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The discrepancy in the relative frequencies of reported complications:

$$\Delta := \left| \frac{Y_1 + Y_2 + \cdots + Y_n}{n} - \frac{Z_1 + Z_2 + \cdots + Z_n}{n} \right|$$

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The heart of the matter:

How likely is that the discrepancy Δ in outcomes between patients given the drug and the placebo is due to just chance fluctuation?