the hazard reduction by the control treatment. The numerical value can be a fraction of 1.0 or it can be greater than 1.0. For example, a hazard ratio of 0.70 means that the study drug provides 30% risk reduction compared to the control treatment (25). A hazard ratio of exactly 1.0 means that the study drug provides zero risk reduction, compared to the control treatment. The *P* value gives the probability of observing an event by chance alone, if the null hypothesis is true. The *P* value expresses the probability of observing a difference as extreme as that observed, if in fact the null hypothesis is true (26). If the *P* value from the study results is smaller than the alpha value, it is concluded that the observed difference is unlikely to be from chance, and that it arose from the treatment used in the clinical trial.

A Kaplan–Meier plot can be used to plot results from only one group. The Kaplan–Meier plot can also be used to plot results from two groups, for example, study drug group and control group. The Kaplan–Meier plot can also be used for data from more than two groups. But an hazard ratio is used to represent the relative difference between only two groups. Please also note that when the hazard ratio is used as a measure for the difference between two survival curves (on one Kaplan–Meier plot), the hazard ratio can be calculated from data collected from the entire study period or, alternatively, from an early time interval or from a late time interval (27). According to Dr Harvey Motulsky (28), the hazard ratio is only meaningful if you assume that the hazard ratio is the same at all time points.

II. DEFINITIONS AND FORMULAS

The following definitions and formulas are used to calculate the hazard ratio (29).

O_1 is the observed number of deaths at time t, for group 1.

O_2 is the observed number of deaths at time t, for group 2.

E_1 is the expected number of deaths at time t, for group 1, where this expectation is based on the number of deaths occurring in this group for the immediately previous time point (the time just before time t).

E_2 is the expected number of deaths at time t, for group 2, where this expectation is based on the number of deaths occurring in this group for the immediately previous time point (the time just before time t).

E_1 is calculated from the following formula (Eqn (9.1)):

$$E_1 = \sum \left[\frac{(r_{1i})(d_i)}{r_i} \right] \tag{9.1}$$

E_2 is calculated from the following formula (Eqn (9.2)):

$$E_2 = \sum \left[\frac{(r_{2i})(d_i)}{r_i} \right] \tag{9.2}$$

The term r_{1i} is the number of subjects alive and not censored in group 1, just before time t_i.

The term r_{2i} is the number of subjects alive and not censored in group 2, just before time t_i.

[25]Kane RC. The clinical significance of statistical significance. The Oncologist. 2008;13:1129–1133.

[26]Kane RC. The clinical significance of statistical significance. The Oncologist. 2008;13:1129–1133.

[27]Kestenbaum B. Epidemiology and biostatistics: an introduction to clinical research. New York, NY: Springer; 2009. p. 227–28.

[28]Motulsky H. E-mail of May 9, 2011.

[29]Machin D, Gardner MJ. Calculating confidence intervals for survival time analyses. Brit. Med. J. 1988;296: 1369–71.