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

The Situation

DLRC supported a global biotech company developing an antisense oligonucleotide for a rare genetic neurodevelopmental disorder. As the programme progressed towards Phase 3, the company needed early insight into whether its pivotal study design would meet both European regulatory and HTA expectations. A parallel Joint Scientific Consultation (JSC) was therefore pursued to help clarify evidence requirements, identify potential challenges at an early stage, and support future marketing authorisation as well as pricing and reimbursement planning.

DLRC's Solution

DLRC guided the client through parallel CHMP/HTA JSC process from initial strategic discussions through to follow-up with the authorities. This included advising on the purpose and value of the procedure, preparing and submitting the JSC request, developing the briefing materials and supporting the client during the consultation meeting itself, including chairing the discussion. Throughout the process, DLRC helped ensure that regulatory and HTA perspectives were considered together and translated into practical implications for the development programme.

The Outcome

The JSC gave the client clearer direction on the evidence-generation strategy needed to support both regulatory review and future reimbursement discussions. It highlighted aspects of the planned Phase 3 programme that could prove challenging from an HTA perspective and helped inform targeted protocol refinements before study start. The process also enabled early and structured engagement with regulators and HTA bodies in Europe, providing a stronger basis for subsequent development, evidence planning, and market access preparation.

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