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Fact Sheet

Nuances in Pharmacovigilance case processing in Early Access Programs

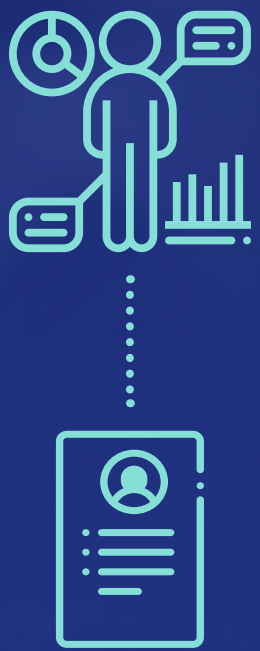
By Harry Woods

Early Access Programs (EAPs) are designed to provide access to drugs for patients who cannot access clinical trials and who have an unmet medical need. They can also be referred to as compassionate use, named patient use, managed access, expanded access programs, etc.

Experienced pharmacovigilance professionals will be familiar with conventional ways of processing Individual Case Safety Reports (ICSRs) from clinical trials or from post-market surveillance (PMS). There are however a number of potential pitfalls and things to think about when processing ICSRs from EAPs.

Early Access Programs (EAPs) are designed to provide access to drugs for patients who cannot access clinical trials and who have an unmet medical need.

The different sources of safety reports in EAPs can have an impact on case processing:



The majority of safety reports we receive from EAPs are solicited reports, when the EAP has an organised data collection system; similar to data collection on clinical trials. These reports often contain a lot of information about the adverse event, contain a causality assessment and it is easy to contact the physician directly for follow up information.

However, we can also receive spontaneous (unsolicited) reports where systematic data collection is not required and is more in line with safety reports from PMS. These reports come from Health Care Professionals (HCPs) or consumers themselves, often contain minimal information, have an assumed causality to the product and requesting follow up information from a reporter can be more difficult.

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Regulatory reporting criteria for ICSRs in EAPs differs from clinical trials:

In clinical trials, we must report Suspected Unexpected Serious Adverse reactions (SUSARs) to regulatory authorities within 7 days for fatal or life-threatening events and 15 days where other seriousness criteria are met.

In the US, the regulatory reporting criteria in EAPs is no different from these clinical trials regulations.

However, EAPs in the EU have reportability criteria that mirrors post marketing regulations. We are required to report any adverse event that is related to the product, regardless of expectedness or seriousness. The timelines for reporting are 15 days for serious adverse events and 90 days for non-serious adverse events.

Be careful with the language – certain terms lend themselves to be more associated with EAPs or clinical trials:

Terms such as investigator, study, trial, sponsor, randomization, IMP, study drug all have connections with clinical trials.

When case processing EAP safety reports it is more appropriate to use broader terms such as physician, HCP, program, company, product and treatment.

EAPs have no blinding or placebo groups:

Given that EAPs are often treating very sick patients who need lifesaving treatment urgently, it is unethical to have blinded trials with some patients on placebo.

Case processing in EAPs has the advantage of no blinded design. We do not have to worry about the associated complications, such as using blinded databases, narrative writing or accidental unblinding.

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