



**Figure 14.1** Kaplan-Meier plot of the Romond study. Panel A shows results for disease-free survival. Panel B shows results for overall survival

## V. DISEASE-FREE SURVIVAL AS AN ENDPOINT IN THE ANALYSIS OF SUBGROUPS – THE ADD-ON BREAST CANCER STUDY OF HAYES

In a clinical trial of breast cancer by Hayes et al. (18) using the add-on drug of paclitaxel, patients received either doxorubicin plus cyclophosphamide (arm A) or doxorubicin plus cyclophosphamide followed by paclitaxel (arm B). This might be contrasted with the above-described study of breast cancer of Romond et al. (19) which also used an add-on study design. But in the case of the Romond study, the added drug was trastuzumab.

The Hayes study of breast cancer included patients with tumor biopsies that were HER2 positive and HER2 negative. All patients had completed surgery before starting the clinical trial and hence were considered to be free of disease. Tissue samples were considered to be HER2 positive if 50% or greater of the cancer cells stained with anti-HER2 antibody, and if the staining was of a 3+ intensity.

<sup>18</sup> Hayes DF, Thor AD, Dressler LG, et al. HER2 and response to paclitaxel in node-positive breast cancer. *New Engl J Med.* 2007;357:1496–1506.

<sup>19</sup> Romond EH, Perez EA, Bryant J, et al. Trastuzumab plus adjuvant chemotherapy for operable HER2-positive breast cancer. *New Engl J Med.* 2005;353:1673–1684.