Do the demands of European HTA regulation necessitate the adoption of AI in the JCA development?

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Findings

We report on a comprehensive review of artificial inteligence (AI)-supported Joint Clinical Assessment (JCA) feasibility. Some level of AI support will be required, primarily to address resource gaps and timeline constraints. The largest efficiencies were found across data extraction and interrogation, and document templates. However, hurdles for successful implementation of AI assistance for JCA creation remain and will be best mitigated by a close partnership between all stakeholders. Exponential growth of AI in this area is likely to prompt a rapid response from policymakers and the eventual development of a consistent framework for assessing AI processes.
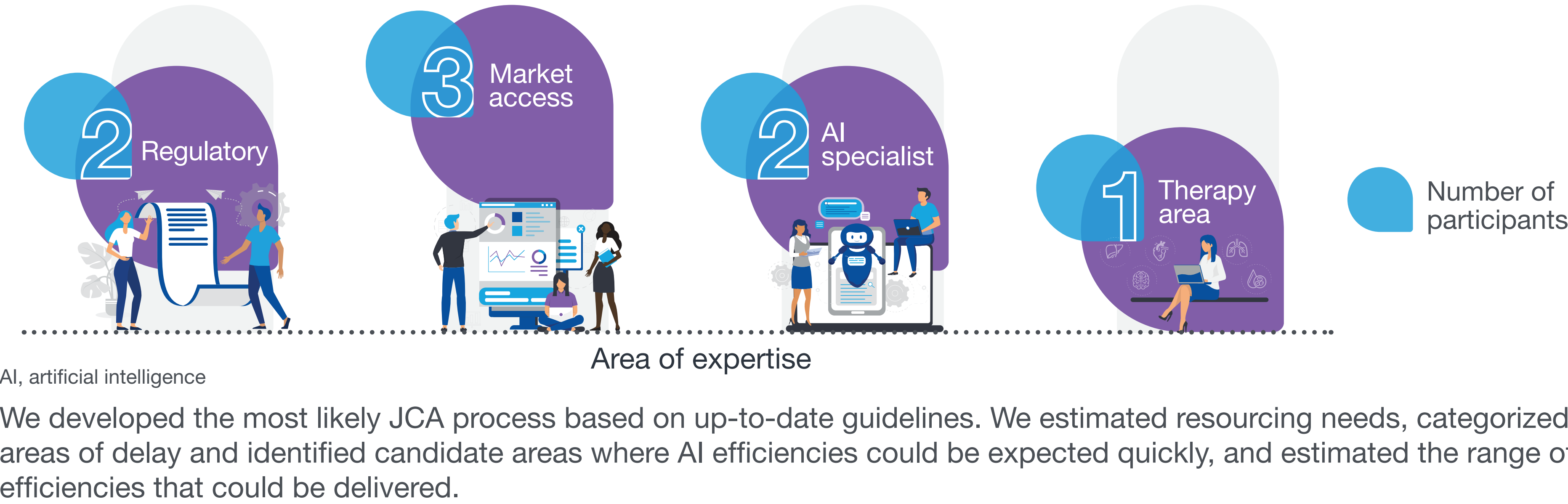
Introduction

With the first stages of JCA rollout beginning in January 2025, the scale of work for countries and manufacturers is expected to be significant. The proposed timescale of the JCA is a key driver of the resource use, with just 80 days between the final scope meeting and JCA dossier submission, and 30 days between market authorization and publication of the JCA report.

Recent research suggests that creating a JCA document will require three to four times more resources than the current equivalent in Spain,[1] and while gaps remain in the literature review process for JCA, case studies have shown that there may be up to 18 PICOs (population, intervention, comparator, outcome) and 720 analyses required per indication.[2] These requirements are an exponential increase from the work currently undertaken by countries and manufacturers across the European Union (EU).

Methods

We first conducted a broad review of existing literature on the topic. Due to lack of available information, once we audited the sources, we workshopped the challenges via a carefully selected multidisciplinary team (Figure 1).
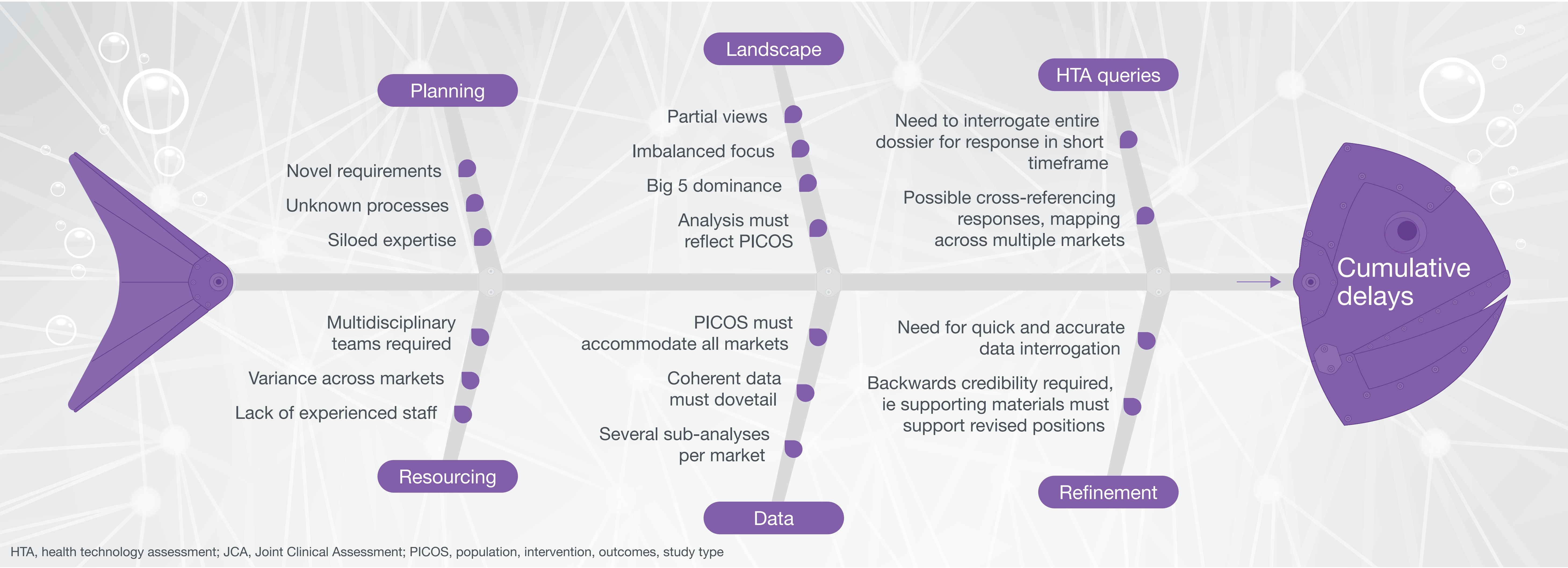
Figure 1: Multidisciplinary workshop composition.

2 Regulatory

3 Market access

2 AI specialist

1 Therapy area

Number of participants

Area of expertise

AI, artificial intelligence

We developed the most likely JCA process based on up-to-date guidelines. We estimated resourcing needs, categorized areas of delay and identified candidate areas where AI efficiencies could be expected quickly, and estimated the range of efficiencies that could be delivered.

Objective: To examine whether organic expansion can meet the challenges of JCA or if only a technical leap such as AI can meet expected needs.
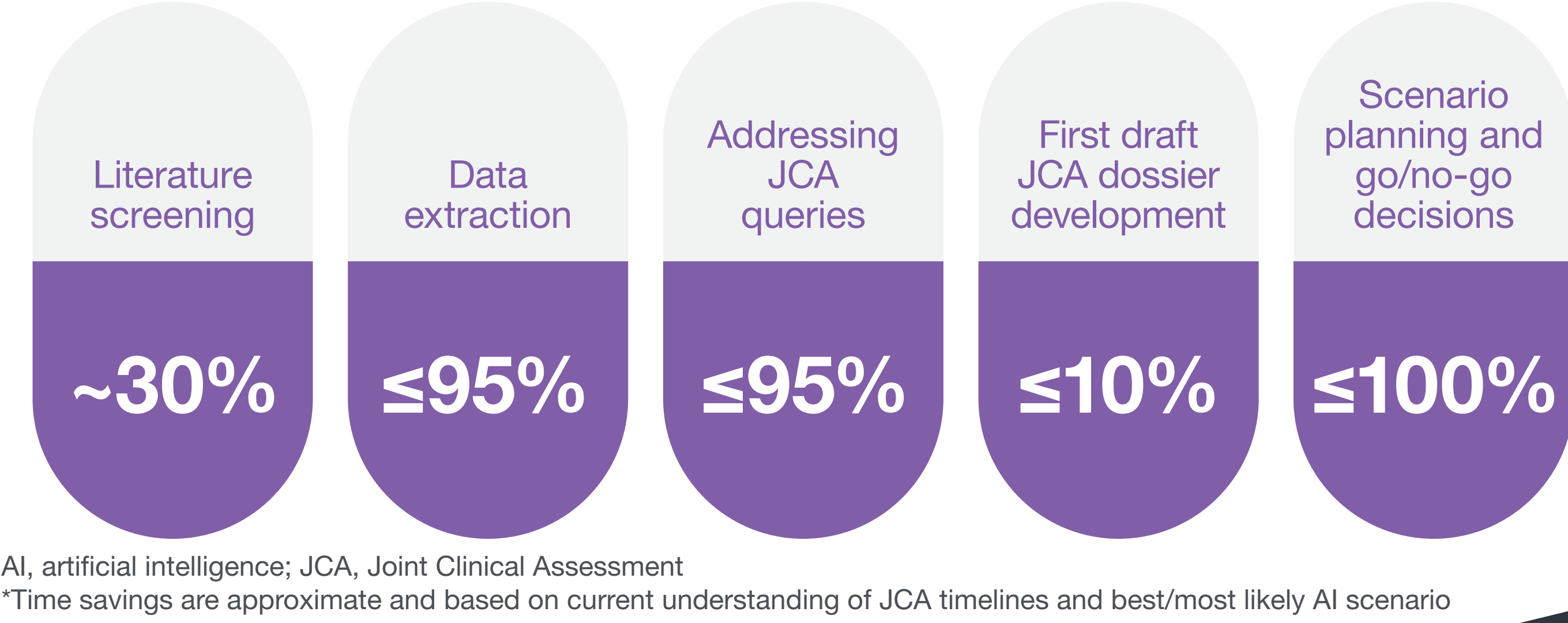
Results and interpretation

Figure 2: Where will time pressures occur during 2025 JCA submissions?

Planning
- Novel requirements
- Unknown processes
- Siloed expertise

Landscape
- Partial views
- Imbalanced focus
- Big 5 dominance
- Analysis must reflect PICOS

HTA queries
- Need to interrogate entire dossier for response in short timeframe
- Possible cross-referencing responses, mapping across multiple markets

Resourcing
- Multidisciplinary teams required
- Variance across markets
- Lack of experienced staff

Data
- PICOS must accommodate all markets
- Coherent data must dovetail
- Several sub-analyses per market

Refinement
- Need for quick and accurate data interrogation
- Backwards credibility required, ie supporting materials must support revised positions

Cumulative delays

HTA, health technology assessment; JCA, Joint Clinical Assessment; PICOS, population, intervention, outcomes, study type

Based on the most likely JCA process, we identified key areas of cumulative delays that will contribute to JCA development (Figure 2). Areas like landscaping, data and health technology assessment (HTA) queries are particularly time-sensitive based on the most likely JCA timelines (Figure S1 in the Supplementary Material), and our findings suggest a significant resource gap between what is currently available and what is expected for JCA. The short period required for JCA dossier creation in particular will prove near impossible with limited resources and without automation/AI.

Focusing on landscaping, data and HTA queries specifically, we identified key areas where AI could provide time and resource savings and the most likely AI process versus current process (Figure 3 and Table S1 in the Supplemental Material). The areas where AI could provide the largest (≤95%) time savings were data extraction, queries and scenario planning activities. Due to the need for explainability and consistent outputs, AI tools that have defined datasets and are guided by 'desirable' templates, ie Retrieval Augmented Generation models and similar are likely to be most beneficial.

Figure 3: Areas of potential time savings with AI versus current process.*

Literature screening	Data extraction	Addressing JCA queries	First draft JCA dossier development	Scenario planning and go/no-go decisions
~30%	≤95%	≤95%	≤10%	≤100%

AI, artificial intelligence; JCA, Joint Clinical Assessment
*Time savings are approximate and based on current understanding of JCA timelines and best/most likely AI scenario

References

1. Diariofarma. Preparing each European JCA requires "between three and four" times more resources than an IPT. 2024 [in Spanish]. Available at: https://diariofarma.com/2024/06/02/elaborar-cada-informe-jca-europeo-requiere-entre-tres-y-cuatro-mas-recursos-que-un-ipt. Accessed October 2024.

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