Aligning Regulatory and HTA Strategy Through a Parallel Joint Scientific Consultation (JSC)

The Situation

DLRC acts as the virtual regulatory department for a global biotech developing an innovative genetic medicine for a rare neurological disorder. As the company prepared to advance into Phase 3, it sought integrated strategic regulatory and HTA guidance to ensure its development programme would support both European approval and future reimbursement.

The company engaged DLRC to bridge regulatory and HTA evidence requirements early, strengthening the evidence strategy by ensuring that key development decisions were informed by both regulatory and HTA requirements under the new EU HTA framework. DLRC leveraged its combined regulatory and HTA expertise to guide the client through this first-of-its-kind procedure and support a robust development strategy for Europe.

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DLRC's Solution

DLRC experts provided strategic support throughout the Parallel HTACG/EMA JSC process, helping the client navigate the complexities of engaging with both regulators and HTA bodies. The team led preparation and submission of the eligibility request, resulting in successful acceptance into the procedure, and subsequently supported development of the briefing package, presentation materials, and meeting strategy. DLRC attended and chaired the JSC meeting, coordinated follow-up interactions with the authorities, and helped the client obtain actionable feedback to inform evidence generation and future access planning. Our approach combined regulatory and HTA expertise with a flexible, hands-on partnership, ensuring efficient navigation of a complex multi-stakeholder process and maximising the value of the consultation.

The Outcome

The Parallel HTACG/EMA JSC outcome provided actionable recommendations regarding study population, endpoint selection, statistical considerations, dosing rationale and long-term evidence generation. These insights supported the optimisation of the clinical development programme and facilitated alignment with both regulatory and HTA expectations.

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