giles®

USE CASE

STRATEGIC EVIDENCE SYNTHESIS

Strategic Evidence Synthesis: Mastering the PICO Framework

Transform vague business questions into precise, submission-ready PICO frameworks for HTA & EU JCA submissions in minutes, not days.

Days to Minutes
Time-to-Protocol

Multi-Jurisdiction
HTA Alignment

Living HTA
Continuous Updates

THE CHALLENGE

The Evidence Synthesis Bottleneck & Scope Creep

Creating a Systematic Literature Review (SLR) is the "marathon" of the HEOR world. Without a rigid PICO framework, HEOR teams risk "scope creep," leading to wasted research cycles. Worse, teams risk missing the specific comparator data required by national HTA bodies or the EU Joint Clinical Assessment (JCA).

Vague Research Questions

Without a rigid PICO framework, teams start with questions like 'Is our drug better than the current stuff?' leading to unfocused SLRs and wasted research cycles.

Missing Critical Comparators

Teams risk missing the specific comparator data required by national HTA bodies (G-BA, HAS) or the EU Joint Clinical Assessment (JCA), undermining submission success.

Multi-Jurisdictional Complexity

Key actors including HEOR Teams, Market Access Managers, and Medical Writers must navigate differing requirements across Germany's G-BA, France's HAS, and EU JCA expectations.

Protocol Misalignment Risk

Locking in an SLR protocol without anticipating HTA behavior leads to structural evidence gaps and the costly need for indirect treatment comparisons later.

THE SOLUTION

Smart Scientific Insight via the PICO Framework by giles®

giles® turns a vague business question, such as "Is our drug better than the current stuff?", into a precise PICO. It applies the PICO framework to formulate a precise and answerable clinical question which will guide your entire SLR process. Users simply ask giles® questions using natural language—no complex or structured queries required.

Precise

Transforms vague questions into structured PICO frameworks with specific populations, interventions, comparators, and outcomes tailored to HTA requirements.

Strategic

Anticipates national HTA behavior, re-weights outcomes by jurisdiction, and identifies structural evidence gaps before your SLR protocol is locked.

Natural Language

Ask questions the way you think. No complex structured queries needed—just conversational inputs that guide your entire evidence synthesis workflow.

DEEP DATA INTEGRATION & DATA SOURCES

Stop Switching Tabs

giles® connects directly to secure internal repositories alongside libraries like PubMed, ClinicalTrials.gov, FDA, and IQWIG (with the list growing), together with web search in a single workspace. It uses AI, machine learning, and natural language processing to rapidly scan, screen, and extract data from clinical trials, literature, and grey literature. All relevant clinical, economic, and real-world evidence is consolidated in a single workspace, reducing manual searching, duplication, and missed insights.

BUSINESS IMPACT & ROI PROJECTIONS

Utilizing giles® for Protocol Design

Speed and Efficiency

Reduce the 'time-to-protocol' with guided deconstruction from days to minutes, accelerating submission timelines significantly.

Tailored Scenarios

Generate tailored PICO variations aligned to G-BA, HAS, and EU JCA expectations. What satisfies Germany won't necessarily satisfy France, and the EU JCA introduces a harmonised but broader evidentiary scope.

Strategic Risk Mitigation

giles® anticipates national HTA behavior, re-weights outcomes by jurisdiction, identifies structural evidence gaps, and signals the early need for indirect treatment comparisons—all before your SLR protocol is locked.

Living HTA Updates

Facilitates a 'living' approach to assessments, allowing for automated, ongoing updates as new, relevant data becomes available, rather than relying on periodic, manual reviews.

Reimbursement Alignment

Aligns protocol design with reimbursement strategy before your SLR protocol is locked, ensuring evidence meets payer requirements across multiple jurisdictions.

REAL-WORLD EXAMPLES OF USAGE

PICO for a Type 2 Diabetes (T2D) EU JCA Submission

Scenario: A Senior HEOR Researcher is preparing an SLR for a new oral Type 2 Diabetes treatment positioned as second-line therapy after metformin, ahead of an EU JCA submission.

The Process: Using the everyday chat function, the researcher asks giles® to structure the research for an SLR using the PICO framework and suggest an actionable research protocol. giles® breaks down the elements:

P — Population

It defines highly specific subpopulations, such as adults with T2D inadequately controlled on metformin monotherapy.

I — Intervention

It ensures precision about the new drug, including the specific dose, frequency, and route of administration.

C — Comparator

It identifies strategic active comparators relevant to EU markets, such as SGLT2 inhibitors (e.g., empagliflozin) or GLP-1 receptor agonists (e.g., semaglutide).

O — Outcomes

It ensures a comprehensive range of JCA outcomes, including glycemic control (HbA1c), Health-Related Quality of Life (HRQoL) using validated instruments like the EQ-5D, and Macrovascular events (MACE).

The Outcome: Submission-Ready Primary Question

giles® generates a tailored primary question using a structured formula. The result is:

> **"In adults with Type 2 Diabetes inadequately controlled on metformin monotherapy, what is the comparative efficacy and safety of adding Drug X versus adding an SGLT2 inhibitor with respect to changes in HbA1c, body weight, and the incidence of adverse events?"**

This primary question is clear, defensible, and submission ready.

COMPETITIVE ADVANTAGE

Why Choose giles® for Evidence Synthesis?

- Automation at Scale: Streamlines the time-intensive process of assembling evidence for drug reimbursement, improving scalability and consistency
- Multi-Jurisdictional Support: Generates PICO variations tailored to specific HTA bodies (G-BA, HAS, EU JCA)
- Living Evidence: Enables continuous updates as new data emerges, maintaining submission readiness
- Accuracy: Reduces human error and leverages Real-World Evidence (RWE) utilization efficiently
- Strategic Foresight: Identifies evidence gaps and comparator needs before protocol lock-in
- Natural Language Interface: No complex queries needed—ask questions conversationally