



MANUFACTURING SUPPORT



PROCESS DEV & COMPARABILITY



ANALYTICAL DEVELOPMENT



QUANTITATIVE MODELING



QUALITY SYSTEMS



DEVICE DEVELOPMENT



REGULATORY SUPPORT



PRECLINICAL DEVELOPMENT



PROJECT & PROGRAM MGMT



MARKET RESEARCH



INTELLECTUAL PROPERTY



FINANCING & DILIGENCE

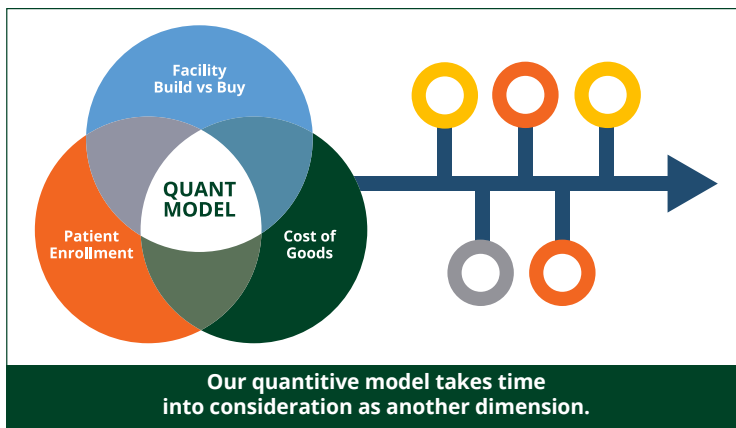
# Quantitative Modeling May Yield the Unexpected

## The Ask

It's common to consider a detailed review as a way to capture problem areas. Sometimes, though, a review can bring to light how little actually needs to be changed. In this example, a client who was beginning enrollment for a clinical trial decided to request a quantitative review with a specific manufacturing focus to help isolate any unforeseen future issues. The answer surprised them.

## DHC's Approach

- This client's preliminary internal review indicated a range of likely limitations that needed confirmation, including the possible need for more manufacturing capacity.
- As is our standard, we required a detailed questionnaire specific to our queries to help isolate input assumptions: materials costs, process duration and yield, clinical enrollment, and probabilities of success. DHC, as always, was able to offer any necessary level of guidance in completing this assessment based on process specifics and industry standards.
- The Dark Horse process is able to not only consider the overlap in manufacturing capacity (build vs. buy), COGs, and patient enrollment, but to follow that overlap through the dimension of time. Whether the timeframe in question is a broad or narrow range depends on the client's current stage and future needs, so the initial questionnaire also requests timeframe ranges for each phase of development.
- After assisting the client in completing the DHC questionnaire, it became clear that the client did not have the set of problems that they expected. DHC's expert consultant therefore adapted the expectations of the "ask." Instead of using our proprietary software (which would have been unnecessarily complex for this situation), she provided a truncated and customized model that was specific to client needs and based on their precise situation.
- Considering the reality of the limitations that existed (rather than perceived or anticipated limitations) made it possible to focus more efficiently on the few necessary solutions, and to plan for immediate and future clinical stages.



## The Impact

Within a very short timeframe, the client received the answers to their questions and discovered a much quicker and easier fix than they had expected. In this case, the model demonstrated that there were significantly fewer changes required to their existing manufacturing strategy than were expected. The client was able to proceed with the trial with peace of mind knowing that not only were they prepared for this stage of clinical trials, but for future stages as well.

## Why DHC?

EXPAND CLIENT BANDWIDTH

PROVIDE ADDITIONAL TECHNICAL EXPERTISE

SOLVE EXISTING PROBLEM (REMEDiate)