

## MadeAi-JCA: Platform Validation

The first AI platform to anticipate EU JCA scoping — identifying comparators, outcomes and PICO sets across all 27 EU Member States with full source traceability — validated against three published EU Joint Clinical Assessment reports using only Population and Intervention as inputs, replicating what a manufacturer knows before the official scope is issued

3 Published JCA Reports · Ground Truth

Tovorafenib · Lurbinectedin · Tarlatamab

Comparators · Outcomes · PICO Sets

HTACG AI Principles Aligned · July 2026

### KEY METRICS

<1 hr

Scope output per product  
— over 200× faster than  
manual cross-referencing  
across 27 Member States

91%

Comparator accuracy — 10  
of 11 unique JCA  
comparators captured  
across all three products

100%

Core outcomes identified —  
OS, PFS, ORR, safety and  
HRQoL across every drug  
tested

100%

Source traceability — every  
comparator, outcome and  
PICO set linked to its exact  
source document

### VALIDATION METHODOLOGY

Three published JCA reports were selected as ground truth: **tovorafenib, lurbinectedin, and tarlatamab**. The platform was run using only the **Population (P) and Intervention (I)** as input, replicating the information available to a manufacturer before the official scope is issued. Platform outputs were compared against the ground truth on three dimensions: **comparator identification, outcome coverage and PICO set structure**.

1

#### Ground truth: Published JCA Assessments

Comparators, outcomes and  
PICO sets from three  
published JCA assessments  
used as the reference  
standard

2

#### MadeAi Input: Population & Intervention

MadeAi-JCA given only the  
product name and licensed  
indication — no prior HTA  
data, no trial results

3

#### MadeAi-JCA Output

MadeAi-JCA output mapped  
against ground truth across  
comparators, outcomes and  
PICO set structure

4

#### Reviewer-ready Standard

Performance judged by  
completeness for dossier  
preparation — not classical  
precision or recall

RESULTS — COMPARATORS, OUTCOMES AND PICO SETS

| DRUG        | <div>T</div> <div>Tovorafenib (Ojemda)</div> <div>Paediatric LGG · BRAF-altered · JCA 202406</div>                                                                                               | <div>L</div> <div>Lurbinectedin (Zepzelca)</div> <div>ES-SCLC · 1L Maintenance · JCA 202416</div>                                                      | <div>T</div> <div>Tarlatamab (Imdylltra)</div> <div>ES-SCLC · 2L+ Post-Platinum · JCA 202417</div>                                                             |
|-------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------|
| COMPARATORS | <div>Comparators</div> <div>7 defined</div> <div>✓ 6 of 7</div> <div>Everolimus: SEGA/TSC only, outside the BRAF-altered indication (edge case)</div> <div>5 — all clinically real options</div> | <div>Comparators</div> <div>1 defined</div> <div>✓ 1 of 1</div> <div>None</div> <div>Durvalumab — valid alternative maintenance</div>                  | <div>Comparators</div> <div>7 defined (3 core)</div> <div>✓ 3 of 3</div> <div>None</div> <div>5 — incl. trial control arm options</div>                        |
| OUTCOMES    | <div>Outcomes</div> <div>✓ Identified</div> <div>✓ Identified</div> <div>✓ Identified</div> <div>Visual acuity preservation additionally surfaced</div> <div>✓ Identified</div>                  | <div>Outcomes</div> <div>✓ Identified</div> <div>✓ Identified</div> <div>✓ Identified</div> <div>Immune-mediated AEs</div> <div>✓ Identified</div>     | <div>Outcomes</div> <div>✓ Identified</div> <div>✓ Identified</div> <div>✓ Identified</div> <div>CRS &amp; ICANS (BiTE-specific)</div> <div>✓ Identified</div> |
| PICO SETS   | <div>Pico Sets</div> <div>✓ Identified</div> <div>✓ BRAF V600E vs fusion</div> <div>8 PICOs across 3 BRAF sub-populations correctly structured</div>                                             | <div>Pico Sets</div> <div>✓ Identified</div> <div>Single population — not applicable</div> <div>PICO set matched the published JCA scope exactly</div> | <div>Pico Sets</div> <div>✓ Identified</div> <div>✓ Platinum-sensitive vs resistant</div> <div>7 PICOs across 4 sub-populations correctly structured</div>     |
|             |                                                                                                                                                                                                  |                                                                                                                                                        |                                                                                                                                                                |

OVERALL PERFORMANCE

|                                                                                                                 |                                                                                                                |                                                                                                             |                                                                                                                  |
|-----------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------|
| <div>91%</div> <div>Comparator accuracy — 10 of 11 unique JCA comparators captured across all three drugs</div> | <div>100%</div> <div>Core outcome coverage — OS, PFS, ORR, safety and HRQoL identified across every drug</div> | <div>100%</div> <div>PICO set structure correctly captured — including complex multi-population cases</div> | <div>100%</div> <div>Source traceability — every output linked to its exact source document with rationale</div> |
|-----------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------|

## WHY MADEAI-JCA

- 1 Scope output in under one hour — not weeks**  
 MadeAi-JCA delivers a reviewer-ready anticipated scope in under an hour. The same output manually takes 3–5 weeks of specialist HEOR effort — over 200× faster
- 2 27 EU Member States covered automatically**  
 The platform synthesises comparators and standard of care from HTA reports, clinical guidelines and drug registries across all 27 Member States in a single automated run
- 3 Every output source-linked and traceable**  
 Full audit trail from comparator to source document — built-in traceability ready for HTACG dossier disclosure and internal governance without additional effort
- 4 Mechanism-aware beyond the standard catalog**  
 Surfaces indication-specific signals — CRS and ICANS for BITE therapies, immune-mediated AEs for checkpoint inhibitors — that generic tools and manual searches miss
- 5 End-to-end: scoping through evidence synthesis**  
 One integrated platform from anticipated PICO scoping through systematic literature review, data extraction and evidence synthesis — no switching between tools or vendors

## REGULATORY ALIGNMENT — HTACG AI PRINCIPLES (JULY 2026)



### Accountability

The human expert retains full responsibility for all outputs. MadeAi-JCA produces a structured starting point — the expert team reviews, finalises and owns every scope decision before it enters the dossier



### Transparency

Every comparator, outcome and PICO set is linked to its exact source document with rationale documented throughout. Full audit trail covering inputs, processes and outputs — nothing is a black box



### Reporting

This validation study provides the empirical performance evidence required for transparent dossier disclosure of AI-assisted JCA scoping, consistent with HTACG AI guidance

## AWARD-WINNING SOLUTIONS

