FROM THE EDITOR’S DESK

Clinical Trial Registry in Pakistan

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The Short Communication on Clinical Trial Registry by Muhammad Osama et al.¹ in this issue of JPMA is a food for thought for all researchers in Pakistan. Clinical Trial Registration is mandatory all over the world. The trial has to be registered according to the laid down rules by the regulatory offices of ICMJE, WMA, WAME and COPE besides many other international institutions. According to the law, a trial cannot be commenced until the application made is considered and approved and a TRIAL NUMBER is provided.

On completion of the Trial, the manuscript is submitted to a journal for publication. All biomedical journals can only accept RCTs when a Trial Number is present.

As stated in the short communication by Osama et al. there is no public trial registry in Pakistan. Earlier an editorial by Akhter Sherin published in the Khyber Medical University Journal in 2012,² brought up this important issue of the lack of a Trial Registry in Pakistan.

As a journal editor, it was rather perplexing for me to decide the fate of RCTs being submitted to the Journal of Pakistan Medical Association for considering publication. Trial Numbers were not provided and a written statement was given by the chairman of the respective Ethics Review Board, that due to non-existence of such an authority in Pakistan, the trial was approved by the Institution’s ERB.

Lately, it was by accident I happened to meet a senior official of the Drug Regulatory Authority of Pakistan and this subject was discussed. He said that DRAP was the registration body for RCTs and a legislation had been made in 1976. I later looked into the website of DRAP and rightly there was the document titled, “Steps involved in processing of clinical Trial Application”, dated April 10, 2017 (Version 1.0).

It is surprising that no institution in the country is aware of this service. I contacted a number of senior researchers and faculty members on this subject but there was no knowledge on this function of DRAP. The question arises as to who is responsible for dispersing the source of this important legislation. Does DRAP have the responsibility of letting the educational institutions know about their duties or otherwise how do the universities learn about it. Also it should be noted that the document on the DRAP website is dated April 10, 2017. What was the state of affairs before this date?

References