E6 (R2) ACCELERATOR

Go-R2 is a comprehensive accelerator package to help organizations reach ICH E6 (R2) compliance in an efficient and cost effective manner. Our package addresses this need through a combination of pre-developed assets, consultation and technology derived from our experience of supporting more than 50 companies in preparing for R2.

	eLearning: A suite of eLearning courses, which can be consumed through TRIs hosted service or can be imported into your internal LMS. Courses include R2 Awareness, GCP for Operations (incl. R2) and GCP for Sites (incl. R2).
	R2 Gap Analysis: A comprehensive review of your existing quality management system including SOPs, Working Practices, Templates etc., to identify gaps with the new R2 requirements. Comprehensive report detailing the findings, recommendations and a plan to reach compliance.
	R2 Compliance Package: Through our existing R2 compliance work, we have identified a set of commonly required assets including SOPs, templates and other documents to speed compliance.
	Risk Assessment and Root Cause Analysis Training: A practical workshop to cover all aspects of risk assessment and root cause analysis. The workshop can be based on a specific protocol or our training protocol.
	Risk Assessment Tool: TRI has developed a simple but comprehensive RACT tool for the assessment of protocol risk and subsequent quality management planning.
	OPRA core KRI package: In order to help companies quickly start managing trials in an R2 compliant manner and benefit from the RBM methodology, we have built a fully validated system containing 15 high-value, commonly used key risk indicators (KRIs).

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

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TRI is a complete solution provider for ICH E6 (R2) compliance, quality management, central monitoring and RBM.