

ARTIFICIAL INTELLIGENCE APPLICATIONS IN OBSERVATIONAL REAL-WORLD STUDIES: AN EXPLORATION OF HOW TO BOOST STUDY DESIGN AND CONDUCTION

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INTRODUCTION

- Since the introduction of ChatGPT, back in 2022, generative artificial intelligence (AI) has gained increasing importance in the healthcare industry (Thirunavukarasu AJ, et al., 2023).
- In 2024, IQVIA™, who has a rich history of developing award-winning AI methodologies validated for healthcare that starts in 2013, has developed a next generation Healthcare-grade AI™ (IQVIA's AI), that leverages advanced AI techniques and large language models like GPT4 to access, analyze, and present business critical information.
- We aim to present the application of such technology in the design and conduction of Italian and international multi-country observational studies.

METHODS

- From the very beginning, the capabilities of this innovative tool were examined to understand how AI could be integrated in the design and conduction of observational studies (Figure 1).
- We focused on specific activities in the setting of observational studies (Table 2) and analyzed how tasks are currently performed and how they can be carried out with AI support.
- In particular, we explored the following activities:
 - research and information extraction;
 - medical coding, data cleaning, and programming of logical data checks;
 - language translation.

RESULTS

- **Bibliographic search:** IQVIA's AI showed to speed up the search process, by providing (as output to a prompt) a list of relevant references from trusted sources, such as PubMed, Food and Drug Administration, ClinicalTrials.gov and World Health Organization (WHO). Moreover, it was possible to converse with a simulated "medical expert" chatbot, to deep diving into specific topics. This innovative functionality was also used to support the elaboration of surveys.
- **Data cleaning, programming and coding:** AI allowed to identify typo errors made during data entry and harmonizing terms to the official language of the study (English). Plus, regarding the medical coding, IQVIA's AI provided a correct MedDRA and WHO term with reduced time. Moreover, through AI, it was possible to speed up the searching of appropriate laboratory parameters ranges and the conversion among multiple units of measurements. Finally, IQVIA's AI was able to review and generate SAS and R codes, which allowed to perform code validation and optimization faster.
- **Language translation:** the power of AI was also exploited for the translation of regulatory documents in multi-country studies. The assessment of its capability of "sounding" as natural as a professional translator is still ongoing.
- A preliminary analysis of the **potential time saved** for each activity was carried out, even considering the time spent to review the output provided by IQVIA's AI (Figure 3).
- Results showed that the largest saving could be obtained from the translation of regulatory documents, with approximately 30% reduction. For the bibliographic search task, a 15%-time reduction was estimated, while for the activities involved in the data cleaning process, an average 10% decrease was assessed. The results showed a trend in the same direction of findings from Dell'Acqua et al., (2023).

CONCLUSIONS

Tests shown that IQVIA's AI has great potential, although not all tasks were performed with the same accuracy.

At present, our approach is to associate human oversight (which is also recommended by the EU AI Act) to AI integration in observational studies to boost efficiency, reduce costs, and potentially lead to more accurate and reliable outcomes.

Future assessments should be addressed to quantify the extent of such improvements and maximize the reliability of using AI in observational studies.

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1. Dell'Acqua, F., McFowland, E., Mollick, E. R., Lifshitz-Assaf, H., Kellogg, K., Rajendran, S., ... & Lakhani, K. R. (2023). Navigating the jagged technological frontier: Field experimental evidence of the effects of AI on knowledge worker productivity and quality. Harvard Business School Technology & Operations Mgt. Unit Working Paper, (24-013).
2. Thirunavukarasu, A. J., Ting, D. S. J., Elangovan, K., Gutierrez, L., Tan, T. F., & Ting, D. S. W. (2023). Large language models in medicine. Nature medicine, 29(8), 1930-1940.

Figure 1: Workflow of methods

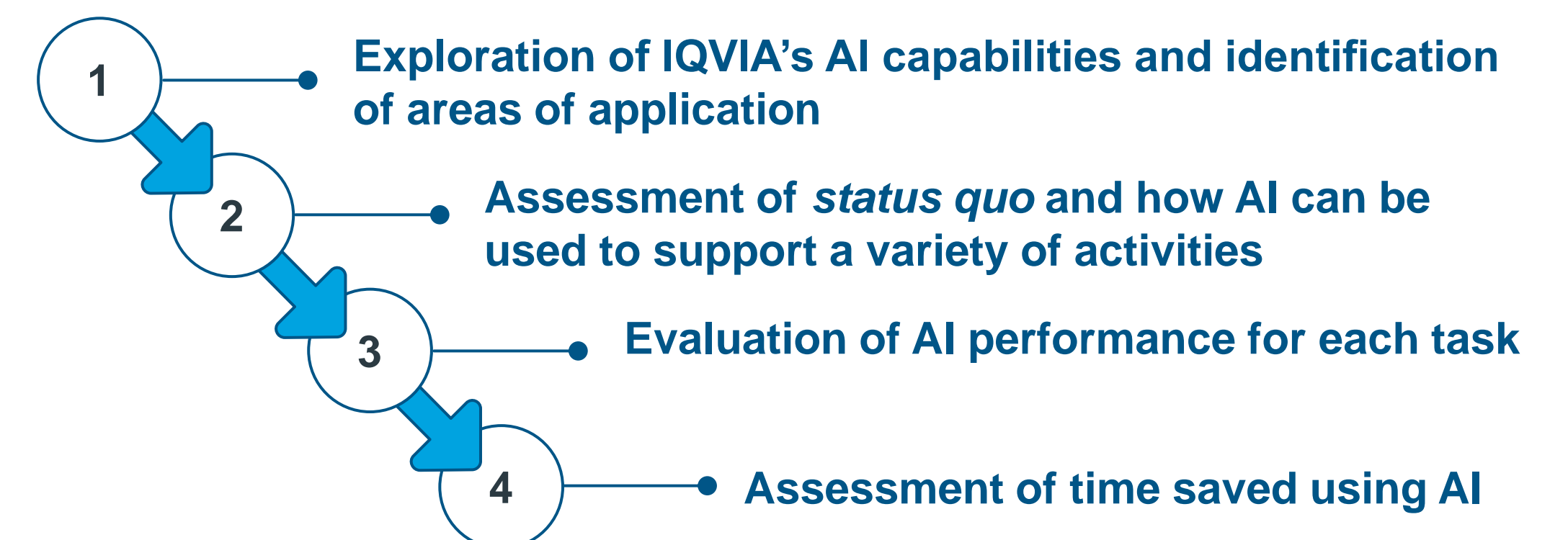


Table 2: A new approach to work using AI

Type of activity	Without AI support	With AI support*
Bibliographic search	Search is done using keywords directly on PubMed or other search engines. References needs to be read to choose the most appropriate	AI provides a list of references from relevant trusted sources with citations. The answer can be progressively improved by giving further prompts
MedDRA/WHO Coding	Coding is done manually or, if possible, partially automated through programming code	AI automatically assigns MedDRA/WHO terms associated to a description of the clinical condition/drug
SAS/R programming	Code writing and revision are performed manually, by using validated templates	AI is used to speed up the revision process and to provide snippet code lines for a faster programming
Laboratory parameters unit conversion/range identification	The activity is performed manually, by consulting relevant literature	AI can handle multiple units of measurement and provide relevant ranges
Translation of regulatory documents	The document is fully translated by a professional translator. Where necessary, a review is performed	The document is fully translated by AI

*At the end of the activity, a human review is always performed.

Figure 3: Time reduction using AI

