

Are you efficiently delivering compliant and effective Signal Management?

Benefits

- A compliant and efficient signal management process
- A signal management system based on a strategic approach to signal identification, assessment and tracking that is enabled through technology and governance
- Identification and implementation of appropriate technology to manage and track signals

- Signal management accounts for 26% of critical MHRA findings, second only to Reference Safety Information (29%)
- Navitas LS research shows that nearly 50% of companies surveyed do not have a formal system in place for signal tracking

An optimized and compliant signal management system using a strategic approach enabled by technology and cross-functional governance to identify, assess and track signals

Key issues addressed

- Incomplete monitoring of all required sources of potential signals
- Inefficient processes / tools for detecting, prioritizing, evaluating, or tracking signals
- Recent inspection & audit findings in signal management
- Non-compliance with revised EU GVP Module IX

Navitas Life Sciences provides an integrated approach leading to impactful results

- Assessment and redesign of signal management processes and tools
- Gap analysis of signal management processes and governance compared to best practice benchmarks and new regulatory requirements like EVDAS
- Implementation of refined signal management processes, tools, and governance
- Sourcing and project management of the implementation of signal management technology

Deliverables

- A strategic approach to signal management from signal to patient that is enabled by fit-for-purpose technology and cross-functional governance
- Strategies for detection and timelines for each step from identification / detection through to decision and recommendation for action
- A tiered approach to signal detection based on structured product portfolio prioritization to deliver compliant and efficient signal management.
- SOPs, work instructions, templates and job aids to support the signal management process from end-to-end
- Simplified oversight through the identification and implementation of fit-for-purpose technology to produce on-demand reports

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 Intelnet—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.

For more information

USA +1 609 720 1002 EU +49 69 668 0300 India +91 44 4590 9000
email contact@navitaslifesciences.com or visit www.navitaslifesciences.com



A TAKE Solutions Enterprise