

Is your Medical Governance framework functioning optimally to ensure patient safety?

Benefits

- The right medical decisions will now be made by the right people/function according to the right standards
- Clear and consistent medical safety positions for a given product within all regulated documents
- Appropriate cross-functional engagement in processes and forums, beyond the Safety org
- Documented routes of communication, specified decision-making authority, and clear escalation criteria

Do you have robust Medical Governance that provides timely and effective oversight at the right organization levels to protect the safety of your patients?

Safety Medical Governance, which supports the safety monitoring of products and scientific processes within Pharmacovigilance such as Risk Management or Benefit Risk Assessment, is critical to achieving an informed, single medical voice for the company

Key issues that drive the need for improvement:

- Lack of cross-functional engagement beyond Pharmacovigilance
- Unclear situational communication and escalation procedures
- Need for improved management of safety science information
- Weak promotion of Pharmacovigilance outside of the function
- Undocumented action tracking and closure

TAKE Solutions provides an integrated approach leading to impactful results

- Assessment of governance charters and members
- Comparison with proven Safety Medical Governance models
- Alignment of cross-functional roles and contributions across interrelated governance forums
- Piloting and implementation of revised Safety Medical Governance procedures
- Implementation of action-tracking solution

Deliverables

- Updated charters, membership and effective escalation/decision mechanisms for each safety governance forum
- RACI for delineating that the right medical decisions are being made by the right role / function according to the right standards
- Risk-based approach to focus activities and resources on the highest risk products at the appropriate point in the product lifecycle
- Clarification of support requirements of codified governance oversight for medical and safety science activities

Medical Governance at all levels in the organization



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).

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