E19-Optimisation of safety data collection: Points to be considered

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Recognising that protection of patient welfare during drug development is critically important, unnecessary data collection may be burdensome to patients, and serve as a disincentive to participation in clinical research. Regulators and industry have a shared interest in reducing the burden to patients and facilitating the conduct of studies that could yield important new medical knowledge and advance public health. In the later stages of drug development, when the common side effects of a drug are well-understood and documented, a more targeted approach to safety data collection may be appropriate, as long as patient welfare is not compromised. Under such circumstances, some of the data routinely collected in clinical studies may provide only limited additional knowledge. These data may include: non-serious adverse events, routine laboratory assessments, physical examinations, vital signs, and concomitant medications. By tailoring safety data collection in some circumstances, the burden to patients would be reduced, a larger number of informative clinical studies could be carried out with greater efficiency, studies could be conducted with greater global participation, and the public health would be better served. A new guideline E19-Optimisation of Safety Data Collection is proposed by ICH to provide internationally harmonised guidance on when it would be appropriate to use a targeted approach to safety data collection in some late-stage pre-marketing or post-marketing studies, and how such an approach would be implemented. It is expected that consultation will be sought from patient representative(s) during development of the Guideline. As guidance is still in consultation stage, inputs from various patient groups and industry associations can enhance the effective utilization of resources. Selective safety data collection will facilitate the conduct of larger trials without compromising the integrity and the validity of trial results or losing important information, facilitate investigators' and patients' participation in clinical trials, and help contain costs.