

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

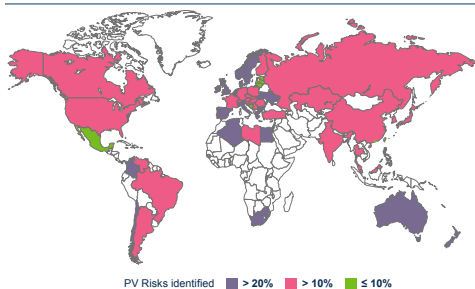
TAKE Solutions provides an integrated approach leading to impactful results

- **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

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

Example of Pharmacovigilance Risk Heat map



About TAKE Solutions

TAKE Solutions delivers domain-intensive services in Life Sciences. In the fast-growing Life Sciences space, TAKE offers clients a unique combination of full-service Clinical, Regulatory and Safety services backed by unique technology expertise. Our range of services span from clinical trials to regulatory submissions to post-marketing safety, all backed by insights derived through proprietary industry networks forums. With a team of leading Life Sciences experts, best-in-class systems and processes, and bespoke, industry-specific technology and analytics, TAKE delivers successful outcomes for clients. Our global roster of clients includes large and small innovator biopharmaceutical companies as well as generics manufacturers. With operations spread across North America, Europe, Asia, and South America, TAKE is a Public Company, listed in India on the Bombay Stock Exchange and the National Stock Exchange. Led by a team of industry stalwarts and domain experts, TAKE has been growing steadily with FY18 revenues touching INR 15,872 Mn, (USD 246 Mn).

For more information

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