Modernizing PV Agreements and SDEA Management with Clinevo

White Paper

Executive Summary

Pharmacovigilance Agreements (PVAs) and Safety Data Exchange Agreements (SDEAs) are foundational to regulatory compliance in drug safety partnerships. Yet, organizations continue to rely on manual methods that are inefficient, prone to errors, and leave them vulnerable to missed obligations.

Clinevo SDEA Management offers a streamlined, automated, and audit-ready solution to centralize agreement tracking, monitor compliance, and enhance cross-functional collaboration.

Challenges in PV Agreement and SDEA Management

1. Time-Consuming Contract Management

Tracking partner agreements, renewals, and periodic safety reporting timelines (e.g., PSURs, DSURs) manually is inefficient and error-prone.

2. Lack of Automated Compliance Alerts

Without real-time notifications, there is a higher risk of missing critical regulatory deadlines, leading to non-compliance.

3. Inefficient Workflow Management

Traditional contract systems offer limited collaboration between legal, regulatory, and safety teams, leading to communication gaps and delays.

4. Audit Readiness Issues

Ensuring all agreements are current, version-controlled, and readily accessible during audits is a major challenge.

The Clinevo Advantage: Smarter SDEA Management

Clinevo provides a comprehensive, AI-enabled solution designed to eliminate manual bottlenecks and ensure complete compliance through intelligent automation and centralized access.

Automated SDEA Tracking

Clinevo's platform uses AI to monitor contract timelines, trigger compliance alerts, and ensure timely submissions of PSURs, DSURs, and other safety commitments.

Centralized Repository

All agreements are stored in a secure, searchable digital library, making it easy to manage, retrieve, and update contracts across departments.

Audit-Ready Reporting

Robust version control and history tracking offer full traceability for every agreement, simplifying audits and inspections.

Seamless Integration

Clinevo integrates with safety databases and regulatory systems to align safety workflows with contractual obligations.

Key Benefits

Challenge	Clinevo Solution
Manual Agreement Tracking	AI-powered automated contract monitoring
Missed Compliance Deadlines	Smart alerts for regulatory timelines
Fragmented Collaboration	Centralized digital repository for legal, safety & regulatory teams
Audit Readiness	Version-controlled, instantly accessible documentation
Lack of Integration	Seamless connection to safety and regulatory platforms

Conclusion

Managing pharmacovigilance agreements shouldn't be a manual or risky process. With **Clinevo SDEA Management**, organizations can:

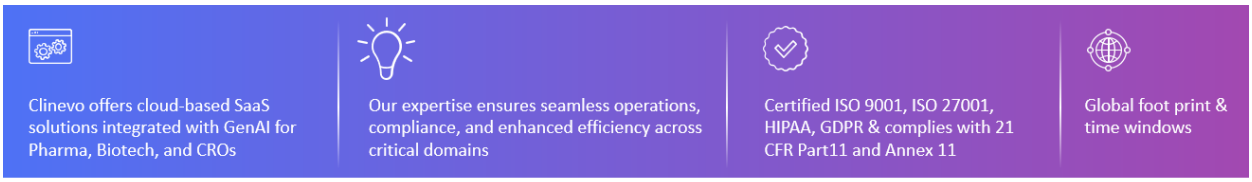
- Reduce administrative burden
- Ensure continuous compliance
- Improve internal collaboration
- Be always audit-ready

In a regulatory landscape that demands accuracy and accountability, Clinevo brings clarity, automation, and control to SDEA management.

Digitize your PV agreements. Ensure compliance. Stay audit-ready — with Clinevo.

Connect with us at info@clinevotech.com

Why Clinevo?



200+	Global clients support in the past 5 years	**50+**	Regulatory audits supported
100%	Customer retention rate YoY	**300+**	Gateway connections with authorities
99%	Customer satisfaction rate	**100+**	Data migrations from various systems
10Mn+	Cases processed till date	**100%**	Validated systems
1000+	Clinical trials supported till date	**24/7**	Unlimited global support