



The Current State of ICH E6 Revision 2

In November 2017, one of the EMA's Inspectors, Sophia Mylona, reiterated the importance of Revision 2 (R2) to the attendees at the 5th Global QA conference in Edinburgh, Scotland. Her message surprised the crowd. Not because ICH E6 (R2) is something new. On the contrary, this revision was finalized in November 2016 and put into effect by the EMA back in June of 2017. The surprise revolved around the EMA's expectations for ongoing trials. The EMA expects R2 standards to be applied to ongoing trials **"to a reasonable and feasible extent, using common sense."** Thus, any Sponsor or CRO running a trial in Europe will need to be R2 compliant. For our Canadian clients, R2 adoption will be mandatory in April of 2018. We are predicting that the United States will also require R2 compliance later this year.

So what does this mean exactly? As an example, if an ongoing trial is inspected today and significant non-compliance with GCP is detected, an EMA inspector will require root cause analysis to be complete and evident. Another example is if a substantial protocol amendment is implemented in an ongoing trial, even though the trial was started prior to R2 adoption, the inspector will expect to see evidence of risk assessment and mitigations being put into practice for elements of the amendment likely to impact subject rights and well-being or data integrity. The inspector will also expect to see monitoring activities (in the wider sense of the word) being adapted (where appropriate) based on safety and quality risks.

How can we help? TRI has developed a comprehensive accelerator package, Go-R2, to help organizations reach ICH E6 (R2) compliance in an efficient and cost effective manner. It will help you quickly realize the benefits of quality planning, quality oversight and risk-based monitoring. The package addresses this need through a combination of pre-developed assets, training, consultation and technology derived from our experience of supporting more than 50 companies in preparing for R2. Visit our website to learn more about Go-R2 at <https://www.tritrials.com/Go-R2>.

R2 is no small change, but with the right plan and the right partner compliance can be just a few months away.

Engage with one of our specialists to find out how we can help your firm become ICH E6 (R2) compliant.

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