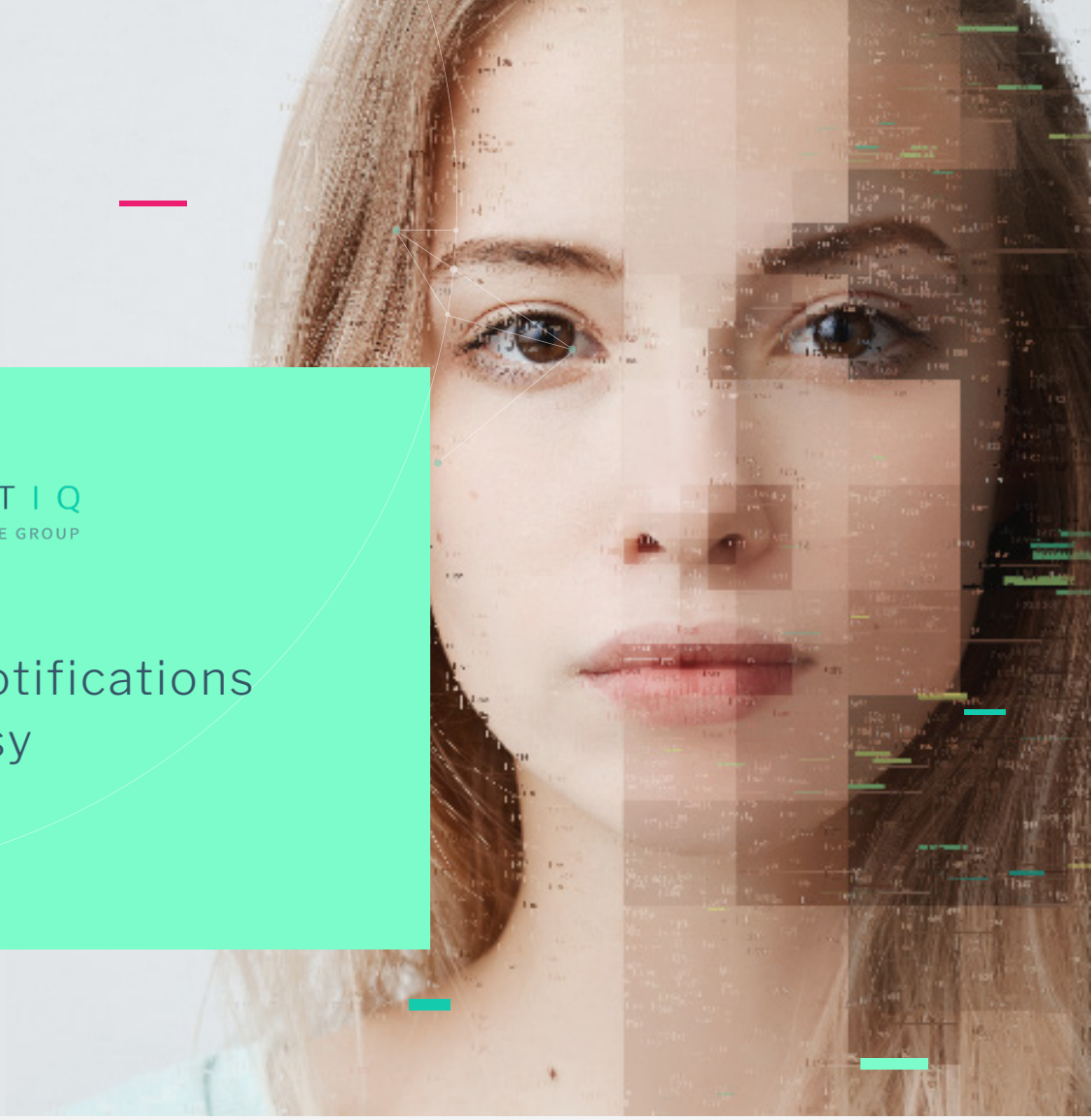


EVIDENTIQ
CLINICAL DATA SCIENCE GROUP

Safety Notifications Made Easy

EVIDENTIQ SAFETY NOTIFICATION SOLUTION E2B MAILER

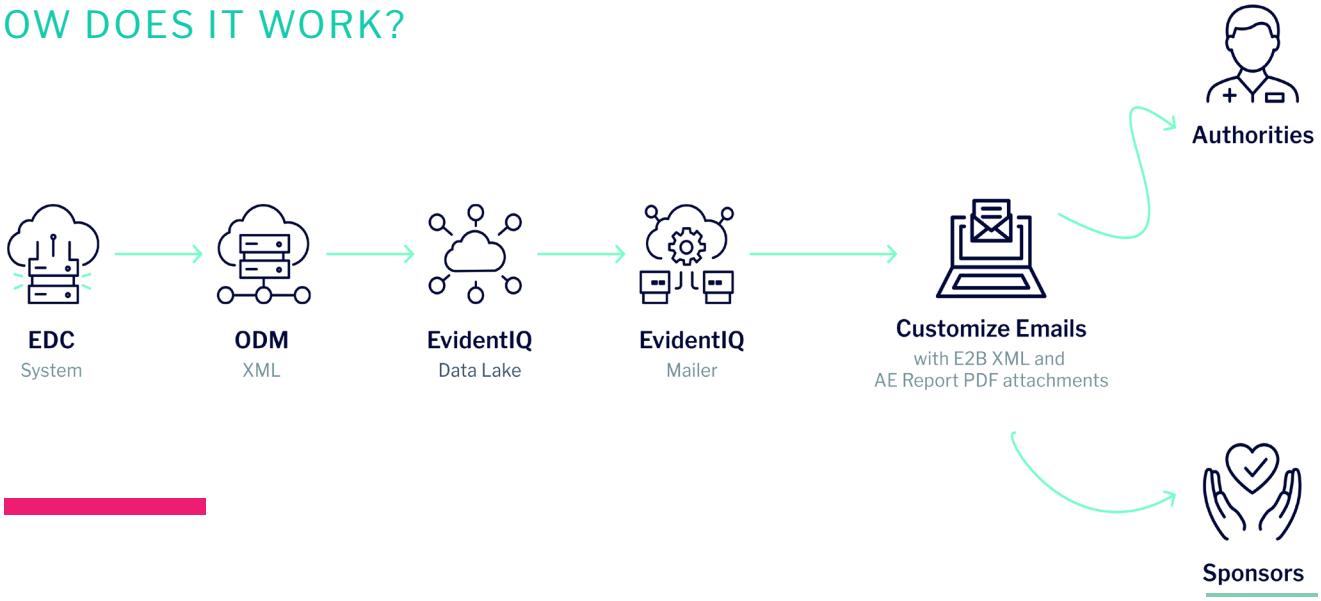
Are you conducting a trial or non-interventional study and need a reliable safety notification tool to monitor adverse drug reactions (ADRs) outside of the scope of a full PV system? Look no further! Our safety notification tool is designed specifically to bridge the gap between a simple reporting and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

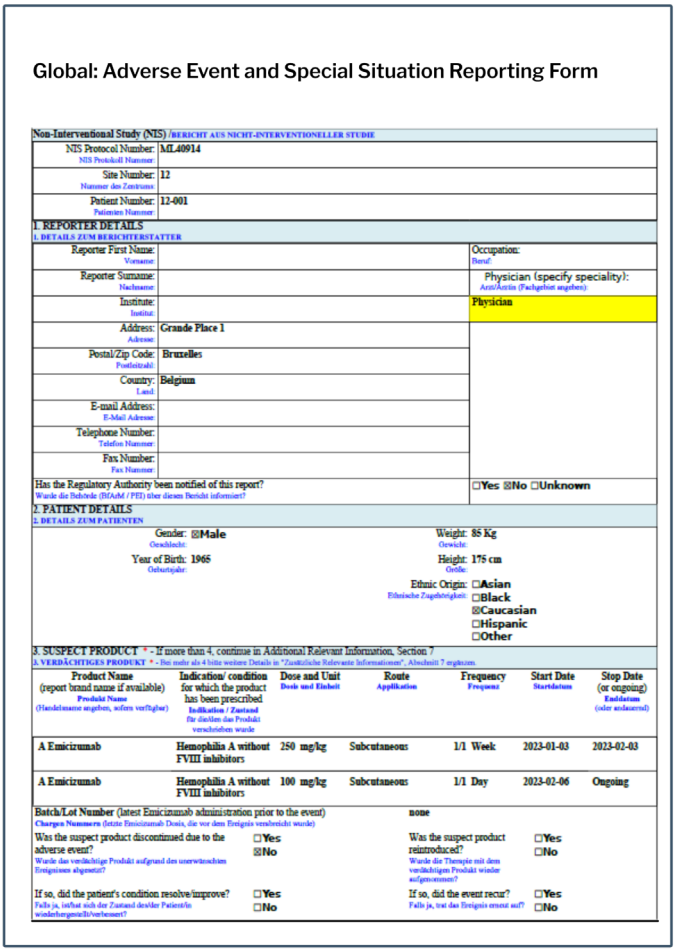
Our new safety notification solution, provides an auto forward functionality of (Serious) Adverse Events in E2B and archivable format. As it is EDC agnostic, it is the perfect notification tool for your studies.

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
Site Number:	12
Patient Number:	12-001

I. REPORTER DETAILS

Reporter First Name:		Occupation:
Reporter Surname:		Physician (specify speciality):
Institute:		Physician
Address:	Grande Place 1	
Postal/Zip Code:	Bruxelles	
Country:	Belgium	
E-mail Address:		
Telephone Number:		
Fax Number:		

Has the Regulatory Authority been notified of this report? ☐Yes ☒No ☐Unknown

II. PATIENT DETAILS

Gender: ☒Male Weight: 85 Kg

Year of Birth: 1965 Height: 175 cm

Ethnic Origin: ☐Asian ☐Black ☒Caucasian ☐Hispanic ☐Other

III. SUSPECT PRODUCT * - If more than 4, continue in Additional Relevant Information, Section 7

Product Name (report brand name if available)	Indication/ condition for which the product has been prescribed	Dose and Unit	Route	Frequency	Start Date	Stop Date (or ongoing)
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

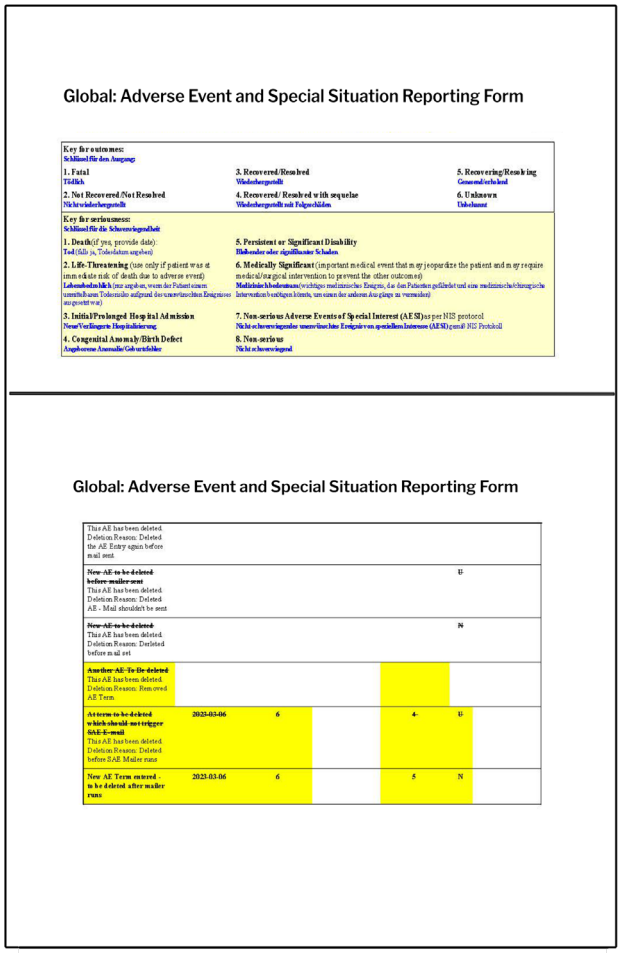
Batch/Lot Number (latest Emicizumab administration prior to the event) none

Was the suspect product discontinued due to the adverse event? ☐Yes ☒No

Was the suspect product reintroduced? ☐Yes ☐No

If so, did the patient's condition resolve/improve? ☐Yes ☐No

If so, did the event recur? ☐Yes ☐No



Global: Adverse Event and Special Situation Reporting Form

Key for outcomes:

1. Fatal
2. Not Recovered/Not Resolved
3. Recovered/Resolved
4. Recovered/ Resolved with sequelae
5. Recovering/Resolving
6. Unknown

Key for seriousness:

1. Death (if yes, provide date)
2. Life-Threatening (use only if patient was at imm ediate risk of death due to adverse event)
3. Initial/Prolonged Hospital Admission
4. Congenital Anomaly/Birth Defect
5. Persistent or Significant Disability
6. Medically Significant (important medical event that m ay jeopardize the patient and m ay require medical/surgical intervention to prevent the other outcomes)
7. Non-serious Adverse Events of Special Interest (AESI) as per NIS protocol
8. Non-serious

Global: Adverse Event and Special Situation Reporting Form

This AE has been deleted. Deletion Reason: Deleted the AE Entry again before mail sent.					
~~New AE to be deleted before mailer sent~~ This AE has been deleted. Deletion Reason: Deleted AE - Mail shouldn't be sent					U
~~New AE to be deleted~~ This AE has been deleted. Deletion Reason: Deleted before mail sent					N
~~Another AE To Be deleted~~ This AE has been deleted. Deletion Reason: Removed AE Term					
~~AE term to be deleted which should not trigger SAE E-mail~~ This AE has been deleted. Deletion Reason: Deleted before SAE Mailer runs	2023-03-06	6		4	U
New AE Term entered ... to be deleted after mailer runs	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.

EVIDENTIQ

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