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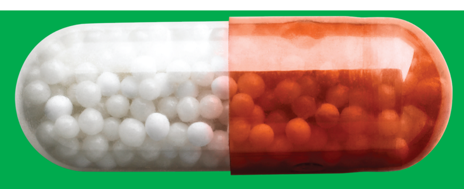

NAVIGATING THE EMA QUALIFICATION PROCESS: OPPORTUNITIES AND CHALLENGES FOR ACCELERATING MARKET ENTRY FOR BREAKTHROUGH TREATMENTS AND VACCINES

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Background

The European Medicines Agency (EMA) Qualification Process is a critical pathway for regulatory endorsement of innovative methodologies, such as digital endpoints, biomarkers, and clinical outcome assessments. However, stakeholders have identified various challenges in navigating this process, particularly as it relates to novel methodologies

Objectives

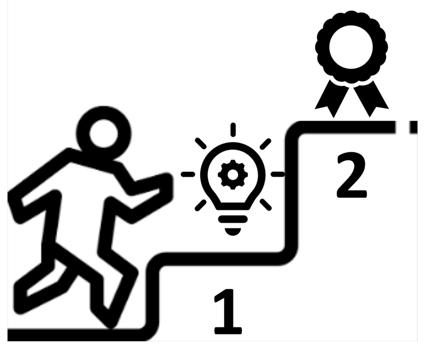
To explore stakeholder perspectives on the EMA qualification process and provide actionable recommendations to enhance its value in supporting the development of innovative treatments and vaccines

Methods

- **Design**: Qualitative study using semi-structured interviews
- **Participants**: Eleven stakeholders involved in the submission for an EMA qualification, as part of a pharmaceutical company and/or consortium (recruitment ongoing)
- **Data Collection (ongoing)**: Interviews were conducted and transcribed verbatim, with data analyzed thematically to identify key perspectives on procedural strengths, limitations, and areas for improvement

Preliminary results

Strategic decision-making in choosing qualification type: pursuing a Qualification Advice vs. Opinion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1. Qualification Advice

- **Guidance with confidentiality**: Offers targeted feedback without public transparency, ideal for companies focusing on proprietary or competitive methods
- **Flexible and cost-effective**: Less resource-intensive, allowing efficient validation without disclosure, helping applicants to retain competitive advantages
- Often preferred by **individual companies**

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2. Qualification Opinion

- **Endorsement for broader adoption**: Seen as a regulatory “stamp of approval” valuable for broad acceptance across the industry
- **Transparency and public benefit**: Enables wider adoption and credibility, especially for applicants aiming to set industry standards. However, public disclosure may limit competitive advantage for proprietary methods
- Often favored by **consortia**

Stakeholder incentives and perceived value

Regulatory validation: The process is seen as valuable for achieving scientific credibility and regulatory acceptance, particularly for methods that require widespread adoption, such as digital endpoints and biomarkers

Broader adoption: EMA endorsement increases the likelihood of acceptance by other regulatory agencies, thus encouraging cross-industry adoption

"The qualification process is crucial for gaining regulatory acceptance; it’s like a bridge between innovative science and real-world application”

"EMA qualification offers validation that goes beyond our company, establishing trust across the industry"

Procedural challenges

"The qualification process is invaluable for bringing innovative methods to the forefront, but without clearer guidance and faster timelines, it risks losing engagement from those who need it most"

Duration and resource intensity: Many found the process to be resource-intensive and time-consuming, with some procedures lasting up to two years. This is a particular barrier for smaller organizations and early-stage projects

Procedural complexity: The qualification process can be challenging due to complex submission requirements and the need for specific dossier formatting, especially for emerging methodologies like digital endpoints

Lack of clear guidance: Stakeholders expressed the need for clearer guidance on dossier content, especially for novel methodologies like AI-enabled tools and digital endpoints

Conclusions

While the EMA Qualification Process is valued for its role in validating innovative methodologies, it poses significant challenges due to its length and the lack of procedural clarity. Recommendations include implementing structured pre-qualification sessions, clearer submission guidelines, and promoting joint regulatory and HTA involvement to enhance process efficiency and accessibility

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