MHRA releases guidance in collaboration with Health Canada to improve patient safety in clinical trials through improving the quality of Development Safety Update Reports

News story

The Medicines and Healthcare products Regulatory Agency (MHRA) and Health Canada have published guidance to improve the safety of patients in clinical trials through improved quality of the periodic safety reports known as Development Safety Update Reports (DSURs).

The Medicines and Healthcare products Regulatory Agency (MHRA) and Health Canada have jointly published new guidance to improve the safety of patients in clinical trials through improved quality of the periodic safety reports known as Development Safety Update Reports (DSURs). The guidance applies to both marketed and non-marketed medicines that are undergoing clinical trials.

Director of Licensing Division at MHRA Dr Siu Ping Lam said:

> This guidance will improve the safety surveillance of clinical trial participants in the UK.
>
> We are committed to working with international partners to increase the quality of the Development Safety Update Reports submitted to regulators.
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> This collaboration highlights the leading role we take in ensuring the safety of clinical trials globally.

DSURs review the safety of medicinal products used in clinical trials and are produced every year. At present, even though trial sponsors will have

conducted assessments regarding safety concerns, these detailed safety assessments are not always included in the DSUR. This makes it difficult for some regulators to find out if all safety concerns have been thoroughly investigated and whether appropriate measures have been taken to mitigate the risks associated with the use of the investigational medicinal products during a trial.

This guidance will improve transparency and ask sponsors to explain in the region-specific information section how they assessed the data included in the DSUR. The guidance builds on relevant existing international standards, including the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) guidance E2F, the Council for International Organizations of Medical Sciences (CIOMS) Working Group VII as well as each country’s relevant clinical trial legislation.

By increasing DSUR transparency requirements globally, patients’ safety is safeguarded, and regulators can monitor how safely medicines are being investigated. This joint publication with Health Canada reflects the UK effort to demonstrate how international collaboration contributes to international research, patient safety and global public health.

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