ETHICAL

eDeviation®

Flexible Protocol Deviation Assessment and Management Software

for Sponsors, CROs, AROs and Ethics Committees/ Institutional Review Boards.

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From Ethical GmbH

Software Solutions for Clinical Research

300+
international clinical trials

10,000+
investigator sites

100,000+
patients involved

24+ years
in Data Management

1 What is eDeviation®?

eDeviation® is a cloud-based software platform that supports all the operations for protocol deviation assessment and management.

With eDeviation®, all the protocol deviations of a given trial are managed **in a single repository** and assessed electronically in **a blinded or unblinded way.** All operations and decisions are recorded in the **Audit Trail and reports can be easily exported at any time.**

eDeviation® is a flexible software that **can be configured to match any study requirements.**

Software Main Features

- Import protocol deviations from source systems
- **Group protocol deviations** by investigational site or relevant EC/IRB
- **Collect and redact** supporting documents from sites or other sources
- **Manage** independent committees' **assessments and disagreements**
- **Monitor** process timelines & KPIs **in real time**
- Report & export protocol deviation data and audit trail

Achieved Results

- Manage all the protocol deviations **within a single repository**
- **Facilitate submission** of protocol deviations to EC/IRBE*
- Save staff time with **a streamlined process**
- Ensure a timely and compliant execution of your deviations' assessments and CAPAs**
- Detect quickly protocol deviation trends
- Ensure **GxP compliance**, Audit Trail and Data Quality
- Support **independent committee and team members** with a simple ad-hoc solution

* Ethics Committees/Institutional Review Boards

** Corrective And Preventive Actions

2 When to use eDeviation®?

Do you find that:

- Managing your study protocol deviations is time-consuming?
- Documenting your study protocol deviations assessments is creating unnecessary overhead?
- There is room for improvement in the way you manage your study protocol deviations?
- It is important to minimize the risks associated to protocol deviations?

eDeviation® is the solution!

eDeviation® is a flexible software that can be configured to match any study requirements.

eDeviation® is suitable for many uses:

Every time a clinical trial team needs support to manage and assess their protocol deviations in a **simple, effective and GxP-compliant way.**

In support of any clinical trial, **whatever the rules and procedures may be.**

Whether the study protocol deviation assessments are performed **by an independent committee or internally** by the sponsor or CRO study team.

Whenever EC/IRB need to **review and classify protocol deviations** submitted by sponsors or CROs and suggest CAPAs.

3 How eDeviation® helps?

Stakeholders	Benefits
Clinical Trial Leaders	• Flexible configuration • Real time oversight of all operations
Deviations Committee Members	• Easy to navigate deviations that are organized by type • Easy submission of assessments • Information update notifications
Quality Assurance Managers	• Validation package documentation • GxP-compliance • Clone system for UAT
Data Managers	• Flexible integration with any EDC and CTMS • Real-time download of structured data and metadata • Integrated quality control

eDeviation® is GxP-compliant, secure and validated

- Complete Audit Trail of all operations performed in the system.
- ISO 27001 hosting, backup and business continuity.
- GAMP5 validation documentation and support.
- Secure 21 CFR Part 11-compliant records management.
- EU GMP Vol. 4 Annex 11 & EU GDPR.

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Interested to know more?

Get a FREE DEMO of the eDeviation® Software Solution

No commitment required!

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