# RBM CASE STUDY

Triumph Research Intelligence 2017

## What was the situation?

Our client, Advanced Clinical a successful, forward looking CRO who were seeing increasing demand from sponsors to offer quality oversight and central monitoring in accordance with the incoming ICH E6 (R2) guidance.

Advanced Clinical wanted to ensure they had both the processes and technology needed to be able to offer and articulate this capability as part of any future clinical trial. They wanted to be able to demonstrate their capability to sponsors, and manage their trials independently but wanted to work with a vendor who could support them through a period of knowledge acquisition and support them as a partner as and when needed in the future.

## What was the predicament?

Advanced Clinical realized that in order to compete in a post ICH E6 (R2) market, embracing regulations and offering a robust central monitoring solution was paramount. They wanted a partner who would be able to define a foundation of R2 compliant processes and practices, and then build on top of that with technology, industry best practice and training.

Our client also understood that as no two trials are the same, and the solution they were looking for was not going to be a 'one size fits all' solution, but that it needed to be something which could be easily tailored to the needs of each customer and each trial.

*"TRI OPRA satisfied three important objectives for our provider selection – the system is agnostic to other data sources, the system is closed in order to document observations/actions, and TRI's operational expertise implementing RBM. This foundation ensured our success from the start."*

Cheryle Evans, - Snr. VP,
Clinical and Medical Operations.

Our RBM consultants are all industry professionals with operations and RBM experience

## Success Factors

- The ability to provide both the technology and consultation required for a 'total' solution
- An implementation team comprised of consultants, users and operational management
- Ongoing partnership between customer and TRI to continue to learn and develop the solution

**Successful RBM is a blend of technology, process, change and continual learning**

## "A True Partner"

*"Triumph Research Intelligence has been a true partner to Advanced Clinical during our discovery, evaluation, and implementation of a robust, reliable, and highly credible RBM platform. The OPRA tool allows us to remain system agnostic, allows us to provide actionable information into the hands of our clients and project teams, ultimately leading to a better clinical experience for all stakeholders."*

Jason Casarella,

EVP Business Development and Marketing

## What was the solution?

An implementation project was established to deliver both the OPRA technology and the process and role changes required for R2 compliance and effective risk based monitoring. Advanced Clinical had already been performing some central monitoring as standard practice, so the move to risk-based monitoring was more of an evolution of current practices rather than a revolution.

The TRI team worked with both operations team members from Advanced Clinical and study team members from the Sponsor side for the first study. The tri-party team performed the protocol risk assessment together and determined the set of KRIs and data sources which would be used to monitor the trial quality and inform monitoring decisions.

Once the first study was set up, TRI worked with Advanced Clinical on a periodic basis to support them in the review and assessment of the data as it was aggregated and visualized in the OPRA platform. This level of on going support helped with adoption of the new processes and the OPRA technology and gave the confidence to make informed monitoring decisions.

## What is the current state?

Advanced Clinical is now using the newly implemented R2 processes and perform full protocol risk assessments and develop quality management plans for all new studies. These plans help inform the set up of the OPRA system and the way in which the data from the system will drive monitoring plans on an ongoing basis.

Advanced Clinical are now working with TRI to define a core KRI offering which will be used with all future studies, saving time and cost at study set up. The next production studies will use those core KRIs, and are expected to use an additional 3-5 study specific KRIs once the quality management plans are finalized.

TRI continue to support Advanced Clinical in the positioning of the solution and Advanced Clinical's capabilities, and will work to further advance the solution based on the lessons learned from all ongoing studies,

## Contact Us

For more information on our ICH E6 (R2) implementation services or OPRA, our RBM platform, please feel free to contacts us on: info@tritrials.com

Or visit us on the web at: www.tritrials.com

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