Since January 2020 Elsevier has created a COVID-19 resource centre with free information in English and Mandarin on the novel coronavirus COVID-19. The COVID-19 resource centre is hosted on Elsevier Connect, the company's public news and information website.

Complexity of clinical trial operationalisation in India

Abhinav Bassi and colleagues (March, 2022)[1] discuss the challenges unique to India in operationalising clinical trials during the COVID-19 pandemic. Ethics committees in India face several challenges, such as lack of adequately trained staff, extensive workload, inadequate space allocated for operations, and a scarcity of administrative support. Committees have difficulty recruiting members who are not affiliated with their team, and seem to function in isolation as self-sufficient bodies that have no communication with the Central Drugs Standard Control Organisation, the Department of Health Research, or other ethics committees.[2] There is an urgent need to establish a consultative mechanism that enables ethics committee members to raise their concerns, and members should be afforded time to complete their research oversight roles. The cultural and linguistic diversity of India, where more than 22 official languages are spoken, adds to the challenge of maintaining uniformity across different ethics committees.

Involvement of health-care units in remote areas and smaller health-care units in the clinical research process is welcome. However, as a result of the fragmented health-care system in India, several barriers exist with regard to expanding the number of research sites.[3] Any unilateral decision by the Ministry of Health and Family Welfare to involve smaller public health units would be considered an additional burden by the health-care workforce that is already overworked and understaffed. For example, the Central Government Health Scheme wellness centres across India function as general practice units and provide comprehensive primary care.[4] As the first point of contact for registered patients, these units would be ideal for evaluating several interventions at the primary care level. However, a collaborative approach and open dialogue with the health-care workforce would be needed to facilitate their participation in the clinical research process.

In the past decade, clinical trials have been the subject of intense scrutiny in India. Trials are often projected as a commercial activity by the media instead of a scientific endeavour to answer public health questions. The discourse has to move towards helping the public make informed choices about trial participation. In this regard, it is commendable that the Indian Council of Medical Research has launched a pan-Indian network of clinical trial sites.[4] The network will conduct large-scale multicentre clinical trials in India in a timely and well-regulated manner. We hope that the network is successful and addresses the crucial research needs of both the country and the world.

We declare no competing interests.

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