

## Letter to the Editor

# Indian physicians' perception of clinical trials

Sir,

The successful completion of clinical trials depends largely on the active participation of physicians. Tharyan has discussed at length, the opportunities, obligations, challenges, and solutions of conducting clinical trials in India.<sup>1-4</sup> In this regard, an online survey was conducted by Docplexus to measure the physicians' awareness, understanding, and inclination towards the involvement in conducting clinical trials in India.

Docplexus conducted a survey on 463 doctors specializing in Pharmacology/Clinical Pharmacology, General Medicine, Cardiology, Orthopedics, Neurology and Urology to understand their inclinations and concerns regarding clinical trials in India. A total of 53 doctors completed the survey. The data obtained from the survey was collected and analyzed to evaluate the parameters involved in inclination or aversion of physician participation and deduce perception.

### *Physicians' awareness & participation*

Robust infrastructure and active participation of physicians and patients is the key to successful completion of clinical trials. Active physician participation is of paramount importance for gaining maximum insights on clinical trial outcomes. However, in India, the situation is not as simple and straightforward. Only 53% physicians access the data from available clinical trials on regular basis, whereas 32% physicians refer to the trial outcomes for evaluation and management in specific cases. 16% doctors refer to the clinical trial data only rarely whereas approx. 5% doctors do not refer to the trials in their practice at all. These data indicate that referring the available trial literature is still not the part of routine clinical decision-making process. Hence, active participation in such trials is an unreasonable expectation. This lack of interest and participation could be the composite effect of several factors governing the Indian healthcare.

From the survey analysis, it can be established that 75% Indian physicians are aware of regulatory requirements of clinical trials. However, among all the physicians who took the survey, only 38% physicians have participated in the clinical trial in their career, although the others (42%) indicated their willingness in participation. Further, out of total participating physicians, 63% have been involved in phase 1, 25% in phase 3 and 13% in phase 4 clinical trials.

### *Physicians' perception of trial participation*

The need of conducting clinical trials revolves around the diverse physician perceptions on improving current clinical practice. Approximately half the doctors state that referring Indian trials for treating local population may aid in better management of highly prevalent diseases using the data obtained from same ethnic groups. According to 23% doctors, Indian clinical trial data may help in providing updates on a specific drug efficacy and safety profiles and pleiotropic benefits for the Indian patients. As many as 15% physicians opine that the outcomes of a clinical trial conducted in the Indian population may trigger revising the drug labels for side-effects and contraindications. Further, 13% doctors suggest that conducting clinical trials targeting different age groups is a possibility in India owing to the wide age demography assisting the age-appropriate dosage standardization.

Despite the persisting interest, certain lacunae exist in the Indian healthcare system that holds Indian physicians from participating in clinical trials. Most physicians believe that stringent laws and tight regulations (30%), followed by lack of funding to the pharmaceutical agency and incentives to academicians (26%) are major hurdles in conducting clinical trials in India. Further, several doctors report (24%) the lack of interest among physicians for participation in such trials. Patient engagement is yet another hurdle the physicians think which exists in conducting a clinical trial in India.

The survey suggests physicians (31%) believe that the educational assistance on regulatory requirements and trial designs may help in improving their participation and an overall understanding of clinical trials. The physicians are also interested in information on novel therapeutics (26%) and updated clinical outcomes of existing therapies (43%) in the Indian context. Further, although India has a large pool of patients and medical infrastructure, the revisions in the policies (2013) that revamped the laws pertaining to informed consent and monetary compensations, drastically reduced the number of clinical trials and halted the progress of the existing trials.<sup>5,6</sup> The government of India has now undertaken the initiative to formulate the policy on conducting clinical trials making them more practical, transparent and efficient, with better patient safety checks.<sup>7</sup> Persistent awareness of such reforms in India may establish a common platform bringing together the patient, physicians as well as pharmaceuticals to function in the most optimum manner.

Evidence-based practice is the core of modern medicine. With a huge population base, medical infrastructure, and booming pharmaceutical industry, India can become global capital for conducting clinical trials. According to physicians, well-planned government initiatives can make the environment conducive to the overall health outcomes.

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