



PROJECT CASE STUDY

CLINICAL TRIAL RECRUITMENT IMPACT ON MARKET ORDER OF ENTRY & SALES



BACKGROUND

Clinical development has always been an uncertain endeavor for the pharmaceutical industry. However, with the COVID pandemic, this uncertainty has only increased.

Clinical trial sponsors have experienced even greater difficulties in recruiting and retaining new subjects, which leads to delays and more profound downstream impacts. COVID-related clinical trial delays are well documented in the public arena and, in a case study from 2020, Captario's Magnus Ytterstad demonstrated the impact of COVID-related delays on portfolio value over time using Captario SUM.

STUDY OBJECTIVE

The aim of this case study is to further explore the downstream impacts of clinical trial recruitment delays. This case study is based on recent client work and highlights how clinical trial recruitment rates impact trial duration and launch timing, but more importantly competitive positioning within the marketplace (e.g., order of entry) and ultimately sales / net present value.

KEY QUESTION

Without knowing the impact of the pandemic on the competitor launch window - what is the monthly recruitment rate we need to be first to market?"

CLIENT SCENARIO

Captario's client is developing a biomarker-driven asset for refractory patients with a rare, orphan disease. There are no targeted therapies for this specific indication today.

Given the size of the patient population, the overall opportunity for launching a pharmaceutical is modest. The top priority for our client is to make their development asset available to these refractory patients as quickly as possible. However, the clinical development landscape for this high unmet disease remains highly competitive and a potential competitor (targeting a similar patient population) is on track to launch during 2024.

Our client has less confidence in their own launch window and this confidence has further deteriorated as the pandemic has progressed. The primary challenge facing our client is recruiting patients for their pivotal trial. Our client forecasted a monthly recruitment rate that would allow them to launch before this potential competitor, giving them a first mover advantage (e.g., greater market share). However, as the pandemic progressed, the client observed actual recruitment rates well below their forecasted rates. Given that this uncertainty in market order of entry significantly decreases the risk-adjusted NPV of the asset, our client is naturally very concerned with proactively addressing this recruiting challenge.

CAPTARIO'S ROLE

Captario first supported our client in constructing a model in Captario SUM that mirrored the clinical development plan for this asset.

The model included key studies, decision points, and underlying assumptions (e.g. probability of success of progressing through activities, etc.). However, instead of inputting a duration range for the clinical trial – the activity that is the primary driver of time to market – Captario used an expression. Using an expression, we were able to make trial duration dependent on both the number of clinical trial study centers and their monthly patient recruitment rates. Doing so allowed us to directly observe the impact of patient recruitment rate on launch timing and ultimately order of entry.

Working with our client, we then introduced a commercial sales forecast into this model. This is one of the powerful features of Captario SUM: all clinical development assumptions, activities, and simulated outcomes directly and dynamically impact the commercial timing and opportunity for an asset.

As part of this commercial sales forecast, we similarly used an expression to reflect our client's market share. The expression allowed for our client's peak market share to significantly increase if it were to launch first versus second. This enabled us to directly observe the impact of recruitment rate on market share and consequently sales and NPV.

KEY FINDINGS & OUTCOMES

Using Captario SUM's simulation engine, we found that if our client maintains their current recruitment rate, the probability of being first to market is very low.



This chart visualizes the probability of launch by a certain time and one can observe that our competitor will likely launch well before our client given current recruitment trends. In order to be a first mover, our client would need to significantly increase monthly recruitment, which would require additional coordination and expense.



However, we then dug a bit deeper to understand how our order of entry probability changed based on our monthly recruitment rate. We framed our analysis around the complex question "what does our monthly recruitment rate need to be to so that we are first to market?"

DISCOVERY ▶

We found that our client would need to increase monthly recruitment by a substantial number of patients each month to have a shot at being first to market. Framed differently, the near-term recruitment cost expenses would be significantly outweighed by downstream sales if they can beat their competitor to market.





CONCLUSIONS

Patient identification and recruitment for clinical trials is a difficult endeavor at the best of times, and even more so for an orphan indication during a global pandemic.

However, with Captario SUM, our client was able to quickly and easily identify the specific recruitment rate required to be first to market in this competitive marketplace and, in turn, understand the downstream impact on sales.

This assessment enabled our client to level set the organization about the true opportunity for this asset given their recruitment challenges and in turn empowered them to make difficult development decisions (e.g., is it worth the extra recruitment costs to get to market first). These decisions would not have been possible without the modeling, simulation and visualization capabilities of Captario SUM.

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