

There is an increasing desire from regulators and health technology assessment (HTA) bodies to provide insight to pharmaceutical and biotechnology companies earlier in the drug development process to allow better alignment of evidence needs for both regulatory approval and market access. While early engagement from regulatory agencies is standard practice, scientific advice from HTA bodies is a relatively recent addition and quickly growing in interest. Providing this consultation in parallel can provide invaluable insight to manufacturers in optimizing evidence generation.

Evidera's Integrated Scientific Advice™ (ISA) offering provides feedback to companies to help optimize their evidence generation plans to develop robust evidence that is relevant to patients, clinicians, regulators, HTA bodies, and payers and supports timely patient access. Our integrated team provides evidence-based support combined with tailored project management to ensure timely delivery of a robust HTA package to maximize the efficiency, quality, and impact of ISA engagement.

Benefits of ISA



Access

- Early formal testing of aspirational value propositions and proposed evidence
- De-risking the clinical development program by better understanding the expectations of regulators and payers
- Internal alignment of stakeholders to effectively manage multiple evidence requirements
- Minimize duplication in evidence generation activities
- Reduce time to HTA decision and patient access



Pricing

- Inform price range testing following feedback on the value proposition
- Early understanding of evidence requirements for pricing models and managed access

Our Experience

45+

Integrated regulatory and HTA advice engagements across 10+ companies



45+ regulatory scientific advice engagements

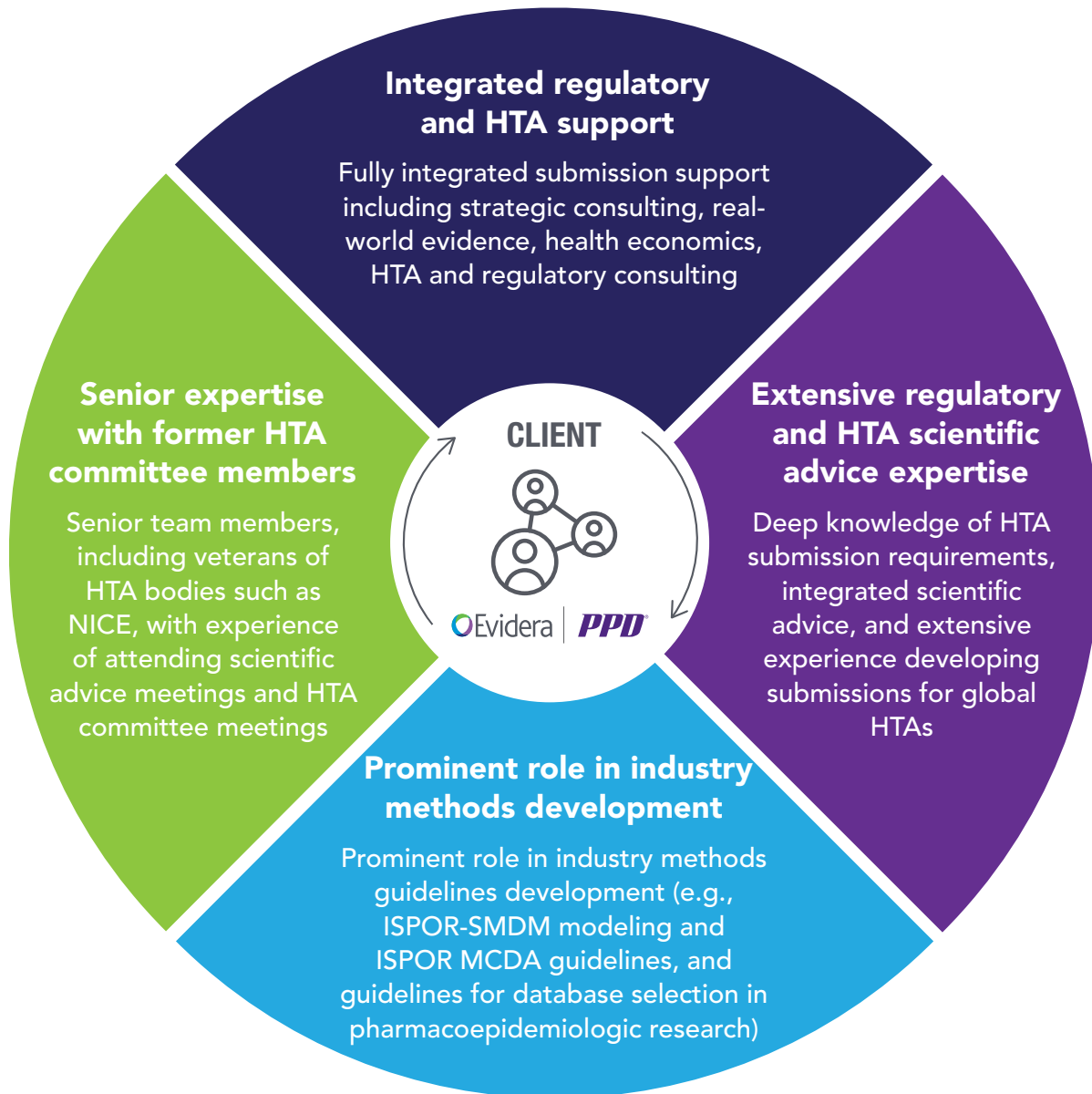
25+

Indications in ISA engagements (oncology, CV, rare diseases, neurology, etc.)



15+ HTA scientific advice engagements

Well Positioned to Support ISA Strategy and Implementation



Our Approach

When working with clients, we take a comprehensive, collaborative approach that is customized to each client's unique needs. This approach includes four key phases with core processes in each to support integrated scientific advice, plus optional tasks tailored to meet specific identified goals.

