

India's Clinical Trial Regulatory Changes, Indian Researchers' Awareness of Recently Changed Regulations, and the Impact of the New Drugs and Clinical Trial Rules

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Abstract

Medical companies consider India is above other countries worldwide as an alternative nation for clinical trials due to easily available sources and infrastructure. However, the developing Indian clinical trial industry has been negatively affected by noncompliance with regulations and by reports of unethical trials. Several studies on Indian clinical trial regulations have been conducted and various articles have been published, but only a few researchers evaluated awareness of investigators and members of the ethics committee about previously amended regulations. No study evaluated the knowledge of researchers on the new drugs and clinical trial rules (NDTC Rules) issued in 2019 and also its impacts. Understanding the knowledge of Indian researchers on NDTC Rules, including its effect is crucial to determine whether the trials are being conducted in compliance with the new rules and regulations. Thus, this review aimed to evaluate India's clinical trial regulatory changes based on the existing literature, Indian researchers' knowledge of the recent changes, and assessment of the impact of the new 2019 regulations, elaborating upon clinical trials in both the global and the Indian context.



Biography:

Vishal Vennu received a bachelor's degree in microbiology from Osmania University in 2002 and a master's degree in clinical research from Sikkim Manipal University in 2010. His work toward a doctorate (Ph.D.) in Clinical Research from Lingaya's Vidyapeeth, India, is ongoing. He has expertise in clinical trials, data management, statistical analysis, and scientific writing. In 2010, he received an award for excellent work and collaboration in the LV Prasad Eye Institute Rub & Rinse study in Hyderabad, Prof. Brien Holden Vision Institute, Australia. So far, he has published more than 20 articles in peer-reviewed international journals.



Speaker Publications:

- 1 "Longitudinal Effects of Physical Inactivity and Obesity on GaitSpeed in Older Adults with Frequent Knee Pain: Data from theOsteoarthritis Initiative", Int. J. Environ. Res. Public Health 2015,12, 1849-1863;doi:10.3390/ijerph120201849
2. "Efficacy of music listening with conventional physiotherapy management on sub-acute stroke patients", Scientific Journal of Medical Science (2013)2(8) 159-164.
3. "Stroke rehabilitation: A call to action in Saudi Arabia", Neurosciences 2016; Vol. 20 (4).
4. "Are Physical Therapy Interns Competent in Patient Management Skills? Assessment of the Views of Clinical and Academic Physical Therapists", J. Phys. Ther. Sci.25: 649-655, 2013.

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