AI and Adverse Event Reporting

This material is produced by the Ethics and Compliance Team at the BHBIA. It is meant as general, not specific, advice on the use of AI. The AI space is evolving rapidly and it is an AI deployer's responsibility to stay current on technical capabilities, limitations, and administrative risks.

Key Principle:

Artificial Intelligence (AI) can support adverse event (AE), product complaint (PC) and special reporting situation (SRS) processes, but it does not change existing pharmacovigilance (PV) obligations, reporting requirements or accountability.

Risk Consideration:

AE review should be considered a high-risk use of AI because errors, omissions or misclassification may have patient safety implications and can result in regulatory, contractual and business consequences.

What stays the same:

- The Marketing Authorisation Holder (MAH), or organisation contracted to perform PV activities, remains responsible for meeting all reporting obligations.
- All identified AEs, PCs and SRSs must be managed and reported in line with applicable client agreements, PV agreements, ABPI guidance and BHBIA guidance.
- AI does not remove the need for trained personnel, documentation, reconciliation, governance and auditability

AI can help:

- Screen large volumes of text, transcripts, social listening outputs and open-ended survey responses.
- Identify potential safety-related keywords, patterns and signals that may indicate an AE, PC or SRS.
- Prioritise and organise potential cases for review.
- Improve efficiency and consistency when handling high volumes of data.
- Support the review of datasets that would otherwise require extensive manual screening.

BHBIA
ETHICS & COMPLIANCE

AI should not be used to:

- Replace human judgement when determining whether information constitutes a reportable event.
- Make final reporting decisions without appropriate human review.
- Assume outputs are complete, accurate or free from error, bias or hallucination.
- Fully automate AE processing without effective oversight and validation.
- Input identifiable personal data into tools that have not been approved under applicable data protection and security requirements.

Human oversight is essential:

- Accountability cannot be transferred to AI providers or AI tools. The organisation that has entered into the PV agreement retains responsibility for the process and outcomes.
- This includes source data verification, processing of large datasets, identification of potential cases, completion of AE documentation and reporting decisions.
- The use of AI as part of the workflow does not reduce the organisation's responsibility to review, validate and act upon potential adverse events identified through the process.
- All potential events identified by AI should be reviewed by appropriately trained personnel.
- Researchers, analysts and PV personnel remain responsible for validating AI outputs and ensuring reportability assessments are correct.
- Clear accountability, audit trails, quality controls and documentation should always be maintained.
- Staff using AI should be trained in both AE reporting requirements and AI governance.

Validation and Testing:

- Where AI is used to support AE, PC or SRS identification, organisations should consider whether validation, testing or other documented quality controls are appropriate for the intended use.
- Expectations may differ between systems used directly within regulated pharmacovigilance processes and those used by market research agencies or fieldwork providers.
- Regardless of the approach taken, organisations should be able to demonstrate that AI-assisted processes are fit for purpose and subject to appropriate human oversight.

Client Alignment:

- Agencies should consider whether the use of AI in AE identification or review processes is consistent with client agreements, PV agreements and training

requirements.

- As a matter of good practice, where AI forms a material part of the workflow, agencies should be transparent with clients and seek alignment on the proposed approach, responsibilities and oversight arrangements, particularly where existing agreements do not explicitly address AI-supported processes.

Reporting timelines:

- Use of AI does not alter the reporting timelines established by the agency's client agreements, PV agreements or internal procedures.
- AI review and processing should be considered part of the reporting workflow, not an extension to reporting deadlines.
- Organisations should clearly assess when "first awareness" occurs within any AI-enabled process.
- Where human involvement occurs in the AI-enabled process, such as downloading a data file and uploading it to another system for review, organisations should consider whether this constitutes first awareness under the relevant client agreement, PV agreement and internal procedure.
- Where the agency/client agreement is tighter than BHBIA guidance, for example requiring reporting within 24 hours of the AE being first mentioned by the respondent, that requirement must still be followed.

Produced by the BHBIA's Ethics & Compliance Committee September 2026

British Healthcare Business Intelligence Association
Fountain Precinct, 4th Floor Orchard Lane Wing, Balm Green, Sheffield, S1 2JA
t: 01727 896085 • admin@bhbia.org.uk • www.bhbia.org.uk
A Private Limited Company Registered in England and Wales No: 9244455