Onsite Serious Adverse Events Reporting: A Seven Year Experience of Institutional Ethics Committee of a tertiary care hospital.

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Abstract

Aims: Over the years, Indian regulations have undergone numerous amendments including stringent reporting deadlines, relatedness requirements, and compensation obligations for Serious Adverse Event (SAE). A historic change, New drugs and trial rules- 2019 was proposed on 19th March 2019. Study aimed to ascertain whether various stakeholders were reporting in accordance with the evolving SAE criteria. Methods: Data was retrieved after Ethics approval between August 2014 and December 2021. Data gathered before 19th March 2019, was categorised as "BEFORE" data while remaining data was categorised as "AFTER". Utilising causality, on-site SAE reporting, and the ethics committee review procedure, we evaluated the compliance. The data was evaluated using descriptive statistics, appropriate statistical tests were used to compare the "BEFORE" and "AFTER" groups. Results: A total of 163 (6.9%) of 2361 studies were drug trials. 26 clinical trials with 77 SAE, 92.3% of which were in Phase-III. Endocrine projects made up 9/26 (34.61%). In the cardiology studies, the greatest SAE distribution was 21 SAEs/ 89 participants (23.59%) with approximately 48% of these being vascular. The "AFTER" group noticed a decrease in the total number and length of SAE sub-committee meetings. In the "AFTER" group, there was significantly higher median number of agenda items/ meetings [8 (4.5 – 10.75)] ($p<0.0001$). The median interval between the onset of SAE and the first reporting date, however, was just 1 day [IQR: 1-5 days]. In non-death SAEs, there was no significant difference in the compensation paid. Conclusion: There is acceptable adherence to SAE reporting criteria.

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