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Fraud and misconduct of clinical trials

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Fraud and misconduct in the research community occur more often than we would wish to believe. While it is impossible to provide a definitive figure for the frequency of its occurrence surveys provide us with consistently (and perhaps surprisingly) high estimates. Fraudulent clinical research affects the validity of data and impacts on the dignity, rights, well-being and safety of research participants. There are a variety of definitions of fraud and scientific misconduct. Often, the terms 'fraud' and 'misconduct' are used interchangeably. Generally, fraud describes acts of omission and commission, consciously not revealing all data and consciously altering or fabricating data. Such falsification of data can occur at any stage of the research process, from initial design through to reporting results. Fraud does not include honest errors or differences in opinion and the usual definitions include an element of intent. Repeated non-compliance with the study protocol and GCP may be considered as an example of misconduct, although the end result may well be similar to deliberate fraud. There are examples, from the beginning of a clinical trial to submission of a final manuscript, of dishonesty and deceit in general practice and primary care research. Patients have been invented to increase numbers (and profits) in clinical trials, ethical guidance on consent and confidentiality have been breached, and duplicate publication crop up from time to time. It is important for us all to be aware of the legal and ethical frameworks within which research is undertaken and of the steps that are available to prevent fraudulent and dishonest research being undertaken and written up.

Biography

Rucha Majmundar Mehta is an Independent GCP auditor (Free Lancer) since 8 years. She developed a Clinical Research Site in a privately owned small sized hospital and heading the site till date. She is providing QA consultation and training to various study sites and QA department of Pharmaceutical Companies. She conducts GCP Sessions during Investigators Meetings globally. She has participated in State, National and International Conferences of Clinical Research as a faculty. She is conducting GCP workshops for Clinical Research Professionals for on-going basis and during conferences. She is active member of EFGCP–AWP and RQA.

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