

EVIDENTIQ
CLINICAL DATA SCIENCE GROUP

Safety Notifications Made Easy

EVIDENTIQ SAFETY NOTIFICATION SOLUTION E2B MAILER

Are you conducting a trial or non-interventional study and need a reliable safety notification tool to monitor adverse drug reactions (ADRs) outside of the scope of a full PV system? Look no further! Our safety notification tool is designed specifically to bridge the gap between a simple reporting and a PV system.

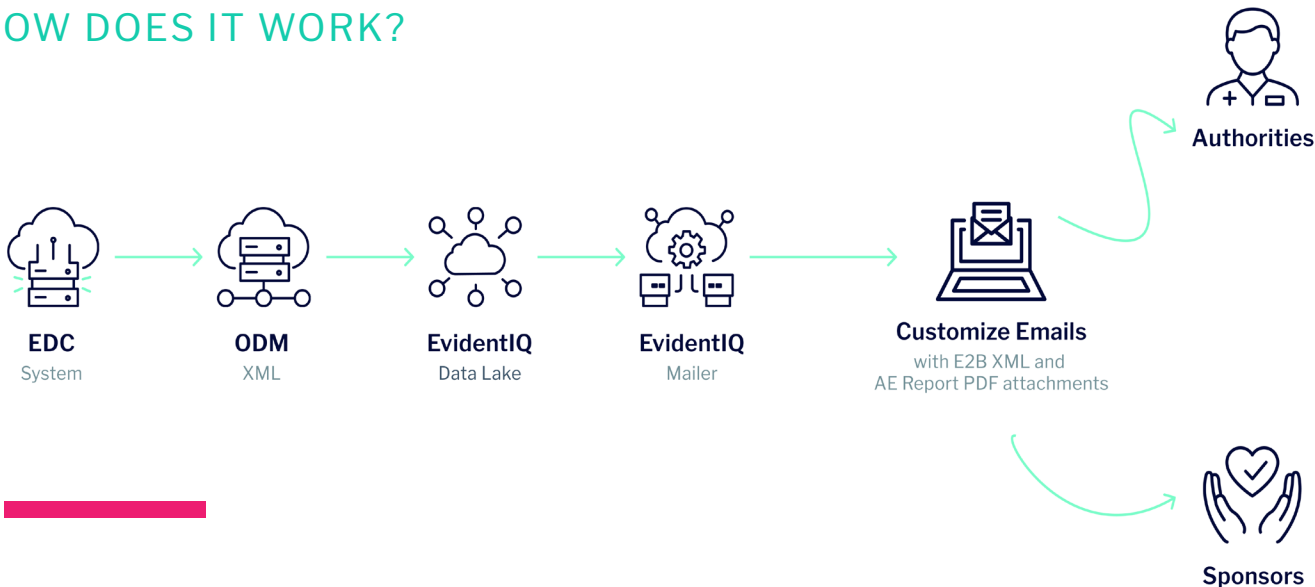
Our new safety notification solution, provides an auto forward functionality of (Serious) Adverse Events in E2B and archivable format. As it is EDC agnostic, it is the perfect notification tool for your studies.

Features

- All EDC data can be referenced in the notification
- E2B attachments to connect to PV Systems
- PDF attachments include highlighting of changes
- High reliability of 99,05%
- Encryption at rest & in transit
- Includes special use cases for non-interventional studies



HOW DOES IT WORK?



Global: Adverse Event and Special Situation Reporting Form

Non-Interventional Study (NIS) / BERICHT AUS NICHT-INTERVENTIONELLER STUDIE

NIS Protocol Number: **ML40914**
 VCI Protocol Number: _____

Site Number: **12**
 Nummer des Zentrums: _____

Patient Number: **12-001**
 Patientennummer: _____

1. REPORTER DETAILS
1. DETAILS ZUM BERICHTERSTATTER

Reporter First Name: _____ Occupation: _____
 Vorname: _____ Beruf: _____

Reporter Surname: _____ Physician (specify speciality): _____
 Nachname: _____ Arzt/Ärztin (Fachgebiet angeben): _____

Institute: _____ Physician: _____
 Institut: _____

Address: **Grade Place 1**
 Adresse: _____

Postal/Zip Code: **Brussels**
 Postleitzahl: _____

Country: **Belgium**
 Land: _____

E-mail Address: _____
 E-Mail-Adresse: _____

Telephone Number: _____
 Telefonnummer: _____

Fax Number: _____
 Faxnummer: _____

Has the Regulatory Authority been notified of this report?
 Wurde die Behörde (EMA/FDA) über diesen Bericht informiert? Yes No Unknown

2. PATIENT DETAILS
2. DETAILS ZUM PATIENTEN

Gender: Male Weight: **85 Kg**
 Geschlecht: _____ Gewicht: _____

Year of Birth: **1965** Height: **175 cm**
 Geburtsjahr: _____ Größe: _____

Ethnic Origin: Asian Black Caucasian
 Ethnische Zugehörigkeit: _____

Hispanic Other

3. SUSPECT PRODUCT * - If more than 4, continue in Additional Relevant Information, Section 7
3. VERDÄCHTIGES PRODUKT * - Bei mehr als 4 bitte weitere Details in "Zusätzliche Relevante Informationen", Abschnitt 7 eingeben

Product Name (report brand name if available) Produkt Name (Handelsname angeben, sofern verfügbar)	Indications/condition for which the product has been prescribed Indikation / Zustand für welchen das Produkt verschrieben wurde	Dose and Unit Dosis und Einheit	Route Application Anwendung	Frequency Frequency	Start Date Startdatum	Stop Date (or ongoing) Enddatum (oder andauernd)
A Emicizumab	Hemophilia A without FVIII inhibitors	250 mg/kg	Subcutaneous	1/1 Week	2023-01-03	2023-02-03
A Emicizumab	Hemophilia A without FVIII inhibitors	100 mg/kg	Subcutaneous	1/1 Day	2023-02-06	Ongoing

Batch/Lot Number (latest Emicizumab administration prior to the event)
 Chargen Nummern (letzte Emicizumab-Dosis, die vor dem Ereignis verschrieben wurde) **none**

Was the suspect product discontinued due to the adverse event? Yes No
 Wurde das verdächtige Produkt aufgrund des unerwünschten Ereignisses abgesetzt? Ja Nein

Was the suspect product reintroduced? Yes No
 Wurde die Therapie mit dem verdächtigen Produkt wieder aufgenommen? Ja Nein

If so, did the patient's condition resolve/improve? Yes No
 Falls ja, verbesserte sich der Zustand des/dieser Patienten/Verlaufes nach dem Ereignis? Ja Nein

If so, did the event recur? Yes No
 Falls ja, trat das Ereignis erneut auf? Ja Nein

Global: Adverse Event and Special Situation Reporting Form

Key Definitions:
 Schlüssel für den Bericht:

1. Fatal Tödlich	3. Recovered/Recovered Wohlergehen	5. Recovering/Recovering Gesamterholt
2. Not Recovered/Not Recovered Nicht-ohlergegangen	4. Recovered/Recovered with sequelae Wohlergehen mit Folgeerkrankung	6. Unknown Unklarheit

Key Definitions:
 Schlüssel für die Schweregrade:

1. Death (if you provide date) Tod (falls ja, Todesdatum angeben)	5. Persistent or Significant Disability Dauerhaft oder signifikante Schädigung
2. Life-Threatening (use only if patient was at least at risk of death due to adverse event) Lebensbedrohlich (nur anzuwenden, wenn der Patient einen unmittelbaren Tod aufgrund des unerwünschten Ereignisses erwartete)	6. Medically Significant (inpatient medical event that may jeopardize the patient and may require medical or surgical intervention to prevent the patient's outcome) Medizinisch/Arztbedeutend (schwere medizinische Ereignisse, die den Patienten gefährden und eine medizinische/ärztliche Intervention erfordern können, um einen der nächsten Ausgänge zu vermeiden)
3. Initial Prolonged Hospital Admission Neuer verlängertes Krankenhausaufenthalt	7. Non-serious Adverse Events of Special Interest (AESI) per NIS protocol Nicht-ernstere Ereignisse/Ergebnisse von speziellem Interesse (AESI) gemäß NIS-Protokoll
4. Congenital anomaly/Birth Defect Angeborene Anomalie/Geburtsfehler	8. Non-serious Nicht-ernstere

Global: Adverse Event and Special Situation Reporting Form

That AE has been deleted
 Dieses Ereignis wurde gelöscht

Before/after event
 Vor/Nach dem Ereignis

How/when deleted
 Wie/Wann gelöscht

Deleted Reason
 Grund für die Löschung

How/when deleted Wie/Wann gelöscht	Deleted Reason Grund für die Löschung	Before/after event Vor/Nach dem Ereignis	How/when deleted Wie/Wann gelöscht	Deleted Reason Grund für die Löschung
Another AE by the deleted This AE has been deleted Deleted Reason: Recovered AE Term				
AE Term to be deleted which should not trigger SAE E-mail This AE has been deleted Deleted Reason: Deleted before SAE Mailer start	2023-03-06	6	4	U
How/when deleted Wie/Wann gelöscht	2023-03-06	6	5	N

EvidentIQ offers highly available, reliable, and secure applications that scale elastically and cost-effectively. Setup of attachments and notifications are based on templates.



HOW DOES THE E2B MAILER MAKE SURE YOUR AE REPORTS ARE ON TIME?

We bridge the gap between a full PV and a simple reporting system. Non-interventional studies are important in assessing the safety and effectiveness of drugs in real-world settings. However, detecting and reporting ADRs in NIS can be challenging due to the lack of control over the medication use and patient selection. Our safety notification tool is tailored to address these challenges and provide a streamlined way to monitor ADRs.

Our tool uses automated algorithms to detect potential ADRs and sends notifications to investigators in real-time. This ensures that potential safety issues are identified and reported promptly, reducing the risk of harm to patients. By being EDC agnostic, our safety notification tool ensures that you can focus on conducting your NIS without having to worry about the compatibility of the ADR monitoring and reporting system.

FLEXIBILITY

- EDC agnostic with the comfort of receiving the information the way you want
- High scalability for amount and type of reports for any datapoint at any point in time
- Cross-study reporting
- Unified model of clinical data from difference EDC Systems
- Integration with other systems
- Multi EDC to multi PV

SECURITY & AVAILABILITY

- State-of-the-art technology provides a high grade of reliability
- High expertise on possible detection scenarios for certain events
- Support of industry standards (e.g. E2B R2/R3) and CDISC ODM-XML
- ISO 27001 certified data centers
- HDS certification ready
- Exclusively built with HIPAA eligible service
- Advanced notification use (without PV system) but custom layout reports
- Hosted in Europe and 100% GDPR compliant

Contact us today to learn more about how our EDC agnostic safety notification tool can benefit your {Non-Interventional} studies.



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