

Statistical Issues in the Evaluation of Blood Products

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Biologics License Application (BLA) for biologics products are submitted to the Center for Biologics Evaluation and Research (CBER) of the US Food and Drug Administration (FDA) for review. The Office of Blood Research and Review (OBRR) within CBER review blood and blood related products. An overview of blood and blood related products will be presented. Statistical issues in the evaluation of these products will be discussed. More specifically, three issues will be discussed: (i) Repeated measures with binary data, (ii) specification of acceptance criteria, (iii) multiple testing.

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