NWEH transforms clinical trial safety reporting with near real-time EHR and E2B technology

Enhancements to ConneXon combine near real-time data with expert clinical oversight for faster, more accurate safety reporting



Traditionally, clinical trial adverse event collection relied on scheduled study visits and participant recall. NWEH's solution flags potential events as soon as they are recorded and transmits them directly to sponsors using ICH E2B(R3).

MANCHESTER, UNITED KINGDOM, September 9, 2026 /EINPresswire.com/ -- NorthWest EHealth (NWEH), the healthcare technology company, has enhanced the clinical trial safety surveillance solution within its ConneXon platform. It means faster, more accurate Individual Case Safety Reports (ICSR), helping sponsors to spot and act upon potential safety signals earlier than ever before.

ConneXon's electronic health record (EHR)-based safety surveillance has been shown to detect up to twice as many serious adverse events as traditional methods, while the updated ICSR capability is estimated to save an average of five hours per report. 1

By combining the power of real-time, electronic health record (EHR) data with expert clinical oversight, ConneXon can improve safety and accuracy, guide timely decision making, and support submission readiness. Importantly, it aligns with FDA guidelines on Risk-Based Monitoring (RBM), which acknowledge the benefits of continuous monitoring for patient safety, accuracy, and trial efficiency. 2

The AE safety gap

Sponsors conducting clinical trials have a duty of care to those who participate, and this includes the timely identification of adverse events (AEs).

Under ICH Good Clinical Practice (GCP), investigators are required to report serious adverse

events (SAEs) to the sponsor promptly after becoming aware of them.3 European and UK guidance further clarifies the timeline for reporting as within 24 hours. 4,5 Failure to meet this target can be classed as a breach of Good Clinical Practice (GCP), and lead to reputational damage and even study postponement.

Traditionally, AEs are often collected by investigators at routine study visits, which, depending on the protocol, can be weeks or even months apart. As such, accuracy is reliant on each individual participant remembering to report potential events. And when potential adverse events are not reported, sponsors do not have access to this vital information about their products. This can put participants and drug development programmes alike at risk.



Claire Williams, head of pharmacovigilance and regulatory services at NWEH, and chair of the Greater Manchester Central Research Ethics Committee.



Siobhan Duncan, head of product at NWEH.

Furthermore, the AE reporting process is often burdensome for sites and sponsors. It tends to involve completing, signing and emailing a form to the sponsor, awaiting acknowledgment, and manually tracking submitted reports. Not only is this slow and resource-hungry, but manual data transcription is also prone to human error and inaccuracies, both in the report content and the target email address. Direct E2B integration streamlines the exchange of safety data and can almost eliminate the shared reconciliation burden between sites and sponsors.

Real-world, real-time, real-person ICSR

NWEH's approach is different. ConneXon links directly to participants' EHR, and its alerting capability detects and flags potential adverse events captured in routinely updated EHR data.

This information is transferred to NWEH's in-house safety team of clinical experts who review the events, along with any available additional information, against the protocol's AE criteria.

Where reporting is required, the new ICH E2B(R3) capability supports faster, standardised generation and transmission to the sponsor. It makes for a faster, more streamlined process that also reduces the risk of transcription errors.

NWEH's EHR-linked, safety surveillance offers participants an additional layer of confidence in their safety, and streamlines the AE reporting process for sites, reducing the administrative burden and freeing investigators up to focus on patient care. For sponsors, the solution provides earlier visibility of potential AEs and safety signals, enabling faster assessment and more timely decision-making.

NWEH continuous safety surveillance provides:

• Real-time EHR connectivity: Connects directly to electronic health records to detect potential AEs in near-real time, rather than at the next scheduled study visit;
• Better protection for participants: Identifies potential adverse events sooner, reduces reliance on participants remembering to report them, and supports faster clinical assessment and action;

• Earlier safety signal detection: Combines continuous monitoring with expert clinical oversight to identify, investigate and act upon potential safety signals sooner;
• Faster, more accurate reporting: Enables standardised E2B ICSR transmission, reducing manual data entry, transcription errors and reporting delays;
• Lower burden and greater submission readiness: Streamlines safety reporting for sites and sponsors while providing consistent, submission-ready safety data.

Claire Williams, head of pharmacovigilance and regulatory services at NWEH, and chair of the Greater Manchester Central Research Ethics Committee, said: "Ultimately, this is about protecting participants. Clinical trials can move quickly, but safety reporting has traditionally relied on manual processes and information gathered at scheduled study visits. By bringing real-time clinical information together with expert safety review, we can help sponsors identify potential safety issues sooner and make faster, better-informed decisions. The technology supports that process, but clinical judgement remains at the heart of it. Patient safety should never be fully automated."

Siobhan Duncan, head of product at NWEH, said: "This new functionality completely streamlines the safety reporting process, from detecting an event in a patient's record through to its transmission to the sponsor. It allows us to ensure potential serious adverse events reach the right people quickly and accurately. This not only reduces the administrative burden and risk of transcription errors, but, most importantly, gives sponsors earlier visibility of potential safety events, supporting ongoing safety assessment and potential signal detection, and meaning they act to protect participants sooner."

For more information: nweh.co.uk

ENDS

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In brief:
NorthWest EHealth (NWEH) has enhanced its clinical trial reporting solution to identify potential adverse events directly from participants' electronic health records (EHRs). Events are investigated by NWEH's in-house clinical safety team, then transmitted to sponsors as standardised ICSRs in ICH E2B(R3) format, meaning the process can take hours, not weeks.

JAMES TATE
Morris Tate for NWEH
james@morristate.co.uk

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