CASE STUDY

# Due Diligence for a Novel Software Used in Clinical Trials

## THE PROBLEM

An investment company was considering a major investment in a company with a novel system for evaluating risk-based monitoring (RBM) in clinical trials. They needed an expert in clinical trials and due diligence to evaluate the software and work with the financial team to ensure the product had a significant potential market. With the latest guidelines ICH E6 (R2) the software had to compete in a newly developing area.

## THE SOLUTION

A complete due diligence report was written in eight weeks that included the following:

- Software evaluation
- Market potential evaluation, examining the regulatory framework and competitive landscape
- Interviews of current customers (x6 to gain clear insight into the pros and cons)
- A marketing survey to gain an understanding of the competitive landscape and the client's name recognition
- Interviews of the CEO and other key staff
- SWOT analysis
- Work with the financial team, who were running Monte Carlo simulations to predict breakeven and time to profit
- Recommendations for a business plan and next steps in gaining market penetration

## Regulatory Expertise

Our team of expert consultants are here to help *you,* leveraging our knowledge for *your solutions.*

Our tailored services range from ad hoc consulting, to providing a virtual C suite (CEO, CFO, CMO, CSO) clinical and regulatory team ready and able to integrate with yours.

By employing a comprehensive and customizable multidisciplinary, problem-solving methodology, we are able to reduce risks and streamline development plans.

The regulatory landscape is tough to navigate---don't go it alone.

## THE RESULT?

Based on the analysis provided the investment group made a confident investment in the software company.

BRACKEN

TheBrackenGroup.com

215.648.1208

12 Penns Trail
Newtown, PA 18940