

INTRODUCTION

- Health Economics and Outcomes Research (HEOR) has become an essential function in demonstrating the value of therapies across global healthcare markets. However, current HEOR workflows remain predominantly manual, fragmented, and heavily dependent on specialized expertise¹
- As global healthcare systems increasingly rely on evidence-based decision-making, HEOR outputs such as cost-effectiveness models, budget-impact analyses, and real-world evidence synthesis play a critical role in informing reimbursement, market access, and policy decisions²
- Health technology assessment (HTA) workflows from evidence synthesis to economic modeling and dossier generation are often fragmented across multiple workflows and software environments³
- Therefore, there is a need for a unified generative AI (GenAI) framework capable of generating HTA-ready outputs while incorporating transparent processes, quality control mechanisms, and expert review

OBJECTIVE

- The objective of this research was to develop and validate a comprehensive GenAI suite capable of producing end-to-end, HTA-ready outputs within a unified and transparent framework, while maintaining human oversight and methodological rigor

METHODOLOGY

- The suite integrates five interconnected modules: (1) Evidence Synthesis, enabling landscape assessment and systematic literature reviews for generating standardized extraction grids; (2) Model Conceptualization, producing model conceptualization protocols with model structure, inputs, and assumptions; (3) Model Development, generating fully functional HTA-ready Excel or R/Python models for decision tree, Markov, semi-Markov and hybrid frameworks; (4) Report Generation, drafting technical reports including sensitivity analyses; and (5) Dossier Generation, for market-specific submissions (Figure 1). The detailed process has been depicted in Figure 2
- The system was tested using diverse therapeutic areas, including oncology, rare diseases, and mental health indications. Validation metrics included traceability, reproducibility, structural accuracy, and narrative coherence

Figure 1. Platform Modules

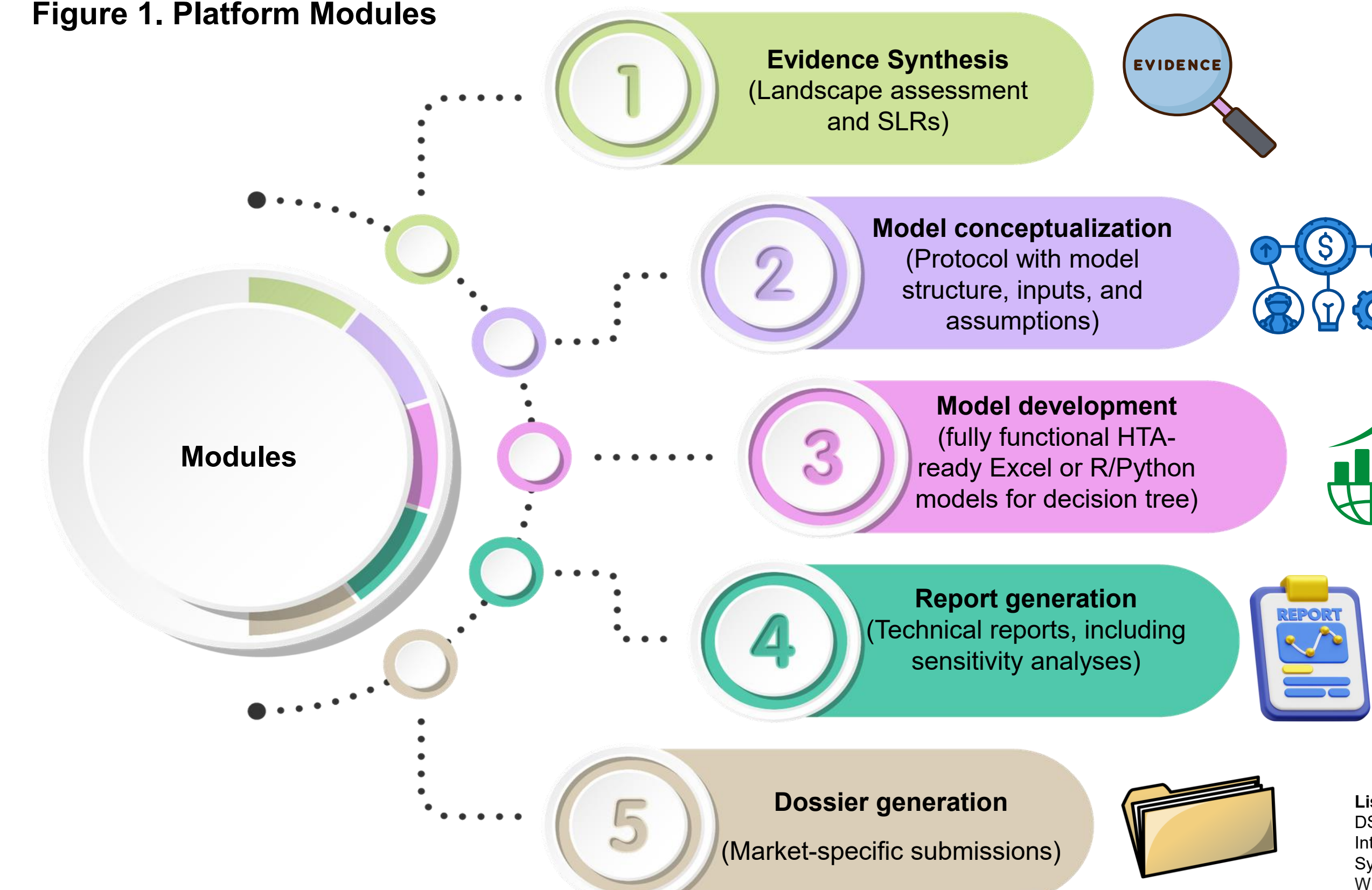
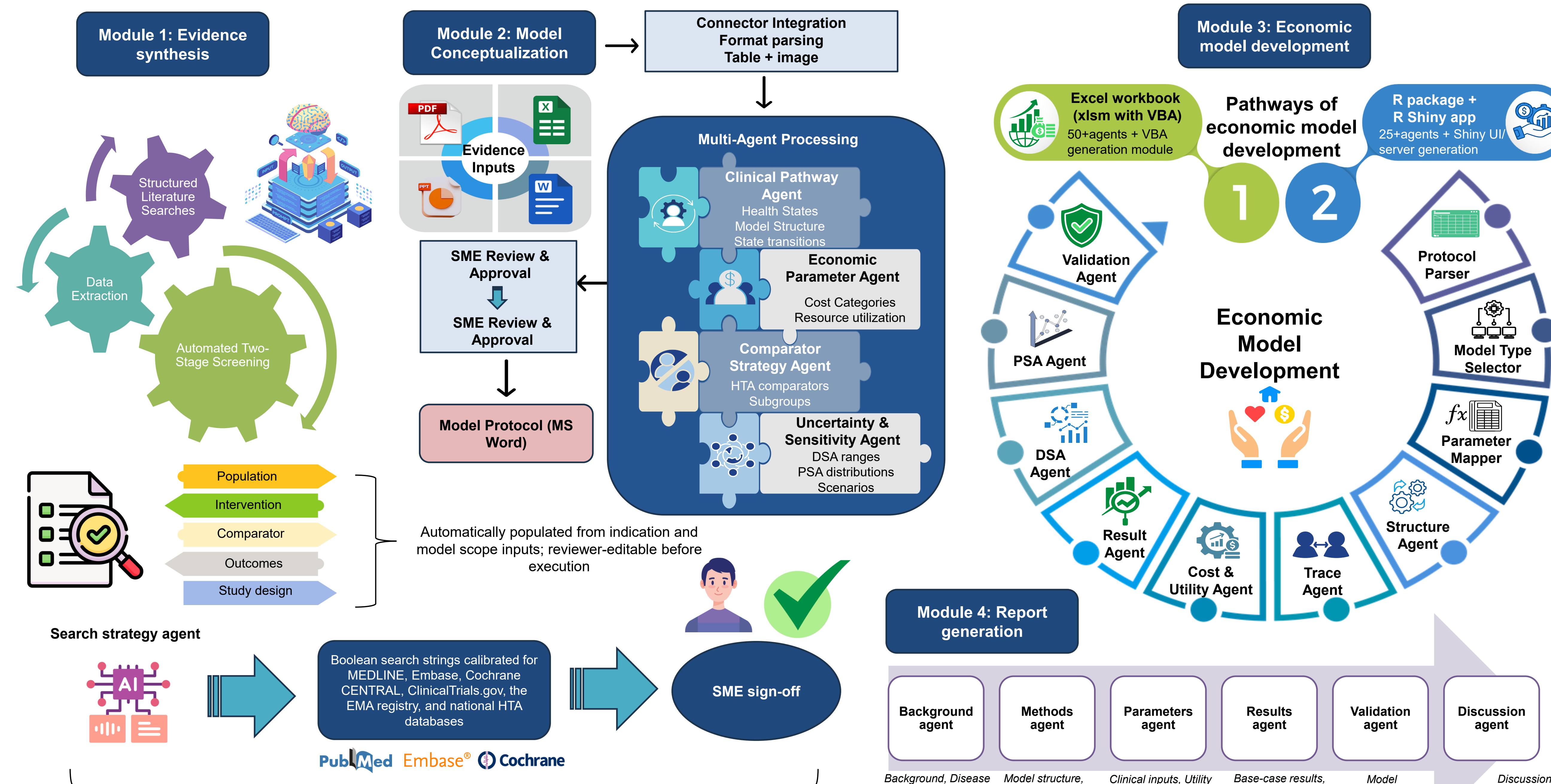


Figure 2. Methodology of end-to-end AI-enabled HEOR modelling workflow



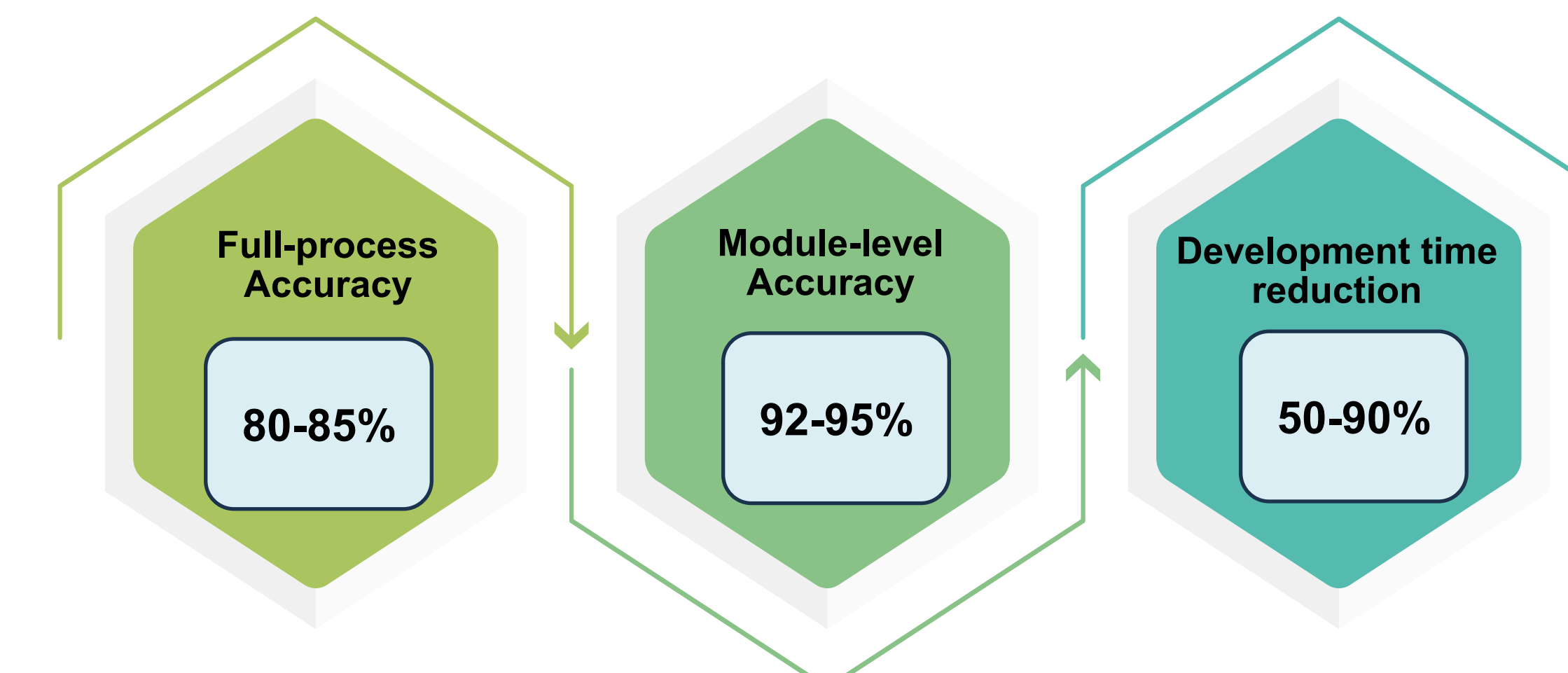
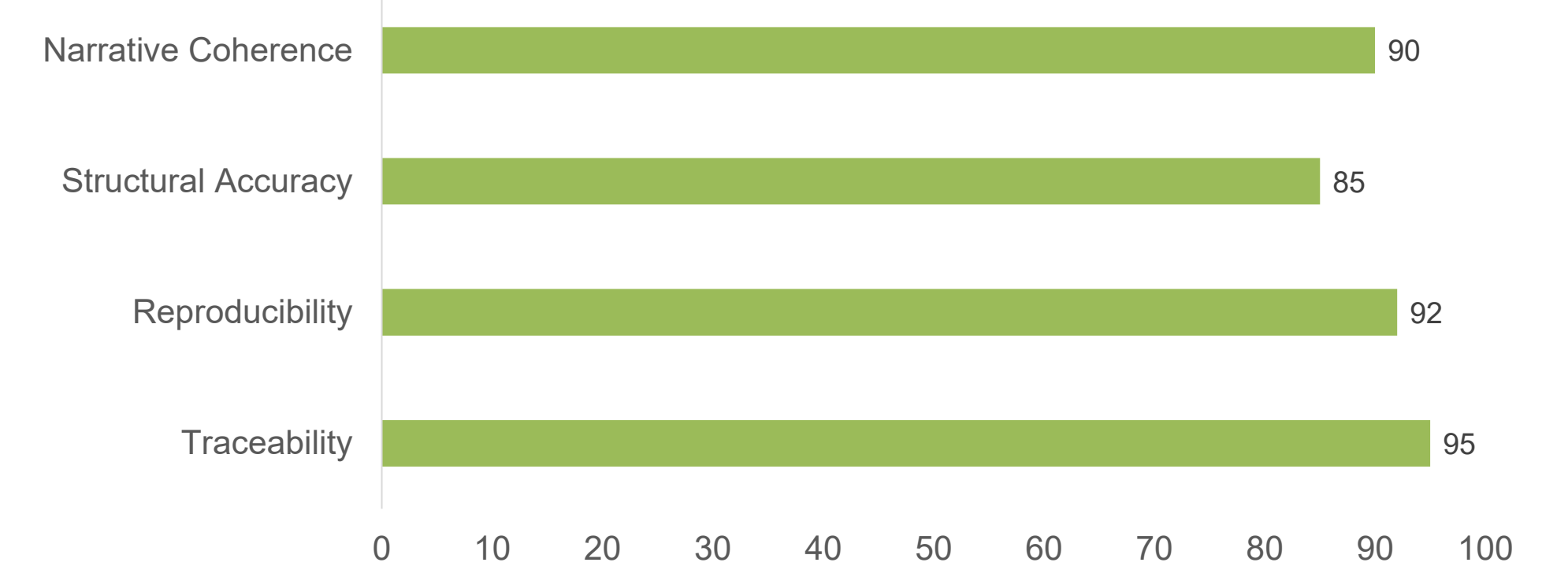
Structured Data Extraction Process

Data Category	Parameters Extracted	Format
Clinical effectiveness	Overall survival, progression-free survival, response rates, time-to-event data, hazard ratios with confidence intervals	Structured Excel table with source citations
Utilities	EQ-5D-3L/5L, SF-6D, condition-specific instruments; baseline values, AE disutilities, treatment disutilities	Utility matrix with instrument details and population characteristics
Resource use	Treatment cycles, monitoring visits, hospitalisation rates, adverse event management, end-of-life care	Resource use table by health state and treatment arm
Unit costs	Drug acquisition, administration, monitoring, hospitalisation (country-specific)	Country-tagged cost table with year of price and source
Safety	Grade 3/4 adverse event rates, dose modifications, treatment discontinuation rates	Safety summary table with incidence per arm
Baseline characteristics	Patient demographics, disease stage, prior treatment lines, baseline utility values	Population characteristics table for model calibration

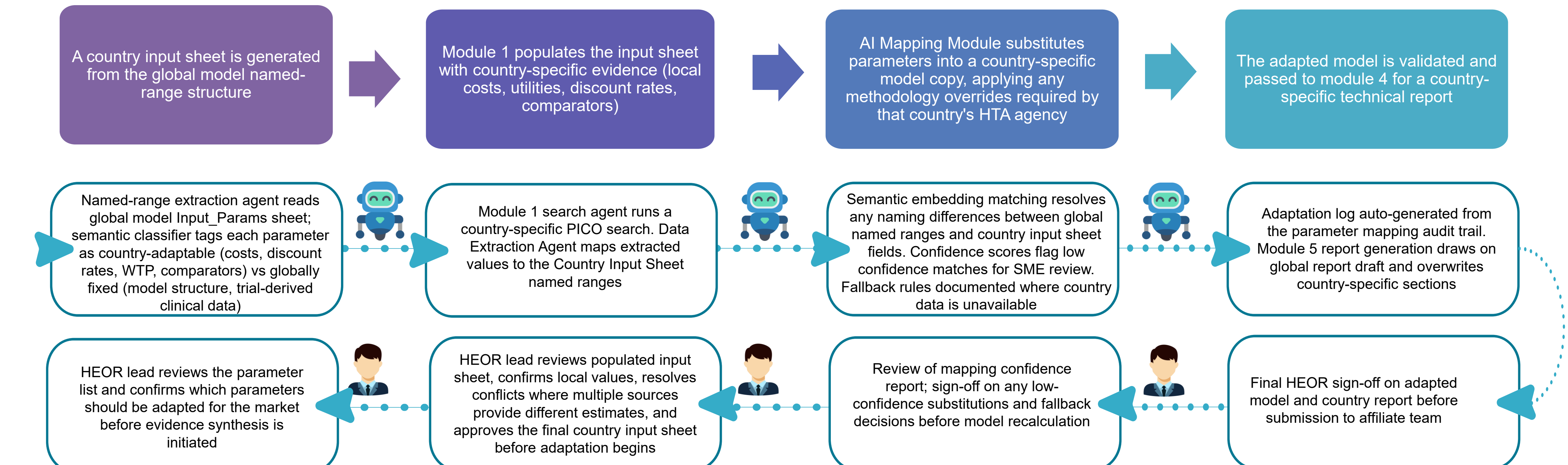
RESULTS

- Across six test cases spanning three therapeutic areas, the suite achieved 80-85% full-process accuracy (from evidence synthesis to dossier generation) and 92-95% partial-process accuracy when individual modules were used independently (Figure 2)
- Automation reduced approximately 50%-85% development time compared with manual workflows across multiple modules (50% in evidence synthesis, 90% in model conceptualization, 75% in model development, 85% in report writing, and 90% in dossier generation) (Figure 3)
- Domain experts verified all AI-generated excel/R models for face validity, structural integrity, and compliance with established HTA methodological standards.

Figure 3. Validation of GenAI Generated Outputs



Module 5: Dossier generation



CONCLUSIONS

Transparency

This GenAI suite demonstrates that comprehensive automation of HTA workflows with human oversight is achievable while preserving methodological rigor and transparency

Time savings

The substantial time savings observed across all modules suggest meaningful potential for accelerating HTA submission timelines while maintaining quality standards

Human-in-loop approach

Through structured SME validation, the approach enables efficient, compliant content generation, supporting responsible AI integration in health economics and outcomes research

Future Directions

Future research will focus on evaluating performance across additional use cases and real-world HTA submissions to further assess robustness, generalizability, and practical applicability

References:

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- Justo N et al., Real-World Evidence in Healthcare Decision Making: Global Trends and Case Studies From Latin America. *Value in Health.* 2019, 22(6):739-749
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