



MMS Support for NCE Data Review

CHALLENGE

During the data review of a New Chemical Entity (NCE), an increased incidence of tumors was observed in one Phase 3 study by the sponsor and the MMS team supporting the submission. The disproportion between the placebo and drug-treated groups in the study raised concerns.

MMS SOLUTION

MMS worked with the sponsor's safety team to analyze the issue in detail. The team reviewed clinical databases and ARGUS data over a 10-year development period and used multiple dictionaries to harmonize terminology. Subsequently, MMS assembled a team of oncologists to evaluate the entire program. The oncologists conducted an unbiased review with causality reporting, investigated the mechanistic aspects of tumor types, and developed a comprehensive report with expert arguments.

OUTCOME

The sponsor had an advisory committee in the US for this compound and determined that the NCE could not be clearly implicated for the incidence increase. Consequently, the NCE received approval without any additional label language.

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