CLINEVO
Safety System

Gathered and Sorted

Sina Talebifar, M.D.

As have been working with many excellent PV software in the past, choosing one for our clients was not an easy task. There were several aspects to be considered as we were searching for PV tool which will support from clients with couple licences to major pharma players with hundreds of active registered and thousands of licences on the market.

We also had to consider current environment and challenges within pharmacovigilance, where continuous support reflecting constant GVP legislation updates from PV software developer is must and a tailored made approach is essential benefit.

Last but not least – cost is one of the key aspects to be considered so cost-effective solution is the motto of CLINEVO, as for our selected partners for US and EU.

***PharmAZet** is honoured to declare itself as the local representative in EU for CLINEVO software. If cost-effectiveness and performance efficiency is your goal as well, you can contact us at anytime and we will be glad to pave this way for you by performing all the necessary procedures to use CLINEVO.*

Contents:

Introduction to CLINEVO:

CLINEVO Technology is an ISO certified tech company providing regulatory compliant, easy to use, and cost-effective software solutions for Clinical Trials and Pharmacovigilance. CLINEVO system complies with the below regulatory guidelines:

- **HIPPA**
- **21 CFR Part11 / Annex 11**
- **GDPR**
- **GxP – Computer System Validation**
- **ICH, R2 and R3 guidelines for PV submissions**

Software Solutions:

CLINEVO presents variety of software solutions, each designed to carry out specialized tasks, which are as followed:

- ***CLINEVO Safety System:*** *Pharmacovigilance Database*
- ***CLINEVO eTMF:*** *electronic Trial Master File*
- ***CLINEVO CTMS:*** *Clinical Trial Management System*
- ***CLINEVO Data-ware and Automation platform***

CLINEVO Clients:

CLINEVO is collaborating with 40+ customers across the globe which are using Safety and Clinical Databases for Health Authorities such as United States Food and Drug Administration (USFDA), European Medicines Agency (EMA),etc. .

What is CLINEVO Safety System

CLINEVO is a cloud based, user-friendly, regulatory Compliant, end-to-end Pharmacovigilance / Drug Safety system. It is an all-in-one system which can provide:

1) Case Reception, Intake and Triage
2) Case processing
3) Review
4) Submissions and Analytics
5) Risk Management such as Signal Detection

Why CLINEVO Safety System

CLINEVO Safety is an automated one-in-all system with various features to lean case processing efforts, case compliance alerts, configurable dynamic workflow for expedited processing, regulatory inspection ready documentation , fast user adoption and user-friendliness and compatibility with any device and any browser which can make the Pharmacovigilance tasks cost-effective and high-performing. Here is a list of key-features of CLINEVO compared to other Databases and Software:

	Key Features	Our SDB (CLINEVO Safety)	Other SDBs
1	**Easy to Use and User-Friendly Software**	a) CLINEVO Safety is very user friendly. b) Business users can be trained in our software within 8 hours.	a) Not very easy to use. b) Needs extensive training.
2	**Inbuilt Gateway for Regulatory Submissions**	a) Software comes with inbuilt Gateway (for USFDA, EMA, RoW).	a) For submissions, an additional tool like Axway has to be obtained and integrated.

3	**One Click Regulatory submissions and Tracking of the submissions**	a) Processed ICSRs can be transmitted to any regulatory agency (USFDA, EMA, RoW) from the user interface with one click. No Admin/IT help needed. b) User can see the responses from the regulatory agencies with Notification and Acknowledgements from the User interface. **c)** In One page, user can track all the submission details and responses from agencies.	a) For transmitting the process case to regulatory, Admin/IT support is required. b) Only Admin/IT person can get the notification and Acknowledgements received from the authority. **c)** Tracking the acknowledgements and regulatory responses are difficult as the IT team and business teams has to discuss and email the artifacts.
4	**Dynamic workflows to help prioritize the serious cases over non serious cases**	a) System supports different workflows for different type of cases. Like the workflow and timelines can be setup differently for Serious cases, Death cases and Non serious cases. b) For serious cases submission deadlines will be shorter so the system can be configured to provide only few days for these cases and provide more days for non-serious cases. With this, serious cases will be prioritized.	a) Only one fixed workflow can be created in other system which will not help prioritizing the serious cases over non serious cases. b) Treats serious and non-serious cases in a same way which is not correct as the priority should always be given to serious cases over non serious cases.
5	**Meeting the Submission deadlines as per the regulatory guidance / Case nearing submission due date alerts**	a) As soon as a case is created, system will automatically calculate the due date for submission of the case and the due date will be displayed throughout the system. b) System also will provide different color coding like Green, Yellow, Red to differentiate the cases which has time for processing, cases which are nearing due dates, cases which are overdue/crossed the due date. c) System also will send alert and notification emails to the Business users about the cases nearing the due date and seeks attention. d) System also sends escalation emails to the Workflow / Project managers if some cases are not processed on time.	Most of the systems in the market does not have this feature.

6	**Regulatory Inspection Ready**	a) System is pre-validated and all the validation documentations are in place to prove that the system complies with regulatory guidelines like a. 21 CFR Part11 / Annex 11 b. GDPR (as a data processor) c. GxP – Computer System Validation d. ICH, R2 and R3 guidelines for PV submissions	Few software doesn't have everything in place and it is a high risk.
7	**Regulatory Acceptance**	a) Our software is used by many clients submitting cases to USFDA, EMA and RoW. b) Our software is accepted by USFDA and EMA for submission standards. c) Our clients have undergone USFDA audits using our database without any findings on our SDB.	Few software may not have the acceptance.
8	**Adoptable to changing global regulatory guidelines**	a) Our system complies with all latest regulatory requirements and supports all required reporting outputs like R2, R3, CIOMS, MedWatch, Medical devices forms, PADER, PSUR, NDA report, Line listings, etc. b) Our SMEs will always watch for any changes in the regulatory guidelines and implement the changes in the system as and when there are some changes in the guidelines.	Few software may not support all the necessary reports required to meet global regulatory needs.

Infrastructure and Data Security:

CLINEVO's servers are in highly secure AWS (Amazon Web Service) data center which ensures the server comply with HIPPA, HITRUST, and/or GxP standards.

AWS data centers support more than 600 life sciences customers and its ISO-9001 certification directly supports customers who develop, migrate and operation their quality-controlled IT systems.

Primary data center and Secondary data center with online data replication and daily incremental and weekly full backup will ensure any Disaster Recovery and Backup and prevents any Data loss.

Data is stored on Oracle database and are completely segregated and restricted to authorized users using Oracles Virtual Private Database (VPD).

Data Migration – From Legacy System:

CLINEVO brings this ability to migrate any business process and data and programs from legacy systems into CLINEVO's GxP cloud platform, regardless how they had been written or maintained.

CLINEVO platform supports all other technology stacks (Oracle PL/SQL, SAS and UNIX platform) in legacy system so the data and business logic can be migrated with some minor changes.