

## Do you have oversight of your SDEAs?

### Benefits

- Documents consolidated into a single, globally accessible repository
- SDEAs reviewed and business relationships with Third Parties clarified
- SDEA procedures and templates harmonized
- System configured to produce metrics and reports for inspections and audits

**SDEAs are a focus area in PV inspections. In recent years, they were one of the most common findings in MHRA PV inspections. Oversight issues are often triggered by:**

- Mergers & Acquisitions (M&As):** When companies merge or are acquired, SDEAs have to be updated to comply with new corporate standards as well as related standardized procedural documents.
- Business evolution:** In global organizations, business relationships are continuously formed and contracts are signed, such as licensing agreements, supply and marketing agreements or distribution agreements. Frequently, obligations to patient safety are an afterthought, and PV departments must retain oversight of when SDEAs have to be created and ensure that SDEAs are up-to-date on both local and global levels.
- Changing regulatory landscape:** Organizations need to ensure that safety related content in SDEAs is compliant with international and national legislation and regulation, depending on the territories and products subject to the contracts.

**Navitas Life Sciences provides an integrated approach leading to impactful results**

- Assessment of current volume and type of agreements/ business relationships
- Review of system landscape and configuration
- Review, updates and development of Agreements



### Deliverables

- Establish a strategic management framework
- Design and implement tailored governance model
- Define standards, mechanisms, and metrics for management oversight
- Clarify roles and responsibilities
- Promote internal cross-functional and external stakeholder collaboration
- Develop procedural documents and SDEA templates
- Assess, evaluate, configure, and implement supporting technology
- Consolidate document repositories

### 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.

### For more information

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