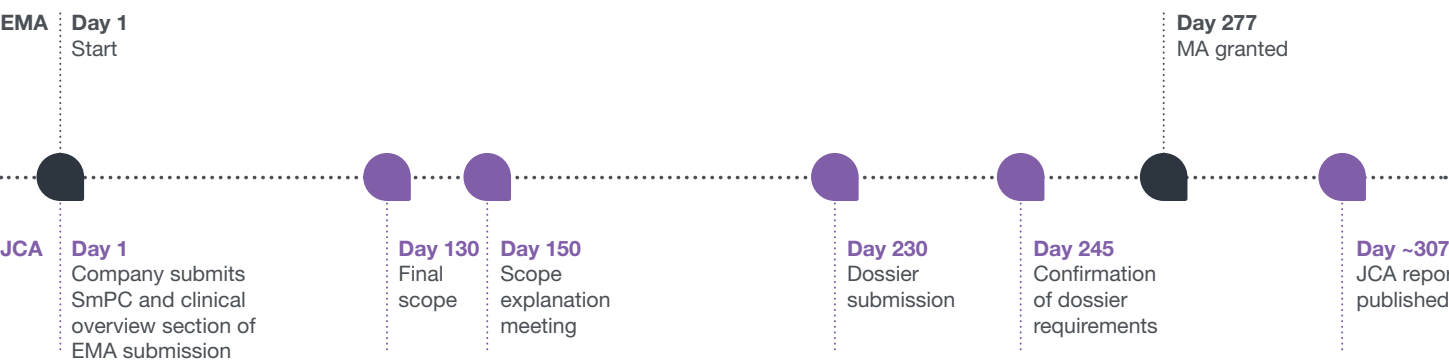


Do the demands of European HTA regulation necessitate the adoption of AI in the JCA development

Supplementary material

Figure S1: JCA timelines.



EMA, European Medicines Agency; JCA, Joint Clinical Assessment; MA, market authorization; SmPC, summary of product characteristics

Table S1: Areas of time savings with AI versus current process.

Areas of AI time savings	Current most likely process	Most likely AI method	Potential time saving*
Literature screening	2 reviewers screening all literature and building consensus	AI screening all literature, 1 reviewer checking	~30% (conservative; with ChatGPT saving is ~30–90%)
Data extraction	1 reviewer extracting, 1 reviewer checking	AI extracting, 1 reviewer checking	≤95%
Addressing JCA queries	Multiple reviewers checking available data to answer query	AI dashboard, 1 reviewer interrogating	≤95%
First draft JCA dossier development	Multiple reviewers develop draft	AI develops template and populates, 1 reviewer updates	≤10%
Scenario planning and go/no-go decisions	Multiple teams develop and plan scenarios	AI dashboard, 1 reviewer interrogating/changing scenarios	≤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