BHBIA Ethics & Compliance Quick Guide

AE/PC/SRS Collection from Market Research

BHBIA

Definitions

An Adverse Event (AE)

- An untoward medical occurrence in a patient or clinical-trial subject - any unfavourable and unintended sign, symptom, or disease – temporally associated with the use of a medicinal product and/or medical device
- Does not necessarily have to have a causal relationship with this treatment

A Product Complaint (PC) is a complaint specific to the medicine and/or device itself, or packaging, as opposed to its effect on the patient e.g. damaged tablets or packaging, missing PIL, bent or broken needle or syringe.

Special Reporting Situations (SRS) associated with the use of a medicine and/or device should be reported, whether or not there is an associated AE:

- Exposure through a parent i.e. drug exposure to a foetus in utero
- Exposure to a drug or device during breast-feeding/lactation
- Overdose, abuse or misuse
- Lack of therapeutic efficacy, including suspected use of counterfeits or tampering
- Medication errors
- Unapproved or off-label use
- Withdrawal syndrome
- Unexpected therapeutic benefit may be considered an SRS by some companies
- Drug-drug or drug-food interactions
- Suspected transmission of an infectious agent
- Occupational and environmental exposure

In this leaflet we have used 'AE/PC/SRS' to refer to adverse events, product complaints and special reporting situations.

What are the criteria for forwarding an AE/PC/SRS?

1. **P** atient – a real patient or patients, whether or not there are specific identifying details

2. **R** eporter – often a healthcare professional (HCP), may also be a patient or carer

3. **E** vent – AEs, PCs or SRSs, as listed above

4. **P** roduct – medicinal product for which the company is or expects to be the marketing authorisation holder (MAH) or medical device for which the company is or expects to be the certificate of conformity holder (CCH).

AEs/PCs/SRSs that meet the above criteria should be forwarded regardless of:

- Seriousness or severity of the event
- Whether or not already reported to the Medicines & Healthcare products Regulatory Agency - MHRA
- Whether or not expected in the Summary of medicinal Product Characteristics (SmPC)

It is not the market researcher's responsibility to assess seriousness or causality – If in doubt forward the event!

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What are our obligations as researchers?

Employees of the commissioning pharmaceutical company and all organisations and individuals contracted to work on their behalf, including market research (MR) agencies and their sub-contractors, are required to forward AEs/PCs/SRSs for products for which the company (sponsoring the market research) is the MAH or CCH.

Researchers must forward AEs/PCs/SRSs raised during a MR study, without compromising respondents' rights to anonymity and confidentiality.

All MR respondents should be informed at recruitment of the requirement to collect AEs/PCs/SRSs, and their consent requested to forward the respondent's contact details if an AE/PC/SRS is identified (assuming consent is the lawful basis for the data processing).

What is the scope of the AE/PC/SRS guidance?

The Guidelines apply to company commissioned/supported primary market research programmes and syndicated studies conducted in the UK irrespective of which functional or geographical area initiated the study or whether the medicine and/or device is prescription bound or available over the counter.

They do not apply to MR activities where a company is not the MAH/CCH, MR conducted in countries other than the UK, clinical trials, or where longitudinal patient databases are used for MR purposes.

What is the process for collection AEs/PCs/SRSs from primary market research?

The AE/PC/SRS Data Collection Form is the main means for AE/PC/SRS collection:

- One form for each respondent (one form can be used for a group of patients with no individual identifiers).
- Record as much information as possible, with the help of the respondent/reporter
- Try to obtain the respondent's contact details, whether they are a HCP or not, so the sponsor company/MAH/CCH can follow up the AE/PC/SRS if necessary – if this is not possible, the form should be forwarded without contact details.
- The respondent's assessment of causality should be recorded but no attempt made by the interviewer to independently assign causality.
- The interview does not need to be interrupted - complete the form at the end of the interview.

Sometimes it may be appropriate to report AE/PC/SRS data in an aggregate format i.e. tabulations of aggregate data. This should be agreed with the sponsoring company at the start of the project.

How quickly do AEs/PCs/SRSs need to be forwarded?

AEs/PCs should be forwarded by the agency to the sponsoring company **within one business day** of any employee of a MR supplier or their sub-contractors becoming aware of the AE/PC/SRS.

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What information should the pharmaceutical company provide?

The company should provide the agency with:

- A list of the medicines and/or medical devices for which they are the MAH/CCH
- A master Data Collection Form and Reconciliation Form (preferably the BHBA/ABPI forms are to be used)
- Contact details of the department to which the forms are to be sent
- Details of any company specific AE/PC/SRS requirements.

How do these guidelines apply to syndicated studies?

There is no legal responsibility for the supplier to forward AEs/PCs/SRSs as they are not the legal agent at the time of data collection. (However, the agency may be requested to prepare data in a format that facilitates the forwarding of AEs/PCs/SRSs by the client researcher).

What about reconciliation?

- Agencies should provide a summary of all AEs/PCs/SRSs at the end of the project, including the total number of AEs/PCs/SRSs, and, for each event, the respondent ID, the product name and the event details.
- MR suppliers should keep a record of all AE/PC/SRS reports sent to the pharmaceutical company so that reconciliation can be performed as required.
- This summary report should be completed even if no events were forwarded.

Further Information and Training

This Guide is based upon the **Guidance notes on collecting adverse events, product complaints and special reporting situations during market research** – Produced by the ABPI Pharmacovigilance Expert Community and British Healthcare Business Intelligence Association, February 2021.

The full guidelines can be found at **www.bhbia.org.uk/guidelines-and-legislation/AE-PC-SRS-Guidance** . You can also download the ABPI/BHBIA standard AE/PC/SRS Data Collection Form, AE/PC/SRS Reconciliation Form and standard paragraphs for use in MR materials.

The BHBIA provides an online AE/PC/SRS training programme and strongly recommends that all market researchers undertake the training and the accompanying Competency Test to become certified.

If you have any queries about this Quick Guide or the BHBIA Legal & Ethical Guidelines for Healthcare Market Research, please visit **www.bhbia.org.uk** and submit your query via the '**My BHBIA**' dashboard. Please note: this ad hoc advisory service is available to full BHBIA members only.

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Forwarding AEs and PCs – steps by stage of the MR study

Request for Proposal	• Require agency and sub-contractors to comply with AE/PC/SRS guidelines • Require competency certification of all project team
Proposal	• Agree to abide by AE/PC/SRS Guidelines (all staff, sub-contractors) • Agree form of proof of competency
Recruitment	• Inform respondents of obligation to collect AEs/PCs/SRSs
Design of Materials	• Identify opportunities for AE/PC/SRS identification within guide/questionnaire • Include standard wording regarding AE/PC/SRS collection in introduction to guide/questionnaire • Agree AE/PC/SRS reporting format and any company-specific requirements • Provide list of medicines and/or devices, Data Collection and Reconciliation Forms to agency • Provide email address to which completed forms should be sent within one business day
Fieldwork	• Identify AEs/PCs/SRSs and record full details on AE/PC/SRS Data Collection Form • Ask consent to pass on respondent/reporter contact details to sponsor company if an AE/PC/SRS is identified • Forward completed forms to sponsor company within one business day • Agency to keep a copy or record of AEs/PCs/SRSs forwarded
Analysis	• AEs/PCs/SRSs identified during coding or analysis to be forwarded to sponsor company within one business day of awareness
Study Closure	• Complete reconciliation using AE/PC/SRS Reconciliation Form • Dispatch completed form to sponsoring company

Disclaimer

This guidance is provided by the BHBIA for information purposes only and is not intended and should not be construed as regulatory or legal advice. It does not cover all legislative and regulatory requirements pertaining to Members and it is the responsibility of all Members to familiarise themselves with these.

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