



FIGURE 2.10 Schema showing a two-arm study. The schema shows the steps of stratification and randomization. The daily administration of bexarotene is unambiguous, as the schema shows a separate arrow for each of the 28 days of administration of this drug.

were different from each other in that different schedules were used for administering the drugs.

The three drugs shown on the schema, cisplatin, irinotecan, and etoposide, are small-molecule drugs. Subjects also received a fourth drug, granulocyte colony stimulating factor (G-CSF). G-CSF is a polypeptide, not a small molecule. For clarity in presentation, G-CSF is not shown on the schema. Blood samples and chest X-rays were taken at various intervals

(not shown). Blood counts were run twice a week, and chest X-rays were conducted once a week. Chest X-rays are used during the diagnosis and treatment of lung cancer (61).

g. Staging—The Blumenschein Schema

The schema of Blumenschein et al. (62) reveals three different steps in the trial design (Fig. 2.10). These are the steps to stratifying patients according to disease stage, the step of

⁶¹Gohagan JK, Marcus PM, Fagerstrom RM, et al. Final results of the Lung Screening Study, a randomized feasibility study of spiral CT versus chest X-ray screening for lung cancer. *Lung Cancer* 2005;47:9–15.

⁶²Blumenschein Jr GR, Khuri FR, von Pawel J, et al. Phase III trial comparing carboplatin, paclitaxel, and bexarotene with carboplatin and paclitaxel in chemotherapy-naive patients with advanced or metastatic non-small-cell lung cancer: SPIRIT II. *J. Clin. Oncol.* 2008;26:1879–85.