

RBM IMPLEMENTATION CASE STUDY: TOP 5 PHARMA



Triumph Research Intelligence

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What was the situation?

Our client had strong ambitions to implement both risk-based monitoring (RBM) systems and processes across the entire global organization by the end of 2015.

They had chosen a system to adapt to their needs and planned to work to the TransCelerate key risk indicators (KRIs).

They needed support in developing the technology to meet their needs, needed guidance on the optimal approach to RBM and needed support in coordinating and educating the multiple autonomous divisions with the organization.

What was the predicament?

The client realized that without impartial, credible consultation, that getting multiple divisions within the organization to align behind a common vision for RBM was going to be very challenging.

The coordination of inputs, needs and wants from each division with a view to developing a technical capability to support all studies would result in an overly complex and expensive technical solution if expert guidance was not made available to focus the team on what really mattered and to help them avoid the pitfalls of over development.

"I would like to THANK YOU on behalf of the entire team. What you have contributed and delivered has been immense and was so crucial for the delivery of the RBM Systems, not just our system but way beyond"

- Head of Innovations and Cross Functional Solutions



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

Success Factors

- Experience and credibility of TRI consultants
- Access to the client's team and key decision makers
- Integrating the TRI team into the client's team



Successful RBM is a blend of technology, process, change and perseverance

What was the solution?

TRI provided senior consultants on both the process and technology implementations work streams of the project.

Bringing Operations and IT together helped Operations to be clear in what their needs were, and gave it the confidence to develop the application to meet those needs.

A web-based version of TransCelerate's risk assessment tool (RACT) was developed as well as enhancement of the RBM system the client had chosen to use.

The monitoring processes across all divisions were evaluated and adjusted to ensure alignment with the RBM vision for the organization. Additionally, all processes across biometrics and medical monitoring were reviewed to help shape processes for a new Central Stats Monitoring team. Such reviews are a prime example and important reminder that risk-based monitoring impacts all disciplines.

What is the current state?

The client is on track to hit the end of 2015 milestone for technology and process implementation.

The tool set is now in place, being used operationally and is fully aligned with the client's approach to RBM. This means the tools are supporting the process, and not driven by it.

Change management and training is ongoing and will continue as the approach to RBM evolves as the client learns more and develops its capabilities over time.

TRI continues to work with the client and support them in the ongoing enhancement of their capabilities.

“Thanks for everything”

“You are kind of the 'brain of RBM' and a STAR BA for me with the priceless experience you possess.”

“It has been a great working with you. I owe my fast track RBM on boarding to you. Your knowledge and insights throughout has made a significant difference to the project. At all stages, you have ensured that concepts are challenged well enough so they stand the test of time.”

Quotes from various team leads on the RBM project.

“A satisfied customer is the best business strategy of all.”

Michael LeBoeuf

Business author and Professor of Business Management

About TRI

TRI was formed in 2013 as a system company to Triumph Consultancy Services, who have been operating in the industry since 2002.

TRI was formed with the explicit vision of enabling companies to successfully adopt risk-based monitoring through the provision of innovative technology, professional services and change management.

TRI developed the first ever truly RBM focused technology—"OPRA". OPRA is a cloud based, 21 CFR part 11 compliant, visual analytics, activity management and data review tool, designed for anyone wishing to take a risk-based approach to monitoring, or perform general operational and quality oversight of their clinical trials.

If you're thinking about RBM, we're here to help

Whether you are looking for technology, business guidance or just want to learn more about RBM and it's importance to industry, then we'd love to hear from you.

Our clients are both Pharma and CRO, large and small—we're here for everyone!

Contact Us

For more information on our RBM implementation services or OPRA, our RBM platform, please feel free to contact us. We'd love to talk to you and share our experience.

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TRI — Where's the Risk?

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