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Navigating Tight Timelines: Managing Extensive Evidence Generation for EU JCA

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The implementation of the EU Joint Clinical Assessment (JCA) under the new EU HTA Regulation imposes stringent timelines on health technology developers. The requirement to generate evidence based on systematic literature reviews (SLRs) and indirect treatment comparisons (ITCs) within a compressed timeframe presents significant challenges. Companies must be prepared to compile extensive and robust data to support their submissions, ensuring that all relevant clinical evidence is comprehensively reviewed and accurately synthesized.

90-Day Crunch: Strategies for Health Technology Developers from PICO Scoping to Submission

Health technology developers will face a critical 90-day window from the completion of PICO (Population, Intervention, Comparator, Outcome) scoping to the submission of their JCA dossier. This narrow timeframe demands precise and efficient workflows to gather, analyze, and compile the necessary evidence. Any delays or inefficiencies during this period could jeopardize the timely submission and acceptance of the JCA dossier.

Early Bird Advantage: Proactive Planning for JCA Success

Given the tight deadlines, health technology developers must start planning for their JCA submissions well in advance. Early planning involves identifying key clinical questions, mapping out the required evidence, and establishing a timeline for evidence generation. By anticipating the needs of the JCA process, developers can ensure that they are adequately prepared to meet the 90-day submission deadline.

Predicting Outcomes: Anticipating Final Labelling and PICO Requirements

Accurately predicting the final approved labelling and anticipating the final PICO parameters will be crucial for health technology developers. Understanding the likely clinical indications and outcomes that regulatory authorities will prioritize allows developers to focus their evidence generation efforts effectively. This foresight enables developers to tailor their clinical assessments to meet the specific criteria that will be evaluated in the JCA.

Resource Allocation: Meeting the Demands of SLRs and ITCs

The process of generating the necessary evidence and conducting SLRs and ITCs requires significant resources. Health technology developers will need to allocate substantial financial, human, and technological resources to ensure the timely and accurate completion of these tasks. This includes hiring or training personnel with expertise in HTA methodologies, investing in advanced data analysis tools, and dedicating sufficient budget to support comprehensive literature reviews and data synthesis.

Agility in Action: Building a Responsive Team for JCA Adjustments

Flexibility and agility are essential for health technology developers as they navigate the JCA process. A well-coordinated team that can quickly adjust to changes in final labelling and PICO parameters is vital. This requires a dynamic approach to project management, with the ability to reallocate resources and modify strategies in response to evolving requirements. An agile team ensures that developers can adapt to new information and maintain the momentum needed to meet submission deadlines.

Proactive Partnership: IMAC's Role in Anticipating Final PICO Scoping

International Market Access Consulting (IMAC) collaborates closely with EU stakeholders to anticipate final PICO scoping. By engaging with regulatory authorities, healthcare professionals, and other relevant parties, IMAC helps health technology developers understand the priorities and expectations of the JCA process. This proactive approach enables developers to align their evidence generation efforts with the anticipated requirements, increasing the likelihood of successful submissions.

Seamless Support: How IMAC Integrates to Assist with EU JCA Submissions

IMAC offers an agile and established process to support health technology developers during the EU JCA. With a team of experienced professionals and a proven methodology, IMAC can seamlessly integrate with your team to provide expert guidance and assistance. Whether it's conducting SLRs, performing ITCs, or advising on submission strategies, IMAC is equipped to help developers navigate the complexities of the JCA process and achieve successful outcomes. Their comprehensive support ensures that developers are well-prepared to meet the stringent requirements and tight deadlines of the EU JCA.

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