

Akanksha Sharma¹, Barinder Singh², Rajdeep Kaur¹, Shubhram Pandey¹
¹Pharmacoevidence, Mohali, India; ²Pharmacoevidence, London, United Kingdom

INTRODUCTION

- Indirect treatment comparisons (ITCs) are a fundamental component of health technology assessment (HTA) when direct head-to-head randomized controlled trials are unavailable. These analyses are widely used to inform reimbursement and market access decisions; however, their validity depends on key methodological assumptions, including similarity of patient populations, consistency of treatment effects across studies, and comparability of trial designs and outcome measures¹
- Feasibility assessment is a critical preliminary step that determines whether an ITC can be conducted in a scientifically robust and credible manner. This process involves a detailed evaluation of clinical and methodological characteristics across studies, including eligibility criteria, baseline patient demographics and disease severity, treatment regimens, follow-up duration, endpoint definitions, and availability of relevant outcomes²
- Conducting feasibility assessments is often complex, resource-intensive, and dependent on substantial expert judgment
- Reviewers must synthesize large volumes of heterogeneous clinical evidence and interpret nuanced differences across trials, which can introduce subjectivity and variability in conclusions³

OBJECTIVE

- To evaluate the use of GenAI in generating structured feasibility assessments for ITCs and its ability to support transparent, HTA-aligned decision-making
- To validate AI-generated outputs against expert human assessments

METHODS

DESIGN & ARCHITECTURE

To automate and standardize feasibility assessments, a multi-agent, Retrieval-Augmented Generation (RAG)-based framework was developed as shown in **Figure 1**

DATA SOURCES & PREPARATION

Clinical trial data from published literature and study reports were standardized and semantically indexed using a RAG pipeline for structured retrieval of trial and outcome data

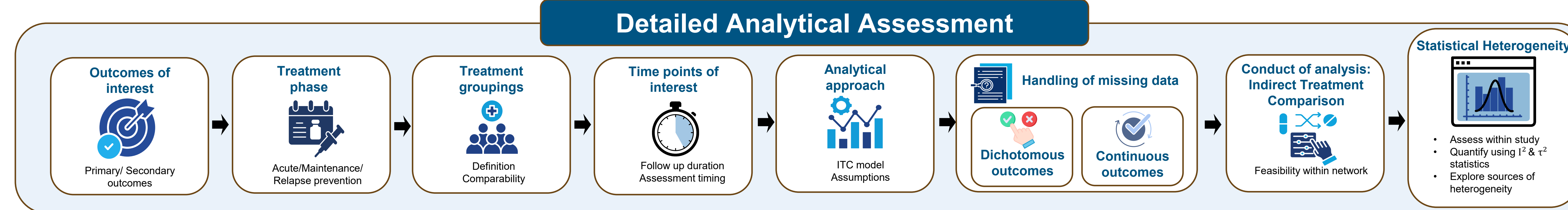
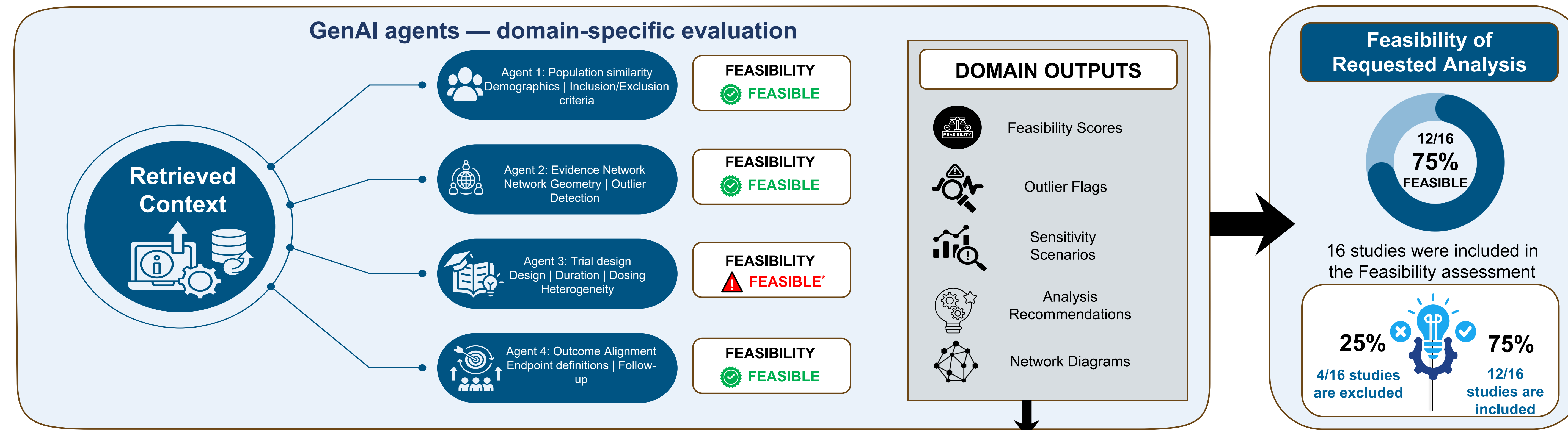
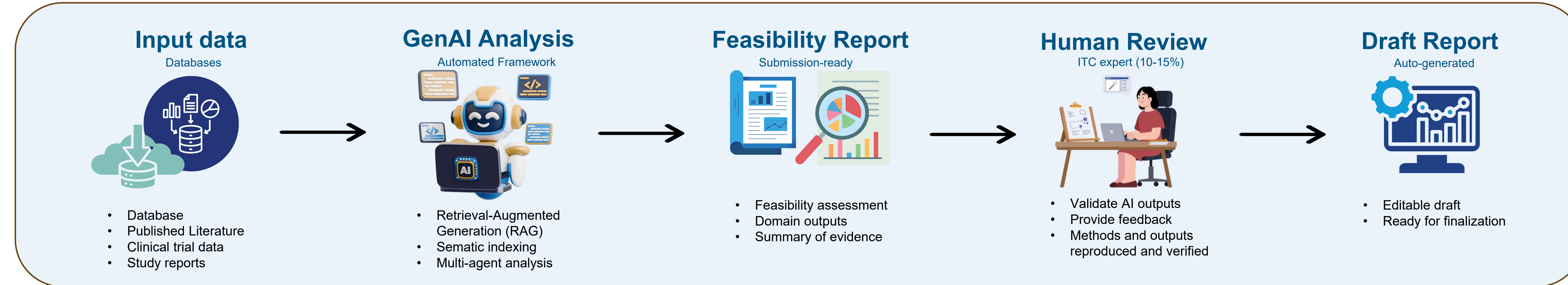
GENAI AGENT CONFIGURATION & FEASIBILITY DOMAINS

Multiple GenAI agents used domain-specific prompts to assess four feasibility categories by retrieving evidence from the indexed corpus and generating structured evaluations as shown in **Figure 1**

VALIDATION AGAINST EXPERT ASSESSMENT

AI feasibility outputs were compared with expert ITC assessments across four components (Network Diagram, Population, Trial Design, Outcomes) as shown in **Figure 2**

Figure 1: GenAI Workflow Diagram



ITC – Indirect Treatment Comparison; GenAI – Generative Artificial Intelligence; * - 4/16 studies are excluded

Figure 2: Sample Interface of AI-generated Feasibility Assessment Report

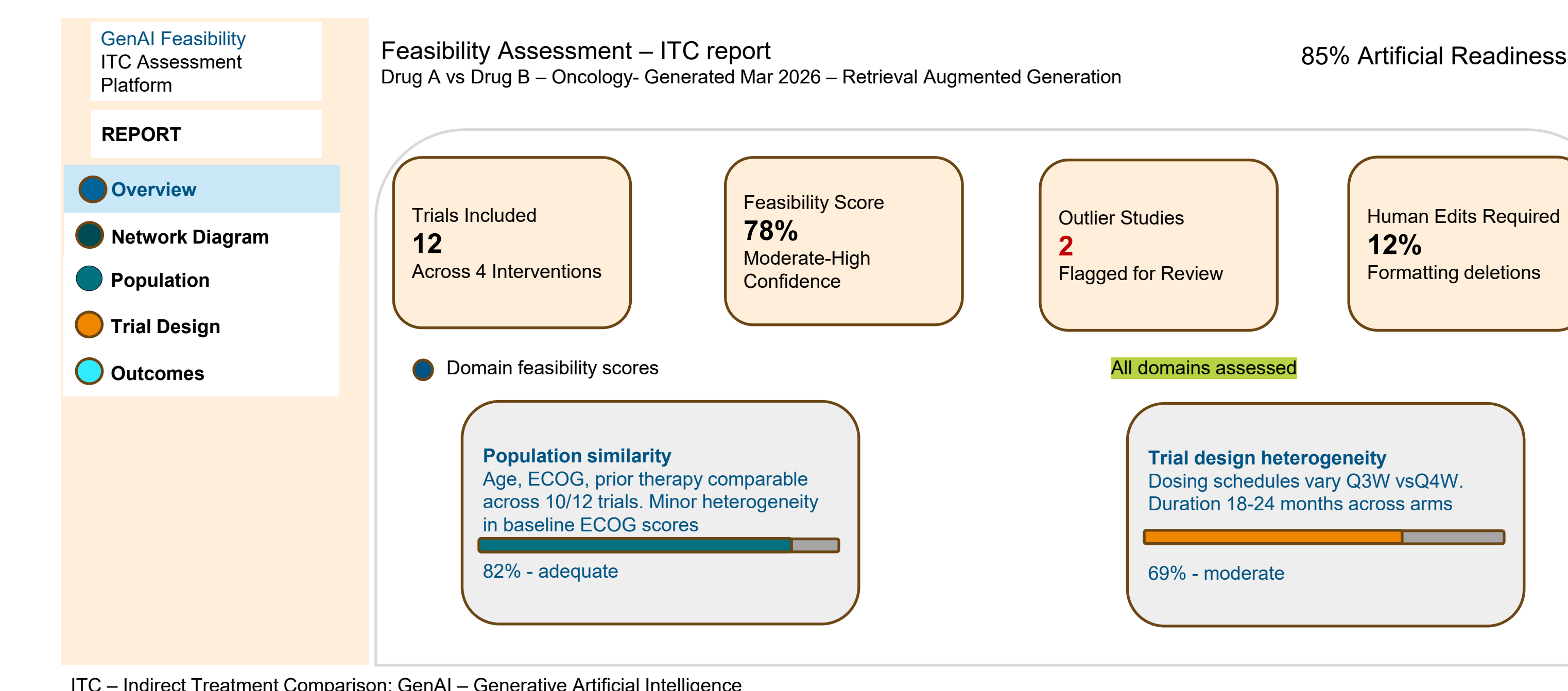
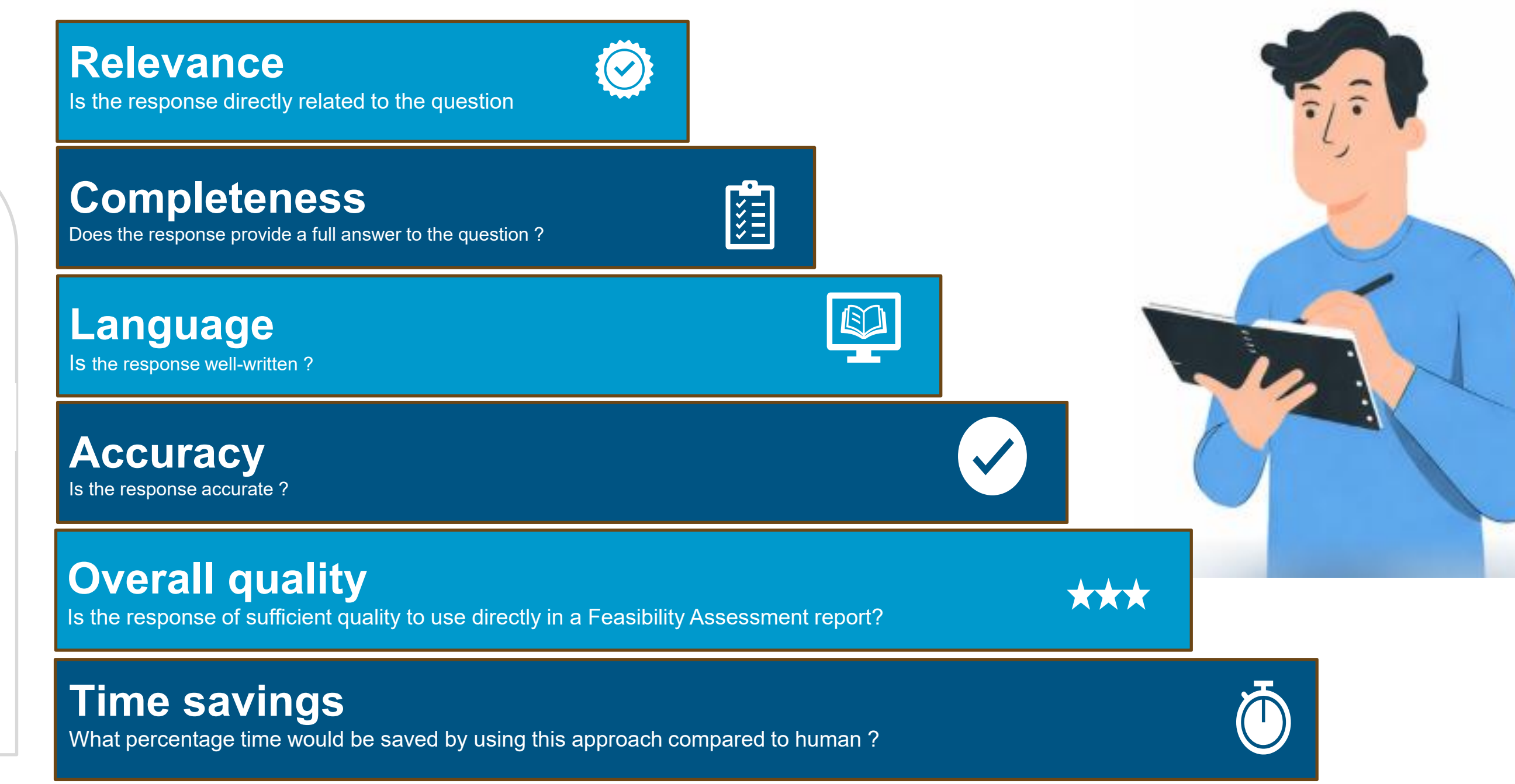


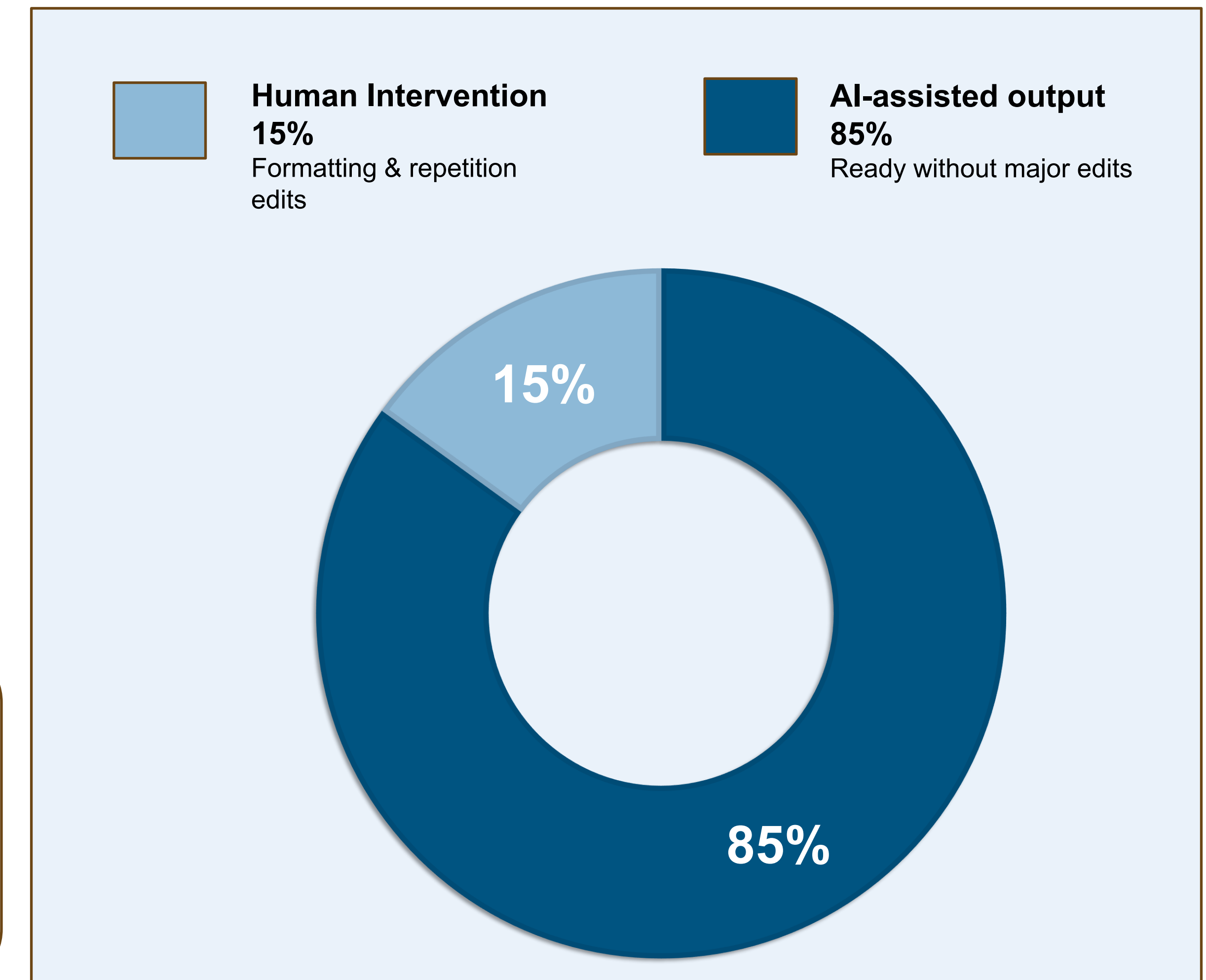
Figure 3: Evaluation parameters of AI-generated Feasibility Assessment Report



RESULTS

- The GenAI framework successfully generated a comprehensive feasibility report encompassing network diagrams, comparisons of study and patient characteristics, statistical tests, and analysis recommendations, including sensitivity analyses as shown in **Figure 2**
- The AI-assisted feasibility assessment demonstrated the ability to identify outlier studies autonomously and propose data-driven sensitivity and scenario analyses, reducing the burden of manual review as shown in **Figure 2**
- Minor human editing was required to address repetitive content and formatting inconsistencies. A human ITC expert rated the AI-assisted feasibility output at 85% readiness, with only 15% human intervention needed to produce a finalized, submission-quality report as shown in **Figure 4**

Figure 4: Proportion of AI-assisted Output versus Human Intervention



AI – Artificial Intelligence

LIMITATIONS

- This study evaluated the GenAI framework using a limited set of clinical trials and feasibility scenarios, which may restrict generalizability across broader HTA settings and therapeutic areas
- The quality and consistency of AI-generated assessments depended heavily on the completeness and accuracy of the source literature and indexed data
- Domain-specific prompting and expert-defined criteria may also introduce bias into the generated outputs
- In addition, expert review and post-generation edits were still required, indicating that the framework currently supports rather than replaces human judgment in ITC feasibility assessment

CONCLUSIONS

- This RAG-based GenAI framework represents a transformative step towards scalable, transparent, and efficient ITC feasibility assessment
- By achieving 85% submission-ready output with minimal human intervention, the study demonstrates that AI-assisted workflows can meaningfully enhance the quality, consistency, and speed of HTA-grade evidence synthesis
- Future work should focus on broader validation across therapeutic areas, refinement of agent prompting strategies, and integration into regulatory submission pipelines to fully realize the framework's potential in supporting timely, high-quality health technology decisions