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ファーマコビジランスの品質を定義する

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Definition of Quality of Pharmacovigilance Based on Processing of Individual Case Safety Reports

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Summary

Pharmacovigilance (PV) has become an important duty of the drug industry, but it is not yet clear how to evaluate the outcomes of PV activities. One of the main reasons is that the term "quality" is not clearly defined in relation to PV activities. We tried to define PV quality in a way that would allow us to evaluate the outcomes of the PV activities fairly and objectively, thereby providing a tool to optimize PV activities in terms of quality, cost, and time.

We developed a list of PV quality definitions consisting of 5 major categories: "accuracy", "deadline/speed", "rules/decision", "detection" and "information content" based on ICSR (individual case safety report) processing. These 5 major categories were subdivided into 13 medium categories and 37 small categories.

In order to verify that the 5 major categories cover all the qualities of the PV activities entrusted to a CRO, we examined past quality-undermining incidents to see whether they would all fit within the 5 categories. There were no entrusted services that could be categorized into "information content", but all other services fell within the other 4 categories.

We interviewed persons in charge of the PV departments of pharmaceutical companies and asked them to grade the importance of 13 activities (medium categories) on a scale of 0 to 10. All activities including "information content" were shown to be important. We were able to sort the activities by their importance.

The PV quality definition list that we have developed should be useful for quality evaluation and quality improvement of PV activities in the future.

Key words

Pharmacovigilance, PV Quality, Evaluation Index, Definition of PV Quality, Individual Case Safety Report (ICSR)