

with established standards for different stages for the cancer. By *restaging*, what is meant is repeating the determination of the size, number, and location of the tumors, and comparing these values with the standard for staging of the cancer in question. Staging encompasses the acts of determining whether the tumors are resectable, locally advanced, or metastatic. Staging can be accomplished using computed tomography, endoscopic ultrasound, and surgical evaluation.

### j. Decision Tree—The Baselga Schema

The schema of Baselga et al. (64) depicts two points where a decision needed to be made (Fig. 2.12). These two points are indicated by the forked arrows. The decision involved assessing the tumor's response to therapy (at that time point) for every individual patient. Based on the tumor's response, the patient was assigned to one of two different therapies.

The Baselga clinical trial could be characterized as a single-arm trial, because there was no control group and no placebo group. The goal of the trial was to detect correlations between gene expression, as determined by measuring gene expression in tumor biopsies, and positive response to drug treatment. The expression of 200 genes was measured, where these genes were chosen before the study. This clinical trial involved neoadjuvant chemotherapy. Neoadjuvant refers to the fact that chemotherapy was administered before surgery (not after surgery). Where the schema reads, "tumors shrink or remain stable" or "tumors progress," this indicates that the physician had examined the patient, determined the status of the tumors, and made the decision to use the treatment that is

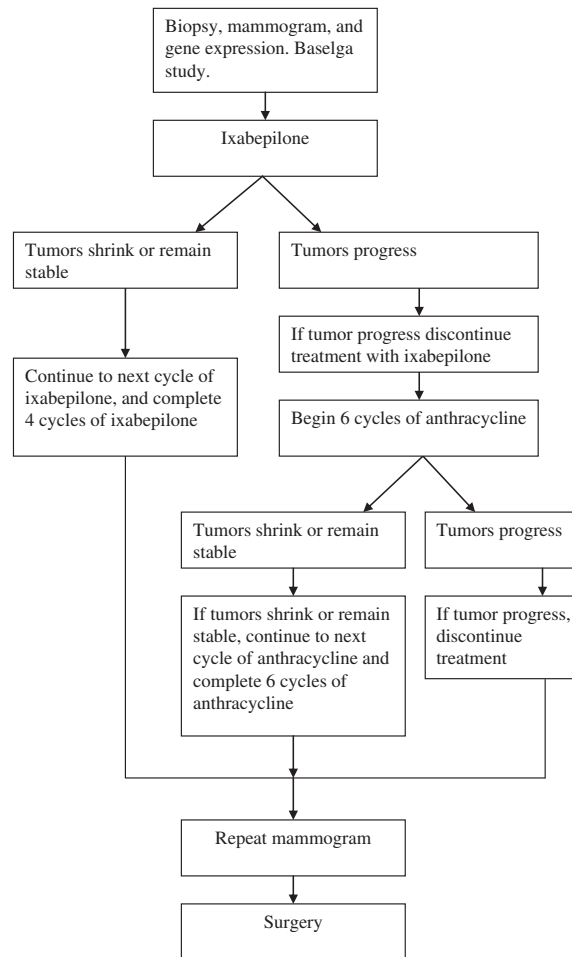


FIGURE 2.12 Schema with boxes showing decision points. Forked arrows indicate time points when tumors were assessed, and when a decision was made to proceed with the indicated course of action.

disclosed in the subsequent (lower) arrows on the flow chart.

Where the trial design includes a decision point or decision tree, the medical writer should use forked arrows in the schema to indicate the decision.

<sup>64</sup>Baselga J, Zambetti M, Llombart-Cussac A, et al. Phase II genomics study of ixabepilone as neoadjuvant treatment for breast cancer. *J. Clin. Oncol.* 2009;27:526–34.