to calculate the posterior odds in favor of a particular drug being the cause of the adverse event; the posterior odds are calculated by considering 6 assessment subsets: "prior odds" as background epidemiological and clinical trials information, and 5 other dealing with case-specific information of possible differential diagnostic value ("likelihood ratios"); → see also ADVERSE DRUG REACTION, STANDARDIZED ASSESSMENT OF CAUSALITY (SAC).

- benefit-risk analysis → see DECISION ANALYSIS.
- Berkson's bias There is an increased chance that hospitalised patients will have other comorbid conditions in addition to the disease of interest, compared with the decreased chance that non-hospitalised patients will have more than one condition; → see also BIAS.
- beta error syn. type II error; "missed difference"; statistical risk of saying there is no difference between two treatments A and B when actually there is one (error of falsely accepting the NULL HYPOTHESIS HO; truth (ONE-SIDED): A > or < B, false judgment: A = B); therefore β is the probability of failing to detect, by mere chance, a treatment difference at least as large as the degree specified (DELTA VALUE) by the ALTERNATIVE HYPOTHESIS Ha; 1-b is usually referred to as the POWER of the statistical test, the probability of detecting the specified difference and, therefore, the probability of rejecting Ho when Ha is true; the probability for a β-error increases with a lower delta, smaller SAMPLE SIZE and larger VARIANCE of the measured (continuous) VARIABLES; → see also ALPHA ERROR, GAMMA ERROR.
- between-subject design opp. WITHIN-PATIENT D.; → see DESIGN.
- bias Errors due to incorrect assumptions (ICH E9: "systematic tendency of any aspect of the design, conduct, analysis, and interpretation of the results of clinical trials to make the estimate of a treatment effect to deviate from its true value"; frequent examples for bias are: recall b. = the more often a SUBJECT is asked the same question, the more likely are differences in the answer due to more intensive reflections or due to a better memory for findings which were important for the subject (which is not necessarily the case for controls, e.g. diagnosis or treatments in cancer); allocation b. = even drugs of the same substance class and being nearly identical may not be "allocated" by prescribing physicians in exactly the same way, new drugs are more likely to find their principle first uses in patients who have not responded satisfactorily to previously available drugs; attrition b. = biased occurrence and handling of protocol deviations and losses to follow-up; changing pattern b. = methods of diagnosis, techniques, treatments a.s.o. may change over time; confounding b. = one or more variable associated, independently

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Edward Parrish

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