h. Exclusion of study subjects because of failure to satisfy the inclusion criteria – the Florescu study

In a study of antibiotic treatment of *Staphylococcus aureus*, Florescu et al. (74) described the ITT group, modified ITT group, and a "microbiological evaluable group." The ITT group consisted of all randomized subjects. The modified ITT group consisted of all subjects who received at least one dose of study drug. The "microbiologically evaluable group" was defined as subjects who met inclusion/exclusion criteria, received no more than one dose of therapy for meticillin-resistant *Staphylococcus aureus* (MRSA) or vancomycin-resistant enterococci (VRE) infection after the first dose of the study drug, and exhibited a pre-therapy culture containing MRSA or VRE that was susceptible to both of the study drugs. This study demonstrates the fact-pattern where the investigator can configure specific definitions of the modified ITT group in order to suit the needs of a specific clinical trial.

i. Excluding subjects who took prohibited drugs during the clinical trial, or who withdrew consent – the Manegold study

In a study of lung cancer reported by Manegold et al. (75) the ITT group contained 117 subjects, but for the modified ITT analysis, the group contained fewer subjects (111 subjects). Thus, six subjects were excluded. The six subjects were excluded for various issues occurring after randomization. These were, taking drugs that were prohibited by the study protocol, declining Karnofsky Performance Status (76) and withdrawal of consent.

j. Excluding subjects who failed to receive the assigned treatment because of a mistake by the health care provider – the Berek study

In a study of ovarian cancer, Berek et al. (77) analyzed the data by modified ITT analysis. Modified ITT analysis was conducted only on subjects who received at least one dose of study treatment. Thus, subjects not exposed to any treatment were excluded from the analysis. According to the authors, the study was blinded using a third party pharmacist who prepared the treatment infusion bags. A few of the subjects were incorrectly started on and completed a full series of the opposite treatment than

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