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PT10

An Integrated Three-Platform AI Workflow for EU Joint Clinical Assessment

AI-Assisted PICO Definition, Real-World Evidence Validation, and AI Dossier Authoring

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BACKGROUND

- Under Regulation (EU) 2021/2282, Joint Clinical Assessments (JCAs) have applied since 12 January 2025 to new oncology medicines and ATMPs, expanding to orphan medicines in 2028 and all centrally authorised medicines in 2030.
- Member states define PICOs through scoping; health technology developers must then respond rapidly in order to develop the JCA dossier.
- Given short timelines within the JCA process, early PICO planning which informs indirect treatment comparisons and dossier writing, is essential.

OBJECTIVE

To evaluate the feasibility of an integrated workflow of three interlinked AI platforms to support developer preparation for JCA, from PICO scenario building, validation with market exoperts through to JCA dossier drafting.

KEY MESSAGE

In an NSCLC proof-of-concept, three integrated AI platforms took EU-27 PICO scenarios through ITC feasibility and payer validation to early, signed-off JCA dossier drafts.

METHODS

INPUTS EUnetHTA 21 methodological guidance · NSCLC clinical study data · EU-27 standard of care and reimbursement landscape

PLATFORM 1 · ONCOSCOPE PICO & evidence planning

STEP 1 — ONCOSCOPE REAL-TIME ONCOLOGY LIBRARY

PICO scenario building

With Oncoscope AI (literature oncology platform) relevant clinical evidence, treatment comparators were identified and sourced as the basis for the NSCLC PICO frameworks for 27 countries.

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STEP 2 — ONCOSCOPE REAL-TIME ONCOLOGY LIBRARY

PICO refinement

With Oncoscope AI subgroups by biomarker status, age and disease severity, and comparators by reimbursement status were selected and groups built.

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PLATFORM 2 · MOOLYA-AI

STEP 3 — Moolya

Real-world PICO validation

Besides literature, PICOs depend on market specifics which are best validated through in-depth interviews. Moolya AI was utilized to screen and run market research across countries within 1 week. Low-relevance PICOs were de-prioritised and dropped.

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PLATFORM 3 · DO-BO

STEP 4 — DO-BO

JCA dossier drafting

After PICOs have been defined, dossier writing was executed by DO-BO®, an AI-powered dossier authoring platform, with which each JCA dossier section was available within 5 working days including human validation and finetuning.

Feedback: low-relevance PICO scenarios de-prioritised; scenario set and ITC plans refined before drafting

AFTER JCA SCOPING
Confirmed PICOs and additional statistical analyses fed the signed-off drafts – inclusion doable within days based on DO-BO.

Evaluation: European payers and clinicians were recruited to finetune PICOs, dossier evaluation and alignment done by human market access experts and human medical writers within 5 days per working step.

AI governance: All outputs traceable to source evidence and reviewed by market access experts. AI model(s) used were secure and deployed in-house (DO-BO).

RESULTS

01
Optimized workflow

The workflow took PICO scenarios through to a draft JCA dossier, with core sections signed off early. Experts judged it faster than conventional sequential preparation, based on their experience of comparable projects (PICO definition within one week; draft JCA per section 5 working days).

02
PICO building up-to-date

Oncoscope AI is upated daily with latest literature and reimbursement decision in oncology. During the JCA process, updates were ran and informed ITC execution (separate work step) and dossier writing.

03
PICO validation during full process

Within Moolya AI, payers across the world including Europe, are available for interviews. Based on latest PICOs, questionnaires, recruitment, interview analyses and PICO adoption was automized within Moolya whenever new evidence was made available through Oncoscope AI..

04
Dossier drafts rapidly available for alignment and ready to adapt

With evidence available for sections 1 to 5 of the JCA dossier, chapters were drafted and reviewed by the client (timing 5 days per chapter including human review). Updated data sources and documents made a rapid alignment and adoption possible.

Independent expert review

DELIVERED BY THE WORKFLOW

- ✓ High structural completeness
- ✓ Traceable evidence sourcing
- ✓ ITC feasibility documented per scenario
- ✓ Cross-platform consistency
- ✓ No fundamental structural inconsistencies

TARGETED HUMAN REFINEMENT

- ✎ Clinical relevance argumentation
- ✎ Country-specific contextualisation

CONCLUSIONS

- A three-platform AI workflow is feasible for supporting developer JCA preparation in oncology.
- Per-scenario ITC feasibility and early payer validation focus effort on the PICOs most likely to matter.
- Early sign-off of core sections lets developers respond quickly once the assessment scope is issued.
- Human experts remain essential for clinical argumentation and national context.

NEXT STEPS

1. Compare AI-built PICO scenarios with the official NSCLC JCA assessment scope
2. Quantitative time and quality benchmarking against standard practice, including EUnetHTA 21 quality criteria
3. Extend payer validation to further member states and add real-world data sources
4. Independent external validation, with reporting aligned to ISPOR ELEVATE-GenAI

ABBREVIATIONS

AI, artificial intelligence; ATMP, advanced therapy medicinal product; EU-27, the 27 EU member states; EUnetHTA, European Network for Health Technology Assessment; HTA, health technology assessment; ITC, indirect treatment comparison; JCA, Joint Clinical Assessment; NMA, network meta-analysis; NSCLC, non-small cell lung cancer; PICO, population, intervention, comparator, outcome; RCT, randomised controlled trial.