The difference in views of various researchers about changes in the new drugs and clinical trial rules in India

Vishal Venu¹, Prem Saini¹, Karan Singh²

¹School of Pharmacy, Lingayas Vidyapeeth, Faridabad, Haryana-121002, India
²School of Basic and Applied Sciences, Lingayas Vidyapeeth, Faridabad, Haryana-121002, India

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ABSTRACT

Some studies detailed the awareness and opinions of investigators and the members of the ethics committee about the previous rules. However, no study surveyed the differences in views of various researchers (such as investigators, co-investigators, members of the ethics committee (EC), research assistants, coordinators, associates, and managers) about the new drugs and clinical trial rules (NDCT Rules). The current study aimed to address this gap. In this online survey, a total of 106 various researchers were chosen randomly from different sources across India between July 2019 and September 2019. The various researchers classified into the following three groups based on their job role: investigators or co-investigators (n=24), members of the ethics committee (n=21), and other researchers (n=61). The difference in views of various researchers has shown in percentages. Out of 106 various researchers, most of the investigators or co-investigators significantly reported that the changes in reducing clinical trial timeline (87.5%, p<.0001) and equality are proper (87.5%, p= 0.028). However, the majority of other researchers significantly said that the severe adverse events report and compensation are adequate (78.6%, p = 0.005). Overall, the majority of members of the ethics committee significantly reported neutral about the changes in NDCT Rules (85.7%, p = 0.037). The results of this study indicate that there is a significant variation in the views of different researchers about the changes of NDCT Rules. Future study is required on the larger sample at a national level to generalize the views of various researchers on the topic.

INTRODUCTIONS

The multinational pharmaceutical companies consider that the Indian market an appropriate ground for clinical trials compared to the other countries worldwide (Fernandes et al., 2019; Porter, 2018). India is the second most populous developing country with various geographical conditions and low-cost infrastructure, and professionals’ availability (Rick, 2015). Thus, various multinational pharmaceutical companies have begun to consider outsourcing clinical trials to India (Splinter et al., 2010). Currently, India is known as a hub for the clinical trial industry (Fernandes et al., 2019; Porter, 2018). However, specific unethical clinical trials on human beings have been reported because of the failure to comply with the clinical trial regulations issued earlier (Gulhati, 2004; Yee, 2012). Therefore, the Indian government had addressed these issues based on an exceptional level of investigation and issued the
new drugs and clinical trial rules (NDCT Rules) (Yee, 2012) as per the recommendations from an expert committee (Chatterjee, 2013). These NDCT Rules aims to ensure clinical trial’s timelines reduction, equality, and adverse severe events compensation by protecting the welfare, well-being, and safety of the participants, specifically vulnerable peoples. Also, NDCT Rules aim to advance the clinical trial industry in the country. Therefore, it is essential to know the views of researchers about the NDCT Rules (Shivayogi, 2013).

Because their views are necessary to decide whether the trials are being conducted as per the NDCT Rules, moreover, these professionals perform an indispensable role in documenting and reporting unethical clinical trials, notably on vulnerable peoples (Shivayogi, 2013). Some earlier studies have detailed the awareness and opinions of investigators and the members of the ethics committee about the past rules (Davis et al., 2017; Kadam et al., 2016; Parikh et al., 2011). However, no study surveyed the views of various researchers about the NDCT Rules. The current study aimed to address this gap by knowing the differences in views of various researchers, such as investigators, co-investigators, members of the ethics committee, research assistants, coordinators, associates, and managers.

MATERIALS AND METHODS

This study was conducted according to the Checklist for Reporting Results of Internet E-Surveys (CHERRIES) (Eysenbach, 2004) and methodology used in previous studies (Eysenbach and Wyatt, 2002; Ritter et al., 2004).

Study population

In this online survey, various researchers (n=106) were chosen randomly from different sources across India between July 2019 and September 2019. According to researchers job role, the various researchers classified into the following three groups: investigators or co-investigators (n=24), members of the ethics committee (n=21), and other researchers (n=61). Various sources are described as the source of the Indian Society for Clinical Research, personal networks, hospitals, institutions, and LinkedIn. The details about the survey questionnaire development and data collection procedure were reported in our case study (Vishal and Dahiya, 2020). The protocol about the intended survey (Vishal and Saini, 2020) was submitted to the independent institutional ethics committee. The committee was excused from the evaluation process because it did not require participants signed informed consent. This study was exempted from the ethics committee’s inspection because of an observational survey involving minimal risks to participants (Grady, 2015). No informed consent was required because it was anonymous data, i.e., no personal data was collected from the target persons.

Outcome

The outcome of this study was an enhanced understanding of the differences in views of various researchers about the changes of NDCT Rules, such as reducing timelines, free post-trial drug access, clinical trial approval validity, welcoming equality, serious adverse event reporting, and compensation.

Analysis

The statistical analysis software (SAS) version 9.4 for Windows (SAS Corporation Inc., NC, USA) was utilized for all the analyses. Descriptive statistics, such as means and standard deviation (SD) were calculated for continuous variables. In contrast, counts and percentages were used with categorical variables. All the outcomes were presented in percentages. Analysis of variance tests for continuous variables and chi-square tests for a categorical variable was used to determine the statistical significance between the differences in views of various researchers. A p-value 0.05 or less was defined as statistically significant.

RESULTS AND DISCUSSION

Table 1 shows the characteristics of various researchers. Out of 106 various researchers, 22.6 percent investigators/co-investigators, 19.8% members of the ethics committee and 57.5% other researchers, such as research assistants, coordinators, associates, and managers. The members of the ethics committee were significantly older than the other researchers. The majority of other researchers were from south India (21.7%).

Figure 1 presents the percentage of differences in views of various researchers about the changes in NDCT Rules. Most of the investigators or co-investigators significantly reported that the changes in reducing the clinical trial timeline (87.5%, p <.0001) and equality are proper (87.5%, p = 0.028). However, the majority of other researchers significantly said that the severe adverse events report and compensation are adequate (78.6%, p = 0.005).

Figure 2 illustrates the percentage of the overall difference in views of various researchers about the changes in NDCT Rules. The majority of members of the ethics committee were significantly reported neutral about the changes in NDCT Rules (85.7%,...
Figure 1: The percentage of differences in the views of various researchers.

Table 1: Demographic characteristics of the study samples according to their job role.

<table>
<thead>
<tr>
<th>Variable</th>
<th>Total (106)</th>
<th>Investigators or Co-investigators N=24 (22.6%)</th>
<th>Members of the Ethics Committee* N=21 (19.8%)</th>
<th>Other researchers** N=61 (57.5%)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age in years, mean (SD)</td>
<td>35.5(14.3)</td>
<td>41.3(16.3)</td>
<td>30.1(6.2)</td>
<td>0.003</td>
<td></td>
</tr>
<tr>
<td>Sex, n(%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>0.162</td>
</tr>
<tr>
<td>Men</td>
<td>73(68.9)</td>
<td>20(18.9)</td>
<td>15(14.1)</td>
<td>38(35.8)</td>
<td></td>
</tr>
<tr>
<td>Women</td>
<td>33(31.1)</td>
<td>4(3.7)</td>
<td>6(5.7)</td>
<td>23(21.7)</td>
<td></td>
</tr>
<tr>
<td>Regions, n(%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>0.003</td>
</tr>
<tr>
<td>North</td>
<td>28(26.4)</td>
<td>5(4.7)</td>
<td>4(3.7)</td>
<td>19(17.9)</td>
<td></td>
</tr>
<tr>
<td>Central</td>
<td>13(12.3)</td>
<td>0(0.0)</td>
<td>0(0.0)</td>
<td>13(12.3)</td>
<td></td>
</tr>
<tr>
<td>West</td>
<td>12(11.3)</td>
<td>0(0.0)</td>
<td>6(5.7)</td>
<td>6(5.7)</td>
<td></td>
</tr>
<tr>
<td>South</td>
<td>53(50)</td>
<td>19(17.9)</td>
<td>11(10.4)</td>
<td>23(21.7)</td>
<td></td>
</tr>
</tbody>
</table>

SD= standard deviation, *Chairpersons, secretaries, others; **Research assistants, coordinators, associates, and managers.

p = 0.037). Around 62 percent of investigators or co-investigators and 50%, other researchers were also neutral. The survey was aimed to know the differences in views of various researchers about the changes in NDCT Rules. The results revealed that most of the investigators or co-investigators reported that the changes in reducing clinical trial timeline and equality are proper. However, the majority of other researchers significantly said that the severe adverse events report and compensation are adequate. Overall majority of members of the ethics committee were significantly reported neutral about the changes of NDCT Rules, followed by the investigators or co-investigators and other researchers. This was the first study that surveyed the differences in views of various researchers about the changes in NDCT Rules. Previous surveys have reported the views of investigators and the ethics committees on the earlier regulatory changes (Davis et al., 2017; Kadam et al., 2016; Parikh et al., 2011).
However, these studies have neglected the views of other researchers, who play a crucial role in clinical trials. The current survey was addressed this gap by including views on the changes in NDCT Rules. In this study, most other researchers supported the changes in severe adverse events and compensation. These findings are similar to the findings of other researchers work. Thus, the investigators and members of the ethics committee must pay attention to a better understanding of changes in the severe adverse event reports and compensation.

CONCLUSIONS

About the changes of NDCT Rules, the investigators or co-investigators believes that the changes in reducing clinical trial timeline and equality are proper. However, other researchers believe that the severe adverse events report and compensation are proper. Nevertheless, most members of the ethics committee were neutral. The results of this study indicate that there is a variation in the views of different researchers about the changes of NDCT Rules. The findings will be of interest to the stakeholders of pharmaceutical companies at national and international levels. Future study is required on the larger sample at a national level to generalize the views of various researchers on the topic.

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Conflict of Interest

The authors declare that they have no conflict of interest for this study.

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