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1. Appendix A

Relationship between the Overall Treatment Effects and the Regional Treatment Effects. Let K be the total number of participating regions and m_i be the total number of patients in the i^{th} region $(i = 1, 2, \ldots, K)$. The difference in the treatment effects between the test product and the placebo in all participating regions (Δ) can be expressed as follows.

$$\Delta = \mu_T - \mu_P$$

$$= \frac{1}{\sum_{i=1}^{K} m_i}\left[\sum_{j=1}^{m_1}(X_{1j} - Y_{1j}) + \sum_{i=2}^{K}\sum_{j=1}^{m_i}(X_{ij} - Y_{ij})\right]$$

$$= \frac{m_1}{\sum_{i=1}^{K} m_i}\frac{\sum_{j=1}^{m_1}(X_{1j} - Y_{1j})}{m_1} + \frac{\sum_{i=2}^{K} m_i}{\sum_{i=1}^{K} m_i}\frac{\sum_{i=2}^{K}\sum_{j=1}^{m_i}(X_{ij} - Y_{ij})}{\sum_{i=2}^{K} m_i}$$

$$= \lambda_1\Delta_1 + (1 - \lambda_1)\Delta_{1c}$$

Where,

$$\lambda_1 = \frac{m_1}{\sum_{i=1}^{K} m_i}, \text{Ä}_{1} = \frac{\sum_{j=1}^{m_1}(X_{1j} - Y_{1j})}{m_1}, \text{Ä}_{1c} = \frac{\sum_{i=2}^{K}\sum_{j=1}^{m_i}(X_{ij} - Y_{ij})}{\sum_{i=2}^{K} m_i}$$