about 50 AEs occur per study subject, with about 2000–3000 AEs in all during the lifetime of the clinical trial (280).

Personnel involved in recording, routing, and evaluating AEs include the study chair (a physician), data monitors, statisticians, as well as the IRB, Data and Safety Monitoring Committee (DSMC), and federal regulatory officials. To reveal one fine-grained detail of the process of AE reporting, this process may involve, "each night, an automated computer program e-mails the study chair, study statistician, and data monitor to notify them of any event that was reported the previous day and to report a cumulative summary of all events observed on that study" (281). Regarding the IRB, some clinical studies may require all AEs that are serious and unanticipated be reported to the IRB within 48 h of the event (282).

The "point man" in this scenario is the clinical research associate (CRA). The CRA (283,284) manages patient recruitment strategies to ensure target patient numbers are met, ensures that SAEs are reported according to standard operating procedures (SOPs), for any amendments to the Clinical Study Protocol, arranges monitoring visits at appropriate time intervals and writes monitoring reports, including deviations and deficiencies, and prepares follow-up letters to investigators, and tracks completed case report forms sent to data management, track issued and resolved data queries. In filling out the case report forms, the CRA records the name of the AE, for example, a seizure, vomiting, or anemia, when it occurred, when it was reported to the investigator, whether the AE was on-going, the severity of the AE, whether the AE can be attributed to the study drug or medical device, whether the AE resulted in hospitalization, or if the AE was reported to the Sponsor or to any regulatory agency (FDA, EMA), or if that particular AE was in the Consent Form (285).

b. The Data Manager's Tasks Include Documenting Missing Data

The data manager is an expert in computer systems, in capturing remote data, and in quality control. The data manager reports missing data and discrepancies to the principal investigator.

Data management also includes making certain that the names of adverse events, and the names of various medications, found on forms provided by various study sites, are consistent with standard names found in appropriate dictionaries. These dictionaries take the form of the MedDRA dictionary, which may be used

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