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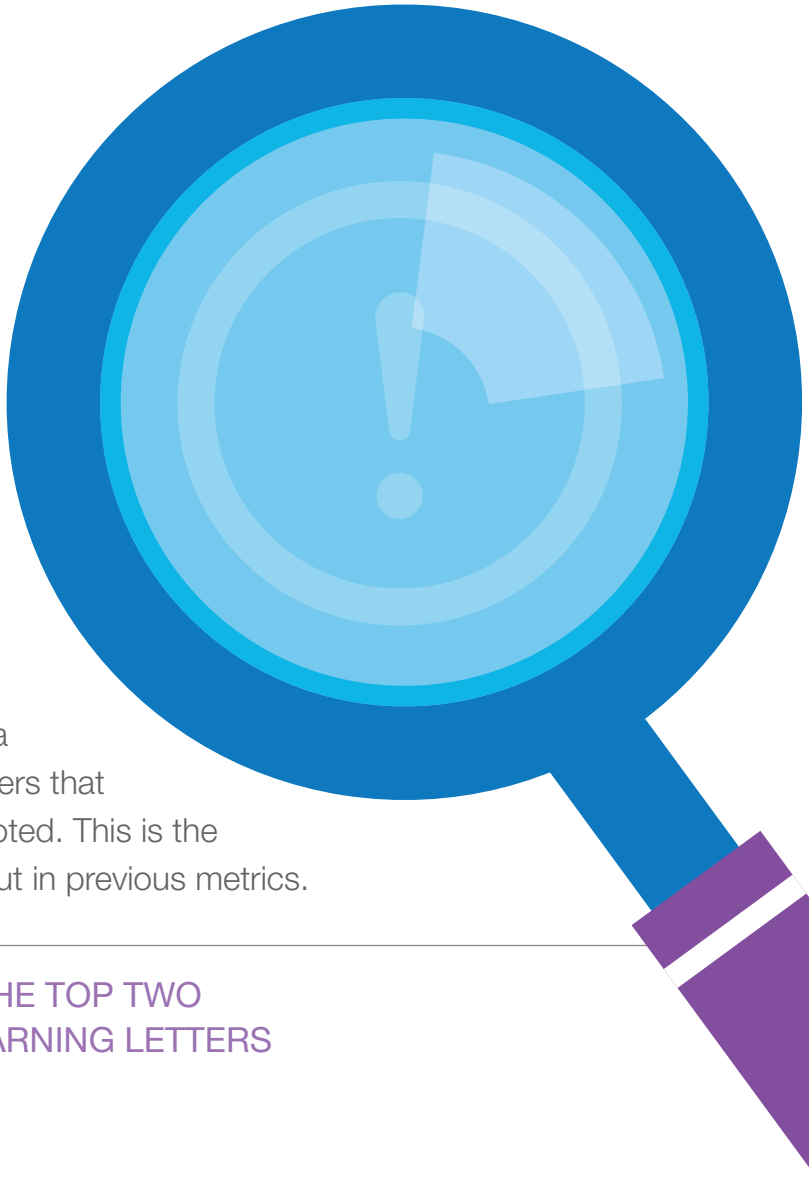
2015 FDA WARNING LETTER

FINDINGS FOR CLINICAL INVESTIGATORS, SPONSORS, AND IRBS

IMARC's Top FDA Warning Letter Findings for Clinical Investigators for Fiscal Year 2015 are in!

After a thorough review of the Food and Drug Administration (FDA) warning letters that were issued to CIs, we have compiled our list of the most frequent findings! In fiscal year (FY) 2015, it was found that only five warning letters were issued to CIs as a result of the FDA's Bioresearch Monitoring Inspectional Program (BIMO).



The purpose of the BIMO program is to inspect FDA-regulated clinical trials to ensure the rights, safety and welfare of human research subjects have been protected and that the validity of research data is accurate to support a marketing application. When serious violations are found during a BIMO inspection, a warning letter is issued. Of the five warning letters that were issued, only two different citations were noted. This is the lowest number of citations we have seen yet, but in previous metrics.

ON THE NEXT PAGE IS A SUMMARY OF THE TOP TWO CITATIONS THAT WERE NOTED IN THE WARNING LETTERS

NUMBER TWO

Failure to maintain adequate and accurate case histories that record all observations and other data pertinent to the investigation on each individual administered the investigational drug or employed as a control in the investigation

(NOTED IN TWO WARNING LETTERS)

A. Failure to maintain adequate and accurate case histories with respect to these study records

B. Failure to document dates related to serious adverse events

NUMBER ONE

Failure to ensure that the investigation was conducted according to the investigational plan

(NOTED IN FIVE WARNING LETTERS)

A. Failure to perform tests at scheduled time points

B. Failure to report serious adverse events within a specified timeframe

C. Failure to verify that subjects meet eligibility criteria

D. Failure to follow the protocol-specified order of study drug administration

E. Failure to collect the protocol-specified screening samples

FDA publishes inspectional metrics on the website each year. For 2015, 1388 BIMO Inspections were completed, with 822 of them for Clinical Investigators. 3% of the Inspections resulted in Official Action Indicted and 33% had Voluntary Action Indicated.
If FDA inspected your study, what would your outcome be?

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