How Will Technology Play A Central Role In The Optimal Implementation Of Joint Clinical Assessment (JCA) Across the European Union (EU) In The Future?

HTA275

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Background

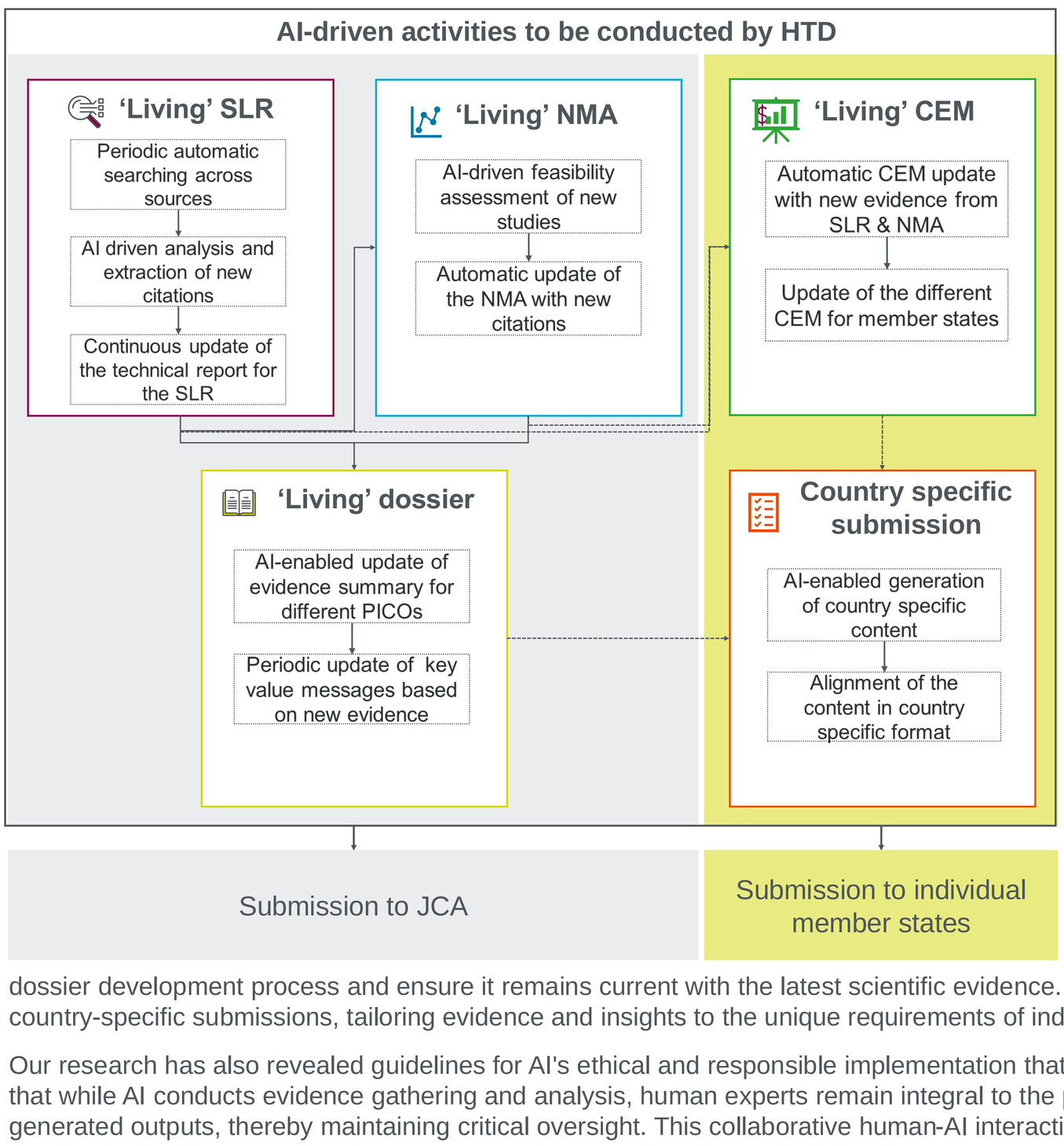
- The European Union Health Technology Assessment Regulation (EU HTAR) 201/2282 is expected to significantly modify the process of evaluating new pharmaceutical products in the European Union (EU). The Joint Clinical Assessment (JCA) across the 27 EU member states is expected to enhance collaboration and harmonize the clinical assessment of drugs.
- JCA will become mandatory for oncology medicines and advanced therapy medicinal products (ATMPs) on January 12, 2025. It will become mandatory for orphan medical products on January 13, 2028, and for all other new medicines on January 13, 2030.
- The accelerated approval pathway offers renewed optimism for patients, promising quicker access to novel treatments. However, this process also presents significant challenges for health technology developers (HTDs). They must now create a dossier that addresses multiple PICOs, satisfying the diverse requirements of 27 EU member states, all within a stringent 90-day timeline. To meet these demanding deadlines and ensure timely submission of JCA dossiers, HTDs are increasingly turning to advanced technological solutions, with Artificial Intelligence (AI) emerging as a particularly promising tool to streamline and expedite this complex process.

Methods

- A rapid literature review, encompassing both scientific publications and gray literature, was performed to identify published articles, opinion papers, and guidance documents that discuss technology applications in evidence synthesis, data analysis, and dossier development.

Results

- Our research identified that a multi-faceted approach covering AI/technology for all tasks to develop a practical solution to support JCA submission is needed. This would include AI for evidence generation or systematic literature reviews (SLRs), cost-effectiveness modeling (CEM), network meta-analysis (NMA), and JCA dossier. A key component for JCA submission is to ensure the evidence and the analysis are always current and updated, i.e., living.



'Living' SLR

Leveraging AI for conducting SLRs was identified to be a crucial element in the development of JCA submission dossiers. AI technology offers significant advantages in efficiently handling and synthesizing evidence across various PICO frameworks. Moreover, AI facilitates the seamless integration of the most recent research findings through automated periodic updates.

'Living' NMA

Our investigation identified evidence supporting the application of AI in automating the update process for both feasibility assessments and NMAs. This AI-driven approach can incorporate the most recent data identified through SLRs across various scenarios. By leveraging AI in this manner, the process becomes more dynamic and responsive to newly available information, ensuring that assessments and analyses remain current and reflect the latest scientific findings in the field.

'Living' CEM

Although a CEM is not required for the JCA submission, it plays a crucial role in subsequent interactions and negotiations with individual member states. Therefore, it is essential to maintain and update the CEM to reflect various scenarios based on the most recent evidence and analytical findings. This proactive approach ensures that the model remains relevant, adaptable, and ready for use in diverse national contexts, facilitating more effective discussions and decision-making processes with individual member states.

'Living' dossier

Considering the stringent timeline of less than 90 days for HTDs to submit a comprehensive dossier addressing all potential PICOs, the integration of AI becomes imperative. AI can significantly expedite the dossier development process and ensure it remains current with the latest scientific evidence. Furthermore, AI technology offers the capability to swiftly generate country-specific submissions, tailoring evidence and insights to the unique requirements of individual member states.

Our research has also revealed guidelines for AI's ethical and responsible implementation that emphasize a '**human-in-the-loop**' approach. This methodology ensures that while AI conducts evidence gathering and analysis, human experts remain integral to the process. Their role is to review, interpret, and contextualize the AI-generated outputs, thereby maintaining critical oversight. This collaborative human-AI interaction safeguards against potential biases or misinterpretations, ensuring that the final evidence and analyses are not only comprehensive and efficient but also appropriately nuanced and aligned with human expertise and judgment.

Conclusion

The integration of AI is anticipated to transform and optimize the JCA submission process significantly. This technological advancement is poised to empower HTDs in expediting the market entry of innovative pharmaceuticals. By leveraging AI's capabilities, HTDs can navigate the complex regulatory landscape more efficiently, potentially reducing time-to-market for novel therapies. This streamlined approach not only benefits the developers but also holds the promise of accelerating patient access to cutting-edge treatments, thereby potentially improving health outcomes and addressing unmet medical needs more rapidly.

References

- Implementing the EU Health Technology Assessment Regulation (europa.eu).
- EUnetHTA-21-D5.4-Timelines-JCA.pdf.
- NICE: Use of AI in evidence generation: NICE position statement | NICE.
- Toward a responsible future: recommendations for AI-enabled clinical decision support. Labkoff S., Oladimeji B., Kannry J., Solomonides A., Leftwich R., Koski E., et al. Journal of the American Medical Informatics Association: JAMIA 2024.
- Clinical artificial intelligence quality improvement: towards continual monitoring and updating of AI algorithms in healthcare. Feng J., Phillips R.V., Malenica I., Bishara A., Hubbard A.E., et al. npj Digital Medicine 2022 5:1 Article Number 66.
- Advancing clinical decision support: The role of artificial intelligence across six domains. Khalifa M., Albadawy M., Iqbal U. Computer Methods and Programs in Biomedicine Update 2024 5 Article Number 100142.
- Living systematic reviews. Living systematic reviews | Cochrane Community.
- Living network meta-analysis. Présentation PowerPoint (cochrane.org)
- MSR58 It's Alive! Feasibility and Benefits of Living Cost-Effectiveness Modeling Following a Living SLR. Poirrier J.E., Sharma S., Bergemann R. Value in Health 2023 26:12 Supplement (S404-).

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