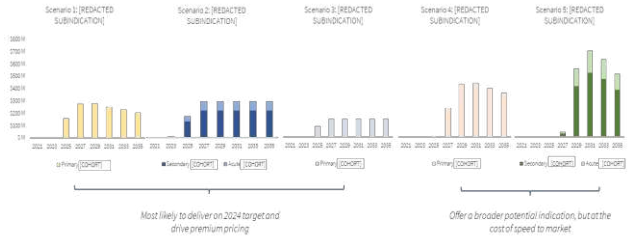
BCE Consulting

Indication Assessment & Phase 3 Clinical Trial Design

Pharmaceutical company seeks indication assessment and associated Phase 3 clinical trial design

Background and Objectives

A pharmaceutical company came to BCE for support in designing its phase 3 clinical trial for a novel asset with potential application across a wide variety of indications. The team had been evaluating sub-indication targets through a funneling process based upon commercial and technical attractiveness, and had landed on two primary opportunity areas for further consideration. The client asked BCE to provide near-term guidance on how to proceed with phase 3 trial design, including indication sequencing and specific design parameters to ensure speed to market and probability of success.

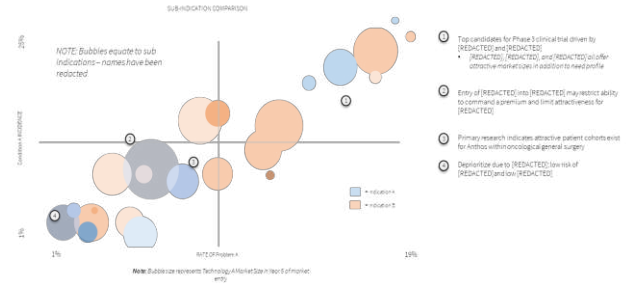


Approach

BCE developed a customized framework with client input to evaluate each opportunity area and prioritize sub indications. After agreeing upon the core analysis framework with the client team, BCE transitioned to primary research with a variety of market participants to evaluate unmet needs associated with standard of care, path to market for future competitive solutions, phase 3 trial requirements for success, and pricing potential for the novel asset. Sources communities included physicians, principal investigators, competitors, and regulatory stakeholders.

Research and analysis drove towards two primary analyses to help build the picture for phase 3 trial options:

- a market model to understand projected adoption rate, 5 year market size, and revenue timing associated with each opportunity area
- a view of where clinical need and customer receptivity would be most likely to ensure phase 3 trial success



Recommendations

BCE developed phase 3 trial design recommendations for two primary scenarios based on findings from research.

The first scenario was designed to deliver a combination of high likelihood of success and speed to market: this would enable the client to get its foot in the door and realize revenue. The second scenario was designed to maximize premium pricing potential and expand addressable market opportunity for the asset.