

Progression-Free Survival and Overall Survival in Oncology Studies

ABSTRACT

In Oncology Studies, OS has been considered as direct evidence of clinical benefit. In most studies, it has been used as the primary endpoint. However, it takes long to finish studies based on OS and thus delays the marketing. With the enactment of accelerated approval regulations, PFS, considered to be a surrogate endpoint, comes to accelerate approval and thus can make more profits for pharmaceutical companies. However, the relationship between PFS and OS has not been established.

In this summer, I have been working at FDA focusing on the relationship between Progression-Free Survival (PFS) and Overall Survival (OS) in oncology biologics.

There are two problems involved in this aspect.

First is a study on the issue whether censoring in PFS affects the OS time. Several past studies have been analyzed with SAS in Survival Analysis being used.

Second is a study on the functional relationships between PFS and OS in Comparison-level and Patient-level. Several simulations have been performed using R.

Also the legislature, biological and statistical background of my work will be introduced.