

Oncology Endpoint: Disease-Free Survival

I. INTRODUCTION

The present chapter further develops the topic of oncology endpoints, and covers the fifth topic, as indicated by the check mark.

- Objective response
- Overall survival
- Progression-free survival
- Time to progression
- Disease-free survival ✓
- Time to distant metastasis

The FDA's Guidance for Industry recognizes the endpoint of DFS, writing, "DFS is defined as the time from randomization until recurrence of tumor or death from any cause" (1). Moreover, this particular FDA document (2) also informs us that, "[t]he most frequent use of this endpoint is in the adjuvant setting after definitive surgery or radiotherapy. Disease-free survival also can be an important endpoint when a large percentage of patients achieve *complete responses* with chemotherapy."

Disease-free survival takes into account the timeframe starting when a subject is rendered free of disease following therapy, until the cancer returns or until the subject dies. However, it is typically the case that the value for DFS is the timeframe from the date of randomization, through the treatment phase of the clinical trial, until relapse following primary treatment.

Regarding the event that tolls the endpoint of DFS, Wee et al. (3) state that, "[i]n the analysis of DFS, a patient was considered to have had an event if he relapsed after the completion of all primary treatment." Regarding the actual time that is measured by DFS, Wee et al. (4) further state that, "[t]he starting point for DFS was the date

¹ U.S. Dept. of Health and Human Services. Food and Drug Administration. Guidance for Industry. Clinical trial endpoints for the approval of cancer drugs and biologics; April 2005.

² U.S. Dept. of Health and Human Services. Food and Drug Administration. Guidance for Industry. Clinical trial endpoints for the approval of cancer drugs and biologics; April 2005.

³ Wee J, Tan EH, Tai BC, et al. Randomized trial of radiotherapy versus concurrent chemoradiotherapy followed by adjuvant chemotherapy in patients with American Joint Committee on Cancer/International Union against cancer stage III and IV nasopharyngeal cancer of the endemic variety. *J Clin Oncol.* 2005;23:6730–6738.

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