Registration Enabling Seamless Phase 1/2 Oncology Trial Design

Lei Cao

Changchun University of Technology
E-mail: caol661@nenu.edu.cn

Abstract: Motivated from the AppRise data, we develop the autoregressive models for the item response and the response time jointly. One of the novelty of the proposed models is to account for the dependence for each of the item response and the response time as well as the dependence between the item response and the response time due to the sequential nature of the AppRise data. In addition, a new deviance information criterion (DIC) and the logarithm of the pseudo-marginal likelihood (LPML) are constructed by integrating out subject-specific ability parameters and speed parameters. We further derive novel decompositions of DIC and LPML into two components, namely, the marginal DIC and LPML and the conditional DIC and the conditional LPML. These new conditional DIC or the conditional LPML can be used to assess the gain in the fit of the response data by using the response time data. We further compute the concordance measures for the response data as well as the response time data. These concordance measures are further used to confirm the gain in the fit of the response data jointly modeled with the response time. A detailed analysis of the AppRise data is carried out to demonstrate the applicability and usefulness of the proposed methodology.