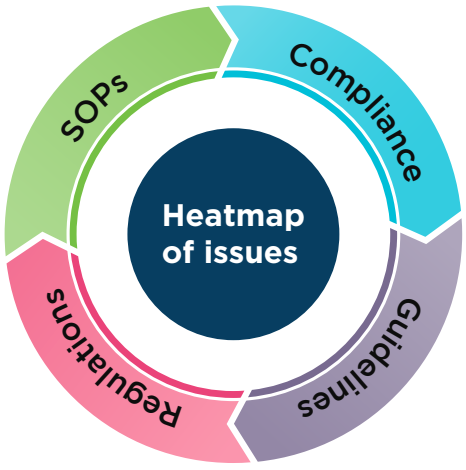
Quality & Compliance

Clinical GCP Rapid Assessment

Are you compliant with the ICH E6 GCP R2 Addendum?

Benefits

- Reduced inspection risk
- Enables effective and efficient compliance with improved visibility and control of risks
- Provides clear and credible roadmap for internal and external communication
- Efficient use of scarce resources to focus on prioritised and systemic risks
- Facilitates continuous improvement



ICH GCP Addendum requires risk based, quality management of clinical trials; quality by design; effective CRO oversight; increased transparency and reduced source data verification

- Our data shows that many companies have not started to implement the ICH GCP Addendum
- Current monitoring services predominantly rely on routinely scheduled site visits to verify source data, resulting in high travel costs, and inefficient processes
- While 100% SDV can cost up to 25% of trial costs, it doesn't contribute to data quality and alternative, risk based, approaches can benefit patient safety

Navitas Life Sciences provides an integrated approach leading to impactful results

- **Engaging cross-functional stakeholders** through interviews to define impact and develop a tailored compliance roadmap
- **Gap analysis using regulatory expert insight** to compile and review all SOPs, templates, work instructions and associated documents against regulations and best practice
- **Systematic methodology** using risk assessments and maturity matrices to produce visual heatmaps of compliance status
- **Customised model for success** that outlines the vision for GCP compliance

Deliverables

- **Detailed description of gaps** between operational procedures and current legislation
- **Risk Heatmap** and spider diagram of criticality and functions in which the gaps reside
- **A clear roadmap** for implementation of changes that outlines how Navitas can help you to become compliant
- **Vendor assessment** if required
- **Business case to senior management** on strategy for successful implementation of quality trial management

About Navitas Life Sciences

As a partner for the industry, Navitas Life Sciences leverages industry insights, consulting and technology capabilities to deliver full service clinical, regulatory and safety solutions and desired outcomes to clients. As the dedicated life sciences brand of TAKE Solutions, Navitas harnesses the combined knowledge and experience of three legacy brands—Ecron Acunova, Navitas, and Intelent—to provide end-to-end services and solutions. Navitas helps clients address their most critical problems by bringing together the capabilities of a full-service CRO, a technology-led life sciences services provider across clinical, regulatory and safety, and a life sciences big data services and analytics provider. Operating from 7 countries across the globe, Navitas works with over 150 customers in Life Sciences.

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