

clinical monitoring change management



challenge



- Translate regulatory guidances without a consistent industry standard.
- Global alignment within a risk-averse organizational culture requiring significant change management.
- Lack of understanding of the tool because the process is new.

solution



We supported the implementation of a customized solution at a top 25 global pharmaceutical organization. Here is an example process:

- Draft study protocol.
- Conduct risk assessment and categorization.
- Identify and allocate critical data.
- Build key risk indicators (KRI) and advanced analytics dashboards.
- Capture data and document observations from the dashboards.
- Review KRI/analytics outputs and flag issues.
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results



- Successful design and implementation of operating models.
- Consistent global processes, procedures, and validated tools.
- Aligned with regulatory requirements and industry.

Contact us to learn how our experienced team can help ensure successful outcomes throughout the product lifecycle.

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