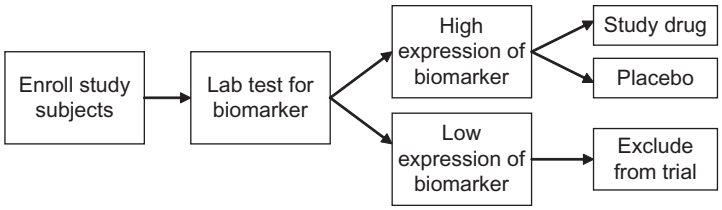

Figure 18.1 Biomarker can be used when determining inclusion criteria or exclusion criteria

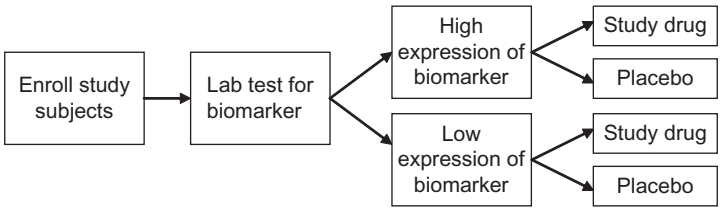

Figure 18.2 Biomarker can be used to stratify study subjects

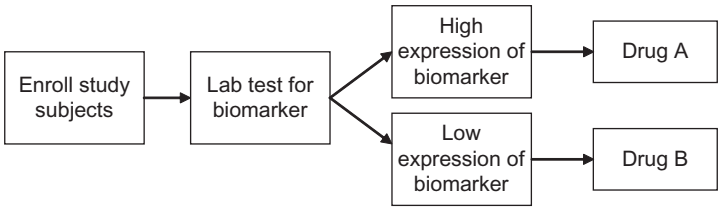

Figure 18.3 Biomarker can be used to dictate treatment

To summarize, colorectal cancer patients with KRAS mutations face two types of bad news. The first bad news is that these mutations are prognostic for worse outcome. The second type of bad news is that anti-EGFR is not indicated, where the cancer expresses KRAS that is mutated at codons 12 or 13.

b. Including biomarker tests in the study design

Biomarker status can be an integral part of trial design, that is, for dictating the nature of the study schema. As indicated by the three study schema, shown in Figs. 18.1–18.3, biomarker status can be used: (1) to serve as an inclusion or exclusion criterion (Fig. 18.1); (2) to stratify subjects (Fig. 18.2); and (3) to dictate the treatment, for example drug A versus drug B (Fig. 18.3) (20).

[20] Freidlin B, McShane LM, Korn EL. Randomized clinical trials with biomarkers: design issues. *J Natl Cancer Inst*. 2010;102:152–160.