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Createspace. Paperback. Condition: New. This item is printed on demand. 80 pages. Dimensions: 11.0in. x 8.5in. x 0.2in. Progression-free survival (PFS) is defined as the time from random assignment in a clinical trial to disease progression or death from any cause. PFS as an outcome is of interest to a variety of disciplines, most especially, for purposes of this project, to oncologists, pharmacologists, trialists, social scientists, and other scientists with interest in designing or interpreting clinical trials. Over the past 10 years there has been increasing interest in the use of outcomes other than OS to study new drugs, including PFS. The interest in PFS stems in part from the challenges associated with OS as an endpoint, but it has also been fueled by the fact that many new drugs are targeted toward molecular mechanisms of action that are cytostatic rather than cytotoxic. These drugs are not expected to provide the same objective response rates of earlier drugs, and instead act to prevent progression rather than cause tumors to regress and thereby impact mortality. Interest in PFS has also been sparked by the increasingly common use of treatment paradigms that allow for multiple rounds of drug treatment (first-, second-, third-, and even fourth-stage therapies), each producing incremental changes difficult to capture in the context of a single study using OS as the primary endpoint. In contrast, PFS can be studied in the short-term context of each treatment, without the confounding influence of the next. The FDA has recently published a regulation (21CFR813, subpart H) that allows the use of PFS or other surrogate clinical endpoints other than survival or irreversible morbidity in the accelerated approval of new drugs for serious or life-threatening illnesses. While this methods project focuses specifically on PFS, it is recognized that there is widespread interest in a...



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