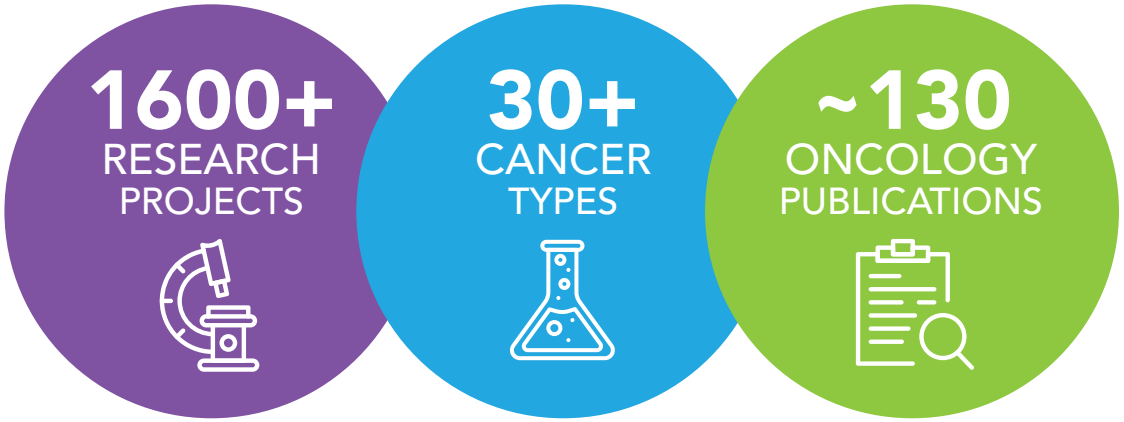
Evidera Experience in Oncology

Evidera scientists are experienced in many areas of oncology, including extensive contributions to hundreds of successful submissions to regulatory agencies and payers. We provide integrated and tailored scientific expertise and global operational capabilities, including interventional studies, real-world evidence, data analytics, patient-centered research, epidemiological studies, modeling and simulation, meta-analysis, literature reviews, market access consulting and communications, and medical writing. We publish 50+ peer-reviewed articles, research posters, and presentations per year on methods, studies, and industry trends in oncology. Evidera experts play an active role in relevant societies and other oncology organizations (e.g., ISPOR's Oncology Special Interest Group, American Society of Clinical Oncology [ASCO], European Society for Medical Oncology [ESMO], etc.) working to identify specific oncology research issues and develop recommendations to address these issues.



We understand the unique challenges associated with oncology product development and market access

Many single arm trials in breakthrough indications making **comparative assessments difficult across competitors**

Lack of trial data for long-term survival outcomes and contamination of survival data by crossover introduces **uncertainty in value assessment**

Diverse, fragmented patient population leads to heterogeneity among study populations and limited generalizability of results

Dynamic treatment landscape reduces the reliance only on trial data and can render historical evidence irrelevant, requiring innovative approaches

U.S. +1 301 654 9729 EUR +44 (0) 208 576 5000 evidera.com

Evidera: A compelling partner with extensive experience in oncology

Our team of researchers offer leadership in the design and execution of oncology and immuno-oncology studies to meet payer and regulator evidence requirements. We offer diverse scientific methods, and high quality project and data management expertise. Whether you are looking for an end-to-end solution or require advice for proof-of-concept research, we can be your partner in your journey to help cure cancer.

20+ Years Experience

- 400+ immuno-oncology projects across 50+ therapies and in support of 13 payer submissions in the last 5 years alone
- Network of oncologists and 2,100 oncology trained research staff

A Leader in Late Phase Oncology Studies

- 200+ IIIb/IV, extended access programs, registries, and large observational studies in oncology
- Supported 7 of the 10 top grossing oncology drugs in 2016

Demonstrated Impact on Payer Decision Making

- Drove reversal of NICE decision in multiple oncology indications (e.g., metastatic castration-resistant prostate cancer, multiple myeloma, thyroid, non-Hodgkins lymphoma, etc.)

Leading Global, Cross-Industry Efforts to Create Value

- Chaired ISPOR Oncology Special Interest Group

A Leader in Patient-Centered Evidence Generation

- Globally recognized experts in preference elicitation to inform development, and in measuring benefits and risks for patients and caregivers
- Opinion leaders in global groups focused on understanding patient experience (e.g., European Organisation for Research and Treatment of Cancer [EORTC] and Common Terminology Criteria for Adverse Events [CTCAE] PROs)

Case Study: Robust Modeling Helped Convince NICE to Reverse Their Decision

Situation

Payers in most markets require an understanding of the economic value of a drug before granting reimbursement. The treatment landscape and clinical pathways for metastatic castration-resistant prostate cancer (mCRPC) were changing rapidly, requiring inclusion of new treatment options across multiple lines of treatment. Our client needed an economic model that could capture the changing treatment landscape, including treatment sequences, and also capture the clinical heterogeneity in mCRPC impact of new treatments.

Approach

Evidera proposed an individual simulation model, powered by risk equations and developed from the pivotal, albeit interim, Phase III trial data.

Outcome

We helped to develop and submit a model, based on the interim, Phase III trial data, to NICE in 2013, which predicted greater benefit for the drug than originally projected. However, NICE did not recommend the drug for reimbursement. When final trial data were ready we were able to show that the model replicated the survival findings seen in the final data.

Impact

NICE recommended the drug for reimbursement. The end result is improved access to a novel mCRPC treatment in a country with traditionally conservative reimbursement for mCRPC therapies.