CHAPTER

6

Blinding, Randomization, and Allocation

I. INTRODUCTION

For any clinical trial, subjects must first be recruited and enrolled. Recruitment is the first step in a study subject's involvement in a clinical trial. Recruiting may involve an interview by a physician or by a clinical research associate (CRA). In a study of subjects enrolling in clinical trials, Wright et al. (1) administered a questionnaire and determined the reasons that motivate subjects to enroll. The most frequent reasons were the beliefs that, "clinical trials are important for future patients," "overall I have a favorable impression of my doctor," and because, "overall I have a favorable impression of the CRA."

Clinical trial design, at least in randomized double-blinded trials, involves randomization, allocation, blinding, and unblinding. The *open-label trial*, another type of trial design, does not involve blinding. In an open-label trial, the fact of whether any given subject receives the drug or control treatment is not shielded from study subjects and is not shielded from clinicians. Yet another type of trial, the *single-arm trial*, is distinguished by the fact that the study design involves only one arm, and not two or more arms, and does not involve randomization. Nonrandomized clinical trials involving two or more arms may also be conducted. But Llovet et al. (2) describe the likely consequence of conducting a nonrandomized study. This consequence is evidence (data) that is not robust, not sufficient to change the existing standard of care, and not sufficient to warrant drug approval.

The events of recruitment, randomization, allocation, drug administration, and unblinding, are indicated in the following time line:

[1]Wright JR, Whelan TJ, Schiff S, et al. Why cancer patients enter randomized clinical trials: exploring the factors that influence their decision. J. Clin. Oncol. 2004;22:4312–8.

[2]Llovet JM, Di Bisceglie AM, Bruix J, et al. Design and endpoints of clinical trials in hepatocellular carcinoma. J. Natl Cancer Inst. 2008;100:698–711.

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