2025) reported that AI-driven platforms integrated with robotics accelerate the identification of optimal excipient blends. Automated laboratories can generate hundreds of formulations daily, with AI predictions based on real-time experimental feedback, thus creating a self-learning excipient optimization system, reducing development cycles, cost and overall experimental workload by up to 70% without influencing robustness (Joshi and Sheth, 2025). This aligns with the study findings by Ghaywat et al. (2025), which confirmed that AI and ML compress development timelines by using historical formulation data to record excipient candidates before any physical experiments are run. As described in the study, this model uses advanced mathematics formulas, to identify the optimal drug with the right dissolution profile, stability and particle size, and consequently establish process design and optimization, scale up, in-process quality controls and batch release. When trained on sufficiently large datasets, these models deliver formulation hypotheses in days rather than months (Ghaywat et al., 2025). Joshi and Sheth (2025)

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report that the use of AI models allows bridging the gap between early screening and scalable manufacturing, enabling transition from milligram-level prototypes to pilot production. Additionally, they conclude that AI models can fasten the dosage calculations in specific population groups such as geriatrics or pediatrics. One example from the study was that AI tools trained on pediatric pharmacokinetic datasets can model drug clearance in neonates and infants more reliably than conventional scaling methods (Joshi and Sheth, 2025). Apart from R&D and manufacturing, AI techniques impact bioequivalence studies (BE) studies as well. Regulatory agencies typically require at least 80% statistical power to detect differences between formulations, necessitating large sample sizes, that increase costs, extend timelines, and raise ethical concerns due to increased drug exposure (Nikolopoulos and Karalis, 2025). Nikolopoulos and Karalis (2025) discuss a promising alternative supported by generative AI, i.e. using AI- virtual subjects that replicate human pharmacokinetic behavior, thus lowering costs, and accelerating timelines, without compromising regulatory standards. Namely, findings of this study show that early predictions of BE failures enable formulators to pivot early, avoiding costly 3-6 months in failed trials. Another way of AI's impact on clinical development is shown in a study by Shon et al. (2025) who found that using ML tools during clinical development can reduce the workload by 57%, by efficiently prioritizing patients for BE screening based on individual clinical laboratory parameters. Ways of using AI to create clinical trial evidence is already accepted by EMA's Committee for Medicinal Products for Human Use (CHMP), as long as it's supervised by human pathologist (Jiang et al., 2022; European Medicines Agency, 2024). Finally, and in addition to development, BE studies and manufacturing, a study by Beierle et al. (2023), further indicates that using AI-tools by manufacturers/sponsors throughout the MA filing process, authoring and submission timelines, could be reduced by as much as 50%, with additional savings realized by enabling faster filings in subsequent markets.

Conclusion

Literature findings demonstrate that AI and ML are affecting various stages of generic medicines development by reducing formulation rehearsal cycles, optimizing BE studies, accelerating manufacturing readiness and shortening overall submission timelines. This significantly accelerates time-to-market for generic medicines affecting timelines that used to span 4 years to just few months.

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