

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

Navitas Life Sciences 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 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.

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