



R2 IMPLEMENTATION AND CRO OVERSIGHT CASE STUDY



E6 (R2) ACCELERATOR

Triumph Research Intelligence

2018

What was the situation?

Our client, a large global biopharmaceutical company had recently merged with another similar company. The QA department of the resulting company was met with the task of both integrating two quality management systems as well as preparing for ICH E6 (R2). To add further complexity to their situation, our client was also looking to streamline the number of strategic CRO partners and wanted to make sure they were selecting partners which were ready to operate under the R2 guidance.

What was the predicament?

Our client was in the final stages of integration of the two original quality management systems, but wanted to ensure they were R2 compliant in time for the EMA adoption in June 2018. They wanted to ensure they covered all aspects of the R2 changes as wanted it doing quickly to meet the EMA timelines. They needed an expert in R2 gap analysis and implementation, and also wanted to ensure that the vendor they chose had worked with R2 implementation for CROs and was able to understand their perspective. TRI had previously provided R2 awareness training for the client which had been very well received and established credibility. Once it was understood that TRI had already performed R2 gap analysis and implementation for both sponsor and CRO organizations it was an easy decision to choose TRI as their implementation partner.



Success Factors

- Rapid assessment of a comprehensive QMS
- The ability to leverage past experience and assets to accelerate implementation timeframes
- Seeing the challenge from both sponsor and CRO perspective and create a solution which works for

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



R2 readiness is a blend of processes, tools, communication and common sense



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Many of the assets used during this project are part of our GoR2 accelerator package.

R2 compliance can be a reality for your organisation in a matter of weeks!

What was the solution?

A comprehensive assessment of the new integrated QMS was performed with a view to identifying those areas where additions or updates were needed in order to be compliant with ICH E6 (R2). A series of recommendations were made using TRI's gap analysis template, developed as part of the Go R2 accelerator package. The recommendations not only detailed the gaps, but the specific R2 references to ensure that the full regulatory context of each recommendation was understood. The findings were presented to a cross functional management team to ensure a full understanding, and to give the opportunity to discuss in more detail.

For the second phase of the project, to help assess the state of R2 readiness of their CRO partners, and ultimately to ensure that they selected partners who were going to be able to operate effectively under R2, TRI developed a CRO assessment framework. This framework consisted of a set of themed questions, each with references to R2. As well as the questions, the framework detailed what should be expected, how a high performing CRO would be expected to respond and what sort of evidence the client should be looking for to be reassured of the CRO's capability.

What is the current state?

The customer now has a fully R2 compliant QMS and is running trials to those updated processes. The client has used the framework developed to assess multiple CRO partners and has used the outputs to make recommendations on CRO selection as well as additional readiness activities. From the CRO perspective, they now have a clear view of what the sponsor is looking for and how to be a better CRO partner going forward.

Contact Us

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

