CASE STUDY:
MARKET ACCESS INSIGHTS
TO SUPPORT A CLINICAL
DEVELOPMENT PLAN

CHALLENGE
Our client, a medical diagnostics company developing a novel In-Vitro Diagnostic (IVD) device for lung cancer screening and diagnosis, required a robust Clinical Development Plan (CDP) informed by key market access considerations. Objectives of the project were to:
▶ Provide insights into key clinical and economic evidence requirements for reimbursement
▶ Develop recommendations to achieve a positive reimbursement decision, optimal pricing and successful market uptake
▶ Estimate the revenue potential for the product over a medium-/long-term time horizon

SOLUTION
A qualitative research project was conducted across three European Union (EU) countries and the US and a simple investment model was developed. The project included:
▶ Desk research: Which identified country-specific treatment and reimbursement pathways, competitor reimbursement applications and pricing, and relevant clinical guidelines for screening and diagnosing patients with lung cancer
▶ Payer and Key Opinion Leader (KOL) interviews (n=12): Which validated desk research, identified areas of clinical unmet need, gathered recommendations for key clinical and economic evidence requirements, and tested a blinded product profile and proposed pricing scenarios for the novel IVD
▶ Report: Which detailed the key findings of the research and provided recommendations on study design, evidence requirements, pricing and downstream market access activities
▶ Investment model: Which calculated market size, revenue and net present value estimates for the two indications of the device through 2030

VALUE
The results of the project were used to inform recommendations on clinical study design and to support strategies for optimal pricing and market uptake.

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