

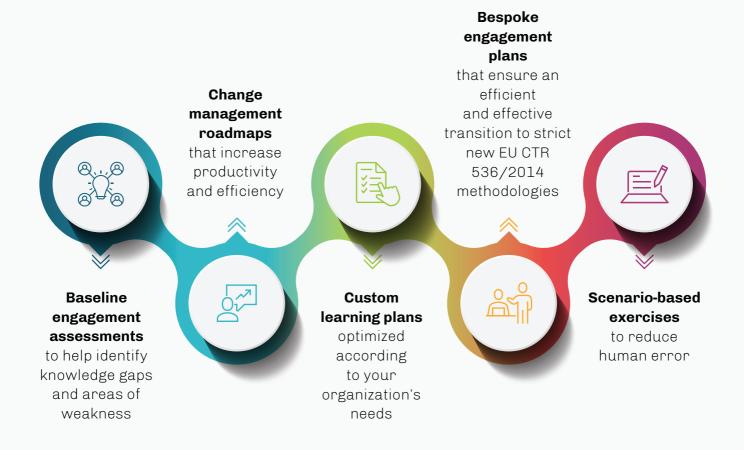
Designed to improve transparency and consistency around clinical trials and improve the approval process, CTR 536/2014 also does more to ensure the safety of participants in clinical trials. The downside? The new process includes a risk-based approach to submission that is currently not used by most pharmaceutical companies. It also requires adherence to tight timelines and new business rules that, if not successfully satisfied, will result in significant delays and cost increases for pharma firms.

The bottom line:
Failure to fully
comply with EU CTR
536/2014 will
render companies
ineligible to launch a
new drug in the
European Union.

## Get the advantage of EU clinical trial training with **360** Eureka

Built on a foundation of brain science and our proven change management strategies, NIIT's 360 Eureka includes a comprehensive gap analysis, change management assessments, self-paced eLearning modules, resources for ongoing support and training reinforcement, as well as analysis and reporting tools that measure effectiveness. These components all come together to provide targeted recommendations that enable your users to be fully prepared for the challenges of EU CTR 536/2014.

With 360 Eureka, your teams receive:



## The **NIIT** difference: Change, ownership, and 90% adoptionguaranteed

High-adoption, technology-driven training has been our only focus for the past 40 years. Our training and change management advisory services accelerate your users' acceptance of new processes and guarantee 90% user adoption every time. We offer custom curricula designed to mitigate apathy, reluctance, and resistance, resulting in high user adoption with the least amount of downtime and disruption.

Need to eliminate risk and increase your chances of EU trial success?

Write to us at **lifesciences@niit.com** for a free consultation today!





© NIIT, 2021

All rights reserved.

Atlanta | Bergen | Chicago | Dublin | Gurgaon | London | Malaga Mumbai | Rochester | Shanghai | Sheffield | Toronto

For questions or comments, please write to businessimpact@niit.com.