

Do you have oversight of your Affiliates?

Benefits

- Affiliate Performance Insight & comparative performance
- Proactive risk management
- Streamlining of worldwide PV Operations
- Identification of resource model fit
- Tailored governance framework
- Active monitoring of risk and resource metrics

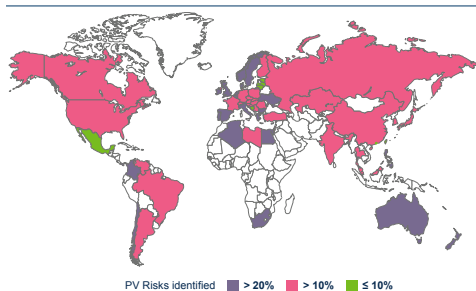
From April 2015 – March 2016, the largest proportion of critical findings from MHRA PV inspectors was in relation to the supervision of the pharmacovigilance system, representing 28% of all critical findings identified

- Lack of clarity on roles and responsibilities
- Lack of oversight for delegated activities
- Lack of process harmonization (e.g. intake/ submission)
- Inaccurate PSMF not giving current status of the system
- Failure to provide complete and accurate information to national competent authorities
- No QPPV access to global safety database
- Lack of system integration

Navitas Life Sciences provides an integrated approach leading to impactful results

- **Affiliate Risk Management:** Standardized questionnaires covering all PV Areas to quickly determine areas of greatest risk exposure
- **Operations and Capacity:** Capacity / Capability Assessment to derive productivity, cost and utilization levels
- **Modeling Affiliate Governance:** Assessment of fit of current affiliate operating model to support the business’s strategic direction
- **Dashboarding:** To ensure ongoing visibility of key performance indicators allowing surfacing issues to be promptly addressed

Example of Pharmacovigilance Risk Heat map



Deliverables

- **Heat map** visualizing local/ regional risks in Affiliates as well as systemic risks across PV functions
- **Charts and graphics** informing management of productivity levels, resourcing patterns and areas for improvement
- **Holistic solution to address gaps in the global operating framework** and approaches to strengthen the relationship between global and local entities including third parties such as Distributors and License Partners

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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