

Case Study: Early Access Strategy

Incorporating market access insight into early assets

Highlights

- Improved early trial design due to inclusion of market access considerations
- Creation of scenario planning for market access facilitated exploration of development trade-offs
- Improved accuracy of new product products

Example: Market Access Risk Mitigation Planning

Phase 1b/2 Risk Mitigation Plan

Event Description and Expected Timing			Risks to Company	Company Response/Risk Mitigation
High Significance	Event Significance			
• Product A launches in 1H 2017 that could potentially become SOC in Compound X's target indication			<ul style="list-style-type: none"> If Product A becomes new SOC, the registrational trial will likely have to test Compound X head-to-head versus Product A Assess feasibility of head-to-head trial Explore other tumors where Compound X demonstrated efficacy Investigate the biomarker/patient segmentation strategies 	
• Transaminase levels higher than that of competitors emerging from phase 2 trials			<ul style="list-style-type: none"> Physicians consider risk/benefit profile untenable Proactive management of clinical trial protocol Supplemental studies to capture long-term AE risks 	

ARTISAN Healthcare Consulting

Improved trade-off evaluation

Early market access insights

Optimized trial design

SITUATION

The head of commercial for a top 20 pharma company was concerned that the adoption for their newly-approved drug were not meeting pre-launch expectations.

The new brand team was tasked with identifying and removing hurdles to reimbursement. The NPP head was charged with determining the reason for the discrepancy between pre-launch guidance and post-launch experience. Artisan was brought into help identify the issues and recommend changes.

ARTISAN APPROACH

A cross-functional team was organized to identify factors driving the difference between pre- and post-launch expectations. Artisan supported the data collection and analysis, and facilitated the overall process. The following issues were identified:

- Development decisions either: a) followed a de-risked pathway, or b) focused on speed to market at the expense of commercial outcomes
- Market access input was not considered until phase 3 design, with input centered around PROs to be included in the pivotal trial
- Recent market access actions and implications were not incorporated into the forecasting process, resulting in inaccurate projections

RESULTS

One recommendation that emerged from the process was that additional market access headcount were to be added, with the following objectives:

- For target indications, identify drug development implications of recent access decisions in key countries (G7)
- Sit on early stage (phase 1b) product teams and provide trial design-related market access insight, such as comparator recommendations, tools and data needed for value demonstration, expected clinical, safety, and patient outcome thresholds, and scenario/risk mitigation planning.

Product teams reported significant trial design improvements after adding market access colleagues