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Patient safety violations and poor record keeping common in clinical trial concerns

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Failure to protect patient safety and poor record keeping were among the most common violations picked up by the US regulator in the running of clinical trials over a period of seven years, reveals a study published online in the *Journal of Medical Ethics*.

The study authors reviewed the content of 84 first warning letters issued by the United States Food and Drug Administration (FDA) following site visits to 46 trial sponsors, 20 lead researchers, and 18 institutional review boards, which assess and monitor safety, between 2005 and 2012.

The analysis revealed that the most common concern raised among clinical trial sponsors was a failure to monitor progress according to the stated schedule (58+%), followed by a failure to obtain the agreement of the principal investigator (35%). One in four of these warnings concerned new drug studies; the rest related to devices.

The most common concerns raised by the FDA to lead researchers were failure to adhere to the stated plan for the investigation (95%) and failure to protect the safety of trial participants, including the reporting of side effects (55%). Some 40% of warnings additionally concerned poor record keeping. Most (80%) of the warnings related to drug trials.

The most common reason for warning institutional review boards (61%) was a failure to follow standard operating procedures and inadequate record keeping (55%).

The researchers compared their findings with previously published research in the same arena, dating back as far as 1997. They found that while regulatory compliance had generally improved, supervision had worsened.

And two new serious violations had cropped up in the interim: failure to get the green light from an institutional review board before pressing ahead; and submitting false data to the FDA and/or sponsors.

In a bid to boost compliance with good clinical practice, the authors suggest that every regulatory agency charged with overseeing clinical trials should pay main participating centres a visit, and regularly publish details of their findings.

"Fair and appropriate procedures for handling violations during clinical trials need to be developed and implemented globally in order to protect human rights, wellbeing and safety, and to raise awareness of ethical behaviour," they conclude.

More information: Analysis of warning letters issued by the US Food and Drug Administration to clinical investigators, institutional review boards and sponsors: a retrospective study, DOI: 10.1136/medethics-2013-101829

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