

CAN REFLECTIVE MCDA CONTRIBUTE TO ACHIEVING EMA'S STRATEGIC OBJECTIVES FOR REGULATORY SCIENCE TO 2025? WHEN THE BOTTOM UP APPROACH CAN BE THE WAY TO GO: INSIGHTS FROM SPANISH EXPERIENCE

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BACKGROUND & OBJECTIVES

- Reflective Multicriteria Decision Analysis (rMCDA) offers a framework that allows to resolve complex healthcare decision-making problems by turning them into a comprehensive set of criteria relevant for establishing the value of decision-making items in an explicit, holistic and systematic way [1,2]. MCDA also allows to elicit the reasoning behind healthcare decision-making by promoting a reflective discussion amongst different stakeholders with diverse perspectives.
- The European Agency of Medicines (EMA) recommends the use of rMCDA as a relevant tool in determining the benefit-risk balance of a medicinal product [3]. EMA's regulatory science 2025 aims to build a more adaptive regulatory system to encourage innovative guidance on medicines development and critically assess the benefits and risks of innovative therapies [4].
- Since 2016, Omakase Consulting has conducted over 30 trainings and value determination exercises using rMCDA methodology at national, regional and local level, working with more than 315 key stakeholders involved in healthcare decision-making, including regulators, clinicians, hospital pharmacists, evaluators, payers, decision-makers and patients.
- The aim of this study is to identify **insights from rMCDA experiences in Spain** representing potential **contributions to achievement of EMA regulatory science to 2025 objectives** and patient access to medicines in Europe.

METHODS

- **Pooled analysis of qualitative results and conclusions** of all rMCDA exercises and trainings conducted in Spain between 2016 and 2019 by Omakase Consulting.
- The **EVIDEM MCDA framework** [5] and specific adaptations of it [6-8] were used in all rMCDA exercises and trainings.
- EMA's regulatory science 2025 report was analysed. Potential rMCDA contributions to report's key strategic goals (SG) and core recommendations (CRs) were formulated in a **descriptive manner**. rMCDA publications in Spain are shown as **illustrative examples** to show how rMCDA can contribute to achieving and operationalizing EMA's key regulatory science strategic goals.

RESULTS

- Pooled analysis of performed exercises suggest that rMCDA could contribute to achieving a number **core recommendations (CRs)** in **4/5 EMA's regulatory science 2025 strategic goals (SG)** [3]:

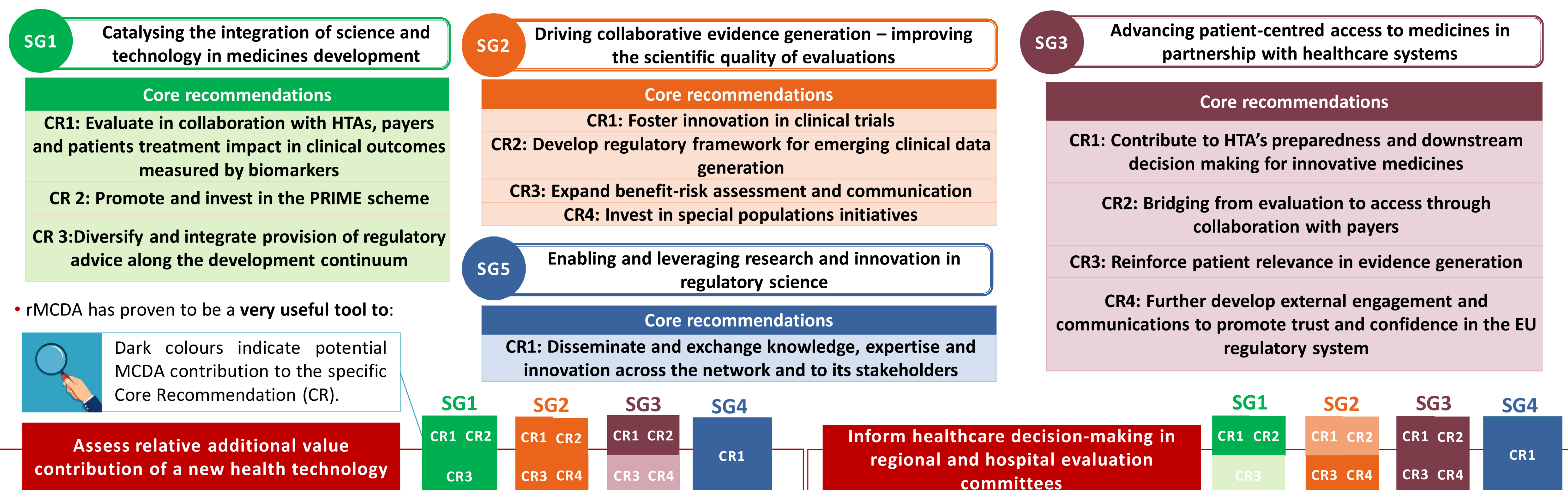
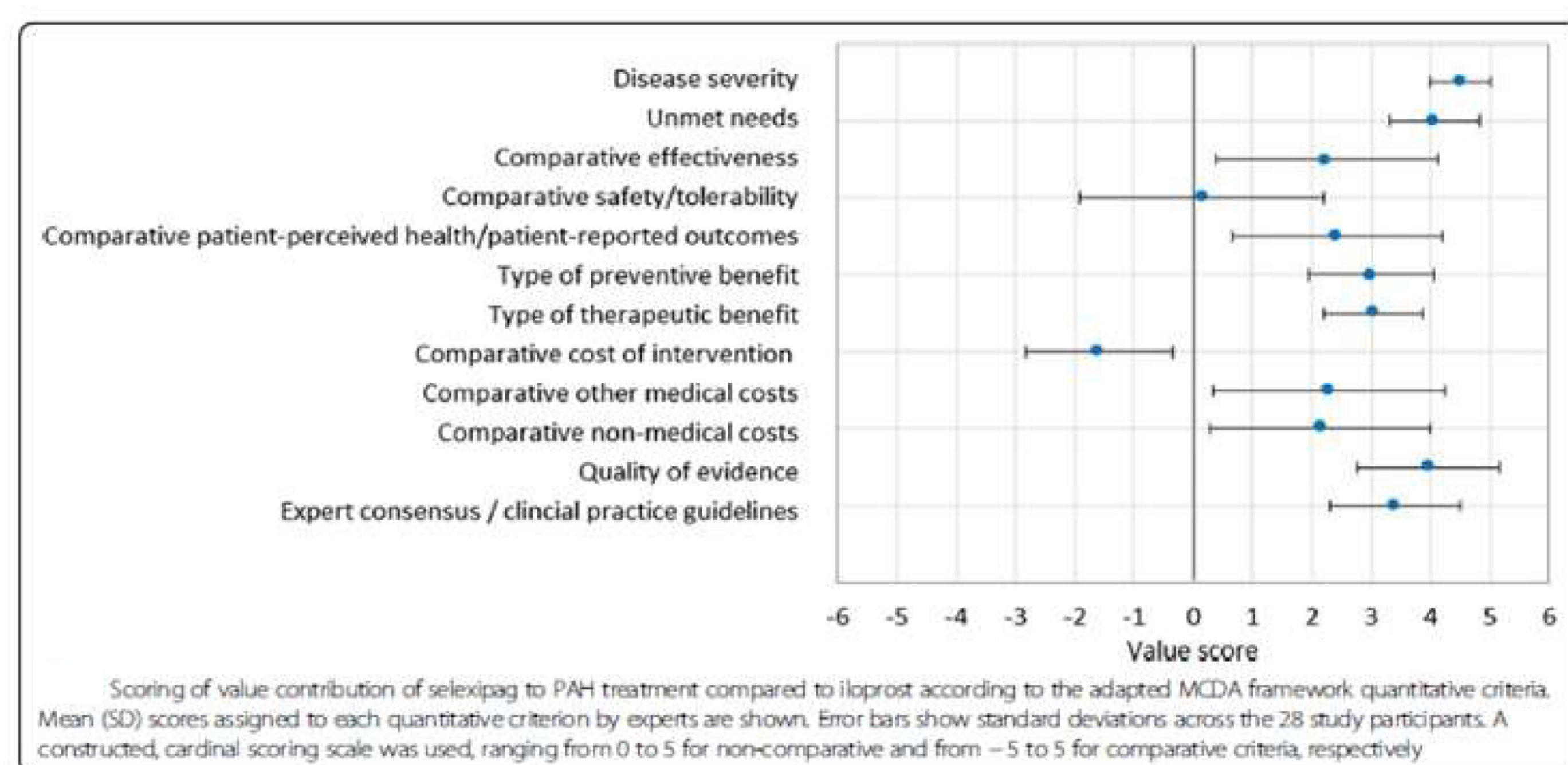
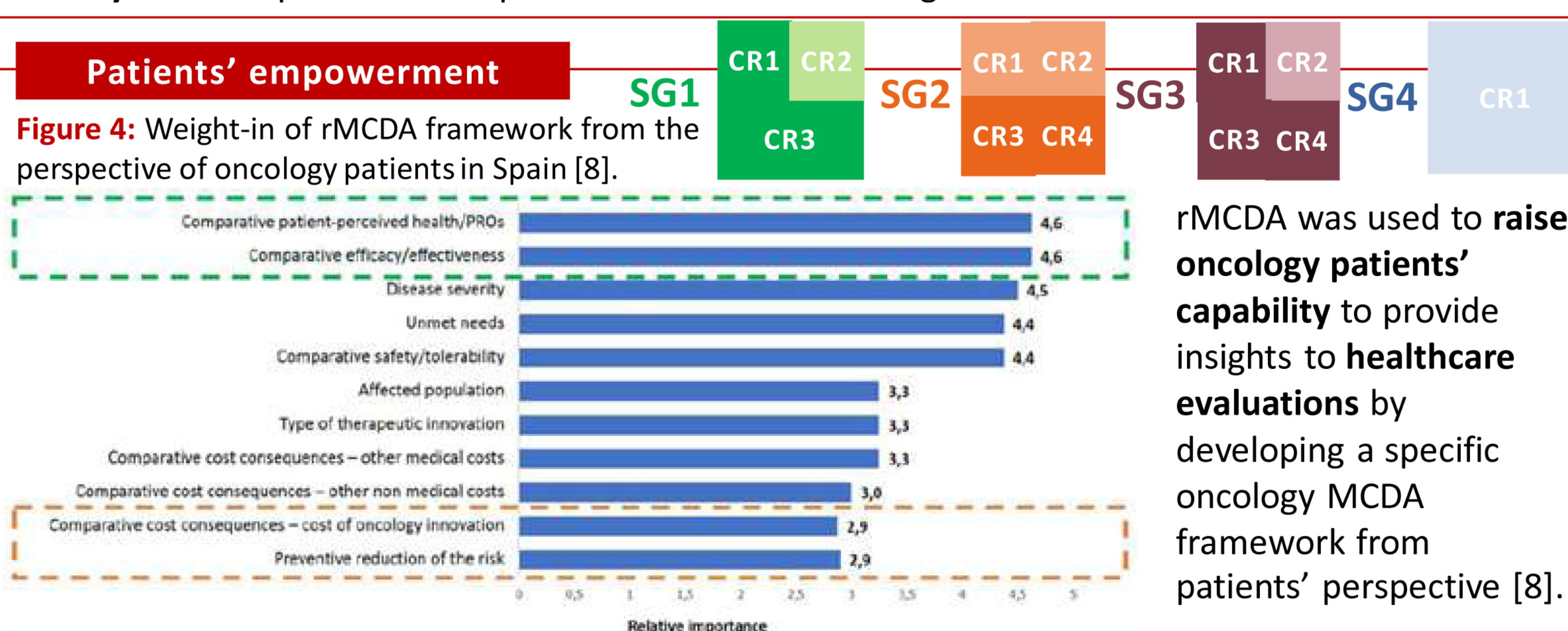


Figure 1: Scoring the value contribution of selexipag in Pulmonary Arterial Hypertension compared to iloprost [9].



The **real value** of a medicinal product can be **captured in a holistic way** through the **product's lifecycle**: from pre-clinical to post-commercialisation stages.



Spanish regional and hospital evaluators perceive rMCDA as a methodology that can **complement healthcare evaluations** and **inform decision-making** by evaluating innovative drugs' relative value contribution in a **structured and transparent** way.

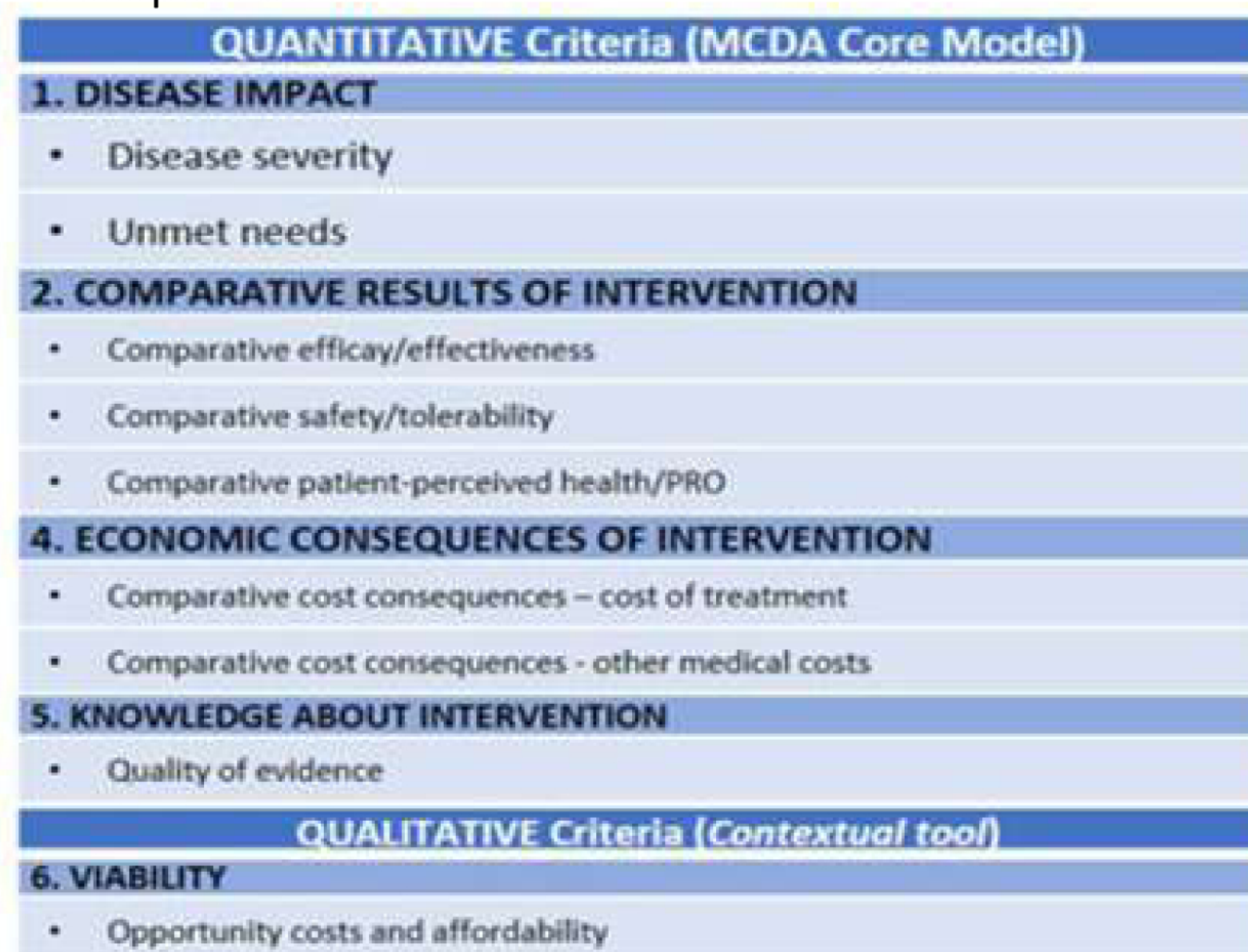
rMCDA is being used in the Spanish region of Catalonia by the Catalan Health Service (CatSalut) to assess the **added value of Orphan Drugs at regional level** (Figure 2) [6].

The rMCDA framework used by CatSalut is an update from a previous rMCDA framework validated by 26 CatSalut members, including clinicians, evaluators, decision-makers and patient representatives (n=2) [10].

Figure 2: rMCDA framework used by CatSalut for assessment of Orphan Drugs at regional level [6].



Figure 3: rMCDA framework used by a pharmaco-therapeutic committee in Spain to support decision-making at hospital level.



rMCDA is being used by at least a hospital in the Spanish region of Andalusia to **support decision-making** among multi-stakeholder members of the **hospital pharmaco-therapeutic committee** [7].

CONCLUSIONS

- Spanish regulators, clinicians, hospital pharmacists, evaluators, payers, decision-makers and patients **consider rMCDA methodology to be relevant and applicable for health technology value assessment and decision-making**.
- Application of **rMCDA methodology** to evaluation and decision-making could be **useful to operationalise EMA's strategic goals to 2025** based on what **really matters to key stakeholders**, enabling advances in empowerment, enhancing contributions to regulatory science and bridging the gap between regulatory approval and patient access to innovative medicines.

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