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GUIDE

Has E2D(R1) Exposed Gaps in Your Pharmacovigilance Governance Framework?

Much of the discussion around the publication of ICH E2D(R1) has focused on new case processing and reporting obligations. However, for many organisations, the more significant challenge may be ensuring that existing governance frameworks are equipped to identify, assess and oversee safety information generated outside traditional pharmacovigilance channels.

With safety data increasingly originating from patient support programmes, organised data collection systems, digital engagement activities, market research programmes and real-world data sources, organisations may need to consider whether their current oversight models remain fit for purpose.

While much attention has focused on reporting requirements, many organisations are now considering a broader question:

Are existing governance frameworks, processes and oversight models equipped to manage modern sources of safety data?

One theme emerging from industry discussions is that while adverse event reporting processes are often well established, governance arrangements for managing safety information generated outside traditional PV-controlled processes may warrant further review. Some key questions to consider include:

- Are safety responsibilities clearly defined across functions that generate or receive safety information?
- Are there effective processes for identifying and escalating adverse events from patient support programmes and digital engagement activities?
- Does vendor oversight adequately address emerging sources of safety data?
- Do SOPs, training programmes and governance documentation reflect evolving regulatory expectations?
- Can compliance monitoring activities identify potential gaps before they become inspection findings?

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HOW ADAMAS CONSULTING CAN HELP

ADAMAS supports organisations in evaluating governance arrangements across evolving safety data sources, helping to ensure that roles, responsibilities and oversight mechanisms remain aligned with regulatory expectations.

OUR SUPPORT INCLUDES:

- E2D(R1) impact and gap assessments
- Review of pharmacovigilance governance frameworks
- SOP and procedural reviews
- Assessment of organised data collection systems and programmes
- Compliance and implementation support
- Targeted training workshops
- Inspection readiness reviews

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Understanding where E2D(R1) intersects with existing systems, processes and organisational responsibilities, third party activities and evolving data sources is often the first step towards an effective and proportionate implementation strategy.

Has your organisation assessed whether its governance framework is ready for the broader implications of E2D(R1)?

Contact ADAMAS to discuss your E2D(R1) readiness and governance framework review.

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