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Sample of Handling Safety Information Received in Clinical Trials

緊急報告のための基準 報告すべきもの 重篤で予測できない副作用は，全て緊急報告の対象となる。これには副作用の自発報告，及びデサイン，目的に関係なく全ての臨床試験または疫学研究中の副作用報告も含まれる。また，治験依頼者または企業に直接報告されない症例についても適用される（例えば出版物中に見られるものなど）。報告の情報源（臨床試験，自発報告など）は，常に明確にされるべきである。 重篤であっても予測できる副作用は，通常，緊急報告の対象とはならない。また，臨床試験中に生じた重篤な事象で当該医薬品との因果関係が否定されたものは，それが予測できるか否かとは関係なく緊急報告の対象とはならない。重篤でない副作用は，それが予測できるか否かとは関係なく，通常，緊急報告の対象とはならない。 治験依頼者または企業は，重篤で予測できない副作用の報告を受けた場合，それが緊急報告の必要条件に当てはまる内容の場合は，情報源が何であれ該当する規制当局に迅速に報告しなければならない。	Standards for Expedited Reports What should be reported Adverse drug reactions that are severe and cannot be expected are all subject to an Expedited Report. Included in these are spontaneous reports of adverse drug reactions, and all reports of adverse drug reactions in clinical trials or in epidemiological research regardless of the design or purpose. And, this is also applicable for patient cases that are not directly reported to the clinical trial sponsor or the company (for example, things seen in publications, etc.). The information source of the report (clinical trial, spontaneous report, etc.) should always be clarified. Adverse drug reactions that can be expected even though they are severe are not normally subject to an Expedited Report. Also, severe events that happened during a clinical trial and in which the causal relationship with the pharmaceutical product has been denied are not subject to an Expedited Report regardless of whether or not they could be expected. Adverse drug reactions that are not severe, regardless of whether or not they could be expected, are not normally subject to an Expedited Report. When the clinical trial sponsor or company has received the report of an adverse drug reaction that is severe and could not be expected, and when the details fit the conditions necessary for an Expedited Report, it must promptly report this to the applicable regulatory authorities whatever the source of the information may be.

治験における症例については，因果関係の評価がなされるべきである。治験担当医師または治験依頼者により当該医薬品と因果関係が示唆されると判断されたものは，全て副作用とみなされる。市販中の医薬品に関する有害事象の報告（自発報告）は，当該医薬品と因果関係がある可能性が大きい。 医薬品と事象との因果関係の大きさを記述するために多くの用語，尺度が用いられるが，「因果関係があるらしい」，「因果関係が疑われる」または「因果関係は否定できない」のような用語は，因果関係を示唆していると考えられる。	An evaluation of the causal relationship should be done for a patient in a clinical trial. Those for which it is judged by the clinical trial investigator or the clinical trial sponsor that a causal relationship with the pharmaceutical product is indicated are all considered to be adverse drug reactions. It is highly possible that there is a causal relationship with the pharmaceutical product for a report (spontaneous report) of an adverse event regarding a pharmaceutical product that is being sold on the market. There are lots of terms and measurements used to describe the magnitude of the causal relationship between the pharmaceutical product and the event, but terms such as “there seems to be a causal relationship,” “a causal relationship is suspected,” or “a causal relationship cannot be denied” are thought to indicate a causal relationship.